



## **Study Protocol**

**P5-C3-004 and P5-C2-002**

# **DARWIN EU® - Burden of meningococcal and gonococcal disease in the general population in European countries**

18/09/2026

Version 5.0

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Public

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|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study title                      | DARWIN EU® - Burden of meningococcal and gonococcal disease in the general population in European countries                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Protocol version                 | V5.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Date                             | 18/09/2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| EUPAS number                     | EUPAS1000001066                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Active Substance                 | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Medicinal Product                | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Research question and objectives | <p>The aim of this study is to assess the availability, quality, and completeness of fit-for-purpose data sources that record invasive meningococcal disease (IMD) to inform the design of meningococcal vaccine effectiveness studies.</p> <p>The specific objectives are:</p> <ol style="list-style-type: none"> <li>1. To estimate incidence rates of IMD in the general population, overall and stratified by calendar year, sex, and age.</li> <li>2. To estimate mortality rates due to IMD in the general population, overall and stratified by calendar year, sex, and age.</li> <li>3. To estimate incidence rates of gonorrhoea in the general population, overall and stratified by calendar year, sex, and age.</li> <li>4. To describe the demographic characteristics and clinical profile of individuals with IMD or gonorrhoea, including treatment with antibiotics.</li> <li>5. To describe the availability of data on meningococcal serogroups and carriage across data sources.</li> </ol> |
| Countries of study               | <p>P5-C3-004: Belgium, Croatia, Denmark, Germany, Norway, Spain</p> <p>P5-C2-002: Finland, Lithuania, Spain, Sweden, the United Kingdom</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
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## LIST OF ABBREVIATIONS

| Acronyms/terms    | Description                                                                                |
|-------------------|--------------------------------------------------------------------------------------------|
| ATC               | Anatomical Therapeutic Chemical                                                            |
| CC                | Coordination centre                                                                        |
| CDM               | Common Data Model                                                                          |
| CIPH              | Croatian Institute of Public Health                                                        |
| CPRD Aurum Linked | Clinical Practice Research Datalink Aurum + Hospital Episode Statistics                    |
| CSF               | Cerebrospinal fluid                                                                        |
| DARWIN EU®        | Data Analysis and Real-World Interrogation Network                                         |
| DK-DHR            | Danish Data Health Registries                                                              |
| DKMA              | Danish Medicines Agency                                                                    |
| DRE               | Digital Research Environment                                                               |
| DTZ               | Data Transfer Zone                                                                         |
| ECDC              | European Centre for Disease Prevention and Control                                         |
| EEA               | European Economic Area                                                                     |
| EHR               | Electronic Health Records                                                                  |
| EMA               | European Medicines Agency                                                                  |
| ENCePP            | European Network of Centres for Pharmacoepidemiology and Pharmacovigilance                 |
| Erasmus MC        | Erasmus Medical Center                                                                     |
| EU                | European Union                                                                             |
| EUPAS             | EU Post-Authorisation Studies Register                                                     |
| FinOMOP-THL       | Finnish Care Register for Health Care                                                      |
| FISABIO           | Fundació per al Foment de la Investigació Sanitària i Biomèdica de la Comunitat Valenciana |
| GDPR              | General Data Protection Regulation                                                         |
| GP                | General Practitioner                                                                       |
| HARPER            | HARmonized Protocol Template to Enhance Reproducibility                                    |
| HI-SPEED          | Health Impact – Swedish Population Evidence Enabling Data-linkage                          |
| HIV               | Human immunodeficiency virus                                                               |
| ICD               | International Classification of Diseases                                                   |
| ICS               | Catalan Institute of Health                                                                |
| IDIAPJGol         | Institut d'Investigació en Atenció Primària de Salut Jordi Gol                             |
| InGef RDB         | InGef Research Database                                                                    |
| IQVIA LPD Belgium | IQVIA Longitudinal Patient Database Belgium                                                |
| IMD               | Invasive meningococcal disease                                                             |
| IRB               | Institutional Review Board                                                                 |
| IUSTI             | International Union Against STI                                                            |
| LDH               | Lithuanian Digital Health Platform                                                         |

| Acronyms/terms | Description                                                              |
|----------------|--------------------------------------------------------------------------|
| LOINC          | Logical Observation Identifiers Names and Codes                          |
| Men B          | Meningococcal group B                                                    |
| Men C          | Meningococcal group C                                                    |
| MCV4           | Quadrivalent meningococcal conjugate vaccine (serogroups A, C, W, and Y) |
| N              | Number                                                                   |
| NA             | Not applicable                                                           |
| NAAT           | Nucleic acid amplification tests                                         |
| NAJS           | Croatian National Public Health Information System                       |
| NLHR           | Norwegian Linked Health Registry data                                    |
| OHDSI          | Observational Health Data Sciences and Informatics                       |
| OMOP           | Observational Medical Outcomes Partnership                               |
| Q25            | 25 <sup>th</sup> Quartile                                                |
| Q75            | 75 <sup>th</sup> Quartile                                                |
| RxNorm         | Medical prescription normalised                                          |
| RWD            | Real-world data                                                          |
| SDA            | State Data Agency                                                        |
| SIDIAP         | The Information System for Research in Primary Care                      |
| SMPA-GU        | Swedish Medical Products Agency - Gothenburg University                  |
| SNOMED         | Systemised Nomenclature of Medicine                                      |
| STI            | Sexually transmitted infections                                          |
| UiO            | University of Oslo                                                       |
| VID            | Valencia Health System Integrated Dataset                                |
| WHO            | World Health Organisation                                                |

## 1. TITLE

DARWIN EU® - Burden of meningococcal and gonococcal disease in the general population in European countries

## 2. DESCRIPTION OF THE STUDY TEAM

| Study team role                                                 | Names                                                                                                  | Organisation                                                               |
|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Principal Investigator                                          | Anna Saura-Lazaro<br>Albert Prats-Urbe                                                                 | University of Oxford                                                       |
| Data Scientist                                                  | Marta Alcalde-Herraiz<br>Edward Burn                                                                   | University of Oxford                                                       |
| Clinical Domain Expert                                          | Anna Saura-Lazaro<br>Albert Prats-Urbe                                                                 | University of Oxford                                                       |
| Study Manager                                                   | Natasha Yefimenko Nosova                                                                               | Erasmus MC                                                                 |
| Data source                                                     | Names                                                                                                  | Data Partner Organisation*                                                 |
| <b>P5-C3-004</b>                                                |                                                                                                        |                                                                            |
| IQVIA Longitudinal Patient Database Belgium (IQVIA LPD Belgium) | Ellen Gerritsen<br>Dina Vojinovic<br>Akram Mendez<br>Gargi Jadhav                                      | IQVIA                                                                      |
| Croatian National Public Health Information System (NAJS)       | Jakov Vuković<br>Ivan Pristaš<br>Antea Jezidžić<br>Anamaria Jurčević<br>Marko Čavlin<br>Karlo Pintarić | Croatian Institute of Public Health (CIPH)                                 |
| Danish Data Health Registries (DK-DHR)                          | Elvira Bräuner<br>Susanne Bruun                                                                        | Danish Medicines Agency (DKMA)                                             |
| InGef Research Database (InGef RDB)                             | Alexander Harms<br>Raeleesha Norris<br>Annika Vivirito                                                 | Institute for Applied Health Research Berlin (InGef)                       |
| Norwegian Linked Health Registry data (NLHR)                    | Hedvig Nordeng<br>Saeed Hayati<br>Petrica Ioan Olteanu                                                 | University of Oslo (UiO)                                                   |
| The Information System for Research in Primary Care (SIDIAP)    | Agustina Giuliodori Picco<br>Elena Roel<br>Talita Duarte Salles<br>Laura Granés                        | Institut d'Investigació en Atenció Primària de Salut Jordi Gol (IDIAPJGol) |
| <b>P5-C2-002</b>                                                |                                                                                                        |                                                                            |
| Finnish Care Register for Health Care (FinOMOP-THL)             | Toni Lehtonen<br>Laura Salonen<br>Tuomo Susi                                                           | FinOMOP                                                                    |

|                                                                                                   |                                                                              |                                                                                                            |
|---------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| Lithuanian Digital Health Platform (LDH)                                                          | Julius Juodakis<br>Justas Trinkunas                                          | State Data Agency (SDA)                                                                                    |
| Clinical Practice Research Datalink<br>Aurum + Hospital Episode Statistics<br>(CPRD Aurum Linked) | Zara Cuccu<br>Daniel Dedman<br>Susan Hodgson                                 | Clinical Practice Research Datalink<br>(CPRD)                                                              |
| Valencia Health System Integrated<br>Dataset (VID)                                                | Fran Llopis-Cardona<br>Celia Robles-Cabaniñas<br>Gabriel Sanfèlix-Gimeno     | Fundació per al Foment de la<br>Investigació Sanitària i Biomèdica de la<br>Comunitat Valenciana (FISABIO) |
| Health Impact - Swedish Population<br>Evidence Enabling Data-linkage (HI-<br>SPEED)               | Fredrik Nyberg<br>Huiqi Li<br>Rickard Ljung<br>Marcel Ballin<br>Mats Talbäck | Swedish Medical Products Agency -<br>Gothenburg University (SMPA-GU)                                       |

\*Data partners do not have an investigator role. Data partners execute code at their data source, review, and approve their results.

### 3. ABSTRACT

#### **Title**

DARWIN EU® - Burden of meningococcal and gonococcal disease in the general population in European countries

#### **Rationale and background**

There is a need to assess the availability, completeness, and suitability of real-world data (RWD) within the DARWIN EU® network to support future meningococcal vaccine effectiveness studies. In particular, the identification of invasive meningococcal disease (IMD), gonorrhoea, IMD-related mortality, and meningococcal carriage in RWD presents methodological challenges due to variability in coding practices, laboratory data capture, and the limited capture of asymptomatic conditions, such as carriage.

#### **Research objectives**

1. To estimate incidence rates of IMD in the general population, overall and stratified by calendar year, sex, and age.
2. To estimate mortality rates due to IMD in the general population, overall and stratified by calendar year, sex, and age.
3. To estimate incidence rates of gonorrhoea in the general population, overall and stratified by calendar year, sex, and age.
4. To describe the demographic characteristics and clinical profile of individuals with IMD or gonorrhoea, including treatment with antibiotics.
5. To describe the availability of data on meningococcal serogroups and carriage across data sources.

#### **Methods**

##### **Study design**

A descriptive cohort study will be conducted.

For Objectives 1–3, the index date will be the start of observation during the study period or the date following a washout period. Individuals will be followed until outcome occurrence, death, end of observation, or end of the study period.

For Objective 4, the index date will be the date of IMD or gonorrhoea diagnosis.

For Objective 5, the index date will be the date of IMD diagnosis or the date of the meningococcal carriage-related record.

##### **Population**

##### **Inclusion criteria**

- Present in the data source during the study period from 01/01/2017 until the end of available data in the selected data sources.
- At least one record of IMD or gonorrhoea (Objective 4)
- At least one record of IMD or meningococcal carriage-related record (Objective 5).
- Minimum 365 days of prior observation (except for children <1 year) (Objective 4).

##### **Variables**

*Exposure:* NA

*Outcome:*

- IMD (Objectives 1, 4).
- IMD-related mortality (Objective 2).
- Gonorrhoea (Objectives 3, 4).
- Meningococcal serogroup (A, B, X, C, W, Y) and meningococcal carriage (Objective 5).

*Relevant covariates:*

- Sex and age (Objectives 1–4).
- Calendar year (Objectives 1–3).
- Predefined risk factors, clinical manifestations/complications, antibiotic treatment, vaccination history, and, for gonorrhoea, concomitant sexually transmitted infections (Objective 4).
- Meningococcal serogroup and laboratory measurements for *Neisseria meningitidis* (Objective 5).

Data sources

1. Belgium: IQVIA Longitudinal Patient Database Belgium (IQVIA LPD Belgium)
2. Croatia: Croatian National Public Health Information System (NAJS)
3. Denmark: Danish Data Health Registries (DK-DHR)
4. Finland: Finnish Care Register for Health Care (FinOMOP-THL)
5. Germany: InGef Research Database (InGef RDB)
6. Lithuania: Lithuanian Digital Health Platform (LDH)
7. Norway: Norwegian Linked Health Registry data (NLHR)
8. Spain: The Information System for Research in Primary Care (SIDIAP)
9. Spain: Valencia Health System Integrated Dataset (VID)
10. Sweden: Health Impact - Swedish Population Evidence Enabling Data-linkage (HI-SPEED)
11. The United Kingdom: Clinical Practice Research Datalink Aurum + Hospital Episode Statistics (CPRD Aurum Linked)

Study size

No sample size has been calculated, as this study will not test a specific hypothesis.

Statistical analysis*Objectives 1–3*

Annual incidence rates will be estimated per 100,000 person-years. Multiple events (except death) will be allowed, with a 30-day washout period applied between episodes. Incidence rates will be presented with 95% Poisson confidence intervals.

*Objective 4*

Covariates will be assessed in predefined time windows around the index date (e.g. [-365, -1] for risk factors and [-7, 30] for clinical characteristics and treatments).

*Objective 5*

Proportion of IMD cases with recorded serogroup and the distribution of serogroups among cases with available data will be estimated. The number of individuals with meningococcal carriage-related records

will be also estimated, and associated laboratory measurements for *Neisseria meningitidis* will be assessed within the window  $[-7, 7]$  relative to the index date.

#### *Sensitivity analysis*

Distinct episodes will be defined using a 90-day washout period.

## 4. AMENDMENTS AND UPDATES

None.

## 5. MILESTONES

### P5-C3-004/P5-C2-002

| Study milestones and deliverables        | Planned dates* |
|------------------------------------------|----------------|
| Final Study Protocol                     | June 2026      |
| Creation of Analytical Code              | August 2026    |
| Execution of Analytical Code on the data | September 2026 |
| Draft Study Report                       | October 2026   |
| Final Study Report                       | November 2026  |

\*Planned dates are dependent on obtaining approvals from the internal review boards of the data sources and deliverables review rounds.

## 6. RATIONALE AND BACKGROUND

*Neisseria meningitidis* and *Neisseria gonorrhoeae* are two clinically important pathogenic species within the same genus, sharing genetic and structural similarities.[1]

*Neisseria meningitidis* is the causative agent of invasive meningococcal disease (IMD), a severe and rapidly progressing infection that typically presents as meningitis or septicaemia and is associated with substantial morbidity and mortality.[2,3] Several vaccines targeting the main disease-causing serogroups (A, B, C, W, and Y) are available; however, their implementation varies across European countries, reflecting differences in national immunisation programmes.[4,5]

*Neisseria meningitidis* is transmitted via respiratory droplets and colonises the mucosa of the upper respiratory tract. This asymptomatic colonisation, referred to as carriage, is common and does not necessarily result in invasive disease. However, effective vaccination strategies and herd protection are also dependent on reducing carriage.[6] Conjugate meningococcal vaccines have been shown to reduce carriage of targeted serogroups, although evidence gaps remain regarding the magnitude and duration of this effect.[7] Data on the prevalence and impact of asymptomatic meningococcal carriage are limited, particularly outside dedicated carriage studies.[8]

*Neisseria gonorrhoeae* is the causative agent of gonorrhoea, one of the most common bacterial sexually transmitted infections (STI). Gonorrhoea affects the genital, rectal, and oropharyngeal sites and may lead to complications, such as pelvic inflammatory disease and disseminated infection, if left untreated.[9] The infection represents a major public health concern due to the rapid emergence of antimicrobial resistance, with *N. gonorrhoeae* classified as a priority antimicrobial resistance pathogen.[10]

Currently, there is no vaccine indicated for the protection against gonorrhoea, but recent real-world evidence suggests that Meningococcal group B vaccines (Men B) containing outer membrane vesicles could provide partial cross-protection against gonococcal infection, with effectiveness of approximately 30–41%.[11,12] In this context, England (the United Kingdom (UK)) became the first country to implement MenB vaccination for populations at a higher risk of gonorrhoea in 2025.[13]

The recent study [DARWIN EU® - Coverage of meningococcal vaccines in the target population in Europe \(P4-C1-006\)](#) examined the coverage of meningococcal vaccines routinely administered to prevent IMD in eligible individuals. This population-level drug utilisation study generated evidence on temporal trends in the coverage of meningococcal vaccines, by brand and/or vaccine composition (as available in the data

sources), and by age group and dose, in six data sources in five countries (Croatia, Spain, UK, Denmark, Finland). [14]

Generating further knowledge on meningococcal vaccine effectiveness through use of real-world data (RWD) may inform regulatory and public health decision making. However, the identification of IMD cases, related mortality, and meningococcal carriage in RWD present methodological challenges due to variability in coding practices, incomplete laboratory data, and the limited capture of asymptomatic conditions, such as carriage.

This study will provide a descriptive overview of IMD and gonorrhoea incidence, IMD-related mortality, and data related to meningococcal serogroups and carriage across multiple European data sources, thereby assessing the availability, quality, and completeness of RWD in the European data sources included in the study. This study does not aim to replace or complement epidemiological data on IMD, which is traditionally generated by European Union (EU)/European Economic Area (EEA) surveillance systems at country level. Together with the results from the previous DARWIN EU® study on vaccine coverage, the results of this study will serve as a proof-of-concept to inform feasibility of conducting future meningococcal vaccine effectiveness studies within the DARWIN EU® framework. This work will contribute to the Vaccine Monitoring Platform research agenda and may inform future regulatory and public health decision-making.[15]

## 7. RESEARCH QUESTION AND OBJECTIVES

### Research questions

1. What is the incidence of and mortality due to IMD, and the incidence of gonorrhoea in European populations?
2. What is the availability of data to identify and characterise meningococcal serogroups and carriage in European real-world data sources?

### Research objectives

The aim of this study is to assess the availability, quality, and completeness of fit-for-purpose data sources that record IMD to inform the design of meningococcal vaccine effectiveness studies.

The specific objectives are:

1. To estimate incidence rates of IMD in the general population, overall and stratified by calendar year, sex, and age.
2. To estimate mortality rates due to IMD in the general population, overall and stratified by calendar year, sex, and age.
3. To estimate incidence rates of gonorrhoea in the general population, overall and stratified by calendar year, sex, and age.
4. To describe the demographic characteristics and clinical profile of individuals with IMD or gonorrhoea, including treatment with antibiotics.
5. To describe the availability of data on meningococcal serogroups and carriage across data sources.

## 8. RESEARCH METHODS

### 8.1. Study design

A cohort study will be conducted using routinely collected health data from 11 data sources from 10 countries across Europe and in 8 EU member states. The study will comprise:

- Population-level descriptive cohort analyses to address Objectives 1–3.
- Patient-level descriptive cohort analyses to address Objectives 4 and 5.

**Figures 1–3** illustrate the study design (HARmonized Protocol Template to Enhance Reproducibility (HARPER) diagrams) corresponding to each objective, with the index date (Day 0) specified in each figure.

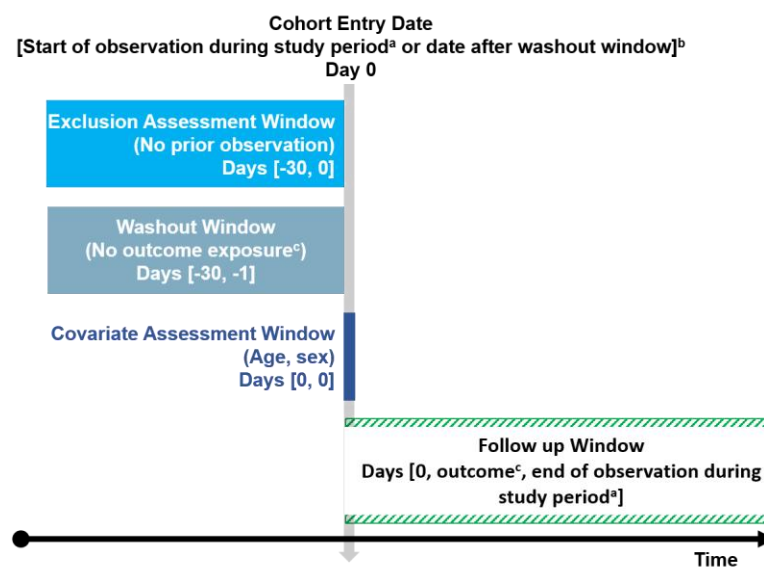


Figure 1. HARPER diagram for descriptive epidemiology study of IMD, gonorrhoea, and mortality due to IMD (Objective 1–3).

- The study period is defined from 01/01/2017 until the end of available data in the selected data sources.
- Cohort entry date is defined as start of observation during the study period or date after washout window, whichever occurs later. Re-entry of an individual into the denominator cohort is allowed, after the post-outcome exposure washout window.
- Outcomes include IMD, gonorrhoea, and mortality due to IMD.

IMD = Invasive meningococcal disease, HARPER = HARmonized Protocol Template to Enhance Reproducibility

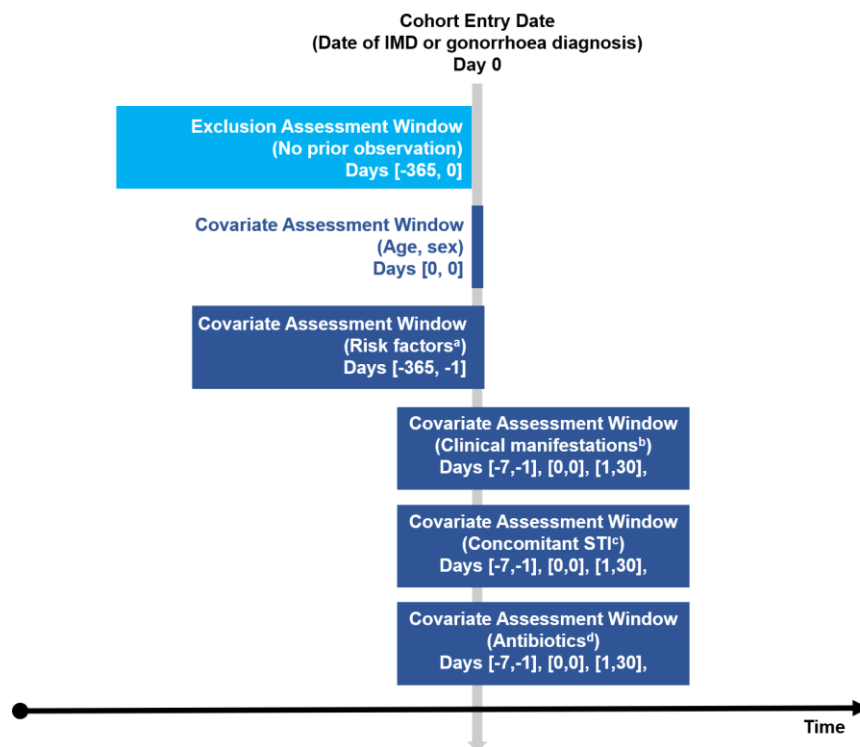


Figure 2. HARPER diagram for characterisation of individuals with IMD or gonorrhoea (Objective 4).

- a. Risk factors of interest for characterisation of individuals with IMD will include HIV infection, functional or anatomic asplenia, persistent complement component deficiencies, and use of complement inhibitors (eculizumab, ravulizumab).
- b. Clinical manifestations of interest for characterisation of individuals with IMD will include meningitis, sepsis/meningococemia, septic shock, haemorrhagic rash/purpura fulminans/petechial lesions, pneumonia, and septic arthritis.  
Clinical manifestations of interest for characterisation of individuals with gonorrhoea will include urethritis, cervicitis, proctitis, pharyngitis, epididymitis/prostatitis, vulvovaginitis, salpingitis, pelvic inflammatory disease, disseminated gonococcal infection, and septic arthritis.
- c. Concomitant STI of interest for characterisation of individuals with gonorrhoea will include Chlamydia trachomatis, Syphilis, HIV, Trichomonas vaginalis, and Mycoplasma genitalium.
- d. Antibiotics of interest for characterisation of individuals with IMD will include ceftriaxone, cefotaxime, benzylpenicillin, chloramphenicol, and meropenem.  
Antibiotics of interest for characterisation of individuals with gonorrhoea will include ceftriaxone, cefixime, azithromycin, doxycycline, gentamicin, and spectinomycin.
- e. Meningococcal vaccines of interest for characterisation of individuals with IMD or gonorrhoea will include 4CMenB (four-component meningococcal serogroup B vaccine), MenC (meningococcal serogroup C conjugate vaccine), and MCV4 (quadrivalent meningococcal conjugate vaccine against serogroups A, C, W, and Y).

IMD = Invasive meningococcal disease, HIV = Human immunodeficiency virus, STI = Sexually transmitted infections, HARPER = HARMonized Protocol Template to Enhance Reproducibility

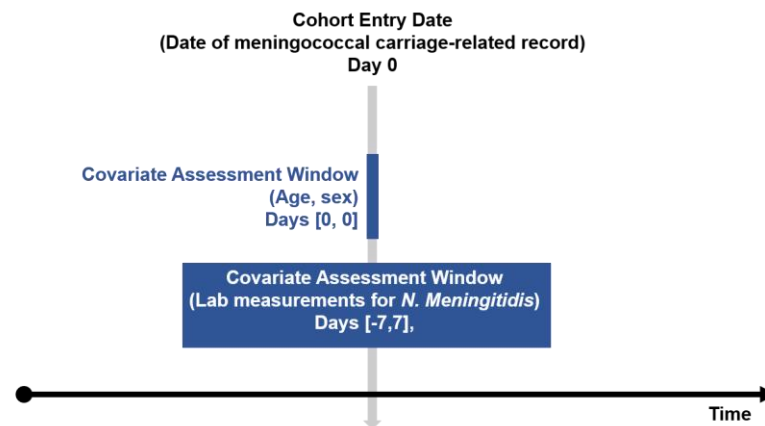


Figure 3. HARPER diagram for characterisation of meningococcal carriage (Objective 5).

N. = Neisseria, HARPER = HARmonized Protocol Template to Enhance Reproducibility

## 8.2. Follow-up

### **Objective 1–3: Descriptive epidemiology of IMD, gonorrhoea, and mortality due to IMD.**

Follow-up for incidence estimation will begin on the latest of:

- the start of the study period (01/01/2017), or
- the start of the individual's observation period.

Follow-up will end at the earliest of:

- the end of the study period (end of available data in the selected data sources),
- the end of the individual's observation period,
- the occurrence of an outcome of interest, or
- death.

Multiple outcomes (other than death) may be recorded per individual during the study period. Distinct events will be defined using a rolling 30-day washout period, such that only outcomes of the same type occurring at least 30 days apart will be considered as separate incident events. Episodes will be constructed using a rolling 30-day gap rule, whereby the episode starts on the date of the first qualifying record, and subsequent records occurring within 30 days of the most recent record are considered part of the same episode.

The use of a 30-day washout period is consistent with surveillance and RWD practices. For gonorrhoea, repeat positive tests are common and may reflect either persistent positivity shortly after treatment or true reinfection; therefore, a 30-day deduplication window is recommended to avoid double counting of the same infection episode.[16] For IMD, reinfection is rare, and no standard episode definition exists in secondary data sources; thus, a pragmatic 30-day window was selected based on the acute and rapidly progressing nature of the disease and to account for potential fragmentation of records across data sources (e.g. laboratory, hospitalisation, and mortality records).[17]

Following a non-fatal event, individuals will re-enter the risk set after completion of the washout period.

Figure 4 shows six hypothetical individuals to illustrate how follow-up and outcome assessment are conducted for incidence estimation of IMD, gonorrhoea, and mortality due to IMD in the general population. Person ID 1 is observed throughout the entire study period but does not experience any outcome and therefore contributes person-time only. Person ID 2 is similar but enters observation after the

start of the study period and contributes person-time from that point onward. Person ID 3 has full observation during the study period and experiences a non-fatal outcome, which is counted as an incident event. After completion of the 30-day washout period, this individual re-enters observation time and may contribute additional person-time. Person ID 4 contributes person-time until the date of death, which is also recorded as an outcome if it is due to IMD. Person ID 5 experiences a non-fatal outcome, followed by another similar outcome within the 30-day washout period. The second event is not considered a distinct incident event, and the individual does not re-enter observation time until the washout period of that second event is completed. Finally, person ID 6 represents an individual who had an outcome before the start of the study period and therefore does not contribute to observation time until the washout period has been completed.

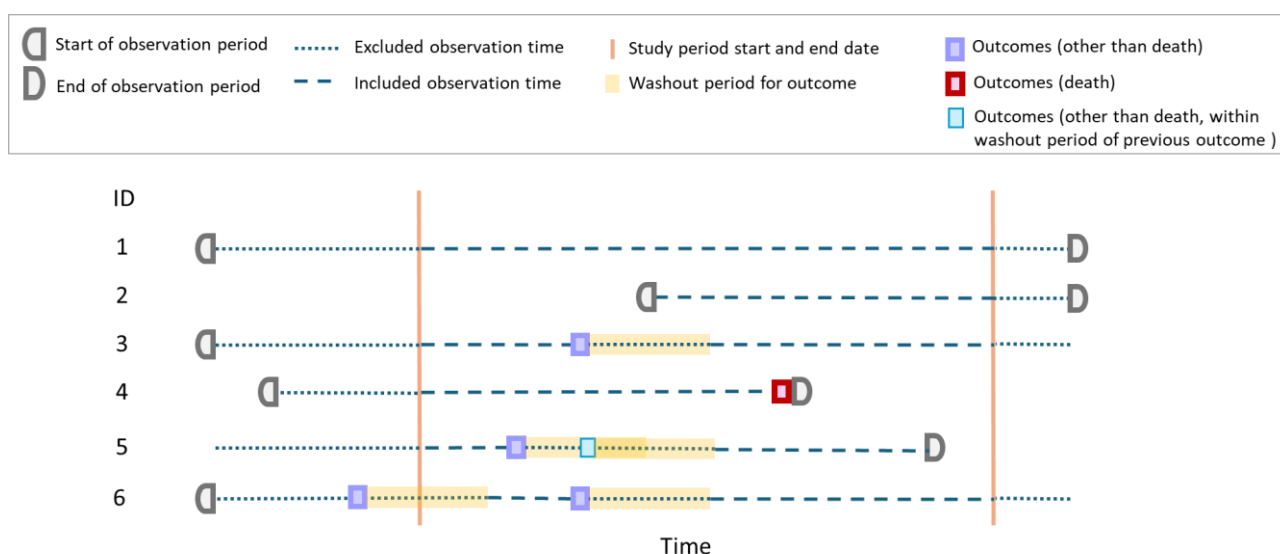


Figure 4. Included observation time for the denominator population.

### 8.3. Study population with inclusion and exclusion criteria

#### **Objectives 1–3: Descriptive epidemiology of IMD, mortality due to IMD, and gonorrhoea**

##### Inclusion criteria

- Present in the study period of 01/01/2017 until the end of available data in the selected data sources.
- Minimum 30 days of available history before index date.

#### **Objective 4: Characterisation of individuals with IMD or gonorrhoea**

##### Inclusion criteria

- At least one record of IMD or gonorrhoea during the study period (01/01/2017 until the end of available data in the selected data sources).
- Minimum 365 days of available history before index date (except for children <1 year during the study period).

## Objective 5: Characterisation of meningococcal serogroup or carriage

### Inclusion criteria

- At least one record of IMD or meningococcal carriage-related record during the study period (01/01/2017 until the end of available data in the selected data sources).

## 8.4. Study setting and data sources

This study will be conducted using routinely collected data from one nationwide primary care data source; seven nationwide data sources covering primary, secondary, and hospital inpatient care; three regional data sources covering primary, secondary, and hospital inpatient care; and one regional primary care data source linked to hospital discharge records within the DARWIN EU® network of data partners from 10 European countries. All data were *a priori* mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM).

Table 1. Data sources.

| Country   | Name of Data source | Health Care setting                                  | Type of Data | Number of active individuals | Calendar period covered by each data source |
|-----------|---------------------|------------------------------------------------------|--------------|------------------------------|---------------------------------------------|
| Belgium   | IQVIA LPD Belgium   | Primary care                                         | EHR          | 165k                         | 2010–30/09/2025                             |
| Croatia   | NAJS                | Primary, secondary, and hospital inpatient care      | Claims       | 4.3M                         | 1998–14/08/2025                             |
| Denmark   | DK-DHR              | Primary, secondary, and hospital inpatient care      | Registry     | 5.98M                        | 1995–18/01/2025                             |
| Germany   | InGef RDB           | Primary, secondary, and hospital inpatient care      | Claims       | 7.43M                        | 2016–01/11/2025                             |
| Norway    | NLHR                | Primary, secondary, and hospital inpatient care      | Registry     | 5.55M                        | 2008–31/12/2023                             |
| Spain     | SIDIAP              | Primary care (linked to hospital discharged records) | EHR          | 6.07M                        | 2006–31/12/2024                             |
| Finland   | FinOMOP-THL         | Primary, secondary, and hospital inpatient care      | Registry     | 5.7M                         | 1998–01/10/2024                             |
| Lithuania | LDH                 | Primary, secondary, and hospital inpatient care      | EHR          | 2.74M                        | 2015–03/02/2026                             |

| Country            | Name of Data source | Health Care setting                             | Type of Data | Number of active individuals | Calendar period covered by each data source |
|--------------------|---------------------|-------------------------------------------------|--------------|------------------------------|---------------------------------------------|
| The United Kingdom | CPRD Aurum Linked   | Primary, secondary, and hospital inpatient care | EHR          | 15.5M                        | 1995–01/09/2025                             |
| Spain              | VID                 | Primary, secondary, and hospital inpatient care | EHR          | 5.58M                        | 2009–01/10/2025                             |
| Sweden             | HI-SPEED            | Primary, secondary, and hospital inpatient care | Registry     | 10.6M                        | 2015–31/08/2025                             |

CPRD Aurum Linked = Clinical Practice Research Datalink Aurum + Hospital Episode Statistics, DK-DHR = Danish Data Health Registries, EHR = Electronic Health Records, FinOMOP-THL = Finnish Care Register for Health Care, HI-SPEED = Health Impact - Swedish Population Evidence Enabling Data-linkage, InGef RDB = InGef Research Database, IQVIA LPD Belgium = IQVIA Longitudinal Patient Database Belgium, LDH = Lithuanian Digital Health Platform, NAJS = Croatian National Public Health Information System, NLHR = Norwegian Linked Health Registry data, SIDIAP = The Information System for Research on Primary Care, VID = Valencia Health System Integrated Dataset.

### Data sources selection

These data sources fulfil the criteria required in terms of data quality, completeness, timeliness, and representativeness for a descriptive study while covering different regions of Europe ([Annex II](#)).

## 8.5. Study period

The overall study period will be from 01/01/2017 until the end of available data in the selected data sources.

For NLHR, accurate hospital data are only available from 2018 onwards; therefore, the study period for this data source will start on 01/01/2018.

## 8.6. Variables

### 8.6.1. Exposure

N/A.

### 8.6.2. Outcome

#### **Objective 1: Descriptive epidemiology of IMD**

The primary outcome for this objective is IMD, defined based on the European Centre for Disease Prevention and Control (ECDC) case definition (Commission Implementing Decision (EU) 2018/945).[17] The ECDC definition distinguishes between clinically compatible (possible) cases and laboratory-confirmed cases. For the purpose of this study, these definitions have been operationalised and adapted to RWD to account for variability in data availability across participating data sources.

To address potential challenges in phenotyping, multiple complementary IMD outcome definitions will be implemented.

IMD outcome definitions:**1. Laboratory evidence of *Neisseria meningitidis***

This definition includes any individual with laboratory evidence of *N. meningitidis* detection (e.g. culture, nucleic acid amplification tests (NAAT), or antigen detection), irrespective of specimen site.

Potential limitation:

This definition may include individuals with non-invasive manifestations of meningococcal infection or asymptomatic carriage, particularly when the specimen site is not specified. As a result, detection of *Neisseria meningitidis* from non-sterile sites may be misclassified as invasive disease, potentially leading to an overestimation of IMD incidence.

**2. Laboratory-confirmed IMD**

This definition includes any individual meeting the ECDC laboratory criteria for a confirmed case, including:

- isolation of *Neisseria meningitidis* from a normally sterile site or purpuric skin lesions;
- detection of *Neisseria meningitidis* nucleic acid from a normally sterile site or purpuric skin lesions;
- detection of *Neisseria meningitidis* antigen in cerebrospinal fluid (CSF); or
- detection of gram-negative diplococci in CSF.

This definition is considered the reference standard for IMD incidence estimation.

Potential limitation:

This definition relies on availability of detailed laboratory data, including test type and, where possible, specimen site. In some data sources, laboratory information may be incomplete or lack specimen site detail, potentially leading to under-ascertainment.

**3. Possible IMD case**

This definition includes individuals with at least one diagnosis or observation code specific to IMD, as well as individuals with at least one code corresponding to a clinical feature compatible with IMD, in line with the ECDC possible case definition. For these clinical features, the underlying aetiology may be specified as bacterial (e.g. bacterial meningitis) but not necessarily meningococcal or may be unspecified.

Clinical features include the presence of at least one of the following:

- meningitis and meningeal signs;
- haemorrhagic rash/purpura fulminans;
- septic shock;
- septic arthritis.

Potential limitation:

The inclusion of clinical features that are non-specific to IMD and may be caused by conditions other than IMD may lead to low specificity and potential overestimation of incidence.

**4. Possible IMD case with mention of meningococcal cause**

This definition includes individuals with diagnosis or observation codes specific to IMD.

Potential limitation:

Diagnosis codes may reflect suspected or treated cases without laboratory confirmation, and coding practices may vary across settings, potentially leading to misclassification. In addition, this approach may

miss laboratory-confirmed cases not recorded using specific diagnosis codes, leading to under-ascertainment.

## 5. Combined clinical and laboratory IMD case

This definition includes individuals meeting both the Laboratory evidence of *Neisseria meningitidis* definition (Definition 1) and the Possible IMD case definition (Definition 3), with the two records occurring within 30 days of each other.

This definition was developed to increase specificity by requiring both microbiological evidence of *Neisseria meningitidis* and a clinically compatible presentation within a clinically relevant time window. It is intended to complement Definitions 1 and 3, which may individually be overly sensitive due to asymptomatic carriage, non-invasive infections, or non-specific clinical manifestations.

The overlap between the different IMD definitions will be assessed across data sources. In particular, this will help determine the extent to which diagnosis-based definitions capture cases identified through laboratory-confirmed definitions, especially in settings where laboratory data are limited. This will inform the validity of using diagnosis-based definitions in future vaccine effectiveness studies.

### **Objective 2: Descriptive epidemiology of mortality due to IMD**

The primary outcome for this objective is mortality due to IMD. Where cause-of-death information is unavailable or not reliably recorded in a given data source, IMD-related mortality will be approximated by all-cause death occurring within 30 days following a diagnosis of IMD (based on the previously defined IMD outcome definitions). This time window was selected as the majority of IMD-related deaths occur within the first 30 days after diagnosis.[20]

### **Objective 3: Descriptive epidemiology of gonorrhoea**

The primary outcome for this objective is gonorrhoea, defined based on the ECDC case definition for confirmed gonorrhoea cases (Commission Implementing Decision (EU) 2018/945).[18,19] For the purpose of this study and to address potential challenges in phenotyping, complementary gonorrhoea outcome definitions based on laboratory data and diagnosis codes will be implemented.

#### Gonorrhoea outcome definitions:

##### **1. Laboratory-confirmed gonorrhoea**

This definition includes individuals with laboratory evidence of *Neisseria gonorrhoeae* detection, including NAAT, culture, or other microbiological methods, in line with the ECDC confirmed case definition.

Potential limitation:

Laboratory data may be incomplete or not systematically captured across all data sources, potentially leading to under-ascertainment.

##### **2. Diagnosis-based gonorrhoea**

This definition includes individuals with diagnosis or observation codes for gonorrhoea.

Potential limitation:

Diagnosis codes may reflect suspected or treated cases without laboratory confirmation, and coding practices may vary across settings, potentially leading to misclassification. In addition, this approach may miss laboratory-confirmed cases not recorded using specific diagnosis codes, leading to under-ascertainment.

The overlap between laboratory-confirmed and diagnosis-based gonorrhoea will be assessed across data sources. In particular, this will help determine the extent to which diagnosis-based definition capture cases identified through laboratory-confirmed definitions, especially in settings where laboratory data are

limited. This will inform the validity of using diagnosis-based definitions in future vaccine effectiveness studies. Based on these findings, which will be assessed during the phenotyping diagnostics phase, a combined gonorrhoea definition including individuals meeting either the laboratory-based or the diagnosis-based definition may be considered for incidence estimation.

#### **Objective 5: Characterisation of meningococcal serogroup and carriage**

The primary outcome for this objective is meningococcal serogroup and carriage. Meningococcal serogroup (A, B, X, C, W, Y) information will be identified using laboratory measurements, where available. In addition, meningococcal carriage will be identified using condition or observation codes explicitly indicating carriage, where available.

Potential limitation:

Standard clinical vocabularies do not include specific laboratory measurement codes for meningococcal carriage and therefore do not distinguish between specimens collected for carriage screening and those obtained for clinical diagnosis. Consequently, detection or isolation of *Neisseria meningitidis* cannot be assumed to represent carriage, as such records may reflect clinically indicated testing or invasive meningococcal disease.

The preliminary concept sets used for the identification of outcomes are described in [Annex IV](#). These codes will be refined during the study execution, following the DARWIN EU<sup>®</sup> phenotyping standard processes, which involve the review of code lists by clinical experts and the review of phenotypes after their execution in the participating data sources.

#### **8.6.3. Covariates**

##### **Objectives 1–3: Descriptive epidemiology of IMD, mortality due to IMD, and gonorrhoea**

The following covariates, assessed on the index date [0, 0], defined as start of the study period (01/01/2017), will be used for stratification:

- Sex
  - Female
  - Male
- Age groups:
  - Below 1 year
  - 1–4 years
  - 5–11 years
  - 12–17 years
  - 18–24 years
  - 25–44 years
  - 45–64 years
  - 65 years and above

These age groups are selected to reflect: i) higher incidence of IMD in infants and young children; ii) age groups targeted by meningococcal vaccination programmes (e.g. infant Men B and adolescent MenACWY vaccination) [5]; and iii) known differences in carriage, transmission dynamics, and social mixing patterns across age groups.

- Calendar year

#### **Objective 4: Characterisation of individuals with IMD**

- Sex
  - Female
  - Male
- Age, assessed on the index date [0, 0], defined as the date of IMD diagnosis.
- Risk factors, assessed during the 12 months prior to index date [-365, -1]:
  - Human immunodeficiency virus (HIV) infection
  - Functional or anatomic asplenia
  - Persistent complement component deficiencies
  - Use of complement inhibitors for which meningococcal vaccination or prophylaxis is recommended in the product information (eculizumab, ravulizumab, pegcetacoplan, iptacopan, danicopan, crovalimab, sutimlimab)

These risk factors were selected based on their established association with increased susceptibility to invasive meningococcal disease, as described by the ECDC.[5,21]

- Clinical manifestations, assessed within the window [-7, 30] relative to the index date. For descriptive purposes, timing will be explored in the following sub-periods: i) pre-index date period: [-7, -1], ii) index date: [0, 0], iii) post-index date period: [1, 30]:
  - Meningitis
  - Sepsis/meningococemia
  - Septic shock
  - Haemorrhagic rash/purpura fulminans/petechial lesions
  - Pneumonia
  - Septic arthritis

These manifestations were selected to characterise the spectrum of clinical presentations that may occur among individuals meeting the IMD case definitions, as described by the ECDC.[17]

- Antibiotics (at ingredient level), assessed within the window [-7, 30] relative to the index date. For descriptive purposes, timing will be explored in the following sub-periods: i) pre-index date period: [-7, -1], ii) index date: [0, 0], iii) post-index date period: [1, 30]:
  - Ceftriaxone
  - Cefotaxime
  - Benzylpenicillin
  - Chloramphenicol
  - Meropenem
  - Ampicillin
  - Amoxicillin

Antibiotics were selected based on European clinical guidance for the management of meningococcal disease and represent key agents used in the treatment of suspected or confirmed IMD.[22,23]

**Objective 4: Characterisation of individuals with gonorrhoea**

- Sex
  - Female
  - Male
- Age, assessed on the index date [0, 0], defined as the date of gonorrhoea diagnosis.
- Concomitant STI/co-infections, assessed within the window [-7, 30] relative to the index date. For descriptive purposes, timing will be explored in the following sub-periods: i) pre-index date period: [-7, -1], ii) index date: [0, 0], iii) post-index date period: [1, 30]:
  - Chlamydia trachomatis
  - Syphilis
  - HIV
  - Trichomonas vaginalis
  - Mycoplasma genitalium

These variables reflect established epidemiological risk factors and co-infections associated with gonorrhoea transmission and recurrence in European surveillance data.[9]

- Clinical manifestations and complications, assessed within the window [-7, 30] relative to the index date. For descriptive purposes, timing will be explored in the following sub-periods: i) pre-index date period: [-7, -1], ii) index date: [0, 0], iii) post-index date period: [1, 30]:
  - Urethritis
  - Cervicitis
  - Proctitis
  - Pharyngitis
  - Epididymitis/prostatitis
  - Vulvovaginitis
  - Salpingitis
  - Pelvic inflammatory disease
  - Disseminated gonococcal infection
  - Septic arthritis

These manifestations reflect recognised sites of infection and complications described in the ECDC and International Union Against STI (IUSTI) guidelines.[9,24]

- Antibiotics (at ingredient level), assessed within the window [-7, 30] relative to the index date. For descriptive purposes, timing will be explored in the following sub-periods: i) pre-index date period: [-7, -1], ii) index date: [0, 0], iii) post-index date period: [1, 30]:
  - Ceftriaxone

- Cefixime
- Azithromycin
- Doxycycline
- Ciprofloxacin
- Gentamicin
- Spectinomycin
- Ertapenem
- Zoliflodacin
- Gepotidacin

Antibiotics were selected based on European clinical guidelines (IUSTI), including first-line, alternative, and emerging treatment options.[9,24]

#### **Objective 5: Characterisation of meningococcal serogroup**

- Meningococcal serogroup (e.g. A, B, C, W, Y).

#### **Objective 5: Characterisation of meningococcal carriage**

- Laboratory measurements for *Neisseria meningitidis*, assessed within the window [-7, 7] relative to the index date.

The preliminary concept sets used for the identification of covariates are described in [Annex IV](#). These codes will be refined during the study execution, following the DARWIN EU® phenotyping standard processes, which involve the review of code lists by clinical experts and the review of phenotypes after their execution in the participating data sources.

## **8.7. Study size**

No sample size has been calculated, as this is a descriptive disease epidemiology study which will not test a specific hypothesis. In addition, we will use already collected available data to estimate the incidence of IMD and gonorrhoea, respectively. Thus, the sample size is driven by the availability of data for individuals with a diagnosis of IMD or gonorrhoea. Based on a preliminary feasibility assessment, using only codes from the condition domain (as of 01/04/2026), the expected number of person counts for IMD in the data sources included in this study ranges from 200 (LDH) to 45,100 (CPRD Aurum Linked). Using only codes from the condition and observation domains (as of 01/04/2026), the expected number of persons counts for gonorrhoea in the data sources included in this study range from 600 (LDH) to 73,500 (DK-DHR).

## **8.8. Analysis**

### **8.8.1. Federated network analyses**

All analyses will be conducted separately for each data source, and will be carried out in a federated manner, allowing analyses to be run locally without sharing individuals' data.

Before sharing the study package, test runs of the analytics will be performed on a subset of the data sources, and quality control checks will be performed. After all the tests are passed (see [Annex III](#)), the final package will be released in a version-controlled study repository for execution against all the participating data sources.

### 8.8.2. Data privacy protection

The data partners will locally execute the analytics against the OMOP CDM in R Studio and review and approve the default aggregated results. They will then be made available to the Principal Investigators and study team in a secure online repository of the Data Transfer Zone (DTZ). All results will be locked and timestamped for reproducibility and transparency. The study results of all data sources will be checked, after which they are made available to the team, and the Study Dissemination Phase can start. All analyses will be conducted separately for each data source, and will be carried out in a federated manner, allowing analyses to be run locally without sharing patient-level data. Cell counts <5 will be suppressed when reporting results to comply with the data source's privacy protection regulations.

### 8.8.3. Statistical model specification and assumptions of the analytical approach considered

#### Objectives 1–3

The incidence of IMD, gonorrhoea, and mortality due to IMD will be calculated based on OMOP CDM mapped data using the *IncidencePrevalence* R package, developed by DARWIN EU®.[25]

Annual incidence rates will be described as the number of individuals with the outcome of interest per 100,000 person-years among the general population for each calendar year. Study participants who enter the denominator population will contribute person-time from the start of follow-up until the earliest of the following: occurrence of the outcome, death, end of observation, or end of study period. Multiple outcomes (except for death) are allowed, with participants' time contribution paused during a defined outcome washout period of 30 days. Participants without outcome exposure will contribute time-at-risk continuously until censoring. Time-at-risk of individuals who die will be censored at the time of death. Similarly, time-at-risk of individuals who are lost to follow-up will be censored at the time of loss to follow-up (i.e. last contact). Incidence rates will be given together with 95% Poisson confidence intervals.

Estimates will only be calculated for complete calendar years.

#### Objective 4 and 5

Patient characteristics of individuals with a diagnosis of IMD or gonorrhoea, as well as of individuals with a meningococcal carriage-related record, will be calculated based on OMOP CDM mapped data using the *CohortCharacteristics* R package, developed by DARWIN EU®.[26]

For individuals with a diagnosis of IMD or gonorrhoea, patient characterisation will be provided by sex, age, risk and predefined risk factors, clinical manifestations/complications, antibiotics, and vaccines of interest before/on/after the index date (date of IMD or gonorrhoea diagnosis). Covariates will be extracted using the following time intervals: predefined risk factors will be assessed during the 12 months prior to the index date [-365,-1]; predefined clinical manifestations/complications will be assessed within the window relative [-7,30] to the index date, with timing explored in the sub-periods [-7,-1], [0,0], and [1,30]; predefined antibiotics will be assessed within the same window [-7,30] and corresponding sub-periods; and meningococcal vaccination history will be assessed at any time prior to the index date [-Inf,-1].

Among individuals with a confirmed diagnosis of IMD, the proportion with a recorded meningococcal serogroup will be estimated. Among those with available serogroup information, the distribution of serogroups (e.g. A, B, C, W, Y) will be described.

The number of individuals with meningococcal carriage-related records will be described. For these individuals, patient characterisation will be provided by sex and age at the index date (defined as the date of the carriage-related record). Laboratory measurements for *Neisseria meningitidis* will be assessed within the window [-7,7] relative to the index date.

A list of predefined covariates of interest are given in [Section 8.6.3](#).

## Sensitivity analysis

A description of sensitivity analyses are presented by means of **Table 2**.

Table 2. Sensitivity analyses – rationale, strengths, and limitations.

|                                                                        | What is being varied?<br>How?                                                                                                                                                                                                                                                                                  | Why?<br>(What do you expect<br>to learn?)                                                                                                                                                                                    | Strengths of the<br>sensitivity analysis<br>compared to the primary                                                                                                                                              | Limitations of the<br>sensitivity analysis<br>compared to the primary                                                                                                                                |
|------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Incidence rate<br>for IMD and<br>gonorrhoea<br>(Objectives 1<br>and 3) | <p><u>Main analysis:</u> Distinct episodes are defined using a rolling <b>30-day washout period</b> between records to avoid double counting of the same clinical episode.</p> <p><u>Sensitivity analysis:</u> Distinct episodes are defined using a rolling <b>90-day washout period</b> between records.</p> | To assess whether incidence estimates are robust to the episode definition, and to evaluate the extent to which the primary estimates are influenced by fragmented records, delayed coding, or repeat records close in time. | More conservative than the primary analysis; further reduces the chance of counting repeated records from the same episode as separate events; may better absorb delayed recording and fragmented care pathways. | May merge truly distinct episodes, particularly for gonorrhoea, where reinfection can occur; likely underestimates incidence relative to the primary analysis; less sensitive to real repeat events. |

IMD = Invasive meningococcal disease.

## 8.8.4. Output

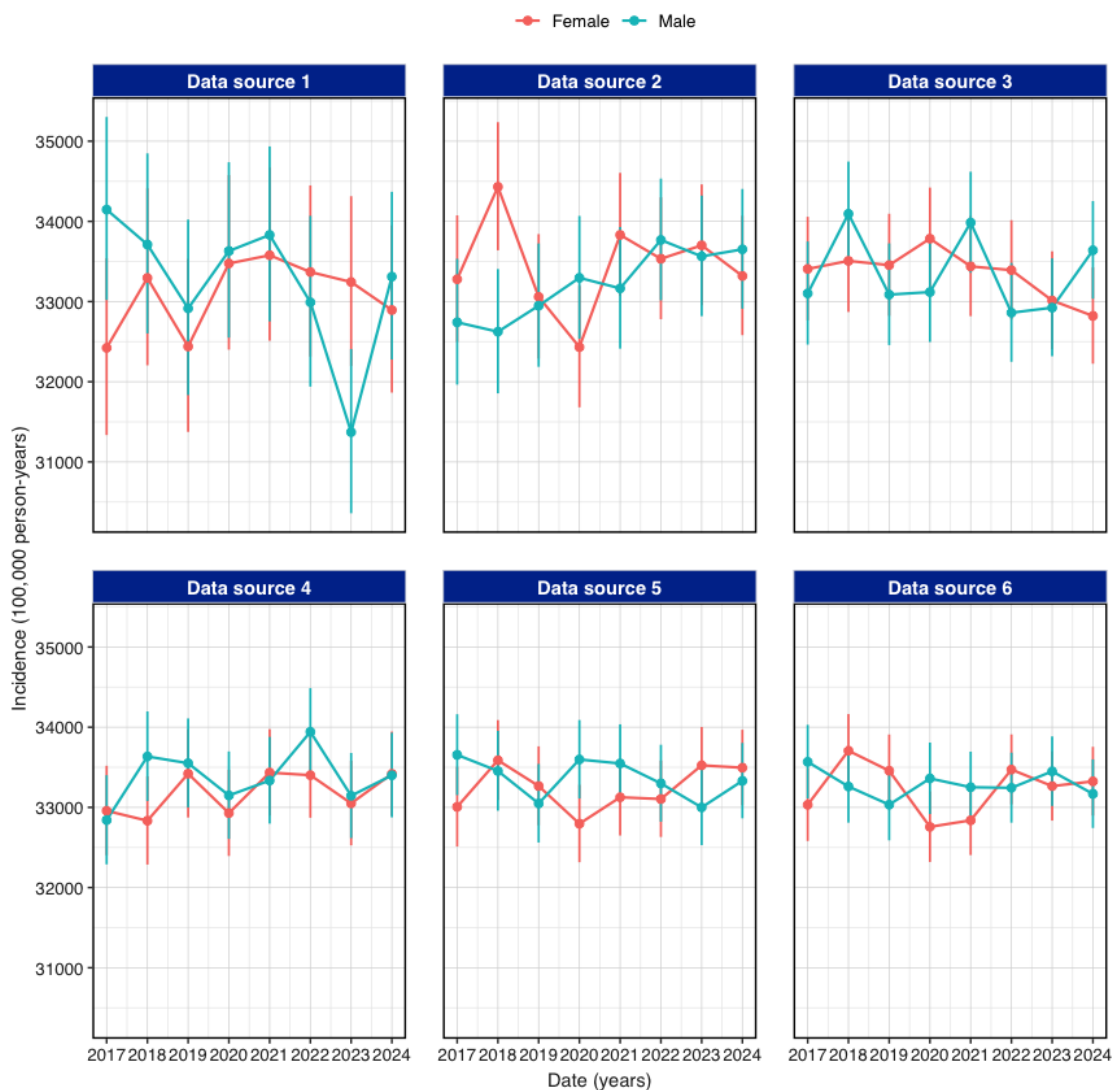
Output will include a PDF report, including an executive summary, as well as the figures and tables described below.

Please note that mock data have been used to generate the figures and tables. In cases where the majority of cells contain values <5, results will be described narratively in the text rather than presented in tabular format.

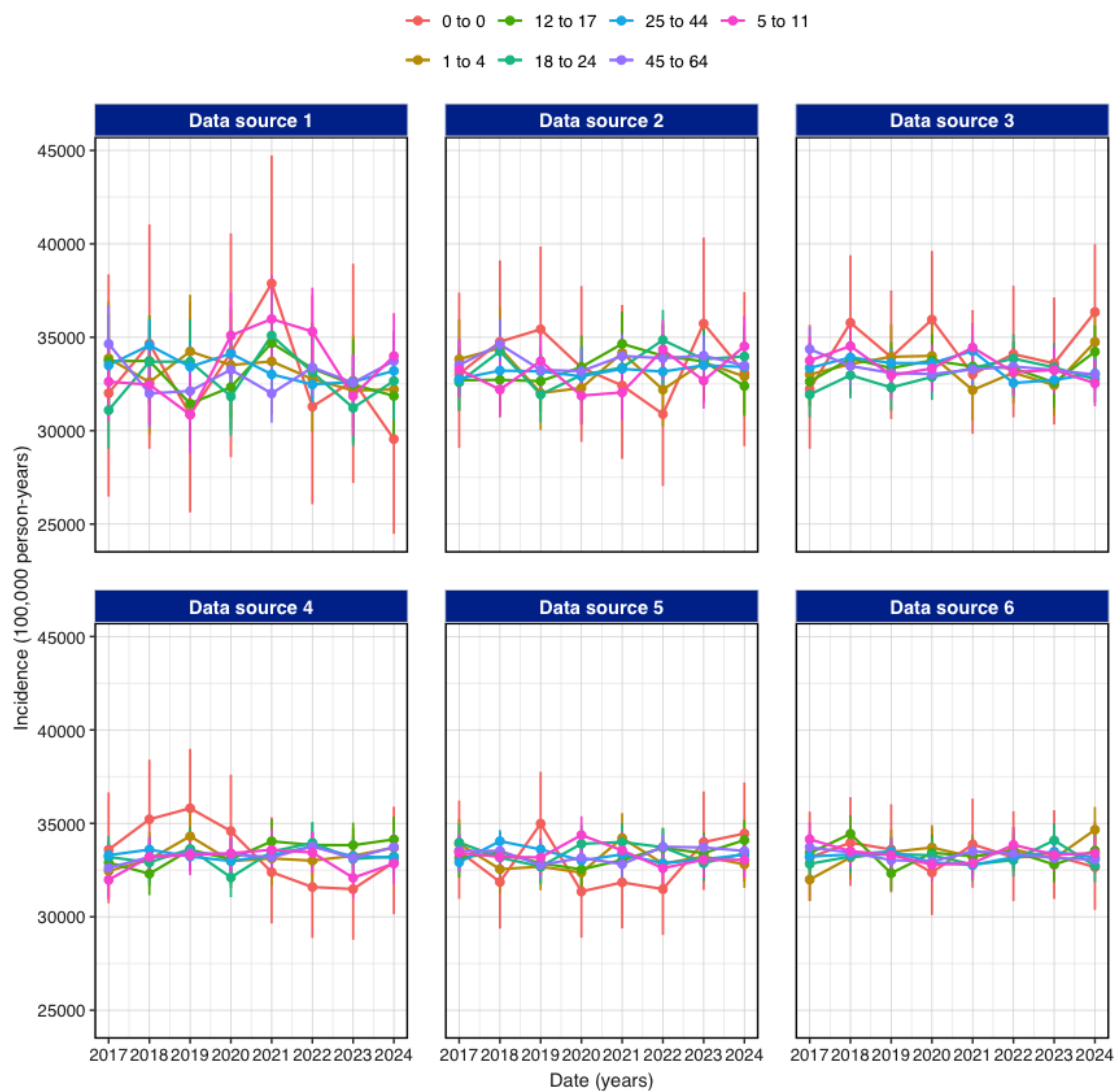
- Figure 1a. Annual incidence rate of invasive meningococcal disease (IMD) from 2017 to 2024, by data source (Objective 1).
- Figure 2a. Annual incidence rate of mortality due to invasive meningococcal disease (IMD) from 2017 to 2024, by data source (Objective 2).
- Figure 3a. Annual incidence rate of gonorrhoea from 2017 to 2024, by data source (Objective 3).



- Figure 1b. Annual incidence rate of invasive meningococcal disease (IMD) from 2017 to 2024, by data source and sex (Objective 1).
- Figure 2b. Annual incidence rate of mortality due to invasive meningococcal disease (IMD) from 2017 to 2024, by data source and sex (Objective 2).
- Figure 3b. Annual incidence rate of gonorrhoea from 2017 to 2024, by data source and sex (Objective 3).



- Figure 1c. Annual incidence rate of invasive meningococcal disease (IMD) from 2017 to 2024, by data source and age group (Objective 1).
- Figure 2c. Annual incidence rate of mortality due to invasive meningococcal disease (IMD) from 2017 to 2024, by data source and age group (Objective 2).
- Figure 3c. Annual incidence rate of gonorrhoea from 2017 to 2024, by data source and age group (Objective 3).



- Table 1a. Number of individuals with invasive meningococcal disease (IMD) during the study period, by study objective (Objective 1 and Objective 4) and data source.

| Reason                                  | Study objective | Data source   |            |               |            |               |            |               |            |               |            |               |            |
|-----------------------------------------|-----------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|
|                                         |                 | Data source 1 |            | Data source 2 |            | Data source 3 |            | Data source 4 |            | Data source 5 |            | Data source 6 |            |
|                                         |                 | N records     | N subjects | N records     | N subjects | N records     | N subjects | N records     | N subjects | N records     | N subjects | N records     | N subjects |
| Initial qualifying events               | 1, 4            | 100           | 65         | 100           | 65         | 100           | 65         | 100           | 65         | 100           | 65         | 100           | 65         |
| Record in observation period            | 1, 4            | 100           | 65         | 100           | 65         | 100           | 65         | 100           | 65         | 100           | 65         | 100           | 65         |
| Not missing record date                 | 1, 4            | 100           | 65         | 100           | 65         | 100           | 65         | 100           | 65         | 100           | 65         | 100           | 65         |
| Drop duplicate records                  | 1, 4            | 99            | 65         | 99            | 65         | 99            | 65         | 99            | 65         | 99            | 65         | 99            | 65         |
| cohort_start_date after 2017-01-01      | 1, 4            | 9             | 8          | 9             | 8          | 9             | 8          | 9             | 8          | 9             | 8          | 9             | 8          |
| Prior observation requirement: 30 days  | 1               | 7             | 6          | 7             | 6          | 7             | 6          | 7             | 6          | 7             | 6          | 7             | 6          |
| Collapse cohort with a gap of 30 days.  | 1, 4            | 7             | 6          | 7             | 6          | 7             | 6          | 7             | 6          | 7             | 6          | 7             | 6          |
| Prior observation requirement: 365 days | 4               | –             | –          | –             | –          | –             | –          | –             | –          | –             | –          | –             | –          |

N = number.

- Table 1b. Number of individuals with gonorrhoea during the study period, by study objective (Objective 3 and 4) and data source.

| Reason                                  | Study objective | Data source   |            |               |            |               |            |               |            |               |            |               |            |
|-----------------------------------------|-----------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|
|                                         |                 | Data source 1 |            | Data source 2 |            | Data source 3 |            | Data source 4 |            | Data source 5 |            | Data source 6 |            |
|                                         |                 | N records     | N subjects | N records     | N subjects | N records     | N subjects | N records     | N subjects | N records     | N subjects | N records     | N subjects |
| Initial qualifying events               | 1, 4            | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         |
| Record in observation period            | 1, 4            | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         |
| Not missing record date                 | 1, 4            | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         |
| Drop duplicate records                  | 1, 4            | 99            | 66         | 99            | 66         | 99            | 66         | 99            | 66         | 99            | 66         | 99            | 66         |
| cohort_start_date after 2017-01-01      | 1, 4            | 11            | 11         | 11            | 11         | 11            | 11         | 11            | 11         | 11            | 11         | 11            | 11         |
| Prior observation requirement: 30 days  | 2               | 7             | 7          | 7             | 7          | 7             | 7          | 7             | 7          | 7             | 7          | 7             | 7          |
| Collapse cohort with a gap of 30 days.  | 1, 4            | 7             | 7          | 7             | 7          | 7             | 7          | 7             | 7          | 7             | 7          | 7             | 7          |
| Prior observation requirement: 365 days | 4               | 5             | 5          | 5             | 5          | 5             | 5          | 5             | 5          | 5             | 5          | 5             | 5          |

N = number.

- Table 1c. Number of individuals with the outcome of death due to invasive meningococcal disease (IMD) during the study period, by study objective (Objective 2) and data source.

| Reason                                 | Data source   |            |               |            |               |            |               |            |               |            |               |            |
|----------------------------------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|
|                                        | Data source 1 |            | Data source 2 |            | Data source 3 |            | Data source 4 |            | Data source 5 |            | Data source 6 |            |
|                                        | N records     | N subjects | N records     | N subjects | N records     | N subjects | N records     | N subjects | N records     | N subjects | N records     | N subjects |
| Initial qualifying events              | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         |
| Record in observation period           | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         |
| Not missing record date                | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         |
| Drop duplicate records                 | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         | 100           | 66         |
| cohort_start_date after 2017-01-01     | 13            | 11         | 13            | 11         | 13            | 11         | 13            | 11         | 13            | 11         | 13            | 11         |
| Prior observation requirement: 30 days | 11            | 10         | 11            | 10         | 11            | 10         | 11            | 10         | 11            | 10         | 11            | 10         |
| Collapse cohort with a gap of 30 days. | 11            | 10         | 11            | 10         | 11            | 10         | 11            | 10         | 11            | 10         | 11            | 10         |

N = number.

- Table 2a. Demographic and clinical characteristics of individuals with the diagnosis of invasive meningococcal disease (IMD) from 2017 to 2024, by data source (Objective 4).

| Variable name                                            | Variable level | Estimate name     | Data source   |               |               |               |               |               |
|----------------------------------------------------------|----------------|-------------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                                          |                |                   | Data source 1 | Data source 2 | Data source 3 | Data source 4 | Data source 5 | Data source 6 |
| Demographics at index date                               |                |                   |               |               |               |               |               |               |
| Number records                                           | –              | N                 | <5            | <5            | <5            | <5            | <5            | <5            |
| Number subjects                                          | –              | N                 | <5            | <5            | <5            | <5            | <5            | <5            |
| Age                                                      | –              | Median [Q25, Q75] | –             | –             | –             | –             | –             | –             |
| Sex                                                      | Female         | N (%)             | <5            | <5            | <5            | <5            | <5            | <5            |
|                                                          | Male           | N (%)             | <5            | <5            | <5            | <5            | <5            | <5            |
| Risk factors (12 months prior to index date)             |                |                   |               |               |               |               |               |               |
| HIV infection                                            | –              | N (%)             | <5            | <5            | <5            | <5            | <5            | <5            |
| Persistent complement component deficiencies             | –              | N (%)             | <5            | <5            | <5            | <5            | <5            | <5            |
| Use of complement inhibitors                             | –              | N (%)             | <5            | <5            | <5            | <5            | <5            | <5            |
| Functional or anatomic asplenia                          | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Clinical manifestations (7 to 1 day prior to index date) |                |                   |               |               |               |               |               |               |
| Meningitis                                               | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Sepsis meningococemia                                    | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Septic shock                                             | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Haemorrhagic rash purpura fulminans petechial lesions    | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Pneumonia                                                | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Septic arthritis                                         | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Clinical manifestations (at index date)                  |                |                   |               |               |               |               |               |               |
| Meningitis                                               | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Sepsis meningococemia                                    | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Septic shock                                             | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Haemorrhagic rash purpura fulminans petechial lesions    | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Pneumonia                                                | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Septic arthritis                                         | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |

| Variable name                                                         | Variable level | Estimate name | Data source   |               |               |               |               |               |
|-----------------------------------------------------------------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                                                       |                |               | Data source 1 | Data source 2 | Data source 3 | Data source 4 | Data source 5 | Data source 6 |
| Clinical manifestations (1 to 30 days after index date)               |                |               |               |               |               |               |               |               |
| Septic shock                                                          | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Meningitis                                                            | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Sepsis meningococemia                                                 | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Haemorrhagic rash purpura fulminans petechial lesions                 | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Pneumonia                                                             | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Septic arthritis                                                      | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Clinical manifestations (7 days prior to index date to 30 days after) |                |               |               |               |               |               |               |               |
| Septic shock                                                          | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Meningitis                                                            | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Sepsis meningococemia                                                 | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Haemorrhagic rash purpura fulminans petechial lesions                 | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Pneumonia                                                             | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Septic arthritis                                                      | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Antibiotics (7 to 1 day prior to index date)                          |                |               |               |               |               |               |               |               |
| Meropenem                                                             | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Benzylpenicillin                                                      | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Ceftriaxone                                                           | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Cefotaxime                                                            | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Chloramphenicol                                                       | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Antibiotics (at index date)                                           |                |               |               |               |               |               |               |               |
| Meropenem                                                             | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Benzylpenicillin                                                      | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Ceftriaxone                                                           | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Cefotaxime                                                            | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Chloramphenicol                                                       | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Antibiotics (1 to 30 days after index date)                           |                |               |               |               |               |               |               |               |
| Meropenem                                                             | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Benzylpenicillin                                                      | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Ceftriaxone                                                           | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Cefotaxime                                                            | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |

| Variable name                                                    | Variable level | Estimate name | Data source   |               |               |               |               |               |
|------------------------------------------------------------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                                                  |                |               | Data source 1 | Data source 2 | Data source 3 | Data source 4 | Data source 5 | Data source 6 |
| Chloramphenicol                                                  | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| <b>Antibiotics (7 days prior to index date to 30 days after)</b> |                |               |               |               |               |               |               |               |
| Meropenem                                                        | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Benzylpenicillin                                                 | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Ceftriaxone                                                      | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Cefotaxime                                                       | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Chloramphenicol                                                  | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| <b>Meningococcal vaccines (any time prior to index date)</b>     |                |               |               |               |               |               |               |               |
| Men B                                                            | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Men C                                                            | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| MCV4                                                             | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |

IMD = invasive meningococcal disease; HIV = human immunodeficiency virus; Men B = meningococcal group B vaccine; MenC = meningococcal group C vaccine; MCV4 = quadrivalent meningococcal conjugate vaccine (serogroups A, C, W, and Y); N = number of individuals; Q25 = 25th percentile; Q75 = 75th percentile. Values <5 are reported as “<5” in accordance with data privacy requirements.

- Table 2b. Demographic and clinical characteristics of individuals with the diagnosis of gonorrhoea from 2017 to 2024, by data source (Objective 4).

| Variable name                                                                | Variable level | Estimate name     | Data source   |               |               |               |               |               |
|------------------------------------------------------------------------------|----------------|-------------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                                                              |                |                   | Data source 1 | Data source 2 | Data source 3 | Data source 4 | Data source 5 | Data source 6 |
| Demographics at index date                                                   |                |                   |               |               |               |               |               |               |
| Number records                                                               | –              | N                 | 5             | 5             | 5             | 5             | 5             | 5             |
| Number subjects                                                              | –              | N                 | 5             | 5             | 5             | 5             | 5             | 5             |
| Age                                                                          | –              | Median [Q25, Q75] | 53 [36 – 62]  | 53 [36 – 62]  | 53 [36 – 62]  | 53 [36 – 62]  | 53 [36 – 62]  | 53 [36 – 62]  |
| Sex                                                                          | Female         | N (%)             | <5            | <5            | <5            | <5            | <5            | <5            |
|                                                                              | Male           | N (%)             | <5            | <5            | <5            | <5            | <5            | <5            |
| Concomitant sexually transmitted infections (7 to 1 day prior to index date) |                |                   |               |               |               |               |               |               |
| Trichomonas vaginalis                                                        | –              | N (%)             | <5            | <5            | <5            | <5            | <5            | <5            |
| HIV infection                                                                | –              | N (%)             | <5            | <5            | <5            | <5            | <5            | <5            |
| Chlamydia trachomatis                                                        | –              | N (%)             | <5            | <5            | <5            | <5            | <5            | <5            |
| Syphilis                                                                     | –              | N (%)             | <5            | <5            | <5            | <5            | <5            | <5            |
| Mycoplasma genitalium                                                        | –              | N (%)             | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |

| Variable name                                                                             | Variable level | Estimate name | Data source   |               |               |               |               |               |
|-------------------------------------------------------------------------------------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                                                                           |                |               | Data source 1 | Data source 2 | Data source 3 | Data source 4 | Data source 5 | Data source 6 |
| Concomitant sexually transmitted infections (at index date)                               |                |               |               |               |               |               |               |               |
| Trichomonas vaginalis                                                                     | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Chlamydia trachomatis                                                                     | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Syphilis                                                                                  | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| HIV infection                                                                             | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Mycoplasma genitalium                                                                     | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Concomitant sexually transmitted infections (1 to 30 days after index date)               |                |               |               |               |               |               |               |               |
| Trichomonas vaginalis                                                                     | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Chlamydia trachomatis                                                                     | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Syphilis                                                                                  | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| HIV infection                                                                             | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Mycoplasma genitalium                                                                     | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Concomitant sexually transmitted infections (7 days prior to index date to 30 days after) |                |               |               |               |               |               |               |               |
| Trichomonas vaginalis                                                                     | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| HIV infection                                                                             | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Chlamydia trachomatis                                                                     | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Syphilis                                                                                  | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Mycoplasma genitalium                                                                     | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Clinical manifestations (7 to 1 day prior to index date)                                  |                |               |               |               |               |               |               |               |
| Urethritis                                                                                | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Vulvovaginitis                                                                            | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Disseminated gonococcal infection                                                         | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Septic arthritis                                                                          | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Cervicitis                                                                                | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Pharyngitis                                                                               | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Epididymitis prostatitis                                                                  | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Proctitis                                                                                 | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |

| Variable name                                                         | Variable level | Estimate name | Data source   |               |               |               |               |               |
|-----------------------------------------------------------------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                                                       |                |               | Data source 1 | Data source 2 | Data source 3 | Data source 4 | Data source 5 | Data source 6 |
| Pelvic inflammatory disease                                           | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Clinical manifestations (at index date)                               |                |               |               |               |               |               |               |               |
| Urethritis                                                            | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Vulvovaginitis                                                        | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Disseminated gonococcal infection                                     | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Septic arthritis                                                      | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Cervicitis                                                            | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Pharyngitis                                                           | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Epididymitis prostaticitis                                            | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Proctitis                                                             | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Pelvic inflammatory disease                                           | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Clinical manifestations (1 to 30 days after index date)               |                |               |               |               |               |               |               |               |
| Urethritis                                                            | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Vulvovaginitis                                                        | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Disseminated gonococcal infection                                     | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Pelvic inflammatory disease                                           | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Septic arthritis                                                      | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Cervicitis                                                            | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Pharyngitis                                                           | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Epididymitis prostaticitis                                            | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Proctitis                                                             | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Clinical manifestations (7 days prior to index date to 30 days after) |                |               |               |               |               |               |               |               |
| Urethritis                                                            | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Vulvovaginitis                                                        | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Disseminated gonococcal infection                                     | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |

| Variable name                                             | Variable level | Estimate name | Data source   |               |               |               |               |               |
|-----------------------------------------------------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                                           |                |               | Data source 1 | Data source 2 | Data source 3 | Data source 4 | Data source 5 | Data source 6 |
| Pelvic inflammatory disease                               | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Septic arthritis                                          | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Cervicitis                                                | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Pharyngitis                                               | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Epididymitis prostaticitis                                | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Proctitis                                                 | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Antibiotics (7 to 1 day prior to index date)              |                |               |               |               |               |               |               |               |
| Ceftriaxone                                               | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Doxycycline                                               | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Gentamicin                                                | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Cefixime                                                  | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Azithromycin                                              | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Spectinomycin                                             | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Antibiotics (at index date)                               |                |               |               |               |               |               |               |               |
| Ceftriaxone                                               | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Doxycycline                                               | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Gentamicin                                                | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Cefixime                                                  | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Azithromycin                                              | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Spectinomycin                                             | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Antibiotics (1 to 30 days after index date)               |                |               |               |               |               |               |               |               |
| Ceftriaxone                                               | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Doxycycline                                               | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Gentamicin                                                | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Cefixime                                                  | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Azithromycin                                              | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Spectinomycin                                             | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Antibiotics (7 days prior to index date to 30 days after) |                |               |               |               |               |               |               |               |
| Ceftriaxone                                               | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Doxycycline                                               | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Gentamicin                                                | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Cefixime                                                  | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Azithromycin                                              | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |

| Variable name                                         | Variable level | Estimate name | Data source   |               |               |               |               |               |
|-------------------------------------------------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                                       |                |               | Data source 1 | Data source 2 | Data source 3 | Data source 4 | Data source 5 | Data source 6 |
| Spectinomycin                                         | –              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
| Meningococcal vaccines (any time prior to index date) |                |               |               |               |               |               |               |               |
| Men B                                                 | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Men C                                                 | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| MCV4                                                  | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |

HIV = human immunodeficiency virus; MCV4 = quadrivalent meningococcal conjugate vaccine (serogroups A, C, W, and Y); Men B = meningococcal group B vaccine; MenC = meningococcal group C vaccine; N = number of individuals; Q25 = 25th percentile; Q75 = 75th percentile. Values <5 are reported as “<5” in accordance with data privacy requirements.

- Table 3. Availability and distribution of meningococcal serogroups among IMD cases, by data source (Objective 5).

| Variable name                        | Variable level | Estimate name | Data source   |               |               |               |               |               |
|--------------------------------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                      |                |               | Data source 1 | Data source 2 | Data source 3 | Data source 4 | Data source 5 | Data source 6 |
| Number IMD cases                     | –              | N             | 5             | 5             | 5             | 5             | 5             | 5             |
| Number IMD cases with serogroup data | –              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
| Serogroup                            | A              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
|                                      | B              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
|                                      | C              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |
|                                      | W              | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |
|                                      | Y              | N (%)         | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      | 0 (0.00)      |

IMD = invasive meningococcal disease; N = number of individuals. Values <5 are reported as “<5” in accordance with data privacy requirements. Percentages for serogroups are calculated among individuals with available serogroup information.

- Table 4. Number of individuals with a meningococcal carriage-related record, overall and with a positive laboratory measurement for *Neisseria meningitidis*, by data source (Objective 5).

| Variable name                                                      | Estimate name | Data source   |               |               |               |               |               |
|--------------------------------------------------------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                                                    |               | Data source 1 | Data source 2 | Data source 3 | Data source 4 | Data source 5 | Data source 6 |
| Number of individuals with a meningococcal carriage-related record | N             | 8             | 8             | 8             | 8             | 8             | 8             |
| Positive laboratory measurement for <i>Neisseria meningitidis</i>  | N (%)         | <5            | <5            | <5            | <5            | <5            | <5            |

N = number of individuals. Values <5 are reported as “<5” in accordance with data privacy requirements. Percentages for positive laboratory measurements are calculated among individuals with a meningococcal carriage-related record.

An interactive dashboard will be generated by incorporating all the results (tables and figures) included in the PDF report mentioned above.

## 8.9. Evidence synthesis

Results from analyses described in [Section 8.8.3](#) will be presented separately for each data source. No meta-analysis of results will be conducted.

## 9. STRENGTHS AND LIMITATIONS

This study will leverage routinely collected healthcare data from multiple European data sources mapped to the OMOP CDM, enabling the generation of standardised and comparable evidence across heterogeneous healthcare systems. The use of a CDM and standardised phenotyping procedures, including expert review and iterative refinement, represents a key strength of the study and supports reproducibility and scalability within the DARWIN EU® network.

Another strength of the study is the use of multiple complementary outcome definitions for IMD and gonorrhoea, including laboratory-based and diagnosis-based approaches. Where data is available, this will allow assessment of the availability, completeness, and validity of different phenotypes across data sources, and will support the identification of pragmatic definitions for future vaccine effectiveness studies. The evaluation of overlap between definitions is a particular strength, as it enables the assessment of the extent to which diagnosis-based definitions may serve as proxies for laboratory-confirmed cases in settings with limited laboratory data. In addition, invasive meningococcal disease is a notifiable condition in EU/EEA countries under national surveillance systems. In principle, this is expected to support the completeness of case ascertainment and recording of IMD diagnoses.

Several limitations inherent to the use of routinely collected data must be considered. Electronic health records are primarily collected for clinical care rather than research purposes and may therefore be subject to incomplete or inconsistent recording of diagnoses, laboratory results, treatments, and comorbidities. In particular, the documentation of comorbidities and risk factors used for patient characterisation may vary across data sources, leading to potential misclassification or under-ascertainment.

Additionally, and specifically for this study, in data sources not linked to hospital data (IQVIA LPD Belgium), cases of IMD occurring in hospital settings or deaths occurring outside of primary care may not be fully captured. Consequently, incidence of mortality due to IMD may be underestimated in some settings. Results will therefore be reported separately for data sources containing only primary care data and those including both primary and hospital data.

Similarly, gonorrhoea diagnoses may be incompletely recorded or not/incompletely linked with data from specialised settings such as sexual and reproductive health services, urology clinics, community testing services, and private healthcare providers. Consequently, gonorrhoea incidence may be underestimated in data sources that do not comprehensively capture these settings.

Furthermore, the results of this study will only reflect the populations covered by the included data sources. Differences in population structure, healthcare access, and surveillance systems across countries should be considered when interpreting the findings.

For meningococcal carriage, important limitations apply. Observations of meningococcal carriage are expected to be rare in this study, as carriage is not routinely monitored in usual care outside of observational studies or clinical trials with this specific objective. In addition, standard clinical vocabularies do not include specific laboratory measurement codes that distinguish between specimens collected for carriage screening and those obtained for clinical diagnosis of meningococcal disease. In this study, meningococcal carriage is therefore operationalised using condition or observation codes explicitly indicating carriage, where available, and analyses are restricted to descriptive characterisation of these

records. Furthermore, the population undergoing testing is not representative of the general population. As a result, carriage prevalence cannot be reliably estimated either at the population level or among tested individuals, since, as explained above, it is not possible to distinguish whether tests were performed for carriage screening or for clinical indications. Accordingly, this study will not estimate carriage prevalence but will instead report the number of individuals with carriage-related records and characterise their laboratory measurements.

Additional limitations relate to data availability for other variables. Information on meningococcal serogroups is expected to be limited or missing in many data sources, based on the preliminary feasibility assessment, and laboratory measurements, including both testing records and test results, may not be completely captured. Similarly, cause-of-death information may not be available in all data sources, requiring the use of proxy definitions for IMD-related mortality. Finally, given the expected heterogeneity in the availability of laboratory and cause-of-death data across data sources, not all outcome definitions will be estimable in all data sources. These limitations may affect the completeness and specificity of case ascertainment and should therefore be considered when interpreting incidence estimates and comparisons across data sources.

Finally, although this study aims to identify IMD cases across multiple electronic healthcare data sources and evaluate alternative case definitions for use in future studies, these data sources were not designed for public health surveillance. Consequently, estimates generated from routinely collected healthcare data may differ from those obtained through dedicated national surveillance systems. Surveillance data remain the primary source for monitoring IMD incidence and mortality at the European level and may provide more complete case ascertainment in some settings.

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## 10. ANNEXES

### ANNEX I. Description of data sources

#### IQVIA Longitudinal Patient Database Belgium (IQVIA LPD Belgium)

| #  | Section                                           | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Data source identification and country            | IQVIA LPD Belgium (IQVIA Longitudinal Patient Database Belgium) Belgium                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2  | Data partner information section                  | IQVIA (IQVIA)<br>IQVIA Europe                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 3  | Coverage and timespan                             | Data collection since: 2005<br>Extent: Nation-wide.<br>Panel of 300 GPs in Belgium. The panel is maintained as a representative sample of the primary care physician population in Belgium, according to three criteria known to influence prescribing: age, sex, and geographical distribution.                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 4  | Healthcare setting / type of data                 | Primary care – General Practitioner.<br>Ambulatory visits, with diagnosis, prescriptions, procedures, and laboratory tests.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 5  | Data collection process                           | Outpatient electronic health records.<br>Records are entered by GPs at the healthcare encounter.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 6  | General representativeness                        | The panel of contributing physicians (a stable 300 GPs) is maintained as a representative sample of the primary care physician population in Belgium, according to three criteria known to influence prescribing: age, sex, and geographical distribution. The panel consists of a stable 300 GPs that are geographically well spread. The total number of active GPs in Belgium is 15,602. The regional geographical spread of physicians in the LPD data is also representative of the distribution across the country: 57% GPs in the North (compared to 54% nationally), 31% in the South (33% nationally), and 12% in Brussels (13%).The provider of the data has more than 2,250 GPs under contract so in case of a drop out a replacement is easily found. |
| 7  | Data content /source coding                       | No information on source coding.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 8  | Data Harmonisation                                | The data has been mapped to the OMOP CDM v5 and the OMOP standard vocabularies. The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network.<br>The patient ID is per practice. So a patient can have different IDs in the DB, one per practice. In Belgium, patients are typically registered at only one GP practice, so duplication should be minimal.                                                                                                                                                                                                                                                                                                                                                  |
| 9  | Quality control (data source specific)            | No QC. Integrity constraints only.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 10 | Linkage                                           | No linkage.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 11 | Vital status                                      | Death information is derived from healthcare events.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 12 | Limitations                                       | Observation period is defined from first to last visit, causing a drop in 'healthy' persons at the end of the interval. This creates an artefactual increase in incidence and prevalence ratios. There is no sociodemographic or over-the-counter medication information.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 13 | Main references                                   | No main reference provided.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 14 | Link to HMA-EMA catalogue and data source webpage | HMA-EMA Catalogue entry: <a href="https://catalogues.ema.europa.eu/data-source/1111116">https://catalogues.ema.europa.eu/data-source/1111116</a><br>Website: <a href="https://iqvia.com">https://iqvia.com</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

## Croatian National Public Health Information System (NAJS)

| # | Section                                | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|---|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Data source identification and country | NAJS (Croatian National Public Health Information System)<br>Croatia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 2 | Data partner information section       | Croatian Institute of Public Health (CIPH)<br>Department of Data Science and Analytics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 3 | Coverage and timespan                  | Data collection since: 1998<br>Extent: Nation-wide.<br>Geographic coverage covers whole Croatia, with various levels of resolution for different registries. Current estimates for the population in Croatia will be available at: <a href="https://podaci.dzs.hr/hr/podaci/stanovnistvo/procjena-stanovnistva/">https://podaci.dzs.hr/hr/podaci/stanovnistvo/procjena-stanovnistva/</a> for each year. The total and active person count in the NAJS data is larger than the current population of Croatia. This explained by: a) the person table included deceased and all previously insured people and b) there is no information about insurance ending, c) healthcare is also used by people with dual citizenship from neighbouring countries It is known that a lot of people emigrated (300k-400k) and weren't included in the last population census but still are in the NAJS database. There is also an influx of immigrant workers that are insured and registered but weren't included in the census.                                                                                                                                                                                                                                                                                                                    |
| 4 | Healthcare setting / type of data      | Primary care – General Practitioner, and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care.<br>Primary care – gps, and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care. For both inpatient and outpatient setting diagnoses, medication, procedures, and measurements are captured. The year of availability of information depends on the setting • 2014-2025 for biochemical lab tests in primary care from EHR patients records (measurements with results) • 2015-2025 for primary care data from EHR patient records (conditions, procedures, and drug prescriptions) • 2015- 2024 for inpatient hospital data from EHR administrative records (conditions, procedures, measurements without results and drug administrations) • 2016-2025 for health risk assessment data entered by GPs (measurements with results - height, weight...) • 2016-2022 for secondary conciliatory care data from EHR administrative records (conditions, procedures, measurements without results and drug administrations) • 2016-2022 for emergency care data from EHR patient records (conditions) • 2017-2025 for hospital records from registry data (conditions and procedures) • 2020-2025 for vaccination data from EHR patient records |
| 5 | Data collection process                | Inpatient hospital billing systems, and Other.<br>Data is entered by clinicians at healthcare contact, then combined by CIPH into the NAJS database and integrated with registries for public health purposes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 6 | General representativeness             | The data is collected from the evidence of public health records collected for public health purposes, as the majority of health care in Croatia is public and under single health insurance provider. Personal details are collected to a better extent for insured individuals compared to uninsured patients, who are excluded in the ETL process.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 7 | Data content /source coding            | Medication prescriptions are recorded with ATC codes with an additional 3 digit code denoting the package. Diagnoses with ICD10 codes (Australian modification). Procedures with local source codes. Lab results with local source codes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 8 | Data Harmonisation                     | The data has been mapped to the OMOP CDM v5 and the OMOP standard vocabularies. The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network.<br>Records from 2017 include insured patients with reliable IDs. Uninsured patients do not have reliable IDs. For example, if a patient changed her status from insured to uninsured, or vice versa, she could be counted several times, as could tracking records from before 2017 and after. By using the unique personal identifier for Croatian citizens, it can be checked and verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 9 | Quality control (data source specific) | There is a network of registry personnel (leaders, administrators, coders, sources) working on data coverage and other quality dimensions. An analytical team routinely checks for erroneous entries in hospital records, removing double entries, false dates, and overlapping stays. Entries                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

| #  | Section                                           | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----|---------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                                                   | without enough data or with obviously erroneous dates from primary care analysis are being excluded.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 10 | Linkage                                           | The national death registry is updated yearly, with one year lag, but the fact of someone's death (just the date) is updated daily, without the cause of death or any other additional details. Primary care is updated weekly and hospital level care monthly. Specific registries are included in NAJS (e.g. diabetes registry), where inclusion criteria vary across these registries.                                                                                                                                                                                                   |
| 11 | Vital status                                      | NAJS is linked to the national death registry.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 12 | Limitations                                       | Hospital data is available from 2017 onwards. This is often used as start of data collection, while laboratory and GP data is captured before that (since 2014 and 2015 respectively). Drug duration is often not available, and set to 1 day for administration and 30 days for prescription. Hospital discharge summaries are currently not captured in NAJS. Hospital drug administration data is less reliable than prescription data from primary care, with some drugs (monoclonal antibodies / precision medicine drugs) that require additional approval not being recorded at all. |
| 13 | Main references                                   | No main reference provided.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 14 | Link to HMA-EMA catalogue and data source webpage | HMA-EMA Catalogue entry: <a href="https://catalogues.ema.europa.eu/data-source/1111155">https://catalogues.ema.europa.eu/data-source/1111155</a><br>Website: <a href="https://www.hzjz.hr/nacionalni-javnozdravstveni-informacijski-sustav-najs/">https://www.hzjz.hr/nacionalni-javnozdravstveni-informacijski-sustav-najs/</a>                                                                                                                                                                                                                                                            |

### Danish Data Health Registries (DK-DHR)

| # | Section                                | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Data source identification and country | DK-DHR (Danish Data Health Registries)<br>Denmark                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 2 | Data partner information section       | Danish Medicines Agency (DKMA)<br>Data & Data Analysis (DAD)                                                                                                                                                                                                                                                                                                                                                                                                           |
| 3 | Coverage and timespan                  | Data collection since: 1995<br>Extent: Nation-wide.<br>The data is representative of the entire Danish population.                                                                                                                                                                                                                                                                                                                                                     |
| 4 | Healthcare setting / type of data      | Community pharmacists, and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care.<br>The following data elements are collected: diagnosis (including rare diseases and pregnancy data), hospital admissions, discharge and ICU data, Cause of death, Drug prescriptions, dispensing, vaccination and contraception, Procedures (surgical and non-surgical hospital), and Sociodemographic information (sex and age only). |
| 5 | Data collection process                | Outpatient electronic health records, and Inpatient hospital electronic health records, and Registries, and Other.<br>All causes of deaths, all retrieved drug prescriptions, all records of vaccinations, all hospital inpatient and outpatients contacts including disease diagnoses and hospital surgical and non-surgical procedures, histologically confirmed incident cancers, laboratory test results for the entire Danish population from 1/1/1995 onwards.   |
| 6 | General representativeness             | The data is representative of the entire Danish population. Healthcare is free in Denmark, so we do not expect any bias in data collection based on socio-economic status.                                                                                                                                                                                                                                                                                             |
| 7 | Data content /source coding            | Diagnoses and causes of death are collected using the ICD-10 vocabulary. ATC and RxNorm are used for Drugs. SNOMED codes are used for Procedures.                                                                                                                                                                                                                                                                                                                      |
| 8 | Data Harmonisation                     | The data has been mapped to the OMOP CDM v5 and the OMOP standard vocabularies. The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network.<br>Patients have unique identifiers used to link datasets.                                                                                                                                                                                                         |

| #  | Section                                           | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9  | Quality control (data source specific)            | The data we have received relating to nationwide Danish Health Data registries offer an opportunity for large-scale, population-based studies with several advantages 1) Their large size improves the precision of estimates and enables the study of rare exposures and outcomes with long-term latency, 2) Inclusion of nearly all individuals in the target population ensures that the data reflect routine clinical care and all clinical segments of the source population, 3) Data are collected independently of each research study, thus minimising certain types of bias, e.g., non-response, and the influence from attention to the research question on the diagnostic process. Before the source data is sent to us, the Danish Health Data Authority runs and does comprehensive checks of the registry table data validity of the variables, breaks in data, changes in variable coding, missingness, etc. We perform checks of missingness/completeness in relation to requested variables. In essence, we are receiving a dump of a mirror of the data that is controlled by the SDS. The documentation performed by SDS is available online, in Danish primarily <a href="https://www.esundhed.dk/Dokumentation">https://www.esundhed.dk/Dokumentation</a> (all variables), but also in English <a href="https://sundhedsdatastyrelsen.dk/da/english/health_data_and_registers/national_health_registers">https://sundhedsdatastyrelsen.dk/da/english/health_data_and_registers/national_health_registers</a> |
| 10 | Linkage                                           | There is no linkage in this data source.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 11 | Vital status                                      | The Cause of Death registry (DAR) is used, the cause of death is collected using ICD-10 codes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 12 | Limitations                                       | <ul style="list-style-type: none"> <li>- Lifestyle factors (such as smoking status and weight) are only complete for pregnant women.</li> <li>- Stillborn children will not have any records in our CDM. This means that e.g. birth weight and birth length of stillborns is not recorded.</li> <li>- There is no information on key socio-economic status (SES) factors, such as occupation, education, and income.</li> <li>- Patient contacts in primary care (visits to the GP) are not included. Consequently, the incidence of chronic diseases like Type 2 Diabetes (T2D) and asthma must be determined using drug prescriptions as a proxy.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 13 | Main references                                   | Schmidt M, Schmidt SAJ, Adelborg K, Sundbøll J, Laugesen K, Ehrenstein V, Sørensen HT "The Danish health care system and epidemiological research: from health care contacts to database records." Clinical epidemiology (2019): 31372058                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 14 | Link to HMA-EMA catalogue and data source webpage | HMA-EMA Catalogue entry: <a href="https://catalogues.ema.europa.eu/data-source/1111217">https://catalogues.ema.europa.eu/data-source/1111217</a><br>Website: <a href="https://sundhedsdatastyrelsen.dk/da/english/health_data_and_registers/healthdatadenmark">https://sundhedsdatastyrelsen.dk/da/english/health_data_and_registers/healthdatadenmark</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

### Finnish Care Register for Health Care (FinOMOP-THL)

| # | Section                                | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|---|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Data source identification and country | FinOMOP-THL (Finnish Care Register for Health Care)<br>Finland                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2 | Data partner information section       | FinOMOP (FinOMOP)<br>The Department of Data and Analytics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 3 | Coverage and timespan                  | Data collection since: 1998<br>Extent: Nation-wide.<br>The current CDM population comprises all persons having been alive and residing in Finland since the beginning of 2011.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 4 | Healthcare setting / type of data      | <p>Primary care – General Practitioner, and primary care specialists (e.g. paediatricians), and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care, and other (specify).</p> <p>THL maintains health registers that cover both public and private, primary, and specialised inpatient, urgent and outpatient health care encounters in Finland, starting from 2011. The entire public sector and private inpatient encounters have been included since 2011, while private outpatient encounters, including occupational care, are included since 2020.</p> <p>Since 1998, the Care Register for Health Care (TerveysHilmo) has covered both public outpatient and inpatient specialized care and private inpatient care. Since 2009, the Finnish National Vaccination Register has covered all vaccinations from the public sector and from a large part of private vaccination providers, with the data coverage from both sections being very good to complete from 2020 onwards.</p> |

| #  | Section                                | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                                        | <p>Since 2011, the Register of Primary Health Care Visits (AvoHilmo) has covered public primary care. Since 2020, the register has also covered private outpatient care and occupational care. In addition, the CDM also contains positive COVID-19 test results from the Finnish National Infectious Diseases Register. The register itself covers all laboratory confirmations for around 70 specific microbes from 1995 onwards, but only COVID-19 has currently been mapped to the CDM. The CDM also includes prescription records from multiple different sources. Both Care Register for Health Care and Register of Primary Health Care Visits contain very basic prescription data recorded during health care encounters that include just the ATC-code and trade name of medication. More comprehensive prescription data from Kanta Prescription Centre, maintained by Social Insurance Institution of Finland (Kela), has been integrated into the CDM since its 2024 release. The Kanta Prescription records are based electronic prescriptions, which were adopted by most public health care providers in 2010 and by most private providers by 2017.</p>                                                                                                                                                                                                                                                                      |
| 5  | Data collection process                | <p>Outpatient electronic health records, and Inpatient hospital electronic health records, and Registries.</p> <p>Data is entered by clinicians upon healthcare contact and processed by THL (Kela in the case of Kanta Prescription Centre).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 6  | General representativeness             | <p>The THL data has national coverage and is therefore well representative of the Finnish population. Using the complete population as a basis for the person table also serves to facilitate calculations on a population level, e.g. incidence rates.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 7  | Data content /source coding            | <p>The following coding systems have been OMOP-mapped, typically to a good level of completeness: ICD10fi Finnish Extension, ICDPC-2, ATC, Toimenpideluokitus (procedure classification adapted from the Nordic Classification of Surgical Procedures (NCSP)), Terveystieteiden tutkimuskeskus (Hilmo specific provider speciality), Rokotustapa (AR/YDIN National classification for vaccine administration), Tupakointistatus (AR/YDIN National classification for smoking status). Vaccinations are identified on product level based on batch number, trade name, vaccine title, and ATC-code. This is mapped on brand and type in the OMOP CDM.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 8  | Data Harmonisation                     | <p>The data has been mapped to the OMOP CDM v5 and the OMOP standard vocabularies. The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network.</p> <p>Each patient in THL has a unique identifier.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 9  | Quality control (data source specific) | <p>The source data collection undergoes a structural and semantic validation before entry into the source database. Additionally, some coded variables undergo quality assessment against the respective code systems post entry into the database. The source registers are also assessed for completeness and coverage, with the aim of improving future collection in the areas where data is lacking.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 10 | Linkage                                | <p>THL is already a linkage of multiple Finnish registries (see above).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 11 | Vital status                           | <p>The National Population registry data forms the basis for forming the patient population. This ensures an up-to-date location (municipality of residence) of patients, as well as complete death occurrences (although not the cause of death).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 12 | Limitations                            | <p>All drug records in the CDM are currently based on prescriptions. Kanta Prescription Centre also includes information on drug dispensings, but these have not currently been converted into OMOP CDM. Depending on the type of the medication, a single prescription can be for up to two years dosage of the drug. This means a patient can have up to two-year breaks between observations while actively using the drug. Observation of a prescription also does not mean that the patient necessarily bought or used the medication.</p> <p>The CDM does not currently have meaningful end dates or days of supply for drug exposure. This information is not available for Care Register for Health Care or Register of Primary Health Care Visits, and for Kanta Prescription Centre it is only available in unstructured, free-form format that has not been converted into OMOP CDM. The source system for prescription drug data is only available to the DP until Dec-2023, therefore drug_exposure records from this source are only available in that time range. Not all private health care records are covered for the CDM's entire follow-up time from 2011 onwards. For Register of Primary Health Care Visits and Finnish National Vaccination Register, records from private health care have been available from 2020 onwards. For Kanta Prescription Centre, the coverage of private health care records has been</p> |

| #  | Section                                           | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
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|    |                                                   | good from 2017 onwards. The inclusion of private health care mainly presents itself as an increase in the number of observations, meaning that it has to be accounted for when interpreting any time series data from the CDM.                                                                                                                                                                                                                                                                                                                                                                       |
| 13 | Main references                                   | Häkkinen, Pirjo; Mölläri, Kaisa; Saukkonen, Sanna-Mari; Väyrynen, Riikka; Mielikäinen, Lasse; Järvelin, Jutta "Hilmo - Sosiaali- ja terveydenhuollon hoitoilmoitus 2020 : Määrittelyt ja ohjeistus : Voimassa 1.1.2020 alkaen" Terveyden ja hyvinvoinnin laitos (2019):                                                                                                                                                                                                                                                                                                                              |
| 14 | Link to HMA-EMA catalogue and data source webpage | HMA-EMA Catalogue entry: <a href="https://catalogues.ema.europa.eu/data-source/1111187">https://catalogues.ema.europa.eu/data-source/1111187</a> ; <a href="https://catalogues.ema.europa.eu/data-source/1111191">https://catalogues.ema.europa.eu/data-source/1111191</a><br>Website: <a href="https://thl.fi/en/statistics-and-data/data-and-services/register-descriptions">https://thl.fi/en/statistics-and-data/data-and-services/register-descriptions</a> ; <a href="https://www.kanta.fi/en/research-and-knowledge-management">https://www.kanta.fi/en/research-and-knowledge-management</a> |

### InGef Research Database (InGef RDB)

| # | Section                                | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|---|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Data source identification and country | InGef RDB (InGef Research Database)<br>Germany                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2 | Data partner information section       | Institute for Applied Health Research Berlin (InGef)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 3 | Coverage and timespan                  | Data collection since: 2016<br>Extent: Nation-wide.<br>The data source contains approximately 10.5 million insured persons from 50 of the 94 statutory health insurances in Germany (as of Oct 2025). Due to data protection laws for personal data in Germany, only the last 10 years of data are available in the RDB and thus in the OMOP CDM.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 4 | Healthcare setting / type of data      | Primary care – General Practitioner, and community pharmacists, and primary care specialists (e.g. paediatricians), and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care, and claims data.<br>In general, the data in the RDB reflects most of the health services paid for by statutory health insurances. In the OMOP CDM, the health services are reduced to primary and secondary care. This means that treatments by GPs and specialists (e.g. paediatricians), prescription medicines dispensed by pharmacies, hospital inpatient and outpatient care, as well as information about all insured individuals are included.<br>The following data elements are presented in the OMOP CDM: demographic information, diagnoses, procedures, dispensing drugs and advanced therapy medicinal products, vaccinations, pregnancy data (via diagnoses and procedures) and contraception. |
| 5 | Data collection process                | Insurance/administrative claims.<br>In Germany, data exchange between medical service providers and statutory health insurances is organized via central data collection centers. In addition to receiving and forwarding data, these centers also store data and provide access to third parties under strict regulations in data warehouses. The RDB contains selected, condensed and anonymized information from one of these data warehouses. Data sovereignty remains with the individual health insurance companies.                                                                                                                                                                                                                                                                                                                                                                                                               |
| 6 | General representativeness             | The RDB covers about 13% of the German population and is comparable to the German population in terms of the distribution of age and sex. Most health insurances that contribute to the RDB have nationwide coverage, meaning that the database covers all regions of Germany. Since almost all services covered by statutory health insurances are specified in national legislation, healthcare provision all over Germany is well represented in the RDB. Additionally, in Germany it is very common to stay with the same health insurance throughout life, which results in a good longitudinal coverage over the entire period of 10 years.                                                                                                                                                                                                                                                                                        |
| 7 | Data content /source coding            | The coding in the research database complies with national classification and coding rules in Germany. Diagnoses are coded according to ICD-10-GM. Inpatient and outpatient surgeries or procedures are recorded as OPS codes (German classification of Operations and Procedures). The dispensing of drugs in pharmacies is recorded using the PZN (pharmaceutical registration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

| #  | Section                                           | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                                                   | number). For drugs that miss a PZN-to-RxNorm mapping, the ATC code is used instead. In some cases, dispensed drugs can be coded using OPS codes (e.g. in hospitals) or EBM codes (fee schedule for outpatient treatments).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 8  | Data Harmonisation                                | <p>The data has been mapped to the OMOP CDM v5 and the OMOP standard vocabularies. The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network.</p> <p>In the German statutory health system, a person can only be enrolled in one health insurance at a time. However, if a person changes from one contributing insurer to another, a new ID number will be generated.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 9  | Quality control (data source specific)            | <p>The data transmitted by healthcare providers complies with the standardized requirements and formats of the Association of Statutory Health Insurances (GKV-SV). Before being imported into the research database, the data elements are checked for data format, completeness and plausibility.</p> <p>After each update of the research database, various counts are compared with the previous update to verify completeness.</p> <p>Due to the anonymity of the database, direct validation of the data (e.g., using medical records as the gold standard) is not possible.</p> <p>Due to the anonymity of the database, direct validation of the data (e.g., using medical records as the gold standard) is not possible.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 10 | Linkage                                           | Due to the anonymization of the source data, linkage is not possible.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 11 | Vital status                                      | <p>The date of death is recorded as the last day of the quarter in which the death occurred (i.e. 30/31st of Mar/Jun/Sept/Dec) as reported to the health insurance (no linkage to death registry). There is also a lag in reporting, making the death records incomplete up to a year before release date. The cause of death is not available.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 12 | Limitations                                       | <p>Ambulatory diagnoses and procedures are summarised in the source on a quarterly basis. Both are mapped to the observation table with the date set to the last day of the respective quarter (i.e. 30/31st of Mar/Jun/Sept/Dec) and the concept "History of event within 3 months" (observation_concept_id 1340222), with the actual diagnosis or procedure concept_id recorded in the field "value_as_concept_id".</p> <p>There is no vocabulary for the German pharmaceutical product codes (PZN). A direct source-to-standard-mapping has been done manually by InGef but is incomplete. The drug exposure duration is unknown. Following OMOP conventions, the end date is always set to dispensing date + 29.</p> <p>Outpatient and inpatient procedures are recorded as OPS codes (German Procedure Classification), for which the vocabulary is incomplete.</p> <p>Pharmacy &amp; Hospital data having a general lag of 2 calendar months, while outpatient data has a lag in delivery of up to 9 calendar months before it can be considered complete. Drugs mostly contain pharmacy-dispensed drugs. We generally don't have records of drugs administered by a healthcare professional as part of a treatment (inpatient as well as outpatient. An exception are drugs that hospitals bill separately using OPS procedures, for example expensive treatments.</p> |
| 13 | Main references                                   | Andersohn F, Walker J "Characteristics and external validity of the German Health Risk Institute (HRI) Database." Pharmacoepidemiology and drug safety (2016): 26530279                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 14 | Link to HMA-EMA catalogue and data source webpage | <p>HMA-EMA Catalogue entry: <a href="https://catalogues.ema.europa.eu/data-source/1111207">https://catalogues.ema.europa.eu/data-source/1111207</a></p> <p>Website: <a href="https://www.ingef.de/en/">https://www.ingef.de/en/</a></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

### Lithuanian Digital Health Platform (LDH)

| #  | Section                                           | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----|---------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Data source identification and country            | LDH (Lithuanian Digital Health Platform)<br>Lithuania                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2  | Data partner information section                  | State Data Agency (SDA)<br>State Data Governance Group                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 3  | Coverage and timespan                             | Data collection since: 2015<br>Extent: Nation-wide.<br>The catchment area is the whole country of Lithuania.                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 4  | Healthcare setting / type of data                 | Primary care – General Practitioner, and community pharmacists, and primary care specialists (e.g. paediatricians), and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care.<br>The following data elements are collected in the source: diagnoses, medications and vaccines, procedures, lab values, hospital admissions (including ICU), pregnancy data, cause of death, biomarker data and devices. For the initial OMOP mapping, only indication and prescription data was included. |
| 5  | Data collection process                           | Outpatient electronic health records.<br>The data is entered by clinicians at healthcare contact (EHR) but can be fully used for analyses by LDH.                                                                                                                                                                                                                                                                                                                                                                                       |
| 6  | General representativeness                        | Near-complete, but varies by dataset (e.g. almost all hospitalizations, reimbursed prescriptions, but not all elective procedures)                                                                                                                                                                                                                                                                                                                                                                                                      |
| 7  | Data content /source coding                       | The following source coding is used: ICD10 (AM) for Diagnoses, Cause of Death and Indication for use, ATC codes for medications, ACHI and national vocabularies for Procedures.                                                                                                                                                                                                                                                                                                                                                         |
| 8  | Data Harmonisation                                | The data has been mapped to the OMOP CDM v5 and the OMOP standard vocabularies. The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network.<br>All Lithuanian citizens have unique IDs. Except: new-born infants (0 days to 28 days), not identified persons and foreigners. It should have very small impact on the data analyses.                                                                                                                                             |
| 9  | Quality control (data source specific)            | Various checks are performed at the time of data creation (hospital or pharmacy EHR systems) and submission to the national EHR system. These may include validation of form fields against input structures, data types, classifiers, and removal of unsigned documents. At the State Data Agency, we additionally remove records marked as retracted due to error, a small number of duplicated death records, clearly erroneous dates, and apply some other minor corrections.                                                       |
| 10 | Linkage                                           | Yes, family linkage can be created on ad hoc basis. If needed, data can be linked to student and school registries, civil registry, tax registries, social welfare data and to medical notes, discharge letters and diagnostic reports. Linkage to Death Registry is possible.                                                                                                                                                                                                                                                          |
| 11 | Vital status                                      | Death and Cause of Death will be captured with a linkage to the Death Registry.                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 12 | Limitations                                       | No data source specific limitations documented. General limitations for the data type applicable.                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 13 | Main references                                   | Juodakis J, Zubavičiūtė S, Dapkutė A, Greičienė S, Masiliūnas R, Narkevičienė I, Trinkūnas J, Žemaitytė J, Literskė G "Data Resource Profile: The Lithuanian health data reuse pathway." International journal of epidemiology (2025): 40618226                                                                                                                                                                                                                                                                                         |
| 14 | Link to HMA-EMA catalogue and data source webpage | HMA-EMA Catalogue entry: <a href="https://catalogues.ema.europa.eu/data-source/1000000683">https://catalogues.ema.europa.eu/data-source/1000000683</a><br>Website: <a href="https://duomenys.stat.gov.lt/health-data/">https://duomenys.stat.gov.lt/health-data/</a>                                                                                                                                                                                                                                                                    |

## Norwegian Linked Health Registry data (NLHR)

| #  | Section                                | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Data source identification and country | NLHR (Norwegian Linked Health Registry data)<br>Norway                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2  | Data partner information section       | University of Oslo (UiO)<br>Faculty of Mathematics and Natural Science – Department of Pharmacy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 3  | Coverage and timespan                  | Data coverage: 2008-2023 (primary care data), 2018-2023 (secondary care data and drug dispensation data)<br><br>Extent: Nationwide. 5.5M active population.<br><br>Norway has a universal public health care system, consisting of primary and specialist health care services covering a population of approximately 5.4 million inhabitants.                                                                                                                                                                                                                                                                    |
| 4  | Healthcare setting / type of data      | Primary care – General Practitioner, and primary care specialists (e.g. paediatricians), and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care. The following registries are included: the Medical Birth Registry of Norway (MBRN), the Norwegian Prescription Registry (NorPD), the Norwegian Patient Registry (NPR), Norway Control and Payment of Health Reimbursement (KUHR), the Norwegian Surveillance System for Communicable Diseases (MSIS), the Norwegian Immunisation Registry (SYSVAK), the National Death Registry, and the National Registry (NR). |
| 5  | Data collection process                | Registries.<br>Many population-based health registries were established in the 1960s, with use of unique personal identifiers facilitating linkage between registries. Data in these health registries are used for health analysis, health statistics, improving the quality of healthcare, research, administration, and emergency preparedness.                                                                                                                                                                                                                                                                |
| 6  | General representativeness             | The NLHR data covers the full Norwegian population.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 7  | Data content /source coding            | NPR: ICD-10 for diagnosis, ATC and some special codes for drug use, Norwegian codes for clinical procedures (surgery (NCSP), medicine (NCMP) and diagnostic imaging, image-guided intervention, and nuclear medicine (NCRP)). KUHR: ICD-10 and ICPC-2 and ICPC-2B for diagnosis/procedure. NorPD: ATC. SYSVAK and MSIS: national classifications. MBRN: custom classifications by questionnaires (incl. check box variables in Maternity health care card)                                                                                                                                                        |
| 8  | Data Harmonisation                     | The data has been mapped to the OMOP CDM v5 and the OMOP standard vocabularies (SNOMED, RxNorm, LOINC). The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network.<br>Linkage between the registries was facilitated using project-specific person IDs generated from unique personal identification assigned at birth or immigration for all legal residents in Norway.                                                                                                                                                                                 |
| 9  | Quality control (data source specific) | In-house data quality checks of rates of common conditions, drug exposures, and outcomes. We compare obtained rates with official national statistics (e.g., birth statistics, yearly rates of drug dispensing, and diagnosis by age and gender). We also review missing data and outliers and inform registry holders of any unusual patterns.                                                                                                                                                                                                                                                                   |
| 10 | Linkage                                | The NLHR is, by definition, a linkage of datasets. Helsedata.no is one central portal to apply for 11 national health registries, including all the registries that have been mapped to the OMOP CDM.                                                                                                                                                                                                                                                                                                                                                                                                             |
| 11 | Vital status                           | The national death registry is linked.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 12 | Limitations                            | No data source specific limitations documented. General limitations for the data type applicable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 13 | Main references                        | Trinh NT, Houghtaling J, Bernal FL, Hayati S, Maglanoc LA, Lupattelli A, Halvorsen L, Nordeng HM "Harmonizing Norwegian registries onto OMOP common data model: Mapping challenges and opportunities for pregnancy and COVID-19 research." International journal of medical informatics (2024): 39153282                                                                                                                                                                                                                                                                                                          |

| #  | Section                                           | Description                                                                                                                                                                                                                                                                                                            |
|----|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 14 | Link to HMA-EMA catalogue and data source webpage | HMA-EMA Catalogue entry: <a href="https://catalogues.ema.europa.eu/data-source/1000000409">https://catalogues.ema.europa.eu/data-source/1000000409</a><br>Website: <a href="https://www.mn.uio.no/farmasi/english/research/groups/pharma-safe/">https://www.mn.uio.no/farmasi/english/research/groups/pharma-safe/</a> |

### The Information System for Research in Primary Care (SIDIAP)

| # | Section                                | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|---|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Data source identification and country | SIDIAP (The Information System for Research in Primary Care)<br>Catalunya, Spain                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2 | Data partner information section       | Institut d'Investigació en Atenció Primària de Salut Jordi Gol (IDIAPJGol)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 3 | Coverage and timespan                  | Data collection since: 2006<br>Extent: Regional.<br>SIDIAP is a database of primary care electronic health records of the population of Catalonia, North-East Spain. It contains pseudo-anonymised records of more than 8 million people, of which 6.1 million are active as of 2022, representing around 76% of the Catalan population.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 4 | Healthcare setting / type of data      | Primary care – General Practitioner, and hospital inpatient care.<br>SIDIAP captured data includes routine visits, socio-demographics, diagnoses, laboratory tests, drugs (prescribed and dispensed), referrals, sick leaves and lifestyle information.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 5 | Data collection process                | Outpatient electronic health records, and Inpatient hospital electronic health records.<br>Data is entered by primary care physicians upon healthcare contact, supplemented with hospital discharge records. The Institut Català de la Salut (Catalan Health Institute) is the data controller.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 6 | General representativeness             | It was previously shown that the captured SIDIAP population is highly representative of the entire Catalan region in terms of geographic, age, and sex distributions.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 7 | Data content /source coding            | SIDIAP data covers all services that occur at the Primary Care Centres, as well as support services, such as sexual and reproductive health or home end-of-life care. Drugs are coded in ATC-WHO terminology in the source data. Health outcomes are captured in ICD-10CM codes. The SIDIAP contains all laboratory tests and results performed in primary health centres. Demographics, geographical, as well as socio-economic factors are recorded for each patient.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 8 | Data Harmonisation                     | The data has been mapped to the OMOP CDM v5 and the OMOP standard vocabularies. The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network.<br>A patient has a unique id, also upon changing practice or re-registration.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 9 | Quality control (data source specific) | Internal and external validation processes are carried out to determine the data quality of the SIDIAP information at each data update.<br>These include stratifying the data by geographical regions and year in order to identify differences in data collection that need to be harmonized (e.g. recording of specific information under different codes).<br>The measurement units of variables measuring one characteristic are also homogenized (e.g. transformation of the data from every laboratory that measures haemoglobin to grams per decilitre).<br>Visual inspection of all data included in the database by week is also conducted, allowing one to see temporal patterns in the registry of a certain variable. With this information, the SIDIAP team can issue recommendations to researchers about the most common variable(s) where certain information is recorded (e.g., there are several variables with information concerning the women's menopausal status and with these visual inspection tools the SIDIAP team can inform the researchers about which related variables have the largest number of records and could be more helpful to capture menopause). Data availability (longitudinally and reliability), plausibility (range checks and unusual values), and consistency are inspected through visualisation tools. In addition, before accessing the data for a requested project, research teams have access to a quality-control report. This document contains counts, years, percentiles, maximums and minimums, incidences, and prevalence of the data requested for the project, allowing detection |

| #  | Section                                           | Description                                                                                                                                                                                                                                                                                                                                                                        |
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|    |                                                   | of inconsistencies in the data extraction prior to data delivery.<br>External validation processes of the SIDIAP database mainly include assessing the data recorded in SIDIAP through linkage to external gold standard data sources, by analysing free text, or by sending questionnaires to health professionals.                                                               |
| 10 | Linkage                                           | SIDIAP is linked to a hospital discharge database, pharmacy dispensation, and primary care laboratories. It can also be linked to other registries in Catalonia on a project by project basis.                                                                                                                                                                                     |
| 11 | Vital status                                      | Mortality is fully captured in SIDIAP. The cause of death is not available, but can be linked to the Spanish death registry on a project by project basis.                                                                                                                                                                                                                         |
| 12 | Limitations                                       | The SIDIAP data is not representative of individuals not using public primary care, and conditions that are usually followed by specialist care might not be properly captured. In addition, there is limited information on lifestyle variables. Patients are followed until Death or when transferring to another primary health care centre that does not contribute to SIDIAP. |
| 13 | Main references                                   | Recalde M, Rodríguez C, Burn E, Far M, García D, Carrere-Molina J, Benítez M, Moleras A, Pistillo A, Bolibar B, Aragón M, Duarte-Salles T "Data Resource Profile: The Information System for Research in Primary Care (SIDIAP)." International journal of epidemiology (2022): 35415748                                                                                            |
| 14 | Link to HMA-EMA catalogue and data source webpage | HMA-EMA Catalogue entry: <a href="https://catalogues.ema.europa.eu/data-source/50190">https://catalogues.ema.europa.eu/data-source/50190</a><br>Website: <a href="https://www.sidiap.org/index.php/en">https://www.sidiap.org/index.php/en</a>                                                                                                                                     |

### Valencia Health System Integrated Dataset (VID)

| # | Section                                | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|---|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Data source identification and country | VID (Valencia Health System Integrated Dataset)<br>Comunitat Valenciana, Spain                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2 | Data partner information section       | Fundació per al Foment de la Investigació Sanitària i Biomèdica de la Comunitat Valenciana (FISABIO)<br>Health Services Research & Pharmacoepidemiology Unit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 3 | Coverage and timespan                  | Data collection since: 2009<br>Extent: Regional.<br>The VID covers the general population of the Valencia region, comprising 10.7% of the Spanish population. The total population is estimated to be around 5,300,000. Note that although BIFAP (Spanish medicines agency) has National coverage, the VID data is more specific and more accurate for the Valencia region.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 4 | Healthcare setting / type of data      | Primary care – General Practitioner, and primary care specialists (e.g. paediatricians), and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care, and other (specify).<br>Both primary and secondary care settings are covered, where visits, diagnoses, medications, measurements, and procedures are recorded. The population information system collects sociodemographics, health coverage, and mortality data. The Electronic prescription and dispensing system captures all information related to medication (active ingredient, strength, duration, indication, etc.). Emergency department and hospital admissions are registered, providing information on dates, diagnoses, and procedures. Measurements are captured additionally from the vaccine information system and the Microbiological surveillance network. Mortality is also captured. |
| 5 | Data collection process                | Outpatient electronic health records, and Inpatient hospital electronic health records, and Registries.<br>Data extraction is performed by clinical IT personnel. Data is released by the health authorities on a project basis and can only be used for such purposes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 6 | General representativeness             | The population captured by the VID should represent the Valencia region well, as the VID contains data of the general population covered by the universal public health care system. About 97% of the population in this region is covered by public care.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

| #  | Section                                           | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7  | Data content /source coding                       | Prescribed and dispensed medications are coded with the ATC system. The indications of each prescription, as well as procedures are coded using ICD9CM and ICD10ES.                                                                                                                                                                                                                                                                                                                  |
| 8  | Data Harmonisation                                | The data has been mapped to the OMOP CDM v5 and the OMOP standard vocabularies. The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network.<br>Patients have a unique id between practices.                                                                                                                                                                                                                                  |
| 9  | Quality control (data source specific)            | The data is reviewed carefully with the IT personnel who perform the extraction of data and then by a senior researcher with expertise in RWD management in the HSRP unit. Several quality check scripts are run against the received data. Finally, a senior researcher with RWD and clinical expertise assesses the completeness, consistency, and quality of the data extraction. If any inconsistency or error is detected, the dataset is requested and extracted again.        |
| 10 | Linkage                                           | VID also contains hospital discharge records, emergency care discharge records, birth registry, congenital anomaly registry, perinatal mortality registry, cancer registry, pharmacy prescription and dispensing records, vaccine records, and microbiology records. . Mother- and father-child linkage is also available. Most databases are updated daily, but certain registries, such as the congenital anomaly registry and perinatal mortality registries, are updated yearly. |
| 11 | Vital status                                      | Mortality dates and causes of death are available in the mortality registry and the perinatal mortality registry.                                                                                                                                                                                                                                                                                                                                                                    |
| 12 | Limitations                                       | A subgroup of women (born before 1953) is not mapped into OMOP CDM yet. FISABIO is not the data owner and data extractions are performed on a project-by-project basis. Biological sex is not captured, only the legal gender. The last year's information for gender is used, and can change upon data refresh.                                                                                                                                                                     |
| 13 | Main references                                   | García-Sempere A, Orrico-Sánchez A, Muñoz-Quiles C, Hurtado I, Peiró S, Sanfélix-Gimeno G, Díez-Domingo J "Data Resource Profile: The Valencia Health System Integrated Database (VID)." International journal of epidemiology (2020): 31977043                                                                                                                                                                                                                                      |
| 14 | Link to HMA-EMA catalogue and data source webpage | HMA-EMA Catalogue entry: <a href="https://catalogues.ema.europa.eu/data-source/1111174">https://catalogues.ema.europa.eu/data-source/1111174</a><br>Website: <a href="https://www.san.gva.es/ca/web/salut-publica">https://www.san.gva.es/ca/web/salut-publica</a>                                                                                                                                                                                                                   |

### Health Impact - Swedish Population Evidence Enabling Data-linkage (HI-SPEED)

| # | Section                                | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Data source identification and country | HI-SPEED (Health Impact - Swedish Population Evidence Enabling Data-linkage) Sweden                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2 | Data partner information section       | Swedish Medical Products Agency - Gothenburg University (SMPA-GU)<br>Pharmacoepidemiology and Analysis Department (FeA) - School of Public Health and Community Medicine, Institute of Medicine                                                                                                                                                                                                                                                                                                                 |
| 3 | Coverage and timespan                  | Data collection since: 2015<br>Extent: Nation-wide.<br>The catchment area includes the whole of Sweden, covering the full population of approximately 11.7 million.                                                                                                                                                                                                                                                                                                                                             |
| 4 | Healthcare setting / type of data      | Primary care – General Practitioner, and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care.<br>Primary care (GPs) is available only for the 2 largest regions (~40% of national population) The following data elements are collected: Socio-demographics, dispensed drug prescriptions, cause of death, diagnoses and procedures from secondary (specialist) care and inpatient visits or clinical events, as well as from primary care visits (40%pop only). |
| 5 | Data collection process                | Registries.<br>The data is acquired from the relevant Swedish national and regional registries, only once all legislative, GDPR and ethical approvals have been granted. Therefore only relevant data is passed                                                                                                                                                                                                                                                                                                 |

| #  | Section                                           | Description                                                                                                                                                                                                                                                                                                                                                                                     |
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|    |                                                   | on, which will then be entered and processed by the study team. The data are updated several times annually.                                                                                                                                                                                                                                                                                    |
| 6  | General representativeness                        | The coverage includes all patients of all sociodemographic characteristics. Therefore it should mirror the source population to a very good extent.                                                                                                                                                                                                                                             |
| 7  | Data content /source coding                       | Medicines are coded with ATC and NPLID (National Product ID), ICD10-SE is used for diagnoses and the Swedish procedure coding system (KVA) is used for clinical procedures.                                                                                                                                                                                                                     |
| 8  | Data Harmonisation                                | The data has been mapped to the OMOP CDM v5 and the OMOP standard vocabularies. The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network.<br>Patients have a uniquely id across datasets.                                                                                                                                             |
| 9  | Quality control (data source specific)            | The source data are obtained from the relevant Swedish National and Regional Registers. The registers perform some regular quality controls on their data. After receiving the data, we perform additional checks and cleaning. We also run regular quality checks on the data we manage.                                                                                                       |
| 10 | Linkage                                           | Data on specialist care is acquired from the National Patient Register, mortality information is provided by the Cause-Of-Death Registry. Drug data is provided by the Patient Drug Register. And similarly for other registers. Data are linked very accurately using the national personal ID number, and pseudonymized before delivery to HI-SPEED. All data are updated 2-4 times per year. |
| 11 | Vital status                                      | Data on death and underlying + contributing causes-of-death are extracted from the Cause-of-Death registry (i.e. based on death certificates).                                                                                                                                                                                                                                                  |
| 12 | Limitations                                       | General limitations for the data type applicable. This is a research project where all studies require ethics approval. Data collection since: 2015 for most data, except prescribed drug register (from 2018), and some COVID-related data (tests, vaccination) from 2020<br>Primary care is only available for a subset.                                                                      |
| 13 | Main references                                   | Nyberg F, Franzén S,Lindh M,Vanfleiteren L,Hammar N,Wettermark B,Sundström J,Santosa A,Björck S,Gisslén M "Swedish Covid-19 Investigation for Future Insights - A Population Epidemiology Approach Using Register Linkage (SCIFI-PEARL)." Clinical epidemiology (2021): 34354377                                                                                                                |
| 14 | Link to HMA-EMA catalogue and data source webpage | HMA-EMA Catalogue entry: <a href="https://catalogues.ema.europa.eu/node/4463/">https://catalogues.ema.europa.eu/node/4463/</a><br>Website: <a href="https://www.gu.se/en/research/scifi-pearl">https://www.gu.se/en/research/scifi-pearl</a>                                                                                                                                                    |

### Clinical Practice Research Datalink Aurum + Hospital Episode Statistics (CPRD Aurum Linked)

| # | Section                                | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Data source identification and country | CPRD Aurum Linked (CPRD Aurum + Hospital Episode Statistics)<br>England, the United Kingdom                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2 | Data partner information section       | Clinical Practice Research Datalink (CPRD)<br>Safety and Surveillance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3 | Coverage and timespan                  | Data collection since: 1995<br>Extent: Nation-wide.<br>The CPRD Aurum database includes just over 17M currently registered patients, or around 25.5% of the UK population. All currently contributing practices (n= 1645) are in England, but coverage varies between English regions. The Aurum OMOP CDM database covers the period from 01/01/1995 to the most recent data collection (June-July 2025). For the Aurum + linked HES APC database, the coverage period is truncated to ensure that all patients are under observation in both the primary care and linked HES data, therefore the maximum allowable coverage period is currently 01/04/1997 to 31/03/2023 NB this will be updated in the next release, expected Jan 2026. <a href="https://www.cprd.com/doi/cprd-aurum-september-2025">https://www.cprd.com/doi/cprd-aurum-september-2025</a> |

| # | Section                           | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|---|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4 | Healthcare setting / type of data | <p>Primary care – General Practitioner and hospital inpatient care.</p> <p>CPRD Aurum includes data captured in UK primary care. In the UK, almost all individuals are registered with a single general practitioner (GP), and around 90% of all healthcare contacts with the UK National Health Service (NHS) occur in primary care (also known as general practice). GPs have a central role as gatekeepers for access to secondary and tertiary services, and other community based services and intervention programmes. Widespread adoption of dedicated computer software in UK primary care began in the late 1980s and was almost universal by 1995. GPs and general practice staff use these software to manage patients' electronic health records which include registration and demographic information, symptoms, diagnoses, clinical investigations and laboratory tests, prescriptions for medicines and appliances, a wide range of behavioural and social factors relevant to health and wellbeing, and administrative information. Some information is captured on contacts with other health services, including referral details and discharge summaries and other communications from those services. CPRD Aurum does not include any associated free text notes, scanned documents or images from the patient record. Hospital Episode Statistics Admitted Patient Care (HES APC) data captures information on inpatient care delivered in NHS hospitals and independent treatment centres funded by the NHS. Key variables include age; sex; ethnicity, episode start/end date; a single primary diagnosis (ICD-10), with up to 19 other comorbidity diagnoses; up to 24 procedures and other interventions (with date), coded using the UK Office of Population Censuses and Surveys Classification of Interventions and Procedures classification (OPCS-4). Medical treatments (drugs and devices) and lab values are not recorded in HES APC.</p> |
| 5 | Data collection process           | <p>Outpatient electronic health records, and Inpatient hospital electronic health records.</p> <p>Patient EHR data are entered by practice staff using the EMIS Web GP practice management software. Data may also be captured automatically via electronic links from pathology and diagnostic laboratories. EMIS Web is a cloud based system, and practice data are uploaded to the vendor data centre. Pseudonymised data is extracted from the vendor system and downloaded to CPRD via a dedicated cloud based interface. CPRD undertake additional checks to ensure data conform to specification, and comply with established data quality metrics, and apply additional pseudonymisation steps. HES APC data are derived from hospital activity data which are abstracted from clinical records and discharge summaries by trained clinical coders according to centrally issued coding rules and standards. The data is collected centrally for monitoring, planning, and payment purposes. For secondary uses including research, additional cleaning and curation is undertaken to generate the HES APC data. This includes linking episodes for the same individual, and addition of a Master Person Service identifier (MPS ID) which allows linkage to primary care and other health datasets for research.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 6 | General representativeness        | <p>CPRD Aurum provides a purposive sample of English general practices using EMIS Web GP software. EMIS Web has an uneven regional coverage. Participation in the CPRD data collection is voluntary. While not a random sample, CPRD Aurum is broadly representative of the overall population in terms of age and gender (<a href="https://pubmed.ncbi.nlm.nih.gov/30859197/">https://pubmed.ncbi.nlm.nih.gov/30859197/</a>), with minor differences in terms of area based deprivation and urban-rural distribution. (<a href="https://pubmed.ncbi.nlm.nih.gov/35902219/">https://pubmed.ncbi.nlm.nih.gov/35902219/</a>)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 7 | Data content /source coding       | <p>Data is captured using READ, EMIS2, SNOMED, DM+D, ICD10 and OPSC4 codes.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 8 | Data Harmonisation                | <p>The data has been mapped to the OMOP CDM v5 and the OMOP standard vocabularies. The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network.</p> <p>Patients can move and receive a different ID number upon changing practice, but a patient can only be registered at one practice at a time. Upon registering at a new practice, a patient's records will be transferred with them, and they will be deregistered at their previous practice. CPRD cannot track patients across practices as the data is de-identified and a patient key is generated for each patient at a practice level, not a country level. The patient key will remain the same for as long as the patient is registered at the practice. The main impact of patients changing practice is to reduce the average follow up time available for each analytical unit (i.e. patient-within-practice). A secondary issue is that records for the same individual split across two or more practices are not strictly independent. The impact on inferential statistics is likely to be very limited, and analytical adjustment is typically not required (or applied).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

| #  | Section                                           | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----|---------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9  | Quality control (data source specific)            | CPRD follows the same three-staged processing pipeline for all the data that it curates: curate individual data collections; integrate data into master database; and extract study specific datasets. For each part of the processing pipeline, CPRD applies checks to ensure that the quality of the data is maintained. At the data curation stage, conducted at both a collection level and at a record level, the data is verified to ensure that the data conforms to an agreed specification. Collection level verification ensures that the collection contains only expected data files, that the collection files are from a known source, and that the collections' files are in the correct sequence. The record level verifications performed at Level 1 are structural in nature and are applied to every data element that CPRD receives without considering the context of the data item against the entirety of the master database. These checks include that the data item is of the correct type, that fields that should have values do indeed contain a value, and that, where specified, the format and length of the data is accurate. Any violations of these checks result in the collection being rejected, the data not being integrated into the master database, and further inspection or recollection of the data taking place. At the data integration stage, the actual content of the data is validated, considering any existing content already collected. These validations are contextual in nature and consider the values of multiple data items within the master database. As CPRD provide real-world data no data is modified before being made available for research. The data is either rejected (as per the data curation checks) or integrated. Once integrated, data is not corrected, but patient, practice, and database level data quality metrics and markers are put in place, based on internal consistency of the data, to aid researchers in deciding if the data is suitable for research. There are some exceptions to this no modification principle. In the case that a patient is validated as being opted out, then their data is removed from future versions of the database to ensure their wishes are respected. Further validation and cleaning of study specific datasets may be undertaken by researchers or as part of good data management, and is dependent upon the research question and the researchers performing the analysis. |
| 10 | Linkage                                           | Linkage of CPRD Aurum to HES APC is undertaken by NHS England. Identifiers for patients in CPRD Aurum (NHS number, gender, full date of birth, residential postcode) flow directly from the vendor data centre to NHS England, and are linked to HES APC via the MPS ID. A bridging file of patient index numbers for each dataset is returned to CPRD to allow linkage of the clinical data. Linkage is undertaken at approximately 6 month intervals, but this may be impacted by organisation factors external to CPRD. Linkage to additional datasets is expected over the next 12-24 months, including linked death registrations (for accurate cause of death), hospital outpatient activity, and cancer registrations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 11 | Vital status                                      | The great majority of deaths are eventually captured in patients' primary care record. Published comparisons found that over 98% of national death registrations (the gold standard) were also captured in the CPRD GOLD primary care database <a href="https://pubmed.ncbi.nlm.nih.gov/30908785/">https://pubmed.ncbi.nlm.nih.gov/30908785/</a> , and results are similar for CPRD Aurum (unpublished). Estimated date of death in the primary care record shows good agreement with registered date of death (within 30 days in 98.8% of occurrences after 2013), but cause of death is captured inconsistently.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 12 | Limitations                                       | CPRD Aurum uses data collected for the primary purpose of managing and delivering safe and effective patient care in general practice. There are requirements and incentives for practice staff to record high quality information, but there is heterogeneity between practices and over time. UK primary care databases have been extensively validated and found to be of sufficient quality to support observational research. CPRD Aurum captures information on prescriptions issued by practice staff, from which drug exposures can only be inferred. There is no information about drug exposures in secondary care via the HES APC.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 13 | Main references                                   | Wolf A, Dedman D, Campbell J, Booth H, Lunn D, Chapman J, Myles P "Data resource profile: Clinical Practice Research Datalink (CPRD) Aurum." International journal of epidemiology (2019): 30859197                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 14 | Link to HMA-EMA catalogue and data source webpage | HMA-EMA Catalogue entry: <a href="https://catalogues.ema.europa.eu/data-source/30008">https://catalogues.ema.europa.eu/data-source/30008</a><br>Website: <a href="https://www.cprd.com/data/primary-care-data/cprd-aurum">https://www.cprd.com/data/primary-care-data/cprd-aurum</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

## ANNEX II. Fitness for use assessment

### **IQVIA Longitudinal Patient Database Belgium (IQVIA LPD Belgium)**

IQVIA LPD Belgium will be included in this study because it is a nationwide primary care data source that provides relevant information for the estimation of IMD and gonorrhoea, as well as for the characterisation of individuals with IMD or gonorrhoea.

Moreover, data availability and follow-up in IQVIA LPD Belgium is sufficient, as data availability in IQVIA LPD Belgium starts in 2010, and the date of the most recent data extraction is 30/09/2025 (as of 04/2026), which aligns with the study period. The median follow-up of the first observation period in IQVIA LPD Belgium is 856 days (IQR 79–2,150).

IQVIA LPD Belgium does not include information on IMD or gonorrhoea laboratory tests, meningococcal serogroups, or meningococcal carriage. Death data are derived from healthcare events recorded in the data source and may therefore be subject to incomplete capture. Information on cause of death is not available.

Lastly, IQVIA LPD Belgium does not need approval for DARWIN EU® studies, which makes the execution of this study feasible within the current study timelines.

### **Croatian National Public Health Information System (NAJS)**

NAJS will be included in this study because it is a nationwide primary, secondary, and hospital inpatient care data source information for the estimation of IMD and gonorrhoea, as well as for the characterisation of individuals with IMD or gonorrhoea.

Moreover, data availability and follow-up in NAJS is sufficient, as data availability in NAJS starts in 1998, and the date of the most recent data extraction is 14/08/2025 (as of 04/2026), which aligns with the study period. The median follow-up of the first observation period in NAJS is 4,020 days (IQR 3,400–4,110).

NAJS does not include information on IMD or gonorrhoea laboratory tests, meningococcal serogroups, or meningococcal carriage.

Lastly, NAJS has umbrella approval for DARWIN EU® studies, which makes the execution of this study feasible within the current study timelines.

### **Danish Data Health Registries (DK-DHR)**

DK-DHR will be included in this study because it is a nationwide primary, secondary, and hospital inpatient care data source that provides relevant information for the estimation of IMD and gonorrhoea, as well as for the characterisation of individuals with IMD or gonorrhoea.

Moreover, data availability and follow-up in DK-DHR is sufficient, as data availability in DK-DHR starts in 1995, and the date of the most recent data extraction is 18/01/2025 (as of 04/2026), which aligns with the study period. The median follow-up of the first observation period in DK-DHR is 7,920 days (IQR 544–10,900).

DK-DHR does not include information on IMD or gonorrhoea laboratory tests, meningococcal serogroups, or meningococcal carriage. Information on cause of death is not available.

Lastly, DK-DHR has umbrella approval for DARWIN EU® studies, which makes the execution of this study feasible within the current study timelines.

### **Finnish Care Register for Health Care (FinOMOP-THL)**

FinOMOP-THL will be included in this study because it is a nationwide primary, secondary, and hospital inpatient care data source that provides relevant information for the estimation of IMD and gonorrhoea, as well as for the characterisation of individuals with IMD or gonorrhoea.

Moreover, data availability in FinOMOP-THL starts in 1998, and the date of the most recent data extraction is 01/10/2024 (as of 04/2026). Therefore, incidence rates for outcomes will not be estimated for 2024, as only complete calendar years will be considered in the analyses. The median follow-up of the first observation period in FinOMOP-THL is 5,020 days (IQR 4,030–5,020).

FinOMOP-THL does not include information on IMD or gonorrhoea laboratory tests, meningococcal serogroups, or meningococcal carriage. Information on cause of death is not available.

Lastly, FinOMOP-THL is estimated to obtain Institutional Review Board (IRB) approval within two months, which makes the execution of this study feasible within the current study timelines.

### **InGef Research Database (InGef RDB)**

InGef RDB will be included in this study because it is a nationwide primary, secondary, and hospital inpatient care data source that provides relevant information for the estimation of IMD and gonorrhoea, as well as for the characterisation of individuals with IMD or gonorrhoea.

Moreover, data availability and follow-up in InGef RDB is sufficient, as data availability in InGef RDB starts in 2016, and the date of the most recent data extraction is 01/11/2025 (as of 04/2026), which aligns with the study period. The median follow-up of the first observation period in InGef RDB 3,380 days (IQR 1,280–3,560).

InGef RDB does not include information on IMD or gonorrhoea laboratory tests, meningococcal serogroups, meningococcal carriage, or meningococcal vaccination by serogroup. Additionally, it should be noted that outpatient diagnoses are recorded using the last day of the corresponding calendar quarter rather than the exact diagnosis date, resulting in an inaccurate index date. Information on cause of death is not available.

Lastly, InGef RDB has umbrella approval for DARWIN EU® studies, which makes the execution of this study feasible within the current study timelines.

### **Lithuanian Digital Health Platform (LDH)**

LDH will be included in this study because it is a nationwide primary, secondary, and hospital inpatient care data source that provides relevant information for the estimation of IMD and gonorrhoea, as well as for the characterisation of individuals with IMD or gonorrhoea.

Moreover, data availability and follow-up in LDH is sufficient, as data availability in LDH starts in 2015, and the date of the most recent data extraction is 03/02/2026 (as of 04/2026), which aligns with the study period. The median follow-up of the first observation period in LDH 4,020 days (IQR 4,020–4,020). However, LDH reported that the data required for this study cover the period 2019–2026. Therefore, the results for LDH will likely be reported from 2019 onwards.

LDH reported to have information on IMD and gonorrhoea laboratory tests and meningococcal vaccination by serogroup in the source data, which would need to be mapped if they are to be analysed. It does not include information on meningococcal serogroups or meningococcal carriage. Additionally, data on medications administered during inpatient hospital stays are not available.

Lastly, LDH does not need approval for DARWIN EU® studies, which makes the execution of this study feasible within the current study timelines.

### **Norwegian Linked Health Registry data (NLHR)**

NLHR will be included in this study because it is a nationwide primary, secondary, and hospital inpatient care data source that provides relevant information for the estimation of IMD and gonorrhoea, as well as for the characterisation of individuals with IMD or gonorrhoea.

Moreover, accurate hospital, vaccination, infectious diseases, and drug data in NLHR are available from 2018 onwards, and the date of the most recent data extraction is 31/12/2023 (as of 04/2026). Therefore,

the study period for this data source will start on 01/01/2018, and incidence rates for outcomes will not be estimated for 2024, as only complete calendar years will be considered in the analyses. The median follow-up of the first observation period in NLHR 5,820 days (IQR 4,200–5,820).

NLHR does not include information on IMD laboratory tests, meningococcal serogroups, or meningococcal carriage.

Lastly, NLHR has an estimated time for the IRB approval of one month, which makes the execution of this study feasible within the current study timelines.

### **The Information System for Research in Primary Care (SIDIAP)**

SIDIAP will be included in this study because it is a regional primary care data source linked to hospital data source that provides relevant information for the estimation of IMD and gonorrhoea, as well as for the characterisation of individuals with IMD or gonorrhoea.

Moreover, data availability and follow-up in SIDIAP is sufficient, as data availability in SIDIAP starts in 2006, and the date of the most recent data extraction is 31/12/2024 (as of 04/2026), which aligns with the study period. The median follow-up of the first observation period in SIDIAP 5,760 days (IQR 2,170–6,940).

SIDIAP does not include information on IMD or gonorrhoea laboratory tests, meningococcal serogroups, or meningococcal carriage. Information on cause of death is not available.

Lastly, SIDIAP is estimated to obtain IRB approval within two months, which makes the execution of this study feasible within the current study timelines.

### **Valencia Health System Integrated Dataset (VID)**

VID will be included in this study because it is a regional primary, secondary, and hospital inpatient care data source that provides relevant information for the estimation of IMD and gonorrhoea, as well as for the characterisation of individuals with IMD or gonorrhoea.

Moreover, data availability and follow-up in VID is sufficient, as data availability in VID starts in 2009, and the date of the most recent data extraction is 01/10/2025 (as of 04/2026), which aligns with the study period. The median follow-up of the first observation period in VID 5,840 days (IQR 4,460–5,840).

VID reported to have information on IMD and gonorrhoea laboratory tests, and meningococcal serogroup in the source data, which would need to be mapped if they are to be analysed. It includes limited information on meningococcal carriage and cause of death. Additionally, a subgroup of women born before 1953 has not yet been mapped to the OMOP CDM, and this needs to be considered when interpreting the results.

Lastly, VID is estimated to obtain IRB approval within 2–3 weeks, which makes the execution of this study feasible within the current study timelines.

### **Health Impact - Swedish Population Evidence Enabling Data-linkage (HI-SPEED)**

HI-SPEED will be included in this study because it is a nationwide primary, secondary, and hospital inpatient care data source that provides relevant information for the estimation of IMD and gonorrhoea, as well as for the characterisation of individuals with IMD or gonorrhoea.

Moreover, data availability and follow-up in HI-SPEED is sufficient, as data availability in HI-SPEED starts in 2015, and the date of the most recent data extraction is 31/08/2025 (as of 04/2026), which aligns with the study period. The median follow-up of the first observation period in HI-SPEED 3,890 days (IQR 3,330–3,890).

HI-SPEED does not include information on IMD or gonorrhoea laboratory tests, meningococcal serogroups, or meningococcal carriage.

Lastly, HI-SPEED is estimated to obtain IRB approval within two months, which makes the execution of this study feasible within the current study timelines.

#### **Clinical Practice Research Datalink Aurum + Hospital Episode Statistics (CPRD Aurum Linked)**

CPRD Aurum Linked will be included in this study because it is a regional primary and hospital inpatient care data source that provides relevant information for the estimation of IMD and gonorrhoea, as well as for the characterisation of individuals with IMD or gonorrhoea.

Moreover, data availability and follow-up in CPRD Aurum Linked is sufficient, as data availability in CPRD Aurum Linked starts in 1997 and the date of the most recent data extraction is 31/03/2025 (as of 04/2026), which aligns with the study period. The median follow-up of the first observation period in CPRD Aurum Linked 1,830 days (IQR 684–4,530).

CPRD Aurum Linked includes limited information on IMD or gonorrhoea laboratory tests undertaken in primary care and does not include information on meningococcal serogroups or meningococcal carriage. Information on cause of death is not available.

Lastly, CPRD Aurum Linked is estimated to obtain IRB approval within two months, which makes the execution of this study feasible within the current study timelines.

## ANNEX III. Operational and reporting considerations

### DATA MANAGEMENT

#### Data management

All data sources have previously mapped their data to the OMOP common data model. This enables the use of standardised analytics and using DARWIN EU® tools across the network, since the structure of the data and the terminology system is harmonised. The OMOP CDM was developed and maintained by the Observational Health Data Sciences and Informatics (OHDSI) initiative and is described in detail on the wiki page of the CDM: <https://ohdsi.github.io/CommonDataModel> and in The Book of OHDSI: <http://book.ohdsi.org>.

The analytic code for this study will be written in R and will use standardized analytics wherever possible. Each data partner will execute the study code against their data source containing patient-level data and then return the results (csv files), which will only contain aggregated data. The results from each of the contributing data sites will then be combined in tables and figures for the study report.

#### Data storage and protection

For this study, participants from various EU member states will process personal data from individuals that is collected in national/regional electronic health record data sources. Due to the sensitive nature of this personal medical data, it is important to be fully aware of ethical and regulatory aspects and to strive to take all reasonable measures to ensure compliance with ethical and regulatory issues on privacy.

All data sources used in this study are already used for pharmaco-epidemiological research and have a well-developed mechanism to ensure that European and local regulations dealing with ethical use of the data and adequate privacy control are adhered to. In agreement with these regulations, rather than combining person level data and performing only a central analysis, local analyses will be run, which generate non-identifiable aggregate summary results.

For the SIDIAP data source, the Catalan Institute of Health (ICS) acts as the Data Controller. Each participating institution remains responsible for its own data.

The output files are stored in the DARWIN EU® Digital Research Environment (DRE). These output files do not contain any data that allow identification of subjects included in the study. The DRE implements further security measures to ensure a high level of stored data protection to comply with the local implementation of the General Data Protection Regulation (GDPR) (EU) 679/2016 in the various member states.

### QUALITY CONTROL

#### Data source quality control

When defining drug cohorts, non-systemic products will be excluded from the list of included codes summarised on the ingredient level.

When defining cohorts for indications, a systematic search of possible codes for inclusion will be identified using the *CodelistGenerator* R package (<https://github.com/darwin-eu/CodelistGenerator>). This package allows the user to define a search strategy and will use this to query the vocabulary tables of the OMOP common data model so as to find potentially relevant codes. In addition, the *PhenotypeR* (<https://github.com/OHDSI/phenotypeR>) R package will be run, if needed, to assess the use of different codes across the data sources contributing to the study and identify any codes potentially omitted in error.

The study code will be based on DARWIN EU® R packages: *IncidencePrevalence* to estimate Incidence and *CohortCharacteristics* to characterise the cohort by indication. These packages will include numerous automated unit tests to ensure the validity of the codes, alongside software peer review and user testing. The R package will be made publicly available via GitHub.

## **PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS**

A PDF report including an executive summary, and the specified tables and/or figures will be submitted to EMA by the DARWIN EU® CC upon completion of the study.

An interactive dashboard incorporating all the results (tables and figures) will be provided alongside the PDF report. The full set of underlying aggregated data used in the dashboard will also be made available, if requested.

## ANNEX IV. Preliminary list of concept sets

Table S1. IMD.

| Concept ID | Concept name                                                                   | Domain ID | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------------------|-----------|---------------|------------------|
| 78956      | Meningococcal arthropathy                                                      | Condition | SNOMED        | standard         |
| 133691     | Meningococchemia                                                               | Condition | SNOMED        | standard         |
| 312543     | Meningococcal pericarditis                                                     | Condition | SNOMED        | standard         |
| 317208     | Meningococcal carditis                                                         | Condition | SNOMED        | standard         |
| 319720     | Meningococcal myocarditis                                                      | Condition | SNOMED        | standard         |
| 380632     | Meningococcal encephalitis                                                     | Condition | SNOMED        | standard         |
| 434275     | Waterhouse–Friderichsen syndrome                                               | Condition | SNOMED        | standard         |
| 436621     | Meningococcal infectious disease                                               | Condition | SNOMED        | standard         |
| 437777     | Meningococcal endocarditis                                                     | Condition | SNOMED        | standard         |
| 438338     | Meningococcal meningitis                                                       | Condition | SNOMED        | standard         |
| 3655275    | Encephalomyelitis caused by Neisseria meningitidis                             | Condition | SNOMED        | standard         |
| 4052546    | Meningococcal pneumonia                                                        | Condition | SNOMED        | standard         |
| 4090689    | Acute meningococchemia                                                         | Condition | SNOMED        | standard         |
| 4108685    | Acute meningococcal pericarditis                                               | Condition | SNOMED        | standard         |
| 4111091    | Acute myocarditis – meningococcal                                              | Condition | SNOMED        | standard         |
| 45768731   | Invasive meningococcal disease                                                 | Condition | SNOMED        | standard         |
| 46270051   | Sepsis caused by Meningococcus                                                 | Condition | SNOMED        | standard         |
| 46273475   | Septic shock co-occurrent with acute organ dysfunction caused by Meningococcus | Condition | SNOMED        | standard         |

Table S2. Meningococcal measurements any.

| Concept ID | Concept name                                                                                     | Domain ID   | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 1002168    | Neisseria meningitidis DNA [Presence] by NAA with probe detection in Positive blood culture      | Measurement | LOINC         | standard         |
| 1988730    | Neisseria meningitidis DNA [Presence] in Cerebral spinal fluid by NAA with probe detection       | Measurement | LOINC         | standard         |
| 3003429    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Specimen by Latex agglutination    | Measurement | LOINC         | standard         |
| 3004084    | Neisseria meningitidis Ag [Units/volume] in Cerebral spinal fluid by Latex agglutination         | Measurement | LOINC         | standard         |
| 3004743    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |
| 3004830    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid                        | Measurement | LOINC         | standard         |
| 3004934    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                            | Domain ID   | Vocabulary ID | Standard concept |
|------------|---------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3006319    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid by Immunoassay                | Measurement | LOINC         | standard         |
| 3006468    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Specimen                                  | Measurement | LOINC         | standard         |
| 3006634    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid by Immunofluorescence         | Measurement | LOINC         | standard         |
| 3006820    | Neisseria meningitidis polyvalent Ag [Presence] in Cerebral spinal fluid                                | Measurement | LOINC         | standard         |
| 3006954    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Urine                                         | Measurement | LOINC         | standard         |
| 3007413    | Neisseria meningitidis serogroup A Ag [Presence] in Specimen by Immunofluorescence                      | Measurement | LOINC         | standard         |
| 3007837    | Neisseria meningitidis serogroup C Ag [Presence] in Specimen by Immunofluorescence                      | Measurement | LOINC         | standard         |
| 3009177    | Neisseria meningitidis serogroup w135 Ag [Presence] in Specimen by Latex agglutination                  | Measurement | LOINC         | standard         |
| 3009740    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Specimen by Latex agglutination | Measurement | LOINC         | standard         |
| 3011277    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Cerebral spinal fluid                         | Measurement | LOINC         | standard         |
| 3011359    | Neisseria meningitidis serogroup w135 Ag [Presence] in Cerebral spinal fluid                            | Measurement | LOINC         | standard         |
| 3011706    | Neisseria meningitidis rRNA [Presence] in Specimen by Probe                                             | Measurement | LOINC         | standard         |
| 3012143    | Neisseria meningitidis serogroup w135 Ag [Presence] in Cerebral spinal fluid by Latex agglutination     | Measurement | LOINC         | standard         |
| 3012768    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid                     | Measurement | LOINC         | standard         |
| 3012772    | Neisseria meningitidis serogroup B Ag [Presence] in Urine                                               | Measurement | LOINC         | standard         |
| 3012941    | Neisseria meningitidis rRNA [Presence] in Cerebral spinal fluid by Probe                                | Measurement | LOINC         | standard         |
| 3013438    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Specimen                        | Measurement | LOINC         | standard         |
| 3013873    | Neisseria meningitidis serogroup C Ag [Presence] in Specimen                                            | Measurement | LOINC         | standard         |
| 3014158    | Neisseria meningitidis serogroup Y Ag [Presence] in Specimen by Latex agglutination                     | Measurement | LOINC         | standard         |
| 3015287    | Neisseria meningitidis serogroup w135 Ag [Presence] in Serum or Plasma                                  | Measurement | LOINC         | standard         |
| 3016497    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Urine                                            | Measurement | LOINC         | standard         |
| 3017555    | Neisseria meningitidis Ag [Presence] in Urine                                                           | Measurement | LOINC         | standard         |
| 3017789    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Cerebral spinal fluid                            | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                         | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3017803    | Neisseria meningitidis [Presence] in Specimen by Organism specific culture                                           | Measurement | LOINC         | standard         |
| 3018266    | Neisseria meningitidis Ag [Presence] in Specimen by Immunofluorescence                                               | Measurement | LOINC         | standard         |
| 3018802    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid by Immunoassay                             | Measurement | LOINC         | standard         |
| 3020550    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |
| 3022069    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                      | Measurement | LOINC         | standard         |
| 3022377    | Neisseria meningitidis Ag [Units/volume] in Cerebral spinal fluid                                                    | Measurement | LOINC         | standard         |
| 3023373    | Neisseria meningitidis serogroup C Ag [Presence] in Specimen by Latex agglutination                                  | Measurement | LOINC         | standard         |
| 3024208    | Neisseria meningitidis serogroup B Ag [Presence] in Urine by Latex agglutination                                     | Measurement | LOINC         | standard         |
| 3024501    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                      | Measurement | LOINC         | standard         |
| 3024554    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                      | Measurement | LOINC         | standard         |
| 3024969    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid by Immunoassay                             | Measurement | LOINC         | standard         |
| 3025079    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination                     | Measurement | LOINC         | standard         |
| 3025108    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid                                            | Measurement | LOINC         | standard         |
| 3025170    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid by Latex agglutination                     | Measurement | LOINC         | standard         |
| 3025462    | Neisseria meningitidis Ag [Presence] in Specimen                                                                     | Measurement | LOINC         | standard         |
| 3025526    | Neisseria meningitidis serogroup w135 Ag [Presence] in Serum or Plasma by Latex agglutination                        | Measurement | LOINC         | standard         |
| 3025700    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid by Immunoassay                             | Measurement | LOINC         | standard         |
| 3025920    | Neisseria meningitidis serogroup w135 Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                   | Measurement | LOINC         | standard         |
| 3026241    | Neisseria meningitidis serogroup A Ag [Presence] in Specimen                                                         | Measurement | LOINC         | standard         |
| 3026245    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid                                            | Measurement | LOINC         | standard         |
| 3026307    | Neisseria meningitidis serogroup B Ag [Presence] in Specimen                                                         | Measurement | LOINC         | standard         |
| 3026422    | Neisseria meningitidis Ag [Presence] in Cerebral spinal fluid                                                        | Measurement | LOINC         | standard         |
| 3026849    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid                        | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                               | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3027498    | Neisseria meningitidis serogroup w135 Ag [Presence] in Specimen                                                            | Measurement | LOINC         | standard         |
| 3027656    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid                                                  | Measurement | LOINC         | standard         |
| 3028323    | Neisseria meningitidis serogroup Y Ag [Presence] in Specimen                                                               | Measurement | LOINC         | standard         |
| 3028828    | Neisseria meningitidis serogroup Z' Ag [Presence] in Isolate by Agglutination                                              | Measurement | LOINC         | standard         |
| 3029096    | Neisseria meningitidis serogroup D Ag [Presence] in Isolate by Agglutination                                               | Measurement | LOINC         | standard         |
| 3029405    | Neisseria meningitidis serogroups Ag panel – Specimen by Latex agglutination                                               | Measurement | LOINC         | standard         |
| 3029484    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Serum                                              | Measurement | LOINC         | standard         |
| 3030041    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Serum                                                        | Measurement | LOINC         | standard         |
| 3030066    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Serum by Latex agglutination                                 | Measurement | LOINC         | standard         |
| 3030090    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Urine by Latex agglutination                                 | Measurement | LOINC         | standard         |
| 3030388    | Neisseria meningitidis DNA [Presence] in Specimen by NAA with probe detection                                              | Measurement | LOINC         | standard         |
| 3030670    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Serum by Latex agglutination                       | Measurement | LOINC         | standard         |
| 3031375    | Neisseria meningitidis serogroup B Ag [Presence] in Isolate by Agglutination                                               | Measurement | LOINC         | standard         |
| 3031665    | Neisseria meningitidis serogroup C Ag [Presence] in Isolate by Agglutination                                               | Measurement | LOINC         | standard         |
| 3031863    | Neisseria meningitidis serogroup w135 Ag [Presence] in Isolate by Agglutination                                            | Measurement | LOINC         | standard         |
| 3032003    | Neisseria meningitidis serogroup Y Ag [Presence] in Isolate by Agglutination                                               | Measurement | LOINC         | standard         |
| 3032239    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid by Agglutination | Measurement | LOINC         | standard         |
| 3032810    | Neisseria meningitidis serogroup A Ag [Presence] in Isolate by Agglutination                                               | Measurement | LOINC         | standard         |
| 3032826    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Urine by Agglutination                 | Measurement | LOINC         | standard         |
| 3033085    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Serum by Agglutination                 | Measurement | LOINC         | standard         |
| 3033129    | Neisseria meningitidis serogroups A+w135 Ag [Presence] in Body fluid                                                       | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                               | Domain ID   | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3033707    | Neisseria meningitidis serogroup Z Ag [Presence] in Isolate by Agglutination                               | Measurement | LOINC         | standard         |
| 3033719    | Neisseria meningitidis serogroup X Ag [Presence] in Isolate by Agglutination                               | Measurement | LOINC         | standard         |
| 3036281    | Neisseria meningitidis serogroup A Ag [Presence] in Specimen by Latex agglutination                        | Measurement | LOINC         | standard         |
| 3036803    | Neisseria meningitidis serogroup B Ag [Presence] in Specimen by Latex agglutination                        | Measurement | LOINC         | standard         |
| 3037414    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |
| 3037665    | Neisseria meningitidis serogroup B Ag [Presence] in Body fluid                                             | Measurement | LOINC         | standard         |
| 3042515    | Neisseria meningitidis DNA [Presence] in Blood by NAA with probe detection                                 | Measurement | LOINC         | standard         |
| 3043092    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Specimen by Latex agglutination                     | Measurement | LOINC         | standard         |
| 3043140    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Specimen by Latex agglutination                  | Measurement | LOINC         | standard         |
| 3044087    | Neisseria meningitidis serogroup B Ag [Presence] in Serum                                                  | Measurement | LOINC         | standard         |
| 3044827    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Urine by Latex agglutination       | Measurement | LOINC         | standard         |
| 3045096    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Specimen                                         | Measurement | LOINC         | standard         |
| 3045828    | Neisseria meningitidis [Identifier] in Isolate by Agglutination                                            | Measurement | LOINC         | standard         |
| 3046026    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Specimen                                            | Measurement | LOINC         | standard         |
| 3046133    | Neisseria meningitidis [Identifier] in Isolate by Organism specific culture                                | Measurement | LOINC         | standard         |
| 3046599    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Urine                                        | Measurement | LOINC         | standard         |
| 3046627    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Urine                              | Measurement | LOINC         | standard         |
| 4007328    | Neisseria meningitidis Y antigen assay                                                                     | Measurement | SNOMED        | standard         |
| 4007961    | Neisseria meningitidis antigen assay                                                                       | Measurement | SNOMED        | standard         |
| 4036388    | Neisseria meningitidis A AND Y antigen assay                                                               | Measurement | SNOMED        | standard         |
| 4039020    | Neisseria meningitidis polyvalent antigen assay                                                            | Measurement | SNOMED        | standard         |
| 4044992    | Neisseria meningitidis W135 antigen assay                                                                  | Measurement | SNOMED        | standard         |
| 4046141    | Neisseria meningitidis A antigen assay                                                                     | Measurement | SNOMED        | standard         |
| 4046142    | Neisseria meningitidis B antigen assay                                                                     | Measurement | SNOMED        | standard         |
| 4046150    | Neisseria meningitidis culture                                                                             | Measurement | SNOMED        | standard         |
| 4047324    | Neisseria meningitidis C antigen assay                                                                     | Measurement | SNOMED        | standard         |
| 4047334    | Neisseria meningitidis rRNA assay                                                                          | Measurement | SNOMED        | standard         |

| Concept ID | Concept name                                                                                                        | Domain ID   | Vocabulary ID | Standard concept |
|------------|---------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 4134741    | Meningococcal nucleic acid assay                                                                                    | Measurement | SNOMED        | standard         |
| 4160457    | PCR test for meningococcus                                                                                          | Measurement | SNOMED        | standard         |
| 21490997   | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Specimen by Latex agglutination | Measurement | LOINC         | standard         |
| 21493351   | Neisseria meningitidis DNA [Presence] in Cerebral spinal fluid by NAA with non–probe detection                      | Measurement | LOINC         | standard         |
| 36203226   | Neisseria meningitidis DNA [Presence] by NAA with non–probe detection in Positive blood culture                     | Measurement | LOINC         | standard         |
| 36203457   | Neisseria meningitidis sodC gene [Presence] in Specimen by NAA with probe detection                                 | Measurement | LOINC         | standard         |
| 36203597   | Neisseria meningitidis serogroup DNA panel – Specimen by NAA with probe detection                                   | Measurement | LOINC         | standard         |
| 36203721   | Neisseria meningitidis serogroup Y synF gene [Cycle Threshold #] in Specimen by NAA with probe detection            | Measurement | LOINC         | standard         |
| 36203853   | Neisseria meningitidis serogroup A sacB gene [Cycle Threshold #] in Specimen by NAA with probe detection            | Measurement | LOINC         | standard         |
| 36203854   | Neisseria meningitidis serogroup B synD gene [Cycle Threshold #] in Specimen by NAA with probe detection            | Measurement | LOINC         | standard         |
| 36203855   | Neisseria meningitidis serogroup C synE gene [Cycle Threshold #] in Specimen by NAA with probe detection            | Measurement | LOINC         | standard         |
| 36203856   | Neisseria meningitidis serogroup w135 synG gene [Cycle Threshold #] in Specimen by NAA with probe detection         | Measurement | LOINC         | standard         |
| 36203857   | Neisseria meningitidis serogroup X xcbB gene [Cycle Threshold #] in Specimen by NAA with probe detection            | Measurement | LOINC         | standard         |
| 36204303   | Neisseria meningitidis [Presence] in Cerebral spinal fluid by Organism specific culture                             | Measurement | LOINC         | standard         |
| 36305005   | Neisseria meningitidis [Presence] in Throat by Organism specific culture                                            | Measurement | LOINC         | standard         |
| 37020949   | Neisseria meningitidis DNA [Presence] in Upper respiratory specimen by NAA with probe detection                     | Measurement | LOINC         | standard         |
| 37021257   | Neisseria meningitidis [Presence] in Upper respiratory specimen by Organism specific culture                        | Measurement | LOINC         | standard         |
| 37159836   | Neisseria meningitidis RNA nucleic acid amplification qualitative result                                            | Measurement | SNOMED        | standard         |
| 37171850   | Neisseria meningitidis culture qualitative result                                                                   | Measurement | SNOMED        | standard         |
| 37171946   | Neisseria meningitidis number concentration by culture                                                              | Measurement | SNOMED        | standard         |
| 37173605   | Neisseria meningitidis DNA nucleic acid amplification qualitative result                                            | Measurement | SNOMED        | standard         |
| 37394344   | Meningococcal polymerase chain reaction                                                                             | Measurement | SNOMED        | standard         |
| 40762512   | Neisseria meningitidis serogroups A+B+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination        | Measurement | LOINC         | standard         |
| 40768451   | Neisseria meningitidis Ag [Presence] in Tissue by Immune stain                                                      | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                 | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 42868646   | Neisseria meningitidis serogroup [Identifier] in Specimen                                    | Measurement | LOINC         | standard         |
| 42869543   | Neisseria meningitidis DNA [Identifier] in Specimen by NAA with probe detection              | Measurement | LOINC         | standard         |
| 43533727   | Neisseria meningitidis serosubtype [Type] in Isolate by Immunoassay                          | Measurement | LOINC         | standard         |
| 44817207   | Neisseria meningitidis serogroup Y DNA [Presence] in Specimen by NAA with probe detection    | Measurement | LOINC         | standard         |
| 44817208   | Neisseria meningitidis serogroup X DNA [Presence] in Specimen by NAA with probe detection    | Measurement | LOINC         | standard         |
| 44817209   | Neisseria meningitidis serogroup w135 DNA [Presence] in Specimen by NAA with probe detection | Measurement | LOINC         | standard         |
| 44817210   | Neisseria meningitidis serogroup C DNA [Presence] in Specimen by NAA with probe detection    | Measurement | LOINC         | standard         |
| 44817211   | Neisseria meningitidis serogroup B DNA [Presence] in Specimen by NAA with probe detection    | Measurement | LOINC         | standard         |
| 44817212   | Neisseria meningitidis serogroup A DNA [Presence] in Specimen by NAA with probe detection    | Measurement | LOINC         | standard         |

Table S3. Meningococcal measurements in sterile site (excluding cerebrospinal fluid).

| Concept ID | Concept name                                                                                    | Domain ID   | Vocabulary ID | Standard concept |
|------------|-------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 1002168    | Neisseria meningitidis DNA [Presence] by NAA with probe detection in Positive blood culture     | Measurement | LOINC         | standard         |
| 3042515    | Neisseria meningitidis DNA [Presence] in Blood by NAA with probe detection                      | Measurement | LOINC         | standard         |
| 36203226   | Neisseria meningitidis DNA [Presence] by NAA with non-probe detection in Positive blood culture | Measurement | LOINC         | standard         |

Table S4. Meningococcal measurements in cerebrospinal fluid.

| Concept ID | Concept name                                                                                     | Domain ID   | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 1988730    | Neisseria meningitidis DNA [Presence] in Cerebral spinal fluid by NAA with probe detection       | Measurement | LOINC         | standard         |
| 3004084    | Neisseria meningitidis Ag [Units/volume] in Cerebral spinal fluid by Latex agglutination         | Measurement | LOINC         | standard         |
| 3004743    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |
| 3004830    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid                        | Measurement | LOINC         | standard         |
| 3004934    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |
| 3006319    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid by Immunoassay         | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                         | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3006634    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                      | Measurement | LOINC         | standard         |
| 3006820    | Neisseria meningitidis polyvalent Ag [Presence] in Cerebral spinal fluid                                             | Measurement | LOINC         | standard         |
| 3011277    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Cerebral spinal fluid                                      | Measurement | LOINC         | standard         |
| 3011359    | Neisseria meningitidis serogroup w135 Ag [Presence] in Cerebral spinal fluid                                         | Measurement | LOINC         | standard         |
| 3012143    | Neisseria meningitidis serogroup w135 Ag [Presence] in Cerebral spinal fluid by Latex agglutination                  | Measurement | LOINC         | standard         |
| 3012768    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid                                  | Measurement | LOINC         | standard         |
| 3012941    | Neisseria meningitidis rRNA [Presence] in Cerebral spinal fluid by Probe                                             | Measurement | LOINC         | standard         |
| 3017789    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Cerebral spinal fluid                                         | Measurement | LOINC         | standard         |
| 3018802    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid by Immunoassay                             | Measurement | LOINC         | standard         |
| 3020550    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |
| 3022069    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                      | Measurement | LOINC         | standard         |
| 3022377    | Neisseria meningitidis Ag [Units/volume] in Cerebral spinal fluid                                                    | Measurement | LOINC         | standard         |
| 3024501    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                      | Measurement | LOINC         | standard         |
| 3024554    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                      | Measurement | LOINC         | standard         |
| 3024969    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid by Immunoassay                             | Measurement | LOINC         | standard         |
| 3025079    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination                     | Measurement | LOINC         | standard         |
| 3025108    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid                                            | Measurement | LOINC         | standard         |
| 3025170    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid by Latex agglutination                     | Measurement | LOINC         | standard         |
| 3025700    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid by Immunoassay                             | Measurement | LOINC         | standard         |
| 3025920    | Neisseria meningitidis serogroup w135 Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                   | Measurement | LOINC         | standard         |
| 3026245    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid                                            | Measurement | LOINC         | standard         |
| 3026422    | Neisseria meningitidis Ag [Presence] in Cerebral spinal fluid                                                        | Measurement | LOINC         | standard         |
| 3026849    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid                        | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                               | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3027656    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid                                                  | Measurement | LOINC         | standard         |
| 3032239    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid by Agglutination | Measurement | LOINC         | standard         |
| 3037414    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination                 | Measurement | LOINC         | standard         |
| 21493351   | Neisseria meningitidis DNA [Presence] in Cerebral spinal fluid by NAA with non-probe detection                             | Measurement | LOINC         | standard         |
| 36204303   | Neisseria meningitidis [Presence] in Cerebral spinal fluid by Organism specific culture                                    | Measurement | LOINC         | standard         |
| 40762512   | Neisseria meningitidis serogroups A+B+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination               | Measurement | LOINC         | standard         |

Table S5. Gonorrhoea.

| Concept ID | Concept name                                 | Domain ID | Vocabulary ID | Standard concept |
|------------|----------------------------------------------|-----------|---------------|------------------|
| 30333      | Gonorrhea of pharynx                         | Condition | SNOMED        | standard         |
| 72562      | Gonococcal spondylitis                       | Condition | SNOMED        | standard         |
| 74864      | Gonococcal infection of joint                | Condition | SNOMED        | standard         |
| 132563     | Gonococcal keratitis                         | Condition | SNOMED        | standard         |
| 133965     | Acute gonorrhea of upper genitourinary tract | Condition | SNOMED        | standard         |
| 135466     | Gonococcal bursitis                          | Condition | SNOMED        | standard         |
| 193132     | Chronic gonorrhea lower genitourinary tract  | Condition | SNOMED        | standard         |
| 193136     | Acute gonococcal cervicitis                  | Condition | SNOMED        | standard         |
| 193140     | Acute gonococcal cystitis                    | Condition | SNOMED        | standard         |
| 194571     | Acute gonococcal prostatitis                 | Condition | SNOMED        | standard         |
| 196345     | Gonococcal peritonitis                       | Condition | SNOMED        | standard         |
| 198972     | Acute gonococcal seminal vesiculitis         | Condition | SNOMED        | standard         |
| 198978     | Acute gonorrhea of lower genitourinary tract | Condition | SNOMED        | standard         |
| 200040     | Acute gonococcal endometritis                | Condition | SNOMED        | standard         |
| 200334     | Acute gonococcal salpingitis                 | Condition | SNOMED        | standard         |
| 321505     | Gonococcal heart disease                     | Condition | SNOMED        | standard         |
| 372842     | Gonococcal conjunctivitis neonatorum         | Condition | SNOMED        | standard         |
| 374283     | Gonococcal infection of eye                  | Condition | SNOMED        | standard         |
| 433417     | Gonorrhea                                    | Condition | SNOMED        | standard         |
| 435746     | Gonococcal tenosynovitis                     | Condition | SNOMED        | standard         |
| 439669     | Gonococcal anal infection                    | Condition | SNOMED        | standard         |
| 442112     | Gonococcal pericarditis                      | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                              | Domain ID   | Vocabulary ID | Standard concept |
|------------|---------------------------------------------------------------------------|-------------|---------------|------------------|
| 442586     | Gonococcal endocarditis                                                   | Condition   | SNOMED        | standard         |
| 443054     | Maternal gonorrhea during pregnancy, childbirth and the puerperium        | Condition   | SNOMED        | standard         |
| 443205     | Gonococcal synovitis                                                      | Condition   | SNOMED        | standard         |
| 443888     | Gonococcal meningitis                                                     | Condition   | SNOMED        | standard         |
| 443911     | Acute gonococcal epididymo–orchitis                                       | Condition   | SNOMED        | standard         |
| 444059     | Gonococcal keratitis                                                      | Condition   | SNOMED        | standard         |
| 444227     | Gonococcal endophthalmitis                                                | Condition   | SNOMED        | standard         |
| 444446     | Gonococcal iridocyclitis                                                  | Condition   | SNOMED        | standard         |
| 605334     | Gonococcal myocarditis                                                    | Condition   | SNOMED        | standard         |
| 618546     | Neisseria gonorrhoeae subspecies kochii                                   | Observation | SNOMED        | standard         |
| 760134     | Periurethral abscess caused by Neisseria gonorrhoeae                      | Condition   | SNOMED        | standard         |
| 760135     | Gonorrhea of kidney and ureter                                            | Condition   | SNOMED        | standard         |
| 761872     | Gonorrhea of upper genitourinary tract                                    | Condition   | SNOMED        | standard         |
| 1245543    | Left gonococcal keratitis                                                 | Condition   | SNOMED        | standard         |
| 1245544    | Bilateral gonococcal keratitis                                            | Condition   | SNOMED        | standard         |
| 1245545    | Right gonococcal keratitis                                                | Condition   | SNOMED        | standard         |
| 1245738    | Neonatal conjunctivitis of right eye caused by Neisseria gonorrhoeae      | Condition   | SNOMED        | standard         |
| 1245739    | Neonatal conjunctivitis of left eye caused by Neisseria gonorrhoeae       | Condition   | SNOMED        | standard         |
| 1245740    | Neonatal conjunctivitis of bilateral eyes caused by Neisseria gonorrhoeae | Condition   | SNOMED        | standard         |
| 1245756    | Infection of right eye caused by Neisseria gonorrhoeae                    | Condition   | SNOMED        | standard         |
| 1245757    | Infection of bilateral eyes caused by Neisseria gonorrhoeae               | Condition   | SNOMED        | standard         |
| 1245758    | Infection of left eye caused by Neisseria gonorrhoeae                     | Condition   | SNOMED        | standard         |
| 4032589    | Gonococcal epididymitis                                                   | Condition   | SNOMED        | standard         |
| 4032590    | Gonococcal epididymo–orchitis                                             | Condition   | SNOMED        | standard         |
| 4033947    | Acute gonococcal vulvovaginitis                                           | Condition   | SNOMED        | standard         |
| 4034007    | Gonococcal cervicitis                                                     | Condition   | SNOMED        | standard         |
| 4034010    | Gonococcal vulvovaginitis                                                 | Condition   | SNOMED        | standard         |
| 4044102    | Neisseria gonorrhoeae antigen                                             | Observation | SNOMED        | standard         |
| 4056174    | Gonococcal prostatitis                                                    | Condition   | SNOMED        | standard         |
| 4059608    | Gonococcal cystitis                                                       | Condition   | SNOMED        | standard         |
| 4061217    | Female gonococcal pelvic inflammatory disease                             | Condition   | SNOMED        | standard         |
| 4066421    | Acute gonorrhea of genitourinary tract                                    | Condition   | SNOMED        | standard         |
| 4079564    | Tetracycline–resistant Neisseria gonorrhoeae                              | Observation | SNOMED        | standard         |
| 4079565    | Spectinomycin–resistant Neisseria gonorrhoeae                             | Observation | SNOMED        | standard         |

| Concept ID | Concept name                                       | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------|-------------|---------------|------------------|
| 4080310    | Gonococcal lymphangitis of penis                   | Condition   | SNOMED        | standard         |
| 4080339    | Neonatal gonococcal infection                      | Condition   | SNOMED        | standard         |
| 4080340    | Gonococcal Cowperitis                              | Condition   | SNOMED        | standard         |
| 4080341    | Gonococcal penile fistula                          | Condition   | SNOMED        | standard         |
| 4080594    | Gonococcal Bartholin's gland abscess               | Condition   | SNOMED        | standard         |
| 4080595    | Gonococcal Skenitis                                | Condition   | SNOMED        | standard         |
| 4080596    | Gonococcal Littritis                               | Condition   | SNOMED        | standard         |
| 4080597    | Gonococcal paraurethral gland abscess              | Condition   | SNOMED        | standard         |
| 4080777    | Gonorrhea with local complication                  | Condition   | SNOMED        | standard         |
| 4080778    | Gonococcal Tysonitis                               | Condition   | SNOMED        | standard         |
| 4080779    | Gonococcal Littr's gland abscess                   | Condition   | SNOMED        | standard         |
| 4080780    | Gonococcal female pelvic infection                 | Condition   | SNOMED        | standard         |
| 4080781    | Cutaneous gonorrhea                                | Condition   | SNOMED        | standard         |
| 4081904    | Gonococcal cellulitis                              | Condition   | SNOMED        | standard         |
| 4082323    | Cephalosporin-resistant Neisseria gonorrhoeae      | Observation | SNOMED        | standard         |
| 4107240    | Acute gonococcal urethritis                        | Condition   | SNOMED        | standard         |
| 4108800    | Acute gonococcal pericarditis                      | Condition   | SNOMED        | standard         |
| 4127390    | Gonococcal salpingitis                             | Condition   | SNOMED        | standard         |
| 4127392    | Gonococcal tubo-ovarian abscess                    | Condition   | SNOMED        | standard         |
| 4128042    | Gonococcal perihepatitis                           | Condition   | SNOMED        | standard         |
| 4128047    | Gonococcal endometritis                            | Condition   | SNOMED        | standard         |
| 4128053    | Neonatal gonococcal vulvovaginitis                 | Condition   | SNOMED        | standard         |
| 4128397    | Gonococcal urethritis                              | Condition   | SNOMED        | standard         |
| 4128399    | Gonococcal urethral abscess                        | Condition   | SNOMED        | standard         |
| 4144034    | Gonococcal pelvic peritonitis                      | Condition   | SNOMED        | standard         |
| 4156057    | Gonococcal arthritis dermatitis syndrome           | Condition   | SNOMED        | standard         |
| 4173827    | Penicillinase-producing Neisseria gonorrhoeae      | Observation | SNOMED        | standard         |
| 4175505    | Gonorrhea of rectum                                | Condition   | SNOMED        | standard         |
| 4176270    | Gonococcemia                                       | Condition   | SNOMED        | standard         |
| 4201692    | Gonococcal seminal vesiculitis                     | Condition   | SNOMED        | standard         |
| 4213204    | Acute gonococcal bartholinitis                     | Condition   | SNOMED        | standard         |
| 4214667    | Neisseria gonorrhoeae, beta lactamase negative     | Observation | SNOMED        | standard         |
| 4216859    | Urethral stricture due to gonococcal infection     | Condition   | SNOMED        | standard         |
| 4231978    | Gonococcal infection of the central nervous system | Condition   | SNOMED        | standard         |
| 4260334    | Fluoroquinolone-resistant Neisseria gonorrhoeae    | Observation | SNOMED        | standard         |
| 4285582    | Neisseria gonorrhoeae                              | Observation | SNOMED        | standard         |

| Concept ID | Concept name                                                                                                | Domain ID | Vocabulary ID | Standard concept |
|------------|-------------------------------------------------------------------------------------------------------------|-----------|---------------|------------------|
| 4291612    | Localized cutaneous gonococcal infection                                                                    | Condition | SNOMED        | standard         |
| 4291613    | Gonococcal bartholinitis                                                                                    | Condition | SNOMED        | standard         |
| 4293282    | Pustular vasculitis due to gonococcal bacteremia                                                            | Condition | SNOMED        | standard         |
| 4335889    | Gonococcal conjunctivitis                                                                                   | Condition | SNOMED        | standard         |
| 4341651    | Abscess gonococcal                                                                                          | Condition | SNOMED        | standard         |
| 4342771    | Gonococcal hepatitis                                                                                        | Condition | SNOMED        | standard         |
| 36685124   | Infection of anus and rectum caused by Neisseria gonorrhoeae                                                | Condition | SNOMED        | standard         |
| 36714497   | Adult gonococcal conjunctivitis                                                                             | Condition | SNOMED        | standard         |
| 36717459   | Neonatal conjunctivitis and dacryocystitis caused by Neisseria gonorrhoeae                                  | Condition | SNOMED        | standard         |
| 37016131   | Sepsis caused by Gonococcus                                                                                 | Condition | SNOMED        | standard         |
| 37017072   | Gingival disease caused by Neisseria gonorrhoeae                                                            | Condition | SNOMED        | standard         |
| 37116425   | Infection of musculoskeletal system caused by Neisseria gonorrhoeae                                         | Condition | SNOMED        | standard         |
| 37166007   | Infection caused by Neisseria gonorrhoeae during puerperium                                                 | Condition | SNOMED        | standard         |
| 37169815   | Gonococcal dacryoadenitis                                                                                   | Condition | SNOMED        | standard         |
| 37309610   | Gonorrhea of lower genitourinary tract                                                                      | Condition | SNOMED        | standard         |
| 37311937   | Gonorrhea of penis                                                                                          | Condition | SNOMED        | standard         |
| 40481109   | Abscess of urethral gland caused by Neisseria gonorrhoeae                                                   | Condition | SNOMED        | standard         |
| 42534945   | Maternal gonorrhea during pregnancy                                                                         | Condition | SNOMED        | standard         |
| 42536585   | Infection of genitourinary system caused by Neisseria gonorrhoeae                                           | Condition | SNOMED        | standard         |
| 42539347   | Disseminated infection caused by Neisseria gonorrhoeae                                                      | Condition | SNOMED        | standard         |
| 45757125   | Gonorrhea in mother complicating childbirth                                                                 | Condition | SNOMED        | standard         |
| 45757248   | Gonococcal abscess of brain                                                                                 | Condition | SNOMED        | standard         |
| 45757249   | Gonococcal osteomyelitis                                                                                    | Condition | SNOMED        | standard         |
| 45757250   | Gonococcal pneumonia                                                                                        | Condition | SNOMED        | standard         |
| 45757712   | Gonococcal iritis                                                                                           | Condition | SNOMED        | standard         |
| 46269909   | Infection of lower genitourinary tract co-occurrent with abscess of periurethral gland caused by Gonococcus | Condition | SNOMED        | standard         |
| 46269940   | Septic shock co-occurrent with acute organ dysfunction due to Gonococcus                                    | Condition | SNOMED        | standard         |

Table S6. Gonorrhoea measurements.

| Concept ID | Concept name                                                                                                                                                                                                                                                    | Domain ID   | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 724570     | Infectious agent (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, multiplex amplified probe technique, vaginal, endocervical, or male urine, each pathogen reported as detected or | Measurement | CPT4          | standard         |
| 1175457    | Chlamydia trachomatis and Neisseria gonorrhoeae rRNA panel – Anorectal by NAA with probe detection                                                                                                                                                              | Measurement | LOINC         | standard         |
| 1175837    | Chlamydia trachomatis and Neisseria gonorrhoeae rRNA panel – Nasopharynx by NAA with probe detection                                                                                                                                                            | Measurement | LOINC         | standard         |
| 1247088    | Detection of Neisseria gonorrhoeae nucleic acid by amplified probe technique                                                                                                                                                                                    | Measurement | SNOMED        | standard         |
| 1259901    | Chlamydia trachomatis and Neisseria gonorrhoeae and Trichomonas vaginalis [Presence] in Genital fluid by NAA with probe detection                                                                                                                               | Measurement | LOINC         | standard         |
| 1552135    | Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected                               | Measurement | CPT4          | standard         |
| 1617533    | Neisseria gonorrhoeae DNA [Presence] in Synovial fluid by NAA with non–probe detection                                                                                                                                                                          | Measurement | LOINC         | standard         |
| 1761594    | Chlamydia trachomatis and Neisseria gonorrhoeae and Trichomonas vaginalis DNA [Identifier] in Specimen by NAA with probe detection                                                                                                                              | Measurement | LOINC         | standard         |
| 1761792    | Chlamydia trachomatis and Neisseria gonorrhoeae rRNA panel – Throat by NAA with probe detection                                                                                                                                                                 | Measurement | LOINC         | standard         |
| 1989512    | Neisseria gonorrhoeae rRNA [Presence] in Conjunctival specimen by NAA with probe detection                                                                                                                                                                      | Measurement | LOINC         | standard         |
| 2213161    | Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, direct probe technique                                                                                                                                                          | Measurement | CPT4          | standard         |
| 2213162    | Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, amplified probe technique                                                                                                                                                       | Measurement | CPT4          | standard         |
| 2213163    | Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, quantification                                                                                                                                                                  | Measurement | CPT4          | standard         |
| 2213186    | Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Neisseria gonorrhoeae                                                                                                                                           | Measurement | CPT4          | standard         |
| 3000866    | Neisseria gonorrhoeae DNA [Presence] in Urethra by NAA with probe detection                                                                                                                                                                                     | Measurement | LOINC         | standard         |
| 3003110    | Neisseria gonorrhoeae [Presence] in Anal by Organism specific culture                                                                                                                                                                                           | Measurement | LOINC         | standard         |
| 3003510    | Neisseria gonorrhoeae DNA [Presence] in Urine by NAA with probe detection                                                                                                                                                                                       | Measurement | LOINC         | standard         |
| 3004755    | Neisseria gonorrhoeae Ag [Presence] in Genital specimen by Immunofluorescence                                                                                                                                                                                   | Measurement | LOINC         | standard         |
| 3006425    | Neisseria gonorrhoeae [Presence] in Vaginal fluid by Organism specific culture                                                                                                                                                                                  | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                             | Domain ID   | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3007751    | Neisseria gonorrhoeae [Presence] in Genital lochia by Organism specific culture          | Measurement | LOINC         | standard         |
| 3007842    | Neisseria gonorrhoeae Ag [Presence] in Genital specimen by Latex agglutination           | Measurement | LOINC         | standard         |
| 3008871    | Neisseria gonorrhoeae [Presence] in Genital specimen by Organism specific culture        | Measurement | LOINC         | standard         |
| 3009000    | Neisseria gonorrhoeae [Presence] in Conjunctival specimen by Organism specific culture   | Measurement | LOINC         | standard         |
| 3010854    | Neisseria gonorrhoeae rRNA [Presence] in Specimen by Probe                               | Measurement | LOINC         | standard         |
| 3011371    | Neisseria gonorrhoeae DNA [Presence] in Specimen by NAA with probe detection             | Measurement | LOINC         | standard         |
| 3014809    | Neisseria gonorrhoeae [Presence] in Endometrium by Organism specific culture             | Measurement | LOINC         | standard         |
| 3016574    | Neisseria gonorrhoeae Ag [Presence] in Urethra                                           | Measurement | LOINC         | standard         |
| 3018142    | Neisseria gonorrhoeae Ag [Presence] in Genital specimen by Immunoassay                   | Measurement | LOINC         | standard         |
| 3022389    | Neisseria gonorrhoeae [Presence] in Cervix by Organism specific culture                  | Measurement | LOINC         | standard         |
| 3023276    | Neisseria gonorrhoeae [Presence] in Semen by Organism specific culture                   | Measurement | LOINC         | standard         |
| 3024885    | Neisseria gonorrhoeae Ag [Presence] in Specimen                                          | Measurement | LOINC         | standard         |
| 3025529    | Neisseria gonorrhoeae Ag [Presence] in Genital specimen                                  | Measurement | LOINC         | standard         |
| 3025582    | Neisseria gonorrhoeae [Presence] in Synovial fluid by Organism specific culture          | Measurement | LOINC         | standard         |
| 3026039    | Neisseria gonorrhoeae Ag [Presence] in Specimen by Immunofluorescence                    | Measurement | LOINC         | standard         |
| 3026966    | Neisseria gonorrhoeae [Presence] in Throat by Organism specific culture                  | Measurement | LOINC         | standard         |
| 3027809    | Neisseria gonorrhoeae [Presence] in Urethra by Organism specific culture                 | Measurement | LOINC         | standard         |
| 3028334    | Neisseria gonorrhoeae [Presence] in Specimen by Organism specific culture                | Measurement | LOINC         | standard         |
| 3028918    | Neisseria gonorrhoeae rRNA [Presence] in Conjunctival specimen by Probe                  | Measurement | LOINC         | standard         |
| 3028963    | Neisseria gonorrhoeae rRNA [Presence] in Specimen from Donor by NAA with probe detection | Measurement | LOINC         | standard         |
| 3029004    | Chlamydia trachomatis rRNA [Presence] in Cervix by NAA with probe detection              | Measurement | LOINC         | standard         |
| 3031356    | Chlamydia trachomatis rRNA [Presence] in Urine by NAA with probe detection               | Measurement | LOINC         | standard         |
| 3033258    | Neisseria gonorrhoeae rRNA [Presence] in Cervix by NAA with probe detection              | Measurement | LOINC         | standard         |
| 3033270    | Neisseria gonorrhoeae DNA [Presence] in Specimen from Donor by NAA with probe detection  | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                                | Domain ID   | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3035800    | Chlamydia trachomatis and Neisseria gonorrhoeae DNA [Identifier] in Specimen by NAA with probe detection                    | Measurement | LOINC         | standard         |
| 3036119    | Neisseria gonorrhoeae DNA [Presence] in Conjunctival specimen by NAA with probe detection                                   | Measurement | LOINC         | standard         |
| 3036736    | Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Specimen by NAA with probe detection                          | Measurement | LOINC         | standard         |
| 3039187    | Neisseria gonorrhoeae rRNA [Presence] in Vaginal fluid by NAA with probe detection                                          | Measurement | LOINC         | standard         |
| 3040285    | Neisseria gonorrhoeae rRNA [Presence] in Urethra by NAA with probe detection                                                | Measurement | LOINC         | standard         |
| 3042761    | Neisseria gonorrhoeae DNA [Presence] in Specimen by Probe with signal amplification                                         | Measurement | LOINC         | standard         |
| 3043290    | Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Specimen by Probe                                            | Measurement | LOINC         | standard         |
| 3043370    | Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Anal by Probe                                                | Measurement | LOINC         | standard         |
| 3043859    | Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Urethra by Probe                                             | Measurement | LOINC         | standard         |
| 3044125    | Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Specimen by Probe with signal amplification                   | Measurement | LOINC         | standard         |
| 3045028    | Neisseria gonorrhoeae rRNA [Presence] in Specimen by NAA with probe detection                                               | Measurement | LOINC         | standard         |
| 3045281    | Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Urine by NAA with probe detection                             | Measurement | LOINC         | standard         |
| 3045367    | Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Cervix by NAA with probe detection                            | Measurement | LOINC         | standard         |
| 3045789    | Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Genital specimen by NAA with probe detection                  | Measurement | LOINC         | standard         |
| 3046408    | Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Genital specimen by Probe                                    | Measurement | LOINC         | standard         |
| 3046462    | Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Tissue by Probe                                              | Measurement | LOINC         | standard         |
| 3046574    | Neisseria gonorrhoeae DNA [Presence] in Vaginal fluid by NAA with probe detection                                           | Measurement | LOINC         | standard         |
| 3047227    | Chlamydia trachomatis and Neisseria gonorrhoeae DNA [Identifier] in Specimen by Probe with signal amplification             | Measurement | LOINC         | standard         |
| 3050361    | Neisseria gonorrhoeae DNA [Presence] in Genital specimen by NAA with probe detection                                        | Measurement | LOINC         | standard         |
| 3052265    | Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Specimen from Donor by NAA with probe detection              | Measurement | LOINC         | standard         |
| 3965719    | Chlamydia trachomatis and Neisseria gonorrhoeae and Trichomonas vaginalis rRNA panel – Specimen by NAA with probe detection | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                                       | Domain ID   | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3966078    | Chlamydia trachomatis rRNA and Neisseria gonorrhoeae rRNA and Trichomonas vaginalis RNA and Candida sp RNA panel                   | Measurement | LOINC         | standard         |
| 4008450    | Neisseria gonorrhoeae antigen assay                                                                                                | Measurement | SNOMED        | standard         |
| 4039713    | Neisseria gonorrhoeae DNA assay                                                                                                    | Measurement | SNOMED        | standard         |
| 4045478    | Neisseria gonorrhoeae culture                                                                                                      | Measurement | SNOMED        | standard         |
| 4046255    | Neisseria gonorrhoeae rRNA assay                                                                                                   | Measurement | SNOMED        | standard         |
| 4161293    | Polymerase chain reaction test for Neisseria gonorrhoeae                                                                           | Measurement | SNOMED        | standard         |
| 4162401    | Neisseria gonorrhoeae nucleic acid detection                                                                                       | Measurement | SNOMED        | standard         |
| 21491446   | Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Urine by NAA with probe detection                                   | Measurement | LOINC         | standard         |
| 21492849   | Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Cervix by NAA with probe detection                                  | Measurement | LOINC         | standard         |
| 21492850   | Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Vaginal fluid by NAA with probe detection                           | Measurement | LOINC         | standard         |
| 21492853   | Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Anorectal by NAA with probe detection                               | Measurement | LOINC         | standard         |
| 21492854   | Neisseria gonorrhoeae rRNA [Presence] in Anorectal by NAA with probe detection                                                     | Measurement | LOINC         | standard         |
| 21492856   | Neisseria gonorrhoeae [Presence] in Anorectal by Organism specific culture                                                         | Measurement | LOINC         | standard         |
| 36031325   | Chlamydia trachomatis and Neisseria gonorrhoeae and Trichomonas vaginalis DNA panel – Specimen by NAA with probe detection         | Measurement | LOINC         | standard         |
| 36032175   | Neisseria gonorrhoeae DNA [Presence] in Cervix by NAA with probe detection                                                         | Measurement | LOINC         | standard         |
| 36303893   | Neisseria gonorrhoeae DNA [Presence] in Throat by NAA with probe detection                                                         | Measurement | LOINC         | standard         |
| 36304245   | Neisseria gonorrhoeae DNA [Presence] in Anorectal by NAA with probe detection                                                      | Measurement | LOINC         | standard         |
| 37019810   | Chlamydia trachomatis and Neisseria gonorrhoeae and Trichomonas vaginalis DNA panel – Urine by NAA with probe detection            | Measurement | LOINC         | standard         |
| 37020456   | Neisseria gonorrhoeae [Presence] in Aspirate by Organism specific culture                                                          | Measurement | LOINC         | standard         |
| 37021472   | Chlamydia trachomatis and Neisseria gonorrhoeae and Trichomonas vaginalis DNA panel – Genital specimen by NAA with probe detection | Measurement | LOINC         | standard         |
| 37160300   | Neisseria gonorrhoeae DNA PCR (polymerase chain reaction) qualitative result                                                       | Measurement | SNOMED        | standard         |
| 37171298   | Neisseria gonorrhoeae number concentration by nucleic acid amplification                                                           | Measurement | SNOMED        | standard         |
| 37172087   | Neisseria gonorrhoeae number concentration by culture                                                                              | Measurement | SNOMED        | standard         |

| Concept ID | Concept name                                                                                           | Domain ID   | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 37172286   | Neisseria gonorrhoeae DNA nucleic acid amplification qualitative result                                | Measurement | SNOMED        | standard         |
| 37172357   | Neisseria gonorrhoeae culture qualitative result                                                       | Measurement | SNOMED        | standard         |
| 37172497   | Neisseria gonorrhoeae microscopy qualitative result                                                    | Measurement | SNOMED        | standard         |
| 37173403   | Neisseria gonorrhoeae RNA nucleic acid amplification qualitative result                                | Measurement | SNOMED        | standard         |
| 37394109   | Neisseria gonorrhoeae polymerase chain reaction                                                        | Measurement | SNOMED        | standard         |
| 37395399   | Neisseria gonorrhoeae microscopy                                                                       | Measurement | SNOMED        | standard         |
| 40760299   | Neisseria gonorrhoeae DNA [Presence] in Nasopharynx by NAA with probe detection                        | Measurement | LOINC         | standard         |
| 40760408   | Neisseria gonorrhoeae rRNA [Presence] in Nasopharynx by NAA with probe detection                       | Measurement | LOINC         | standard         |
| 40760570   | Neisseria gonorrhoeae rRNA [Presence] in Anal by NAA with probe detection                              | Measurement | LOINC         | standard         |
| 40763310   | Neisseria gonorrhoeae rRNA [Presence] in Throat by NAA with probe detection                            | Measurement | LOINC         | standard         |
| 40763311   | Neisseria gonorrhoeae rRNA [Presence] in Urine by NAA with probe detection                             | Measurement | LOINC         | standard         |
| 40765597   | PhenX – assay for chlamydia – gonorrhea protocol 160101                                                | Measurement | LOINC         | standard         |
| 40766734   | Chlamydia trachomatis and Neisseria gonorrhoeae rRNA panel – Specimen by NAA with probe detection      | Measurement | LOINC         | standard         |
| 42868635   | Chlamydia trachomatis and Neisseria gonorrhoeae rRNA panel – Urine by NAA with probe detection         | Measurement | LOINC         | standard         |
| 42868636   | Chlamydia trachomatis and Neisseria gonorrhoeae rRNA panel – Urethra by NAA with probe detection       | Measurement | LOINC         | standard         |
| 42868637   | Chlamydia trachomatis and Neisseria gonorrhoeae rRNA panel – Cervix by NAA with probe detection        | Measurement | LOINC         | standard         |
| 42868638   | Chlamydia trachomatis and Neisseria gonorrhoeae rRNA panel – Vaginal fluid by NAA with probe detection | Measurement | LOINC         | standard         |
| 43055688   | Chlamydia trachomatis and Neisseria gonorrhoeae DNA panel – Specimen                                   | Measurement | LOINC         | standard         |
| 44811868   | Neisseria gonorrhoeae nucleic acid detection assay                                                     | Measurement | SNOMED        | standard         |
| 46236265   | Chlamydia trachomatis and Neisseria gonorrhoeae DNA panel – Urethra by NAA with probe detection        | Measurement | LOINC         | standard         |

Table S7. Meningococcal serogroup A.

| Concept ID | Concept name                                                                                     | Domain ID   | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3003429    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Specimen by Latex agglutination    | Measurement | LOINC         | standard         |
| 3004934    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                               | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3006468    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Specimen                                                     | Measurement | LOINC         | standard         |
| 3006634    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                            | Measurement | LOINC         | standard         |
| 3007413    | Neisseria meningitidis serogroup A Ag [Presence] in Specimen by Immunofluorescence                                         | Measurement | LOINC         | standard         |
| 3012768    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid                                        | Measurement | LOINC         | standard         |
| 3016497    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Urine                                                               | Measurement | LOINC         | standard         |
| 3017789    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Cerebral spinal fluid                                               | Measurement | LOINC         | standard         |
| 3018802    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid by Immunoassay                                   | Measurement | LOINC         | standard         |
| 3025108    | Neisseria meningitidis serogroup A Ag [Presence] in Cerebral spinal fluid                                                  | Measurement | LOINC         | standard         |
| 3026241    | Neisseria meningitidis serogroup A Ag [Presence] in Specimen                                                               | Measurement | LOINC         | standard         |
| 3030041    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Serum                                                        | Measurement | LOINC         | standard         |
| 3030066    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Serum by Latex agglutination                                 | Measurement | LOINC         | standard         |
| 3030090    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Urine by Latex agglutination                                 | Measurement | LOINC         | standard         |
| 3032239    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid by Agglutination | Measurement | LOINC         | standard         |
| 3032810    | Neisseria meningitidis serogroup A Ag [Presence] in Isolate by Agglutination                                               | Measurement | LOINC         | standard         |
| 3032826    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Urine by Agglutination                 | Measurement | LOINC         | standard         |
| 3033085    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Serum by Agglutination                 | Measurement | LOINC         | standard         |
| 3033129    | Neisseria meningitidis serogroups A+w135 Ag [Presence] in Body fluid                                                       | Measurement | LOINC         | standard         |
| 3036281    | Neisseria meningitidis serogroup A Ag [Presence] in Specimen by Latex agglutination                                        | Measurement | LOINC         | standard         |
| 3037414    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination                 | Measurement | LOINC         | standard         |
| 3043092    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Specimen by Latex agglutination                                     | Measurement | LOINC         | standard         |
| 3046026    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Specimen                                                            | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                        | Domain ID   | Vocabulary ID | Standard concept |
|------------|---------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3046599    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Urine                                                 | Measurement | LOINC         | standard         |
| 4036388    | Neisseria meningitidis A AND Y antigen assay                                                                        | Measurement | SNOMED        | standard         |
| 4046141    | Neisseria meningitidis A antigen assay                                                                              | Measurement | SNOMED        | standard         |
| 21490997   | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Specimen by Latex agglutination | Measurement | LOINC         | standard         |
| 36203853   | Neisseria meningitidis serogroup A sacB gene [Cycle Threshold #] in Specimen by NAA with probe detection            | Measurement | LOINC         | standard         |
| 40762512   | Neisseria meningitidis serogroups A+B+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination        | Measurement | LOINC         | standard         |
| 44817212   | Neisseria meningitidis serogroup A DNA [Presence] in Specimen by NAA with probe detection                           | Measurement | LOINC         | standard         |

Table S8. Meningococcal serogroup B.

| Concept ID | Concept name                                                                                                         | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3006319    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid by Immunoassay                             | Measurement | LOINC         | standard         |
| 3009740    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Specimen by Latex agglutination              | Measurement | LOINC         | standard         |
| 3012772    | Neisseria meningitidis serogroup B Ag [Presence] in Urine                                                            | Measurement | LOINC         | standard         |
| 3013438    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Specimen                                     | Measurement | LOINC         | standard         |
| 3020550    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |
| 3022069    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                      | Measurement | LOINC         | standard         |
| 3024208    | Neisseria meningitidis serogroup B Ag [Presence] in Urine by Latex agglutination                                     | Measurement | LOINC         | standard         |
| 3025170    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid by Latex agglutination                     | Measurement | LOINC         | standard         |
| 3026245    | Neisseria meningitidis serogroup B Ag [Presence] in Cerebral spinal fluid                                            | Measurement | LOINC         | standard         |
| 3026307    | Neisseria meningitidis serogroup B Ag [Presence] in Specimen                                                         | Measurement | LOINC         | standard         |
| 3026422    | Neisseria meningitidis Ag [Presence] in Cerebral spinal fluid                                                        | Measurement | LOINC         | standard         |
| 3026849    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid                        | Measurement | LOINC         | standard         |
| 3029484    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Serum                                        | Measurement | LOINC         | standard         |
| 3030670    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Serum by Latex agglutination                 | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                               | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3031375    | Neisseria meningitidis serogroup B Ag [Presence] in Isolate by Agglutination                                               | Measurement | LOINC         | standard         |
| 3032239    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid by Agglutination | Measurement | LOINC         | standard         |
| 3032826    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Urine by Agglutination                 | Measurement | LOINC         | standard         |
| 3033085    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Serum by Agglutination                 | Measurement | LOINC         | standard         |
| 3036803    | Neisseria meningitidis serogroup B Ag [Presence] in Specimen by Latex agglutination                                        | Measurement | LOINC         | standard         |
| 3037665    | Neisseria meningitidis serogroup B Ag [Presence] in Body fluid                                                             | Measurement | LOINC         | standard         |
| 3044087    | Neisseria meningitidis serogroup B Ag [Presence] in Serum                                                                  | Measurement | LOINC         | standard         |
| 3044827    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Urine by Latex agglutination                       | Measurement | LOINC         | standard         |
| 3046627    | Neisseria meningitidis serogroup B+Escherichia coli K1 Ag [Presence] in Urine                                              | Measurement | LOINC         | standard         |
| 4046142    | Neisseria meningitidis B antigen assay                                                                                     | Measurement | SNOMED        | standard         |
| 21490997   | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Specimen by Latex agglutination        | Measurement | LOINC         | standard         |
| 36203854   | Neisseria meningitidis serogroup B synD gene [Cycle Threshold #] in Specimen by NAA with probe detection                   | Measurement | LOINC         | standard         |
| 40762512   | Neisseria meningitidis serogroups A+B+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination               | Measurement | LOINC         | standard         |
| 44817211   | Neisseria meningitidis serogroup B DNA [Presence] in Specimen by NAA with probe detection                                  | Measurement | LOINC         | standard         |

Table S9. Meningococcal serogroup C.

| Concept ID | Concept name                                                                                     | Domain ID   | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3003429    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Specimen by Latex agglutination    | Measurement | LOINC         | standard         |
| 3004743    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |
| 3006468    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Specimen                           | Measurement | LOINC         | standard         |
| 3006954    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Urine                                  | Measurement | LOINC         | standard         |
| 3007837    | Neisseria meningitidis serogroup C Ag [Presence] in Specimen by Immunofluorescence               | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                               | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3011277    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Cerebral spinal fluid                                            | Measurement | LOINC         | standard         |
| 3012768    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid                                        | Measurement | LOINC         | standard         |
| 3013873    | Neisseria meningitidis serogroup C Ag [Presence] in Specimen                                                               | Measurement | LOINC         | standard         |
| 3023373    | Neisseria meningitidis serogroup C Ag [Presence] in Specimen by Latex agglutination                                        | Measurement | LOINC         | standard         |
| 3024501    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                            | Measurement | LOINC         | standard         |
| 3025700    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid by Immunoassay                                   | Measurement | LOINC         | standard         |
| 3027656    | Neisseria meningitidis serogroup C Ag [Presence] in Cerebral spinal fluid                                                  | Measurement | LOINC         | standard         |
| 3030041    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Serum                                                        | Measurement | LOINC         | standard         |
| 3030066    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Serum by Latex agglutination                                 | Measurement | LOINC         | standard         |
| 3030090    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Urine by Latex agglutination                                 | Measurement | LOINC         | standard         |
| 3031665    | Neisseria meningitidis serogroup C Ag [Presence] in Isolate by Agglutination                                               | Measurement | LOINC         | standard         |
| 3032239    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid by Agglutination | Measurement | LOINC         | standard         |
| 3032826    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Urine by Agglutination                 | Measurement | LOINC         | standard         |
| 3033085    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Serum by Agglutination                 | Measurement | LOINC         | standard         |
| 3037414    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination                 | Measurement | LOINC         | standard         |
| 3043140    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Specimen by Latex agglutination                                  | Measurement | LOINC         | standard         |
| 3045096    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Specimen                                                         | Measurement | LOINC         | standard         |
| 3046599    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Urine                                                        | Measurement | LOINC         | standard         |
| 4047324    | Neisseria meningitidis C antigen assay                                                                                     | Measurement | SNOMED        | standard         |
| 21490997   | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Specimen by Latex agglutination        | Measurement | LOINC         | standard         |
| 36203855   | Neisseria meningitidis serogroup C synE gene [Cycle Threshold #] in Specimen by NAA with probe detection                   | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                 | Domain ID   | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 40762512   | Neisseria meningitidis serogroups A+B+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |
| 44817210   | Neisseria meningitidis serogroup C DNA [Presence] in Specimen by NAA with probe detection                    | Measurement | LOINC         | standard         |

Table S10. Meningococcal serogroup X.

| Concept ID | Concept name                                                                                             | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3033719    | Neisseria meningitidis serogroup X Ag [Presence] in Isolate by Agglutination                             | Measurement | LOINC         | standard         |
| 36203857   | Neisseria meningitidis serogroup X xcbB gene [Cycle Threshold #] in Specimen by NAA with probe detection | Measurement | LOINC         | standard         |
| 44817208   | Neisseria meningitidis serogroup X DNA [Presence] in Specimen by NAA with probe detection                | Measurement | LOINC         | standard         |

Table S11. Meningococcal serogroup W.

| Concept ID | Concept name                                                                                        | Domain ID   | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3003429    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Specimen by Latex agglutination       | Measurement | LOINC         | standard         |
| 3006468    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Specimen                              | Measurement | LOINC         | standard         |
| 3006954    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Urine                                     | Measurement | LOINC         | standard         |
| 3009177    | Neisseria meningitidis serogroup w135 Ag [Presence] in Specimen by Latex agglutination              | Measurement | LOINC         | standard         |
| 3011277    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Cerebral spinal fluid                     | Measurement | LOINC         | standard         |
| 3011359    | Neisseria meningitidis serogroup w135 Ag [Presence] in Cerebral spinal fluid                        | Measurement | LOINC         | standard         |
| 3012143    | Neisseria meningitidis serogroup w135 Ag [Presence] in Cerebral spinal fluid by Latex agglutination | Measurement | LOINC         | standard         |
| 3012768    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid                 | Measurement | LOINC         | standard         |
| 3015287    | Neisseria meningitidis serogroup w135 Ag [Presence] in Serum or Plasma                              | Measurement | LOINC         | standard         |
| 3025526    | Neisseria meningitidis serogroup w135 Ag [Presence] in Serum or Plasma by Latex agglutination       | Measurement | LOINC         | standard         |
| 3025920    | Neisseria meningitidis serogroup w135 Ag [Presence] in Cerebral spinal fluid by Immunofluorescence  | Measurement | LOINC         | standard         |
| 3027498    | Neisseria meningitidis serogroup w135 Ag [Presence] in Specimen                                     | Measurement | LOINC         | standard         |
| 3030041    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Serum                                 | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                               | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3030066    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Serum by Latex agglutination                                 | Measurement | LOINC         | standard         |
| 3030090    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Urine by Latex agglutination                                 | Measurement | LOINC         | standard         |
| 3031863    | Neisseria meningitidis serogroup w135 Ag [Presence] in Isolate by Agglutination                                            | Measurement | LOINC         | standard         |
| 3032239    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid by Agglutination | Measurement | LOINC         | standard         |
| 3032826    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Urine by Agglutination                 | Measurement | LOINC         | standard         |
| 3033085    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Serum by Agglutination                 | Measurement | LOINC         | standard         |
| 3033129    | Neisseria meningitidis serogroups A+w135 Ag [Presence] in Body fluid                                                       | Measurement | LOINC         | standard         |
| 3037414    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination                 | Measurement | LOINC         | standard         |
| 3043140    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Specimen by Latex agglutination                                  | Measurement | LOINC         | standard         |
| 3045096    | Neisseria meningitidis serogroups C+w135 Ag [Presence] in Specimen                                                         | Measurement | LOINC         | standard         |
| 3046599    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Urine                                                        | Measurement | LOINC         | standard         |
| 4044992    | Neisseria meningitidis W135 antigen assay                                                                                  | Measurement | SNOMED        | standard         |
| 21490997   | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Specimen by Latex agglutination        | Measurement | LOINC         | standard         |
| 36203856   | Neisseria meningitidis serogroup w135 synG gene [Cycle Threshold #] in Specimen by NAA with probe detection                | Measurement | LOINC         | standard         |
| 40762512   | Neisseria meningitidis serogroups A+B+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination               | Measurement | LOINC         | standard         |
| 44817209   | Neisseria meningitidis serogroup w135 DNA [Presence] in Specimen by NAA with probe detection                               | Measurement | LOINC         | standard         |

Table S12. Meningococcal serogroup Y.

| Concept ID | Concept name                                                                                  | Domain ID   | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3003429    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Specimen by Latex agglutination | Measurement | LOINC         | standard         |
| 3004830    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid                     | Measurement | LOINC         | standard         |
| 3006468    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Specimen                        | Measurement | LOINC         | standard         |

| Concept ID | Concept name                                                                                                               | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3012768    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid                                        | Measurement | LOINC         | standard         |
| 3014158    | Neisseria meningitidis serogroup Y Ag [Presence] in Specimen by Latex agglutination                                        | Measurement | LOINC         | standard         |
| 3016497    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Urine                                                               | Measurement | LOINC         | standard         |
| 3017789    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Cerebral spinal fluid                                               | Measurement | LOINC         | standard         |
| 3024554    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid by Immunofluorescence                            | Measurement | LOINC         | standard         |
| 3024969    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid by Immunoassay                                   | Measurement | LOINC         | standard         |
| 3025079    | Neisseria meningitidis serogroup Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination                           | Measurement | LOINC         | standard         |
| 3028323    | Neisseria meningitidis serogroup Y Ag [Presence] in Specimen                                                               | Measurement | LOINC         | standard         |
| 3030041    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Serum                                                        | Measurement | LOINC         | standard         |
| 3030066    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Serum by Latex agglutination                                 | Measurement | LOINC         | standard         |
| 3030090    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Urine by Latex agglutination                                 | Measurement | LOINC         | standard         |
| 3032003    | Neisseria meningitidis serogroup Y Ag [Presence] in Isolate by Agglutination                                               | Measurement | LOINC         | standard         |
| 3032239    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Cerebral spinal fluid by Agglutination | Measurement | LOINC         | standard         |
| 3032826    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Urine by Agglutination                 | Measurement | LOINC         | standard         |
| 3033085    | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Serum by Agglutination                 | Measurement | LOINC         | standard         |
| 3037414    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination                 | Measurement | LOINC         | standard         |
| 3043092    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Specimen by Latex agglutination                                     | Measurement | LOINC         | standard         |
| 3046026    | Neisseria meningitidis serogroups A+Y Ag [Presence] in Specimen                                                            | Measurement | LOINC         | standard         |
| 3046599    | Neisseria meningitidis serogroups A+C+w135+Y Ag [Presence] in Urine                                                        | Measurement | LOINC         | standard         |
| 4007328    | Neisseria meningitidis Y antigen assay                                                                                     | Measurement | SNOMED        | standard         |
| 4036388    | Neisseria meningitidis A AND Y antigen assay                                                                               | Measurement | SNOMED        | standard         |

| Concept ID | Concept name                                                                                                        | Domain ID   | Vocabulary ID | Standard concept |
|------------|---------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 21490997   | Neisseria meningitidis serogroups A+B+C+w135+Y+Escherichia coli K1 Ag [Presence] in Specimen by Latex agglutination | Measurement | LOINC         | standard         |
| 36203721   | Neisseria meningitidis serogroup Y synF gene [Cycle Threshold #] in Specimen by NAA with probe detection            | Measurement | LOINC         | standard         |
| 40762512   | Neisseria meningitidis serogroups A+B+C+w135+Y Ag [Presence] in Cerebral spinal fluid by Latex agglutination        | Measurement | LOINC         | standard         |
| 44817207   | Neisseria meningitidis serogroup Y DNA [Presence] in Specimen by NAA with probe detection                           | Measurement | LOINC         | standard         |

Table S13. Meningococcal carriage.

| Concept ID | Concept name          | Domain ID   | Vocabulary ID | Standard concept |
|------------|-----------------------|-------------|---------------|------------------|
| 4016357    | Meningococcus carrier | Observation | SNOMED        | standard         |

Table S14. HIV.

| Concept ID | Concept name                                                                                  | Domain ID   | Vocabulary ID  | Standard concept |
|------------|-----------------------------------------------------------------------------------------------|-------------|----------------|------------------|
| 432554     | Human immunodeficiency virus II infection                                                     | Condition   | SNOMED         | standard         |
| 439727     | Human immunodeficiency virus infection                                                        | Condition   | SNOMED         | standard         |
| 604782     | Human immunodeficiency virus Centers for Disease Control and Prevention undifferentiated type | Condition   | SNOMED         | standard         |
| 604976     | World Health Organization human immunodeficiency virus infection clinical stage               | Condition   | SNOMED         | standard         |
| 605345     | Psoriasis exacerbated by human immunodeficiency virus infection                               | Condition   | SNOMED         | standard         |
| 606040     | Primary human immunodeficiency virus infection                                                | Condition   | SNOMED         | standard         |
| 606041     | Pityriasis rubra pilaris due to human immunodeficiency virus infection                        | Condition   | SNOMED         | standard         |
| 606044     | Parasitic disease due to human immunodeficiency virus infection                               | Condition   | SNOMED         | standard         |
| 606047     | Human immunodeficiency virus modified skin disease                                            | Condition   | SNOMED         | standard         |
| 606930     | Disorder of skin due to human immunodeficiency virus infection                                | Condition   | SNOMED         | standard         |
| 607384     | Primary effusion lymphoma due to human immune deficiency virus infection                      | Condition   | SNOMED         | standard         |
| 762532     | Maternal human immunodeficiency virus infection                                               | Observation | SNOMED         | standard         |
| 762873     | Documentation of human immunodeficiency virus infection medication action plan                | Observation | SNOMED         | standard         |
| 1340516    | Progression of Human immunodeficiency virus infection                                         | Condition   | OMOP Extension | standard         |
| 2101850    | HIV RNA control plan of care, documented (HIV)                                                | Observation | CPT4           | standard         |
| 2107601    | History of AIDS–defining condition (HIV)                                                      | Observation | CPT4           | standard         |

| Concept ID | Concept name                                                                                                                | Domain ID   | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 2107613    | History of nadir CD4+ cell count <350 cells/mm3 (HIV)                                                                       | Observation | CPT4          | standard         |
| 2107614    | No history of nadir CD4+ cell count <350 cells/mm3 and no history of AIDS-defining condition (HIV)                          | Observation | CPT4          | standard         |
| 2107615    | CD4+ cell count <200 cells/mm3 (HIV)                                                                                        | Observation | CPT4          | standard         |
| 2107616    | CD4+ cell count 200 – 499 cells/mm3 (HIV)                                                                                   | Observation | CPT4          | standard         |
| 2107617    | CD4+ cell count ≥500 cells/mm3 (HIV)                                                                                        | Observation | CPT4          | standard         |
| 2107618    | CD4+ cell percentage <15% (HIV)                                                                                             | Observation | CPT4          | standard         |
| 2107619    | CD4+ cell percentage ≥15% (HIV)                                                                                             | Observation | CPT4          | standard         |
| 2107623    | CD4+ cell count or CD4+ cell percentage documented as performed (HIV)                                                       | Observation | CPT4          | standard         |
| 2107647    | Documentation that tuberculosis (TB) screening test performed and results interpreted (HIV) (IBD)                           | Observation | CPT4          | standard         |
| 2107650    | Chlamydia and gonorrhea screenings documented as performed (HIV)                                                            | Observation | CPT4          | standard         |
| 2107663    | Syphilis screening documented as performed (HIV)                                                                            | Observation | CPT4          | standard         |
| 2107666    | Hepatitis B screening documented as performed (HIV)                                                                         | Observation | CPT4          | standard         |
| 2107669    | Hepatitis C screening documented as performed (HIV)                                                                         | Observation | CPT4          | standard         |
| 2107692    | Patient has documented immunity to Hepatitis C (HIV)                                                                        | Observation | CPT4          | standard         |
| 2108660    | Hepatitis B vaccine injection administered or previously received (HEP-C, HIV) (IBD)                                        | Observation | CPT4          | standard         |
| 2108798    | Patient receiving potent antiretroviral therapy for 6 months or longer (HIV)                                                | Observation | CPT4          | standard         |
| 2108799    | Patient receiving potent antiretroviral therapy for less than 6 months or not receiving potent antiretroviral therapy (HIV) | Observation | CPT4          | standard         |
| 2108802    | Influenza immunization administered or previously received (HIV) (P-ESRD)                                                   | Observation | CPT4          | standard         |
| 2108803    | Hepatitis B vaccine injection administered or previously received (HIV) (Deprecated)                                        | Observation | CPT4          | standard         |
| 2108804    | Potent antiretroviral therapy prescribed (HIV)                                                                              | Observation | CPT4          | standard         |
| 2108805    | Pneumocystis jiroveci pneumonia prophylaxis prescribed (HIV)                                                                | Observation | CPT4          | standard         |
| 2108812    | Pneumocystis jiroveci pneumonia prophylaxis prescribed within 3 months of low CD4+ cell count or percentage (HIV)           | Observation | CPT4          | standard         |
| 2108832    | Patient screened for injection drug use (HIV)                                                                               | Observation | CPT4          | standard         |
| 2108833    | Patient screened for high-risk sexual behavior (HIV)                                                                        | Observation | CPT4          | standard         |
| 3000771    | Family embarrassed [Living with HIV]                                                                                        | Observation | LOINC         | standard         |
| 3000964    | Medications are taking over my life [Living with HIV]                                                                       | Observation | LOINC         | standard         |
| 3001470    | Not enjoying life [Living with HIV]                                                                                         | Observation | LOINC         | standard         |
| 3002381    | Strength from family [Living with HIV]                                                                                      | Observation | LOINC         | standard         |
| 3002557    | No energy to fight back [Living with HIV]                                                                                   | Observation | LOINC         | standard         |

| Concept ID | Concept name                                                            | Domain ID   | Vocabulary ID | Standard concept |
|------------|-------------------------------------------------------------------------|-------------|---------------|------------------|
| 3002941    | No good church experience [Living with HIV]                             | Observation | LOINC         | standard         |
| 3003652    | Need help letting go [Living with HIV]                                  | Observation | LOINC         | standard         |
| 3005887    | No purpose in life [Living with HIV]                                    | Observation | LOINC         | standard         |
| 3009439    | Comfortable and well cared for [Living with HIV]                        | Observation | LOINC         | standard         |
| 3010098    | Financial situation is distressing [Living with HIV]                    | Observation | LOINC         | standard         |
| 3010626    | Frightened over little control [Living with HIV]                        | Observation | LOINC         | standard         |
| 3010876    | Afraid of pain and suffering [Living with HIV]                          | Observation | LOINC         | standard         |
| 3012018    | Afraid to die [Living with HIV]                                         | Observation | LOINC         | standard         |
| 3012293    | Live life day to day [Living with HIV]                                  | Observation | LOINC         | standard         |
| 3012675    | Feel spiritual as I near the end [Living with HIV]                      | Observation | LOINC         | standard         |
| 3013789    | Use time wisely [Living with HIV]                                       | Observation | LOINC         | standard         |
| 3013937    | Independence [Living with HIV]                                          | Observation | LOINC         | standard         |
| 3017480    | Losing my looks is devastating [Living with HIV]                        | Observation | LOINC         | standard         |
| 3018022    | Loss of independence [Living with HIV]                                  | Observation | LOINC         | standard         |
| 3018579    | Lots of regrets [Living with HIV]                                       | Observation | LOINC         | standard         |
| 3019125    | May choose to self-deliver at the end [Living with HIV]                 | Observation | LOINC         | standard         |
| 3019581    | Don't have to keep fighting [Living with HIV]                           | Observation | LOINC         | standard         |
| 3019806    | Embarrassed by the way I look [Living with HIV]                         | Observation | LOINC         | standard         |
| 3019951    | Important to be surrounded by those I love [Living with HIV]            | Observation | LOINC         | standard         |
| 3020016    | Pain is hard to manage [Living with HIV]                                | Observation | LOINC         | standard         |
| 3020462    | Giving up things [Living with HIV]                                      | Observation | LOINC         | standard         |
| 3021281    | Want to die at home [Living with HIV]                                   | Observation | LOINC         | standard         |
| 3021585    | Family does what needs done [Living with HIV]                           | Observation | LOINC         | standard         |
| 3022609    | My hometown means a lot [Living with HIV]                               | Observation | LOINC         | standard         |
| 3023073    | Take time for important things [Living with HIV]                        | Observation | LOINC         | standard         |
| 3023145    | Don't want high technology to keep me alive [Living with HIV]           | Observation | LOINC         | standard         |
| 3026386    | Extra effort to do things [Living with HIV]                             | Observation | LOINC         | standard         |
| 3030100    | Medication or other side effects associated with HIV treatment          | Observation | LOINC         | standard         |
| 3032194    | Symptom, diagnosis, or opportunistic infection related to HIV treatment | Observation | LOINC         | standard         |
| 3032423    | Date determined medically eligible to start HIV treatment               | Observation | LOINC         | standard         |
| 3032426    | Date determined medically eligible and ready to start HIV treatment     | Observation | LOINC         | standard         |
| 3032508    | Reason for stopping HIV treatment                                       | Observation | LOINC         | standard         |
| 3032701    | Severity of side effect to HIV treatment                                | Observation | LOINC         | standard         |

| Concept ID | Concept name                                                                 | Domain ID   | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3032799    | HIV Antiretroviral therapy Antiretroviral therapy status section             | Observation | LOINC         | standard         |
| 3034463    | I live for today [Living with HIV]                                           | Observation | LOINC         | standard         |
| 3034753    | Important to be in charge [Living with HIV]                                  | Observation | LOINC         | standard         |
| 3034820    | Meaningful life [Living with HIV]                                            | Observation | LOINC         | standard         |
| 3035391    | So many things yet undone [Living with HIV]                                  | Observation | LOINC         | standard         |
| 3035989    | Somewhat disconnected [Living with HIV]                                      | Observation | LOINC         | standard         |
| 3036507    | Stay at home and receive treatment [Living with HIV]                         | Observation | LOINC         | standard         |
| 3042729    | Date original clinic HIV treatment start                                     | Observation | LOINC         | standard         |
| 3042776    | Current HIV treatment therapy duration                                       | Observation | LOINC         | standard         |
| 3043170    | Reason medically eligible for HIV treatment                                  | Observation | LOINC         | standard         |
| 3043352    | Reason for missing HIV treatment administration schedule                     | Observation | LOINC         | standard         |
| 3043545    | District where patient entered HIV treatment                                 | Observation | LOINC         | standard         |
| 3044754    | HIV treatment cohort                                                         | Observation | LOINC         | standard         |
| 3045247    | Date dropped from HIV treatment                                              | Observation | LOINC         | standard         |
| 3045548    | Number of HIV antiretroviral medication doses missed 4 days ago ACTG         | Observation | LOINC         | standard         |
| 3045553    | HIV treatment prior to enrollment                                            | Observation | LOINC         | standard         |
| 3045578    | Number of HIV antiretroviral medication doses missed 2 days ago ACTG         | Observation | LOINC         | standard         |
| 3045941    | Date eligible and selected to start HIV treatment                            | Observation | LOINC         | standard         |
| 3046153    | World Health Organization HIV stage                                          | Observation | LOINC         | standard         |
| 3046216    | HIV treatment prior clinic transferred from Address                          | Observation | LOINC         | standard         |
| 3046257    | Number of HIV antiretroviral medication doses missed yesterday ACTG          | Observation | LOINC         | standard         |
| 3046739    | Number of HIV antiretroviral medication doses missed 3 days ago ACTG         | Observation | LOINC         | standard         |
| 3046792    | HIV treatment clinic transferred to Address                                  | Observation | LOINC         | standard         |
| 3046827    | Date lost to HIV treatment therapy                                           | Observation | LOINC         | standard         |
| 3046960    | Date lost to HIV treatment follow-up                                         | Observation | LOINC         | standard         |
| 3047275    | HIV ART medication                                                           | Observation | LOINC         | standard         |
| 3052004    | Living with HIV (LIV-HIV) panel                                              | Observation | LOINC         | standard         |
| 3654645    | Bacterial infection due to human immunodeficiency virus infection            | Condition   | SNOMED        | standard         |
| 3654682    | Chronic hepatitis C co-occurrent with human immunodeficiency virus infection | Condition   | SNOMED        | standard         |
| 3654900    | Encephalitis caused by human immunodeficiency virus type 2                   | Condition   | SNOMED        | standard         |
| 3654950    | Encephalitis caused by human immunodeficiency virus type 1                   | Condition   | SNOMED        | standard         |

| Concept ID | Concept name                                                                      | Domain ID   | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------------------------|-------------|---------------|------------------|
| 3655330    | Eosinophilic folliculitis due to human immunodeficiency virus infection           | Condition   | SNOMED        | standard         |
| 3655331    | Esophagitis due to human immunodeficiency virus disease                           | Condition   | SNOMED        | standard         |
| 3655580    | Mycosis due to human immunodeficiency virus infection                             | Condition   | SNOMED        | standard         |
| 3655867    | Seborrheic dermatitis due to human immunodeficiency virus infection               | Condition   | SNOMED        | standard         |
| 3661697    | Papular pruritic eruption of skin due to human immunodeficiency virus infection   | Condition   | SNOMED        | standard         |
| 3663234    | Pruritus due to human immunodeficiency virus infection                            | Condition   | SNOMED        | standard         |
| 4008081    | Acute HIV infection                                                               | Condition   | SNOMED        | standard         |
| 4013106    | HIV detected                                                                      | Condition   | SNOMED        | standard         |
| 4047624    | Human immunodeficiency virus leukoencephalopathy                                  | Condition   | SNOMED        | standard         |
| 4048033    | Neuropathy caused by human immunodeficiency virus                                 | Condition   | SNOMED        | standard         |
| 4078242    | Human immunodeficiency virus                                                      | Observation | SNOMED        | standard         |
| 4083350    | HIV-related sclerosing cholangitis                                                | Condition   | SNOMED        | standard         |
| 4087603    | Human immunodeficiency virus infection constitutional disease                     | Condition   | SNOMED        | standard         |
| 4087604    | Human immunodeficiency virus infection with neurological disease                  | Condition   | SNOMED        | standard         |
| 4092686    | Human immunodeficiency virus infection with secondary clinical infectious disease | Condition   | SNOMED        | standard         |
| 4128060    | Acquired immune deficiency syndrome-related nephropathy                           | Condition   | SNOMED        | standard         |
| 4161950    | Human immunodeficiency virus encephalitis                                         | Condition   | SNOMED        | standard         |
| 4171124    | Congenital acquired immune deficiency syndrome                                    | Condition   | SNOMED        | standard         |
| 4171125    | Congenital human immunodeficiency virus positive status syndrome                  | Condition   | SNOMED        | standard         |
| 4172009    | HIV infection with infectious mononucleosis-like syndrome                         | Condition   | SNOMED        | standard         |
| 4180254    | Congenital human immunodeficiency virus infection                                 | Condition   | SNOMED        | standard         |
| 4186235    | Leukoplakia of tongue associated with HIV disease                                 | Condition   | SNOMED        | standard         |
| 4188151    | Hairy leukoplakia of tongue associated with HIV disease                           | Condition   | SNOMED        | standard         |
| 4201627    | Aseptic meningitis due to human immunodeficiency virus infection                  | Condition   | SNOMED        | standard         |
| 4211956    | Neutropenia with AIDS (acquired immunodeficiency syndrome)                        | Condition   | SNOMED        | standard         |
| 4220603    | Skin rash with AIDS (acquired immunodeficiency syndrome)                          | Condition   | SNOMED        | standard         |
| 4221489    | Acquired immunodeficiency syndrome-associated disorder                            | Condition   | SNOMED        | standard         |
| 4221503    | Pneumococcal pneumonia with AIDS (acquired immunodeficiency syndrome)             | Condition   | SNOMED        | standard         |
| 4221607    | Mycobacteriosis with AIDS (acquired immunodeficiency syndrome)                    | Condition   | SNOMED        | standard         |

| Concept ID | Concept name                                                                                | Domain ID | Vocabulary ID | Standard concept |
|------------|---------------------------------------------------------------------------------------------|-----------|---------------|------------------|
| 4221911    | Fatigue with AIDS (acquired immunodeficiency syndrome)                                      | Condition | SNOMED        | standard         |
| 4222062    | Candidiasis of lung with AIDS (acquired immunodeficiency syndrome)                          | Condition | SNOMED        | standard         |
| 4222224    | Hepatomegaly with AIDS (acquired immunodeficiency syndrome)                                 | Condition | SNOMED        | standard         |
| 4222250    | Encephalitis with AIDS (acquired immunodeficiency syndrome)                                 | Condition | SNOMED        | standard         |
| 4222383    | Intestinal malabsorption with AIDS (acquired immunodeficiency syndrome)                     | Condition | SNOMED        | standard         |
| 4222402    | Hematopoietic system disease with AIDS (acquired immunodeficiency syndrome)                 | Condition | SNOMED        | standard         |
| 4222405    | Acute endocarditis with AIDS (acquired immunodeficiency syndrome)                           | Condition | SNOMED        | standard         |
| 4222712    | Cryptococcosis with AIDS (acquired immunodeficiency syndrome)                               | Condition | SNOMED        | standard         |
| 4222717    | Subacute adenoviral encephalitis with AIDS (acquired immunodeficiency syndrome)             | Condition | SNOMED        | standard         |
| 4223031    | Anemia associated with AIDS                                                                 | Condition | SNOMED        | standard         |
| 4223032    | Bacterial pneumonia with AIDS (acquired immunodeficiency syndrome)                          | Condition | SNOMED        | standard         |
| 4223276    | Central nervous system demyelinating disease with AIDS (acquired immunodeficiency syndrome) | Condition | SNOMED        | standard         |
| 4223597    | Strongyloidiasis with AIDS (acquired immunodeficiency syndrome)                             | Condition | SNOMED        | standard         |
| 4223738    | Noninfectious gastroenteritis with AIDS (acquired immunodeficiency syndrome)                | Condition | SNOMED        | standard         |
| 4223918    | Retinal vascular changes with AIDS (acquired immunodeficiency syndrome)                     | Condition | SNOMED        | standard         |
| 4224078    | Myelopathy with AIDS (acquired immunodeficiency syndrome)                                   | Condition | SNOMED        | standard         |
| 4224096    | Kaposi's sarcoma with AIDS (acquired immunodeficiency syndrome)                             | Condition | SNOMED        | standard         |
| 4224240    | Presenile dementia with AIDS (acquired immunodeficiency syndrome)                           | Condition | SNOMED        | standard         |
| 4224425    | Subacute myocarditis with AIDS (acquired immunodeficiency syndrome)                         | Condition | SNOMED        | standard         |
| 4224553    | Agranulocytosis with AIDS (acquired immunodeficiency syndrome)                              | Condition | SNOMED        | standard         |
| 4224566    | Skin disorder with AIDS (acquired immunodeficiency syndrome)                                | Condition | SNOMED        | standard         |
| 4224578    | Nocardiosis with AIDS (acquired immunodeficiency syndrome)                                  | Condition | SNOMED        | standard         |
| 4224740    | Coccidioidomycosis with AIDS (acquired immunodeficiency syndrome)                           | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                                              | Domain ID   | Vocabulary ID | Standard concept |
|------------|-------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 4224860    | Organic dementia with AIDS (acquired immunodeficiency syndrome)                           | Condition   | SNOMED        | standard         |
| 4225017    | Salmonella infection with AIDS (acquired immunodeficiency syndrome)                       | Condition   | SNOMED        | standard         |
| 4225027    | Malaise with AIDS (acquired immunodeficiency syndrome)                                    | Condition   | SNOMED        | standard         |
| 4225170    | Histoplasmosis with AIDS (acquired immunodeficiency syndrome)                             | Condition   | SNOMED        | standard         |
| 4225193    | Microsporidiosis associated with acquired immunodeficiency syndrome                       | Condition   | SNOMED        | standard         |
| 4225318    | Viral pneumonia with AIDS (acquired immunodeficiency syndrome)                            | Condition   | SNOMED        | standard         |
| 4225643    | Respiratory disorder with AIDS (acquired immunodeficiency syndrome)                       | Condition   | SNOMED        | standard         |
| 4225810    | Aplastic anemia with AIDS (acquired immunodeficiency syndrome)                            | Condition   | SNOMED        | standard         |
| 4225989    | Infectious gastroenteritis with AIDS (acquired immunodeficiency syndrome)                 | Condition   | SNOMED        | standard         |
| 4226110    | Central nervous disorder with AIDS (acquired immunodeficiency syndrome)                   | Condition   | SNOMED        | standard         |
| 4226111    | Cachexia associated with AIDS                                                             | Condition   | SNOMED        | standard         |
| 4226357    | Malignant neoplasm with AIDS (acquired immunodeficiency syndrome)                         | Condition   | SNOMED        | standard         |
| 4226388    | Reticulosarcoma with AIDS (acquired immunodeficiency syndrome)                            | Condition   | SNOMED        | standard         |
| 4226502    | Pneumocystosis with AIDS (acquired immunodeficiency syndrome)                             | Condition   | SNOMED        | standard         |
| 4226629    | Salivary gland disease with AIDS (acquired immunodeficiency syndrome)                     | Condition   | SNOMED        | standard         |
| 4226631    | Progressive multifocal leukoencephalopathy with AIDS (acquired immunodeficiency syndrome) | Condition   | SNOMED        | standard         |
| 4226658    | Tuberculosis with AIDS (acquired immunodeficiency syndrome)                               | Condition   | SNOMED        | standard         |
| 4226662    | Polyneuropathy with AIDS (acquired immunodeficiency syndrome)                             | Condition   | SNOMED        | standard         |
| 4226787    | Abnormal weight loss associated with AIDS                                                 | Observation | SNOMED        | standard         |
| 4226790    | Blindness with AIDS (acquired immunodeficiency syndrome)                                  | Condition   | SNOMED        | standard         |
| 4226792    | Candidiasis of mouth with AIDS (acquired immunodeficiency syndrome)                       | Condition   | SNOMED        | standard         |
| 4226905    | Thrombocytopenia with AIDS (acquired immunodeficiency syndrome)                           | Condition   | SNOMED        | standard         |
| 4227053    | Myocarditis with AIDS (acquired immunodeficiency syndrome)                                | Condition   | SNOMED        | standard         |

| Concept ID | Concept name                                                               | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------|-------------|---------------|------------------|
| 4227072    | Radiculitis with AIDS (acquired immunodeficiency syndrome)                 | Condition   | SNOMED        | standard         |
| 4227077    | Nutritional deficiency with AIDS (acquired immunodeficiency syndrome)      | Condition   | SNOMED        | standard         |
| 4227205    | Organic brain syndrome with AIDS (acquired immunodeficiency syndrome)      | Condition   | SNOMED        | standard         |
| 4227229    | Dermatomycosis with AIDS (acquired immunodeficiency syndrome)              | Condition   | SNOMED        | standard         |
| 4227350    | Subacute endocarditis with AIDS (acquired immunodeficiency syndrome)       | Condition   | SNOMED        | standard         |
| 4227380    | Disseminated candidiasis with AIDS (acquired immunodeficiency syndrome)    | Condition   | SNOMED        | standard         |
| 4227519    | Neuritis with AIDS (acquired immunodeficiency syndrome)                    | Condition   | SNOMED        | standard         |
| 4227539    | Herpes zoster with AIDS (acquired immunodeficiency syndrome)               | Condition   | SNOMED        | standard         |
| 4227969    | Primary lymphoma of brain with AIDS (acquired immunodeficiency syndrome)   | Condition   | SNOMED        | standard         |
| 4227974    | Myelitis with AIDS (acquired immunodeficiency syndrome)                    | Condition   | SNOMED        | standard         |
| 4228115    | Retinopathy with AIDS (acquired immunodeficiency syndrome)                 | Condition   | SNOMED        | standard         |
| 4228133    | Dementia with AIDS (acquired immunodeficiency syndrome)                    | Condition   | SNOMED        | standard         |
| 4228272    | Failure to thrive in infant with AIDS (acquired immunodeficiency syndrome) | Condition   | SNOMED        | standard         |
| 4228277    | Pneumonia with AIDS (acquired immunodeficiency syndrome)                   | Condition   | SNOMED        | standard         |
| 4228290    | Infective arthritis with AIDS (acquired immunodeficiency syndrome)         | Condition   | SNOMED        | standard         |
| 4228440    | Encephalopathy with AIDS (acquired immunodeficiency syndrome)              | Condition   | SNOMED        | standard         |
| 4228444    | Acquired hemolytic anemia associated with AIDS                             | Condition   | SNOMED        | standard         |
| 4228612    | Encephalomyelitis with AIDS (acquired immunodeficiency syndrome)           | Condition   | SNOMED        | standard         |
| 4228745    | Neuralgia with AIDS (acquired immunodeficiency syndrome)                   | Condition   | SNOMED        | standard         |
| 4228754    | Dyspnea with AIDS (acquired immunodeficiency syndrome)                     | Condition   | SNOMED        | standard         |
| 4228757    | Low vision with AIDS (acquired immunodeficiency syndrome)                  | Condition   | SNOMED        | standard         |
| 4228760    | Hyperhidrosis with AIDS (acquired immunodeficiency syndrome)               | Condition   | SNOMED        | standard         |
| 4230974    | Human immunodeficiency virus type I                                        | Observation | SNOMED        | standard         |
| 4236860    | Pediatric human immunodeficiency virus infection                           | Condition   | SNOMED        | standard         |

| Concept ID | Concept name                                                                                    | Domain ID   | Vocabulary ID | Standard concept |
|------------|-------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 4239722    | Asymptomatic human immunodeficiency virus infection in pregnancy                                | Condition   | SNOMED        | standard         |
| 4241530    | Asymptomatic human immunodeficiency virus infection                                             | Condition   | SNOMED        | standard         |
| 4253472    | Human immunodeficiency virus I infection                                                        | Condition   | SNOMED        | standard         |
| 4262297    | Human immunodeficiency virus encephalopathy                                                     | Condition   | SNOMED        | standard         |
| 4262565    | Human immunodeficiency virus type 2                                                             | Observation | SNOMED        | standard         |
| 4267414    | AIDS                                                                                            | Condition   | SNOMED        | standard         |
| 4295637    | HIV CDC category                                                                                | Observation | SNOMED        | standard         |
| 4298853    | Oral hairy leukoplakia associated with HIV disease                                              | Condition   | SNOMED        | standard         |
| 4299318    | HIV WHO class                                                                                   | Observation | SNOMED        | standard         |
| 4314426    | HIV infection with acute lymphadenitis                                                          | Condition   | SNOMED        | standard         |
| 4340791    | Human immunodeficiency virus enteropathy                                                        | Condition   | SNOMED        | standard         |
| 4347288    | Human immunodeficiency virus myopathy                                                           | Condition   | SNOMED        | standard         |
| 36674238   | Human immunodeficiency virus entry inhibitor                                                    | Observation | SNOMED        | standard         |
| 36674252   | Infection caused by Coccidia co-occurrent with acquired immunodeficiency syndrome               | Condition   | SNOMED        | standard         |
| 36674253   | Infection caused by Toxoplasma gondii co-occurrent with acquired immunodeficiency syndrome      | Condition   | SNOMED        | standard         |
| 36674254   | Infection caused by Isospora co-occurrent with acquired immunodeficiency syndrome               | Condition   | SNOMED        | standard         |
| 36675072   | Human immunodeficiency virus entry inhibitor                                                    | Observation | SNOMED        | standard         |
| 36687122   | Human immunodeficiency virus infection with cognitive impairment                                | Condition   | SNOMED        | standard         |
| 36714339   | Candidiasis of upper respiratory tract co-occurrent with human immunodeficiency virus infection | Condition   | SNOMED        | standard         |
| 36715476   | Human immunodeficiency virus complicating pregnancy childbirth and the puerperium               | Condition   | SNOMED        | standard         |
| 36716522   | Sequela of infection caused by Human immunodeficiency virus                                     | Condition   | SNOMED        | standard         |
| 36716524   | Parkinsonism due to human immunodeficiency virus infection                                      | Condition   | SNOMED        | standard         |
| 37017071   | Subacute adenoviral encephalitis co-occurrent with human immunodeficiency virus infection       | Condition   | SNOMED        | standard         |
| 37017082   | Splenomegaly co-occurrent with human immunodeficiency virus infection                           | Condition   | SNOMED        | standard         |
| 37017092   | Candidiasis of esophagus co-occurrent with human immunodeficiency virus infection               | Condition   | SNOMED        | standard         |
| 37017093   | Heart disease co-occurrent with human immunodeficiency virus infection                          | Condition   | SNOMED        | standard         |
| 37017094   | Disorder of gastrointestinal tract co-occurrent with human immunodeficiency virus infection     | Condition   | SNOMED        | standard         |

| Concept ID | Concept name                                                                                              | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------------------------------------------------|-----------|---------------|------------------|
| 37017106   | Eruption of skin co-occurrent with human immunodeficiency virus infection                                 | Condition | SNOMED        | standard         |
| 37017108   | Myocarditis co-occurrent with human immunodeficiency virus infection                                      | Condition | SNOMED        | standard         |
| 37017112   | Primary cerebral lymphoma co-occurrent with human immunodeficiency virus infection                        | Condition | SNOMED        | standard         |
| 37017124   | Infection caused by Strongyloides co-occurrent with human immunodeficiency virus infection                | Condition | SNOMED        | standard         |
| 37017125   | Disorder of skin co-occurrent with human immunodeficiency virus infection                                 | Condition | SNOMED        | standard         |
| 37017126   | Myelitis co-occurrent with human immunodeficiency virus infection                                         | Condition | SNOMED        | standard         |
| 37017132   | Anemia co-occurrent with human immunodeficiency virus infection                                           | Condition | SNOMED        | standard         |
| 37017209   | Hemophagocytic syndrome with human immunodeficiency virus infection                                       | Condition | SNOMED        | standard         |
| 37017210   | Chronic infection caused by herpes simplex virus co-occurrent with human immunodeficiency virus infection | Condition | SNOMED        | standard         |
| 37017243   | Reticulosarcoma co-occurrent with human immunodeficiency virus infection                                  | Condition | SNOMED        | standard         |
| 37017244   | Disorder of respiratory system co-occurrent with human immunodeficiency virus infection                   | Condition | SNOMED        | standard         |
| 37017246   | Progressive multifocal leukoencephalopathy co-occurrent with human immunodeficiency virus infection       | Condition | SNOMED        | standard         |
| 37017247   | Presenile dementia co-occurrent with human immunodeficiency virus infection                               | Condition | SNOMED        | standard         |
| 37017248   | Infection caused by Pneumocystis co-occurrent with human immunodeficiency virus infection                 | Condition | SNOMED        | standard         |
| 37017249   | Organic brain syndrome co-occurrent with human immunodeficiency virus infection                           | Condition | SNOMED        | standard         |
| 37017254   | Candidiasis of mouth co-occurrent with human immunodeficiency virus infection                             | Condition | SNOMED        | standard         |
| 37017259   | Disorder of spinal cord co-occurrent with human immunodeficiency virus infection                          | Condition | SNOMED        | standard         |
| 37017260   | Disorder of kidney co-occurrent with human immunodeficiency virus infection                               | Condition | SNOMED        | standard         |
| 37017261   | Gastrointestinal malabsorption syndrome co-occurrent with human immunodeficiency virus infection          | Condition | SNOMED        | standard         |
| 37017262   | Neuritis co-occurrent with human immunodeficiency virus infection                                         | Condition | SNOMED        | standard         |
| 37017263   | Lymphadenopathy co-occurrent with human immunodeficiency virus infection                                  | Condition | SNOMED        | standard         |
| 37017265   | Enlargement of liver co-occurrent with human immunodeficiency virus infection                             | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                                                             | Domain ID | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------------|-----------|---------------|------------------|
| 37017266   | Acute endocarditis co-occurrent with human immunodeficiency virus infection                              | Condition | SNOMED        | standard         |
| 37017276   | Cardiomyopathy co-occurrent with human immunodeficiency virus infection                                  | Condition | SNOMED        | standard         |
| 37017278   | Recurrent bacterial pneumonia co-occurrent with human immunodeficiency virus infection                   | Condition | SNOMED        | standard         |
| 37017279   | Disorder of peripheral nervous system co-occurrent with human immunodeficiency virus infection           | Condition | SNOMED        | standard         |
| 37017282   | Agranulocytosis co-occurrent with human immunodeficiency virus infection                                 | Condition | SNOMED        | standard         |
| 37017283   | Visual impairment co-occurrent with human immunodeficiency virus infection                               | Condition | SNOMED        | standard         |
| 37017284   | Infective arthritis co-occurrent with human immunodeficiency virus infection                             | Condition | SNOMED        | standard         |
| 37017285   | Acquired hemolytic anemia co-occurrent with human immunodeficiency virus infection                       | Condition | SNOMED        | standard         |
| 37017294   | Demyelinating disease of central nervous system co-occurrent with human immunodeficiency virus infection | Condition | SNOMED        | standard         |
| 37017295   | Infection caused by Nocardia co-occurrent with human immunodeficiency virus infection                    | Condition | SNOMED        | standard         |
| 37017296   | Isosporiasis co-occurrent with human immunodeficiency virus infection                                    | Condition | SNOMED        | standard         |
| 37017318   | Infectious gastroenteritis co-occurrent with human immunodeficiency virus infection                      | Condition | SNOMED        | standard         |
| 37017319   | Disorder of central nervous system co-occurrent with human immunodeficiency virus infection              | Condition | SNOMED        | standard         |
| 37017320   | Malignant neoplastic disease co-occurrent with human immunodeficiency virus infection                    | Condition | SNOMED        | standard         |
| 37017424   | Nephrotic syndrome co-occurrent with human immunodeficiency virus infection                              | Condition | SNOMED        | standard         |
| 37017425   | Renal failure syndrome co-occurrent with human immunodeficiency virus infection                          | Condition | SNOMED        | standard         |
| 37017442   | Diffuse non-Hodgkin immunoblastic lymphoma co-occurrent with human immunodeficiency virus infection      | Condition | SNOMED        | standard         |
| 37017446   | Infection caused by Cytomegalovirus co-occurrent with human immunodeficiency virus infection             | Condition | SNOMED        | standard         |
| 37017453   | Coccidiosis co-occurrent with human immunodeficiency virus infection                                     | Condition | SNOMED        | standard         |
| 37017454   | Infection caused by herpes simplex virus co-occurrent with human immunodeficiency virus infection        | Condition | SNOMED        | standard         |
| 37017455   | Pyrexia of unknown origin co-occurrent with human immunodeficiency virus infection                       | Condition | SNOMED        | standard         |
| 37017456   | Aspergillosis co-occurrent with human immunodeficiency virus infection                                   | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                                                                     | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------------------------------------------------------------------|-----------|---------------|------------------|
| 37017457   | Infection caused by herpes zoster virus co-occurrent with human immunodeficiency virus infection                 | Condition | SNOMED        | standard         |
| 37017549   | Dementia co-occurrent with human immunodeficiency virus infection                                                | Condition | SNOMED        | standard         |
| 37017550   | Infection caused by Cryptosporidium co-occurrent with human immunodeficiency virus infection                     | Condition | SNOMED        | standard         |
| 37017579   | Opportunistic mycosis co-occurrent with human immunodeficiency virus infection                                   | Condition | SNOMED        | standard         |
| 37017580   | Microsporidiosis co-occurrent with human immunodeficiency virus infection                                        | Condition | SNOMED        | standard         |
| 37017586   | Focal segmental glomerulosclerosis co-occurrent with human immunodeficiency virus infection                      | Condition | SNOMED        | standard         |
| 37017595   | Burkitt lymphoma co-occurrent with human immunodeficiency virus infection                                        | Condition | SNOMED        | standard         |
| 37017652   | Multidermatomal infection caused by Herpes zoster co-occurrent with human immunodeficiency virus infection       | Condition | SNOMED        | standard         |
| 37017655   | Disseminated atypical infection caused by Mycobacterium co-occurrent with human immunodeficiency virus infection | Condition | SNOMED        | standard         |
| 37018063   | Immune reconstitution inflammatory syndrome caused by human immunodeficiency virus infection                     | Condition | SNOMED        | standard         |
| 37018711   | Disorder of eye proper co-occurrent with human immunodeficiency virus infection                                  | Condition | SNOMED        | standard         |
| 37018714   | Radiculitis co-occurrent with human immunodeficiency virus infection                                             | Condition | SNOMED        | standard         |
| 37018721   | Polyneuropathy co-occurrent with human immunodeficiency virus infection                                          | Condition | SNOMED        | standard         |
| 37018755   | Recurrent salmonella sepsis co-occurrent with human immunodeficiency virus infection                             | Condition | SNOMED        | standard         |
| 37018935   | Dermatophytosis co-occurrent with human immunodeficiency virus infection                                         | Condition | SNOMED        | standard         |
| 37019034   | Neuralgia co-occurrent with human immunodeficiency virus infection                                               | Condition | SNOMED        | standard         |
| 37019042   | Infection caused by Salmonella co-occurrent with human immunodeficiency virus infection                          | Condition | SNOMED        | standard         |
| 37019052   | Disseminated infection caused by Strongyloides co-occurrent with human immunodeficiency virus infection          | Condition | SNOMED        | standard         |
| 37019055   | Aplastic anemia co-occurrent with human immunodeficiency virus infection                                         | Condition | SNOMED        | standard         |
| 37019058   | Bacterial pneumonia co-occurrent with human immunodeficiency virus infection                                     | Condition | SNOMED        | standard         |
| 37116830   | Invasive carcinoma of uterine cervix co-occurrent with human immunodeficiency virus infection                    | Condition | SNOMED        | standard         |
| 37116831   | Extrapulmonary tuberculosis co-occurrent with human immunodeficiency virus infection                             | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                                                       | Domain ID   | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 37162220   | Infectious mononucleosis caused by human immunodeficiency virus                                    | Condition   | SNOMED        | standard         |
| 37162221   | Infectious mononucleosis caused by human immunodeficiency virus type I                             | Condition   | SNOMED        | standard         |
| 37162263   | Periodontitis exacerbated by human immunodeficiency virus infection                                | Condition   | SNOMED        | standard         |
| 37162512   | Enteritis of small intestine due to human immunodeficiency virus disease                           | Condition   | SNOMED        | standard         |
| 37162513   | Enteritis of intestine due to human immunodeficiency virus disease                                 | Condition   | SNOMED        | standard         |
| 37166066   | Autonomic disorder due to HIV infection                                                            | Condition   | SNOMED        | standard         |
| 37166798   | AIDS (acquired immunodeficiency syndrome) wasting syndrome                                         | Condition   | SNOMED        | standard         |
| 37167026   | Motor neuron disease due to human immunodeficiency virus infection                                 | Condition   | SNOMED        | standard         |
| 37168542   | Human immunodeficiency virus management program                                                    | Observation | SNOMED        | standard         |
| 40482214   | Hepatitis B associated with Human immunodeficiency virus infection                                 | Condition   | SNOMED        | standard         |
| 40484012   | Non-Hodgkin lymphoma associated with Human immunodeficiency virus infection                        | Condition   | SNOMED        | standard         |
| 40493262   | Infectious disease with acquired immune deficiency syndrome                                        | Condition   | SNOMED        | standard         |
| 42536092   | HIV fusion inhibitor                                                                               | Observation | SNOMED        | standard         |
| 42536590   | Human immunodeficiency virus World Health Organization 2007 stage 1 co-occurrent with tuberculosis | Condition   | SNOMED        | standard         |
| 42536591   | Human immunodeficiency virus World Health Organization 2007 stage 1 co-occurrent with malaria      | Condition   | SNOMED        | standard         |
| 42536592   | Human immunodeficiency virus World Health Organization 2007 stage 2 co-occurrent with tuberculosis | Condition   | SNOMED        | standard         |
| 42536593   | Human immunodeficiency virus World Health Organization 2007 stage 2 co-occurrent with malaria      | Condition   | SNOMED        | standard         |
| 42536594   | Human immunodeficiency virus World Health Organization 2007 stage 3 co-occurrent with malaria      | Condition   | SNOMED        | standard         |
| 42536595   | Human immunodeficiency virus World Health Organization 2007 stage 4 co-occurrent with tuberculosis | Condition   | SNOMED        | standard         |
| 42536596   | Human immunodeficiency virus World Health Organization 2007 stage 4 co-occurrent with malaria      | Condition   | SNOMED        | standard         |
| 42538959   | Asymptomatic human immunodeficiency virus A1 infection                                             | Condition   | SNOMED        | standard         |
| 42538960   | Asymptomatic human immunodeficiency virus A2 infection                                             | Condition   | SNOMED        | standard         |
| 42539031   | Human immunodeficiency virus World Health Organization 2007 stage 3 co-occurrent with tuberculosis | Condition   | SNOMED        | standard         |
| 42870071   | Emotional well-being – living with HIV [FACIT]                                                     | Observation | LOINC         | standard         |

| Concept ID | Concept name                                                                                           | Domain ID   | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------------------------------------------|-------------|---------------|------------------|
| 42870077   | Functional Assessment of HIV Infection Questionnaire – version 4 (FAHI) [FACIT]                        | Observation | LOINC         | standard         |
| 43531586   | Symptomatic human immunodeficiency virus infection                                                     | Condition   | SNOMED        | standard         |
| 44783356   | Human immunodeficiency virus carrier                                                                   | Observation | SNOMED        | standard         |
| 44783623   | Pulmonary arterial hypertension associated with HIV infection                                          | Condition   | SNOMED        | standard         |
| 44783780   | Cholangitis with AIDS (acquired immunodeficiency syndrome)                                             | Condition   | SNOMED        | standard         |
| 44784137   | Sepsis with acquired immunodeficiency syndrome                                                         | Condition   | SNOMED        | standard         |
| 44802785   | Human immunodeficiency virus monitoring                                                                | Observation | SNOMED        | standard         |
| 44802786   | Human immunodeficiency virus annual review                                                             | Observation | SNOMED        | standard         |
| 44802787   | Human immunodeficiency virus positive general health check service declined                            | Observation | SNOMED        | standard         |
| 44803613   | People with human immunodeficiency virus or acquired immune deficiency syndrome                        | Observation | SNOMED        | standard         |
| 44809802   | Human immunodeficiency virus infection monitoring invitation                                           | Observation | SNOMED        | standard         |
| 44809803   | Human immunodeficiency virus infection monitoring telephone invitation                                 | Observation | SNOMED        | standard         |
| 44809804   | Human immunodeficiency virus infection monitoring first telephone invitation                           | Observation | SNOMED        | standard         |
| 44809810   | Human immunodeficiency virus infection monitoring second telephone invitation                          | Observation | SNOMED        | standard         |
| 44809870   | Human immunodeficiency virus infection monitoring third telephone invitation                           | Observation | SNOMED        | standard         |
| 44810989   | Facial lipoatrophy associated with human immunodeficiency virus                                        | Condition   | SNOMED        | standard         |
| 45757102   | Acquired immune deficiency syndrome complicating childbirth                                            | Condition   | SNOMED        | standard         |
| 45757132   | Human immunodeficiency virus in mother complicating childbirth                                         | Condition   | SNOMED        | standard         |
| 45769864   | Symptomatic human immunodeficiency virus (HIV) I infection                                             | Condition   | SNOMED        | standard         |
| 46284256   | HIV (human immunodeficiency virus) disease resulting in haematological and immunological abnormalities | Condition   | SNOMED        | standard         |

Table S15. Asplenia.

| Concept ID | Concept name                                                                                                                            | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------|-----------|---------------|------------------|
| 604712     | Agenesis of spleen                                                                                                                      | Condition | SNOMED        | standard         |
| 2108425    | Splenectomy; total, en bloc for extensive disease, in conjunction with other procedure (List in addition to code for primary procedure) | Procedure | CPT4          | standard         |

| Concept ID | Concept name                                                                                                                                                                                                                                                    | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---------------|------------------|
| 2108427    | Laparoscopy, surgical, splenectomy                                                                                                                                                                                                                              | Procedure | CPT4          | standard         |
| 2109402    | Pancreatectomy, distal subtotal, with or without splenectomy; without pancreaticojejunostomy                                                                                                                                                                    | Procedure | CPT4          | standard         |
| 2109403    | Pancreatectomy, distal subtotal, with or without splenectomy; with pancreaticojejunostomy                                                                                                                                                                       | Procedure | CPT4          | standard         |
| 2109423    | Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arte | Procedure | CPT4          | standard         |
| 4001894    | Excision of accessory spleen                                                                                                                                                                                                                                    | Procedure | SNOMED        | standard         |
| 4018300    | Total splenectomy                                                                                                                                                                                                                                               | Procedure | SNOMED        | standard         |
| 4018301    | Total splenectomy and reimplantation of fragments                                                                                                                                                                                                               | Procedure | SNOMED        | standard         |
| 4044879    | Splenorrhaphy with partial splenectomy                                                                                                                                                                                                                          | Procedure | SNOMED        | standard         |
| 4125482    | Splenectomy                                                                                                                                                                                                                                                     | Procedure | SNOMED        | standard         |
| 4143166    | Distal subtotal pancreatectomy with splenectomy and pancreaticojejunostomy                                                                                                                                                                                      | Procedure | SNOMED        | standard         |
| 4195648    | Laparoscopic total splenectomy                                                                                                                                                                                                                                  | Procedure | SNOMED        | standard         |
| 4218096    | Excision of cyst of spleen                                                                                                                                                                                                                                      | Procedure | SNOMED        | standard         |
| 4242866    | Functional asplenia                                                                                                                                                                                                                                             | Condition | SNOMED        | standard         |
| 4244020    | Congenital absence of spleen                                                                                                                                                                                                                                    | Condition | SNOMED        | standard         |
| 4247169    | Distal subtotal pancreatectomy with splenectomy                                                                                                                                                                                                                 | Procedure | SNOMED        | standard         |
| 4281839    | Partial splenectomy                                                                                                                                                                                                                                             | Procedure | SNOMED        | standard         |
| 4283229    | Excision of lesion of spleen                                                                                                                                                                                                                                    | Procedure | SNOMED        | standard         |
| 37110396   | Asplenia following surgical procedure                                                                                                                                                                                                                           | Condition | SNOMED        | standard         |
| 37111653   | Familial isolated congenital asplenia                                                                                                                                                                                                                           | Condition | SNOMED        | standard         |
| 37163587   | Diaphragmatic hernia, short bowel, asplenia syndrome                                                                                                                                                                                                            | Condition | SNOMED        | standard         |
| 37165101   | Robot assisted excision of spleen                                                                                                                                                                                                                               | Procedure | SNOMED        | standard         |
| 40487820   | Laparoscopic partial splenectomy                                                                                                                                                                                                                                | Procedure | SNOMED        | standard         |
| 44511354   | Other specified total excision of spleen                                                                                                                                                                                                                        | Procedure | OPCS4         | standard         |
| 44511358   | Other specified other excision of spleen                                                                                                                                                                                                                        | Procedure | OPCS4         | standard         |
| 45768671   | Asplenia                                                                                                                                                                                                                                                        | Condition | SNOMED        | standard         |
| 46272950   | Thrombocytopathy, asplenia and miosis                                                                                                                                                                                                                           | Condition | SNOMED        | standard         |

Table S16. Persistent complement deficiencies.

| Phenotype                          | Concept name                  | Concept ID (including descendants) | Vocabulary |
|------------------------------------|-------------------------------|------------------------------------|------------|
| Persistent complement deficiencies | Complement deficiency disease | 4083784                            | SNOMED     |

Table S17. Use of complement inhibitors.

| Substance Name | Concept name              | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|---------------------------|-----------------------------------------------|------------|
| Eculizumab     | eculizumab                | 19080458                                      | RxNorm     |
| Ravulizumab    | ravulizumab               | 1356009                                       | RxNorm     |
| Pegcetacoplan  | pegcetacoplan             | 1537122                                       | RxNorm     |
| Iptacopan      | iptacopan                 | 747398                                        | RxNorm     |
| Danicopan      | <a href="#">danicopan</a> | 42609527                                      | RxNorm     |
| Crovalimab     | crovalimab                | 1734659                                       | RxNorm     |
| Sutimlimab     | sutimlimab                | 1758949                                       | RxNorm     |

Table S18. Meningitis.

| Concept ID | Concept name                                                     | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------------------|-----------|---------------|------------------|
| 435785     | Meningitis                                                       | Condition | SNOMED        | standard         |
| 436091     | Bacterial meningitis                                             | Condition | SNOMED        | standard         |
| 438133     | Bacterial meningitis caused by Gram–negative bacteria            | Condition | SNOMED        | standard         |
| 438338     | Meningococcal meningitis                                         | Condition | SNOMED        | standard         |
| 438418     | Non–pyogenic meningitis                                          | Condition | SNOMED        | standard         |
| 762621     | Basilar meningitis                                               | Condition | SNOMED        | standard         |
| 3654686    | Chronic bilateral vestibulopathy due to and following meningitis | Condition | SNOMED        | standard         |
| 3655276    | Epilepsy due to infectious meningitis                            | Condition | SNOMED        | standard         |
| 4002336    | Acute purulent meningitis                                        | Condition | SNOMED        | standard         |
| 4030396    | Adhesive arachnoiditis                                           | Condition | SNOMED        | standard         |
| 4043739    | Hydrocephalus due to and following meningitis                    | Condition | SNOMED        | standard         |
| 4093593    | Pachymeningitis                                                  | Condition | SNOMED        | standard         |
| 4104546    | Meningoencephalomyelitis                                         | Condition | SNOMED        | standard         |
| 4138318    | Spinal arachnoiditis                                             | Condition | SNOMED        | standard         |
| 4171126    | Neonatal meningitis                                              | Condition | SNOMED        | standard         |
| 4174766    | Lymphocytic meningoencephalitis                                  | Condition | SNOMED        | standard         |
| 4175368    | Lymphocytic meningitis                                           | Condition | SNOMED        | standard         |
| 4207307    | Infective meningitis                                             | Condition | SNOMED        | standard         |
| 4218912    | Arachnoiditis                                                    | Condition | SNOMED        | standard         |
| 4228785    | Nuchal rigidity due to meningitis                                | Condition | SNOMED        | standard         |
| 4254268    | Meningomyelitis                                                  | Condition | SNOMED        | standard         |
| 4256114    | Hemorrhagic meningitis                                           | Condition | SNOMED        | standard         |
| 4282138    | Leptomeningitis                                                  | Condition | SNOMED        | standard         |
| 4310547    | Meningoeruptive syndrome                                         | Condition | SNOMED        | standard         |
| 4322814    | Meningoencephalitis                                              | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                              | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------|-----------|---------------|------------------|
| 36715532   | Meningitis caused by gram–negative aerobic coccus         | Condition | SNOMED        | standard         |
| 37166487   | Cranial arachnoiditis                                     | Condition | SNOMED        | standard         |
| 40481574   | Bacterial meningomyelitis                                 | Condition | SNOMED        | standard         |
| 40483321   | Bacterial meningoencephalitis                             | Condition | SNOMED        | standard         |
| 42538552   | Hypertrophic pachymeningitis due to infection             | Condition | SNOMED        | standard         |
| 44784567   | Postoperative bacterial meningitis                        | Condition | SNOMED        | standard         |
| 44784570   | Obstructive hydrocephalus due to and following meningitis | Condition | SNOMED        | standard         |
| 44813564   | Acute meningitis                                          | Condition | SNOMED        | standard         |
| 46285143   | Bacterial meningoencephalomyelitis                        | Condition | SNOMED        | standard         |

Table S19. Sepsis/meningococemia.

| Concept ID | Concept name                                                    | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------|-----------|---------------|------------------|
| 132797     | Sepsis                                                          | Condition | SNOMED        | standard         |
| 133691     | Meningococemia                                                  | Condition | SNOMED        | standard         |
| 196236     | Septic shock                                                    | Condition | SNOMED        | standard         |
| 434275     | Waterhouse–Friderichsen syndrome                                | Condition | SNOMED        | standard         |
| 4000938    | Bacterial sepsis                                                | Condition | SNOMED        | standard         |
| 4029251    | Intrauterine sepsis of fetus                                    | Condition | SNOMED        | standard         |
| 4029281    | Sepsis syndrome                                                 | Condition | SNOMED        | standard         |
| 4071063    | Sepsis of the newborn                                           | Condition | SNOMED        | standard         |
| 4090689    | Acute meningococemia                                            | Condition | SNOMED        | standard         |
| 4120937    | Hyperdynamic septic shock                                       | Condition | SNOMED        | standard         |
| 4120938    | Hypodynamic septic shock                                        | Condition | SNOMED        | standard         |
| 4154698    | Transient respiratory distress with sepsis                      | Condition | SNOMED        | standard         |
| 4155957    | Endotoxic shock                                                 | Condition | SNOMED        | standard         |
| 4324412    | Pyrogenic shock                                                 | Condition | SNOMED        | standard         |
| 35622880   | Early–onset neonatal sepsis                                     | Condition | SNOMED        | standard         |
| 35622881   | Late–onset neonatal sepsis                                      | Condition | SNOMED        | standard         |
| 36716312   | Acute kidney injury due to sepsis                               | Condition | SNOMED        | standard         |
| 36716754   | Transient neonatal neutropenia due to neonatal bacterial sepsis | Condition | SNOMED        | standard         |
| 36717263   | Sepsis without acute organ dysfunction                          | Condition | SNOMED        | standard         |
| 37017557   | Perinatal sepsis                                                | Condition | SNOMED        | standard         |
| 37151377   | Lung injury with sepsis                                         | Condition | SNOMED        | standard         |
| 37163128   | Myocardial dysfunction with sepsis                              | Condition | SNOMED        | standard         |
| 37163129   | Gastrointestinal lesion with sepsis                             | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                                               | Domain ID | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------------------------------|-----------|---------------|------------------|
| 37163130   | Left ventricular failure with sepsis                                                       | Condition | SNOMED        | standard         |
| 37163131   | Encephalopathy with sepsis                                                                 | Condition | SNOMED        | standard         |
| 37163132   | Gastrointestinal hemorrhage with sepsis                                                    | Condition | SNOMED        | standard         |
| 37163133   | Gastritis with sepsis                                                                      | Condition | SNOMED        | standard         |
| 37163134   | Gastrointestinal ulceration due to sepsis                                                  | Condition | SNOMED        | standard         |
| 37163135   | Right ventricular failure with sepsis                                                      | Condition | SNOMED        | standard         |
| 37164410   | Sepsis of premature infant                                                                 | Condition | SNOMED        | standard         |
| 37312594   | Sepsis without septic shock                                                                | Condition | SNOMED        | standard         |
| 37394658   | Severe sepsis                                                                              | Condition | SNOMED        | standard         |
| 37395517   | Acute kidney injury due to acute tubular necrosis due to sepsis                            | Condition | SNOMED        | standard         |
| 37395520   | Acute kidney injury due to acute tubular necrosis due to sepsis with histological evidence | Condition | SNOMED        | standard         |
| 40484176   | Neutropenic sepsis                                                                         | Condition | SNOMED        | standard         |
| 40487101   | Clinical sepsis                                                                            | Condition | SNOMED        | standard         |
| 40493038   | Sepsis caused by Gram negative bacteria                                                    | Condition | SNOMED        | standard         |
| 44782630   | Sepsis in asplenic subject                                                                 | Condition | SNOMED        | standard         |
| 44782631   | Sepsis with cutaneous manifestations                                                       | Condition | SNOMED        | standard         |
| 44805136   | Biliary sepsis                                                                             | Condition | SNOMED        | standard         |
| 46270051   | Sepsis caused by Meningococcus                                                             | Condition | SNOMED        | standard         |
| 46273475   | Septic shock co-occurrent with acute organ dysfunction caused by Meningococcus             | Condition | SNOMED        | standard         |
| 46284901   | Uncomplicated sepsis                                                                       | Condition | SNOMED        | standard         |

Table S20. Septic shock.

| Concept ID | Concept name                                                                   | Domain ID | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------------------|-----------|---------------|------------------|
| 196236     | Septic shock                                                                   | Condition | SNOMED        | standard         |
| 434275     | Waterhouse–Friderichsen syndrome                                               | Condition | SNOMED        | standard         |
| 4120937    | Hyperdynamic septic shock                                                      | Condition | SNOMED        | standard         |
| 4120938    | Hypodynamic septic shock                                                       | Condition | SNOMED        | standard         |
| 4155957    | Endotoxic shock                                                                | Condition | SNOMED        | standard         |
| 4324412    | Pyrogenic shock                                                                | Condition | SNOMED        | standard         |
| 46273475   | Septic shock co-occurrent with acute organ dysfunction caused by Meningococcus | Condition | SNOMED        | standard         |

Table S21. Haemorrhagic rash/purpura fulminans/petechial lesions.

| Concept ID | Concept name                    | Domain ID | Vocabulary ID | Standard concept |
|------------|---------------------------------|-----------|---------------|------------------|
| 4028488    | Purpura fulminans               | Condition | SNOMED        | standard         |
| 4154597    | Purpuric rash                   | Condition | SNOMED        | standard         |
| 4155911    | Petechiae                       | Condition | SNOMED        | standard         |
| 4216866    | Infection-associated purpura    | Condition | SNOMED        | standard         |
| 4308009    | Petechiae of skin               | Condition | SNOMED        | standard         |
| 36716825   | Acute purpuric eruption of skin | Condition | SNOMED        | standard         |
| 37117819   | Acquired purpura fulminans      | Condition | SNOMED        | standard         |
| 37161440   | Fetal purpura                   | Condition | SNOMED        | standard         |

Table S22. Pneumonia.

| Concept ID | Concept name                                      | Domain ID | Vocabulary ID  | Standard concept |
|------------|---------------------------------------------------|-----------|----------------|------------------|
| 255848     | Pneumonia                                         | Condition | SNOMED         | standard         |
| 256722     | Bronchopneumonia                                  | Condition | SNOMED         | standard         |
| 257315     | Bacterial pneumonia                               | Condition | SNOMED         | standard         |
| 258180     | Pneumonia caused by Gram negative bacteria        | Condition | SNOMED         | standard         |
| 259992     | Ventilator associated pneumonia                   | Condition | SNOMED         | standard         |
| 443410     | Infective pneumonia                               | Condition | SNOMED         | standard         |
| 1340436    | Exacerbation of pneumonia                         | Condition | OMOP Extension | standard         |
| 4025165    | Abscess of lung with pneumonia                    | Condition | SNOMED         | standard         |
| 4046011    | Focal pneumonia                                   | Condition | SNOMED         | standard         |
| 4048052    | Necrotizing bronchopneumonia                      | Condition | SNOMED         | standard         |
| 4048517    | Acute bronchopneumonia                            | Condition | SNOMED         | standard         |
| 4048518    | Confluent bronchopneumonia with abscess formation | Condition | SNOMED         | standard         |
| 4048519    | Confluent pneumonia                               | Condition | SNOMED         | standard         |
| 4050869    | Atypical pneumonia                                | Condition | SNOMED         | standard         |
| 4051335    | Hemorrhagic pneumonia                             | Condition | SNOMED         | standard         |
| 4051337    | Neonatal pneumonia                                | Condition | SNOMED         | standard         |
| 4052546    | Meningococcal pneumonia                           | Condition | SNOMED         | standard         |
| 4102253    | Right middle zone pneumonia                       | Condition | SNOMED         | standard         |
| 4111119    | Hemorrhagic bronchopneumonia                      | Condition | SNOMED         | standard         |
| 4116488    | Left lower zone pneumonia                         | Condition | SNOMED         | standard         |
| 4117114    | Right lower zone pneumonia                        | Condition | SNOMED         | standard         |
| 4133224    | Lobar pneumonia                                   | Condition | SNOMED         | standard         |
| 4135197    | Hypostatic bronchopneumonia                       | Condition | SNOMED         | standard         |
| 4138769    | Bilateral basal pneumonia                         | Condition | SNOMED         | standard         |

| Concept ID | Concept name                                                                 | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------------------------------|-----------|---------------|------------------|
| 4143092    | Hospital acquired pneumonia                                                  | Condition | SNOMED        | standard         |
| 4145369    | Lingular pneumonia                                                           | Condition | SNOMED        | standard         |
| 4153356    | Postobstructive pneumonia                                                    | Condition | SNOMED        | standard         |
| 4174309    | Congenital bacterial pneumonia                                               | Condition | SNOMED        | standard         |
| 4175598    | Catarrhal pneumonia                                                          | Condition | SNOMED        | standard         |
| 4204819    | Secondary bacterial pneumonia                                                | Condition | SNOMED        | standard         |
| 4205578    | Peribronchial pneumonia                                                      | Condition | SNOMED        | standard         |
| 4212120    | Unresolved pneumonia                                                         | Condition | SNOMED        | standard         |
| 4236311    | Bilateral pneumonia                                                          | Condition | SNOMED        | standard         |
| 4245006    | Bilateral bronchopneumonia                                                   | Condition | SNOMED        | standard         |
| 4245499    | Pleurobronchopneumonia                                                       | Condition | SNOMED        | standard         |
| 4248807    | Healthcare associated bacterial pneumonia                                    | Condition | SNOMED        | standard         |
| 4256236    | Pneumonia caused by aerobic bacteria                                         | Condition | SNOMED        | standard         |
| 4276663    | Terminal bronchopneumonia                                                    | Condition | SNOMED        | standard         |
| 4280213    | Unresolved lobar pneumonia                                                   | Condition | SNOMED        | standard         |
| 4293463    | Community acquired pneumonia                                                 | Condition | SNOMED        | standard         |
| 4310964    | Hypostatic pneumonia                                                         | Condition | SNOMED        | standard         |
| 37017277   | Recurrent bacterial pneumonia                                                | Condition | SNOMED        | standard         |
| 37019058   | Bacterial pneumonia co-occurrent with human immunodeficiency virus infection | Condition | SNOMED        | standard         |
| 44782989   | Recurrent pneumonia                                                          | Condition | SNOMED        | standard         |
| 46269709   | Bronchopneumonia caused by bacteria                                          | Condition | SNOMED        | standard         |

Table S23. Septic arthritis (IMD).

| Concept ID | Concept name                                      | Domain ID | Vocabulary ID | Standard concept |
|------------|---------------------------------------------------|-----------|---------------|------------------|
| 72988      | Pyogenic arthritis of hand                        | Condition | SNOMED        | standard         |
| 73838      | Pyogenic arthritis of multiple sites              | Condition | SNOMED        | standard         |
| 78829      | Pyogenic arthritis of the ankle and/or foot       | Condition | SNOMED        | standard         |
| 78956      | Meningococcal arthropathy                         | Condition | SNOMED        | standard         |
| 80177      | Pyogenic arthritis of the pelvic region and thigh | Condition | SNOMED        | standard         |
| 80482      | Suppurative arthritis                             | Condition | SNOMED        | standard         |
| 81099      | Pyogenic arthritis of shoulder region             | Condition | SNOMED        | standard         |
| 607427     | Bacterial spondyloarthritis                       | Condition | SNOMED        | standard         |
| 608808     | Bilateral arthritis of feet caused by Bacteria    | Condition | SNOMED        | standard         |
| 759808     | Pyogenic bacterial arthritis of shoulder          | Condition | SNOMED        | standard         |
| 760722     | Bacterial arthritis of vertebral column           | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                               | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------------|-----------|---------------|------------------|
| 761892     | Pyogenic bacterial arthritis of knee                       | Condition | SNOMED        | standard         |
| 761944     | Pyogenic bacterial arthritis of foot                       | Condition | SNOMED        | standard         |
| 761945     | Pyogenic bacterial polyarthritis                           | Condition | SNOMED        | standard         |
| 761946     | Pyogenic bacterial arthritis of pelvis                     | Condition | SNOMED        | standard         |
| 761965     | Pyogenic bacterial arthritis                               | Condition | SNOMED        | standard         |
| 761982     | Pyogenic bacterial arthritis of wrist                      | Condition | SNOMED        | standard         |
| 762781     | Infectious synovitis                                       | Condition | SNOMED        | standard         |
| 764919     | Pyogenic bacterial arthritis of elbow                      | Condition | SNOMED        | standard         |
| 764920     | Pyogenic bacterial arthritis of hip                        | Condition | SNOMED        | standard         |
| 765024     | Pyogenic bacterial arthritis of hand                       | Condition | SNOMED        | standard         |
| 765813     | Pyogenic bacterial arthritis of patella                    | Condition | SNOMED        | standard         |
| 1244725    | Infective arthritis of joint of left shoulder region       | Condition | SNOMED        | standard         |
| 1244726    | Infective arthritis of joint of right shoulder region      | Condition | SNOMED        | standard         |
| 1244727    | Infective arthritis of left glenohumeral joint             | Condition | SNOMED        | standard         |
| 1244728    | Infective arthritis of right glenohumeral joint            | Condition | SNOMED        | standard         |
| 1245532    | Infective arthritis of joint of bilateral shoulder regions | Condition | SNOMED        | standard         |
| 1245534    | Bilateral infective arthritis of hands                     | Condition | SNOMED        | standard         |
| 1245535    | Bilateral infective arthritis of hips                      | Condition | SNOMED        | standard         |
| 1245539    | Arthritis of joint of bilateral ankles caused by bacteria  | Condition | SNOMED        | standard         |
| 1245540    | Bilateral infective arthritis of wrist regions             | Condition | SNOMED        | standard         |
| 1246240    | Infective arthritis of hip                                 | Condition | SNOMED        | standard         |
| 1246668    | Infective arthritis of joint of vertebral column           | Condition | SNOMED        | standard         |
| 4001490    | Infectious arthritis of temporomandibular joint            | Condition | SNOMED        | standard         |
| 4023947    | Pyogenic arthritis of pelvic region                        | Condition | SNOMED        | standard         |
| 4034672    | Acute infective polyarthritis                              | Condition | SNOMED        | standard         |
| 4041516    | Subacute infective arthritis                               | Condition | SNOMED        | standard         |
| 4068237    | Pyogenic arthritis of ankle                                | Condition | SNOMED        | standard         |
| 4077425    | Acute bacterial arthritis                                  | Condition | SNOMED        | standard         |
| 4094226    | Acute infective arthritis                                  | Condition | SNOMED        | standard         |
| 4158412    | Acute suppurative arthritis                                | Condition | SNOMED        | standard         |
| 4160643    | Acute suppurative arthritis caused by bacteria             | Condition | SNOMED        | standard         |
| 4167984    | Bacterial arthritis                                        | Condition | SNOMED        | standard         |
| 4177365    | Infective arthritis of joint of hand                       | Condition | SNOMED        | standard         |
| 4180873    | Infective arthritis of shoulder region                     | Condition | SNOMED        | standard         |
| 4188412    | Suppurative arthritis caused by bacteria                   | Condition | SNOMED        | standard         |
| 4188413    | Pyogenic arthritis of hip                                  | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                                 | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------------------------------|-----------|---------------|------------------|
| 4196020    | Bacterial arthritis of elbow                                                 | Condition | SNOMED        | standard         |
| 4197765    | Bacterial arthritis of hip                                                   | Condition | SNOMED        | standard         |
| 4201074    | Bacterial arthritis of patellofemoral joint                                  | Condition | SNOMED        | standard         |
| 4243832    | Subacute infective polyarthritis                                             | Condition | SNOMED        | standard         |
| 4262590    | Infective arthritis                                                          | Condition | SNOMED        | standard         |
| 4266078    | Infective polyarthritis                                                      | Condition | SNOMED        | standard         |
| 4288479    | Pyogenic arthritis of foot                                                   | Condition | SNOMED        | standard         |
| 4328019    | Bacterial arthritis of sacroiliac joint                                      | Condition | SNOMED        | standard         |
| 4344398    | Wrist pyogenic arthritis                                                     | Condition | SNOMED        | standard         |
| 4346970    | Knee pyogenic arthritis                                                      | Condition | SNOMED        | standard         |
| 4346971    | Elbow pyogenic arthritis                                                     | Condition | SNOMED        | standard         |
| 36685015   | Arthritis of right foot caused by bacteria                                   | Condition | SNOMED        | standard         |
| 36685016   | Arthritis of left foot caused by bacteria                                    | Condition | SNOMED        | standard         |
| 36715561   | Infection causing spondyloarthritis                                          | Condition | SNOMED        | standard         |
| 37017284   | Infective arthritis co-occurrent with human immunodeficiency virus infection | Condition | SNOMED        | standard         |
| 37108583   | Arthritis of right shoulder caused by bacteria                               | Condition | SNOMED        | standard         |
| 37108584   | Arthritis of left shoulder caused by bacteria                                | Condition | SNOMED        | standard         |
| 37108585   | Arthritis of right hip caused by bacteria                                    | Condition | SNOMED        | standard         |
| 37108586   | Arthritis of left hip caused by bacteria                                     | Condition | SNOMED        | standard         |
| 37108587   | Arthritis of right knee caused by bacteria                                   | Condition | SNOMED        | standard         |
| 37108588   | Arthritis of left knee caused by bacteria                                    | Condition | SNOMED        | standard         |
| 37108589   | Infective arthritis of left knee                                             | Condition | SNOMED        | standard         |
| 37110004   | Pyogenic arthritis, pyoderma gangrenosum, acne syndrome                      | Condition | SNOMED        | standard         |
| 37117135   | Infective arthritis of right knee                                            | Condition | SNOMED        | standard         |
| 37208263   | Arthritis of left sacroiliac joint caused by bacteria                        | Condition | SNOMED        | standard         |
| 37208264   | Arthritis of right sacroiliac joint caused by bacteria                       | Condition | SNOMED        | standard         |
| 37209324   | Arthritis of bilateral hips caused by bacteria                               | Condition | SNOMED        | standard         |
| 37209325   | Arthritis of bilateral knee joints caused by bacteria                        | Condition | SNOMED        | standard         |
| 37209326   | Arthritis of bilateral shoulders caused by bacteria                          | Condition | SNOMED        | standard         |
| 37209327   | Arthritis of bilateral sacroiliac joints caused by bacteria                  | Condition | SNOMED        | standard         |
| 37309743   | Bilateral infective arthritis of knees                                       | Condition | SNOMED        | standard         |
| 37309744   | Bilateral arthritis of wrists caused by Bacteria                             | Condition | SNOMED        | standard         |
| 37310481   | Infective arthritis of right foot                                            | Condition | SNOMED        | standard         |
| 37310482   | Infective arthritis of left foot                                             | Condition | SNOMED        | standard         |
| 37310483   | Infective arthritis of right hand                                            | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                    | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------|-----------|---------------|------------------|
| 37310484   | Infective arthritis of left hand                                | Condition | SNOMED        | standard         |
| 37310485   | Infective arthritis of right wrist                              | Condition | SNOMED        | standard         |
| 37310486   | Infective arthritis of left wrist                               | Condition | SNOMED        | standard         |
| 37310487   | Infective arthritis of right elbow                              | Condition | SNOMED        | standard         |
| 37310488   | Infective arthritis of left elbow                               | Condition | SNOMED        | standard         |
| 40481619   | Infective arthritis of pelvis                                   | Condition | SNOMED        | standard         |
| 40481620   | Infective arthritis of ankle and/or foot                        | Condition | SNOMED        | standard         |
| 40483813   | Infective arthritis of elbow                                    | Condition | SNOMED        | standard         |
| 40483847   | Infective arthritis of wrist                                    | Condition | SNOMED        | standard         |
| 40486203   | Infective arthritis of proximal interphalangeal joint of finger | Condition | SNOMED        | standard         |
| 40489491   | Infective arthritis of interphalangeal joint of toe             | Condition | SNOMED        | standard         |
| 40489947   | Infective arthritis of distal interphalangeal joint of finger   | Condition | SNOMED        | standard         |
| 40489948   | Infective arthritis of first metatarsophalangeal joint          | Condition | SNOMED        | standard         |
| 40493024   | Infective arthritis of metatarsophalangeal joint of lesser toe  | Condition | SNOMED        | standard         |
| 42534821   | Arthritis of left elbow caused by bacteria                      | Condition | SNOMED        | standard         |
| 42534822   | Arthritis of right wrist caused by bacteria                     | Condition | SNOMED        | standard         |
| 42534823   | Arthritis of left wrist caused by bacteria                      | Condition | SNOMED        | standard         |
| 42534824   | Arthritis of left hand caused by bacteria                       | Condition | SNOMED        | standard         |
| 42534825   | Arthritis of right ankle caused by bacteria                     | Condition | SNOMED        | standard         |
| 42534826   | Arthritis of left ankle caused by bacteria                      | Condition | SNOMED        | standard         |
| 42534829   | Infective arthritis of left hip                                 | Condition | SNOMED        | standard         |
| 42534830   | Infective arthritis of right hip                                | Condition | SNOMED        | standard         |
| 42534831   | Infective arthritis of left ankle                               | Condition | SNOMED        | standard         |
| 42534832   | Infective arthritis of right ankle                              | Condition | SNOMED        | standard         |
| 42534954   | Infective polyarthritis caused by bacteria                      | Condition | SNOMED        | standard         |
| 42539287   | Arthritis of right hand caused by bacteria                      | Condition | SNOMED        | standard         |
| 42539396   | Arthritis of right elbow caused by bacteria                     | Condition | SNOMED        | standard         |
| 44783204   | Post infectious osteoarthritis                                  | Condition | SNOMED        | standard         |
| 46271147   | Bacterial arthritis of costotransverse joint                    | Condition | SNOMED        | standard         |
| 46273196   | Bacterial arthritis of atlantoaxial joint                       | Condition | SNOMED        | standard         |
| 46273200   | Bacterial arthritis of costovertebral joint                     | Condition | SNOMED        | standard         |
| 46273215   | Bacterial arthritis of facet joint of thoracic spine            | Condition | SNOMED        | standard         |
| 46273216   | Bacterial arthritis of facet joint of lumbar spine              | Condition | SNOMED        | standard         |
| 46273622   | Bacterial arthritis of facet joint of cervical spine            | Condition | SNOMED        | standard         |

Table S24. Ceftriaxone.

| Substance Name | Concept name | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|--------------|-----------------------------------------------|------------|
| Ceftriaxone    | ceftriaxone  | 1777806                                       | RxNorm     |

Table S25. Cefotaxime.

| Substance Name | Concept name | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|--------------|-----------------------------------------------|------------|
| Cefotaxime     | cefotaxime   | 1774470                                       | RxNorm     |

Table S26. Benzylpenicillin.

| Substance Name   | Concept name | Ingredient Concept ID (including descendants) | Vocabulary |
|------------------|--------------|-----------------------------------------------|------------|
| Benzylpenicillin | penicillin G | 1728416                                       | RxNorm     |

Table S27. Chloramphenicol.

| Substance Name  | Concept name    | Ingredient Concept ID (including descendants) | Vocabulary |
|-----------------|-----------------|-----------------------------------------------|------------|
| Chloramphenicol | chloramphenicol | 990069                                        | RxNorm     |

Table S28. Meropenem.

| Substance Name | Concept name | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|--------------|-----------------------------------------------|------------|
| Meropenem      | meropenem    | 1709170                                       | RxNorm     |

Table S29. Ampicillin.

| Substance Name | Concept name | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|--------------|-----------------------------------------------|------------|
| Ampicillin     | ampicillin   | 1717327                                       | RxNorm     |

Table S30. Amoxicillin.

| Substance Name | Concept name | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|--------------|-----------------------------------------------|------------|
| Amoxicillin    | amoxicillin  | 1713332                                       | RxNorm     |

Table S31. Chlamydia trachomatis.

| Concept ID | Concept name                                      | Domain ID | Vocabulary ID | Standard concept |
|------------|---------------------------------------------------|-----------|---------------|------------------|
| 23137      | Chlamydial pharyngitis                            | Condition | SNOMED        | standard         |
| 72245      | Chlamydial infection of lower genitourinary tract | Condition | SNOMED        | standard         |
| 79732      | Genitourinary chlamydia infection                 | Condition | SNOMED        | standard         |
| 194287     | Lymphogranuloma venereum                          | Condition | SNOMED        | standard         |
| 194288     | Chlamydial infection of anus and rectum           | Condition | SNOMED        | standard         |
| 372550     | Chlamydial conjunctivitis                         | Condition | SNOMED        | standard         |
| 375184     | Trachoma, initial stage                           | Condition | SNOMED        | standard         |
| 375736     | Trachoma, active stage                            | Condition | SNOMED        | standard         |
| 380640     | Trachoma                                          | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                                  | Domain ID | Vocabulary ID | Standard concept |
|------------|-------------------------------------------------------------------------------|-----------|---------------|------------------|
| 437221     | Chlamydia trachomatis infection                                               | Condition | SNOMED        | standard         |
| 438066     | Chlamydial infection                                                          | Condition | SNOMED        | standard         |
| 439686     | Urethritis caused by Chlamydia trachomatis                                    | Condition | SNOMED        | standard         |
| 443581     | Chlamydia trachomatis infection of genital structure                          | Condition | SNOMED        | standard         |
| 608803     | Bilateral chlamydial conjunctivitis                                           | Condition | SNOMED        | standard         |
| 765217     | Conjunctivitis of left eye caused by Chlamydia trachomatis                    | Condition | SNOMED        | standard         |
| 1245525    | Conjunctivitis of right eye caused by Chlamydia trachomatis                   | Condition | SNOMED        | standard         |
| 4032266    | Chlamydial dermatological disorders                                           | Condition | SNOMED        | standard         |
| 4032591    | Chlamydial epididymo–orchitis                                                 | Condition | SNOMED        | standard         |
| 4034002    | Chlamydial perihepatitis                                                      | Condition | SNOMED        | standard         |
| 4080425    | Neonatal chlamydial infection                                                 | Condition | SNOMED        | standard         |
| 4080427    | Early lymphogranuloma venereum                                                | Condition | SNOMED        | standard         |
| 4080600    | Late lymphogranuloma venereum                                                 | Condition | SNOMED        | standard         |
| 4084947    | Neonatal chlamydial conjunctivitis                                            | Condition | SNOMED        | standard         |
| 4084952    | Latent lymphogranuloma venereum                                               | Condition | SNOMED        | standard         |
| 4096510    | Pelvic inflammation with female sterility caused by Chlamydia trachomatis     | Condition | SNOMED        | standard         |
| 4096951    | Chlamydial pelvic inflammatory disease                                        | Condition | SNOMED        | standard         |
| 4098881    | Trachomatous follicular conjunctivitis                                        | Condition | SNOMED        | standard         |
| 4126282    | Chlamydial urethritis                                                         | Condition | SNOMED        | standard         |
| 4127403    | Chlamydial cervicitis                                                         | Condition | SNOMED        | standard         |
| 4127408    | Chlamydial vulvovaginitis                                                     | Condition | SNOMED        | standard         |
| 4127725    | Chlamydial balanitis                                                          | Condition | SNOMED        | standard         |
| 4127731    | Chlamydial epididymitis                                                       | Condition | SNOMED        | standard         |
| 4128394    | Chlamydial prostatitis                                                        | Condition | SNOMED        | standard         |
| 4130332    | Chlamydial salpingitis                                                        | Condition | SNOMED        | standard         |
| 4130345    | Chlamydial Bartholinitis                                                      | Condition | SNOMED        | standard         |
| 4138450    | Acute genitourinary infection caused by Chlamydia                             | Condition | SNOMED        | standard         |
| 4138475    | Acute genitourinary Chlamydia trachomatis infection                           | Condition | SNOMED        | standard         |
| 4146848    | Neonatal dacryocystitis or conjunctivitis caused by chlamydiae                | Condition | SNOMED        | standard         |
| 4171249    | Neonatal chlamydial dacryocystitis                                            | Condition | SNOMED        | standard         |
| 4210034    | Trachomatous pannus                                                           | Condition | SNOMED        | standard         |
| 4212724    | Urine chlamydia trachomatis test positive                                     | Condition | SNOMED        | standard         |
| 4227344    | Chlamydia trachomatis infection of anus and rectum                            | Condition | SNOMED        | standard         |
| 36716495   | Non–ulcerative sexually transmitted infection caused by Chlamydia trachomatis | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                      | Domain ID | Vocabulary ID | Standard concept |
|------------|-------------------------------------------------------------------|-----------|---------------|------------------|
| 37160680   | Dacryoadenitis caused by Chlamydia trachomatis                    | Condition | SNOMED        | standard         |
| 37160712   | Chlamydial colitis                                                | Condition | SNOMED        | standard         |
| 37160815   | Intestinal Chlamydia trachomatis infection                        | Condition | SNOMED        | standard         |
| 37162747   | Colitis caused by Chlamydia trachomatis                           | Condition | SNOMED        | standard         |
| 37312673   | Inflammation of pelvis caused by Chlamydia trachomatis            | Condition | SNOMED        | standard         |
| 40487890   | Infection of epididymis caused by Chlamydia trachomatis           | Condition | SNOMED        | standard         |
| 40488377   | Infection of pharynx caused by Chlamydia trachomatis              | Condition | SNOMED        | standard         |
| 40488811   | Infection of anus caused by Chlamydia trachomatis                 | Condition | SNOMED        | standard         |
| 40490303   | Infection of testis caused by Chlamydia trachomatis               | Condition | SNOMED        | standard         |
| 40492346   | Infection of cervix caused by Chlamydia trachomatis               | Condition | SNOMED        | standard         |
| 40492367   | Infection of rectum caused by Chlamydia trachomatis               | Condition | SNOMED        | standard         |
| 40492382   | Infection of vulva caused by Chlamydia trachomatis                | Condition | SNOMED        | standard         |
| 40492401   | Infection of vagina caused by Chlamydia trachomatis               | Condition | SNOMED        | standard         |
| 42872403   | Chlamydia trachomatis infection in pregnancy                      | Condition | SNOMED        | standard         |
| 43021996   | Endocarditis caused by Chlamydia                                  | Condition | SNOMED        | standard         |
| 45757108   | Chlamydia trachomatis infection in mother complicating childbirth | Condition | SNOMED        | standard         |
| 45757283   | Venereal disease caused by Chlamydia trachomatis                  | Condition | SNOMED        | standard         |
| 45772089   | Cystitis caused by Chlamydia                                      | Condition | SNOMED        | standard         |
| 46270132   | Perihepatitis caused by Chlamydia trachomatis                     | Condition | SNOMED        | standard         |

Table S32. Syphilis.

| Concept ID | Concept name                               | Domain ID | Vocabulary ID | Standard concept |
|------------|--------------------------------------------|-----------|---------------|------------------|
| 73409      | Primary anal syphilis                      | Condition | SNOMED        | standard         |
| 74862      | Syphilis of bone                           | Condition | SNOMED        | standard         |
| 76032      | Syphilis of muscle                         | Condition | SNOMED        | standard         |
| 79742      | Primary genital syphilis                   | Condition | SNOMED        | standard         |
| 133959     | Syphilitic alopecia                        | Condition | SNOMED        | standard         |
| 137212     | Cardiovascular syphilis                    | Condition | SNOMED        | standard         |
| 194861     | Syphilis of liver                          | Condition | SNOMED        | standard         |
| 198345     | Syphilitic peritonitis                     | Condition | SNOMED        | standard         |
| 201506     | Secondary syphilis of viscera              | Condition | SNOMED        | standard         |
| 312823     | Secondary syphilitic adenopathy            | Condition | SNOMED        | standard         |
| 313416     | Syphilitic endocarditis of mitral valve    | Condition | SNOMED        | standard         |
| 313698     | Syphilitic endocarditis of tricuspid valve | Condition | SNOMED        | standard         |
| 313964     | Syphilitic endocarditis of pulmonary valve | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                                                         | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------------------------------------------------------|-----------|---------------|------------------|
| 315467     | Syphilitic aortitis                                                                                  | Condition | SNOMED        | standard         |
| 318689     | Syphilitic endocarditis of aortic valve                                                              | Condition | SNOMED        | standard         |
| 320025     | Syphilitic pericarditis                                                                              | Condition | SNOMED        | standard         |
| 320646     | Syphilitic aneurysm of aorta                                                                         | Condition | SNOMED        | standard         |
| 372243     | Late congenital neurosyphilis                                                                        | Condition | SNOMED        | standard         |
| 373139     | Syphilitic parkinsonism                                                                              | Condition | SNOMED        | standard         |
| 375738     | Neurosyphilis                                                                                        | Condition | SNOMED        | standard         |
| 376335     | Asymptomatic neurosyphilis                                                                           | Condition | SNOMED        | standard         |
| 377788     | General paresis – neurosyphilis                                                                      | Condition | SNOMED        | standard         |
| 377789     | Syphilitic retrobulbar neuritis                                                                      | Condition | SNOMED        | standard         |
| 378349     | Syphilitic encephalitis                                                                              | Condition | SNOMED        | standard         |
| 378686     | Syphilitic optic atrophy                                                                             | Condition | SNOMED        | standard         |
| 380030     | Syphilitic acoustic neuritis                                                                         | Condition | SNOMED        | standard         |
| 380943     | Rupture of syphilitic cerebral aneurysm                                                              | Condition | SNOMED        | standard         |
| 381794     | Congenital syphilitic encephalitis                                                                   | Condition | SNOMED        | standard         |
| 432561     | Latent syphilis with positive serology                                                               | Condition | SNOMED        | standard         |
| 433410     | Primary syphilis                                                                                     | Condition | SNOMED        | standard         |
| 433705     | Early latent syphilis, positive serology, negative cerebrospinal fluid, with relapse after treatment | Condition | SNOMED        | standard         |
| 434274     | Chorioretinitis due to secondary syphilis                                                            | Condition | SNOMED        | standard         |
| 434279     | Congenital syphilis                                                                                  | Condition | SNOMED        | standard         |
| 434570     | Early congenital syphilis with symptoms                                                              | Condition | SNOMED        | standard         |
| 435179     | Secondary syphilis relapse                                                                           | Condition | SNOMED        | standard         |
| 435465     | Early latent congenital syphilis, positive serology, negative spinal fluid                           | Condition | SNOMED        | standard         |
| 435739     | Late syphilis                                                                                        | Condition | SNOMED        | standard         |
| 436031     | Syphilitic endocarditis                                                                              | Condition | SNOMED        | standard         |
| 436033     | Syphilis                                                                                             | Condition | SNOMED        | standard         |
| 436624     | Late congenital syphilis, latent (+ sero., – C.S.F., 2 years OR more)                                | Condition | SNOMED        | standard         |
| 436632     | Early congenital syphilis (less than 2 years)                                                        | Condition | SNOMED        | standard         |
| 437787     | Secondary syphilis                                                                                   | Condition | SNOMED        | standard         |
| 437794     | Late congenital syphilis (2 years or more)                                                           | Condition | SNOMED        | standard         |
| 438348     | Syphilitic interstitial keratitis                                                                    | Condition | SNOMED        | standard         |
| 438968     | Secondary syphilis of mucous membrane                                                                | Condition | SNOMED        | standard         |
| 438971     | Syphilitic disseminated retinochoroiditis                                                            | Condition | SNOMED        | standard         |
| 439670     | Acute secondary syphilitic meningitis                                                                | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                                                              | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------------------------------------------------|-----------|---------------|------------------|
| 439671     | Uveitis due to secondary syphilis                                                                         | Condition | SNOMED        | standard         |
| 439729     | Late syphilis, latent (+ sero., – C.S.F. 2 years after)                                                   | Condition | SNOMED        | standard         |
| 439731     | Secondary syphilitic iridocyclitis                                                                        | Condition | SNOMED        | standard         |
| 441228     | Syphilitic meningitis                                                                                     | Condition | SNOMED        | standard         |
| 441507     | Early latent syphilis, positive serology, negative cerebrospinal fluid, less than 2 years after infection | Condition | SNOMED        | standard         |
| 442066     | Hepatitis in secondary syphilis                                                                           | Condition | SNOMED        | standard         |
| 442296     | Secondary syphilis of skin                                                                                | Condition | SNOMED        | standard         |
| 442345     | Syphilis of kidney                                                                                        | Condition | SNOMED        | standard         |
| 442630     | Congenital syphilitic meningitis                                                                          | Condition | SNOMED        | standard         |
| 443291     | Maternal syphilis during pregnancy, childbirth and the puerperium                                         | Condition | SNOMED        | standard         |
| 444083     | Syphilitic myocarditis                                                                                    | Condition | SNOMED        | standard         |
| 444087     | Syphilitic episcleritis                                                                                   | Condition | SNOMED        | standard         |
| 444280     | Secondary syphilitic periostitis                                                                          | Condition | SNOMED        | standard         |
| 444294     | Syphilis of lung                                                                                          | Condition | SNOMED        | standard         |
| 444394     | Atypical Argyll–Robertson pupil                                                                           | Condition | SNOMED        | standard         |
| 600575     | Gastritis due to secondary syphilis                                                                       | Condition | SNOMED        | standard         |
| 600578     | Proctocolitis due to secondary syphilis                                                                   | Condition | SNOMED        | standard         |
| 605192     | Late syphilis of lung                                                                                     | Condition | SNOMED        | standard         |
| 605340     | Secondary syphilis of nervous system                                                                      | Condition | SNOMED        | standard         |
| 605341     | Secondary syphilis of digestive system                                                                    | Condition | SNOMED        | standard         |
| 605342     | Secondary syphilis of eye                                                                                 | Condition | SNOMED        | standard         |
| 605343     | Secondary syphilis of musculoskeletal system                                                              | Condition | SNOMED        | standard         |
| 606028     | Late congenital syphilitic optic atrophy                                                                  | Condition | SNOMED        | standard         |
| 606038     | Late syphilitic pulmonary regurgitation                                                                   | Condition | SNOMED        | standard         |
| 606068     | Late congenital syphilitic osteochondropathy                                                              | Condition | SNOMED        | standard         |
| 606070     | Late congenital cardiovascular syphilis                                                                   | Condition | SNOMED        | standard         |
| 606074     | Secondary syphilis of synovium                                                                            | Condition | SNOMED        | standard         |
| 606085     | Sensorineural deafness due to late congenital syphilis                                                    | Condition | SNOMED        | standard         |
| 619069     | Iris papulosa caused by Treponema pallidum                                                                | Condition | SNOMED        | standard         |
| 619070     | Iris roseola caused by Treponema pallidum                                                                 | Condition | SNOMED        | standard         |
| 1245456    | Interstitial keratitis due to congenital syphilis                                                         | Condition | SNOMED        | standard         |
| 1245748    | Interstitial keratitis of right eye due to congenital syphilis                                            | Condition | SNOMED        | standard         |
| 1245749    | Interstitial keratitis of bilateral eyes due to congenital syphilis                                       | Condition | SNOMED        | standard         |
| 1245750    | Interstitial keratitis of left eye due to congenital syphilis                                             | Condition | SNOMED        | standard         |
| 3654625    | Bursitis due to late syphilis                                                                             | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                | Domain ID | Vocabulary ID | Standard concept |
|------------|-------------------------------------------------------------|-----------|---------------|------------------|
| 3655351    | Episcleritis due to late syphilis                           | Condition | SNOMED        | standard         |
| 3655622    | Meningomyelitis caused by Treponema pallidum                | Condition | SNOMED        | standard         |
| 3655637    | Interstitial keratitis due to late congenital syphilis      | Condition | SNOMED        | standard         |
| 3655646    | Lues maligna                                                | Condition | SNOMED        | standard         |
| 3655813    | Posterior uveitis due to late syphilis                      | Condition | SNOMED        | standard         |
| 3655830    | Myelitis caused by Treponema pallidum                       | Condition | SNOMED        | standard         |
| 3655844    | Optic atrophy due to late syphilis                          | Condition | SNOMED        | standard         |
| 3655854    | Panuveitis caused by Treponema pallidum                     | Condition | SNOMED        | standard         |
| 3655870    | Retrobulbar neuritis due to late syphilis                   | Condition | SNOMED        | standard         |
| 3657843    | Retinitis of bilateral eyes due to secondary syphilis       | Condition | SNOMED        | standard         |
| 3662318    | Chorioretinitis of right eye due to secondary syphilis      | Condition | SNOMED        | standard         |
| 3662319    | Chorioretinitis of bilateral eyes due to secondary syphilis | Condition | SNOMED        | standard         |
| 3662320    | Chorioretinitis of left eye due to secondary syphilis       | Condition | SNOMED        | standard         |
| 3662323    | Iritis of right eye caused by Treponema pallidum            | Condition | SNOMED        | standard         |
| 3662324    | Iritis of left eye caused by Treponema pallidum             | Condition | SNOMED        | standard         |
| 3662325    | Bilateral iritis of eyes caused by Treponema pallidum       | Condition | SNOMED        | standard         |
| 3662329    | Bilateral retinitis of eyes caused by Treponema pallidum    | Condition | SNOMED        | standard         |
| 4000061    | Clutton's joints                                            | Condition | SNOMED        | standard         |
| 4001478    | Syphilitic bursitis                                         | Condition | SNOMED        | standard         |
| 4013413    | Primary syphilis of tonsils                                 | Condition | SNOMED        | standard         |
| 4028042    | Taboparesis                                                 | Condition | SNOMED        | standard         |
| 4029910    | Syphilis of breast                                          | Condition | SNOMED        | standard         |
| 4032996    | Moon's molar teeth                                          | Condition | SNOMED        | standard         |
| 4034224    | Primary syphilis of nipple                                  | Condition | SNOMED        | standard         |
| 4035746    | Tabetic joint                                               | Condition | SNOMED        | standard         |
| 4045978    | Late syphilitic encephalitis                                | Condition | SNOMED        | standard         |
| 4046242    | Late congenital syphilitic polyneuropathy                   | Condition | SNOMED        | standard         |
| 4047472    | Late congenital syphilitic meningitis                       | Condition | SNOMED        | standard         |
| 4048790    | Syphilitic cerebral arteritis                               | Condition | SNOMED        | standard         |
| 4051481    | Nasal syphilis                                              | Condition | SNOMED        | standard         |
| 4053079    | Syphilitic cirrhosis                                        | Condition | SNOMED        | standard         |
| 4055221    | Hepatitis in late syphilis                                  | Condition | SNOMED        | standard         |
| 4056324    | Female syphilitic pelvic inflammatory disease               | Condition | SNOMED        | standard         |
| 4058682    | Syphilitic portal cirrhosis                                 | Condition | SNOMED        | standard         |
| 4059131    | Late syphilis of kidney                                     | Condition | SNOMED        | standard         |
| 4059744    | Syphilitic prostatitis                                      | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                 | Domain ID | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------|-----------|---------------|------------------|
| 4062900    | Syphilitic gumma of central nervous system                   | Condition | SNOMED        | standard         |
| 4078519    | Congenital syphilitic hepatomegaly                           | Condition | SNOMED        | standard         |
| 4080333    | Juvenile tabes dorsalis                                      | Condition | SNOMED        | standard         |
| 4080334    | Primary extragenital syphilis                                | Condition | SNOMED        | standard         |
| 4080335    | Secondary neurosyphilis                                      | Condition | SNOMED        | standard         |
| 4080336    | Meningovascular syphilis – quaternary stage                  | Condition | SNOMED        | standard         |
| 4080337    | Syphilitic polyneuropathy                                    | Condition | SNOMED        | standard         |
| 4080592    | Acquired syphilis                                            | Condition | SNOMED        | standard         |
| 4080593    | Syphilitic coronary artery disease                           | Condition | SNOMED        | standard         |
| 4080774    | Macular syphilide                                            | Condition | SNOMED        | standard         |
| 4080775    | Syphilitic mucosal ulceration                                | Condition | SNOMED        | standard         |
| 4080776    | Asymptomatic secondary neurosyphilis                         | Condition | SNOMED        | standard         |
| 4080886    | Congenital syphilitic rhinitis                               | Condition | SNOMED        | standard         |
| 4083187    | Quaternary syphilis                                          | Condition | SNOMED        | standard         |
| 4084820    | Hutchinson's triad                                           | Condition | SNOMED        | standard         |
| 4084821    | Papular syphilide                                            | Condition | SNOMED        | standard         |
| 4084822    | Corona veneris                                               | Condition | SNOMED        | standard         |
| 4084823    | Pustular syphilide                                           | Condition | SNOMED        | standard         |
| 4084824    | Gummatous neurosyphilis                                      | Condition | SNOMED        | standard         |
| 4087751    | Late congenital syphilitic oculopathy                        | Condition | SNOMED        | standard         |
| 4087756    | Late latent syphilis                                         | Condition | SNOMED        | standard         |
| 4089980    | Early congenital syphilis – latent                           | Condition | SNOMED        | standard         |
| 4089985    | Early symptomatic syphilis                                   | Condition | SNOMED        | standard         |
| 4089994    | Serological relapse after treatment of latent early syphilis | Condition | SNOMED        | standard         |
| 4092828    | Latent early syphilis                                        | Condition | SNOMED        | standard         |
| 4093309    | Secondary syphilis of skin and mucous membrane               | Condition | SNOMED        | standard         |
| 4099924    | Primary syphilis of breast                                   | Condition | SNOMED        | standard         |
| 4100817    | Congenital syphilitic periostitis                            | Condition | SNOMED        | standard         |
| 4105194    | Secondary syphilitic meningitis                              | Condition | SNOMED        | standard         |
| 4105744    | Urethral stricture due to syphilis                           | Condition | SNOMED        | standard         |
| 4108798    | Acute syphilitic pericarditis                                | Condition | SNOMED        | standard         |
| 4109568    | Keratitis due to syphilis                                    | Condition | SNOMED        | standard         |
| 4111090    | Acute syphilitic myocarditis                                 | Condition | SNOMED        | standard         |
| 4114429    | Post-infective arthropathy in syphilis                       | Condition | SNOMED        | standard         |
| 4119459    | Syphilitic valve disease                                     | Condition | SNOMED        | standard         |
| 4121325    | Syphilitic acoustic neuritis – quaternary stage              | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                        | Domain ID | Vocabulary ID | Standard concept |
|------------|---------------------------------------------------------------------|-----------|---------------|------------------|
| 4122210    | Syphilitic gumma of oral cavity                                     | Condition | SNOMED        | standard         |
| 4122751    | Syphilitic oral leukoplakia                                         | Condition | SNOMED        | standard         |
| 4122760    | Oral syphilis                                                       | Condition | SNOMED        | standard         |
| 4124848    | Syphilitic aneurysm                                                 | Condition | SNOMED        | standard         |
| 4126928    | Syphilitic oral snail track ulcer                                   | Condition | SNOMED        | standard         |
| 4130195    | Paroxysmal cold hemoglobinuria associated with tertiary syphilis    | Condition | SNOMED        | standard         |
| 4132494    | Ocular syphilis                                                     | Condition | SNOMED        | standard         |
| 4141483    | Acquired syphilis – early latent                                    | Condition | SNOMED        | standard         |
| 4141484    | Late quaternary neurosyphilis                                       | Condition | SNOMED        | standard         |
| 4145475    | Rash of secondary syphilis                                          | Condition | SNOMED        | standard         |
| 4145477    | Acquired syphilis – late latent                                     | Condition | SNOMED        | standard         |
| 4151215    | Primary syphilis of lip                                             | Condition | SNOMED        | standard         |
| 4151918    | Progressive locomotor ataxia                                        | Condition | SNOMED        | standard         |
| 4160083    | Syphilitic skin disorder                                            | Condition | SNOMED        | standard         |
| 4167920    | Congenital syphilitic chronic coryza                                | Condition | SNOMED        | standard         |
| 4176161    | Syphilis of tricuspid valve                                         | Condition | SNOMED        | standard         |
| 4177963    | Syphilis of tendon                                                  | Condition | SNOMED        | standard         |
| 4182201    | Secondary syphilis of vulva                                         | Condition | SNOMED        | standard         |
| 4183997    | Primary syphilis of fingers                                         | Condition | SNOMED        | standard         |
| 4185826    | Syphilitic leukoderma                                               | Condition | SNOMED        | standard         |
| 4189211    | Secondary syphilis of mouth                                         | Condition | SNOMED        | standard         |
| 4189522    | Syphilitic aortic incompetence                                      | Condition | SNOMED        | standard         |
| 4195054    | Syphilitic chorioretinitis                                          | Condition | SNOMED        | standard         |
| 4196116    | Tertiary syphilitic chorioretinitis                                 | Condition | SNOMED        | standard         |
| 4200072    | Secondary syphilis of pharynx                                       | Condition | SNOMED        | standard         |
| 4201172    | Tabetic neurosyphilis                                               | Condition | SNOMED        | standard         |
| 4203916    | Congenital syphilitic mucous patches                                | Condition | SNOMED        | standard         |
| 4210320    | Congenital syphilitic splenomegaly                                  | Condition | SNOMED        | standard         |
| 4215747    | Secondary syphilis of liver                                         | Condition | SNOMED        | standard         |
| 4218123    | Gummatous osteitis of yaws                                          | Condition | SNOMED        | standard         |
| 4218560    | Secondary syphilis of tonsil                                        | Condition | SNOMED        | standard         |
| 4219047    | Syphilitic aortic stenosis                                          | Condition | SNOMED        | standard         |
| 4227251    | Syphilis test finding                                               | Condition | SNOMED        | standard         |
| 4236862    | Late syphilis with clinical manifestations other than neurosyphilis | Condition | SNOMED        | standard         |
| 4239550    | Condyloma latum                                                     | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                         | Domain ID | Vocabulary ID | Standard concept |
|------------|----------------------------------------------------------------------|-----------|---------------|------------------|
| 4240733    | Syphilis of mitral valve                                             | Condition | SNOMED        | standard         |
| 4241576    | Congenital syphilitic osteochondritis                                | Condition | SNOMED        | standard         |
| 4242126    | Congenital syphilitic pemphigus                                      | Condition | SNOMED        | standard         |
| 4259500    | Syphilitic retinitis                                                 | Condition | SNOMED        | standard         |
| 4260509    | Syphilitic punched out ulcer                                         | Condition | SNOMED        | standard         |
| 4261611    | Syphilis of pulmonary valve                                          | Condition | SNOMED        | standard         |
| 4261688    | Chancriform pyoderma                                                 | Condition | SNOMED        | standard         |
| 4265210    | Syphilitic ostial coronary disease                                   | Condition | SNOMED        | standard         |
| 4268187    | Secondary syphilis, relapse (untreated)                              | Condition | SNOMED        | standard         |
| 4273876    | Syphilitic gumma                                                     | Condition | SNOMED        | standard         |
| 4274335    | Secondary syphilis of bone                                           | Condition | SNOMED        | standard         |
| 4288611    | Juvenile taboparesis                                                 | Condition | SNOMED        | standard         |
| 4288727    | Acute syphilitic meningitis                                          | Condition | SNOMED        | standard         |
| 4291175    | Syphilis of synovium                                                 | Condition | SNOMED        | standard         |
| 4294448    | Syphilitic chancre of penis                                          | Condition | SNOMED        | standard         |
| 4294449    | Syphilitic chancre of oral mucous membranes                          | Condition | SNOMED        | standard         |
| 4294552    | Condylomata lata of perianal skin                                    | Condition | SNOMED        | standard         |
| 4294553    | Condylomata lata of vulva                                            | Condition | SNOMED        | standard         |
| 4294554    | Late secondary syphilis                                              | Condition | SNOMED        | standard         |
| 4294555    | Nodular syphilide                                                    | Condition | SNOMED        | standard         |
| 4297450    | Secondary syphilis of anus                                           | Condition | SNOMED        | standard         |
| 4298860    | Syphilitic chancre of vulva                                          | Condition | SNOMED        | standard         |
| 4298861    | Syphilitic balanitis                                                 | Condition | SNOMED        | standard         |
| 4298862    | Condylomata lata of penis                                            | Condition | SNOMED        | standard         |
| 4298863    | Nail dystrophy due to secondary syphilis                             | Condition | SNOMED        | standard         |
| 4299115    | Syphilitic saddle nose                                               | Condition | SNOMED        | standard         |
| 4300223    | Syphilitic leukoplakia of tongue                                     | Condition | SNOMED        | standard         |
| 4300224    | Oral mucous membrane lesion due to late syphilis                     | Condition | SNOMED        | standard         |
| 4300225    | Anetoderma secondary to syphilis                                     | Condition | SNOMED        | standard         |
| 4305738    | Treponema pallidum detected by enzyme-linked immunosorbent assay     | Condition | SNOMED        | standard         |
| 4307791    | Dementia paralytica juvenilis                                        | Condition | SNOMED        | standard         |
| 4308379    | Treponema pallidum not detected by enzyme-linked immunosorbent assay | Condition | SNOMED        | standard         |
| 4311929    | Secondary syphilis, relapse (treated)                                | Condition | SNOMED        | standard         |
| 4313730    | Hutchinson's teeth                                                   | Condition | SNOMED        | standard         |
| 4322865    | Congenital syphilitic choroiditis                                    | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                    | Domain ID | Vocabulary ID | Standard concept |
|------------|-------------------------------------------------|-----------|---------------|------------------|
| 4326735    | Spastic spinal syphilitic paralysis             | Condition | SNOMED        | standard         |
| 4335454    | Endocochlear syphilis                           | Condition | SNOMED        | standard         |
| 4337953    | Congenital syphilis with gumma                  | Condition | SNOMED        | standard         |
| 4342775    | Pericellular fibrosis of congenital syphilis    | Condition | SNOMED        | standard         |
| 35610376   | Otosyphilis                                     | Condition | SNOMED        | standard         |
| 36715815   | Mucocutaneous early congenital syphilis         | Condition | SNOMED        | standard         |
| 37017065   | Gingival disease caused by Treponema pallidum   | Condition | SNOMED        | standard         |
| 37161128   | Syphilitic infectious intermediate uveitis      | Condition | SNOMED        | standard         |
| 37161155   | Neurosyphilitic tic disorder                    | Condition | SNOMED        | standard         |
| 37161172   | Syphilitic dacryoadenitis                       | Condition | SNOMED        | standard         |
| 37161176   | Mulberry molar teeth                            | Condition | SNOMED        | standard         |
| 37169226   | Right syphilitic retinitis                      | Condition | SNOMED        | standard         |
| 37169227   | Left syphilitic retinitis                       | Condition | SNOMED        | standard         |
| 37169448   | Right iritis due to secondary syphilis          | Condition | SNOMED        | standard         |
| 37169449   | Left iritis due to secondary syphilis           | Condition | SNOMED        | standard         |
| 37169450   | Bilateral iritis due to secondary syphilis      | Condition | SNOMED        | standard         |
| 37311902   | Ocular late syphilis                            | Condition | SNOMED        | standard         |
| 37311923   | Late syphilis of skin                           | Condition | SNOMED        | standard         |
| 37312548   | Late syphilis of mucous membrane                | Condition | SNOMED        | standard         |
| 40485064   | Latent syphilis                                 | Condition | SNOMED        | standard         |
| 42536584   | Symptomatic late congenital syphilis            | Condition | SNOMED        | standard         |
| 42537335   | Syphilitic chancre                              | Condition | SNOMED        | standard         |
| 42709901   | Interstitial glossitis                          | Condition | SNOMED        | standard         |
| 42709904   | Luetic glossitis                                | Condition | SNOMED        | standard         |
| 43021833   | Syphilitic valvular endocarditis                | Condition | SNOMED        | standard         |
| 44784559   | Dementia associated with neurosyphilis          | Condition | SNOMED        | standard         |
| 45757152   | Syphilis in mother complicating childbirth      | Condition | SNOMED        | standard         |
| 45757696   | Syphilitic choroiditis                          | Condition | SNOMED        | standard         |
| 45766049   | Hypoplasia of enamel due to congenital syphilis | Condition | SNOMED        | standard         |
| 46273126   | Syphilitic iritis                               | Condition | SNOMED        | standard         |
| 46273503   | Charcot arthropathy due to syphilis             | Condition | SNOMED        | standard         |

Table S33. *Trichomonas vaginalis*.

| Concept ID | Concept name                                         | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------|-----------|---------------|------------------|
| 78073      | Urogenital infection by <i>Trichomonas vaginalis</i> | Condition | SNOMED        | standard         |
| 194871     | Trichomonal vulvovaginitis                           | Condition | SNOMED        | standard         |
| 200657     | Trichomonal urethritis                               | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                   | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------------------------------|-----------|---------------|------------------|
| 201798     | Trichomonal prostatitis                        | Condition | SNOMED        | standard         |
| 605344     | Female genital Trichomonas vaginalis infection | Condition | SNOMED        | standard         |
| 4056400    | Cervical smear – trichomonas                   | Condition | SNOMED        | standard         |
| 4056610    | Trichomonal cystitis                           | Condition | SNOMED        | standard         |
| 4074179    | Trichomonal cervicitis                         | Condition | SNOMED        | standard         |
| 4081056    | Trichomonal vaginitis                          | Condition | SNOMED        | standard         |
| 4084950    | Asymptomatic trichomoniasis                    | Condition | SNOMED        | standard         |
| 4087164    | Trichomonal balanitis                          | Condition | SNOMED        | standard         |
| 4096690    | Trichomonal balanoposthitis                    | Condition | SNOMED        | standard         |
| 4130344    | Trichomonal vulvitis                           | Condition | SNOMED        | standard         |
| 4137441    | Intestinal infection by Trichomonas vaginalis  | Condition | SNOMED        | standard         |
| 4323204    | Trichomonal vaginitis in pregnancy             | Condition | SNOMED        | standard         |

Table S34. Mycoplasma genitalium.

| Concept ID | Concept name                                                       | Domain ID | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------|-----------|---------------|------------------|
| 4032460    | Mycoplasma balanitis                                               | Condition | SNOMED        | standard         |
| 4080426    | Genital mycoplasma infection                                       | Condition | SNOMED        | standard         |
| 4150781    | Mycoplasmal pelvic inflammatory disease                            | Condition | SNOMED        | standard         |
| 36717567   | Female pelvic inflammatory disease caused by Mycoplasma genitalium | Condition | SNOMED        | standard         |
| 37160826   | Mycoplasma genitalium infection                                    | Condition | SNOMED        | standard         |

Table S35. Urethritis.

| Concept ID | Concept name                | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------|-----------|---------------|------------------|
| 195862     | Urethritis                  | Condition | SNOMED        | standard         |
| 196733     | Urethral syndrome           | Condition | SNOMED        | standard         |
| 4032445    | Infective urethritis        | Condition | SNOMED        | standard         |
| 4080340    | Gonococcal Cowperitis       | Condition | SNOMED        | standard         |
| 4080595    | Gonococcal Skenitis         | Condition | SNOMED        | standard         |
| 4080596    | Gonococcal Littritis        | Condition | SNOMED        | standard         |
| 4107240    | Acute gonococcal urethritis | Condition | SNOMED        | standard         |
| 4128397    | Gonococcal urethritis       | Condition | SNOMED        | standard         |
| 4233236    | Follicular urethritis       | Condition | SNOMED        | standard         |

| Concept ID | Concept name           | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------|-----------|---------------|------------------|
| 4240578    | Skene's gland adenitis | Condition | SNOMED        | standard         |
| 4264352    | Cowperitis             | Condition | SNOMED        | standard         |
| 4324904    | Bacterial urethritis   | Condition | SNOMED        | standard         |
| 37311937   | Gonorrhea of penis     | Condition | SNOMED        | standard         |

Table S36. Cervicitis.

| Concept ID | Concept name                       | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------------------|-----------|---------------|------------------|
| 193136     | Acute gonococcal cervicitis        | Condition | SNOMED        | standard         |
| 196163     | Cervicitis and endocervicitis      | Condition | SNOMED        | standard         |
| 444078     | Inflammation of cervix             | Condition | SNOMED        | standard         |
| 4034007    | Gonococcal cervicitis              | Condition | SNOMED        | standard         |
| 4061049    | Endocervicitis with Nabothian cyst | Condition | SNOMED        | standard         |
| 4061209    | Cervicitis with Nabothian cyst     | Condition | SNOMED        | standard         |
| 4078704    | Acute cervicitis                   | Condition | SNOMED        | standard         |
| 4151600    | Endocervicitis                     | Condition | SNOMED        | standard         |
| 4171188    | Acute endocervicitis               | Condition | SNOMED        | standard         |
| 4272466    | Endocervicitis with erosion        | Condition | SNOMED        | standard         |
| 4308278    | Cervicitis with erosion            | Condition | SNOMED        | standard         |

Table S37. Proctitis.

| Concept ID | Concept name                                                 | Domain ID | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------|-----------|---------------|------------------|
| 4166480    | Ulcerative proctocolitis                                     | Condition | SNOMED        | standard         |
| 4168036    | Proctocolitis                                                | Condition | SNOMED        | standard         |
| 4175505    | Gonorrhea of rectum                                          | Condition | SNOMED        | standard         |
| 4215578    | Proctitis                                                    | Condition | SNOMED        | standard         |
| 4322061    | Hemorrhagic proctitis                                        | Condition | SNOMED        | standard         |
| 4340263    | Infective proctitis                                          | Condition | SNOMED        | standard         |
| 36685124   | Infection of anus and rectum caused by Neisseria gonorrhoeae | Condition | SNOMED        | standard         |
| 37160012   | Ulcerative proctitis                                         | Condition | SNOMED        | standard         |
| 45773397   | Acute proctitis                                              | Condition | SNOMED        | standard         |

Table S38. Pharyngitis.

| Concept ID | Concept name                  | Domain ID | Vocabulary ID | Standard concept |
|------------|-------------------------------|-----------|---------------|------------------|
| 23798      | Acute laryngopharyngitis      | Condition | SNOMED        | standard         |
| 25297      | Acute pharyngitis             | Condition | SNOMED        | standard         |
| 259153     | Pain in throat                | Condition | SNOMED        | standard         |
| 4109893    | Acute phlegmonous pharyngitis | Condition | SNOMED        | standard         |
| 4110358    | Acute gangrenous pharyngitis  | Condition | SNOMED        | standard         |
| 4112342    | Acute ulcerative pharyngitis  | Condition | SNOMED        | standard         |
| 4131441    | Exudative pharyngitis         | Condition | SNOMED        | standard         |
| 4147326    | Sore throat                   | Condition | SNOMED        | standard         |
| 4190176    | Ulcerative pharyngitis        | Condition | SNOMED        | standard         |
| 4193318    | Infective pharyngitis         | Condition | SNOMED        | standard         |
| 4197268    | Nasopharyngitis               | Condition | SNOMED        | standard         |
| 4226263    | Pharyngitis                   | Condition | SNOMED        | standard         |
| 4240728    | Suppurative pharyngitis       | Condition | SNOMED        | standard         |
| 4241328    | Phlegmonous pharyngitis       | Condition | SNOMED        | standard         |
| 4247910    | Gangrenous pharyngitis        | Condition | SNOMED        | standard         |

Table S39. Epididymitis/prostatitis.

| Concept ID | Concept name                                        | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------|-----------|---------------|------------------|
| 75310      | Epididymo—orchitis associated with another disorder | Condition | SNOMED        | standard         |
| 77029      | Epididymo—orchitis without abscess                  | Condition | SNOMED        | standard         |
| 78193      | Orchitis and epididymitis                           | Condition | SNOMED        | standard         |
| 193522     | Acute prostatitis                                   | Condition | SNOMED        | standard         |
| 194571     | Acute gonococcal prostatitis                        | Condition | SNOMED        | standard         |
| 194997     | Prostatitis                                         | Condition | SNOMED        | standard         |
| 198807     | Prostatocystitis                                    | Condition | SNOMED        | standard         |
| 200446     | Prostatitis associated with another disorder        | Condition | SNOMED        | standard         |
| 443879     | Epididymo—orchitis with abscess                     | Condition | SNOMED        | standard         |
| 443911     | Acute gonococcal epididymo—orchitis                 | Condition | SNOMED        | standard         |
| 606433     | Asymptomatic prostatitis                            | Condition | SNOMED        | standard         |
| 4032589    | Gonococcal epididymitis                             | Condition | SNOMED        | standard         |
| 4032590    | Gonococcal epididymo—orchitis                       | Condition | SNOMED        | standard         |
| 4056174    | Gonococcal prostatitis                              | Condition | SNOMED        | standard         |
| 4056182    | Epididymitis associated with another disorder       | Condition | SNOMED        | standard         |
| 4082614    | Epididymitis without abscess                        | Condition | SNOMED        | standard         |
| 4150043    | Epididymitis                                        | Condition | SNOMED        | standard         |
| 4184319    | Acute epididymitis                                  | Condition | SNOMED        | standard         |

| Concept ID | Concept name                 | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------------|-----------|---------------|------------------|
| 4207308    | Infective epididymo–orchitis | Condition | SNOMED        | standard         |
| 4207310    | Infective epididymitis       | Condition | SNOMED        | standard         |
| 4217187    | Epididymitis with abscess    | Condition | SNOMED        | standard         |
| 37161518   | Prostatitis category I       | Condition | SNOMED        | standard         |
| 37168756   | Acute epididymo–orchitis     | Condition | SNOMED        | standard         |
| 37395581   | Bacterial prostatitis        | Condition | SNOMED        | standard         |

Table S40. Vulvovaginitis.

| Concept ID | Concept name                                    | Domain ID | Vocabulary ID  | Standard concept |
|------------|-------------------------------------------------|-----------|----------------|------------------|
| 1340503    | Exacerbation of vulvovaginitis                  | Condition | OMOP Extension | standard         |
| 4033947    | Acute gonococcal vulvovaginitis                 | Condition | SNOMED         | standard         |
| 4034010    | Gonococcal vulvovaginitis                       | Condition | SNOMED         | standard         |
| 4056903    | Vaginitis associated with another disorder      | Condition | SNOMED         | standard         |
| 4056904    | Vulvovaginitis associated with another disorder | Condition | SNOMED         | standard         |
| 4061210    | Vulvitis associated with another disorder       | Condition | SNOMED         | standard         |
| 4081648    | Acute vaginitis                                 | Condition | SNOMED         | standard         |
| 4088316    | Infective vulvitis                              | Condition | SNOMED         | standard         |
| 4127406    | Infective vaginitis                             | Condition | SNOMED         | standard         |
| 4128053    | Neonatal gonococcal vulvovaginitis              | Condition | SNOMED         | standard         |
| 4140828    | Acute vulvitis                                  | Condition | SNOMED         | standard         |
| 4149084    | Vaginitis                                       | Condition | SNOMED         | standard         |
| 4180978    | Vulvovaginitis                                  | Condition | SNOMED         | standard         |
| 4213204    | Acute gonococcal bartholinitis                  | Condition | SNOMED         | standard         |
| 4234233    | Acute vulvovaginitis                            | Condition | SNOMED         | standard         |
| 4269221    | Vulvitis                                        | Condition | SNOMED         | standard         |
| 4286510    | Mucopurulent vaginitis                          | Condition | SNOMED         | standard         |
| 4291613    | Gonococcal bartholinitis                        | Condition | SNOMED         | standard         |
| 4294445    | Acute pyococcal bartholinitis                   | Condition | SNOMED         | standard         |

Table S41. Salpingitis.

| Concept ID | Concept name                      | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------------|-----------|---------------|------------------|
| 196468     | Acute salpingo–oophoritis         | Condition | SNOMED        | standard         |
| 197602     | Tubo–ovarian inflammatory disease | Condition | SNOMED        | standard         |
| 200334     | Acute gonococcal salpingitis      | Condition | SNOMED        | standard         |
| 4056205    | Acute perisalpingitis             | Condition | SNOMED        | standard         |
| 4060948    | Subacute salpingo–oophoritis      | Condition | SNOMED        | standard         |
| 4061192    | Subacute perisalpingitis          | Condition | SNOMED        | standard         |

| Concept ID | Concept name           | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------|-----------|---------------|------------------|
| 4127390    | Gonococcal salpingitis | Condition | SNOMED        | standard         |
| 4210477    | Perisalpingitis        | Condition | SNOMED        | standard         |
| 4230473    | Acute salpingitis      | Condition | SNOMED        | standard         |
| 4266028    | Pyosalpinx             | Condition | SNOMED        | standard         |
| 4321565    | Subacute salpingitis   | Condition | SNOMED        | standard         |
| 4338958    | Salpingitis            | Condition | SNOMED        | standard         |

Table S42. Pelvic inflammatory disease.

| Concept ID | Concept name                                  | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------|-----------|---------------|------------------|
| 196468     | Acute salpingo-oophoritis                     | Condition | SNOMED        | standard         |
| 197602     | Tubo-ovarian inflammatory disease             | Condition | SNOMED        | standard         |
| 199067     | Female pelvic inflammatory disease            | Condition | SNOMED        | standard         |
| 200040     | Acute gonococcal endometritis                 | Condition | SNOMED        | standard         |
| 200334     | Acute gonococcal salpingitis                  | Condition | SNOMED        | standard         |
| 4031820    | Acute endomyometritis                         | Condition | SNOMED        | standard         |
| 4040830    | Acute oophoritis                              | Condition | SNOMED        | standard         |
| 4056204    | Acute perioophoritis                          | Condition | SNOMED        | standard         |
| 4056205    | Acute perisalpingitis                         | Condition | SNOMED        | standard         |
| 4056206    | Subacute perioophoritis                       | Condition | SNOMED        | standard         |
| 4060948    | Subacute salpingo-oophoritis                  | Condition | SNOMED        | standard         |
| 4061192    | Subacute perisalpingitis                      | Condition | SNOMED        | standard         |
| 4061203    | Subacute endometritis                         | Condition | SNOMED        | standard         |
| 4061204    | Subacute endomyometritis                      | Condition | SNOMED        | standard         |
| 4061217    | Female gonococcal pelvic inflammatory disease | Condition | SNOMED        | standard         |
| 4080780    | Gonococcal female pelvic infection            | Condition | SNOMED        | standard         |
| 4127390    | Gonococcal salpingitis                        | Condition | SNOMED        | standard         |
| 4128047    | Gonococcal endometritis                       | Condition | SNOMED        | standard         |
| 4130331    | Acute pelvic inflammatory disease             | Condition | SNOMED        | standard         |
| 4194612    | Acute endometritis                            | Condition | SNOMED        | standard         |
| 4210477    | Perisalpingitis                               | Condition | SNOMED        | standard         |
| 4220361    | Perioophoritis                                | Condition | SNOMED        | standard         |
| 4230473    | Acute salpingitis                             | Condition | SNOMED        | standard         |
| 4249442    | Subacute oophoritis                           | Condition | SNOMED        | standard         |
| 4302765    | Endometritis                                  | Condition | SNOMED        | standard         |
| 4321565    | Subacute salpingitis                          | Condition | SNOMED        | standard         |
| 4338958    | Salpingitis                                   | Condition | SNOMED        | standard         |
| 4339120    | Endomyometritis                               | Condition | SNOMED        | standard         |

Table S43. Disseminated gonococcal infection.

| Concept ID | Concept name                                                             | Domain ID | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------------------|-----------|---------------|------------------|
| 4156057    | Gonococcal arthritis dermatitis syndrome                                 | Condition | SNOMED        | standard         |
| 4176270    | Gonococcemia                                                             | Condition | SNOMED        | standard         |
| 37016131   | Sepsis caused by Gonococcus                                              | Condition | SNOMED        | standard         |
| 42539347   | Disseminated infection caused by Neisseria gonorrhoeae                   | Condition | SNOMED        | standard         |
| 46269940   | Septic shock co-occurrent with acute organ dysfunction due to Gonococcus | Condition | SNOMED        | standard         |

Table S44. Septic arthritis (gonorrhoea).

| Concept ID | Concept name                                          | Domain ID | Vocabulary ID | Standard concept |
|------------|-------------------------------------------------------|-----------|---------------|------------------|
| 72988      | Pyogenic arthritis of hand                            | Condition | SNOMED        | standard         |
| 73838      | Pyogenic arthritis of multiple sites                  | Condition | SNOMED        | standard         |
| 74864      | Gonococcal infection of joint                         | Condition | SNOMED        | standard         |
| 78829      | Pyogenic arthritis of the ankle and/or foot           | Condition | SNOMED        | standard         |
| 80177      | Pyogenic arthritis of the pelvic region and thigh     | Condition | SNOMED        | standard         |
| 80482      | Suppurative arthritis                                 | Condition | SNOMED        | standard         |
| 81099      | Pyogenic arthritis of shoulder region                 | Condition | SNOMED        | standard         |
| 443205     | Gonococcal synovitis                                  | Condition | SNOMED        | standard         |
| 607427     | Bacterial spondyloarthritis                           | Condition | SNOMED        | standard         |
| 608808     | Bilateral arthritis of feet caused by Bacteria        | Condition | SNOMED        | standard         |
| 759808     | Pyogenic bacterial arthritis of shoulder              | Condition | SNOMED        | standard         |
| 760722     | Bacterial arthritis of vertebral column               | Condition | SNOMED        | standard         |
| 761892     | Pyogenic bacterial arthritis of knee                  | Condition | SNOMED        | standard         |
| 761944     | Pyogenic bacterial arthritis of foot                  | Condition | SNOMED        | standard         |
| 761945     | Pyogenic bacterial polyarthritis                      | Condition | SNOMED        | standard         |
| 761946     | Pyogenic bacterial arthritis of pelvis                | Condition | SNOMED        | standard         |
| 761965     | Pyogenic bacterial arthritis                          | Condition | SNOMED        | standard         |
| 761982     | Pyogenic bacterial arthritis of wrist                 | Condition | SNOMED        | standard         |
| 762781     | Infectious synovitis                                  | Condition | SNOMED        | standard         |
| 764919     | Pyogenic bacterial arthritis of elbow                 | Condition | SNOMED        | standard         |
| 764920     | Pyogenic bacterial arthritis of hip                   | Condition | SNOMED        | standard         |
| 765024     | Pyogenic bacterial arthritis of hand                  | Condition | SNOMED        | standard         |
| 765813     | Pyogenic bacterial arthritis of patella               | Condition | SNOMED        | standard         |
| 1244725    | Infective arthritis of joint of left shoulder region  | Condition | SNOMED        | standard         |
| 1244726    | Infective arthritis of joint of right shoulder region | Condition | SNOMED        | standard         |
| 1244727    | Infective arthritis of left glenohumeral joint        | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                 | Domain ID | Vocabulary ID | Standard concept |
|------------|--------------------------------------------------------------|-----------|---------------|------------------|
| 1244728    | Infective arthritis of right glenohumeral joint              | Condition | SNOMED        | standard         |
| 1244738    | Sexually acquired reactive arthritis of joint of ankle       | Condition | SNOMED        | standard         |
| 1244739    | Sexually acquired reactive arthritis of joint of foot        | Condition | SNOMED        | standard         |
| 1244740    | Sexually acquired reactive arthritis of joint of pelvic wall | Condition | SNOMED        | standard         |
| 1244741    | Sexually acquired reactive arthritis of joint of hip         | Condition | SNOMED        | standard         |
| 1245532    | Infective arthritis of joint of bilateral shoulder regions   | Condition | SNOMED        | standard         |
| 1245534    | Bilateral infective arthritis of hands                       | Condition | SNOMED        | standard         |
| 1245535    | Bilateral infective arthritis of hips                        | Condition | SNOMED        | standard         |
| 1245539    | Arthritis of joint of bilateral ankles caused by bacteria    | Condition | SNOMED        | standard         |
| 1245540    | Bilateral infective arthritis of wrist regions               | Condition | SNOMED        | standard         |
| 1246240    | Infective arthritis of hip                                   | Condition | SNOMED        | standard         |
| 1246668    | Infective arthritis of joint of vertebral column             | Condition | SNOMED        | standard         |
| 4001490    | Infectious arthritis of temporomandibular joint              | Condition | SNOMED        | standard         |
| 4023947    | Pyogenic arthritis of pelvic region                          | Condition | SNOMED        | standard         |
| 4034672    | Acute infective polyarthritis                                | Condition | SNOMED        | standard         |
| 4041516    | Subacute infective arthritis                                 | Condition | SNOMED        | standard         |
| 4068237    | Pyogenic arthritis of ankle                                  | Condition | SNOMED        | standard         |
| 4077425    | Acute bacterial arthritis                                    | Condition | SNOMED        | standard         |
| 4094226    | Acute infective arthritis                                    | Condition | SNOMED        | standard         |
| 4156057    | Gonococcal arthritis dermatitis syndrome                     | Condition | SNOMED        | standard         |
| 4158412    | Acute suppurative arthritis                                  | Condition | SNOMED        | standard         |
| 4160643    | Acute suppurative arthritis caused by bacteria               | Condition | SNOMED        | standard         |
| 4167984    | Bacterial arthritis                                          | Condition | SNOMED        | standard         |
| 4177365    | Infective arthritis of joint of hand                         | Condition | SNOMED        | standard         |
| 4180873    | Infective arthritis of shoulder region                       | Condition | SNOMED        | standard         |
| 4188412    | Suppurative arthritis caused by bacteria                     | Condition | SNOMED        | standard         |
| 4188413    | Pyogenic arthritis of hip                                    | Condition | SNOMED        | standard         |
| 4196020    | Bacterial arthritis of elbow                                 | Condition | SNOMED        | standard         |
| 4197765    | Bacterial arthritis of hip                                   | Condition | SNOMED        | standard         |
| 4201074    | Bacterial arthritis of patellofemoral joint                  | Condition | SNOMED        | standard         |
| 4243832    | Subacute infective polyarthritis                             | Condition | SNOMED        | standard         |
| 4262590    | Infective arthritis                                          | Condition | SNOMED        | standard         |
| 4266078    | Infective polyarthritis                                      | Condition | SNOMED        | standard         |
| 4288479    | Pyogenic arthritis of foot                                   | Condition | SNOMED        | standard         |
| 4328019    | Bacterial arthritis of sacroiliac joint                      | Condition | SNOMED        | standard         |
| 4344398    | Wrist pyogenic arthritis                                     | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                                 | Domain ID | Vocabulary ID | Standard concept |
|------------|------------------------------------------------------------------------------|-----------|---------------|------------------|
| 4346970    | Knee pyogenic arthritis                                                      | Condition | SNOMED        | standard         |
| 4346971    | Elbow pyogenic arthritis                                                     | Condition | SNOMED        | standard         |
| 36685015   | Arthritis of right foot caused by bacteria                                   | Condition | SNOMED        | standard         |
| 36685016   | Arthritis of left foot caused by bacteria                                    | Condition | SNOMED        | standard         |
| 36715561   | Infection causing spondyloarthritis                                          | Condition | SNOMED        | standard         |
| 37017284   | Infective arthritis co-occurrent with human immunodeficiency virus infection | Condition | SNOMED        | standard         |
| 37108583   | Arthritis of right shoulder caused by bacteria                               | Condition | SNOMED        | standard         |
| 37108584   | Arthritis of left shoulder caused by bacteria                                | Condition | SNOMED        | standard         |
| 37108585   | Arthritis of right hip caused by bacteria                                    | Condition | SNOMED        | standard         |
| 37108586   | Arthritis of left hip caused by bacteria                                     | Condition | SNOMED        | standard         |
| 37108587   | Arthritis of right knee caused by bacteria                                   | Condition | SNOMED        | standard         |
| 37108588   | Arthritis of left knee caused by bacteria                                    | Condition | SNOMED        | standard         |
| 37108589   | Infective arthritis of left knee                                             | Condition | SNOMED        | standard         |
| 37110004   | Pyogenic arthritis, pyoderma gangrenosum, acne syndrome                      | Condition | SNOMED        | standard         |
| 37117135   | Infective arthritis of right knee                                            | Condition | SNOMED        | standard         |
| 37208263   | Arthritis of left sacroiliac joint caused by bacteria                        | Condition | SNOMED        | standard         |
| 37208264   | Arthritis of right sacroiliac joint caused by bacteria                       | Condition | SNOMED        | standard         |
| 37209324   | Arthritis of bilateral hips caused by bacteria                               | Condition | SNOMED        | standard         |
| 37209325   | Arthritis of bilateral knee joints caused by bacteria                        | Condition | SNOMED        | standard         |
| 37209326   | Arthritis of bilateral shoulders caused by bacteria                          | Condition | SNOMED        | standard         |
| 37209327   | Arthritis of bilateral sacroiliac joints caused by bacteria                  | Condition | SNOMED        | standard         |
| 37309743   | Bilateral infective arthritis of knees                                       | Condition | SNOMED        | standard         |
| 37309744   | Bilateral arthritis of wrists caused by Bacteria                             | Condition | SNOMED        | standard         |
| 37310481   | Infective arthritis of right foot                                            | Condition | SNOMED        | standard         |
| 37310482   | Infective arthritis of left foot                                             | Condition | SNOMED        | standard         |
| 37310483   | Infective arthritis of right hand                                            | Condition | SNOMED        | standard         |
| 37310484   | Infective arthritis of left hand                                             | Condition | SNOMED        | standard         |
| 37310485   | Infective arthritis of right wrist                                           | Condition | SNOMED        | standard         |
| 37310486   | Infective arthritis of left wrist                                            | Condition | SNOMED        | standard         |
| 37310487   | Infective arthritis of right elbow                                           | Condition | SNOMED        | standard         |
| 37310488   | Infective arthritis of left elbow                                            | Condition | SNOMED        | standard         |
| 40481619   | Infective arthritis of pelvis                                                | Condition | SNOMED        | standard         |
| 40481620   | Infective arthritis of ankle and/or foot                                     | Condition | SNOMED        | standard         |
| 40483813   | Infective arthritis of elbow                                                 | Condition | SNOMED        | standard         |
| 40483847   | Infective arthritis of wrist                                                 | Condition | SNOMED        | standard         |

| Concept ID | Concept name                                                    | Domain ID | Vocabulary ID | Standard concept |
|------------|-----------------------------------------------------------------|-----------|---------------|------------------|
| 40486203   | Infective arthritis of proximal interphalangeal joint of finger | Condition | SNOMED        | standard         |
| 40489491   | Infective arthritis of interphalangeal joint of toe             | Condition | SNOMED        | standard         |
| 40489947   | Infective arthritis of distal interphalangeal joint of finger   | Condition | SNOMED        | standard         |
| 40489948   | Infective arthritis of first metatarsophalangeal joint          | Condition | SNOMED        | standard         |
| 40493024   | Infective arthritis of metatarsophalangeal joint of lesser toe  | Condition | SNOMED        | standard         |
| 42534821   | Arthritis of left elbow caused by bacteria                      | Condition | SNOMED        | standard         |
| 42534822   | Arthritis of right wrist caused by bacteria                     | Condition | SNOMED        | standard         |
| 42534823   | Arthritis of left wrist caused by bacteria                      | Condition | SNOMED        | standard         |
| 42534824   | Arthritis of left hand caused by bacteria                       | Condition | SNOMED        | standard         |
| 42534825   | Arthritis of right ankle caused by bacteria                     | Condition | SNOMED        | standard         |
| 42534826   | Arthritis of left ankle caused by bacteria                      | Condition | SNOMED        | standard         |
| 42534829   | Infective arthritis of left hip                                 | Condition | SNOMED        | standard         |
| 42534830   | Infective arthritis of right hip                                | Condition | SNOMED        | standard         |
| 42534831   | Infective arthritis of left ankle                               | Condition | SNOMED        | standard         |
| 42534832   | Infective arthritis of right ankle                              | Condition | SNOMED        | standard         |
| 42534954   | Infective polyarthritis caused by bacteria                      | Condition | SNOMED        | standard         |
| 42539287   | Arthritis of right hand caused by bacteria                      | Condition | SNOMED        | standard         |
| 42539396   | Arthritis of right elbow caused by bacteria                     | Condition | SNOMED        | standard         |
| 44783204   | Post infectious osteoarthritis                                  | Condition | SNOMED        | standard         |
| 46271147   | Bacterial arthritis of costotransverse joint                    | Condition | SNOMED        | standard         |
| 46273196   | Bacterial arthritis of atlantoaxial joint                       | Condition | SNOMED        | standard         |
| 46273200   | Bacterial arthritis of costovertebral joint                     | Condition | SNOMED        | standard         |
| 46273215   | Bacterial arthritis of facet joint of thoracic spine            | Condition | SNOMED        | standard         |
| 46273216   | Bacterial arthritis of facet joint of lumbar spine              | Condition | SNOMED        | standard         |
| 46273622   | Bacterial arthritis of facet joint of cervical spine            | Condition | SNOMED        | standard         |

Table S45. Cefixime.

| Substance Name | Concept name | Ingredient Concept ID | Include descendants |
|----------------|--------------|-----------------------|---------------------|
| Cefixime       | cefixime     | 1796435               | RxNorm              |

Table S46. Azithromycin.

| Substance Name | Concept name | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|--------------|-----------------------------------------------|------------|
| Azithromycin   | azithromycin | 1734104                                       | RxNorm     |

Table S47. Doxycycline.

| Substance Name | Concept name | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|--------------|-----------------------------------------------|------------|
| Doxycycline    | doxycycline  | 1738521                                       | RxNorm     |

Table S48. Gentamicin.

| Substance Name | Concept name | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|--------------|-----------------------------------------------|------------|
| Gentamicin     | gentamicin   | 45892419                                      | RxNorm     |

Table S49. Spectinomycin.

| Substance Name | Concept name  | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|---------------|-----------------------------------------------|------------|
| Spectinomycin  | spectinomycin | 1701651                                       | RxNorm     |

Table S50. Ciprofloxacin.

| Substance Name | Concept name  | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|---------------|-----------------------------------------------|------------|
| Ciprofloxacin  | ciprofloxacin | 1797513                                       | RxNorm     |

Table S51. Ertapenem.

| Substance Name | Concept name | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|--------------|-----------------------------------------------|------------|
| Ertapenem      | ertapenem    | 1717963                                       | RxNorm     |

Table S52. Zoliflodacin.

| Substance Name | Concept name | Ingredient Concept ID (including descendants) | Vocabulary        |
|----------------|--------------|-----------------------------------------------|-------------------|
| Zoliflodacin   | ZOLIFLODACIN | 36857466                                      | RxNorm Extensions |

Table S53. Gepotidacin.

| Substance Name | Concept name | Ingredient Concept ID (including descendants) | Vocabulary |
|----------------|--------------|-----------------------------------------------|------------|
| Gepotidacin    | gepotidacin  | 1465823                                       | RxNorm     |

## ANNEX V. ENCePP checklist for study protocols

### ENCePP Checklist for Study Protocols (Revision 4)

**Study title:** DARWIN EU® - Burden of meningococcal and gonococcal disease in the general population in European countries

**EU PAS Register® number:** EUPAS1000001066

**Study reference number (if applicable):** P5-C3-004/P5-C2-002

| <b>Section 1: Milestones</b>                | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|---------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-----------------------|
| 1.1 Does the protocol specify timelines for |                                     |                          |                                     |                       |
| 1.1.1 Start of data collection <sup>1</sup> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.5                   |
| 1.1.2 End of data collection <sup>2</sup>   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.5                   |
| 1.1.3 Progress report(s)                    | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 1.1.4 Interim report(s)                     | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 1.1.5 Registration in the EU PAS Register®  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            |                       |
| 1.1.6 Final report of study results.        | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 5, 8.8.4              |

Comments:

| <b>Section 2: Research question</b>                                                                                                                             | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-----------------------|
| 2.1 Does the formulation of the research question and objectives clearly explain:                                                                               | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/>            |                       |
| 2.1.1 Why the study is conducted? (e.g. to address an important public health concern, a risk identified in the risk management plan, an emerging safety issue) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 6                     |
| 2.1.2 The objective(s) of the study?                                                                                                                            | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 7                     |
| 2.1.3 The target population? (i.e. population or subgroup to whom the study results are intended to be generalised)                                             | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.3                   |
| 2.1.4 Which hypothesis(-es) is (are) to be tested?                                                                                                              | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 2.1.5 If applicable, that there is no <i>a priori</i> hypothesis?                                                                                               | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |

Comments:

<sup>1</sup> Date from which information on the first study is first recorded in the study dataset or, in the case of secondary use of data, the date from which data extraction starts.

<sup>2</sup> Date from which the analytical dataset is completely available.

| <b>Section 3: Study design</b> |                                                                                                                                                                                                   | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-----------------------|
| 3.1                            | Is the study design described? (e.g. cohort, case-control, cross-sectional, other design)                                                                                                         | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.1                   |
| 3.2                            | Does the protocol specify whether the study is based on primary, secondary or combined data collection?                                                                                           | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.4                   |
| 3.3                            | Does the protocol specify measures of occurrence? (e.g. rate, risk, prevalence)                                                                                                                   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.8.3                 |
| 3.4                            | Does the protocol specify measure(s) of association? (e.g. risk, odds ratio, excess risk, rate ratio, hazard ratio, risk/rate difference, number needed to harm (NNH))                            | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 3.5                            | Does the protocol describe the approach for the collection and reporting of adverse events/adverse reactions? (e.g. adverse events that will not be collected in case of primary data collection) | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |

Comments:

| <b>Section 4: Source and study populations</b> |                                                                                                                                            | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>               | <b>Section Number</b> |
|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|-----------------------|
| 4.1                                            | Is the source population described?                                                                                                        | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                       |
| 4.2                                            | Is the planned study population defined in terms of:                                                                                       |                                     |                          |                          |                       |
| 4.2.1                                          | Study time period                                                                                                                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8.3, 8.5              |
| 4.2.2                                          | Age and sex                                                                                                                                | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8.3                   |
| 4.2.3                                          | Country of origin                                                                                                                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8.3, 8.4              |
| 4.2.4                                          | Disease/indication                                                                                                                         | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8.3, 8.6.2            |
| 4.2.5                                          | Duration of follow-up                                                                                                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8.2, 8.3              |
| 4.3                                            | Does the protocol define how the study population will be sampled from the source population? (e.g. event or inclusion/exclusion criteria) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8.3                   |

Comments:

| <b>Section 5: Exposure definition and measurement</b> |                                                                                                                                                                                                 | <b>Yes</b>               | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|-------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|-------------------------------------|-----------------------|
| 5.1                                                   | Does the protocol describe how the study exposure is defined and measured? (e.g. operational details for defining and categorising exposure, measurement of dose and duration of drug exposure) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 5.2                                                   | Does the protocol address the validity of the exposure measurement? (e.g. precision, accuracy, use of validation sub-study)                                                                     | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 5.3                                                   | Is exposure categorised according to time windows?                                                                                                                                              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |

| <b><u>Section 5: Exposure definition and measurement</u></b>                                                                                       | <b>Yes</b>               | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|-------------------------------------|-----------------------|
| 5.4 Is intensity of exposure addressed?<br>(e.g. dose, duration)                                                                                   | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 5.5 Is exposure categorised based on biological mechanism of action and taking into account the pharmacokinetics and pharmacodynamics of the drug? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 5.6 Is (are) (an) appropriate comparator(s) identified?                                                                                            | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |

Comments:

| <b><u>Section 6: Outcome definition and measurement</u></b>                                                                                                                                                              | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-----------------------|
| 6.1 Does the protocol specify the primary and secondary (if applicable) outcome(s) to be investigated?                                                                                                                   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.6.2                 |
| 6.2 Does the protocol describe how the outcomes are defined and measured?                                                                                                                                                | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.6.2                 |
| 6.3 Does the protocol address the validity of outcome measurement? (e.g. precision, accuracy, sensitivity, specificity, positive predictive value, use of validation sub-study)                                          | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 6.4 Does the protocol describe specific outcomes relevant for Health Technology Assessment? (e.g. HRQoL, QALYs, DALYS, health care services utilisation, burden of disease or treatment, compliance, disease management) | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |

Comments:

| <b><u>Section 7: Bias</u></b>                                                                                        | <b>Yes</b>               | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|----------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|-------------------------------------|-----------------------|
| 7.1 Does the protocol address ways to measure confounding? (e.g. confounding by indication)                          | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 7.2 Does the protocol address selection bias? (e.g. healthy user/adherer bias)                                       | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 7.3 Does the protocol address information bias? (e.g. misclassification of exposure and outcomes, time-related bias) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |

Comments:

| <b><u>Section 8: Effect measure modification</u></b>                                                                                                     | <b>Yes</b>               | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|-------------------------------------|-----------------------|
| 8.1 Does the protocol address effect modifiers? (e.g. collection of data on known effect modifiers, sub-group analyses, anticipated direction of effect) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |

Comments:

| <b><u>Section 9: Data sources</u></b>                                                                                                                                    | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-----------------------|
| 9.1 Does the protocol describe the data source(s) used in the study for the ascertainment of:                                                                            |                                     |                          |                                     |                       |
| 9.1.1 Exposure? (e.g. pharmacy dispensing, general practice prescribing, claims data, self-report, face-to-face interview)                                               | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 11, 8.6.1             |
| 9.1.2 Outcomes? (e.g. clinical records, laboratory markers or values, claims data, self-report, patient interview including scales and questionnaires, vital statistics) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 11, 8.6.2             |
| 9.1.3 Covariates and other characteristics?                                                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 11, 8.6.3             |
| 9.2 Does the protocol describe the information available from the data source(s) on:                                                                                     |                                     |                          |                                     |                       |
| 9.2.1 Exposure? (e.g. date of dispensing, drug quantity, dose, number of days of supply prescription, daily dosage, prescriber)                                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 11, 8.6.1             |
| 9.2.2 Outcomes? (e.g. date of occurrence, multiple event, severity measures related to event)                                                                            | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 11, 8.6.2             |
| 9.2.3 Covariates and other characteristics? (e.g. age, sex, clinical and drug use history, co-morbidity, co-medications, lifestyle)                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 11, 8.6.3             |
| 9.3 Is a coding system described for:                                                                                                                                    |                                     |                          |                                     |                       |
| 9.3.1 Exposure? (e.g. WHO Drug Dictionary, Anatomical Therapeutic Chemical (ATC) Classification System)                                                                  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 11                    |
| 9.3.2 Outcomes? (e.g. International Classification of Diseases (ICD), Medical Dictionary for Regulatory Activities (MedDRA))                                             | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 11                    |
| 9.3.3 Covariates and other characteristics?                                                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 11                    |
| 9.4 Is a linkage method between data sources described? (e.g. based on a unique identifier or other)                                                                     | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |

Comments:

| <b><u>Section 10: Analysis plan</u></b>                                     | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|-----------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-----------------------|
| 10.1 Are the statistical methods and the reason for their choice described? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.8.3                 |
| 10.2 Is study size and/or statistical precision estimated?                  | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 10.3 Are descriptive analyses included?                                     | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.8.3                 |

| <b><u>Section 10: Analysis plan</u></b>                                                | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|----------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-----------------------|
| 10.4 Are stratified analyses included?                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.8.3                 |
| 10.5 Does the plan describe methods for analytic control of confounding?               | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 10.6 Does the plan describe methods for analytic control of outcome misclassification? | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 10.7 Does the plan describe methods for handling missing data?                         | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 10.8 Are relevant sensitivity analyses described?                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.8.3                 |

Comments:

| <b><u>Section 11: Data management and quality control</u></b>                                                                                             | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-----------------------|
| 11.1 Does the protocol provide information on data storage? (e.g. software and IT environment, database maintenance and anti-fraud protection, archiving) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 11                    |
| 11.2 Are methods of quality assurance described?                                                                                                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 11                    |
| 11.3 Is there a system in place for independent review of study results?                                                                                  | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |

Comments:

| <b><u>Section 12: Limitations</u></b>                                                                                                                                                         | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-----------------------|
| 12.1 Does the protocol discuss the impact on the study results of:                                                                                                                            |                                     |                          |                                     |                       |
| 12.1.1 Selection bias?                                                                                                                                                                        | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 9                     |
| 12.1.2 Information bias?                                                                                                                                                                      | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 12.1.3 Residual/unmeasured confounding?<br>(e.g. anticipated direction and magnitude of such biases, validation sub-study, use of validation and external data, analytical methods).          | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 12.2 Does the protocol discuss study feasibility?<br>(e.g. study size, anticipated exposure uptake, duration of follow-up in a cohort study, patient recruitment, precision of the estimates) | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |

Comments:

| <b><u>Section 13: Ethical/data protection issues</u></b>                               | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>               | <b>Section Number</b> |
|----------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|-----------------------|
| 13.1 Have requirements of Ethics Committee/ Institutional Review Board been described? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 11                    |

| <b><u>Section 13: Ethical/data protection issues</u></b>            | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>                          | <b>Section Number</b> |
|---------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-----------------------|
| 13.2 Has any outcome of an ethical review procedure been addressed? | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                       |
| 13.3 Have data protection requirements been described?              | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | 8.8.2                 |

Comments:

| <b><u>Section 14: Amendments and deviations</u></b>                             | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>               | <b>Section Number</b> |
|---------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|-----------------------|
| 14.1 Does the protocol include a section to document amendments and deviations? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4                     |

Comments:

| <b><u>Section 15: Plans for communication of study results</u></b>                          | <b>Yes</b>                          | <b>No</b>                | <b>N/A</b>               | <b>Section Number</b> |
|---------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|-----------------------|
| 15.1 Are plans described for communicating study results (e.g. to regulatory authorities)?  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 11                    |
| 15.2 Are plans described for disseminating study results externally, including publication? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 11                    |

Comments:

Name of the main author of the protocol: Anna Saura-Lazaro, Albert Prats-Urbe

Date: 29/05/2026

Signature: Anna Saura-Lazaro

## ANNEX VI. Glossary

Additional definitions are available in the EMA Glossary of terms <https://www.ema.europa.eu/en/about-us/glossaries>.

### Aggregated Data

Data collected and combined from multiple sources to generate summary information, typically anonymised.

### Benefit-Risk Assessment

Evaluation of the positive therapeutic effects of a medicine compared to its risks (e.g. side effects).

### Common Data Model (CDM)

A standardised data structure that enables data from multiple sources to be harmonised, making analysis consistent and reproducible. DARWIN EU® utilises the OMOP CDM maintained by the OHDSI community.

### Complex Studies (C3)

Studies requiring the development or customisation of specific study designs, outlines, and Statistical Analysis Plans (SAPs), with extensive collection or extraction of data. Examples include etiological studies measuring the strength and determinants of an association between an exposure and the occurrence of a health outcome in a defined population considering sources of bias, potential confounding factors, and effect modifiers.

### Coordination Centre (CC)

The central hub responsible for managing and overseeing the activities within DARWIN EU®. It is based at Erasmus University Medical Center in Rotterdam, the Netherlands.

### Data Access

The process of obtaining permission to use specific datasets for regulatory or scientific studies.

### Data Quality Framework

A set of standards and procedures to ensure accuracy, completeness, timeliness, and consistency of data used in DARWIN EU®.

### Data Source

A data source or repository of structured health-related data, such as electronic health records (EHRs), insurance claims, or registries.

### DARWIN EU®

The European Medicines Agency's (EMA) federated network of real-world data sources designed to generate evidence to support regulatory decision-making.

### EMA (European Medicines Agency)

The regulatory body responsible for the evaluation and supervision of medicinal products in the EU, overseeing DARWIN EU®.

### Evidence Generation

The process of analysing real-world data to produce scientific information that can inform healthcare or regulatory decisions.

### Federated Network

A data infrastructure where data remain at their original location but can be analysed in a harmonised way across multiple partners using a common model and tools.

### GDPR (General Data Protection Regulation)

The EU regulation governing the protection of personal data and privacy, crucial to how DARWIN EU® handles health data.

### Health Technology Assessment (HTA)

A systematic evaluation of properties and impacts of health technology, often using DARWIN EU® data to support assessments.

### Metadata

Descriptive information about a data source (e.g. its content, quality, and structure), essential for identifying relevant data sources in DARWIN EU® studies.

### Off-the-Shelf Studies (OTS)

Studies for which a standard outline per study/analysis type and standardised analytics may be developed and applied or adapted, typically relating to a descriptive research question. This includes studies on disease epidemiology, for example, the estimation of the prevalence or incidence of health outcomes in defined time periods and population groups, or drug utilisation studies at the population or patient level.

### OHDSI (Observational Health Data Sciences and Informatics)

An open-science collaborative community that develops tools and standards (including the OMOP CDM) to enable large-scale analytics of observational health data. OHDSI provides the technical and scientific foundation for DARWIN EU®'s analytical ecosystem.

### Patient-Level Data

Data related to individuals, de-identified, used for longitudinal or detailed analyses.

### OMOP (Observational Medical Outcomes Partnership)

A common data model (CDM) that standardises the structure and content of observational healthcare data, enabling systematic analysis across disparate datasets. DARWIN EU® uses the OMOP CDM to ensure interoperability and consistency in real-world evidence generation.

### Real-World Data (RWD)

Data relating to individual health status or healthcare delivery that is collected from routine clinical practice rather than from randomised controlled trials.

### Real-World Evidence (RWE)

Clinical evidence derived from the analysis of RWD, used to inform decisions by regulators, payers, or clinicians.

### Regulatory Decision-Making

The process by which authorities like EMA assess data to authorise, monitor, or modify the use of medicines in the EU.

### Routine Repeated Studies (RR)

Studies that are either Off-the-Shelf or Complex studies repeated on a regular basis, following the same outline and study code, but with updated data and/or different data partners.

## Study Outline

A detailed plan describing how a specific real-world study will be conducted, including objectives, design, data sources, and analyses.

### Very Complex Studies (C4)

Studies which cannot rely only on electronic health care data sources, or which would require complex methodological work, for example, due to the occurrence of events that cannot be defined by existing diagnosis codes, including events that do not yet have a diagnosis code, where it may be necessary to combine a diagnosis code with other data such as results of laboratory investigations. These studies might require the collection of data prospectively, or the inclusion of new (not previously onboarded) data sources.