Study Protocol

P4-C1-006

DARWIN EU® - Uptake of meningococcal vaccines by the target population in Europe

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Version 3.0

Public

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Study title	DARWIN EU® - Uptake of meningococcal vaccines by the target population in Europe
Protocol version	V3.0
Date	14/07/2025
EUPAS number	EUPAS1000000675
Active substance	Meningococcal vaccines including: • Monovalent Meningococcal group B surface protein vaccine • Meningococcal serogroup C conjugate vaccines or Meningococcal serogroup C /Haemophilus influenzae B (Hib) combination vaccine • Quadrivalent Meningococcal conjugate vaccine (groups A, C, W-135, and Y)
Medicinal product	Licensed meningococcal vaccines including: • Menveo® (meningococcal groups A, C, W-135, and Y conjugate vaccine) • Nimenrix® (meningococcal groups A, C, W-135, and Y conjugate vaccine) • Bexsero® (meningococcal group B surface protein vaccine) • Trumemba® (meningococcal group B surface protein vaccine)
Objectives	1. To examine the coverage of MenB vaccines in children at age one and two years by dose received (⩾1 dose, ⩾2 doses, ⩾3 doses, =1 dose, =2 doses, =3 doses) 2. To examine the coverage of MenC or Hib/MenC conjugate vaccines in children at age two years (⩾1 dose, =1 dose) 3. To examine the coverage of MCV4 vaccines in individuals at age 18 years (⩾1 dose, =1 dose) 4. To estimate the coverage of specific brand of MenB vaccines (Bexsero® and Trumemba®) in individuals aged two years and MCV4 vaccines (Menveo® and Nimenrix®) in individuals aged 18 years 5. To characterise the age distribution of receival of MenB, MenC, and MCV4 vaccines Due to potential data availability, objective 4 of this study will only be examined on the Clinical Practice Research Datalink GOLD, UK.
Countries of study	Croatia, Denmark, Finland, Germany, Spain, United Kingdom
Authors	Ivan Lam (i.lam@darwin-eu.org) Albert Prats-Uribe (a.prats-uribe@darwin-eu.org) Anna Saura-Lazaro (a.sauralazaro@darwin-eu.org)

LIST OF ABBREVIATIONS

Acronyms/terms	Descriptions
BIFAP	Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público
CDM	Common Data Model
CPRD	Clinical Practice Research Datalink
DARWIN EU®	Data Analysis and Real-World Interrogation Network
DK-DHR	Danish Data Health Registries
FinOMOP-THL	Finnish Care Register for Health Care
Hib/MenC	Haemophilus influenzae type b/Meningococcal group C
InGef	InGef Research Database
IMD	Invasive Meningococcal Disease
MenB	*Neisseria Meningitidis* group B
MenC	*Neisseria Meningitidis* group C
MCV4	Meningococcal group ACWY vaccines
NAJS	Croatian National Public Health Information System
NHS	National Health Services, UK
OHDSI	Observational Health Data Sciences and Informatics
OMOP	Observational Medical Outcomes Partnership
UK	United Kingdom
SIDIAP	Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària
SNOMED	Systematized Nomenclature of Medicine

1. TITLE

DARWIN EU® - Uptake of meningococcal vaccines by the target population in Europe

2. DESCRIPTION OF THE STUDY TEAM

Study team role	Names	Organisation
Principal Investigators	Ivan Lam Albert Prats-Uribe	University of Oxford
Data Scientists	Xihang Chen Edward Burn	University of Oxford
Epidemiologist	Albert Prats-Uribe	University of Oxford
Clinical Domain Expert	Anna Saura-Lazaro	University of Oxford
Study Manager	Natasha Yefimenko	Erasmus MC
Data Partner*	**Names**	**Organisation**
NAJS	Jakov Vuković Ivan Pristaš, Antea Jezidžić Jakov Vuković	Croatian Institute of Public Health
DK-DHR	Claus Møldrup Elvira Bräuner Susanne Bruun	Danish Medicines Agency
FinOMOP – THL	Gustav Klingstedt Tiina Wahlfors Toni Lehtonen	Finnish Care Register for Health Care
InGef	Alexander Harms Annika Vivirito Josephine Jacob	Institut für angewandte Gesundheitsforschung Berlin GmbH
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SIDIAP	Talita Duarte Salles	IDIAPJGol

	Elena Roel Herranz Irene López Sánchez Augustina Giuliodori Picco	
CPRD GOLD	Antonella Delmestri Marta Pineda Moncusí Wai Yi Man	University of Oxford

*Data partners' role is only to execute code at their data source, review and approve their results. They do not have an investigator role. Data analysts/programmers do not have an investigator role and thus declaration of interests (DOI) for them is not needed.

3. ABSTRACT

Title

DARWIN EU® – Uptake of meningococcal vaccines by the target population in Europe

Rationale and background

Meningococcal vaccines are recommended in the immunisation schedule in targeted children and adolescent population to prevent Invasive Meningococcal Disease (IMD). Various Meningococcal vaccines have been developed to target distinct serogroups of the bacteria *Neisseria Meningitidis* including groups A, B, C, W, and Y responsible for IMD. The current vaccination schedule in countries within Europe have recommended the uptake of three doses of Meningococcal group B (MenB) vaccines for children at age 2, 4 and 12 months, a single dose of MenC or Haemophilus influenzae type b/Meningococcal group C (Hib/MenC) vaccines at age 12 months, and quadrivalent Meningococcal groups ACWY (MCV4) vaccines as a single dose scheduled for adolescents between 14 and 18 years of age as the main vaccination schedule, but given as early as age 11 in certain countries, for the prevention of severe meningococcal infection. MCV4 is also included as part of the immunisation schedule in children aged two years or below in multiple countries in the EU including Austria, Belgium, Cyprus, and Italy. This study aims to generate comprehensive evidence on the coverage of these separate types of meningococcal vaccines within the target population across six countries within Europe.

Research question and objectives

The general objective of this study is to examine the coverage of meningococcal vaccines routinely administered in countries across Europe for preventing IMD in eligible individuals.

The specific objectives of this study are:

1. To examine the coverage of MenB vaccines in children at age one and two years by dose received (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses)
2. To examine the coverage of MenC or Hib/MenC conjugate vaccines in children at age two years (≥1 dose, =1 dose)
3. To examine the coverage of MCV4 vaccines in individuals at age 18 years (≥1 dose, =1 dose)
4. To estimate the coverage of specific brand of MenB vaccines (Bexsero® and Trumemba®) in individuals aged two years and MCV4 vaccines (Menveo® and Nimenrix®) in individuals aged 18 years
5. To characterise the age distribution of receival of MenB, MenC, and MCV4 vaccines

Due to potential data availability, objective 4 of this study will only be examined on the Clinical Practice Research Datalink GOLD, UK.

Methods

Study design

Population-level drug utilisation study (DUS) and patient-level characterisation

Population

The study population will include all individuals within each database reaching the age of one year and two years for assessing the coverage of MenB vaccines, and individuals reaching the age of 18 for assessing the coverage of MCV4 vaccines at each quarterly and yearly sampling window.

Data source

1. Croatian National Public Health Information System (NAJS), Croatia
2. Danish Data Health Registries (DK-DHR), Denmark
3. Finnish Care Register for Health Care (FinOMOP-THL), Finland
4. InGef Research Database (InGef), Germany
5. Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (BIFAP), Spain
6. Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària (SIDIAP), Spain
7. Clinical Practice Research Datalink (CPRD) GOLD, United Kingdom (UK)

Statistical analysis

Objective 1 of this study examines the point prevalence of individuals who have received a different number of doses of MenB vaccines (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses) in separate age groups (age 1 year and 2 years of age). Objective 2 examines the point prevalence of eligible individuals aged 2 who have received at least one dose of MenC or Hib/MenC vaccines (≥1 dose, =1 dose). Objective 3 examines the point prevalence of MCV4 recipients in individuals at 18 years of age. Objective 4 of this study examines the point prevalence of MenB and MCV4 vaccines by brand (MenB: Bexsero®, Trumemba®; MCV4: Menveo®, Nimenrix®). Objective 5 examines the age distribution of cohorts of individuals who have received the MenB vaccine (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses), one dose of the MenC vaccine (≥1 dose, =1 dose) and one dose of the MCV4 vaccine.

The analyses stated above will be conducted in separate quarterly and yearly observation windows.

4. AMENDMENTS AND UPDATES

None.

5. MILESTONES

Study milestones and deliverables	Planned dates*
Final Study Protocol	To be confirmed by EMA
Creation of Analytical code	July 2025
Execution of Analytical Code on the data	August 2025
Draft Study Report	September 2025
Final Study Report	To be confirmed by EMA

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

6. RATIONALE AND BACKGROUND

Background of Meningococcal infection

Meningococcal infection, caused by the bacteria *Neisseria meningitidis*, is one of the leading causes for invasive meningococcal disease (IMD). IMD is a major cause for severe adverse clinical conditions, including bacterial meningitis and septicaemia, resulting in high case fatality rates of up to 80% in untreated case worldwide. Furthermore, IMD is also associated with significant life-long complications among survivors.[1] IMD affects individuals of all ages, however, infants and young children were among the patient group with the highest incidence of case fatality rates (CFR).[2] Many, but not all countries, also had a small peak in IMD incidence during late adolescence and early adulthood.[3] Twelve serogroups are recognised, of which six (A, B, C, W, X, and Y) are responsible for the vast majority of cases of IMD.

Epidemiology of Invasive Meningococcal disease in Europe

The incidence of IMD and responsible serogroups vary widely both geographically within Europe and over time. The reported incidence of IMD in cases per a population of 100,000 across Europe ranges from 0.45 in Northern and Southern Europe to 1.33 in the UK and Ireland. There were 282 fatal cases reported across the EU, accounting to a case fatality of 9.7%. The reported incidence of IMD was highest amongst infants aged <1 year (8.2/100,000) followed by toddlers aged 1-4 years (2.5/100,000) and with a second peak in 15–24 year-olds (1.0/100,000).[4] Meningococcal group B bacteria is currently the predominating serogroup in the majority of countries across Europe, including Spain and the UK. Nonetheless, MenW and MenY were also identified as predominate serogroups in other European countries, including Denmark and Finland.

Meningococcal Vaccines

Meningococcal vaccination has been a major public health measure in preventing IMD. Various meningococcal vaccines targeting different serogroups of *Neisseria Meningitidis* are currently offered as routine vaccination schedules for children and adolescents aged 25 or below in certain countries across Europe.[5]

The existing meningococcal vaccines against Meningococcal group C (MenC) and quadrivalent meningococcal conjugate vaccines (MCV4) include polysaccharide vaccines composed of capsular polysaccharides from one or more meningococcal serogroups. These vaccines have been shown to be immunogenic and safe in older children and adults. The subsequently developed polysaccharide-protein conjugate vaccines provided additional benefits in inducing immunity in younger children from birth, conferring longer lasting protection, and providing a booster response with subsequent doses. In addition, the direct protection against acquisition of carriage from protein-conjugate vaccines disrupts the transmission to others, thus providing indirect (herd) protection across the population. A single dose of

MenC vaccination has been recommended as a routine schedule for children at the age of one year in Germany and the UK. MenC vaccinations were typically offered by combined *Haemophilus influenzae* type b/Meningococcal group C (Hib/MenC) vaccines in the UK. In Spain, children are advised to receive two doses of MenC vaccine at 4 months and one year of age.

The MCV4 vaccines, including Menveo® and Nimenrix®, protect against four serogroups of meningococcal disease —A, C, W-135, and Y. These are part of the routine vaccination programmes for children with a single dose of vaccination typically given at ages 12-18 in the UK and Spain.

Table 1. Types, serogroups covered, doses recommended and brands of meningococcal vaccines.

Meningococcal vaccines	Serogroup covered	Doses recommended	Brands
MenB	B	Three	Bexsero® and Trumemba®
MenC	C	One (Two in Spain)	Menjugate® and Meningitec®
MCV4	A, C, W-135, and Y	One	Menveo® and Nimenrix®

Note: Coverage of specific brand of MenC vaccines will not be examined in this study

More recently, multi-component protein-based vaccine has been developed with the aim of providing broad protection of various strains of *Neisseria Meningitidis* group B with diverse immunodominant Porin A (PorA) antigen. Three doses of the Meningococcal, serogroup B (MenB) vaccine have been introduced in the immunisation programme in several countries across the EU, including Germany, Spain, and the UK for children at 2 months, 4 months, and at one year. The novel multi-component protein-based vaccine, Bexsero®, was licensed for use in the UK and within the EU in 2013 for children aged 2 months or above.[6] This vaccine consisted of multiple subcapsular recombinant protein antigens providing protection against most MenB strains of up to 91% across the globe. Another subcapsular meningococcal antigen vaccine, Trumenba®, was later licensed in the EU in 2017 for children from 10 years of age. Despite only being licensed to protect against MenB responsible meningococcal disease, both vaccines have the potential to protect against any meningococcal serogroup possessing a vaccine-related surface antigen.

Justification for this study

Immunisation against meningococcal disease forms a crucial public health measure in preventing IMD, especially amongst vulnerable populations. Nevertheless, the coverage of meningococcal vaccines within Europe remains largely unclear and inconsistent due to the variation in the vaccination schedule recommended in countries within Europe and the UK. This study aims to generate comprehensive evidence on the coverage of MenB, MenC, and MCV4 meningococcal vaccines as part of the immunisation schedule amongst eligible individuals across a number of European countries as illustrated in **Figure 1** below. The coverage of Meningococcal vaccines will be examined in countries including Croatia, Denmark, and Finland where Meningococcal vaccines are only administered to selected individuals with specific medical need and those with increased risk of meningococcal disease due to underlying health conditions or medications rather than as part of the routine vaccination schedule. Given the administration of meningococcal vaccines provided to individuals outside the standard age-based immunisation schedule in certain countries, this study will additionally investigate the age distribution of vaccine receivals to identify patterns of off-schedule administration in separate countries across Europe.

Countries	Age																
	Months						Year										
	2	4	6	8	10	12	2	4	6	8	10	12	13	14	16	17	18
UK	MenB (Dose 1)	MenB (Dose 2)				MenB (Dose 3) and MenC							MCV4				
Spain	MenB (Dose 1)	MenB (Dose 2) and MenC				MenB (Dose 3) and MenC						MCV4					
Germany	MenB (Dose 1)	MenB (Dose 2)				MenB (Dose 3) and MenC											
Croatia	MenB, MenC and MCV4 not included in immunisation schedule																
Denmark	MenB, MenC and MCV4 not included in immunisation schedule																
Finland	MenB, MenC and MCV4 not included in immunisation schedule																

Figure 1. Meningococcal vaccination schedule in the UK, Spain, Germany, Croatia, Denmark, and Finland.

7. OBJECTIVES

The general objective of this study is to generate vaccine coverage data on MenB, MenC, and MCV4 vaccines in their respective target populations from seven healthcare databases across six European countries.

The specific objectives of this study are:

1. To examine the coverage of MenB vaccines in children at age one and two years by dose received (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses)
2. To examine the coverage of MenC or Hib/MenC conjugate vaccines in children at age two years (≥1 dose, =1 dose)
3. To examine the coverage of MCV4 vaccines in individuals at age 18 years (≥1 dose, =1 dose)
4. To estimate the coverage of specific brand of MenB vaccines (Bexsero® and Trumemba®) in individuals aged two years and MCV4 vaccines (Menveo® and Nimenrix®) in individuals aged 18 years =
5. To characterise the age distribution of receival of MenB, MenC, and MCV4 vaccines.

Due to potential data availability, objective 4 of this study will only be examined on the Clinical Practice Research Datalink GOLD, UK.

Table 2. Primary and secondary objectives.

Objective	1. To examine the coverage of MenB vaccine in children at age one and two years by dose received (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses) 2. To examine the coverage of MenC or Hib/MenC conjugate vaccines in children at age two years (≥1 dose, =1 dose) 3. To examine the coverage of MCV4 vaccines in individuals at age 18 years (≥1 dose, =1 dose) 4. To estimate the coverage of specific brand of MenB vaccines (Bexsero® and Trumemba®) in individuals aged two years and MCV4 vaccines (Menveo® and Nimenrix®) in individuals aged 18 years 5. To characterise the age distribution of receival of MenB, MenC, and MCV4 vaccines Due to potential data availability, objective 4 of this study will only be examined on CPRD GOLD, UK.
Hypothesis	N/A
Population *(mention key inclusion-exclusion criteria)*	Study population for the coverage of Men B vaccination includes all individuals aged 1 and 2 with continuous enrolment since birth. The coverage of Bexsero® and Trumemba® includes all individuals aged 2 with continuous enrolment since birth. Study population for the coverage of Men C and Hib/MenC vaccination includes all individuals aged 2 with continuous enrolment since birth.

	Study population for the coverage of MCV4 (including Menveo® and Nimenrix®) vaccination includes all individuals aged 18 with continuous enrolment between age 12 and 18 years. Children born on or after 01/01/2015 with two years of enrolment from birth are eligible for inclusion for the examination of coverage of MenB (including Bexsero® and Trumemba®) and MenC (and Hib/MenC) vaccines. Individuals reaching 12 years of age on or after 01/01/2011 with six years of enrolment from birth are eligible for inclusion for the examination of coverage of MCV4 (including Menveo® and Nimenrix®) vaccines.
Exposure	N/A
Comparator	N/A
Outcome	Records of MenB, MenC, or MCV4 vaccinations
Time *(when follow up begins and ends)*	Study period starts on 01/01/2017 and ends on the last quarterly and yearly sampling window prior to the data lock for the last update of each corresponding database.
Setting	The study will use routinely collected health data from seven nationwide or regional databases in six European countries (Croatia, Denmark, Germany, Spain, Norway, United Kingdom). Inpatient, outpatient hospital setting and primary care setting will be used for the study.
Main measure of effect	Meningococcal vaccine coverage

8. RESEARCH METHODS

8.1 Study type and study design

We will conduct a drug utilisation cohort study using routinely collected health data from seven nationwide or regional databases in six European countries.

8.2 Study setting and data sources

This study will be conducted using routinely collected health data from seven databases in six European countries. All databases were previously mapped to the OMOP CDM.

Data sources:

1. Croatian National Public Health Information System (NAJS), Croatia
2. Danish Data Health Registries (DK-DHR), Denmark
3. Finnish Care Register for Health Care (FinOMOP-THL), Finland
4. InGef Research Database (InGef), Germany
5. Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (BIFAP), Spain
6. Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària (SIDIAP), Spain
7. Clinical Practice Research Datalink (CPRD) GOLD, United Kingdom (UK)

We selected seven out of the 30 databases onboarded in DARWIN EU® in 2025. The selection of databases for this study was performed based on data reliability and relevance for the proposed research question.[7] The selected databases fulfil the criteria required for a population-level DUS, while covering different settings and regions of Europe. Two separate databases from Spain, one covering a single region and the other representing the national population, were included to ensure a comprehensive assessment of Meningococcal vaccine coverage across the country. Detailed information on the selected data sources and their ability to answer the study research questions are described in **Table** .

Table 3. Description of the selected data sources.

Country	Name of Database	Justification for Inclusion	Health Care setting	Type of Data	Number of active subjects	Feasibility counts of meningococcal vaccination record	Data lock for the last update
CR	NAJS	The database has information on meningococcal vaccination record from primary care or hospital. The denominator is suitable for population rates as it includes population insured.	Primary care, secondary care specialists, hospital inpatient care	Claims	2.68 million	6.59 million	07/08/2024
DK	DK-DHR	The database has information on meningococcal vaccination record from hospitals, specialist offices, and community pharmacies and treatments administered in hospital. The denominator is suitable for population rates as it includes the entire population.	Community pharmacies, secondary care – specialists, hospital inpatient care	Registries	5.96 million	1.01 million	19/02/2025
FL	FinOMOP-THL	The database has information on meningococcal vaccination record from hospitals and specialist offices, GPs, and primary care specialist and treatments administered in hospital. The denominator is suitable for population rates as it includes the entire population.	Secondary care – specialists (ambulatory or hospital OP care), hospital IP care	HER, Registries	7.3 million	0.50 million	24/06/2024
DE	InGef	The database has information on meningococcal vaccination record from primary care or hospital. The denominator is suitable for population rates as it includes the entire population insured.	Primary care, community pharmacists, primary care specialists, secondary care specialists, hospital inpatient care	Claims	7.6 million	0.1 million	03/12/2024
ES	BIFAP	The database has information on meningococcal vaccination record from primary care or hospital. The denominator is suitable for population rates as it includes the entire population.	Primary care – GPs, community pharmacies, hospital inpatient care, primary care specialists	EHR	22.58 million	5.41 million	01/10/2024
ES	SIDIAP	The database has information on meningococcal vaccination record from primary care treatments. Denominator is suitable for population rates as it includes all people registered in the GP practice.	Primary care	EHR	5.95 million	6.07 million	17/03/2025
UK	CPRD GOLD	The database has information on meningococcal vaccination record from primary care or feedbacked to the GP from the specialists. The denominator is suitable for population rates as it includes all people registered in the GP practice.	Primary care	EHR	2.92 million	4.54 million	12/12/2024

CR = Croatia, DK = Denmark, ES = Spain, UK = United Kingdom, BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

Croatian National Public Health Information System (NAJS), Croatia

The National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav - NAJS) is an organised system of information services by Croatian Institute of Public Health (CIPH). NAJS enables data collecting, processing, recording, managing, and storing of health-related data from health care providers as well as production and management of health information. NAJS contains medical and public health data collected and stored in health registries and other health data collections including cancer registry, mortality, work injuries, occupational diseases, communicable and non-communicable diseases, health events, disabilities, psychosis and suicide, diabetes, drug abuse, and others. NAJS will have their IRB approval by early to mid-January.

Danish Data Health Registries (DK-DHR), Denmark

Danish health data is collected, stored, and managed in national health registers at the Danish Health Data Authority and covers the entire population, which makes it possible to study the development of diseases and their treatment over time. There are no gaps in terms of gender, age, and geography in Danish health data due to mandatory reporting on all patients from cradle to grave, in all hospitals and medical clinics. Personal identification numbers enable linking of data across registers, so we have data on all Danes throughout their lives, regardless of whether they have moved around the country. High data quality due to standardization, digitization and documentation means that Danish health data is not based on interpretation. The Danish Health Data Authority is responsible for the national health registers and for maintaining and developing standards and classifications in the Danish healthcare system. Legislation ensures balance between personal data protection and use. In the present data base, we have access to the following registries for the entire Danish population of 5.9 million persons from 1/1/1995: The central Person Registry (CPR), The National Patient Registry (LPR), The Register of Pharmaceutical Sales (LSR), The National Cancer Register (CAR), The Cause of Death registry (DAR), The Clinical Laboratory Information Register (LAB), COVID-19 test and vaccination Registries (SSI-OVD, SSI-DDV), The complete Vaccination registry (DDV_all).

Finnish Care Register for Health Care (FinOMOP - THL), Finland

The THL database covers both public and private, primary and specialised inpatient 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. The main content of the THL CDM is The Finnish Care Register for Health Care (fi:Hoitoilmoitusrekisteri, HILMO). It is a continuation of the former Hospital Discharge Register, which originally gathered data on patients discharged from hospitals. The Care Register has comprehensive data on the use of services and service users from Finnish public inpatient and outpatient primary and specialised care nationwide. Since 1998 the register has covered both public outpatient and inpatient specialized care and private inpatient care (TerveysHilmo). From 2011 the register has covered public primary care (AvoHilmo). From 2020 the register has covered private outpatient care and occupational care. In addition, the CDM also contains the vaccination data from the Finnish National Vaccination Register, and positive COVID-19 test results from the Finnish National Infectious Diseases Register, which is maintained by THL. The CDM is currently produced from the above-mentioned and limited to observation periods commencing after 1/1/2011. The National Population registry is also used as a source for the CDM database. The National Population registry data forms the basis for forming the patient population. This ensures up-to-date location (municipality of residence) of patients as well as complete death occurrences (although not the cause of death). Using the complete population as a basis for the person table also serves to facilitate calculations on a population level, e.g. incidence rates. The current CDM population comprises all persons having been alive and residing in Finland since the beginning of 2011.[10]

Specific limitation for this study: Records of MCV4 vaccines in this database may be captured by separate records of Meningococcal groups A, C, W-135, and Y vaccination records.

InGef Research Database (InGef), Germany

The InGef database comprises anonymized longitudinal claims data of about ten million individuals across more than 70 statutory health insurance providers (SHIs) throughout Germany. Data are longitudinally linked over a period of currently ten years. Patients can be traced across health care sectors. All patient level and provider-level data in the InGef research database are anonymised to comply with German data protection regulations and German federal law. German SHI claims data available in the InGef database includes information on demographics (year of birth, gender, death date if applicable, region of residence on administrative district level); hospitalizations; outpatient services (diagnoses, treatments; specialities of physicians); dispensing of drugs; dispensing of remedies and aids; and sick leave and sickness allowance times. In addition, costs or cost estimates from SHI perspective are available for all important cost elements. All diagnoses in Germany are coded using the International Classification of Diseases, version 10 in the German Modification (ICD-10-GM). The persistence (membership over time) is rather high in the InGef database: During a time period of 5 years (2009 to 2013), 70.6% of insurance members survived and remained insured with the same SHI without any gap in their observational time. Persons leaving one of the participating SHIs and entering another participating SHI, can be linked during yearly database consistency updates, and are thus not lost over time. The InGef database is dynamic in nature, i.e. claims data are updated in an ongoing process and new SHIs may join or leave the database.

Record of Meningococcal vaccination from this database will be mapped to concepts from the procedure domain.

Specific limitation for this study: This database only recorded month of birth of individuals every quarterly (in either January, April, July, or October). Individuals in this database are therefore assumed to be born on the first day of the recorded month and year of birth. Records of MCV4 vaccines in this database may be captured by separate records of Meningococcal groups A, C, W-135, and Y vaccination records.

Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (BIFAP), Spain

BIFAP (http://www.bifap.org/index_EN.html) is a longitudinal population-based data source of medical patient records of the Spanish National Health Service (SNS) from 9 participating Regions throughout Spain out of the 17 Spanish Regions. The population currently included represents 36% of the total Spanish population. Spain has a SNS that provides universal access to health services through the Regional Healthcare Services. Primary care physicians (PCPs), both general practitioners and paediatricians, have a central role. They act as gatekeepers of the system and also exchange information with other levels of care to ensure the continuity of care. Most (98.9%) of the population is registered with a PCP and, in addition, most drug prescriptions are written at the primary care level. BIFAP includes a collection of databases linked at individual patient level. The main one is the Primary care Database given the central role of PCPs in the SNS. Linked, there are additional important structural databases like the medicines dispensed at community pharmacies and the patients' hospital diagnosis at discharge. 7 out of the 9 regions have linkage to hospital data. However, hospital data is available for different time periods for each region. From 2014 onwards, linkage to hospital data is available for >68% of patients Linkage to SARS-CoV-2 diagnostics test and COVID-19 vaccination registries are also included. Additional databases are also linked for a subset of patients (hospital pharmacy, cause of death registry). BIFAP program is a non-profit program financed by the Spanish Agency of Medicines and Medical Devices (AEMPS), a government agency belonging to the Ministry of Health in collaboration with the regional health authorities. The main use of BIFAP is for research purposes to evaluate the adverse and beneficial effects of drugs and drug utilization patterns in the general population under real conditions of use.

Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària (SIDIAP), Spain

The Information System for Research in Primary Care (SIDIAP) is a clinical database of anonymized patient records in Catalonia, Spain. The Spanish public healthcare system covers more than 98% of the population, and more than two thirds of the Catalan population see their GP at least once a year. The computerisation of the primary care patient records of the Catalan Health Institute (CHI) was complete in 2005. SIDIAP was designed to provide a valid and reliable database of information from clinical records of patients registered in primary care centres for use in biomedical research. SIDIAP contains data of anonymized patients' healthcare records for nearly six million people (approximately 80% of the Catalan population) registered in 287 primary care practices throughout Catalonia since 2005. It includes data collected by health professionals during routine visits in primary care, including anthropometric measurements, clinical diagnoses (International Classification of Diseases 10th revision ICD-10), laboratory tests, prescribed and dispensed drugs, hospital referrals, demographic, and lifestyle information. It was previously shown that SIDIAP population is highly representative of the entire Catalan region in terms of geographic, age, and sex distributions. The high quality of these data has been previously documented, and SIDIAP has been successfully applied to epidemiological studies of key exposures and outcomes. Quality checks to identify duplicate patient IDs are performed centrally at each SIDIAP database update. Checks for logical values and data harmonisation are performed. For biochemistry data, consistency for measurements taken in different laboratories is assessed, and unit conversion is undertaken when needed.

Specific limitation for this study: This database only recorded the month and year of birth of individuals. Individuals in this database are therefore assumed to be born on the first day of the recorded month and year and birth.

Clinical Practice Research Datalink GOLD, United Kingdom

The Clinical Practice Research Datalink (CPRD) is a governmental, not-for-profit research service, jointly funded by the National Institute for Health and Care Research and the Medicines and Healthcare products Regulatory Agency, a part of the Department of Health, United Kingdom (UK) (https://cprd.com). CPRD GOLD comprises computerized records of all clinical and referral events in primary care in addition to comprehensive demographic information and medication prescription data in a sample of UK patients (predominantly from Scotland (52% of practices) and Wales (28% of practices).[8] The prescription records include information on the type of product, date of prescription, strength, dosage, quantity, and route of administration. Data from contributing practices are collected and processed into research databases. Quality checks on patient and practice level are applied during the initial processing. Data are available for 21 million patients, including 3.1 million currently registered patients. Access to CPRD GOLD data requires approval via the Research Data Governance Process.

Specific limitation for this study: This database only recorded the month and year of birth of individuals. Individuals in this database are therefore assumed to be born on the first day of the recorded month and year and birth.

8.3 Study period

The study period will cover from 01/01/2017 until the end of available data in each of the data sources. (see **Table 4**) The study start date chosen covers the period of which meningococcal vaccines were introduced as part of the routine childhood immunisation program in countries across Europe where Meningococcal vaccines are administered as part of the routine immunisation schedule and allowed for the examination of potential disruptions on vaccine uptake over the COVID-19 pandemic. Individuals included for analysis of the coverage of MenB and MenC vaccines will require a look back period of two years, analysis on individuals at 1 year of age will require one year of look back period from the study start date. Individuals included for analysis of the coverage of MCV4 vaccines will require a look back period of 6 years from the study start date. (based on the eligibility of MCV4 in children between age 12 and 18).

Table 4. Study period by database.

Database	Start date	End date
NAJS	01/01/2017	07/08/2024
DK-DHR	01/01/2017	19/02/2025
FinOMOP-THL	01/01/2017	24/06/2024
InGef	01/01/2017	03/12/2024
BIFAP	01/01/2017	01/10/2024
SIDIAP	01/01/2017	17/03/2025
CPRD GOLD	01/01/2017	12/12/2024

8.4 Follow-up

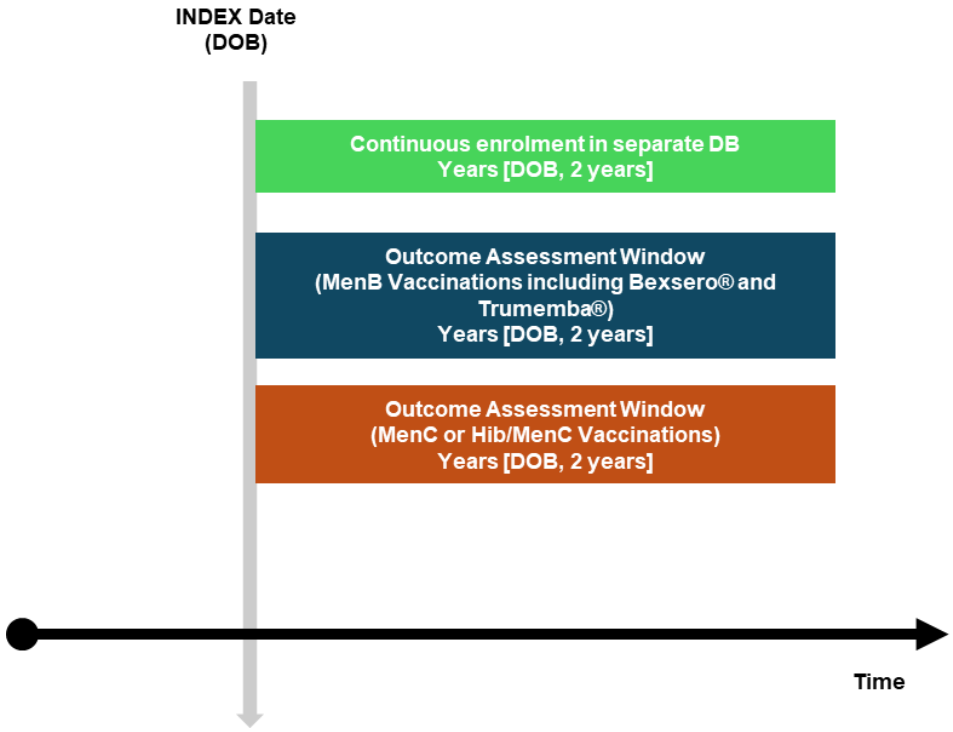
The index date is defined as the date of birth for the examination of the coverage of MenB, MenC, or Hib/MenC vaccines and when individuals turn 12 years of age for the examination of the coverage of MCV4 vaccines. Each individual will be followed for records of MenB, MenC vaccines, or when individuals reach the age of two. Individuals reaching the age of 12 will be followed for records of MCV4 vaccination until reaching 18 years of age. The index date for characterising the age distributions for separate meningococcal vaccines is defined as the date of complete vaccination of separate meningococcal vaccines by type (MenB, MenC, and MCV4). The index date for each cohort of study populations is illustrated in **Table 5**, **Figure 2,** and **Figure 3** below.

Table 5. Operational definition of time 0 (index date) and other primary time anchors.

Study population name(s)	Time Anchor Description	Number of entries	Type of entry	Washout window	Care Setting[1]	Measurement characteristics/validation
Coverage of MenB vaccines at in individuals aged one years old	Date of birth	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as the date of birth record of individuals
Coverage of MenB vaccines at in individuals aged	Date of birth	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as the date of birth record of

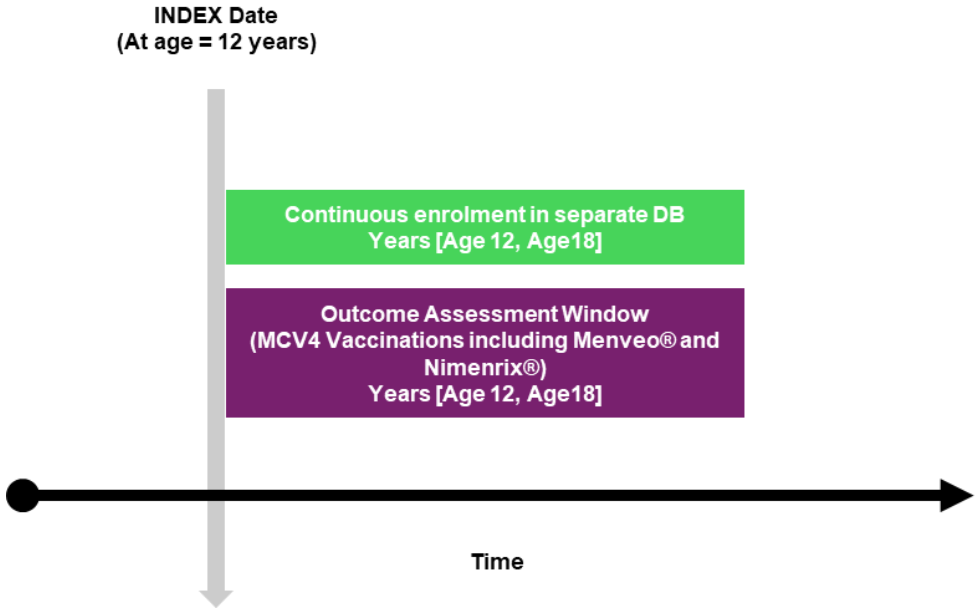
Study population name(s)	Time Anchor Description	Number of entries	Type of entry	Washout window	Care Setting[1]	Measurement characteristics/validation
two years old						individuals
Coverage of MenC vaccines at in individuals aged two years old	Date of birth	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as the date of birth record of individuals
Coverage of MCV4 vaccines at in individuals aged 18 years old	Date of reaching 12 years of age	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as 12 years after the date of birth of individuals
Age distribution of individuals receiving one dose of MenB vaccines	Date of receiving first doses of MenB vaccine	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as date of first vaccination record of MenB vaccination
Age distribution of individuals receiving two doses of MenB vaccines	Date of receiving second doses of MenB vaccine	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as date of second vaccination record of MenB vaccination
Age distribution of individuals receiving full schedule of MenB vaccines	Date of receiving third doses of MenB vaccine	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as date of third vaccination record of MenB vaccination
Age distribution of individuals receiving full schedule of MenC vaccines	Date of receiving first doses of MenC vaccine	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as date of first vaccination record of MenC vaccination
Age distribution of individuals receiving full schedule of MCV4 vaccines	Date of receiving first doses of MCV4 vaccine	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as date of first vaccination record of MCV4 vaccination

[1] IP = inpatient, OP = outpatient, ED = emergency department, OT = other, n/a = not applicable



Note: MenB: Meningococcal group B; MenC: Meningococcal group C; Hib/MenC: Combined Haemophilus influenzae type b/Meningococcal group C; DOB: Date of birth

Figure 2. Study design diagram illustrating the index date of study participants period for meningococcal group B (MenB) and Meningococcal group C (MenC) vaccinations.



Note: MCV4: Quadrivalent meningococcal conjugate vaccines

Figure 3. Study design diagram illustrating the index date of study participants period for quadrivalent meningococcal conjugate (MCV4) vaccines.

8.5 Study population with inclusion and exclusion criteria

This study will include all individuals present in their respective database who reach two years of age for examining the coverage of MenB or Hib/MenC vaccines, and 18 years of age for examining the coverage of MCV4 vaccines. The coverage of separate Meningococcal vaccines will be evaluated at each quarterly and/or yearly sampling window. The study population for the analysis of age distribution among recipients of MenB, MenC, and MCV4 vaccines will include all individuals with documented records of receiving any of these specific meningococcal vaccine types. The operational definitions of the inclusion criteria are presented by in **Table** below.

Table 6. Operational definitions of inclusion criteria.

Criterion	Details	Order of application	Assessment window	Care Settings[1]	Applied to study populations:
Aged =1 years	Study participants will include eligible individuals for MenB vaccines based on the ECDC and NHS vaccine schedule.	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected databases
Aged =2 years	Study participants will include eligible individuals for MenB, and MenC or Hib/MenC vaccines based on the ECDC and NHS vaccine schedule.	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected databases
Aged =18 years	Study participants will include eligible individuals for MCV4 vaccines based on the ECDC and NHS vaccine schedule	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected databases
Continuous enrolment since birth until reaching two years of age	Study participants for assessing the coverage of MenB and MenC will be required to have a full continuous history observed from the start of assessment windows before contributing to the study population	After index date is determined	[Date of birth, Age 2 years] for MenB and MenC vaccination;	IP, OP, OT	All study participants included for assessing the coverage of MenB and Men C vaccination aged 2 years
Continuous enrolment from age 12 until age 18	Study participants for assessing the coverage of MCV4 will be required to have a full continuous history observed from the start of assessment windows before contributing to the study population	After index date is determined	[Age 12 years, Age 18 years] for MCV4 vaccination	IP, OP, OT	All study participants included for assessing the coverage of MCV4 vaccination aged 18 years
Receiving MenB vaccination	Study participants for assessing the age distribution of receival of MenB vaccines (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses)	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected databases
Receiving MenC vaccination	Study participants for assessing the age distribution of receival of	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected databases

Criterion	Details	Order of application	Assessment window	Care Settings[1]	Applied to study populations:
	MenC vaccines (≥1 dose, =1 dose)				
Receiving MCV4 vaccination	Study participants for assessing the age distribution of recipient of MCV4 vaccines (≥1 dose, =1 dose)	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected databases

[1] IP = inpatient, OP = outpatient, ED = emergency department, OT = other, n/a = not applicable

8.6 Variables

8.6.1 Exposure/s

The exposure of this study is defined as the record of birth for the examination of coverage of MenB and MenC vaccination and reaching 12 years of age for the examination of coverage of MCV4 vaccination from separate databases.

8.6.2 Outcomes

- The outcome of interest for objective 1 will be defined as 1) At least one dose, 2) At least two doses, 3) Complete vaccination (at least three doses), 4) exactly one dose, 5) exactly two doses, 6) exactly three doses of MenB vaccination. (**Annex I Table S1**). Analysis for this objective will be stratified by age in individuals aged one year and aged two years.
- The outcome for objective 2 is defined as the uptake of 1) at least one dose, 2) exactly one dose of either MenC or Hib/MenC vaccine.
- The outcome for objective 3 is defined as the uptake of MCV4 meningococcal vaccines (**Annex I Table S2**). MCV4 uptake is defined 1) as at least one record and, 2) exactly one record of MCV4 vaccines or separate exposure records of meningococcal groups A, C, W-135, and Y vaccination on the same date given the possibility where the records of MCV4 vaccination are captured separately by the distinct meningococcal serogroups in certain databases, including InGef and FinOMOP-THL. (**Annex I Table S3**)
- The outcome for objective 4 will be defined as the uptake of MenB and MCV4 meningococcal vaccines by brand (Menveo®, Nimenrix®, Bexsero®, Trumemba®) in CPRD GOLD, UK due to the potential limitation on the availability of relevant data in other databases. The definition of vaccine brand can be found in **Annex Tables S4-7**.
- The outcome for objective 5 will be defined as the age of receival of MenB (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses), MenC (≥1 dose, =1 dose), and MCV4 vaccination (≥1 dose, =1 dose).

The definitions of outcomes are illustrated in **Table** .

Table 7. Operational definitions of outcomes.

Outcome name	Details	Primary outcome?	Type of outcome	Washout window	Care Settings[1]	Code Type	Diagnosis Position[2]	Applied to study populations
MenB vaccination	Coverage of specific type (MenB) of Meningococcal vaccines	Y	Cumulative number of records or dose received (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses)	N/A	IP, OP, OT	RxNorm, SNOMED	N/A	All individuals aged 2 years included in the study population
MenC or Hib/MenC vaccination	Coverage of specific type (MenC) of Meningococcal vaccines	Y	≥1 dose or =1 dose	N/A	IP, OP, OT	RxNorm, SNOMED	N/A	All individuals aged 2 years included in the study population
MCV4 vaccination	Coverage of specific type (MCV4) of Meningococcal vaccines	Y	≥1 dose or =1 dose	N/A	IP, OP, OT	RxNorm, SNOMED	N/A	All individuals aged 18 years included in the study population
Bexsero® vaccination	Coverage of specific brand (Bexsero®) of Meningococcal vaccines	Y	Binary	N/A	IP, OP, OT	RxNorm	N/A	All individuals aged 2 years included in the study population
Trumemba® vaccination	Coverage of specific brand (Trumemba®) of Meningococcal vaccines	Y	Binary	N/A	IP, OP, OT	RxNorm	N/A	All individuals aged 2 years included in the study population
Menveo® vaccination	Coverage of specific brand (Menveo®) of Meningococcal vaccines	Y	Binary	N/A	IP, OP, OT	RxNorm	N/A	All individuals aged 18 years included in the study population
Nimenrix® vaccination	Coverage of specific brand (Nimenrix®) of Meningococcal vaccines	Y	Binary	N/A	IP, OP, OT	RxNorm	N/A	All individuals aged 18 years included in the study population

[1] IP = inpatient, OP = outpatient, ED = emergency department, OT = other, n/a = not applicable
[2] Specify whether a diagnosis code is required to be in the primary position (main reason for encounter)

8.6.3 Other covariates, including confounders, effect modifiers and other variables

Additional variables considered in this study includes the date of vaccination, brand of vaccines, date of birth of individuals, sex of individuals

Study size

This population-level DUS and patient-level characterisation study reports descriptive coverage of meningococcal vaccines and the age distribution of vaccines recipients at each quarterly and yearly sampling window. Sample size calculation is therefore not required for this study.

8.7 Analysis

Federated Network Analyses

Analyses will be conducted separately for each database. Before study initiation, test runs of the analytics are performed on a subset of the data sources or on a simulated set of patients, and quality control checks are performed. Once all the tests are passed, the final package is released in the version-controlled Study Repository for execution against all the participating data sources.

The data partners locally execute the analytics against the OMOP Common Data Model (CDM) in R Studio and review and approve the by default aggregated results before returning them to the Coordination Centre. Sometimes multiple execution iterations are performed, and additional fine tuning of the code base is needed. A service desk will be available during the study execution for support. The study results of all data sources are checked after which they are made available to the team in the Digital Research Environment and the Study Dissemination Phase can start. All results are locked and timestamped for reproducibility and transparency.

Patient privacy protection

Cell suppression will be applied as required by databases to protect people's privacy. Cell counts < 5 will be masked.

Statistical model specification and assumptions of the analytical approach considered

Population-level DUS

Objective 1 of this study examines the point prevalence of individuals who have received different numbers of doses of MenB vaccines (≥1 dose, ≥2 doses and ≥3 doses, =1 dose, =2 doses, =3 doses) in separate age groups (age 1 year and 2 years of age). Individuals included for this analysis are required to have a continuous enrolment from the date of birth.

Objective 2 of this study examines the point prevalence of MenC or Hib/MenC vaccination (≥1 dose, =1 dose) in individuals at two years of age. Individuals included for this analysis are required to have a continuous enrolment from the date of birth.

Objective 3 examines the point prevalence of MCV4 vaccination (≥1 dose, =1 dose) in individuals at 18 years of age. Individuals included for this analysis are required to have at continuous enrolment from the date of turning age 12.

Objective 4 of this study examines the point prevalence of MenB and MCV4 vaccines by brand (MenB: Bexsero®, Trumemba®; MCV4: Menveo®, Nimenrix®). Individuals included for the analyses of separate brands of MenB vaccines will be defined as individuals at two years of age with continuous enrolment from the date of birth. Individuals included for the analyses of separate brands of MCV4 vaccines will be defined as individuals at 18 years of age with continuous enrolment from the date of turning age 12.

All estimates will be provided overall and stratified by sex.

Patient-level Characterisation

Objective 5 of this study examines the age distribution of cohorts of individuals who have received three or more doses of a MenB vaccine, one dose of a MenC vaccine, and one dose of a MCV4 vaccine.

The analyses stated above will be conducted in separate quarterly and yearly observation windows from the start of the study period on 01/01/2017 until the end of available data in each of the data sources.

The age distribution illustrated will be presented overall and stratified by sex.

Software

All analyses will be performed with R. We will use the following R packages:

- "*IncidencePrevalence*" (https://github.com/darwin-eu/IncidencePrevalence) for the computation of prevalence.[11]

- "*CohortCharacteristics*" (https://darwin-eu-dev.github.io/CohortCharacteristics) for patient-level characterisation of age distribution.

8.8 Evidence synthesis

Results from analyses described in section 8.8 will be presented separately for each database and no meta-analysis of results will be conducted.

9. DATA MANAGEMENT

Data management

All databases are mapped to the OMOP CDM. This enables the use of standardised analytics and tools across the network since the structure of the data and the terminology system is harmonised. The OMOP CDM is 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. Each data partner will execute the study code against their database containing patient-level data and will then return the results set 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 European Union member states will process personal data from individuals which is collected in national/regional electronic health record databases. 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 databases 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 nonidentifiable aggregate summary results.

Note: Standard text will be generated on Data Management which will fit all studies run by the DARWIN EU® CC.

10. QUALITY CONTROL

General database quality control

A number of open-source quality control mechanisms for the OMOP CDM have been developed (see Chapter 15 of The Book of OHDSI http://book.ohdsi.org/DataQuality.html). In particular, it is expected that data partners will have run the OHDSI Data Quality Dashboard tool (https://github.com/OHDSI/DataQualityDashboard). This tool provides numerous checks relating to the conformance, completeness, and plausibility of the mapped data. Conformance focuses on checks that describe the compliance of the representation of data against internal or external formatting, relational, or computational definitions, completeness in the sense of data quality is solely focused on quantifying missingness, or the absence of data, while plausibility seeks to determine the believability or truthfulness of data values. Each of these categories has one or more subcategories and are evaluated in two contexts: validation and verification. Validation relates to how well data align with external benchmarks with expectations derived from known true standards, while verification relates to how well data conform to local knowledge, metadata descriptions, and system assumptions.

Study specific quality control

When identifying Meningococcal vaccines, a systematic search of possible codes for inclusion will be identified using CodelistGenerator R package (https://github.com/darwin-eu/CodelistGenerator). This software allows the user to define a search strategy and using this will then query the vocabulary tables of the OMOP Common Data Model so as to find potentially relevant codes. The codes returned will be reviewed by two clinical epidemiologists and/or pharmacists to consider their relevance. In addition, we will run phenotype diagnostics to assess the use of different codes across the databases contributing to the study and identify any codes potentially omitted in error.

The study code will be based on an R package currently being developed to estimate prevalence. The package 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 accessible through GitHub.

11. LIMITATIONS OF THE RESEARCH METHODS

The study will rely on routinely collected healthcare data, and as such, data quality issues must be carefully considered. In particular, the vaccination schedule against Meningococcal diseases varies greatly between countries within Europe. Such disparity could result in the considerable variability in the vaccines coverage between countries. Furthermore, several countries have their own approved brands of meningococcal vaccines. Information regarding specific brands of meningococcal vaccines may not be available in certain databases used for this study, either due to the unavailability of such details in the raw data or because the information was lost during the conversion process into the OMOP common data model.

The requirement for full continuous follow-up of study participants have resulted in the relatively narrow age cut-offs for the selection of individuals eligible for vaccination. Nevertheless, the selected age cut-off for examining separate meningococcal vaccines were chosen based on the vaccination schedule recommended in certain countries taking into account the potential delayed administration and catch-up vaccination schemes.

12. MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS

Adverse events/adverse reactions will not be collected or analysed as part of this evaluation. The nature of this non-interventional evaluation, through the use of secondary data, does not fulfil the criteria for reporting adverse events, according to module VI, VI.C.1.2.1.2 of the Good Pharmacovigilance Practices (https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports_en.pdf).

13. GOVERNANCE BOARD ASPECTS

All data sources are subject to approval from their respective Institutional Review Boards (IRBs), with the exception of DK-DHR and NAJS, which operate under an existing umbrella approval for DARWIN studies. InGef is not subject to IRB approval requirements.

14. 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.

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16. ANNEXES

ANNEX I. List of Stand-Alone documents (e.g. lists with concept definitions (conditions & drugs), validation procedures, questionnaires, etc.)

Table S1. Preliminary code list for Meningococcal group B vaccines (MenB).

Concept name	Concept ID	Domain	Vocabulary
meningococcal group B vaccine Injectable Suspension	36272005	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Injectable Suspension [Bexsero]	36277147	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Injectable Solution [Bexsero]	36405016	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Injectable Suspension [Trumenba]	36810838	Drug Exposure	RxNorm Extension
meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine Injectable Suspension	40745348	Drug Exposure	RxNorm Extension
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension	44055776	Drug Exposure	RxNorm Extension
0.1 ML Influenza A virus vaccine, A-Texas-50-2012 (H3N2)-like virus 0.15 MG/ML / influenza A-California-7-2009-(H1N1)v-like virus vaccine 0.15 MG/ML / meningococcal group B vaccine 0.15 MG/ML Injectable Suspension	44132429	Drug Exposure	RxNorm Extension
meningococcal group B vaccine	45775636	Drug Exposure	RxNorm
meningococcal group B vaccine Prefilled Syringe	45775639	Drug Exposure	RxNorm
meningococcal group B vaccine Prefilled Syringe [Trumenba]	45775643	Drug Exposure	RxNorm
0.5 ML Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe [Trumenba]	45775644	Drug Exposure	RxNorm
meningococcal group B vaccine Prefilled Syringe [Bexsero]	45892098	Drug Exposure	RxNorm
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogr...	45892099	Drug Exposure	RxNorm
Administration of meningitis B vaccine	36715063	Procedure	SNOMED
Booster meningitis B vaccination	37394691	Procedure	SNOMED
First meningitis B vaccination	46284905	Procedure	SNOMED
Second meningitis B vaccination	46287032	Procedure	SNOMED
Third meningitis B vaccination	46284906	Procedure	SNOMED
Fourth meningitis B vaccination	46284907	Procedure	SNOMED
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningit	35414612	Drug	RxNorm Extension

idis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspe nsion [Bexsero]			
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [B oostrix]	36281011	Drug	RxNorm Extension
meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Nei sseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML [Bexsero]	44067190	Drug	RxNorm Extension
meningococcal group B vaccine 0.03 MG/ML	44091734	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Rec ombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [B exsero]	35406900	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML	35411056	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Boostrix]	36267567	Drug	RxNorm Extension
meningococcal group B vaccine / Neisseria meningitidis Group B Membrane vesicles External Omv / Neisseria meningitidis Recombinant Fusion Protein F hbp Group B Injectable Suspension	43189720	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Rec ombinant Fusion Protein Fhbp Group B 0.1 MG/ML [Bexsero]	35408055	Drug	RxNorm Extension
meningococcal group B vaccine 0.15 MG/ML	44117588	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningit idis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspe nsion [Bexsero] Box of 1	35414625	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1 by Orifarm Leverkus	44197172	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML Injectable Suspension	36277400	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis s erogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG /ML / Neisseria meningitidis serogr...	45892095	Drug	RxNorm
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogr...	45892095	Drug	RxNorm
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension [Bexsero]	44108372	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero]	44132794	Drug	RxNorm Extension
meningococcal group B vaccine / Neisseria meningitidis Group B Membrane vesicles External Omv / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B Injectable Suspension [Bexsero]	35411236	Drug	RxNorm Extension

0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension Box of 1	35414559	Drug	RxNorm Extension
meningococcal group B vaccine Injectable Solution	36405729	Drug	RxNorm Extension
meningococcal group B vaccine Injectable Suspension	36272005	Drug	RxNorm Extension
meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension	44123073	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension Box of 1	35411322	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension	35414651	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension	36281092	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Boostrix] by GSK	36281200	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension	35409014	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero] Box of 1	35409987	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / ... Injectable Suspension [Bexsero] Box of 1 by Novartis	35414646	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML	36264077	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML [Boostrix]	36274314	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero]	36275190	Drug	RxNorm Extension
meningococcal group B vaccine 0.1 MG/ML	45892091	Drug	RxNorm
meningococcal group B vaccine Prefilled Syringe [Bexsero]	45892098	Drug	RxNorm
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogr...	45892099	Drug	RxNorm
meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B s...	45892100	Drug	RxNorm

meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B s...	45892101	Drug	RxNorm
meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine Injectable Suspension [Bexsero]	40745347	Drug	RxNorm Extension
meningococcal group B vaccine Injectable Suspension [Trumenba]	36810838	Drug	RxNorm Extension
meningococcal group B vaccine 0.09 MG/ML	44078776	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension	44132650	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML [Bexsero]	36271732	Drug	RxNorm Extension
meningococcal group B vaccine Prefilled Syringe	45775639	Drug	RxNorm
meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B s...	45892097	Drug	RxNorm
meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine Injectable Suspension	40745348	Drug	RxNorm Extension
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension [Trumenba]	40745346	Drug	RxNorm Extension
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension	44055776	Drug	RxNorm Extension
meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero]	44111622	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero] by Glaxosmithkline	44132814	Drug	RxNorm Extension
meningococcal group B vaccine Injectable Suspension [Boostrix]	36274617	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero] by GSK	36281177	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero]	36281212	Drug	RxNorm Extension
Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe	45775645	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML	45892093	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML	45775637	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML	45775638	Drug	RxNorm

Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe [Trumenba]	45775646	Drug	RxNorm
meningococcal group B vaccine Injectable Product	36248612	Drug	RxNorm
0.5 ML Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe	45775640	Drug	RxNorm
0.5 ML Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe [Trumenba]	45775644	Drug	RxNorm
Neisseria meningitidis serogroup B strain NZ98/254 outer membrane vesicle 0.05 MG/ML	45892094	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML [Trumenba]	45775642	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML	45892092	Drug	RxNorm
Bexsero Injectable Product	36248757	Drug	RxNorm
Trumenba Injectable Product	36248645	Drug	RxNorm
meningococcal B, unspecified formulation	40213175	Drug	CVX
meningococcal B vaccine, recombinant, OMV, adjuvanted	40213173	Drug	CVX
meningococcal B vaccine, fully recombinant	40213174	Drug	CVX
meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine Injectable Suspension	40745348	Drug	RxNorm Extension

Table S2. Preliminary code list for Meningococcal group C vaccines (MenC) or combined Haemophilus influenzae type b/Meningococcal group C (Hib/MenC).

Concept name	Concept ID	Domain	Vocabulary
Meningococcal group C polysaccharide	509081	Drug Exposure	RxNorm
Haemophilus B Conjugate Vaccine / meningococcal group C polysaccharide Injectable Solution	40731787	Drug Exposure	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution [Meningitec]	40987113	Drug Exposure	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension [Neisvac C]	41018101	Drug Exposure	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution	41079916	Drug Exposure	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension [Menjugate]	43643018	Drug Exposure	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension [Meningitec]	43768802	Drug Exposure	RxNorm Extension

meningococcal group C polysaccharide Injectable Suspension	43840964	Drug Exposure	RxNorm Extension
Administration of first dose of meningitis C vaccine	4197151	Procedure	SNOMED
Administration of meningitis C vaccine	36714392	Procedure	SNOMED
Administration of single dose of meningitis C vaccine	4199650	Procedure	SNOMED
meningococcal group C polysaccharide / tetanus toxoid vaccine, inactivated Injectable Suspension [Neisvac C]	44056939	Drug Exposure	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1 by Kohlpharma	44197087	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10 by European	44197088	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1 by Emra-Med	44197229	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension	43714860	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension Box of 5	43612171	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] by Glaxosmithkline	43594210	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 5	43791957	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 10 by Novartis	41407699	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe [Meningitec] Box of 1	41408975	Drug	RxNorm Extension
0.5 ML Meningitis vaccine 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1	41409709	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10	40839323	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe Box of 1	40864902	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 10	40932623	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution Box of 1	40958354	Drug	RxNorm Extension
Haemophilus B Conjugate Vaccine / meningococcal group C polysaccharide Injectable Solution [Menitorix]	40731786	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension Box of 10	43804769	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate]	43679124	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate]	43714859	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 10	43840965	Drug	RxNorm Extension

0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] by Nuron Biotech	43791851	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 10	43594089	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension	43720048	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] Box of 10 by Glaxosmithkline	43612172	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 20	41408246	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe [Meningitec] Box of 1 by Orifarm Leverkus	41408318	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution	41409870	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution	40989640	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 1	41120141	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.04 MG/ML Injectable Suspension [Neisvac C] by Pfizer	36281080	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension	43840964	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Suspension	36281147	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension Box of 5	43750812	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 2 by Nuron Biotech	43846133	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 10 by Nuron Biotech	43666359	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension Box of 10	43648340	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10 by European	41407909	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe Box of 1	41408203	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe Box of 20	41409129	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe Box of 1 by Gerke	41409421	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1 by Eurim-Pharm	44197228	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10 by Eurim-Pharm	44197086	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Suspension [Meningitec]	36264987	Drug	RxNorm Extension

meningococcal group C polysaccharide 0.02 MG/ML Injectable Suspension	36267195	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.04 MG/ML Injectable Suspension	36281204	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 10	43661175	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension	43828192	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] Box of 5 by Glaxosmithkline	43648339	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 10	41407826	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution Box of 1	41407586	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10	41408785	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension [Neisvac C]	41018101	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.04 MG/ML Injectable Suspension	36274839	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Suspension [Meningitec] by Nuron Biotech	36281198	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] Box of 10	43606890	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 2	43661174	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension	43732882	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 5	43859089	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 10	43588843	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec]	43630178	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate]	43756130	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 5 by Glaxosmithkline	43702342	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate]	41407420	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1	41407623	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe Box of 1	41407789	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 1 by Novartis	41409031	Drug	RxNorm Extension

0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe Box of 10	41409325	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution Box of 10	41409667	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1	40901528	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML / tetanus toxoid vaccine, inactivated 0.04 MG/ML Injectable Suspension [Neisvac C]	44132620	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe [Meningitec] Box of 1	41182795	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML / tetanus toxoid vaccine, inactivated 0.04 MG/ML Injectable Suspension	44025498	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec]	43643019	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension Box of 5	43696938	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 10	43594087	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension	43719955	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension Box of 10	43702341	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 10	43684333	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe [Meningitec] Box of 20	41407421	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1 by European	41409991	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe Box of 1	40989642	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution	41079916	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1 by European	44197015	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe Box of 10	41208649	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution Box of 10	41239588	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension [Meningitec]	43768802	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] Box of 5	43859087	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension Box of 10	43750813	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 2	43679125	Drug	RxNorm Extension

0.5 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] by Glaxosmithkline	43756040	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 2	43594088	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 2	43810019	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension Box of 5	43756131	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate]	41307103	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 1	41407419	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 20	41409668	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution [Menjugate]	40955877	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution [Neisvac C]	35745357	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe Box of 20	41114614	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 20	41151732	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Suspension [Meningitec]	36281126	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.04 MG/ML Injectable Suspension [Neisvac C]	36281185	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe [Meningitec] Box of 20	41276009	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension	43624782	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension	43864393	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate]	43810018	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] Box of 5	43810115	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate]	43666462	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] by Glaxosmithkline	43846229	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 10 by Glaxosmithkline	43594211	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 20	40864903	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution [Meningitec]	40987113	Drug	RxNorm Extension

Meningitis vaccine 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10	41182793	Drug	RxNorm Extension
Meningitis vaccine Prefilled Syringe [Menjugate]	41049406	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG/ML [Menjugate]	40827669	Drug	RxNorm Extension
0.5 ML Meningitis vaccine 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10	41408245	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1	40932622	Drug	RxNorm Extension
meningococcal C conjugate	40213176	Drug	CVX
meningococcal group C polysaccharide Injectable Suspension [Neisvac C]	41018101	Drug	Drug Exposure
Haemophilus influenzae type b, capsular polysaccharide inactivated tetanus toxoid conjugate vaccine / meningococcal group C polysaccharide Injectable Solution [Menitorix]	36066373	Drug	RxNorm Extension
influenza B virus antigen, Hong Kong 330-2001 / meningococcal group C polysaccharide Injectable Solution [Menitorix]	36407337	Drug	RxNorm Extension
influenza B virus antigen, Hong Kong 330-2001 / meningococcal group C polysaccharide Injection [Menitorix]	21129872	Drug	RxNorm Extension
Haemophilus B Conjugate Vaccine / meningococcal group C polysaccharide Injectable Solution [Menitorix]	40731786	Drug	RxNorm Extension
meningococcal group C polysaccharide Injection	21046234	Drug	RxNorm Extension
meningococcal group C polysaccharide Prefilled Syringe [Neisvac C]	40893613	Drug	RxNorm Extension

Table S3. Preliminary code list for Meningococcal group A,C,W,Y vaccines (MCV4).

Concept name	Concept ID	Domain	Vocabulary
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injection [ACWY Vax]	21031231	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Nimenrix]	35753882	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Menveo]	35766293	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [ACWY Vax]	35766294	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-	36788305	Drug Exposure	RxNorm Extension

135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Prefilled Syringe [Mencevax Acwy]			
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Prefilled Syringe	36788306	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Mencevax Acwy]	36788307	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / meningococcal polysaccharide vaccine group W-135 / meningococcal polysaccharide vaccine group Y Injectable Solution	40055280	Drug Exposure	RxNorm
Administration of meningitis A, C, W135 and Y vaccine	3656246	Procedure	SNOMED
Meningococcal group A polysaccharide	509079	Drug Exposure	RxNorm
Meningococcal group C polysaccharide	509081	Drug Exposure	RxNorm
Meningococcal polysaccharide vaccine group W-135	514012	Drug Exposure	RxNorm
Meningococcal polysaccharide vaccine group Y	514015	Drug Exposure	RxNorm
Meningitis vaccine 0.02 MG Intramuscular Solution [Nimenrix] by Pfizer	36261151	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG Intramuscular Solution [Menveo] by GSK	36276392	Drug	RxNorm Extension
meningococcal group A polysaccharide 2.5 MG / meningococcal group C polysaccharide 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 2.5 MG Injectable Solution by Aventis	44036973	Drug	RxNorm Extension
meningococcal group A polysaccharide 0.5 MG / meningococcal group C polysaccharide 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.5 MG Injectable Solution	44032490	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.1 MG/ML / meningococcal group C polysaccharide 0.1 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.1 MG/ML / ... Injectable Solution by Sanofi	44132815	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / meningococcal polysaccharide vaccine group W-135 / meningococcal polysaccharide vaccine group Y Injectable Solution [Menomune A/C/Y/W-135]	40055281	Drug	RxNorm
meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix]	44124986	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.01 MG/ML / ... Injectable Solution	44132839	Drug	RxNorm Extension

meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.01 MG/ML / ... Injectable Solution	44058468	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix]	44132854	Drug	RxNorm Extension
meningococcal group A polysaccharide 0.5 MG / meningococcal group C polysaccharide 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.5 MG Injectable Solution	44032490	Drug	RxNorm Extension
meningococcal group A polysaccharide 2.5 MG / meningococcal group C polysaccharide 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 2.5 MG Injectable Solution by Aventis	44036973	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / meningococcal polysaccharide vaccine group W-135 / meningococcal polysaccharide vaccine group Y Injectable Solution [Menquadfi]	36923646	Drug	RxNorm Extension
meningococcal group A polysaccharide 0.5 MG / meningococcal group C polysaccharide 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.5 MG Injectable Solution by Sanofi	44050095	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.008 MG/ML / meningococcal group C polysaccharide 0.008 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.008 MG/ML / ... Intramuscular Solution [Menactra] by Sanofi	44132687	Drug	RxNorm Extension
meningococcal group A polysaccharide 0.1 MG/ML / meningococcal group C polysaccharide 0.1 MG/ML / meningococcal polysaccharide vaccine group W-135 0.1 MG/ML / meningococcal polysaccharide vaccine group Y 0.1 MG/ML Injectable Solution [Menomune A/C/Y/W-...	19035048	Drug	RxNorm
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Menactra]	35146370	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y / tetanus toxoid vaccine, inactivated Injectable Solution	44055806	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y / tetanus toxoid vaccine, inactivated Injectable Solution [Nimenrix]	44056941	Drug	RxNorm Extension
meningococcal group A polysaccharide 2.5 MG / meningococcal group C polysaccharide 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 2.5 MG Injectable Solution	44058469	Drug	RxNorm Extension
hyaluronate 5 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 20 MG/ML Ophthalmic Solution [Hylo-Dual] by Scope Ophthalmics	40746599	Drug	RxNorm Extension
meningococcal group A polysaccharide 0.1 MG/ML / meningococcal group C polysaccharide 0.1 MG/ML / meningococcal polysaccharide vaccine group	509104	Drug	RxNorm

W-135 0.1 MG/ML / meningococcal polysaccharide vaccine group Y 0.1 MG/ML Injectable Solution			
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Nimenrix]	35753882	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Menveo]	35766293	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Mencevax Acwy]	36788307	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [ACWY Vax]	35766294	Drug	RxNorm Extension
10 ML hyaluronate 5 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 20 MG/ML Ophthalmic Solution [Hylo-Dual] by Scope Ophthalmics	40715959	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.1 MG/ML / meningococcal group C polysaccharide 0.1 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.1 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.1 MG/ML Injectable Solution	44132517	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix] by Pfizer	44132631	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG Intramuscular Solution [Menveo] by GSK	36276392	Drug	RxNorm Extension
Meningitis vaccine Intramuscular Solution [Menveo]	36264497	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG Intramuscular Solution [Menveo]	36267930	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG [Menveo]	36269304	Drug	RxNorm Extension
Meningitis vaccine Injectable Solution [Menveo]	41112106	Drug	RxNorm Extension
Meningitis vaccine Prefilled Syringe [Menveo]	40955876	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG Intramuscular Solution [Nimenrix]	36259812	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG Intramuscular Solution [Nimenrix] by Pfizer	36261151	Drug	RxNorm Extension
Meningitis vaccine Intramuscular Solution [Nimenrix]	36269516	Drug	RxNorm Extension
Meningitis vaccine Injectable Solution [Nimenrix]	41112105	Drug	RxNorm Extension

Meningitis vaccine 0.02 MG [Nimenrix]	36264116	Drug	RxNorm Extension
Meningococcal, MCV4, unspecified conjugate formulation (groups A, C, Y and W-135)	40213178	Drug	CVX
meningococcal ACWY vaccine, unspecified formulation	40213172	Drug	CVX
meningococcal group A polysaccharide / meningococcal group C polysaccharide / meningococcal polysaccharide vaccine group W-135 / meningococcal polysaccharide vaccine group Y Injection	46275260	Drug	RxNorm
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injection [Nimenrix]	21021512	Drug	RxNorm Extension

Table S4. Preliminary code list for Bexsero®.

Concept name	Concept ID	Domain	Vocabulary
meningococcal group B vaccine Injectable Suspension [Bexsero]	36277147	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Injectable Solution [Bexsero]	36405016	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Prefilled Syringe [Bexsero]	45892098	Drug Exposure	RxNorm
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero]	35414612	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML [Bexsero]	35408055	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero] Box of 1	35414625	Drug	RxNorm Extension
meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML [Bexsero]	44067190	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero]	35406900	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero] Box of 1	35409987	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / ... Injectable Suspension [Bexsero] Box of 1 by Novartis	35414646	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero]	36275190	Drug	RxNorm Extension
meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine Injectable Suspension [Bexsero]	40745347	Drug	RxNorm Extension

meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero]	44111622	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero] by Glaxosmithkline	44132814	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero] by GSK	36281177	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero]	36281212	Drug	RxNorm Extension
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension [Bexsero]	44108372	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero]	44132794	Drug	RxNorm Extension
meningococcal group B vaccine / Neisseria meningitidis Group B Membrane vesicles External Omv / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B Injectable Suspension [Bexsero]	35411236	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML [Bexsero]	36271732	Drug	RxNorm Extension
Bexsero Injectable Product	36248757	Drug	RxNorm

Table S5. Preliminary code list for Trumemba®.

Concept name	Concept ID	Domain	Vocabulary
meningococcal group B vaccine Injectable Suspension [Trumenba]	36810838	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Prefilled Syringe [Trumenba]	45775643	Drug Exposure	RxNorm
meningococcal group B vaccine Prefilled Syringe [Trumenba]	45775643	Drug	RxNorm
meningococcal group B vaccine Injectable Suspension [Trumenba]	36810838	Drug	RxNorm Extension
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension [Trumenba]	40745346	Drug	RxNorm Extension
Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe [Trumenba]	45775646	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML [Trumenba]	45775642	Drug	RxNorm
Trumenba Injectable Product	36248645	Drug	RxNorm
0.5 ML Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe [Trumenba]	45775644	Drug	RxNorm

Table S6. Preliminary code list for Menveo®.

Concept name	Concept ID	Domain	Vocabulary
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Menveo]	35766293	Drug Exposure	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injection [Menveo]	21100028	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG Intramuscular Solution [Menveo] by GSK	36276392	Drug	RxNorm Extension
Meningitis vaccine Intramuscular Solution [Menveo]	36264497	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Menveo]	35766293	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG Intramuscular Solution [Menveo]	36267930	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG [Menveo]	36269304	Drug	RxNorm Extension
Meningitis vaccine Injectable Solution [Menveo]	41112106	Drug	RxNorm Extension
Meningitis vaccine Prefilled Syringe [Menveo]	40955876	Drug	RxNorm Extension

Table S7. Preliminary code list for Nimenrix®.

Concept name	Concept ID	Domain	Vocabulary
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Nimenrix]	35753882	Drug Exposure	RxNorm Extension
Meningitis vaccine 0.02 MG Intramuscular Solution [Nimenrix]	36259812	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG Intramuscular Solution [Nimenrix] by Pfizer	36261151	Drug	RxNorm Extension
Meningitis vaccine Intramuscular Solution [Nimenrix]	36269516	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix]	44132854	Drug	RxNorm Extension
meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.01 MG/ML / ... [Nimenrix]	44041273	Drug	RxNorm Extension
Meningitis vaccine Injectable Solution [Nimenrix]	41112105	Drug	RxNorm Extension

meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix]	44124986	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y / tetanus toxoid vaccine, inactivated Injectable Solution [Nimenrix]	44056941	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Nimenrix]	35753882	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injection [Nimenrix]	21021512	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix] by Pfizer	44132631	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG [Nimenrix]	36264116	Drug	RxNorm Extension

ANNEX II. ENCePP checklist for study protocols

Study title: DARWIN EU® - Uptake of meningococcal vaccines by the target population in Europe

EU PAS Register® number: EUPAS1000000675
Study reference number (if applicable): P4-C1-006

Section 1: Milestones	**Yes**	**No**	**N/A**	**Section Number**
1.1 Does the protocol specify timelines for				
1.1.1 Start of data collection[1]	☒	☐	☐	8.3
1.1.2 End of data collection[2]	☒	☐	☐	8.3
1.1.3 Progress report(s)	☐	☐	☒	
1.1.4 Interim report(s)	☐	☐	☒	
1.1.5 Registration in the EU PAS Register®	☐	☒	☐	
1.1.6 Final report of study results.	☒	☐	☐	5

Comments:

Section 2: Research question	**Yes**	**No**	**N/A**	**Section Number**
2.1 Does the formulation of the research question and objectives clearly explain:	☒	☐	☐	
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)	☒	☐	☐	7
2.1.2 The objective(s) of the study?	☒	☐	☐	7
2.1.3 The target population? (i.e. population or subgroup to whom the study results are intended to be generalised)	☒	☐	☐	8.5
2.1.4 Which hypothesis(-es) is (are) to be tested?	☐	☒	☐	
2.1.5 If applicable, that there is no *a priori* hypothesis?	☐	☒	☐	

Comments:

Section 3: Study design	**Yes**	**No**	**N/A**	**Section Number**
3.1 Is the study design described? (e.g. cohort, case-control, cross-sectional, other design)	☒	☐	☐	8.1

[1] 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.
[2] Date from which the analytical dataset is completely available.

Section 3: Study design		**Yes**	**No**	**N/A**	**Section Number**
3.2	Does the protocol specify whether the study is based on primary, secondary or combined data collection?	☒	☐	☐	8.2
3.3	Does the protocol specify measures of occurrence? (e.g., rate, risk, prevalence)	☒	☐	☐	8.6
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))	☐	☐	☒	
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)	☐	☐	☒	

Comments:

Section 4: Source and study populations		**Yes**	**No**	**N/A**	**Section Number**
4.1	Is the source population described?	☒	☐	☐	8.2
4.2	Is the planned study population defined in terms of:				
	4.2.1 Study time period	☒	☐	☐	
	4.2.2 Age and sex	☒	☐	☐	
	4.2.3 Country of origin	☐	☐	☐	
	4.2.4 Disease/indication	☐	☐	☐	
	4.2.5 Duration of follow-up	☒	☐	☐	
4.3	Does the protocol define how the study population will be sampled from the source population? (e.g. event or inclusion/exclusion criteria)	☒	☐	☐	8.5

Comments:

Section 5: Exposure definition and measurement		**Yes**	**No**	**N/A**	**Section Number**
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)	☐	☐	☒	
5.2	Does the protocol address the validity of the exposure measurement? (e.g. precision, accuracy, use of validation sub-study)	☐	☐	☒	
5.3	Is exposure categorised according to time windows?	☐	☐	☒	

Section 5: Exposure definition and measurement	**Yes**	**No**	**N/A**	**Section Number**
5.4 Is intensity of exposure addressed? (e.g. dose, duration)	☐	☐	☒	
5.5 Is exposure categorised based on biological mechanism of action and taking into account the pharmacokinetics and pharmacodynamics of the drug?	☐	☐	☒	
5.6 Is (are) (an) appropriate comparator(s) identified?	☐	☐	☒	

Comments:

Section 6: Outcome definition and measurement	**Yes**	**No**	**N/A**	**Section Number**
6.1 Does the protocol specify the primary and secondary (if applicable) outcome(s) to be investigated?	☒	☐	☐	
6.2 Does the protocol describe how the outcomes are defined and measured?	☒	☐	☐	
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)	☐	☐	☐	
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)	☐	☐	☐	

Comments:

Section 7: Bias	**Yes**	**No**	**N/A**	**Section Number**
7.1 Does the protocol address ways to measure confounding? (e.g. confounding by indication)	☐	☐	☒	
7.2 Does the protocol address selection bias? (e.g. healthy user/adherer bias)	☐	☐	☒	
7.3 Does the protocol address information bias? (e.g. misclassification of exposure and outcomes, time-related bias)	☐	☐	☒	

Comments:

Section 8: Effect measure modification	**Yes**	**No**	**N/A**	**Section Number**
8.1 Does the protocol address effect modifiers? (e.g. collection of data on known effect modifiers, sub-group analyses, anticipated direction of effect)	☐	☐	☒	

Comments:

Section 9: Data sources	**Yes**	**No**	**N/A**	**Section Number**
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)	☐	☐	☒	
9.1.2 Outcomes? (e.g. clinical records, laboratory markers or values, claims data, self-report, patient interview including scales and questionnaires, vital statistics)	☒	☐	☐	8.6
9.1.3 Covariates and other characteristics?	☐	☐	☒	
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)	☐	☐	☒	
9.2.2 Outcomes? (e.g. date of occurrence, multiple events, severity measures related to event)	☐	☐	☐	
9.2.3 Covariates and other characteristics? (e.g. age, sex, clinical and drug use history, co-morbidity, co-medications, lifestyle)	☐	☐	☐	
9.3 Is a coding system described for:				
9.3.1 Exposure? (e.g. WHO Drug Dictionary, Anatomical Therapeutic Chemical (ATC) Classification System)	☐	☐	☒	
9.3.2 Outcomes? (e.g. International Classification of Diseases (ICD), Medical Dictionary for Regulatory Activities (MedDRA))	☒	☐	☐	8.6
9.3.3 Covariates and other characteristics?	☒	☐	☐	8.6
9.4 Is a linkage method between data sources described? (e.g. based on a unique identifier or other)	☐	☐	☒	

Comments:

Section 10: Analysis plan	**Yes**	**No**	**N/A**	**Section Number**
10.1 Are the statistical methods and the reason for their choice described?	☒	☐	☐	8
10.2 Is study size and/or statistical precision estimated?	☐	☐	☒	

Section 10: Analysis plan	**Yes**	**No**	**N/A**	**Section Number**
10.3 Are descriptive analyses included?	☒	☐	☐	8
10.4 Are stratified analyses included?	☐	☐	☒	
10.5 Does the plan describe methods for analytic control of confounding?	☐	☐	☒	
10.6 Does the plan describe methods for analytic control of outcome misclassification?	☐	☐	☒	
10.7 Does the plan describe methods for handling missing data?	☐	☐	☒	
10.8 Are relevant sensitivity analyses described?	☒	☐	☐	8

Comments:

Section 11: Data management and quality control	**Yes**	**No**	**N/A**	**Section Number**
11.1 Does the protocol provide information on data storage? (e.g. software and IT environment, database maintenance and anti-fraud protection, archiving)	☒	☐	☐	9
11.2 Are methods of quality assurance described?	☒	☐	☐	10
11.3 Is there a system in place for independent review of study results?	☐	☐	☒	

Comments:

Section 12: Limitations	**Yes**	**No**	**N/A**	**Section Number**
12.1 Does the protocol discuss the impact on the study results of:				
12.1.1 Selection bias?	☐	☐	☒	
12.1.2 Information bias?	☒	☐	☐	11
12.1.3 Residual/unmeasured confounding? (e.g. anticipated direction and magnitude of such biases, validation sub-study, use of validation and external data, analytical methods).	☐	☐	☒	
12.2 Does the protocol discuss study feasibility? (e.g. study size, anticipated exposure uptake, duration of follow-up in a cohort study, patient recruitment, precision of the estimates)	☒	☐	☐	8

Comments:

Section 13: Ethical/data protection issues	**Yes**	**No**	**N/A**	**Section Number**
13.1 Have requirements of Ethics Committee/ Institutional Review Board been described?	☒	☐	☐	13
13.2 Has any outcome of an ethical review procedure been addressed?	☐	☐	☒	
13.3 Have data protection requirements been described?	☒	☐	☐	9

Comments:

Section 14: Amendments and deviations	**Yes**	**No**	**N/A**	**Section Number**
14.1 Does the protocol include a section to document amendments and deviations?	☒	☐	☐	4

Comments:

Section 15: Plans for communication of study results	**Yes**	**No**	**N/A**	**Section Number**
15.1 Are plans described for communicating study results (e.g. to regulatory authorities)?	☒	☐	☐	14
15.2 Are plans described for disseminating study results externally, including publication?	☒	☐	☐	14

Comments:

Name of the main author of the protocol: Ivan Lam

Date: 17/June/2025

Signature: Ivan Lam