09 August 2022

Data analysis plan

Title: Immune thrombocytopenia following vaccination with DTaP-IPV or TdaP-IPV in children

Administrative details of the data analysis	
Substance(s)	Diphtheria / tetanus / pertussis (acellular, component) / poliomyelitis (inactivated) vaccine (adsorbed), diphtheria / tetanus / pertussis (acellular, component) / poliomyelitis (inactivated) vaccine (adsorbed) reduced antigens content
Condition/ADR(s)	Immune thrombocytopenia
Short title of topic	Immune thrombocytopenia and DTaP-IPV / TdaP-IPV vaccines
TDA-DAT lead analyst (and reviewer)	Robert Flynn Karin Hedenmalm
Contact mailbox	RWE@ema.europa.eu

1. List of abbreviations

MAH	*Marketing Authorisation Holder*
EMA	*European Medicines Agency*
PRAC	*Pharmacovigilance Risk Assessment Committee*
RDA	*Rapid Data Analysis*

2. Rationale and background

Immune thrombocytopenia (ITP) is known to occur after many types of infections, including numerous vaccine-preventable diseases.(1) In approximately two-thirds of ITP cases, there is a history of a preceding infectious illness in the days to weeks before ITP onset.(1) Because vaccines are designed to induce an immune response that mimics natural infection to produce immunologic protection, it is possible that vaccines besides might trigger ITP.(1) There have been case reports of ITP after childhood vaccines, including MMR, hepatitis B vaccine (HBV), diphtheria-tetanus pertussis vaccine (DTP), and hepatitis A vaccine (Hep A).(2-5) However, the risk of ITP after childhood vaccines other than MMR is not well known. (3) The World Health Organization (WHO) recommends diphtheria, tetanus, and pertussis and poliomyelitis immunization during infancy for all children worldwide.(6) The combined vaccine diphtheria / tetanus / pertussis (acellular, component) / poliomyelitis (inactivated) vaccine (adsorbed), also referred to as DTaP-IPV, is indicated for primary vaccination in infants and for booster in children who have previously received a primary vaccination. The diphtheria / tetanus / pertussis (acellular, component) / poliomyelitis (inactivated) vaccine (adsorbed), reduced antigens content, also referred to as TdaP-IPV, is indicated for re-vaccination of children (≥4 years). (7)

During routine signal detection activities, it has been identified case reports of thrombocytopenia or immune thrombocytopenia with a WHO Possible causality to a DTaP-IPV or TdaP-IPV vaccine from EudraVigilance. To address the current signal for these combined vaccines (DTaP-IPV or TdaP-IPV), it is proposed to generate estimates on the use of these combined vaccines in the general population, and incidence rates for ITP in the general and exposed population across the in-house European databases with available data.

3. Research question and objectives

This study aims to describe:

- How are the diphtheria / tetanus / pertussis (acellular, component) / poliomyelitis (inactivated) vaccines (DTaP-IPV or TdaP-IPV) used in the general population?
- How has use of the vaccine changed with time?
- What is the event rate of immune thrombocytopenia in the general population?
- What is the event rate in the population exposed to the vaccine?

4. Research methods

4.1. Study design

This will be a cohort study describing vaccine exposure, population incidence rates of immune thrombocytopenia, and (where possible) incidence rates of immune thrombocytopenia in the vaccine exposed population.

4.2. Setting and study population

The study population will be the general population (UK) and patients visiting general practices (France and Germany). It is worth mentioning that analyses will be run in France, Germany, and UK databases provided that sufficient numbers of exposures/events are recorded.

4.3. Data sources

The following databases will be used: IQVIA™ Medical Research Data (UK), IQVIA™ Disease Analyser France, and IQVIA™ Disease Analyser Germany. Brief descriptions of these databases are provided in Annex 1.

4.4. Variables

Exposure

In IMRD (UK) database, vaccine exposure will be identified using diagnostic Read codes (READ Coded Clinical Terms, datadictionary.nhs.uk), which are commonly used to record administered vaccines in general practice (i.e., as diagnostic). Although less common, vaccine exposure can also be identified from prescription data, and this will be explored in the analysis as well.

In the IQVIA™ Disease Analyser France and Germany databases, vaccine exposure will be identified from prescription data. Paediatric practices and GP practices will be included in Germany based on prescribing data showing that 92.7% of patients that received a prescription for the vaccines of interest since 2011 (59,883 out of 64,615 patients) were identified in these practices.

Annex 2 shows the codes that will be used for each database.

Outcome

Immune thrombocytopaenia will be identified through Read codes for IMRD database and ICD10 codes for the IQVIA™ Disease Analyser databases (See Annex 2). The main analysis will be based on codes considered to be more specific for immune thrombocytopenia, and exclude codes for secondary thrombocytopenia and thrombocytopenia, unspecified. In a sensitivity analysis these codes will be included.

Other variables

Vaccine utilisation and event rates for immune thrombocytopenia will be stratified by age group, gender, and year of general practice visit. Age will be categorised as: <3 years, 3-6 years, 7-11 years, 12-17 years, 18 years and more.

4.5. Statistical analysis

4.5.1. Main statistical methods

a. **Vaccine exposure:** We will describe vaccine exposure as counts of patients with a first exposure stratified by age, sex, and year of general practice visit. See Table shell 1.

b. **Event rates in the general population**: We will describe the incidence of new onset immune thrombocytopenia in patients contributing patient time to the databases listed above. Patients will be required to have a minimum observation time of 365 days prior to entering into each period in order to establish whether events observed during the period are incident (first-ever) cases. Patients will be excluded from the analysis if they have any prior history of any of the selected codes for thrombocytopenia in the database. The study period will vary according to the years of coverage in the three databases (UK, France and Germany). For IMRD (UK) database, the covered period will be from a minimum of 2004 to 2020. For the French and German databases, the covered period will be from 2011 to 2020.

- Numerator: The numerator will consist of the number of patients who experience the event of interest (immune thrombocytopenia) during the yearly or quarterly time period. Patients with a baseline history of immune thrombocytopenia will be excluded. Included patients will only be able to contribute one event.
- Denominator: The denominator will be defined as patient follow-up time. As with the numerators, patients with a baseline history of immune thrombocytopenia at the start of each quarter will be excluded. Patient follow-up time will be truncated at the occurrence of the first event after which they will not contribute to the analysis.

  Follow-up time will be calculated using the following formula:

  Follow up time (years) = ((end date for the period – start date for the period + 1))/365

  Time will be truncated where patients enter or leave the study cohort part way through a time period or where they have an event.

The incidence rate for immune thrombocytopenia will be defined as the number of events divided by the total follow up time. The incidence rate will be calculated using the following formula:

Incidence rate = (number of new onset events)/(total follow up time (years))

This will be presented as the number of events per 100,000 person-years and will be calculated for the entire population as well as stratified by year, gender, and age group. See Table shell 2. Confidence intervals around incidence rates will be calculated using exact method.

c. **Event rates among exposed patients:** To describe the event rate of new onset immune thrombocytopenia following exposure to the vaccine, a rate will be calculated using a similar methodology described in section (b) above but restricted to only those patients known to have been exposed to the vaccine. Exposed patients will be followed up for a maximum of 3-months following first exposure. Thus, the incidence rate will be calculated as new onset events divided by the total duration of follow-up time in years (See Table shell 3). Patient will be censored from the analysis if they leave the population (i.e., moved practice, die, or reached the end of follow-up for their practice).

Analyses will be done using SAS for IMRD (UK) and the IHD platform for IQVIA™ Disease Analyser France and Germany.

4.5.2. Sensitivity analysis

A sensitivity analysis will include event rates in exposed subjects over 6-month and 12-month follow-up periods (See Table shell 3).

4.5.3. Table shells

Table shell 1. Vaccine utilisation. Number of recorded exposures stratified by age, sex and year [all data sources]. Where available, results will be provided separately by type of vaccine (reduced antigen content or not).

Year	Age									
	< 3 years		3-6 years		7-11 years		12-17 years		18 years +	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
2004										
2005										
2006										
…										
2021										
All										

Table shell 2. Population event rates for immune thrombocytopenia stratified by age and sex [all data sources].

Strata	Person-time in Years	Number of Events	IR (95% CI) per 100,000 person-years
Overall			
Female			
Male			
0-2 years			
3-6 years			
7-11 years			
13-17 years			
18+ years			

Table shell 3. Event rates for immune thrombocytopenia following vaccination [where there is sufficient exposure data: For IMDR (UK) it is possible].

Strata	Person-time in Years	Number of Events	IR (95% CI) per 100,000 person-years
Data source – 1-month follow-up			
Data source – 3-month follow-up			

4.6. Quality control

The study will be conducted according to the ENCePP code of conduct (European Medicines Agency 2018). Standard operating procedures or internal process guidance will be adhered to for the conduct of the study. These procedures include rules for secure and confidential data storage, quality-control procedures for all aspects of the study from protocol development to the reporting of the results.

All documents will undergo at least one round a review by an experienced reviewer, while the results from the statistical analysis will be either reviewed or checked via double coding.

The quality control of the data is the responsibility of the data holder.

4.7. Limitations of the research methods

Incomplete ascertainment of vaccine exposure in all data sources, particularly in the IQVIA™ Disease Analyser Germany and France databases. These databases contain data on patient encounters from primary care, i.e., data are mostly based on general practitioner's prescriptions. Vaccines covered by national vaccination schemes might, however, be administered without an individual patient prescription or the vaccine might be administered outside of the GP practice, and such vaccinations would not be recorded in the databases. Thus, these data may play a subordinate role, particularly for vaccinations covered by the national health insurance (NHI), and the extent to which the available information in our databases reflects the true use of the vaccines of interest in the population is unknown. It is also possible that the vaccine utilization pattern is different in patients that have received the vaccine through a prescription compared to all patients that have received the vaccine. Hence, the generalizability of our results may be limited. In the IMRD (UK) database, the use of a surrogate for vaccine exposure (i.e. diagnostic coding) might be subject to misclassification and potentially inaccurate recoding of date of vaccination. In addition, it is not possible to distinguish between the DTaP-IPV and TdaP-IPV (reduced antigens content) versions of the vaccine in the IMRD (UK) database.

A high level of uptake of the vaccine in the pre-school age group (typically 85% in the UK) and incomplete ascertainment of exposure means that a meaningful unexposed cohort cannot be identified, so a comparative analysis will not be possible. For IQVIA™ Disease Analyser Germany, where patients are identified only on the basis of primary care consultations the size of the general population might be underestimated as persons not visiting primary care are not included in the database.

5. Protection of human subjects

Patient confidentiality will be protected according to the EU General Data Protection Regulation (GDPR) on the protection of individuals.

6. Management and reporting of adverse events/adverse reactions

Pursuant to the requirements for reporting of adverse events for secondary data (GVP module VI, VI.C.1.2.1.2), adverse event reporting will not be conducted as part of this study given the study objectives will be met using secondary data.

7. Plans for disseminating and communicating study results

The analysis plan and study results will be published in EUPAS registries upon completion.

8. References

1. O'Leary ST, Glanz JM, McClure DL, Akhtar A, Daley MF, Nakasato C, et al. The risk of immune thrombocytopenic purpura after vaccination in children and adolescents. Pediatrics. 2012;129(2):248-55.
2. Akbik M, Naddeh D, Ashour AA, Ashour A. Severe Immune Thrombocytopenia Following MMR Vaccination with Rapid Recovery: A Case Report and Review of Literature. Int Med Case Rep J. 2020;13:697-9.
3. Di Pietrantonj C, Rivetti A, Marchione P, Debalini MG, Demicheli V. Vaccines for measles, mumps, rubella, and varicella in children. Cochrane Database Syst Rev. 2020;4:CD004407.
4. Mantadakis E, Farmaki E, Buchanan GR. Thrombocytopenic purpura after measles-mumps-rubella vaccination: a systematic review of the literature and guidance for management. J Pediatr. 2010;156(4):623-8.
5. Miller E, Waight P, Farrington CP, Andrews N, Stowe J, Taylor B. Idiopathic thrombocytopenic purpura and MMR vaccine. Arch Dis Child. 2001;84(3):227-9.
6. World Health Organization. WHO recommendations for routine immunization 2021 [Available from: https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/who-recommendations-for-routine-immunization---summary-tables.
7. Drutz JE. Diphtheria, tetanus, and pertussis immunization in children 6 weeks through 6 years of age 2022 [Available from: https://www.uptodate.com/contents/diphtheria-tetanus-and-pertussis-immunization-in-children-6-weeks-through-6-years-of-age?search=TdaP-IPV&topicRef=2876&source=see_link.

Annexes

Annex 1 - Information on Databases and Healthcare systems included

IQVIA™ Medical Research Data (IMRD) EMIS UK

IQVIA™ Medical Research Data (IMRD) EMIS UK is a primary care database from the UK. GPs play a gatekeeper role in the healthcare system in the UK, as they are responsible for delivering primary health care and specialist referrals. Over 98% of the UK-resident population is registered with a GP, so that GP patient records are broadly representative of the UK population in general. Patients are affiliated to a practice, which centralizes the medical information from GPs, specialist referrals, hospitalizations, and tests.

IQVIA™ Disease Analyzer Germany

IQVIA™ Disease Analyzer Germany collects computerised information from specialised and general primary care practices throughout Germany since 1992. Around 3% of general practitioners (GP) practices are included, which covers all patients consulting a practice. Data from IQVIA™ Disease Analyzer Germany have been shown to be reasonably representative of German healthcare statistics for demographics and certain diseases and is considered one of the largest national medical databases worldwide. IQVIA™ Disease Analyzer Germany includes more than 2,500 practices and 3,100 physicians (13 speciality groups) representing over 15,000,000 patients. This database used to be named IMS® Germany and some use of this terminology may persist.

The quality of IQVIA™ Disease Analyzer data is ensured by a series of continuous QA controls and data refinement. These include checking incoming data for criteria such as completeness and correctness, (e.g. linkage between diagnoses and prescriptions), and standardizing certain data values such as laboratory test results in order to enable reliable analysis.

IQVIA™ Disease Analyzer France

IQVIA™ Disease Analyzer France collects anonymised patient medical records since 1997 through a representative panel of GPs. The physician sample represents approximately 2% of physicians and is weighted by age and gender of the physician, doctor region and the SNIR of the physician (National Official Indicator of the GP volume of activity in terms of visits and consultations). Some 99% of the French population is insured, but there are differences regarding level of coverage. IQVIA™ Disease Analyzer France includes around 1,000 GPs and represents more than 4,000,000 of patients and considered representative for the French population. This database used to be named IMS France and some use of this terminology may persist.

The quality of IQVIA™ Disease Analyzer data is ensured by a series of continuous QA controls and data refinement. These include checking incoming data for criteria such as completeness and correctness, (e.g. linkage between diagnoses and prescriptions), and standardizing certain data values such as laboratory test results in order to enable reliable analysis.

Annex 2 - Codelists

CODES USED TO IDENTIFY EXPOSURE

IMRD (UK) database — Drug codes

drugcodeid	description
3178941000033118	Repevax vaccine suspension for injection 0.5ml pre-filled syringes (Sanofi Pasteur)
3198741000033110	Infanrix-IPV vaccine suspension for injection 0.5ml pre-filled syringes (GlaxoSmithKline UK Ltd)
9298541000033119	Boostrix-IPV suspension for injection 0.5ml pre-filled syringes (GlaxoSmithKline UK Ltd)

IMRD (UK) database – Read ("diagnostic") codes

readtermid	term
CODES INCLUDED	
65I4	Booster diphtheria, tetanus, acellular pertussis (DTaP) and polio vaccination
65I5	First diphtheria, tetanus, acellular pertussis (DTaP) and polio vaccination
65I6	Second diphtheria, tetanus, acellular pertussis (DTaP) and polio vaccination
65I7	Third diphtheria, tetanus, acellular pertussis (DTaP) and polio vaccination
65I8	Low dose diphtheria, tetanus, five component acellular pertussis and inactivated polio vaccination
65I9	Booster diphtheria, tetanus, acellular pertussis and inactivated polio vaccination
^ESCT1348496	Administration of diphtheria and pertussis and poliomyelitis and tetanus vaccine
^ESCT1348680	Administration of booster dose of diphtheria and acellular pertussis and poliomyelitis and tetanus vaccine
^ESCT1408279	Administration of low dose diphtheria and acellular pertussis five component and inactivated poliomyelitis and tetanus vaccine
CODES EXCLUDED: pattern of use is triple DTP and polio vaccinations used separately	
65I	DTP (triple)+polio vaccination
65I3	Third DTP (triple)+polio vaccination
65I2	Second DTP (triple)+polio vaccination
ZV063	Diphtheria, pertussis and tetanus triple and polio vaccination
65IZ	Diphtheria, pertussis and tetanus triple and polio vaccination
65I1	First DTP (triple)+polio vaccination
EMISQPR3	Pre-school triple DTaP+polio vaccination
^ESCTFI463311	First diphtheria, pertussis and tetanus triple and polio vaccination
^ESCTSE463313	Second diphtheria, pertussis and tetanus triple and polio vaccination
^ESCTTH463315	Third diphtheria, pertussis and tetanus triple and polio vaccination
CODES EXCLUDED: seldom used in this patient cohort	
EMISNQTH5	Third DTaP and polio vaccination
EMISNQSE6	Second DTaP and polio vaccination
65IA	Post exposure diphtheria, tetanus, acellular pertussis and inactivated polio vaccination
^ESCT1245743	[V]Diphtheria-tetanus-pertussis with poliomyelitis (DTP + polio) vaccination
^ESCT1348700	Administration of first dose of diphtheria and acellular pertussis and poliomyelitis and tetanus vaccine

readtermid	term
^ESCT1348704	Administration of second dose of diphtheria and acellular pertussis and poliomyelitis and tetanus vaccine
^ESCT1348708	Administration of third dose of diphtheria and acellular pertussis and poliomyelitis and tetanus vaccine
^ESCT1348716	Administration of diphtheria and acellular pertussis and inactivated poliomyelitis and tetanus vaccine
^ESCT1396218	Administration of second dose of diphtheria and pertussis and poliomyelitis and tetanus vaccine
^ESCT1396222	Administration of third dose of diphtheria and pertussis and poliomyelitis and tetanus vaccine
^ESCT1396226	Administration of first dose of diphtheria and pertussis and poliomyelitis and tetanus vaccine

IQVIA™ Disease AAnalyser Germany database

Diphtheria / tetanus / pertussis (acellular, component) / poliomyelitis (inactivated) vaccines *with reduced antigen content (TdaP-IPV)*

Therapy_No	Therapy_Name
GE11373313	REPEVAX GRK>> FE.SPR.M.KAN .5ML (N1)
GE9685922	BOOSTR.P.ALT GRK>> FERT SPR 10 .5ML (N2)
GE6614665	REPEVAX KHP>> FE.SPR.M.KAN .5ML (N1)
GE15557681	REPEVAX ORI>> FE.SPR.M.KAN .5ML (N1)
GE9471276	REPEVAX ORI>> FE.SPR.M.KAN 20 .5ML (N3)
GE5971080	REPEVAX EUP>> FE.SPR.M.KAN ALT 10 .5ML (N2)
GE10352021	BOOSTRIX POL.ORI>> FERT SPR ALT 10 .5ML (N2)
GE2623226	REPEVAX FE.SPR.O.KAN .5ML (N1)
GE12616043	REPEVAX GRK>> FE.SPR.M.KAN 20 .5ML (N3)
GE3724640	REPEVAX FE.SPR.O.KAN 10 .5ML
GE17582448	BOOSTRIX POL.ORI>> FERT SPR 10 .5ML (N2)
GE9216858	REPEVAX ORI>> F.SP.M.K.ALT ALT 10 .5ML (N2)
GE1406554	BOOSTRIX POLIO FERT SPR .5ML (N1)
GE9550344	BOOSTRIX POL.CC4>> FERT SPR 10 .5ML (N2)
GE20665036	REPEVAX ORI>> FE.SPR.M.KAN 10 .5ML
GE10075364	BOOSTRIX POL.ORI>> FERT SPR .5ML (N1)
GE6407747	BOOSTRIX POL.EUP>> FERT SPR 10 .5ML (N2)
GE11045043	REPEVAX CC4>> FERT SPR 10 .5ML (N2)
GE16339451	BOOSTR.P(GRK)EU0>> FERT SPR 10 .5ML (N2)
GE11525279	REPEVAX GRK>> FE.SPR.O.KAN 10 .5ML (N2)
GE6787291	REPEVAX KHP>> FE.SPR.M.KAN ALT 20 .5ML
GE7929871	BOOSTRIX POL.KHP>> FERT SPR .5ML (N1)
GE8062894	BOOSTRIX POL.KHP>> FERT SPR 10 .5ML (N2)
GE16199159	BOOSTR.P(GRK)EU0>> FERT SPR .5ML (N1)
GE8193035	REPEVAX E-M>> FE.SPR.M.KAN .5ML (N1)
GE18098870	REPEVAX ORI>> FE.SPR.M.KAN ALT 10 .5ML
GE21023974	REPEVAX KHP>> FE.SPR.M.KAN 20 .5ML
GE5071243	BOOSTRIX POL.CC4>> FERT SPR .5ML (N1)
GE9370813	REPEVAX ORI>> FE.SPR.M.KAN ALT .5ML (N1)

GE47756	REPEVAX DURCHSTECHFL .5ML (N1)
GE5809233	REPEVAX EUP>> FE.SPR.M.KAN .5ML (N1)
GE5873256	REPEVAX EUP>> FE.SPR.M.KAN ALT 20 .5ML (N3)
GE9636567	BOOSTR.P.ALT GRK>> FERT SPR .5ML (N1)
GE8211332	REPEVAX E-M>> FE.SPR.M.KAN 10 .5ML (N2)
GE10051777	BOOSTRIX POL.E-M>> FERT SPR .5ML (N1)
GE6177006	BOOSTRIX POL.EUP>> FERT SPR .5ML (N1)
GE10347685	BOOSTRIX POL.ML8>> FERT SPR .5ML (N1)
GE19880976	REPEVAX A4X>> FE.SPR.M.KAN 10 .5ML
GE10808037	REPEVAX CC4>> FERT SPR .5ML (N1)
GE4274941	REPEVAX FE.SPR.M.KAN 10 .5ML
GE11078230	BOOSTRIX POL.E-M>> FERT SPR 10 .5ML (N2)
GE15917397	REPEVAX ORI>> FE.SPR.O.KAN ALT 10 .5ML (N2)
GE11396018	REPEVAX GRK>> FE.SPR.O.KAN 20 .5ML (N3)
GE6753317	REPEVAX KHP>> FE.SPR.M.KAN 10 .5ML
GE12266298	REPEVAX GRK>> FE.SPR.M.KAN 10 .5ML (N2)
GE4137383	REPEVAX FE.SPR.M.KAN .5ML (N1)
GE13021189	REPEVAX CC4>> FERT SPR 20 .5ML (N3)
GE446491	BOOSTRIX POLIO FERT SPR 10 .5ML (N2)
GE3084377	REPEVAX FE.SPR.O.KAN 20 .5ML
GE17773926	REPEVAX EUP>> FE.SPR.M.KAN 10 .5ML
GE50425	REPEVAX DURCHSTECHFL 10 .5ML
GE257495	REPEVAX DURCHSTECHFL 20 .5ML
GE8221291	REPEVAX E-M>> FE.SPR.M.KAN ALT 20 .5ML (N3)
GE19885931	REPEVAX A4X>> FE.SPR.M.KAN .5ML (N1)

Diphtheria / tetanus / pertussis (acellular, component) / poliomyelitis (inactivated) vaccines *without reduced antigen content (DTaP-IPV)*

Therapy_No	Therapy_Name
GE489129	TETRAVAC FERT SPR 25 .5ML
GE7980966	TETRAVAC ORI>> FE.SPR.M.KAN 10 .5ML (N2)
GE168136	TETRAVAC FERT SPR .5ML (N1)
GE13373428	TETRAVAC E-M>> FE.SPR.M.KAN 10 .5ML (N2)
GE13178310	TETRAVAC E-M>> FE.SPR.M.KAN .5ML (N1)
GE2491127	TETRAVAC EUP>> FE.SPR.M.KAN 10 .5ML (N2)
GE6416649	TETRAVAC ORI>> FE.SPR.M.KAN .5ML (N1)
GE340416	TETRAVAC FERT SPR 10 .5ML
GE1431776	TETRAVAC EUP>> FE.SPR.M.KAN .5ML (N1)
GE9543906	TETRAVAC AC9>> FE.SPR.M.KAN 10 .5ML (N2)
GE853361	TETRAVAC FERT SPR 50 .5ML
GE8808837	TETRAVAC AC9>> FE.SPR.M.KAN .5ML (N1)

IQVIA™ Disease Analyser France database

Diphtheria / tetanus / pertussis (acellular, component) / poliomyelitis (inactivated) vaccines *with reduced antigen content (TdaP-IPV)*

Therapy_No	Therapy_Name
FR16942	REPEVAX SER.PRE+AIGU 0.5ML 1
FR17913	BOOSTRIXTETRA SER PREREMPL 0.5ML 1

Diphtheria / tetanus / pertussis (acellular, component) / poliomyelitis (inactivated) vaccines *without reduced antigen content (DTaP-IPV)*

Therapy_No	Therapy_Name
FR8080	INFANRIX POLIO SER PREREMPL 0.5ML ENF 1
FR9527	TETRAVAC ACELLUL. SER.PRE+AIGU 0.5ML 1
FR12217	INFANRIX TETRA SER PREREMPL 0.5ML 1

Diphtheria, tetanus, pertussis (acellular) and polio (inactivated) vaccines without unknown antigen content

Therapy_No	Therapy_Name
FR14546	VAC DTCAP LAB. IND SER PREREMPL 0.5ML 1

OUTCOMES CODES

IMRD (UK) database

IMRD codes corresponding to ICD10 D69.3

Read Code	Description
D3130	Idiopathic thrombocytopenic purpura
D3130-1	Idiopathic purpura
42P2-1	Autoimmune thrombocytopenia
D3130-2	ITP - idiopathic thrombocytopenic purpura
D313-5	Thrombocytopenic purpura
D313-1	Evan's syndrome
D313-3	Idiopathic purpura
D313-2	Idiopathic thrombocytopenic purpura
C3912-1	Thrombocytopenic eczema with immunodeficiency
^ESCTIM301968	Immune thrombocytopenic purpura
^ESCTEV372490	Evans syndrome

IMRD codes corresponding to ICD10 D69.4

Read Code	Description
D3133	[X]Essential thrombocytopenia NOS
Dyu32	[X]Other primary thrombocytopenia
D313z-1	Essential thrombocytopenia NOS
D3131-1	Hereditary thrombocytopenia NEC

Read Code	Description
D313	Primary thrombocytopenia
D3131	Congenital thrombocytopenic purpura
D313z	Primary thrombocytopenia NOS
D313y	Other specified primary thrombocytopenia

IMRD codes corresponding to ICD10 D69.5 & D69.6

Read Code	Description
D3133	[X]Essential thrombocytopenia NOS
Dyu32	[X]Other primary thrombocytopenia
D313z-1	Essential thrombocytopenia NOS
D3131-1	Hereditary thrombocytopenia NEC
D313	Primary thrombocytopenia
D3131	Congenital thrombocytopenic purpura
D313z	Primary thrombocytopenia NOS
D313y	Other specified primary thrombocytopenia
Read Code	Description

IQVIA™ Disease Analyser Germany and France databases

ICD10	Description
D69.3	Idiopathic thrombocytopenic purpura
D69.4	Other primary thrombocytopenia
D69.5	Secondary thrombocytopenia
D69.6	Thrombocytopenia, unspecified