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European Medicines Agency

Vaccine Monitoring Platform (VMP)

List of EMA-funded studies under the VMP

Studies funded by the **European Medicines Agency** under the **Vaccine Monitoring Platform (VMP)** are listed below.

EMA generates Real-world evidence for the VMP through two main pathways: **DARWIN EU®** (Data Analysis and Real World Interrogation Network) and studies commissioned via **EMA framework contracts**.

In the table:

- **Safety** studies are shaded in yellow
- **Effectiveness** studies in blue
- **Combination** studies (safety + effectiveness) in green
- **Preparedness** studies are shaded in orange

The **EUPAS numbers** in the second column can be used to find the study protocols and reports in the Catalogue of RWD studies. The third column lists some of the scientific publications from each study, further output can be found in the section “resources” in the Catalogue of RWD studies

Studies funded by the European Centre for Disease Prevention and Control under the **VMP** can be found on the following webpage: Vaccine Effectiveness, Burden and Impact Studies (VEBIS)

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Pathogen	EUPAS number and status	Title; study description and regulatory impact; scientific publications arising from the study	Countries
SARS-CoV-2	EUPAS39798 (finalised)	**Early cohort-event monitoring of COVID-19 vaccines in European countries** This study is about understanding the side effects of the different COVID-19 vaccines. Vaccinated people were asked to report vaccine reactions through electronic questionnaires (for up to 6 months after their first vaccine dose). The study looks at two cohorts: general population, and special populations (pregnant and lactating women, children and adolescents, immunocompromised, people with history of allergy, people with prior SARS-CoV-2 infection). This study paved the way and set up the infrastructure for study EUPAS42504 (see below). Raethke M et al. Drug Saf. 2023	Belgium, Croatia, France, Germany, Italy, Luxembourg, Netherlands, United Kingdom
SARS-CoV-2	EUPAS42504 (finalised)	**Cohort-event monitoring of COVID-19 vaccines in European countries (building on EUPAS39798)** This study is about understanding the side effects of the different COVID-19 vaccines. Vaccinated people were asked to report vaccine reactions through electronic questionnaires (for up to 6 months after their first vaccine dose). The study looks at two cohorts: general population, and special populations (pregnant and lactating women, children and adolescents, immunocompromised, people with history of allergy, people with prior SARS-CoV-2 infection). This project demonstrated that collaboration for vaccine safety monitoring is feasible at EU level between member states. Cohort event monitoring allows to obtain near real-time evidence directly from vaccinated subjects. Lessons learnt will support pandemic preparedness and may also inform vaccine safety monitoring outside of public health emergencies. Ahmadizar F et al. Drug Safety 2023 Ciccimarra F et al. Vaccines 2024 Bellitto C et al. Drug Safety 2024 Luxi N et al. Vaccines 2024 Raethke M et al. Vaccine 2024 Maisonneuve E et al. Front. Drug Saf. Regul. 2025	Ireland, Italy, Netherlands, Portugal, Romania Slovakia, Spain, Switzerland

SARS-CoV-2	EUPAS42467 (finalised)	**Rapid Safety Assessment of SARS-CoV-2 vaccines in EU Member States using electronic healthcare data sources** This study was a separate work package of EUPAS42504. If a possible safety issue is signalled by researchers, regulators or clinicians, this network allows to quickly analyse the matter. A first phase consisted of readiness: setting up a system to use electronic healthcare data sources for rapid investigation of possible safety issues that require further investigation. The second phase looked at three possible safety issues that required further investigation: Multi-inflammatory syndrome (MIS); incidence rates of serious COVID-19 in children; Myocarditis and pericarditis. The network was used to generate results to contribute to the overall body of evidence to support regulatory and public health decision making. Bots SH et al. Front Pharmacol. 2022 Schultze A et al. Vaccine 2024 Bots SH et al. American Journal of Epidemiology, 2025 Durán C. E. et al. Eur J Pediatr 2025.	Belgium, Italy, Netherlands, Norway, Spain, United Kingdom
SARS-CoV-2	EUPAS44469 (finalised)	**Association between COVID-19 vaccines and thromboembolic events** This study used large healthcare data sources to investigate the risk of rare blood clots as a possible safety issue from COVID-19 vaccines. The study also investigated possible difference in such a risk between various brands of vaccines and personal characteristics (such as age and concurrent medication). The evidence generated in this study further supported signal evaluation of thromboembolic events and contributed to body of evidence on these safety issues. Li X et al. BMJ 2022 Xie J et al. J Thromb Haemost. 2022 Markus AF et al. Front Pharmacol. 2023	Spain, Netherlands, Germany, France, United Kingdom, United States

SARS-CoV-2	EUPAS46537 (finalised)	**Comparative effectiveness of heterologous and homologous primary- and booster SARS-CoV-2 vaccination schedules in the Nordic countries** This study used data from nationwide healthcare registries in Nordic countries to understand how well COVID-19 vaccines protect against mild or severe COVID-19, and how that protection changes over time. It also checks how mixing different vaccine brands impacts their protective effect. This study contributed to the totality of evidence on the effectiveness of COVID-19 vaccination. Andersson NW et al. BMJ 2023; Poukka E et al. Pediatrics 2024	Denmark, Finland, Norway, Sweden
SARS-CoV-2	EUPAS4775 (finalised)	**Effectiveness of heterologous and booster COVID-19 vaccination in non-Nordic European countries** This study used electronic healthcare data to understand how well COVID-19 vaccines protect against mild or severe COVID-19, and how that protection changed over time. It also looked at how mixing vaccine brands in the primary schedule impacted the protective effect. The findings of this study contributed to the totality of evidence on effectiveness of COVID-19 vaccination. Riefolo F et al. Vaccine 2023 Castillo-Cano B et al. Pharmacoepidemiol Drug Saf 2025	Italy, Netherlands, Spain, United Kingdom
SARS-CoV-2	EUPAS48979 (finalised)	**Association between COVID-19 vaccines and paediatric safety outcomes in children and adolescents in the Nordic countries.** This study used electronic health data from children and adolescents across Denmark, Finland, Norway, and Sweden to examine whether COVID-19 vaccines are associated with new occurrence of myocarditis, pericarditis, or thromboembolic events. The study also explored whether COVID-19 vaccines are linked to the new occurrence of rare immune-related conditions (like type 1 diabetes, Guillain-Barré syndrome, and juvenile arthritis) and whether existing conditions worsened after vaccination. This study adds important and reassuring evidence on the safety of COVID-19 vaccines in young people. This study adds robust and largely reassuring evidence on the safety of COVID-19 vaccines in children and adolescents, supporting continued use while acknowledging the need for ongoing monitoring of very rare adverse events. https://www.medrxiv.org/content/10.1101/2025.03.09.25323620v1	Denmark, Finland, Norway, Sweden

MPXV	EUPAS50093 (finalised)	**Safety and Effectiveness of MVA-BN vaccination against MPXV infection in at-risk individuals in Germany** This was a prospective Cohort Study in Germany that looked at how well the MVA-BN vaccine protects against mpox and how safe it is. It also examined how an individual's characteristic like HIV status, PrEP use, and sexual behaviour influence vaccine protection and safety. These findings of this study support the safety and benefit of MVA-BN and contribute to the wider understanding of how well it works in real-world conditions. The findings also demonstrated the benefits of combining primary data collection and secondary use of data to monitor new vaccines and contributed to the totality of evidence on effectiveness and safety of MVA-BN at a crucial time during the 2022 outbreak. The learnings on methodologies will support future preparedness. Hillus D et al. 2025	Germany
MPXV	EUPAS104386 (finalised)	**Effectiveness and safety of MVA-BN vaccination against Mpox in at-risk individuals in the United States (USMVAc)** This study looked at how well the MVA-BN vaccine protects against mpox and how safe it is in people at higher risk of the disease -especially men who have sex with men (MSM) and transgender women- in the United States. Using electronic healthcare data, vaccinated people were matched to unvaccinated people and then followed for the occurrence of mpox or pre-specified adverse events of special interest (AESIs). The findings of this study support the effectiveness and safety of MVA-BN vaccination in at-risk populations and contribute to ongoing public health efforts to monitor vaccine performance in real-world settings. Back S et al. 2024	United States
SARS-CoV-2	EUPAS106558 (finalised)	**Effectiveness of bivalent Covid-19 booster vaccines in the Nordic countries 2023** This study used nationwide health data from Denmark, Finland, Norway, and Sweden to evaluate how well bivalent COVID-19 booster vaccines protect people aged 50 and older from severe COVID-19 related illness and death, up to one year after vaccination. Researchers compared people who got a fourth dose with BA.1 or BA.4-5 bivalent to people who only got three dose. The study also looked at how vaccine protection changes over time and how it varies by age, sex, health status, infection history, and vaccine brand. This study provided strong evidence to guide booster vaccination strategies and public health policies across Europe. Gram MA et al. 2024 Andersson NW et al. 2023 Andersson NW et al. 2024	Denmark, Finland, Norway, Sweden

SARS-CoV-2	EUPAS1000000043 (finalised)	**Effectiveness of bivalent Covid-19 booster vaccines in the Nordic countries 2024** This study used nationwide health data from Denmark, Finland, and Sweden to evaluate how well the XBB.1.5-containing COVID-19 vaccine protected people aged 65 and older from severe COVID-19 related illness and death. This study contribution to totality of evidence on benefit/risk of COVID-19 vaccines. Andersson NW, et al. BMJ Med 2024	Denmark, Finland, Sweden
SARS-CoV-2	EUPAS107615 (finalised)	**DARWIN EU®: Effectiveness of COVID-19 vaccines on severe COVID-19 and post-acute outcomes of SARS-CoV-2 infection** This study tested whether it's possible to use existing health data from three European countries—the UK, Netherlands, and Spain—to monitor how well COVID-19 vaccines protect people over time. The researchers looked at whether extra vaccine doses helped prevent serious COVID-19 illness, death, and other health problems like diabetes and heart disease after a COVID-19 infection. This study shows that large-scale health data can be used to study vaccine effectiveness in DARWIN EU, and it provides a foundation for future work to better understand the long-term benefits and limitations of COVID-19 vaccines.	United Kingdom, Spain, Netherlands
RSV	EUPAS107708 (finalised)	**DARWIN EU®: Age specific incidence rates of RSV related disease in Europe** This study used electronic healthcare data from six European countries to understand how respiratory syncytial virus (RSV) affects people of different ages, especially infants and older adults. It looked at how often RSV leads to hospitalisations, ICU admissions, co-infections with other viruses, and deaths. The study also explored how this burden has changed over the last decade. The findings of this study can inform future monitoring of RSV vaccine effectiveness and supporting public health decisions across Europe.	United Kingdom, Spain, Germany, France, Estonia
HPV	EUPAS1000000080 (finalised)	**DARWIN EU®: Effectiveness of Human Papillomavirus Vaccines (HPV) to prevent cervical cancer.** This study used electronic healthcare data from the UK, Spain, and Norway to evaluate how well different HPV vaccines protect girls and young women from cervical cancer. It focused on outcomes like cervical cancer, precancerous lesions (CIN2+) and conisation (a treatment for abnormal cells), comparing vaccinated and unvaccinated individuals over time. This study adds real-world evidence on the performance of HPV vaccines in Europe and helps inform future monitoring and prevention strategies.	Norway, Spain, United Kingdom

Multiple pathogens	EUPAS1000000254 (finalised)	**DARWIN EU®: Background incidence rates of selected vaccine adverse events of special interest (AESIs) in Europe** This study used electronic healthcare data from five European countries to estimate background incidence rates of selected vaccine adverse events of special interest (AESIs). These background rates are crucial for evaluating vaccine safety signals rapidly and accurately, especially for new vaccine platforms like mRNA technology. The study analysed data by age, sex, calendar time, and region, describing the characteristics of individuals experiencing AESIs compared to matched controls. The results of this study can be used to inform ongoing and future vaccine safety monitoring.	Germany, Netherlands, Norway, Spain, United Kingdom
Multiple pathogens	EUPAS1000000193 (finalised)	**SAFETY-VAC, Network of Data Sources for Vaccine Safety Evaluation** Studies EUPAS1000000193, EUPAS1000000233, and EUPAS1000000288 are part of the same project. This part of the project assessed how well different European healthcare data sources are fit to support future vaccine safety studies. Using data from over 53 million people across nine datasets in six countries, it evaluated data quality, vaccine coverage, and the ability to detect safety outcomes for 39 conditions. The results of this study can inform future studies that investigate potential safety concerns by showing which data sources can support timely and reliable real-world evidence generation.	Denmark, Finland, Italy, Norway, Spain, United Kingdom
Multiple pathogens	EUPAS1000000233 (finalised)	**SAFETY-VAC, Background incidence estimation of flares of pre-existing chronic diseases** Studies EUPAS1000000193, EUPAS1000000233, and EUPAS1000000288 are part of the same project. This part of the project used electronic health records from five European countries to estimate how often patients with certain chronic autoimmune diseases experience flare-ups of those diseases. Ten chronic autoimmune diseases were studied, including rheumatoid arthritis, multiple sclerosis, and ulcerative colitis. The results provide background rates of flares, including in pregnant women, and highlight differences between countries and data sources. The findings of this study help establish a real-world evidence framework to support future vaccine safety evaluations.	France, Italy, Norway, Spain, United Kingdom
Multiple pathogens	EUPAS1000000288 (finalised)	**SAFETY-VAC, Phenotype proposal and rates of immunocompromised populations in real-world data sources.** Studies EUPAS1000000193, EUPAS1000000233, and EUPAS1000000288 are part of the same project. This part of the project reviewed existing literature to develop a standardized, machine-readable definition (phenotype) to identify immunocompromised individuals in large electronic health record databases. The resulting algorithm combines diagnoses, treatments, and clinical tests, and is designed to be flexible for use across different data sources and research settings. The findings of this study can be used to support more consistent identification of immunocompromised populations in real-world data studies, improving the quality of future vaccine safety and effectiveness research.	Not applicable

Influenza viruses	EUPAS1000000481 (finalised)	**Brand-specific influenza vaccine effectiveness in the Nordic countries: feasibility and estimates** This study had two aspects. The first was related to exploring whether annual brand-specific flu vaccine effectiveness studies can be carried out using electronic health data from Denmark, Finland, and Sweden. It found that Denmark, Finland and Sweden have high quality data on vaccinations, flu infections, and health outcomes (although sometimes only for certain regions). These linked data sources make it possible to track how well different flu vaccine brands work in the real world. The study also identified methods to handle challenges like data delays and missing information. Overall, it shows that the Nordic countries are well-positioned to support future flu vaccine monitoring and guide public health decisions. The second aspect looked at how well various flu vaccines worked during the 2024–2025 flu season in Denmark, Finland, and Sweden. It focused on older adults (65+) and younger adults at high risk of serious flu complications. Using national health records, researchers compared people who were vaccinated to those who weren't, to measure how effective each vaccine brand was at preventing severe flu such as flu-relate hospitalizations or death. These results help guide vaccine recommendations in Europe and show how Nordic health data can support timely monitoring of vaccine effectiveness. Ongoing yearly studies are important to ensure vaccines continue to protect the people who need them most. Faksova K, et al. Lancet Reg Health Eur. 2025	Denmark, Finland, Sweden
Neisseria Meningitidis	EUPAS1000000675 (finalised)	**DARWIN EU® - Coverage of meningococcal vaccines by the target population in Europe** This study uses electronic healthcare data from six European countries to assess coverage of meningococcal vaccines. Meningococcal vaccines are part of the routine immunisation schedule to prevent invasive meningococcal disease (Meningitis and/or Septicaemia), but immunisation coverage varies across regions and age groups. This study will examine vaccine coverage in children at ages one and two years and adolescents at age 18. The findings of this study can inform future monitoring of meningococcal vaccine effectiveness and supporting public health decisions across Europe.	Croatia, Denmark, Finland, Germany, Spain, United Kingdom

Varicella	EUPAS000000813 (ongoing)	**DARWIN EU® - Encephalitis risk in paediatric varicella vaccine recipients** This non-interventional cohort study uses routinely collected healthcare data from four European countries to examine the use and safety of varicella-containing vaccines in children and adolescents. Varicella (V) and measles-mumps-rubella-varicella (MMRV) vaccines are widely used in paediatric immunisation programmes, and this study focuses on their uptake and the occurrence of encephalitis in the paediatric population. The study will describe vaccine uptake, coverage, and recipient characteristics by age group, vaccine type, dose, and country, and estimate background rates of encephalitis in the general paediatric population as well as crude incidence following varicella infection. Using self-controlled risk interval analyses, the study will assess the association between varicella infection, V/MMRV vaccination, and encephalitis across age groups and countries. The findings of this study will contribute to post-authorisation safety monitoring of varicella-containing vaccines and support evidence-based evaluation of vaccine safety in children and adolescents across Europe.	Denmark, Finland, Norway, Spain
Influenza viruses	EUPAS1000000803 (ongoing)	**DARWIN EU® - Proof-of-concept: Preparedness for annual seasonal influenza vaccine effectiveness studies - Vaccine coverage and incidence of influenza-related outcomes** This non-interventional cohort study uses routinely collected electronic healthcare data from six European countries to describe the use of influenza vaccines and the epidemiology of influenza-related outcomes. Influenza vaccines are widely used as part of seasonal immunisation programmes, but uptake, vaccine type, and timing vary by age group, sex, and influenza season. The study will estimate seasonal influenza vaccination coverage in the general population from 2015/16 to 2023/24, characterise vaccine use by month, brand, and route of administration, and describe the demographic and clinical characteristics of vaccine recipients. In addition, it will assess the background incidence of influenza-related clinical outcomes, hospitalisations, and deaths in both vaccinated and unvaccinated populations across influenza seasons. The findings of this study will support ongoing monitoring of influenza vaccination patterns and influenza-related outcomes, and can inform public health planning and evaluation of seasonal influenza immunisation strategies across Europe.	Croatia, Denmark, Finland, Norway, Spain, United Kingdom