Meeting summaries of the Immunisation and Vaccine Monitoring Advisory Board (IVMAB)

This document provides a summary of each of the meetings of the Immunisation and Vaccine Monitoring Advisory Board (IVMAB) of the EU Vaccine Monitoring Platform (VMP). Many of the highlighted studies are included in the EMA VMP list of studies or the ECDC VMP list of studies and registered in the HMA-EMA Catalogue of real-world data studies.

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First IVMAB meeting, 6/7 December 2022, Amsterdam (hybrid)

The Executive Director of EMA and the Director of ECDC made opening statements highlighting the importance of the VMP as a forum of collaboration at EU level between stakeholders in vaccine research, where ideas, experiences and synergies are discussed. The platform should facilitate the generation of real-world evidence (RWE) on vaccines that is independent from industry.

Session 1: The EU vaccine monitoring landscape.
The VMP structure and the IVMAB's role were explained, along with the role of EMA's Emergency Task Force (ETF) under EU Regulation 2022/1263 and ECDC networks. The need for complementarity and to avoid duplication between post-authorisation studies as part of the VMP was highlighted. Selected relevant ECDC and EMA studies were presented, in the context of integrating such work into the VMP. IVMAB members presented a selection of their countries' vaccine studies and observational research experience, setting the stage for collaborative efforts. Key discussion points included horizon scanning for planned studies, considerations for common protocols, and capacity building including mapping capabilities at national level.

Session 2: Evidence generation by the VMP, update and lessons learnt.
Pathways for generating evidence were discussed: ECDC presented its procurement tools and selection process for awarding tenders related to vaccine effectiveness studies was presented, and EMA presented its generation of Real-World Evidence through in-house databases, framework contracts, and DARWIN EU.

ECDC presented a selection of their COVID-19 vaccine effectiveness studies conducted under the “Vaccine Effectiveness, Burden and Impact Studies” (VEBIS) project and highlights on previous work conducted in relation to vaccine effectiveness studies, under the I-MOVE, SpidNet and PERTINENT networks. ECDC summarised the epidemiology of mpox and the status of mpox vaccination rollout in the EU.

EMA provided an overview of COVID-19 vaccine effectiveness and safety studies funded by EMA, including plans for 2023. EMA outlined the published evidence on mpox vaccine effectiveness and safety, highlighting two VMP case studies: a primary data collection study in Germany (SEMVAc) and a secondary data analysis in US databases (USMVAc).
Session 3: VMP Research Agenda
EMA and ECDC jointly presented the draft of the VMP Research Agenda, categorising research questions into short, medium, and long-term. Breakout sessions were organised to discuss the agenda's comprehensiveness, clarity, and prioritisation of research questions. Improvements were suggested regarding granularity and prioritisation criteria and included adding research topics on COVID-19 vaccine safety and effectiveness, hybrid immunity, and long-term effectiveness of various vaccines. Clarity on topics outside VMP’s scope and the need for a robust communication plan were highlighted for effective stakeholder engagement.

Wrap-up & conclusions
Next steps included communication, finalisation of the Research Agenda and Terms of Reference of the IVMAB based on advice and feedback from the IVMAB, a potential post-meeting survey/mapping to gather further information on national infrastructures for vaccine evaluation, and next meetings/opportunities for consultation.

Second IVMAB meeting, 01 June 2023, virtual
The importance of conducting industry independent vaccine research to support maintaining vaccination confidence in the post-COVID-19 era was emphasised in the meeting introduction.

ECDC-coordinated studies
ECDC gave an update of its (VEBIS project, in which studies focus on COVID-19 and influenza vaccine effectiveness in different populations and settings, looking at a wide range of outcomes. Challenges include data protection and timely approval by ethical committees. Specifically for COVID-19 studies, additional challenges are sample size for newer SARS-CoV-2 variants, impact of self-testing, and presence of hybrid immunity. Notable added values of VEBIS include capacity-building, efforts to increase sample sizes, and investigation of methodological issues.

EMA-coordinated studies
EMA outlined its plan for short- and long-term studies, which include studies on COVID-19 vaccine effectiveness, safety evaluation for all vaccines, and readiness for future RSV vaccine studies. The ongoing 3-component mpox research programme was discussed: SEMVAc (prospective, German centres); TEMVAc (retrospective, same German centres); USMVAc (retrospective, US data sources). The IVMAB emphasised that readiness activities are a priority to allow swift action in case of new public health emergencies.

VMP Research Agenda
Synergies/complementarity between the ECDC and EMA research programmes were discussed. The various COVID-19 VE studies coordinated by both Agencies are complementary as they use different data sources, different study designs and are conducted in different countries and population groups. Vaccine manufacturers are required to provide brand-specific vaccine effectiveness data, which has proven challenging in the past. The topic of brand-specific results was discussed (especially for newer vaccines), and that DARWIN EU’s role in supporting the VMP is expected to keep growing.

Discussion & conclusions
The Public health emergency of international concern caused by COVID-19 has officially ended. It is now crucial to continue research on COVID-19 vaccine effectiveness (especially newer/adapted vaccines) and long-term monitoring. Priorities for research should focus on special populations (e.g. immunocompromised) and research on influenza, COVID-19, RSV and Streptococcus pneumoniae vaccines. The Research Agenda should remain flexible to allow adaptation to emerging circumstances.
Potential topics for a next IVMAB meeting include methodological approaches for real-world data studies, safety of vaccination in pregnant people, and mapping ongoing vaccine research activities in the EU/EEA.

### Third IVMAB meeting, 18/09/2023, Stockholm (hybrid)

#### ECDC-coordinated studies
In addition to the VEBIS project which focuses on COVID-19 and influenza vaccine effectiveness, ECDC also monitors mpox vaccine uptake in EU/EEA countries. In September 2023, a pilot project on genomic surveillance of invasive meningococcal disease was launched, with the aim of connecting genomic and epidemiological data for enhanced surveillance and subsequent public health actions. In Autumn 2023, the establishment of an EU Reference Laboratory Network started. The important challenges of collecting data to estimate vaccine effectiveness for each of the influenza vaccine brands were discussed for future action.

#### EMA-coordinated studies
Real-world data studies presented by EMA include studies on COVID-19 vaccine effectiveness in children, respiratory syncytial virus (RSV) epidemiology, human papillomavirus vaccine effectiveness, and Mpox vaccine effectiveness. Key results of the completed 2-year COVID-19 vaccine safety monitoring program were presented, which confirmed the favourable safety profile of the vaccines. EMA generates evidence using various pathways, including DARWIN EU. Future plans include the set-up of a framework for post-authorisation safety evaluation of vaccines, and continuing to address the VMP Research Agenda. The importance of lessons learned from the pandemic regarding methodological challenges for vaccine studies was highlighted.

#### Presentations from IVMAB members on topics addressing the Research Agenda
Presentations addressing the VMP Research Agenda included a hospital-based case-control study on COVID-19 vaccine effectiveness (Germany), RSV surveillance in the EU/EEA (ECDC), and COVID-19 vaccine effectiveness protocol for the paediatric population (part of VEBIS, ECDC). Discussions focused on improving study methodologies, refining case definitions, and addressing challenges related to multiple vaccines and variants in circulation.

#### Strengthening the VMP infrastructure for the future
This was considered a priority and should include efforts to map existing data sources, leverage other European initiatives in vaccine research, and enhance communication and collaboration with all relevant stakeholders.

#### Conclusions
The VMP Research Agenda, which was published on the VMP webpages of ECDC and EMA following the meeting, will be updated annually and ad hoc as needed in order to reflect emerging needs for data. The IVMAB recommended to reflect on how to increase agility in terms of preparedness. Ways to increase the sample size and completeness of data collected for vaccine effectiveness studies need to be identified to possibly generate type and brand-specific vaccine effectiveness and safety data. The IVMAB could provide advice to encourage healthcare systems and the Member States to record data on vaccine uptake, and by vaccine brand.

### Fourth IVMAB meeting, 16/05/2024, virtual
This meeting was cancelled due to unforeseen circumstances.