EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 February 2024
EMA/30999/2024
ENCePP Secretariat

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

ENCePP Activity Report

January – December 2023

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1. Introduction

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP®) is a network coordinated by the European Medicines Agency (EMA). Its members (the ENCePP partners) are public institutions and contract research organisations (CROs) involved in research in pharmacoepidemiology and pharmacovigilance.

The aim of this document is to provide a summary of ENCePP activities performed in 2023. Related documentation can be found on the ENCePP website.

2. ENCePP Steering Group

2.1. Mandate

The ENCePP Steering Group (SG) defines and safeguards the objectives and principles of ENCePP and decides on operational tasks of the network. The Steering Group is the highest authority of ENCePP and thus is its final decision-making body.

2.2. Meetings

The ENCePP SG meets 2-3 times per year to discuss ongoing work and agree on future activities of the network. In 2023, two virtual SG meetings were organised, on 20 June and 4 October.

The following **key topics** were discussed:

- ENCePP workplan for 2023 and for the upcoming new mandate (2024-2026)
- Update of the ENCePP mandate and SG mandate to reflect the evolution of ENCePP in a changing environment
- Development of the new Heads of Medicines Agencies (HMA)-EMA Catalogues of real-world data (RWD) sources and studies, building on the ENCePP Resource Database and EU PAS Register, to be migrated to the EMA website in early 2024
- Development of the new ENCePP website

All SG minutes are published on the ENCePP website: https://encepp.europa.eu/about-us/steering-group_en#steering-group-meeting-reports

2.3. Election

The ENCePP SG is elected every 3 years for the following term. The election for the 2024-2026 term was organised in Q3 2023 via the EU Survey online tool, and the results were announced at the December ENCePP Plenary meeting in Amsterdam. The newly elected members are: Alejandro Arana (RTI Health Solutions), Annalisa Landi (TEDDY European Network of Excellence for Paediatric Clinical Research), Christos Kontogiorgis (Democritus University of Thrace), Helga Gardarsdottir (Utrecht Institute for Pharmaceutical Sciences), Marco Tuccori (University hospital of Pisa) and Vera Ehrenstein (Aarhus University, Dept of Clinical Epidemiology).

The list of appointed representatives: Catherine Cohet (EMA), Thomas Goedecke (EMA), Nadia Amaouche (EMA), Annette Cleveland Nielsen (HMA), Carla Torre (CHMP), Frauke Naumann-Winter (COMP), Ulla Wändel Liminga (PRAC), Iryna Vlasenko (PCWP), Arnold K. Chan (ISPE), Gianluca Trifirò

(ISoP), Laura Pizzi (ISPOR), Gianmario Candore (Pharmaceutical industry), Hui-Lee Wong (FDA), Craig Simon (Health Canada).

Furter information on the Steering Group: https://encepp.europa.eu/about-us/steering-group_en

3. ENCePP Plenary hybrid meeting

EMA organised the annual ENCePP Plenary hybrid meeting at its premises in Amsterdam on 1 December. Thirty-five ENCePP partner representatives attended the meeting in person, and a further >100 joined via Webex.

The **objectives** of the meeting were:

- To reflect on the work of ENCePP in recent years, and present and agree on proposed changes to the ENCePP mandate;
- To present and agree on proposed changes to the Steering Group mandate, and introduce the newly elected SG members for the 2024-2026 term;
- To present the ENCePP Workplan for 2024, including activities of the Working Groups, and seek feedback and contribution from ENCePP Partners on planned activities and deliverables;
- To update on, and seek feedback from ENCePP Partners, on the new ENCePP website and the EMA catalogues on RWD sources and RWD studies (former ENCePP Resource Database and EU PAS Register);
- To learn about, and discuss, current key data- and method-related initiatives;
- To place the work of ENCePP in the broader context of a changing regulatory environment.

ENCePP Plenary meetings: https://encepp.europa.eu/documents/plenary-meetings_en (to be updated with 2023 Plenary meeting documents)

4. ENCePP Guide on Methodological Standards in Pharmacoepidemiology

The Guide on Methodological Standards in Pharmacoepidemiology offers a single web resource for methodological guidance in pharmacoepidemiology.

The **11th Revision** of the Guide was published in July 2023. The table of contents has been restructured to better reflect the evidence generation flow and provide greater emphasis on important methodology. New recommendations include the use of the causal inference target trial emulation approach to improve internal validity and increase transparency on study designs; the use of the estimand framework to inform study design and analysis choices; and the use of the HARPER protocol template to foster transparency, reproducibility and harmonisation of non-interventional study protocols and facilitate their assessment.

The ENCePP Guide is published on the ENCePP website: https://encepp.europa.eu/encepp-toolkit/methodological-guide_en

The next revision is planned for 2025, and improvements to the Guide will be a priority for WG1.

5. Projects

5.1. RWD catalogues – migration of EU PAS Register and ENCePP Resource Database

The EMA has been working since 2021 on the development of new catalogues on RWD studies and data sources, replacing the EU PAS Register and the ENCePP Resource database, respectively, with planned launch in 2024. The catalogues are moving away from the supervision of ENCePP and can be accessed via the EMA website.

The catalogues will help medicines regulators, researchers, and pharmaceutical companies to identify the most suitable data sources to address specific research questions and support the assessment of study protocols and results. The aim is to promote transparency, encourage the use of good practices, and build trust in research based on RWD.

External users from the ENCePP community have contributed to the user acceptance testing. Updates were presented at the ENCePP Plenary meeting on 1 December 2023. Further communication was published on the ENCePP website news section, and emails were sent to the EU PAS Register and ENCePP Resource Database contact points from metadata@ema.europa.eu with information about the upcoming changes and action points.

5.2. ENCePP website update

The original ENCePP website was built over 10 years ago. As technologies have improved significantly since the launch, and the current website is facing technical issues and gaps e.g., in terms of searchability, it became necessary to upgrade the website. The change is also timely due to the move of the catalogues to the EMA website. The new ENCePP website is planned to be launched at a new URL (https://encepp.europa.eu) early 2024, on the same day as the new RWD catalogues (https://catalogues.ema.europa.eu/).

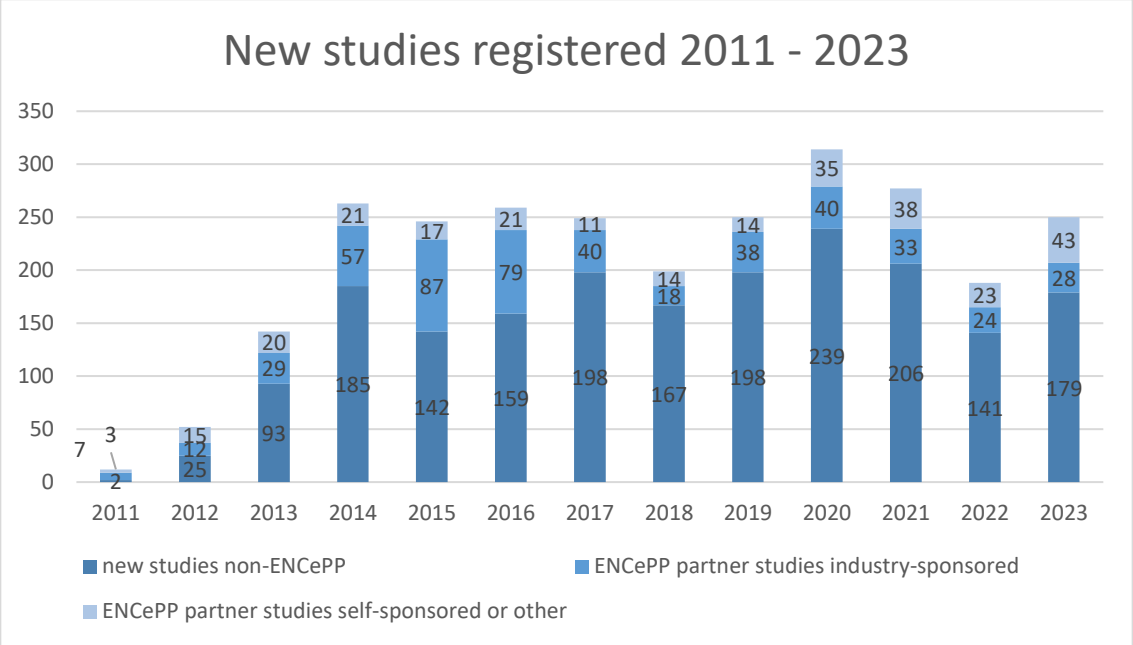
An update was presented at the ENCePP Plenary meeting on 1 December 2023.

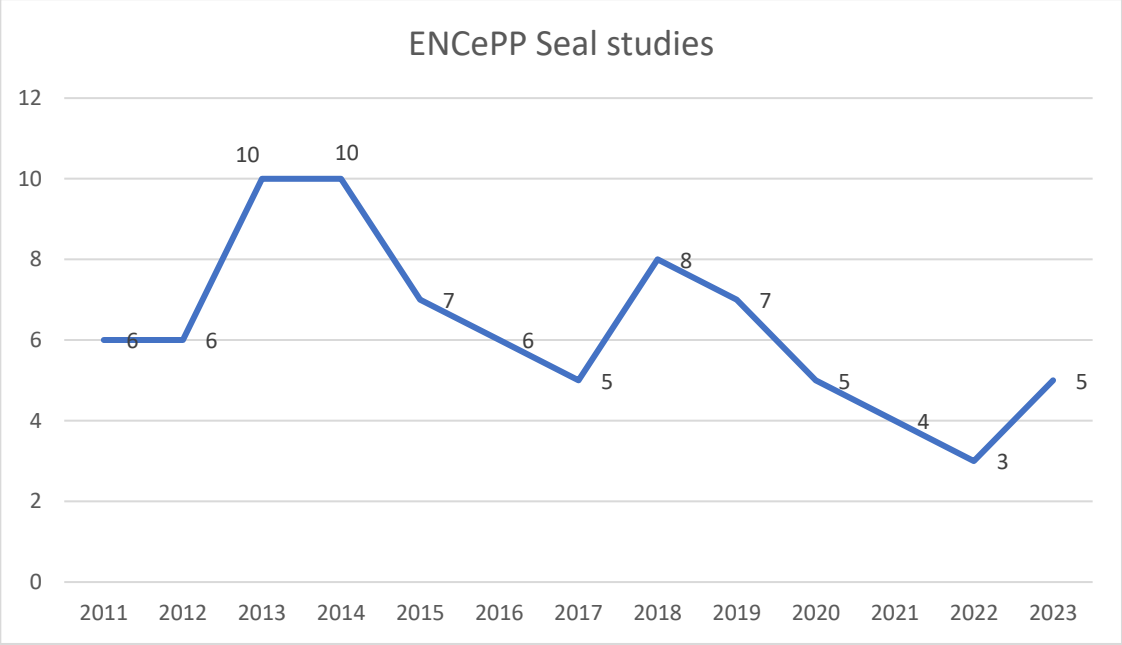
6. EU PAS Register studies

The EU PAS Register was a publicly available register of post-authorisation studies (PAS). The Register had a focus on observational research, and its purpose was to increase transparency, reduce publication bias, promote the exchange of information and facilitate collaboration among stakeholders, including academia, sponsors and regulatory bodies, ensure compliance with EU pharmacovigilance legislation requirements.

Study registrations in the EU PAS Register in 2023:

Study	Total	New in 2023
ALL studies in the EU PAS Register (registered by ENCePP Partners and others)	**2,775**	**250**
Studies Registered by ENCePP Partners	**811**	**71**
ENCePP Seal studies	**78**	**5**





7. ENCePP Resources Database

The Resources Database was an electronic index of available EU research organisations, networks and data sources, including patient registries, in the fields of pharmacoepidemiology and pharmacovigilance.

Registration of centres, networks and data sources in the database in 2023:

Resources database	Total number	New in 2023
Centres	**220**	**12**
Networks	**37**	**2**
Data sources	**172**	**5**

8. Day-to-day work

- Addressing ENCePP and EU PAS Register related queries
- Analysing with IT the EU PAS Register system related improvements and solutions for fixing bugs
- Processing of submissions to ENCePP resources database and EU PAS Register
- Maintenance of lists and statistics relating to ENCePP centres, networks and data sources, and EU PAS Register studies
- Literature survey by the editor for next updates to the ENCePP Guide
- Regular updates and planning between the SG co-chairs