ENCePP Activity Report
January – December 2022

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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). The members of this network (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 the ENCePP activities performed in 2022.

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.

The Steering Group mandate was updated with minor changes (e.g. the number of members and election process) and published on the website in June 2022:

2.2. Meetings

The ENCePP SG typically meets 2-3 times per year to discuss the key ongoing tasks and agree on future activities of the network. In 2022, three meetings were organised:

- 18 May: pre-SG virtual meeting for the elected members and EMA representatives, preparation of the September SG meeting
- 29 September: SG virtual meeting
- 29 November: SG hybrid meeting, preparation of the 30 November Plenary meeting

The following key topics were discussed:

- 10th Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology
- Rebuilding of the ENCePP catalogues (ENCePP Resource Database, EU PAS Register)
- Upgrade of the ENCePP website
- Updates from the Working Groups chairs
- ENCePP plans on visibility and external interactions
- ENCePP work plan for 2023

The reports of the SG meetings can be found here.
3. ENCePP Plenary hybrid meeting

After several years of virtual meetings, the EMA organised its first ENCePP Plenary hybrid meeting, which was held at the EMA’s premises in Amsterdam. About 70 ENCePP network representatives joined the meeting via Webex, and 30 SG, WG and EMA representatives attended the Plenary in person.

The key objectives of the meeting were:

- To present and discuss the activities of the ENCePP Steering Group and Working Groups and exchange ideas to populate the ENCePP workplan for 2023 and beyond;
- To update and seek input from ENCePP partners on upcoming developments including the new ENCePP website and the upgrading of the EU PAS Register and ENCePP Resources Database catalogues into the new RWD sources and RWD studies catalogues;
- To exchange views on the future of ENCePP and how to improve visibility, enhance collaborations with learned societies, and consider current and future guidance initiatives in the ENCePP work plan;
- To inform the ENCePP community about latest developments on COVID-19 and monkeypox vaccines and therapeutics and the contribution of pharmacoepidemiology to EMA’s decision-making;
- To update on DARWIN EU® and discuss the interface with ENCePP activities;
- To learn about, and discuss, current methodological hot topics.

The Plenary meeting report along with the presentations have been published here.

4. Publications

4.1. ENCePP Guide on Methodological Standards in Pharmacoepidemiology


The 10th Revision of the Guide was published on 30 June 2022. It includes two new chapters on the use of artificial intelligence in pharmacoepidemiology (Chapter 15.5) and on real-world evidence and pharmacoepidemiology (15.6), and a new comprehensive Annex 2 on Methods for the evaluation of medicines in pregnancy and breastfeeding. Besides the updating of nearly all existing chapters, including considerations on methodological standards for COVID-19 studies, two chapters have been extensively revised: Comparative effectiveness research (15.1) and Vaccine research (15.2). Recommendations on the use of statistical significance for the interpretation of evidence have been added in the Overview of study designs (4.1). The Foreword from the co-chairs of the ENCePP Steering Group highlights the continued involvement of ENCePP in sound pharmacoepidemiological research, including into COVID-19, and real-world evidence studies. This 10th Revision of the Guide provides a useful resource for researchers, regulators, marketing authorisation holders and applicants.

4.2. Publications led by ENCePP WG3

Background: The European post-authorisation study (EU PAS) register is a repository launched in 2010 by the European Medicines Agency (EMA). All EMA-requested PAS, commonly observational studies, must be recorded in this register. Multi-database studies (MDS) leveraging secondary data have become an important strategy to conduct PAS in recent years, as reflected by the type of studies registered in the EU PAS Register. The objective of this publication was to analyse and describe PAS in the EU PAS register, with focus on MDS.


Background: A large proportion of medicine product labels lack information on safety in pregnancy and breastfeeding. To address this gap, pharmaceutical companies are requested to develop post-approval studies regarding the use of drugs by pregnant and breastfeeding women. The objective of the study aims to review key features of observational studies in pregnancy and breastfeeding and their impact on the respective medicine product labels.

5. Projects

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

The EMA has been working on the development of new catalogues for both the data sources and the EU PAS studies. This project aims to bring enhanced transparency and discoverability with regards to observational studies and data sources in the regulatory context and to increase their quality. This will also enhance the ability to evaluate the level of evidence provided by observational studies and RWD sources, an important benefit considering the more complex needs of data and the lack of standardised information and statistics on RWD sources and studies.

The last update on the project can be found in the presentation on the Update on the RWD sources and RWD studies catalogues, as presented in the ENCePP Plenary 2022 meeting.

5.2. ENCePP website update

The current ENCePP website was built over 10 years ago at the inception of ENCePP. As technologies and needs from the pharmacoepidemiology community have improved/increased significantly since the launch of the website, it is necessary to improve and upgrade the current site in the near future. The plan is to deliver the new website in 2023/24 (TBC).

The last update of this project can be found in the ENCePP website update slides, as presented in the ENCePP Plenary 2022 meeting.
6. EU PAS Register studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Total</th>
<th>New in 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL studies in the EU PAS Register (registered by ENCePP Partners and others)</td>
<td>2,497</td>
<td>188</td>
</tr>
<tr>
<td>Studies Registered by ENCePP Partners</td>
<td>732</td>
<td>47</td>
</tr>
<tr>
<td>ENCePP Seal studies</td>
<td>77</td>
<td>3</td>
</tr>
</tbody>
</table>

New studies registered (by sponsorship) 2011 - 2022

- new studies non-ENCePP
- ENCePP partner studies industry-sponsored
- ENCePP partner studies self-sponsored or other
7. ENCePP Resources Database

<table>
<thead>
<tr>
<th>Resources database</th>
<th>Total number</th>
<th>New in 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centres</td>
<td>209</td>
<td>6</td>
</tr>
<tr>
<td>Networks</td>
<td>35</td>
<td>1</td>
</tr>
<tr>
<td>Data sources</td>
<td>165</td>
<td>7</td>
</tr>
</tbody>
</table>
8. ENCePP website and ENCePP Guide statistics

8.1. Website statistics

<table>
<thead>
<tr>
<th>Month</th>
<th>Unique visitors</th>
<th>Number of visits</th>
<th>Pages viewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>10.765</td>
<td>28.824</td>
<td>260.571</td>
</tr>
<tr>
<td>2013</td>
<td>21.980</td>
<td>49.348</td>
<td>228.337</td>
</tr>
<tr>
<td>2014</td>
<td>36.372</td>
<td>73.005</td>
<td>362.310</td>
</tr>
<tr>
<td>2015</td>
<td>42.594</td>
<td>87.335</td>
<td>377.110</td>
</tr>
<tr>
<td>2016</td>
<td>54.588</td>
<td>103.836</td>
<td>426.099</td>
</tr>
<tr>
<td>2017</td>
<td>109.859</td>
<td>185.760</td>
<td>535.610</td>
</tr>
<tr>
<td>2018</td>
<td>108.730</td>
<td>197.606</td>
<td>736.053</td>
</tr>
<tr>
<td>2019</td>
<td>148.812</td>
<td>295.277</td>
<td>933.826</td>
</tr>
<tr>
<td>2020</td>
<td>213.021</td>
<td>350.856</td>
<td>1.583.539</td>
</tr>
<tr>
<td>2021</td>
<td>48.682</td>
<td>79.911</td>
<td>542.962</td>
</tr>
<tr>
<td>2022</td>
<td>159.217</td>
<td>281.113</td>
<td>2.092.424</td>
</tr>
</tbody>
</table>

Notes:

- There was no data available between April to November 2021, due to faulty analytics tools;
- **Unique Visitors** are the number of people that visited the site over the selected time period; a person visiting the site multiple times during the time period is only counted once;
- **Pageview** is recorded whenever a full page of the website is viewed or refreshed. The count of pageviews is the total number of times the pages of the website were viewed or refreshed within the selected time period;
- A **Visit** is a single browsing session. If a visitor views another page on the site within 30 minutes of the last pageview, it is counted as the same visit. If a visitor returns to the site after 30 minutes have passed since the last pageview, it is counted as separate visit.
8.2. **ENCePP Guide statistics**

The highest peak of the views and downloads of the Guide was in July, associated with the publication of the 10th revision of the Guide on 30 June:
Top 10 visits of main chapters of the 10th revision in 2022 (from 1 July to 31 December 2022):
Top 10 visits of subchapters of the 10th revision in 2022 (from 1 July to 31 December 2022):

9. Day-to-day work

- Addressing ENCePP and EU PAS Register related queries
- Discussions with IT on improvements and solutions for fixing bugs in the EU PAS Register system
- 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
- Preparation of monthly ENCePP website statistics
- Regular updates between the SG co-chairs