

# ENCePP activity report

January – December 2025

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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. They are registered in the [HMA-EMA Catalogue of institutions](#). As of 20 January 2025, 228 ENCePP Partners (203 institutions and 25 networks) are registered.

The aim of this report is to provide a summary of ENCePP activities performed in 2025. Related documentation with further information is available on the [ENCePP website](#).

## 2. Steering Group (SG)

In the second year of the 2024-26 three-year mandate, the SG continued to closely follow, or work on, the deliverables set in the workplan, with key focus on the establishment of new Working Groups (WGs) and Special Interest Groups (SIGs). The most recent progress of the workplan is published in the December 2025 version of the [ENCePP workplan](#).

There was a change in the SG membership in February, with Melissa Kampman replacing Craig Simon as Health Canada representative.

The SG held 4 virtual meetings in 2025. Agenda topics included:

- Setting up the new WGs/SIGs – governance (see [Terms of Reference](#)), call for interest survey, review and endorsement of the mandates and objectives drafted by the groups
- Reflection on the findings of the Qualitative research on the role and impact of ENCePP – see [Report](#) and [Webinar](#)
- [Discontinuation of the ENCePP Seal](#)
- ENCePP Guide: publication of selected chapters in *Pharmacoepidemiology and Drug Safety* and *Value in Health* (led by a dedicated SIG)
- ENCePP Plenary meeting preparation

For other topics, see the [SG meeting minutes](#) and related documents available on the ENCePP website.

## 3. New Working Groups and Special Interest Groups

Following the [2024 ENCePP Plenary Meeting](#), the key focus in 2025 was on the creation of new groups aiming to address continued and new priority areas, such as artificial intelligence, pragmatic trials, diversity and equity in pharmacoepidemiology, or communications.

After endorsement by the SG of the topics agreed in Plenary for the new groups, a [call for interest](#) was launched among ENCePP Partners in Q1 2025 to join the new WGs/SIGs, including willingness to act as co-chair (response rate: 20%).

The new groups are organised and led by co-chairs and report to the SG. The mandates and objectives drafted by the groups and a progress update were presented at the 2025 ENCePP Plenary by the WGs/SIGs co-chairs. The presentation is available in the [ENCePP Plenary documents](#).

### WGs:

- Communications and Outreach

- Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology
- Independence and Transparency
- Artificial Intelligence (AI) in Pharmacoepidemiology
- Diversity and Health Equity
- Real World Data (RWD) sources in non-interventional studies

#### **SIGs:**

- Pragmatism in Clinical Trials
- Update of the ENCePP Checklist for Study Protocols
- Supplement to the Good Practice Guide for the use of the HMA-EMA Catalogues of real-world data (RWD) sources and studies
- Publication of selected chapters of the ENCePP Guide in Pharmacoepidemiology and Drug Safety and Value in Health

## **4. ENCePP Plenary hybrid meeting**

EMA organised the annual ENCePP Plenary hybrid meeting at its premises in Amsterdam on December 1<sup>st</sup>, 2025. The objectives were:

- To reflect on the progress of the ENCePP Work plan since the 2024 Plenary;
- To present the new Working Groups and Special Interest Groups, and seek feedback from the ENCePP community on their objectives and completed/upcoming deliverables;
- To continue placing the work of ENCePP in the context of the ever-changing regulatory and real-world evidence (RWE) environment, by sharing updates on DARWIN EU<sup>1</sup>, the EHDS, and new EU and international guidance relevant to ENCePP;
- Following up on methodological sessions in past years Plenary meetings<sup>2</sup>, to dive deeper into topics of current interest.

The presentations and meeting report are available on the ENCePP website in the [ENCePP Plenary documents](#) section.

## **5. Communication**

### **5.1. News items**

In addition to the annual and plenary reports, SG minutes, and targeted surveys, the ENCePP Secretariat continuously publishes news items on ENCePP activities and deliverables, publications, and topics of interest to ENCePP Partners. In 2025, 17 [news items](#) in total were published.

### **5.2. Publication of selected chapters of the ENCePP Guide**

The first article of the *Pharmacoepidemiology and Drug Safety (PDS)* and *Value in Health* publication series on the ENCePP Guide was published in PDS: [Strengthening Pharmacoepidemiology in a Changing Research Environment](#). Several other articles are under development, submitted, or under peer review. All articles will be published simultaneously as part of the publication series.

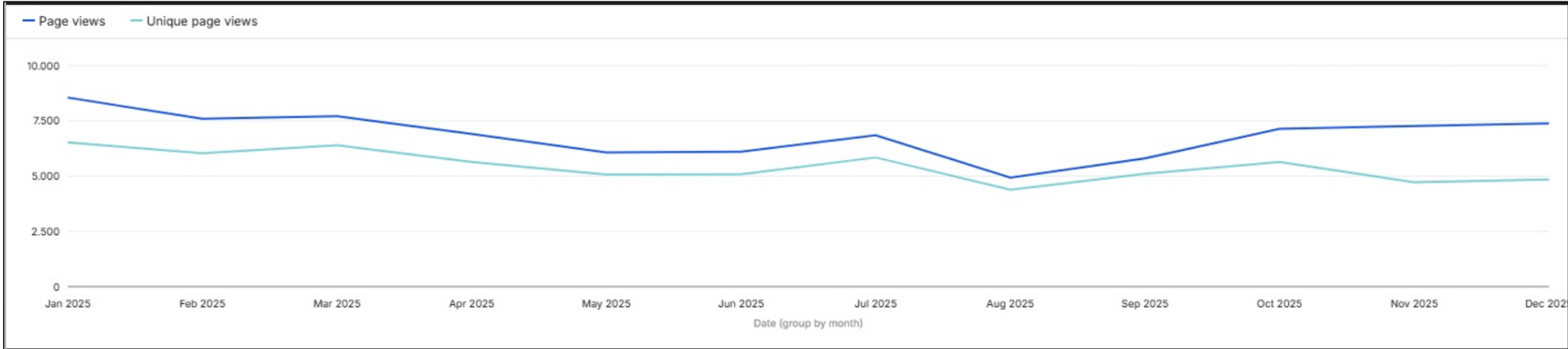
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<sup>1</sup> [Real-world evidence | European Medicines Agency \(EMA\)](#)

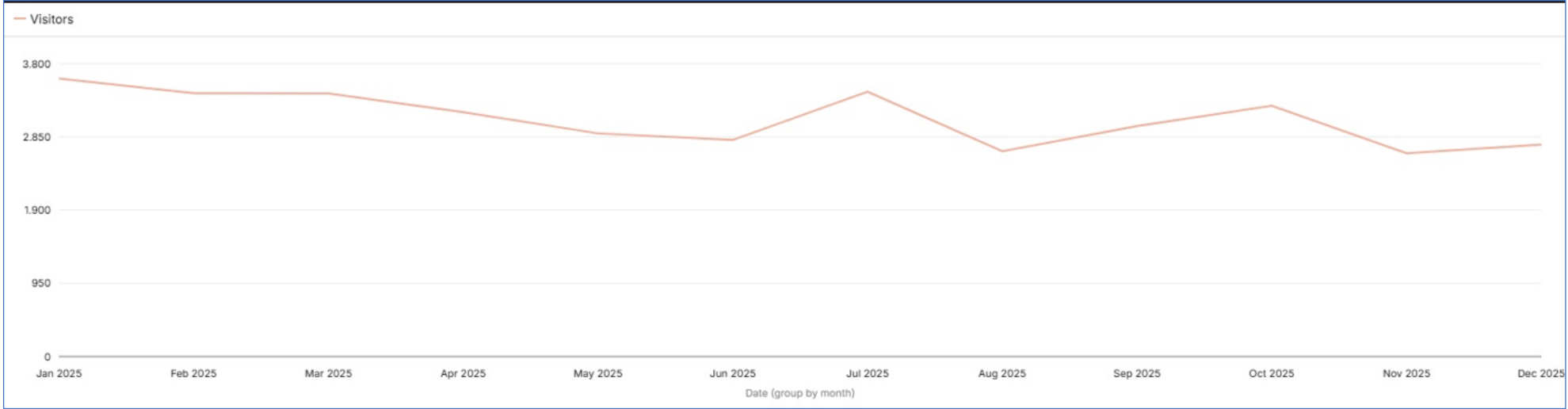
<sup>2</sup> [Plenary Meetings - European Network of Centres for Pharmacoepidemiology and Pharmacovigilance](#)

## 6. Website statistics

Page views<sup>3</sup> (82.304) and unique pages views<sup>4</sup> (65.276)



Visitors (34.089)



<sup>3</sup> Page view represents the total number of times a page has been viewed. It occurs each time a user visits a page.

<sup>4</sup> Unique page view represents the number of unique users who viewed a page.

- Top 10 page views

<b>Page title</b>	<b>Page views</b>	<b>Unique page views</b>
<a href="#">ENCePP homepage</a>	21.850	13.999
<a href="#">Methodological Guide (main page)</a>	6.410	5.304
<a href="#">Chapter 7: Effect modification and interaction</a>	3.191	2.830
<a href="#">Chapter 11: Signal detection methodology and application</a>	2.559	2.144
<a href="#">ENCePP Checklist for Study Protocols</a>	2.406	2.114
<a href="#">Chapter 6: Methods to address bias and confounding</a>	1.863	1.665
<a href="#">Publications</a>	1.509	1.260
<a href="#">Migration of the EU PAS Register and ENCePP Resource Database and launch of the new ENCePP website in early 2024</a>	1.413	844
<a href="#">News</a>	1.403	1.271
<a href="#">Code of Conduct</a>	1.073	876

- Top 5 downloads

<b>Document</b>	<b>Unique downloads</b>
ENCePP Guide on Methodological Standards in Pharmacoepidemiology (Revision 11)	1.921
ENCePP Checklist for Study Protocols (Revision 4)	1.080
ENCePP Code of Conduct	270
Annex 2 to the Guide on Methodological Standards in Pharmacoepidemiology – Guidance on methods for the evaluation of medicines in pregnancy and breastfeeding (2 <sup>nd</sup> Edition)	154
ENCePP Guide on Methodological Standards in Pharmacoepidemiology - References	131