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## ENCePP annual activity summary

January – December 2024

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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 (ENCePP partners) are public institutions and contract research organisations (CROs) involved in research in pharmacoepidemiology and pharmacovigilance. The aim of this report is to provide a summary of ENCePP activities performed in 2024. Related documentation with further information of the activities can be found on the [ENCePP website](#).

## 2. First year of the ENCePP Steering Group 2024-2026

### 2.1. New ENCePP workplan

A new Steering Group (SG) started its mandate in January 2024. For the first time, all members are now active representatives, as the observer (Health Canada, FDA, industry) role was ceased, to increase contribution to the strategy and work of ENCePP. Helga Gardarsdottir (Utrecht University) was nominated by the SG as the new SG co-chair. During the year there were two changes to the membership: due to her new role as PRAC chair, Ulla Wändel Liminga (Swedish Medical Products Agency, representing PRAC) was replaced by Hedvig Marie Egeland Nordeng (Norwegian Institute of Public Health); Annette Cleveland Nielsen (Danish Medicines Agency) stepped down as HMA representative due to other duties (her replacement is pending).

The new SG's main task was to develop a [workplan](#), with a focus on concrete and measurable deliverables. Several milestones were achieved (detailed in the presentation 'ENCePP workplan 2024 achievements' given by Catherine Cohet at the [2024 ENCePP Plenary](#)), including:

- Terms of reference for the establishment and maintenance of the **Working Groups** and **Special Interest Groups** ([presented at the ENCePP Plenary](#))
- **Qualitative research** on the role and impact of ENCePP (first results presented at the ENCePP Plenary)
- Co-branded events with **learned societies** (ENCePP symposium at ICPE 2024, and presentation to the RWE SIG at ISPOR EU 2024)
- Opening of ENCePP partnership to public bodies in current **EU candidate countries**/potential candidates (first institutions have joined)
- **Podcasts** "Conduct your study" ([first two episodes](#) published on the ENCePP website)

The SG, along with the ENCePP partners, are continuing the work on the deliverables in 2025.

### 2.2. ENCePP SG meetings

The SG held 3 virtual meetings in 2024, where the following topics were discussed:

- Election of the ENCePP co-chair representing ENCePP partners
- Update and publication of the ENCePP SG and ENCePP mandates
- Launch of the new ENCePP website and logo
- ENCePP workplan for the 2024-2026 mandate of the SG

- Qualitative research on the role and impact of ENCePP
- Planning of co-branded events with learned societies (ISPE, ISPOR)
- Mandate of the current ENCePP WGs 1, 2 and 3, Terms of Reference
- ENCePP Plenary agenda
- Next revision of the ENCePP Guide and strategy for publication of selected chapters in peer-reviewed journals
- Update of the Checklist for Study protocols

The ENCePP [SG meeting minutes](#) and related documents are available on the ENCePP website.

### 3. ENCePP Plenary hybrid meeting

EMA organised the annual ENCePP Plenary hybrid meeting at its premises in Amsterdam on 22 November 2024, with around a hundred participants (58 Webex, 43 in-person - 33 ENCePP partner, 10 EMA and guests)

The objectives of the meeting were:

- To reflect on the work of ENCePP since the December 2023 Plenary, and inform the ENCePP community on recent progress;
- To provide an update on milestones and deliverables of the ENCePP workplan, and seek feedback and contribution from ENCePP Partners on governance aspects and future activities and deliverables;
- To continue placing the work of ENCePP in the context of an ever-changing regulatory environment;
- To learn about, and discuss, the strategy for the 2025 revision and dissemination of the ENCePP Methods Guide, as well as methodological topics of current interest.

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

## 4. ENCePP website

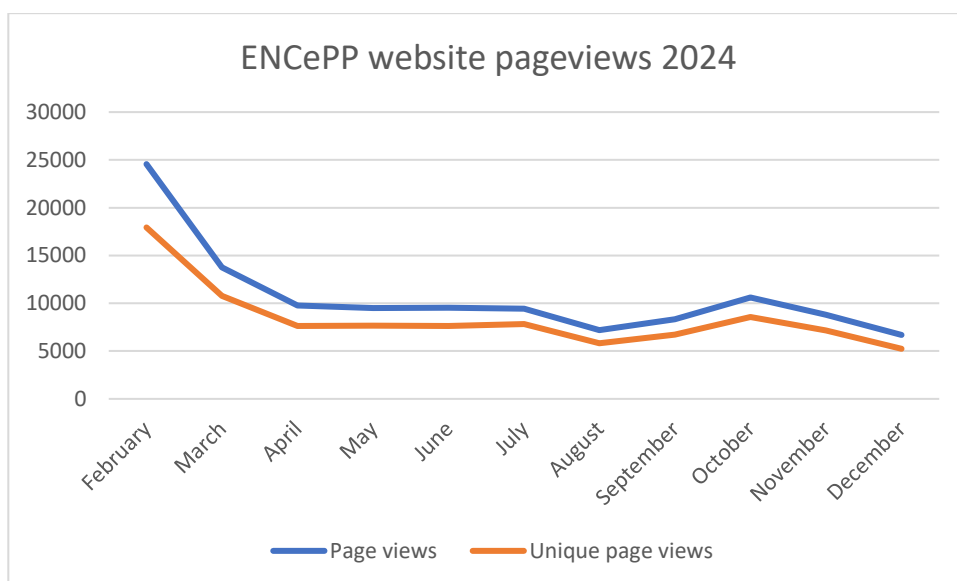
### 4.1. New website and logo

A new ENCePP website was launched with a new logo on 15 February, along with the [HMA-EMA Catalogues of real-world data sources and studies](#) (RWD Catalogues). The new website is more user-friendly in terms of structure and provides a built-in search function. At the time of the launch, all published content available in the ENCePP Resource Database and the EU PAS Register was migrated in parallel to the RWD Catalogues. As of the date of the migration, ENCePP stopped having supervision over the RWD Catalogues and their contents. All related queries should be submitted to the RWD Catalogues team at the EMA, via the online [contact form](#).

### 4.2. Website statistics

*As of 15 February 2025 (launch of the new ENCePP website)*

- Pageviews<sup>1</sup>: 118.185 (unique pageviews<sup>2</sup>: 92.985)



- Visitors: 43.070
- Top page visits

Page title	Page views	Unique page views
<a href="#">ENCePP homepage</a>	25353	18928
<a href="#">Methodological Guide (main page)</a>	7798	5735
<a href="#">ENCePP Checklist for Study Protocols</a>	3190	2665
<a href="#">Chapter 7: Effect modification and interaction</a>	3052	2683
<a href="#">News</a>	2646	2081
<a href="#">Publications</a>	2389	1878
<a href="#">Migration of the EU PAS Register and ENCePP Resource Database and launch of the new ENCePP website in early 2024</a>	2270	1197
<a href="#">Chapter 11: Signal detection methodology and application - European Union</a>	2210	1759
<a href="#">Chapter 6: Methods to address bias and confounding - European Union</a>	2089	1813
<a href="#">Documents</a>	1584	1268
<a href="#">Code of Conduct</a>	1579	1228
<a href="#">Launch of the HMA-EMA real-world data (RWD) catalogues and the new ENCePP website</a>	1407	1155
<a href="#">ENCePP toolkit</a>	1406	1045

<sup>1</sup> Pageview is the total number of views for one webpage. Repeated views of a single page by the same user are counted.  
<sup>2</sup> A unique page view represents the number of sessions during which that page was viewed one or multiple times.

- ENCePP Guide on Methodological Standards in Pharmacoepidemiology, top 10 chapters (by number of page views):

<b>Chapter</b>	<b>Page views</b>	<b>Unique page views</b>
Chapter 7: Effect modification and interaction	3052	2683
Chapter 11: Signal detection methodology and application	2210	1759
Chapter 6: Methods to address bias and confounding	2089	1813
Chapter 4: Study design	824	710
Chapter 2: Formulating the research question and objectives and assessing study feasibility	657	553
Chapter 3: Development of the study protocol	284	212
Chapter 12: Statistical analyses	278	236
Chapter 1: Introduction	249	202
Chapter 5: Definition and validation of drug exposure, outcomes and covariates	233	197
Annex 2. Guidance on methods for the evaluation of medicines in pregnancy and breastfeeding	223	185