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ENCePP Secretariat

European Network of Centres for  
Pharmacoepidemiology and  
Pharmacovigilance

## ENCePP Activity Report

January – December 2021

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# 1. Meetings and networking

## 1.1. ENCePP Steering Group (SG) meetings

The newly elected Steering Group started its work in January 2021.

There were three meetings organised on 18 January, 16 April and 15 June where the following **key topics** were discussed:

- Discussion and finalisation of the ENCePP mandate
- 9<sup>th</sup> Revision of the ENCePP Guide on Methodological Standards
- Reactivation of the Working Groups (WG) with renewed composition and recruitment
- Input in the discussions on rebuilding of catalogues (ENCEPP Resource Database, EU PAS Register)

The meeting reports of the SG meetings can be found [here](#).

## 1.2. ENCePP webinar for Academia

The aim of the [ENCEPP webinar](#) held on 8 March 2021 was to provide the opportunity for academic communities and learned societies to gain a better understanding of:

- What the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP) is;
- How ENCePP contributes to improving pharmaco-epidemiological research, particularly in a pandemic situation.

## 1.3. ENCePP Plenary webinar

On 18 November 2021 the ENCePP Secretariat organised a WebEx Plenary meeting for the representatives of the ENCePP network. Over 100 people attended the meeting, including SG members, EMA representatives and members of the ENCePP network.

The **key objectives** of the meeting were:

- To learn about key results from observational studies on COVID-19, methodological challenges that remain to be addressed, and how ENCePP could further promote best practice for COVID-19 research
- To present the recently finalised CHMP Guideline on registry-based studies
- To update on the work programme of the HMA-EMA Big Data Task Force and discuss the interface with ENCePP activities. Topics for discussion include the creation of curricula in Data Science, Pharmacoepidemiology and Biostatistics, an update on the Real-World Interrogation Network in the European Union (DARWIN EU) and the pilots for data analytics with EMA committees
- To discuss the result of the surveys and agree on the amendments needed for the metadata and functionalities of the new EU PAS Register and ENCePP Resources Database
- To exchange views on the activities of the ENCePP Steering Group and Working Groups (WGs), the renewal of the WGs, and the proposed new ENCePP activities (e.g. new SIGs)

The **key areas of focus** were presented by the ENCePP SG chairs:

- Strengthening the network
- Reactivating the Working Groups
- Access to data
  - Input in supporting the data discoverability and data quality recommendations of the HMA-EMA Big Data Steering Group
- High quality studies
  - Support the upgrade of the EU PAS Register
  - Support the provision of training curricula in pharmacoepidemiology
- Methods and governance
  - Developing and maintaining methodological standards and governance principles for research in pharmacoepidemiology and pharmacovigilance
  - Strengthening collaborations with existing ENCePP stakeholders and interact with new networks (DARWIN EU, coordinated registry networks,...)
  - Strengthen recommendations on analytic methods on multi-database studies
- New data sources and approaches
  - Ensure the network embraces field like artificial intelligence and pharmacogenomics

The Plenary meeting report along with the presentations have been published [here](#).

#### **1.4. ENCePP Working Groups**

The ENCePP SG agreed that the membership of the [ENCePP Working Groups](#) need to be reviewed, in order to be able to activate the work of the groups effectively. At the beginning of the year several SG members volunteered to join the WGs, and later, after the confirmation of the current members if they want to stay or leave, a call for expression of interest for WG2 was circulated to the ENCePP Partners (no expression of interest call for WG1 and WG3 due to the size of the groups).

The exercise was successfully closed by November and WG2 had their first introduction meeting with the new members.

## **2. Publication**

### **2.1. ENCePP Guide on Methodological Standards in Pharmacoepidemiology**

The [Guide on Methodological Standards in Pharmacoepidemiology](#) offers a single web resource for methodological guidance in pharmacoepidemiology. For each topic covered, direct electronic access is given to internationally agreed recommendations, and key points from important guidelines, published articles and textbooks are highlighted. Where relevant, gaps in existing guidance are addressed with what ENCePP considers good practice.

The **9<sup>th</sup> Revision** of the ENCePP Guide (published in July 2021) includes extensive amendments, new references in most of the chapters, and an improved structure.

The Foreword highlights the importance of the Guide in the context of the COVID-19 pandemic and vaccination campaigns. Nearly all chapters contain relevant guidance on methodological standards to

be used in COVID-19 studies, with references to selected publications illustrating relevant methodological aspects.

### 3. EU PAS Register and ENCePP website

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

The EMA is 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.

There were discussions with the ENCePP SG on how ENCePP could be best consulted in the requirement gathering for these new catalogues. As a result of the agreement the EMA:

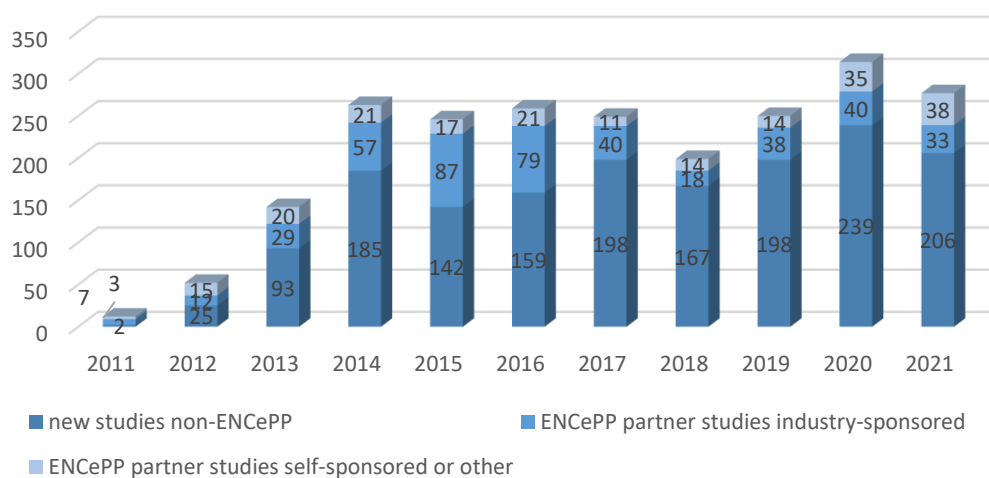
- Organised a meeting in July with WG1 and WG3 to discuss the main functionalities and metadata of the new catalogues;
- Circulated surveys to the ENCePP Partners to understand what improvement is needed to the current existing EU PAS Register and ENCePP resources database; get feedback on the usefulness and feasibility of some data elements proposed in the current 'metadata list' of the MINERVA project; and collect requirements related to functionalities and common use scenarios;
- Further clarified some relevant points with the ENCePP Partners during the November ENCePP Plenary meeting.

The group agreed during the ENCePP Plenary webinar on further discussions with the WGs in the beginning on 2022 (post-note: WG1-WG3 meeting was held on 7 January 2022).

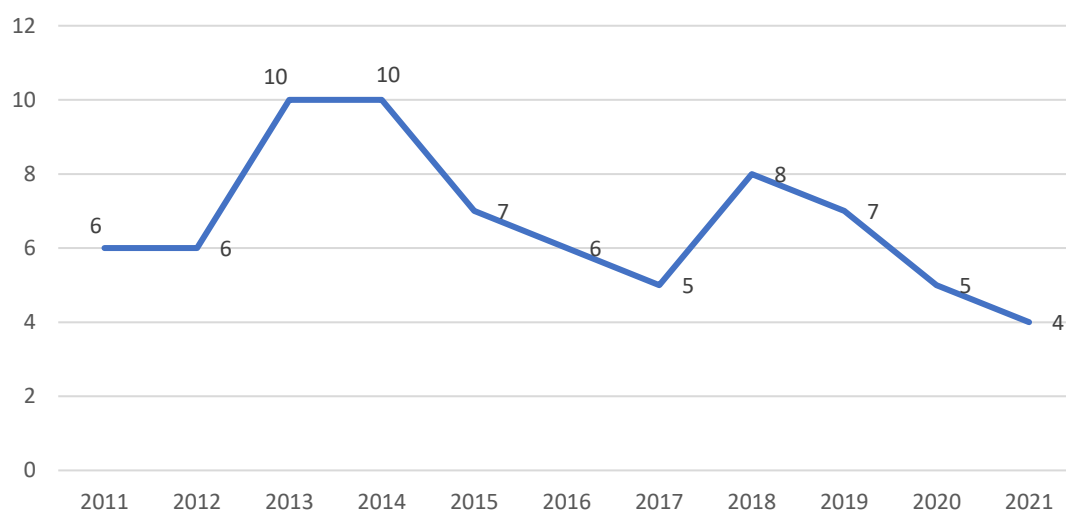
#### 3.2. EU PAS Register studies

Study	Total	New in 2021
All studies in the EU PAS Register	<b>2,282</b>	<b>277</b>
Studies Registered by ENCePP Partners	<b>685</b>	<b>71</b>
ENCePP Seal studies	<b>73</b>	<b>4</b>

## New studies registered



## ENCePP seal studies



### 3.3. ENCePP Resources Database

Resources database	Total number	New in 2021
Centres	<b>205</b>	<b>7</b>
Networks	<b>34</b>	<b>5</b>
Data sources	<b>160</b>	<b>8</b>

### **3.4. ENCePP website**

Due to faulty analytics tool, we are unable to provide statistics for 2021 on the ENCePP website, including the ENCePP Guide visits.

## **4. Ongoing everyday work**

- Handling of general ENCePP queries and, more specifically, queries related to EU PAS Register
- Discussions with IT on improvements and bugs fixing in the EU PAS Register
- 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 statistic (only for Q1 due to faulty analytics tool)