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ENCePP Secretariat

## ENCePP Activity Report

January - December 2020

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# 1. EMA BCP<sup>1</sup> and ENCePP activities

Following the Agency's BCP phase in connection with its relocation to the Netherlands, some of the usual activities of ENCePP have remained reduced due to the COVID-19 outbreak. The BCP restrictions included a temporary suspension of the activities of non-product related working parties and the development on some of the of guideline revisions, and ENCePP related activities requiring EMA organisational and meeting support.

Due to the COVID outbreak though, the ENCePP Steering Group started its discussions again in April, focusing on how the ENCePP SG could provide support during the COVID-19 pandemic in terms of scientific and methodological work. Discussions started on developing a mandate for ENCePP in the context of the pandemic.

The ENCePP secretariat also organised an ENCePP Plenary webinar titled '*ENCePP in the Time of COVID*', which was the first meeting since the Brexit-related EMA Business Continuity Plan had started in 2018. During the meeting the composition of the new ENCePP Steering Group was also announced.

## 2. Meetings and networking

### 2.1. Steering Group teleconferences

There were 2 informal meetings organised in 2020 by SG member Rosa Gini from Agenzia regionale di sanità della Toscana, followed by 4 formal discussions organised by the ENCePP Secretariat related to COVID-19. The key objective of the formal meetings was to discuss the mandate of ENCePP and the support to COVID-19 activities.

Outputs of the discussions in the context of COVID-19 activities:

- News item on the ENCePP website on registration of COVID-related studies
- Regular circulation of table of observational studies to ENCePP Partners, PRAC and researchers from March 2020
  - 224 studies included in the table until end of 2020
  - 67 studies registered in the EU PAS Register

#### 2.1.1. Election of the new Steering Group (2021-2023)

The last SG was operating for 4 years, as due to BCP there was no election taken place in 2019. The election in 2020 was held virtually. We received 9 applications and 67 ENCePP Partners took part in the election.

The composition of the new ENCePP Steering Group can be found [here](#).

### 2.2. ENCePP Plenary webinar

An ENCePP Plenary Webinar titled '*ENCePP in the Time of COVID*' was organised on 20 November 2020 as the first Plenary meeting since the BCP had started.

The objectives of the meeting were:

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<sup>1</sup> Business Continuity Plan

- To discuss key methodological considerations for observational studies on Covid-19 and how ENCePP could promote best practice, especially in the current context of preparedness for the monitoring of the safety and effectiveness of Covid-19 vaccines.
- To present the recommendations of the HMA-EMA Big Data Task Force and the proposed platform for a Data Analysis and Real-World Interrogation Network in the European Union (DARWIN EU), and discuss the interface between ENCePP activities and the Task Force recommendations.
- To summarise the achievements of the current ENCePP Steering Group at the end its term, introduce the members of the new ENCePP SG and discuss proposals for a draft ENCePP mandate.

The full report and the presentations of the meeting are available [here](#).

## 3. Publications

### 3.1. Article

Gini R, Sturkenboom MC, Sultana J, Cave A, Landi A, Pacurariu A, Roberto G, Schink T, Candore G, Slattery J, Trifirò G; Working Group 3 of ENCePP. [Different strategies to execute multi-database studies for medicines surveillance in real world setting: a reflection on the European model](#). Clin Pharmacol Ther. 2020 Apr 3. doi: 10.1002/cpt.1833

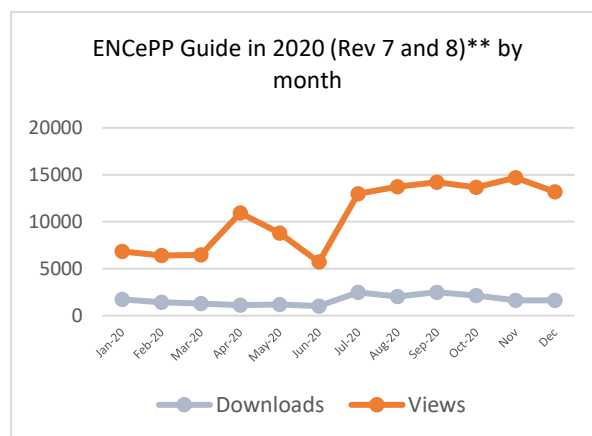
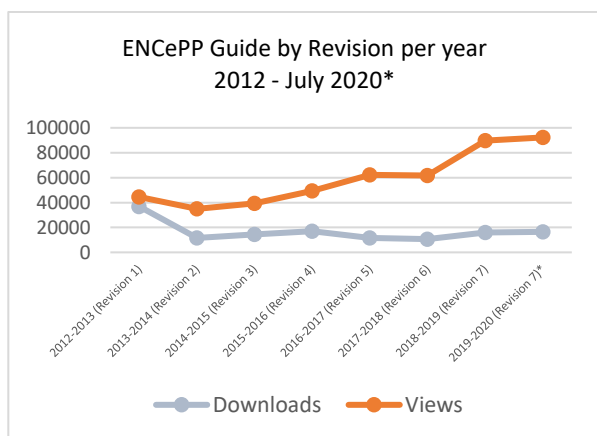
### 3.2. ENCePP Guide on Methodological Standards in Pharmacoepidemiology

The 8<sup>th</sup> revision of the ENCePP Guide was published in July 2020.

In the new revision a foreword highlights the importance of the Guide for pharmacoepidemiological studies carried-out in the context of the COVID-19 pandemic in order to provide valid results useful for clinicians and regulators.

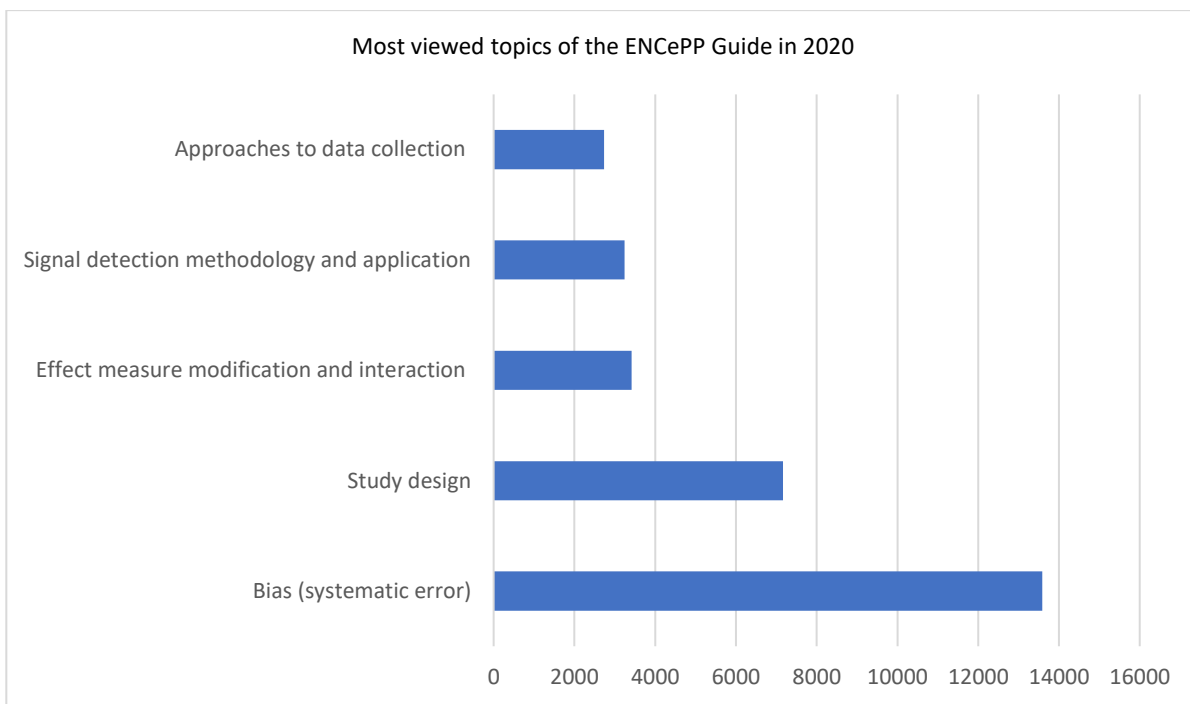
The Guideline is available [here](#).

#### 3.2.1. ENCePP Guide statistics



\*The first chart shows data from revision 1 to revision 7 per year, as full data for revision 8 will only be available after July 2021, once revision 9 has been published.

\*\*The second chart shows data for whole 2020 per month (Rev. 8 was published in July 2020).



## 4. EU PAS Register and ENCePP website

### 4.1. EU PAS Register upgrade in January 2020

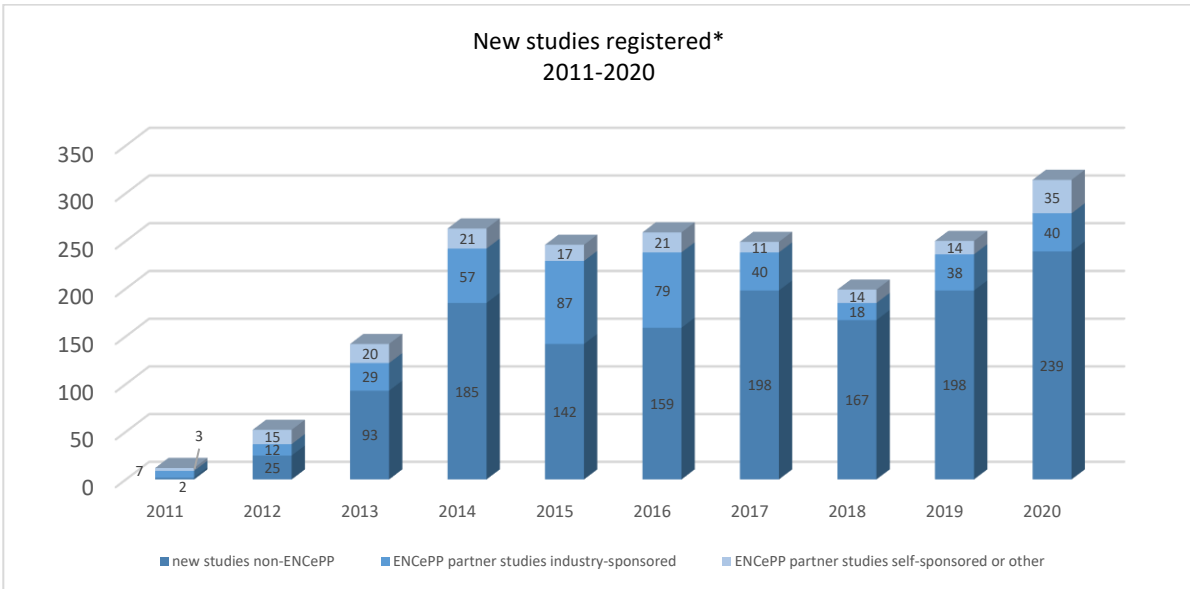
Functionality	Comment
<b>Date of first registration</b>	The date of first registration of a study in the EU PAS Register® is displayed on screen and printout
<b>Delayed protocol publication</b>	After protocol upload users may choose to make the protocol public only at the study end date, or immediately
<b>Search by country</b>	Allows searching for studies conducted in a specific country
<b>Search by (primary) lead investigator</b>	Allows searching for studies conducted by a specific (primary) lead investigator
<b>Regulatory procedure number</b>	New data field to facilitate compliance with regulatory requirements for RMP category 1 and 2 post-authorisation safety studies (PASS) and facilitate regulatory oversight
<b>Medical conditions studied</b>	New free text data field to provide medical conditions in addition to the maximum of ten conditions available from a drop-down list
<b>EU PAS Register® study number in search results</b>	The unique EU PAS Register® number instead of the (primary) lead investigator name is displayed for search results on screen

### 4.2. EU PAS Register statistics

Total number of studies published in the EU PAS Register: **2004**

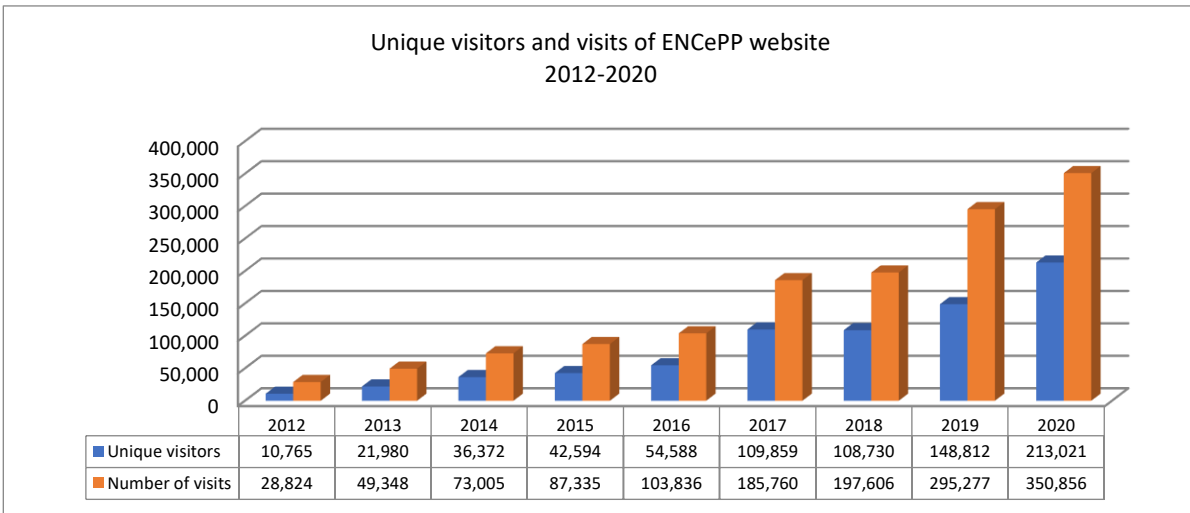
Studies registered in the EU PAS Register	2020
<b>All new studies</b> (ENCEPP partners + others)	315 (76 + 239)

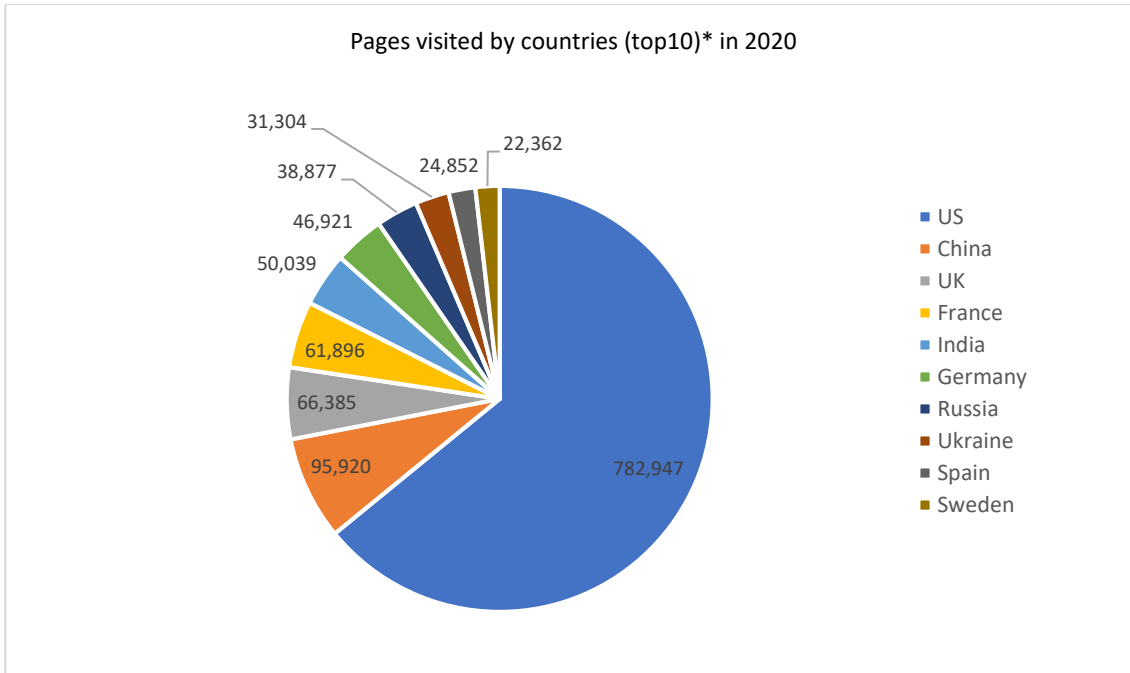
<b>Seal studies**</b>	3
<b>Covid-related studies</b>	67



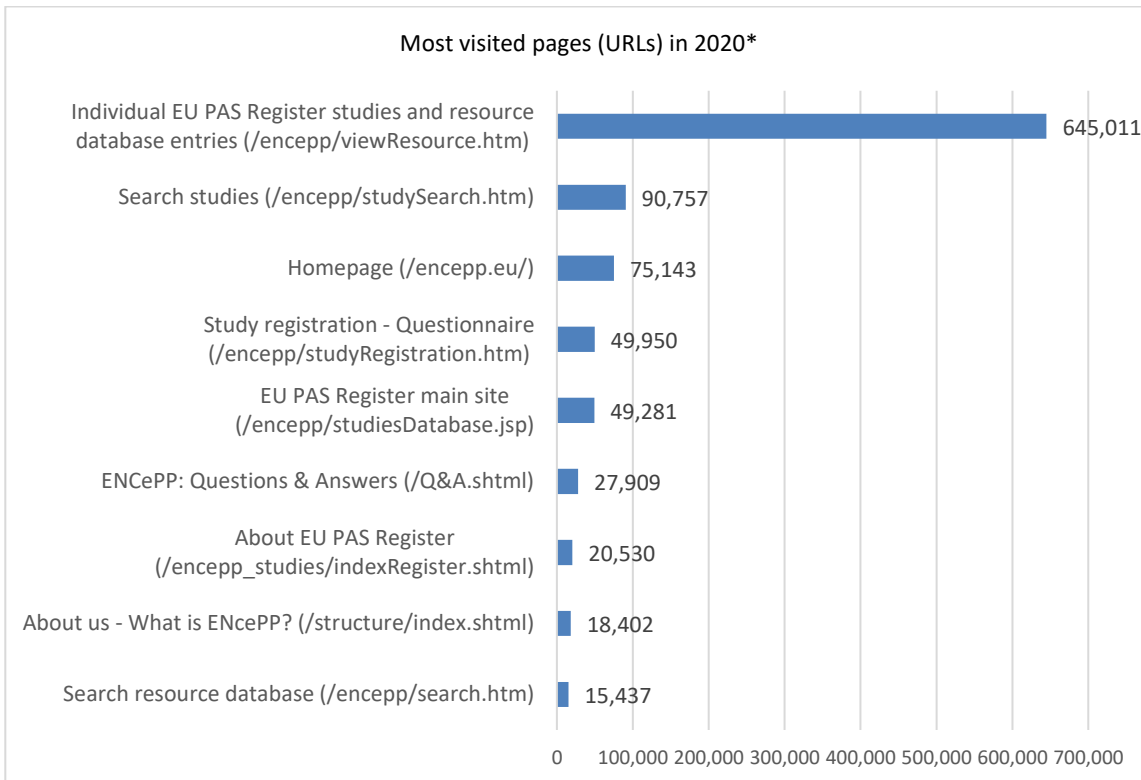
\*All new studies registered by ENCePP partners (divided into those funded partly or entirely by industry and those that are self-funded or funded by other sources) and new studies registered by others (e.g. industry, universities etc.).

**4.3. ENCePP website visits**





\* The count of pageviews is the total number of times the pages of the website were viewed or refreshed in a browser



\*Note: the different pages of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology altogether were viewed over 107,000 times. As these are on separate pages of the ENCePP website, the number is not listed in the above chart.