



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

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ENCePP Secretariat

ENCePP Activity Report

January – December 2019

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1. EMA BCP and ENCePP activities 2019

During 2019 ENCePP activities remained affected by measures of the Agency's BCP phase in connection with its move to the Netherlands. These included a temporary suspension of the activities of non-product related working parties and the development and revision of guidelines. This decision had a temporary impact on ENCePP related activities requiring EMA organisational and meeting support. This affected meetings and teleconferences of the ENCePP Plenary, its Steering Group, Working Groups and Special Interest Groups. ENCePP activities undertaken by partners and not requiring EMA organisational and meeting support were able to continue as before.

In view of these developments the ENCePP Steering Group had agreed an [action plan](#) for all ongoing and outstanding activities of the current ENCePP work plan which would allow a smooth continuation once EMA resumes its organisational support to ENCePP activities after BCP.

2. Achievements

2.1. Milestones

- Publication of the article "The ENCePP Code of Conduct: a best practice for scientific independence and transparency in non-interventional post-authorisation studies" in PDS (March 2019) <https://doi.org/10.1002/pds.4763>
- The 1,500th study was registered in the EU PAS Register (study EUPAS29415) in April 2019.

2.2. Meetings

ENCePP activities during 2019 continued to be affected by the European Medicines Agency's (EMA) Brexit preparedness business continuity plan (BCP) which entered into its third phase on 1 October 2018 and which had an impact on ENCePP related activities requiring EMA organisational and meeting support. Meetings and teleconferences of the ENCePP Steering Group, Working Groups and Special Interest Groups were affected. In lieu of the ENCePP Plenary meeting, the elected members of the ENCePP SG organised a webinar for ENCePP partners in March 2019 (see section 'Networking').

- Steering Group Meetings:
 - Informal TC meetings (organised by SG member Rosa Gini): 28/01/2019; 12/03/2019; 15/04/2019; 07/10/2019; 18/12/2019
- Working Group and Special Interest Group Meetings:
 - WG1 (TC: 04/10/2019 – kick-off meeting ENCePP Methods Guide 8th Revision)
 - WG2 (none)
 - WG3 (TC: 11/01/2019; 26/02/2019; 17/04/2019; 12/06/2019)
 - Joint ENCePP-EnprEMA WG (none)
 - SIG 'Pregnancy' (none)
 - SIG 'Impact' (none)

2.3. Networking

- Web meeting of ENCePP Plenary on 19/03/2019, organised by elected members of ENCePP Steering Group (including updates from working groups and SIGs); a [meeting report](#) has been published on the ENCePP website.

2.3.1. Presentations

- ISPOR 2019: *ENCEPP and EU PAS Register* (Massoud Toussi – 11 October 2019)

2.3.2. Meetings

- Meeting with ISPOR discussing a potential role of the EU PAS Register in the ISPOR transparency initiative, including online demo of EU PAS Register functionalities (24 July 2019) and follow up on business requirements.

2.3.3. Articles referencing ENCePP

Gini R, Fournie X, Dolk H, et al. The ENCePP Code of Conduct: A best practise for scientific independence and transparency in noninterventional postauthorisation studies. *Pharmacoepidemiol Drug Saf.* 2019;1–12. <https://doi.org/10.1002/pds.4763>

3. Other Activities

- Publication of ENCePP Activity Report 2018
- Regular contact with EMA IT regarding prioritisation of change requests relating to EU PAS Register and ENCePP Resources Database.
- WG1 review of changes in ENCePP resources database (to allow better classification and search of ENCePP Data Sources)
- Kick-off Revision 8 of [ENCEPP Guide on Methodological Standards in Pharmacoepidemiology](#)

4. Ongoing Work

- Handling of general ENCePP queries and, more specifically, queries related to EU PAS Register.
- Processing of submissions to ENCePP resources database and EU PAS Register.
- Maintenance of a list and statistics relating to ENCePP centres and EU PAS Register studies.
- Notification to 'All Human PhV' of PAS requested by regulators and registered in the EU PAS Register.
- EU PAS Register: compliance checks with transparency requirements for imposed PASS and ENCePP Seal studies.
- Preparation of monthly ENCePP website statistics.

5. Statistics

5.1. ENCePP Resources database

	2018	2019
Centres	176	183
Networks	24	26
Data Sources	134	141 ^{*)}
<i>Total Resources</i>	<i>334</i>	<i>350</i>

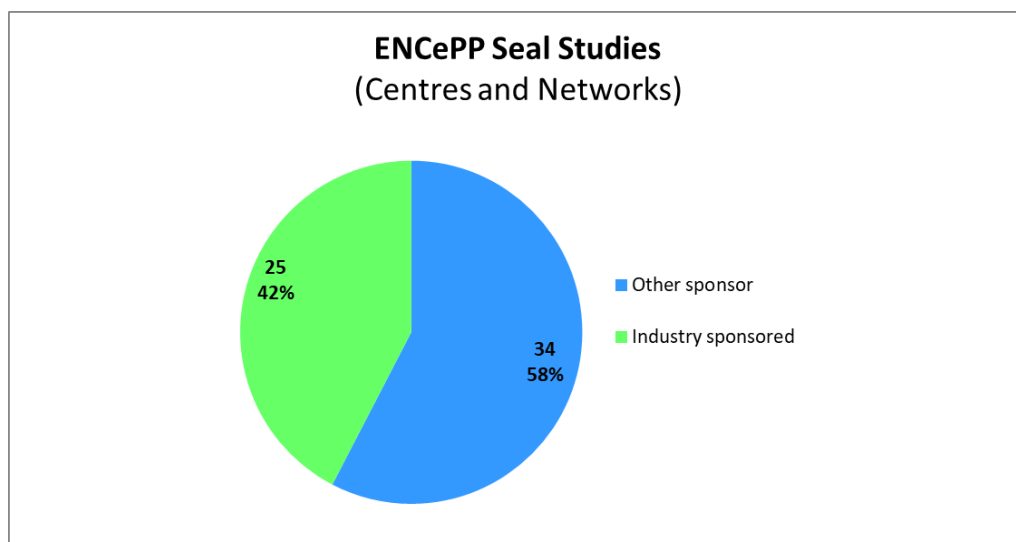
^{*)} increase is due to registration of patient registries in ENCePP database (initiated by EMA)

5.2. EU PAS Register

- ENCePP Seal Studies**

	2018	2019
ENCePP Seal Studies	54 ^{*)}	59

^{*)} total number of ENCePP Seal Studies registered by ENCePP Centres or ENCePP Networks



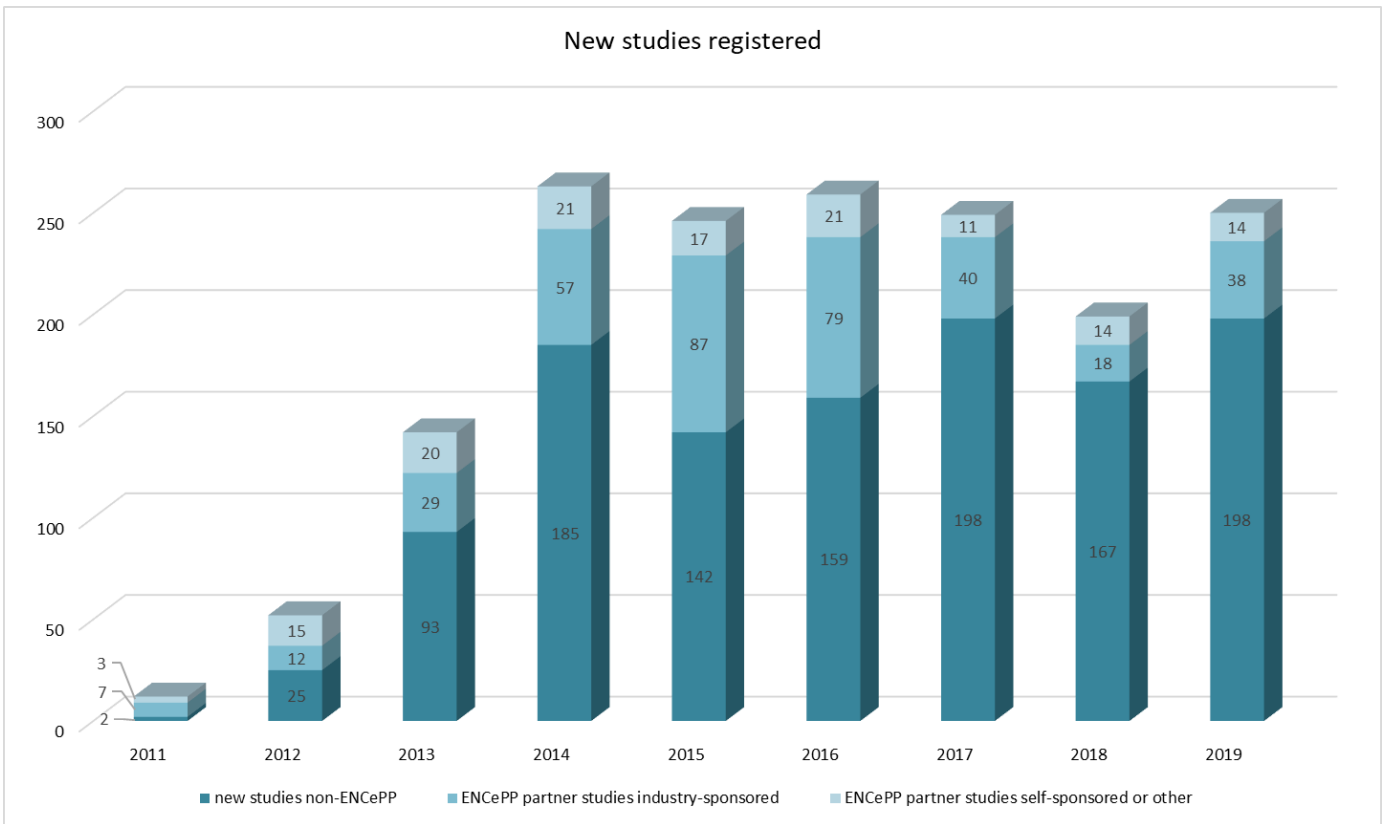
- Total studies registered**

	2018	2019	% change
Studies registered by ENCePP partners	451	503	+ 12%
- number of which are industry-sponsored studies	329	367	

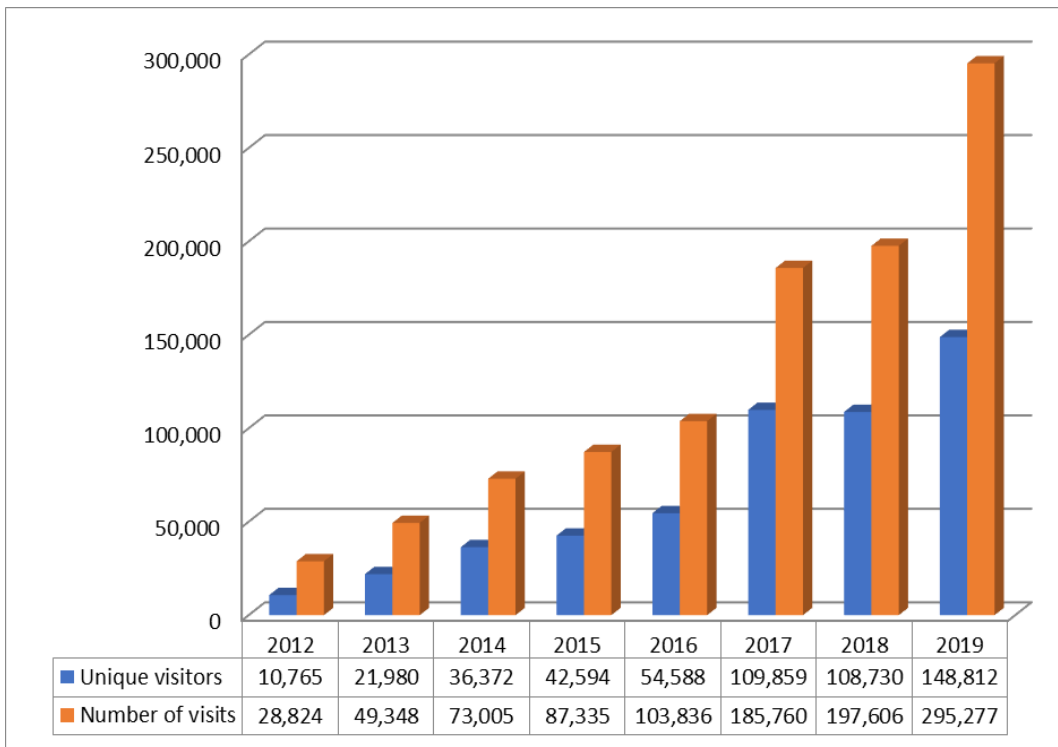
Studies registered by others	971	1169	+ 20%
<i>Total Studies registered</i>	<i>1422</i>	<i>1672</i>	<i>+ 18%</i>

- New studies registered**

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.).

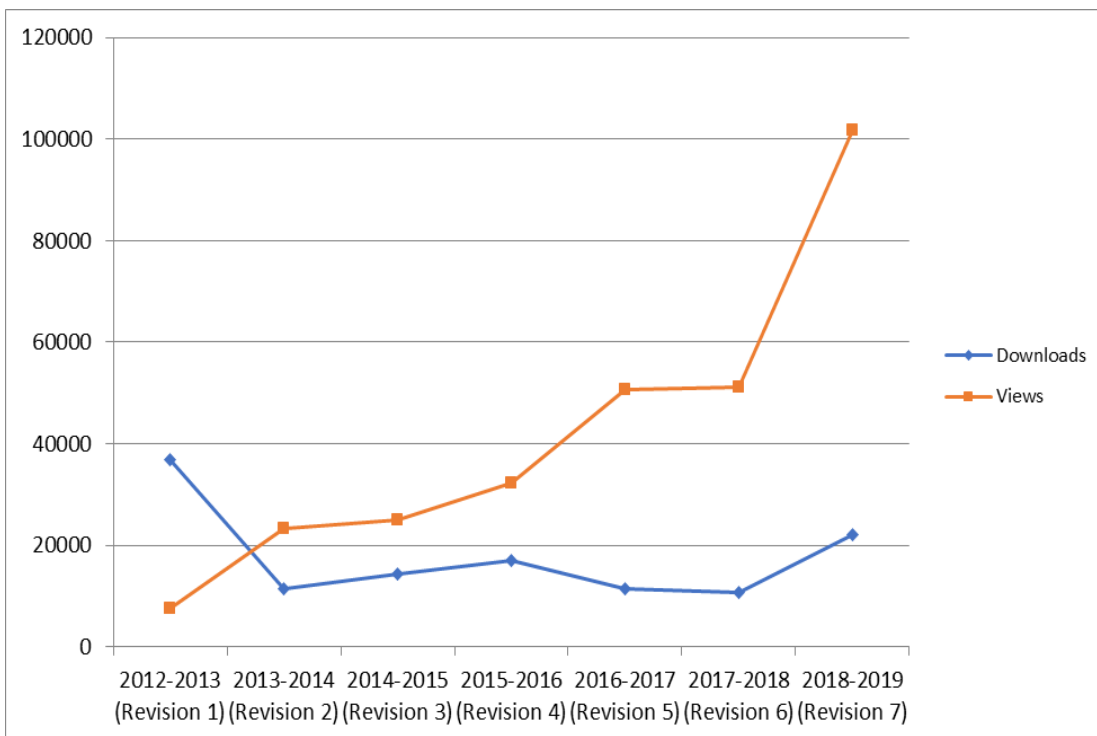


5.3. ENCePP website statistics



5.4. ENCePP Methods Guide statistics

- ENCePP Methods Guide – Downloads and Views by Version** (of note - no revision of the Guide took place in July 2019; hence the numbers relating to Revision 7 include downloads and views from July 2018 until December 2019, rather than only a twelve month period as is the case with other revisions)



- **ENCePP Methods Guide – top ten hits per chapter**

