



ENCePP Activity Report

January – December 2022

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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 \(EMA\)](#). The members of this network (the ENCePP partners) are public institutions and contract research organisations (CROs) involved in research in pharmacoepidemiology and pharmacovigilance.

The aim of this document is to provide a summary of the ENCePP activities performed in 2022.

2. ENCePP Steering Group

2.1. Mandate

The [ENCePP Steering Group](#) (SG) defines and safeguards the objectives and principles of ENCePP and decides on operational tasks of the network. The Steering Group is the highest authority of ENCePP and thus is its final decision making body.

The Steering Group mandate was updated with minor changes (e.g. the number of members and election process) and published on the website in June 2022:

<https://www.encepp.eu/structure/documents/ENCePPSGmandate.pdf>

2.2. Meetings

The ENCePP SG typically meets 2-3 times per year to discuss the key ongoing tasks and agree on future activities of the network. In 2022, three meetings were organised:

- 18 May: pre-SG virtual meeting for the elected members and EMA representatives, preparation of the September SG meeting
- 29 September: SG virtual meeting
- 29 November: SG hybrid meeting, preparation of the 30 November Plenary meeting

The following **key topics** were discussed:

- 10th Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology
- Rebuilding of the ENCePP catalogues (ENCePP Resource Database, EU PAS Register)
- Upgrade of the ENCePP website
- Updates from the [Working Groups](#) chairs
- ENCePP plans on visibility and external interactions
- ENCePP work plan for 2023

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

3. ENCePP Plenary hybrid meeting

After several years of virtual meetings, the EMA organised its first ENCePP Plenary hybrid meeting, which was held at the EMA's premises in Amsterdam. About 70 ENCePP network representatives joined the meeting via Webex, and 30 SG, WG and EMA representatives attended the Plenary in person.

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

- To present and discuss the activities of the ENCePP Steering Group and Working Groups and exchange ideas to populate the ENCePP workplan for 2023 and beyond;
- To update and seek input from ENCePP partners on upcoming developments including the new ENCePP website and the upgrading of the EU PAS Register and ENCePP Resources Database catalogues into the new RWD sources and RWD studies catalogues;
- To exchange views on the future of ENCePP and how to improve visibility, enhance collaborations with learned societies, and consider current and future guidance initiatives in the ENCePP work plan;
- To inform the ENCePP community about latest developments on COVID-19 and monkeypox vaccines and therapeutics and the contribution of pharmacoepidemiology to EMA's decision-making;
- To update on DARWIN EU® and discuss the interface with ENCePP activities;
- To learn about, and discuss, current methodological hot topics.

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

4. Publications

4.1. ENCePP Guide on Methodological Standards in Pharmacoepidemiology

The [Guide on Methodological Standards in Pharmacoepidemiology](#) offers a single web resource for methodological guidance in pharmacoepidemiology.

The **10th Revision** of the Guide was published on 30 June 2022. It includes two new chapters on the use of artificial intelligence in pharmacoepidemiology (Chapter 15.5) and on real-world evidence and pharmacoepidemiology (15.6), and a new comprehensive Annex 2 on Methods for the evaluation of medicines in pregnancy and breastfeeding. Besides the updating of nearly all existing chapters, including considerations on methodological standards for COVID-19 studies, two chapters have been extensively revised: Comparative effectiveness research (15.1) and Vaccine research (15.2). Recommendations on the use of statistical significance for the interpretation of evidence have been added in the Overview of study designs (4.1). The Foreword from the co-chairs of the ENCePP Steering Group highlights the continued involvement of ENCePP in sound pharmacoepidemiological research, including into COVID-19, and real-world evidence studies. This 10th Revision of the Guide provides a useful resource for researchers, regulators, marketing authorisation holders and applicants.

4.2. Publications led by ENCePP WG3

- [Overview of the European post-authorisation study register post-authorization studies performed in Europe from September 2010 to December 2018](#) (Pharmacoepidemiol Drug Saf. 2022 Jun;31(6):689-705).

Background: The European post-authorisation study (EU PAS) register is a repository launched in 2010 by the European Medicines Agency (EMA). All EMA-requested PAS, commonly observational studies, must be recorded in this register. Multi-database studies (MDS) leveraging secondary data have become an important strategy to conduct PAS in recent years, as reflected by the type of studies registered in the EU PAS Register. The objective of this publication was to analyse and describe PAS in the EU PAS register, with focus on MDS.

- [A Landscape Analysis of Post-Marketing Studies Registered in the EU PAS Register and ClinicalTrials.gov Focusing on Pregnancy Outcomes or Breastfeeding Effects: A Contribution from the ConcePTION Project](#) (Drug Saf. 2022; 45(4): 333–344)

Background: A large proportion of medicine product labels lack information on safety in pregnancy and breastfeeding. To address this gap, pharmaceutical companies are requested to develop post-approval studies regarding the use of drugs by pregnant and breastfeeding women. The objective of the study aims to review key features of observational studies in pregnancy and breastfeeding and their impact on the respective medicine product labels.

5. Projects

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

The EMA has been 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.

The last update on the project can be found in the presentation on the [Update on the RWD sources and RWD studies catalogues](#), as presented in the ENCePP Plenary 2022 meeting.

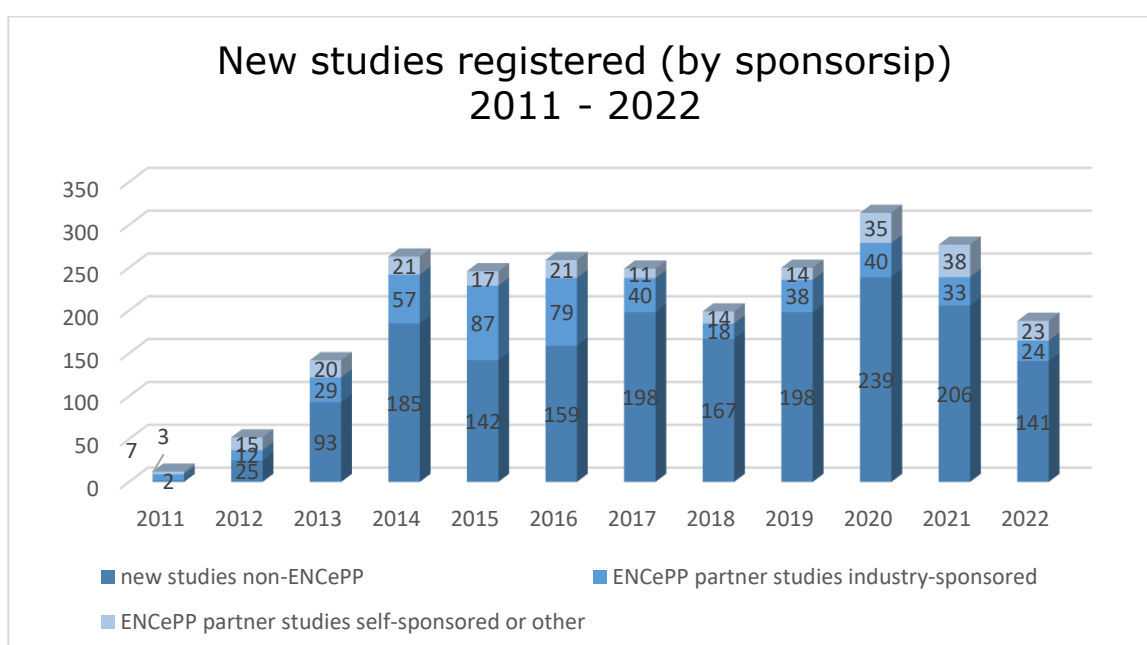
5.2. ENCePP website update

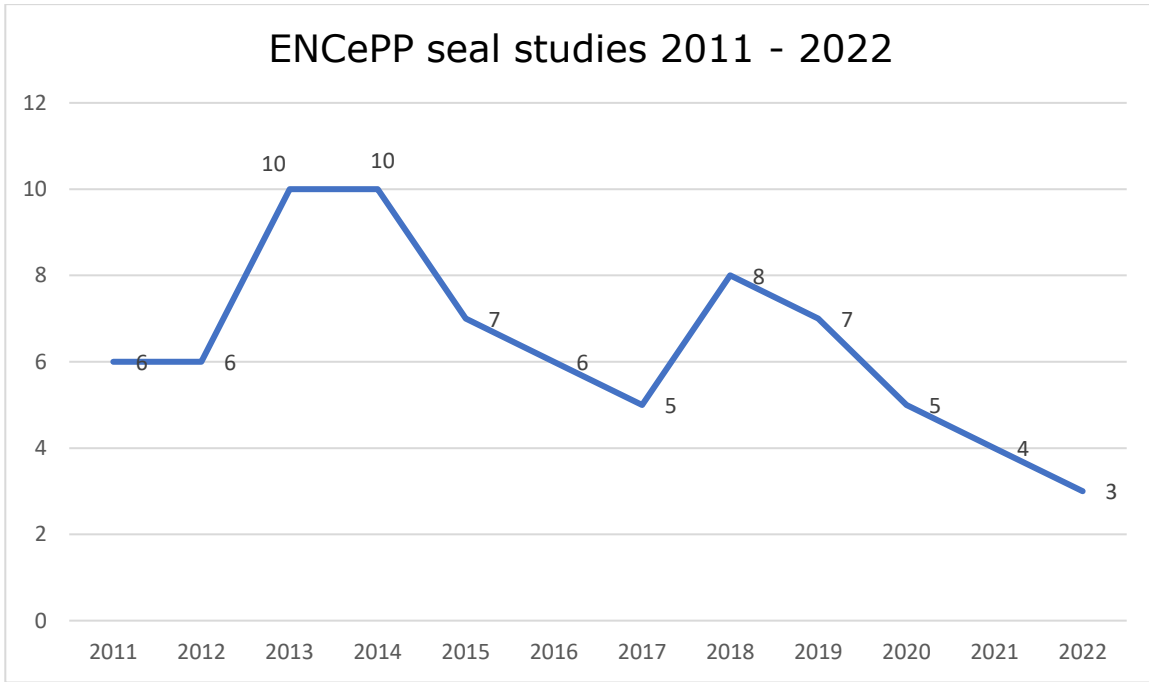
The current ENCePP website was built over 10 years ago at the inception of ENCePP. As technologies and needs from the pharmacoepidemiology community have improved/increased significantly since the launch of the website, it is necessary to improve and upgrade the current site in the near future. The plan is to deliver the new website in 2023/24 (TBC).

The last update of this project can be found in the [ENCePP website update](#) slides, as presented in the ENCePP Plenary 2022 meeting.

6. EU PAS Register studies

Study	Total	New in 2022
ALL studies in the EU PAS Register (registered by ENCePP Partners and others)	2,497	188
Studies Registered by ENCePP Partners	732	47
ENCePP Seal studies	77	3



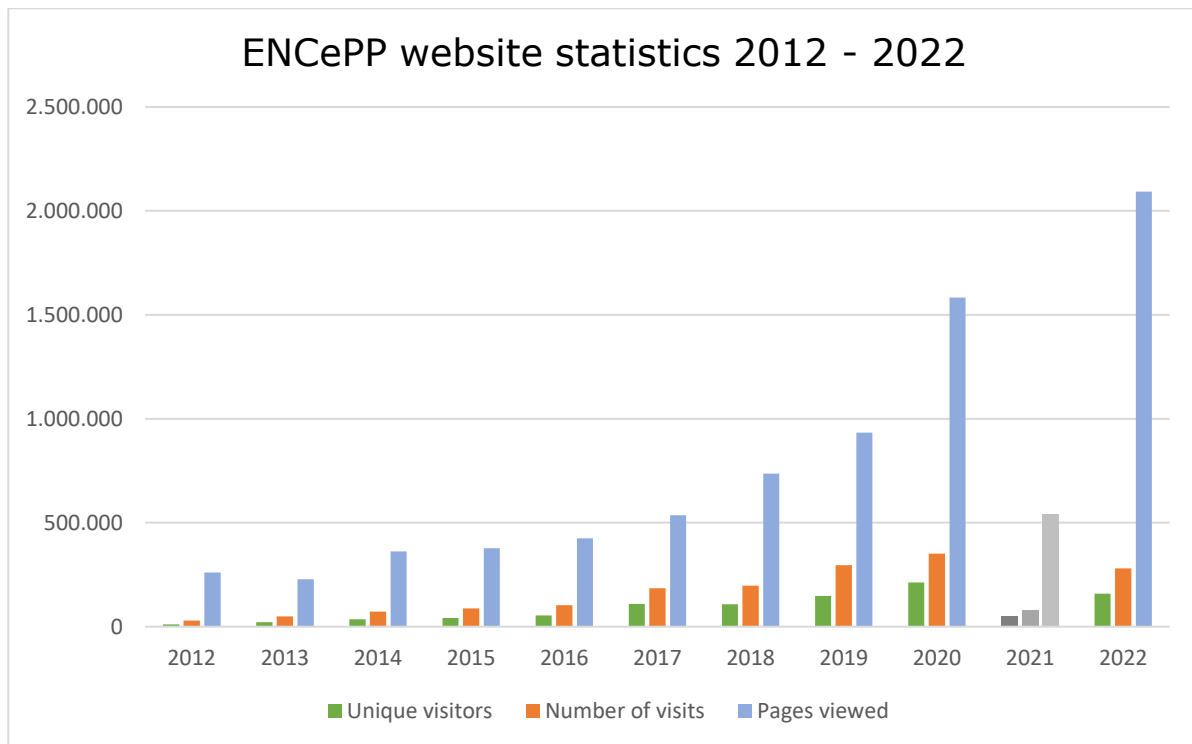


7. ENCePP Resources Database

Resources database	Total number	New in 2022
Centres	209	6
Networks	35	1
Data sources	165	7

8. ENCePP website and ENCePP Guide statistics

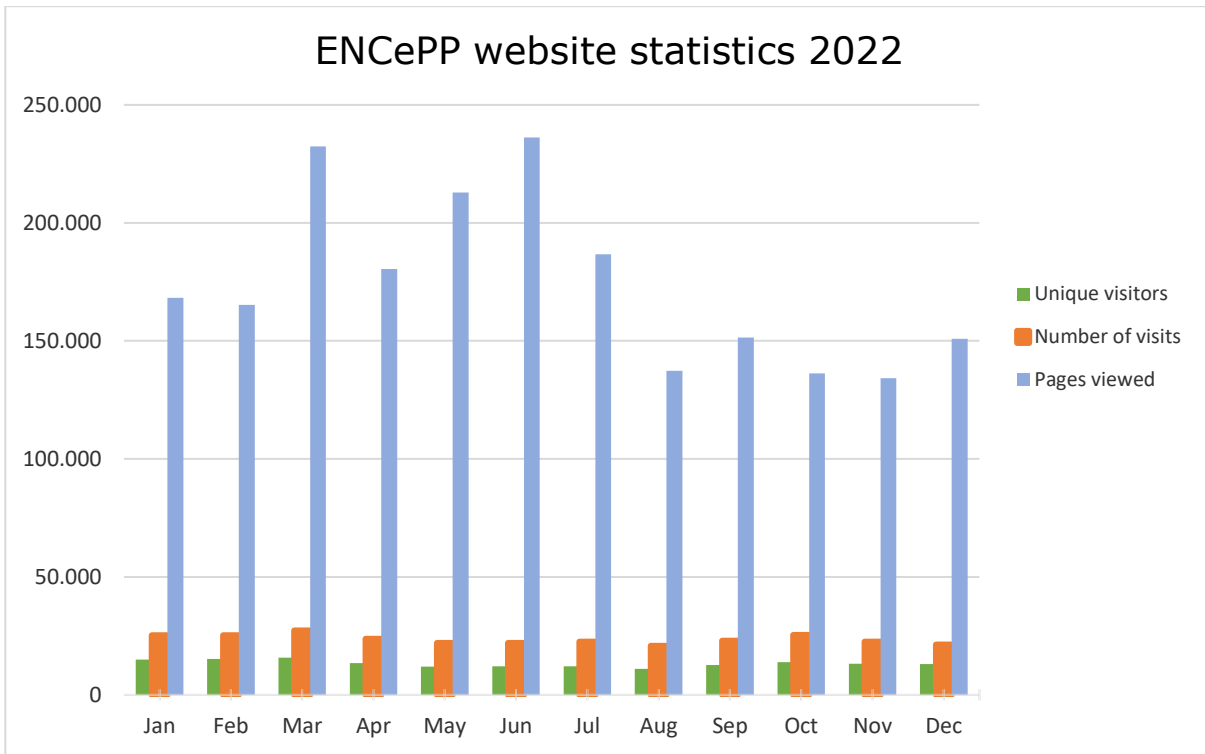
8.1. Website statistics



Month	Unique visitors	Number of visits	Pages viewed
2012	10.765	28.824	260.571
2013	21.980	49.348	228.337
2014	36.372	73.005	362.310
2015	42.594	87.335	377.110
2016	54.588	103.836	426.009
2017	109.859	185.760	535.610
2018	108.730	197.606	736.053
2019	148.812	295.277	933.826
2020	213.021	350.856	1.583.539
2021	48.682	79.911	542.962
2022	159.217	281.113	2.092.424

Notes:

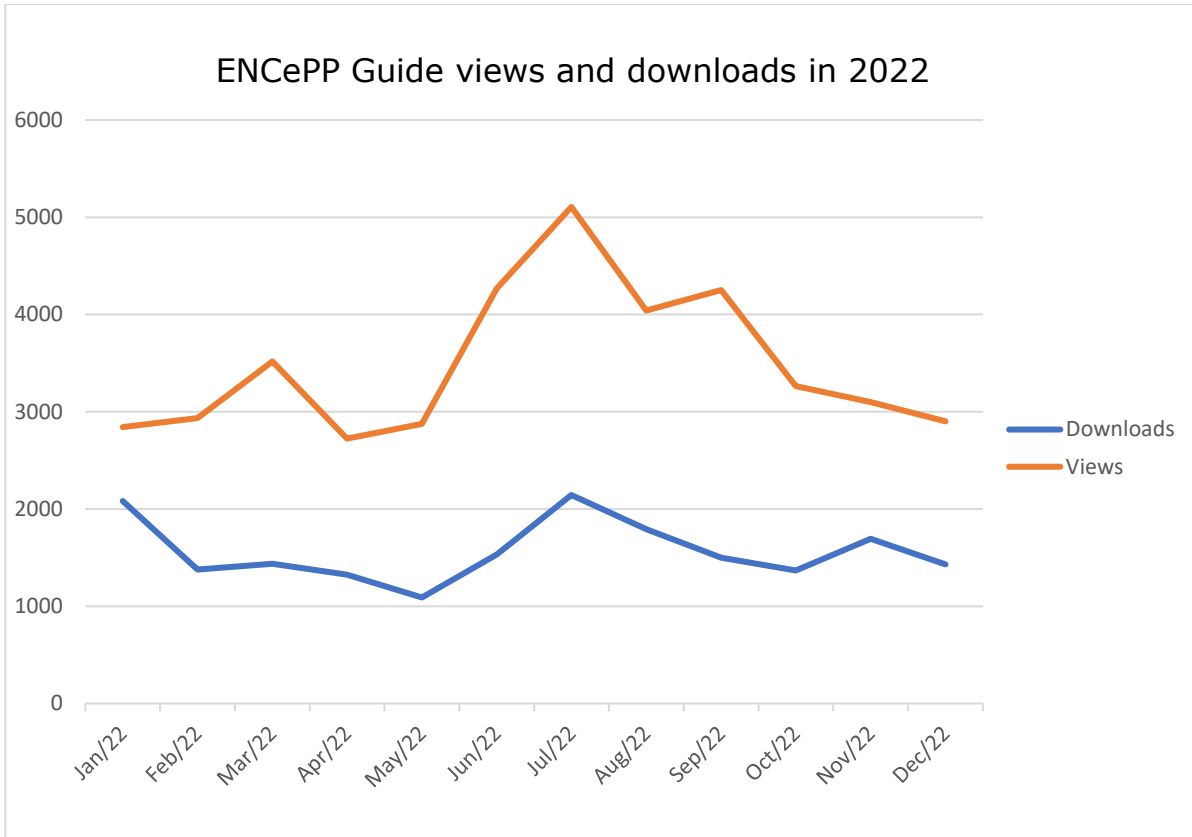
- There was no data available between April to November 2021, due to faulty analytics tools;
- *Unique Visitors* are the number of people that visited the site over the selected time period; a person visiting the site multiple times during the time period is only counted once;
- *Pageview* is recorded whenever a full page of the website is viewed or refreshed. The count of pageviews is the total number of times the pages of the website were viewed or refreshed within the selected time period;
- A *Visit* is a single browsing session. If a visitor views another page on the site within 30 minutes of the last pageview, it is counted as the same visit. If a visitor returns to the site after 30 minutes have passed since the last pageview, it is counted as separate visit.



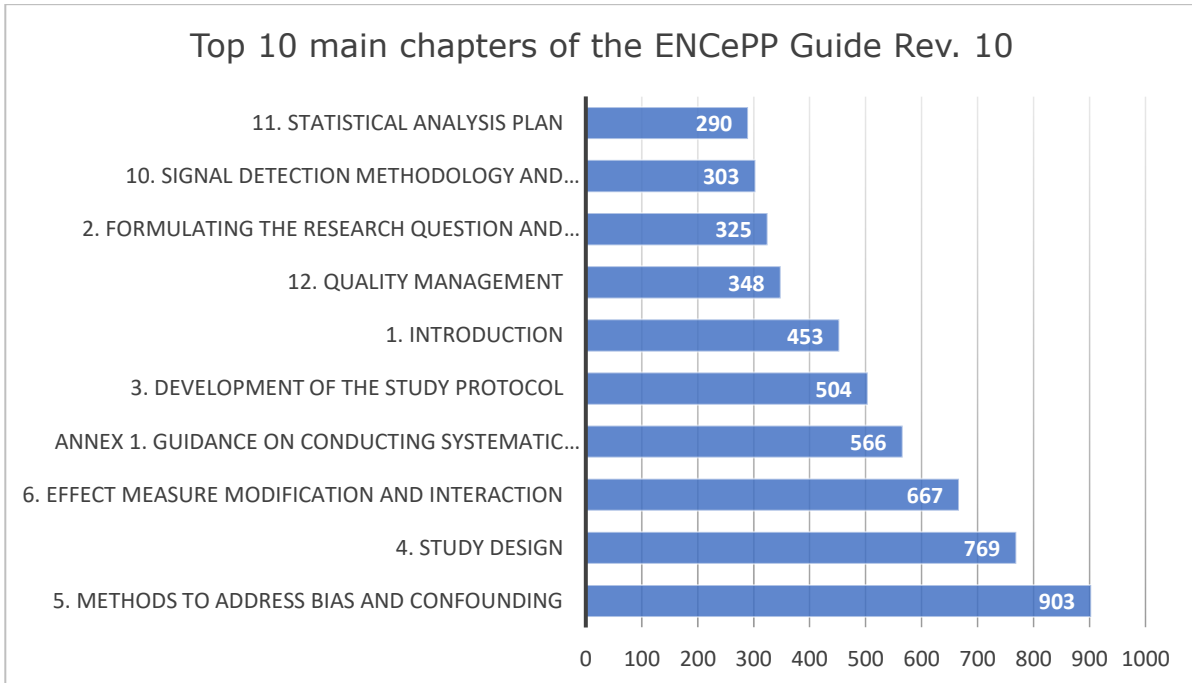
Month	Unique visitors	Number of visits	Pages viewed
Jan	14.920	25.256	168.239
Feb	15.190	25.230	165.308
Mar	15.702	27.288	232.458
Apr	13.475	23.785	180.435
May	11.920	21.952	212.930
Jun	12.038	22.003	236.240
Jul	12.130	22.588	186.725
Aug	11.053	20.787	137.344
Sep	12.655	23.004	151.472
Oct	13.862	25.334	136.267
Nov	13.184	22.558	134.173
Dec	13.088	21.328	150.833

8.2. ENCePP Guide statistics

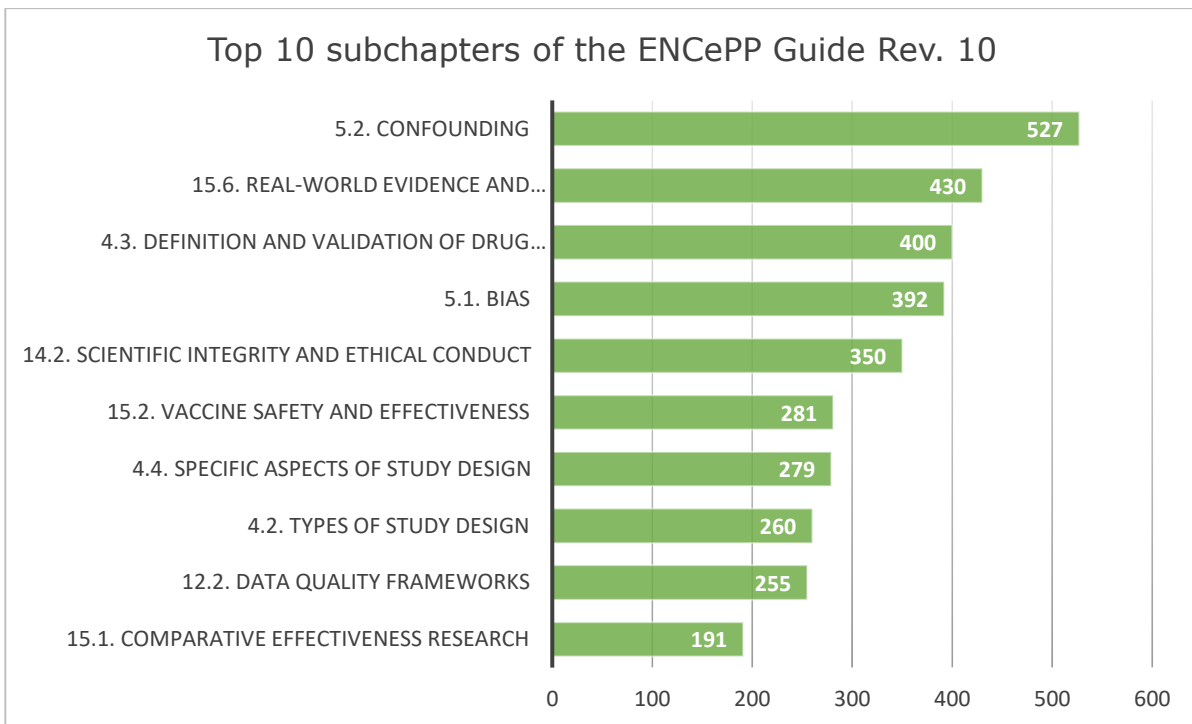
The highest peak of the views and downloads of the Guide was in July, associated with the publication of the 10th revision of the Guide on 30 June:



Top 10 visits of **main chapters** of the **10th revision** in 2022 (from 1 July to 31 December 2022):



Top 10 visits of **subchapters** of the **10th revision** in 2022 (from 1 July to 31 December 2022):



9. Day-to-day work

- Addressing ENCePP and EU PAS Register related queries
- Discussions with IT on improvements and solutions for fixing bugs in the EU PAS Register system
- 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 statistics
- Regular updates between the SG co-chairs