Utrecht University

European Network of Centres for Pharmacoepidemiology

Investigating the role and impact of ENCePP in an evolving Real-World Data landscape – a qualitative study

Supplementary Material

Author:	Sharanya Rao (6549241)
Project:	MSc Drug Innovation, Major Research Internship
Department:	Pharmacoepidemiology and Clinical Pharmacology, Faculty of Science, Utrecht University, The Netherlands
First Examiner:	Prof. Dr. Helga Gardarsdottir
Second Examiner:	Prof. Dr. Olaf Klungel
Date:	06.01.2025

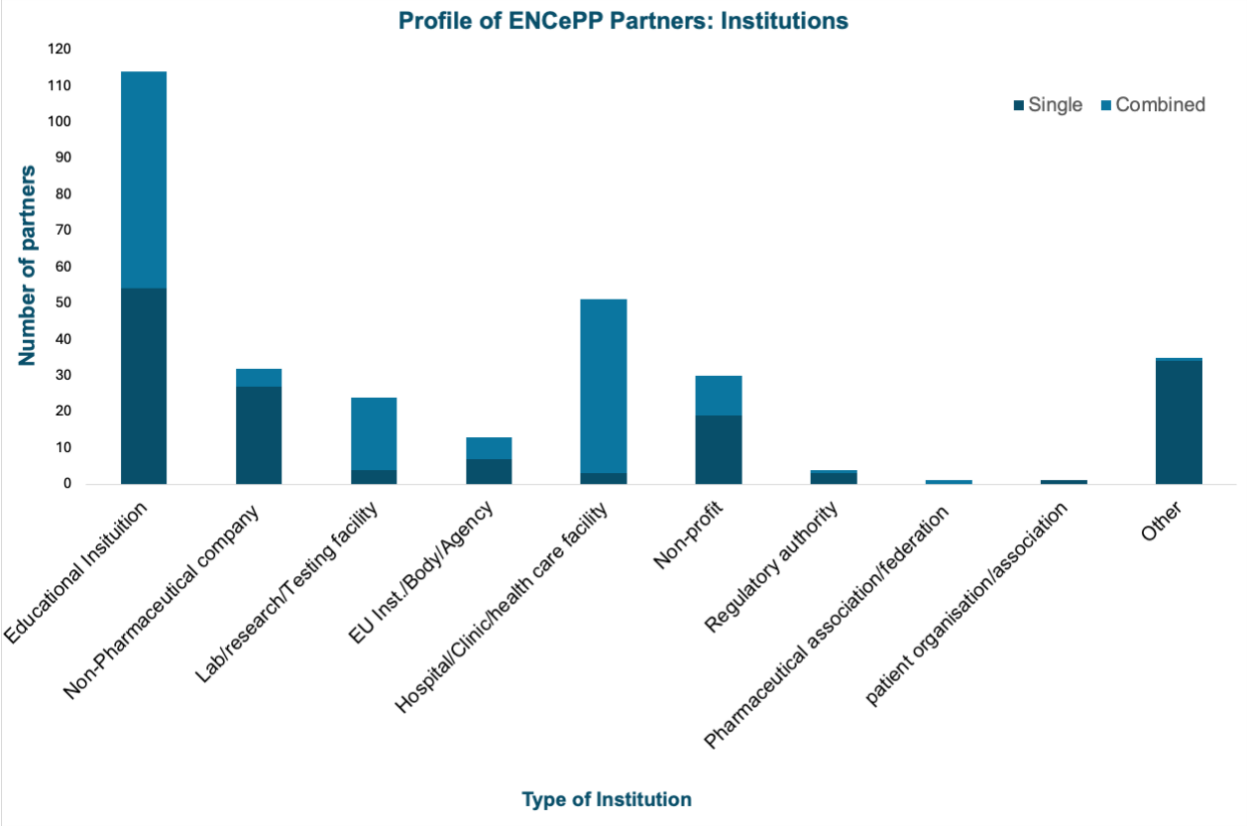
Table of Contents

1. ENCePP Partner Profile

A search for ENCePP Partners revealed 226 institutions and 36 networks as registered in HMA-EMA Catalogues. An analysis of the descriptions of the institutions led to the following categories -

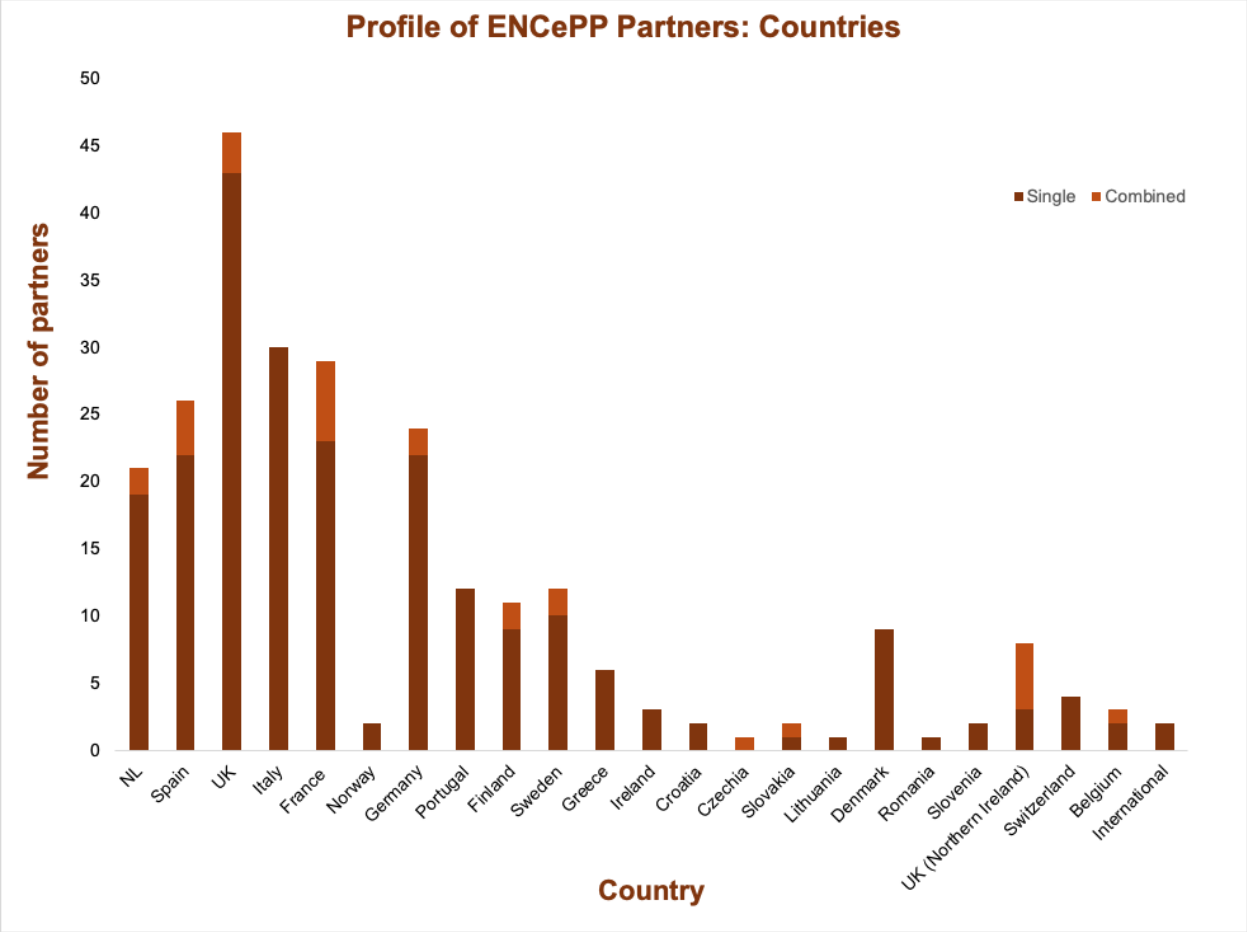
1. Educational institutions
2. Non-pharmaceutical companies
3. Laboratory/Research/Testing facility
4. EU Institution/Body/Agency
5. Hospital/Clinic/Other healthcare facility
6. Not-for-profit institutions
7. Regulatory authorities
8. Pharmaceutical association/federation
9. Patient organization/association
10. Other

Of these, the main ones were Educational Institutions, Non-pharmaceutical companies, Hospital/Clinic/Other healthcare facilities (though these were mainly in combination with educational institutions), and laboratory/research/testing facilities. An overview can be seen below:



The highest number of partners (114 in total) are educational institutions. Of these, 60 have mixed roles, for example as an educational institution as well as a healthcare facility. An investigation into the

spread of partners across countries was also conducted. It is important to note that ENCePP also has partners that are networks and not institutions. These are fewer in number and include collaborations across several different countries. Therefore, for this analysis I only looked at institutions. An overview of the countries that have institutions that are ENCePP partners can be seen below.



A differentiation was made for the countries as well as to how many times it appeared on its own vs in combination with other countries. The highest number of partners was found to come from the UK, followed by Italy, France, Spain, Germany, and then the Netherlands. There were also two international collaborations, which included the United States, Thailand, Colombia, and South Africa.

2. Interview Package

2.1 Interview Guide

Topic	***Question***
Introduction to interview	Prior to the interview, informed consent form has been signed for participation in the study, recording and transcription of interviews, and use of anonymized quotes in the report. ○ Introduction to researchers and scope of study, space for questions from the interviewee for researcher. ○ *"We are conducting a qualitative study to investigate the role and impact of ENCePP in an evolving Real World Data landscape. So we are speaking to representatives from different institutions active in the PE and PV field to gain an understanding of how they view and use ENCePP. "* ○ *"Do you have any questions before we begin?"*
Background	1. What is your experience with non-interventional studies using Real World Data?
Knowledge and familiarity with ENCePP	2. How familiar are you with ENCePP? a. What do you know about it? b. How involved are you with it?
Use of ENCePP tools	3. How familiar are you with the tools developed by ENCePP? a. How do / could you implement them in your work? *In case they are unfamiliar, provide a short description of each tool. Note: EU PAS Register is moved to HMA-EMA Catalogues since Feb 2024 and is no longer under ENCePP's remit.*
Experience of ENCePP	4. What benefit do you get from ENCePP? 5. What would improve your experience with ENCePP? [*how can the existing network/tools be improved?*] a. Is there something you lack in your relationship with ENCePP? [*are there additional tools/resources that could be developed?*]
Role of ENCePP today	6. What do you see as the key role of ENCePP today? [*personally, or from the perspective of their institution, or in general*]
Future of ENCePP	7. Where do you see ENCePP 5-10 years from now? 8. Considering the increasing use of Real World Data in studies, how would you see ENCePP contributing to these developments?
Closing	9. Is there anything else you would like to add? *Thank you for your time and for sharing your thoughts with me.*

2.2 Invitational Letter

Dear [*interviewee*],

My name is Shar Rao, and I am a Master's student at Utrecht University. I am conducting a research study on the role and impact of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), under the supervision of Prof. Dr. Helga Gardarsdottir. This will be a qualitative research study and will include interviews with stakeholders across Europe.

We are reaching out to you to ask if you are interested in participating in an interview yourself, or if you can refer us to someone else within your organization who might be. The interview will take a maximum of 45 minutes, through which we would like to understand your opinions of and experiences with ENCePP. The interviews will be anonymously analysed, and no interview recordings or transcripts will be shared outside of those involved directly with the project. All data will be stored at the UU under the responsibility of the UU Data Manager.

The information you provide will give us a deeper understanding of the current and future standing of ENCePP, and help us define a path forward for the network. Ultimately, the results of the study will provide the EMA and European policymakers with important knowledge to evaluate current pharmacovigilance policies and research methodologies through the platform provided by ENCePP. Your input would therefore be highly appreciated!

If you (or someone you know) would be willing to participate in this study, please fill out this form by [*2 weeks from date of invite*] **–**

https://survey.uu.nl/jfe/form/SV_8uABVo0DuQq0dgO

I look forward to hearing back from you, and hopefully speaking with you in the near future!

Kind regards,
Shar Rao

2.3 Consent form

The following text is the informed consent form. Please read through the form and if you consent, sign off with your name and the date of signing at the bottom of this page.

Dear participant,

Purpose of the research
You have been invited to take part in an interview series conducted by the Utrecht University on behalf of the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP), on further behalf of the European Medicines Agency (EMA). It is important that you understand why we conduct this research and what it entails. Please carefully read the information outlined in this document and ask questions if something is

unclear or if you would like to receive more information.

The aim of the study is to arrive at an overview of the current and future role of ENCePP in a Real world data (RWD) and Evidence (RWE) landscape, consideration the recent developments in how RWD and RWE are used for regulatory decision making. The study aims to uncover the benefit the network provides to its partners, while also understanding areas for improvement or ways to increase its relevance in a fast-evolving environment. We aim to do this not only at an EU-level, but also at a global level. By speaking to stakeholders at varying degrees of involvement with ENCePP, we also hope to gain an insight into the challenges faced by the network to stay relevant and adaptable to the changing environment.

Procedure and data protection

The interview will take approximately forty-five minutes and will take place via teleconference using Microsoft Teams. The interview will be audio-recorded. The recording will be stored at an encrypted server of the Utrecht University. The audio-file will be transcribed verbatim and pseudonymized after transcription. The pseudonymized file will not contain direct personal identifiers (e.g., name, company names), and will only be available to the Utrecht University research team. Other researchers may request access to aggregated (summarized and pseudonymized) information, which may be provided only if the confidentiality of the information can be maintained. Dissemination of research findings through publicly available scientific articles or website items will be anonymized (i.e., these files will not include company names, personal names, product names or information that could reasonably identify individuals). Note, however, that quotations may be used to contextualize findings. However, these quotations will not be traceable to individual participants.

Voluntary participation

Your participation is highly appreciated. Participation to this research project is voluntarily and you are free to withdraw at all times, also after consenting to participate. You are free to withdrawn without consequences or providing a reason. Withdrawal of informed consent may not affect analyzed data on the basis of the provided informed consent before withdrawal.

Consent

I understand the information outlined in this form. I understand that my participation is voluntary, and I consent to the processing of the data I provide as a part of this study in the manner in described above.

Name: _____

Date (dd/mm/yyyy): _____

3. Survey Questions

Page 1: Introduction to survey

Thank you for your interest in participating! This survey is part of a larger qualitative research study investigating the role and impact of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). The study, and the survey, are conducted by Shar Rao, Master's student at Utrecht University (UU), under the supervision of Prof. Dr. Helga Gardarsdottir.

The survey contains several questions regarding your use of, and experience with, ENCePP. It should take approximately 10-15 minutes to complete. All answers will be anonymous, and data will be stored at the UU under the responsibility of the UU Data Manager.

The questions cover ENCePP in general, and the ENCePP tools (Code of Conduct, Seal, Checklist for Study Protocols, and the Guide on Methodological Standards in Pharmacoepidemiology)*. The information you provide will give us a deeper understanding of the current and future standing of ENCePP, and help us define a path forward for the network. Ultimately, the results of the survey will help guide ENCePP in its mission to bring together capacity and expertise in pharmacoepidemiology and pharmacovigilance research across Europe, and develop methodological standards and governance principles. Your time and input are highly appreciated!

For any questions or clarification, please feel free to reach out to us via email:
s.n.rao@students.uu.nl (Shar Rao)
h.gardarsdottir@uu.nl (Prof. Dr. Helga Gardarsdottir)

**Note: since February 2024, the European Post-Authorisation Study (EU PAS) Register and ENCePP Resources Database have migrated to the HMA-EMA Catalogues for Real World Data Studies and Sources. The Catalogues are now managed by the European Medicines Agency (EMA) and are no longer under ENCePP's remit. Therefore, the Catalogues are not addressed in this survey.*

Page 2: Participant information

Q1. Which country do you currently work in?

[*Drop down menu with country options*]

Q2. How many years of experience do you have with conducting or evaluating non-interventional studies?

a. < 1 year
b. 1 – 5 years
c. 6 – 15 years
d. > 15 years
e. No experience

Q3. What type of institution do you currently work for?

In the case of multiple affiliations, please select your primary employment.

a. Academic institution
b. Hospital / clinic
c. Contract research organisation (for profit)
d. Contract research organisation (not-for-profit)
e. Regulatory body
f. Pharmaceutical company

Other (please specify)

[*Text box*]

Q4. Is your institution an ENCePP Partner?

a. Yes
b. No
c. Other (please elaborate)

Q5. For how many years have you been involved in ENCePP?

This could be personally, by use of the tools or community, or as a Partner institution / network.

a. < 1 year
b. 1 – 5 years
c. 6 – 10 years
d. 10 - 15 years
e. Not involved

Page 3: ENCePP overall

The questions on this page are related to ENCePP in general. More information about the network can be found here - ENCePP.

Q6. How do you make use of ENCePP?

You can select multiple answers.

a. Attend Plenary meetings
b. Participate in the Working Groups, Steering Group, or former Special Interest Group
c. Use ENCePP tools
d. I don't attend ENCePP Meetings or use ENCePP tools
e. Other (Please specify)

[*Text box*]

Q7. What benefit(s) do you get from ENCePP?

You can select multiple answers.

a. I keep track of the most recent developments in the field of pharmacoepidemiology/pharmacovigilance

b. The tools developed by ENCePP are beneficial to my work
c. I have the opportunity to connect with other researchers
d. I can identify collaborators or research centres for my research projects
e. Other (please specify)
[*Text box*]

Q8. What would improve your experience of ENCePP?
You can select multiple answers.

a. In-person meetings of ENCePP Partners besides the annual Plenary
b. In-person meetings of the Working Groups
c. More frequent communication on ENCePP work, tools, and guidance
d. Organisation of different events for ENCePP Partners (please specify)
[*Text box*]
e. Other (please specify)
[*Text box*]

Q9. What do you think ENCePP should focus on in the future?
You can select multiple answers. The current work plan can be found here: *ENCePP workplan - Version June 2024*.

a. Increase international collaboration with similar entities and/or professional societies
b. Increase international collaborations
c. Increase visibility of ENCePP and ENCePP tools
Continue working towards the Objectives as outlined in the current Work Plan (please elaborate)
[*Text box*]
d. Adapt the Work Plan to include different/additional topics (please elaborate)
[*Text box*]
e. Develop educational material (please elaborate)
[*Text box*]
f. Other (please elaborate)
[*Text box*]

Page 4: Code of Conduct

The questions on this page are related to the ENCePP Code of Conduct. More information about the Code of Conduct can be found here - ENCePP Code of Conduct

Q10. How do you use the Code of Conduct?
You can select multiple answers.

a. When designing studies (i.e. protocol language)
b. When collaborating with partner institutions

c. When collaborating with sponsors / funders
d. When conducting studies with a regulatory purpose
e. When conducting studies with a non-regulatory purpose
f. As an educational tool
g. As input when drafting contracts (i.e. legal context)
h. I don't use the Code of Conduct
i. Other (please specify)
[*Text box*]

Q11. What benefit(s) do you get from using the Code of Conduct?
Please use the text box below to elaborate.
[*Open text box*]

Q12. Do you face any barriers in using the Code of Conduct?
Please use the text box below to elaborate.
[*Open text box*]

Q13. What would increase your use of the Code of Conduct?
Please use the text box below to elaborate.
[*Open text box*]

Page 5: ENCePP Seal

The questions on this page are related to the ENCePP Seal. The Seal serves as a measure of quality and transparency in conducting research. More information about the Seal can be found here - ENCePP Seal

Q14. How many times have you applied for the ENCePP Seal?

a. Never
b. 1 – 5 times
c. 6 – 10 times
d. > 10 times

Q15. For what reasons do you apply for the ENCePP Seal?

a. When submitting studies for a regulatory purpose
b. Other reasons (please specify)
[*Text box*]

Q16. Do you face any barriers in applying for the ENCePP Seal?
Please use the text box below to elaborate.
[*Open text box*]

Q17. What would increase your use of the ENCePP Seal?
Please use the text box below to elaborate.
[*Open text box*]

Page 6: Checklist for Study Protocols

The questions on this page are related to the ENCePP Checklist for Study Protocols. More information about the Checklist can be found here - ENCePP Checklist for Study Protocols

Q18. How frequently do you use the ENCePP Checklist for Study Protocols?

a. Never
b. Rarely
c. Occasionally
d. Regularly
e. Always/very regularly

Q19. How do you use the Checklist for Study Protocols?

You can select multiple answers.

a. When designing studies
b. As an educational tool
c. Other (please specify)
   [*Text box*]

Q20. What benefit(s) do you get from using the Checklist for Study Protocols?

Please use the text box below to elaborate.

[*Open text box*]

Q21. Do you face any barriers in using the Checklist for Study Protocols?

You can select multiple answers.

a. I don't face any barriers in using the Checklist for Study Protocols
b. The ENCePP Checklist is too extensive
c. The ENCePP Checklist doesn't cover enough aspects
d. There are other checklists more applicable to my research (please specify)
   [*Text box*]
e. Other (please specify)
   [*Text box*]

Q22. What would increase your use of the Checklist for Study Protocols?

Please use the text box below to elaborate.

[*Open text box*]

Page 7: For Regulators

Note: The questions on this page were only shown to respondents who selected 'regulatory body' for their type of institution (Q3).

Q23. Do you see ENCePP tools used in your work as a regulator?

a. Yes
b. No
c. Other (please elaborate)
[*Text box*]

Q24. As a regulator, do/would you perceive studies conducted according to the ENCePP Code of Conduct differently?

a. Yes, I consider them to be of a higher quality than studies that don't follow the Code of Conduct.
b. No, I consider them to be of the same quality as studies that don't follow the Code of Conduct.
c. Other (please elaborate)
[*Text box*]

Q25. As a regulator, do you perceive studies that have the ENCePP Seal differently?

a. Yes, I consider them of a higher quality than studies conducted without the ENCePP Seal
b. No, I consider them the same as studies conducted without the ENCePP Seal
c. Other (please elaborate)
[*Text box*]

Page 8: Methodological Guide

The questions on this page are related to the ENCePP Guide on Methodological Standards in Pharmacoepidemiology. More information about the Methodological Guide can be found here - ENCePP Methodological Guide

Q26. How frequently do you use the Methodological Guide?

a. Never
b. Rarely
c. Occasionally
d. Regularly
e. Always/very regularly

Q27. For what purpose(s) do you use the Methodological Guide?
You can select multiple answers.

a. When designing/conducting studies
b. When communicating with collaborators
c. As an educational tool
d. Other (please specify)
[*Text box*]

Q28. What are the key benefits that using the Methodological Guide provides?
You can select multiple answers.

a. A way to learn about new methods

b. A way to refresh knowledge
c. Supports a common understanding of quality standards
d. Supports study design
e. Serves as a base for the harmonisation of other guidelines
f. Provides valuable insight into what regulatory agencies may be expecting
g. Facilitates communication and education between researchers
h. Other (please elaborate)
[*Text box*]

Q29. Do you face any barriers in using the Methodological Guide?
You can select multiple answers.

a. I don't face any barriers in using the Methodological Guide
b. It's too extensive
c. It's difficult to access
d. It doesn't cover enough topics
e. It doesn't address novel/innovative topics
f. There is other guidance more relevant for my research (if so, please specify)
[*Text box*]
g. Other (please specify)
[*Text box*]

Q30. Are there any topics you find missing from the Methodological Guide?
Please use the text box below to elaborate.
[*Open text box*]

Q31. Is the format of the Methodological Guide, based on literature reference, beneficial to you?
Please use the text box below to elaborate.
[*Open text box*]

Q32. Do you have any suggestions for how the Methodological Guide could be improved?
Please use the text box below to elaborate.
[*Open text box*]

Page 9: Open question

Q33. Please use the text box below for any final comments on the role, functioning, or tools developed by ENCePP.
[*Open text box*]

Page 10: Closing

We thank you for your time spent taking this survey. Your response has been recorded.

4. Participant information

4.1 Country

Country	**Count**	
	Survey respondents	*Interviewees*
Belgium	1	
Canada	1	2
Croatia	2	
Denmark	5	
Estonia	1	
Finland	2	1
France	2	
Germany	5	2
Greece	3	2
Iceland	1	
Italy	4	2
Latvia	1	
Lithuania	1	1
Montenegro	1	
Netherlands	8	3
Norway	4	
Portugal	1	1
Spain	7	2
Sweden	1	1
Switzerland	1	1
United States of America	1	
United Kingdom	1	
Missing	*1*	
Total	***51***	***18***

4.2 Years of experience with NIS (n = 52)

	Options	Count (%)
Years of experience with non-interventional studies	No experience	1 (1.9)
	Less than 1 year	1 (1.9)
	1 – 5 years	15 (28.8)
	6 – 15 years	21 (40.4)
	More than 15 years	14 (26.9)

4.3 Years of involvement with ENCePP (n = 52)

	Options	Count (%)
Years of involvement with ENCePP (through network or use of tools)	Not involved	5 (9.6)
	Less than 1 year	7 (13.5)
	1 – 5 years	19 (36.5)
	6 – 10 years	10 (19.2)
	10 – 15 years	11 (21.2)

5. Survey responses

5.1 Benefits, barriers, and improvements Code of Conduct

What benefit(s) do you get from using the Code of Conduct? (n = 21)	**Do you face any barriers in using the Code of Conduct? (n = 20)**	**What would increase your use of the Code of Conduct? (n = 16)**
NA / I don't use the Code of Conduct (n = 2)	NA / I don't use the Code of Conduct (n = 2)	NA / I don't use the Code of Conduct (n = 3)
Provides a clear outline of a collaborative agreements	No (n = 8)	I already use it to the fullest possible extent in my role (n = 5)
Helps establish mutual understanding of study requirements between CRO (us) and Sponsor, increased credibility of research in publications	Sometimes not flexible enough but mostly applicable and useful.	Should be updated and more visible
Clearly defined rules and constraints on how studies can be conducted, that are transparent and can be communicated easily	Different interpretations concerning who can interpret the results and be an author in the pharma sponsored manuscripts	More recognition of the importance / role of the tool amongst Sponsor teams.
Transparency throughout my research	No. It will not be worth collaborating with someone who doesn't accept it.	If there was a more compact file, which could lead to the main document for further details
More targeted design of the study	Some difference in interpretation Code of Conduct regarding industry partners as co-authors	Make it mandatory for at least regulatory studies
Argumentation on transparency	Should be updated and more visible	More visibility measures
Clear guidance on potentially controversial contractual and coordination topics between a research centre and the sponsor	Misinterpretation about authorships of industry partners when code is used	It should be more visible. There are several guidelines/checklists for observational studies, the Code of Conduct have not been my first choice.
Have a regulation that explicitly states how and when sponsors can be involved in regulatory studies, and which rights the institutions conducting the studies have.	Yes, many sponsors prefer not to include the Code of Conduct because they do not see direct nor practical regulatory recognition and/or benefits for its use	That EMA, PRAC, HMAs give value/recognition to its use. E.g. asking about the transparency and independence practice at the time of protocol and report reviews.
Endorsed by EMA, thus good tool to force partners from pharmaceutical industry to do something they usually do not want to (publications, ethical conduct etc.)	in some instances (albeit not too recent) sponsors felt restricted in their freedom to use data obtained with "their" products	Adaptation by wider stakeholder groups for observational research (local governmental institutions, MAH and academics).

Standardised rules on how to conduct PE and PV studies	Lack of knowledge / understanding of Code from sponsor teams	
It is very important as a tool to secure high quality of protocols of PAS studies. The people who has developed the Code of Conduct has made a tremendous/impressive bit of work, and I trust the work and expertise they have and implemented into the Code of Conduct	Yes. Since it's not mandatory to follow, it is at the end of the day a recommendation. Sponsors don't have to follow it	
Legal model for my work		
Easier collaboration with industry partners		
Clear regulation		
Clarity about roles/responsibilities and instrument to use		
Systematic approach in protocol work		
Transparency, support in drafting contracts		
Scientific rigor, it promotes the implementation of best practices from study protocol to publication of results.		
Trustable reference point for collaborations with industrial partners. However, it may be limited to industry studies. Colleagues have started using osf.io pre-registration for general studies not sponsored by industry.		

5.2 Survey responses on future of ENCePP

What do you think ENCePP should focus on in the future?	**Count (%)**	**Open text answers**
Increase international collaboration with similar entities and/or professional societies	23 (45.1)	
Increase international collaborations	18 (35.3)	
Increase visibility of ENCePP and ENCePP tools	39 (76.5)	
Continue working towards the Objectives as outlined in the current Work Plan [open text]	5 (9.8)	○ Work Plan has good objectives ○ Support the conduct of PAS studies ○ Show knowledge & competencies towards EHDS ○ Activate the working groups ○ Updates, communication and collaborations with other partners are essential

Develop educational material [open text]	8 (15.7)	○ Webinars with concrete examples /journal club ○ Webinars for young scientists ○ For all shareholders (industry, regulatory bodies, patients)
Other [open text]	4 (7.8)	○ Increase enforcement of ENCePP standard in studies (esp. regulatory) ○ Keep strong focus on methodological best practice in pharmacoepi studies ○ There are several guidelines, checklists for drug safety or drug utilization studies. They should be aligned ○ Focus more on academic research/science. In later years it has been to many partners/members outside the academic environment

6. Interview quotes

6.1 Future – visibility – communication

Relevant quotes from interviewees
“At the end, one could see all the tools going from text and graphs to videos or podcasts or other types of communications that are, let's say, more contemporary.” [L106]
“I have seen, let's say, chats or other forms of communication in ISPE, but at the end, if they are too public or too or too easy for the public to use, they don't result in such, let's say, formal tools. So I am not sure if they will be implemented [in ENCePP] but I can see, let's say, different ways of disseminating our work and more discussions on how to get more people involved in the discussion of ENCePP.” [L106]
“So from podcasts, from social media and from networks. From different, European networks – for example, European Medicines Agency could also help disseminating [ENCePP] more intensively.” [L108]
“I think that although [ENCePP] has done a great job in these toolkits, they are quite long. I would rather have a schematic way of presenting these procedures, these rules or these guidelines. And then explained at different levels. But I need that, since we are in the age of Instagram and TikTok, we have to make information shorter.” [L109]
“So I would assume, could assume that [for] the networking, some alignment with a LinkedIn profile or LinkedIn groups could be beneficial.” [L201]
“I think for right now it's a good learning experiment for us that ENCePP has the website and has all the links and you can find everything in one place. It's easier to navigate the website as well.” [L301]
“I noticed that it has been improvement that we have a kind of a podcasts from some working groups, which I think is work very, very nicely. So we perhaps we have to take advantage of the social media, of the podcast channels, etc., in order to, to disseminate the tools of ENCePP.” [L303]
“Definitely, I think we should be a bit more active with the communication in terms of webinars, events, not just posting [on] Twitter. That is great. What they are doing is great, but a bit more webinar, events, meeting somehow - because then we have created a bit more of enthusiasm.” [L110]
“It would be really nice [to receive] some newsletters - what is going on, and sometimes possibilities to join [some projects], maybe sometimes somebody is asking for certain information. And also possibility to maybe ask some questions to all ENCePP members...just all activities that were performed during the last three months, and maybe some important announcements for the future. It's really nice to know that at the end of three months, I will receive some newsletter and will. be updated." [L202]

6.2 Future – new avenues – new tools

Main points	Relevant quotes
Academic / educational material	“So, what is Eu2P now being moved to ENCePP and having all academic centres attend collaborating in a sort of online masters or pharmacoepi courses. I think that ENCePP as a network has the capacity to merge all those skills and produce a very good learning tool.” [L106]
	"We need to open the gates for young researchers, either by organizing training schools or by organizing summer schools or by giving some opportunities of collaboration." [L109]
	“We develop a training curricula for all the partners so that the pharmacoepi level of study will increase. Very specific, very concrete like that. We can also measure the impact. Maybe we could leverage what EMA did rather than starting again from scratch.” [L110]
	"I think many of these organizations often grow into sort of a knowledge based training institute [so] that's an obvious candidate [for ENCePP's future role]. But not sure if that's not already covered in academia - why would that have to be separate in, again, this institution?" [L201]
	“I see ENCePP as a kind of academic platform? Academic in the sense of training. It could have perhaps a different role in what comes to training researchers to boost some capacity of European centres... they could somehow liase much better with some centres.. I see a partnership to have [a] more experienced centre to boost the capacity of the not-so-much-experience center in order to boost, to leverage the capacity. So I think I could see a role there, to more disseminate, to training students, to be much more involved in academia series, across the EMA, across the pharma.” [L303]
New groups	"Maybe also a task force on artificial intelligence could be really interesting.” [L101]
	"Maybe organizing a fifth working group, which maybe is referring to patients." [L109]
Influence on regulators	“Every year there’s a new tool to evaluate something. It would be easier to have like a checklist, some place that you go directly... Like how to search for the right tool to evaluate the results of this study.” [L301]
	“A guidance on the RWE appraisal - we have many tools to evaluate, like cohorts and systematic reviews. Each of them have their own [checklist] like STROBE or Harper – [so ENCePP could] have like a document saying, 'oh, this is how it should be appraised', because I think that's what regulatory agencies use a lot, too, and there's a need.” [L301]
	“[Having] really fully open communication with regulators...ensuring that advances in methods are worked together and with clear objectives, making sure that whenever better methodologies are tested and confirmed through research [that] ENCePP and regulators [are on] the same page.” [L111]
Influence on reviewers	“What I probably also would like is if ENCePP had more influence on reviewers of journals.” [L103]
Access to data	“There are many databanks [and] a big production of data - the difficulty is to analyze them... we have built the guidelines, how to do it, but we are not yet highly involved to find this data and to analyze this data. I know that this is organized from Darwin Network. that they use real world data. But I think also that there is more than enough space for ENCePP to use such data. For example,

	we might have something similar that like FAERs, which is the databank of FDA for pharmacovigilance FARs, maybe organise something similar for European Union in terms of EMA." [L109]"
	"There are many other organizations trying to do it but maybe ENCePP could have a role [in trying] to facilitate access to data. Because now we have the catalogue, but how we contact potential data partners or trying to figure out how to make it easier to work with data might be one area where ENCePP could work." [L110]
	"Maybe have, at least for members, like a members registry where I can see who's a member, do they have access to data and what's the expertise. For example, I would want to do some study on vaccines, I could just go kind of Google within ENCePP 'vaccine' and see who's an expert. Maybe that would be helpful, something like that." [L103]
	"[It] would be helpful that ENCePP can take a role there to look at transportability or transferability...from one set of results in one geography to another...if there was some version of a 'feasibility' dashboard, that would be great." [L304]
Generate RWD	"In five years, I think the potential is really to have ENCePP utilise Darwin or more in general, the European health data space to be able to generate- I mean it will be a paradise right? For [the] generation of real world evidence, which is fantastic as an opportunity and also a great risk [in the sense that] you can generate any sort of wrong evidence if you are not methodologically strong using Real World Data. I see ENCePP at the forefront of this challenge and hopefully triumphing." [L104]
Data quality measures	"What the data allows and what it doesn't allow is extremely important, and for that I think we still would need better tools. For instance, some kind of data quality measures as a part of the data catalogue - to avoid the situation where big datasets are extracted and analyzed and then report is nonsense, because that kind of analysis wasn't supposed to be possible based on the data." [L202]
	"Also the quality of data, I don't know if ENCePP has anything specific [to] data protection, like with the collection of data, you know, registries, the electronic health records. Because usually systems are not for research or made for it, and then we use it for the RWE. Maybe also have some change in [these] systems, [they have] more quality - so improve the data quality and then we improve the methodological, the conduction of the study quality, and then it's easier to just have RWE ready to use by, for decisions." [L301]