Directions for ENCePP and impact on the work plan development

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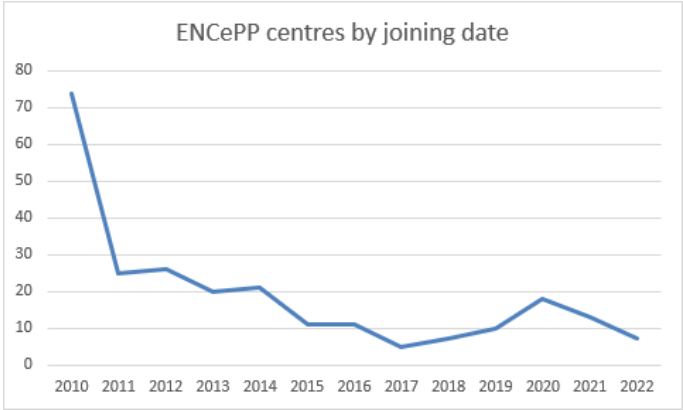
Main achievements of ENCePP

- ENCePP eRegister of studies → EU PAS Register → New metadata catalogue of studies
- ENCePP resource databases → New metadata catalogue of data sources
- ENCePP Guide of Methodological Standards in Pharmacoepidemiology
- ENCePP Checklist for Study protocol
- ENCePP Code of Conduct
- ENCePP Seal
- ENCePP Website → re-built with recent technological solutions
- References to ENCePP in many guidelines and articles

Reflections on possible directions for ENCePP

Membership

- ENCePP centres (n=209) with stagnation in the number of new centres joining ENCePP
- ENCePP partners are known contact persons in each centre (n=454)
- List of ENCePP partners updated only if contact updates its information
- No direct involvement of broader network of pharmacoepidemiologists, PV specialists, etc.
- PE and PV experts from companies not allowed



Should ENCePP remain a "closed" community of centres or open up to membership of individuals? Should ENCePP be open to centres/individuals from pharmaceutical companies?

2. Coordination

- Coordination and secretariat by EMA together with SG/WG co-chairs in addition to normal business
- Involvement of ENCePP Partners: voluntary work on top of other tasks, time constraints

How to involve more persons to collect new ideas? How can ENCePP partners involve more persons from their centre?

3. Interactions with learned societies

- Limited visibility and few interactions between ENCePP and ISPE, ISPOR and ISoP (except individual levels) – differences in status (e.g. industry members not allowed in ENCePP)

How to better interact with learned societies?

4. Visibility and presentation of ENCePP

- Link between ENCePP and the EU PAS Register and resources database may become less visible
- Re-building of ENCePP website

Opportunity to redefine values/purpose of ENCePP and how it is presented?

5. Declarations of interests

- Increasing public scrutiny over post-authorisation activities for medicinal products → need to provide assurance/transparency about possible CoIs → DoIs at individual level for EMA-funded studies
- ENCePP CoC applies at study level (signed by PI) and does not define personal interests that could influence the outcome of a study

Revision of ENCePP Code of conduct needed?

6. ENCePP Seal

- 72 studies with an ENCePP Seal on 28/11/2022
- Limited use of ENCePP Seal for regulatory studies
- Studies funded by pharmaceutical companies often not viewed eligible – to be clarified
- No mechanisms to check commitments made with ENCePP Seal

Better communication on objective of ENCePP Seal?

RMP Cat	No. studies with ENCePP Seal	Total no. of studies	ENCePP Seal studies (%)
1	7	125	5,6
2	0	40	0,0
3	9	658	1,4
non-EU	1	140	0,7
n/a	51	1365	3,7
unknown	4	147	2,7
Total	72	2475	2,9

ENCePP work plan 2023

- ENCePP community to support EMA through surveys/webinars/consultations on the migration/development of:
    - the RWD sources and RWD studies catalogues
    - the ENCePP website
- ENCePP community to steer the ENCePP through a changing environment

  → qualitative study with interviews of the relevant stakeholders – experts, centers active in ENCePP, stakeholders involved in other EU initiatives (DARWIN EU®, etc), EMA personel, pharmaceutical industry
- Leverage ENCePP activities and deliverables through collaboration with learned societies and study registration initiatives
- Increase the visibility of ENCePP

Working Group 1 – Research Standards and Guidances

- Revision of the ENCePP Checklist for Study protocols based on recent methodological and guidance developments
- Include in the yearly review of the Guide on Methodological Standards in Pharmacoepidemiology new relevant areas identified by the WG:
    - Use of the estimand framework for observational studies: relevance, influence on study design and analysis
    - Clone-censor-weight approach to prevent immortal time bias
    - Structured presentation of study designs (including visualisation)
    - HARPER recommendations

Working Group 2 – Independence and Transparency

- Promote and support compliance with the ENCePP Code of Conduct in pharmacoepidemiology research contributing to regulatory decisions
    - Teaching material to facilitate compliance
    - Inclusion in EU PAS Register of explicit fields
    - Revision/update of checklists for the ENCePP Seal
    - Public presentations (EMA Committees, national regulators, research funders)
- Investigation on barriers to compliance with the ENCePP Code of Conduct and application to the ENCePP Seal

Working Group 3 – Data sources and multi-source studies

- Support the revision of the structure and functionalities of the EU PAS register
- Analysis of publications included in the EU PAS register - final goal to also explore better options for the identification of key information for the conduct of observational studies exploring specific research questions and the linkage with other relevant repositories (e.g. PRAC minutes)
- Several publications, including short-term: 'Regulatory outcomes of registered PASs using distributed database networks'
- Liaison with ISOP Big Data and RWE SIG to better explore the role of distributed database networks in the context of signal management, and especially signal detection

Discussion