



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2024 ENCePP Workplan

ENCePP Plenary
Friday 1 December 2023

Catherine Cohet, RWE Workstream, Data Analytics and Methods Task Force, EMA
On behalf of the Steering Group



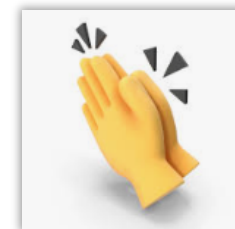


Background

ENCePP Work Plans

- ENCePP Work Plan 2017-2019 - BCP Action Plan
- ENCePP Work Plan 2017-2019
- ENCePP Work Plan 2015-2016
- ENCePP Work Plan 2013-2014
- ENCePP Work Plan 2011-2012
- ENCePP Work Plan 2010
- ENCePP Work Plan 2009

- 2020-2023: working through/post the pandemic and the EMA BCP (Business Continuity Plan)
- Nevertheless, many achievements (see Session 1)




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11 January 2023
EMA/919625/2022
ENCePP Secretariat


European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

ENCePP Activity Report
January – December 2022

**2023
upcoming**

→ Work of the Steering Group along 2023 to develop a work plan adapted to the current RWE/regulatory environment, while considering (realistic) contribution/resources in the ENCePP Community

Next slides: objectives **as of December 1st, 2023** (work in progress)



ENCePP kept growing in 2023

- EU PAS Register studies

Study category	Total	New in 2023 (up to 30 Nov)
ALL studies in the EU PAS Register (registered by ENCePP Partners and others)	2,738	235
Studies Registered by ENCePP Partners	801	67
ENCePP Seal studies	83	4

- ENCePP Resources Database

Resources database	Total number	New in 2023 (up to 30 Nov)
Centres	219	11
Networks	37	2
Data sources	169	4



Objective 1

Objective	Milestones/Deliverable(s)	Timelines	Leads/co-leads
1) As part of the Data discoverability objective of the HMA/EMA Big Data work plan 2022-2025, support the migration of the EU PAS Register and ENCePP resource database to the new catalogues , on NIS and data sources , resp.	<ul style="list-style-type: none">a) Progress updates at SG meetings (and to the ENCePP community, see Obj. 3)b) Validation of catalogues by ENCePP partners representatives of the ≠ organisationsc) Summary of feedback from ENCePP community and relevant stakeholders (building on Objectives 3 and 4) to SG	<ul style="list-style-type: none">a) June 20th and Oct. 4th, 2023b) Nov. 2023c) Continuous from Q1 2024	EMA: A. Cochino/J. Fogd



Objective 2

Objective	Milestones/Deliverable(s)	Timelines	Leads/co-leads
2) Support (embrace) the re-building of the ENCePP website and embed solutions for increased visibility , as well as cross-fertilisation and input from ENCePP partners	<ul style="list-style-type: none">a) Logo updateb) Website to comprise link to PV/PE training initiativesc) Website promotion (e.g., EMA website/EMA LinkedIn)d) Posting of deliverables, publications, presentations, videos	<ul style="list-style-type: none">a) Endorsed at SG meeting Oct. 4thb) Q1 2024c) Q1 2024d) Continuous from Q1 2024	EMA: J. Fogd/A. Segec SG: TBD



Objective 3

Objective	Milestones/Deliverable(s)	Timelines	Leads/co-leads
3) Inform the ENCePP community and other relevant stakeholders on the new catalogues and website	a) Presentation at Plenary b) Webinar on the catalogues including Q&A (or posting of recording from Plenary)	a) Dec. 1 st , 2023 b) Q1 2024	EMA: A. Cochino/J. Fogd



Objective 4

Objective	Milestones/Deliverable(s)	Timelines	Leads/co-leads
4) Inform on place and impact of ENCePP in a fast-evolving environment (support to Objective 5)	a) Positioning of ENCePP in RWE/regulatory environment (Methodology Working Party, BDSG, DARWIN EU, EHDS, Vaccine Monitoring Platform) b) Qualitative survey: stakeholder interviews	a) Brainstorming session (format TBD, Q1 2024) b) Q1 2024	EMA: C. Cohet SG: H. Gardarsdottir for b) + TBD



Objective 5

Objective	Milestones/Deliverable(s)	Timelines	Leads/co-leads
5) Strategic review: re-define/finetune ENCePP scope and activities	<ul style="list-style-type: none">a) Revision of mandates and group composition (SG, WGs, SIGs)b) Revisit Seal (WG2)c) Develop guidance to partners (centre/network leads) on how to share info about ENCePP and foster participation in WGs and other activitiesd) Support and integrate learnings from RWE/PhEpi guidance (e.g., GVP VIII update/Protocol Checklist → WG1)e) Individual registration to an ENCePP distribution list	Plenary Dec. 2023 and continuous from Q1 2024	EMA lead: P. Verpillat EMA subtopic leads: TBD SG: TBD



Objective 6

Objective	Milestones/Deliverable(s)	Timelines	Leads/co-leads
6) Increase visibility of ENCePP activities and deliverables through collaboration with learned societies and study registration initiatives	<ul style="list-style-type: none">a) New website and logob) Webinars (see Obj. 2d)c) Explore co-branded events with learned societies (ISPE, ISPOR, ISOP)d) Consider additional communication tools	<ul style="list-style-type: none">a) See Obj. 2 Other topics for implementation in 2024/once website available	EMA topic leads: TBD SG: TBD



Objectives of the Working Groups

- Discussed in Session 1
- To be fully embedded in Workplan and published on the new website



How can the ENCePP Community help?

- All ENCePP Partners invited to contribute
- Please contact the Secretariat and/or the Working Group chairs if you would like to volunteer on a specific milestone/deliverable and/or join a WG



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