



Terms of reference of the WGs and SIGs Proposal for new groups

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Background and rationale

- Deliverable under Objective 1 of the ENCePP Workplan: update governance and way of working
- Aims to provide a clear and transparent structure that allows for establishment of Working Groups (WGs) and Special Interest Groups (SIGs)
- Includes concrete and measurable deliverables, with attached timelines missing from the current mandate
- WGs/SIGs could be established in accordance with the work plan and be better aligned with EMA strategy and needs/activities
- Plan is to revisit the current WGs



Establishment and membership of the WGs



	Who can propose a WG/SIG	What should be included in the proposal	Who decides
Establishment	<ul style="list-style-type: none">Steering GroupENCePP Partners	<ul style="list-style-type: none">MandateDraft objectives, deliverables and timelinesNomination for co-chairs	<ul style="list-style-type: none">Discussed and voted by the Steering Group
	<p>✓ Once objectives achieved and all deliverables provided, WG/SIG is closed</p>		
	Who can become a member	Who decide and how	What we would like to see
Membership	<ul style="list-style-type: none">Steering Group membersENCePP Partners	<ul style="list-style-type: none">WG co-chairs and/or SGCriteria include active interest and contributionMembership revised by co-chairs annually	<ul style="list-style-type: none">Distribution between types of PartnersMembership encouragedReasonable size reflecting the mandate





Do you agree with the proposed ToR?

- Yes
- No
- I somewhat agree and would like to propose edits



Ideas received for new WGs / SIGs - Examples

Topic	WG/SIG	Focus
ENCePP Communications	WG	Podcasts (launched by former WG2), webinars, synergies with learned societies, website, ...
ENCePP Guide 2025	SIG	12 th Revision/2025
	WG	including the longer term PDS/Value in Health publications
ENCePP checklist update	SIG	Activity with defined start/end, link to GVP VIII update
AI	SIG or WG	
TTE	SIG or WG	
...		
...		



Do you have any proposals for potential WGs or SIGs?



Back-up: ToR in detail



Terms of Reference

Scope

- **Aim:** address the objectives and deliverables of the ENCePP workplan
- **Temporary** nature, in line with continued development of ENCePP and the changing environment in pharmacoepidemiology and PV
- Each WG or SIG has a **mandate**, defined by the chairs and members, and reflected in clearly outlined objectives and **deliverables**, with specified **timelines**
- For both WGs and SIGs, the mandate along with the planned activities are endorsed by the Steering Group

Establishment of the WGs

- New WGs based on emerging topics of interest, proposed by Steering Group or ENCePP Partners
- Proposals should include mandate, draft objectives/deliverables/timelines, nomination for co-chairs. Proposals discussed and voted upon by the Steering Group
- Steering Group and/or WG may decide on case-by-case basis about tenure and composition, in collaboration with WG leads
- Once objectives achieved and all deliverables provided, WG is closed



Terms of Reference

Chairs and EMA representative(s)

- Each WG has a chair and co-chair, providing **leadership** and liaising with the SG
- **Election** of the co-chairs: in case of new WG, nomination part of the WG proposal; in case of already established WG, elected or re-elected by WG members. Any ENCePP Partner may be elected as co-chair
- Depending on mandate/duration of the WG, co-chairs **re-elected** every 3 years
- Each WG includes (a) **representative(s) from EMA** nominated by the EMA Secretariat, to closely collaborate and ensure alignment with EMA policies and strategy

Membership

- Broad membership encouraged, **distributed** between the various types of **ENCePP Partners**
- WG co-chairs will examine requests; criteria include active interest and sustained contribution to WG meetings and deliverables
- Number of members should reflect the mandate of the WG and be of a reasonable size, e.g., based on **concrete contribution** to the deliverable(s). **Membership** shall be revised by the co-chairs on an **annual** basis



Terms of Reference

Organisation

- Meetings organised by the co-chairs on a **frequency** suitable to address the objectives of the WG
- **Minutes** taken by the co-chairs and circulated for revision to WG members, final minutes communicated to the SG
- WG co-chairs report to the **SG** at a minimum annually, including attending SG meetings as applicable

Special Interest Groups (SIGs)

- SIGs follow similar ToR as the WGs, but have a narrower focus, such as addressing one specific objective/deliverable
- On completion of the deliverable, the SIG will be closed

