

24 January 2025

Terms of Reference of the ENCePP Working Groups and Special Interest Groups

Scope

- The aim of the ENCePP Working Groups (WGs) and Special Interest Groups (SIGs) is to address the objectives and deliverables of the ENCePP workplan.
- The WGs and SIGs are of a temporary nature, in line with the continued development of the ENCePP network and the changing environment in the field of pharmacoepidemiology and pharmacovigilance.
- 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 shall be established based on emerging topics of interest, and may be proposed by the Steering Group or by ENCePP Partners.
- Proposals should include a mandate, draft objectives/deliverables/timelines, as may include a nomination for co-chairs. The proposals are discussed and voted upon by the Steering Group.
- The Steering Group may decide on a case-by-case basis about the tenure and composition of the WGs, in collaboration with the WG co-chairs.
- Once objectives are achieved and all deliverables provided, the WG is closed, unless additional objective(s) to expand the mandate is/are foreseen.

Chairs and EMA representative(s)

- Each WG has a chair and a co-chair, who will provide leadership and liaise with the Steering Group.
- Election of the co-chairs: in case of a newly created WG, nomination of co-chairs may be part of the WG proposal; in case of an already established WG, the co-chairs shall be elected or re-elected by the WG members. Any ENCePP Partner may be elected. Depending on the mandate/duration of the WG, co-chairs shall be re-elected every 3 years.
- Each WG includes (a) representative(s) from EMA, nominated by the EMA Secretariat, who will closely collaborate with the co-chairs and ensure alignment with EMA policies and strategy.



Membership

- Broad membership from ENCePP Partners is encouraged and should ideally be distributed between the various types of ENCePP Partners.
- The WG co-chairs will examine requests for membership; criteria include active interest (such as reflected in a proposal on how to address the mandate of the WG) and sustained contribution to WG meetings and deliverables.
- While the size of the WGs is flexible, the number of members within a given WG 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.

Organisation

- Meetings shall be organised by the co-chairs on a frequency that is suitable to address the objectives of the WG.
- Meeting minutes are taken by the co-chairs and circulated for revision to the WG members, and final minutes are communicated to the Steering Group.
- WG co-chairs report to the Steering Group on at a minimum annually, including attending Steering Group meetings as applicable.

Special Interest Groups (SIGs)

- SIGs follow similar terms of reference as the WGs, but have a narrower focus, such as addressing one specific objective that cannot be addressed as a deliverable of a WG. A SIG cannot be a subset of a WG.
- On completion of the deliverable, the SIG will be closed.