

Clinical trial methodology - guidance roadmap

Overview of collaboration on clinical trial methodology guidance

February 2026

Scope

Consistent guidance on clinical trials from the perspective of clinical trial approval, marketing authorisation and reimbursement facilitates the conduct of impactful clinical trials in Europe.

Therefore, experts from the Clinical Trial Coordination Group (CTCG), MedEthics EU, the EMA Methodology Working Party (MWP) and Health Technology Assessment Coordination Group's (HTACG) Methodological and Procedural Guidance Subgroup (MPG SG) regularly exchange information on their activities under the umbrella of ACT EU and collaborate in the preparation of clinical trial methodology guidance on high-impact topics.

Collaboration ranges from early review and consultation to co-drafting, depending on the topic and its relevance for the mandate of the respective expert group.

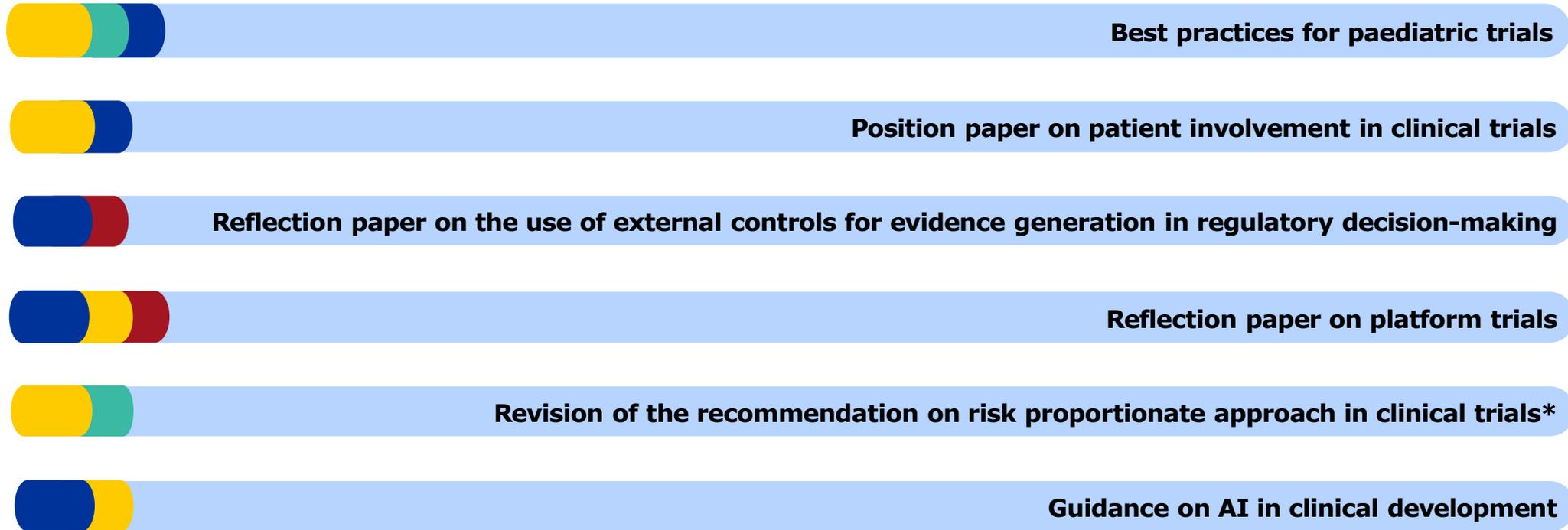
This roadmap summarises the topics from the expert groups' workplans identified for collaboration, highlighting the leading and collaborating groups.

For reference, the workplans of the CTCG and MWP can be assessed here:

[CTCG workplan](#)

[MWP workplan](#)

Collaboration on clinical trial methodology guidance



Additional relevant expert groups will be involved as needed based on the topic.

CTAG MWP MedEthics EU HTA

*Adoption by CTAG

Note: the first icon indicates the lead of the respective activity

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