ACT EU workplan 2025/2026 – status update and feedback from the MSP AG

Revision of ACT EU workplan

Since launch of ACT EU in 2022, we have developed 2 versions of the workplan:

- 1st workplan covering 2022-2026
- 2nd workplan covering 2023 - 2026

Proposal for the third version of the workplan is to cover 2025-2026

Programme structure > Priority Actions organisation

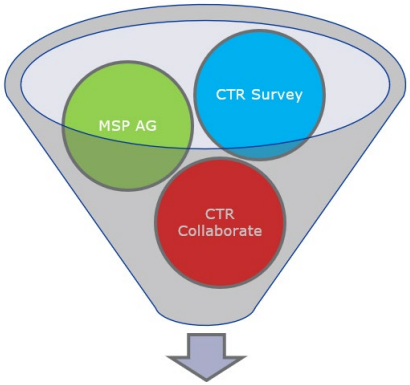
✓ Proposal on revamping, having some overarching and underpinning activities and bringing some priority actions closer together

Programme content > Deliverables in short and medium term.

✓ The revision will consider existing deliverables (as per current workplan) as well as new input provided by stakeholders on priorities for clinical trials

Stakeholders' channels to communicate needs

Input provided by the stakeholders has been collected in a master-list with issues categorised by urgency and criticality



CTR Survey

- Conducted under ACT EU Priority Action on CTR implementation and led by the CTAG (COM)
- Audience: CTIS users
- Scope: technical CTR/CTIS

MSP AG

- Coordinated by EMA secretariat and embedded into ACT EU
- Audience: clinical trial stakeholders
- Scope: broadly covering issues affecting the development and conduct of clinical trials

CTR Collaborate

- Led by CTCG, collaboration with MedEthicsEU and anchored to ACT EU
- Audience: NCAs and ethics committees; clinical trial stakeholders
- Scope: work processes between NCAs/ethics, including CTIS issues; has also collected broader external stakeholder feedback via public event

Issues reported by stakeholders

Significant overlap in feedback from stakeholders.

The implementation of the Clinical Trials Regulation remains the top priority to be addressed.

* Low Interventional Clinical Trials, as per CTR

Revised ACT EU workplan 2025/2026

Points considered as part of the ACT EU workplan revision:

- Joint effort in the CTR implementation together with CTCG (CTR collaborate)/MedEthicsEU/CTAG
- Dedicated priority action to support non-commercial sponsors, including regulatory helpdesk and continuous mapping of existing initiatives
- Focused change management, training activities on revised ICH E6 (R3) and dedicated workshops
- Continuation of consolidated pilot initiative SAWP/CTCG and pre-CTA, with lessons learnt to be published
- Workshops on methodological aspects, to address stakeholders needs as well as the development of an overview document bringing together CTCG/MWP/HTA documents
- Training activities with particular focus on academia

European Medicines Agency

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