Update from MSP Advisory Group (4 July meeting)

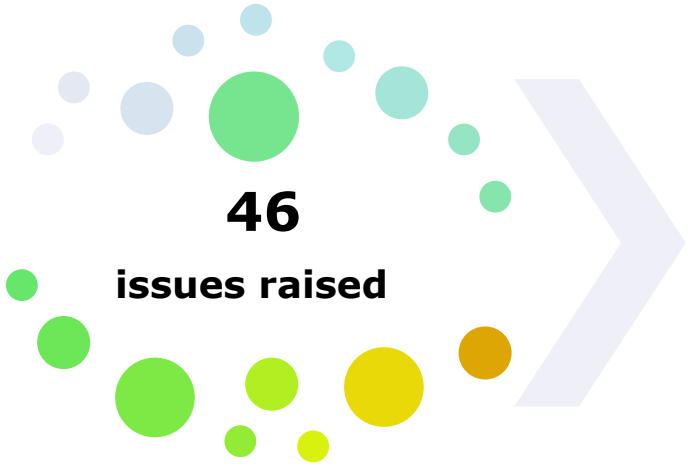
MSP AG meeting, 27 September 2024

Presented by Denis Lacombe (EORTC), Ana Zanoletty (EMA) and Tarec El-Galaly (EHA)

4 July MSP AG meeting

- Objective: Set baseline understanding of programme for stakeholders & listen to concerns and challenges.
- Full day meeting attended by permanent members, some ad-hoc, trilateral, coordinators & co-leads, EMA.
- Overview of ACT EU with deep dives and selected stakeholder presentations + discussion.
- Out of scope: technical CTIS topics, CTR/IVDR/MDR topics.
- All submissions will be analysed.
- Strong engagement and strong sense of urgency.

Overview of issues



14
categories

Main issues

1. CTR implementation

a) Lack of harmonisation of assessment

b) National requirement

c) Lack of flexibility

1. Amendments, IMPD-Q
2. Low risk trials, public health trials

2. Investigator Initiated Trials/Academia

a) Operational barriers: training on CTIS, GCP requirements

b) Early interactions with regulators, scientific advice fees

c) Funding schemes, multi-national infrastructure

d) Support mechanisms

3. Methodological innovations

a) Complex trial designs, incl. for paediatric trials, rare diseases

b) Use of RWD/E

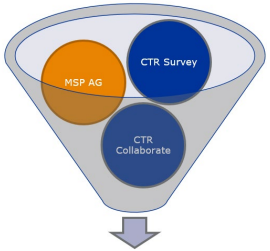
c) Digital health technologies

Remaining categories

4. Regulatory & scientific advice
5. Regulation interface challenges
6. Training
7. Patient engagement
8. Cross-border clinical trials
9. Off-patent drugs
10. Access to CT data
11. Clarifying CT landscape
12. Diversity, equity and inclusion
13. Embedding CTs in Healthcare
14. Ethical challenges

Stakeholder feedback channels

MSP AG feedback complements input received via other channels and will be integrated into a larger plan to drive improvements in the EU CT environment



MSP AG

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

CTR Survey

- Led by CTAG under ACT EU PA2
- Audience: CTIS users
- Scope: technical CTR-CTIS

CTR Collaborate

- Led by CTCG, collaboration with MedEthicsEU and anchored to PA1
- 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

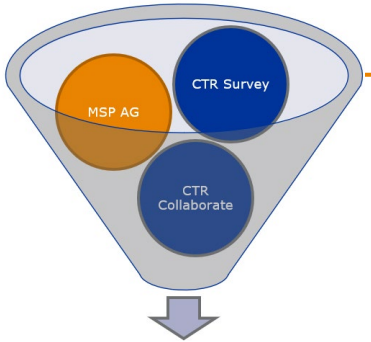
From MSP AG feedback to actions

MSP AG feedback complements input received via other channels and will be integrated into a larger plan to drive improvements in the EU CT environment

27 Sep

MSP AG follow up discussion

Prioritisation
Importance
Urgency



Development of master plan

ACT EU | CTR Collaborate | CTAG |CTCG | MedEthicsEU

Update during MSP Annual meeting

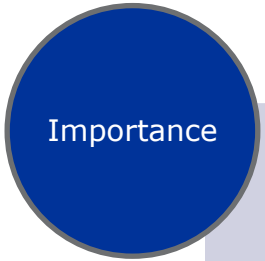
22 Oct

Consolidation | Prioritisation | Allocation | Timing

From MSP AG feedback to actions

Prioritisation
Importance
Urgency

MSP AG members requested to critically appraise the issues



Critical: Blocking issues impacting the initiation and conduct of the trial and severely affecting the clinical trials research environment in the EU

Major: Non blocking issues causing delays that can be addressed with additional resources and/or workarounds

Minor: issues that indicate the need for improvements of practices and processes

High: resolution within 1 year

Medium: resolution within 2 years

Low: resolution within 3 years or more

Next steps

- Launch consultation on prioritisation
  - Platform: Slido - circulated via direct link to MSP AG members
  - Deadline: 11 October COB
  - Audience: MSP AG permanent and ad hoc representatives – 1 response per organisation
- Results will be
  - integrated into the development of a master plan
  - provided to the ACT EU Steering group as formal advice from the MSP AG
- MSP AG will continue to be consulted on the delivery of solutions