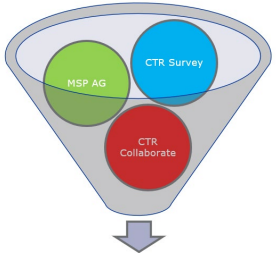
Addressing stakeholder challenges - what's next?

Stakeholder feedback channels

Input received will be integrated into a larger plan to drive improvements in the EU CT environment



CTR Survey

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

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 Collaborate

- Led by CTCG, collaboration with MedEthicsEU and anchored to ACT EU 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

Common issues reported through different channels

Significant overlap in feedback from stakeholders.

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

CTR Survey - practical aspects to improve at CTIS level or at CTR implementation level?

The overall feedback on the implementation of the CTR and CTIS is mixed, with both positive and negative aspects mentioned.

1. **CTIS User Experience and Functionality:** Negative feedback

2. **Harmonisation and Coordination:** Negative feedback: lack of harmonisation across MSs, particularly regarding document requirements and timelines for Part I / II submissions.

3. **Timelines and Deadlines:** Negative feedback: Timelines for responding to RFIs and submitting modifications are too short, and that there is a need for more flexibility.

4. **Training and Guidance:** Mixed feedback: Some respondents found the available training materials helpful, while others felt overwhelmed by the amount of information and requested more concise, user-friendly guidance.

Overall, while there are some positive aspects mentioned, the majority of the feedback highlights areas for improvement in the CTIS system, harmonisation and coordination, timelines, and training provided.

Main issues reported by MSP AG

1. **CTR implementation**
   a) Lack of harmonisation of assessment
   b) National requirements
   c) Lack of flexibility
      1. Modifications, 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

(46 issues reported over 14 categories)

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

CTR COLLABORATE - Issues and Criticality

- CTIS issues (SM, second RFI visibility, safety cooperation, notification publication, IMPD-Q only)
- CTR (timelines, Art. 11)
- Collaboration (DAR delivery, considerations, conditions)
- Harmonisation in the EU Clinical Trials Framework
- New strategies for streamlining clinical trial review and approval processes
- Fostering innovation in clinical trial
- Enhancing CTIS functionality and operational efficiency

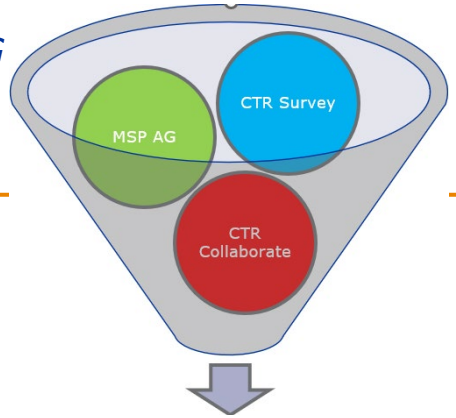
Issue priority category	Number of issues
Critical	18
Major	14
Minor	15

Stakeholder feedback to actions

Feedback from all channels is considered to drive improvements in the EU CT environment

11 Oct

Complete MSP AG feedback



Prioritisation
Importance
Urgency

Development of a compiled list of issues to inform work of
ACT EU | CTR Collaborate | CTAG |CTCG | MedEthicsEU

Update during
ACT EU Annual meetings

22 and 23 Oct

Consolidation | Prioritisation | Allocation | Timing

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**