Patient involvement during life cycle of clinical trials

Brief update on the current activities

Marianne Lunzer, AGES MEA

Multi-stakeholder platform Advisory Group meeting ,
18 September 2025

Analysis stakeholder sessions finalised

- Patients' representatives: 8 participants, 3 patients' representatives, most of the other participants work for organisations that support patients' representation.
- Commercial sponsors and CROs: 18 participants who were employees of fifteen different pharmaceutical companies and CROs, those representing a global company have a role that is dedicated to patient involvement
- Academics/Non-commercial sponsors: 9 participants came from academia, liaised via an association or non-commercial organisations. For the majority patient involvement is part of their daily job, their organisations or departments are dedicated to patient involvement. 1 participant academic researcher.
- Members of medical research ethics committees (MRECs): 8 members of MRECs participated, most as lay member in their local medical research ethics committee, some participants also identified as patient representative.
- National Competent Authorities: 33 participants from 24 member states, approximately half of the participants fulfilled a clinical or safety assessor role.
- Stakeholder session reports finalised

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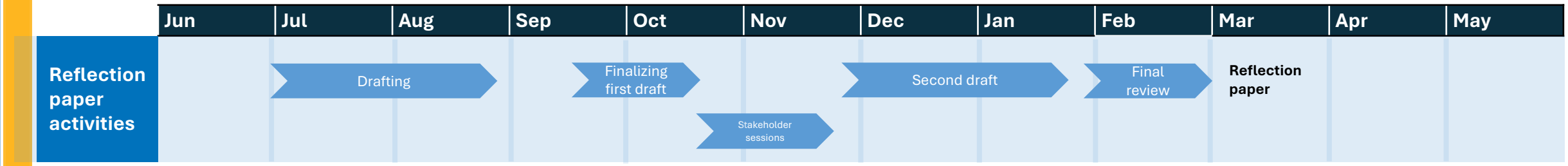
Reflection paper – update



- Summer: drafting -> on track
- Some relevant chapters currently envisaged:
  - Status quo
  - Potential opportunities and challenges
  - Reflections and considerations for medical ethical review
  - Recommendations for those involved in clinical trials

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Thank you for your attention!

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RMS, RFI, AxMP

Updates

Monique Al, vice-chair CTCG/co-chair MedEthicsEU

Multi-stakeholder platform Advisory Group meeting ,
18 September 2025

RMS, RFI, AxMP paper

CTR collaborate project:

- Work on the following tracks, ready for endorsement by CTCG/MedEthicsEU:
  - Categorisation elements CTR, Annex I elements (mandatory, critical, non-critical considerations)
  - Principles and examples for considerations never to include or never to delete in RFI by RMS
- Work on strengthen role RMS continues

ACT EU workplan: frequently asked RFI

- List of frequent issues identified during assessment by assessors of Part I and/or Part II
  - Part I list of issues and recommendations – finalised
  - Part II list of issues and recommendations – under review
  - Aim to have it finalised for the MSP annual meeting 29 October 2025

Revision Recommendation paper on the use of Auxiliary Medicinal Products in Clinical Trials

- Endorsed by CTCG
- Endorsement CTAG postponed due to outstanding legal issue from COM legal staff.

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Thank you for your attention!

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