Session 2, current landscape

Impact of initiatives: a start with need for increased focus, resource, alignment and measurable outcomes

ACT EU Y1: The positives

- Pragmatic approach to Expedited Transition to EU CTR requirements
- Redefining the transparency rules has improved application preparation:
  - More meaningful transparency with focus on key documents benefiting patients/HCPs
  - Reduction in efforts for redaction and justifications over CCI helps speed up application preparation and RFI management
- Pragmatism in implementation of CTR – MedEthics EU a welcome update

The Ask: Need for focus and direction at EC and EMA as well as National level through simplification and convergence critical to reversing a long term decline in enrollment share of clinical trials in the EU

- Allocate resource and enable enforcement of harmonisation and simplification for Part 1 and 2 submissions
- Enforce the role of RMS leading to streamlined communication and more efficient RFI process
- Set clear goals and timelines to resolve critical, major and minor issues affecting CT conduct in the EU

Industry needs: ACT EU, CTR Collaborate, CTCG and CTAG, MedEthics EU, COMBINE are Identifying key issues that need prioritization. Critical items highlighted below:

- CTR implementation: inconsistent processes, varied national requirements, amendment management, interface between MDR, IVDR and CTR
  - **True harmonisation** of submission requirements needed
  - Timing and consistency of RFIs for part 1 vs part 2
  - **Timelines are key –** a secondary application for part 2 ICF update + lack of parallel amendments slows down study start + management
  - CTIS System performance and functionalities still needs improvement (beyond MVP)
  - CTIS capability to manage large study and file volumes needs improvement
- Lack of interface between CTR, MDR and IVDR is slowing trial start up
  - IVDR submission as country competency needs CTR interface to truly harmonise the submission process
  - Remove unnecessary administrative burden where amendments do not impact IVD use
  - Consistent interpretation of AI Act required to agree what is exempt under R&D vs uncertainty with case by case requirements