ACRO Panel discussion topics

1. From your stakeholder group perspective, what needs to be put in place to create an invigorated clinical trials environment?

- Increased predictability in the CTIS environment for CTR submissions:

  - Timelines
  - Sequence and co-ordination of RFIs between Part 1 and 2
  - System performance and functionalities
  - Enabling the pending enhancement backlog to CTIS

- Pragmatism in implementation of CTR

  - True harmonisation of submission requirements
  - Consistency in part 2 submission documents
  - Integrating all parts of reviews that require approvals prior to study conduct

- Lack of harmonisation between CTR and IVDR is slowing trials

  - IVDR submission as country competency needs CTR interface to truly harmonise the submission process

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