

ACRO Panel discussion topics

2. How can your stakeholder group contribute to the successful implementation of the CTR, and what does success look like?

- Preparedness: CTIS, Admin and technical concerns may be a hinderance in the event of a public health emergency
- Timelines as per expectation:
 - Currently the system non-functionality is increasing burden on submissions and approvals
 - Ongoing CTD trials may end earlier to avoid transition to EU CTR
 - Transition and challenges with the deadline: ref EFPIA letter
 - Remove the deadline to transition trials by 31st Jan 2025 or enable solutions.
- Device aspects of trials are still causing significant delays as these are national competencies
- Harmonisation of DCT requirements across member states:
 - EMA recommendation paper needs further agreement across MSs
 - More clarity on use of remote health care providers/utilization by site of staff provided by a vendor