An invigorated CT environment requires collaboration on key shared priorities

Identified priorities for

Ad-hoc groups under MSP	Pilots under MSP
● Implementation of IVDR/CTR interface ● Link to Qualification of Novel Methodology (QoNM) to receive multi-stakeholders input to ongoing procedures ● Prioritisation and input to methodology guidances	● Complex Clinical Trial Pilot (focus on CT methodology) ● Scientific Advice pilots to connect to CTA ● Use of novel technologies in clinical trials

Key priority: Implementation of IVDR & CTR interface

- Critical impact on CTs in Europe, with data suggesting hundreds of trials and thousands of patients will be impacted by related delays.
- Challenges include lack of coordinated process and clarity for Performance Studies (PS), and lack of alignment of clinical trial and PS approvals.
- We have identified clear roadblocks for the preparation, submission and assessment of PS Applications and a suite of complementary solutions that can decrease the delay.
- Challenges and solutions shared with the EC, MDCG, HMA, CTCG and other stake-holders. ACT-EU MSP uniquely positioned to advance solutions in a collaborative way.
- Urgent action needed.

Proposal: IVDR/CTR interface to be prioritised by the MSP to facilitate multi-stakeholder input to drive solutions to the challenges, including convening a Multi-stakeholder Workshop on this topic.

EFPIA role to support ACT-EU and the Multi Stakeholders Platform (MSP): help identifying priority topics, provide experts to join ad-hoc groups, designing and participating in pilot programs, contribute to stakeholder analysis

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