ACT EU multi-stakeholder platform annual meeting

Session 2 - the current landscape for clinical trials in Europe – ACT EU and beyond

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innovative health initiative

Clinical trials in funded projects

- Funded projects constraints
  - Time
  - Budget

- Experience show for large multicentre, multinational clinical trial(s)
  - ambitious timelines for start-up phase (finalisation protocol, consent, CDA, contract…) and regulatory and ethical approvals
  - overestimation of the recruitment rate.
  - challenges with schedule of activities (e.g scientific advice, CTA, amendments)

- Consequences of delay on the overall project workplan, timing, budget and ultimately impacting the project results

- Consortia still get familiarised with the new submission system

Clinical trials enablers

- Ongoing initiatives that ensure coordination, smooth the approval processes and facilitate interface between legislations welcome

Some further thoughts:

- Repository of agreed templates, practices
- Possibilities for more direct interaction to support trials
- Collaborative clinical trials networks open to industry and non-industry sponsors with a clear path for sustainability and embedded into healthcare systems
  (one stop shop, sites selection, templates for sites, capacity building, quality standards for study sites…)
- Next generation investigators