Setting the scene
with an introduction to the CCTs Q&A

23.11.2023

Clinical Trials Coordination Group (CTCG)

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federal agency for medicines and health products

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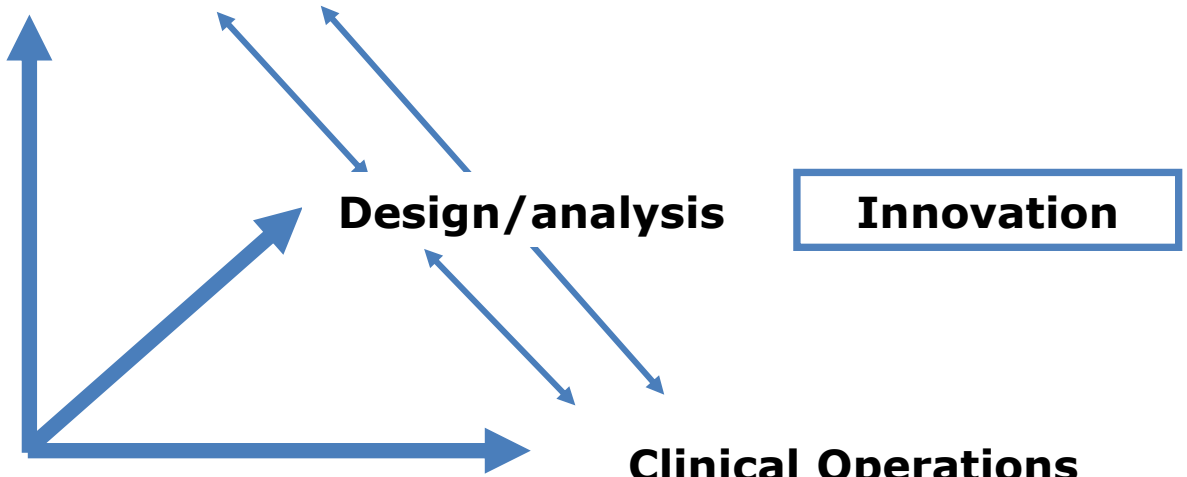
Evolving clinical trials: increasing complexity and role of innovation in clinical trial designs and beyond

Participants/Patients/Population
Interventions/Investigational medicinal products



Evolving clinical trials ecosystem and innovation

Methodological ⟷ **Operational**

Participants/Interventions

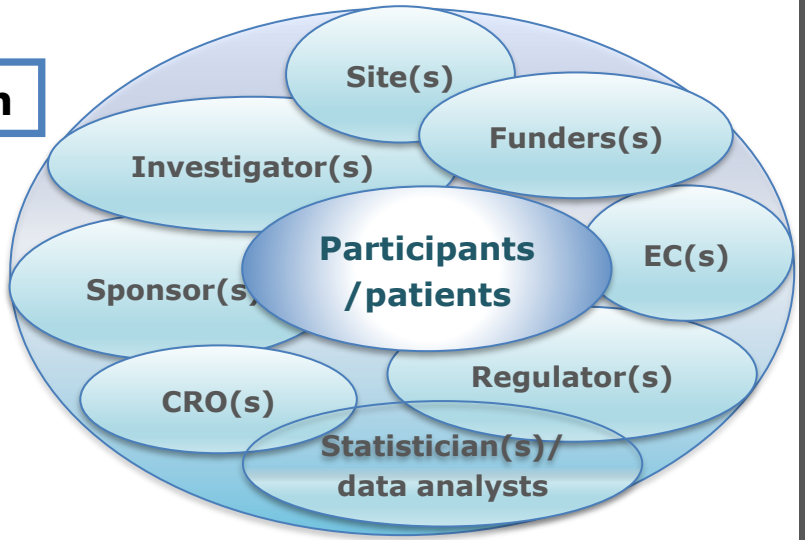
Innovation

Innovation

Design/analysis

Clinical Operations

Complexity-associated risks mitigation



Innovation in collaboration

Use of available and development of new best practices, methodological tools, technologies

Evolving collaborative regulatory guidance for CCTs

- **CTFG recommendations for initiation and conduct of complex clinical trials (2019)**
  https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group.html

- Q&A on Complex clinical trials (May 2022)

  This document has been developed in close collaboration between the European Medicines Agency, the Clinical Trials Coordination Group and the Clinical Trial Expert Group. It was endorsed by those groups and by the ACT EU Steering Group.

  https://health.ec.europa.eu/latest-updates/questions-and-answers-complex-clinical-trials-2022-06-02_en

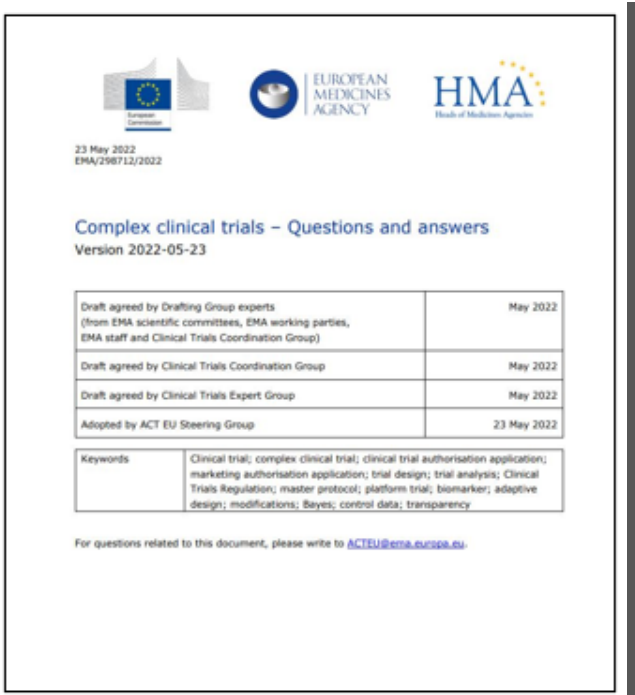
- **ACT EU priority action 8**:

Develop and publish key methodologies guidance e.g. on AI/ML impacted CTs, **complex trials**, decentralised CTs and IVDR/CTR interface (to strengthen links between innovation and scientific advice fora)

Reflection paper on platform trials (concept paper EMA/CHMP/840036/2022)
Breakout session: Complex Clinical Trials, focus on platform trials

Complex Clinical Trials (CCTs) – Questions and answers

1. Important considerations for the **planning** and **conduct** of complex clinical trials
2. Which **additional considerations** are needed for the design and conduct of master protocol studies?
3. How to describe and explain **Bayesian** approaches in complex clinical trials?
4. What are the considerations for planning, collection and use of **control data** from within a complex clinical trial for regulatory purposes?
5. Which principles apply, and which regulatory pathways should be considered when using **biomarkers** and biomarker assays in complex clinical trials and consequently applying for marketing authorisations?
6. **Safety, rights** and **well-being** of participants
7. **Transparency** (balance with integrity) and **communication** between regulators, sponsors and investigators



23 May 2022
EMA/298712/2022

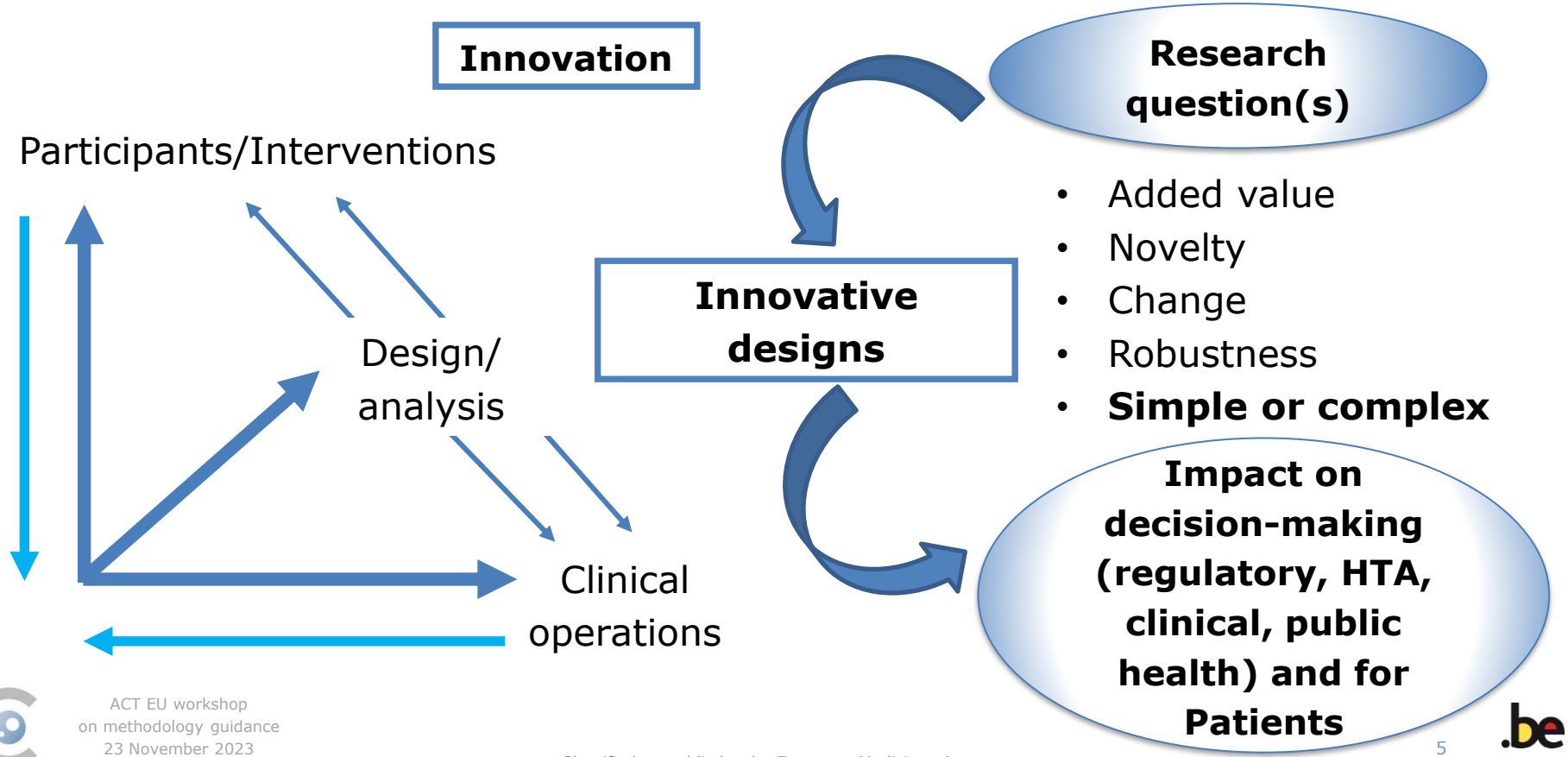
Complex clinical trials – Questions and answers
Version 2022-05-23

Draft agreed by Drafting Group experts (from EMA scientific committees, EMA working parties, EMA staff and Clinical Trials Coordination Group)	May 2022
Draft agreed by Clinical Trials Coordination Group	May 2022
Draft agreed by Clinical Trials Expert Group	May 2022
Adopted by ACT EU Steering Group	23 May 2022

Keywords	Clinical trial; complex clinical trial; clinical trial authorisation application; marketing authorisation application; trial design; trial analysis; Clinical Trials Regulation; master protocol; platform trial; biomarker; adaptive design; modifications; Bayes; control data; transparency

For questions related to this document, please write to ACTEU@ema.europa.eu.

Enabling innovative designs and multi-stakeholder collaboration



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