How can ACT EU best support multi-national academic clinical trials?

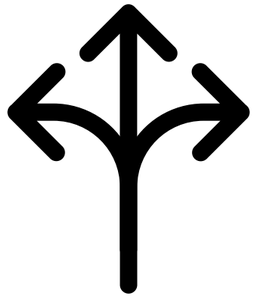
By involving funders, sponsors, regulators, members states, clinical professionals, patients, participants and the public, and creating a platform for holistic, inclusive engagement with key challenges and opportunities (including, for example, data infrastructure, ethics and contracting issues).

Common purpose and goals

Derived from common understanding of key principles and priorities

Shared responsibility

Enacted by, across and for all actors and the whole system

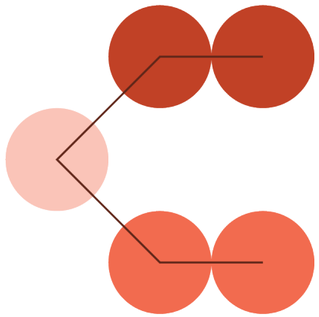


Flexibility and proportionality

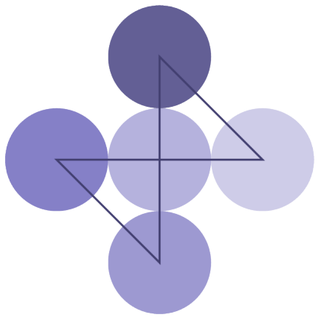
Recognition that methods and approaches will differ in small or large ways from trial to trial

Five Principles of Good Randomized Clinical Trials

https://www.goodtrials.org/guidance



1. **Good RCTs are designed to produce scientifically sound answers to relevant questions:** RCTs should help resolve important uncertainties about the effects of health interventions. This requires the combination of key design features such as proper randomisation to avoid selection bias, adequate sample size to minimise the play of chance, unbiased assessment of outcomes, and intention-to-treat analyses.



2. **Good RCTs respect the rights, safety, and wellbeing of participants:** Ethical clinical trials combine seeking answers to important questions with scientific validity and appropriate protection and respect for all involved, especially participants. Independent review of proposals for new research, through a research ethics committee (or equivalent), is an important governance tool and can help ensure appropriate steps are taken to protect the rights and welfare of participants. Accessible, clear communication and relevant consent at all stages of an RCT are at the heart of this principle.

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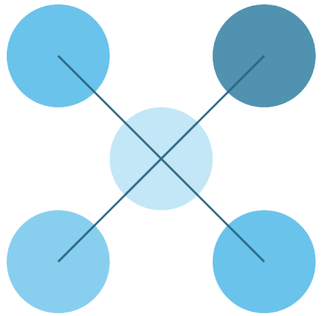
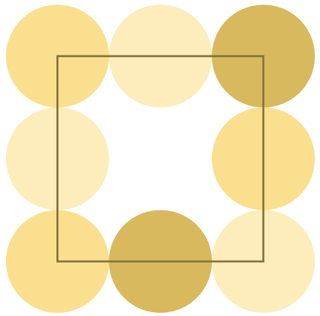
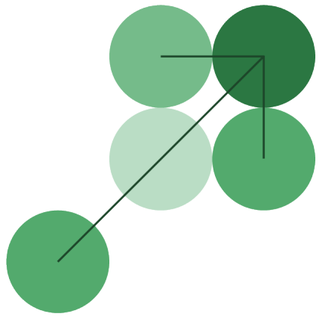


3. **Good RCTs are collaborative and transparent:** All those involved in RCTs share responsibility for building and sustaining the trust of collaborating partner organisations and clinical communities, participants, and the wider public. Trust is undermined by lack of relevance or transparency and lack of respect for the rights and values of participants and those whose care will be influenced by the results.



4. **Good RCTs are designed to be appropriate for their context:** Ensuring that a trial is set up to be practicable and produce reliable, actionable results is an important scientific and ethical duty. Consideration of context and existing resources in a proposed trial setting can better inform effective trial design.



5. **Good RCTs manage quality effectively and efficiently:** Delivery of a high-quality trial requires competent decision making and coordinated execution. Good governance and good trial quality management can help achieve these features. The focus should be on adopting risk-based proportionate approaches, identifying the key issues that would have a meaningful impact on participant wellbeing and safety or on decision making based on the trial results.