Guidance for Good Randomized Clinical Trials: using five principles of a good trial to avoid the harm and waste of missed research opportunities and uninformative trials

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URL: https://tghncollections.pubpub.org/pub/hqgkyzws

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Faced with spiraling costs, burdensome bureaucracy and siloed research culture, the power of clinical trials is not reaching its potential to save and improve lives and is not ready to fully embrace powerful new tools, technologies and methods. The Good Clinical Trials Collaborative (GCTC) has set out to collectively refocus the system on five fundamental scientific and ethical principles of good randomized clinical trials and avoid the harm and waste of missed research opportunities and uninformative trials.

The Guidance presents five key principles for any trial and supports delivery of a well-planned, well-run, and clinically-relevant trial in any setting and for any type of intervention.

The GCTC has worked with a diverse, multi-disciplinary, global community to identify and describe five principles, and the Guidance advises on:

• the component design characteristics of an RCT that combine to robustly answer a research question
• key considerations that support a trial to fulfil its ethical responsibilities
• the practices and behaviours that help develop trust between stakeholders
• the benefits of ensuring that a trial is both fit-for-purpose and accounts for and utilises the inherent characteristics of the trials setting(s)
• the importance of competent decision-making and coordinated execution

The Guidance can be a foundation of common understanding that good healthcare is informed by good evidence from good trials – and help improve not only the standards of clinical trials but the way in which we learn from and utilise their results, across the world.