Guidance for Good Randomized Clinical Trials

Evaluation Tool

A tool to support application of the key   
principles of good RCTs

# About this tool

The Good Clinical Trials Collaborative’s Guidance for Good Randomized Clinical Trials[[1]](#footnote-2) sets out five principles of good RCTs, where good is defined as being: informative, ethical and efficient. This tool supports high-level reflection on and evaluation of the degree to which key elements of those principles have been considered and embedded in the design, delivery, analysis and reporting of an RCT (planned, underway or completed).

## When to use this tool

* **Prospectively:** to assess plans and prompt improvements in trial design and delivery.
* **Concurrently:** to consider changes to protocols and plans in the light of experience and new information e.g. enrolment, event rates, participant experience, new data from other trials.
* **Retrospectively:** to support evaluation of the trial's conduct and results – and to prompt lessons that can be applied to future trials.

## Who can use this tool?

* **Research teams and sponsors** – to help review and optimise planned or ongoing trials.
* **Funders** – to support funding prioritization decisions and constructive feedback to applicants.
* **Regulators** – to help set expectations of best practice and support holistic review of a trial’s attributes.
* **Reviewers and journal editors** – to support review of and commentary on trial manuscripts and reports.
* **Patients, participants and communities** – to help review a trial’s quality and identify opportunities for improvement.
* **Students** – to develop skills in design and critical appraisal of clinical trials and their results.
* **Any combination of the above**– to support dialogue about purpose, priorities and expectations.

# How to use this tool

Using relevant available information (e.g. draft or final protocol, manuscript, reports) and with reference to the full text of the Good Clinical Trials Collaborative’s Guidance for Good Randomized Clinical Trials, review the ‘Key points to consider’ column.

Use the final two columns to indicate whether the ‘Key points to consider’ have been fulfilled (by indicating ‘Yes’, ‘Partially’ or ‘No’). You may wish to support your answer with reference to relevant sections of available documentation or with a brief comment.

## Assessment

Answering ‘**Yes**’ should indicate the ‘Key point to consider’ has been **fully addressed**, and the comment should briefly **explain how**.

Answering ‘**Partially**’ should indicate the ‘Key point to consider’ has been **addressed to some extent**, and the comment should briefly **explain why** it has not been fully addressed (e.g. some aspect is not relevant or feasible, or describing plans to correct or mitigate).

Answering ‘**No**’ should indicate that the ‘Key point to consider’ has **not been addressed** at all, and the comment should briefly **explain why** (e.g. not applicable, or describing plans to correct or mitigate). Where ‘**Not applicable**’ is listed as a separate option, the comment should **explain** or refer to clear **justification**.

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|  |  | Good RCTs are **designed to produce scientifically sound answers to relevant questions** | |
| Sub-principle | Key points to consider | Fulfilled? | Comment | | |
| * 1. Appropriate trial population | * + 1. Eligibility criteria are tailored to the trial question and are not unnecessarily restrictive. | Yes  No  Partially |  | |
| * + 1. Efforts are made to include a broad population unless there is a good medical (e.g. safety) or scientific (e.g. mechanism of action) reason for restriction. | Yes  No  Partially |  | |
| * 1. Robust intervention allocation | The process of randomly assigning trial interventions is impossible for participants or study personnel to predict and ensures concealment of the allocated intervention prior to the point of randomization. | Yes  No  Partially |  | |
| * 1. Adequate size | The trial has the necessary number of participants in each group (i.e. sufficient size) to have good statistical power to provide a reliable answer to the trial question. | Yes  No  Partially |  | |
| * 1. Blinding and masking | Following randomization, treatment allocation is masked through use of placebo or dummy interventions (where feasible) and/or by ensuring that individuals and processes used to assess the effects of the intervention are unaware of the allocated intervention. | Yes  No  Partially  N/A (please explain) |  | |
| * 1. Adherence | Strategies are implemented to facilitate and encourage adherence to the allocated intervention(s) (e.g. optimising acceptability for participants). | Yes  No  Partially |  | |
| * 1. Completeness  of follow-up | Participant outcomes are ascertained for the full duration of the trial (regardless of adherence to the intervention). | Yes  No  Partially |  | |
| * 1. Relevant measures of outcomes | Outcomes are relevant to and focused on the trial question and are chosen to be sensitive to the anticipated effects of the intervention. | Yes  No  Partially |  | |
| * 1. Proportionate data capture | The nature, volume, frequency, level of detail, and methods of data collection during the trial are focused and optimised to assess the study question while avoiding excessive or low value data collection. | Yes  No  Partially |  | |
| * 1. Ascertainment  of outcomes | * + 1. Processes for ascertaining study outcomes (including the methods and timing) are the same in all randomized groups. | Yes  No  Partially |  | |
| * + 1. The people and systems responsible for assessing, clarifying, and adjudicating study outcomes are blind to the allocated intervention. | Yes  No  Partially |  | |
| Statistical analysis | * + 1. Statistical analysis plan developed prior to knowledge of the trial results, with analyses then conducted and reported in accordance with that plan. | Yes  No  Partially |  | |
| * + 1. Main analyses follow the intention-to-treat principle. | Yes  No  Partially |  | |
| * + 1. Subgroup, subsidiary, and exploratory analyses are pre-specified where possible and interpreted cautiously (especially if not pre-specified or multiple in number). | Yes  No  Partially |  | |
| Assessing effects | * + 1. Assessment of possible beneficial or harmful effects of the intervention during an ongoing RCT should focus on comparisons between the intervention and control groups, and be conducted by a group that is sufficiently independent of the trial team. | Yes  No  Partially |  | |
| * + 1. As the trial is ongoing, information about potential harms of the intervention is considered alongside potential benefits and in the wider clinical and health context. | Yes  No  Partially |  | |
| Monitoring emerging information | As the trial is ongoing, there are clear processes for evaluating the emerging safety and efficacy data (e.g. an independent Data Monitoring Committee), including unblinded comparisons of relevant events and consideration of external sources of information, without prematurely unblinding any of those involved in the trial unless there is a need to provide them with actionable information. | Yes  No  Partially |  | |

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|  |  | Good RCTs **respect the rights and  well-being of participants** | | |
| Sub-principle | Key points to consider | Fulfilled? | Comment |
| * 1. Appropriate participant communication | Relevant, easily understandable information is (or will be) shared with trial participants before, during and after the trial in ways, languages and formats that take account of the audience and clinical context, and which avoid information overload. | Yes  No  Partially |  |
| * 1. Relevant consent | * + 1. Consent processes clearly explain to potential trial participants the reasons for the trial, the question(s) it is seeking to answer, what is involved for them, and the potential benefits and risks of participation to the extent that they are additional to those involved in the context of usual clinical care so that the participant can make an informed, voluntary, and competent decision about whether to enter the trial or not. | Yes  No  Partially |  |
| * + 1. For circumstances in which it is not possible for an individual to give informed consent (e.g. infants or individuals lacking mental capacity, medical emergencies), appropriate safeguards have been put in place to protect the rights of individuals while not unnecessarily precluding participation. | Yes  No  Partially |  |
| * 1. Changing consent | Processes are in place to allow participants to stop or change their participation, and to determine the intended meaning of and required actions relating to such decisions. | Yes  No  Partially |  |
| * 1. Implications  of changing consent | During the consent process before enrolment, participants are informed that relevant data they contribute up to the point they choose to stop participating will be retained and used (in accordance with the protocol) if they choose to leave the trial early. | Yes  No  Partially |  |
| * 1. Safety of individual participants | Trial processes for detecting and managing the safety of individual trial participants (including the mechanisms to unblind the randomised intervention if necessary) are tailored to the trial population and what is already known about the effects of the intervention, and are reviewed and may be modified if new information emerges as the trial is ongoing. | Yes  No  Partially |  |
| * 1. Communication of new information | * + 1. Mechanisms are in place for identifying new information about the effects of the intervention, from within and outside the trial, and for considering whether it materially changes what is known about the effects of the intervention for some or all participants. | Yes  No  Partially |  |
| * + 1. Processes are in place for informative, timely and actionable communication of new information that materially changes what is known about the effects of the intervention to those for whom it is relevant or who may need to take action. | Yes  No  Partially |  |

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|  |  | Good RCTs are **collaborative  and transparent** | | |
| Sub-principle | Key points to consider | Fulfilled? | Comment |
| * 1. Working in partnership with patients and communities | Potential participants and/or members of the relevant community have been able to contribute to the design, execution, and interpretation of the trial. | Yes  No  Partially |  |
| * 1. Collaboration among organizations | Broad-based collaboration and engagement of a range of relevant individuals and/or organisations to identify and address those factors that are critical to trial quality and enable a delivery approach that is appropriate to the trial setting and context. | Yes  No  Partially |  |
| * 1. Transparency | * + 1. Trial registered on a publicly available database prior to enrolment of the first participant. | Yes  No  Partially |  |
| * + 1. Additional trial information, including the trial protocol and other trial documentation, is made publicly available if feasible. | Yes  No  Partially |  |
|  | * + 1. Trial report describing the study design, methods, and results have been made publicly available (ideally open access) in a timely manner (target within 12 months). | Yes  No  Partially |  |
| * + 1. Making trial data available for use by other researchers considered and put in place at a suitable time if ethical, feasible, and scientifically appropriate. | Yes  No  Partially |  |

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|  |  | Good RCTs are **designed to be feasible  for their context** | | |
| Sub-principle | Key points to consider | Fulfilled? | Comment |
| * 1. Setting and context | The trial design and implementation take account of the setting and context in which the trial takes place, including the health needs and preferences of communities, their ability to access health care, and their understanding of clinical trials (as identified through appropriate involvement, consultation and engagement with patients and the public). | Yes  No  Partially |  |
| * 1. Use of existing resources | * + 1. The trial is tailored to be practicable and makes optimal use of pre-existing resources and facilities, including (where relevant) the expertise, skills, professional standards, and oversight mechanisms associated with routine healthcare practice. | Yes  No  Partially |  |
| * + 1. Trial-specific training focuses on relevant areas of knowledge, skills or procedures that are materially different to routine or established competencies. | Yes  No  Partially |  |

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|  |  | Good RCTs **manage quality effectively  and efficiently** | | |
| Sub-principle | Key points to consider | Fulfilled? | Comment |
| * 1. Competent advice and decision-making | Effective and efficient governance structures are in place with necessary diversity of expertise to support delivery of a good RCT in line with these Principles and to avoid, correct, or mitigate problems. | Yes  No  Partially |  |
| * 1. Protecting trial integrity | Clear procedures ensure that key decisions about trial design, delivery and analysis are not influenced by premature access to unblinded information about the emerging results by any group or individual for whom such knowledge could introduce bias or the perception of bias into the trial. | Yes  No  Partially |  |
| * 1. Planning for success and focusing on issues that matter | * + 1. The trial is designed in a well-articulated, concise, and operationally viable protocol which is tailored to be practicable in the relevant circumstances. | Yes  No  Partially |  |
| * + 1. Key issues that would have a meaningful impact on participant well-being and safety or on decisions made in response to the trial results (‘issues that matter’) are identified in a risk assessment. | Yes  No  Partially |  |
| * + 1. Quality management is focused on minimising, mitigating and monitoring identified key issues (with other activities that do not impact these key issues deprioritised or omitted accordingly). | Yes  No  Partially |  |
| * 1. Monitoring, auditing and inspection of study quality | The nature and timing of trial monitoring and auditing activities are focused on, and proportionate to, ‘issues that matter’ (i.e. those that might have a material impact on the participants in the trial and the reliability of the results) and the findings are used to further improve quality. | Yes  No  Partially |  |

1. Guidance for Good Randomized Clinical Trials (May 2022), developed by the Good Clinical Trials Collaborative: <https://www.goodtrials.org/guidance> [↑](#footnote-ref-2)