The planning and design of clinical trials

Clinical trial planning and design require meticulous attention to ensure a successful outcome.

Study plan

The plan drawn up for a clinical trial should cover the following points:

- Objectives – definition of the primary research question and any secondary questions to be answered
- Justification of the sample size – sample size calculation, power analysis, potential dropout rate
- Randomization methodology – suitable randomization methods (e.g. simple, block, adaptive, stratified), plus planning of the allocation concealment process
- Statistical analysis – methods for analyzing primary and secondary questions, handling missing data
- Handling and structuring collected data – processes for data entry, storage and validation
- Handling serious adverse events (SAEs) – the criteria for identifying, reporting and managing SAEs

Planning includes the development of a publication policy to publish trial findings in journals and at conferences.

Administration

The administrative aspects include:

- Trial registration – ensures transparency and compliance (e.g. ClinicalTrials.gov, ISRCTN)
- Ethical approval – approval from ethics committees (ECs) and institutional review boards before the start of the trial
- Setting up trial steering and monitoring committees
- Audit – implementation of internal and external audits to ensure compliance with the study protocol
- Handling SAEs and amendments – outline of the methods for reporting and managing SAEs and making any adjustments to trial processes
- Procedures for sourcing, storing and dispensing medicinal products used in the trial
- Guidelines for handling and using medical devices used in the trial

Participant information

There are two principal sets of information that relate to study participants. The planning and design should cover:

- Informed consent – design of informative sheets to be given to participants explaining information on the trial objectives, risks, benefits and rights of participants
- Data sharing with regulatory authorities and researchers – policies for sharing data with regulatory authorities and other researchers, while maintaining participant confidentiality

Further information

National Institute for Health and Care Research Clinical Trials Toolkit, https://www.ct-toolkit.ac.uk/routemap/trial-planning-and-design