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| **Study type** | **Description** | **Sample size and power** | **Example uses** | **Appropriate analyses** | **Relevant protocol/reporting guidelines** |
| **Feasibility** | A feasibility study is used to inform whether it is possible to conduct a larger future study. It should aim to resolve the key uncertainties in the design and conduct of a future such study. | No formal sample size calculation but sample size should be justified in terms of the feasibility objectives e.g. estimating the proportion retained to final follow up to a specified level of precision.  Typically tens of participants depending on objectives.  Could be smaller for less variable populations, e.g. model organisms). | Testing processes (e.g. recruitment methods).  Assessing multiple possible outcomes in search of a good primary outcome for a full study.  To collect initial data to inform sample size calculations for future studies. | Descriptive statistics and confidence intervals. | Clinical trials: [CONSORT Extension for Pilot and Feasibility trials](http://www.consort-statement.org/extensions/overview/pilotandfeasibility). |
| **Pilot** | A small-scale version of a planned larger study conducted before the larger study to ensure the planned protocol is viable. | No formal sample size calculation but, as above, the selected sample size needs to be justified.  Typically tens of participants depending on objectives.  Could be smaller for less variable populations, e.g. model organisms). | Testing processes (e.g. the planned recruitment method).  Checking that the selected primary outcome can be collected as expected and is an appropriate measure for the study population (e.g. has no obvious floor or celling effects).  Checking that attrition/loss to follow up has not been underestimated.  To check assumptions made for sample size calculations for future studies are realistic and adequately precise.  Pilots for clinical trials should follow the CONSORT extension for pilot and feasibility studies. | Descriptive statistics and confidence intervals. | Clinical trials: [CONSORT Extension for Pilot and Feasibility trials](http://www.consort-statement.org/extensions/overview/pilotandfeasibility). |
| **Exploratory** | A study without pre-defined outcomes, analyses or sample size.  Or studies technically powered to observe a difference between groups, but with insufficient participants to allow analysis models with appropriate complexity to be fitted. | Indicative sample size calculations may be performed.  Power for given situations, or detectable effect size may be considered. (e.g. 40 participants would provide Y power to detect an effect size of X). | Situations necessitating compromise between study design and cost/availability of participants.  Small studies technically powered to detect a stated effect size but with insufficient numbers to allow appropriately complex modelling (e.g. a study comparing disease occurrence between two groups but without sufficient numbers to include important demographic characteristics in the modelling).  Studies where many outcomes are being measured (e.g. gene expression studies) and it is not clear how many will show differences between groups. | Descriptive statistics and confidence intervals.  Hypothesis testing within simple models, with careful consideration of the high risks of type I and type II errors, and the subsequent risk of biased conclusions. |  |
| **Full scale study** | A fully-powered (i.e. usually at least 80%) confirmatory study with pre-defined outcomes, analyses, sample size calculation (for specified power), and stated minimum biologically/clinically important difference(s). | Sample size determined by formal calculation relevant to primary outcome, design and thence analysis method, taking into account attrition/loss to follow up.  Could be tens to tens of thousands of participants. | Clinical trials.  Large observational studies. | Descriptive statistics and confidence intervals.  Pre-defined hypothesis testing and estimation within appropriately complex modelling.  (Some secondary exploratory analyses may be appropriate). | Clinical trials: [SPIRIT](https://www.spirit-statement.org/) and [CONSORT](file:///C:\Users\Chris\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\GI4RJICU\CONSORT) guidelines.  Observational studies: [STROBE](https://www.equator-network.org/reporting-guidelines/strobe/) guidelines.  Lab studies: [RIPOSTE](https://elifesciences.org/articles/05519v2#s7) guidelines. |
| **Secondary analysis of pre-existing or routinely collected data** | Studies involving the secondary analysis of pre-existing datasets that were not collected specifically for the current study, or data not collected primarily for research purposes. | Maximum sample size set by size of pre-existing dataset.  Consideration of calculations for power and/or detectable effect size should be presented to show objectives are realistic and allow for missing data. | Examining relationships between exposures and disease in routinely collected patient data.  Re-analysing previously published data with new objectives or methods.  Studies involving Machine Learning methods.  Clinical audits. | Descriptive statistics and confidence intervals.  Pre-defined hypothesis testing within appropriately complex modelling.  (Some exploratory analyses may be appropriate. |  |
| **Systematic reviews and meta-analyses** | Studies that collect and analyse published results from the literature. | n/a  Availability of published results is determined by the extent of the literature. | Used to summarise extent and quality of available literature. Meta-analyses combine evidence from similar studies. | Descriptive statistics and confidence intervals (in particular, forest plots). | [PRISMA](http://www.prisma-statement.org/) guidelines.  [Cochrane Handbook for Systematic Reviews of Interventions](https://training.cochrane.org/handbook). |