Definitions for Clinical Trials

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Term	Definition	Explanation
Assessed for eligibility	Potential participant has been formally checked for eligibility.	The "screening" process will vary by study. Potential participants may be identified by clinical or research staff, or participants may self-refer (registration of interest). Assessment may involve screening of patient records or face-to-face interview. If screening data are collected without consent, this should have ethical approval. In some studies, it may not be possible to quantify the screening denominator, but a plan should be made to estimate the eligibility and consent rate.
Not eligible	Potential participant has been assessed and does not meet the eligibility criteria for entry /randomisation.	One or more inclusions = no *OR* one or more exclusions = yes Participants who are randomised and subsequently found to be ineligible at the time of randomisation are designated as "randomised in error".
Declined	Potential participant is eligible but has stated they do not want to participate in the trial.	All inclusions = yes; All exclusions = no
Declined under waiver	Participant has been randomised but (written) consent was not obtained during the waiver period.	Generally, identifiable data cannot be collected without consent.
Consented	Participant has provided (written) consent to enter / continue in the study.	Generally, identifiable data cannot be collected without consent.
Not enrolled for other reasons	Potential participant is eligible but was not enrolled for other reasons.	All inclusions = yes; All exclusions = no Other reasons may be recorded and coded, depending on the trial.
Randomised	Participant has been randomised.	
Randomised in error	Participant has been randomised but subsequently found to be ineligible at the time of randomisation, or has not provided consent (if prospective required).	One or more inclusions =no *OR* one or more exclusions =yes Not included in modified ITT analysis. Does not include participants randomised within the wrong stratum (=protocol deviation).
Received allocated intervention	Participant received the "minimum treatment protocol".	"Minimum treatment protocol" to be defined for each trial individually.
Did not receive allocated intervention	Participant has been randomised and allocated to intervention but did not receive the "minimum treatment protocol" or received the incorrect intervention.	Reasons should be recorded and coded, including: • Death before intervention • Withdrawal before intervention • Intervention not administered, other reasons • Incorrect intervention • Intervention discontinued • Non-compliant
Incorrect intervention	Participant received the wrong intervention, i.e., different to what they were allocated.	May only be know when allocation code is unmasked.

Non-compliant	Evidence indicates the participant has not achieved the “minimum treatment protocol”	
Intervention discontinued	Participant commenced the intervention, but the intervention was formally stopped by clinician or participant prior to "minimum treatment protocol”.	Does not include poor compliance unless the participant has formally discontinued the intervention.
Reduced participation	Participant has stated they do not want to take part in one or more assessment. Some data is available for this participant.	Randomised participant has declined one or more components of trial activity which may include future follow up.
Overseas	Participant is overseas but has not withdrawn.	Data may still be collected.
Lost	After all attempts, there are no positive leads regarding the participant’s whereabouts for current assessment point.	Unlikely to acquire data for current assessment point, although a further attempt may be made at subsequent assessment points.
Withdrawn	Participant has made an informed decision they do not want any further involvement in the study.	Participant should not be contacted again in the future. Data collected up to point of withdrawal may be able to be used, depending on withdrawal type.
Died	Participant death	
True intention to treat	Randomised and consented	ITT should be defined in the protocol. Infants who are withdrawn are still part of the ITT analysis even though some data may be missing.
Modified intention to treat	Randomised and consented less randomised in error.	ITT should be defined in the protocol. Does not include those declined under waiver. Infants who are withdrawn are still part of the ITT analysis even though some data may be missing.
Per protocol analyses	Analyses with participants who completed predefined minimum treatment protocol	"Completed minimum treatment protocol” to be defined for each trial individually.
Reached minimum assessment age	Reached minimum age for outcome assessment.	Includes those who have died (if part of primary outcome).