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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Clinical trial versus interventional study?

ClinicalTrials.gov was launched in 2000 for registration of trials. It has two categories of studies:

Interventional studies (clinical trials)

and

Observational studies

Defined in the site glossary:

Interventional study

A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Observational study

A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment.

Clinical trial in the glossary is simply defined as: "another name for an interventional study".

Why not clinical trial instead of interventional study?

A clinical trial, defined in Merriam Webster, is a scientifically controlled study of the safety and effectiveness of a therapeutic agent (such as a drug or vaccine) using consenting human subjects. Interventional study does not appear in the dictionary.

The trouble with interventional is the base term, *intervene*, meaning to come between so as to prevent or alter a result or course of events. The meaning is contrary to intent in trials.

\Blog\CT v interventional study.WPD