Adaptive clinical trial

An adaptive clinical trial is a clinical trial that evaluates a medical device or treatment by observing participant outcomes (and possibly other measures, such as side-effects) on a prescribed schedule, and modifying parameters of the trial protocol in accord with those observations. The adaptation process generally continues throughout the trial, as prescribed in the trial protocol. Modifications may include dosage, sample size, drug undergoing trial, patient selection criteria and “cocktail” mix.

In some cases, trials have become an ongoing process that regularly adds and drops therapies and patient groups as more information is gained.

Importantly, the trial protocol is set before the trial begins; the protocol pre-specifies the adaptation schedule and processes.

The aim of an adaptive trial is to more quickly identify drugs or devices that have a therapeutic effect, and to zero in on patient populations for whom the drug is appropriate.

A key modification is to adjust dosing levels.

Traditionally, non-adverse patient reactions are not considered until a trial is completed.