Interim analysis

In clinical trials and other scientific studies, an interim analysis is an analysis of the current data from an ongoing trial, in which the primary research question is addressed. It has the potential to modify the conduct of the study. Depending on the results, an interim analysis may lead to changes, such as stopping one treatment arm or changing the number of participants in a group, or stopping the trial altogether.

An example of an interim analysis leading to the early stopping of a study comes from a trial to better identify patients with coronary heart disease who would benefit from an implantable device. The trial compared the devices to treatment with medicines in patients who had survived life-threatening coronary events. The trial was stopped when interim analysis showed a significant reduction in all causes of death in patients assigned to treatment with the implantable device.

An interim analysis requires careful advanced planning and appropriate adjustments to the statistical approach. An interim analysis and any anticipated changes to the trial must be described and justified in the study protocol. The option to modify the design of an ongoing clinical trial is becoming increasingly common and is known as adaptive design.