Overview

Clinical Trials

A study is considered a *clinical trial* when it contemplates the controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, or comparisons of approved drugs, devices, treatments, or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. This clinical trial definition is used for calculating indirect cost (IDC) Rate for PI-initiated Clinical Trials.

In addition, a clinical trial is most often used in conjunction with obtaining new drug or device approval from the U.S. Food and Drug Administration, although they can be designed with the sole purpose of collecting and analyzing data about an approved drug or device in order to contribute to medical knowledge about the treatment of a disease or medical conditions.

PI-Initiated vs. Industry-Initiated Clinical Trials

Studies may be conducted under an **industry-developed protocol** or a **principal investigator-developed protocol**.

For details, go to the **PI-Initiated vs. Industry-Initiated Clinical Trials Quick-Reference** Guide.

National Institutes of Health (NIH)

The National Institutes of Health (NIH) has recently clarified its clinical trials definition.

Go to the NIH Clinical Trials page for more information.

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