Clinical feasibility trials

What is a clinical feasibility trial?

Also known as first-in-human studies, or early clinical experience trials, clinical feasibility trials are a step in the development of a new medical device or therapy or in testing an existing product for a new indication.

A clinical feasibility trial is a research study in which the product is used in a small number of human patients who are carefully monitored. It is typically conducted after bench testing and/or pre-clinical animal testing have demonstrated expected safety of the investigational product. The feasibility trial is meant to provide enough information to determine whether the product is safe enough to proceed with larger studies of more patients and whether the product seems to function as intended. Importantly, it is meant to show if a device or therapy does not function as intended so that improvements can be made to its design prior to investing in large pivotal clinical trials or regulatory marketing applications.

A feasibility trial is *not* designed to confirm that the product is safe on a larger scale or that its benefits outweigh its risks. A feasibility trial may provide preliminary signals of efficacy to help make business decisions about whether to continue with the development of the product, but it is *not* designed to *prove* the device or therapy is effective.

Clearly, not all products require a feasibility study. For example, a device may just be an iteration of an existing technology, and the manufacturer is confident enough in its expected performance to move directly into a pivotal (confirmatory) study to demonstrate its effectiveness and safety. But sometimes there is information needed to finalize your device design that cannot be gathered any other way than by conducting a small study in humans.

For example, assume you are developing a device with a coating intended to relieve local pain due to the presence of the device. No bench test can tell you if it is working, and animal testing is not likely to be helpful. The only one who can tell you if it hurts another human. The necessary pivotal clinical trial may require hundreds of patients. Therefore, you may want to first conduct a small preliminary proof-of-principle study in humans to determine if your device shows potential effectiveness before you commit to a full-scale pivotal clinical trial.

Another advantage to using a clinical feasibility trial to evaluate your product design is that you may be able to defer some non-clinical testing, if appropriate, until the device design has been finalized, thereby saving time and expense. The feasibility study may also serve to refine the patient population that is most suitable for treatment with the product (i.e., may help define the inclusion/exclusion criteria to be used in the subsequent pivotal study). And the investigators who participate in the feasibility study may later act as proctors to train investigators in the use of the product for the subsequent pivotal trial or to train other physicians once the product is commercially available.

Clinical Feasibility Trials in the U.S.

The United States has been falling behind other nations with respect to initial clinical evaluation of novel medical devices. Therefore, the device and biologic product branches of the FDA (CDRH and CBER) have been encouraging early feasibility studies as a strategic priority in an effort to bring novel medical devices to the American public sooner. FDA's goal is to increase the number of early feasibility studies/first in human IDE studies submitted to each CDRH and CBER division.

In 2013, FDA released a guidance outlining a new pathway to initiate early feasibility studies in the U.S. For products whose continued development requires human clinical data, but are early enough in the development process that they might still need significant design changes, early feasibility studies may be initiated with less non-clinical data than would otherwise be required. The understanding is that these devices or therapies may be so novel, the appropriate non-clinical testing program has not yet been validated and must be developed on a case-by-case basis. The guidance encourages manufacturers to work with FDA prior to submissions, to evaluate the potential risks together and decide on mitigation strategies. The new process also allows for easier course-corrections throughout the study as data are collected and reveal potentially unexpected characteristics of the device. [1]

With this support from FDA, it may be economical to conduct your feasibility study locally (at least in the U.S.), possibly saving money on overseas travel, and possibly maintaining better control over the study and the resulting data.

Our Services

Our expert personnel can help you and your team design and conduct efficient clinical trials. Services include the following:

- Protocol development
- Imaging consulting
- Site assessment
- Site training and support
- Case report form/database creation, implementation, and management
- Reporting and final data summary
- Document preparation for Institutional Review Board submission

The clinical team at MED Institute can help you decide when clinical data may be necessary and how to collect the data most effectively. We bring significant experience to executing your trials.

Contact us so that we can work together to make products and therapies that will improve patient outcomes.

If you have any questions or need any additional information, please contact:

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[1] U.S. Food and Drug Administration/Center for Devices and Radiological Health. (1 Oct 2013). *Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies*. Washington, DC: Author.