

5 Key Characteristics of Medical Device Clinical Trials

Existing data can partially substitute for prospective Trial Data.

Regulators such as the FDA consider the clinical data that are available external to prospective studies for the specific purpose of supporting marketing applications. This is particularly relevant for consideration of expanded indications for approved devices in cases where there is a body of evidence supporting the "off-label" use.

Device design or procedure may be modified during the trial.

In some cases, early clinical events or feedback from physicians or patients may lead to changes in the device or the protocol. Validation of the changes may require additional clinical data beyond the original plan but may not require an entirely new study if it can be shown that data on the original device is appropriate.

Many Device Trials assess improvements on previous-generation devices.

Although some devices are truly new, the nature of device development is an improvement on existing technologies as clinical experience grows. clinical data is required to evaluate the risk-benefit profile of the new device.

Fewer Participants Enrolment

End-points designed to show a "reasonable assurance of safety and effectiveness" lead to modest sample sizes.

Device trials are less likely to be blinded or randomized than drug trials

Blinding or randomization is impractical owing to the nature of the device or the condition under study. For other studies, FDA based on the device type, allows for single-group studies that compare results with established performance criteria.



Clinical Trials Of Medical Devices Part 1 Regulatory Environment

J Elliott



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