

IMPERIAL

# MedTechONE Knowledge Base



# What are the essential steps to initiate a Clinical Trial for medical devices?

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- 2 Obtain Ethics Committee Approval
- 3 Secure Regulatory Approval
- 4 Obtain Participant and Site Consent
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Launching a clinical trial for a medical device requires following structured steps to ensure regulatory compliance, participant safety, and robust data collection. Here are the essential steps involved.

## 1. Develop a Clinical Investigation Plan (CIP)

- **Outline the Trial's Purpose and Objectives:** The Clinical Investigation Plan (CIP) specifies the primary goals, such as evaluating safety, effectiveness, and device performance.
- **Detail the Study Design:** The CIP includes the study design (e.g., randomized, controlled, observational), and it outlines methods for monitoring, data collection, and analysis.
- **Define Eligibility Criteria and Procedures:** It includes inclusion and exclusion criteria for participants, protocols for administering the device, and instructions for monitoring and recording outcomes.
- **Set Data Management and Privacy Guidelines:** Specify data collection methods, storage, and privacy measures, ensuring compliance with regulations like GDPR or HIPAA.

## 2. Obtain Ethics Committee Approval

- **Submission to the Ethics Committee (EC) or Institutional Review Board (IRB):** This committee assesses the study to ensure that it is ethically sound, prioritizing participant welfare and ensuring informed consent processes.
- **Review of Participant Protections:** The EC/IRB reviews safety protocols, risk-benefit assessments, and measures for protecting participants' rights.
- **Receive Approval and Implement Required Adjustments:** After review, the EC/IRB may request revisions to the CIP for greater participant protection or transparency, which must be addressed before proceeding.

### 3. Secure Regulatory Approval

- **Prepare Regulatory Documentation:** Compile technical details of the device, preclinical results, the CIP, and risk assessments to submit to regulatory agencies.
- **Apply for Investigational Device Exemption (IDE) or Equivalent:** In the U.S., this application is submitted to the FDA; in Europe, it might go to the relevant National Competent Authorities or EMA. Approval allows the device to be used for testing in human trials.
- **Implement Agency Feedback:** Regulatory authorities may request modifications to protocols, data handling, or safety monitoring to meet approval standards.

### 4. Obtain Participant and Site Consent

- **Recruit Participants According to Eligibility Criteria:** Identify participants who meet the study's criteria (e.g., age, health condition), ensuring the population reflects the intended device users.
- **Conduct Informed Consent Process:** Each participant must be thoroughly informed about the study's purpose, procedures, potential risks, and their rights. Signed consent is mandatory before participation.
- **Site Consent and Compliance:** Clinical sites involved in the study must also consent to comply with trial protocols, including device handling, data collection, and participant monitoring.

## 5. Obtain and Assign a Clinical Investigation Verification Identifier (CIV-ID)

- **Register the Trial:** In some regions, the trial must be registered with a Clinical Investigation Verification Identifier (CIV-ID) or similar tracking code for transparency and accountability.
- **Assign CIV-ID to the Study Protocol:** The CIV-ID provides a unique identifier for the clinical trial, used in documentation, reporting, and regulatory submissions to track and manage study data.

## 6. Which Classes of Medical Devices Must Undergo Clinical Trials?

The need for clinical trials largely depends on the classification of the medical device, which is based on the level of risk it poses to patients. Medical device classifications vary by region, but generally fall into three main categories:

- **Class I (Low Risk):** Devices that pose minimal risk to users, such as bandages, tongue depressors, or basic surgical instruments, often do not require clinical trials. Instead, they may only need to meet general safety and manufacturing standards.
- **Class II (Moderate Risk):** These include devices that present a higher level of risk than Class I, such as infusion pumps, imaging equipment, or blood pressure monitors. Some Class II devices may require clinical trials, especially if they are novel or have a new indication, to provide evidence of safety and effectiveness.
- **Class III (High Risk):** High-risk devices, including pacemakers, heart valves, implantable defibrillators, and certain orthopedic implants, typically must undergo rigorous clinical trials. Due to their direct impact on health and life-supporting functions, these devices require extensive testing to ensure they meet safety and efficacy standards.

## 6.1 Additional Factors Influencing Trial Requirement

In addition to device class, the need for clinical trials can depend on:

- **Intended Use:** Devices with critical or therapeutic functions are more likely to require clinical testing.
- **New Technology or Novel Function:** Devices with no existing equivalent or a new mechanism of action often require trials to confirm safety and effectiveness.
- **Regulatory Jurisdiction:** Different regions have unique regulatory requirements, so trial mandates can vary. For example, the FDA in the U.S. and the EMA in Europe may have differing requirements based on device class, use, or risk profile.

In summary, Class III devices and certain Class II devices with new indications or high-risk functions typically require clinical trials before they can be approved for market. These trials provide critical data on performance, safety, and benefits, ensuring that high-risk devices meet stringent regulatory standards.