

IMPERIAL

MedTechONE Knowledge Base



What defines pre-clinical trials in the context of medical devices?

- 1 Definition
- 2 What do pre-clinical trials entail
- 3 Planning for Pre-Clinical Trials
- 4 Purpose of Pre-Clinical Trials

1. Definition

Pre-clinical trials are research activities conducted on a medical device before it is tested in humans. Unlike clinical trials, which involve human subjects, pre-clinical trials focus on laboratory-based and often animal studies to assess the device's basic safety, efficacy, and functional integrity. For medical devices, pre-clinical trials aim to demonstrate that the device can perform safely and effectively as intended, aligning with regulatory standards like the UK MDR, EU MDR, and FDA's CDRH requirements.

2. What do pre-clinical trials entail

Pre-clinical trials cover various tests and evaluations that validate the safety, quality, and performance of a device. These trials vary based on device classification, intended use, and risk level but generally include:

- **Biocompatibility Testing:** Ensures that materials used in the device are compatible with human tissue and do not cause adverse reactions.
- **Mechanical and Functional Testing:** Verifies that the device performs reliably under anticipated stress, pressure, or operational conditions.
- **Animal Studies:** For devices that contact sensitive tissues or systems, animal studies help evaluate the device's biological interactions and functionality in a living organism.
- **Software and Electronic Testing:** For devices with embedded software, tests are conducted to ensure that the software functions reliably and securely.

3. Planning for Pre-Clinical Trials

Careful planning is critical to ensure pre-clinical trials are efficient, regulatory-compliant, and provide reliable data. Key planning steps include:

- **Define Objectives and Endpoints:** Establish clear objectives, such as proving safety and basic functionality, and determine the specific endpoints (e.g., acceptable performance thresholds).
- **Engage with Regulatory Bodies:** Consult with regulatory authorities (e.g., MHRA, FDA) to understand specific requirements and expectations for the device classification and ensure compliance from the outset.
- **Select Models and Methodologies:** Choose appropriate in vitro (laboratory) and in vivo (animal) models that best simulate human conditions. Develop methodologies that provide reproducible and reliable results.
- **Risk Assessment and Management:** Perform a preliminary risk assessment per ISO 14971, identifying potential risks and planning mitigation strategies before trials begin.

4. Purpose of Pre-Clinical Trials

The primary purpose of pre-clinical trials for medical devices is to generate evidence that supports the device's transition to human trials and regulatory review. Specific purposes include:

- **Safety Validation:** Demonstrate that the device does not cause harm under expected use and conditions.
- **Efficacy and Functional Assurance:** Prove that the device performs reliably and effectively as intended.
- **Regulatory Preparation:** Gather the necessary data to support regulatory submissions, including safety reports, risk analyses, and design documentation.
- **Design Verification and Refinement:** Identify potential design improvements early in the process to optimize device safety and performance.

Pre-clinical trials provide the data required to verify a medical device's fundamental safety and performance, forming a critical step toward clinical trials and regulatory approval. A well-planned and thoroughly executed pre-clinical phase establishes a foundation of confidence in the device's ability to perform safely and effectively.