

Clinical Trial Process Checklist for Medical Devices

- Define clinical trial objectives and endpoints
- Determine device risk classification (significant vs non-significant risk)
- Develop a Clinical Investigation Plan (CIP)
- Obtain Institutional Review Board (IRB)/Ethics Committee approval
- Secure FDA IDE approval if required
- Prepare informed consent documents
- Select and train trial sites and investigators
- Implement monitoring and data collection systems
- Ensure compliance with Good Clinical Practice (GCP) and ISO 14155
- Conduct feasibility study (if needed) before pivotal trial
- Collect, analyze, and validate trial data
- Submit results as part of FDA marketing application (e.g. PMA) or MDR clinical evaluation/EUDAMED reporting

