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Knowledge Base

How do you ensure safety and regulatory compliance during clinical trials?

1 ISO 14155:2020

2 Medical Device Regulation (MDR) – EU 2017/745

3 SI 2004/1031 – UK Clinical Trials Regulations

4 Good Clinical Practice (GCP) / ICH E6

5 ISO 10993 Series – Biological Evaluation of Medical Devices

6 Other Immediately Important Regulations

Several international and regional standards govern the conduct of clinical trials for medical devices to ensure participant safety and data integrity. Here's an overview of the most important regulations and standards:

1. ISO 14155:2020

- **Overview:** ISO 14155:2020 is the international standard that provides guidelines for the design, conduct, recording, and reporting of clinical investigations involving medical devices intended for human use.

- **Key Focus Areas:**
  - **Ethical Considerations:** Aligns with the Declaration of Helsinki to ensure participant rights, safety, and well-being.
  - **Clinical Investigation Plan (CIP):** Sets requirements for developing and maintaining a CIP, including risk management, data collection, and analysis plans.
  - **Safety Monitoring:** Emphasizes continuous monitoring of adverse events and risk assessments throughout the trial.

- **Importance for Compliance:** Ensures that clinical investigations meet global standards for quality, safety, and ethical conduct, making the data acceptable for regulatory submissions worldwide.

2. Medical Device Regulation (MDR) – EU 2017/745

- **Overview**: The MDR is a regulation by the European Union that governs the manufacturing, distribution, and clinical investigation of medical devices in the EU.

- **Key Requirements**:
  - **Pre-Market Clinical Evidence**: Requires robust clinical evidence to demonstrate the safety and performance of medical devices before they can be marketed.
  - **Post-Market Surveillance:** Establishes stringent post-market surveillance requirements, including periodic safety updates and vigilance reporting.
  - **Clinical Evaluation and Investigation:** Mandates that clinical trials are conducted in compliance with ISO 14155, ensuring consistency with international standards.

- **Impact on Clinical Trials:** The MDR places significant emphasis on clinical evidence for high-risk devices (Class III and some Class IIb), requiring manufacturers to conduct well-designed clinical trials and demonstrate ongoing compliance through post-market surveillance.

3. SI 2004/1031 – UK Clinical Trials Regulations

- **Overview**: SI 2004/1031 is the Statutory Instrument in the UK that transposes the EU Clinical Trials Directive (Directive 2001/20/EC) into UK law. It provides a legal framework for conducting clinical trials on medicinal products, but its principles are often extended to device trials.

- **Key Provisions:**
  - **Ethics Committee Approval**: Requires ethical approval from a recognized ethics committee before commencing any clinical trial.
  - **Safety Reporting**: Specifies timelines and processes for reporting serious adverse events and other safety concerns.
  - **Informed Consent**: Mandates that all participants must provide informed consent, following clear communication about the study's risks and benefits.

- **Relevance to Medical Device Trials:** Although originally focused on medicinal products, the principles are applied to ensure ethical and regulatory compliance in device trials conducted in the UK.

4. Good Clinical Practice (GCP) / ICH E6

- **Overview:** GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials involving human subjects, established by the International Council for Harmonisation (ICH) in the E6 guideline.

- **Core Principles:**
  - **Participant Safety and Ethics**: Ensures that clinical trials are conducted in accordance with ethical standards and that participants' rights, safety, and well-being are prioritized.
  - **Data Integrity and Quality**: Sets standards for accurate data collection, monitoring, and reporting to ensure reliable trial results.
  - **Compliance with Regulatory Requirements**: GCP compliance is often a legal requirement in many jurisdictions for regulatory approval of new devices.

- **Application in Device Trials**: GCP principles are integrated into ISO 14155 for device-specific trials, ensuring the same level of rigor as in pharmaceutical trials.

5. ISO 10993 Series – Biological Evaluation of Medical Devices

- **Overview:** The ISO 10993 series of standards focuses on the biological evaluation of medical devices, addressing testing procedures for assessing potential biological risks.

- **Key Elements:**
  - **Biocompatibility Testing**: Evaluates the device's materials to ensure they do not pose toxic or harmful effects on human tissue.
  - **Risk Assessment Framework**: Provides a structured approach to identifying and mitigating biological risks associated with device materials.

- **Pre-Clinical Requirements**: Many regulatory bodies require compliance with ISO 10993 standards before allowing a device to enter clinical trials.

- **Relevance to Clinical Trials**: Ensures that the device is biologically safe for human use, serving as a prerequisite for conducting human trials, especially for implantable or high-risk devices.

6. Other Immediately Important Regulations

- **FDA 21 CFR Part 812 – Investigational Device Exemptions (IDE):**
  - **Scope:** Governs clinical trials of investigational medical devices in the U.S. to ensure participant safety and regulatory compliance.
  - **Key Requirements:** Includes submission of an IDE application, monitoring of adverse events, and reporting obligations.

- **Health Canada – Medical Devices Regulations (SOR/98-282):**
  - **Regulatory Oversight:** Specifies the requirements for clinical trials involving medical devices in Canada, including safety monitoring, ethics review, and device classification-based requirements.

- **Japan Pharmaceuticals and Medical Devices Act (PMDA):**
  - **Clinical Trial Requirements:** Enforces standards for conducting clinical trials in Japan, emphasizing participant protection and data integrity.