Clinical Trial Regulations - AI Studies

Clinical trials for AI medical devices require **different considerations than traditional devices**

🔬 Trial Design

Selection of appropriate methodology including prospective, RCT, observational studies

📋 Ethics Approval

IRB/IEC approval, obtaining patient consent

Special Considerations for AI Clinical Trials

- **Locked Algorithm:** Algorithm must be locked during trial period
- **Version Control:** Clear documentation of software version
- **Integration Validation:** Performance evaluation within actual clinical workflow
- **User Training:** Providing appropriate training for clinicians
- **Subgroup Analysis:** Performance evaluation across diverse populations

Regulatory Submission Requirements

- **Protocol:** Detailed trial protocol and statistical analysis plan
- **Case Report Forms (CRF):** Standardized data collection forms
- **Safety Monitoring:** DSMB composition and interim safety analysis
- **GCP Compliance:** Good Clinical Practice compliance

💡 **Key Point:** The key to AI clinical trials is demonstrating algorithm transparency, reproducibility, and generalizability, with appropriate control group setup being crucial