Medical Device Research Workshop

Day 1 — FDA Regulatory Framework & Conduct of Device Studies

Overall learning objectives:

By the end of Day 1, participants should be able to:

1. Distinguish medical device classifications and major FDA regulatory pathways.
2. Explain when an IDE is required and distinguish SR from NSR device studies.
3. Describe the respective responsibilities of sponsors, investigators, IRBs, monitors, and sites.
4. Identify key FDA requirements for informed consent, device accountability, documentation, reporting, and monitoring.
5. Recognize common compliance risks in the conduct of device studies.

8:00–8:15 | Welcome, Introductions & Workshop Orientation

15 minutes

- Introduction
- Participant experience with medical device research
- What makes device research different from drug research?
- Review of learning objectives

8:15–8:50 | What Is a Medical Device?

35 minutes

FDA vs. CMS/Medicare perspectives

- FDA definition of a medical device
- CMS/Medicare perspective
- Medical device vs. drug vs. biologic
- Combination products
- Examples of devices encountered in clinical research

- Device classification:
    - Class I
    - Class II
    - Class III
- Why classification matters

FDA regulatory pathways

- 510(k)
- De Novo
- PMA
- Humanitarian Use Device (HUD)
- Humanitarian Device Exemption (HDE)
- Investigational Device Exemption (IDE)

8:50–9:35 | Investigational Device Exemption: When Is an IDE Required?

45 minutes

- Purpose of an IDE
- IDE vs. marketing authorization
- IDE exemptions
- Significant Risk (SR) vs. Non-Significant Risk (NSR)
- Who determines SR/NSR?
- Role of the IRB
- FDA role in SR determinations
- IDE application
- FDA and IRB approval requirements
- Abbreviated IDE requirements for NSR studies
- When a device study can proceed without an FDA-approved IDE

9:35–9:50 | BREAK

15 minutes

9:50–10:35 | Sponsor-Initiated vs. Investigator-Initiated Device Studies

45 minutes

Sponsor responsibilities

- Selecting investigators
- Investigator agreements
- Device distribution/control
- Monitoring
- IRB oversight
- Regulatory submissions
- Safety reporting
- Records
- Device disposition

Investigator/site responsibilities

- Protecting subject rights, safety, and welfare
- Following the investigational plan
- Obtaining informed consent
- Supervising device use
- Device accountability
- Maintaining records
- Reporting
- Compliance with IRB/FDA requirements

Investigator-initiated studies

- When the investigator becomes the sponsor
- Sponsor-investigator responsibilities
- Additional regulatory burden
- FDA submissions
- Monitoring
- Safety oversight

10:35–11:15 | Good Clinical Practice, IRB Oversight & Informed Consent

40 minutes

- 21 CFR Part 812
- Relationship to Parts 50 and 56
- GCP principles
- IRB responsibilities
- Initial review
- Continuing oversight
- Amendments
- Informed consent
- Re-consent
- New risk information
- Emergency use
- Unanticipated problems
- Protocol deviations/noncompliance

11:15–11:45 | Monitoring, Auditing & FDA Inspections

30 minutes

- Sponsor monitoring

- Site monitoring visits
- Risk-based monitoring concepts
- What monitors look for
- Audits vs. monitoring
- FDA inspections
- Inspection readiness
- Common findings
- Responding to findings
- CAPA

11:45–12:00 | Day 1 Case Challenge & Knowledge Check

15 minutes

Participants receive a short scenario involving:

- An investigational device
- A protocol deviation
- A device malfunction
- An informed-consent issue
- A reporting question

Day 2 — Device Operations, Documentation, Medicare & Billing

Overall learning objectives

By the end of Day 2, participants should be able to:

1. Describe the operational requirements for acquisition, storage, use, accountability, and disposition of investigational devices.
2. Identify essential device-study documentation.
3. Distinguish investigational device costs from routine costs.

4. Explain Medicare coverage considerations for Category A and Category B IDE studies.
5. Apply coverage-analysis and billing principles to device-study scenarios.
6. Identify and mitigate common operational, regulatory, financial, and patient-safety risks.

8:00–8:15 | Day 1 Recap & Warm-Up

15 minutes

- Review of Day 1
- Questions
- Five-question knowledge check

8:15–9:00 | Device Acquisition, Set-Up & Accountability

45 minutes

Device acquisition

- Who orders the device?
- Who receives it?
- What documentation is required?
- Shipping/receiving records

Storage

- Temperature/environmental requirements
- Security
- Access
- Calibration/maintenance

Device accountability

- Receipt
- Inventory

- Assignment
- Use
- Return
- Repair
- Replacement
- Destruction/disposition
- Lost or damaged devices

9:00–9:40 | Research Documentation & Data Integrity

40 minutes

- Essential documents
- Source documentation
- Device-specific source data
- Case histories
- Protocol deviations
- Device accountability records
- Training documentation
- Monitoring documentation
- Correspondence
- Safety documentation
- IRB documentation
- Regulatory binder/electronic repository
- ALCOA+ principles
- Data integrity
- Retention requirements
- Inspection readiness

9:40–9:55 | BREAK

15 minutes

9:55–10:40 | Medicare Coverage of Investigational Device Studies

45 minutes

Medicare and clinical research

- What Medicare may cover
- Routine costs
- Investigational device costs
- Qualifying clinical trials
- Coverage analysis

IDE categories

- Category A — Experimental
- Category B — Nonexperimental/Investigational

Important distinction

For CMS-approved IDE studies, Category A permits coverage of routine care items/services but not the Category A device itself. Category B may permit coverage of the Category B device as well as routine care items and services.

CMS approval process

- FDA IDE approval
- CMS submission
- Study documentation
- Site additions
- Protocol changes
- Study termination
- ClinicalTrials.gov considerations

10:40–11:20 | Billing: What Gets Paid?

40 minutes

Routine costs

- Items/services ordinarily provided in clinical care
- Services required for the investigational intervention
- Monitoring of effects
- Management of complications

Non-covered costs

- Investigational device
- Sponsor-paid items
- Services not meeting coverage requirements
- Items excluded under applicable Medicare policies

Billing workflow

- Coverage analysis
- Budget/CTA
- Billing grid
- Research billing review
- Claims submission
- Documentation
- MAC requirements
- Denials and reconciliation

CMS's definition of routine clinical-trial costs includes customary care, services required to provide or monitor the investigational intervention, and reasonable and necessary care for complications.

11:20–11:45 | Risk Management: Site & Sponsor Perspectives

25 minutes

Site risks

- Incorrect SR/NSR determination
- Inadequate consent
- Device accountability problems
- Protocol deviations
- Missed safety reports
- Incorrect billing
- Inadequate documentation
- Staff training gaps
- Device malfunction
- Loss of investigational devices

Sponsor risks

- Inadequate monitoring
- Poor investigator selection
- Failure to report
- Device distribution problems
- Inadequate safety oversight
- Inadequate records
- Failure to address noncompliance

Risk-management framework

Identify → Assess → Control → Monitor → Document → Correct → Prevent recurrence

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11:45–12:00 | Final Integrated Device Study Challenge

15 minutes

Give one complex case containing:

- Investigational device
- SR/NSR question
- IRB issue
- Device accountability problem
- Safety event
- Protocol deviation
- Medicare beneficiary
- Billing question

Ask the group to determine:

1. Regulatory pathway
2. Responsible party
3. Required action
4. Required report
5. Required documentation
6. Billing consequence
7. Risk-control action

Close out