The Sponsor: Responsibilities in Medical Device Clinical Trials

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Objectives

- Define “medical device research sponsor.”
- Identify the 10 sponsor responsibilities discussed in the presentation.
- Contrast the role of monitoring with the role of a Data Monitoring Committee.
- Identify the six categories of records sponsors may be required to maintain.

Presentation Topics

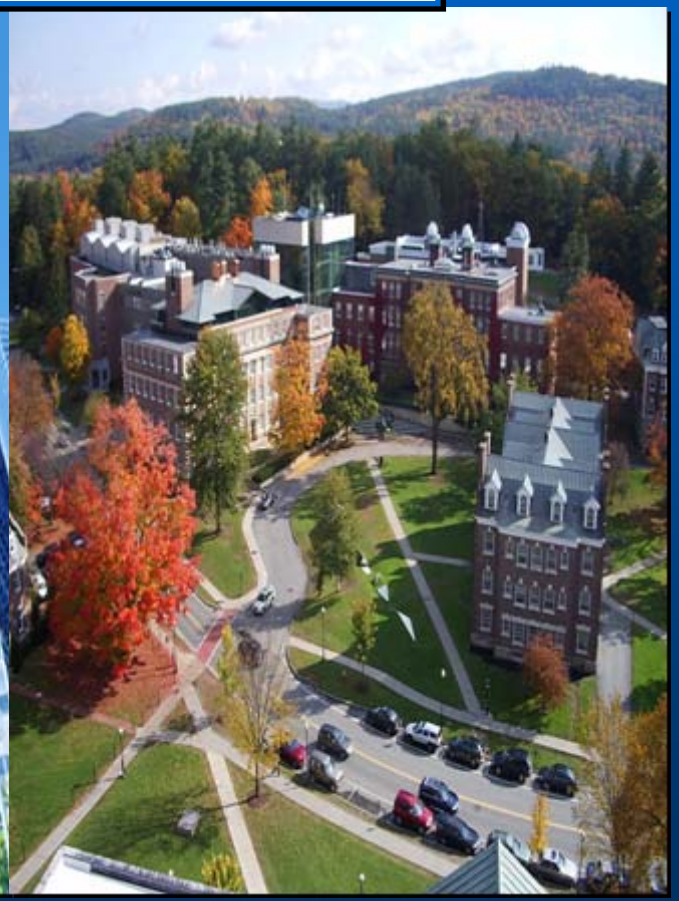
- Regulatory Definition of a Sponsor
- Sponsor Responsibilities
- Monitoring
  - Monitoring vs. Data Monitoring Committee
- Sponsor Records
- Documentation
- Inspections
- Sponsor Reports

A Sponsor Initiates a Study

21 C.F.R. 812.3(n)

A Sponsor is a Person

21 C.F.R. 812.3(l)



General Sponsor Responsibilities

21 C.F.R. 812.40

- Select qualified investigators
- Provide them with the information they need to conduct the study

General Sponsor Responsibilities

21 C.F.R. 812.40

- Ensure proper monitoring
- Ensure IRB review and approval
- Submit IDE application to FDA
- Ensure IRB and FDA are informed of significant new information about an investigation

Sponsor Responsibilities

21 C.F.R. 812.43

- Ship investigational device(s) only to qualified investigator(s)
- Obtain signed investigator agreements and financial disclosure from all investigators
- Select qualified monitors

Monitor

- An individual designated by a sponsor or CRO to oversee the progress of an investigation
- It is a sponsor's responsibility to select monitors that are qualified by training and experience

21 C.F.R. 812.3(j)

21 C.F.R. 812.43(d)

Monitoring

21 C.F.R. 812.3(j)

- The act of overseeing the progress of an investigation.
- Used to assure the protection of human subjects and data integrity
- Ongoing continuous process
- The task of monitoring can be delegated but, it is ultimately the sponsor's responsibility

Monitors Review

- IRB approvals
- Informed Consent Documents
- Source documents
- Case Report Forms (CRF)

Monitoring Investigations

21 C.F.R. 812.46

- Secure investigator compliance
- Conduct an evaluation of any unanticipated adverse device effects
- Obtain FDA and IRB approval before resuming a terminated study

Monitoring vs. DMC

Data Monitoring Committee (DMC)

Sometimes referred to as a Data and Safety Monitoring Board

- Monitoring is a different process then oversight by a Data Monitoring Committee

Data Monitoring Committee

- A group that reviews data from a trial
- They advise the sponsor regarding the continuing safety of trial subjects
- Evaluate data for continuing validity and scientific merit

Sponsor Records

21 C.F.R. 812.140(b)

- All correspondence with another sponsor, monitor, CI, IRB, and FDA
- Shipment and disposition of the device

Sponsor Records

21 C.F.R. 812.140(b)

- Shipment
  - Name and address of consignee
  - Type and quantity of device
  - Date of shipment
  - Batch number or code
- Disposition
  - Batch number or code
  - Reasons for
  - Method of disposal

Sponsor Records

21 C.F.R. 812.140(b)

- Signed investigator agreements & financial disclosure information
- Non-significant risk device records

21 C.F.R. 812.140(b)(4)

Sponsor Records

21 C.F.R. 812.140

- Adverse device effects and complaints
- Other records required by FDA

Sponsor Records

21 C.F.R. 812.140

- Retention period is 2 years after
  - end of the study
  - pre-market approval application
- Custody can be transferred

Documentation

If it is not documented, it never happened.

Inspections

21 C.F.R. 812.145

- Permit access to FDA
- Permit inspection and copying of documents

Sponsor Required Reports

21 C.F.R. 812.150(b)

- Unanticipated Adverse Device Effects (UADE)
- Withdrawal of IRB approval
- Withdrawal of FDA approval

Sponsor Required Reports

21 C.F.R. 812.150(b)

- Investigator list
- Annual progress report
- Recall and device disposition
- Final report

Sponsor Required Reports

21 C.F.R. 812.150(b)

- Use of device without informed consent
- Significant risk determination
- Other reports

Summary

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  - Promote the collection of quality data

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