Data Management in Support of A Clinical Event Committee (CEC)

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Study Parameters

- 2000 patients
- 150 sites
- 15 patients per site
- Phase IIIB
- Primary Endpoint:
  - Cardiovascular Endpoints
    - Stroke
    - MI
    - CHF Hospitalization
First Thoughts

Oh No! Another acronym!
Clinical Event Committee (CEC)

- AKA Clinical Endpoint Committee
- Adjudication of Cardiovascular Events
  - based on review of:
    - CRF
    - Serious Adverse Events
    - Source documents
      - Hospital Discharge Summary
      - EKGs
      - Other supporting documents
Clinical Event Committee (CEC)

- Regularly Scheduled Meetings
- Review of documentation packets
- Objective determination
- Was Endpoint Met?
- Does Event Meet Definition?
Assessing CEC Needs

• Documentation
  – External document (CEC & Project Team)
    • CEC Process Document
  – Internal document (Project Team)

• Conference Calls
  – Review of documentation
  – Review of work-flows
  – Review of needs
CEC Process Document

- Initiated by the CEC
- Included the following:
  - Endpoint definition
  - CEC Process
  - CRF Triggers
  - Documentation Needs
  - Sample adjudication forms
    - Stroke/MI/CHF Hospitalization
Team Review of CEC Process Document

- Needed to address the following concerns:
  - Regulatory
    - HIPAA & Informed Consent
  - Clinical
    - Needs of CRCs & CRAs
  - Medical
    - Impact on SAE Handling
Team Review of CEC Process Document

• Needed to address the following concerns:
  – Data Management
    • What needs to be done
      – SAE Categorization
      – CRF Triggering
      – Source document collection & coordination
      – Overall CEC coordination
  
  – Statistical
    • Listings
    • What is the role?
Where does CEC fit in DM?

- Receive CRF
- Track CRF Pages
- Create CRF Inventory
  - Manual/SAE Review
  - Data Processing
    - Validation
    - Validation
    - Clean Patient
    - Audit Trail Updated
    - QC of Update
      - Database Updated
      - Resolved DQF Received
      - Make Query
  - Error Generation
  - DQF to Site
  - Updated
  - Updated
  - Validation
  - Validation
  - Clean Patient
  - Validate Database
  - QC Audit
Development of CEC & DM Workflow

• Where do we start?
  – Who
    • What role or DM Function
      – Data Manager
        » Responsible for Overall Study DM
      – Data Coordinator
        » Responsible for Day to Day DM
      – CEC Coordinator?
        » Dedicated and Focused
        » Based on number of anticipated CEC events
CEC & SAE Processing

• Where do we start?
  – How
    • What needs to be done
      – Identification of Appropriate SAEs
        » All Cardiovascular Events
        » MedDRA Code List
CEC & SAE Process

1. Receive SAE
2. Track SAE Forms
3. Notification of SAE Receipt
4. Data Processing
5. Manual Review (text fields)
6. Issue Generation
7. Make Request
8. Request to Site
9. Tracking Database Updated
10. CEC Cover Sheet Generated
11. CEC Adjudication
12. Shipment to CEC
13. CEC Form Processing
14. CEC Processing Complete
15. Adjudication Returned

CEC Form Processing Complete
CEC & CRF Processing

• Where do we start?
  – How
    – CRF/Database Triggers
      » Yes responses indicates potential event
      » Review of listings to identify events from text fields
CEC & CRF Trigger Process

1. Receive CRF
2. Track CRF Pages
3. Notification of Trigger CRF Receipt
5. Data Processing
6. Validation
7. Issue Generation
8. Make Request
9. Request to Site
10. Request Received
11. CEC Cover Sheet Generated
12. Tracking Database Updated
13. Shipment to CEC
14. CEC Adjudication
15. CEC Processing Complete
16. CEC Form Processing
17. Adjudication Returned

Flowchart:
- Receive CRF -> Track CRF Pages -> Notification of Trigger CRF Receipt -> Manual Review (text fields) -> Data Processing -> Validation -> Issue Generation -> Make Request -> Request to Site -> Request Received
- Shipment to CEC -> CEC Adjudication
- CEC Processing Complete -> CEC Form Processing
- Adjudication Returned
CEC & Site Coordinator

– Training
  • Overview of CEC Process
  • Study Specific Needs

– Study Aids
  • Creation of Checklists
  • Creation of CEC Packets

– Assistance
  • What can CRAs, Project Directors, DM do to help?

– Support
CEC Workflow - Tracking

• Tracking
  – Needed to create database for storage
    • what needs to be tracked?
  – How to ensure removal of identifiers
    • review current procedure and change?
  – How to ensure timeliness of receipt
    • CEC Packet
    • Interaction with site
CEC Workflow - CRF Triggers

• CRF Trigger
  – Triggers identified by CEC
  – Developed program to identify responses
  – QC of program
  – What is frequency of:
    • Running
    • Reviewing
  – How to handle updates?
CEC Workflow - SAE Processing

- SAE Handling
  - Review to identify appropriate SAEs?
    - Based on text review
    - Based on code review
  - Track Status of SAEs
    - Initial
    - Follow Up
  - What is turn-around time?
CEC Workflow - DQF Processing

• Issue Identification
  – Need to be aware of query status
  – Generate queries as needed
  – Do we need to flag CEC queries?
  – Do CEC queries need to be expedited?
  – How do we track status of CEC queries?
The CEC Packet Request

• CEC Packet Request
  – Checklist of Necessary Source Documents
    • Different checklist for each event
  – Sent to CRC
  – Two week turn-around
  – Phone call follow up after three weeks
  – Includes return mail materials
CEC Packet Receipt (Site)

• CEC Packet Receipt
  – Documents tracked as received
    • date and user
  – Reviewed for completeness
    • by CEC coordinator
  – Copies/Images made for safekeeping
    • Which is most appropriate?
CEC Packet Shipment

- CEC Packet Shipment
  - Updated Checklist Generated
  - CEC Adjudication Form Attached
  - Packets grouped in batches
  - Batches Forwarded to CEC
    - traceable mail
CEC Packet Receipt (CEC)

• CEC Adjudication Form Receipt
  – Tracked as Received
  – Forwarded for Data Processing
    • Double Data Entry
    • Database availability
      – DSMB
      – Interim Analysis
  – Update CEC Tracking Database
    • Event Completed
The CEC & Changes

• Changes resulting from:
  – SAE Processing
  – CRF Trigger Values
  – Coding
  – Queries
  – Normal Study Changes
What made it work?

• Understanding Of Needs
  – CEC
  – Project Team
• Interactive Process
• Communication
• Flexibility
  – Accommodate changes/revisions as needed