



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

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DIA Data Management

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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

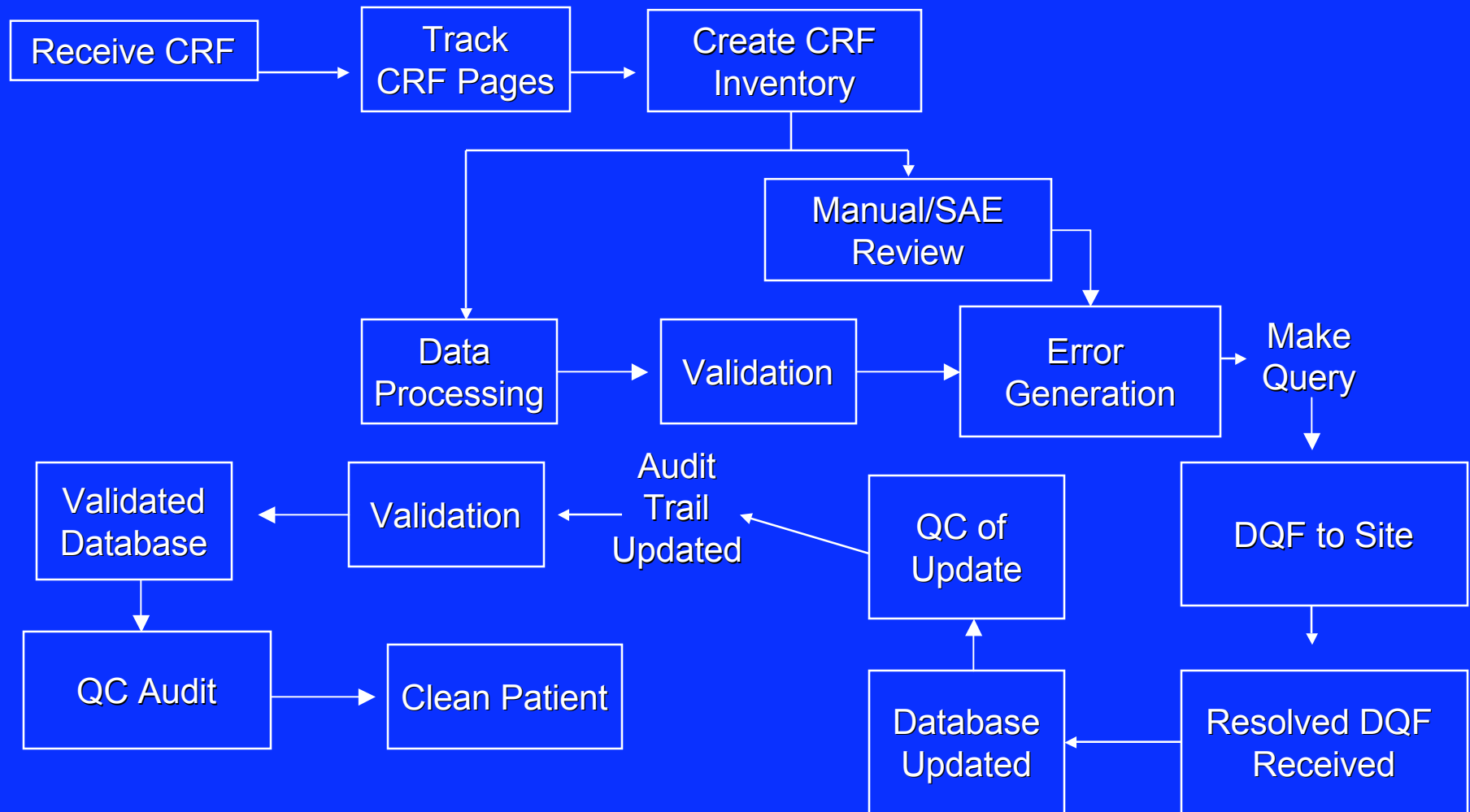
Team Review of CEC Process Document

- 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?



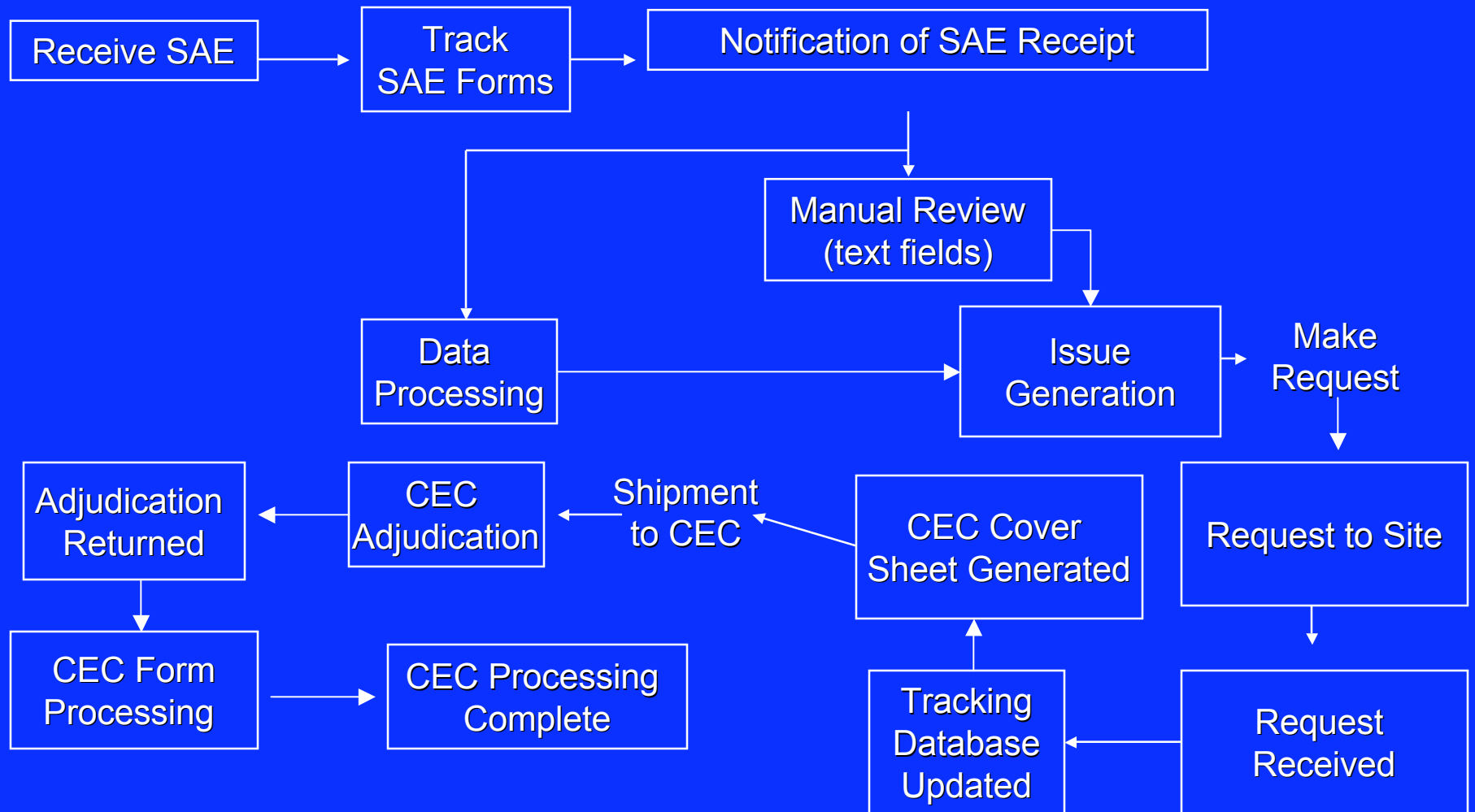
Development of CEC & DM Workflow

- 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

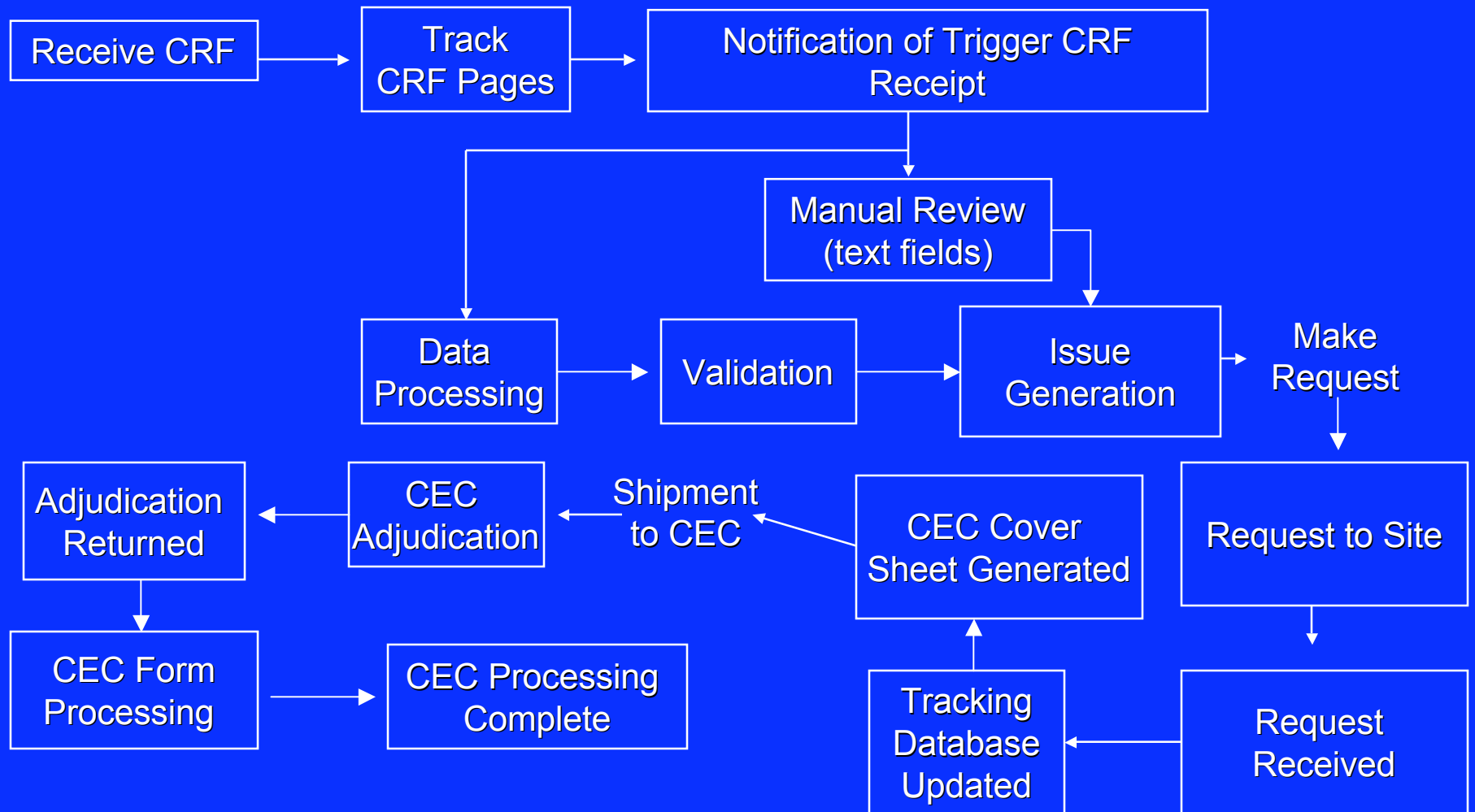
CEC & SAE Process



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



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