

# ClinEDC

An Electronic Data Capture System for  
DataFax

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## Electronic Data Capture

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- For this presentation, electronic data capture is defined as:  
*“The process of collecting clinical data by electronic means in a form that allows automatic application of edit rules and validation procedures.”*
- Electronic data collection describes the process.
- Electronic data capture (commonly referred to as EDC) describes the method.



## DataFax-EDC

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- Developed using Adobe Acrobat for data capture at the clinical centers and Java for receipt of data at the project office.
- Tools
  - Electronic Case Report Form (eCRF) – manages data capture.
  - Electronic Subject Binder (eSB) – manages eCRFs.
  - EDC Server – manages submitted data.
- Piloted in 2004 to evaluate implementation and user acceptance.



## What Happened To DataFax-EDC?

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- Acrobat® too bloated hindering future development.
- Forms engine constantly in flux.
- Inadequate application programming interface.
- XML Forms Architecture not finalized.
- Apparent shift to enterprise-wide model.
- No way to secure JavaScript code.
- Too many technical problems to solve.



## ClinEDC

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- Use the basic concepts and lessons learned from DataFax-EDC.
- Reevaluate the process.
- Reevaluate the requirements.
- Reevaluate the architecture.



## Rethinking Process – Project Office

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- Create and configure studies.
- Distribute studies – originals and revisions.
- Receive data submissions.
- Update DataFax.
- Distribute quality control queries.
- Distribute disaster recovery data.



## Rethinking Process – Clinical Centers

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- Receive study configuration files – originals and revisions.
- Set up studies, users, and access privileges.
- Collect and manage study data.
- Submit study data.
- Receive quality control queries.
- Receive disaster recovery data.



## Rethinking Requirements – Study Integrity

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- **Study Configuration**
  - Protect from unauthorized modification.
  - Attribute content to the project office.
  - Certify content authenticity.
- **Subject Data**
  - Protect from unauthorized access or modification.
  - Attribute content and modifications to authorized individuals.
  - Certify content authenticity.
- **Disaster Recovery**
  - Provide clinical centers with submitted study data in the event of a catastrophe.
  - Identify source of recovered data.



## Rethinking Requirements – Security

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- **Regulate User Access**
  - Assign logins.
  - Assign permissions.
- **Authenticate Users**
  - Digital signatures to attribute data to users.
  - Digital certificates to verify authenticity.
- **Encrypt Electronic Communications**



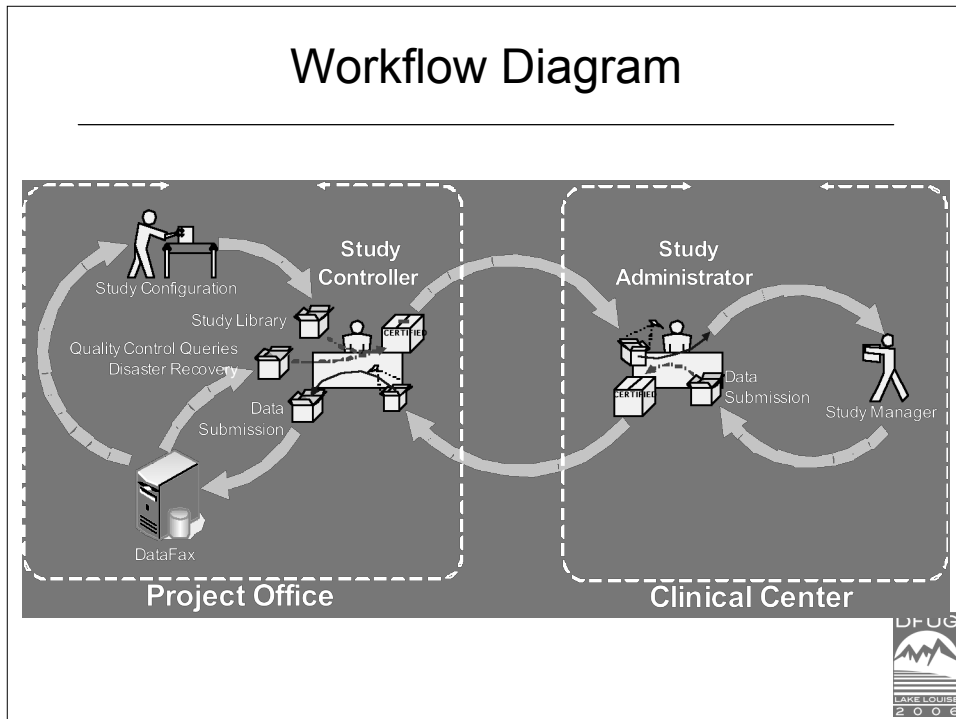
## Rethinking Architecture

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- **Electronic Case Report Forms (eCRF)**
  - Describe eCRF data items and properties using extensible markup language (XML).
  - Display non-data items (text, labels, *etc.*) as a background graphic.
  - Store data as XML in a separate file.
- **Electronic Subject Binders (eSB)**
  - Store eCRF data in a protected location.
- **Information/Data Exchange**
  - Bundle into a single, protected file.
  - Authenticate creator.



## Workflow Diagram



## ClinEDC Objects

- **Study Library** – A set of XML and PNG files describing the study's electronic case report forms (eCRFs) stored in a signed and encrypted Java Archive (JAR) file.
- **eCRF Data** – An signed, and possibly encrypted, XML file containing eCRF data and revision history for a given subject.
- **Electronic Subject Binder** – A complete set of eCRF data files for a given subject on a given study stored in a signed, and possibly encrypted, JAR file.
- **Data Submission Batch** – A set of eCRF data files stored in a signed and encrypted JAR file.
- **Quality Control Batch** – A set of XML files containing queries on data items stored in a signed and encrypted JAR file.
- **Disaster Recovery Batch** – A set of eCRF data files used to rebuild a study.



## ClinEDC Procedures

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- **Study Configuration**
  - Maintained by the project office.
  - Distributed to the clinical sites as an encrypted and digitally signed Java Archive file called a Study Library.
- **System Administration**
  - Performed by the project office and each clinical center independently and autonomously from each other.
  - Defined as a "closed" systems per 21 CFR Part 11 §11.3.
- **Subject Data Collection**
  - Performed by the clinical center.
  - Transmitted to the project office as encrypted and digitally signed Java archive files called Data Submission Batches.
- **Quality Control Queries**
  - Generated by the project office.
  - Transmitted to the clinical centers as encrypted and digitally signed Java archive files called Quality Control Batches.
- **Disaster Recovery**
  - Generated by the project office.
  - Transmitted to the clinical centers as encrypted and digitally signed Java archive files.



## ClinEDC Tools

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- **Project Office/Coordinating Center**
  - Study Configurator
  - Study Controller
- **Clinical Site**
  - Study Administrator
  - Study Manager



## Study Configurator

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- Used to create and maintain study configurations.
- Supports importing study configuration from the DataFax.
- Generates individual study libraries.
- Manages study version control.



## Study Controller

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- Provides system administration at the project office.
  - Maintains users and permissions at the project office.
  - Generates public/private key pairs for digital signatures and certificates.
- Manages electronic communications.
  - Encrypts and digitally signs study libraries.
  - Receives and certifies data submission batches from clinical center.
  - Encrypts and digitally signs quality control queries.
  - Encrypts and digitally signs disaster recovery files.
- Manages interface with DataFax
  - Processes data submissions.
  - Processes quality control queries.



## Study Administrator

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- Provides system administration at the clinical center.
  - Manages study set up and maintenance.
  - Maintains users and permissions at the clinical center.
  - Generates public/private key pairs for digital signatures and certificates.
  - Creates data submission batches.
  - Manages disaster recovery.
- Manages electronic communications.
  - Encrypts and digitally signs data submission batches to the project office.
  - Receives and certifies quality control queries.
  - Receives and certifies disaster recovery files.



## Study Manager

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- Provides individual study management.
- Manages electronic subject binders.
- Manages preparation of eCRF data for submission.
- Manages quality control queries.



## ClinEDC Technologies

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- **Java™ 2 Platform Standard Edition 5.0**
  - Rapid development using NetBeans Integrated Development Environment (IDE).
  - Reusable and extensible objects.
  - Portable – runs on any system configuration that supports the Java Virtual Machine (JVM).
- **Extensible Markup Language (XML)**
  - Published specification commonly used throughout the world.
  - Public domain Java classes; ClinEDC use the Java Document Object Model (JDOM).
- **Cryptography**
  - Public key encryption (Diffie-Hellman Encryption).
  - Native Java support.



## Task List

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- **Current Status**
  - Complete cryptography implementation.
  - Incorporate DataFax Edit Check Language.
  - Functional test entire system.
  - Validate entire system.
- **Future Plans**
  - Pilot using an existing study.
  - Evaluate potential demand.

