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# DataFax-EDC Update

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## Presentation Content

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- DataFax-EDC product overview and update.
- Impact of emerging technologies and products on DataFax-EDC.
- DataFax-EDC project team.
- DataFax-EDC pilot.

## What is DATAFAX-EDC?

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DATAFAX-EDC is a set of programs, tools and specifications designed to extend DataFax's electronic data collection capabilities to include electronic data capture (EDC).

## What is Electronic Data Capture?

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*“The direct recording of clinical data into an electronic device (e.g. computer) at the time of observation in a form that allows immediate application of edit rules and validation procedures.”*

## DataFax-EDC Features

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- **Electronic Case Report Forms (eCRF)**
  - PDF form version of DataFax paper CRF.
  - Uses Validation Tool field types, range checks, and edit checks where possible.
- **Electronic Subject Binder (eSB)**
  - PDF subject binder booklet for managing subject eCRF's.
  - PDF study configuration booklet for managing study eSB's.
- **DataFax-EDC Server**
  - Receives data sent from the eSB's.
  - Parses received data into individual data items (ICR analog).
  - Logs receipt of data and routes data items to appropriate DataFax study (DFrouter analog).

## New Features

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- **Batch eCRF submission** – Previous version only supported one-at-a-time eCRF submission.
- **Improved Forms Schedule (EDC visit map)** – More information on the current status of each eCRF.
- **Regeneration of eSB** – Facility to regenerate eSB from submitted data.

## Future Directions

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- **Form Creation**
  - Convert DataFax study files to XML.
  - Forms specifications (*e.g.* field type, location, *etc.*) in XML.
  - eSB's and eCRF's generated from XML specification.
- **Data Management**
  - Store eCRF forms and data in a separate files. Currently, data is embedded in the forms.
  - Store forms and data as XML.
- **Application Program Interface (API)**
  - Provide secure access to eSB data.
  - Provide secure access to eCRF templates.

## Emerging Technologies & Products

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- W3C XForms
- Microsoft InfoPath
- Cardiff LiquidOffice
- Adobe XML Forms Architecture

## W3C XForms

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- **Specification using XML to describe presentation and interaction of Web forms.**
  - Represents an open standard for electronic forms.
  - Is not a product or application.
- **Pros**
  - Not applicable.
- **Cons**
  - Not applicable.
- **Impact**
  - Provides an open standard for modeling electronic forms.

## Microsoft InfoPath

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- **Application that implements XForms for use with Microsoft Office and XML Web services.**
- **Pros**
  - Imports and exports XML.
  - Supports digital signatures.
- **Cons**
  - Web-centric – physical layout using HTML tables.
  - No data encryption.
  - Designed as an “enterprise” solution.
  - Expensive.
- **Impact**
  - Not a viable alternative for implementing DataFax-EDC at this time.

## Cardiff LiquidOffice

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- Applications for designing and managing electronic forms using XML.
- Pros
  - Forms designer supports explicit physical layout.
  - Supports digital signatures.
  - Can export forms to InfoPath.
- Cons
  - Proprietary despite XML claims.
  - Advantage over Acrobat unclear.
  - Cost is unknown.
- Impact
  - Not a viable alternative for implementing DataFax-EDC at this time.

## Adobe XML Forms Architecture

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- Specifications and applications that extends XForms for use with PDF.
  - Uses XML to describe forms, data handling, text handling and data binding.
  - "XML Data Package" provides the ability to package units of PDF content within XML.
- Pros
  - Designed to work with Acrobat.
  - Open architecture provides independence.
- Cons
  - Still a "draft" specification.
  - Slow product implementation.
- Impact
  - Best method for implementing DataFax-EDC using XML.

## Project Team

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- Joint project between
  - Statistical Center for HIV/AIDS Research & Prevention (SCHARP) and
  - Frontier Science & Technology Research Foundation (FSTRF)
- Team Members
  - Dave Gaston – FSTRF
  - Zekai Otles – FSTRF
  - Bob Thomas – SCHARP
  - Al Williams – SCHARP

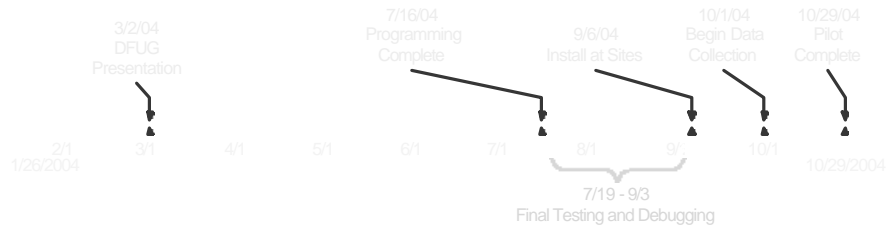
## DataFax-EDC Pilot

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- Purpose: Evaluate EDC regarding
  - User acceptance.
  - QC query rate.
  - Mean time required to “clean” data.
  - Integrity of data at the clinical site.
  - Installation, training and administration.
- Location: SCHARP clinical site.
- Method: Collect data using fax and EDC.

## DataFax-EDC Pilot Timeline

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## Next Steps

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- Dave Gaston and Bob Thomas will be available during the conference to discuss DataFax-EDC in greater detail.
- Results of the pilot at DFUG 2005.