
Electronic Data Collection Tools as a DFUG Open Source Project

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What Is Electronic Data Collection?

- For this presentation, electronic data collection 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 (now commonly known as EDC) describes the method.

Industry Interest

- Economics
 - Better
 - Faster
 - Cheaper
- Improved data quality
 - Fewer queries, resolved faster
 - Fewer errors
- Increased productivity
 - Improved workflow
 - Timely decision-making

Web Clinical Trials Break Through The Forrester Report, July 2001

“A decade in the making, electronic data capture in clinical trials is set to take off. Smart firms will exploit Web EDC to speed trials, boost profits, and rekindle collaborative ties with doctors and other partners.”

– A Forrester Research survey by Michael J. Barrett with Eric G. Brown and Allison E. Twist, conducted in cooperation with the Association of Clinical Research Professionals.

Forrester Report Summary

- **Interviews**
 - More than 50% of trial professionals would prefer to do trials using Web-enabled EDC in place of paper.
 - Two-thirds think sponsors should make the change happen.
- **Analysis**
 - Web EDC drives 14% of trial starts in 2003; 24% in 2004.
 - Web EDC use will see double-digit growth nearly every year through 2006.

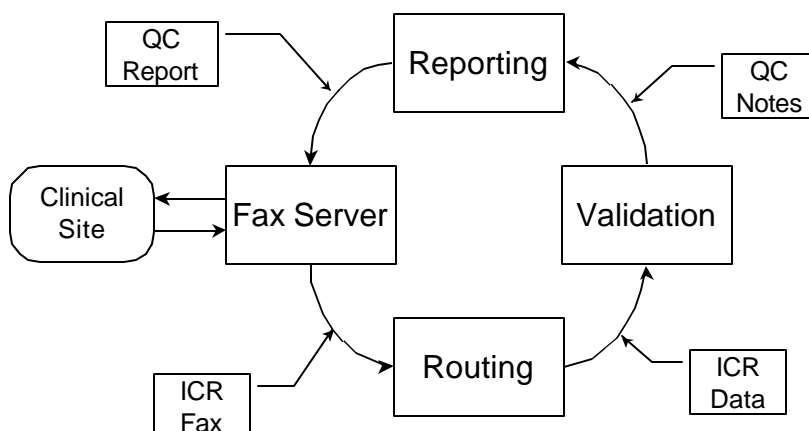
Some Current Methods

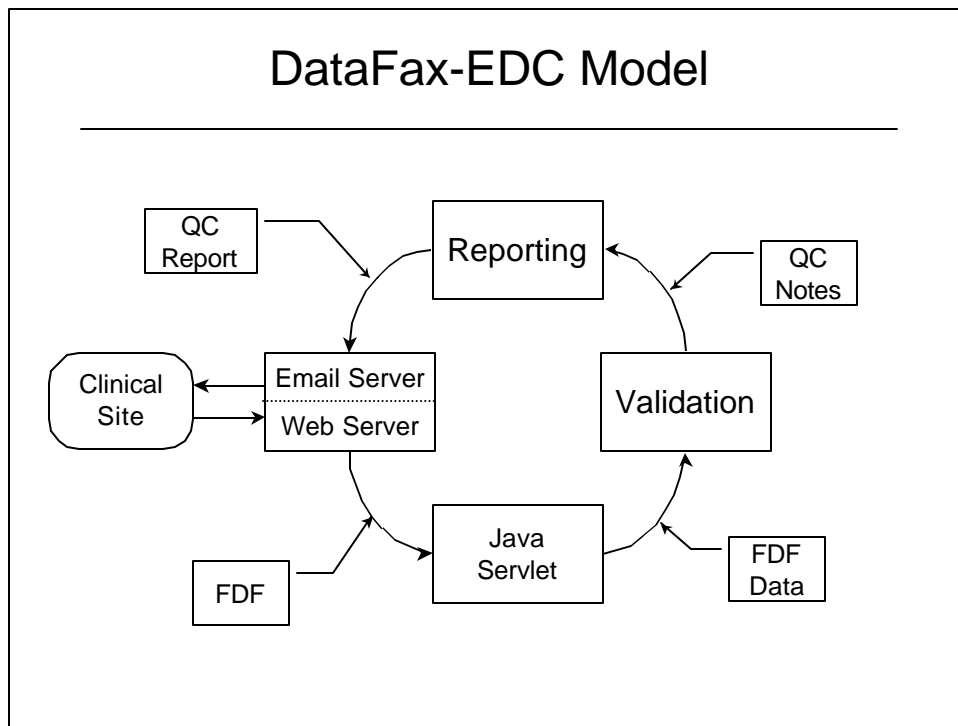
- **Remote Data Entry (RDE)**
 - Complex labor and support issues.
 - Relatively unsuccessful, but apparently widely used.
- **Fax/Scanning**
 - Success varies with implementation.
 - DataFax is the leader in this technology.
- **Voice Response (VR, IVR)**
 - Limited applicability.
 - Very successful if used properly.
- **Direct Data Capture (DDC)**
 - Historically associated with laboratory equipment.
 - Advances in computing technology opening other opportunities.

DataFax-EDC

- What is it?
 - A set of programs and specifications that allows clinical data to be captured electronically and sent to DataFax via the Internet using Hypertext Transfer Protocol (http).
- How does it work?
 - Replaces the fax server (Hylafax), with a Web server using Java servlet technology.
 - Replaces data identified by ICR on a fax image with data exported from Adobe Acrobat in Adobe's Forms Data Format (FDF).
 - Replaces paper CRFs with Adobe Acrobat Portable Document Format (PDF) forms.
 - Uses email instead of fax to communicate with clinical sites.

Standard DataFax Model





Current DataFax-EDC Components

- EDC Server
- CRF Converter
- Electronic Subject Binder

EDC Server

- Collects FDF data and sends to DataFax using DFimport.rpc.
- Java servlet
- Software requirements
 - Web server: Apache HTTP Server (httpd.apache.org)
 - Servlet container: Apache Jakarta Tomcat (jakarta.apache.org/tomcat/)
 - Java compiler and runtime (java.sun.com)
 - Adobe FDF Toolkit (partners.adobe.com/asn/developer/acrosdk/forms.html)
- Server requirements
 - Unix or Windows (untested) computer.
- Available

CRF Converter

- Converts existing DataFax plates to PDF forms.
- Software requirements
 - Perl (www.perl.org)
 - Ghostscript (www.cs.wisc.edu/~ghost/)
- Software technologies
 - Javascript (developer.netscape.com/tech/javascript/)
 - PDFmark (partners.adobe.com/asn/developer/acrosdk/docs.html)
- Available

Electronic Subject Binder

- User-friendly interface to version control systems.
- Software requirements
 - Java2 compiler and runtime (java.sun.com)
 - Version control system such as
 - Microsoft Visual SourceSafe (msdn.microsoft.com/ssafe/), or
 - CVS/WinCVS (www.cvshome.org/)
- In development

Site Issues Raised by DataFax-EDC

- Technology
 - Computing equipment with appropriate software, support and backup.
 - Internet access and email.
- Electronic CRF (e-CRF)
 - Auditable electronic record instead of paper.
 - Electronic document repository (electronic subject binders) with version control.
- Security
 - Restricted and logged access to electronic documents.
 - Electronic/digital signatures.

Regulatory Issues Raised by DataFax-EDC

- **Regulatory Compliance**
 - Title 21 CFR Part 11 – Electronic Records/Signatures (www.access.gpo.gov/nara/cfr/waisidx_00/21cfr11_00.html)
 - FDA Office of Regulatory Affairs: Guidance for Industry, Computerized Systems Used in Clinical Trials (www.fda.gov/ora/compliance_ref/bimo/ffinalcct.htm)
- **GCP Section 4.9, Records and Reports**
 - Submitted data attributable to the investigator (4.9.1, 4.9.4).
 - Audit trail (4.9.3).
 - Storage and backup (4.9.4, 4.9.5).
- **HIPAA**
 - Standards for the Privacy of Individually Identifiable Health Information.

Proposal

- A project to develop and distribute electronic data collection tools for DataFax.
- A mechanism to allow DataFax users to freely participate in the development and use of these tools.
- Frontier Science will give the source code to DataFax-EDC to DFUG.

Rationale

- Electronic data capture inevitable (unavoidable?).
- Big project; limited resources.
- Collective DFUG experience and knowledge.

Benefit

- Enables implementation of EDC using existing DataFax system.
- Comfortable transition to EDC at sites already using DataFax.
- Access to EDC tools developed and tested by a team with a production capacity much larger than any single company could afford to assemble.

DataFax-EDC License

- **Permission**
 - Use, copy and modify.
 - License and copyright notices must appear in all copies of the software and related documentation.
- **Warranty**
 - Provided "AS-IS".
 - No warranty of any kind, expressed, implied or otherwise.
- **Liability**
 - USE AT YOUR OWN RISK - Frontier Science makes no claims to nor assumes any responsibility for its accuracy.
- **Complete license will be included with the source code.**

Suggested Organization

- **Project Coordination**
 - Contributed code review and inclusion.
 - Distribution registration.
- **Software Development**
 - Server
 - Client
 - Validation
- **Regulatory Issues**
 - 21 CFR Part 11
 - HIPAA
- **Operational Issues**
 - Documentation
 - Standard Operating Procedures
 - Electronic Document Control

How To Proceed?

- Frontier Science will make the source code available on the Web.
- Is there interest in forming a DFUG subgroup for DataFax-EDC?
- Suggestions?