
SynCapture 1.5

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Overview

- What is SynCapture?
- Version history and highlights
- High-level technical overview
- Version 1.5 highlights
- SynCapture 1.5 demo



What is SynCapture?

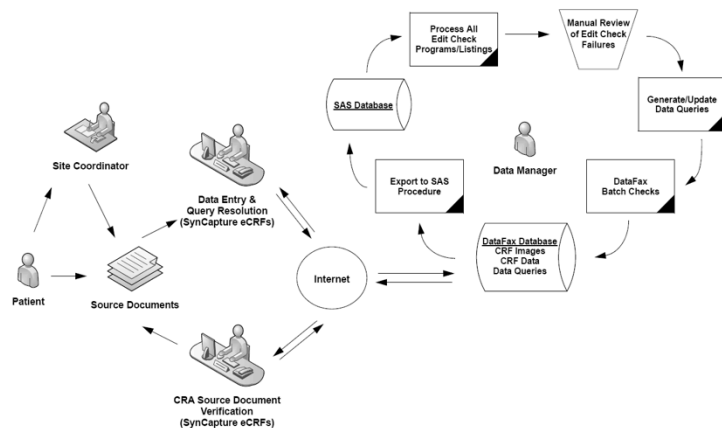
- Browser-based EDC interface developed on DataFax 3.7 platform
- DataFax provides study configuration, backend database and audit trail
- SynCapture provides an interface for entering and retrieving data remotely



SynCapture data flowchart



SynCapture CRF Flowchart



Why we developed SynCapture

- Leverage DataFax rapid study deployment model
- Reduce costs for sponsors based on efficient data flow and real-time query resolution
- Offer EDC and faxing in single database



Initial goals

- Provide on screen forms that look like actual CRFs
- Define roles based on workflow
 - Site coordinator – enter data, view/respond to queries in real-time
 - Monitor – add queries and source document verify records
 - Investigator – enter data, view/respond to queries in real-time
- Make it easy to use for sites and sponsors



Initial goals (continued)

- Require as little additional setup as possible
 - Create html pages from FrameMaker MIF file
 - SynCapture functions added to DFedits file
- Leverage as much of the DataFax study setup process as possible
- Offer traditional faxing
 - Sites that do not have broadband capabilities
 - Subject diaries and VAS



eCRF Navigation and Entry

Summary for Subject #99990002
Click on an eCRF to open that page's data or to enter new data.

- View Legend
- Refresh
- Screen
- Cycle 1
 - Week 1
 - Week 2
 - Week 3
 - Vital Signs
 - Laboratory Tests
 - Study Drug Administration
 - Term
- End Cycle
 - AE pg1
 - AE pg02-99
 - CM pg1
 - CM pg02-99

Subject 99990002, Week 3 - Windows Internet Explorer

Previous Form | Save as Complete | Save as Incomplete | Next Form | Clear This Visit

Syntrack, Inc. Demo Protocol 1

Syntrack DataFax Demo #032 Vital Signs #004

Site No: 0003 Subject No: 0034 Subject Initials: 0114 Visit #: 04

Visit Date: 14 APR 2008 CO: 1488 YYYF

VITAL SIGNS Mark "X" if Not Done

Heart Rate: 60 bpm Respiration: 20 breaths/min Blood Pressure: 120 / 80 mmHg
Systolic Diastolic

Temperature: 99.0 °F Weight: 170.0 lb Height: 5.10 cm
°F °C lb kg in cm

BSA: . . . m²
[Mostellar Formula: Height (cm) X Weight (kg)/3600^{1/2}]

BSA: . . . kg/m²
[p^{1.75} (Weight in kilograms)/(height in meters)²]

Height Units: Lb, 24kg Form Title: 032M



History

- Development and validation in 2004 and 2005
- March 2005 - presented at DFUG in Sun Valley, ID
- June 2005 – version 1.0 released
- Jan 2008 – version 1.1 released
 - Allowed for direct connection
 - Administration page implemented for study and user administration activities



History (continued)

- March 2008 – version 1.2 released
 - Focused on performance improvements
- October 2009 – version 1.3 released
 - Reporting capabilities added
 - Similar to DataFax reporting model of global and study-specific reports
 - PDF, Excel and html
 - API for IVRS and IWRS integration
 - Allows IVRS and IWRS to query and update SynCapture database

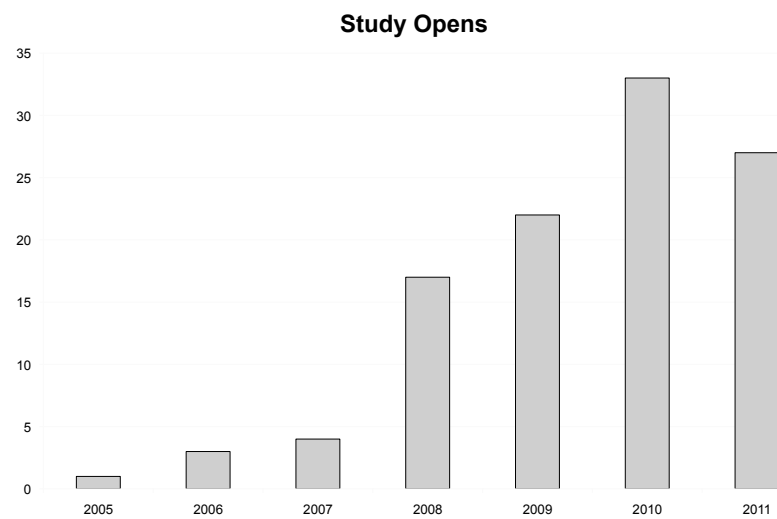


History (continued)

- February 2010 – version 1.4 released
 - Allows for single sign on
- January 2012 – version 1.5 released
 - Updated to use DataFax version 4.1.1



SynCapture growth



SynCapture 1.4 Architecture

- SPARC Solaris 10 server
 - DataFax 3.7002
 - SynCapture frontend and backend
 - Apache
 - MySQL database
- User authentication and permissions handled by SynCapture
 - Unix account
 - DataFax account
 - SynCapture account



SynCapture 1.4 Architecture (continued)

- DFimport.rpc and DFexport.rpc used to interface with DataFax database



SynCapture 1.5 Architecture

- Intel Solaris 10 server
 - DataFax 4.1.1
 - SynCapture backend
- Windows 2008 server
 - SynCapture frontend
 - MySQL database
 - IIS
- User authentication and permissions handled via iDataFax protocol
 - Streamlines user maintenance



SynCapture 1.5 Architecture (continued)

- DFimport.rpc and DFexport.rpc still used to interface with DataFax database



SynCapture 1.5 enhancements

- **Client feedback**
 - Re-query feature implemented
 - Improved interface for audit trail
 - Implemented reason for change
 - Changes after a record has been verified
 - Allow sponsor queries



SynCapture 1.5 enhancements (continued)

- **Internal efficiencies**
 - Streamlined user account process
 - Single DataFax 4.1.1 environment
 - Edit checks enhanced
 - Allow for registered external programs to be called
 - Update safety and DM roles



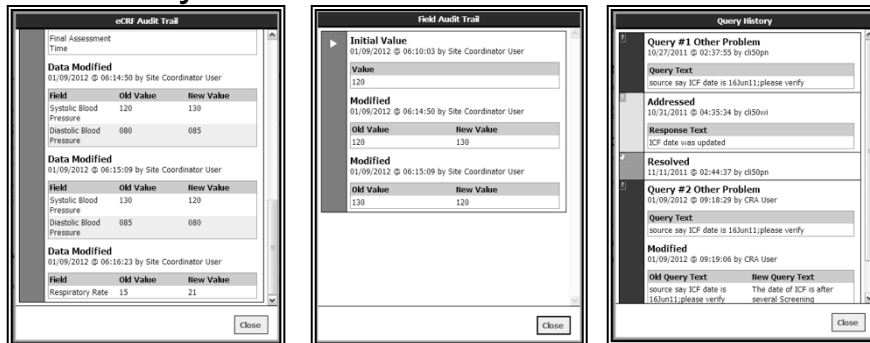
SynCapture 1.5 enhancements (continued)

- Due to record locking at subject level in DataFax, internal users can't use iDataFax
- New SynCapture roles created:
 - Safety - View only access to data through the SynCapture interface. Allowed to add and resolve role-based queries.
 - Sponsor – View only access to data through the SynCapture interface. Allowed to add and resolve role-based queries.
 - Data Manager – for Synteract DM staff to perform DM tasks.



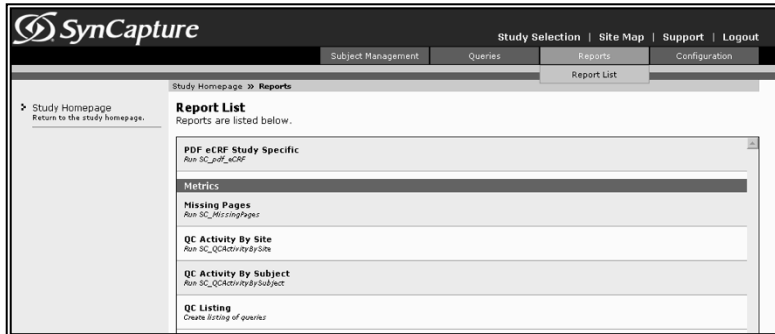
Audit Trail

- Users may view the eCRF Audit Trail, a Field History, and a field level Query History.



Reports

- Reports may be customized for a given study.



Reports (continued)

- Run a report by selecting the report criteria and clicking **View Report**.

The screenshot shows the 'Adverse Events' report view in a web browser. It includes search filters for Subject, AE Term, Date Range Start, and Date Range End. Below the filters are view options and a table of adverse events.

Subject	Visit	AE Term	Start Date	End Date	Continuing	Revised	Severity	Action Taken	Outcome	Suspect Study Drugs
99990009	AE pg1	FLU	03JUN2010	03JUN2010		Yes	Mild	None	Subject Remains in Study	No
99990075	AE pg1	COUGH								
99990201	AE pg1	HEADACHE	03MAY2010		X	No	Mild	None	Subject Remains in Study	Yes
99990204	AE pg1	HEADACHE	03MAY2010		X	No	Mild	None	Subject Remains in Study	Yes
99990205	AE pg1	HEADACHE	05APR2010							
99990307	AE pg1	FLU	13NOV2010	13NOV2010		No	Mild	None	Subject Remains in Study	No
99990005	AE pg1	HEADACHE	01MAY2010			No	Mild	None		No
99990009	AE pg1	NAUSEA								
99990009	AE pg02	HEARTBURN								
99990075	AE pg1	HEADACHE								
99990000	AE pg1	TIRE								



SynCapture 1.5 migration

- ~50 studies migrated from DataFax 3.7002 to DataFax 4.1.1
 - Upgraded DataFax version 3.7002 to 3.9.1 in October 2009 (non-SynCapture studies)
 - Upgraded DataFax version 3.9.1 to 4.1.1 in July 2011 (non-SynCapture studies)
- ~1,800 users
- 5 executors and 4 reviewers
- 1 weekend
- 1 long weekend



SynCapture 1.5 demonstration

