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# SynCapture

## Multiple Data Capture

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## What is SynCapture?

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A system built around DataFax that allows electronic data entry through the Internet

- **DataFax provides** data store, study configuration, screen definitions (audit trail, etc...)
- **SynCapture provides** a method for retrieving & entering data remotely, without direct access to DataFax (i.e. DFlite)



## Goals of the SynCapture project

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- Provide on-screen forms that look like actual CRFs
- Allow site coordinators to enter data, view/ respond to queries on-screen, in real-time
- Allow monitors to add queries & source-document-verify records
- Require **little additional development work** for set-up; leverage the DataFax setup process



## Setting up a SynCapture Database

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1. Create the DataFax database, as usual.
2. Add the necessary SynCapture functions in the study's edit checks.
3. Convert FrameMaker screens to MIF and transfer to the DataFax server.
4. Add study to the SynCapture server.
5. Set up users for the study.
6. Schedule the nightly update script.



## Nightly Updates

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- The update runs QCupdate, which recreates DF\_XXkeys and other work files, and updates the QC database
- Batch checks are run
- If QCs are added to a source-verified record, the nightly update brings that record's level down to indicate it is no longer source-verified



## Forms

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- FrameMaker CRFs are converted to MIF, brought over to UNIX, then converted to HTML
- Before retrieving a form, the DataFax index file for that plate (plt###.idx) is checked to see if a lock exists; if not, that plate is locked by SynCapture



## Forms (continued)

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- When a form is retrieved from the SynCapture server, fields (defined in DFtips & DFschema) are attached to the blank HTML form, along with the data and QCs from DataFax
- Fields defined using IE-only HTCs
- SynCapture uses standard DataFax colors to show field query status & illegal/blank values



## Edit Checks

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- DataFax edit checks are compiled into an intermediate XML object file
- The compiled XML document is transferred to the web server, for the SynCapture interface
- A JavaScript edit check interpreter processes the XML edit checks in real-time
- All edit checks that would fire in DataFax (with a few exceptions for security) fire in SynCapture



## Adding SynCapture Data to DataFax

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- When a screen is saved in SynCapture, a command for each record/QC is issued to the SynCapture server
- SynCapture server executes DFimport.rpc as the calling user to enter the record/QC into DataFax
- An image is generated of the imported data using DFprintdb
- Field definitions from DFschema are used to determine formatting of values added to the DataFax database



## But Does it Work?

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Yes! This design has been implemented and works. Two mock trials and a validation run have been completed, with trials on the horizon.



## Mock Trials

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- **Mock1**
  - 3 sites, all Electronic
- **Mock2**
  - 5 sites, 3 Electronic, 1 DDE, 1 Fax
- **Validation complete**
- **Mock3 under construction**



## Future Trials

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- **PK study for post-menopausal women, 1 site - U.S., n=45**
- **Device study, 10 sites - Europe, n=50**
- **Device study, 25 sites - U.S., n=320**
- **Normal Volunteers, 1 site - U.S., n=12**

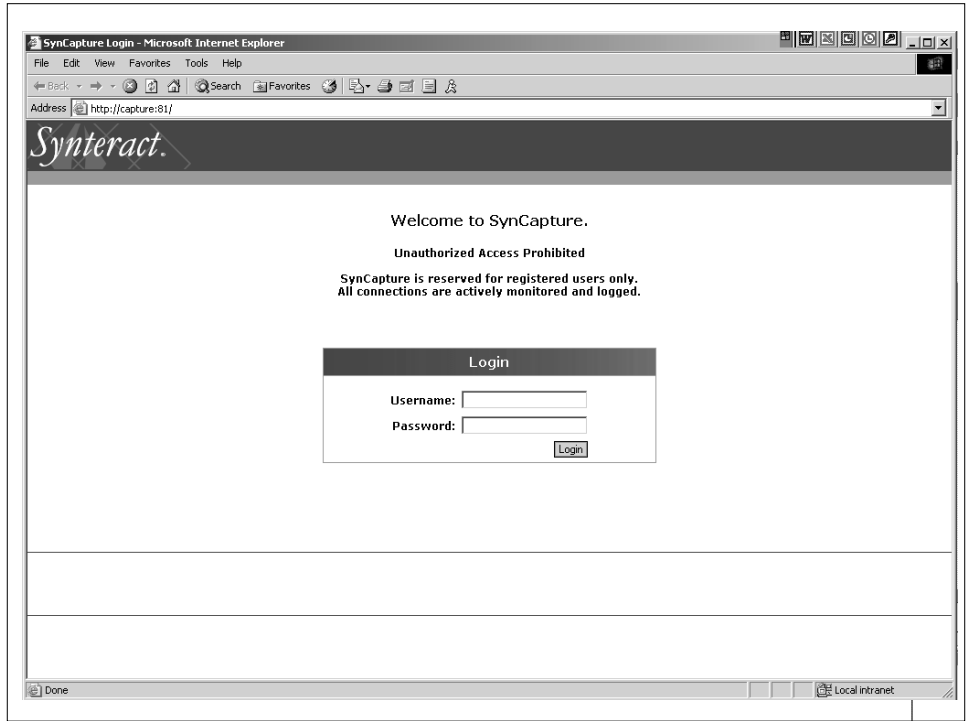


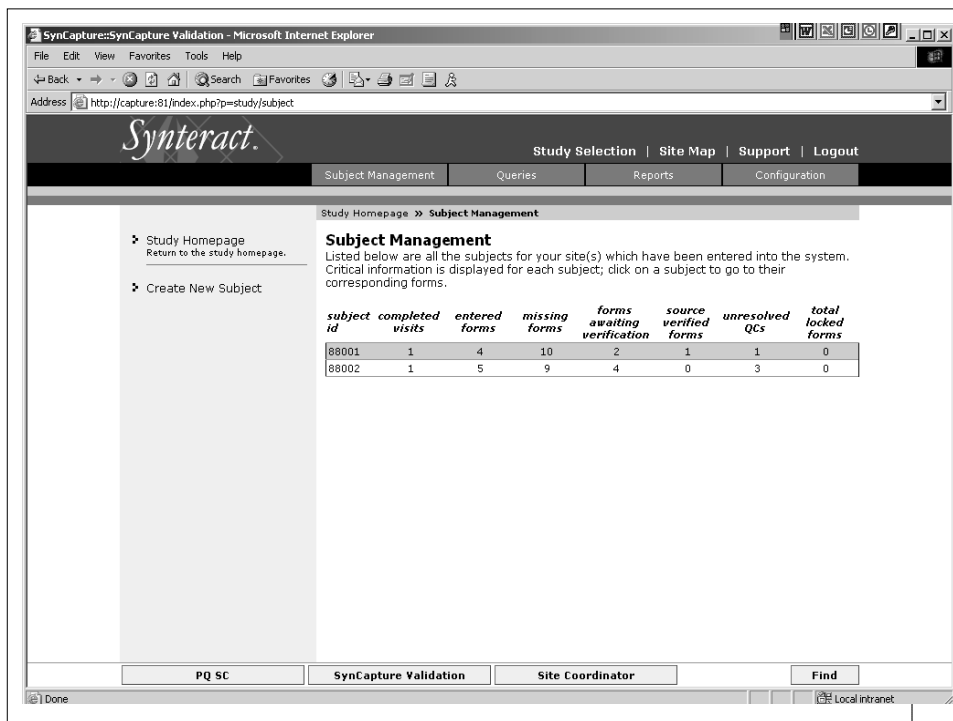
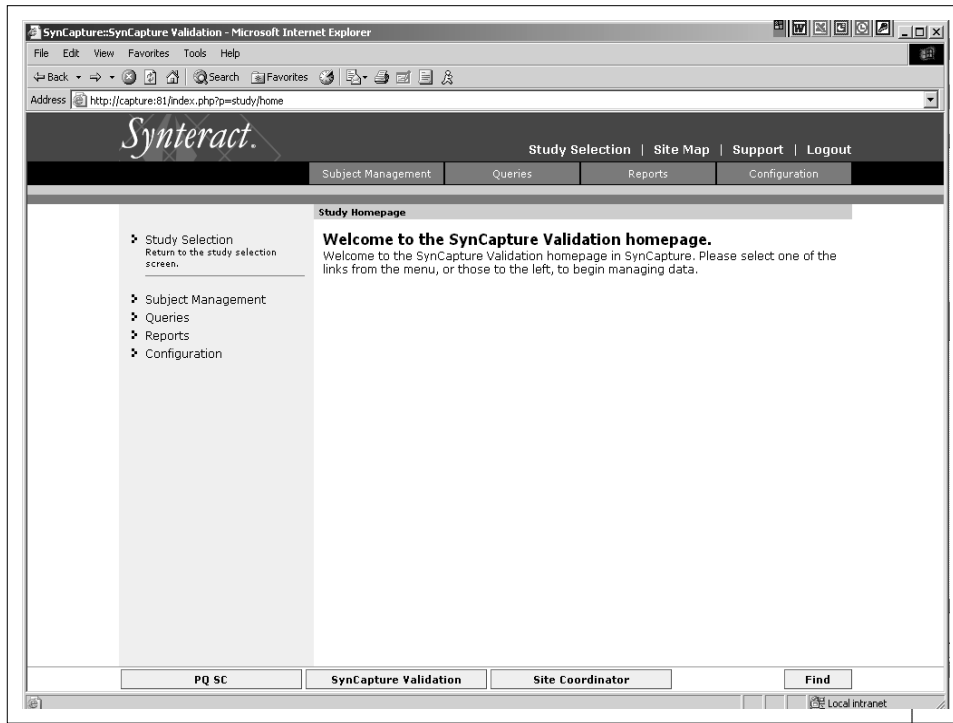
## SynCapture Data Flow

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- Mimics existing process
- Validation levels automated based on the action in SynCapture
- CRF is locked once coding and monitoring are complete







**Summary for Subject #88001**  
Click on a form to open that record's data:

- View Legend
- Screening
  - Screening PSG NIGHT -2
  - Screening PSG DAY -2
  - Screening PSG NIGHT -1
  - Screening PSG DAY -1
  - TX 1 NIGHT 1
  - TX 1 DAY 2
  - TX 1 NIGHT 2
  - TX 1 DAY 3

SynCapture Mock Trial 2 - Microsoft Internet Explorer  
v Favorites Tools Help  
://duffman:81/index.php?p=study/subject/summary&subject=88001

**Syneract** Study Selection | Site Map | Support | Logout  
Subject Management | Queries | Reports | Configuration

Study Homepage » Subject Management » **Subject Summary**

Subject Management  
Return to the subject management screen.

**Summary for Subject #88001**  
Click on a form to open that record's data or to fill in a blank form.

- View Legend
- Screening
  - INCLUSION CRITERIA
  - EXCLUSION CRITERIA
  - EXCLUSION CRITERIA, CONTINUED
  - STUDY EXEMPTION/DEMOGRAPHICS
  - VITAL SIGNS/NEUROLOGICAL ASSESSMENT
  - PHYSICAL EXAM
  - MEDICAL HISTORY (PAGE 1 OF 3)
  - MEDICAL HISTORY (PAGE 2 OF 3)

Subject 88001, Screening -- Web Page Dialog

Previous Form | Save as Complete | Save as Incomplete

SynCapture MOCK2 #244 VS/Neurological Ass

Site No. Patient No. Patient Initials

8 8 0 0 1 R H T

Visit Date: 0 2 F E B 2 0 0 5  
D D M M Y Y Y Y

**VITAL SIGNS**  
NOTE: Blood pressure, heart rate, respiratory rate, and

Blood Pressure: 1 2 0 / 0 5 5 mmH  
systolic diastolic

Heart Rate: 0 4 0 beats/min

Weight: 1 7 5  kg  lb

Done Loading.

SynCapture MOCK2 #244 VS/Neurological Assess

Site No. Patient No. Patient Initials

Visit Date:

**VITAL SIGNS**  
NOTE: Blood pressure, heart rate, respiratory rate, and o

Blood Pressure: / mmHg  
systolic diastolic

Heart Rate: beats/min

Weight:  kg  lb

DFUG SUN VALLEY 05  
1 2 3 4 5 6

Subject 88001, Screening -- Web Page Dialog

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

Protocol No. MOCK2

SynCapture MOCK2 #244 VS/Neurological Assessment Plate #005

Site No. Patient No. Patient Initials

8 8 0 0 1 R H T

Visit Date: 0 2 F E B 2 0 0 5  
D D M M Y Y Y Y

Screening Day -15 to -11  
 Screening PSG Night: -  
 Screening PSG Day: -  
 Treatment Night:  
 Treatment Day:  
 Early Termination

**VITAL SIGNS**  
 NOTE: Blood pressure, heart rate, respiratory rate, and oral temperature done after sitting for 5 minutes.

Blood Pressure: 1 2 0 / 0 5 5 mmHg  
systolic diastolic

Respiratory Rate: 1 5 breaths/min

Heart Rate: 0 4 0 beats/min

Temperature: 0 9 8 . 0  °F  °C

Weight: 1 7 5  kg  lb

Height: 0 6 0  cm  in

Done Loading. Form Time: 00:04

Subject 88001, Screening -- Web Page Dialog

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

Protocol No. MOCK2

SynCapture MOCK2 #244 VS/Neurological Assessment Plate #005

Site No. Patient No. Patient Initials

8 8 0 0 1 R H T

Visit Date: 0 2 F E B 2 0 0 5  
D D M M Y Y Y Y

Screening Day -15 to -11  
 Screening PSG Night:  
 Screening PSG Day:  
 Treatment Night:  
 Treatment Day:  
 Early Termination

**VITAL SIGNS**  
 NOTE: Blood pressure, heart rate, respiratory rate, and oral temperature done after sitting for 5 minutes.

Blood Pressure: 1 2 0 / 0 5 5 mmHg  
systolic diastolic

Respiratory Rate: 1 5 breaths/min

Heart Rate: 0 4 0 beats/min

Temperature: 0 9 8 . 0  °F  °C

Weight: 1 7 5  kg  lb

Height: 0 6 0  cm  in

QC Window -- Web Page Dialog

Heart Rate [40] is out of expected range. Please confirm or correct pulse.

Status: Unresolved

Note:  
 Confirm pulse.

Close

Heart Rate: Legal values are: 50~110 Form Time: 00:35

SynCapture:SynCapture Validation - Microsoft Internet Explorer

Address: http://capture:81/index.php?p=study/queries/unresolved

**Syneract.** Study Selection | Site Map | Support | Logout

Subject Management | **Queries** | Reports | Configuration

Queries Filter

Study Homepage » **Unresolved Queries**

Unresolved Queries  
Resolved Queries  
All Queries

Queries  
Return to the queries filter.

**Unresolved Queries**  
Listed below are all the queries for your site(s). Click on a query to go to its corresponding form.

<p>Subject Identifier: 88001 Visit: Screening Plate: STUDY EXEMPTION/DEMOGRAPHICS Field: Gender Status: <b>Unresolved</b></p>	<p>Gender result of Female is inconsistent with source documentation. Please reconcile.</p>
<p>Subject Identifier: 88002 Visit: Screening Plate: VITAL SIGNS/NEUROLOGICAL... Field: Diastolic Blood Pressure Status: <b>Unresolved</b></p>	<p>Diastolic Blood Pressure [100] recorded is out of expected range. Please confirm or correct result.</p>
<p>Subject Identifier: 88002 Visit: Screening Plate: VITAL SIGNS/NEUROLOGICAL... Field: Heart Rate Status: <b>Unresolved</b></p>	<p>Heart Rate [150] is out of expected range. Please confirm or correct pulse.</p>
<p>Subject Identifier: 88002 Visit: Screening Plate: PHYSICAL EXAM Field: Skin specify Status: <b>Unresolved</b></p>	<p>Source document also indicates ACNE from childhood. Please provide ACNE to the SKIN comment.</p>

PQ SC | SynCapture Validation | Site Coordinator | Find

SynCapture:SynCapture Mock Trial 2 - Microsoft Internet Explorer

Address: http://duffman:81/index.php?p=study/reports

**Syneract.** Study Selection | Site Map | Support | Logout

Subject Management | Queries | **Reports** | Configuration

Study Homepage » **Reports**

Study Homepage  
Return to the study homepage.

- Study Homepage
- Patient Query Summary
- Site Query Summary
- Missing Report

**Reports**  
The 'Reports' page provides a variety of reports available to the user. All information is updated nightly.

OQ Coordinator | SynCapture Mock Trial 2 | Site Coordinator | Find

Local Intranet

**SynCapture Validation**  
Site Query Summary

March 14, 2005

SITE NUMBER	TOTAL RECORDS	TOTAL QCs	RATE 100 REC	RESOLVED QCs		AGE (Days of Unresolved QCs)					OUTSTANDING QCs	
				#	%	<=10	11-20	21-30	31-60	>60		
88	9	5	56	1	20	4						4
<b>TOTAL</b>	<b>9</b>	<b>5</b>	<b>56</b>	<b>1</b>	<b>20</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>4</b>

## Why use SynCapture?

- **1 study can have 3 modes of data capture**
  - **Site's technical capabilities can be assessed**
    - In multi-center trials, not all sites want to do EDC
  - **CRF is familiar (don't have to get used to using an eCRF format)**
- **1 database set-up**
- **Internal processes and workflow remain the same**



## Questions?

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