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# SynCapture

Update – MDC Experience

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## SynCapture Background

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- Development began in 2004
- At time, there was no EDC solution that met our needs
- DataFax was primary DMS
  - Wanted to leverage experience
- Went live in 2005



## SynCapture Background (cont.)

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- SynCapture is validated and is 21 CFR Part 11 compliant
- Have closed 3 studies and have several concurrently ongoing studies
- Currently offered as a service

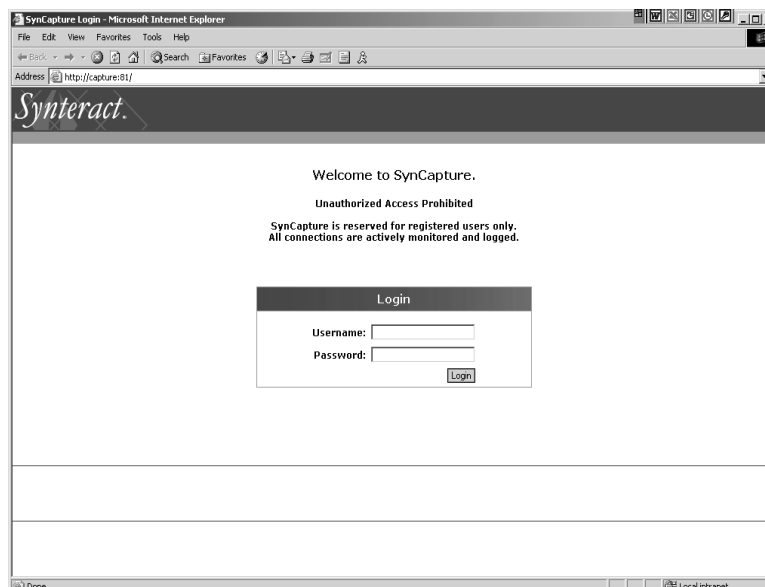


## Technical Overview

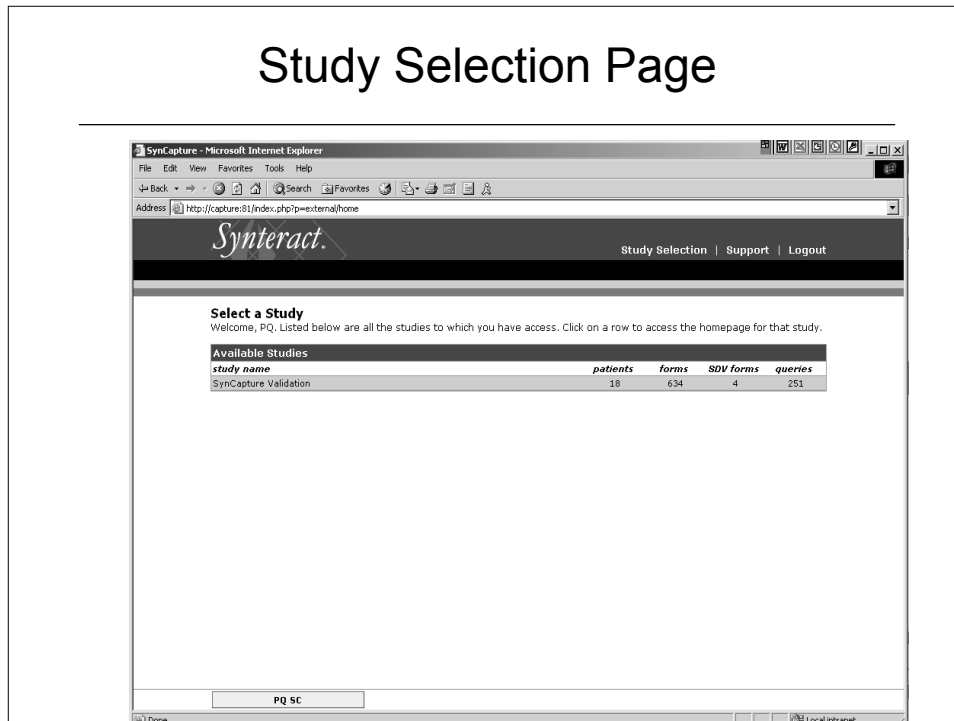
- Sites login to project specific website
- Launch SynCapture Citrix application which takes them directly to SynCapture login screen
- Login with SynCapture credentials which is tied to a UNIX (DataFax) account
  - Audit trail entries appear as normal DataFax audit trail records
- Clients access Web front-end, not DataFax server directly



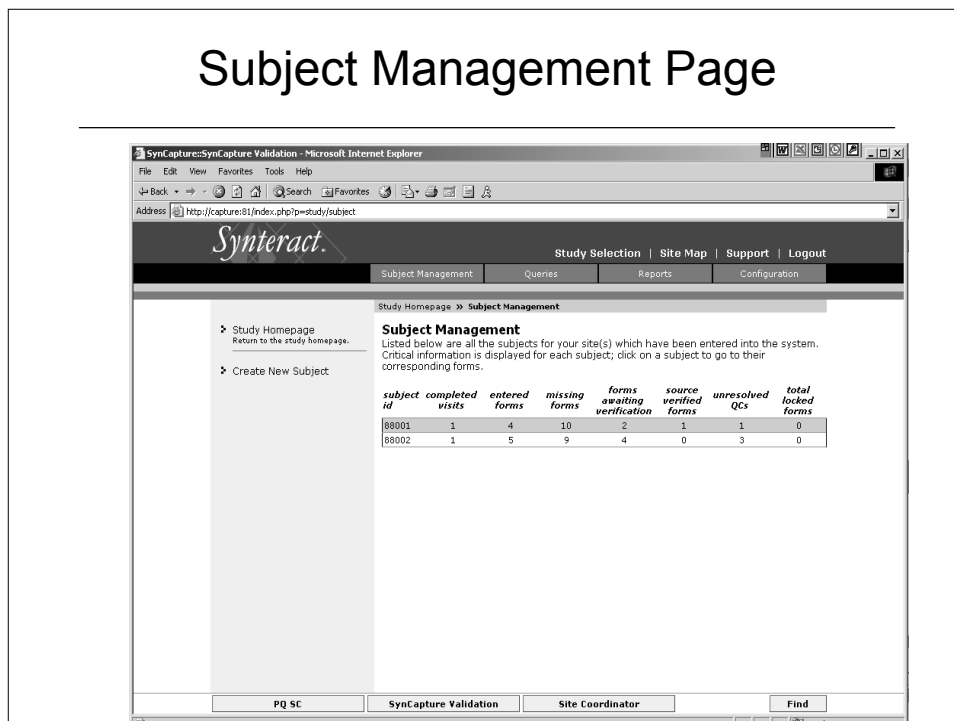
## Login Page



## Study Selection Page



## Subject Management Page



## Study Setup

- Follow normal development SOPs
- Additional SOPs for SynCapture development created
- Study setup takes 2 weeks longer
  - Generate and QC 100% Web screens and edit checks



## CRF Page

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  Screening Day -15 to -11

Site No. Patient No. Patient Initials

88 001 RHT

Visit Date: 02 FEB 20

**VITAL SIGNS**

NOTE: Blood pressure, heart rate, respiratory

Blood Pressure: 120 / 05  
systolic diastolic

Heart Rate: 040 beats/min

Weight: 175 kg

**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

## Data Management Experience: Site Requirements

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- Site equipment qualification
  - Low minimum requirements (Ability to run Citrix, Windows 2000 or greater, with 128 MB or RAM, and Internet Explorer 4.0 or above)
  - Site verification website to test Citrix
- System Requirements Checklist provided for qualification visits requiring site sign off



## Data Management Experience: Training

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- Study personnel training
  - Overview provided at Investigator/Kick Off Meetings
  - An in depth web based training using GoToAssist provided closer to database opening date
  - Type of training is based on the role of the individual in the study: Study Coordinator, CRA, Sponsor, Data Management, etc.
  - Initial instruction occurs in training database followed by assisting/observing study coordinator with entry of first patient data
  - Training usually accomplished in 30-60 minutes and documented by signature log (faxed back to Synteract)



## Data Management Experience: Training

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- SynCapture User's Manual
  - General User's Manual for study personnel that will be entering data
  - CRA User's Manual with monitor specific instruction
  - Manual is provided prior to training and also includes sign off (read and comprehend)
- SOP development
- 24/7 support option



## Data Management Experience: Entry of Data

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- Case Report Form Completion Guidelines can be created
- Data can be entered directly off of the source documents
- Study specific worksheets can also be created to assist with entry of data
- Source doc entry is 100% verified by the CRA
- Source docs and/or worksheets are retained by the site, along with PDF of all CRF images (provided at end of study using PDF function in DataFax)
- The only hardcopy CRF pages are the Investigator Signature or SAE Forms



## Data Management Experience: Role of Data Management

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- Point of entry checks lower the overall query rate over the life of the study
- SAS Checks are run externally and applied to the database through DataFax
- Medical Coding completion and queries
- SAE Reconciliation
- Lock CRF pages (DataFax level 5) upon 100% query resolution, all pages verified by CRA, Coding and SAE Recon complete



## Data Management Experience: Database Close

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- Quicker database close
  - On average of 2 days after LPO
- Typical database QC not required since all data has already been source document verified by the CRA
- PDF images of CRF provided to site at end of study through DataFax



## Data Management Experience: Lessons Learned

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- Verify connectivity settings up front
- 14-day password was too short
- Speed of screens to load
- Study Coordinator/CRA communication
- More real time reports and/or custom reports (not all DataFax reports are accurate when EDC is used)
- Lost data log functionality



## Objectives for 2007

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- 3-5 more studies
  - International
- Removing Citrix requirement
- ASP hosting



## Questions

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