
Training for EDC Studies / SynCapture Update

Bridget Merrill
Synteract, Inc.



Training for SynCapture (EDC) Studies

- Training the Trainer
- Training Site Personnel
- Training the CRA
- Training the Sponsor
- Timing and Method of Training Sessions
- Content of Training
- Training Documentation

Training the Trainer

- The trainer should be fully trained on the EDC system being used
- At Synteract, SynCapture trainers are *typically* the MCDM or Lead Data Manager for a given study
- Due to availability the trainer may not always be involved with the given study, but **MUST** be thoroughly knowledgeable of SynCapture or applicable EDC system

Training the Trainer, cont.

- Synteract trainers are trained internally
- Through the work experience of opening an EDC database
- 1:1 trainings with an experienced trainer
- Reading/understanding the user manual and EDC documentation
- Observing training sessions conducted by an experienced trainer
- User groups

Training the Trainer, cont.

- A demonstration training database is available for SynCapture
- The sponsor may elect to conduct training or have the CRA conduct training
- If this is the case, the outside trainer is provided 1:1 training with an experienced Synteract MCDM or Lead DM
- Access to the SynCapture training database is provided for the proposed trainer to practice

Training Site Personnel

- Site personnel are probably the most important users being trained in the SynCapture database
- Site personnel will spend the most time in SynCapture and are responsible for the entry of all data
- Site personnel must thoroughly understand the functions of the EDC system: logging in, data entry functions, addressing queries, data updates

Training Site Personnel, cont.

- Improperly trained site personnel may cause a delay in the entry of data
- Improperly trained site personnel may increase the number of help desk calls or calls to the lead data manager
- In turn, this takes up more time and resources
- Improperly trained site personnel may create frustration at the site, with the CRA, and with data management

Training the CRA

- The CRA should be trained on all CRA functions: adding queries and CRA notes, reviewing addressed queries and setting to a resolved status, source document verification
- It is helpful for the CRA to also learn and understand the site coordinator functions
 - CRA training begins with an overview of the Study Coordinator role and the functions they may perform
 - It is important for the CRA to understand what a site coordinator may or may not do within the EDC system

Training the CRA, cont.

- Improperly trained CRAs may result in a longer database close out time
- Improperly trained CRAs may incorrectly close out queries

Training the Sponsor

- The sponsor is typically provided view access only
- The sponsor should be trained on how to log in to the database, view data and access reports
- Some sponsors may request permissions to add queries to the database and therefore will need CRA training

Timing of Training

- It is ideal to provide training close to when the user will actually work in the database
- Just prior to database opening is ideal
- This helps to ensure that the user will retain the training information
- If training is conducted too far in advance, the user typically forgets
- Retraining may be required, utilizing extra time and resources

Timing of Training

- Access to the demonstration training database may be provided to the trainee
- Practicing in a SynCapture database is the best way to become familiar with the functions available to the user

Methods of Training

- Traditional SynCapture training is conducted via web-based instructor training
- Synteract uses iLinc software which allows the trainer to share their desktop
- The trainee will view the training session from a remote location
- Trainers will conduct training from their own desktop either in the demonstration database or the actual study database if available at the time of training

Methods of Training, cont.

- Web based training is efficient and may be done in groups
 - The main issue with this type of training is that the trainee only views the training presentation and does not get to perform the functions within the EDC system
 - Questions typically arise if the trainee is not ready to work in the database in a timely manner

Methods of Training, cont.

- Training may also occur in a face to face setting
 - Investigator or kick off meetings
- If at an Investigator or kick off meeting, typically more of an overview training is completed with more formal training provided at a later date
 - The main issue with this type training is it may occur too early on
 - The database is typically not ready at this time and the trainee will not retain all the information

Methods of Training, cont.

- Users also have the option to train within a SynCapture demo database
 - Allows user to become familiar with navigating through a SynCapture database and the functions they may perform
 - Allows a trainer to review the eCRFs that were entered and instruct on any questions
- In some cases the user may review the SynCapture User Manual and sign off that they have read and understand

Methods of Training, cont.

- Occasionally scheduling may be a conflict
- In these cases the user may review the SynCapture User Manual and sign off that they have read and understand prior to entering the database

Content of Training

- Training should cover the functions of the SynCapture database
- Training may be catered to the user
- Only functions accessible to a user need to be trained on (Site Coordinators do not need CRA training, etc.)

Content of Training, cont.

- Training may also include any study specific instructions, not just the SynCapture functions
- If eCRF completion guidelines are created for a study, it is helpful to incorporate those into the SynCapture training

Training Documentation

- Each user must complete training prior to entering and working within the database
- It is important to document when trainings occurred and who was trained
- Synteract SOPs require training to be documented

Training Documentation, cont.

- At the end of SynCapture trainings, the trainee is required to sign a training log
- This log is provided to Synteract for study documentation
- A copy should also be retained at the site

Training – Lessons Learned

- Schedule training as close to database opening as possible
 - Training too early may require additional re-training
- Cover all functions that may be performed by a given user
- Web-based training instructor training has been efficient, however, does not allow user to actually train in the EDC system
- Documentation of training
 - Ensure this process is defined in your SOPs

Training – Lessons Learned

- **Have multiple trainers available for your EDC system**
 - Synteract had a significant increase in EDC studies through 2007
 - Many more users needed to be trained
 - Training takes time and can present issues with scheduling if there are not enough training resources
 - As a CRO we need to be as flexible as we can with providing training and strive to complete in a timely manner

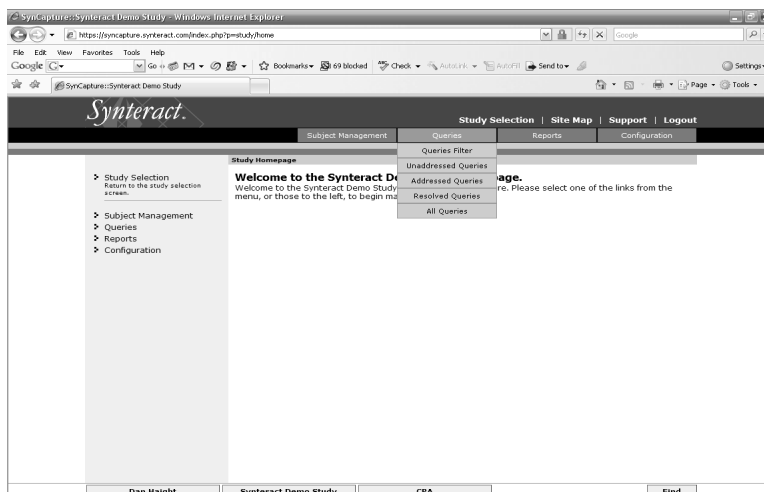
SynCapture Update

- **The needs of sponsors are changing and SynCapture has provided a solution to some of these needs**
 - Hard-copy images can be captured in the database along with the eCRF
 - Example: ECG tracings
- **8 studies conducted in SynCapture through 2007**
- **3 databases closed in 2007**
- **Average time to database closure was within 1 week of last query resolved**
- **19 databases currently in production**
- **Approximately 40 new users trained in 2007**

SynCapture Update: Version 1.1

- SynCapture user group created for Synteract personnel involved with SynCapture studies
- SynCapture Version 1.1 was released in December 2007
- A number of features were added based on user feedback
- The query tool was enhanced to help site coordinators and CRAs complete their tasks

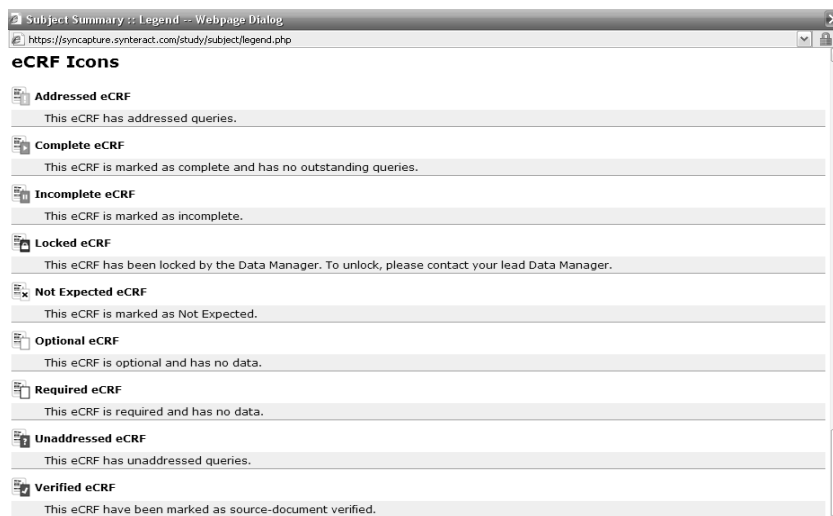
SynCapture Update: Version 1.1



SynCapture Update: Version 1.1

- Icons and symbols updated to include new query status
- Lost log is being utilized for unexpected eCRF pages
- Sophisticated visit map

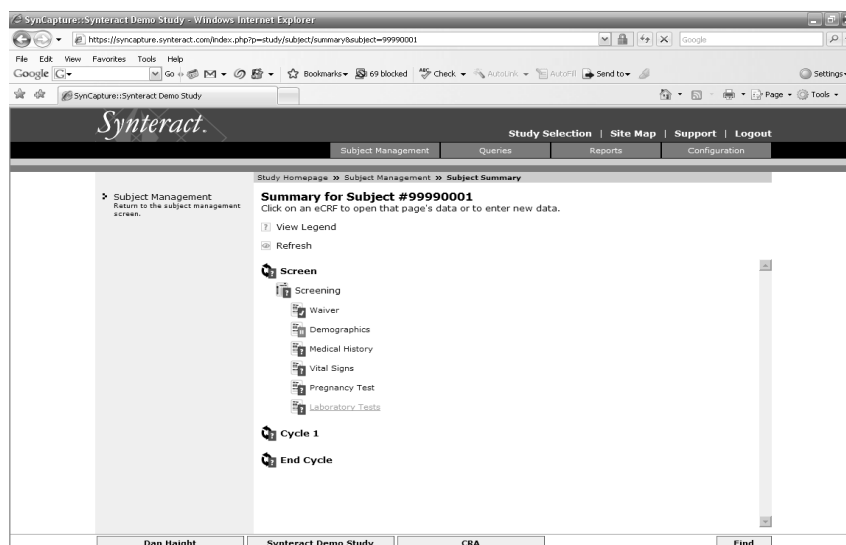
SynCapture Update: Version 1.1



SynCapture Update: Version 1.1

- Screen Icons refresh and update immediately
 - Previously, the Icon updates occurred in the evening or upon request
- Central Help Desk created through Synteract IT to help call resolution upon first call

SynCapture Update: Version 1.1



SynCapture Update

- New upgrade is currently in the works
- Upgrade will address the eCRF page load speed

Thank you, Questions?
