CTDS
Clinical Trial Data Services

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Purpose: Setting up new users and deactivating current users in the EDC System.

Scope: This procedure applies to all new EDC users, all current users, and all CTDS personnel.

Responsibilities:

The following roles are referenced in this document:

Functional Role	Responsibilities
Technical Support Representative	• Facilitating the activation, setup and deactivation of users • Training and retraining of new and existing users • Resolving system issues experienced by users

References: FM DM018.1 User Authorization Form
Study-specific User Logs

Procedure:

1.0   Activation

1.1   At the beginning of each study, the technical support representative will create a customized User Authorization Form (UAF) from the template FM DM018.1 User Authorization Form.

1.2   Whenever a new user request is received, the request should be relayed to technical support, who will then send the new user a UAF.

1.2.1   Technical support will collect the completed UAF, and review it for completion and accuracy. If it is filled out incorrectly and/or incompletely, technical support will liaise with the user until the forms are correctly filled out and complete.

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1.2.2 Technical support will save a copy of the completed UAF on the server.

1.2.3 Technical support will then record the new user's information on the study-specific user log (columns A - G).

1.2.4 Technical support will forward the completed UAF to the CTDS programmer.

1.3 The CTDS programmer will set up the new user based on the roles and privileges outlined in the UAF.

1.3.1 Once this is done, the CTDS programmer will complete the bottom section of the UAF ("Activation: Set up in system").

1.3.2 The CTDS programmer will then send the UAF back to technical support.

1.4 Quality assurance will be performed to ensure that the roles and privileges stipulated on the UAF are correctly reflected in the database. If not, technical support will work together with the CTDS programmer to correct this.

1.4.1 Once this verification process is complete, technical support will complete the bottom section of the UAF ("Activation: QA Verification").

1.4.2 Technical support will now update the study-specific user log.

1.5 Technical support will create a training certificate for the new user, and upload it onto the server.

1.6 Technical support will now send an email to the new user, containing the following:

- Notification that the user has been set up in the system.
- Querying whether the user has received the confirmation email from the database hosting company, and prompting the user to log on to the system.
- The training certificate (as an email attachment), which is to be printed out and kept in the site regulatory binder if applicable.

1.7 Technical support will receive confirmation that the user has received the email from the database hosting company and is able to successfully log on to the system.

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1.8 Technical support will now update the bottom section of the UAF ("Activation: User Notification").

1.9 Technical support will now file printouts of the UAF and training certificate in the user log binder.

1.10 Technical support will now update the study-specific user log.

1.11 Technical support will periodically monitor the study-specific user logs for completeness and for breakdowns in the process.

2.0 Deactivation

2.1 Whenever a user deactivation request is received, the request should be relayed to technical support.

2.2 Technical support will send a new UAF to the client. Once the completed form is sent back to technical support, it will be reviewed for completion and accuracy.

2.3 Technical support will forward the completed UAF to the CTDS programmer.

2.4 The CTDS programmer will remove the new user from the system.

2.4.1 Once this is done, the CTDS programmer will complete the bottom section of the UAF ("Deactivation: Set up in system").
2.4.2 The CTDS programmer will then send the UAF back to technical support.

2.5 Quality assurance will be performed to ensure that the user has been removed from the system.

2.5.1 Once the verification process is complete, technical support will complete the bottom section of the UAF ("Deactivation: QA Verification").

2.6 Technical support will respond to the user deactivation request (e.g. via email) and confirm that the user has been removed from the system.

2.7   Technical support will now update the bottom section of the UAF ("Deactivation: User Notification") and file it in the binder together with the original UAF form (Activation).

2.8   Technical support will now update the study-specific user log.

2.9   Technical support will periodically monitor the study-specific user logs for completeness and for breakdowns in the process.

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Recordkeeping: In accordance with SOP QA005: General Recordkeeping Requirements

Revision History:

REVISION	RELEASE DATE	AUTHOR	SUMMARY OF CHANGES
A	April 2014	Tracey Wood	New
B	July 2014	Tracey Wood	QA removed from training certificate steps
C	Sep 2014	Tracey Wood	QA removed from verification steps

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