Neurostatus-UHB

Title:

Neurostatus e-Test - Instructions for Study Administrators

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1   General Information

1.1   Access Information

Link to Neurostatus: www.neurostatus.net

Direct Link to Login page: www.neurostatus.net/login

PLEASE NOTE: A permanently actualized version of these instructions is provided in your study administration sector on Neurostatus.net. Select link 'Instructions/Help'!

To assist Investigators seeking Neurostatus Qualification, Administrators should also be familiar with the online instructions for Investigators and the Neurostatus e-Test program on Neurostatus.net!

The Neurostatus administration section provides various tools for tracking an Investigator's e-Test Qualification and for assisting the Investigators.

1.2   The Qualification Procedure

EDSS Training on Neurostatus Training DVD-ROM:

It is essential that Investigators obtain EDSS training via the Neurostatus Training DVD-ROM and the assessment manual for Neurostatus and EDSS prior to taking the Neurostatus e-Test. Therefore it is important to provide your Investigators with the DVD-ROM and the assessment manual.

E-Test and certification procedure on Neurostatus.net:

- THREE TRIALS: Investigators have three e-Test attempts to pass the e-Test and to obtain Neurostatus e-Test Qualification.
- E-TEST FEEDBACK: After each test attempt the Investigator is asked to improve his skills in EDSS rating by completing a personal training program related to the last test taken. This personal training is offered on the Neurostatus Training DVD-ROM (via login to e-Test feedback).
- FOURTH TRIAL: Investigators who have not been successful in three e-Test trials can request one additional, fourth trial after completing a questionnaire providing us with information about potential problems having turned up during the test (Status in administration list 'blocked' until the fourth test is unlocked).

1.3   Additional Training by Telephone

In very rare cases Investigators do not pass the exam after four trials. They are asked to contact their study administration for further advice. Study administration may send a request for additional training to neurostatus-support@usb.ch.

A personal EDSS Training is offered via telephone, provided by a member of the MS Team of the University Hospital Basel (UHBS), Switzerland. Duration of training is 45 minutes. The training offers (in short form) the presentation held at Investigator meetings, with focus on questions of the Investigator. After the training, the Investigator receives a new e-Test on Neurostatus.net website (three trials).

1.4   Levels of Qualification

The Neurostatus e-Test contains three different Levels of Qualification. Based on the phase (1, 2 or 3) of the clinical trial, these levels reflect the expected knowledge of an Investigator in performing a standardised examination and EDSS rating.

The Steering Committee of each study will decide which level is needed for a successful Neurostatus Qualification.

Level A = passing 30 of a possible 50 points: Allows re-certification for studies asking for a level A Qualification.

Level B = passing 34 of a possible 50 points: Allows re-certification for studies asking for a level A or B Qualification.

Level C = passing 38 of a possible 50 points: Allows re-certification for studies asking for a level A, B or C Qualification.

2   The Administration Section

2.1   Role and Tasks of the Study Administrators

The Global Study Administrator:

- Main contact person for Neurostatus Systems regarding e-Test application/administration/support.
- Managing and monitoring the Sponsor/CRO Study administration team in dedicated study administration section on Neurostatus.net.
- Add, remove, replace (backup) Global Study Administrators and/or Regional/Country Study Administrators.
- Assign access rights to other Study Administrators (read/write/delete).
- Send Login information to Study Administrators.

If regional or country Study Administrators are assigned:

- Handover of responsibilities to regional/country Study Administrators.
- Train the regional/country Study Administrators according to their access rights.

Tasks of a Study Administrator:

- Track EDSS Raters, their status, and certificates (automated email notification, list for download available).
- Confirm EDSS Raters requests for certification (or re-certification).
- Add EDSS Raters already registered on Neurostatus.net to the study (Add Investigator).
- Resend expiration emails to EDSS Rater if re-testing has not been performed despite of automated notifications (expired Qualification).nk to Neuro

2.2   Overview on Administration Tools

Investigator list

The list shows all Investigators registered for certification in your study, as well as important information for each Investigator. The registration counter (Results 0-50 of XXX) shows the total number of registered Investigators independent of their test status.

NOTE: You can sort the list by Name, Country, Site Nr, Status, Test date, Entry.

Info/Contacts

Provides study contact information and edit options for Global Administrators.

- **Study Information** provides an overview on general study information.
- **Administrators** offers diverse edit options to Global Administrator.
- **Contacts** shows Sponsor's contact information.
- **Activities** tracks all changes performed in this section.

Download Center

Download Investigator list, scoring documents, qualification documents and instructions for Investigators.

Mailing

A mailing tool for Administrators to contact participating Investigators and/or the administration team.

Status (pulldown) / Search

These functions enable you to sort all Investigators by test status or to search by name, email, country or centre/site number.

Add Investigator

The study administration can request automatic re-certification for Investigators, who previously obtained EDSS certification via Neurostatus e-Test or via a Neurostatus papertest at an Investigator meeting.

Print Preview

When printing the overview sheet, please change your print setup to landscape in order to optimize printing. Some printers offer the option to save print previews as a PDF-file.

NOTE: Before printing the overview sheet you are allowed to sort the list by Status (pulldown), and/or by Name, Country, Site Nr, Status, Test date, Entry.

Info/Actions

Various icons provide you with important functions/tools to easily administrate the Investigators registered in your study.

3 Edit Tools

3.1 Add/Edit Administrators, send Activation/Invitation Emails

During the course of a project the administration personnel may change, or contact details of an Administrator needs to be updated.

Global Administrators are offered to:

- Edit personal contact details by selecting link *My Account*
- Maintain Administrator accounts by selecting link *Administrators* offering the following options:
  - Add Administrators

  - Remove Administrators by selecting the icon 🗑

  - Determine administration settings and access rights by selecting the icon ✎

  - Send activation/invitation emails by selecting → Send invitation email

Regional/Country Administrators are offered to:

- Edit personal contact details by selecting link My Account

NOTE: Administrators are responsible for their personal data!

3.2 Change Site Number, Region or Function of an Investigator

Click on 👤 of the respective Investigator and select link Study data in the menu bar to modify data specific to your study.

NOTE: Investigators are responsible for their personal data and have the necessary tools to perform any modifications!

4 Add Investigators

4.1 Automatic re-certification of an Investigator / Add Investigator

The study administrator can process automatic re-certification for an Investigator obtaining a valid Neurostatus e-Test Qualification on Neurostatus database.

- Select menu ADD INVESTIGATOR
- You are asked to enter the Investigator's email address or his/her first and last name, to check if the Investigator has previously obtained EDSS qualification on Neurostatus.net.
- Follow procedure and submit.
- An email is automatically sent to the Investigator, informing him/her of the successful recertification.
- The new data will automatically appear in menu Investigators as "confirmed (re-A)"

Please note that re-certification can be refused:

- If the last e-Test of an Investigator has been taken prior to the allowed time window for recertification set in parameters of your study (e.g. 12 or 24 months)! Study parameters can be viewed in 'Info/Contacts', 'Study information'.
- If the e-Test of an Investigator does not represent the qualification level requested by your study or a higher level (Qualification levels A, B, C)!

5 View, Confirm, Reject, Deactivate or Delete Investigators

5.1 View Details of Investigator's E-Test

Click on ▤ to view the e-Test archive for a specific Investigator.

The e-Test archive provides you with detailed information about the e-Test trials and achieved scores for this specific Investigator.

5.2 Confirm or reject request for Qualification

A request for qualification is sent to the study administration if an Investigator has successfully passed the Neurostatus e-Test and requests participation or automatic recertification for this particular study.

Confirmation of a request: ✔

- An email informs you of an Investigator's request for qualification in your study. This Investigator has a valid Neurostatus qualification for your study (with requested test level A, B or C).
- If this Investigator is a registered participant in your study, you must confirm his/her request in order to validate it.
- After confirming the request, this qualification will be valid for your study. An email confirmation will be sent to the Investigator.

Rejection of a request: ✘

- An email informs you of an Investigator's request for qualification in your study. This Investigator has a valid Neurostatus qualification for your study (with requested test level A, B or C).
- If this Investigator is not a registered participant in your study, you can reject his/her request.
- After rejecting the request, this Investigator's data will be removed from your administration sector. An email notification will be sent to the Investigator.

5.3 Deactivate Investigators in your List

Click on ☒ to deactivate or on ☐ to reactivate an Investigator's data in your study administration sector.

The Investigator will receive a notification in his/her personal e-Test account.

Investigators whose status is deactivated will no longer receive email notifications for reminded/expired e-Tests.

5.4 Delete Investigators from your List

Click on 🗑 to delete an Investigator's data from your study administration sector. The Investigator will receive a notification in his/her personal e-Test account.

NOTE: Once an Investigator's data have been deleted, earlier Qualifications for this study will not be trackable anymore.

6 Expiration of an Investigator's Qualification

6.1 Expiration of a Neurostatus E-Test Qualification

The period of validity of a Neurostatus e-Test Qualification is defined by the Steering Committee of the respective study.

Process:

- Investigator receives a first email notification (reminder) one month before his/her certification is expiring.
- A second notification is sent on the day of expiry.
- Additional reminders have to be triggered by the Study Administrator.

6.2   Resend expiration notification to an Investigator

Click on 🔄 icon to resend expiry notification to an Investigator. An email window will pop-up, stating that this particular Investigator needs to retake the test. Administrators are allowed to modify the email.

7   Download Options

7.1   Print/Download Qualification Document

To view, print or download the qualification document of an Investigator, click on 🗎 in your Investigator's list.

7.2   Download Center

Download Investigator list, Scoring documents, Qualification documents and Instructions for Investigators.

NOTE: Before downloading the excel file you are allowed to sort the list by Status (pulldown), and/or by Name, Country, Site Nr, Status, Test date, Entry.

8   Support

8.1   Neurostatus Support Contacts

Technical support: neurostatus-support@usb.ch

General EDSS questions: ludwig.kappos@usb.ch | Prof. Dr. L. Kappos