Neurostatus-UHB

NeuroCert -
Manual for Study Administrators

Version NC_2026.0

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1. Introduction

This is the NeuroCert manual for Study Administrators. It explains the processes and system functionality. There are distinct Study Administrator roles in NeuroCert with distinct tasks and permissions. Depending on which role has been assigned to you, different parts of this manual apply to you:

- **Rater Administrators** are requested to read Chapter 2, the Quick Guide for Rater Administrators. If they are interested in additional reading, refer to the Chapters for Head Administrators.

- **Viewers** should also read Chapter 2, the Quick Guide for Rater Administrators. While the Chapter on how to add Raters does not apply to them – as the name of the role suggests, Viewers have only read permissions –it is a recommended reading for them too, as it helps understanding the concepts.

- Finally, **Head Administrators** are requested to read all Chapters (including the Quick Guide for Raters Administrators) except for the "Advanced topics" described at the end of this manual which are an optional reading.

Refer to the frequently asked questions (FAQ)[1] for additional information.

[1] https://support.neurostatus-uhb.com/administration-section/

2. Quick guide for Rater Administrators and Viewers

This chapter…

…is the must read for Rater Administrators. It explains the basic steps to set up your account, get around the application, and manage Raters.

If you have been invited as Rater Administrator to NeuroCert, your task is to manage Raters in one or more regions. You need to:

- invite them to the Study in NeuroCert so that they can obtain Neurostatus-EDSS certificates,
- remove them from the Study when no longer active, and
- monitor their certification status while the Study is in status live.

2.1. Registering

When you are first invited to join a Study on the NeuroCert platform, you receive an email with a personal link that allows you to enter the information required to create an account for you. The name you enter during registration will be used to identify you towards other Administrators, Raters or health authorities, when applicable. We request additional information (academic title, country of origin, year of birth, company affiliation and phone) for internal processes such as, e.g., account recovery.

After you have completed the registration, we verify your account. Most importantly, we ensure that there is no duplicate account. Duplicates create additional effort for both you and the Study sponsor since certificates might not be recognized correctly. You will be notified by email about completion of the account verification and can then use the NeuroCert platform.

By the way: all Raters you will manage go through the very same registration process.

2.2. Log in

NeuroCert can be opened in any common modern internet browser (Edge, Chrome, Firefox, Safari) by navigating to neurocert.neurostatus-uhb.com.

To log in, click on the corresponding button on the top right (see Figure 1). Your credentials consist of the registered email address and the password set during registration. Refer to the FAQs[2] if you have forgotten your password.

[2] https://support.neurostatus-uhb.com/administration-section/

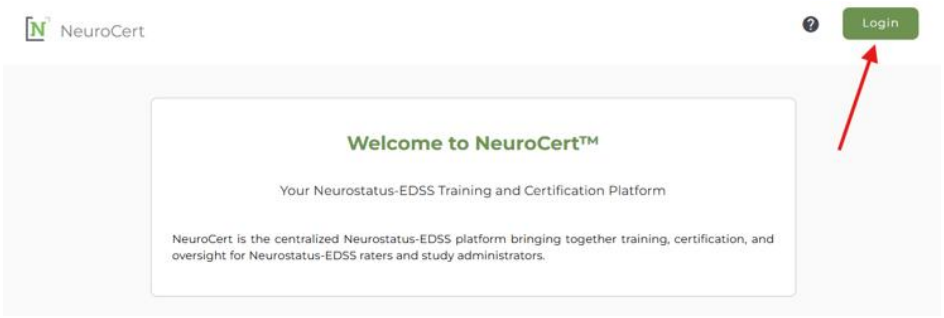


Figure 1: NeuroCert Welcome screen

2.3. Basic navigation

This chapter…

…explains how to find your way around on the NeuroCert platform after logging in. It describes the most important elements that you will encounter in the application

After logging in, you will see the *Home* screen (Figure 2). In this Chapter we use this screen to explain the application's main elements.

The header on top of the page contains the **main menu** listing the application's main screens: *Home*, *Studies / Certifications* and *Exams*. Each of these screens is described in detail in the Chapters below. The header also contains the **help and profile menus** on the right-hand side. See the respective Chapters below for details.

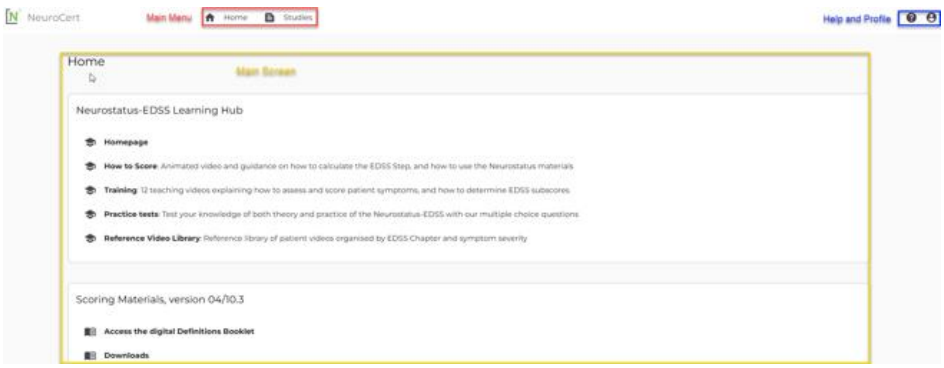


Figure 2: Main navigation elements. Shown here is the "Home" screen.

Finally, the content of the **main screen** depends on the screen chosen. For the *Home* screen shown in Figure 2, the main screen consists of three sections: *Tasks, Neurostatus-EDSS Learning Hub,* and *Scoring Materials, version 04/10.3* all of which are described in detail below.

Some more common user elements shall be described at the example of the *User Profile* view shown in Figure 3. You can reach this view by selecting "Profile" from the *Profile* menu. This view contains two so-called tabs, namely the *Info* tab (this tab is opened in Figure 3) and the *Activities* tab (this tab is closed in Figure 3). Click on the tab's name to open it.

On the *Info* tab, there are two so-called accordions, namely the *Account* accordion and the *Personal Info* accordion. In Figure 3, the accordions are expanded (note the upward pointing arrow on the right-hand side). Click on the arrows to expand or collapse accordions.

Finally, Figure 3 shows how to make edits to a field. By double-clicking on the field (here: *email*), you enter the edit mode. When done with your edits, you need to confirm or discard the new value by clicking on the checkmark or cross, respectively.



Figure 3: Example for tabs, accordions and the editing of individual fields.

2.4. Important remarks about your account

1. Never share your credentials: Your account is personal and Good Clinical Practice (GCP) prohibits sharing credentials. Report any suspicious activity to Neurostatus support[3].

2. Keep your personal data up to date to ensure other users of the platform can reach you.

3. You are requested to change your password every 12 months. Please open the *Profile* screen (select "Profile" from the *Profile* menu in Figure 2) and click "Change password" in the *Accounts* accordion. You need to verify your password by entering it twice.

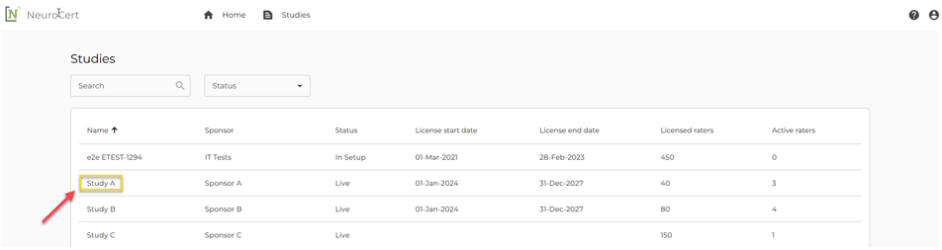
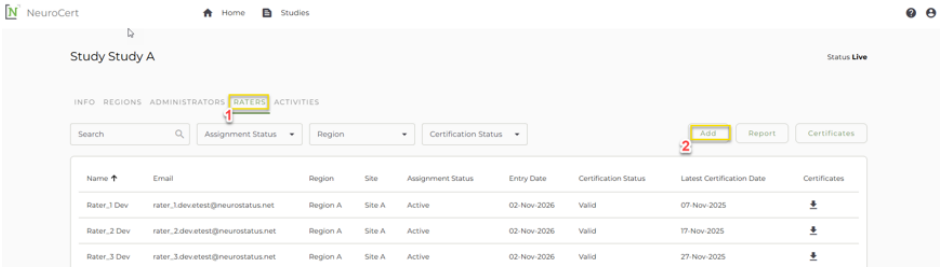
4. To avoid abuse, log out manually when done with your work by clicking on "Log out" in the *Profile* menu (see Figure 2). You are automatically logged out every three hours. Hint: If a Rater happens to be logged out during an exam attempt, they can simply log in again and resume the exam.

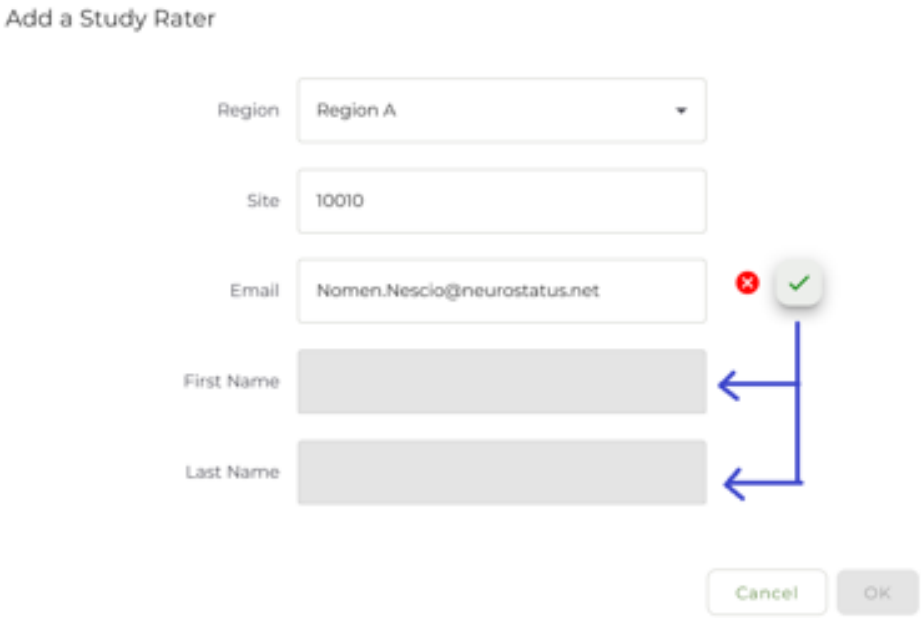
[3] mailto: support-neurocert@neurostatus-uhb.com

2.5. How to invite a Rater to a Study

In order to invite a Rater to a Study you manage, follow the steps below. You will need to know

- The Rater's full name.
- The Rater's email address. Many Raters are already registered on the NeuroCert platform, and we only allow for one account per person. Please ensure that you use the email address by which the Rater is already registered on NeuroCert, if applicable, to avoid a delay in the registration process.
- The site ID that applies for this Rater (also known as site number or Study centre code)
- The region this Rater shall be included in (see Chapter 3.2 Regions for details)

1	Select the Study of interest from the Table in the *Studies* View by clicking on the Study's name 
2	Open the dialog to add Raters: • Open the tab *Raters* • Click on the "add" button 

3	Provide the Rater's Study assignment data • Site • Region • Email  When confirming the email address, the NeuroCert system will search for existing users with the email address provided. If the email address is already registered, the system will automatically complete the name. Otherwise complete these fields and submit the form. The NeuroCert system will display an error message if the user cannot be invited to the Study. Refer to the FAQs[4] for explanations. If you know that the given Rater has already registered in NeuroCert but the name is not auto-filled, please ensure that you use the email address by which the Rater registered on NeuroCert to avoid a delay in the registration process. If you cannot select the Region that the Rater shall be assigned to, please reach out to one of the Study head Administrators

After completing these steps, the system sends an email asking the Rater to register on the NeuroCert platform (unless they have done so already). You will immediately find them listed on the *Raters* tab with *assignment status* "invited". This status will change to "active" once the Rater has accepted the Study invitation.

[4] https://support.neurostatus-uhb.com/administration-section/

2.6. How to verify a Rater's certification status

The certification status displayed in the *Raters* tab allows Study Administrators to verify that Raters hold a valid certificate when examining patients.

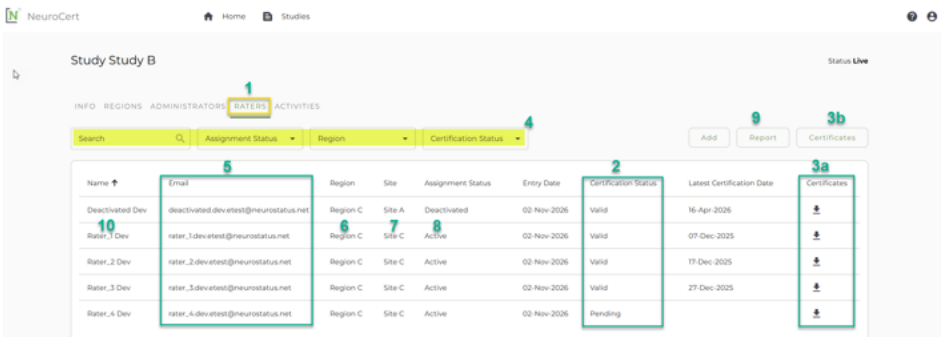


Figure 4: Raters tab of a Study

1	Navigate to Study of interest and open the *Raters* tab (See label (1) in Figure 4)
2	Check the column *Certification status* This column (labelled (2) in Figure 4) informs you about the current certification state for each Rater. The possible values for certification status are explained in the next subchapter.

Remarks

- you can filter the table by Certification status and other criteria (labelled (4) in Figure 4)
- you can open an email by clicking on the Rater's email address (labelled (5) Figure 4)
- Raters are automatically informed by email on the date the certification status reaches "expiration upcoming" or "expired".

2.6.1. Certification status

Certification status	Business meaning	Certificate is currently
pending	Rater does not have a certificate for the Study. In order to obtain a certificate, the Rater needs to accept the Study invite and potentially also to pass an exam. Refer to Chapter 3.5 Certificate validity and recognition of past exams for details	invalid (more precisely: there is none)
valid	Rater currently has a valid certificate for the given Study	valid
expiration upcoming	Rater has a certificate for the given Study that will expire within the next month	valid
expired	Rater has an expired certificate for the given Study	invalid

2.7. How to download certificates

1	Navigate to the Study of interest and open the *Raters* tab (see label (1) in Figure 4)
2	Download • To download all certificates **of this Study** for the regions you are assigned to: Click on "Certificates" (labelled (3b) in Figure 4) • To download all certificates **of a given Rater** assigned to your region, find the Rater in the table and click on the download symbol in the respective table row (labelled (3a) in Figure 4).

2.8. How to modify a Rater's site

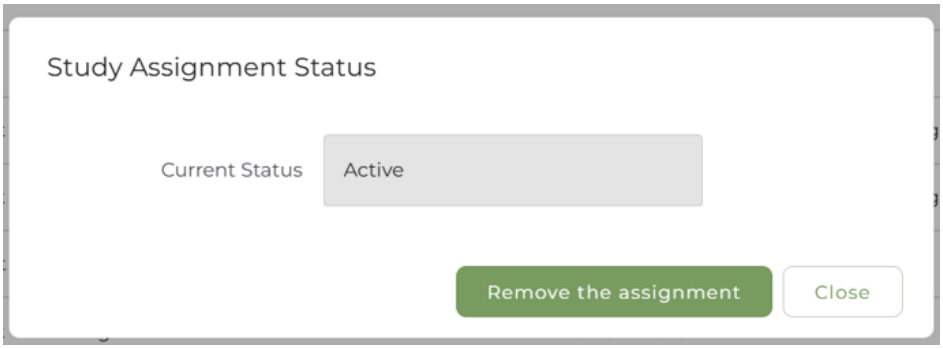
If a Rater changes site or the site assigned is incorrect, you can edit this field as described below. Note that the change will only affect future certificates.

1	Navigate to the Study of interest and open the *Raters* tab (see label (1) in Figure 4)
2	Click on the Rater's site (see label (7) in Figure 4)
3	In the dialog that opens, modify the entry and submit the changes. Note that the change will only affect future certificates.

2.9. How to remove (deactivate) or re-invite a Rater

When a Rater no longer participates in a Study and should therefore not receive any more certificates, you should deactivate their Study assignment.

1	Navigate to the Study of interest and open the *Raters* tab (see label (1) in Figure 4).
2	Click on the *Current status* (see label (8) in Figure 4)

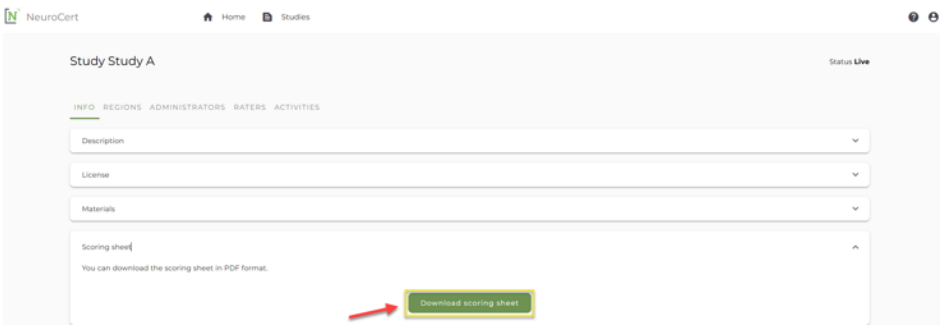
3	In the dialog that opens click on the button that corresponds to the action you want to perform. Example for removal from a Study: Click on “Remove the assignment” 

Remarks

- Removing a Rater from a Study does not limit your access to their certificates (for the given Study) and list of exams.
- Once removed, no new certificates are generated for the Rater for this Study and no reminders about certificate expiration are sent.
- Removing a Rater from a Study does not impact the user’s access to the NeuroCert platform.

2.10. How to download a Study’s scoring sheet

The Neurostatus-EDSS Scoring sheet applicable to each Study is available for downloading and printing. When an eCOA tool is implemented, the Neurostatus-EDSS assessment must be recorded electronically in the eCOA device.

1	Navigate to the Study of interest and open the *Info* tab
2	Open the *Scoring sheet* accordion on the *Info* tab and download the scoring sheet from here 

2.11. How to export a list of all Raters' exams and certificates

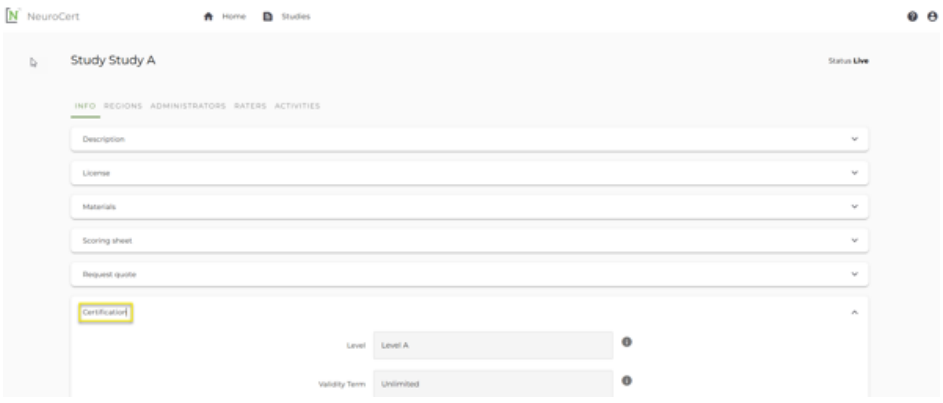
This list contains all Raters that are or have been active in a Study at one point. For each Rater, it provides a complete list of their exam attempts with score reached. If for the given Study there is a certificate associated with an attempt, the certificate validity details (as valid when the certificate was issued) are listed as well.

For clarity and usability, the report includes the *Site* and *Region* fields. These fields reflect the current information recorded in the system and may differ from the values displayed on the original certificate if either field has been modified since the certificate was issued.

1	Navigate to the *Raters* tab (see label (1) in Figure 4)
2	Create report: Click on the “Report” button (labelled (9) in Figure 4)

2.12. How to find the Study’s certification criteria

These settings are chosen by the Sponsor based on the Study profile and risk assessment. You can find more information on the Study configuration in Chapter 4.2.2 Study certification levels

1	Navigate to the Study of interest and open the *Info* tab.
2	Open the *Certification* tab 

With this the mandatory readings for Rater Administrators and Viewers end. For more information, please refer to the Chapters below and the FAQ on the support page[5].

[5]https://support.neurostatus-uhb.com/

3. Basic concepts

This chapter…

…explains some concepts behind the NeuroCert application. It is geared towards Study Head Administrators and will facilitate their usage of the NeuroCert platform.

- All users must be invited to the system; there is no self-registration.
- Every user has exactly one *system role* in NeuroCert: Study Administrator or Rater.
- In addition to this *system* role, Study Administrators hold a specific role in a specific *Study* role – Study Head Administrator, Study Rater Administrator, or Viewer. This Study role can differ between studies.
- *Rater Administrators* have been introduced to allow for well-framed delegation of Study administration tasks. See Chapter 3.2 Regions for details
- Certificates are issued for a specific Study. However, a given passed exam can result in certificates for several studies provided it meets these studies' certification requirements.

3.1. Roles

System role	Study role	Business meaning
Rater	Rater	Neurologist or other Study participants that need proof of Neurostatus-EDSS certification **Main tasks** • Pass exam to obtain certificate • Observing own certification status in each Study **Permissions** • Take exams • Access their own certificates
Study Administrator	Study Head Administrator	Sponsor-side Administrator with full privileges for the given Study. **Main tasks** • Study setup and configuration • Management of Study Administrators • Management of Raters • Monitor Raters' certification status • Export certificates • Export a list of all Raters' exams and certificates **Permissions** • Write access to Study configuration (until it is approved; then read access) • Write access to Study assignments of Study Administrators and Raters (i.e. manage them) • Read access to certificates and lists of exams of Raters that joined the Study

	Study Rater Administrator	Sponsor-side Administrator with limited privileges for the given Study. **Main tasks** • Management of Raters • Observing Raters' certification status • Export certificates • Export a list of all Raters' exams and certificates **Permissions** • Read access to Study configuration • Write access to Study assignments of Raters (i.e. manage them) • Read access to certificates and lists of exams of Raters that joined the Study (within their regions)
	Viewer	Sponsor-side user with read-only access to Study Administrator views of the given Study. A Viewer can access all views a Head Administrator can access but cannot perform actions other than downloads/exports **Main tasks** • Monitor Study settings and participants • Monitor Raters' certification status • Export certificates • Export a list of all Raters' exams and certificates **Permissions** • Read access to Study configuration • Read access to certificates and lists of exams of Raters that joined the Study

3.2. Regions

Studies can choose to create so-called regions in such a way that each region has a sensible number of Raters. Regions are often chosen to correspond to countries (e.g., Burundi, Tuvalu, etc.) or continents (Asia, Africa, etc.) but every Study can define whatever fits best - the system accepts free text.

Every Study has at least one region, which, by default, is called “default”.

Raters are necessarily assigned to exactly one region. Rater Administrators are assigned to one or more regions. All views and permissions of Rater Administrators are restricted to these regions. For example, Rater Administrators cannot invite Raters to a region they are not part of or see and download certificates of Raters that are assigned to a different region.

3.3. Study life cycle

Overall, a Study undergoes the following steps in NeuroCert:

Study status	Business meaning	Can Raters obtain certificates?
In setup	Study configuration is being defined	No
Approved	Study configuration is completed; the Neurostatus-EDSS licence is not yet active.	No
Live	Study is on-going. The Neurostatus-EDSS licence is active. Typically this state is reached shortly before first patient first visit (FPFV).	Yes
Closed	The Study has been completed or terminated.	No
On hold	The Study has been suspended by Neurostatus-UHB	No

3.4. Basic concepts regarding exams, attempts and certificates

this subChapter…

… provides you with the most important ideas regarding exams and certificates so you can understand the tables you will see. More details are given in the “Advanced topics” below.

- Upon passing the exam on the NeuroCert platform, Raters obtain certificates for the studies they participate in. An exam within NeuroCert is the basis for any certificate issued by the platform.
- Based on the Study risk (including Study phase, Study size, intervention), Study-specific certification requirements are defined.
- Thus, certificates are issued for a specific Study.
- Exams are granted when a Rater joins a Study or needs to re-certify. To enforce testing rigour, the number of allowed attempts to pass the exam is limited and an escalation procedure is implemented:
    - After three consecutive failed attempts, a Rater must complete a short questionnaire
    - After four consecutive failed attempts, a Rater must take individual training with a Neurostatus-EDSS expert from the Neurostatus-UHB team. This training is a shortened version of the group session that focuses on the Rater’s specific questions and challenges encountered during the exam. In such cases, Raters are requested to contact their Study Administrator to arrange the required training. Study Administrators must contact the Operations team to request the training and confirm budget approval.

Raters with a qualifying exam can be automatically re-certified for additional studies if the certification requirements are met (i.e. no new exam needed).

3.5. Certificate validity and recognition of past exams

As per GCP best practice, training should be periodically refreshed and the Raters re-certified as proof of their current knowledge. To manage this process automatically, certificates on the NeuroCert platform have a validity term that is defined during the Study configuration. The validity term determines therefore how long certificates are valid and controls the re-certification.

Raters with a valid, existing exam on NeuroCert (passed when participating in another Study) may use their exam to directly certify for a new Study, granted that the parameters of the term and level passed match those established by the new Study.

4. Study configuration

This Chapter…

…describes how to configurate your Study in NeuroCert. This process encompasses the Study status “in setup” and “approved” and ends with the go-live see Chapter “Study life cycle”

4.1. Process overview

The Study setup process is an interaction between Neurostatus-UHB and you as the Study sponsor or the sponsor’s delegate (e.g. a CRO) holding a *Study Head Administrator* role in NeuroCert. The output of this phase are

1. the contracts that will govern the use of NeuroCert during the Study live phase and
2. the configuration of the Study space within the NeuroCert platform so that Raters can be managed during the Study live phase.

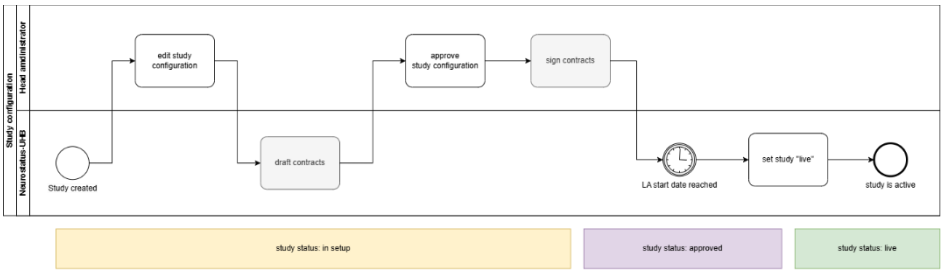


Figure 5: Study configuration workflow

	Step	Responsible	Description
1	Enter Study configuration	Sponsor (CRO)	During this step, the Study Head Administrator fills the *Study Configuration*. See below for an explanation of data necessary. This step end with requesting a quote (see Chapter 4.3 How to request a quote).
2	Draft contracts	Neurostatus-UHB	During this step, Neurostatus-UHB personnel drafts the License Agreement (LA) based on the information provided in the previous step. While the contract negotiation take place outside the platform, use the NeuroCert platform to communicate changes to the Study configuration that impact the contract using, again, the request a quote function (see Chapter 4.3 How to request a quote) There might be several rounds of requests before proceeding to the approval step.
3	Approve Study configuration	Sponsor	The sponsor confirms the final configuration for the Study. The approval completes the Study set up process and freezes the configuration. See Chapter 4.4 How to approve the Study configuration for details
4	Sign contracts	Sponsor	During this step, contracts are fully executed. If needed, Neurostatus-UHB personnel will ask you for re-approval of the Study configuration in NeuroCert. Otherwise, no action in NeuroCert is necessary.
5	Set Study live	Neurostatus-UHB	On the license start date, Neurostatus-UHB personnel will set the Study status to “live”. From now on you can add Raters, they will get exams assigned and certificates for your Study based on their exam results. Apart from regions, the Study configuration is frozen.

4.2. Edit Study configuration

At this process step, the Study is configured and contracts are created based on the input provided. It ends with the approval of the configuration by the sponsor.

1	Navigate to the Study of interest and open the *Info* tab
2	Fill the individual sections (accordions) See the table below for the business meaning explanation of the individual fields. **Important:** The *Materials* accordion allows you to order printed scoring and training materials. We are aiming to reduce our production of physical materials for shipment. While we still offer to ship paper training and scoring materials, we strongly recommend Sponsors to use the free downloads from NeuroCert instead. The Neurostatus-EDSS Scoring sheet applicable to each Study is available to Raters and Administrators for downloading and printing directly on the Study platform. Contact Neurostatus operations[6] for more details.
3	Request a quote (see Chapter 4.3 How to request a quote)

4.2.1. Study configuration fields

Field	Business meaning	Remarks
Accordion *Description*		
Study name	The name by which the Study is identified	This name will be printed on the Raters' certificates. Please ensure it is aligned with the Study protocol.
Sponsor	The Study sponsor legal entity	This is how the sponsor will be shown to Study Administrators and Raters in NeuroCert. It is also used in the contracts.
Official title	The Study official title (aka full title)	As per Study protocol, clinicaltrials.gov etc.
Investigational product name	The drug name or medical device at Study focus. Also enter if the product is no longer investigational but already available.	As per Study protocol, Leave blank for non-interventional studies.
Study type	Whether the Study is a clinical trial or an academic Study	As per Study protocol
Phases	Select all phases that this Study encompasses.	As per Study protocol. Note that you can select more than one phase if needed.
Diseases studied	Select the diseases that this Study investigates	As per Study protocol. Please indicate all that apply.

[6] mailto: operations@neurostatus-uhb.com

EDSS use	Indicate which role(s) the EDSS plays in the Study	As per Study protocol
Pediatric	Whether the Study target population is people living with MS under the age of 18	As per Study protocol
NCT number	ClinicalTrials.gov identifier, if registered there	
EUCT number	Identifier used in EudraCT, if registered there	
eCOA tool	The eCOA tool that shall be used in the Study	Please select the tool you plan to use. If no eCOA tool is planned to be implemented for the Study, please select "paper only"
Definition booklet version	This field is controlled by Neurostatus-UHB	Exists for legacy reasons. It defines the way Raters assess the EDSS and impacts the Study materials they receive and use.
Scoring sheet version	This field is controlled by Neurostatus-UHB	Exists for legacy reasons.
Section *License*		
First Patient First Visit Date	This will affect the license start date since the concerned Raters have to hold a valid certificate by the FPFV.	Enter the expected FPFV
License start date	Contract start date. Always the first day of a month	We recommend one month before FPFV
License duration	Contract duration in months.	Align with Study protocol but take into consideration that the LA typically starts one month in advance and lasts one month longer to allow for preparative and wrap-up tasks.
License end date	Contract end date. Always the last day of a month	This value is calculated and only displayed for informative purpose
Number of Raters participating	Select the tier which corresponds to the expected number of Raters (*not* patients)	
Number of sites participating	Enter the number of sites (Study centres) that participate in the Study	
Related studies	Studies under the same Study program running simultaneously.	
Section *Materials*		
Number of definition booklets	Number of hard-copy items to be shipped as training material for Raters.	Note that Raters now have various alternatives for self-printing, including a handy foldable version of the definition booklet. See the NeuroCert home screen
Number of training media	Exists for legacy reasons.	All Raters of your Study will have access to the Learning Hub. There is no need to distribute physical copies of training media.

Number of scoring pads (Study name imprinted)	Number of hard-copy items to be shipped as training and scoring material for Raters.	Note that Raters can print scoring sheets with the Study name imprinted themselves.
Number of scoring pads (Study name blank)	Number of hard-copy items to be shipped as training and scoring material for Raters.	Note that Raters can print scoring sheets with the Study name imprinted themselves.
Shipping country	Country where to ship above materials to, if applicable	
Section *Certification*		
Certification level	Minimum level Raters must reach to obtain a certificate for the Study. Must align with the Study profile and risk assessment.	See Chapter 4.2.2 Study Certification Levels for a list of levels Note that this parameter is considered critical to quality. Contact Neurostatus operations[7] for guidance on the implicit intricacies.
Certification term	Validity term of certificates. Determines the frequency at which Raters need to re-certify. Must be aligned with the Study profile and risk assessment.	See Chapter 4.2.3 Certificate validity term for a discussion on the re-certification procedure. Note that this parameter is considered critical to quality. Contact Neurostatus operations[8] for guidance on the implicit intricacies.

[7] mailto: operations@neurostatus-uhb.com

[8] mailto: operations@neurostatus-uhb.com

4.2.2. Study certification levels

These levels reflect the expected proficiency of a Rater in performing a Neurostatus-EDSS assessment and are determined by the number of points achieved in the certification exam. The required certification level is defined by the Sponsor on a Study-by-Study basis, taking into consideration the Study profile and risk assessment.

Qualification level	Minimum score (out of 50)
Level A	30
Level B	34
Level C	38

4.2.3. Certificate validity term

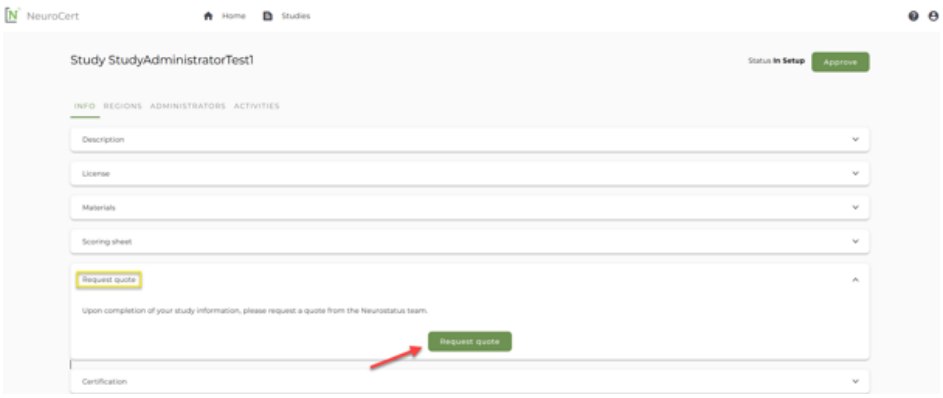
The Study-specific validity term determines how long certificates earned for the Study will be valid. Raters are requested to re-certify when their certificate expires. The validity term is defined by the Sponsor on a Study-by-Study basis, taking into consideration the Study profile and risk assessment. If you have no reference values, please reach out to Neurostatus Operations[9] for advice.

For a detail explanation on the validity term and its impact on the certification process, refer to Chapter 3.5 Certificate validity and recognition of past exams .

4.3. How to request a quote

With this action, you inform Neurostatus-UHB that you have completed or updated the Study configuration and, as far as the license agreements and other contracts are concerned, you would like to get a new version of the contracts and quotes.

[9] mailto: operations@neurostatus-uhb.com

1	Navigate to the Study of interest and open the *Info* tab
2	Open the *Request quote* accordion and click on the button 

Remarks:

- Certain information is obligatory to draft the contracts. You are prompted if and which mandatory information is missing. If so, you will need to fill this information and then request again.
- This does not impact your ability to change the Study configuration. We will always base the contract on the current settings.

4.4. How to approve the Study configuration

With this action you complete the Study setup process. Once approved, you can no longer edit the configuration.

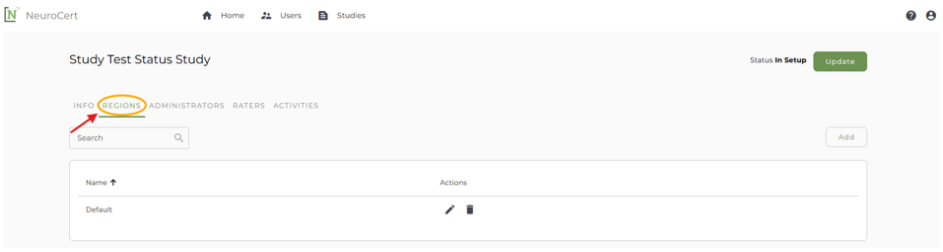
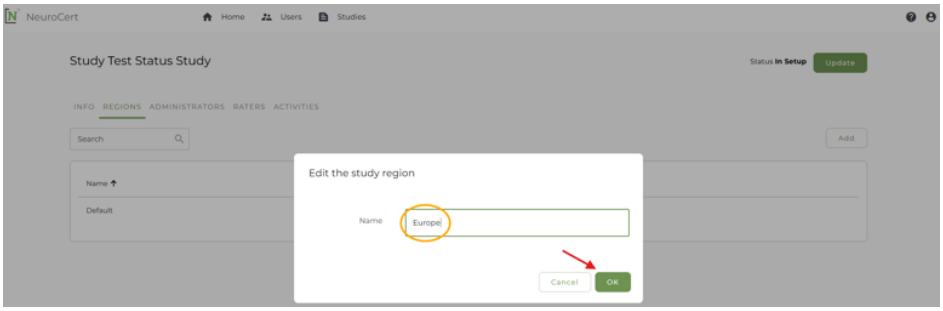
1	Navigate to the Study of interest and open the *Info* tab
2	Click on the “Approve” button 

Remarks:

- Certain information is obligatory to approve the Study setup. You are prompted if and which mandatory information is missing. If so, you will need to fill this information and then approve.

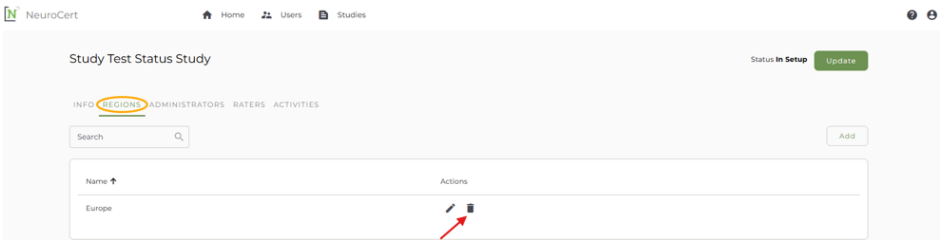
- If you need to modify the configuration of an approved Study, contact Neurostatus Operations[10] to go back to the Study setup process.
- In contrast to the rest of the Study configuration, Regions can be managed during the entire Study lifecycle.

4.5. How to create or update regions

1	Navigate to the Study's *Regions* tab 
2	To create a new region, click on the *Add* button. To modify an existing region, click on the pen symbol of the region you want to modify. When modifying an existing region, changes immediately cascade throughout the system, i.e. all Rater Administrators and Raters appear as members of the modified region
3	In the dialog that opens, provide a name for the region (or modify the existing one) and confirm. 

[10] mailto: operations@neurostatus-uhb.com

4.6. How to delete regions

1	Navigate to the Study's *Regions* tab 
2	Click on the basket symbol of the region you want to delete Note that you cannot delete a region if one or more *Raters* or *Rater Administrators* are assigned to it. Navigate to the *Administrators* and *Raters* tabs and filter by the region you want to delete to find out who is left to be removed or reassigned to another region.

5. Managing a live Study

This Chapter…

…describes the Study administration task when a Study is "live" (see Chapter 3.3 Study life cycle for the placement in the Study life cycle).

During this phase, Study Administrators need to

- Manage Rater Study assignments
- Monitor Rater certification status across studies and regions
- Track certification expiration dates and identify upcoming renewals
- Access and download all certification documents for your Study
- Generate and export comprehensive reports

See the corresponding subchapters in Chapter 2 Quick Guide for Rater Administrators and Viewers as well as Chapter 7 Managing Raters and Study Administrators

Remarks:

- Please ensure there are at least two Study head Administrators assigned to a Study at any point in time. You risk losing access to the Study including all certificates if no head admin is available.
- Please ensure all Raters participating in the Study are invited and their certifications are valid before conducting patient examinations.

- While Raters are reminded by the system to renew their certificates (one month before expiration and once again upon expiration), it is best practice to monitor the qualification status closely and remind them personally where applicable.
- While a Rater has an active Study assignment, certificates are generated for this Study upon every new exam (provided the exam meets the certification level criteria).
- You can freely modify regions (add, rename, delete) during this Study phase.

6. Study closure

This Chapter…

…describes the Study administration task after Study closure (See Chapter X “Study life cycle” for the placement in the Study life cycle).

Upon expiration of the Study’s license, the Study will be moved to status “Closed”. Study Administrators have then approximately two weeks to download all certificates (see Chapter 2.7 How to download certificates for details). We recommend you download the list of Raters and their exams (see Chapter 2.11 How to export a list of all Raters' exams and certificates for details). After two weeks, the Study data will no longer be available.

7. Managing Raters and Study Administrators

This Chapter…

…is for Study Head Administrators and complements the Chapters about Rater management in the Rater Administrator’s Quick Guide. Rater management is extensively described above. Only Study Head Administrators can manage Study Administrators for a given Study. If you don’t hold Study Administrator permission for the given Study, you cannot see the view and perform the actions described below.

7.1. How to read the Study assignment status

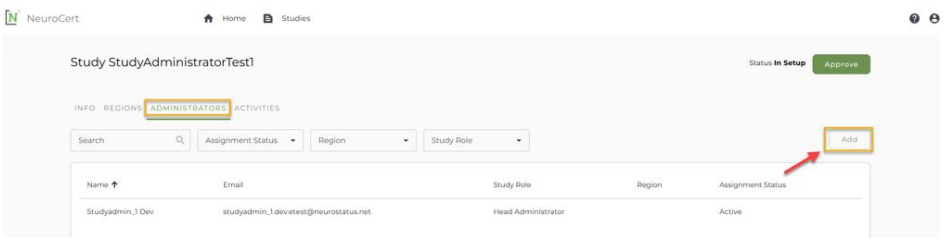
On the *Raters* tab and the *Administrators* tab, you can find the column *Study assignment status* which informs about the respective user's current participation state.

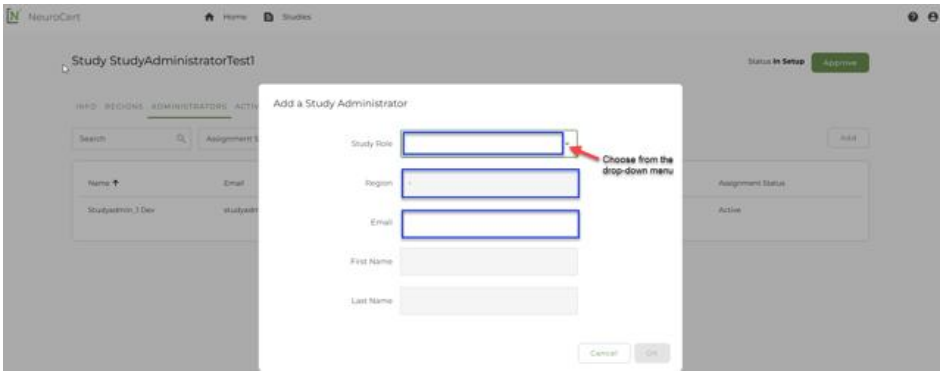
Status	Description
invited	The Rater/Administrator has been asked to join the Study but not answered the request
active	The Rater/Administrator is currently active in the Study. Raters are asked to pass exams and obtain certificates (as applicable). Administrators have access to the relevant screens to perform their Study-role-specific tasks
deactivated	The Rater/Administrator has been removed from the Study.
declined	The Rater/Administrator has declined the Study invite. This user has never been active in the Study
canceled	The Rater's/Administrator's Study invite has been revoked before they accepted the invite. This user has never been active in the Study Note: Migrated users that did not complete the invitation process are set to this status. Please invite these Raters if you want them to join your Study.

7.2. How to add a Study Administrator

You will need to know

- The Administrator's full name.
- The Administrator's email address. Please make sure that you use the email address by which the Administrator is registered on NeuroCert to avoid a delay in the registration process.
- The Study role the Administrator shall hold. This affects their permission, as described in Chapter 3.1 Roles
- The region this Administrator shall be managing (see Chapter 3.2 Regions for details)

1	Select the Study of interest from the Table in the *Studies* View (see Figure 2)
2	Open the dialog to add Administrators • Switch to the tab *Administrators* • Click on the "add" button 

3	Provide the Administrator's Study assignment data • Study role • Region • Email  For an explanation of Study roles and regions, see Chapters 3.1 Roles and 3.2 Regions, respectively. Region is a mandatory setting for Rater Administrators but does not apply to Head Administrators and Viewers as these are "global" roles. When confirming the email address, the NeuroCert system will search for existing users with this email address. If the email address is registered the system, it will automatically complete the name. Otherwise complete these fields and submit the form. The NeuroCert system will display an error message if the user cannot be invited to the Study. Refer to the FAQs[11] for explanations. If you know that the given Administrator has already registered in NeuroCert but the name is not auto-filled, please ensure that you use the email address by which the Administrator registered on NeuroCert to avoid a delay in the registration process.

[11] https://support.neurostatus-uhb.com/administration-section/

8. Advanced topics

This Chapter…

…is intended to assist with any troubleshooting and as further reading

8.1. Details on the registration process

Part of the registration process is a duplicate check. The purpose of the duplicate check is to avoid confusion among Study Administrators and Raters. Exams and Study invitations are associated with a specific account. A user having multiple accounts of the same role will struggle to understand why they cannot see these entities, exam recognition is not possible, etc. Aim of the duplicate check is to have them use their existing, active account instead of activating an additional one.

8.2. Details on exams

Exams are a container for attempts. Since most Raters pass the exam on their first attempt, this is more of a theoretical concept for most discussions. If, however, a Rater should fail an exam attempt, the process depicted in Figure 6 is observed.

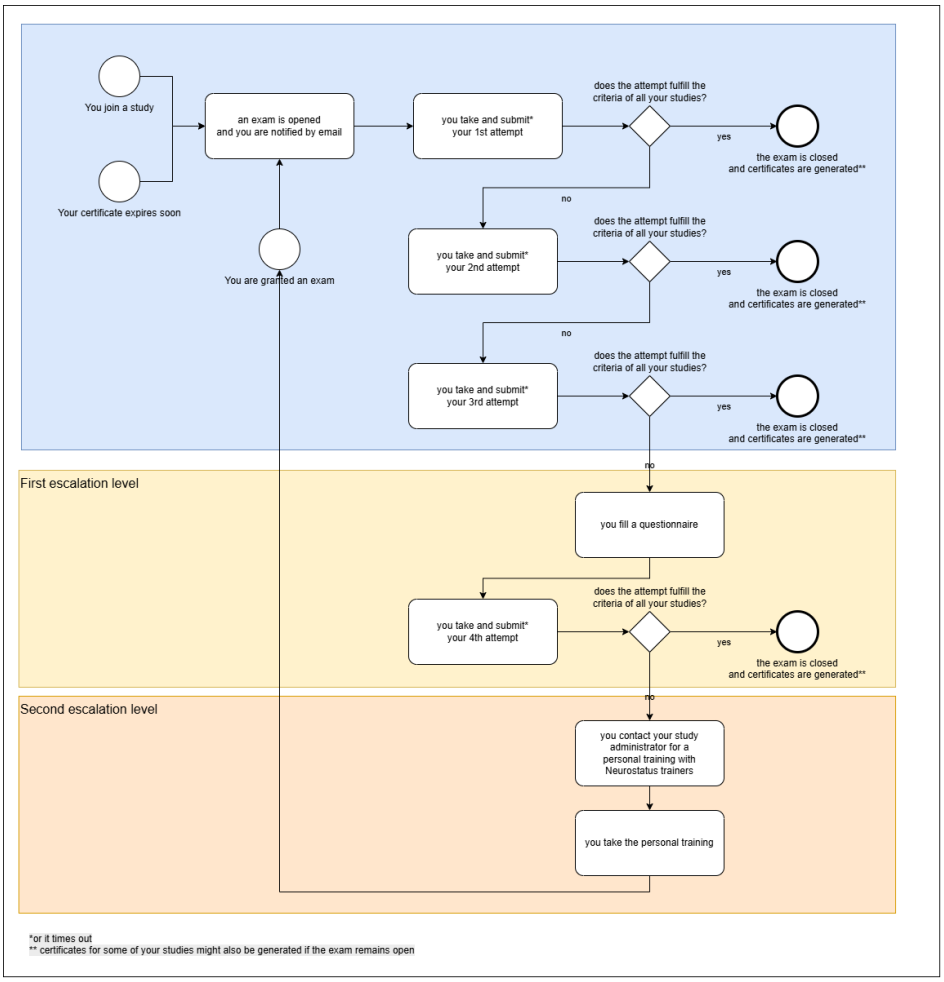


Figure 6: Escalation process for failed exam attempts

8.2.1. Blocked exams

Raters facing difficulties passing the exam are asked to answer a questionnaire before being granted a fourth attempt (see Figure 6). This questionnaire is intended to help Neurostatus and Study sponsors identify potential shortcomings in trainings, the access to training materials, or other issues Raters might have faced.

8.2.2. Personal training after four failed attempts

Raters who fail the exam after four attempts must take individual training with a Neurostatus-EDSS expert from the Neurostatus-UHB team. This training is a shortened version of the group session that focuses on the Rater's specific questions and challenges encountered during the exam.

In such cases, Raters need to contact the Study Administrator to arrange the required training with the Operations team at Neurostatus-UHB.

9. Background information on certificate generation

Certificates are generated when all the following criteria are met:

1. the Study is in status *live*
2. the Rater has a Study assignment in status *active*
3. the Rater has an attempt that meets the Study certification requirements (level of certification and validity term)

Certificates preserve the state of data that was applicable when the certificate was issued, e.g. the Rater's name.