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**User guide for data entry into CLADE-IS**

**Created by:**

Institute of Biostatistics and Analyses, Ltd.

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## ELECTRONIC DATA CAPTURE SYSTEM (CLADE-IS)

Conventional data collection for clinical trials traditionally focused on paper-based case report forms (CRF) followed by double data entry into a relational database. Electronic data capture (EDC) systems represent an intriguing alternative, which allow investigators to enter and to review data in real time, and to implement on-line data validation checks, thus assuring data quality more effectively at the point of entry.



CLADE-IS (Clinical Data Warehousing Information System) belongs to the class of the most modern and progressive EDC systems. It comes with EAV data-model of the database (Entity–Attribute–Value model), which allows to switch quickly between various topics and clinical fields where data need to be collected, verified, analysed and visualized on-line. The inherent data-access model is robust enough to allow countless configurations of user privileges, roles, and data flow. In the default configuration, the following user roles are recognized inside CLADE-IS: (i) investigator, (ii) site manager, (iii) regional coordinator, (iv) data manager, (v) monitor, (vi) administrator.

With the use of responsive web design, CLADE-IS provides its users with an easy and ergonomic interface. Navigation and reading require only a minimum of resizing, panning, and scrolling; a wide range of devices can be used: from desktop computer monitors to tablets and smartphones. CLADE-IS will work with the majority of available web browsers – there is no need to install any other software. It is recommended to use only up-to-date browsers running on up-to-date operation systems.

CLADE-IS and related data management services are provided by the Institute of Biostatistics and Analyses, Ltd. in Brno, Czech Republic<sup>1</sup>. This institution's integrated system of management has been certified in terms of quality of products and services (EN ISO 9001:2009), IT services (ISO IEC 20000-1:2006) and information security management (ISO IEC 270001:2006). The interfaces of CLADE-IS can be accessed only by authorized users based on their login and password. The registered data are anonymous: for each patient/case, a unique

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<sup>1</sup> <http://www.biostatistika.cz/>

ID is always generated. The communication between CLADE-IS and its users is encrypted with the use of SSL (Secure Sockets Layer).

- The system is user-friendly; all data can be entered using web forms analogical to paper CRF/DCFs.
- It is not necessary to install any additional software on client's computer.
- The database can be accessed only by authorized users via login and password.
- Registered data are anonymous. For each patient/case, a unique ID will be generated. Personal identification of patients will not be possible - requirements for personal data protection are satisfied.
- Whole data transfer is encrypted and the system is designed to prevent unauthorized use of data during the transfer.
- Institute of biostatistics and analyses, Ltd., Brno, Czech Republic – is the provider of technology and related data management services.
- Users of the registry can print the forms they submitted.

## 1. LOGIN PAGE

The database can be accessed from the website<sup>2</sup>

<https://restand.data-warehouse.cz>

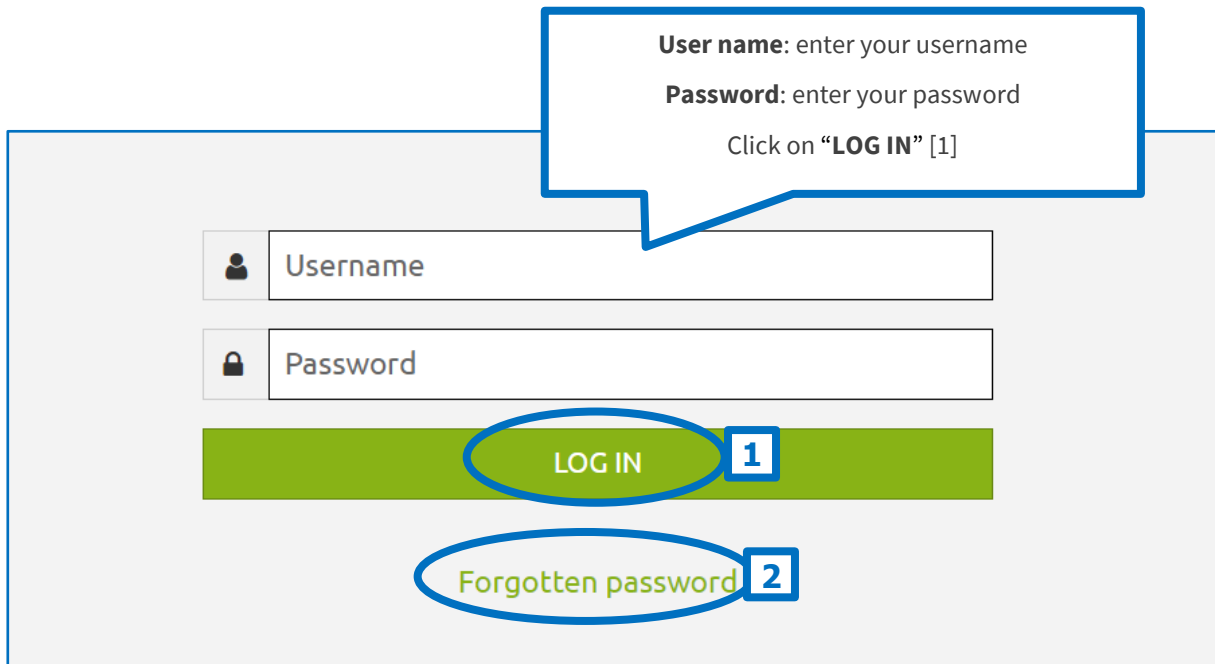


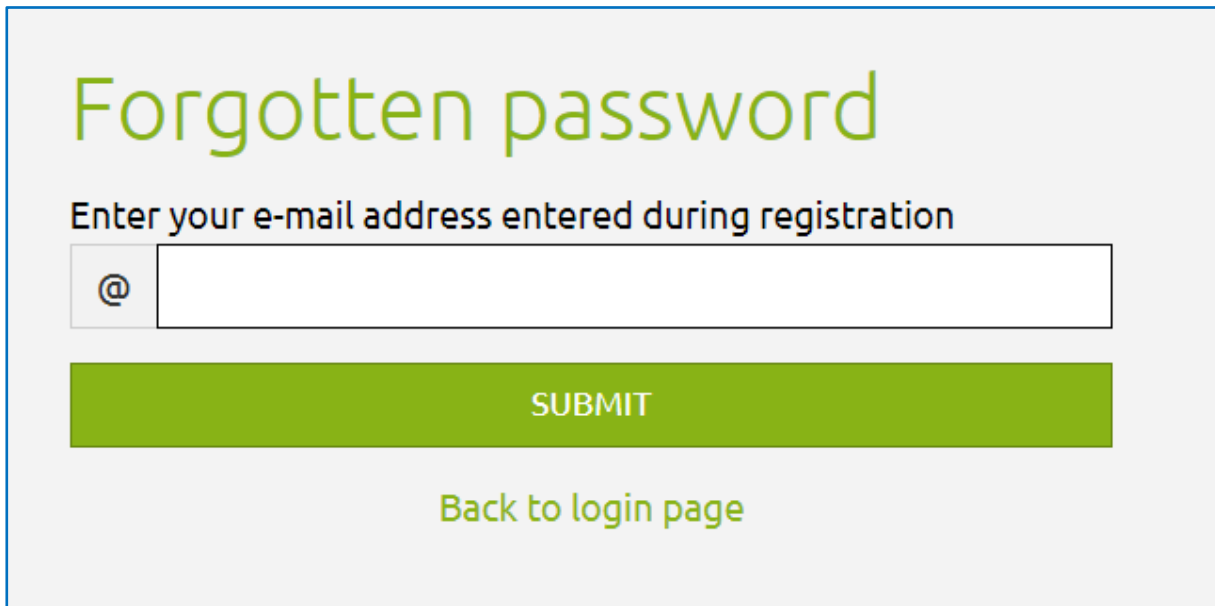
Figure 1: Connection to the database and the forgotten password

### 1.1 FORGOTTEN PASSWORD

In case of forgotten password, you can restore it or change it any time by clicking on the text "Forgotten password" (see [2] – Figure 1). You will be asked to enter your email address in the next step (see Figure 2).

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<sup>2</sup> To access the database, please use any up-to-date stable web browser supporting JavaScript and secured communication. In this user guide, Mozilla Firefox 48.0 has been used for the screenshots.



Forgotten password

Enter your e-mail address entered during registration

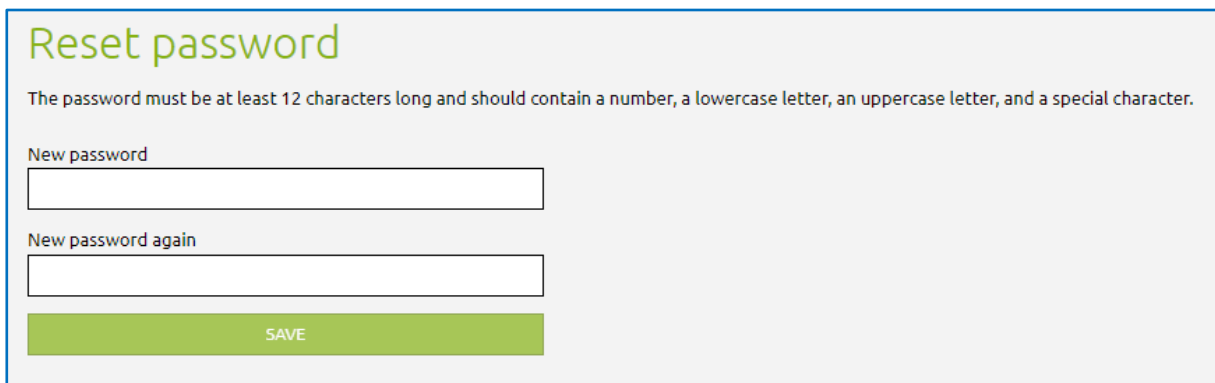
@

SUBMIT

[Back to login page](#)

Figure 2: Enter e-mail address

You will receive an e-mail with subject “Clade-IS (project name): password restore” with a link. After clicking on this link, you can create a new password (see Figure 3).



Reset password

The password must be at least 12 characters long and should contain a number, a lowercase letter, an uppercase letter, and a special character.

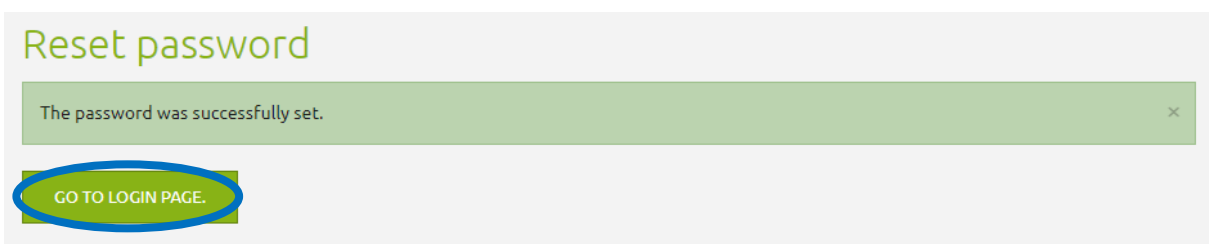
New password

New password again

SAVE

Figure 3: Creation of a new password

As a final step, system will confirm you the setup of new password. By clicking on “Go to login page.” (see Figure 4), you will be redirected to the login page (see Figure 1).



Reset password

The password was successfully set. ×

[GO TO LOGIN PAGE.](#)

Figure 4: Confirmation of successful creation of new password

## 2. BASIC APPLICATION WINDOW

After you log in, a basic application window (also called “Dashboard”) will appear (see Figure 5). This window navigates you to all the necessary functions:

- searching for submitted patients and their forms – “Search”
- creating new patients in the database – “Patient”
- reading the structure of the registry – “Tools”
- contacts for helpdesk – “Help”
- and other

Access to these functions is described in the following chapters.

You can log out<sup>3</sup> the system using the “**LOGOUT**” button in the upper right corner (see [1] in Figure 5).

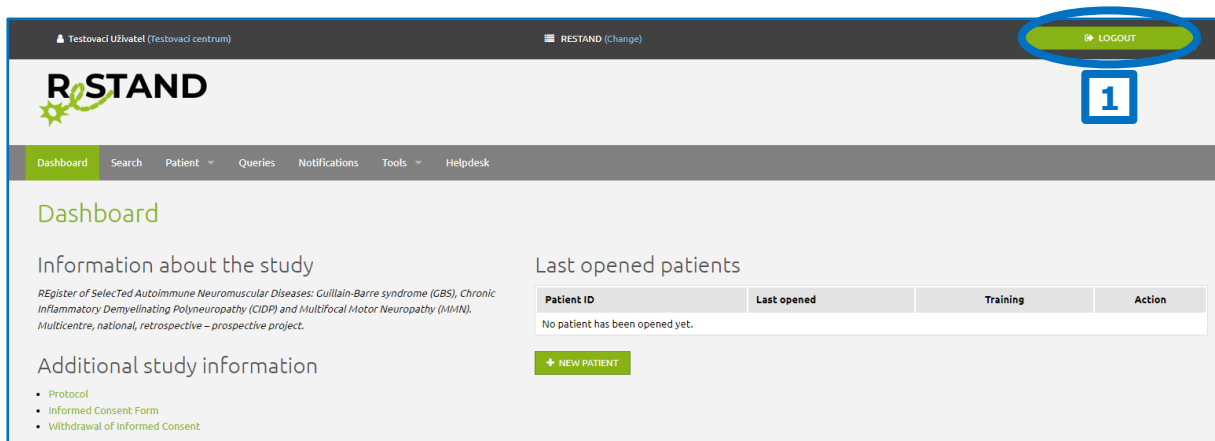


Figure 5: Basic application window

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<sup>3</sup> **Automatic logout** – When you do not work in the system for a longer period, close the browser window or shut your computer down, you will be logged out automatically after 10 minutes - not saved records will be deleted. To continue with your work, it is necessary to log in again. The purpose of this function is to prevent unauthorized access to the system.

## 2.1 NEW PATIENT REGISTRATION

You can add a new patient by clicking the large **“NEW PATIENT”** button (see [1] in Figure 6) or via drop down menu: **“Patient”** -> **“Create patient”** (see [2] in Figure 6).

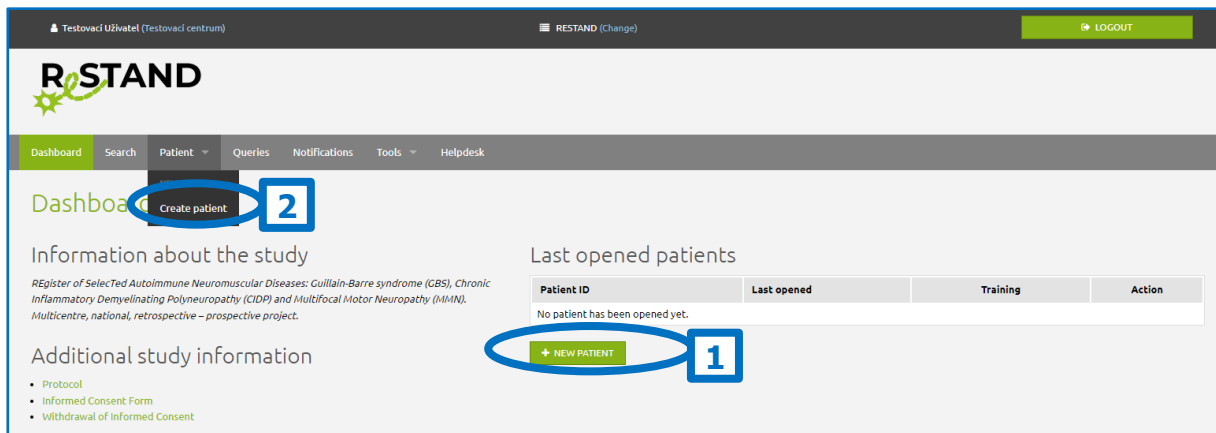


Figure 6: New patient registration

A subject form to enter personal data about new patient will appear after selecting one of these options. Please fill in available information about the patient. Mandatory items are marked by asterisk \* (see Figure 7).

## 2.2 PERSONAL DATA

The screenshot shows the 'New patient' registration form. The form is divided into two main sections: 'PATIENT DATA' and 'PATIENT SETTINGS'. The 'PATIENT DATA' section includes the following fields and options:

- \* Case type:  Chronic immune-mediated neuropathy  CBS
- \* Date of birth:
- \* Sex:  male  female  not specified
- First name:
- Last name:
- \* Initials:
- \* Country of residence:  Czech Republic  Slovakia
- \* Patient signed Informed Consent Form for RESTAND :  Yes  No

The 'PATIENT SETTINGS' section includes the following field:

- Training patient

At the bottom right of the form, there are 'SAVE' and 'CANCEL' buttons.

Figure 7: New patient registration

### 2.3 PATIENT SETTINGS SETUP

- **Study arm** – in case they exist chose select from drop-down list (see Figure 8)

**“Training patient”**: check this box (see [1] in Figure 8) if you wish to create a dummy/test patient’s record (e. g. when you are learning or testing the registry). This patient won’t be included into the study analysis and won’t be paid to the investigator, i. e. the person who enter the data.

### 2.4 FINISH THE JOB

When you are done, click the **“SAVE”** button (see [2] in Figure 8). If you wish to clear the form and start again, click on the **“CANCEL”** button (see [3] in Figure 8).

Figure 8: New patient registration

By clicking on the **“SAVE”** button, a unique “Patient ID” will automatically be generated in a prescribed form. The form consists of study abbreviation and eventually suffix “TEST” that indicates a training patient.

### 3. PATIENT SEARCH

If you wish to search for the submitted patients and their records, click on **“SEARCH”** in the upper menu (see Figure 9).

Figure 9: Patient search

You can search by patient ID and by various other parameters that can be combined together for a more precise search. If you wish to see a list of all patient that you have the access to then press the button **“Q SEARCH”** (see [6] - Figure 10).

The searching process is the following:

1. Enter at least a part of patient ID or leave the question empty to search among all training/non-training patients (see [1] – Figure 10). Search process is a case sensitive. If patient ID is ABC-001 and you a enter abc-001, then the system will not find him.
2. If you are looking for training patients, don't forget to check the respective box (see [2] - Figure 10)
3. Choose one from the provided search parameters (see [3] - Figure 10)
4. Select the search operator (is equal to, is not equal to, ...) (see [4] - Figure 10)
5. Enter the value (see [5] - Figure 10)
6. Click on the **“Q SEARCH”** (see [6] - Figure 10)

The 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> step are not mandatory.

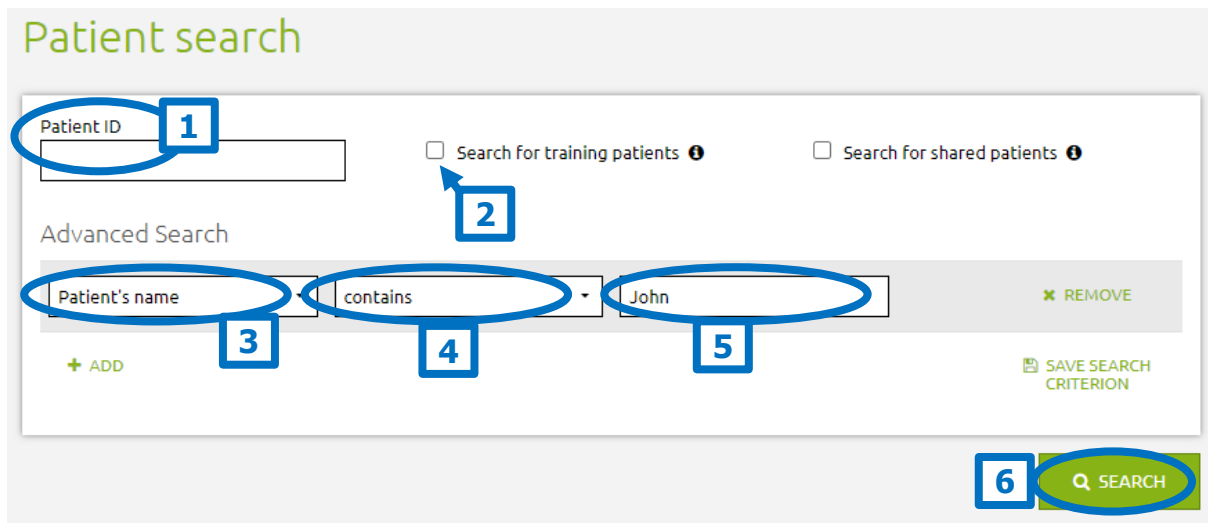


Figure 10: Basic search

For a more precise search, you can add one or multiple parameters, clicking on the **“ADD”** button (see [1] - Figure 11). This option is useful in case of many patients in the database, as the result of basic search may not get you to the target. To remove a parameter, click on **“REMOVE”** (see [2] - Figure 11).

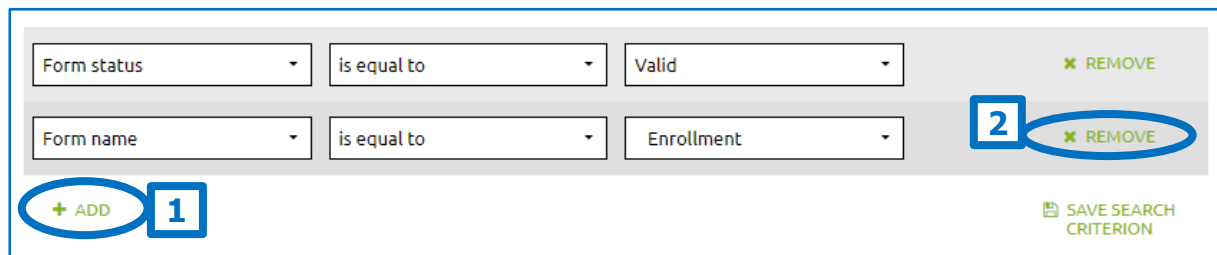


Figure 11: Advanced search - adding a parameter

### 3.1 SEARCH RESULTS

By clicking on the **“SEARCH”** button, the system will list all submitted records, that you have access to and that correspond to the submitted criteria.

You can choose the number of listed records in one page (25, 50 or 100 records – see [1] - Figure 12). To move between the pages with results, click on the **“Previous”** or **“Next”** links on the right-bottom corner of table (see [2] - Figure 12).

Search results can be ordered in *ascending* or *descending* order according to various criteria. You can order them by clicking on the small arrows in the heading of the table with (see [3] - Figure 12).

Finally, you can export the search result as an \*.xls file by clicking on the **“EXPORT RECORDS TO XLS”** button (see [4] - Figure 12).

Patient ID / Forms	Site	Enrolled by	Diagnosis	Sex	Date of birth	Date of patient creation	Actions
RES-0000004	Testovací centrum	Testovací Uživatel	CIDP	male	09/01/1981	21/03/2023 12:18:42	Open
RES-0000005	Testovací centrum	Testovací Uživatel	GBS	female	24/11/1975	21/03/2023 12:41:41	Open
RES-0000007	Testovací centrum	Testovací Uživatel	MMN	female	02/07/1989	24/03/2023 10:08:32	Open
RES-0000030	Testovací centrum	Testovací Uživatel	CIDP	female	15/09/1999	18/09/2023 10:23:16	Open
RES-0000064	Testovací centrum	Testovací Uživatel	GBS	female	07/06/1991	19/01/2024 08:31:12	Open

Figure 12: Search results

After finding the patient/form you were looking for, click on the **“Open”** link (see [5] - Figure 12). The main part of the system will be displayed containing all the electronic patient forms that have been saved so far.

### 3.2 RECENTLY OPENED PATIENT RECORDS

For a quick access to the recently opened patient records, please use the table on the right part of the application (Dashboard) where the patient records are ordered chronologically (see Figure 13).

Patient ID	Last opened	Training	Action
RES-0000007	22 Jan 2024, 13:00	No	Open
RES-0000005	22 Jan 2024, 13:00	No	Open
RES-0000004	22 Jan 2024, 13:00	No	Open
RES-0000006	22 Jan 2024, 12:54	Yes	Open

Figure 13: Last opened patients

#### 4. WORKING WITH THE FORMS (CREATING, EDITING, DELETING)

The working window of the application consists of the header (see [1] in Figure 14) and from the main section (see [2] in Figure 14).

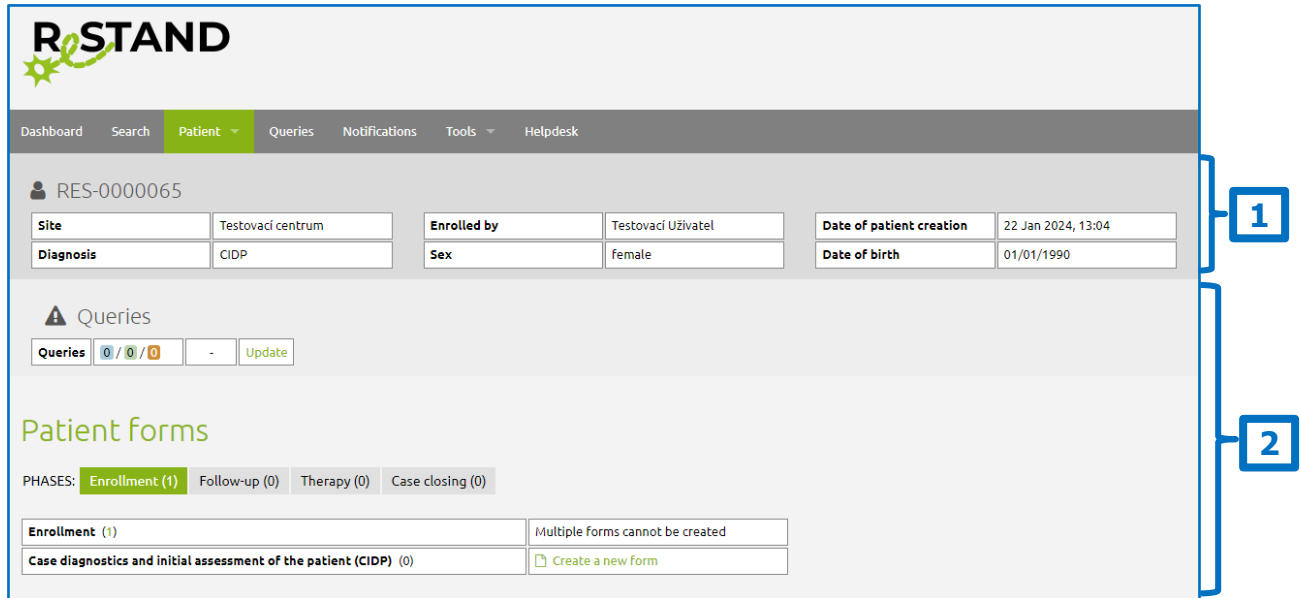


Figure 14: Working window of the application

The header contains basic information about the patient, which is automatically copied from the data submitted in the form for the registration of a new patient (see Chapter 2.1). It is also possible to edit (modify)<sup>4</sup> personal data of a patient here, using the dropdown menu: **Patient** -> **Personal data** (see Figure 15).

<sup>4</sup> Only in case it is allowed by concrete project.

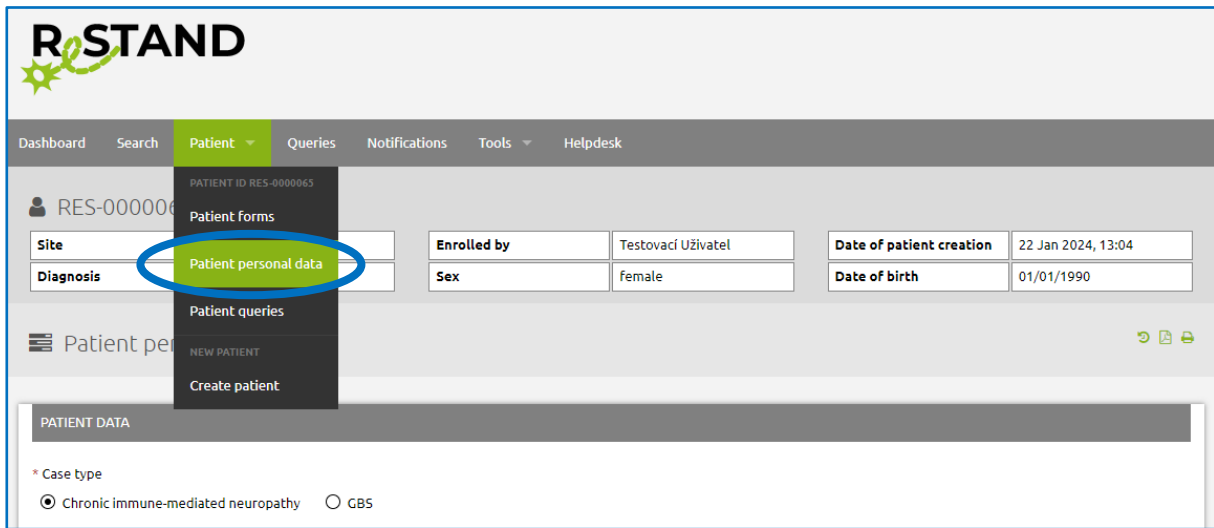


Figure 15: Working window of the application

When personal data are modified, click on **“SAVE”** button. Information about saving data will appear. Clicking on the Patient Forms button (see [1] in Figure 16) you can get back to the working window.

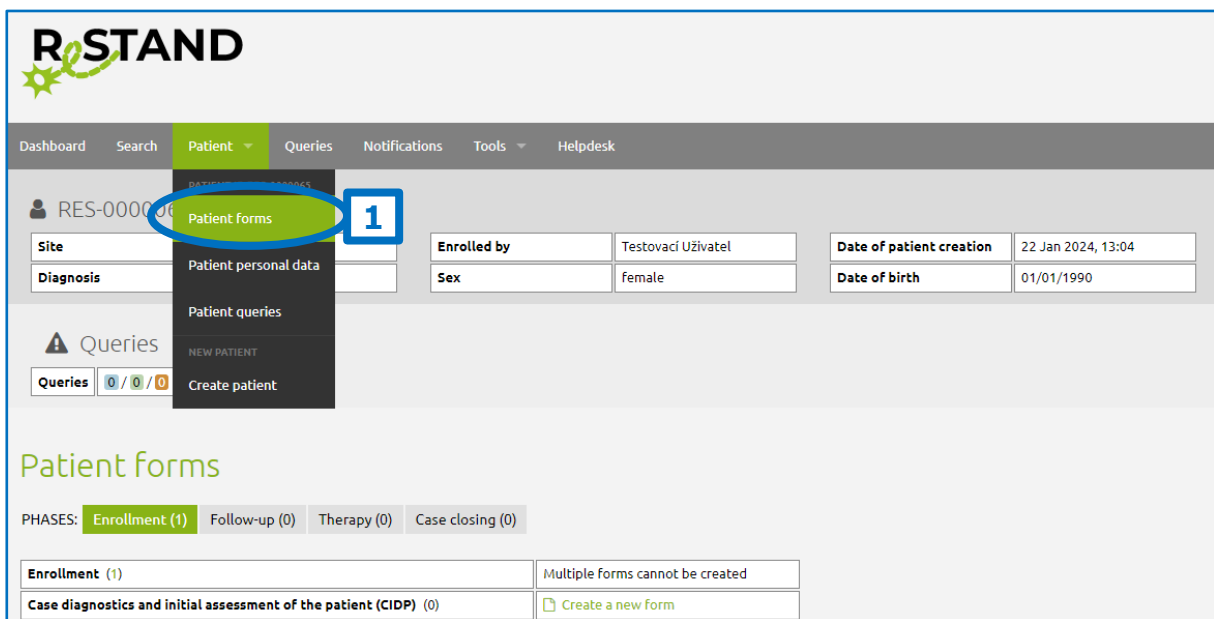


Figure 16: Personal data modification

If you want to delete<sup>5</sup> the patient, click on the **“Delete this patient and all of his/her forms”** link (see Figure 17); the confirmation window will be displayed (see Figure 18), containing reason for patient deletion.

<sup>5</sup> Only in case it is allowed by concrete project.

\* Patient signed Informed Consent Form for RESTAND **i**      \* Date of informed consent  
 Yes     No      01/01/2023

**PATIENT SETTINGS**

Patient ID  
RES-0000065

**SAVE**    **CANCEL**

[Delete this patient and all of his/her forms](#)

Figure 17: Delete the patient

Do you really wish to delete this patient? **RES-0000065?**

Reason for patient deletion

**YES, DELETE**    **NO**

Figure 18: Delete the patient - confirmation

In the main section of each patient (see Figure 19):

1. You can switch between the study phases, by clicking on their names (see [1] in Figure 19).
2. For each phase, there is a review of existing forms and forms to be established. You can **create a new form** by clicking on the **“Create a new form”** link (see [2] in Figure 19).
3. Further on the page, there is a more detailed review of the forms. If you wish to **edit the form**, click on **“Open”**. If you wish to delete the form, click on **“Delete”** (see [3] in Figure 19).

**Caution: Form deletion is an irreversible action.** We recommend using this function only after careful consideration.

Dashboard Search Patient Queries Notifications Tools Helpdesk

RES-000065

Site	Investigator IBA	Enrolled by	Testovací Uživatel	Date of patient creation	22 Jan 2024, 13:04
Diagnosis	CIDP	Sex	female	Date of birth	01/01/1990

Queries 0 / 0 / 0 - Update

### Patient forms

PHASES: Enrollment (1) Follow-up (3) Therapy (1) Case closing (0) **1**

Enrollment (1)	Multiple forms cannot be created
Case diagnostics and initial assessment of the patient (CIDP) (0)	<b>Create a new form</b> <b>2</b>

#### Enrollment

Date of enrollment	Current diagnosis	Weight	Height	Status	Action
22/01/2024	CIDP	70	175	Pending	<b>3</b> Open Delete

Figure 19: Working with the forms

## 5. FORM COMPLETION

The form contains questions and entry fields beneath the questions. There are several ways of data input (see A-F, Figure 20, 21):

- A. Direct writing
- B. Selecting an option from a dropdown menu
- C. Selecting an option from radio buttons
- D. Dates can be written (in the mandatory format – dd/mm/yyyy) or selected from the calendar
- E. Checking a checkbox
- F. Repeating group

Figure 20: Field types

Some sections of forms consist of repeating groups of questions. You can add new items to this group by clicking the **“Add”** button (see [1] - Figure 21). A row of blank questions appears to fill.

Clicking the **“Delete”** button (see [2] - Figure 21) then deletes the selected group of questions.

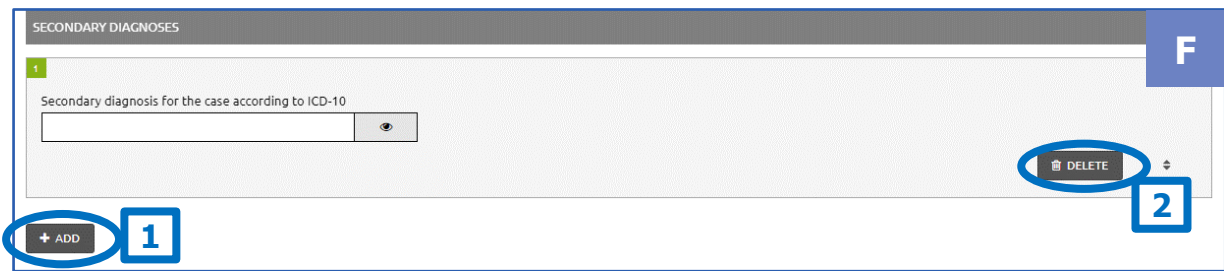


Figure 21: Repeat group

### 5.1 SPECIFIC FUNCTIONS

- **Mandatory questions** – are marked by an asterisk (see [\*] in Figure 22). In the other case is impossible to save the form as complete.
- If the **entry field is grey**, data cannot be entered – the question is calculated (see Figure 23).
- In the case of mandatory question which is impossible to fill in there is a slider switch indicating that the information is **not known** (see [B] - Figure 24). The question is turned on if information is known (see [A] - Figure 24). By clicking on the slider we can turn the question off or on.
- For some questions, there is **additional information** available via the ⓘ icon next to the question (see [i] in Figure 25).

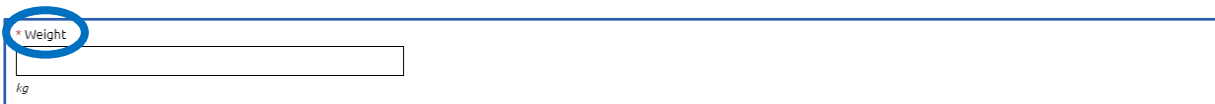


Figure 22: Specific function – mandatory question



Figure 23: Specific function – calculated question

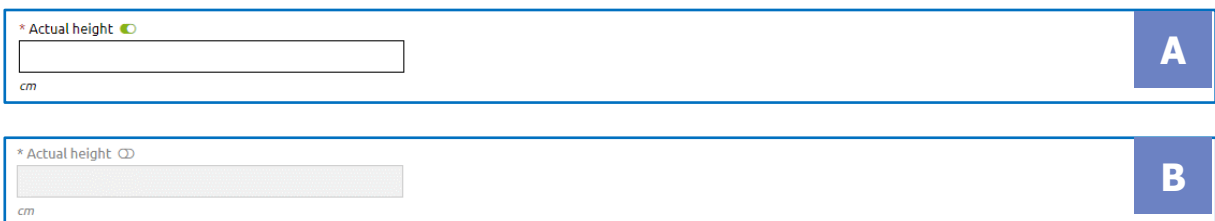


Figure 24: Specific function – the information is not known

Figure 25: Specific function – additional information

## 5.2 FORM STATUS

The last question in each form is the **“Form status”** (see [1] - Figure 26).

Figure 26: Form status

The following states of form are possible:

- **Pending** – form is not finished yet and you still need to return to it and complete the entry (may contain incomplete and invalid data). **“Pending”** forms are not counted in the analyses and are not honoured.
- **Completed** – select this option when you have completed all the questions (or at least the ones required) and you will not return to the form.
- **Valid** – the form will go to this state automatically only after it has been saved in a complete state where all validations set (see Chapter 6) are performed without error.

## 5.3 SAVING

There are three buttons - **“SAVE”**, **“SAVE AND EDIT”** and **“CANCEL”** at the top and bottom of the form (see [2], [3] and [4] - Figure 26). By clicking on **“SAVE”** button, you will save all the data you have entered and return to the working window of the patient. By clicking on **“SAVE AND RETURN”** button you save the records and stay on this form for further edits. By clicking on **“CANCEL”** button you leave the form without saving your entered data.

Once the form is in Valid state, all data on this form is read-only (cannot be edited). If you need to change the data on the form, it is necessary to change the status of the form to **“Pending”**, click on the **“SAVE AND EDIT”** (see [3] - Figure 26) (only for state **“Valid”**) data edit and form again save as **“Completed”**.

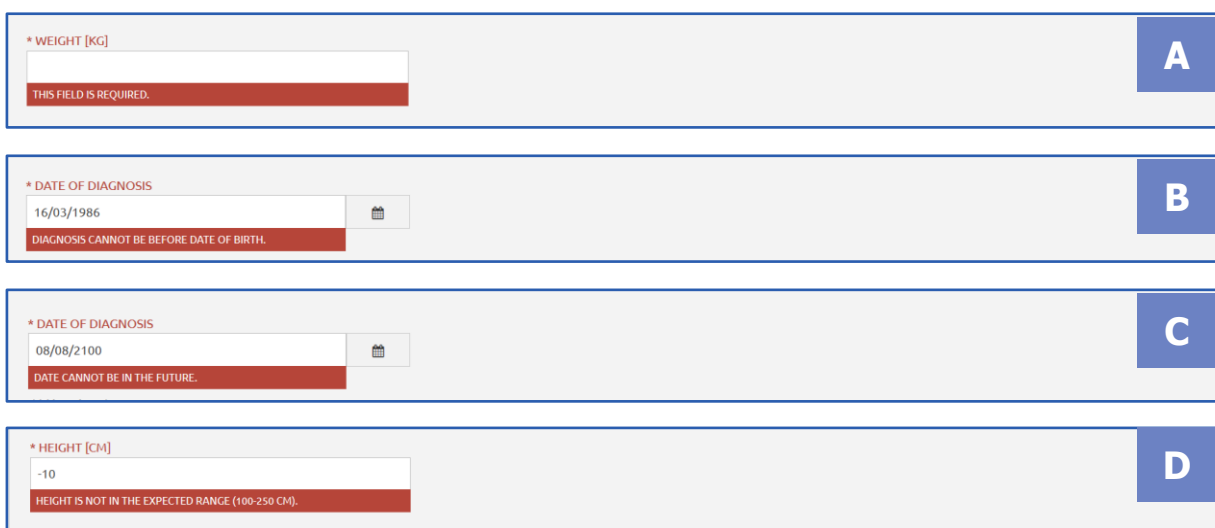
## 6. VALIDATION OF RECORDS

When entering data into a form these data are automatically regulated by validation rules. If you do not comply with these validation rules, the system will notify you with an error messages and the form cannot be saved as **“Completed”** or **“Valid”** until they are resolved and remains in the **“Pending”** state.

### 6.1 CHECKING DATA FORMAT

The values entered in the form are compared in real time with the set validation criteria. Examples of validation criteria for real-time control (see A-D - Figure 27):

- A. **Mandatory field** – the value must be given
- B. **Special checks** – for example, data must be matched to one another
- C. **Dates** – the value must be given in a predefined format (dd/mm/yyyy) and the value must not refer to a future date
- D. **Numeric values** – some numeric value has a minimum and maximum warning limit



The figure shows four examples of validation errors in a form:

- A:** A text input field for '\* WEIGHT [KG]' is empty. A red error bar below it says 'THIS FIELD IS REQUIRED.'
- B:** A date input field for '\* DATE OF DIAGNOSIS' contains '16/03/1986'. A calendar icon is to its right. A red error bar below it says 'DIAGNOSIS CANNOT BE BEFORE DATE OF BIRTH.'
- C:** A date input field for '\* DATE OF DIAGNOSIS' contains '08/08/2100'. A calendar icon is to its right. A red error bar below it says 'DATE CANNOT BE IN THE FUTURE.'
- D:** A numeric input field for '\* HEIGHT [CM]' contains '-10'. A red error bar below it says 'HEIGHT IS NOT IN THE EXPECTED RANGE (100-250 CM).'

Figure 27: Validation of records

If this validation criterion is not met, the error message is displayed directly at the related question where the error occurred.

### 6.2 CHECKINC DATA COHERENCE

Checking of data coherence occur after data format check is done. These controls are usually proceeded among two or more data forms. They are started when data form is saved in to the status **“Completed”**. The validation is done in real-time. In case of any discrepancies, the system will not allow the automatic change of status from **“Completed”** in to the **“Valid”**. The system will leave the form in status **“Pending”**.

An error message will appear in the section **“QUERIES”** (see [A] - Figure 29). The error message is located on the form that validation failed (or on the subject itself if the query does not refer to a specific instance of the form and/or the specific question).

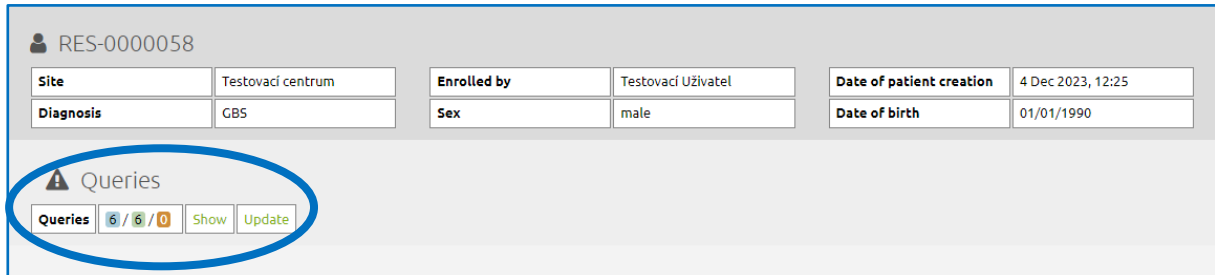


Figure 28: Queries

Each query contains a status describing whether it has already been resolved or not. Since the query is created until the moment it is resolved, the status is **“new”** (see Figure 29). The error message should contain the instruction how to resolve each query. Once the issue is solved and the form is attempt again to be saved in **“Completed”** status, then data are checked by the system. In case of success, the query status is automatically changed to status **“closed”** (see B - Figure 29).



Figure 29: Query states

In addition to queries triggered by saving the form to the "Completed" state, there are also queries evaluated regularly every day after midnight. These are mainly checks to see if the forms are created at the required intervals, etc. After correcting the error mentioned in the query, it is possible to start the process of a new evaluation manually using the "Update" button in the "Queries" section, so there is no need to wait for a regular evaluation. If the system evaluates that the given error has already been corrected, it automatically closes the corresponding query.

### 6.3 LISTING OF THE QUERIES

All queries for the patient that you have the access to can be shown and it is also possible search among them. The listing of queries can be accessed when you click on the **“Queries”** option in the header (see [1] - Figure

30). It is possible to search the queries for all non-Training patients or for all Training patients (see [2] - Figure 30). Queries can take states **“new”** (see A - Figure 29) or **“closed”** (see B - Figure 29). It is possible to search **“opened”** or **“closed”** (see [3] – Figure 30). Results of the search are shown after you click on **“SEARCH”** (see [4] – Figure 30). The order of results work under the same rules as the Patient search (see subchapter 3.1).

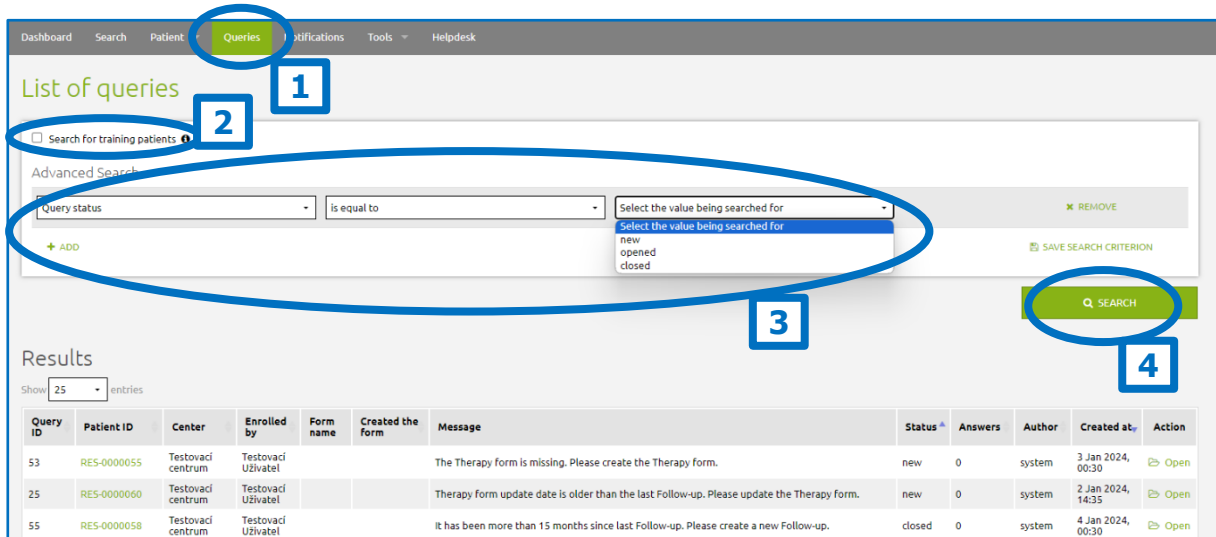


Figure 30: Overview queries

## 7. SPECIFICATION OF THE RESTAND PROJECT

### 7.1 DISPLAYING PHASES AND FORMS DEPENDING ON THE CHOSEN CASE TYPE AND DIAGNOSIS

Based on the answer to the question “Case type” in the “Patient” form (and in the case of the answer “Chronic immune-mediated neuropathy”, also the answer to the question “Current diagnosis” in the “Enrollment” form), the relevant phases and forms that are displayed for the given patient, which can be filled in. A list of all forms for each diagnosis is in the table below.

Case type	Diagnosis	Phase	Form
GBS		Enrollment	GBS / Case diagnostics
		Treatment	GBS / Treatment
		Evaluation	GBS / Evaluation
		Case closing	GBS / Case closing
Chronic immune-mediated neuropathy	*	Enrollment	Enrollment [0]
	CIDP	Enrollment	Case diagnostics and initial assessment of the patient (CIDP) [1] <i>(shown if Current diagnosis in [0] = CIDP)</i>
		Follow-up	CIDP Follow-up <i>(shown if [1] is created)</i>
	MMN	Enrollment	Case diagnostics and initial assessment of the patient (MMN) [2] <i>(shown if Current diagnosis in [0] = MMN)</i>
		Follow-up	MMN Follow-up <i>(shown if [2] is created)</i>
	Nodopathy /paranodopathy	Enrollment	Nodopathy/Paranodopathy Case diagnostics and initial assessment of the patient [3] <i>(shown if Current diagnosis in [0] = Nodopathy/Paranodopathy)</i>
		Follow-up	Nodopathy/Paranodopathy Follow-up <i>(shown if [3] is created)</i>
	Anti-MAG neuropathy	Enrollment	Anti-MAG Case diagnostics and initial assessment of the patient [4] <i>(shown if Current diagnosis in [0] = Anti-MAG neuropathy)</i>
		Follow-up	Anti-MAG neuropathy Follow-up <i>(shown if [4] is created)</i>
	*	Treatment	Treatment
	*	Case closing	End of monitoring

### 7.2 CHANGE OF THE DIAGNOSIS BY THE “RE-EVALUATION OF THE DIAGNOSIS” IN FOLLOW-UP FORM

In case of re-evaluation of the diagnosis in the "Follow-up" form, the patient's diagnosis on his "Enrollment" form will also be automatically changed to this new value (except for the "Other" option).

RE-EVALUATION OF THE DIAGNOSIS

Re-evaluation of the diagnosis

\* Re-evaluation of the diagnosis

GBS  MMN  Anti-MAG neuropathy  Nodopathy/paranodopathy  Other

Figure 31: Re-evaluation of the diagnosis

### 7.3 RELATIONS BETWEEN MULTIPLE CASES OF THE SAME PATIENT (GBS SPECIFIC)

Because one patient may have multiple cases of GBS, it is necessary to make relationships between all forms of each of his cases. This is done by selecting the associated case in the GBS forms, in which it is necessary to select the case by typing year of patient hospitalization in this question and selecting the associated case from the options offered:

ASSOCIATED CASE

\* Choose the associated case

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2023-02-28: Guillain-Barre syndrome [form 436]

2020-08-07: Guillain-Barre syndrome [form 437]

Figure 32: Selecting the associated GBS case

### 7.4 TREATMENT FORM FOR CHRONIC IMMUNE-MEDIATED NEUROPATHY

All treatment of Chronic immune-mediated neuropathy is added continuously to the same form by adding rows of the repeated group of the questions. Therefore, this form does not have the option of switching between common states (i.e. "Pending", "Completed", "Valid"). In order to be able to continuously edit and update it, it has only one fixed state, which is constantly editable and always validated. This means that this form must always be valid and cannot be saved as "Pending".

## 8. HELPDESK

### TECHNOLOGICAL BACKGROUND

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In case of technical difficulties, please contact our **HelpDesk**.

HelpDesk is a user support department whose staff is available every weekday from 8:00 to 16:00 (phone, e-mail). The professional distribution system requirements helps ensure fastest possible response even for complex problems.

### HelpDesk

E-mail: [helpdesk@biostatistika.cz](mailto:helpdesk@biostatistika.cz)

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