MyDyS: Clinical registry of patients with MyeloDysplastic Syndrome

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User guide for data entry into CLADE-IS

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CONTENTS

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 DATAWAREHOUSE

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[1]. 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

[1] 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[2]

https://mydys.data-warehouse.zone

Log in to the system with putting your username and password into the appropriate fields and click on „**LOG IN**“ button (see [1] – Figure 1).

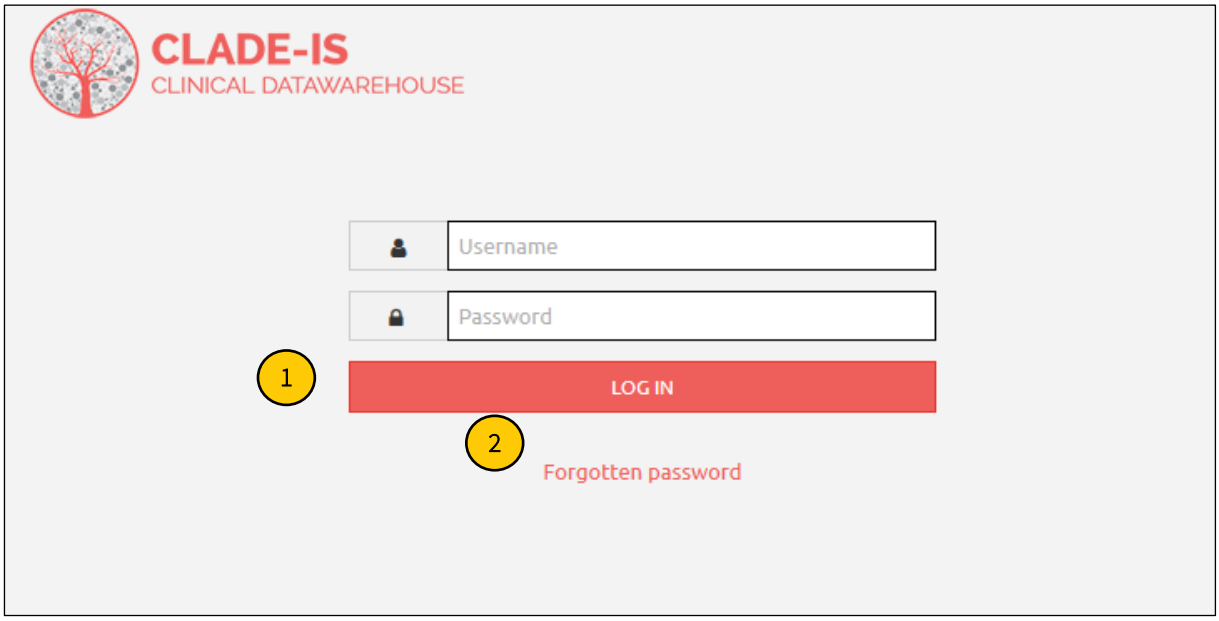

Figure 1: Connection to the database and the forgotten password

1.1 FORGOTTEN PASSWORD

In case of forgotten password, you can restore it or change id 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).

[2] To access the database, please use any up-to-date stable web browser supporting JavaScript and secured communication. In this user guide, Mozilla Firefox 74.0 has been used for the screenshots.

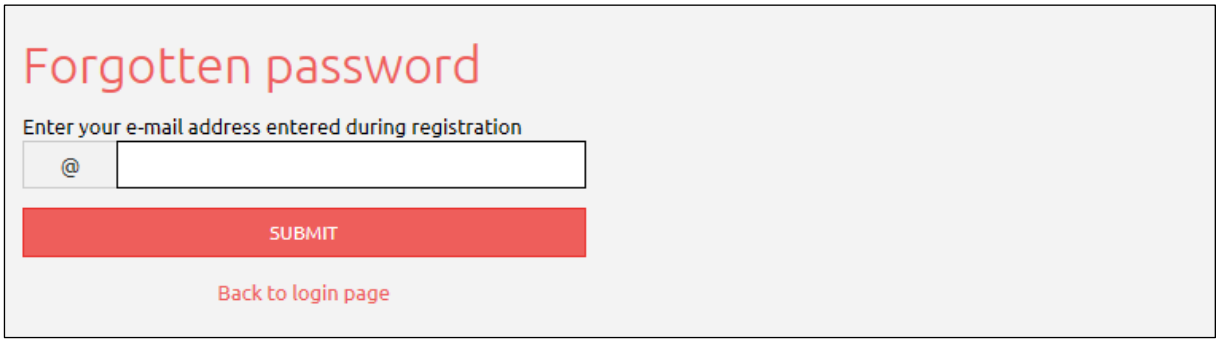

Figure 2: Enter email address

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).

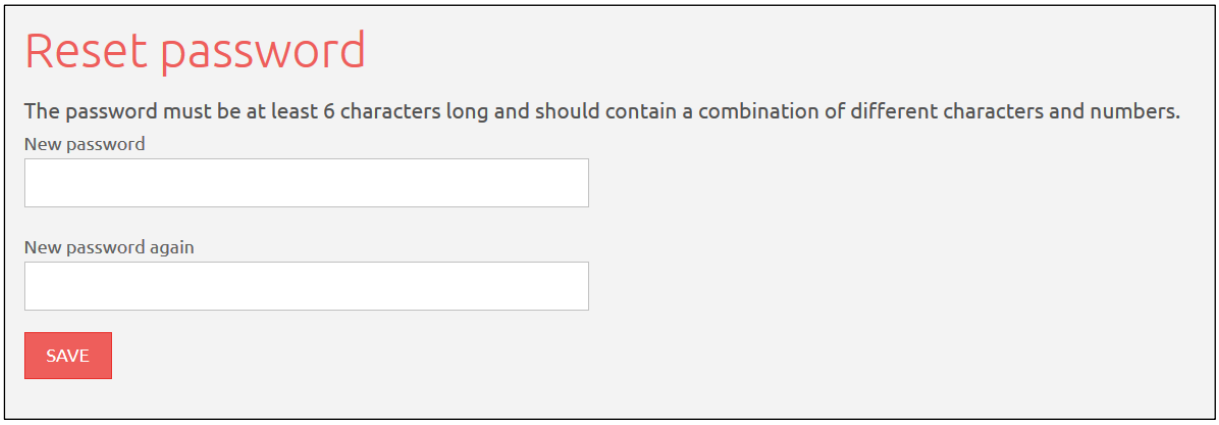

Figure 3: Creation of a new password

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).

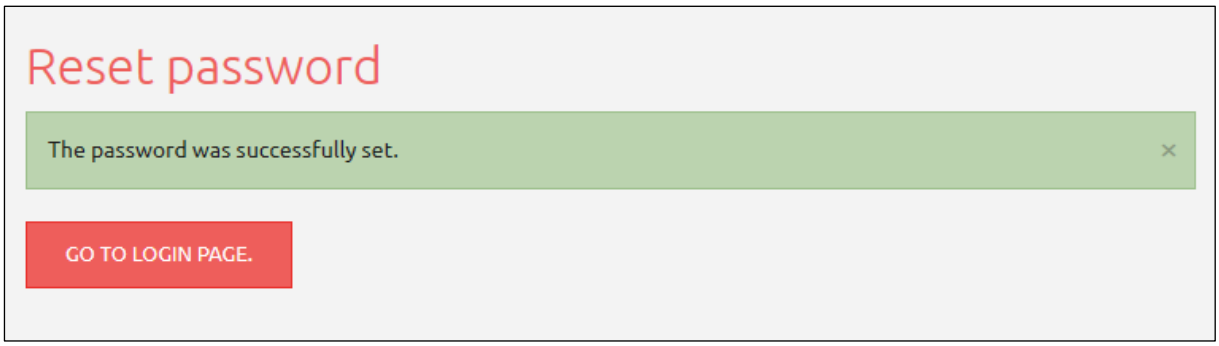

Figure 4: Confirmation of successful creation of new password

2. MAIN APPLICATION WINDOW

After you log in, a main 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.

If the study is part of connected group of studies, you can switch the study with the button **"CHOOSE"** (see [1] – Figure 5). You can log out[3] the system using the **"LOGOUT"** button in the upper right corner (see [2] – Figure 5).

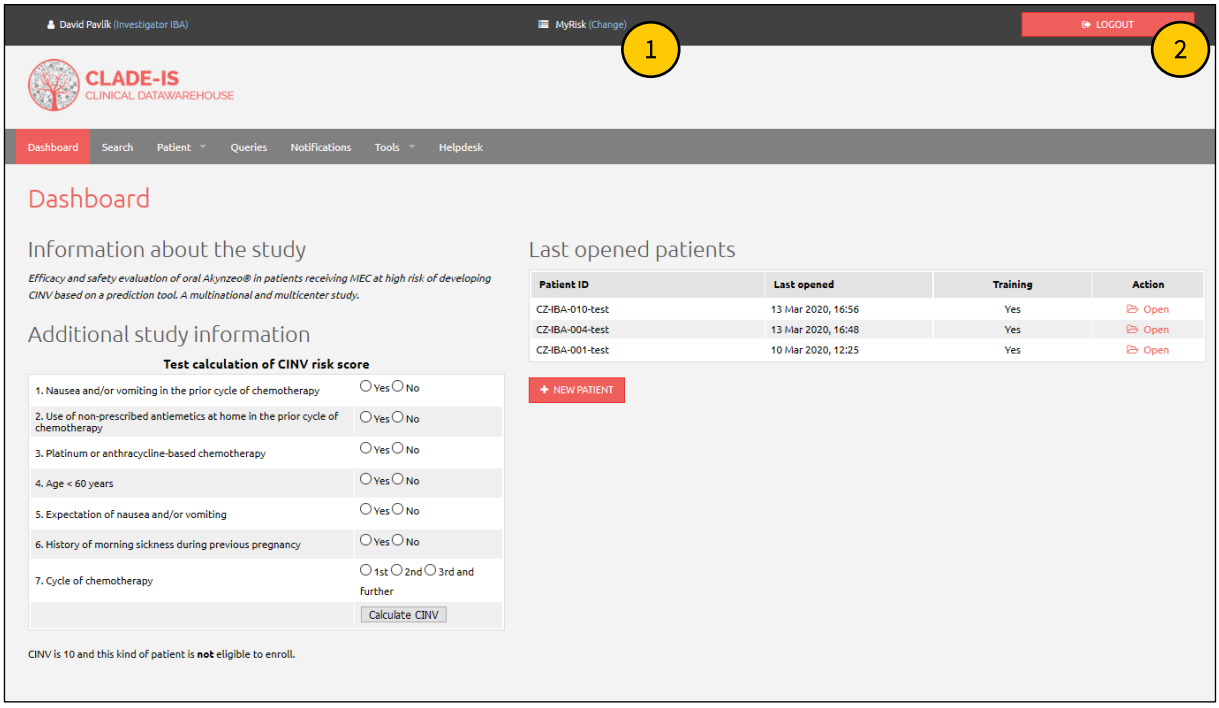

Figure 5: Main application window

[3] **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] - Figure 6) or via drop down menu: **"Patient"** -> **"Create patient"** (see [2] - Figure 6).

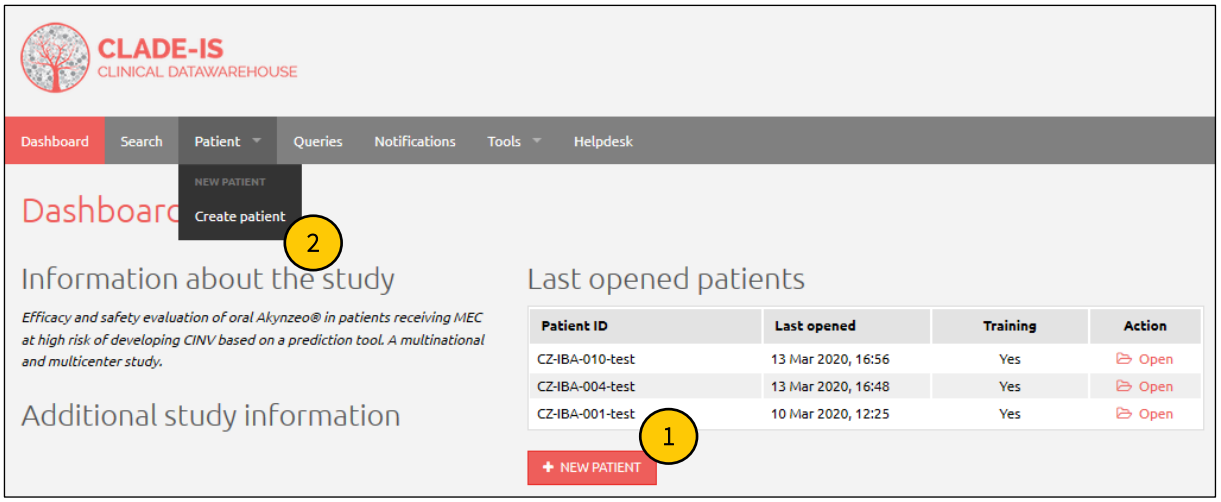

Figure 6: New patient registration

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

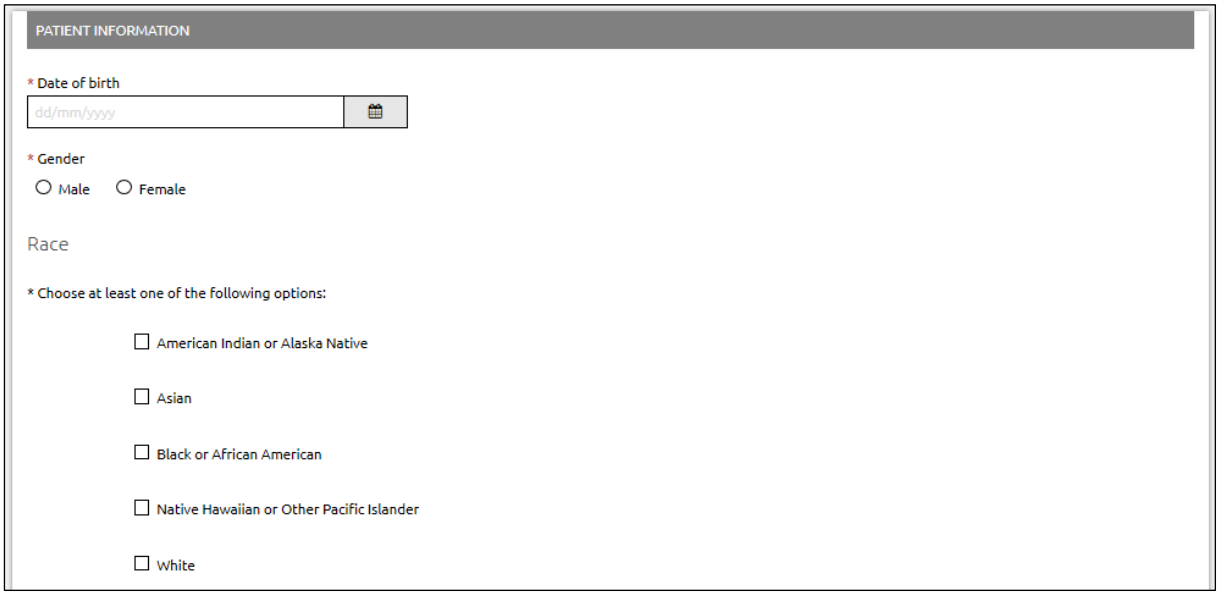

Figure 7: Personal data (always specific according to the particular study)

2.3 PATIENT SETTINGS SETUP

- **Study arm –** in case they exist and are to be selected when enrolling the patient choose select from drop-down list (see [1] - Figure 8)
- **Training patient** (see [2] - Figure 8) - check this box 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 FINISHING ENROLLMENT

When you are done, click the **"SAVE"** (see [3] - Figure 8). If you wish to clear the form and start again, click on the **"CANCEL"** button (see [4] – Figure 8).

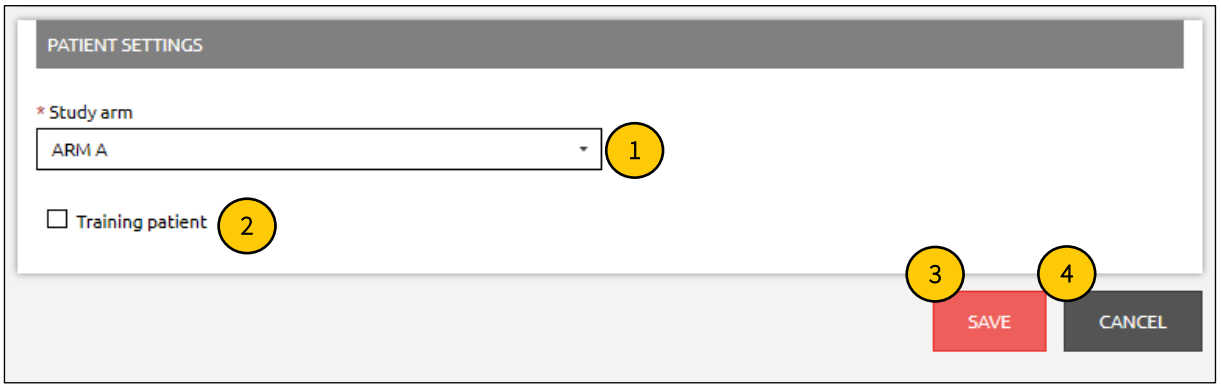

Figure 8: New patient enrolment – final settings

By clicking on the "**SAVE**" button, a unique "Patient ID" will automatically be generated in a prescribed form. The form consists of country abbreviation, site alias, patient number within the site 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 [1] - Figure 9).

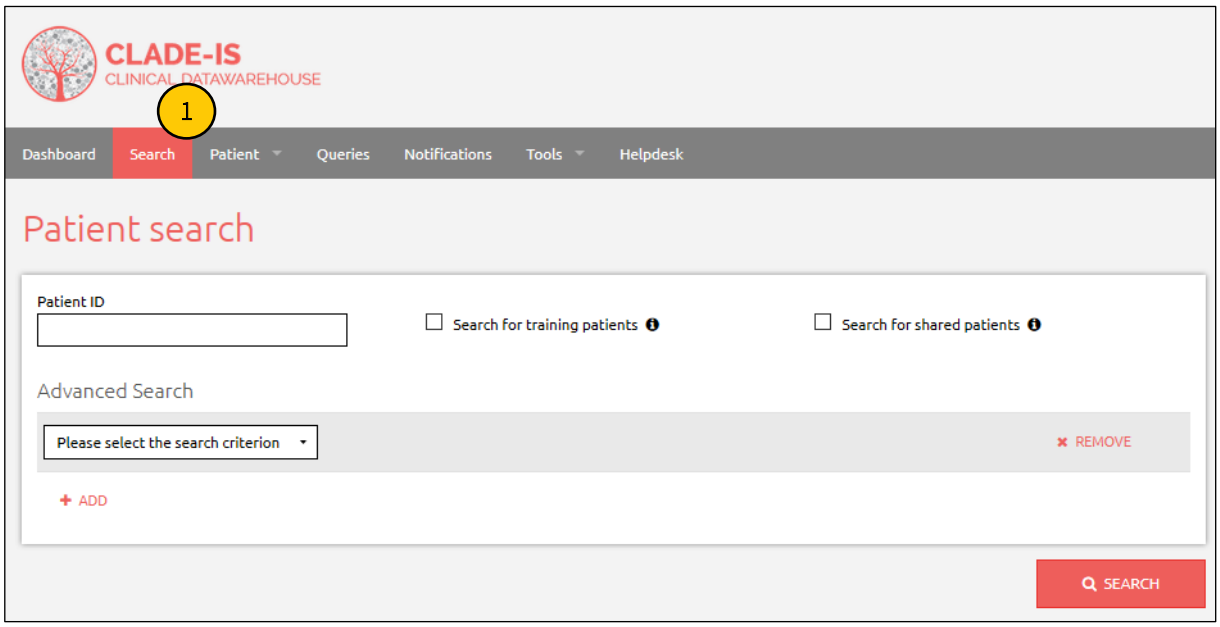

Figure 9: Patient search

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 **"🔍 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) - *optional*
4. Select the search operator (is equal to, is not equal to, …) (see [4] - Figure 10) - *optional*
5. Enter the value (see [5] - Figure 10) - *optional*
6. Click on the **"🔍 SEARCH"** (see [6] - Figure 10)

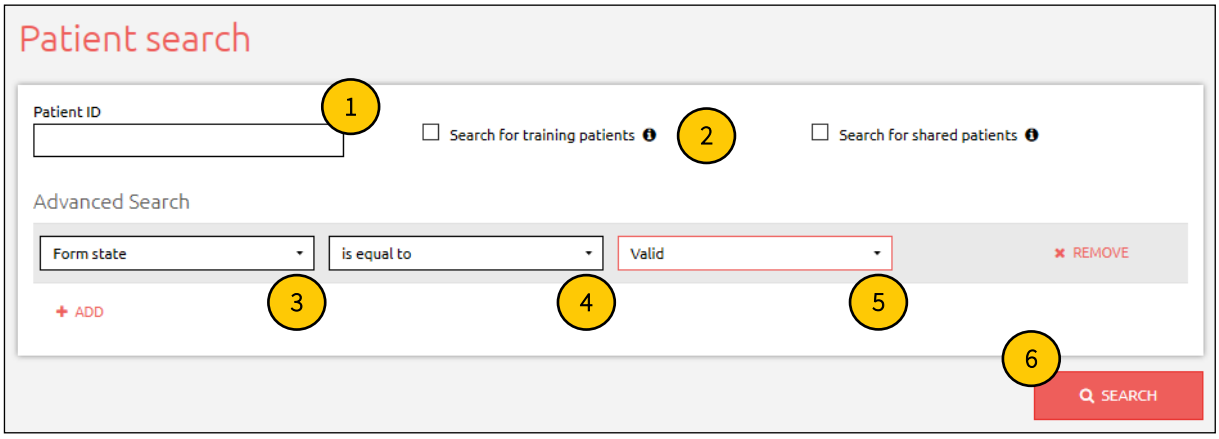

Figure 10: Basic search

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).

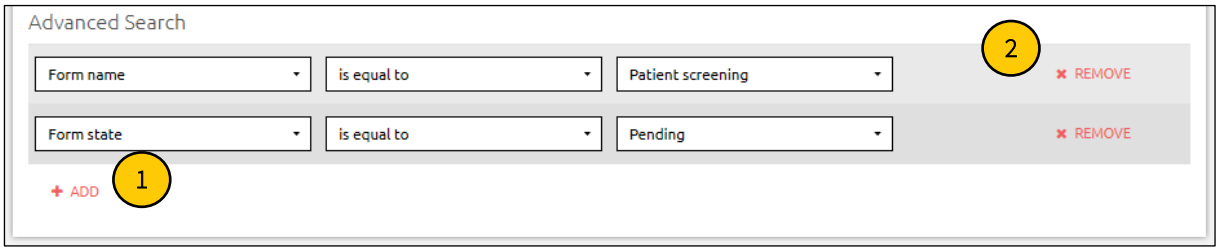

Figure 11: Advanced search – adding parameters

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 *.xlsx file by clicking on the **"EXPORT RECORDS TO XLSX"** button (see [4] - Figure 12).

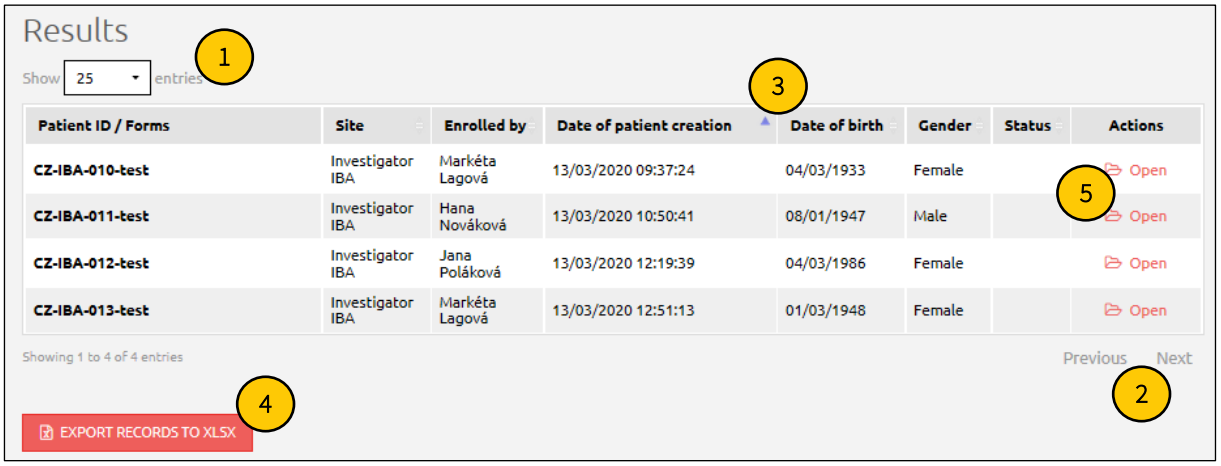

Figure 12: Search results

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).

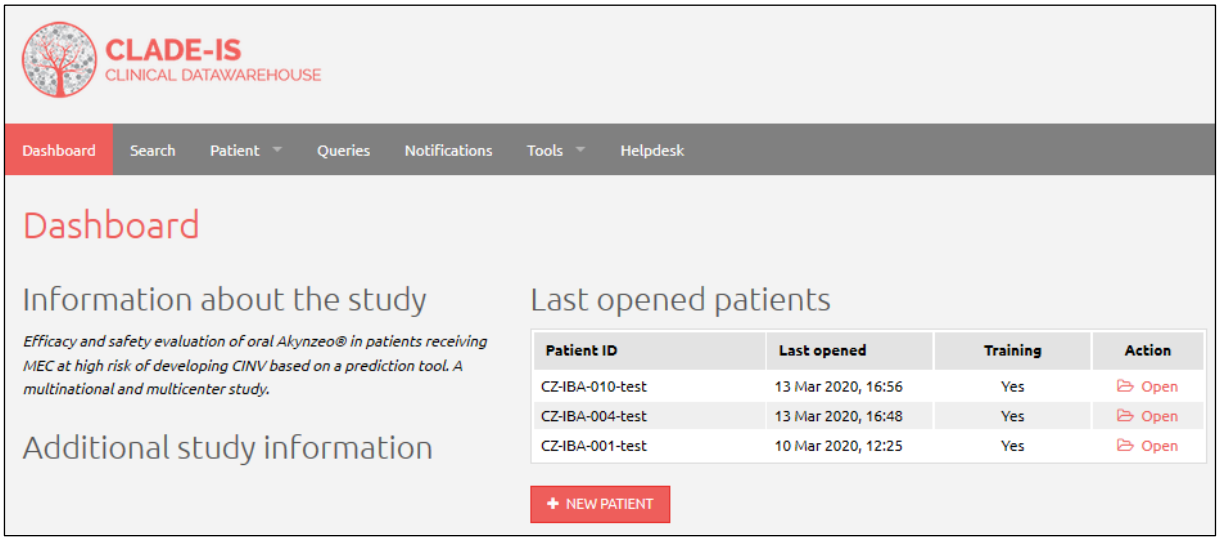

Figure 13: Last opened patients

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

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

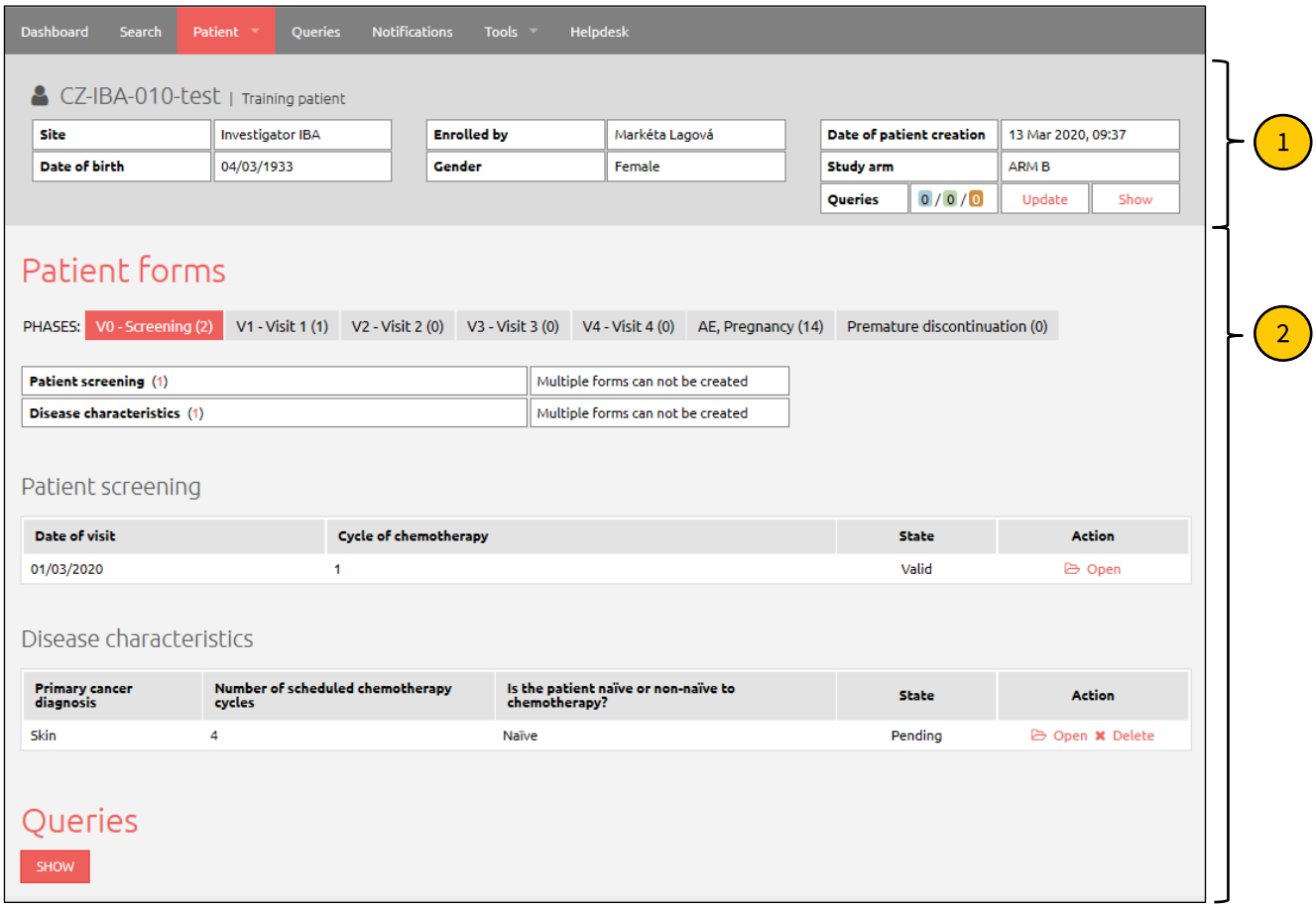

Figure 14: Working window of the application

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 1). It is also possible to edit (modify)[4] personal data of a patient here, using the dropdown menu: **Patient** -> **Personal data** (see [1] Figure 15).

[4] Only in case it is allowed by project.

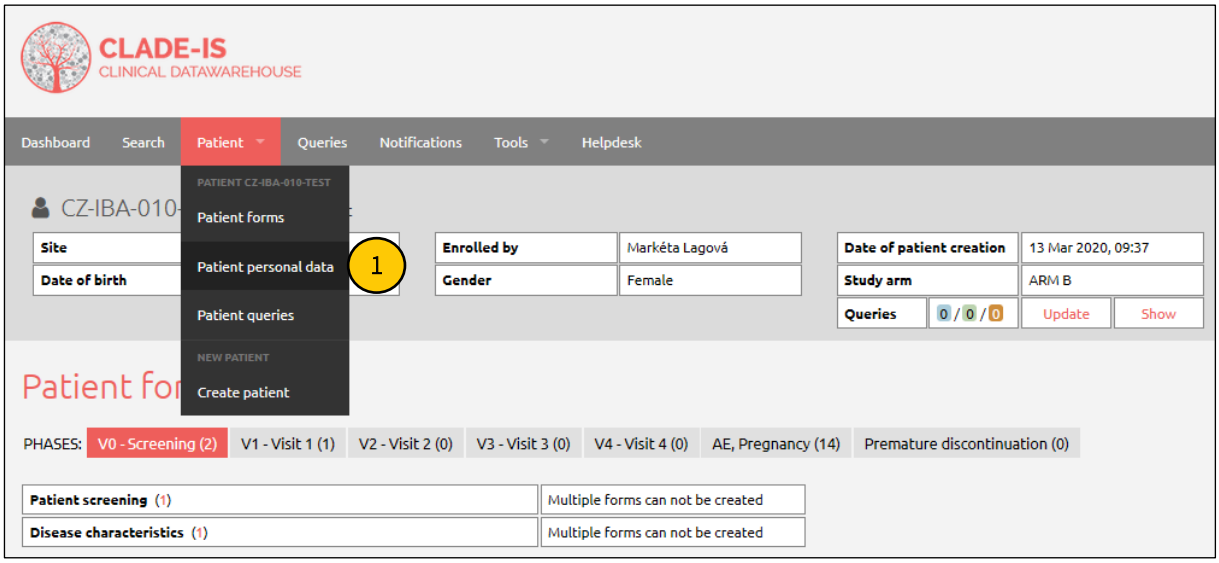

Figure 15: Entering patient personal data

When personal data are modified, click on **"SAVE"** button. Information about saving data will appear. Clicking on the Patient Forms link (see [1] - Figure 16).

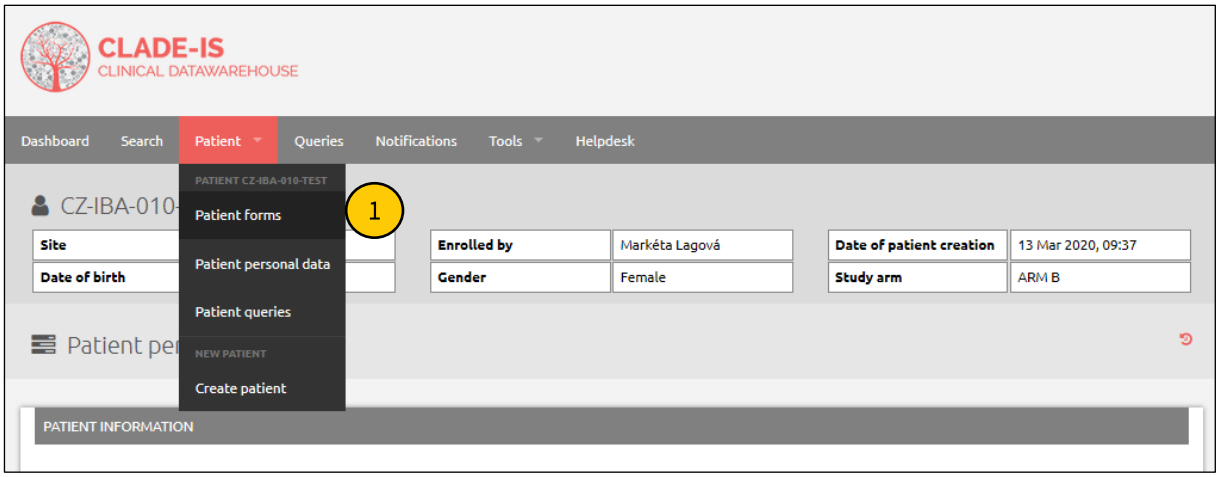

Figure 16: Leaving patient personal data

If you want to delete[5] the patient, click on the "**Delete this patient and all of his/her forms**" link (see [1] - Figure 17). The confirmation window will be displayed (see Figure 18), containing reason for patient deletion.

[5] Only in case it is allowed by concrete project.

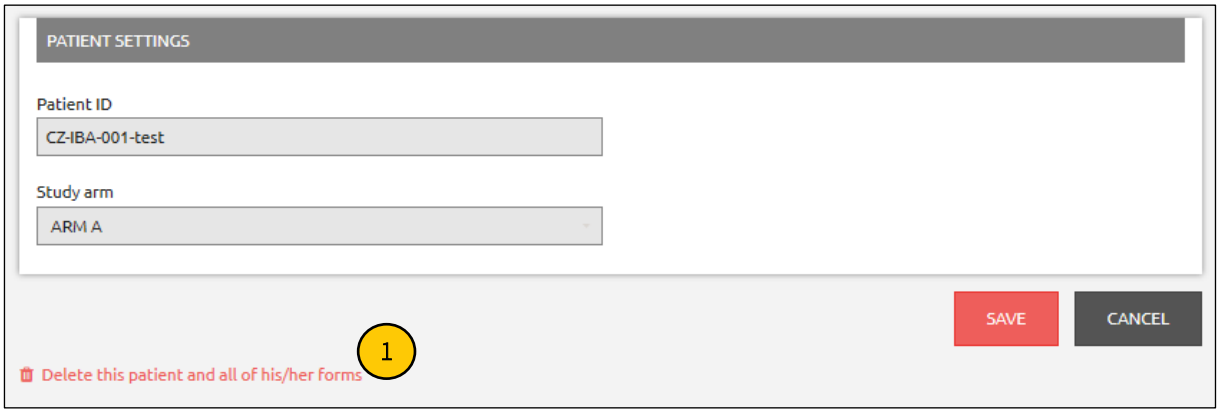

Figure 17: Delete the patient

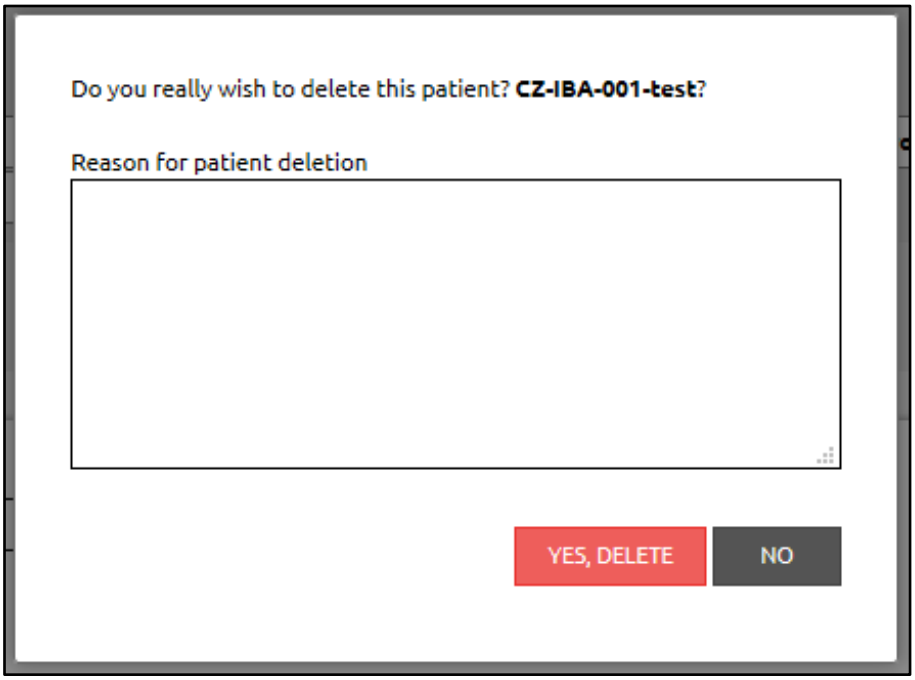

Figure 18: Delete the patient - confirmation

In the main section of each patient:

1. You can switch between the study phases, by clicking on their names (see [1] - 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] - Figure 19), until a specific limit for this form is reached.
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] - Figure 19).

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

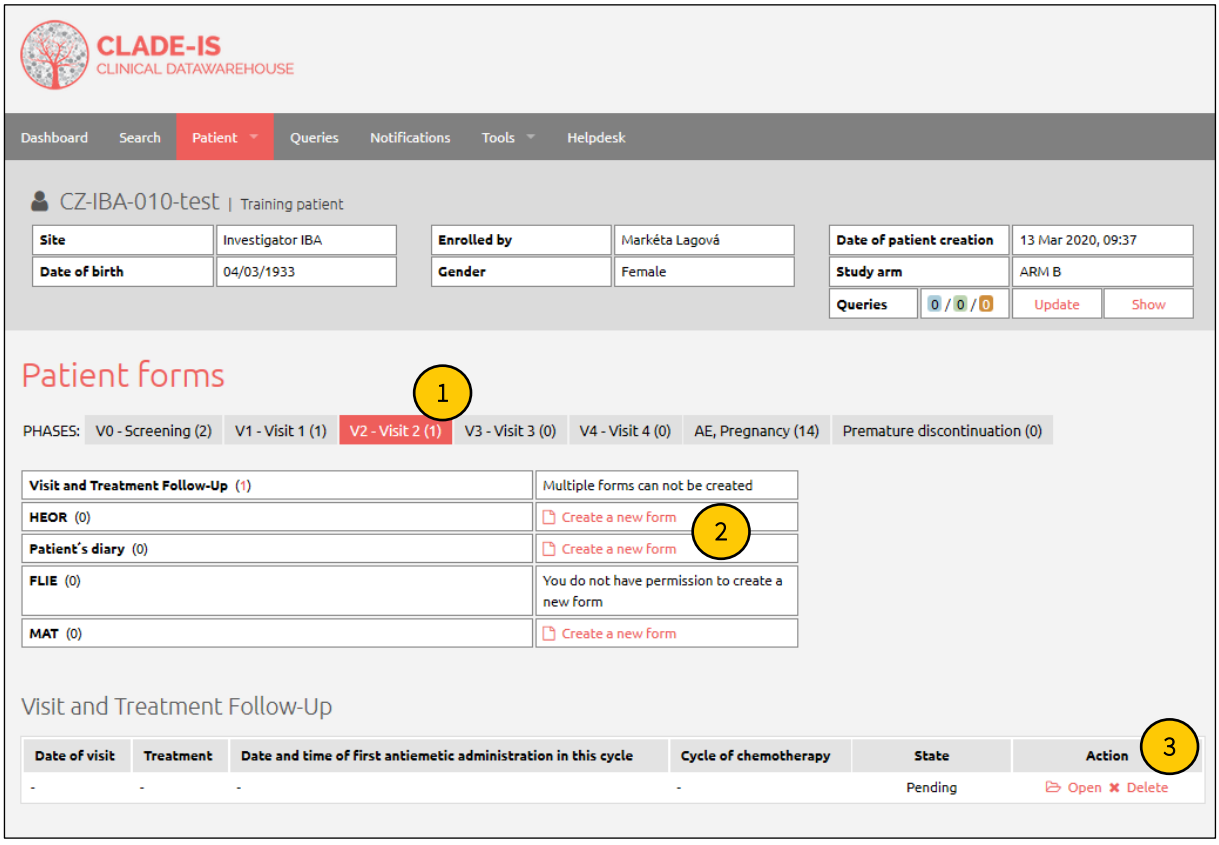

Figure 19: Working with the forms

5. FORM COMPLETION

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

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

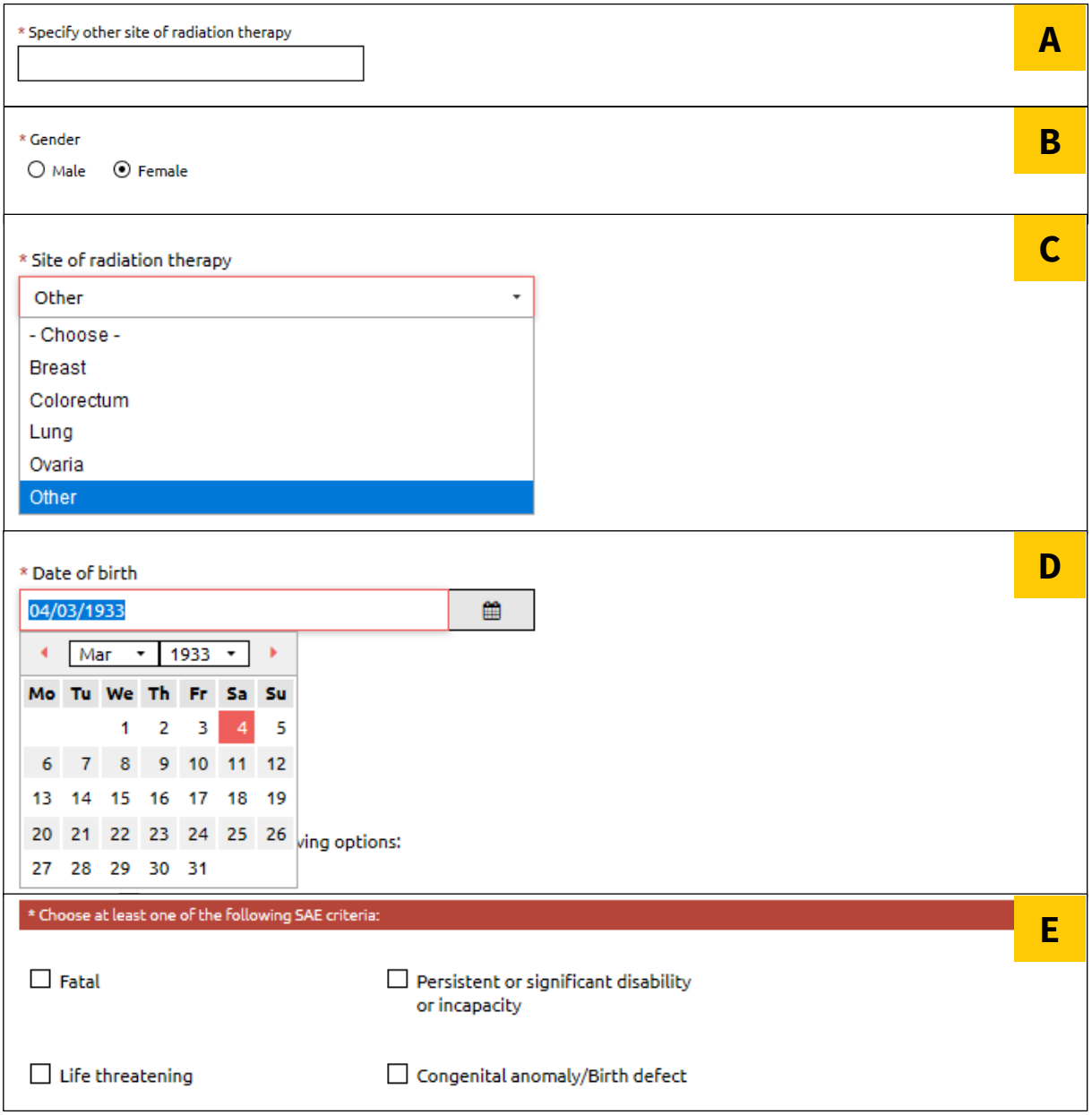

Figure 20: Basic question types

5.1 REPEATING GROUP OF QUESTIONS

Some form sections contain repeating group 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.

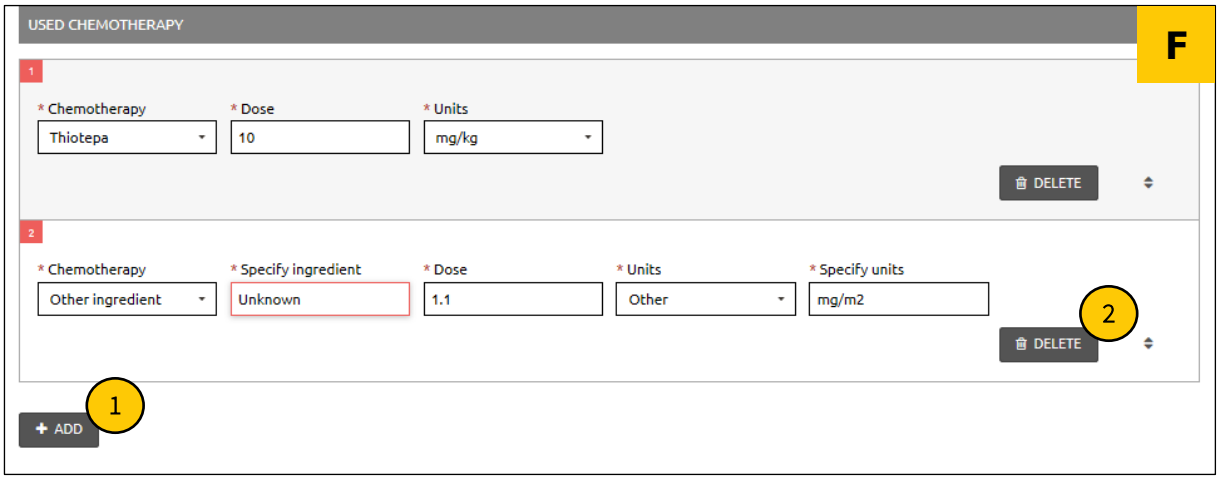

Figure 21: Repeating group of questions

5.2 SPECIFIC FUNCTIONS

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

*Figure 22: Specific functions – mandatory question (marked by an asterix *)*

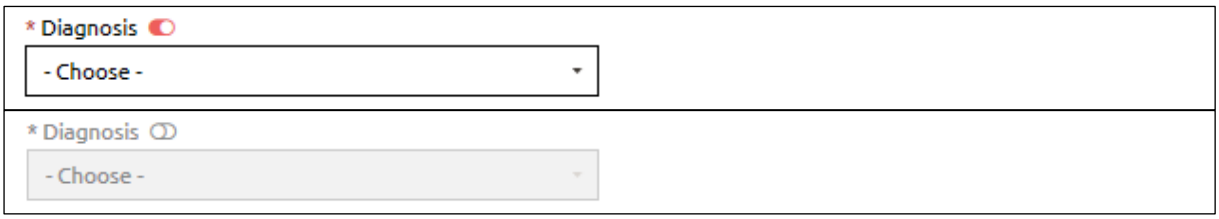

Figure 24: Specific functions – answer is not known

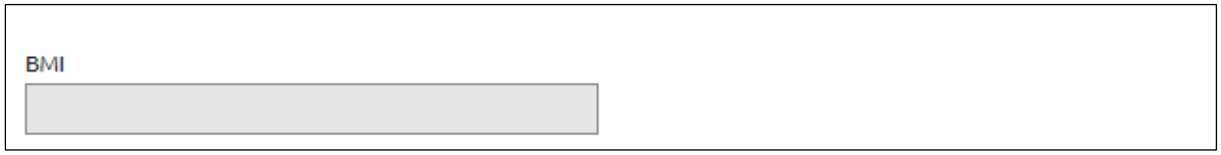

Figure 23: Specific functions – read only question

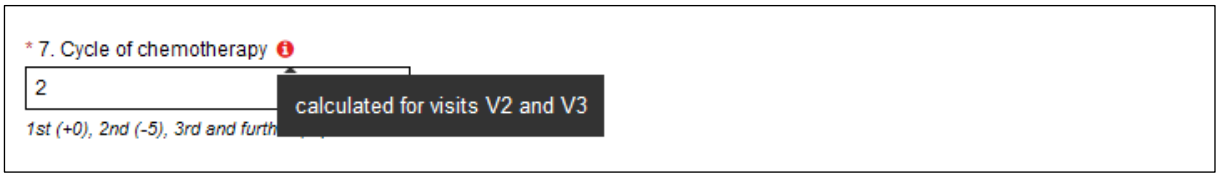

Figure 25: Specific functions – additional info

5.3 FORM STATUS

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

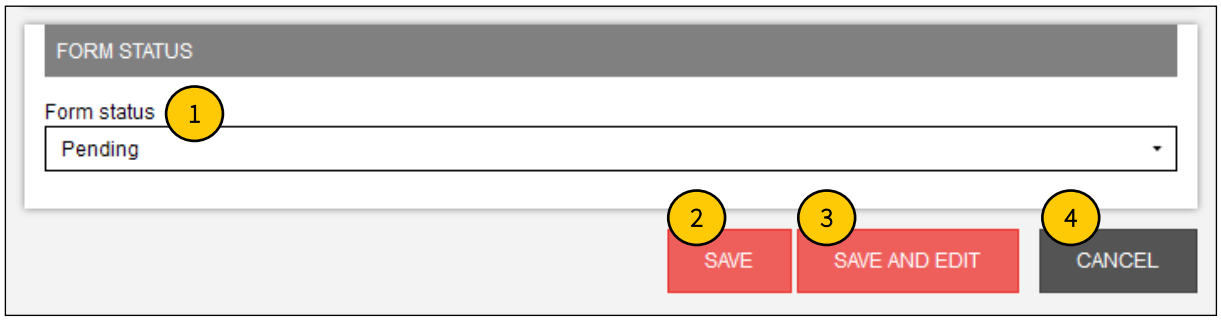

Figure 26: Form status

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Valid from / platná od: **2017-08-04**

Registered e-document

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.
- Other customizable statuses are also possible when it is needed for the study.

5.4 SAVING

There are three buttons - **"SAVE"**, **"SAVE AND EDIT"** and **"CANCEL"** at the top and bottom of the form (see [2], [3] a [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

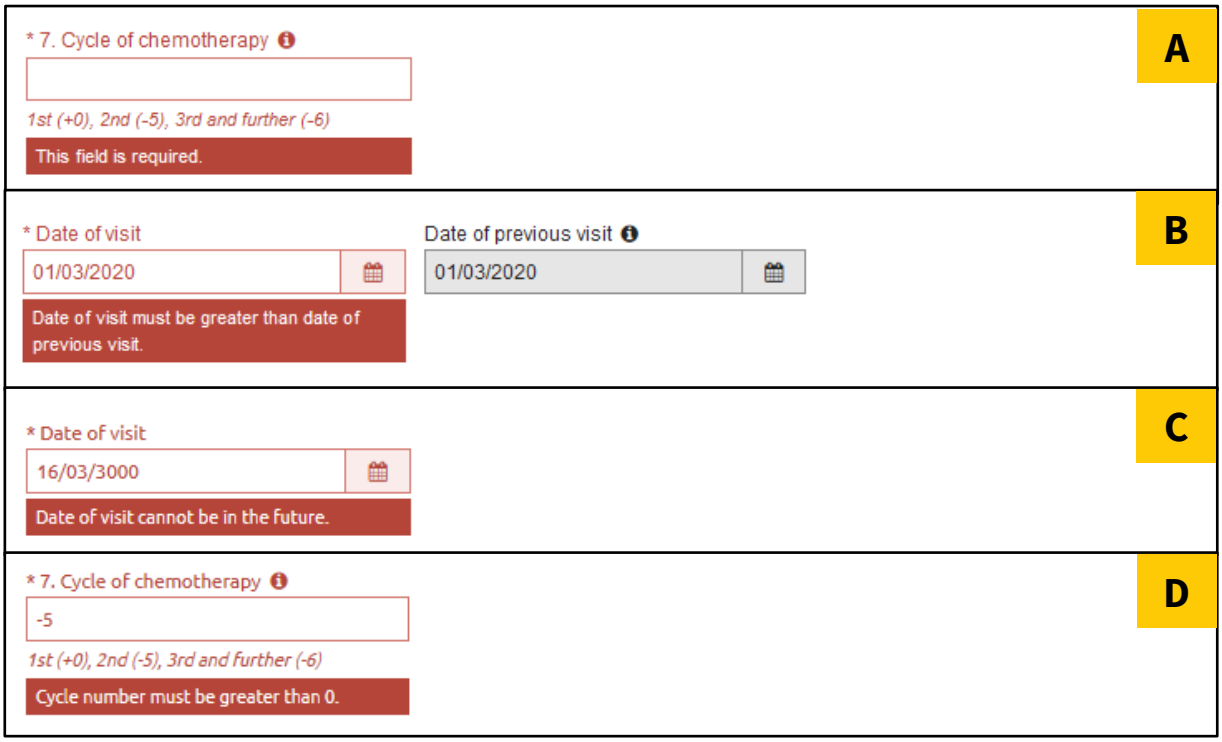


Figure 27: Validation criteria

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

6.2 CHECKING 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"**.

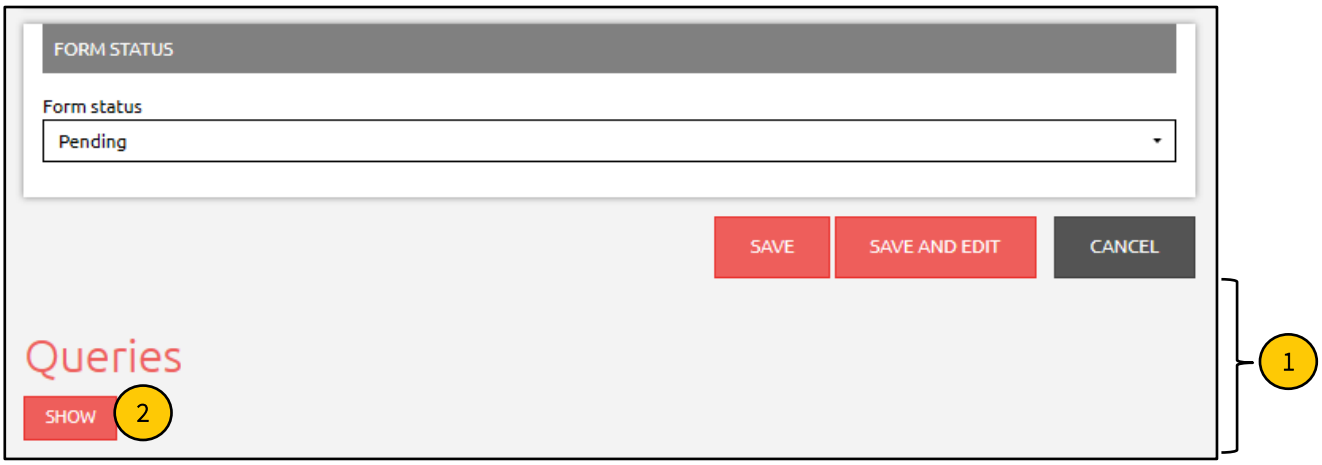


Figure 28: Queries on form

An error message will appear at the bottom of the form in the section **"QUERIES"** (see [1] - Figure 28). The error message is located on the form that validation failed. To view the error message, you need to click on **"SHOW"** button (see [2] – Figure 28). An alternative way to view the queries is from the header of the form where the **"SHOW"** button (see [1] – Figure 29).

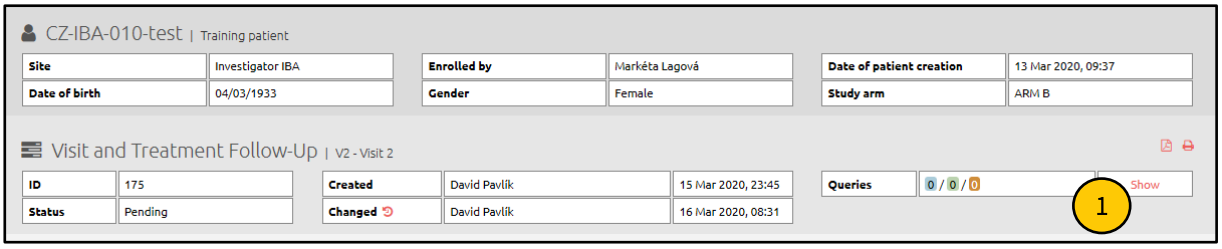


Figure 29: Queries on form – an alternative way to view

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 A – Figure 30), 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 30).

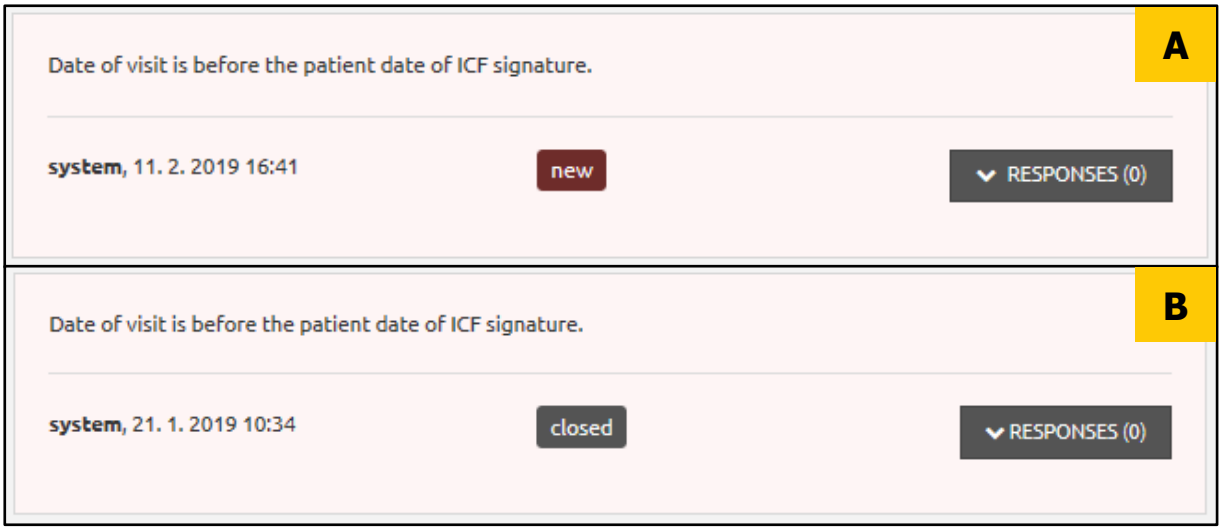


Figure 30: Query states

6.3 MANUAL QUERIES

Manual queries are not generated automatically by the system however inserted manually in each form once a data review is done by IBA analyst or after Monitor or PV responsible person finds any discrepancy. To respond a manual query please correct the information in the specific form first. As a second step please insert a notice to the specific query (see A – Figure 31). Person responsible for inserting the manual query will check queries with responses (i.e. analyst during the next data review) then decide whether the response is sufficient or not. Eventually will ask investigator for further details (see B – Figure 31).

Figure 31: Manual Queries

6.4 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 32). It is possible to search the queries for all non-Training patients or for all Training patients (see [2] – Figure 32). Results of the search are shown after you click on **"SEARCH"** (see [3] – Figure 32)The order of results work under the same rules as the Patient search (see Chapter 3.1). You can search only new queries, queries for specific patient only or for specific form only (based on chosen criteria).

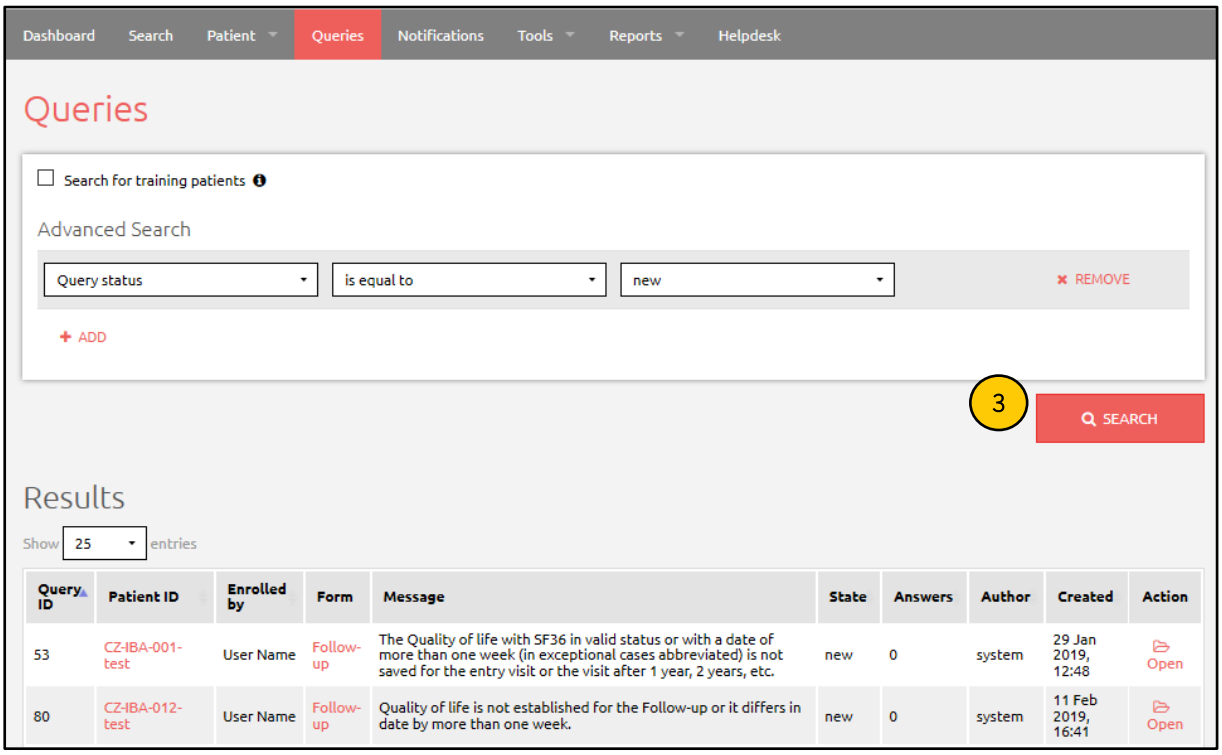


Figure 32: Queries search results

7. STUDY SPECIFIC SETTINGS

7.1 NOTIFICATIONS

In order for user to have actual information about project and all related things, there is functionality called notifications. These notifications are showing as messages placed under main menu (see [A1] – Figure 33) or as a notification bubble on section "**Notifications**" (see [A2] – Figure 33). If there is a bubble with number it says how many unread notifications the user currently has. User confirms he read notification by clicking on a button (see [A3] – Figure 33). Inside "**Notifications**" user can find overview of all read and unread notifications and their history (see [B] – Figure 33).

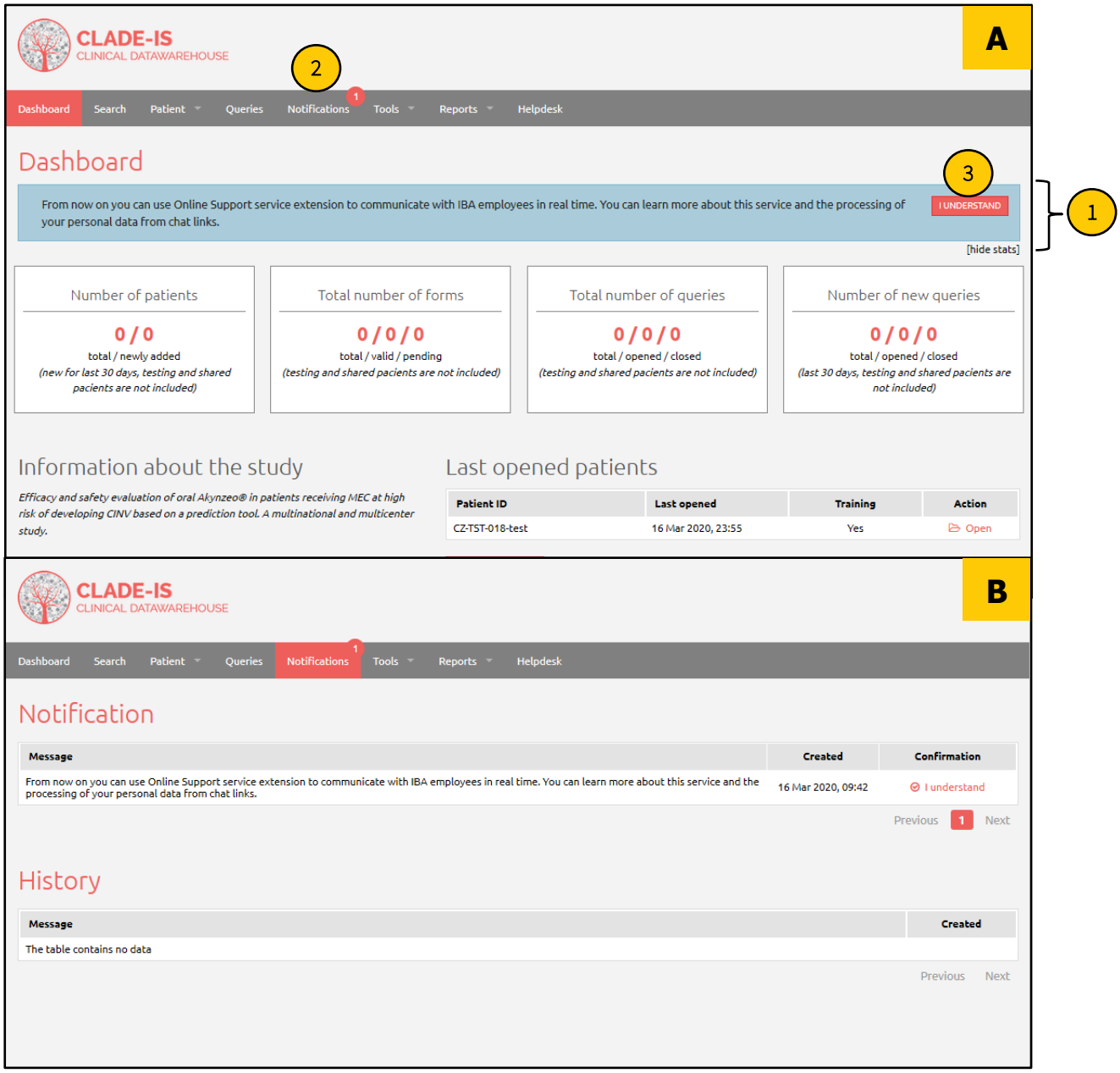


Figure 33: Notifications

7.2 DASHBOARD STATISTICS

For actual overview of current study status, user can see basic statistics straight on study dashboard. These statistics show count of study forms, patients and queries currently present or that have been created within the last 30 days. Statistics work based on permission setup for current logged user. If user permissions are limited to data of his site then statistics show numbers relevant for that site only.

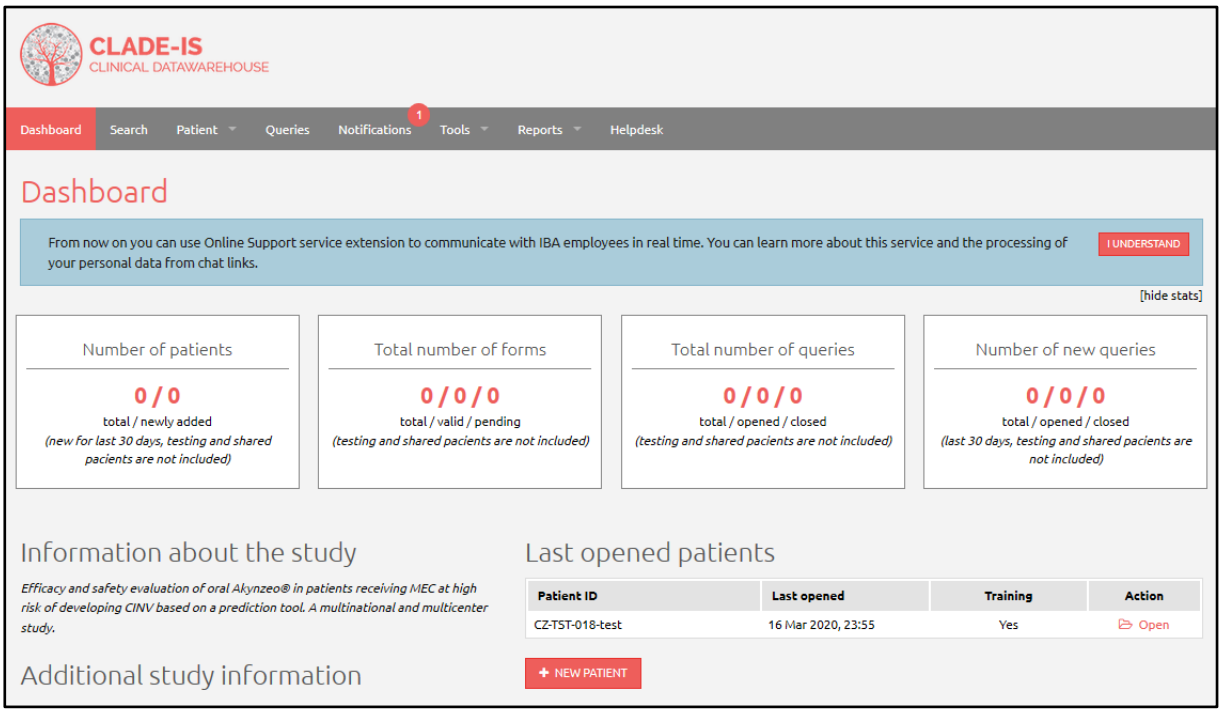


Figure 34: Dashboard statistics

7.3 ONLINE REPORTS

For more detailed overview of actual study status, user can see predefined online reports. These can be found in the section "**Reports**" of main menu. They show the whole number of patients, increase in patients within last three months – section "**Patient's enrollment**" (see Figure 35), then section called "**Forms**" with number of created forms of each site divided by the state they are actually in (see Figure 36). Last section shows "**Queries**" for each site and overview of sums based on their state as well (see Figure 37) All online reports work based on permission setup for current logged user. User can only see subset of data that he is permitted to.

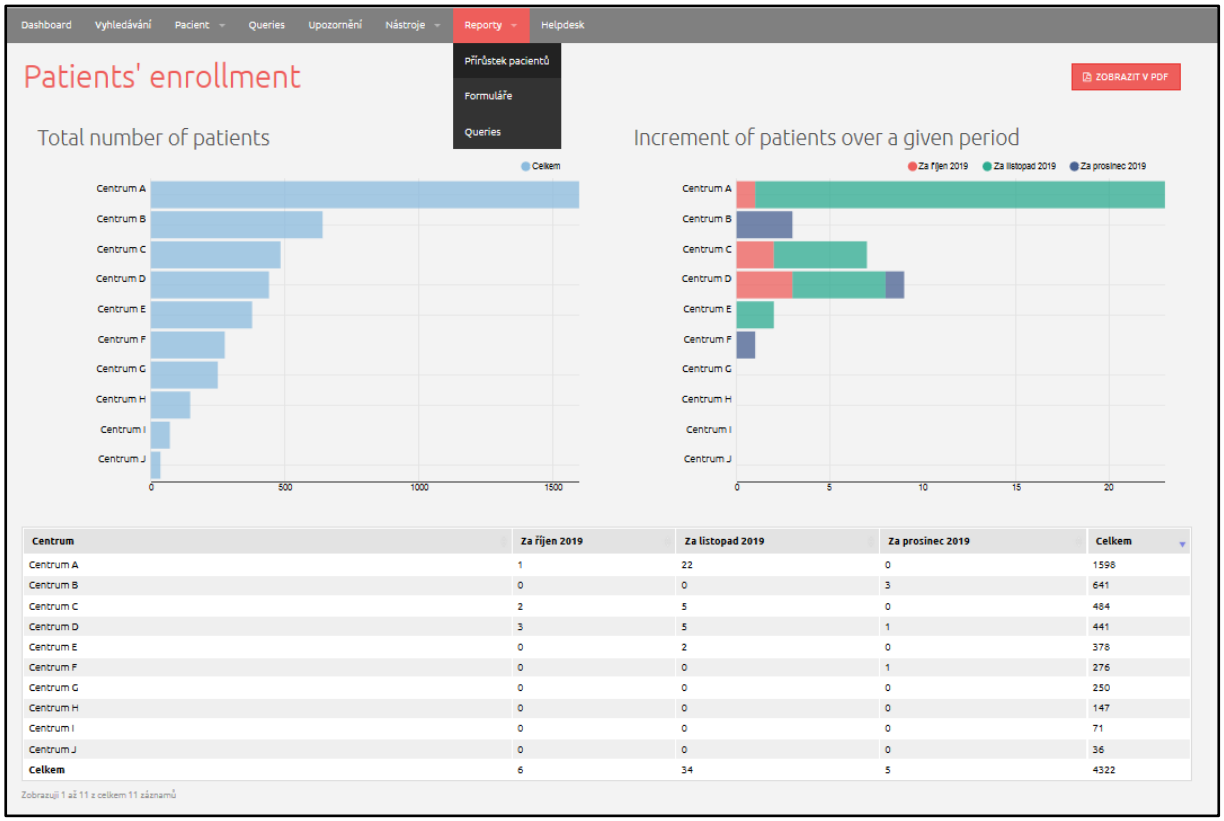
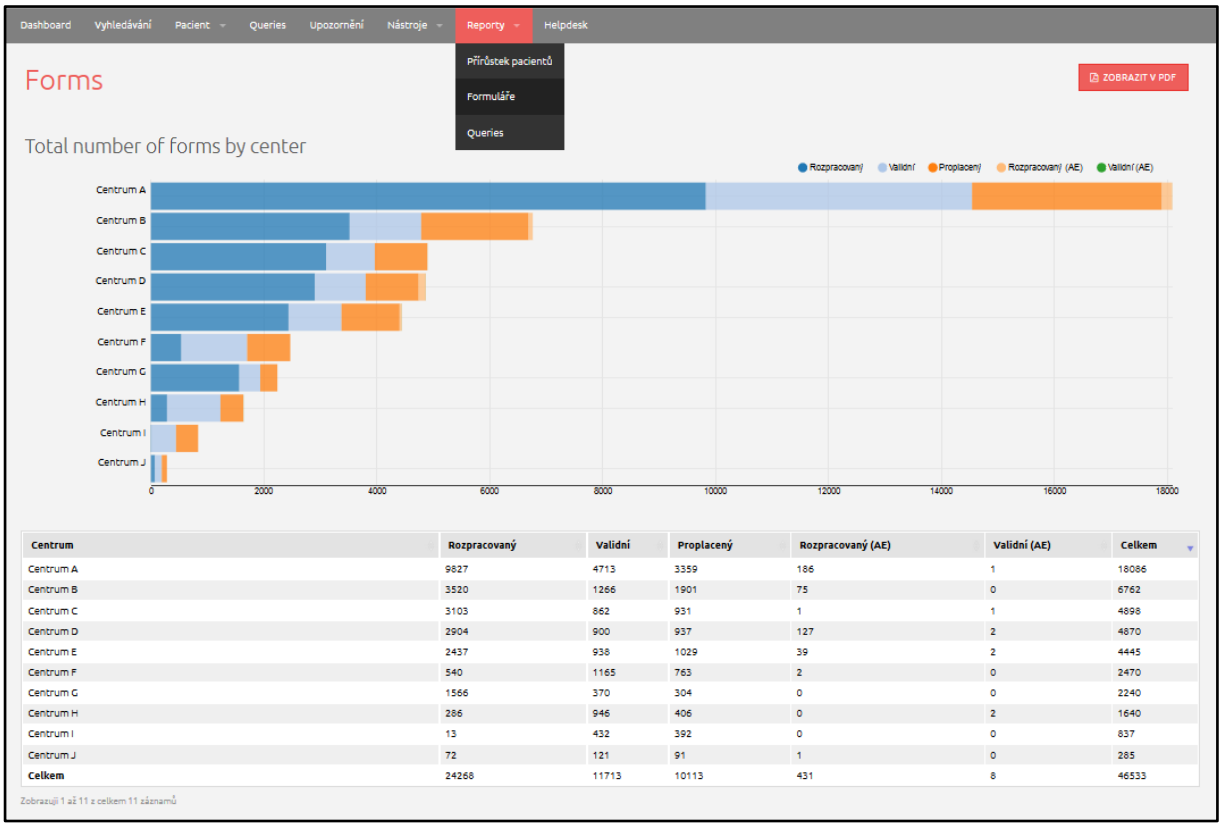


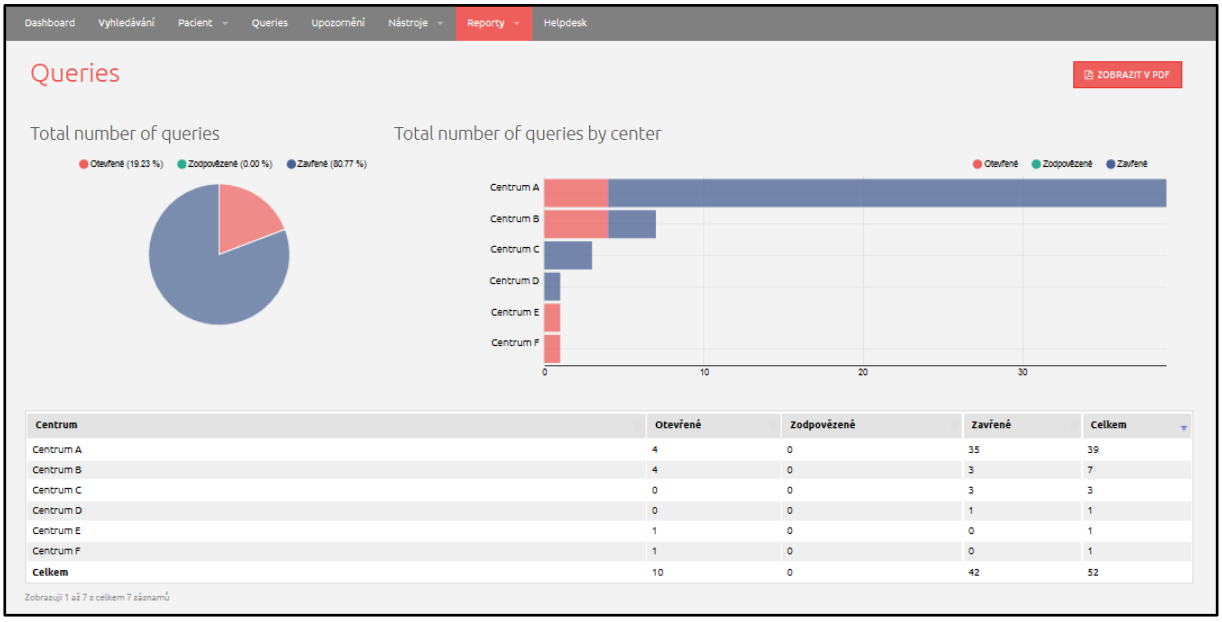
Figure 35: Online reports – Patients' enrollment



Centrum	Rozpracovaný	Validní	Proplacený	Rozpracovaný (AE)	Validní (AE)	Celkem
Centrum A	9827	4713	3359	186	1	18086
Centrum B	3520	1266	1901	75	0	6762
Centrum C	3103	862	931	1	1	4898
Centrum D	2904	900	937	127	2	4870
Centrum E	2437	938	1029	39	2	4445
Centrum F	540	1165	763	2	0	2470
Centrum G	1566	370	304	0	0	2240
Centrum H	286	946	406	0	2	1640
Centrum I	13	432	392	0	0	837
Centrum J	72	121	91	1	0	285
Celkem	24268	11713	10113	431	8	46533

Zobrazuji 1 až 11 z celkem 11 záznamů

Figure 36: Online reports – Forms



Centrum	Otevřené	Zodpovězené	Zavřené	Celkem
Centrum A	4	0	35	39
Centrum B	4	0	3	7
Centrum C	0	0	3	3
Centrum D	0	0	1	1
Centrum E	1	0	0	1
Centrum F	1	0	0	1
Celkem	10	0	42	52

Zobrazuji 1 až 7 z celkem 7 záznamů

Figure 37: Online reports – Queries

8. HELPDESK

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 help ensure fastest possible response even for complex problems.

8.1 ONLINE SUPPORT

After successfully logging in user can contact our HelpDesk team via online support that can be found on any page within the study always in the bottom right corner (see [1] – Figure 38). Inside that pop-up window user communicates with HelpDesk in real time manner. Online support is active even afterhours and generates an email to our HelpDesk department and will be processed in a standard way as any other support request.

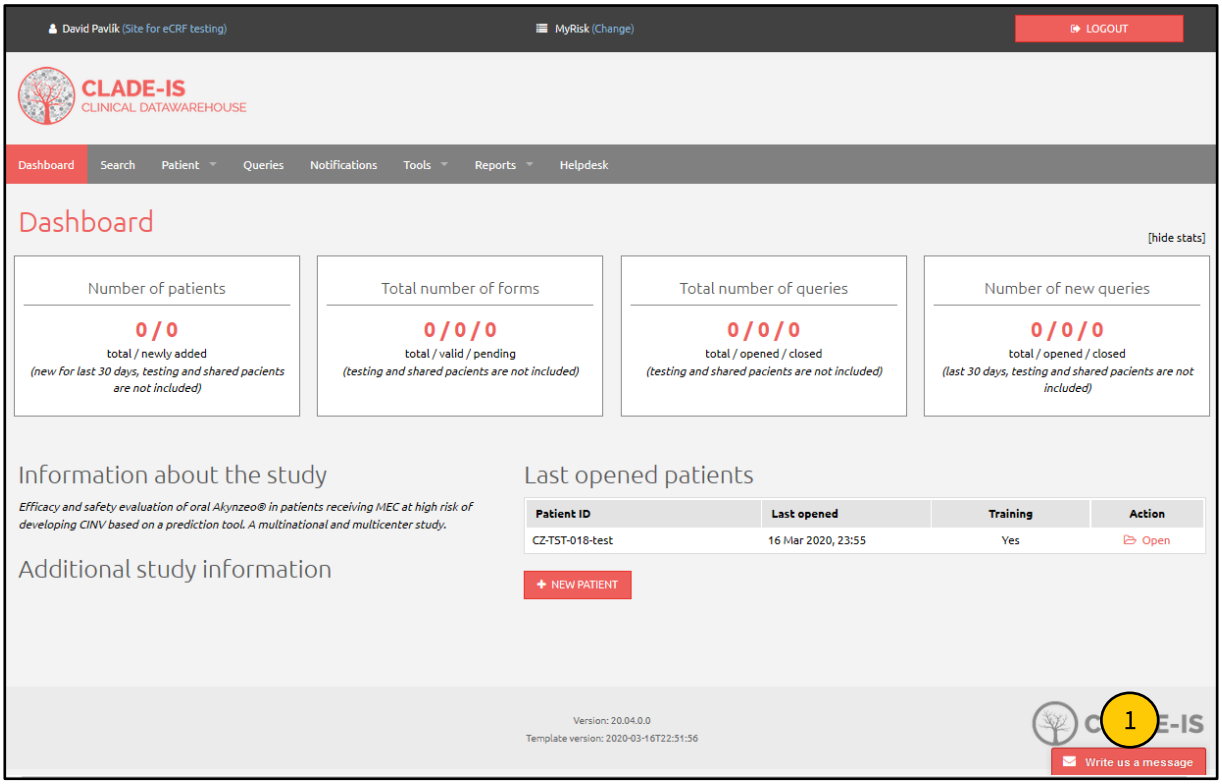


Figure 38: Online support location

HelpDesk

E-mail: helpdesk@biostatistika.cz

Tel.: (+420) 515 915 100