EMPIRE

User Guide

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Created by:

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Online Data Collection – General Information

➢ On-line data collection is based on a TRIALDB system developed on Yale University, Connecticut, USA, which is widely used for this purpose.

➢ The system is user-friendly; all data will be entered using web forms analogical to paper CRF/DCFs.

➢ Data can be entered from any computer with Internet access equipped with a web browser supporting communication secured with a 128 bit cipher.

➢ It is not necessary to install any additional computer software.

➢ The database can be accessed only by authorized persons using their user name and password.

➢ Data in the database are anonymous. For each patient, a unique ID will be generated and the personal identification of patients will not be possible. All requirements for personal data protection will be met.

➢ All data transfer is encrypted and the system is designed to prevent their unauthorized use during data transfer.

➢ Data will be stored on the central server on Masaryk University in Brno in Oracle 11g database.

➢ The technological aspect of the project, that is data collection, storage and backup and their analysis will be provided by the Institute of biostatistics and analyses, Masaryk University, Brno, Czech Republic (IBA MU). During the course of the study, data are owned by health care institutions and are allowed to use them in any way. After the cooperation with the particular site is finished, data will be withdrawn from the database and sent to the respective site.

➢ Database users can print the submitted patient forms.

Contents

1   Database Connection

The database can be accessed from the website

http://empire.registry.cz/index-en.php

Please enter your username and password and click on the "Login" button (see Figure 1).
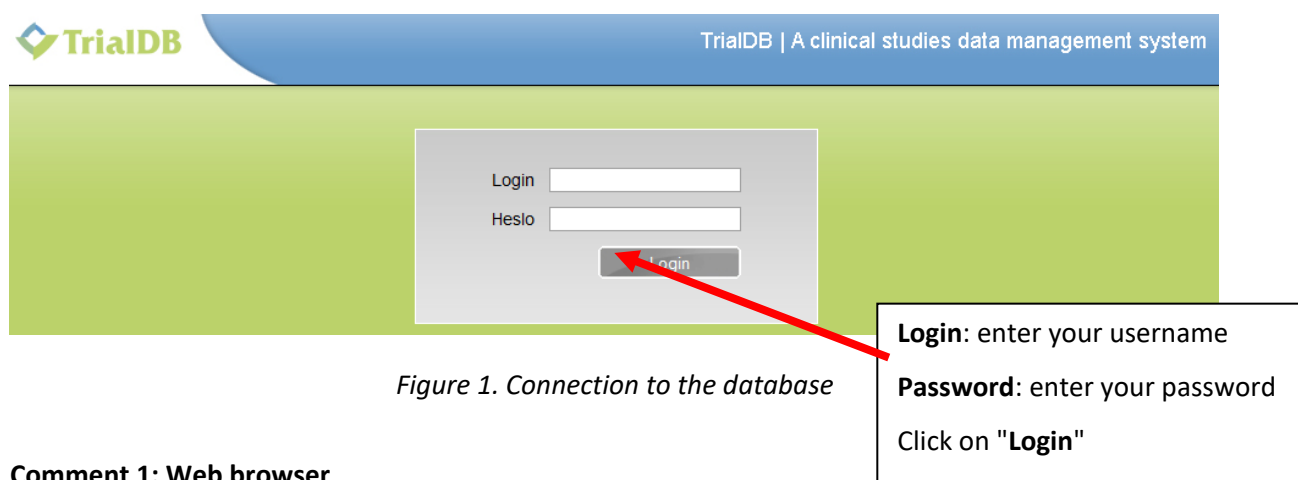
Figure 1. Connection to the database

Login: enter your username
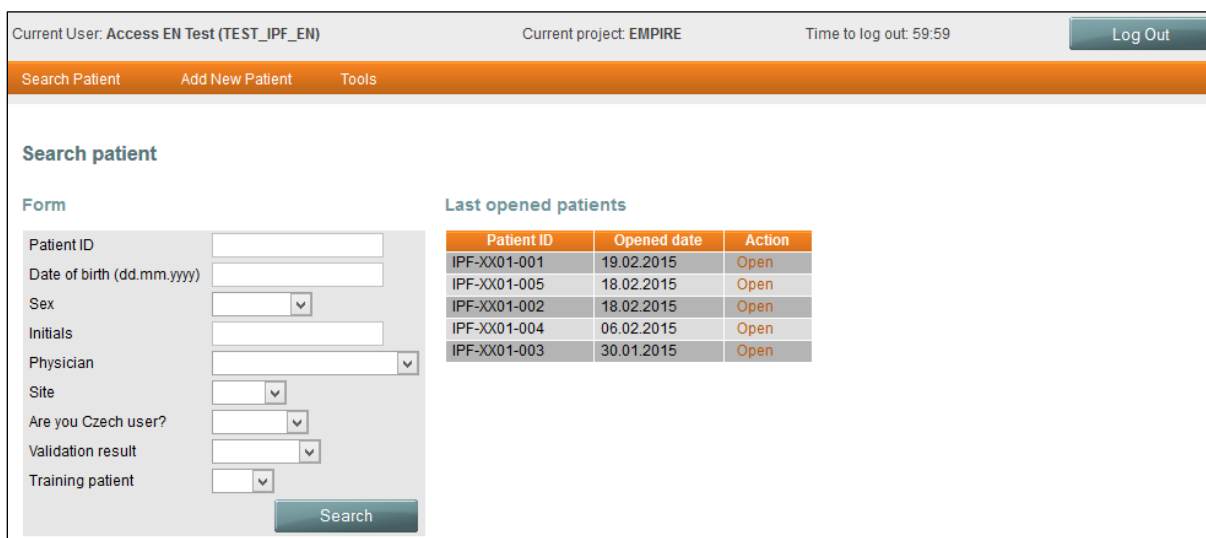Password: enter your password
Click on "Login"

Comment 1: Web browser

To access the database, use the Internet browser supporting JavaScript and secured communication (https protocol). Internet Explorer version 5.5 or higher or Mozilla Firefox version 2.0 or higher are examples of such browsers. In this user guide, the web browser Mozilla Firefox version 27.0.1 is used to demonstrate the work with the database.

After clicking on "**Login**" button, you will be logged in the system (see Figure 2). It is possible to start work with the basic application window immediately (see Chapter 2, Basic Application Window).

2 Basic Application Window

After you connect to the database, the basic application window will display (see Figure 2). This window makes it possible to search submitted patient forms (see Chapter 4, Patient Search), register a new patient (see Chapter 3, New Patient Registration), change your password (see **A** in Figure 3) and display information about Helpdesk (see **B** in Figure 3). You can also find some additional information under the Help button, for example list of drugs, Informed Consent Form, Health questionnaire EuroQoL etc. (see **C** in Figure 3). You can log out the system using the button "**Log Out**" in the upper right corner (see red ellipse in Figure 3).
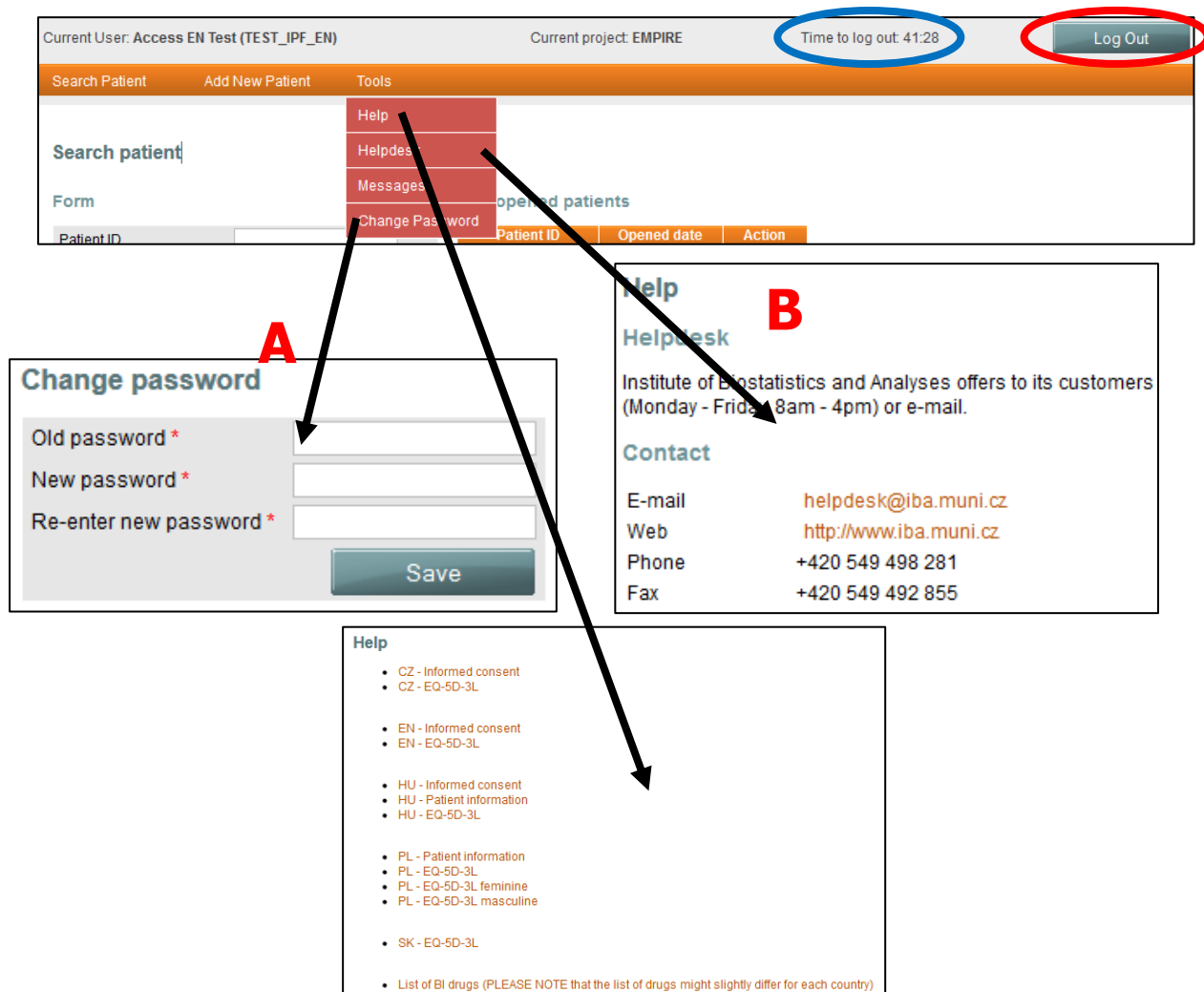

Figure 2. Basic application window

Figure 3. Initial page of the system

Comment 2: **Automatic logout**

When you are inactive for a rather long period of time, you will be logged out automatically. 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.

The log out time is displayed next to the project title in the screen header (blue ellipse in Figure 3). You can select from these options when entering data into the forms:

    a)   Submit a new patient form (see Chapter 3, New Patient Registration)

    b)   Search submitted patient forms (see Chapter 4, Patient Search)

3   New Patient Registration

By clicking the "**Add New Patient**" link (see red ellipse in Figure 4) in the initial page of the system, a form to submit information about a new patient will be displayed. Please enter all required data in the form, the system will generate a unique ID based on these data:

1. "**Date of birth**" of the patient has to be entered in the required form (dd.mm.yyyy), otherwise the system will not accept it

2. "**Sex**" of the patient

3. Patient's "**Initials**", using first letters of name and surname (NS, NameSurname)

In the next step, please check or select the particular "**Physician**" (green parenthesis in Figure 4), the particular "**Site**" (brown parenthesis in Figure 4) in which the patient had been registered from the preset list and whether you are Czech user or not. If you only want to try work with the database, check the box "**Training patient**" (brown rectangle in Figure 4).
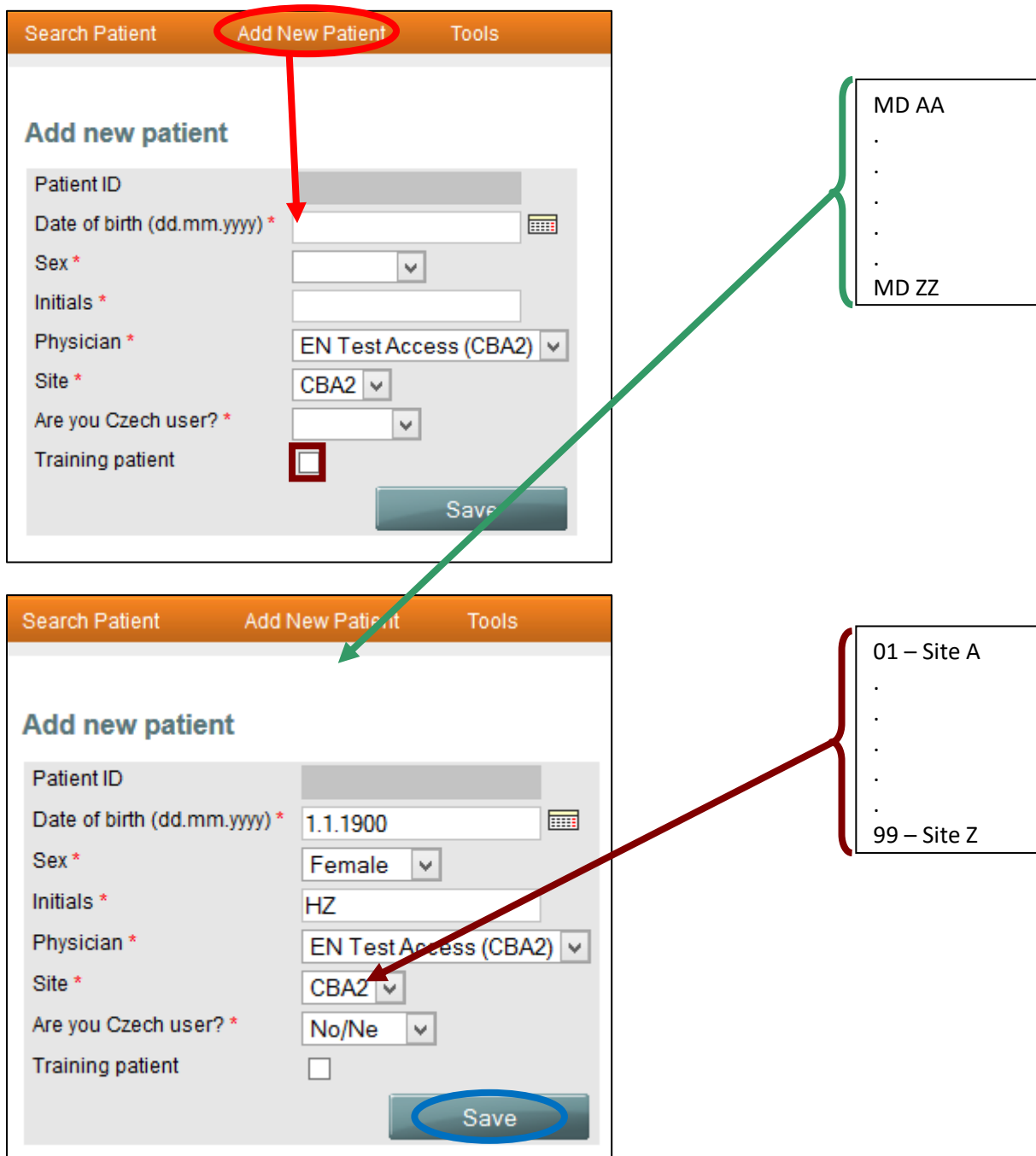
By clicking the "**Save**" link (blue ellipse in Figure 4), a unique "**Patient ID**" will be generated. The patient ID will be generated in the following form:

IPF-XX01-001 (see the Figure), meaning:

  IPF **- Project EMPIRE abbreviation**

  XX01 **- Site acronym (country according to ISO 3166-2 + number of centre in that country)**

  001 **- Patient order in the current site (generated automatically from 001 to 999)**
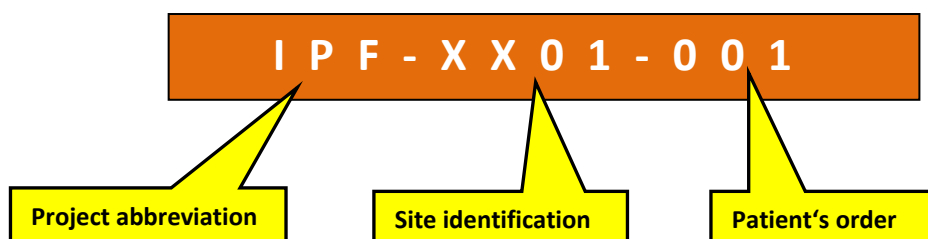
The example of a new patient registration is presented in Figure 4.

Figure 4. New patient registration
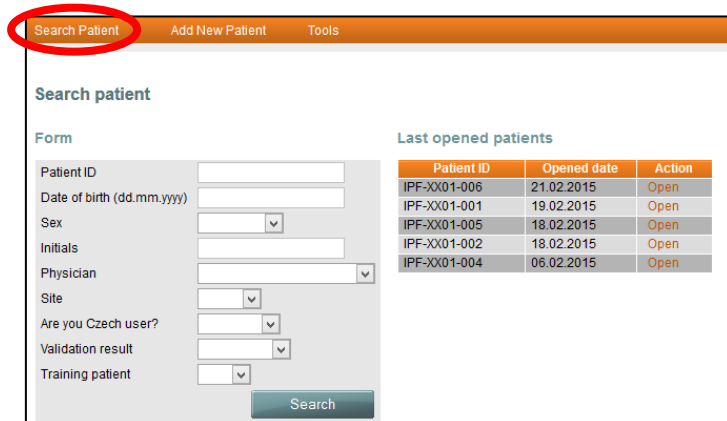
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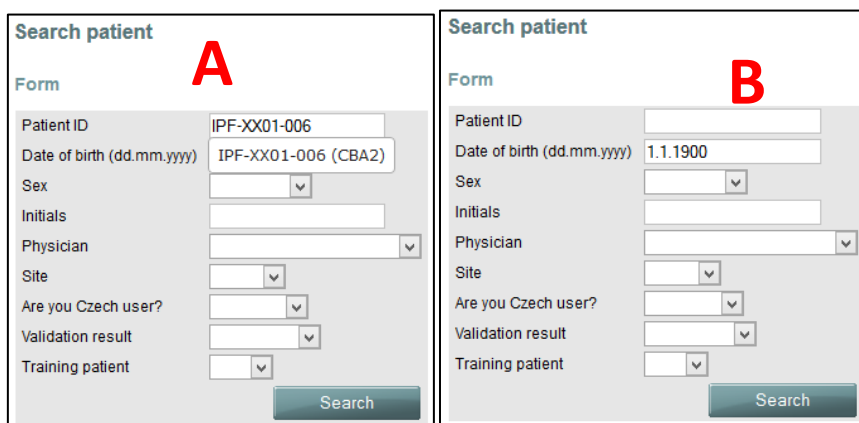
4 Patient Search

There are two ways to find the registered patient/patients (see the link "**Search Patient**", red ellipse in Figure 5):

A) **If you know the patient's ID,** please enter this ID in the respective field and click the "**Search**" button (see **A** in Figure 5). The record of this patient will be displayed.

B) **If you know it was you personally who had registered the patient**, please select the respective site and click the "**Search**" link (see **B** in Figure5). Records of all patients registered in the particular site will be displayed. If too many records are displayed, we recommend to enter as many additional information about a patient as possible to limit the number of displayed records, that is "**Date of birth**," "**Sex**" or "**Initials**" and click on the **"Search"** button again. The number of records found will be notably reduced.

After you have found the patient, click on the "**Open**" link (see blue ellipse in Figure 5) and you will be brought to the main part of the system in which all electronic patient forms are saved.

Figure 5. Patient search
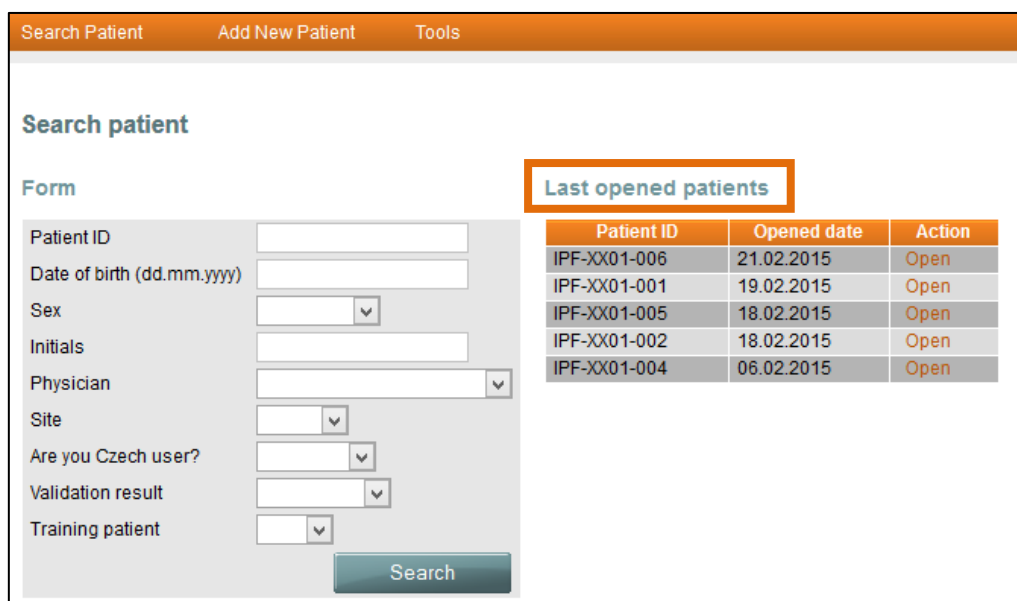
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By clicking the **"Search"** button, the system will list all submitted patient records, to which you have access and which correspond to the submitted criteria. There is a maximum of 50 patient records in one page. To move to the next page of records found, click on the range of numbers which are tinged with blue (see red rectangle in Figure 6).

Figure 6. Moving to the next page of the records found

Comment 3: Quick access to recently opened patient records

For quick access to the recently opened patient records, there is a table in the right part of the basic application window in which the patient records are ordered chronologically (Figure 7).

Figure 7. Last opened patient records

Comment 4

Search results (see Figure 8) can be ordered in ascending order or descending order according to various criteria: **Patient ID** (see **A** – descending order according to patient ID), **Site**, **Date of birth**, **Sex**, **Date of submission** to the study and name of the person who had submitted the patient record (see **B** – ascending order according to the criterion **Date of Birth**).

Result of the search

Number of records found 6

Records: 1-6

A

Patient ID	Site	Date of birth (dd.mm.yyyy)	Sex	Are you Czech user?	Date of enrollment	Enrolled by	Validity	Action
IPF-XX01-006	CBA2	01.01.1900	Female	No/Ne	21.02.2015	EN Test A.	Not known	Open
IPF-XX01-005	CBA2	15.06.1975	Male	No/Ne	09.02.2015	EN Test A.	Valid	Open
IPF-XX01-004	CBA2	02.02.1950	Male	No/Ne	02.02.2015	EN Test A.	Valid	Open
IPF-XX01-003	CBA2	15.06.1982	Male	No/Ne	29.01.2015	EN Test A.	Valid	Open
IPF-XX01-002	CBA2	01.01.1965	Female	No/Ne	10.12.2014	EN Test A.	Valid	Open
IPF-XX01-001	CBA2	01.01.1990	Female	No/Ne	10.12.2014	EN Test A.	Valid	Open

Result of the search

Number of records found 6

Records: 1-6

B

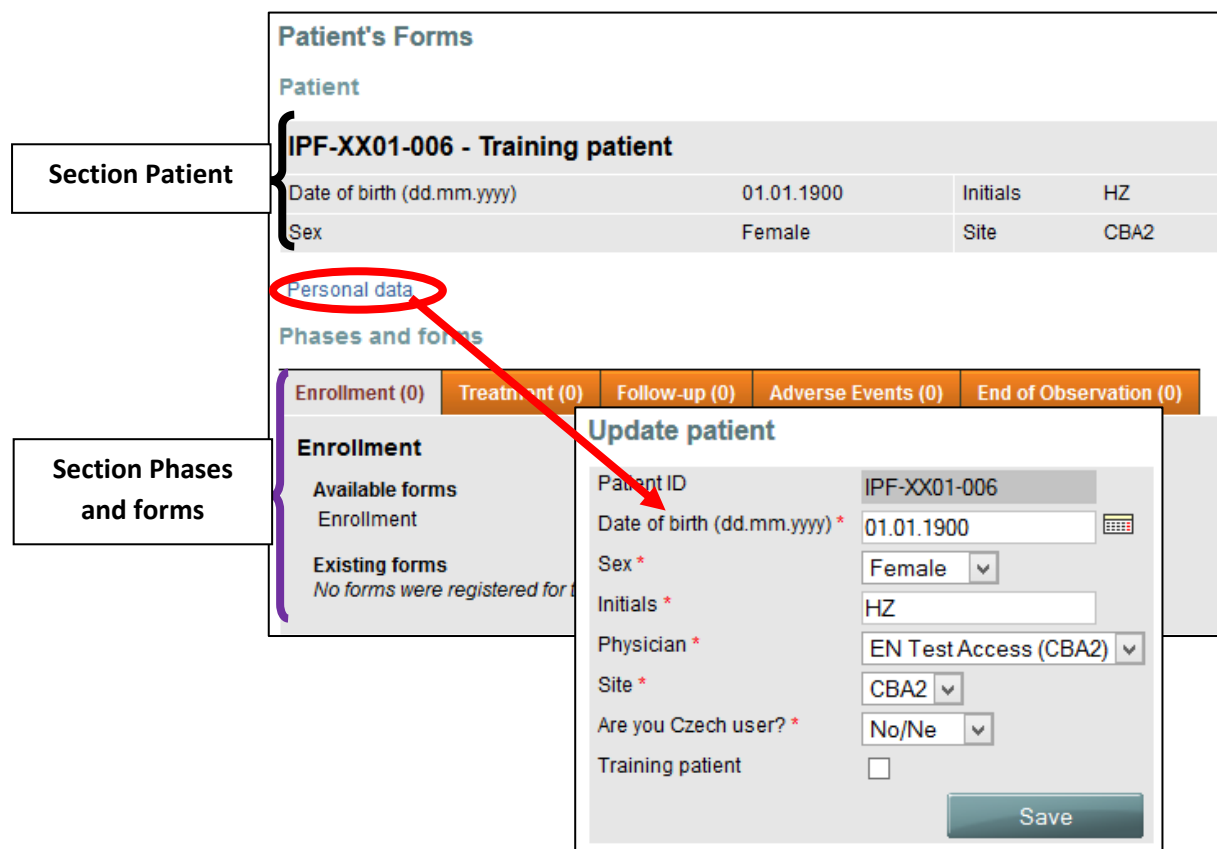| Patient ID	Site	Date of birth (dd.mm.yyyy)	Sex	Are you Czech user?	Date of enrollment	Enrolled by	Validity	Action
IPF-XX01-006	CBA2	01.01.1900	Female	No/Ne	21.02.2015	EN Test A.	Not known	Open
IPF-XX01-004	CBA2	02.02.1950	Male	No/Ne	02.02.2015	EN Test A.	Valid	Open
IPF-XX01-002	CBA2	01.01.1965	Female	No/Ne	10.12.2014	EN Test A.	Valid	Open
IPF-XX01-005	CBA2	15.06.1975	Male	No/Ne	09.02.2015	EN Test A.	Valid	Open
IPF-XX01-003	CBA2	15.06.1982	Male	No/Ne	29.01.2015	EN Test A.	Valid	Open
IPF-XX01-001	CBA2	01.01.1990	Female	No/Ne	10.12.2014	EN Test A.	Valid	Open

Figure 8. Order of patients

5 Working Window of the Application

The working window of the application is divided into two interconnected sections:

> a) section Patient
>
> b) section Phases and forms

The Patient section contains basic information about a patient which are automatically copied from the data submitted in a new patient registration form (see Chapter 3, New Patient Registration). In this section, it is also possible to edit (modify) personal data of a patient by clicking the "**Personal data**" link (see red ellipse in Figure 9).
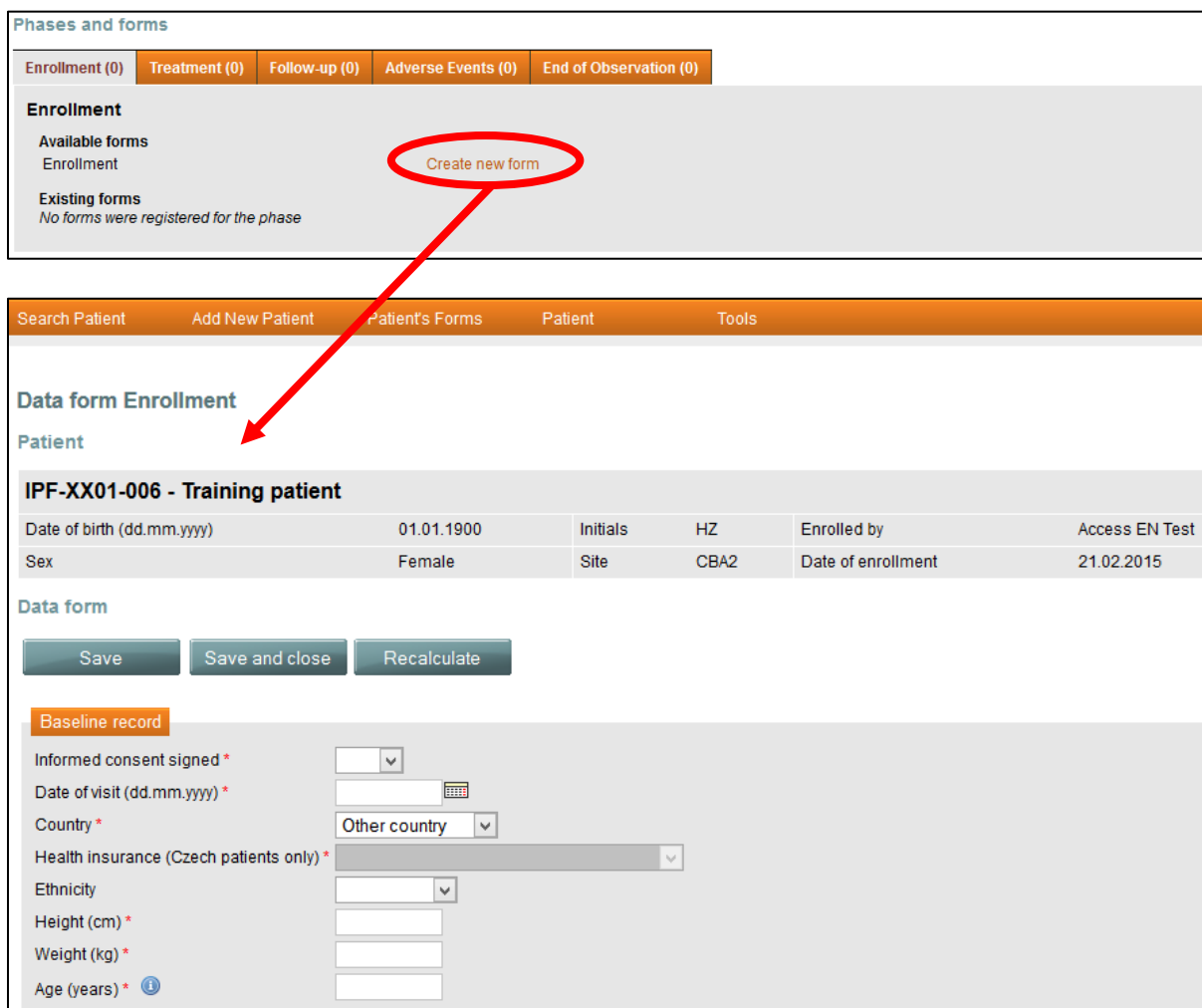
Figure 9. Personal data update

In the section **Phases and forms,** you can:

> a) Create a new form (see Chapter 6, Creation of a New Form)
>
> b) Edit the existing form (see Chapter 8, Work with Submitted Forms)

6   Creation of a New Form

In order to create a new form, it is necessary to search for the respective patient (see Chapter 4, Patient Search). Create a new form by clicking on the "**Create new form**" button (see red ellipse in Figure 10).

Figure 10. Creation of a new form

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7   Form Completion

The window of each form is divided into three sections (see example in Figure 11 with the form called Questionnaires displayed):
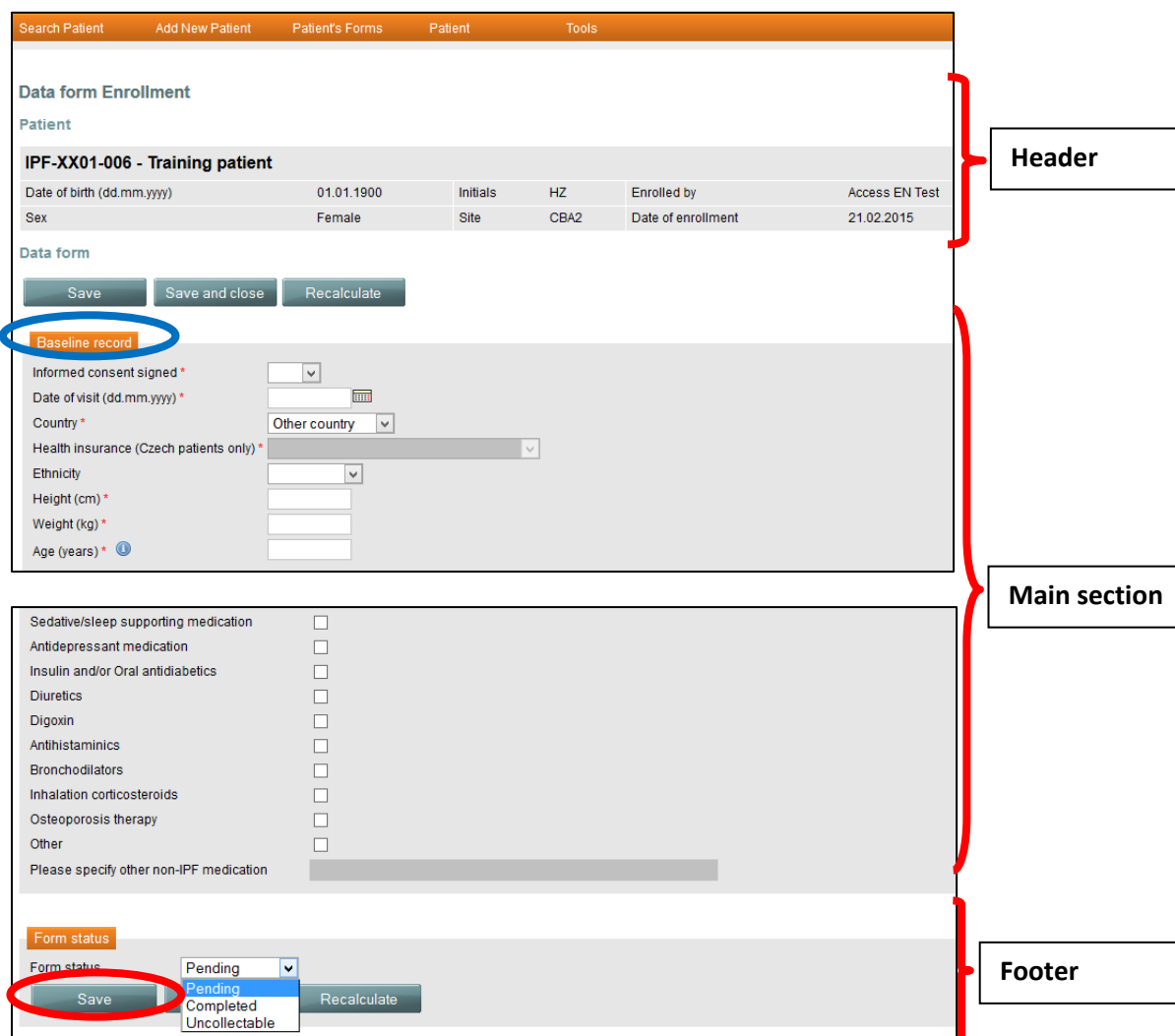
> 1) **header** – contains basic information about the patient
>
> 2) **main section** – contains the respective form where the patient data are to be submitted
>
> 3) **footer** – contains information about the form status

The <u>header</u> contains basic information, that is **Patient ID, Date of Birth, Sex, Initials, Date of Submission, Enrolled by** and **Site**

The <u>main section</u> contains the respective form where the patient data are to be submitted. It is divided into subsections emphasized in bold (see blue ellipse in Figure 11). You can move within the form using the arrows of the scrollbar on the right. The form contains white and grey entry fields to enter the data.

The <u>footer</u> contains the selection menu specifying the status of the form. The options **Pending, Completed** and **Uncompletable** provide the information about the status of your work with the form. You can save data entered in the form by clicking on "**Save**" button (see red ellipse in Figure 11).

> ➢ In case you did not manage to complete the whole form for any reason, select the "**Pending**" option.
>
> ➢ In case all entry fields are entered and the form is complete, select the "**Completed**" option.
>
> ➢ In case it is not possible to obtain information necessary for proper completion of the form, select the "**Uncollectable**" option.

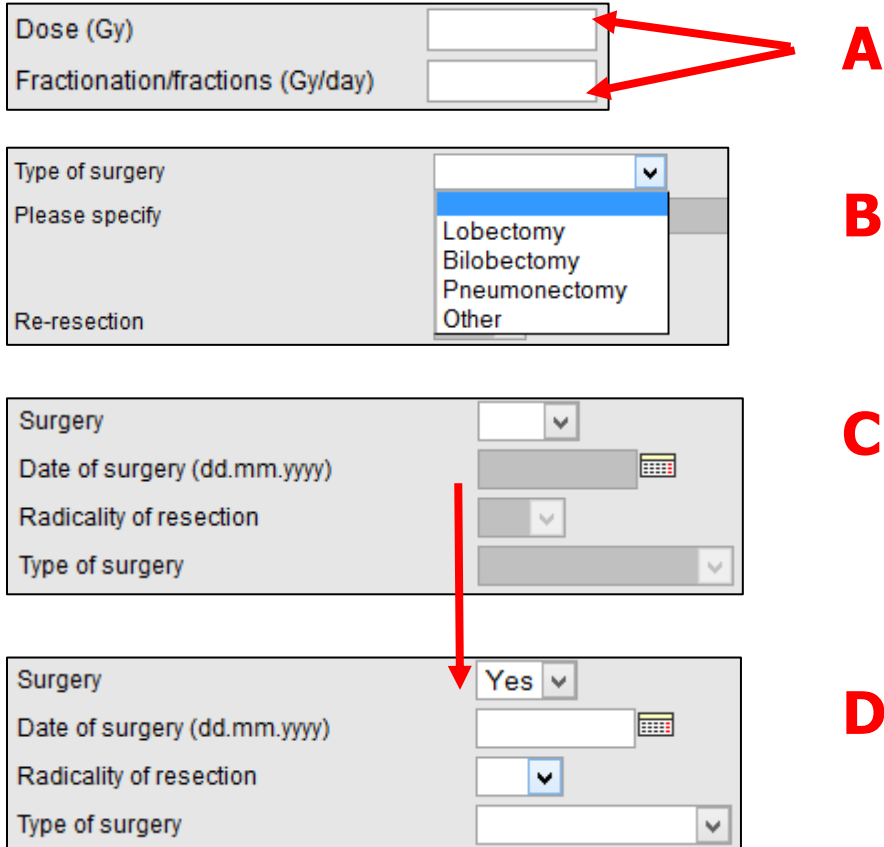*Figure 11. Form completion*

Comment 5: Saving changes

Click on the "**Save**" button in order to save changes. Automatic saving of data cannot be guaranteed if work with the form is finished without saving it.

Comment 6:

If you enter data into a form, do not save it and quit the registry without clicking on the "**Log Out**" button, the system will usually save the data and will ask you at your next login whether you want to save the data you have entered (but not saved yet) previously.

Data are entered on the same principle in all forms. Forms contain entry fields tinged with white and grey. In basic *White fields,* data are filled in directly (see **A** in Figure 12) or by selecting the option in the

15

selection menu (see **B** in Figure 12). *Grey fields* depend on the answer to the previous question (see **C** in Figure 12). If the completion of the grey field is required based on the previous answer, the grey field will change its color to white (see **D** in Figure 12) which will enable to enter the data or to select data from the preset options.

Figure 12. Field types

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8   Work with Submitted Forms

Submitted forms can be modified/edited using the "**Open**" button (see **A** in Figure 13), printed using the "**Printable**" (see **B** in Figure 13) or deleted using the "**Delete**" button (see **C** in Figure 13).

CAUTION: Deletion of the form/all record

Deletion of the form is an irreversible action. We recommend to use this function only after careful consideration. **Deletion of whole patient record** including the ID from the database can be perfomed by HelpDesk employees only. Such request has to be sent to the HelpDesk by email. The stored record can not contain any forms (all submitted forms must be deleted using the "**Delete**" button).

Figure 13. Work with the form

9 Sharing of Patient Record

Physicians within one site share patient records automatically, so there is no need to use any tools to display/edit patient records submitted by other physician at the same site.

If you decide to share the patient record with other physicians from different sites, find the respective patient and click on "**Share Patient**"(blue ellipse in Figure 14). This function is useful when the patient had been transferred to another health care institution which continues in the patient data submission.

There is the following procedure of sharing the patient record: first, find the respective patient record, use the tab "**Patient**" → "**Share Patient**", and select the site and the authorized physician with which the patient will be shared. Finally, confirm these steps by clicking on the "**Save**" button (red ellipse in Figure 14). The procedure of sharing the patient record with the particular physician is presented in Figure 14.

There are <u>two possibilities of authorization</u> when sharing the patient record:

➢ **Read only** – the sharing physician can only read the patient information

➢ **Read/Write** – the sharing physician can read and edit the patient information (that is complete or specify it)
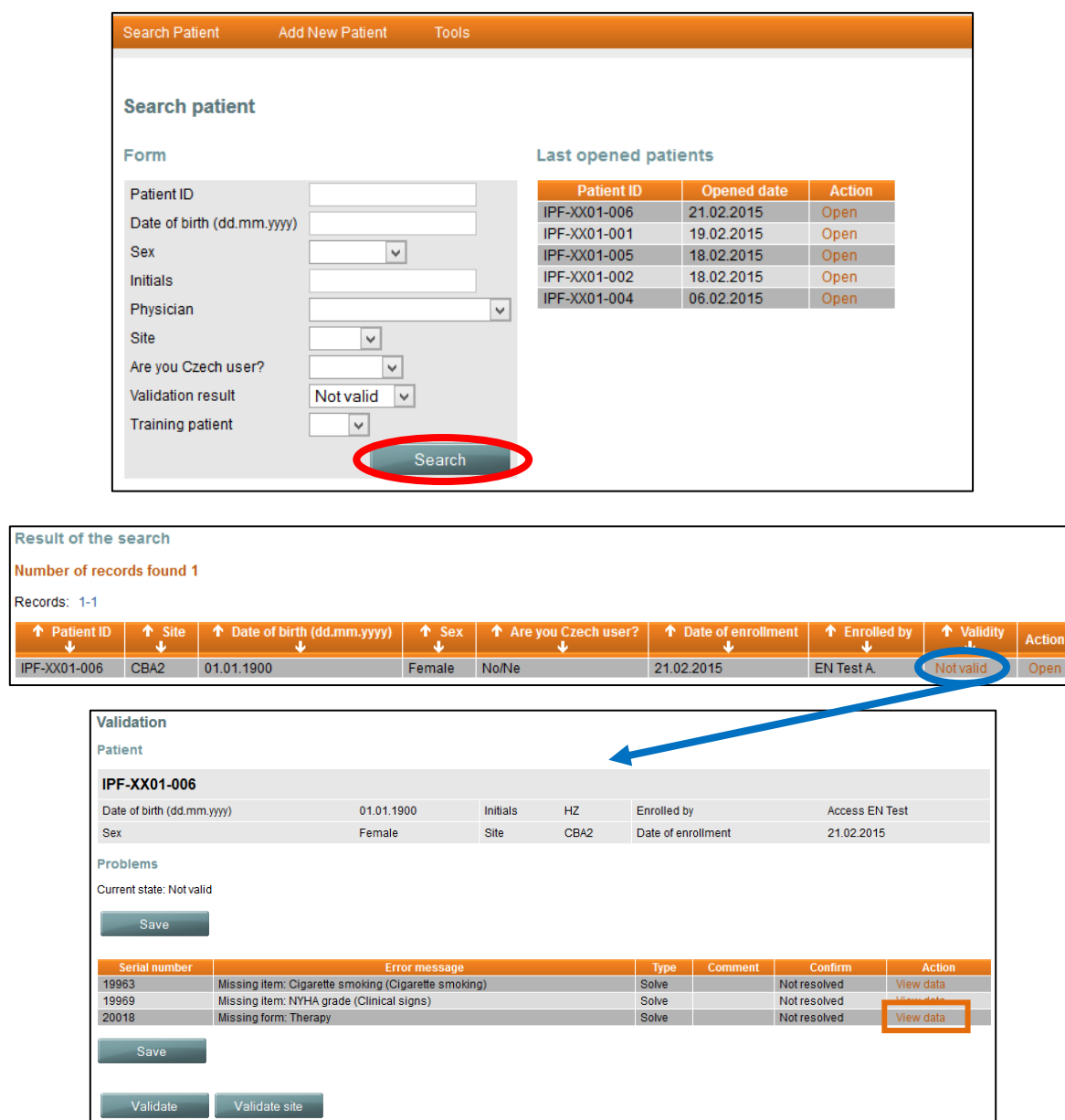
Figure 14. Sharing of patient record

10 Validation of records

If you want to look up patient records that are not valid, select the item "**Not valid**" in the "**Validation result**" in the search form (see Chapter 4, Patient Search) and click on the "**Search**" button (red ellipse in Fig. 15). Then click on the "**Not valid**" item (blue ellipse in Fig. 15). The system will then list problems found in the records of that specific patient. In order to remedy the problem right away, click on "**View data**" (orange rectangle in Fig. 15) and you will be moved into the "Forms" section.

Figure 15. Search of patient according to validation result

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In practice, data is validated according to several previously defined rules. The function "**Validation**" in the registry looks for items which must be entered if any given record has to be assessed as valid; mutual relationships among entered data are also assessed. All found problems <u>must be</u> **addressed** (see green rectangle in Figure 15); alternatively, <u>correctness of data or impossibility of entering that data must be</u> **confirmed**. The field "**Comment**" can be used to specify in more detail why that data cannot be entered.

The function "**Validate site**" validates all patients recorded within a specific centre (see red ellipse in Figure 16).

If the patient's validity status is "**Not known**", the record can be validated using the button "**Validate**". Apart from this possibility, **the system checks the validity of patients automatically once a day** (at night).
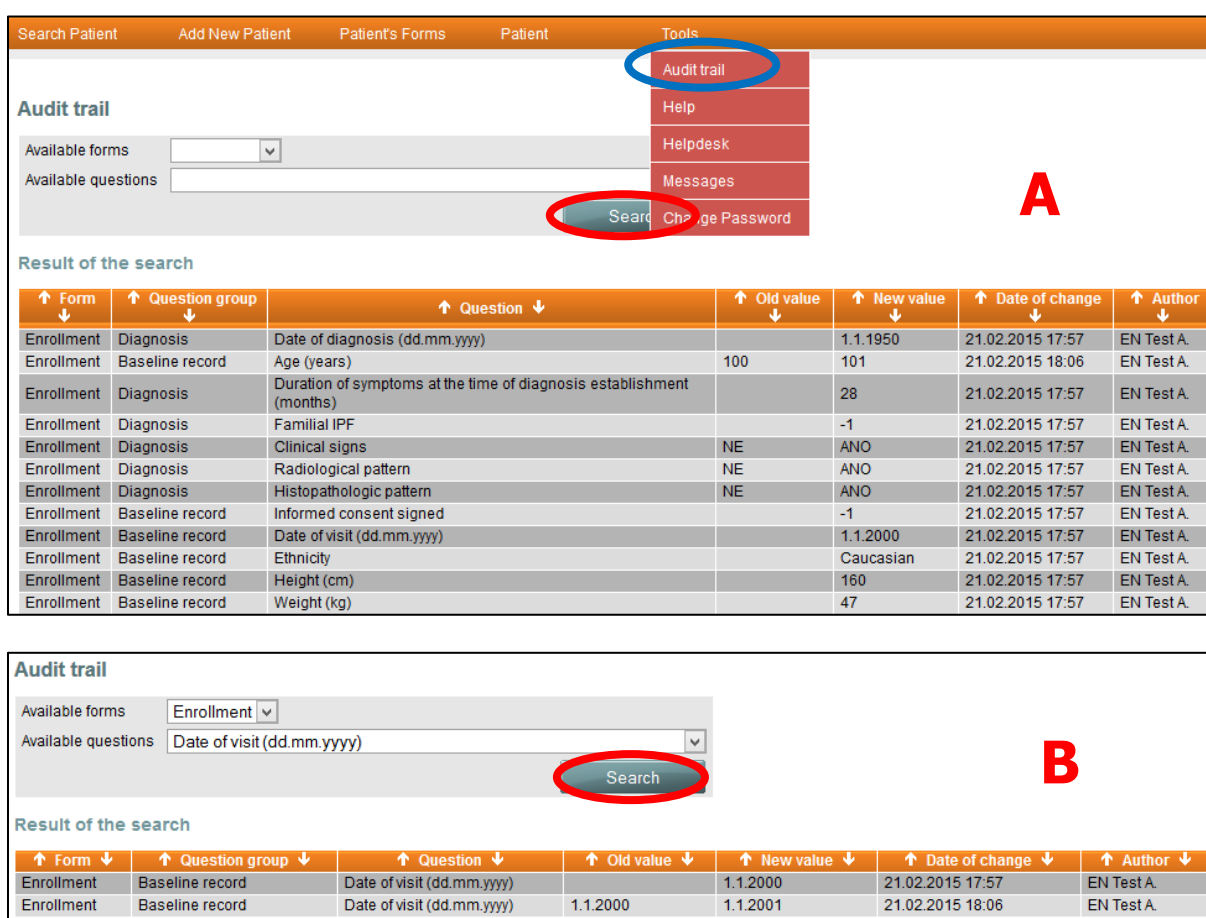

Figure 16. Validation of patients

11 Audit trail

There is a function Audit trail to track changes made in the forms. First, select the patient, then move to the "**Tools**" section menu and select "**Audit trail**" (see blue ellipse in Figure 17). If you want to track all changes made in the patient record forms, leave both fields empty and click on the "**Search**" button (see red ellipse in Figure 17). In this case, any changes made in the forms will be listed under the window Audit trail (see **A** in Figure 17). If you want to limit the listed changes to the particular form or question, fill in the entry fields "**Available forms**" and "**Available questions**" (see **B** in Figure 17).

Figure 17. Audit trail

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12   Problem Reporting

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