

Registry INTERB

USER GUIDE

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Online Data Collection – General Information

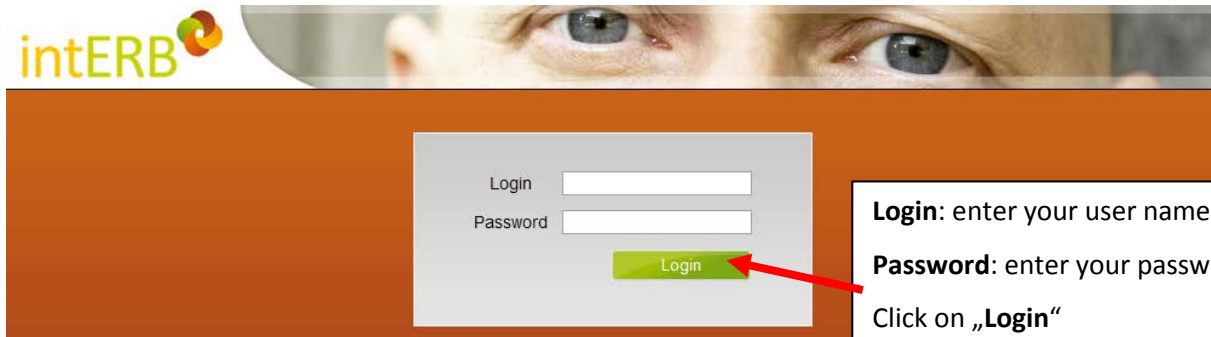
- On-line data collection is based on a TRIALDB system developed on Yale University, Connecticut, USA, which is widely used for this purpose
- The system is user-friendly; all data will be entered using web forms analogical to paper CRF/DCFs.
- Data can be entered from any computer with Internet access 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 9i 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 After the cooperation with the particular site is finished, data will be withdrawn from the database and sent to the respective site.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

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1 Database Connection

The database can be accessed from a web page <http://interb.registry.cz/> by clicking the “Registry entry” button. After you click on the „Enter the registry” you will be redirected to the Login Page (see Picture 1).

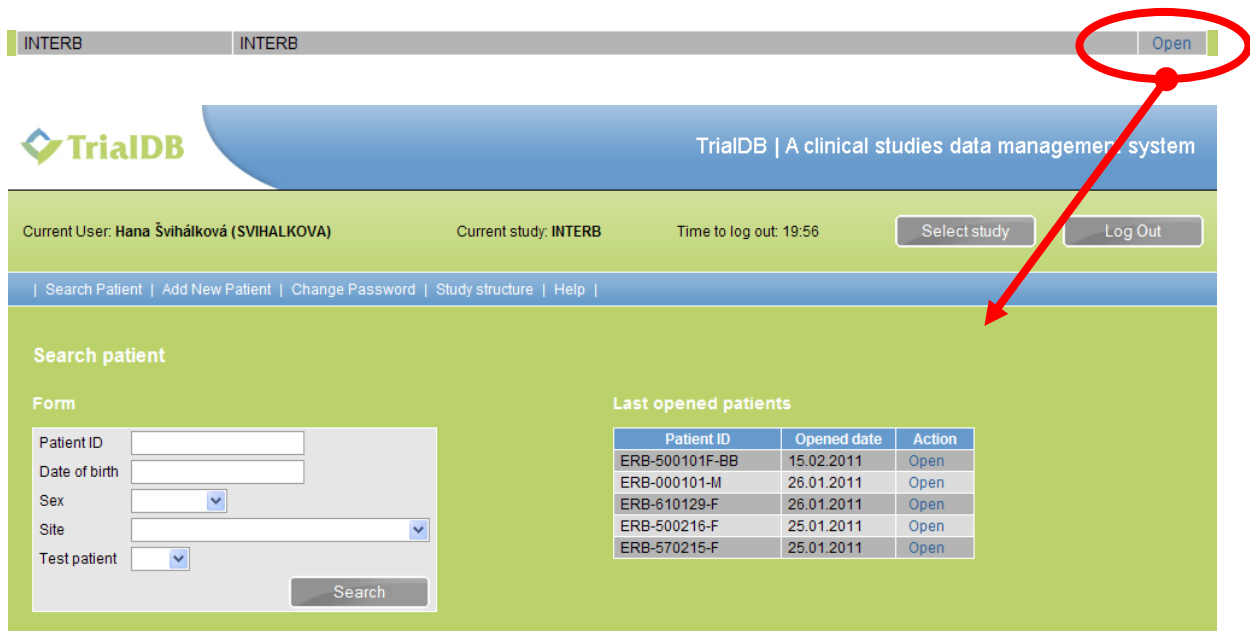


Picture 1. Connection to the database

Comment 1:

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 MS Internet Explorer version 7 is used to demonstrate the work with the database.

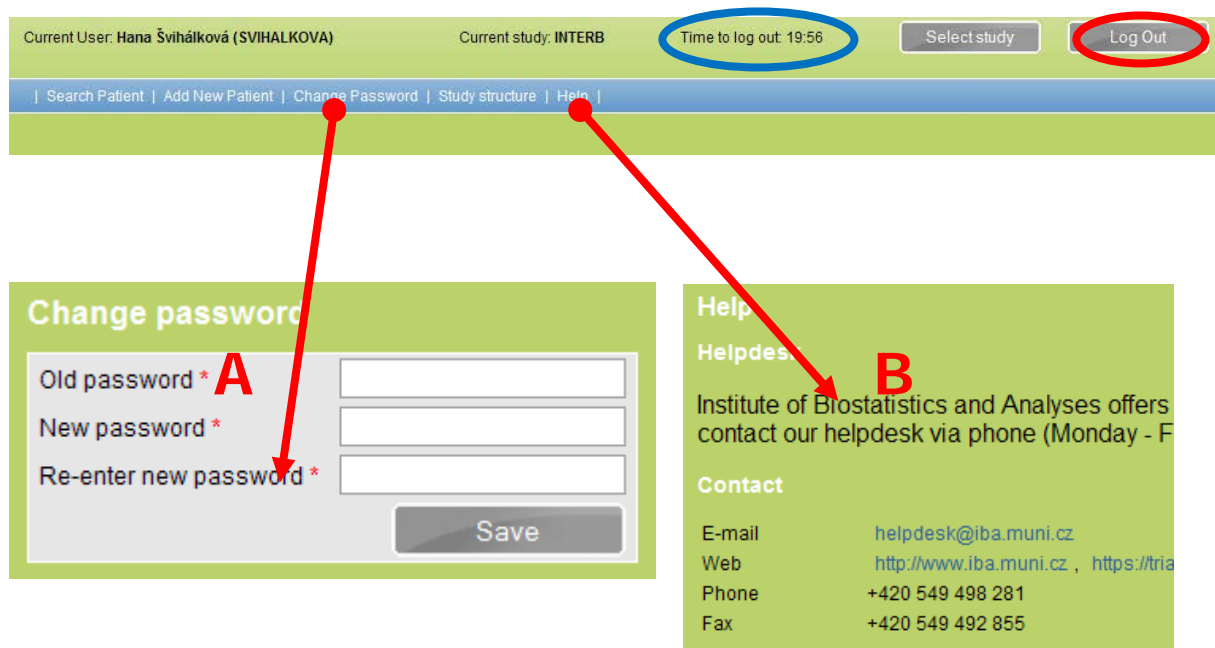
After clicking on „Login“ button, you will be logged in the system. A window will be displayed in which the user can select a project to enter data (see red ellipsis in Picture 2). If the user has rights to access only one project database, it is possible to start work with the basic application window immediately (see [Chapter 2, Basic Application Window](#)).



Picture 2. Project selection

2 Basic Application Window

After you connect to the database, the basic application window will display (see Picture 3). This window enables to search submitted patient forms (see [Chapter 4, Patient Search](#)), register a new patient (see [Chapter 3, New Patient Registration](#)), change personal password (see **A** in Picture 3) and display Help (see **B** in Picture 3). You can log out the system using the button „Log Out“ in the upper right corner (see red ellipsis in Picture 3).



Picture 3. Initial page of the system

Comment 2

When you are inactive for a rather long period of time, you will be logged out automatically. To continue working, 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 ellipsis in Picture 3)

You can select from these options when entering data into the forms:

- Submit a new patient form (see [Chapter 3, New Patient Registration](#))
- Search submitted patient forms (see [Chapter 4, Patient Search](#))

3 New Patient Registration

By clicking the „**Add New Patient**“ link (see red ellipsis in Picture 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:

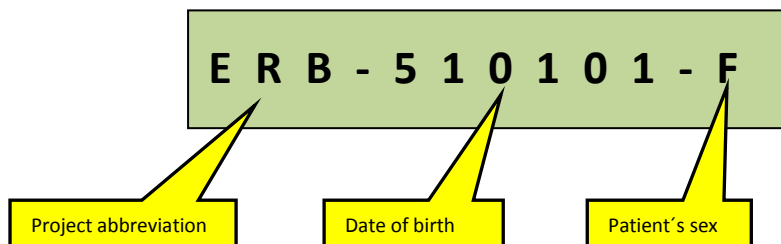
1. „**Date of birth**“ of the patient has to be entered in the required form (DD.MM.YYYY), otherwise the system will not accept it
2. „**Sex**“ of the patient
3. Patient’s „**Initials**“, using first letters of name and surname (NS, NameSurname)

In the next step, please check or select the particular „**Physician**“ (green parenthesis in Picture 4) and the particular „**Site**“ (brown parenthesis in Picture 4) in which the patient had been registered from the preset list. If you only want to try work with the database, check the box „**Test patient**“ (brown rectangle in Picture 4).

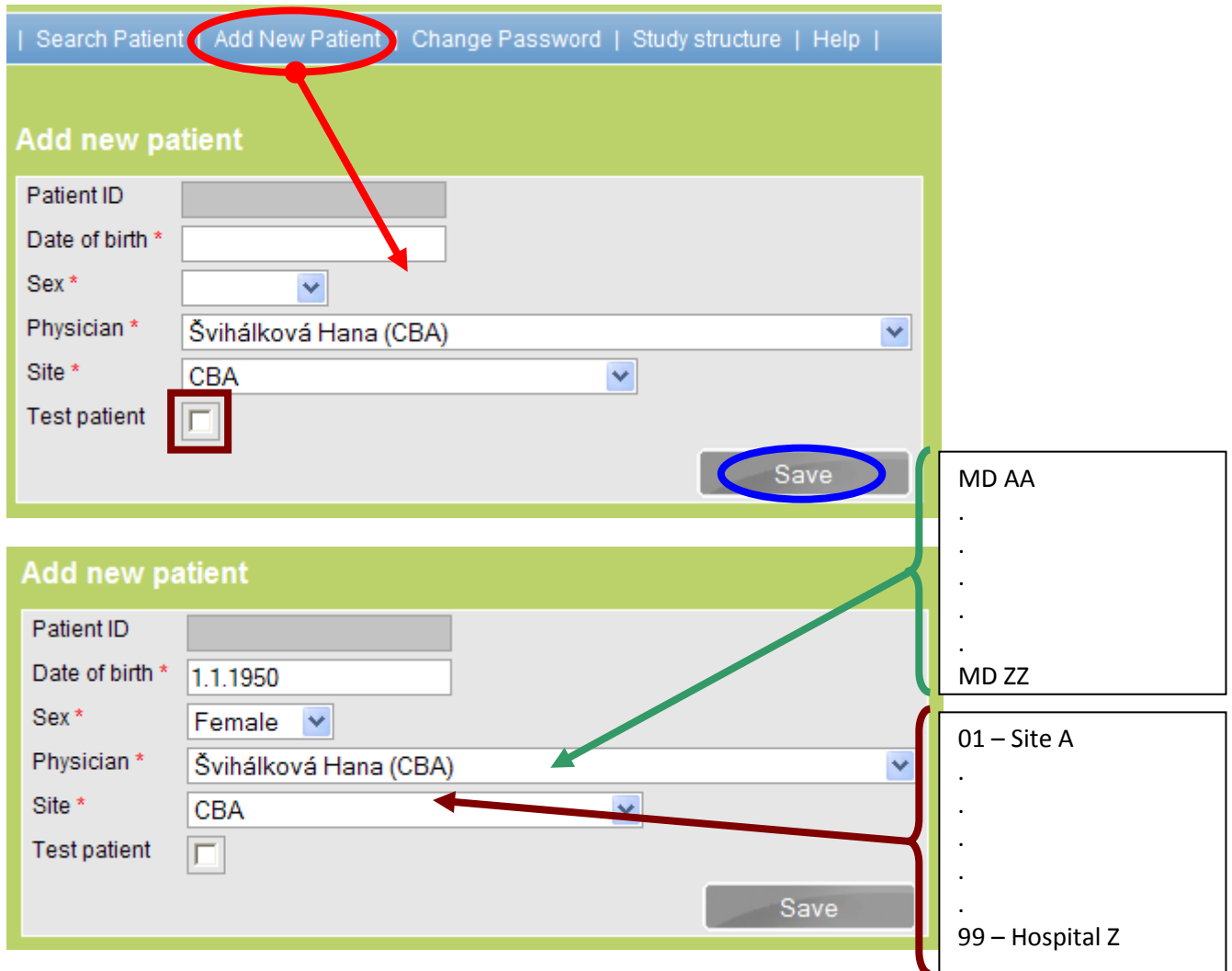
By clicking the „**Save**“ link (blue ellipsis in Picture 4), a unique „**Patient ID**“ will be generated (purple ellipsis in Picture 4). The patient ID will be generated in the following form:

ERB-CZ00-123-NS (see the Picture), meaning:

ERB	- Project INTERB abbreviation
510101	- Date of birth (YYMMDD)
F	- Patient’s sex (M/F)



The example of a new patient registration is presented in Picture 4.



Picture 4. New patient registration

Comment 3:

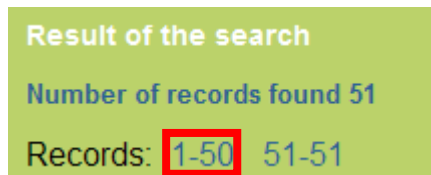
If you directly want to work with the database (e.g. to complete patient forms), button **“Save”**. You will be brought to the main part of system (see Working Window of the Application), in which all forms are stored. This main part of the system can also be accessed by clicking the **„Patient forms“** button.

4 Patient Search

There are two ways to find the registered patient/patients (see the link „**Search Patient**“, red ellipsis in Picture 7):

- A) **If you know the patient's ID**, please enter this ID in the respective field and click the „**Search**“ button (see **A** in Picture 7). 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 Picture 7). 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.

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 Picture 5).



Picture 5. Moving to the next page of the records found

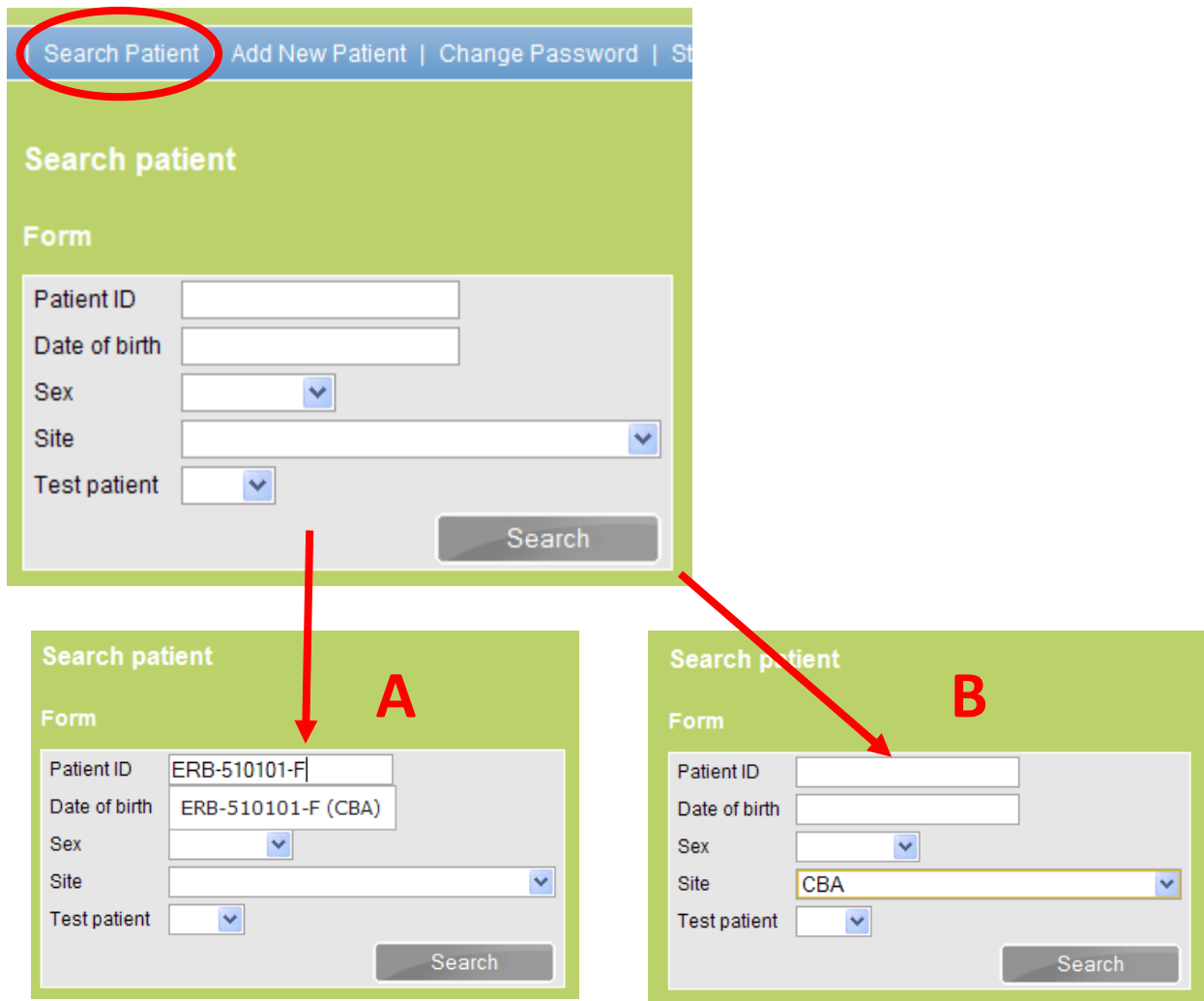
After you have found the patient, click on the „**Open**“ link and you will be brought to the main part of the system in which all electronic patient forms are saved.

Comment 4:

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.

Last opened patients		
Patient ID	Opened date	Action
ERB-860405-M	14.03.2011	Open
ERB-620201-F	14.03.2011	Open
ERB-510101-F	14.03.2011	Open
ERB-500101F-BB	15.02.2011	Open
ERB-000101-M	26.01.2011	Open

Picture 6. Last opened patient records



The screenshot displays the 'Search patient' interface. At the top, a navigation bar contains 'Search Patient', 'Add New Patient', 'Change Password', and 'St'. The 'Search Patient' link is circled in red. Below the navigation bar is the 'Search patient' section with a 'Form' containing the following fields:

- Patient ID:
- Date of birth:
- Sex: (dropdown)
- Site: (dropdown)
- Test patient: (dropdown)
- Search:

Two red arrows point from the 'Search' button in the main form to two smaller screenshots labeled 'A' and 'B'.

A shows the search results for Patient ID 'ERB-510101-F'. The Date of birth field is populated with 'ERB-510101-F (CBA)'. The other fields are empty.

B shows the search results for Site 'CBA'. The Patient ID field is populated with 'CBA'. The other fields are empty.

Picture 7. Patient/s search

Comment 5:

Search results (see Picture 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 **Enrolled by**).

A

Result of the search

Number of records found 28

Records: 1-28

↑ Patient ID ↓	↑ Site ↓	↑ Date of birth ↓	↑ Sex ↓	↑ Date of enrollment ↓	↑ Enrolled by ↓	Action
22	CBA	04.04.1972	Male	19.01.2009	Test T.	Open
123	CBA	12.12.1956	Female	10.11.2008	Test T.	Open
101010	CBA	10.10.1950	Male	24.11.2008	Test T.	Open
test7	CBA	03.03.2003	Male	16.10.2008	Brabec P.	Open
TEST231	CBA	15.02.1975	Female	14.10.2008	Brabec P.	Open
TEST_LAPATINIB	CBA	01.01.2000	Unknown	10.10.2008	Kluska A.	Open
TEST_DK2	CBA	01.10.2000	Female	14.10.2008	Administrátor C.	Open
Kalna Arija	CBA	02.02.1950	Female	24.11.2008	Test T.	Open
ERB-860405-M	CBA	05.04.1986	Male	14.03.2011	Švihálková H.	Open
ERB-771230-F	CBA	30.12.1977	Female	08.06.2010	Krčmařová O.	Open

B

Result of the search

Number of records found 28

Records: 1-28

↑ Patient ID ↓	↑ Site ↓	↑ Date of birth ↓	↑ Sex ↓	↑ Date of enrollment ↓	↑ Enrolled by ↓	Action
TEST_DK2	CBA	01.10.2000	Female	14.10.2008	Administrátor C.	Open
TEST231	CBA	15.02.1975	Female	14.10.2008	Brabec P.	Open
test7	CBA	03.03.2003	Male	16.10.2008	Brabec P.	Open
ERB-500101F-BB	CBA	01.01.1950	Female	30.03.2009	Bureš P.	Open
ERB-500101M-AA	CBA	01.01.1950	Male	30.03.2009	Bureš P.	Open
ERB-500101-F	CBA	01.01.1950	Female	11.03.2011	IBA M.	Open
ERB-751105-F	CBA	05.11.1975	Female	14.06.2010	Kandrnal V.	Open
TEST_LAPATINIB	CBA	01.01.2000	Unknown	10.10.2008	Kluska A.	Open
ERB-000101-M	CBA	01.01.2000	Male	04.06.2010	Kokrment L.	Open

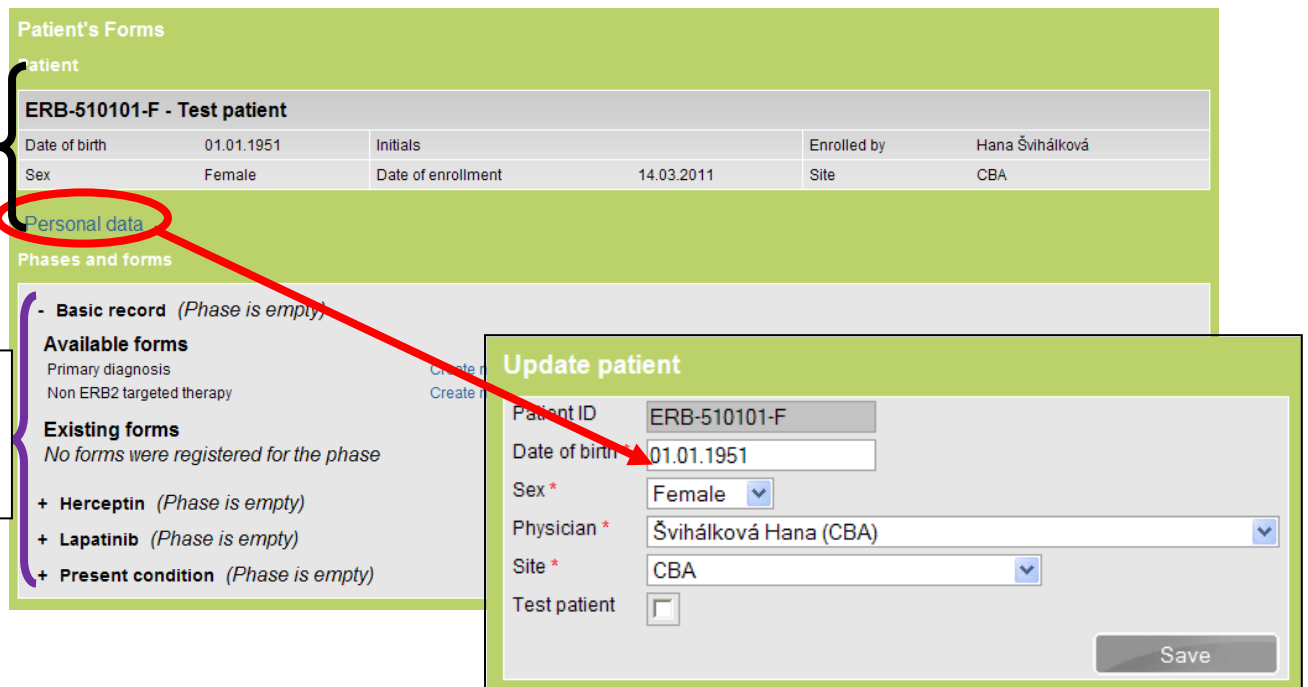
Picture 8. Order of patients

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 ellipsis in Picture 9).



Patient's Forms

Patient

ERB-510101-F - Test patient

Date of birth	01.01.1951	Initials	Enrolled by	Hana Švihálková
Sex	Female	Date of enrollment	Site	CBA

Personal data

Phases and forms

- **Basic record** (Phase is empty)
- Available forms**
 - Primary diagnosis
 - Non ERB2 targeted therapy
- Existing forms**
 - No forms were registered for the phase
- + **Herceptin** (Phase is empty)
- + **Lapatinib** (Phase is empty)
- + **Present condition** (Phase is empty)

Update patient

Patient ID: ERB-510101-F

Date of birth: 01.01.1951

Sex: Female

Physician: Švihálková Hana (CBA)

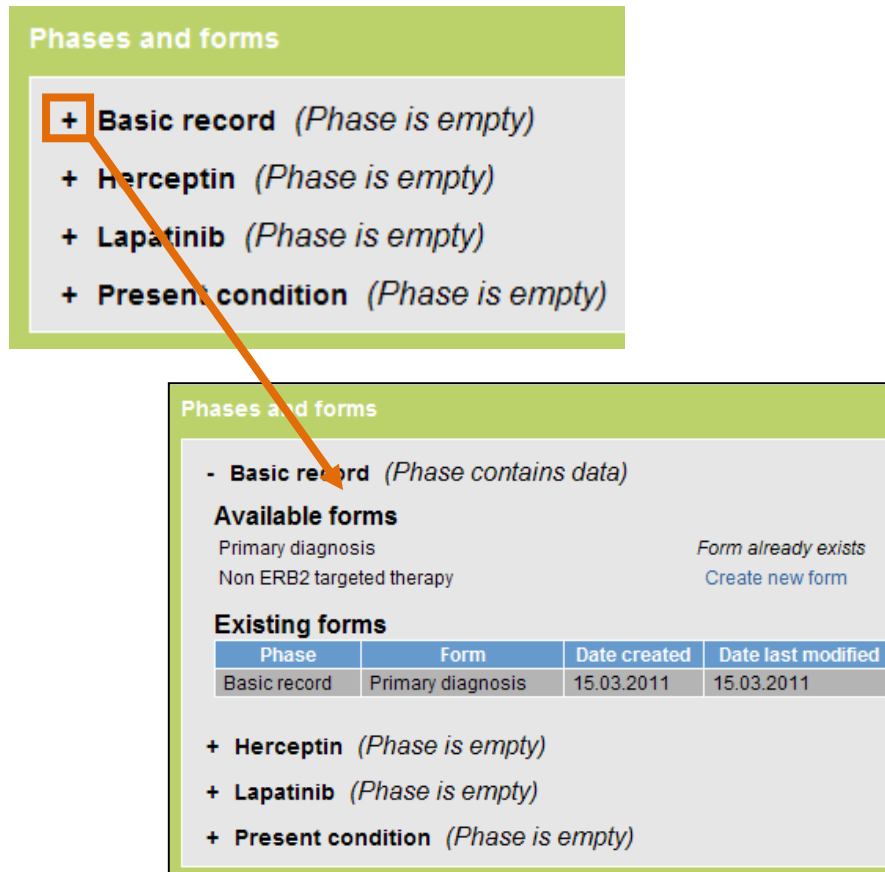
Site: CBA

Test patient:

Save

Picture 9. Personal data update

In the section **Phases and forms** (purple parenthesis in Picture 9), all patient forms that can be completed are stored. These forms are „packed“ in units called „phases“, e.g. „**Enrollment**“, „**Follow-up**“ and „**Discontinuation**“. The particular phases can be unpacked by clicking on the particular phase and the names of the particular forms will be displayed. Phases can be unpacked also by clicking on the „+“ sign located in front of the phase title (see orange square in Picture 10).



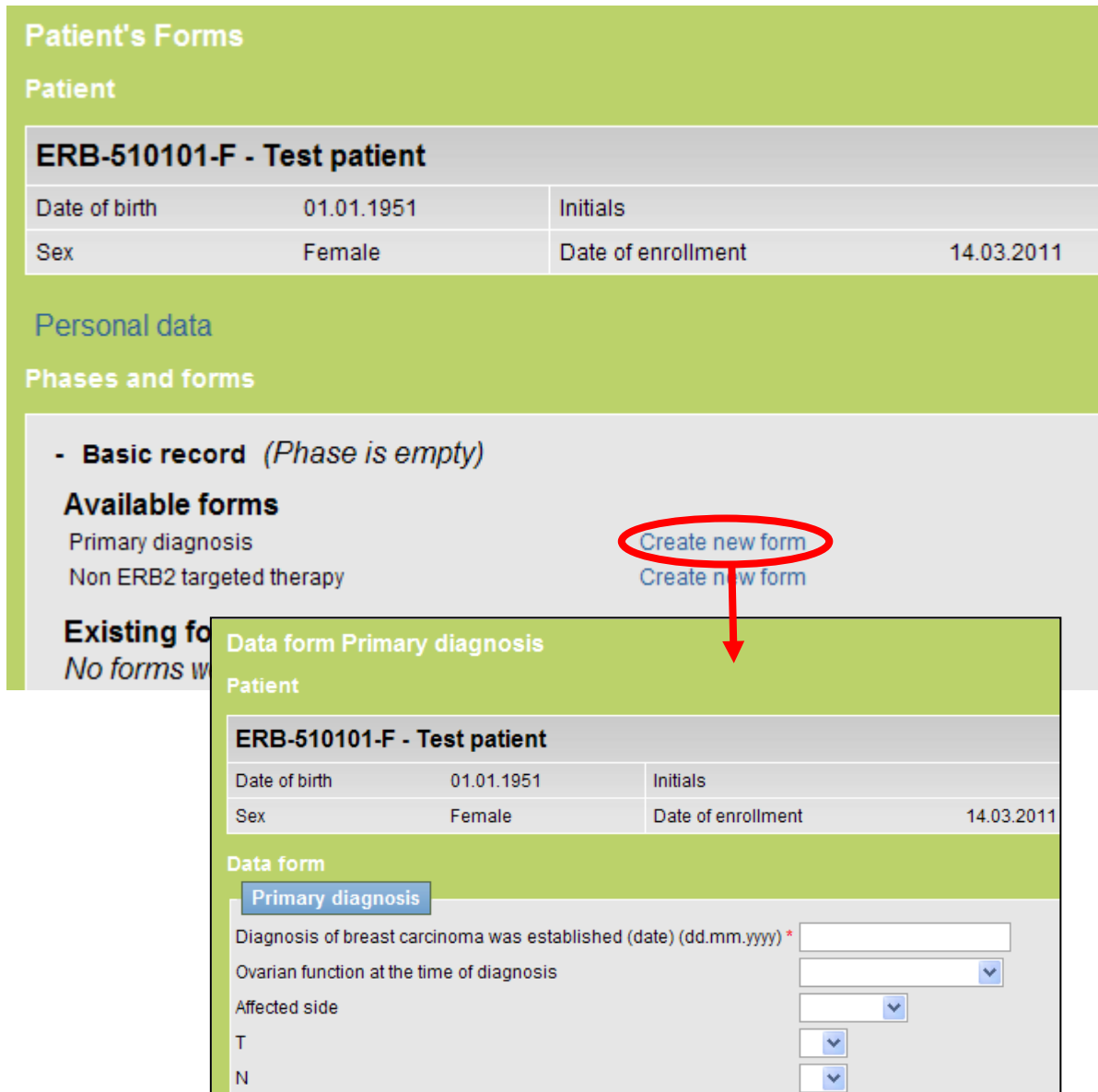
Picture 10. "Unpacking" a phase

There are two possibilities when working with the forms:

- Create a new form (see [Chapter 6, Creation of a New Form](#))
- Edit the existing form (see [Chapter 8, Work with Submitted Forms](#))

6 Creation of a New Form

After you have created a new form, it is necessary to search for the respective patient (see [Chapter 4, Patient Search](#)) and “unpack” the respective study phase (see [Chapter 5, Working Window of the Application](#)). You can create the new form by clicking on „**Create new form**“ button (see red ellipsis in Picture 11).



The screenshot shows the 'Patient's Forms' interface. At the top, there is a section for 'Patient' with details for 'ERB-510101-F - Test patient', including Date of birth (01.01.1951), Sex (Female), and Date of enrollment (14.03.2011). Below this is the 'Phases and forms' section, which lists 'Available forms' such as 'Primary diagnosis' and 'Non ERB2 targeted therapy'. A red circle highlights the 'Create new form' button next to 'Primary diagnosis', with a red arrow pointing to a detailed view of this form. The detailed view shows the form title 'Data form Primary diagnosis' and the same patient information. The form fields include 'Diagnosis of breast carcinoma was established (date) (dd.mm.yyyy) *', 'Ovarian function at the time of diagnosis', 'Affected side', and radio buttons for 'T' and 'N'.

Picture 11. Creation of a new form

7 Form Completion

The window of each form is divided into three sections (see example **A** in Picture 12 with the form called Discontinuation 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

Header contains basic information, that is **Patient ID, Date of Birth, Sex, Initials, Date of Submission, Enrolled by** and **Site**

Main section contains the respective form where the patient data are to be submitted. It is divided into subsections emphasized in bold (see red square in Picture 12). 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.

Footer contains the selection menu specifying the status of the form. The options **Pending, Completed** and **Uncollectable** 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 ellipsis in Picture 12).

- In case you did not manage to complete the whole form for any reason, select the „**Pending**“ option (see **B** in Picture 12).
- 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.

Data form Primary diagnosis

Patient

ERB-510101-F - Test patient

Date of birth	01.01.1951	Initials	Enrolled by	Hana Švihálková	
Sex	Female	Date of enrollment	14.03.2011	Site	CBA

Primary diagnosis

Diagnosis of breast carcinoma was established (date) (dd.mm.yyyy) *

Ovarian function at the time of diagnosis

Affected side

T
N
M

Right
Left
Bilateral

Clinical stage before any treatment was commenced *

Examination of primary tumour

Histological type of carcinoma

If other, please specify

Grade

ER (estrogen receptors)

PR (progesteron receptors)

HER-2/neu - immunohistochemical

HER-2/neu - FISH

HER-1

Ejection fraction (EF) before any treatment was commenced

Date of Ejection Fraction (EF) assessment

Ejection fraction (EF) (%)

Form status

Form status

Pending
Completed
Uncollectable

Save Save and close

Picture 12. Form completion

Comment 6:

Entry fields in the forms marked with a red asterisk are mandatory (see blue square in Picture 12), therefore they have to be completed. If you do not enter the respective entry field and try to save the form as “Completed”, an error notice will notify you of this fact.

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 Picture 13) or by selecting the option in the selection menu (see **B** in Picture 13). **Grey fields** depend on the answer to the previous question (see **C** in Picture 13). 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 Picture 13) which will enable to enter the data or to select data from the preset options.

Primary diagnosis

Diagnosis of breast carcinoma was established (date) (dd.mm.yyyy) * **A**

Ovarian function at the time of diagnosis **B**

Affected side

T

N

M

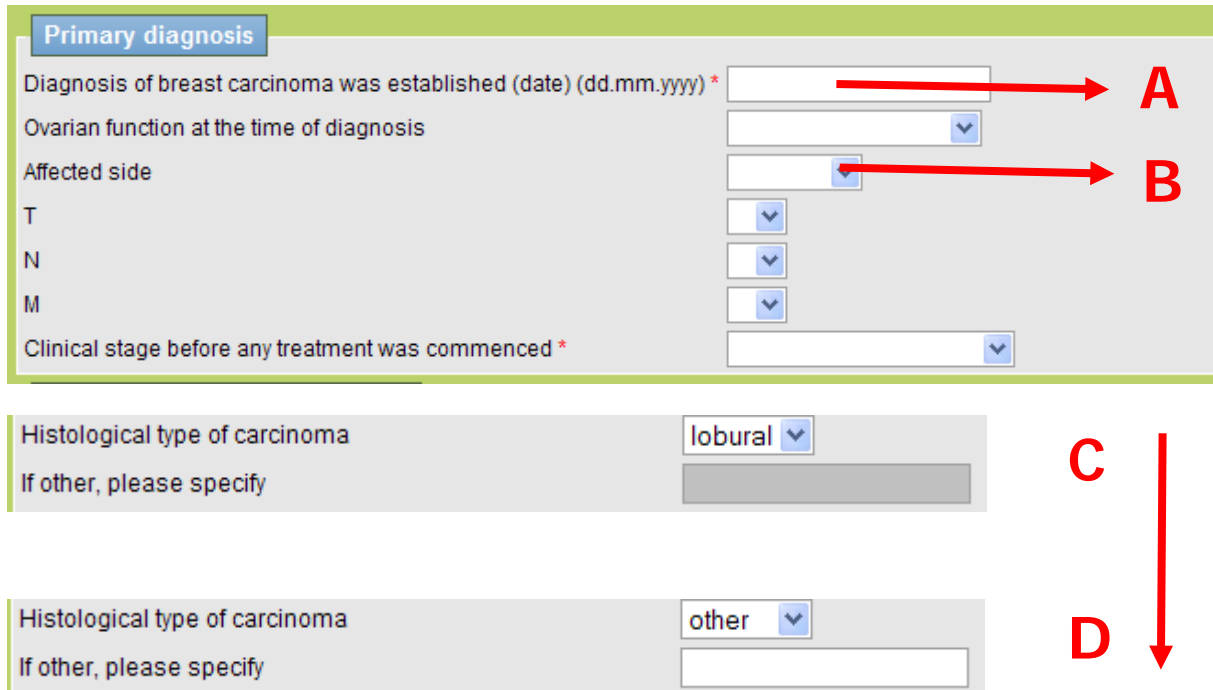
Clinical stage before any treatment was commenced *

Histological type of carcinoma **C**

If other, please specify

Histological type of carcinoma **D**

If other, please specify



Picture 13. Field types

8 Work with Submitted Forms

Submitted forms can be modified/edited using the „Open“ button (see **A** in Picture 14), printed using the „Printable form“ (see **B** in Picture 14) or deleted using the „Delete“ button (see **C** in Picture 14).

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 performed 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).

Existing forms							
Phase	Form	Date created	Date last modified	Created by	Problems	Status	Action
Basic record	Primary diagnosis	15.03.2011	15.03.2011	Švihálková H.		Pending	Open Delete Printable Form

Data form Primary diagnosis

Patient

ERB-510101-F - Test patient

Date of birth: 01.01.1951 Initials: **A**

Sex: Female Date of enrollment: 14.03.2011

Data form

Primary diagnosis

Diagnosis of breast carcinoma was established (date) (dd.mm.yyyy): 1.1.2000

Ovarian function at the time of diagnosis: after menopause

Affected side: Right

T: 0

N: 2

M: X

Clinical stage before any treatment was commenced: IIA

Data form Primary diagnosis

Patient

ERB-510101-F - Test patient

Date of birth: 01.01.1951 Initials: **B**

Sex: Female Date of enrollment: 14.03.2011

Formulář

Primary diagnosis

Diagnosis of breast carcinoma was established (date) (dd.mm.yyyy):

Ovarian function at the time of diagnosis:

Affected side:

T:

N:

M:

Clinical stage before any treatment was commenced:

Stránka na webu https://trials.cba.muni.cz ři...

Are you sure you want to delete this form?

C OK Zrušit

Picture 14. 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 using the „**Search**“ tool (see Chapter 4, Patient Search) or „**Last opened patients**“ (see Comment 4), move to a tab „**Patient**“ and click on „**Share Patient**“ (red ellipsis in Picture 15).

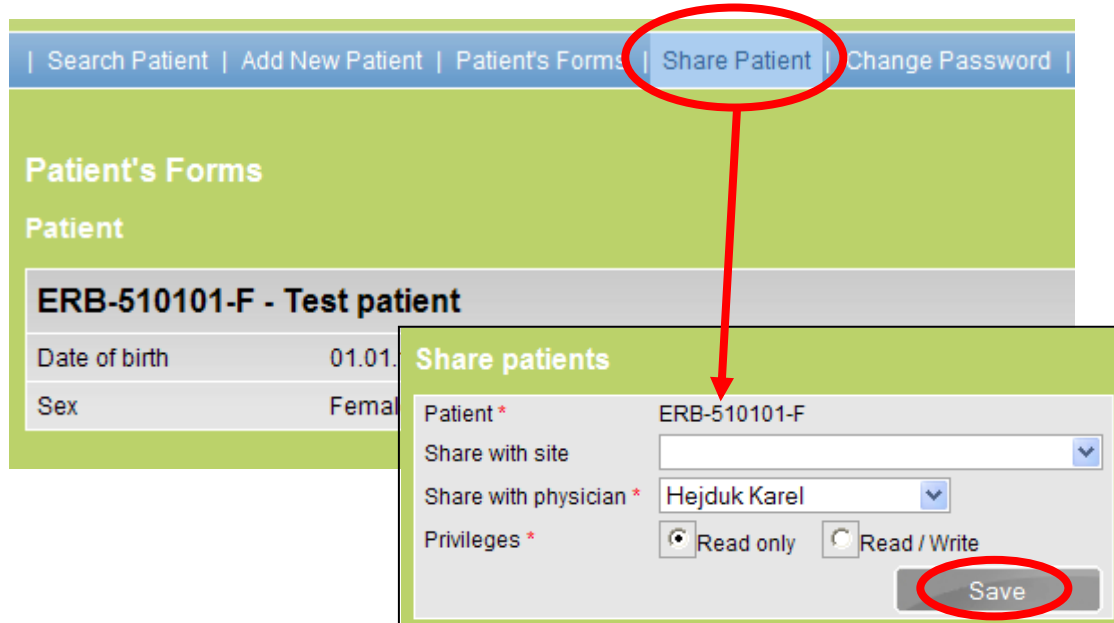
The function „**Share Patient**“ is useful when the patient had been transferred to another health care institution which continues in the patient data submission.

There is the following procedure of sharing the patient record: first, find the respective patient record, use the tab „Patient“ → „Share Patient“, select the site with which the patient will be shared and the authorized physician. In conclusion, confirm these steps by clicking the „**Save**“ button. It is not necessary to select the site, however, such specification will reduce the number of patient records.

There are two possibilities of authorization 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)

The procedure of sharing the patient record with the particular physician is presented in Picture 15.



The screenshot shows a web application interface. At the top, there is a navigation bar with several menu items: "Search Patient", "Add New Patient", "Patient's Forms", "Share Patient", and "Change Password". The "Share Patient" item is circled in red. Below this, the "Patient's Forms" section is visible, showing a patient record for "ERB-510101-F - Test patient" with details like "Date of birth: 01.01." and "Sex: Female". A "Share patients" dialog box is open, with a red arrow pointing from the "Share Patient" menu item to it. The dialog box contains the following fields: "Patient *" (ERB-510101-F), "Share with site" (empty dropdown), "Share with physician *" (Hejduk Karel dropdown), and "Privileges *" (Read only and Read / Write radio buttons, with Read / Write selected). A "Save" button is at the bottom right of the dialog box and is also circled in red.

Picture 15. Sharing of Patient Record

10 Problem Reporting



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