

EUTOS eCRF-System

Instruction Sheet

The **EUTOS – eCRF – System** can be started from the **EUTOS Homepage** at the **www** address:

http://www.eutos.org/content/registry/data_entry

Here you will find a short description and some information about the EUTOS Project.

The eCRF System can be started by clicking on **Start eCRF**.

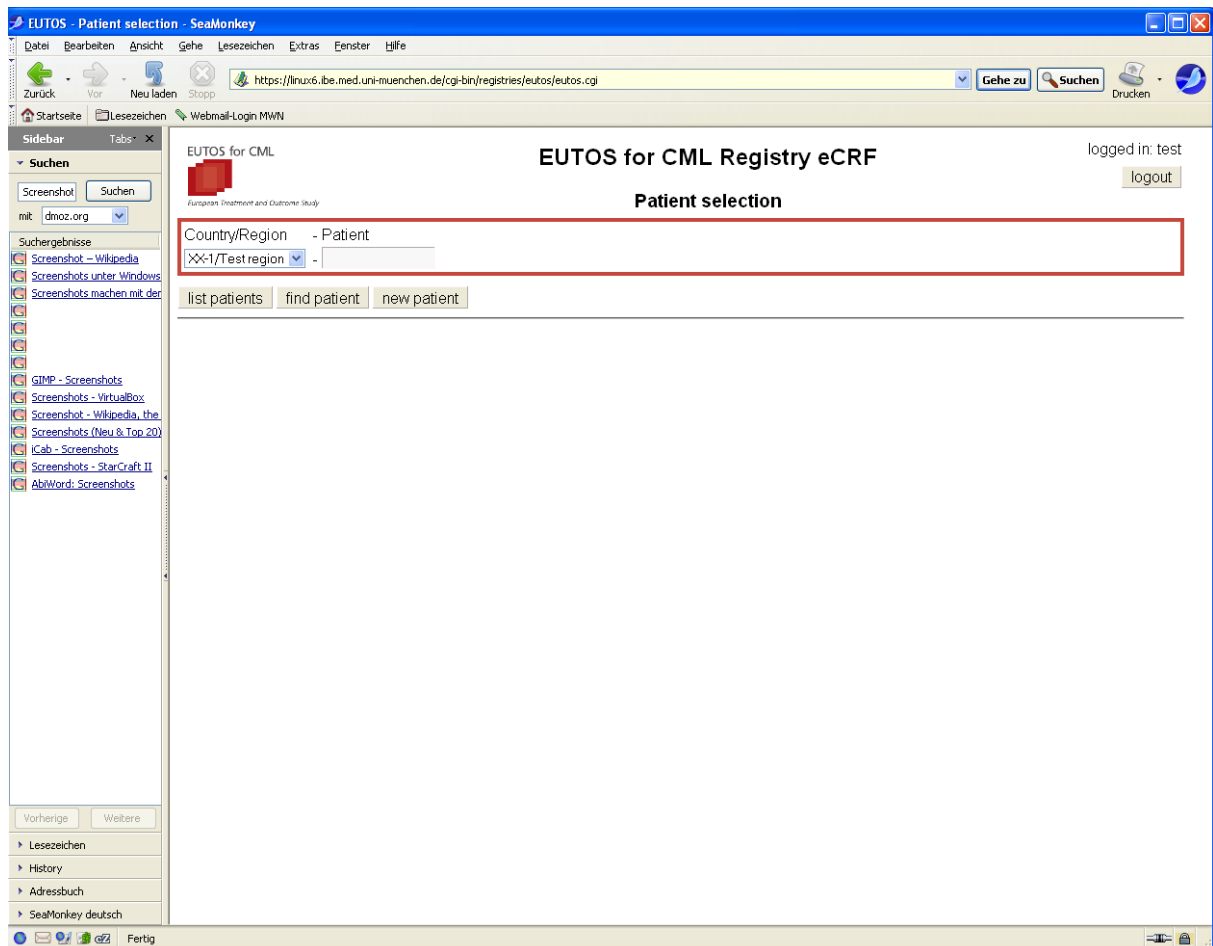
You can change your password by clicking on **Change your own Password**.

The **Instruction Sheet** you will also find at the **EUTOS Homepage**.

First the System asks for **username** and **password**

After logging in, the first site of the system appears.

Depending on the browser you use it looks like the following:



General remarks:

Patient-Id:

- The system creates a unique patient id for each new patient. Please note this number in your documents, because nobody except you knows this number and only with this patient id you can later find the patient data in the eCRF-System. Thus it is of utmost importance that you save this patient-ID in an absolutely secure place as long as the registry is active.

Dates:

- All dates must be inserted with points (.) or slashes (/) between date, month and year, e.g. 02.09.2009, or 02/09/2009.
- You can select dates from a calendar by clicking on the small icon at the right side of each data field.
- By double-click on the field you can insert the actual date of the day.
- If it is not allowed (for example by law), to report the full birth date, you can also report only mm.yyyy or only yyyy.

On the webscreen there are several buttons:

home

This brings you always back to the starting point.

list patients

The inserted patients will be listed.

In small countries without regions all patients of the study group will be listed.

In big countries with several regions only the patients of the selected region will be listed.

If you click at the blue arrow at the left side of the listed patients you can select a patient.

find patient

This helps you to find a special patient, if you insert the patient id.

new patient

By clicking this button a crf for a new patient will be created.

confirm new patient

It must be confirmed if a new patient shall be created in the system

cancel

If you want to delete the actual entries you can do this by clicking cancel

save changes

With save changes the actual entries will be saved and stored

change

Click change if you want to change something in this page

close

By clicking close this page will be closed, later modifications are allowed, but for the moment this page will be closed. It is for your own and our information, that you are ready with this page.

back to section

By clicking this button you will get to the menu of the **baseline** or the **follow-up** section.

back to patient overview

By clicking this button you will get to the top level of the actual patient.

show all: Follow-up section

All already inserted (yearly) Follow-up sections of the actual patient will be listed. You can select a follow-up section by clicking at the blue arrow at the left side.

add: Follow-up section

By clicking this button you can add a new (yearly) Follow-up section to the actual patient.

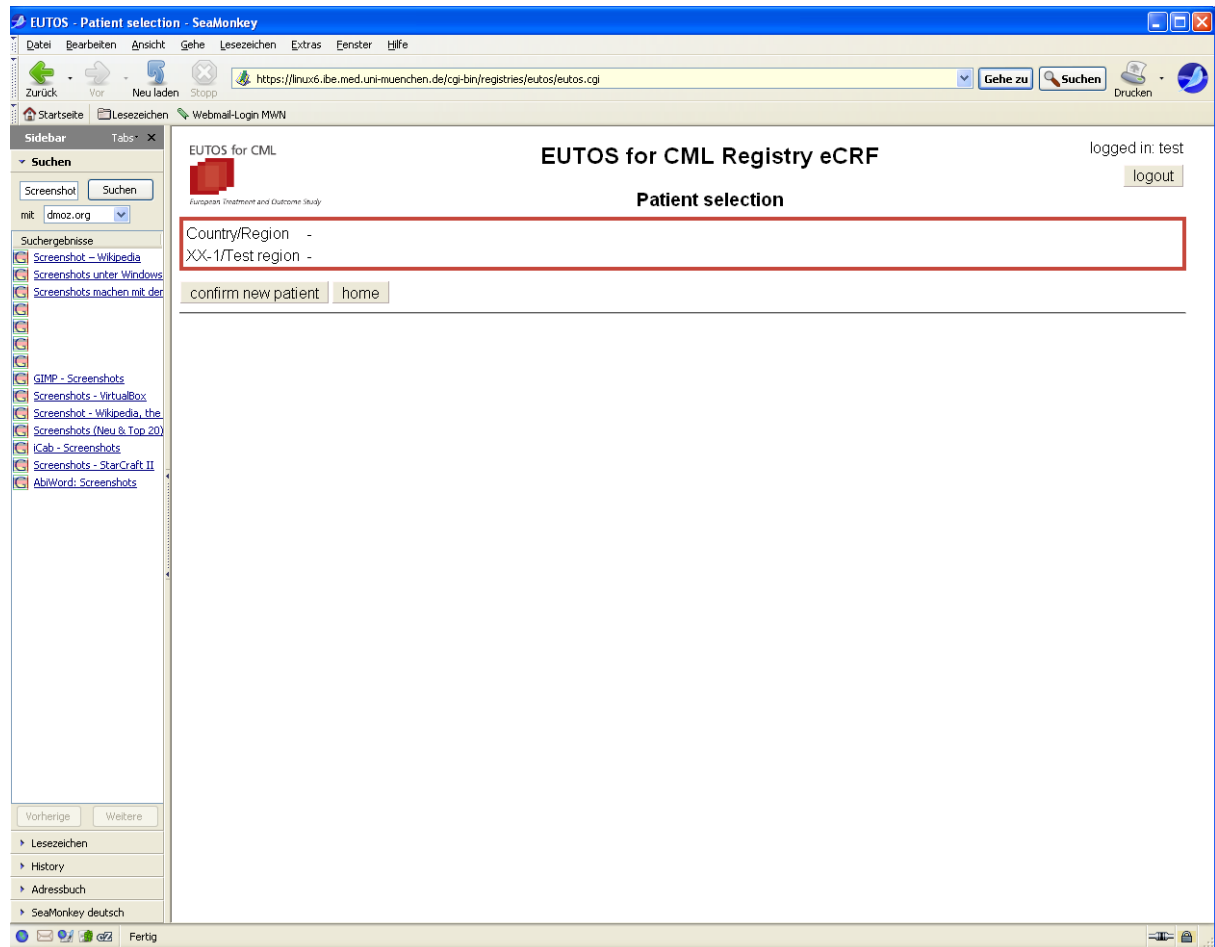
You can leave the system by clicking the button **logout** at the above right corner.

An example: Enter a new patient:

In big countries (over 10 million inhabitants) we capture only patients from selected regions. The region must be selected at the very beginning when a new patient is applied in the system.

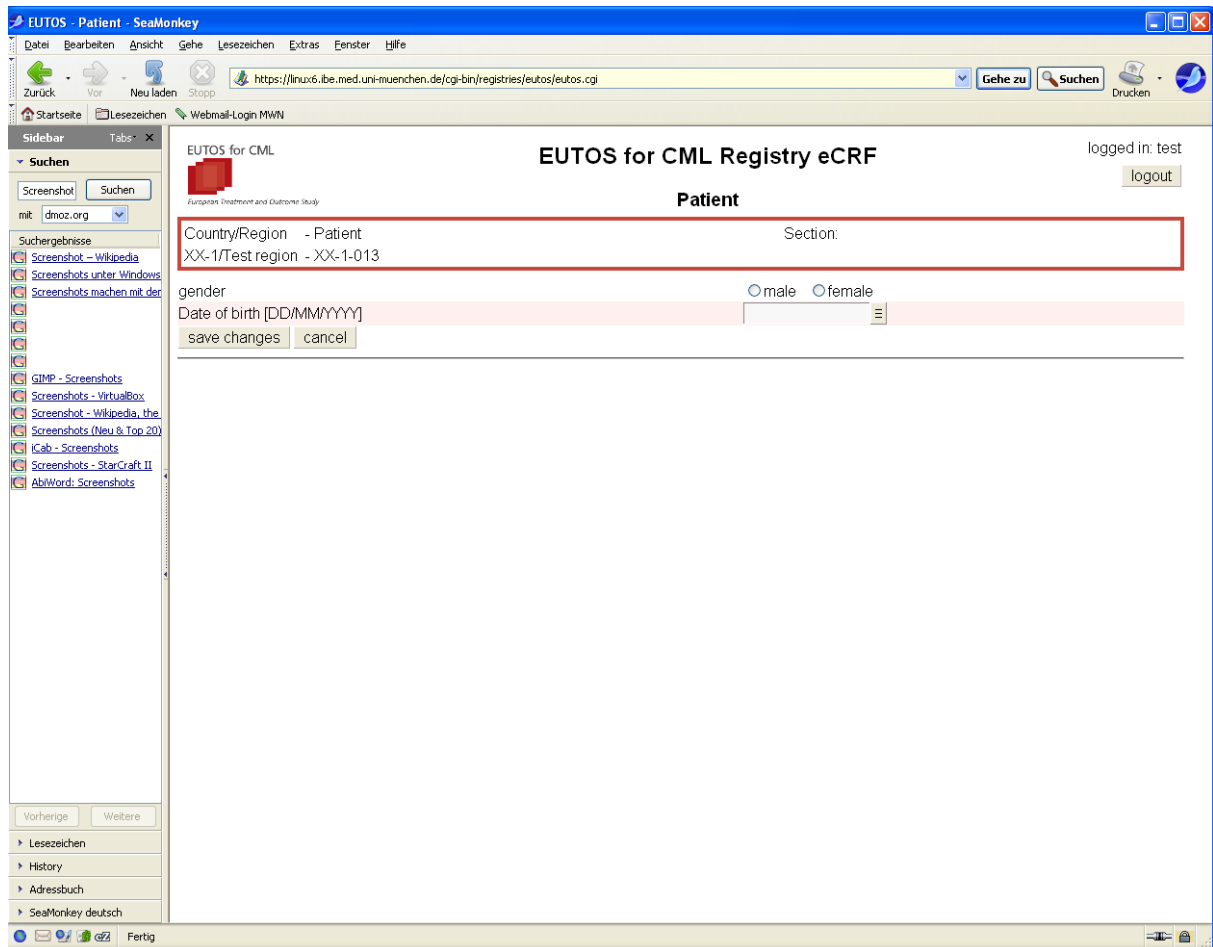
So **first select the region** from which the patient comes from and then click the button **new patient** to generate a new patient in the system.

Then you will get the following screen:



And then click **confirm new patient** if you really want to insert a new patient in the system, (by clicking cancel you can avoid this).

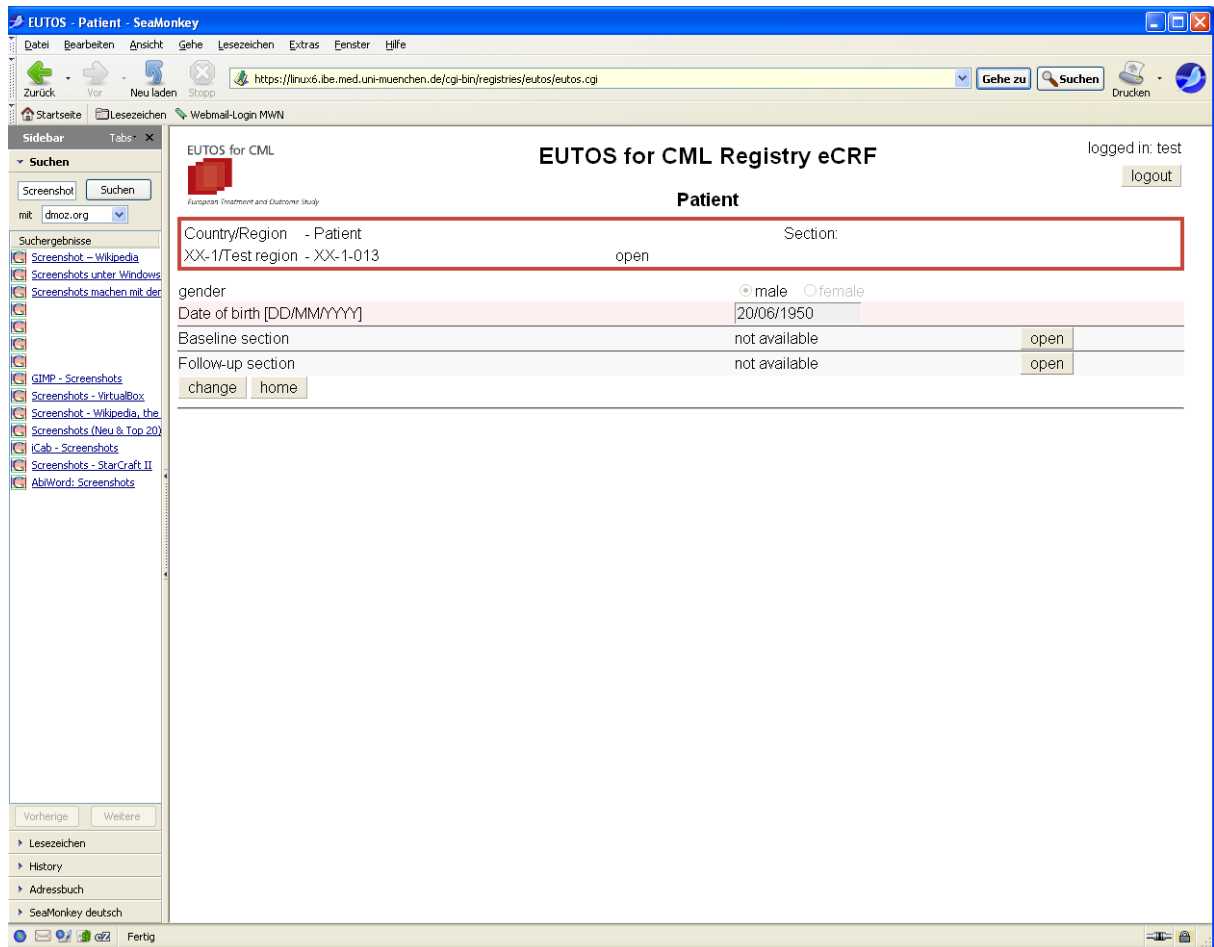
Then you get the following screen:



→ **Please save this patient number in your documents or patient files too! You will need this number if you want to enter follow-up data. Only you know this patient id.**

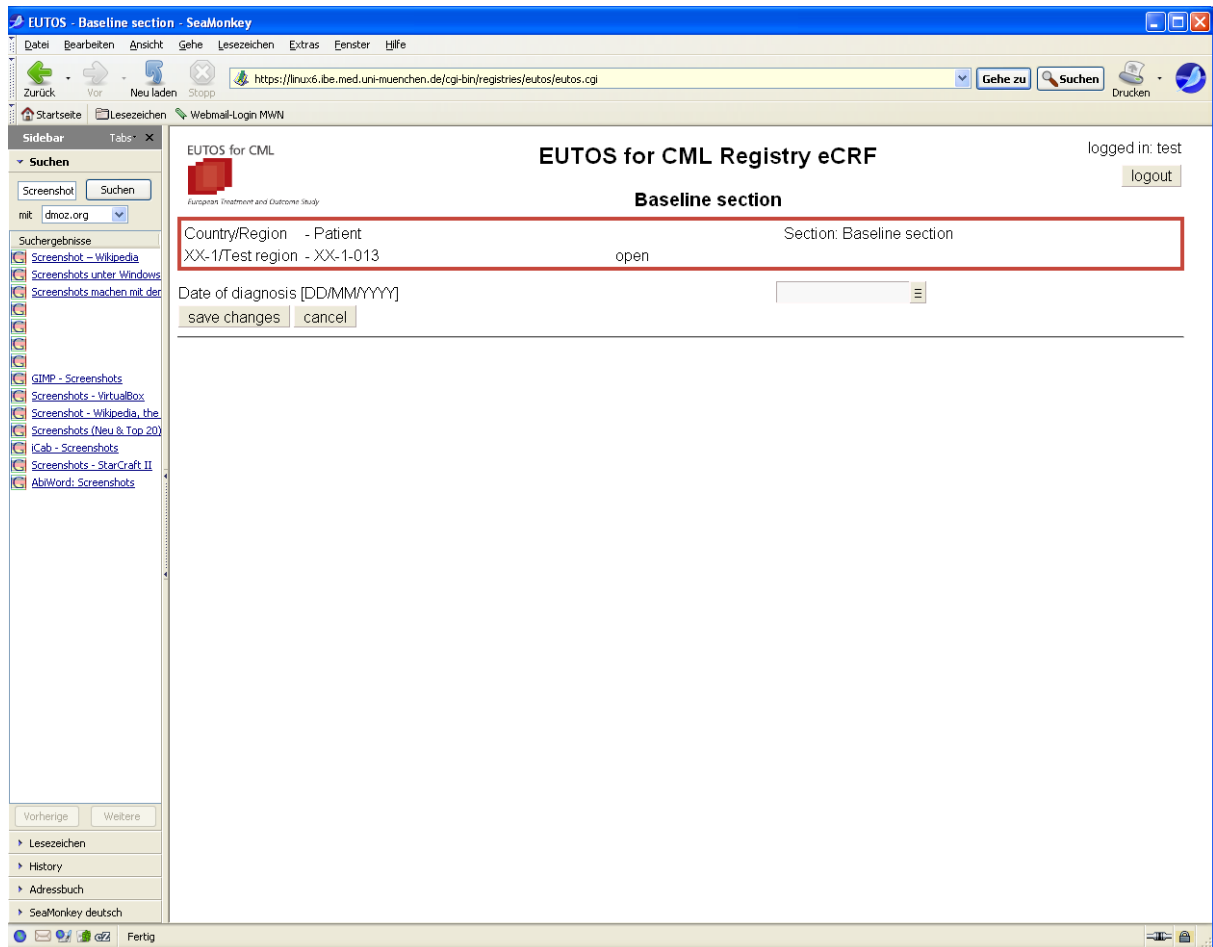
Here you can enter the patients **gender** and **date of birth**. After having entered the data click **save changes** so that the patient is linked with these data. By clicking **cancel** you can avoid this.

After clicking **save changes**, you get the following screen:



Now you can enter more data by clicking the button **open** behind **Baseline** and accordingly behind **Follow-up**, to enter Follow-up data.

After clicking **open** behind **Baseline** the following screen appears:



Please insert the **date of diagnosis** of CML.

This date is important for several reasons and from this date the reporting period of the first follow-up after one year (12 months) will be calculated.

After inserting the **date of diagnosis** and clicking **save changes** you will get the following screen:

EUTOS for CML Registry eCRF

logged in: test

logout

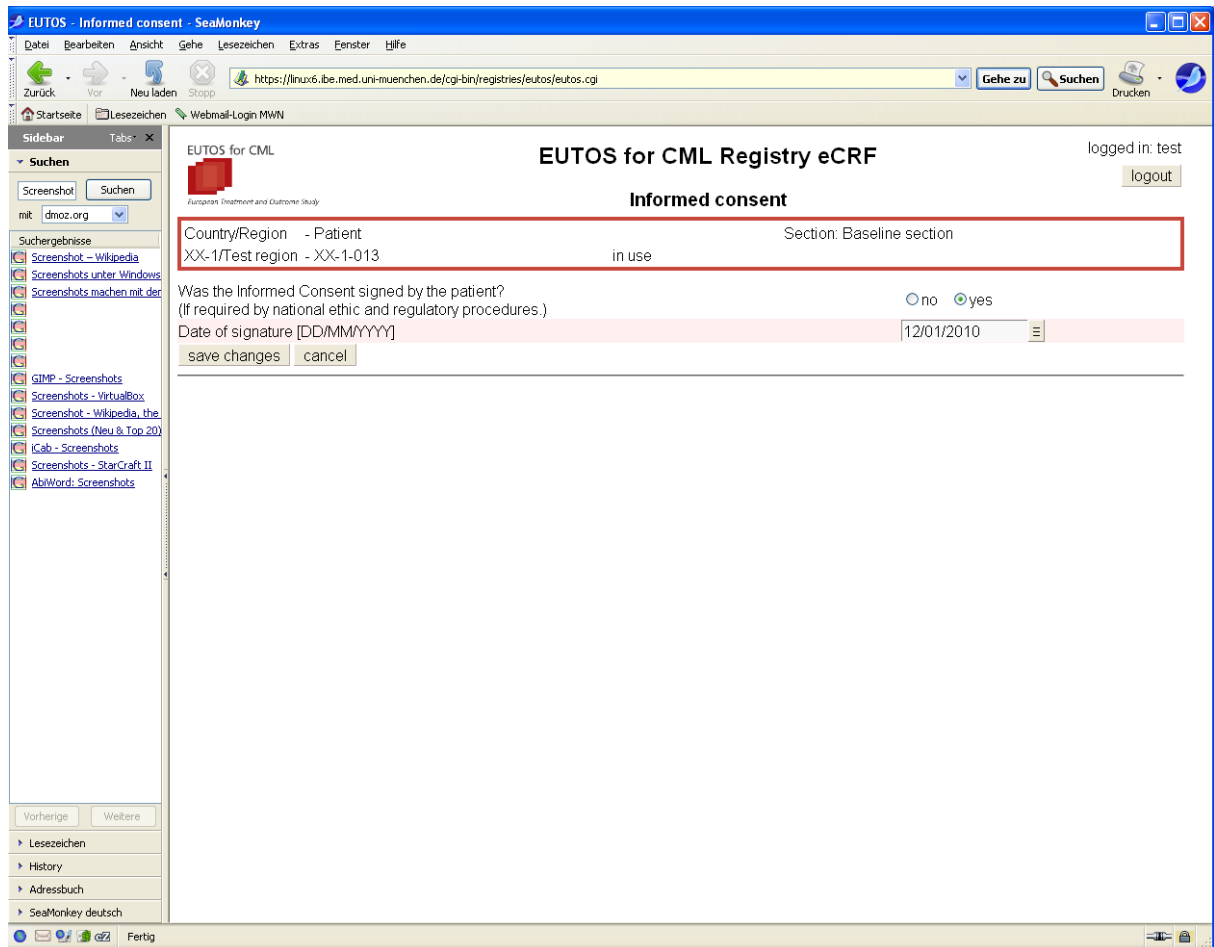
Baseline section

Country/Region - Patient	Section: Baseline section	
XX-1/Test region - XX-1-013	open	
Date of diagnosis [DD/MM/YYYY]	12/01/2010	
Informed consent	not available	open
Demographic data	not available	open
Clinical data before any treatment	not available	open
Hematologic data	not available	open
Risk score	not available	open
Cytogenetic data	not available	open
Fish data	not available	open
Molecular biology	not available	open

change | back to patient overview | home

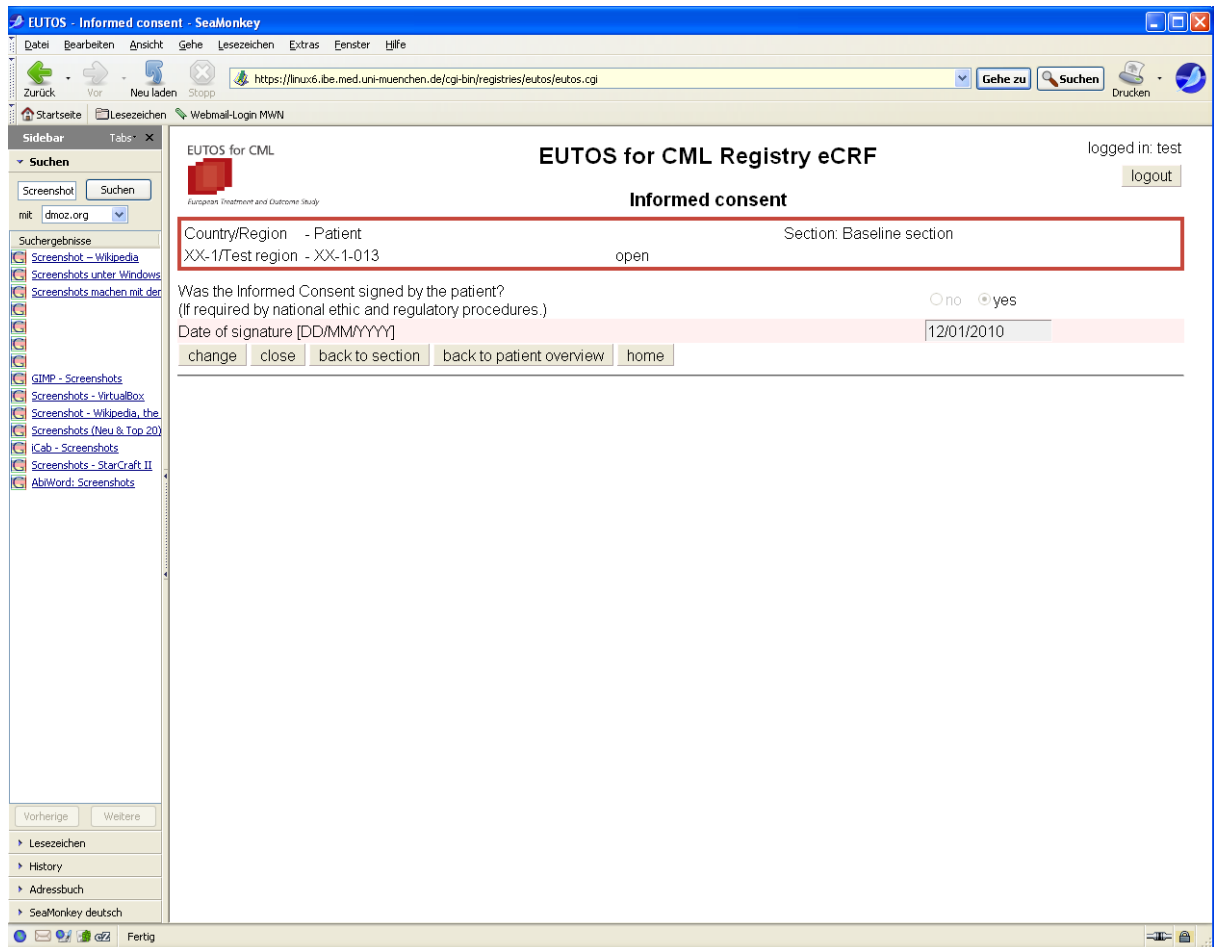
By clicking the **open** Button you can open the different Panels and insert the data.

In the first panel we ask for Informed Consent:

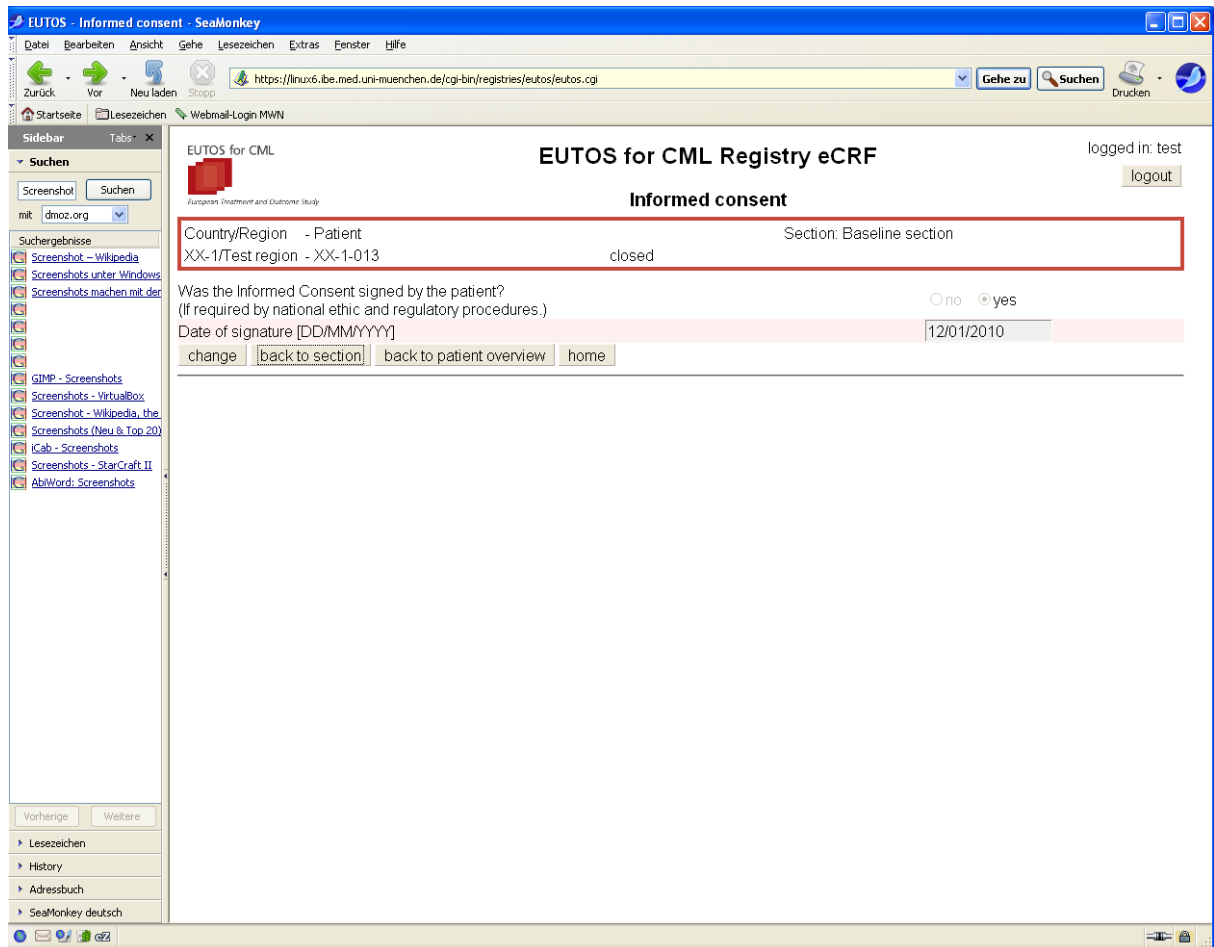


Please fill in the data and click **save changes**.

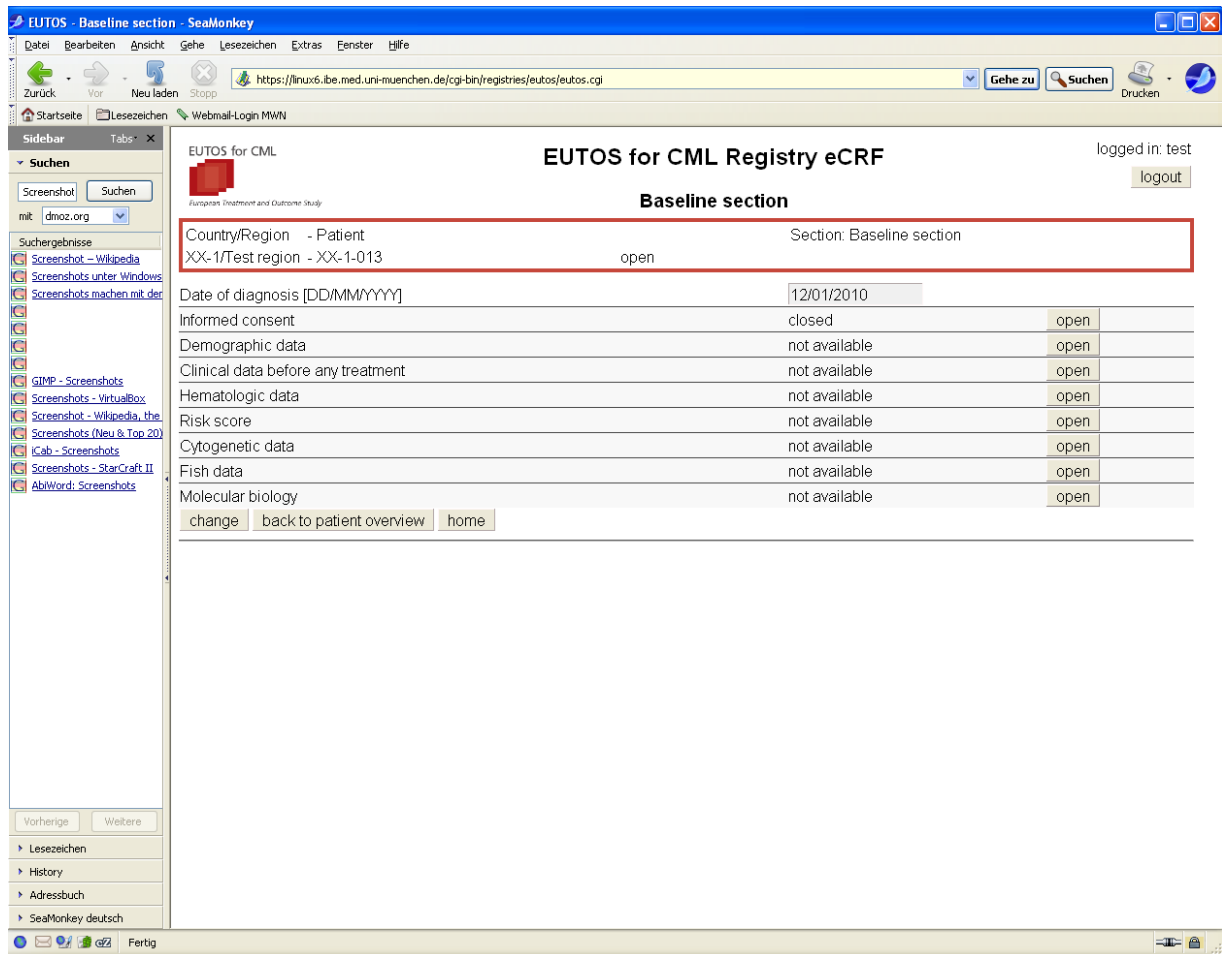
Then your entries will be stored and you will get the following page:



With **change** you can change your entries, with **close** you close this page (later modifications are allowed, but it is for your own and our information, that you are ready with this page). If you are ready with your entries, click **close**, then you will get the following page:



And now click **back to section** to get back to the **Baseline** section and enter more data:



Now you can see that the **Informed consent** panel is closed. Click on the **open** button behind **Demographic data** to continue with entering data. And do so with all the other panels.

Risk score

The Risk score cannot be calculated directly in the eCRF-System at the moment. We'll calculate it offline.

If you are interested in the Risk score, you can calculate it at the following www page:

<http://www.pharmacoepi.de/cml-score>

If you are ready with the Baseline section you can click **back to patient overview** to go to the top level of the patient or **home** to go to the top level of all your patients and for example enter a new patient.

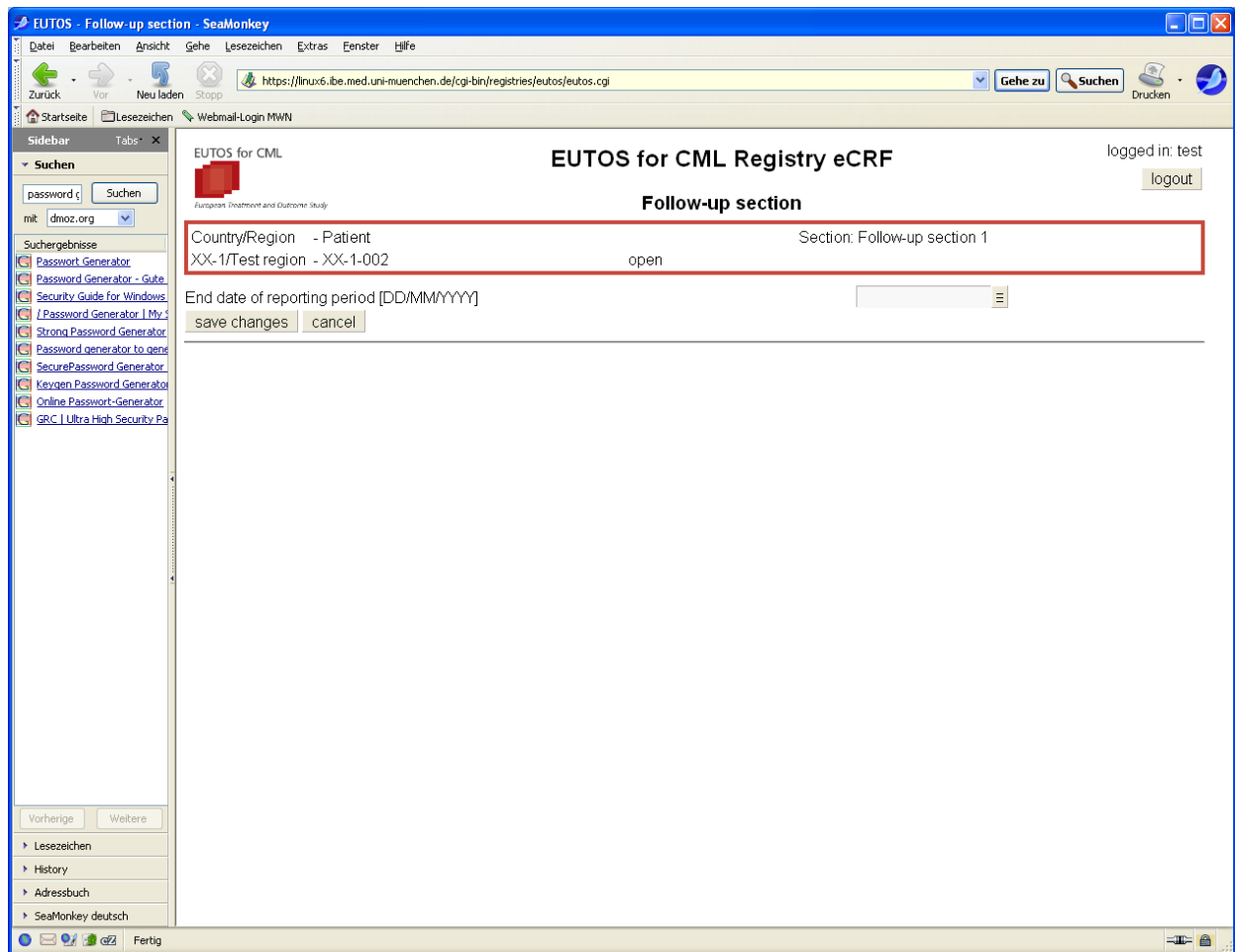
By clicking **logout** you leave the system.

Enter follow-up data

Approximately after one year you will enter Follow-up data for the same patient in the **Follow-up** section.

By clicking the button **list patients**, the ids of all documented patients will be listed. You can select one patient by clicking at the arrow at the left side.

First insert the **end date of the reporting period**. Then click **save changes**.



The screenshot shows a web browser window titled "EUTOS - Follow-up section - SeaMonkey". The address bar shows the URL "https://linux6.ibe.med.uni-muenchen.de/cgi-bin/registries/eutos/eutos.cgi". The page content includes the EUTOS logo, the text "EUTOS for CML Registry eCRF", and "logged in: test" with a "logout" button. The main section is titled "Follow-up section" and contains a table with the following data:

Country/Region	Patient	Section: Follow-up section 1
XX-1/Test region	XX-1-002	open

Below the table, there is a form field for "End date of reporting period [DD/MM/YYYY]" and two buttons: "save changes" and "cancel".

In the first panel **Study enrollment** we want to know if the patient was enrolled in a clinical study.

In the Treatment panel we ask for the Treatment the patient received, and very important the **start date of first TKI Treatment**.

We ask for this date in the first follow-up section, because some patients first receive HU for some months before they get a TKI.

We are interested in getting the treatment data as soon as possible so please enter these data as soon as they available and then complete the follow-up section with the other data after one year from baseline.

We want to collect all **cytogenetic, molecular, fish** etc tests. These tests can be entered in the specific data entry screens by clicking the button **new** in the corresponding panels.

For example: Open the panel **Cytogenetic data follow-up** and fill in the data. The % will be calculated automatically after clicking **save changes**.

EUTOS - Cytogenetic data follow-up - SeaMonkey

https://linux6.ibe.med.uni-muenchen.de/cgi-bin/registries/eutos/eutos.cgi

Gehe zu Suchen Drucken

Webmail-Login MWN

loggedin in: test
logout

EUTOS for CML Registry eCRF

Cytogenetic data follow-up

Country/Region - Patient
XX-1/Test region - XX-1-002 in use Section: Follow-up section 1
Entry #: 1

Date of cytogenetic analysis [DD/MM/YYYY]

Number of evaluated metaphases unknown

Number of Ph+ metaphases

% of Ph+ metaphases [%]

Clonal chromosome abnormalities in Ph+ cells no yes unknown

save changes cancel

Vorherige Weitere

Suchen

mit dmoz.org

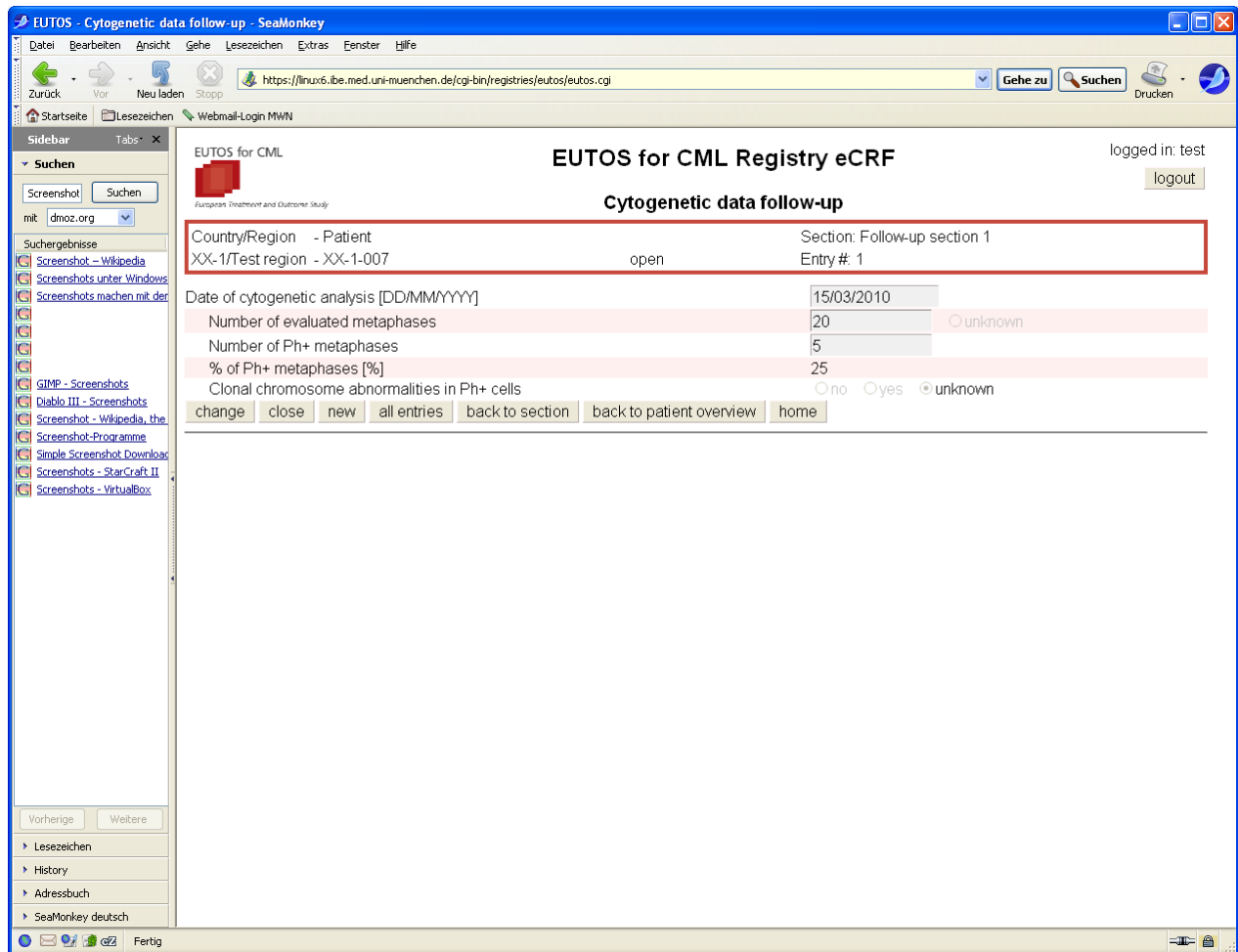
Suchergebnisse

- bahn.de - Ihr Mobilitätsport...
- Deutsche Bahn: Alle Inform...
- Reiseauskunft der Bahn
- Bahn-Verweis für 16-Jährige
- Bahn-Chef Grube: Bahn-Ch...
- Bahn kindig: Entschädigung
- Deutsche Bahn AG
- Fahrplanauskunft Deutsche
- DB BAHN Railway Simulatio...
- bahn.de
- Willkommen bei der NordWe...
- S-Bahn Berlin GmbH - Ihr Na...
- Bahn-Verweis für 16-Jährige

Lesezeichen

- History
- Adressbuch
- SeaMonkey deutsch

Fertig



If there are more tests done during the year, you can insert them by clicking the button **new**. Then a new screen opens and you can insert the test results.

If you click the button **all entries** you get a list of all inserted cytogetic tests of this patient of the actual follow-up section.
Click at the blue arrow at the left side to select a specific test.

In the panels **Fish data follow-up**, **Molecular biology follow-up** and **Mutational analysis** we also want to collect all tests and you can insert them in the same way.

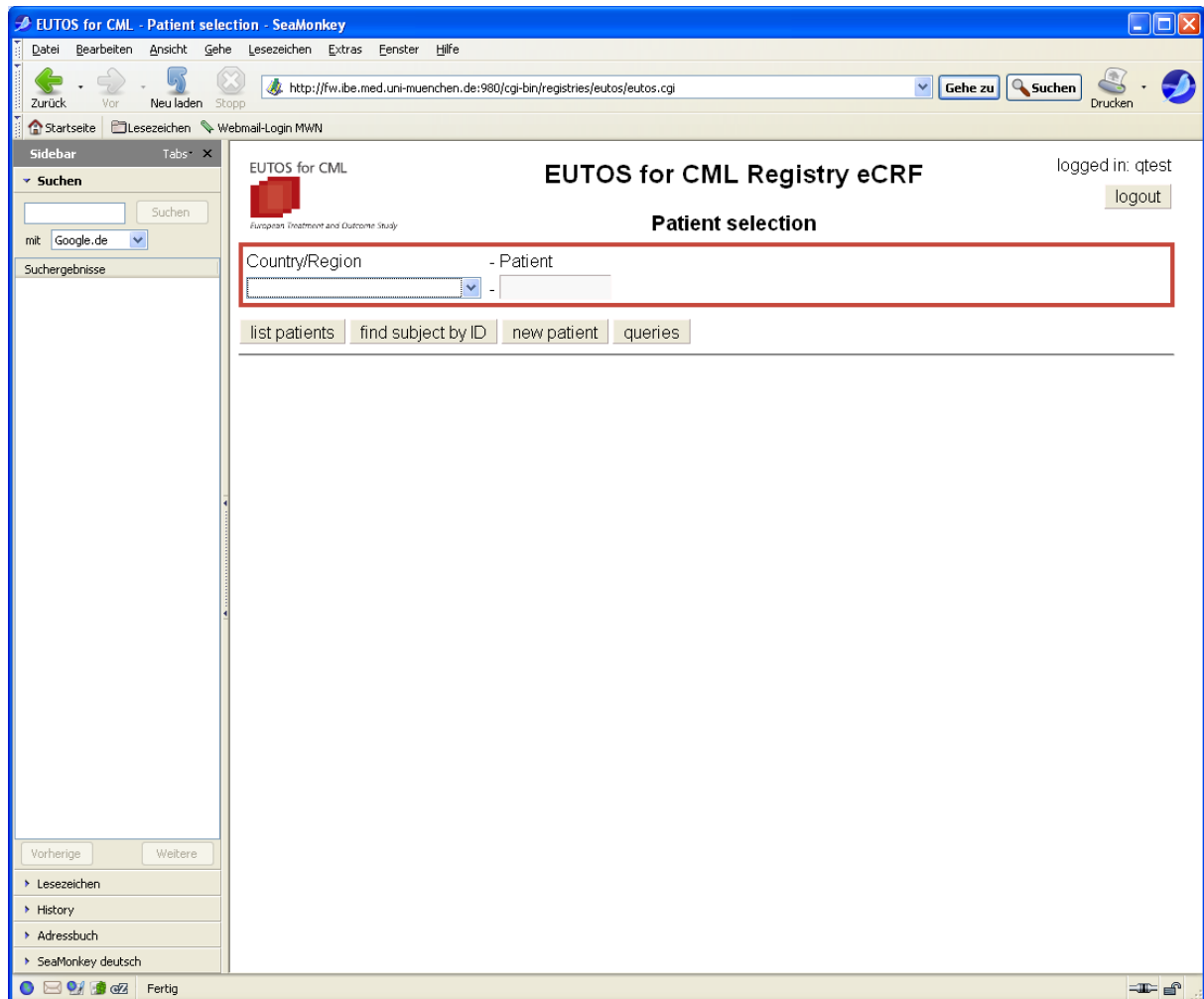
By clicking the button **home** you will get to the top level.

By clicking **logout** you leave the system.

Queries

We generated queries to improve the data quality.

After you entered your username and your password you get the following page:



Click the button **queries** to get the queries of your country or region.

The screenshot shows the EUTOS for CML - Queries - SeaMonkey web application. The interface includes a search sidebar on the left and a main table of queries. The table has columns for Country/Region, Patient, Section, eCRF part, eCRF item(s), Query date, and Query. The 'Section' column is filtered to 'Baseline section'. The 'Query' column contains various instructions and missing value warnings.

Country/Region	Patient	Section	eCRF part	eCRF item(s)	Query date	Query
		3 Baseline section	Molecular biology	BCR-ABL / control gene %	20/10/2011	Please check value for variable BCR-ABL / control gene %, since it is >100
		3 Follow-up section	Cytogenetic data follow-up 1	Number of evaluated metaphases is unknown, Number of Ph+ metaphases	20/10/2011	Missing value
		3 Follow-up section	Cytogenetic data follow-up 1	Date of cytogenetic analysis	20/10/2011	Missing value
		3 Follow-up section	Cytogenetic data follow-up 1	Number of evaluated metaphases is unknown, Number of evaluated metaphases	20/10/2011	Missing value
		3 Follow-up section	Molecular biology follow-up 1	Date of molecular analysis	20/10/2011	Missing value
		3 Follow-up section	Molecular biology follow-up 1	BCR-ABL / control gene %	20/10/2011	Missing value
		3 Follow-up section	Visit		20/10/2011	Missing value. End date of reporting period follow-up section 2 is missing.
		4 Follow-up section	Survival status	Progression to AP/BC, Progression date	20/10/2011	Please check implausibility. Progression to AP/BC = YES but no specification of Progression date
				Investigator		Please check for missing

You can apply a filter, to constrain the queries for example to Baseline section.

Select a query by clicking at the blue arrow at the left side.

Then you will get the following screen:

The screenshot shows the 'EUTOS for CML - Queries - SeaMonkey' web application. The interface is divided into several sections:

- Searchbar (Left):** Includes a search input field, a search button, and a dropdown menu for search engines (currently set to Google.de).
- Query Form (Center):** A detailed form for editing a query. It includes fields for 'Country/Region', 'Patient', 'Section' (with checkboxes for 'Baseline section' and 'Follow-up section'), 'eCRF part', 'eCRF item(s)', 'Query date', 'Query', 'Response' (radio buttons for 'Data confirmed without change' and 'Data changed'), and 'Response date'. A 'Reason' text area is also present.
- Form Controls (Right):** Contains various clinical data points with input fields and radio buttons:
 - Date of first cytogenetic test: 20/05/2008
 - Chromosome banding analysis: Radio buttons for 'no', 'yes', 'unknown'.
 - Philadelphia translocation: Radio buttons for 'Ph not found', 'Ph+ t(9;22)(q34;q11)', 'Variant translocation', and 'Unknown'.
 - Number of evaluated metaphases: Input field with value 20.
 - Number of Ph+ metaphases: Input field with value 20.
 - % of Ph+ metaphases [%]: Input field with value 100.
 - Clonal chromosome abnormalities in Ph+ cells: Radio buttons for 'no', 'yes', 'unknown'.
- Buttons (Bottom Center):** 'apply filter', 'save data and send reply', and 'close'.
- Table (Bottom):** A table with columns: Country/Region, Patient, Section, eCRF part, eCRF item(s), Query date, and Query. It lists three queries:

Country/Region	Patient	Section	eCRF part	eCRF item(s)	Query date	Query
		3 Follow-up section	Cytogenetic data follow-up 1	Number of evaluated metaphases is unknown, Number of evaluated metaphases	20/10/2011	Missing value
		3 Follow-up section	Visit		20/10/2011	Missing value. End date of reporting period follow-up section 2 is missing.
		4 Follow-up section	Survival status	Progression to AP/BC, Progression date	20/10/2011	Please check implausibility. Progression to AP/BC = YES but no specification of Progression date

Supply missing values and/or correct errors (top right).

Select the proper Query Response and give a reason (top left).

Send off the reply by pressing the button **save data and send reply**.

The system asks you again, if you are sure, if yes please confirm with **ok**.

If there isn't any error message the results are stored automatically in the database and the query is removed from the list.

Then you can continue with answering the other queries.

If you have doubts understanding the queries please send an email or call the helpdesk.

24.10.2011 Doris Lindörfer