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The ENERCA-TIF Registry

User's Manual

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Author Note

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Introduction

Why an eRegistry?

- In the EC Recommendation on an action in the field of rare diseases, (2009/C151/02), there was political commitment to develop national plans and strategies for rare diseases based on epidemiological data derived from 'definition, codification and inventorying of these diseases'.
- There is insufficient implementation of comprehensive data collection and analysis systems for rare anaemias. Even for those more prevalent, such as the haemoglobinopathies, which are today the most common genetic disorder in Europe, there are poor data on their precise prevalence, overall burden and trends.
- Inventory of expert centres and epidemiological figures will provide health authorities with comparable data at national and also international level, allowing the promotion of specific actions for primary prevention of rare anaemias.
- This registry for rare hereditary anaemias was developed as a task within the EU funded project ENERCA (European Network for Rare and Congenital Anaemias) through a specific working group (WP4). Other members of the Executive Committee have provided comments and suggestions.
- The final system was developed with consideration of EU regulations and current state of the art for standards and legal issues for Electronic Health Records (EHR) and personal data protection.

The eRegistry

For epidemiological surveillance

Our Objectives

- To create an interoperable electronic Registry for Rare Anaemias based on a patient-centred philosophy.
- To develop an extendible and functional model of a database which will enable entering of certified medical data from the available sources.
- Make it available on-line through a specific web portal to users throughout Europe and the world.

Your benefits

- Set up your own electronic registry of patients, following the EC requirement for centres of expertise, by downloading the application and adapting it to your needs.
- Share your information in a harmonized way with your colleagues and other experts in Europe and other countries.
- Contribute to the national or European registry and have access to relevant clinical information in a timely manner.
- Get informed and involved in several European initiatives that will facilitate the provision of care.

Legal and ethical considerations

- e-Health systems give rise to legal and ethical considerations regarding the use and protection of personal data. An important issue when implementing a new electronic

registry which includes patient data, is the system's compliance with the law on the rights of patients.

- Although each country has its own system of law, all Member States (MS) should comply with the guidelines, standards and legislative framework set by European directives. Therefore MS have to study the adequacy of the national legislation to the European directives and present amendments accordingly which might promote the development of EHR systems at national level.
- These studies must be also in compliance with any e-Registry based on an interoperable, extensible and functional model of a database which will enable entering certified medical data from available sources.
- The system is developed in Django which is a scalable high-level Python Web framework that encourages rapid development and clean, pragmatic design and it incorporates a MySQL database for auditing and data storage.

The ENERCA-TIF Registry

User's Manual

An electronic registry can be designed to serve the objective of epidemiological surveillance but also to facilitate research and especially clinical trials. In order to allow users to satisfy more than one objective the Enerca-TIF Registry has been designed as a modular database.

The Registry modules

There are 5 modules which may be used as a whole registry or each separately in conjunction with module 1 which is the only obligatory module.

The system is entered through a user login with clearly defined user levels which includes:

- Doctors responsible for the patient
- Nurses caring for the patient
- Data entry officer/data manager

Module 1

This module consists of 4 parts:

1. Patient consent (obligatory)
2. This is not obligatory but highly recommended, since inaccurate diagnosis will lead to inaccurate data, either for epidemiology or for research. (obligatory)
3. The sub-menu: proof of diagnosis (not obligatory)
4. Family history and pedigree chart

Patient consent: this is a legal requirement, since the owner of patient data is the patient. Inclusion of personal information must therefore be initiated by full explanation to the patient of the purpose of the registry and how this will benefit the individual patient as well as the medical professionals who are responsible. The patient should know that data can be used with full patient identification by authorized users, or as anonymized data and as aggregate data for survey purposes. It is up to the patient to decide after full explanation. Another possible use of data, identified or anonymized, is consultation between centres, for the purpose of obtaining a second opinion and for cross border health services.

Once the patient has signed a manual consent form, then an electronic record of this is added before the system can be initiated

The minimum common dataset

This is an obligatory part of the registry since it is based on the patient summary set of data, for electronic exchange under the European cross-border directive. The contents of the dataset were recommended by the Health Ministerial Conference held in Dublin in 2013. Similar common datasets were also recommended by the EPIRARE project in collaboration with the National Institute of Health (NIH) in the USA, the PRISM project EUCERD and others. This module is also essential for epidemiological studies. It includes demographics, patient characteristics (such as age, sex), contacts and clinical centres responsible. The diagnosis (automatically coded by ICD10 and Orphacode) is essential information.

The proof of diagnosis

This part consists of a droplist of tests that have been used to confirm the diagnosis. This is not obligatory but highly recommended, since inaccurate diagnosis will lead to inaccurate data, either for epidemiology or for research.

Family history

Non-obligatory but useful information in hereditary conditions, especially in populations where consanguineous marriage is customary.

Module 2 (not obligatory)

In this module annual clinical data summary data are recorded, from patients who are regularly or irregularly transfused, because of a chronic anaemia such as thalassaemia or one of the rare congenital anaemias. The information can be used to follow progress or to follow the response to treatment, for example during a clinical trial. Mortality information is included here.

Module 3 (not obligatory)

In this module annual clinical summary data are recorded, from patients suffering from sickle cell syndromes. They are used in a similar way as module 2

Module 4. **(not obligatory)**

This modules records patient reported outcomes, elements of quality of life. Especially useful for clinical trials.

Module 5

This is the statistical package with set queries which can be supplemented

Module 6: Aggregate data

This module includes a summary questionnaire that records a meta-analysis of total patient data of centers that don't use this eRegistry as a reference software but want to provide anonymous data for statistical purposes.

Using the database

Regarding the potential users, there are two ways to use it.

- The first one is to install the system on a private server and use it as an in-house web accessible software. In that way the interested stakeholder is responsible to install and configure the source code on its server. In case you select this option we will kindly ask you to provide us annual report regarding the statistical data resulting from the anonymous input data. Another option to collect statistical data is to create as a user only for this purpose.
- The second option is to use the platform hosted on TIF's server using the provided link. For this option you have to provide us some information to create you an account in the system. This information includes a username, your reference center, a valid e-mail and your role {doctor/nurse/external center for aggregate data insertion}. It's important to note here that users from the same haematology centre have access to all patients of the centre except if something different is declared while registering to the system. Please inform us for any other specification.

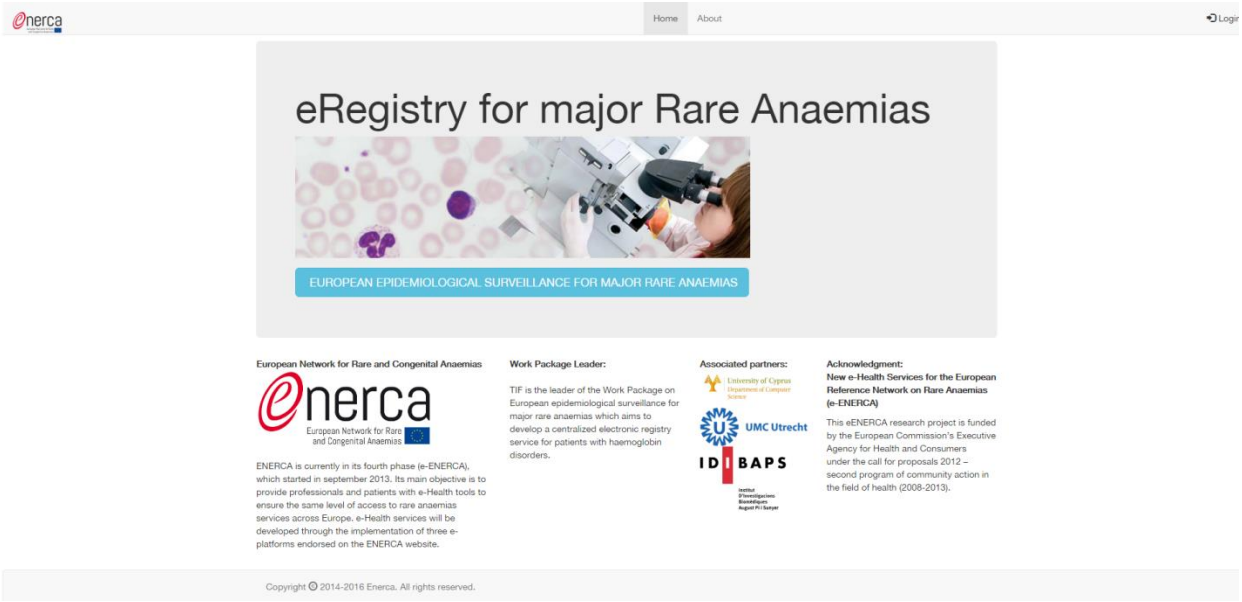
Use eRegistry platform on TIF's server

Access to the eRegistry platform

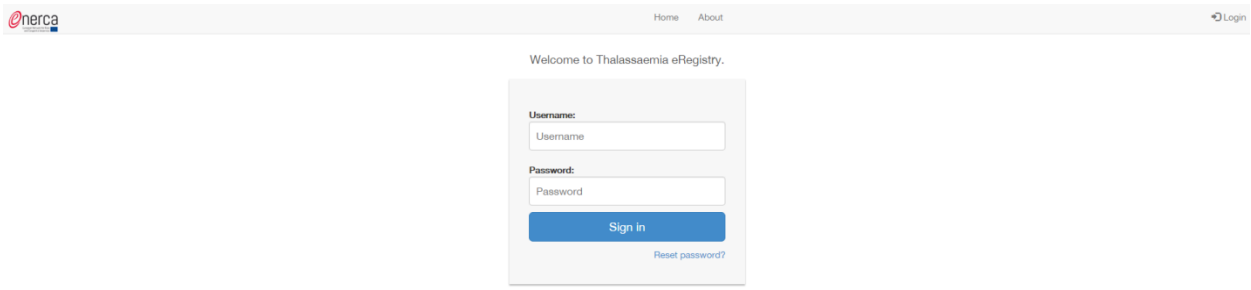
If you want to access to the eRegistry platform please contact Dr Michael Angastiniotis at michael.angastiniotis@thalassaemia.org.cy and provide him your preferred username and your haematology centre. Next, we will create your password to access the platform and contact you via email to give instructions on its use.

Login to the eRegistry platform

1. Access the platform using a web browser: www.enerca-tif.com. You will see the homepage like the screenshot below.

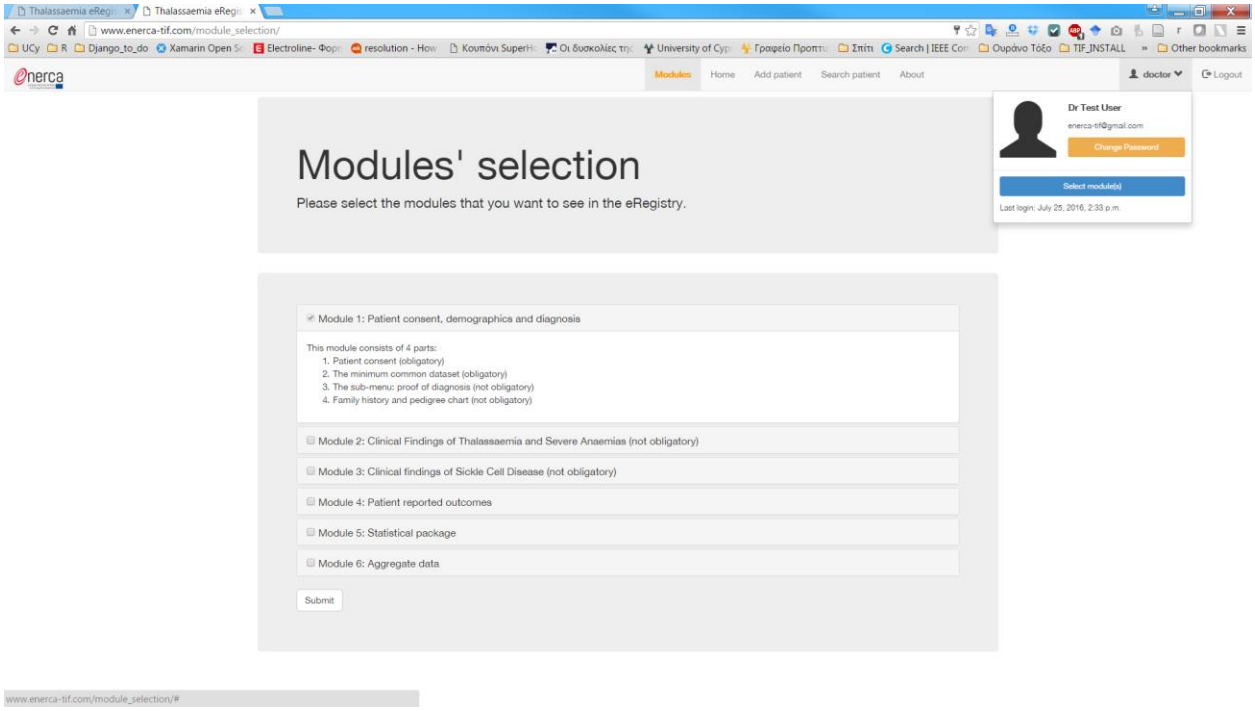


2. Move your mouse cursor the right corner an click the "Login" button. You will see the login page depicted below.

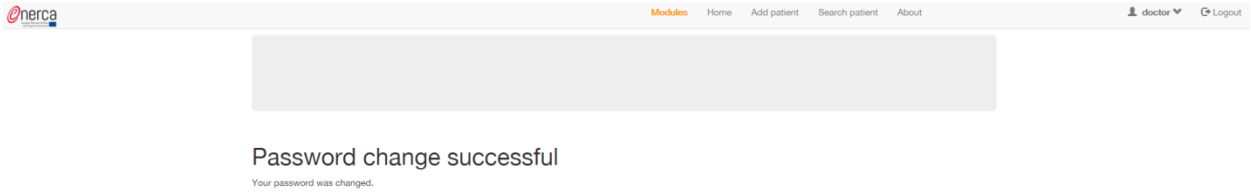


3. As long as you have a username and a password you have to login to the platform.

    a. If this is your first time in the platform please click your username on the right corner and select “Change Password”. This process is for security reasons.

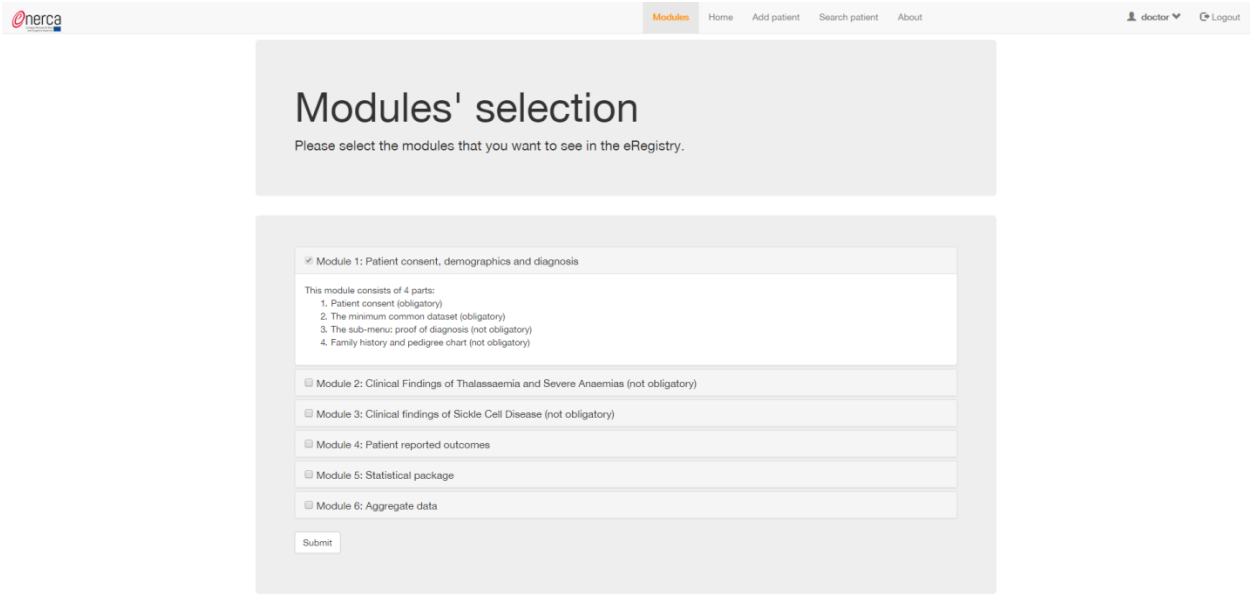


    b. Next, please write you old password and the new one. You have to write your new password two time. The second one is for validation. If your password changed successfully you will see the next page.



c. Before proceeding to the eRegistry platform, if you change your password please logout and login again using your new password this time. “Logout” button is located on the right corner of your page.

4. Once you login to the system you are automatically redirected to the “Module’s selection” page. Here you have to select one or more modules. More information about the modules can be find in the previous section. This the “Modules” page.

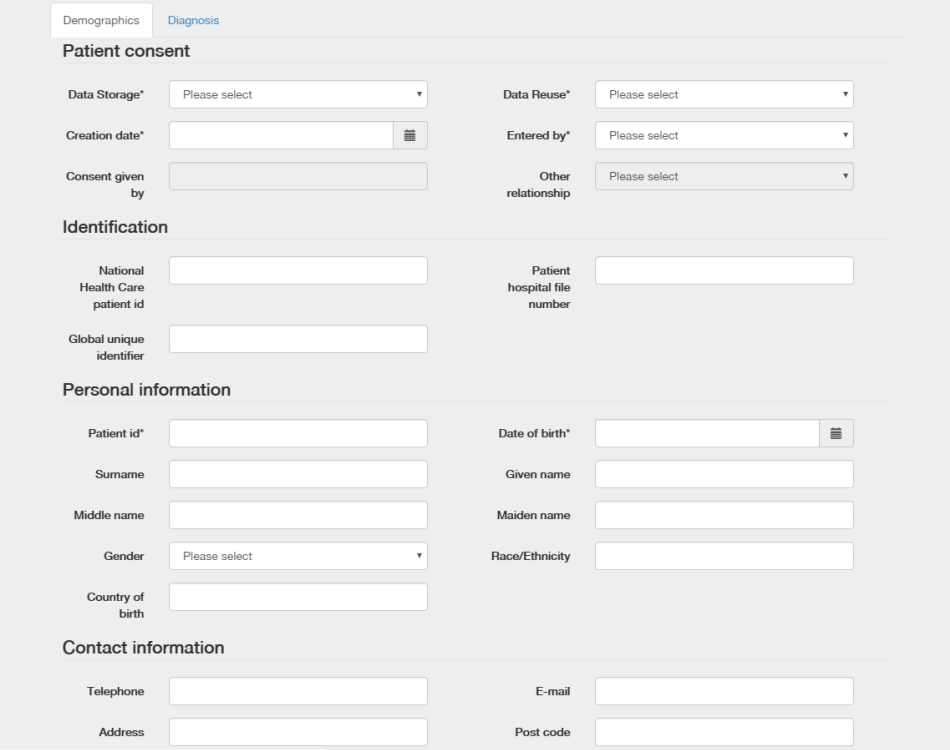


5. Changing modules can only be achieved after clicking the ‘save changes’ instruction at the bottom of the page. After selecting the module press ‘submit’ the ‘demographics’ module will appear but with the title of the selected module at the top. Clicking the title will open the desired module.

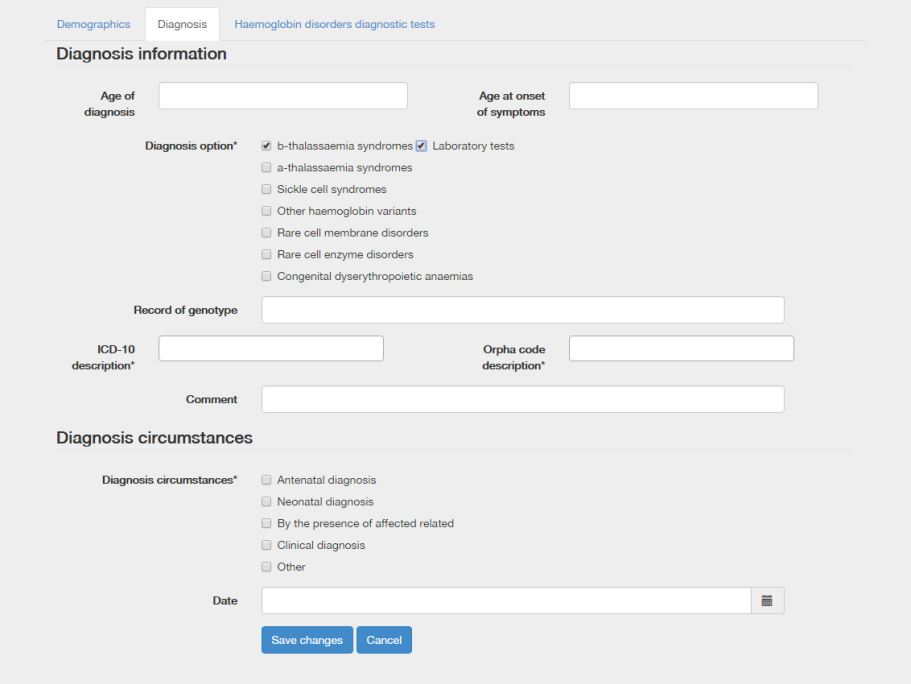
6. The Module1: patient consent, demographics and diagnosis is obligatory. Once the patient has signed the written consent form, the electronic form in Module 1 is filled in and the registry is activated. The demographics can be written manually by the doctor or authorized staff of the centre, or the data can be transferred from the hospital database in which the patient is registered. This section can be viewed only by the doctor/authorized

staff of the centre caring for the patient. An automatically allocated number is then given to the patient and any other connected centre will be able to view the data through this number, thus for all other users the patient is anonymized. Demographic data are shared between centres only if there is shared care, for example in a cross border collaboration, or in an authorized referral to a centre of excellence.

a. This module supports two forms. “Demographics” and “Diagnosis”. This is a screenshot of the “Demographics” form.

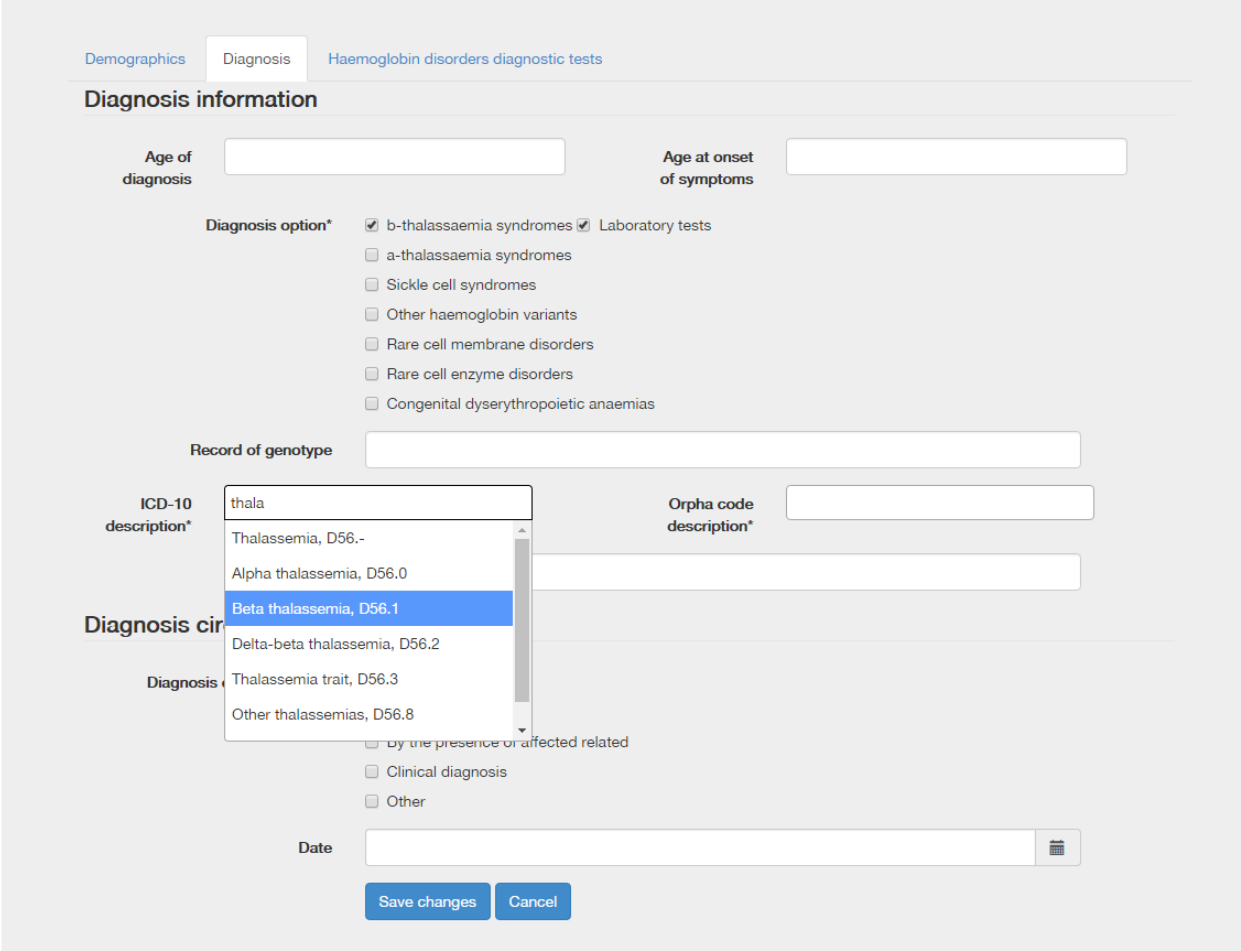


And this is a screenshot of diagnosis form.



b. As you can see in the previous picture you have to select one or more “Diagnosis options”. For each diagnosis option there are further “Laboratory tests” that validate the diagnosis. If you select “Laboratory tests” of a diagnosis option a new form is shown right of the “Diagnosis” form. In this new form you can fill in all the tests you performed for this patient.

c. The “ICD-10 description” and “Orpha code description” bot support autocomplete functionality. Once you start writing your diagnosis all the available codes are shown to select one or more. See an example in the figure below.



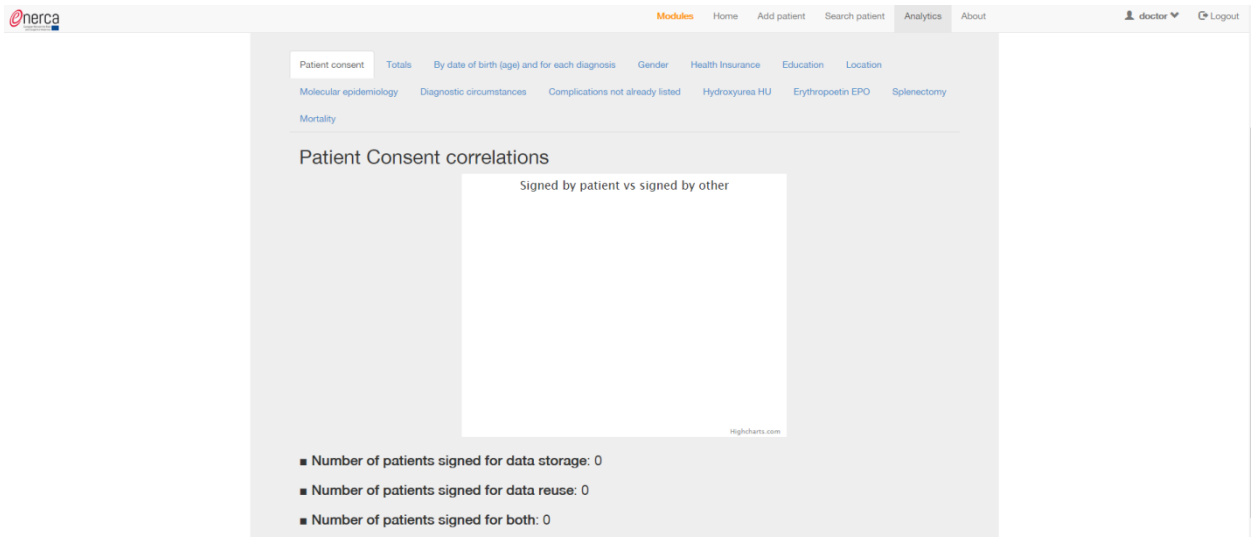
d. All elements in form that have the "*" sign are obligatory.

e. Once you are finished you have to click "Save changes" button in one of your forms to store the patient's data. If you want to cancel patient registration click "Cancel button".

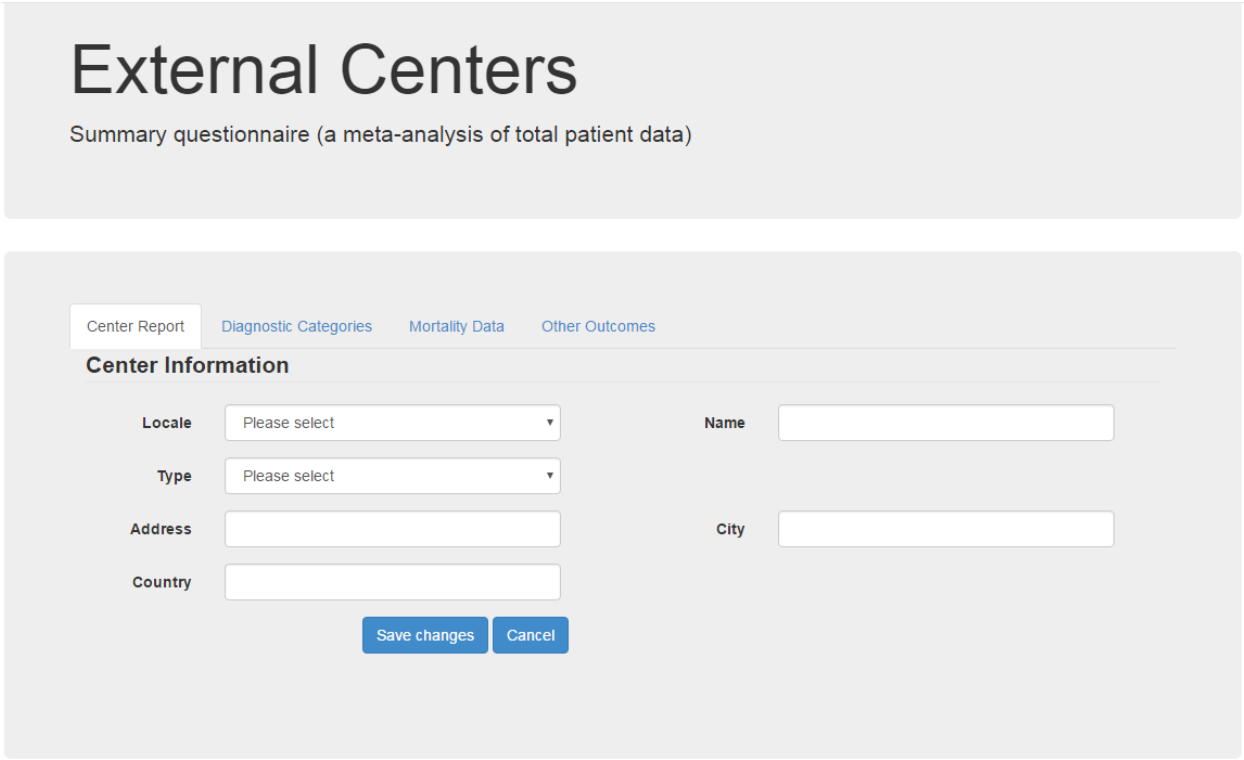
7. The Module 2: Clinical findings of Thalassaemia and Severe Anaemias is not obligatory. This module enables the "Annual Summary of Thalassaemia and Severe Anaemias" form that stores the clinical findings for these anaemias.

8. The Module 3: Clinical findings of Sickle Cell Disease is not obligatory. This module enables the "Annual Summary of Sickle Cell Disease" form that stores the clinical findings of Sickle Cell Disease.

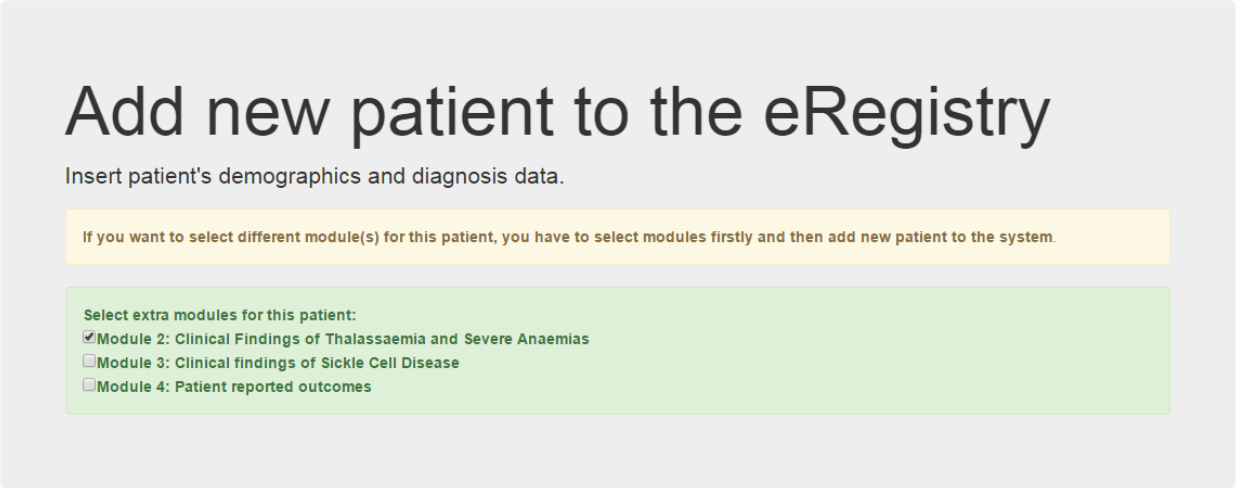
9. The Module 4: Patient reported outcomes enables the form that stores the patient reported outcomes.
10. The Module 5: Statistical package enables analytics packages uses preset queries regarding the patient's recorded data in order to get correlated groupings. This module can be accessed from the button on the upper menu of the page like the screenshot below.

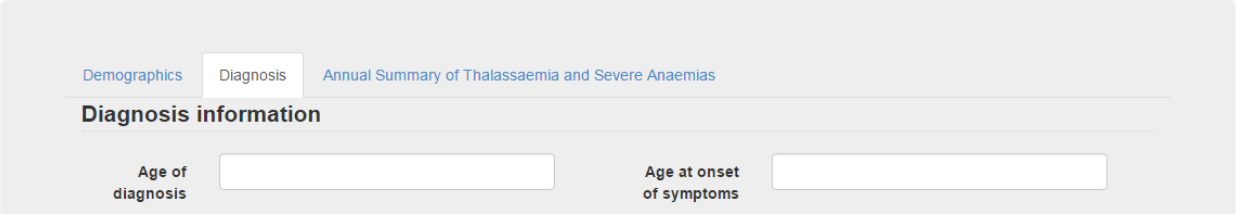


11. The Module 6: Aggregate data is not obligatory and is used only for external centres that do not store patients' data in the eRegistry but the want to share them anonymously for statistical purposes. A screenshot of the supported forms for this module in shown below.



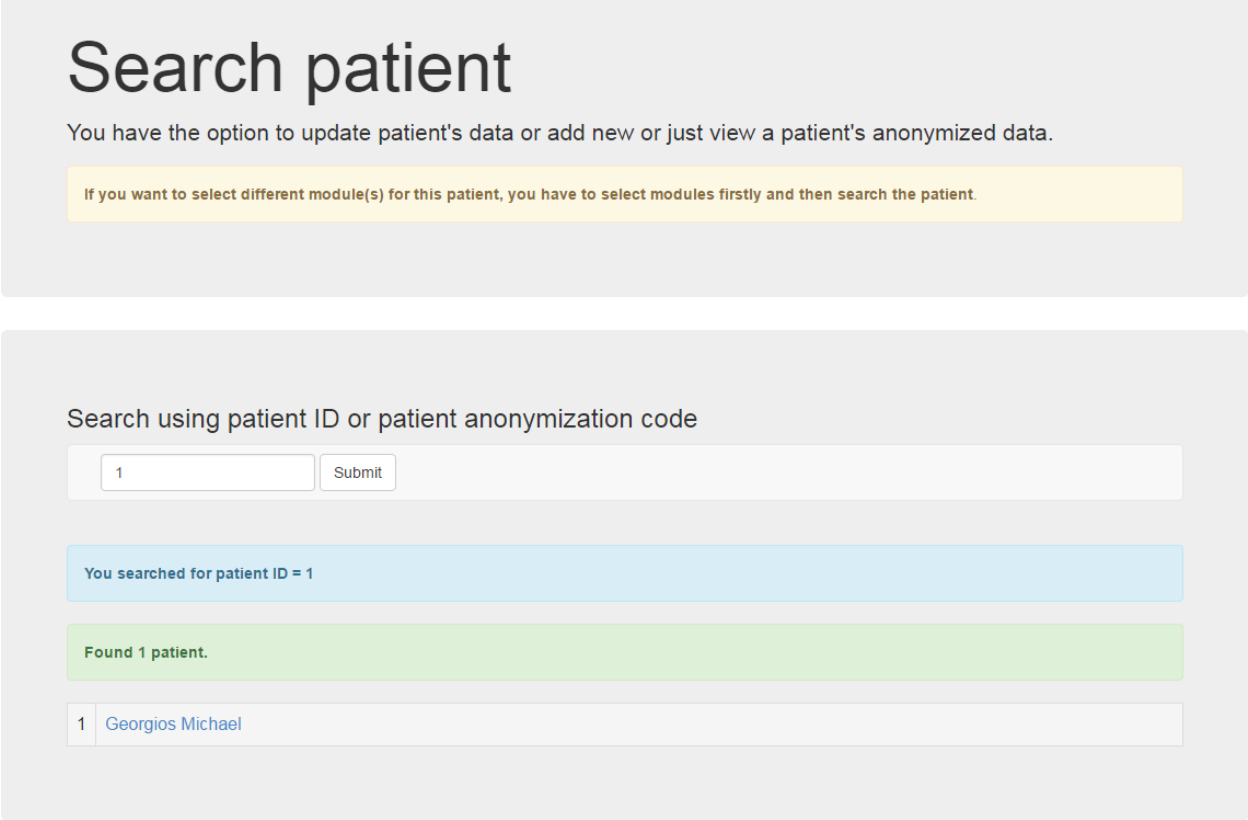
12. It's important to mention here that if you want to select different module(s) for a new patient, you have to select modules firstly and then add new patient to the system. This is followed by clicking the orange '**Modules**' at the top of the page, which leads to the menu of modules.
    a. Also, there in case that you are adding information about a new patient and for this patient you need to add values regarding a module that you have not selected initially, now you have the option to do it by selecting the appropriate module from the "Add new patient to the eRegistry" page. As you can see in the image below we have incorporated a new menu in the beginning of the input page.
    b. The same menu is shown when you are updating any patient's data and you need to add some more information to the system.



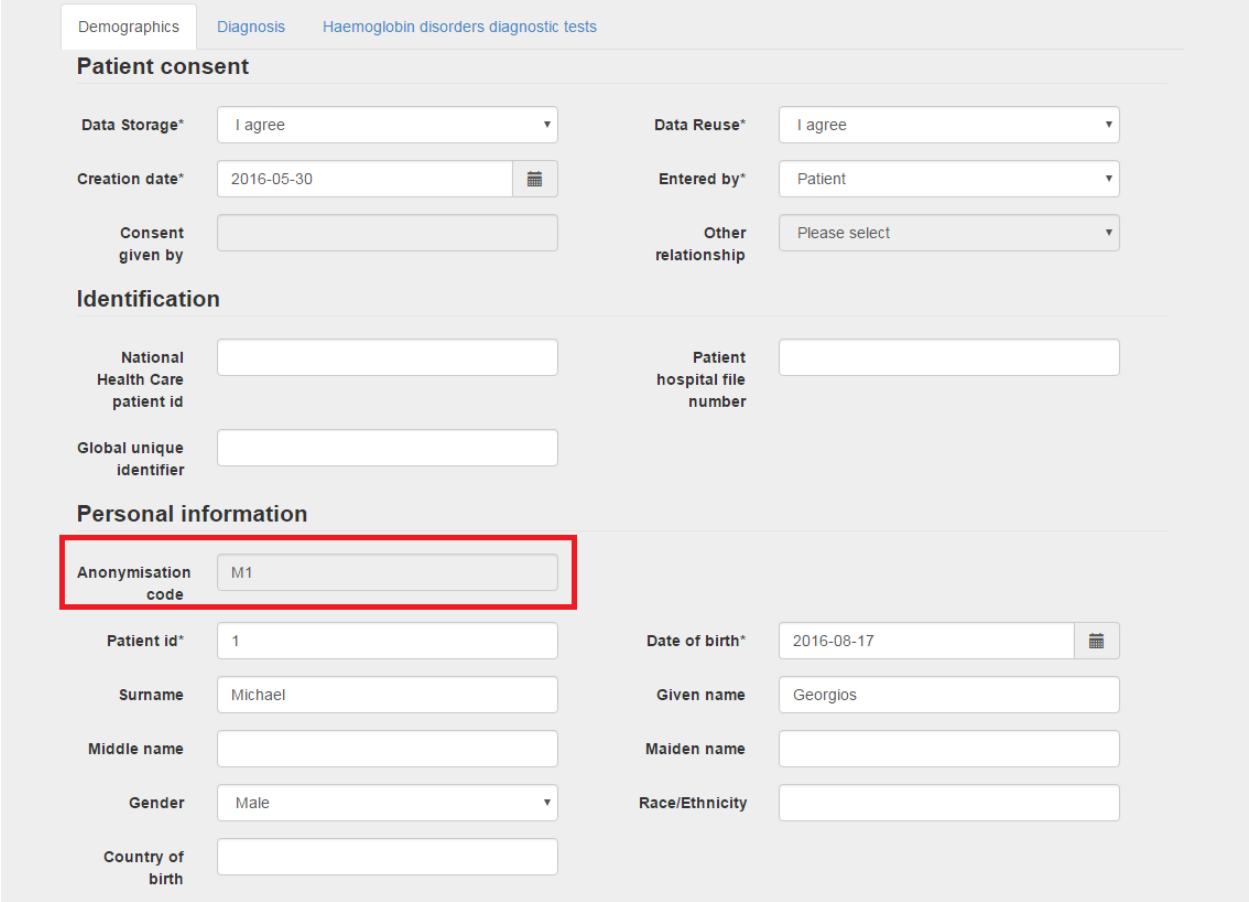


13. The platform supports a search engine for patients using his/her id or patient anonymization code.

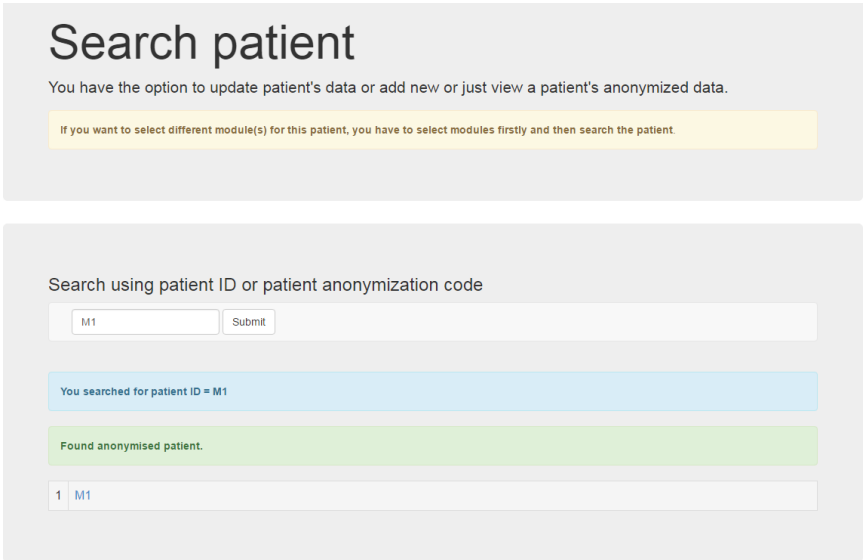
    a. The anonymization code is an auto generated code of the system using the initial letter of the patient's surname and a counter number. For example if your input patient is "Georgios Michael" the anonymization code will be something like "M1". You can see this patient code if you search to the platform the patient using his/her id. For example if the patient id is "1" you can see the page below.



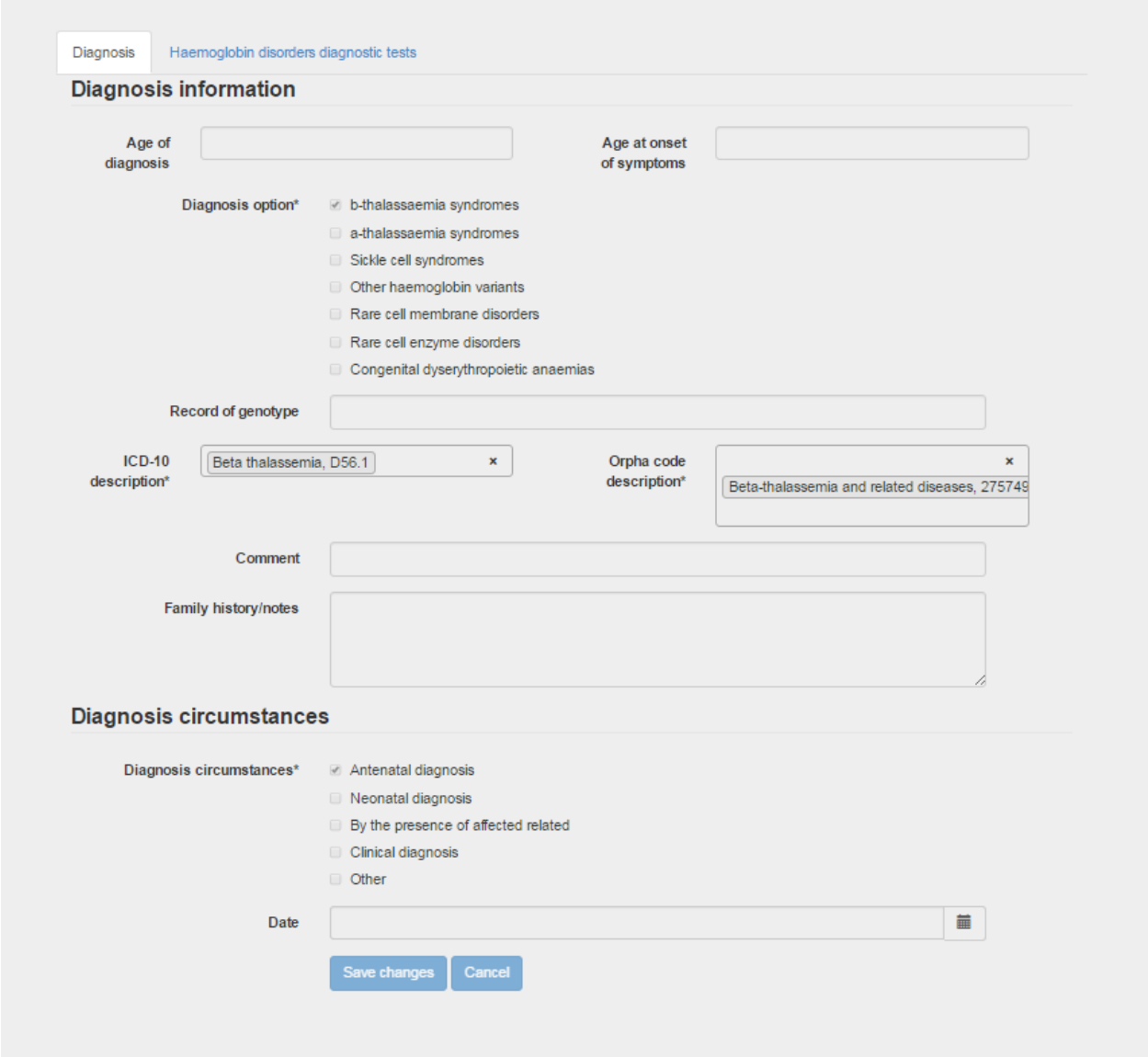
b. If you click the patient's name you will be redirected to a new page to view the patient's data. Here you can view the anomymization code and/or update any data and next click "Save changes" button.



c. Search using the anonymization code of the patient you can view the patient's data without any demographics data.



d. By clicking the anonymization code you will get the patient's stored data anonymized and not editable like the image below. Once a doctor of the platform needs a second opinion for the patient, he will have the option to provide the anonymized code of his patient to another doctor signed in the system. to check the anonymized patient's data.



14. Once you finish using the eRegistry platform you have to logout using “Logout” button on the right corner of the page. This will clear from your browser any selections you made while using the eRegistry platform.