EB Registry

How-to Guide & User Manual

Version 0.1 – March 2016

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Introduction

The EB Registry is user-friendly and intuitive to use. This How-to guide gives a brief introduction to the registry and offers advice on how to use it.

What is the EB Registry?

The EB Registry is a database of data elements related to patients suffering from EB. A core set of data elements have been included following extensive investigation into the requirements of the system. This dataset is still evolving as discussions take place between OpenApp developers and experienced Dermatologists.

Patient records are stored in a secure hosting service as used for all OpenApp Registry products.

How do I get started the EB Registry?

Once you have been authorised to use the EB Registry, you'll receive your own personalised domain or url. You will also receive a username and password. This will allow you access to the registry.

For optimal user experience we advise using the latest version of Google Chrome, Firefox or Microsoft Internet Explorer version 9 or higher as your browser.

Once you click on the url, you will be presented with the login page.

Enter your individual username and password and click '***Secure Login***'.

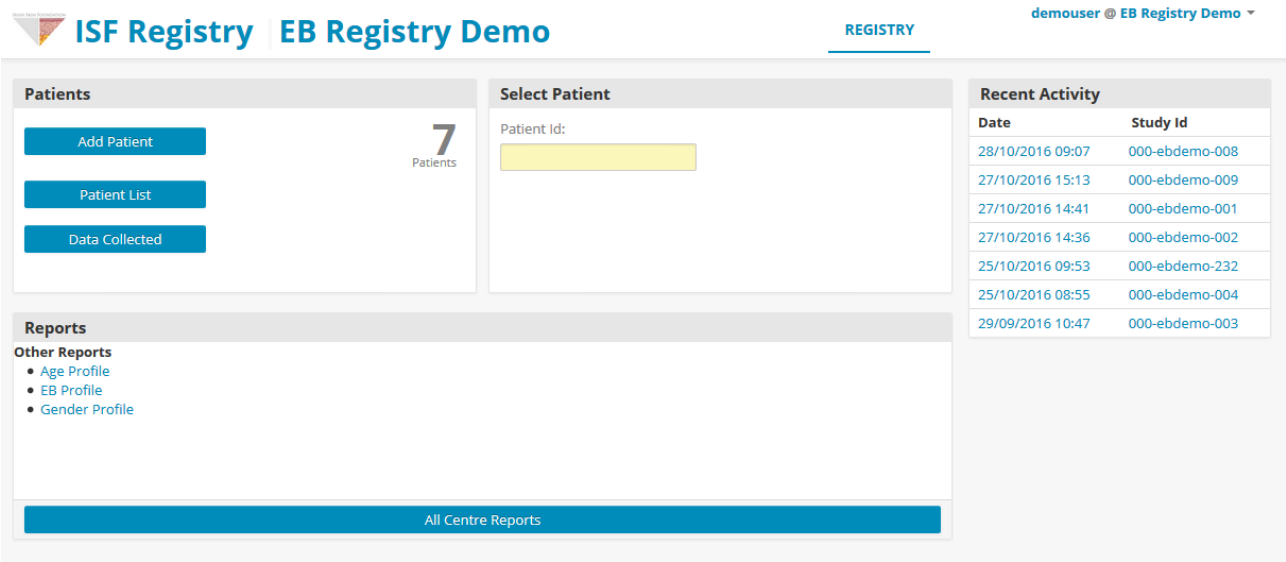
You will be presented with the home page.

For Demonstration purposes login credentials can be found beneath the login box.

Basic Navigation

There's two main Dashboards within the registry.

The EB Registry, is the home page of your centre and the first main dashboard.



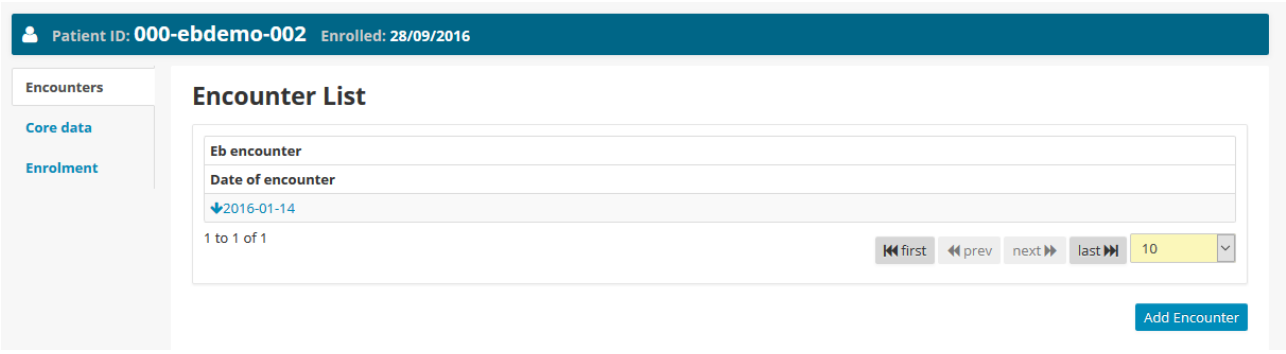
From here you can access all the main sections:

- **Patients panel** that will allow you to:
  - enrol patients and input core data
  - see your patient list
  - view the Data Collected
  - see the number of Patients and Patient Lists in the Centre
- **Select Patient panel** allows you to search for a patient by patient ID
- **Recent Activity panel**, where you can see a list of the patient meetings that you have had lately.
- **Reports panel**, where you can generate standard reports, such as enrolment numbers.

Navigation from the Centre Dashboard can be achieved by clicking on the relevant active button.

To ***return to*** the Centre Dashboard at any time, simply click on the ISF icon.

When selecting a Patient record from the home page panels, you'll access the second main dashboard, the Patient's dashboard.

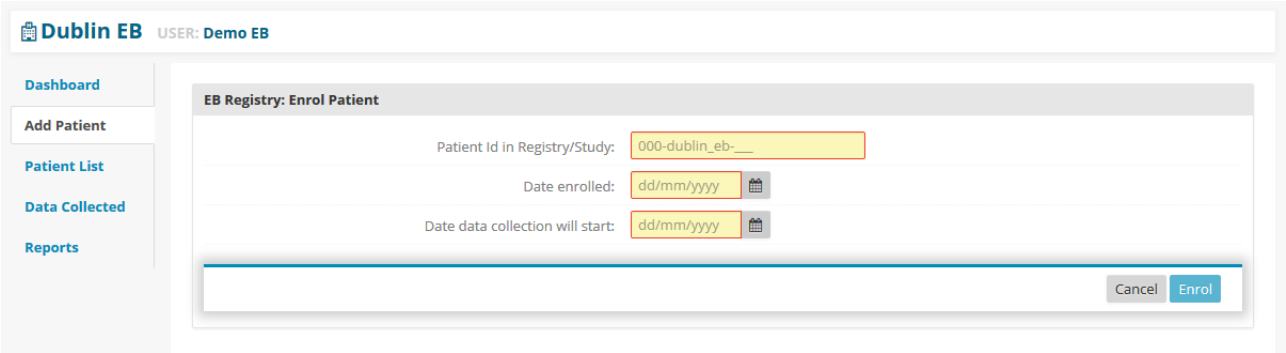


From here you can:

- Access all **patient encounters** to view and/or edit data from previous encounters;
- Add **new encounters** to the patient record;
- Access **Core Data** elements with possibility to Edit;
- **View Patient Enrolment Details.**

Side Tab Menus

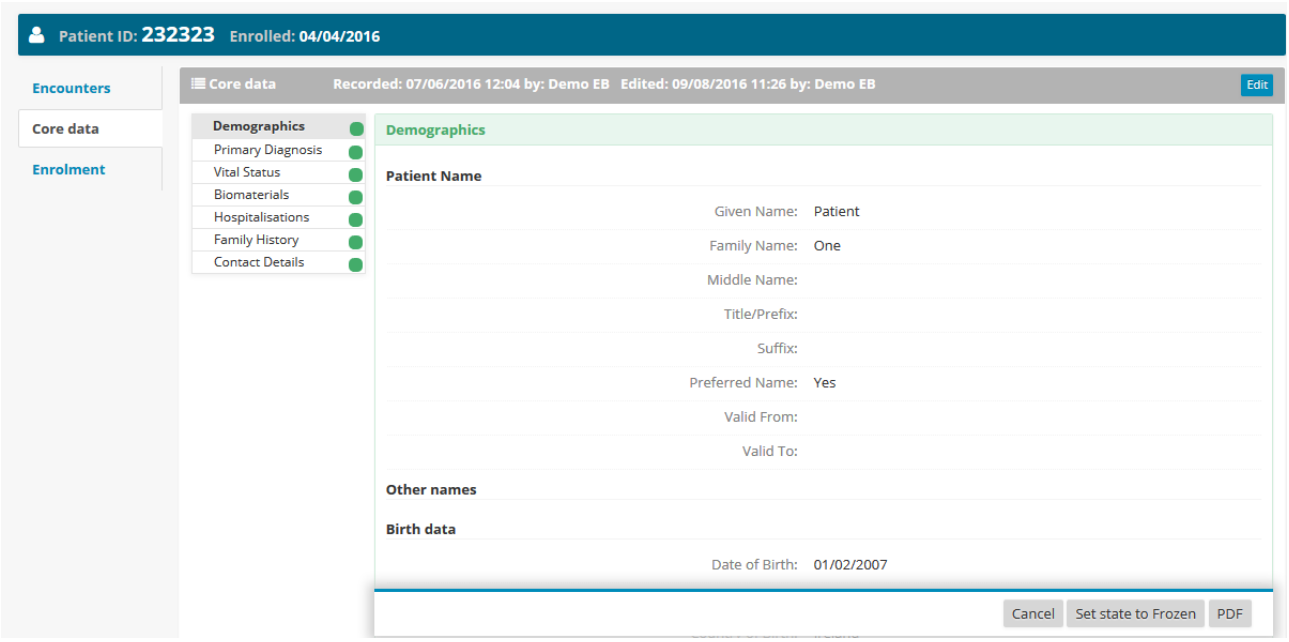
When moving around the register, you will see screens that use Side Tab Menus.



The menu in black font indicates this menu is currently selected, and the blue font menus indicates other screens that are available.

Above you can see Side Tab Menus for a Centre.

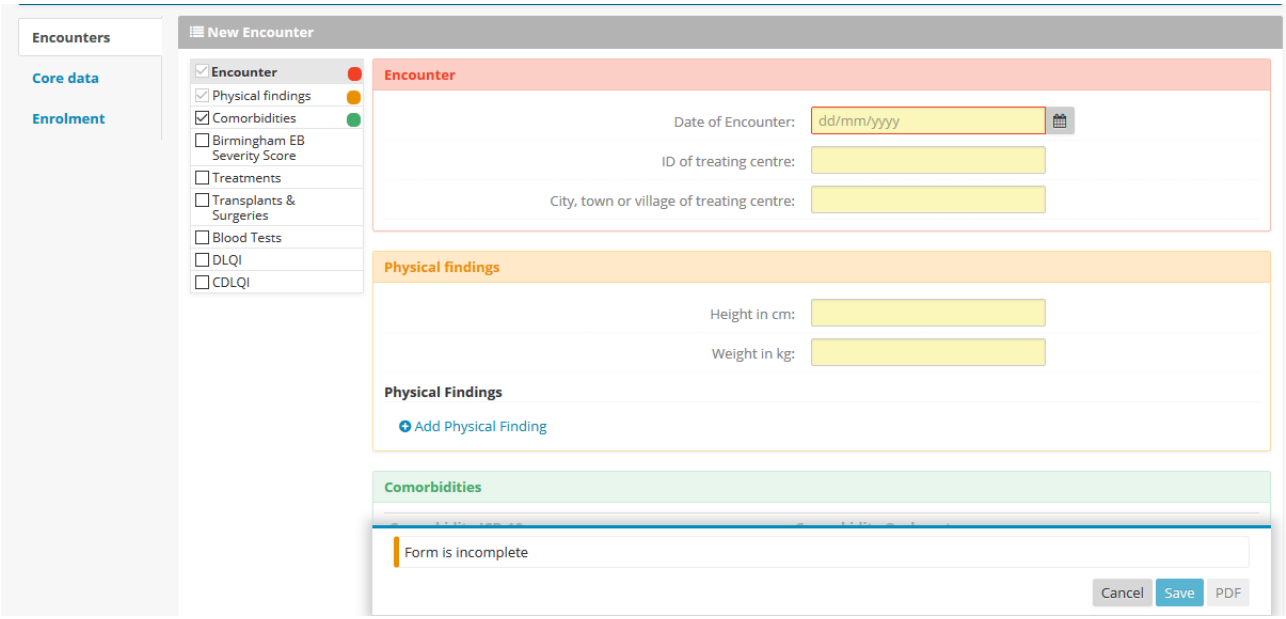
The options for the Side Tab Menu for a Patient are different but work in the same way.



Red/Amber/Green

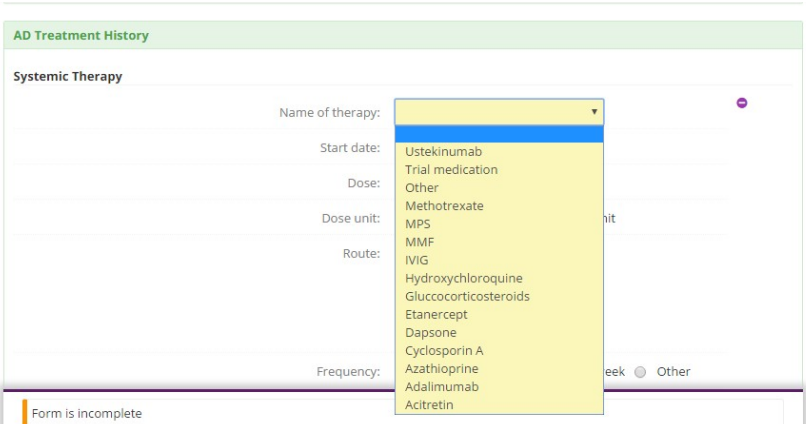
When you enrol a new Patient or add a new encounter (see image below) you will notice that some input fields in the registry are highlighted in Red or Green. This is because the registry uses a Red/Amber/Green colour system to indicate if the information in the section is required but incomplete, expected but incomplete, or completed/optional.

The same colouring system is used throughout the system.

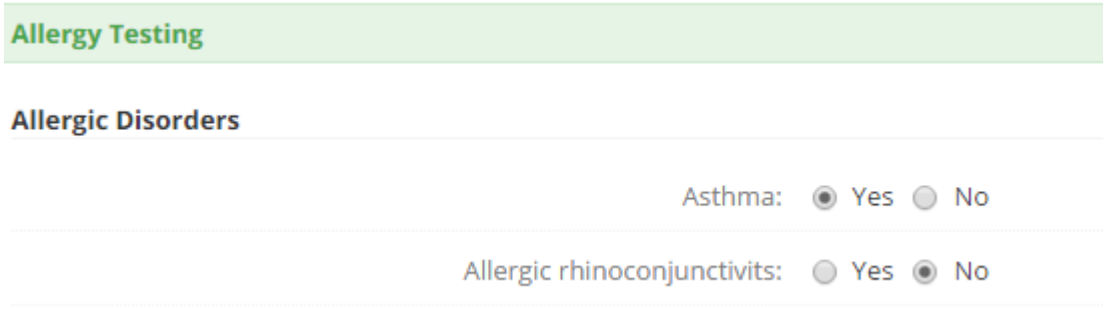


Data Entry

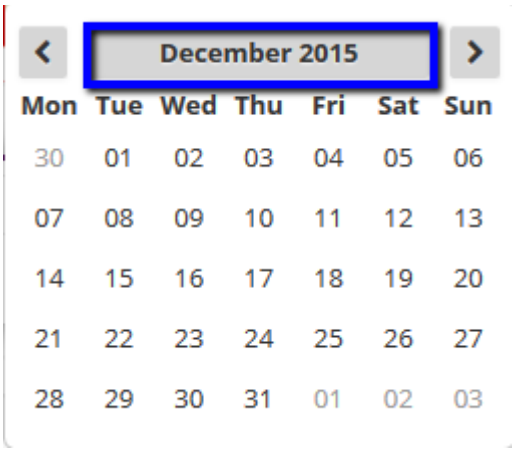
Data can be entered using a combination of **drop-down lists**, **check boxes**, **radio buttons** and **date input fields**. Here you can see a drop-down list being used.



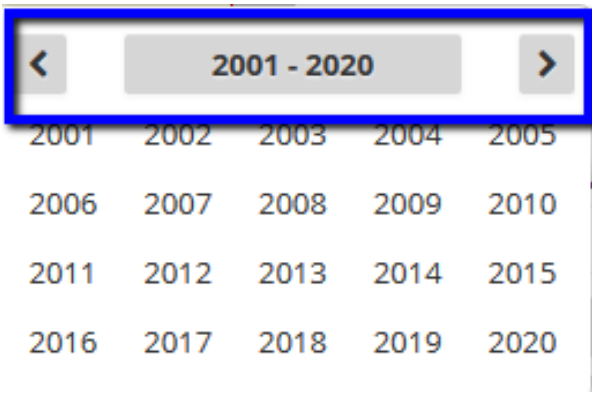
Radio buttons can also be used to select options in lists.



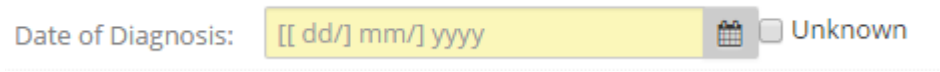
The **Date input fields** (date pickers) allow quick access to the relevant date. Initially they open on the current month but then clicking on that month gives access to other months in that year.



Clicking on that year, gives access to adjacent years, and the arrows can be used to find years in groups of 20.



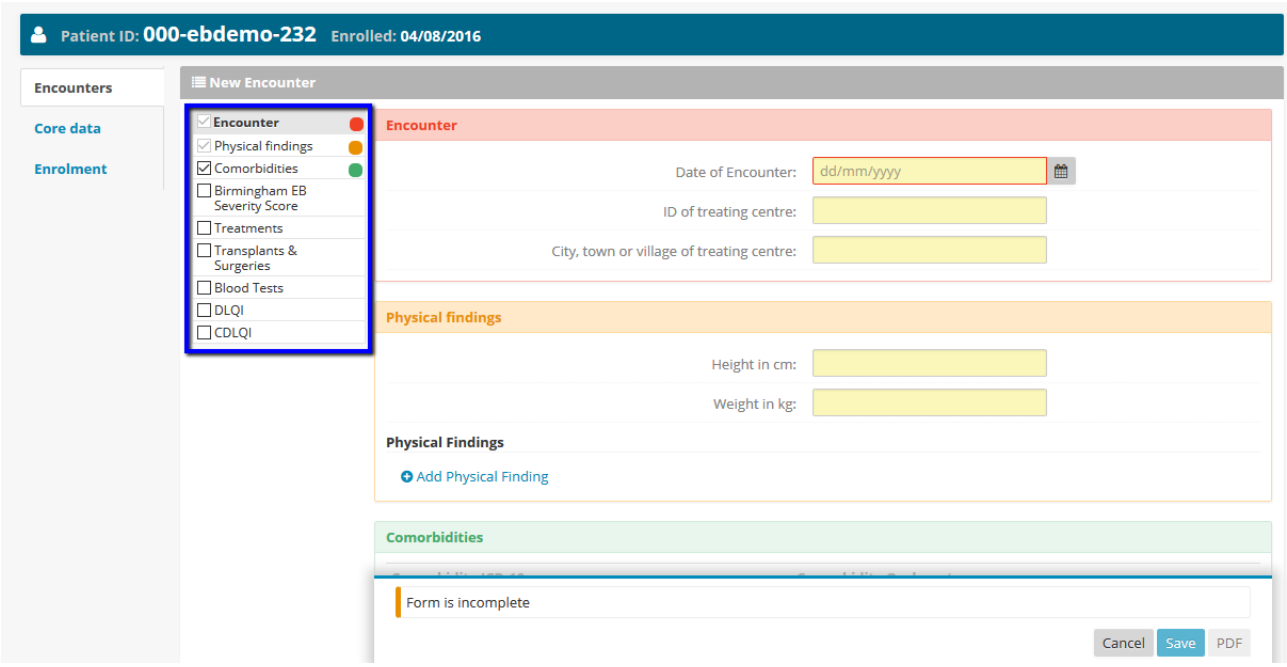
Note: Date pickers are used where an exact date is required. However, there are some instances where the month or year are sufficient.



For example, the patient records may not hold the exact date for some data fields. So it is possible to type into the input field and record the month and year, or use the date picker if the exact date is known.

Check boxes are used in adding a New Encounter. A tick initiates an Anchor Link to the relevant Encounter Section.

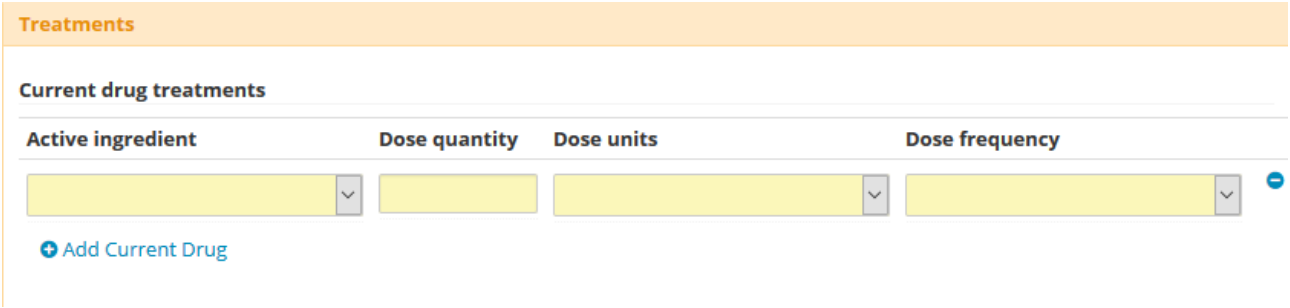
The only Anchor Link selected by default is the Encounter section. To indicate sections of the Encounter that you wish to complete, you must tick the check box, and the relevant Encounter section will open on screen.



Only those sections that have the check box ticked will appear on screen.

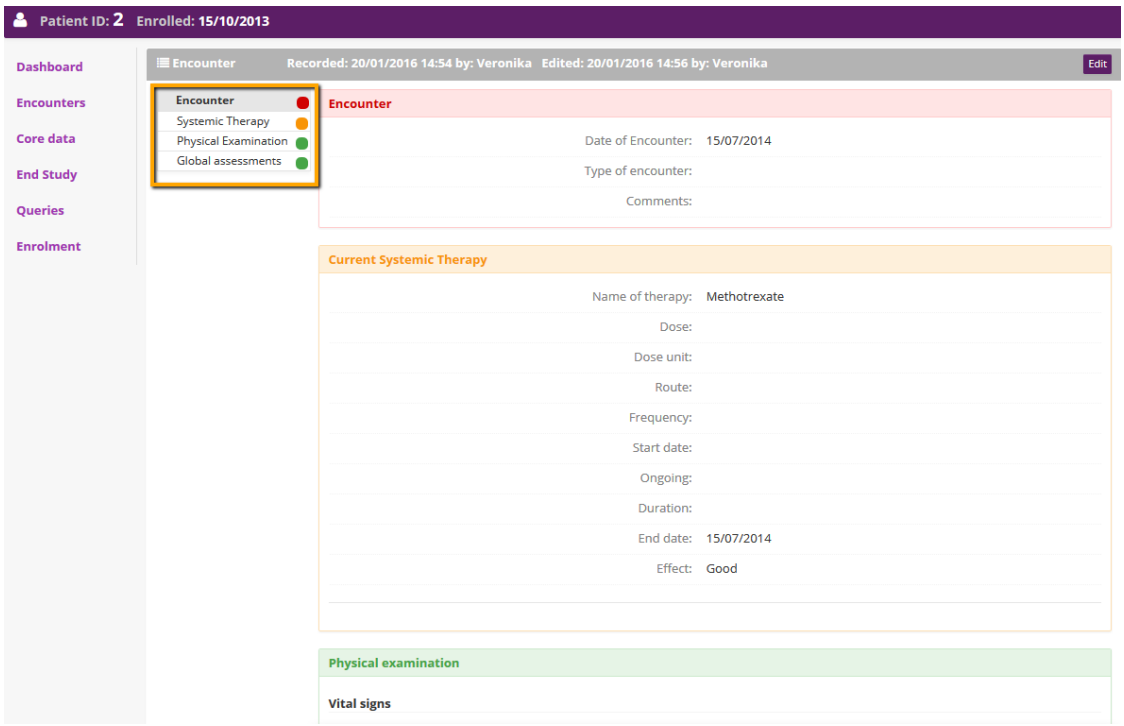
Repeating fields can be find throughout the forms when there 's the need to be able to add more than one entry for that field.

For example in Treatments, where you can add multiple drug treatments as part of the same encounter/visit.



Section Validation Indicators

The Section Validation Indicators also use the Red/Amber/Green colour system.



In the image above, highlighted by the orange box, you can see three sections of the Encounter Form that the Clinician has indicated he intends to include in this Encounter:

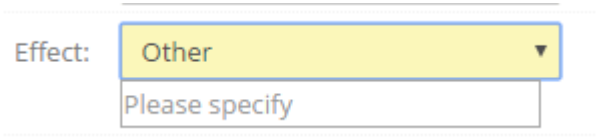
Red: More information in this section is required

Amber: More information in the section is expected but has not been entered

Green: Data fields in this section are completed

The Encounter cannot be saved if any of Section Validation Indicators are Red.

Other (specify): Occasionally in the system, it is possible to add additional information to a text box. This will be indicated by an Other (specify) input field.



Hard / Soft Checks

[Note: Dependant on Customization based on client requirements]

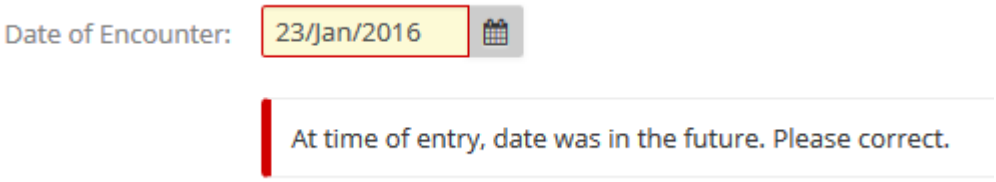
The system compares the values you have entered with validations in the system.

These comparisons can be what are known as "Hard Checks" or "Soft checks".

If you make an error when entering data, the system will send you a message. It will describe the value that it did not expect, and may ask you to enter the correct value.

For example, if you enter a Date of Encounter in the future, the system sends you a message "At time of entry, date was in the future. Please correct".

And the relevant field is highlighted in Red

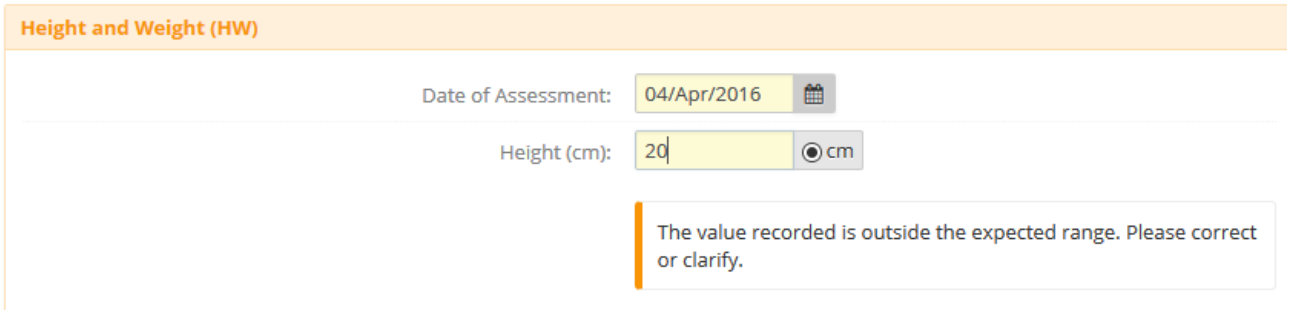


The Red highlighting indicates that the entry in the data field must be changed to allow the form to be saved, also called Hard Check.

So, you **must** resolve "Hard Check" issues immediately during data entry, before you can save the data.

If the values entered are outside the expected range,"The value is out of the expected range. Please correct or clarify". In this case the relevant field is highlighted in Amber.

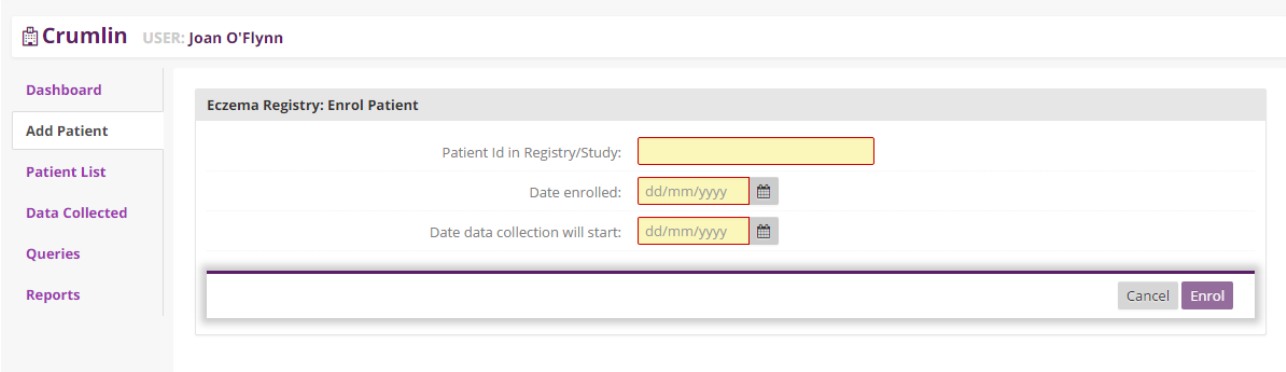
This indicates that the entry in the field may be changed, or if the value is correct, it can be confirmed, to allow the form to be saved, also called Soft Check.



How do I enrol a patient?

Click the ***Add Patient*** button in the Patients panel, and the Enrol Patient form opens.

Here, you enter the Patient Id, which must uniquely identify the patient.

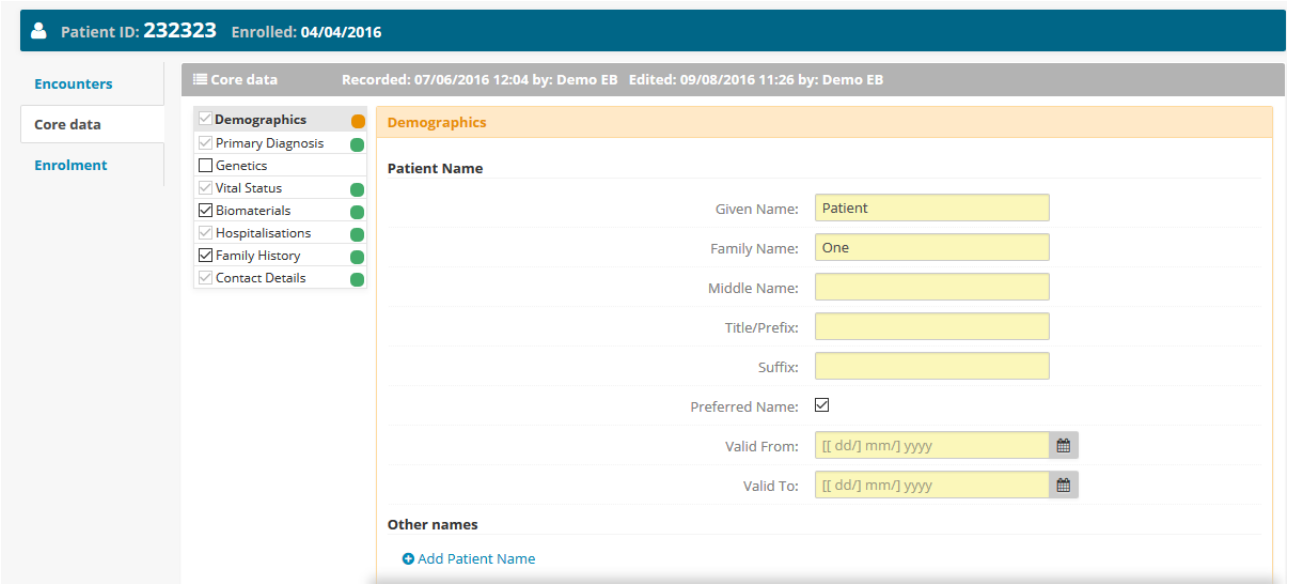


And you enter the Date of Enrolment and the Date data collection will start.

You click the *Enrol* button and all information is saved.

Once you have enrolled your Patient you can then begin to add in a multitude of information on your patient. You can enter the information as you enrol a patient or you can enter data at a later stage.

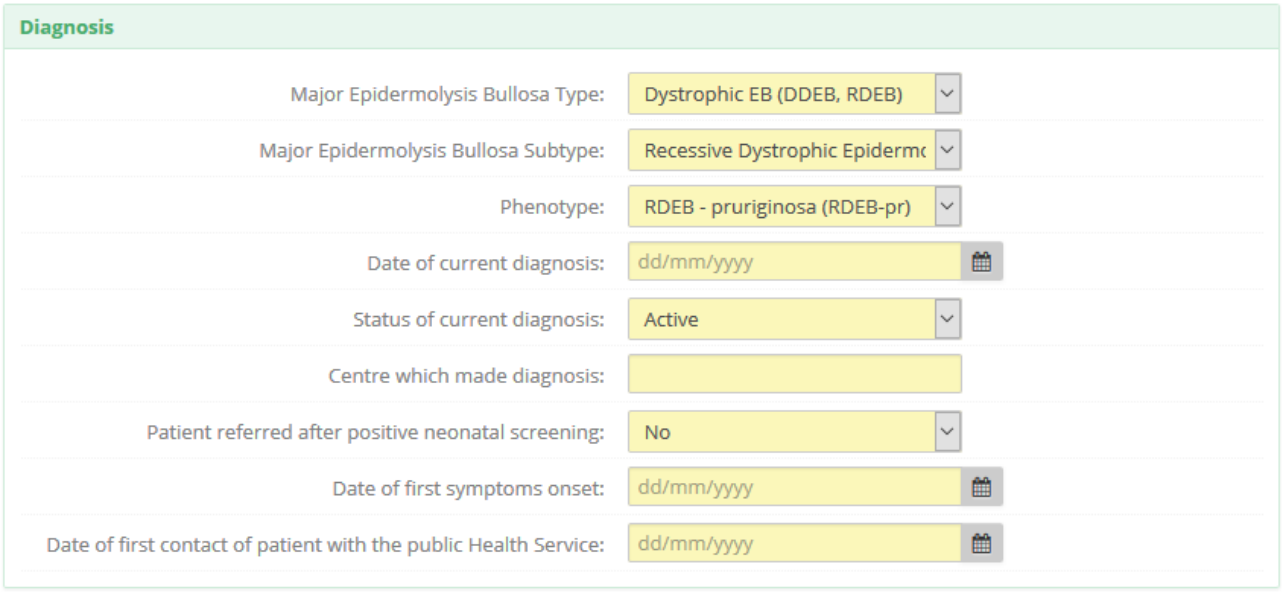
Below you see the sections of the Core data form that need to be completed.



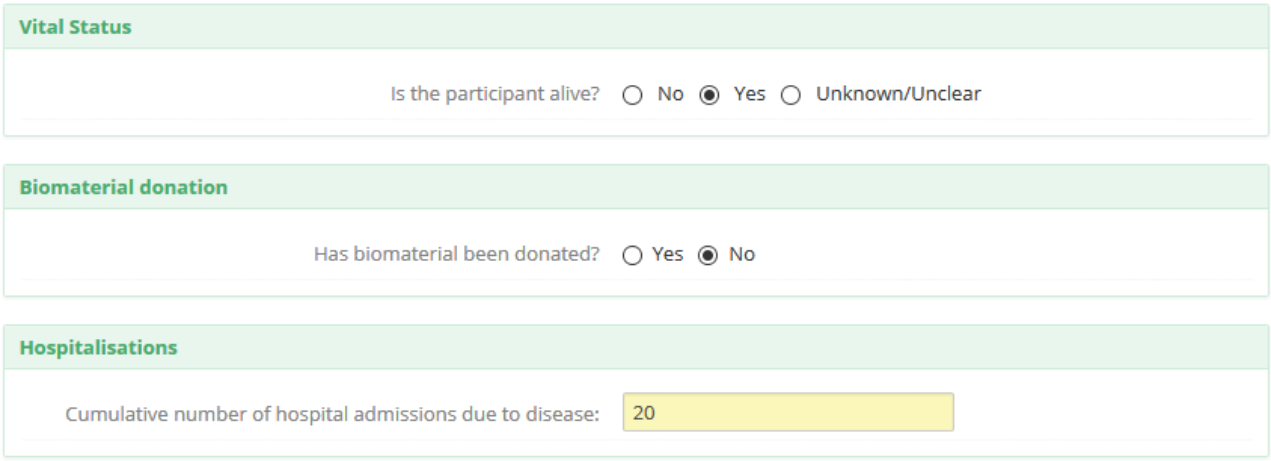
The Core Data form is designed to have recorded “static” information, that doesn’t change often. The user will come back to it to edit only if any changes or updates happen.

In the Demographics section, you enter data associated with the patient.

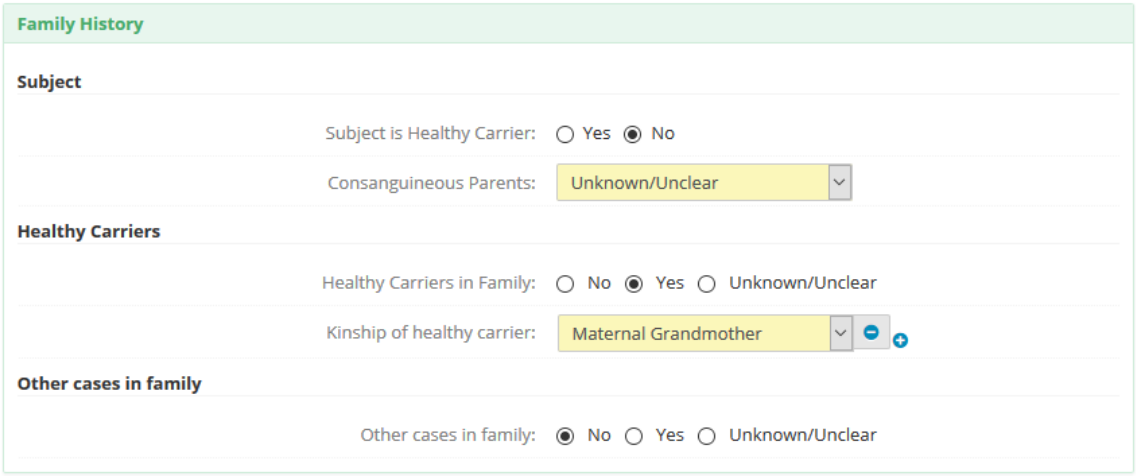
Diagnosis Information records the types and sub types of EB, based on the Onion Skin classification, date of diagnosis and the diagnosis criteria.



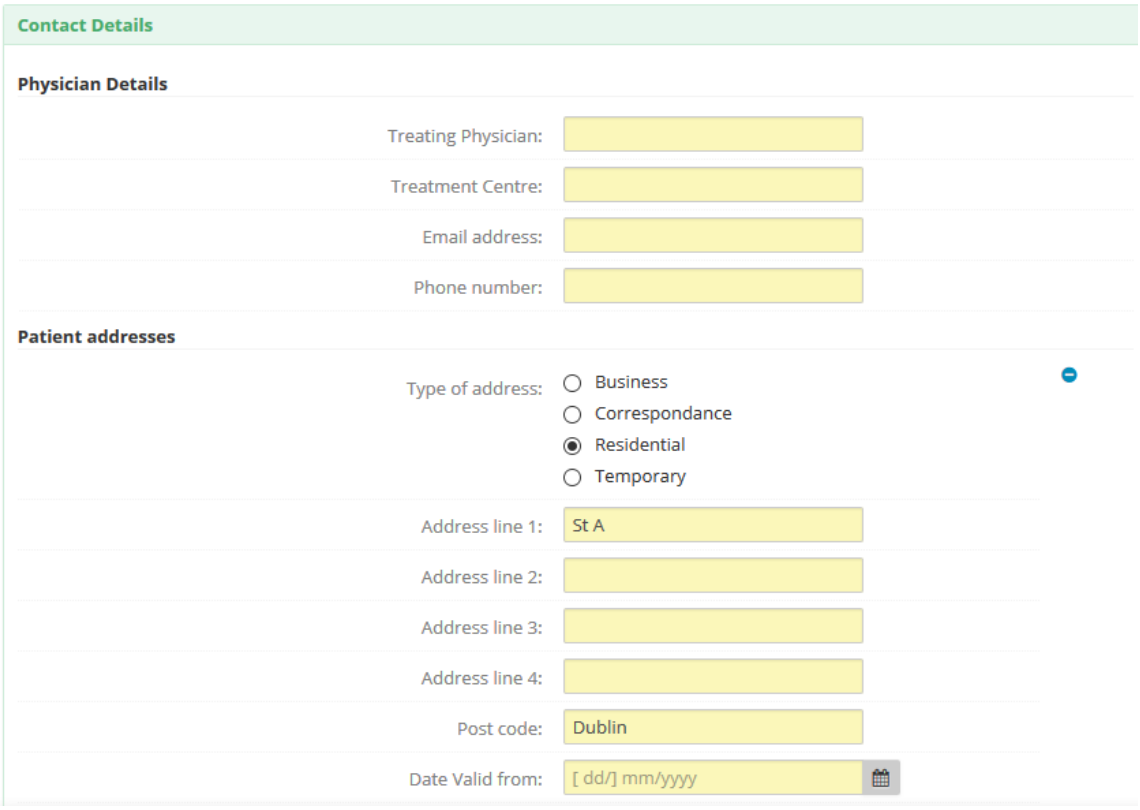
This is followed by Vital status, Biomaterial donation and Hospitalisations.



In the Family History section the user will document relevant information regarding other carriers or cases in the family.



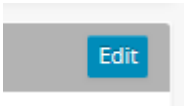
And the Contact Details section for both the patient and the treating physician.



If you had made an error when entering demographic information, you can always make changes to the form.

You reopen the Patient Record and select Core Data on the Patient Side Tab Menu.Y

You then click the ***Edit*** button in the top right hand corner, go to the section you wish to alter, make the required changes and then click ***Save***.



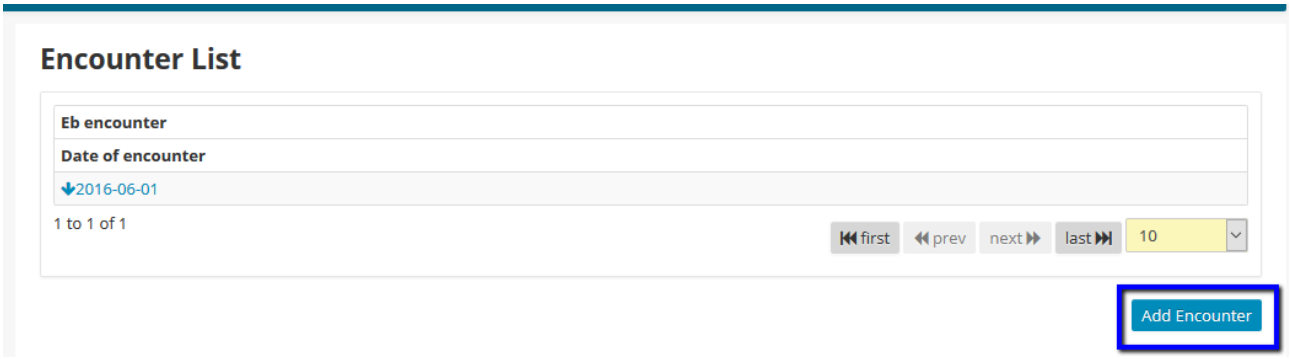
How do I enter a Patient Encounter?

A patient encounter allows you to add information every time there is a different or separate patient encounter. Using the Encounter option, you can add the following information about every encounter:

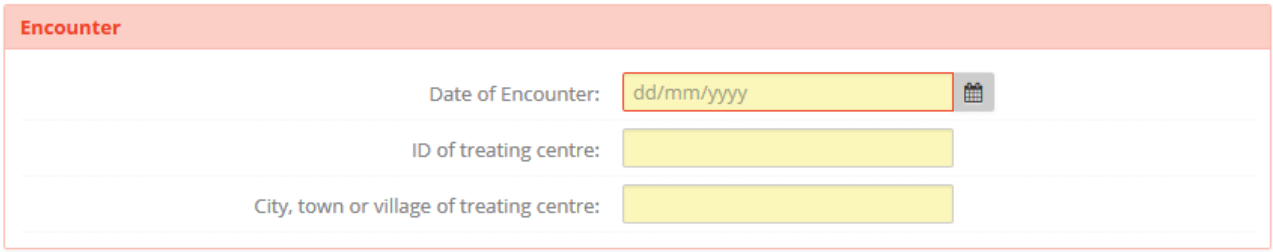
- Physical Findings
- Comorbidities
- Birmingham EB Severity Score
- Treatments
- Transplants & Surgeries

- Blood Tests
- Health Related Quality of Life Indices

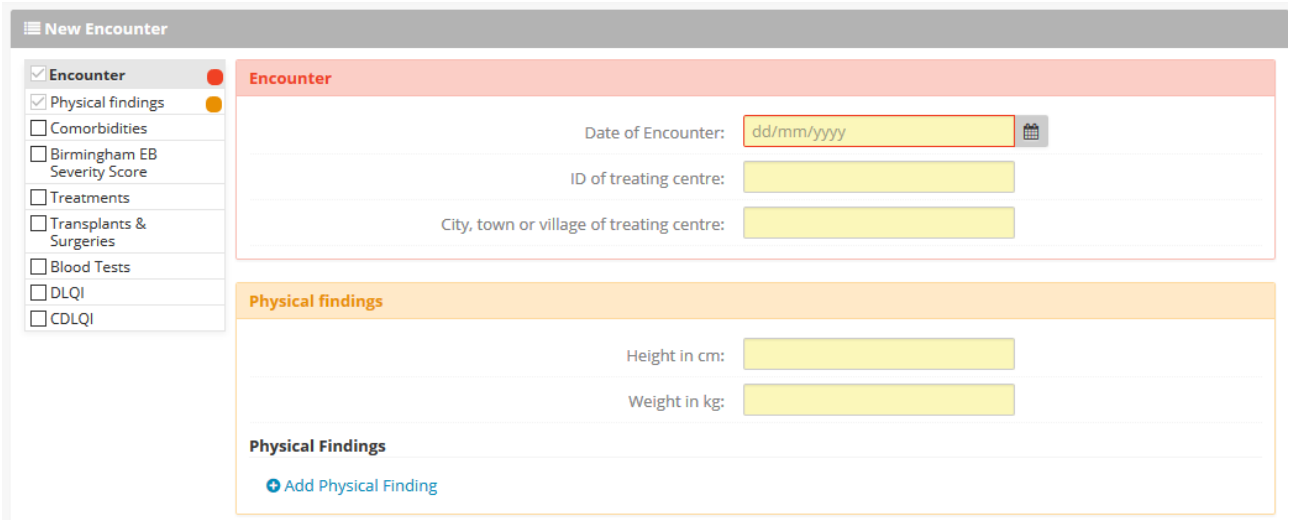
To enter a new encounter, you click on the Add Encounter button.



Date and Treating centre are the first details to enter.

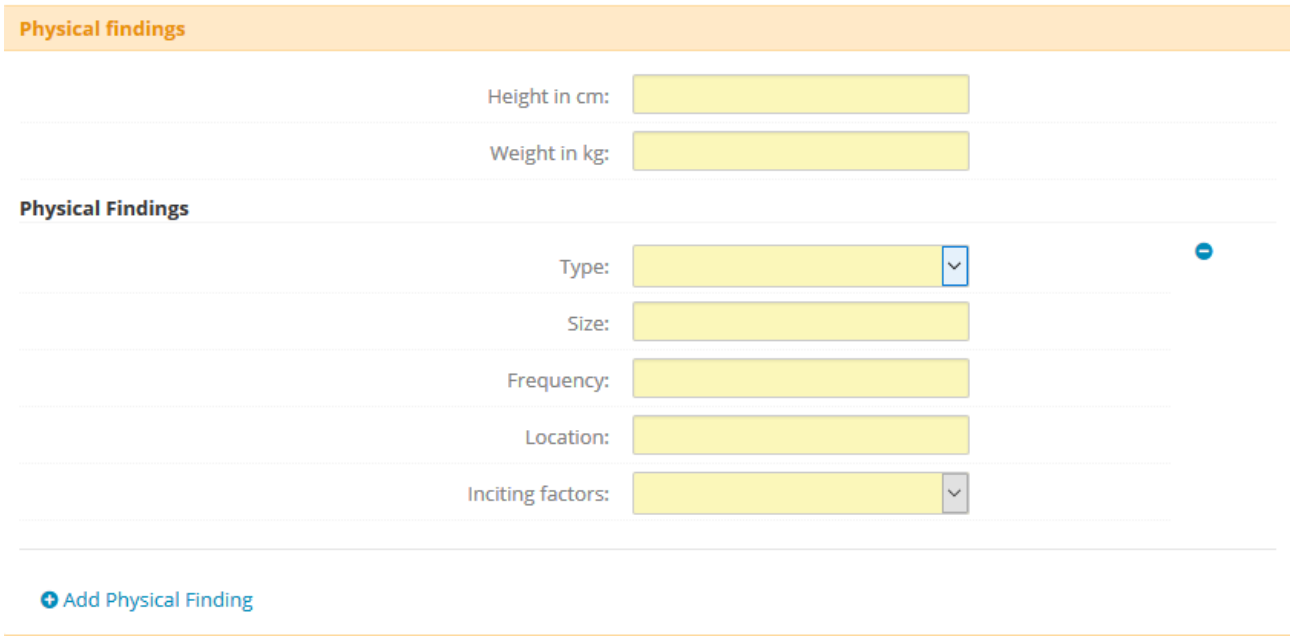


And then you use the check boxes beside Anchor links to indicate which sections of the encounter form you wish to complete.

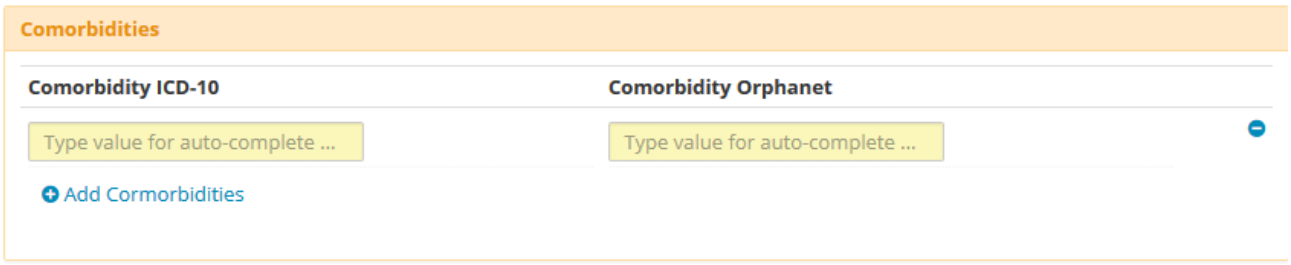


In Physical Findings, besides the height and weight, you can document any infections, wounds, blisters, etc and how they're characterized (size, frequency, location and inciting factors).

Being a repeating field, you can add multiple physical findings according to your clinical assessment.



In Comorbidities or other problems, after selecting the add button, the user will have auto-complete fields to document ICD-10 and/or Orphanet diagnosis.



For the Birmingham EB severity score, the system will give you the total score after you've enter the data for the different systems. The same happens with DLQI /CDLQI.

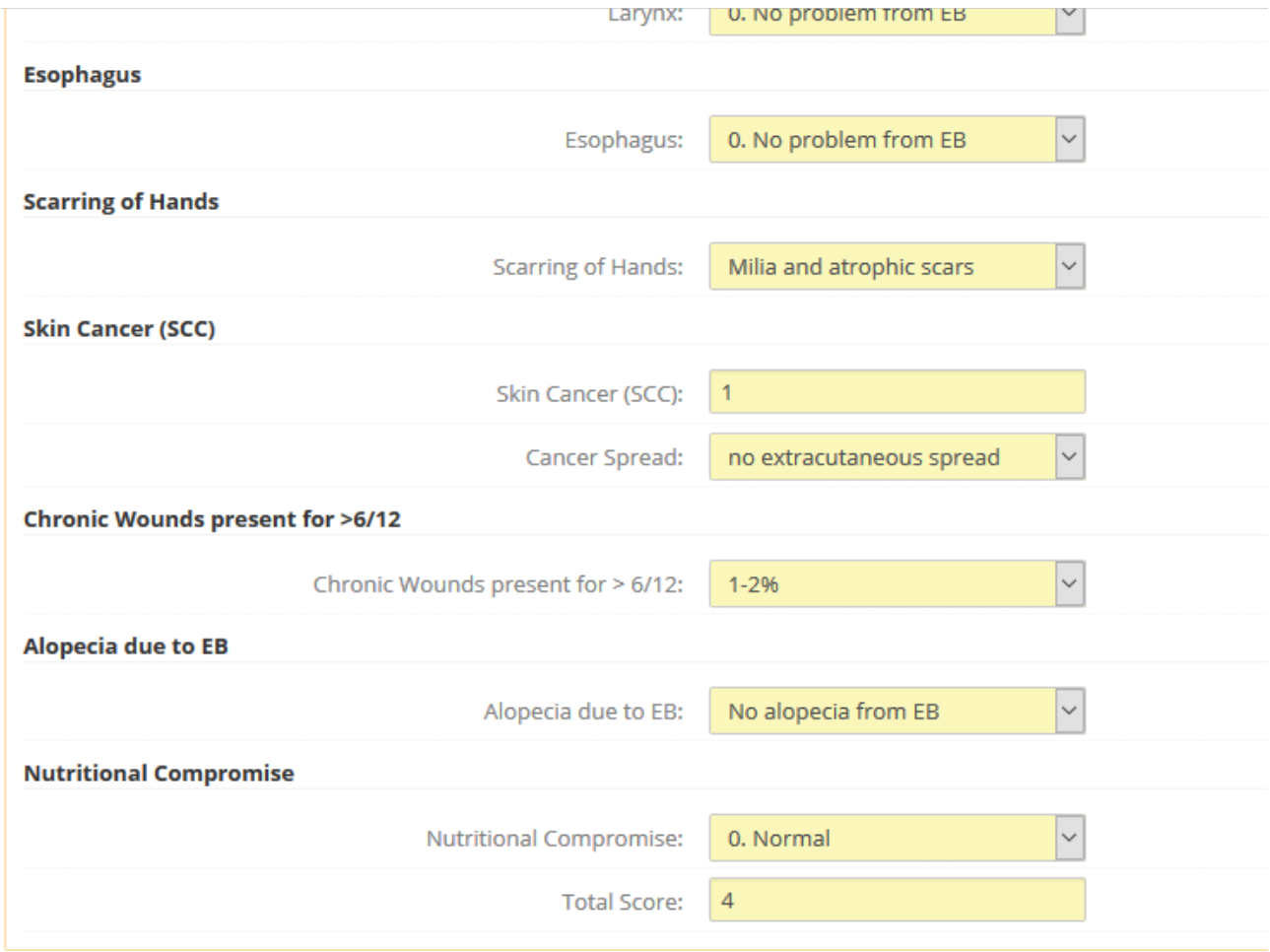
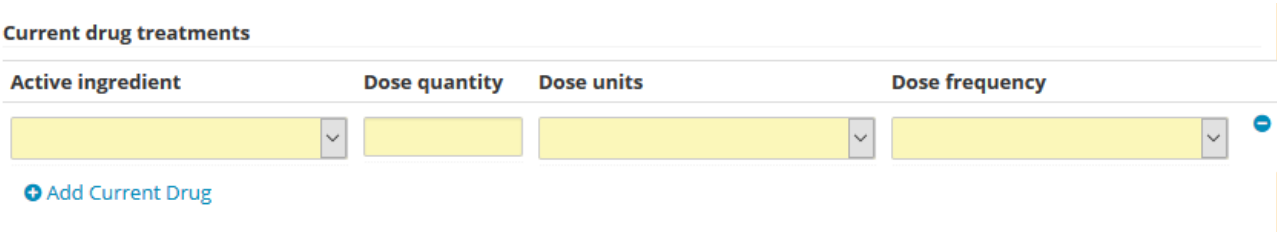
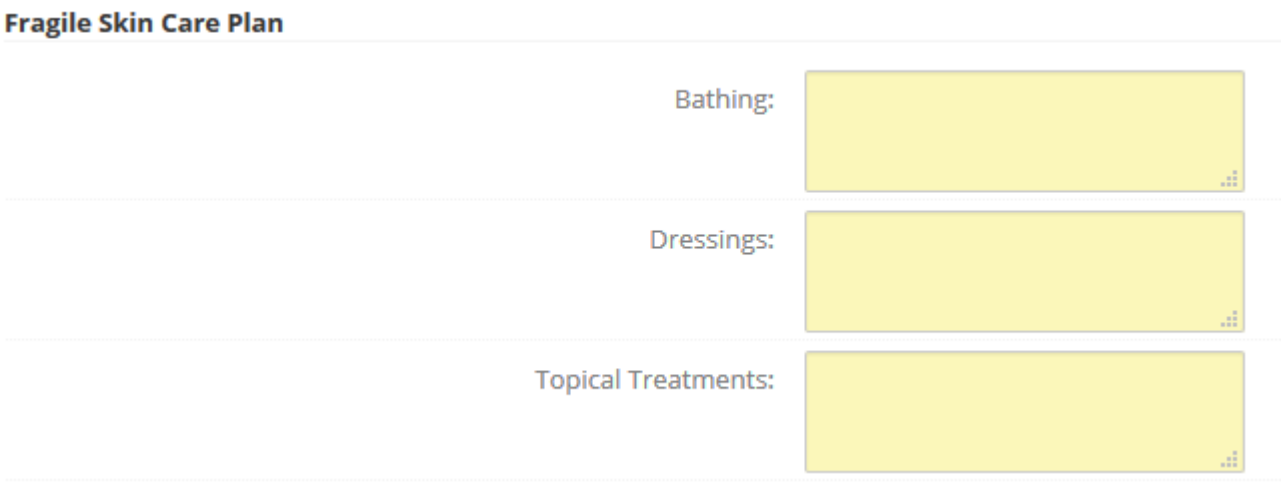


Illustration 1: Birgmingham EB Severity Score

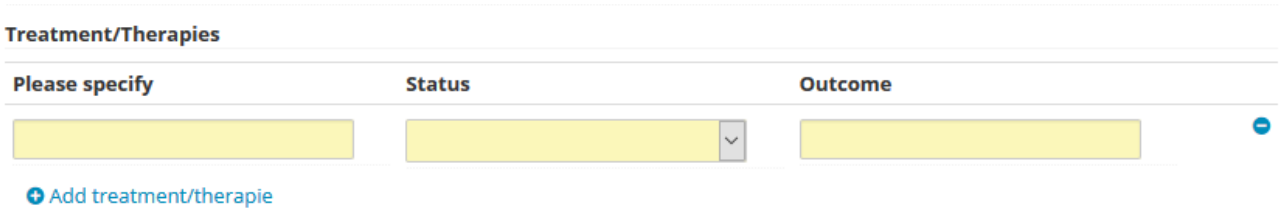
Under the Treatments sections there's different sub-sections. Starting with drug treatments, the user can record current, orphan or off label drug treatments.



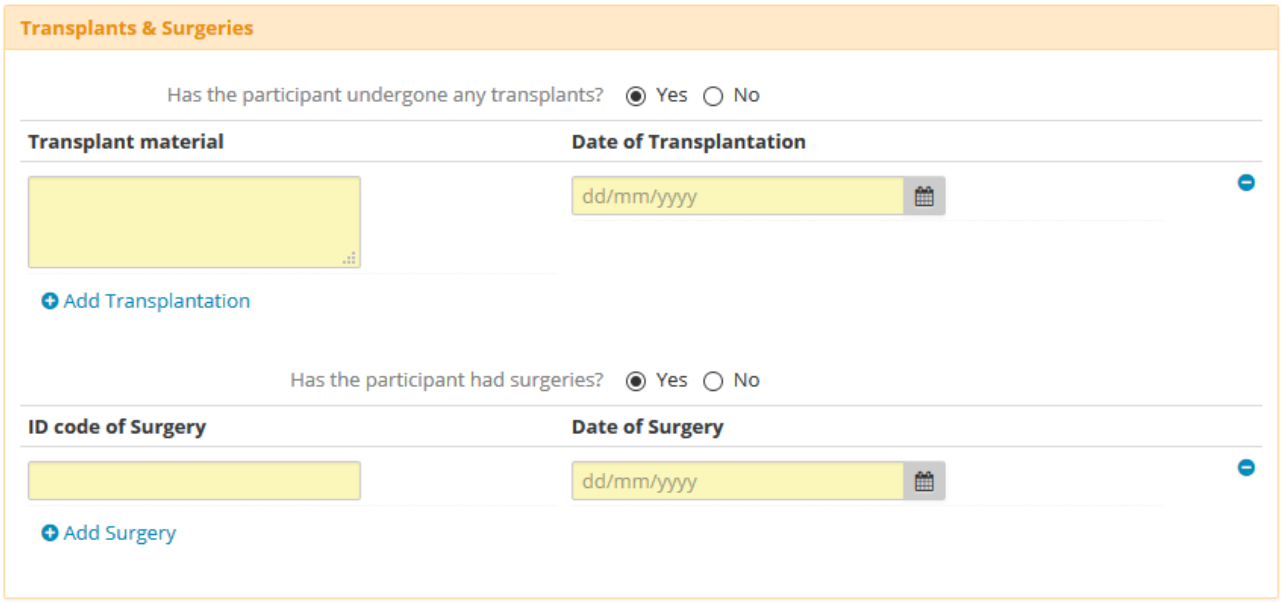
A fragile skin care plan is also available where details on bathing, dressing and topical treatments can be documented. Outcomes of the care plan can also be recorded in free text within each field.



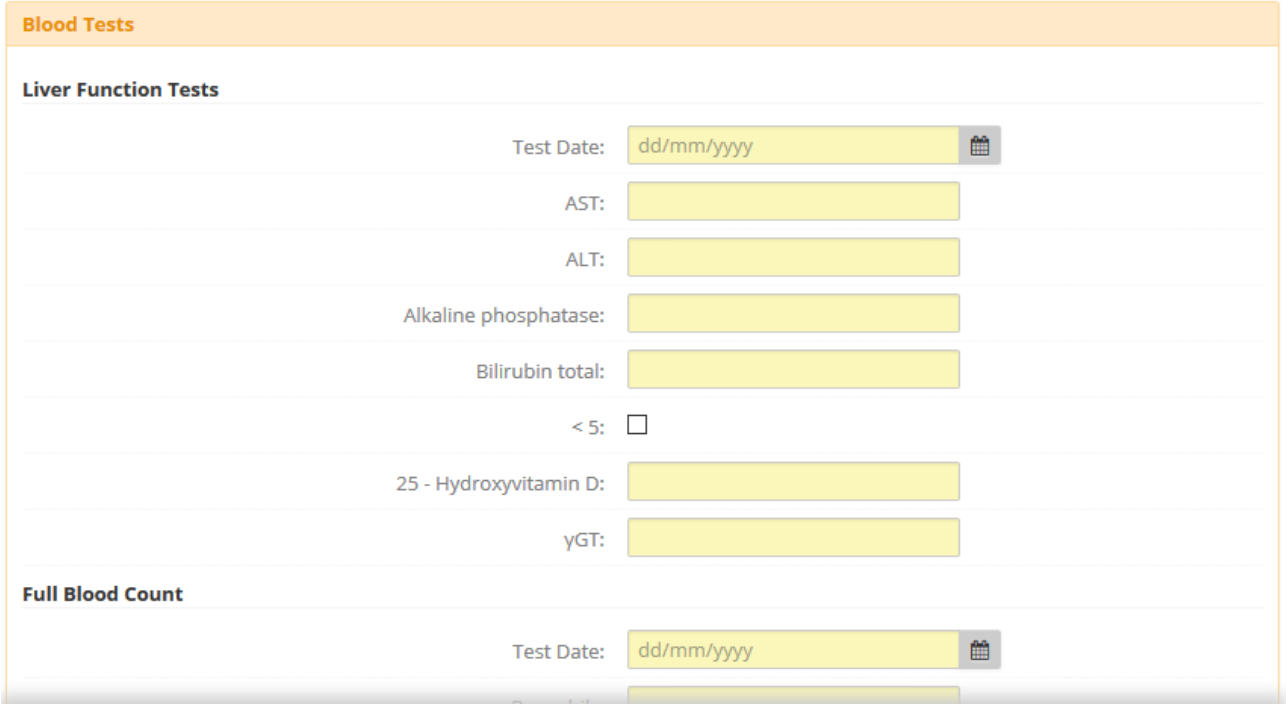
Additional treatments and/or therapies can de recorded multiple times when selecting the blue add button. The user is asked to specify the treatment/therapy, their status (planned, completed, ongoing) and outcome, for each entry.



With Transplants & Surgeries these can be documented along with the dates they've been performed.



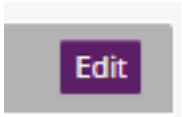
Within Blood Tests, different lab tests are available to be recorded (Liver function, Full blood count, B12 abd folate testing among others). Date and results are captured.



How do I edit a previous Encounter?

If you click 'Save' or forgot to add information at the time of entering, you can edit an Encounter document at a later stage.

For example, click on the Encounter you want to edit. The Encounter document appears so select '*Edit*' on the top right of the box.



The Audit Trail

If you performed any changes to previous documented fields, when you click save a box will appear and ask you the reason for editing. This is for auditing purposes.

How do I get back to Patient List from an individual Patient Record?

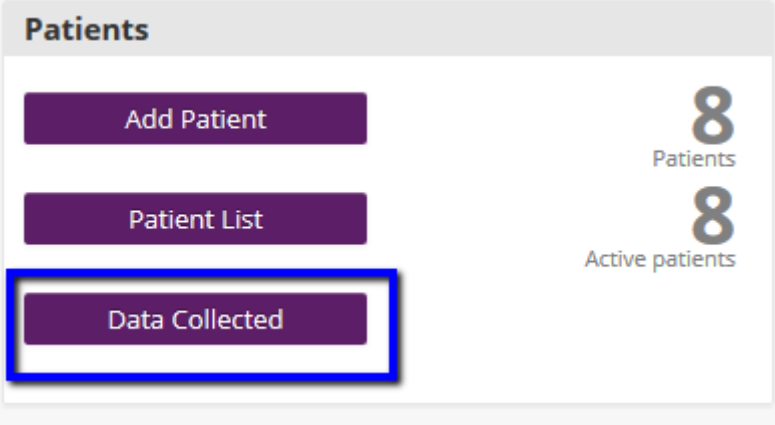
When you are in the patient individual record, you can return to the patient list by returning to the homepage and selecting patient list button

To return to the homepage simply click on the NISR icon on the top left corner.

You are brought back to the home page where you can search for a patient, enrol a patient or go to the Patient List.

Data Collected

In the Patients panel of the main Dashboard, you can access the Data Collected menu.



This will show, by Month/Year, the number of documents (Core Data and Encounters) created, verified and frozen.

Different user roles will allow for the actions above mentioned. General User will create the documents while the Data Manager will verify and freeze the same, once satisfied with the quality of the data collected.

EB Registry

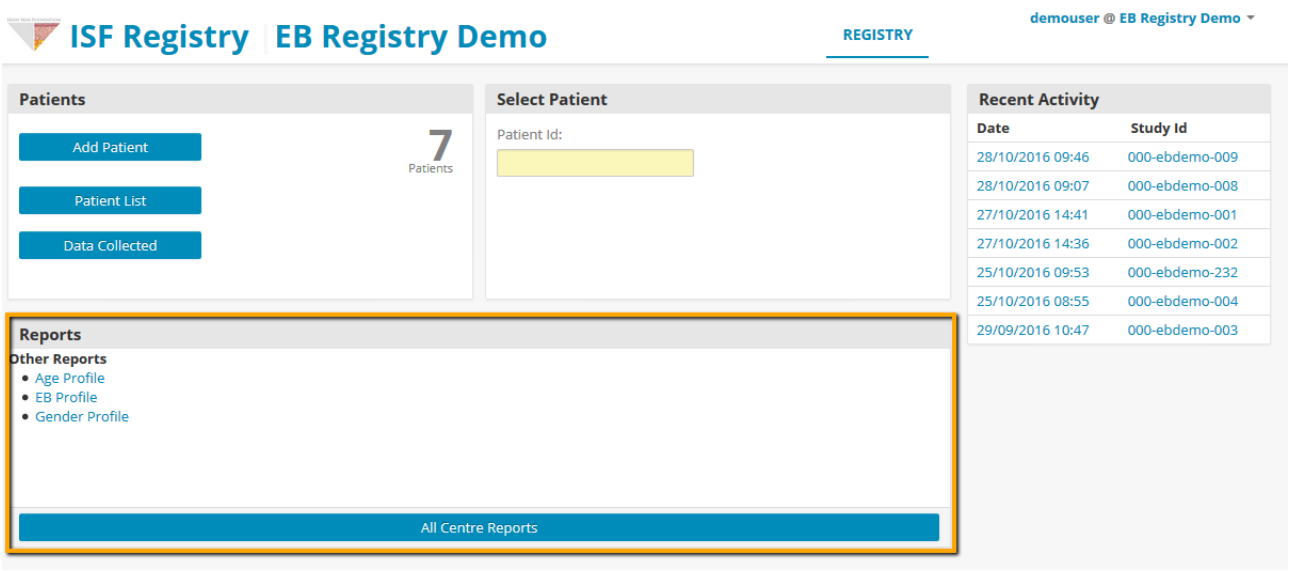
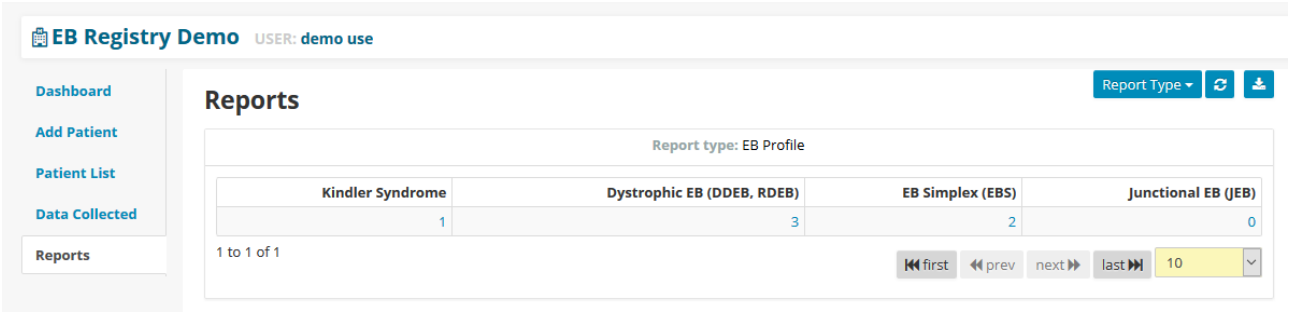
Month	Document	Created	Verified	Frozen
06/2016	Core data	1	0	0
06/2016	Encounter	1	0	0

By selecting a month, you'll see the list of encounters for that month and which encounter forms are complete (green) or incomplete (amber) or not initiated (grey).

Reports

From the home page, in the reports panel you'll have access to several reports, demographics and clinical related. They are customized based on client requirements.

For demonstration purposes we have created 3 reports.



They can be downloaded and printed.