

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.

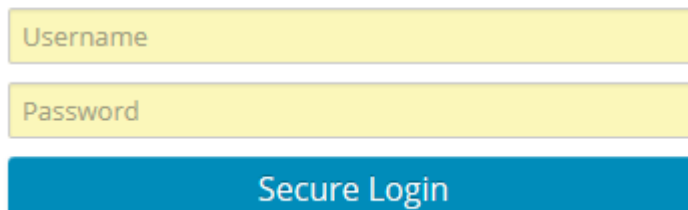
How do I get started the EB Registry?

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.

Secure Login

A login form with a light blue header 'Secure Login'. Below it are two yellow input fields: 'Username' and 'Password'. At the bottom is a blue button labeled 'Secure Login'.

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.

The screenshot shows the EB Registry Demo dashboard. At the top, there is a header with the ISF Registry logo, the text 'EB Registry Demo', a 'REGISTRY' tab, and a user profile 'demouser @ EB Registry Demo'. The main content area is divided into four sections: 1. Patients: A panel with three buttons ('Add Patient', 'Patient List', 'Data Collected') and a large number '7' with the word 'Patients' below it. 2. Select Patient: A panel with a 'Patient Id:' label and a yellow input field. 3. Reports: A panel with a heading 'Other Reports' and a list of links: 'Age Profile', 'EB Profile', and 'Gender Profile'. At the bottom of this panel is a blue button labeled 'All Centre Reports'. 4. Recent Activity: A table with two columns, 'Date' and 'Study Id', containing a list of recent patient meetings.

Date	Study Id
28/10/2016 09:07	000-ebdemo-008
27/10/2016 15:13	000-ebdemo-009
27/10/2016 14:41	000-ebdemo-001
27/10/2016 14:36	000-ebdemo-002
25/10/2016 09:53	000-ebdemo-232
25/10/2016 08:55	000-ebdemo-004
29/09/2016 10:47	000-ebdemo-003

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.

Add Patient

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.

A screenshot of a web application interface for a patient's dashboard. At the top, a dark blue header bar contains a user icon, the text "Patient ID: 000-ebdemo-002", and "Enrolled: 28/09/2016". Below the header, on the left, is a vertical sidebar with three menu items: "Encounters" (highlighted), "Core data", and "Enrolment". The main content area is titled "Encounter List". It contains a table with one row: "Eb encounter" with a "Date of encounter" of "2016-01-14". Below the table, it says "1 to 1 of 1". To the right of the table are navigation buttons: "first", "prev", "next", "last", and a dropdown menu showing "10". At the bottom right of the main area is a blue button labeled "Add Encounter".

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.

Dublin EB USER: Demo EB

Dashboard

Add Patient

Patient List

Data Collected

Reports

EB Registry: Enrol Patient

Patient Id in Registry/Study: 000-dublin_eb-

Date enrolled: dd/mm/yyyy

Date data collection will start: dd/mm/yyyy

Cancel Enrol

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.

Patient ID: 232323 Enrolled: 04/04/2016

Encounters

Core data

Enrolment

Core data

Recorded: 07/06/2016 12:04 by: Demo EB Edited: 09/08/2016 11:26 by: Demo EB Edit

Demographics

Primary Diagnosis

Vital Status

Biomaterials

Hospitalisations

Family History

Contact Details

Demographics

Patient Name

Given Name: Patient

Family Name: One

Middle Name:

Title/Prefix:

Suffix:

Preferred Name: Yes

Valid From:

Valid To:

Other names

Birth data

Date of Birth: 01/02/2007

Cancel Set state to Frozen PDF

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.

The screenshot shows the 'New Encounter' form. On the left is a sidebar with 'Encounters' selected, and sub-sections 'Core data' and 'Enrolment'. The main form has three colored sections: 'Encounter' (red header), 'Physical findings' (orange header), and 'Comorbidities' (green header). The 'Encounter' section has fields for 'Date of Encounter' (highlighted in red), 'ID of treating centre', and 'City, town or village of treating centre'. The 'Physical findings' section has fields for 'Height in cm' and 'Weight in kg'. The 'Comorbidities' section has a list of checkboxes for 'Birmingham EB Severity Score', 'Treatments', 'Transplants & Surgeries', 'Blood Tests', 'DLQI', and 'CDLQI'. At the bottom, a status bar says 'Form is incomplete' and there are 'Cancel', 'Save', and 'PDF' buttons.

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.

The screenshot shows the 'AD Treatment History' form. It has a section titled 'Systemic Therapy'. Within this section, there is a 'Name of therapy:' label followed by a drop-down menu. The menu is open, showing a list of options: Ustekinumab, Trial medication, Other, Methotrexate, MPS, MMF, IVIG, Hydroxychloroquine, Glucocorticosteroids, Etanercept, Dapsone, Cyclosporin A, Azathioprine, Adalimumab, and Acitretin. There are also fields for 'Start date:', 'Dose:', 'Dose unit:', 'Route:', and 'Frequency:'. At the bottom, a status bar says 'Form is incomplete'.

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

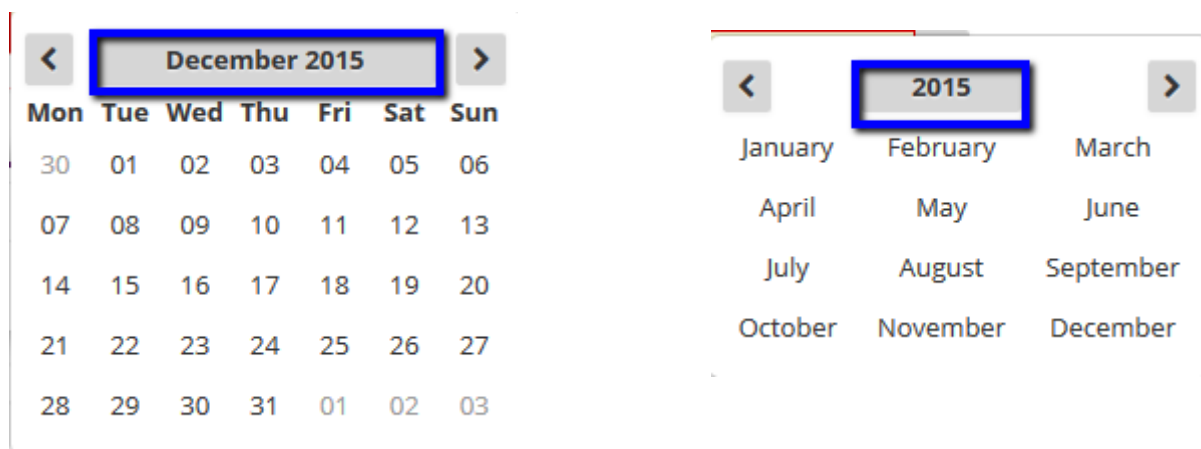
Allergy Testing

Allergic Disorders

Asthma: ☒ Yes ☐ No

Allergic rhinoconjunctivitis: ☐ Yes ☒ No


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.



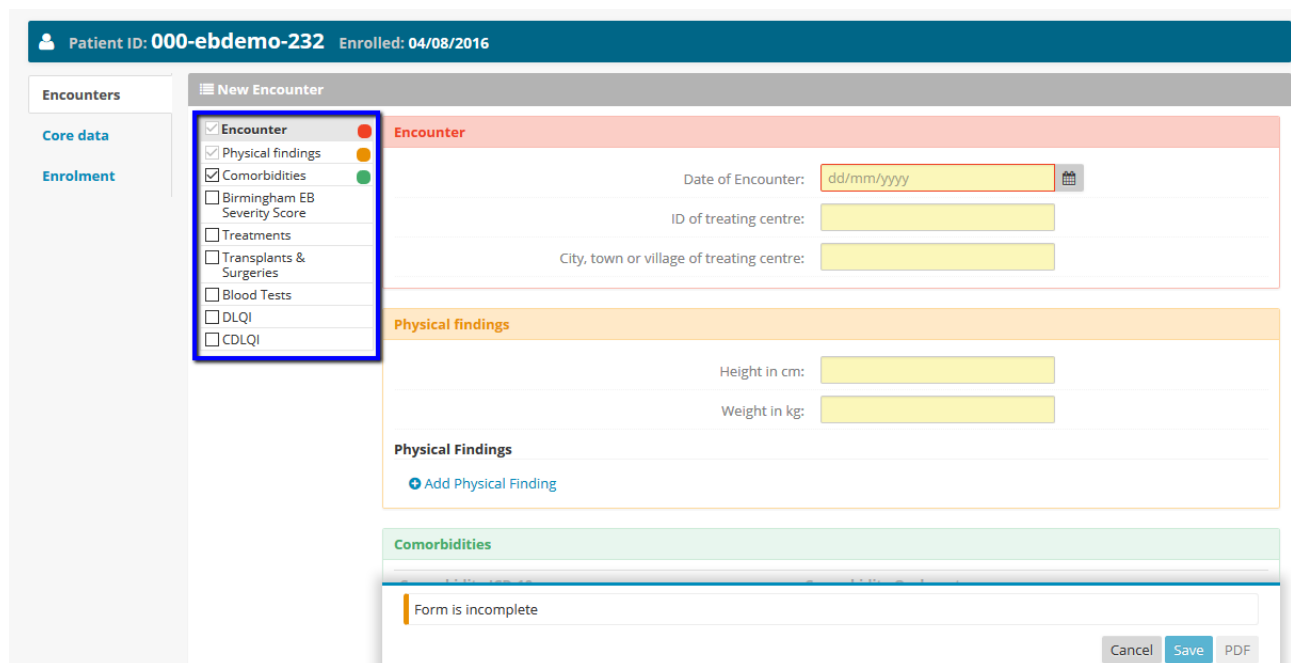
Note: Date pickers are used where an exact date is required. However, there are some instances where the month or year are sufficient.

Date of Diagnosis:  ☐ Unknown

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 found 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.

Treatments

Current drug treatments

Active ingredient	Dose quantity	Dose units	Dose frequency
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

+ Add Current Drug

Section Validation Indicators

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

Patient ID: 2 Enrolled: 15/10/2013

Encounter Recorded: 20/01/2016 14:54 by: Veronika Edited: 20/01/2016 14:56 by: Veronika

Encounter

Encounter

Date of Encounter: 15/07/2014

Type of encounter:

Comments:

Current Systemic Therapy

Name of therapy: Methotrexate

Dose:

Dose unit:

Route:

Frequency:

Start date:

Ongoing:

Duration:

End date: 15/07/2014

Effect: Good

Physical examination

Vital signs

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:

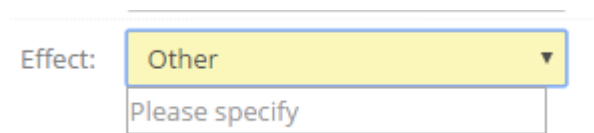
Red: More information in this section is required

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.



Effect: Other ▼
Please specify

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

Date of Encounter: 23/Jan/2016 

At time of entry, date was in the future. Please correct.

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.

Height and Weight (HW)

Date of Assessment:

04/Apr/2016



Height (cm):

20

☒ cm

The value recorded is outside the expected range. Please correct or clarify.

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.

The screenshot shows the 'Eczema Registry: Enrol Patient' form. The sidebar on the left contains the following links: Dashboard, Add Patient, Patient List, Data Collected, Queries, and Reports. The main form area has the following fields:

- Patient Id in Registry/Study:
- Date enrolled:
- Date data collection will start:

At the bottom right of the form are two buttons: Cancel and Enrol.

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.

Patient ID: 232323 Enrolled: 04/04/2016

Encounters

Core data

Enrolment

Core data Recorded: 07/06/2016 12:04 by: Demo EB Edited: 09/08/2016 11:26 by: Demo EB

☒ Demographics ☐ Primary Diagnosis ☐ Genetics ☒ Vital Status ☒ Biomaterials ☒ Hospitalisations ☒ Family History ☒ Contact Details

Demographics

Patient Name

Given Name: Patient

Family Name: One

Middle Name:

Title/Prefix:

Suffix:

Preferred Name: ☒

Valid From: [[dd/] mm/] yyyy

Valid To: [[dd/] mm/] yyyy

Other names

[Add Patient Name](#)

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.

Diagnosis

Major Epidermolysis Bullosa Type: Dystrophic EB (DDEB, RDEB)

Major Epidermolysis Bullosa Subtype: Recessive Dystrophic Epiderm

Phenotype: RDEB - pruriginosa (RDEB-pr)

Date of current diagnosis: dd/mm/yyyy

Status of current diagnosis: Active

Centre which made diagnosis:

Patient referred after positive neonatal screening: No

Date of first symptoms onset: dd/mm/yyyy

Date of first contact of patient with the public Health Service: dd/mm/yyyy

This is followed by [Vital status](#), [Biomaterial donation](#) and [Hospitalisations](#).

Vital Status
Is the participant alive? <input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Unknown/Unclear


Biomaterial donation
Has biomaterial been donated? <input type="radio"/> Yes <input checked="" type="radio"/> No

Hospitalisations
Cumulative number of hospital admissions due to disease: <input type="text" value="20"/>

In the [Family History](#) section the user will document relevant information regarding other carriers or cases in the family.

Family History
Subject
Subject is Healthy Carrier: <input type="radio"/> Yes <input checked="" type="radio"/> No
Consanguineous Parents: <input type="text" value="Unknown/Unclear"/>
Healthy Carriers
Healthy Carriers in Family: <input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Unknown/Unclear
Kinship of healthy carrier: <input type="text" value="Maternal Grandmother"/> <input type="button" value="-"/> <input type="button" value="+"/>
Other cases in family
Other cases in family: <input checked="" type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown/Unclear

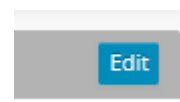
And the [Contact Details](#) section for both the patient and the treating physician.

Contact Details	
Physician Details	
Treating Physician:	<input type="text"/>
Treatment Centre:	<input type="text"/>
Email address:	<input type="text"/>
Phone number:	<input type="text"/>
Patient addresses	
Type of address:	<input type="radio"/> Business <input type="radio"/> Correspondance <input checked="" type="radio"/> Residential <input type="radio"/> Temporary
Address line 1:	<input type="text" value="St A"/>
Address line 2:	<input type="text"/>
Address line 3:	<input type="text"/>
Address line 4:	<input type="text"/>
Post code:	<input type="text" value="Dublin"/>
Date Valid from:	<input type="text" value="[dd/] mm/yyyy"/> 

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.

Encounter List

Eb encounter
Date of encounter
2016-06-01

1 to 1 of 1

first prev next last 10

[Add Encounter](#)

[Date](#) and [Treating centre](#) are the first details to enter.

Encounter

Date of Encounter:

ID of treating centre:

City, town or village of treating centre:

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

New Encounter

- ☒ Encounter
- ☒ Physical findings
- ☐ Comorbidities
- ☐ Birmingham EB Severity Score
- ☐ Treatments
- ☐ Transplants & Surgeries
- ☐ Blood Tests
- ☐ DLQI
- ☐ CDLQI

Encounter

Date of Encounter:

ID of treating centre:

City, town or village of treating centre:

Physical findings

Height in cm:

Weight in kg:

Physical Findings

[Add Physical Finding](#)

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.

Physical findings

Height in cm:

Weight in kg:

Physical Findings

Type:

Size:

Frequency:

Location:

Inciting factors:

[+ Add Physical Finding](#)

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.

Comorbidities

Comorbidity ICD-10

Comorbidity Orphanet

Type value for auto-complete ...

Type value for auto-complete ...

[+ Add Comorbidities](#)

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](#).

Larynx:	0. No problem from EB
Esophagus	
Esophagus:	0. No problem from EB
Scarring of Hands	
Scarring of Hands:	Milia and atrophic scars
Skin Cancer (SCC)	
Skin Cancer (SCC):	1
Cancer Spread:	no extracutaneous spread
Chronic Wounds present for >6/12	
Chronic Wounds present for > 6/12:	1-2%
Alopecia due to EB	
Alopecia due to EB:	No alopecia from EB
Nutritional Compromise	
Nutritional Compromise:	0. Normal
Total Score:	4

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.

Current drug treatments			
Active ingredient	Dose quantity	Dose units	Dose frequency
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
+ Add Current Drug			

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.

Fragile Skin Care Plan

Bathing:	<div></div>
Dressings:	<div></div>
Topical Treatments:	<div></div>

Additional treatments and/or therapies can be 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.

Treatment/Therapies

Please specify	Status	Outcome
<div></div>	<div></div>	<div></div>

[+ Add treatment/therapie](#)

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

Transplants & Surgeries

Has the participant undergone any transplants? ☒ Yes ☐ No

Transplant material

[+ Add Transplantation](#)

Date of Transplantation

dd/mm/yyyy

Has the participant had surgeries? ☒ Yes ☐ No

ID code of Surgery

[+ Add Surgery](#)

Date of Surgery

dd/mm/yyyy

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

The screenshot shows a web form titled "Blood Tests" with an orange header. Below the header, there are two main sections: "Liver Function Tests" and "Full Blood Count".

Liver Function Tests

- Test Date: A text input field with the placeholder "dd/mm/yyyy" and a calendar icon.
- AST: A text input field.
- ALT: A text input field.
- Alkaline phosphatase: A text input field.
- Bilirubin total: A text input field.
- < 5: A checkbox.
- 25 - Hydroxyvitamin D: A text input field.
- γGT: A text input field.

Full Blood Count

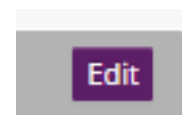
- Test Date: A text input field with the placeholder "dd/mm/yyyy" and a calendar icon.

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

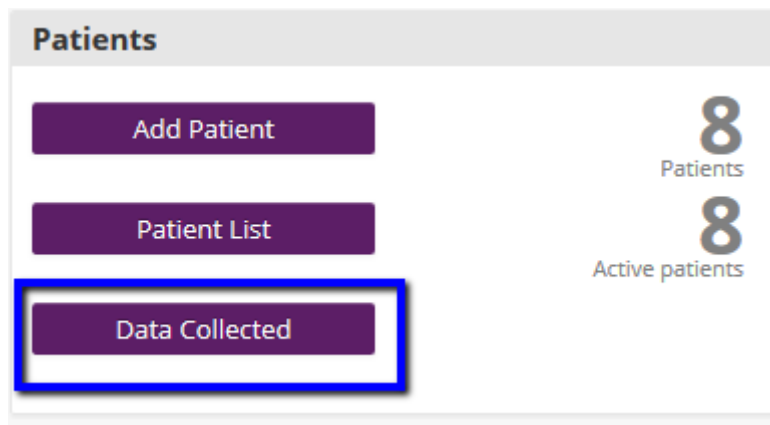
To return to the homepage simply click on the NISR icon on the top left corner.

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.

Patients

Add Patient

Patient List

Data Collected

7

Patients

Select Patient

Patient Id:

Recent Activity

Date	Study Id
28/10/2016 09:46	000-ebdemo-009
28/10/2016 09:07	000-ebdemo-008
27/10/2016 14:41	000-ebdemo-001
27/10/2016 14:36	000-ebdemo-002
25/10/2016 09:53	000-ebdemo-232
25/10/2016 08:55	000-ebdemo-004
29/09/2016 10:47	000-ebdemo-003

Reports

Other Reports

- Age Profile
- EB Profile
- Gender Profile

All Centre Reports

They can be downloaded and printed.

EB Registry Demo

USER: demo use

Dashboard
Add Patient
Patient List
Data Collected
Reports

Reports

Report Type

Report type: EB Profile

Kindler Syndrome	Dystrophic EB (DDEB, RDEB)	EB Simplex (EBS)	Junctional EB (JEB)
1	3	2	0

1 to 1 of 1

first
prev
next
last
10