Association for Haemophilia and Allied Disorder- Asia Pacific (AHAD-AP)

Haemophilia and Allied Disorder Registry

Data Capture System – User Manual

Clinical Data Management Centre (CDMC)
Department of Biostatistics
Christian Medical College (CMC)
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Introduction

Association for Haemophilia and Allied Disorder – Asia Pacific (AHAD-AP)

Association for Haemophilia and Allied Disorder – Asia Pacific (AHAD-AP) is an independent body which exists to promote better Haemophilia care in the Asia Pacific Region. The AHAD-A) is currently formed by clinicians drawn from countries across the Asia Pacific region including Australia, Brunei, China, India, Korea, Malaysia, Singapore, Thailand, Vietnam, and Japan. It is governed by the Steering Committee, led by appointed Chair (Dr. Alok Srivastava is the current chair). Financial administration is being managed under a MOU with WFH. The objectives for the AHAD-AP are to:

- Develop a common principles of care document for the Asia Pacific Region and publish the works
- Development of a data registry template
- Assess the educational needs of the region and plan relevant training activities
- Form a definition and accreditation process, to support the establishment of Haemophilia Treatment Centre and Comprehensive Care Centres

Haemophilia and Allied Disorder Registry (HADR)

Haemophilia and Allied Disorder Registry is a registry for patients with Haemophilia in Asia Pacific Region. This registry will be used to collect patient data from Haemophilia Treatment Centres (HTC).Data collection template for HADR was developed by adapting Universal-Case Report Form (UCRF) from World Federation of Haemophila (WFH).

Web based Data Capture System

Based on HADR data collection template, web based data capture system was developed, tested and launched to capture Haemophila data across Asia Pacific region. This document was developed to help Haemophilia Treatment Centre (HTC) by steps to provide treatment and follow-up data through web based data capture system. This system was developed by Clinical Data Management Centre, Department of Biostatistics, Christian Medical College, Vellore, India.

Section 1: Logging in to the system

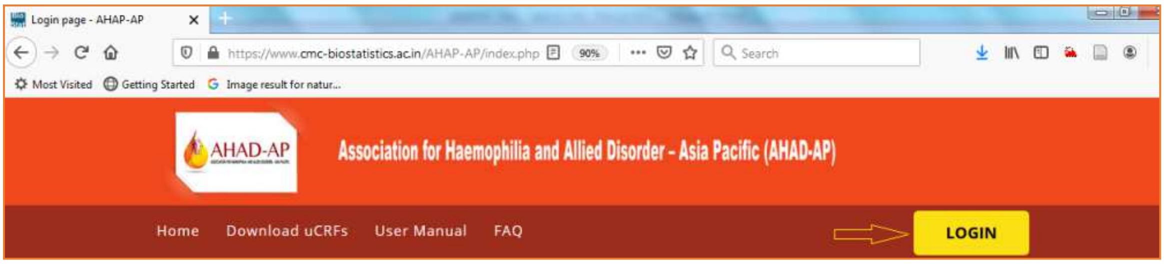
1.1: Software requirements and Web URL:

Web based system was developed to capture patient data from Haemophilia Treatment Centres (HTCs) across Asia Pacific Region. Data provided by HTCs will be stored in the central database at CMC Vellore. To access the Beta version of this system, HTCs should have following connectivity and software requirements:

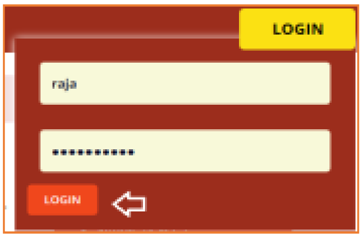
- Good internet connectivity.
- Web browser (Mozilla Fire Fox / Google Chrome /Microsoft Edge)
  (Please note that 'Microsoft Internet Explorer' not supported by this web based system)

The user need to access below mentioned web site to provide their centre data, User ID will be created by Clinical Data Management Centre (CDMC) for each HTCs on request.

http://cmc-biostatistics.ac.in/AHAD-AP



Click the **LOGIN** button and provide User name and Password to access the data capture system as follows:



raja

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The system may display *'Invalid Login'* message for the following reasons:

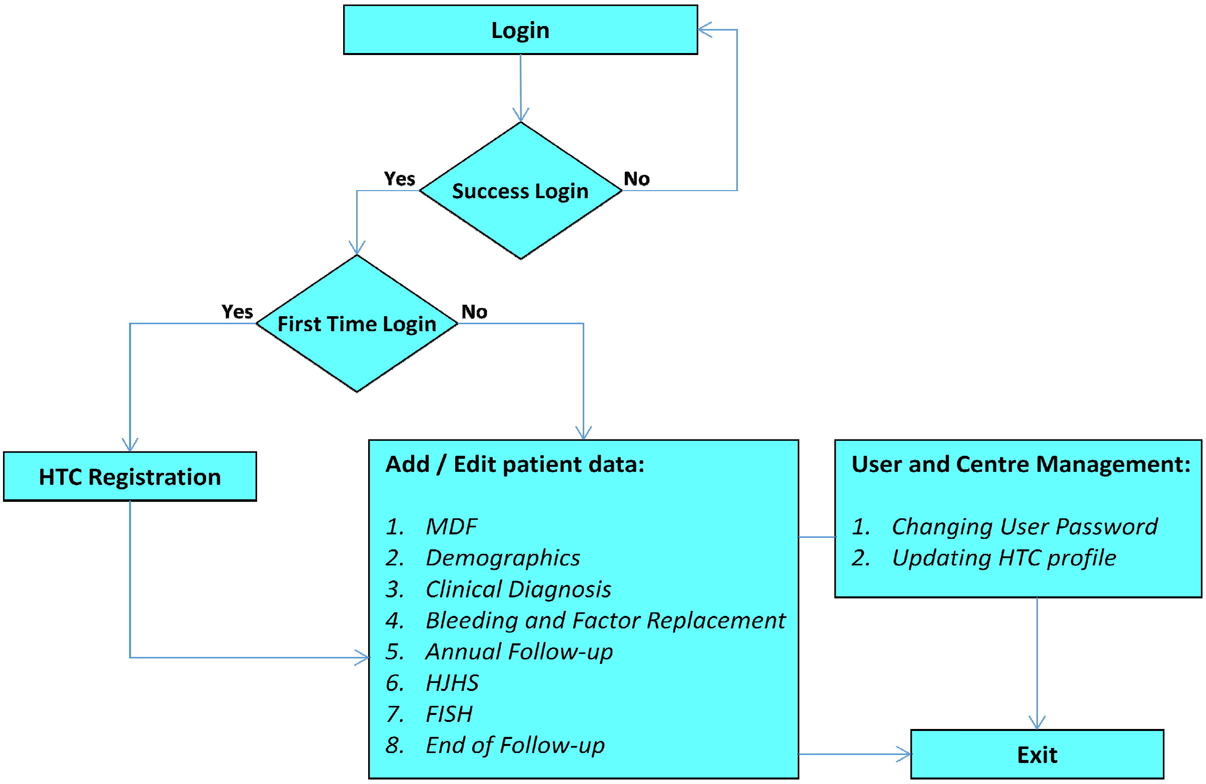
Invalid Login!

- User ID does not exits
- User ID and Password combination is wrong

After successful login the system will take the control to register *Haemophilia Treatment Centre (HTC).* User needs to provide HTC information only once, later on they can update these information if required.

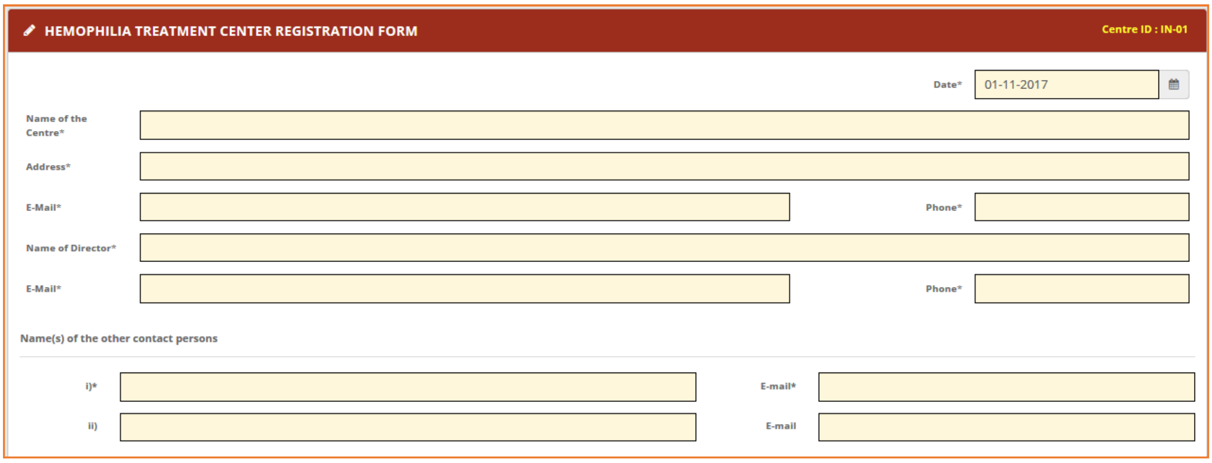
Section 1.2: Data Capture – Flow Chart

Below chart explains flow of the data capture in the web based system:



Section 2: Haemophilia Treatment Centre (HTC) registration

Below screenshot shows the data collection form for “*Haemophilia Treatment Centre (HTC)*” registration:



Centre ID : IN-01

Date* 01-11-2017

The user needs to provide required information to register their centre detail in the registry database.

- *Please note that the data points marked as ‘*’ are mandatory and the user needs to provide information compulsorily.*

- *HTC registration will be done only once for each centre.*

After providing all required information, the user need to click any one of the below mentioned button to save data into registry database

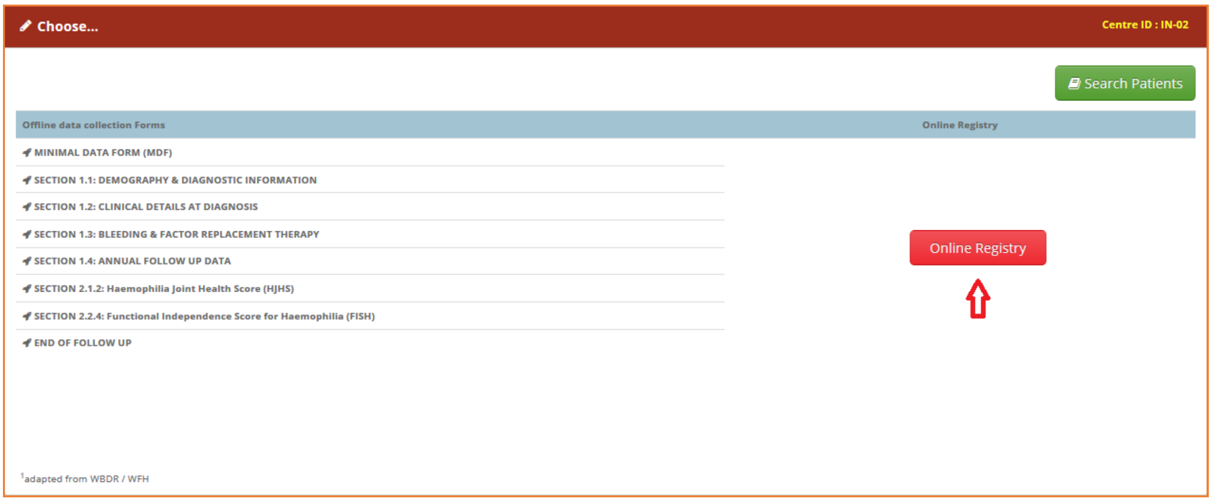
- Save Data - Data will be saved in to the database and can be updated later on

- Save & Finalize - Data will be saved in to the database, but cannot be updated later.

- Exit - To exit the system without saving the data

Section 3: Adding patient data

After providing all required information for *Haemophilia Treatment Centre (HTC)* , system will take the control to *'Main Menu'* as follows:



Choose... | Centre ID : IN-02

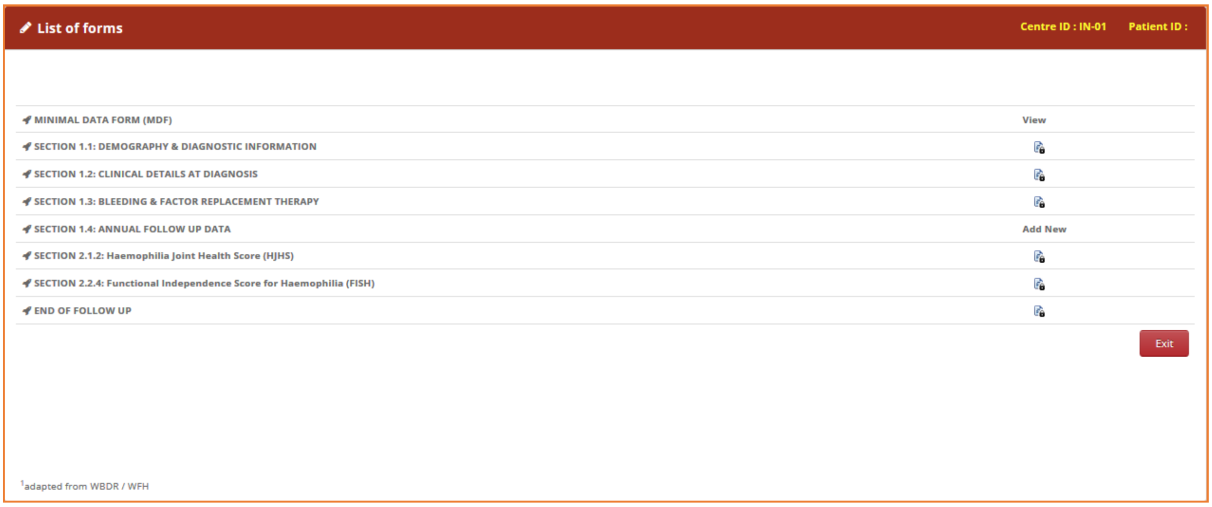
Search Patients

Offline data collection Forms	Online Registry
MINIMAL DATA FORM (MDF)	
SECTION 1.1: DEMOGRAPHY & DIAGNOSTIC INFORMATION	
SECTION 1.2: CLINICAL DETAILS AT DIAGNOSIS	
SECTION 1.3: BLEEDING & FACTOR REPLACEMENT THERAPY	Online Registry
SECTION 1.4: ANNUAL FOLLOW UP DATA	
SECTION 2.1.2: Haemophilia Joint Health Score (HJHS)	
SECTION 2.2.4: Functional Independence Score for Haemophilia (FISH)	
END OF FOLLOW UP	

[1]adapted from WBDR / WFH

Please click the Online Registry button to create new patient and to provide data for the following forms:

1) Minimal Data Form (MDF)
2) Section 1.1 : Demography and Diagnostic Information
3) Section 1.2 : Clinical Details at Diagnosis
4) Section 1.3: Bleeding and Factor Replacement Therapy
5) Section 1.4: Annual Follow-up Data
6) Section 2.1.2: Haemophilia Joint Health Score (HJHS)
7) Section 2.2.4: Functional Independence Score for Haemophilia (FISH)
8) End of Follow-up



List of forms | Centre ID : IN-01 | Patient ID :

MINIMAL DATA FORM (MDF)	View
SECTION 1.1: DEMOGRAPHY & DIAGNOSTIC INFORMATION	
SECTION 1.2: CLINICAL DETAILS AT DIAGNOSIS	
SECTION 1.3: BLEEDING & FACTOR REPLACEMENT THERAPY	
SECTION 1.4: ANNUAL FOLLOW UP DATA	Add New
SECTION 2.1.2: Haemophilia Joint Health Score (HJHS)	
SECTION 2.2.4: Functional Independence Score for Haemophilia (FISH)	
END OF FOLLOW UP	

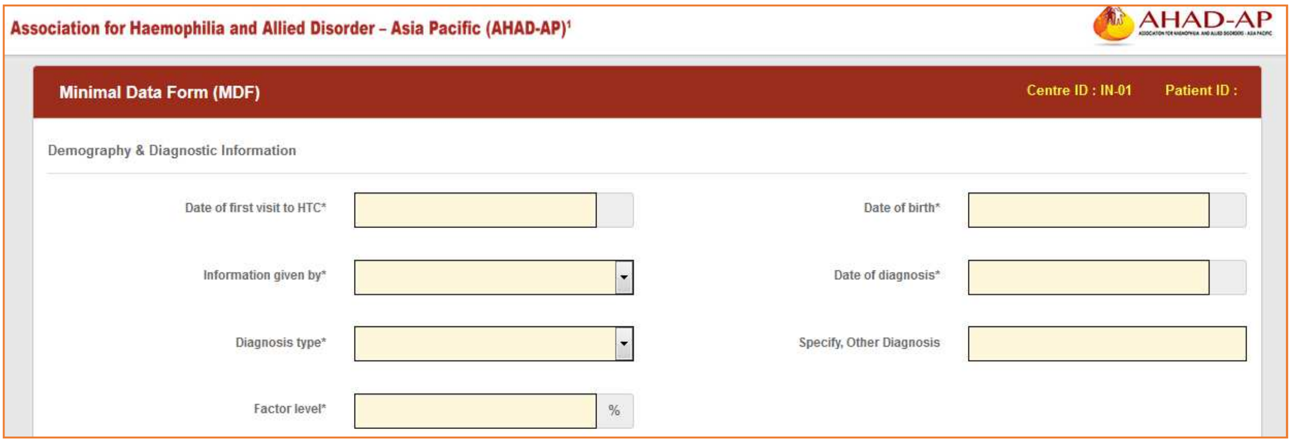
Exit

[1]adapted from WBDR / WFH

- *By default, only ' MDF' and 'Annual Follow-up data' forms will be enabled for data capture, once MDF was completed the remaining forms will be activated.*

3.1 : Minimal Data Form (MDF)

Minimal Data Form (MDF) is the basic form, which is used to create new patient with ID . For that user needs to click **View** button next to *'Minimal Data Form (MDF)'* as follows:



Association for Haemophilia and Allied Disorder – Asia Pacific (AHAD-AP)[1]

Minimal Data Form (MDF) Centre ID : IN-01 Patient ID :

Demography & Diagnostic Information

Date of first visit to HTC*		Date of birth*	
Information given by*		Date of diagnosis*	
Diagnosis type*		Specify, Other Diagnosis	
Factor level*	%		

During data entry please use below mentioned buttons, if you need to add / alter multiple data points.

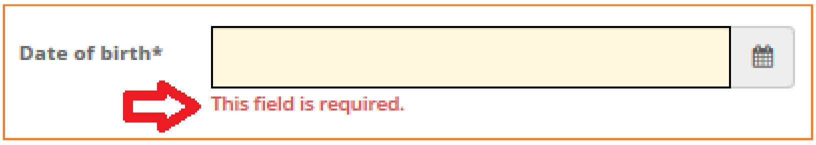
- Add row - Click this button to provide one row of additional data points
- Delete row - Click this button to delete one row of data points.

After providing all required information, the user need to click any one of the below mentioned button to save data into registry database

- Save Data - Data will be saved in the database and can be updated later on
- Save & Finalize - Data will be saved in the database, but cannot be updated later.
- Exit - To exit the system without saving the data

Inbuilt data validation checks are incorporated in the system to confirm complete data and capture relevant data across data points.

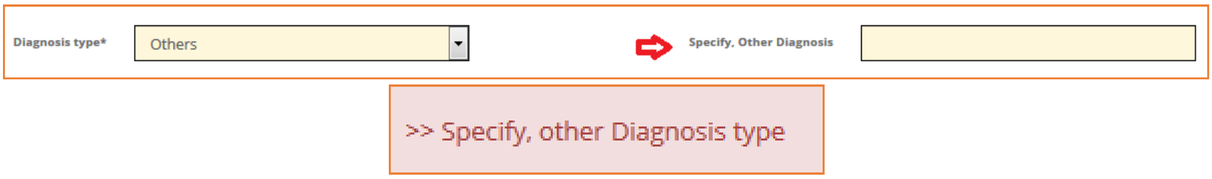
- System will display *'The field is required'* error message as displayed below if the user did not provide value for mandatory field:



Date of birth*

This field is required.

- System will display, *'Specify value'* error message as displayed below if the user did not provide value for an data point which is relevant to another data point:

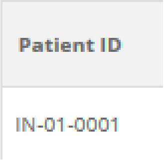


Diagnosis type* Others

Specify, Other Diagnosis

>> Specify, other Diagnosis type

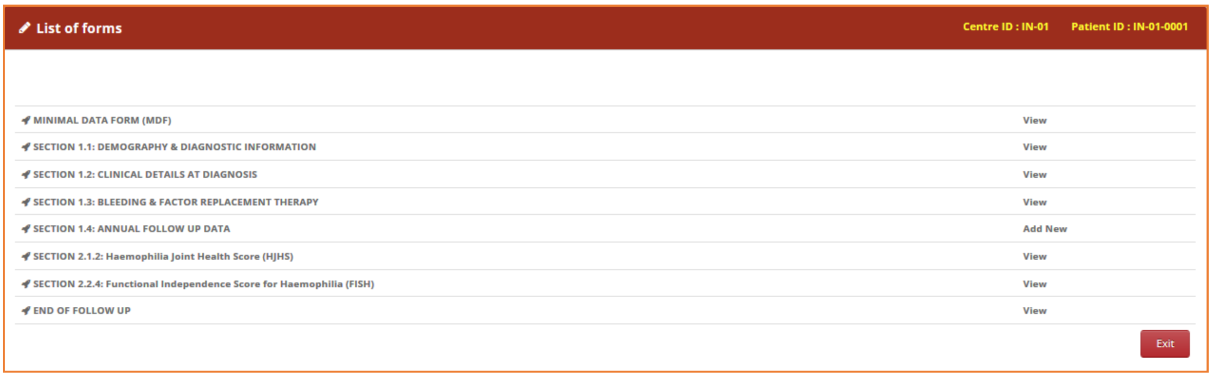
After providing all required information system will automatically create new patient with ID number, for example:



Patient ID
IN-01-0001

IN (India)- 01-(Centre)- 0001(Patient Number)

All the forms will be activated for data capture as follows:



List of forms Centre ID : IN-01 Patient ID : IN-01-0001

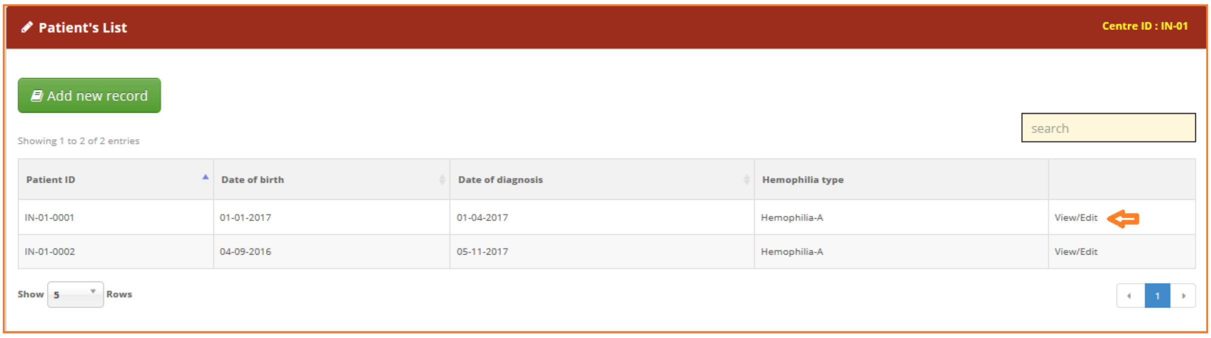
MINIMAL DATA FORM (MDF)	View
SECTION 1.1: DEMOGRAPHY & DIAGNOSTIC INFORMATION	View
SECTION 1.2: CLINICAL DETAILS AT DIAGNOSIS	View
SECTION 1.3: BLEEDING & FACTOR REPLACEMENT THERAPY	View
SECTION 1.4: ANNUAL FOLLOW UP DATA	Add New
SECTION 2.1.2: Haemophilia Joint Health Score (HJHS)	View
SECTION 2.2.4: Functional Independence Score for Haemophilia (FISH)	View
END OF FOLLOW UP	View

To enter data for currently created new patient:

- Choose the required form by clicking View button and start entering data.

To enter data for existing patients:

- Click the Exit button return to *main menu*
- Click the Search Patients button and user can see list of patients already entered in the database for particular centre as follows:



Patient's List — Centre ID : IN-01

Showing 1 to 2 of 2 entries

Patient ID	Date of birth	Date of diagnosis	Hemophilia type	
IN-01-0001	01-01-2017	01-04-2017	Hemophilia-A	View/Edit
IN-01-0002	04-09-2016	05-11-2017	Hemophilia-A	View/Edit

To update / enter data for the already registered patients, please follow below steps:

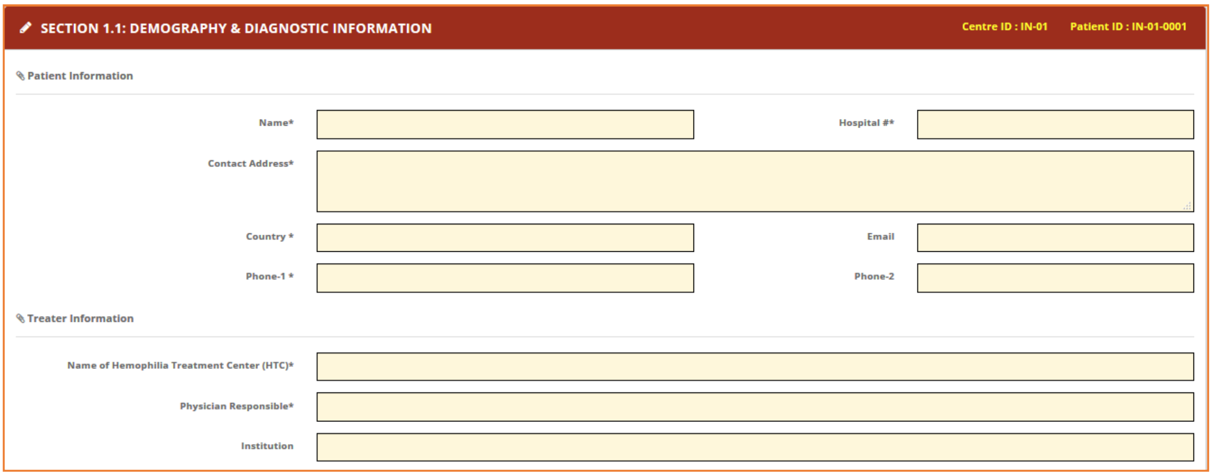
1. Click View/Edit button of a particular patient to provide data by forms
2. Click relevant form's View button

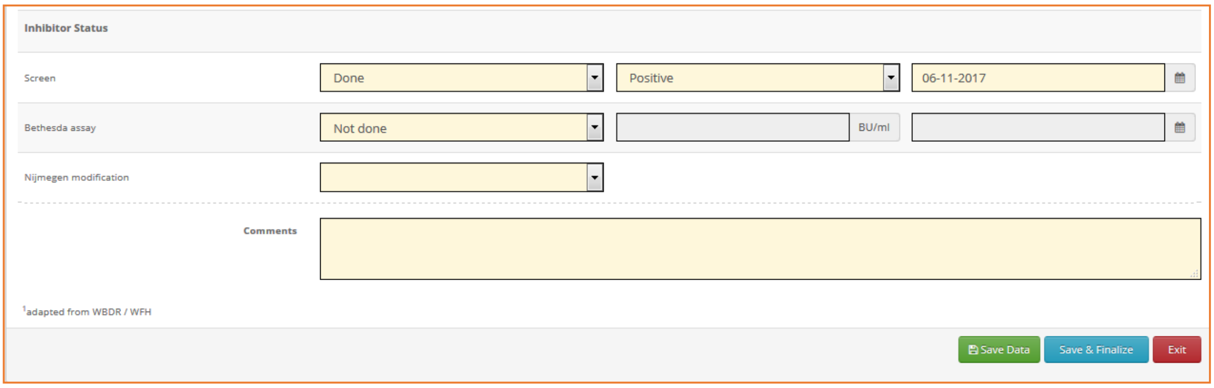
List of forms — Centre ID : IN-01 — Patient ID : IN-01-0001

MINIMAL DATA FORM (MDF)	View
SECTION 1.1: DEMOGRAPHY & DIAGNOSTIC INFORMATION	View
SECTION 1.2: CLINICAL DETAILS AT DIAGNOSIS	View
SECTION 1.3: BLEEDING & FACTOR REPLACEMENT THERAPY	View
SECTION 1.4: ANNUAL FOLLOW UP DATA	Add New
SECTION 2.1.2: Haemophilia Joint Health Score (HJHS)	View
SECTION 2.2.4: Functional Independence Score for Haemophilia (FISH)	View
END OF FOLLOW UP	View

3.2: Demography and Diagnostic Information (Section 1.1)

In the *'List of Forms'* menu, Click the View button next to *' Section 1.1 : Demography and Diagnostic Information'* and provide required information as follows:





Screen: Done, Positive, 06-11-2017

Bethesda assay: Not done, BU/ml

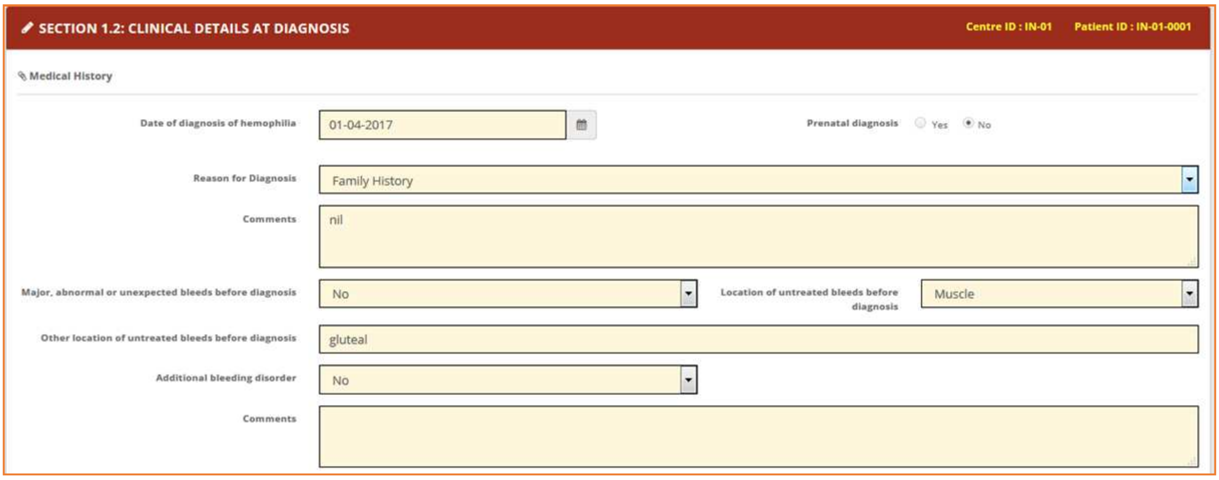
[1]adapted from WBDR / WFH

After providing all required information, the user need to click any one of the below mentioned button to save data into registry database

- Save Data - Data will be saved in to the database and can be updated later on
- Save & Finalize - Data will be saved in to the database, but cannot be updated later.
- Exit - To exit the system without saving the data

3.3 Clinical Details at Diagnosis (Section 1.2)

In the *'List of Forms'* menu, Click the View button next to *' Section 1.2 : Clinical Details at Diagnosis'* and provide required information as follows:



SECTION 1.2: CLINICAL DETAILS AT DIAGNOSIS

Centre ID : IN-01 Patient ID : IN-01-0001

Medical History

Date of diagnosis of hemophilia: 01-04-2017

Prenatal diagnosis: ○ Yes ● No

Reason for Diagnosis: Family History

Comments: nil

Major, abnormal or unexpected bleeds before diagnosis: No

Location of untreated bleeds before diagnosis: Muscle

Other location of untreated bleeds before diagnosis: gluteal

Additional bleeding disorder: No

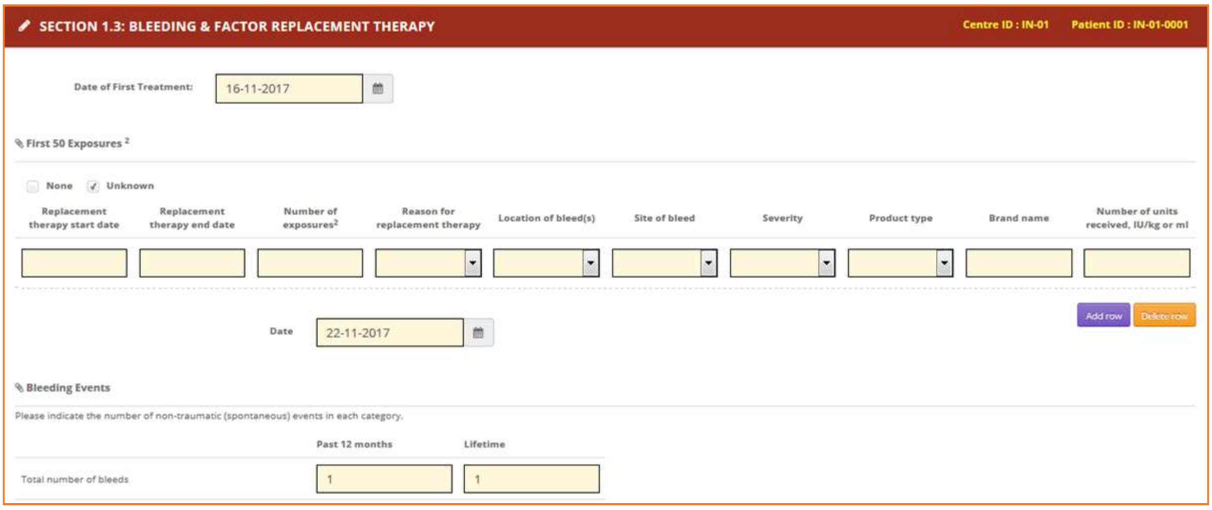
Comments:

After providing all required information, the user need to click any one of the below mentioned button to save data into registry database

- Save Data - Data will be saved in the database and can be updated later on
- Save & Finalize - Data will be saved in the database, but cannot be updated later.
- Exit - To exit the system without saving the data

3.4 Bleeding and Factor Replacement Therapy (Section 1.3)

In the *'List of Forms'* menu, Click the View button next to *' Section 1.3 : Bleeding and Factor Replacement Therapy'* and provide required information as follows:



SECTION 1.3: BLEEDING & FACTOR REPLACEMENT THERAPY

Centre ID : IN-01 Patient ID : IN-01-0001

Date of First Treatment: 16-11-2017

First 50 Exposures [2]

☐ None ☑ Unknown

Replacement therapy start date	Replacement therapy end date	Number of exposures[2]	Reason for replacement therapy	Location of bleed(s)	Site of bleed	Severity	Product type	Brand name	Number of units received, IU/kg or ml

Date 22-11-2017

Bleeding Events

Please indicate the number of non-traumatic (spontaneous) events in each category.

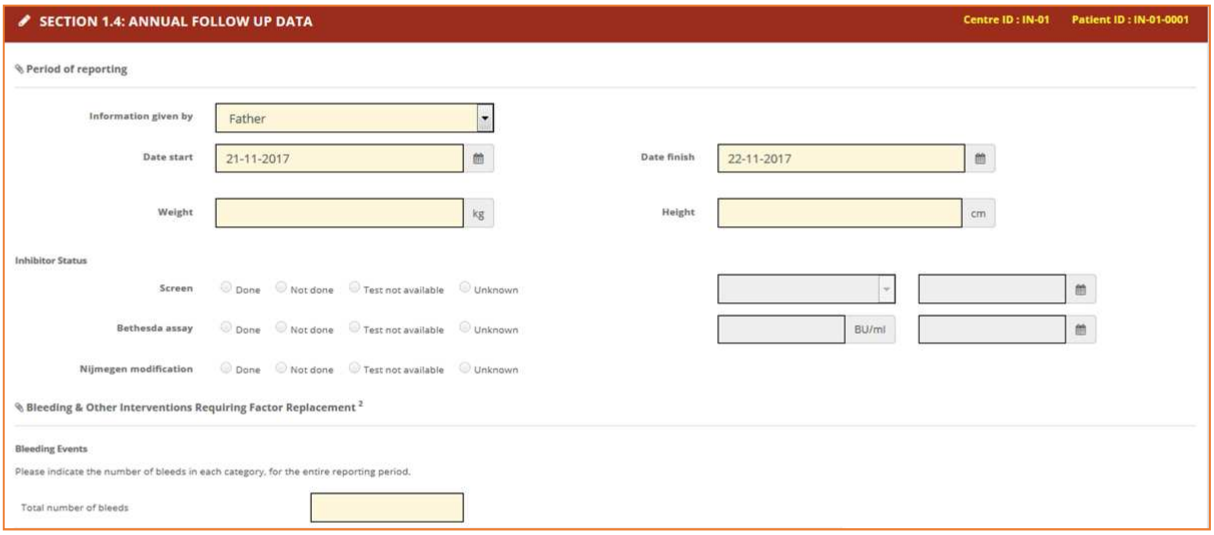
	Past 12 months	Lifetime
Total number of bleeds	1	1

After providing all required information, the user need to click any one of the below mentioned button to save data into registry database

- Save Data - Data will be saved in the database and can be updated later on
- Save & Finalize - Data will be saved in the database, but cannot be updated later.
- Exit - To exit the system without saving the data

3.5 Annual Follow-up Data (Section 1.4)

In the *'List of Forms'* menu, Click the **Add New** button next to *' Section 1.4 : Annual Follow-up Data'* and provide required information as follows:



SECTION 1.4: ANNUAL FOLLOW UP DATA

Centre ID : IN-01 Patient ID : IN-01-0001

Period of reporting

Information given by: Father

Date start: 21-11-2017

Date finish: 22-11-2017

Weight: kg

Height: cm

Inhibitor Status

Screen ○ Done ○ Not done ○ Test not available ○ Unknown

Bethesda assay ○ Done ○ Not done ○ Test not available ○ Unknown BU/ml

Nijmegen modification ○ Done ○ Not done ○ Test not available ○ Unknown

Bleeding & Other Interventions Requiring Factor Replacement[2]

Bleeding Events

Please indicate the number of bleeds in each category, for the entire reporting period.

Total number of bleeds

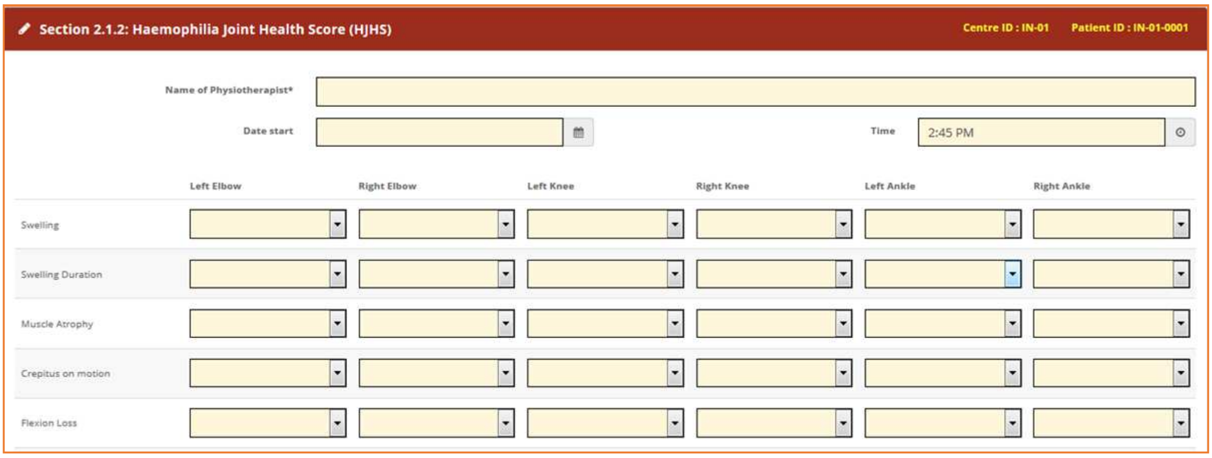
Please note that the user can enter multiple 'Annual follow-up data' for each patient.

After providing all required information, the user need to click any one of the below mentioned button to save data into registry database

- **Save Data** - Data will be saved in the database and can be updated later on
- **Save & Finalize** - Data will be saved in the database, but cannot be updated later.
- **Exit** - To exit the system without saving the data

3.6: Haemophilia Joint Health Score (HJHS) (Section 2.1.2)

In the *'List of Forms'* menu, Click the View button next to *' Section 2.1.2 : Haemophilia Joint Health Score'* and provide required information as follows:



Section 2.1.2: Haemophilia Joint Health Score (HJHS)

Centre ID : IN-01 Patient ID : IN-01-0001

Name of Physiotherapist*

Date start

Time 2:45 PM

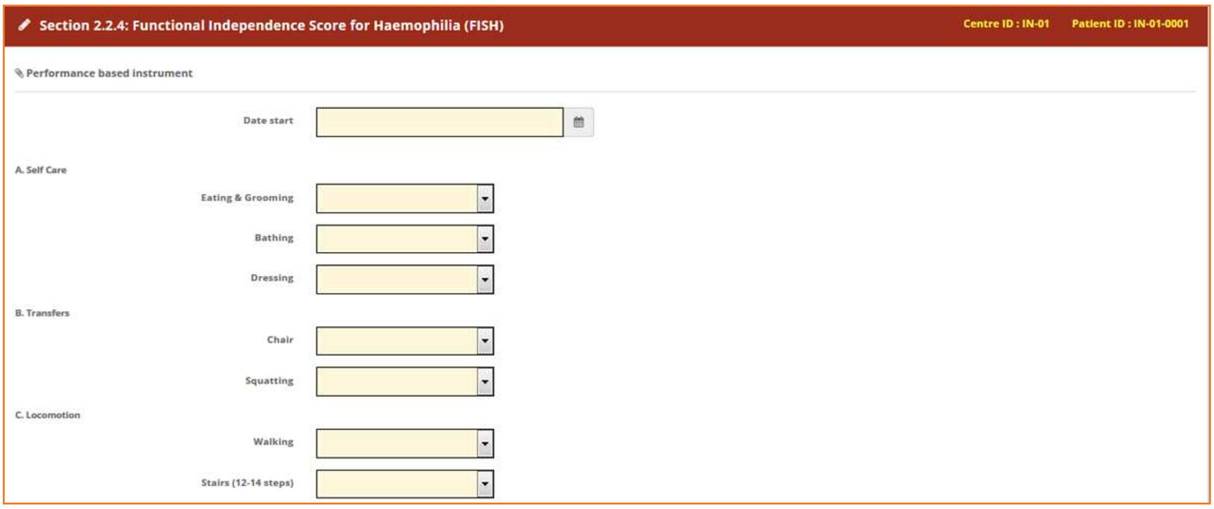
	Left Elbow	Right Elbow	Left Knee	Right Knee	Left Ankle	Right Ankle
Swelling						
Swelling Duration						
Muscle Atrophy						
Crepitus on motion						
Flexion Loss						

After providing all required information, the user need to click any one of the below mentioned button to save data into registry database

- Save Data - Data will be saved in the database and can be updated later on
- Save & Finalize - Data will be saved in the database, but cannot be updated later.
- Exit - To exit the system without saving the data

3.7: Functional Independence Score for Haemophilia (FISH) (Section 2.2.4)

In the *'List of Forms'* menu, Click the View button next to *' Section 2.2.4 : Functional Independence Score for Haemophilia (FISH)'* and provide required information as follows:

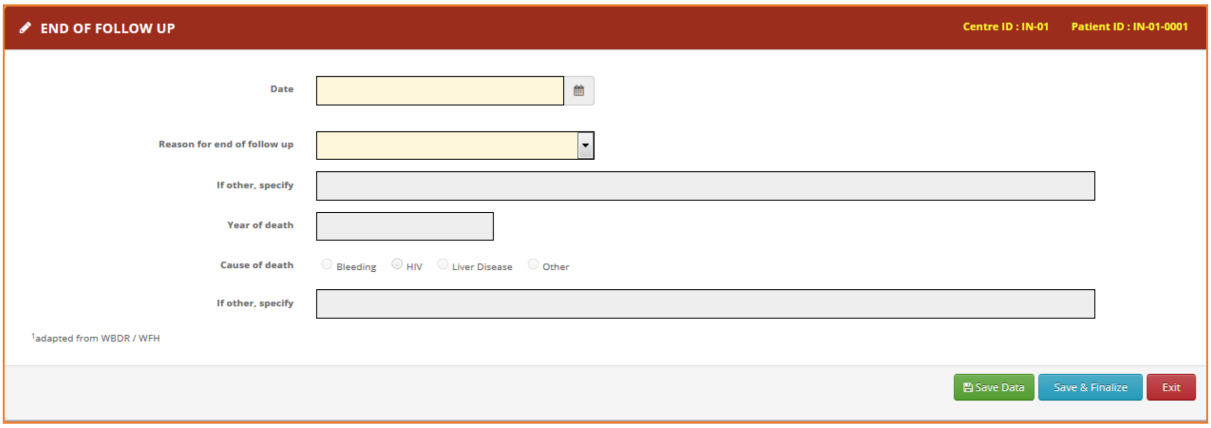


After providing all required information, the user need to click any one of the below mentioned button to save data into registry database

- Save Data - Data will be saved in the database and can be updated later on
- Save & Finalize - Data will be saved in the database, but cannot be updated later.
- Exit - To exit the system without saving the data

3.8: End of Follow-up

In the *'List of Forms'* menu, Click the View button next to *'End of Followup'* and provide required information as follows:



END OF FOLLOW UP

Centre ID : IN-01 Patient ID : IN-01-0001

Date
Reason for end of follow up
If other, specify
Year of death
Cause of death ○ Bleeding ○ HIV ○ Liver Disease ○ Other
If other, specify

[1] adapted from WBDR / WFH

After providing all required information, the user need to click any one of the below mentioned button to save data into registry database

- Save Data - Data will be saved in the database and can be updated later on
- Save & Finalize - Data will be saved in the database, but cannot be updated later.
- Exit - To exit the system without saving the data

Section 4: User and Centre Management

4.1 : Changing user password

To change the password, the user needs to click the *'Change my password'* option which located in the top right corner.

User needs to provide *Old Password, New Password* and *Retype New Password* as follows:

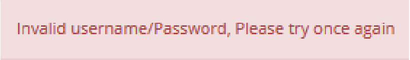
Your Old Password * ******

New Password * **********

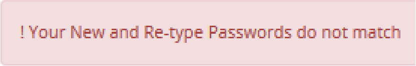
Retype Password * **********

After providing all required information, please click  button to update the password.

System may display error message for the following reasons:

-  - Old password is incorrect

Invalid username/Password, Please try once again

-  - Mismatch between New Password and Retype New Password

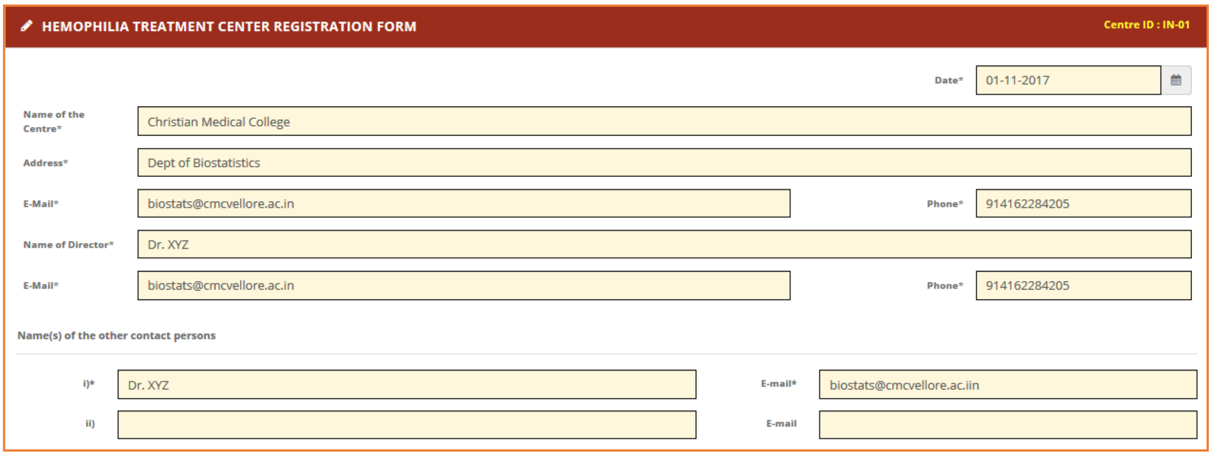
! Your New and Re-type Passwords do not match

The user will get confirmation message after successful completion of password update.

4.2: Updating HTC profile

If the HTC wanted to update their profile, the user needs to click *'Update Centre Details'* which is located at right top corner.

Please update relevant field(s)


HEMOPHILIA TREATMENT CENTER REGISTRATION FORM

Centre ID : IN-01

Date* 01-11-2017

Name of the Centre* Christian Medical College

Address* Dept of Biostatistics

E-Mail* biostats@cmcvellore.ac.in

Phone* 914162284205

Name of Director* Dr. XYZ

E-Mail* biostats@cmcvellore.ac.in

Phone* 914162284205

Name(s) of the other contact persons

i)* Dr. XYZ

E-mail* biostats@cmcvellore.ac.iin

ii)

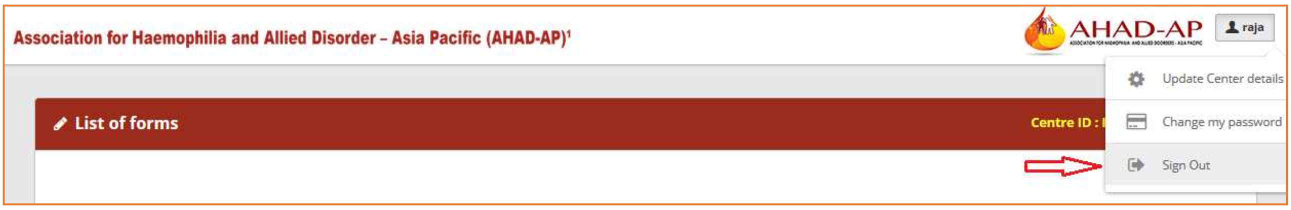
E-mail

After updating all required information, the user need to click any one of the below mentioned button to save data into registry database

- Save Data - Data will be saved in the database and can be updated later on
- Save & Finalize - Data will be saved in the database, but cannot be updated later.
- Exit - To exit the system without saving the data

4.3: Exit from the system

To exit from the system, user needs to click *'Sign out'* option located at right top corner as follows:



Section 5. Technical Support

Web based data capture and management system was developed by:

Clinical Data Management Centre (CDMC)
Department of Biostatistics
Christian Medical College (CMC)
Bagayam, Vellore 632 002
Tamilnadu, India

Ph: 91 416 2284205
Email: biostats@cmcvellore.ac.in

For any technical support in accessing the web based system, the user can contact:

1) Primary Contact : Mr. K. Omprakash – omprakash@cmcvellore.ac.in
2) Secondary Contact : Mr. A. Rajagopal – a.rajagopal@cmcvellore.ac.in