WFH
WORLD BLEEDING DISORDERS REGISTRY
USER HANDBOOK
Version 1.1, August 2019

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Introduction

Welcome to the WFH World Bleeding Disorders Registry (WBDR). The WFH WBDR is a web-based data entry system that provides a platform for a network of hemophilia treatment centres (HTC) to collect uniform and standardized data on people with hemophilia. This registry will bring together privacy-protected patient data from countries around the world, storing it in one central location. The real-world data generated in the registry will be used to advance the understanding and care of people with hemophilia worldwide and support evidence-based advocacy initiatives. An accessible patient registry strengthens our capacity to diagnose, treat, and care for people living with hemophilia.

Enrolling Patients in the WBDR – remember to invite all your patients with hemophilia at your HTC to enrol in the WBDR. Inviting all patients to enrol in the WBDR will provide the best assurance that the data in the WBDR are representative of all patients with hemophilia.

WBDR Access – only authorized individuals at your HTC will have access to the WBDR database. These individuals will be able to view and enter data for your HTC only. Patient data from your HTC cannot be viewed by anyone except the WBDR Steering Committee and the database provider.

Security – please do not disclose your username or password to anyone. All access and transactions are logged by username and any misuse will be attributed to the person the username is allocated to.

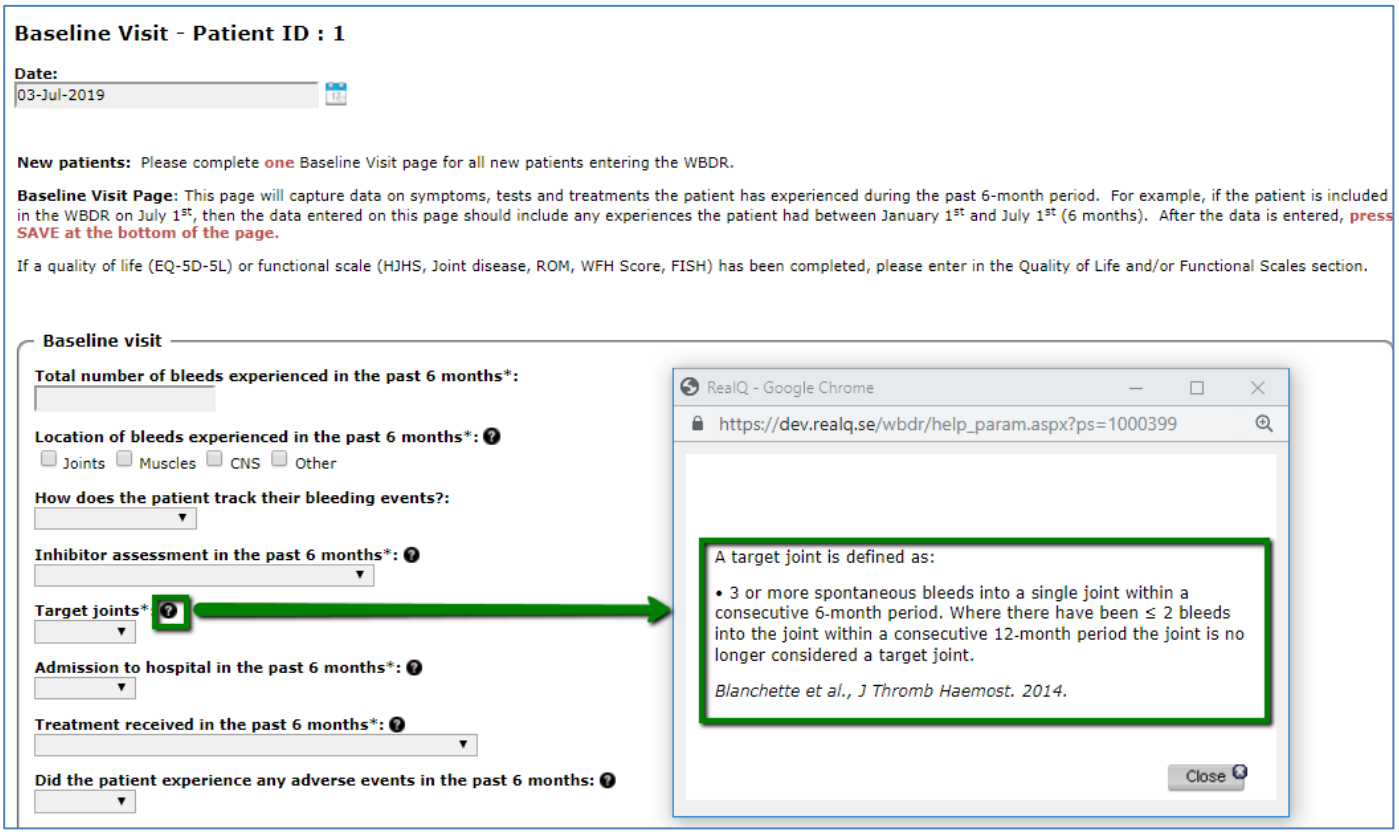
Data Privacy – no one other than authorized HTC personnel can access a patient's WBDR data, unless that person has been properly authorized by the WBDR Steering Committee. It is the responsibility of each HTC to ensure that patient privacy and confidentiality is maintained at the centre. Never provide a patient, or anyone else, except authorized HTC personnel, access to the WBDR system.

Your feedback on the registry and the database is welcome. Please send us comments and questions to wbdr@wfh.org.

General Information on the WBDR

On screen help

Important: On each data entry page in the WBDR, there are instructions to help guide your data entry. If you see a **question mark (?)** please click on it for additional help text.



Mandatory Fields

Each page of data in the WBDR requires a minimum set of data to be collected. Fields identified with an asterisk (*) are part of the Minimal Dataset of the WBDR. These fields are mandatory for all patients. If one of the mandatory fields has not been completed, the database will prompt you to complete these fields when you press SAVE. Fields that do not have an asterisk (*) are part of the Extended Dataset. These fields are recommended but not mandatory.

Saving Data

At the bottom of each page of the WBDR is a SAVE button. Please press SAVE when you have finished entering the data. If you do not SAVE your data, you will lose it.

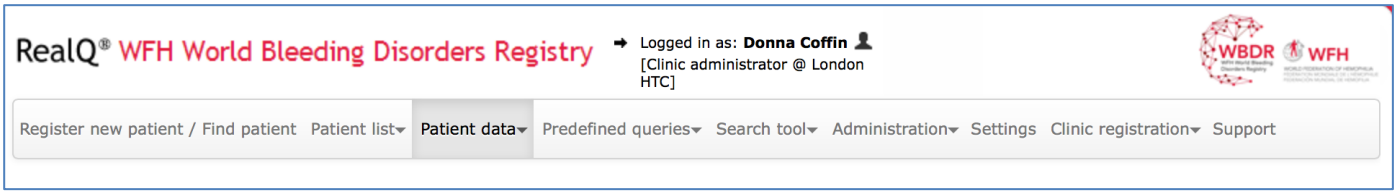
Automatic Edit Checks

When you enter patient data in the WBDR, the database performs automatic edit checks to ensure the data is valid. These checks include:

- ✓ Ensuring all mandatory fields have been entered
- ✓ Ensuring that data fits within allowable ranges, e.g. a month cannot be outside of the range 1-12
- ✓ Ensuring that data is logical, e.g. date of entry into the WBDR cannot occur before date of birth.

WBDR Screen Orientation

The following information is displayed at the top of the WBDR database screen:



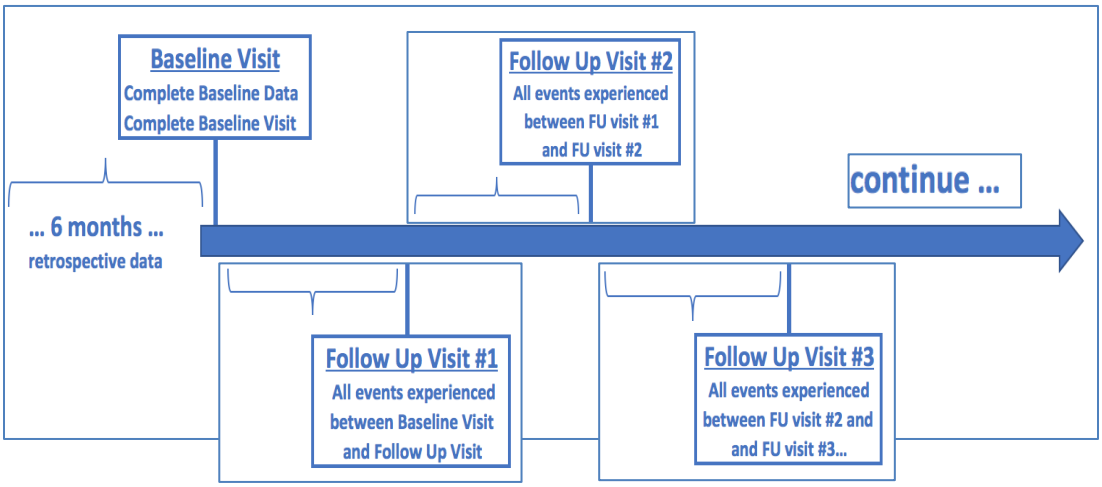
Logged in as: This is the name of the WBDR user from your HTC currently logged into the database, with the type of user attributed to them in brackets. To switch between users, click on the name, and then GO TO SETTINGS to switch user; click on LOG OUT to log out of the WBDR database.

At the top of each screen in the WBDR, there are 9 tabs**:**

TAB NAME	DEFINITION
Register new patient/Find patient	To register new patients and find existing patients
Patient list	Listing of all patients in the WBDR from your HTC
Patient data	This tab contains all the patient data pages to complete. *(This tab only appears once you are in a patient data file.)*
Predefined queries	Summary statistics of all of the patients at your HTC
Search tool	Allows you to generate reports based on your HTC data
Administration	Allows a clinic administrator to create new users at your HTC
Settings	Provides information on user roles and allows you to change your password
Clinic Registration	Registration form to be completed once per year: at enrollment into the WBDR and then every January
Support	Information on how to ask questions

Schematic Diagram of the WBDR

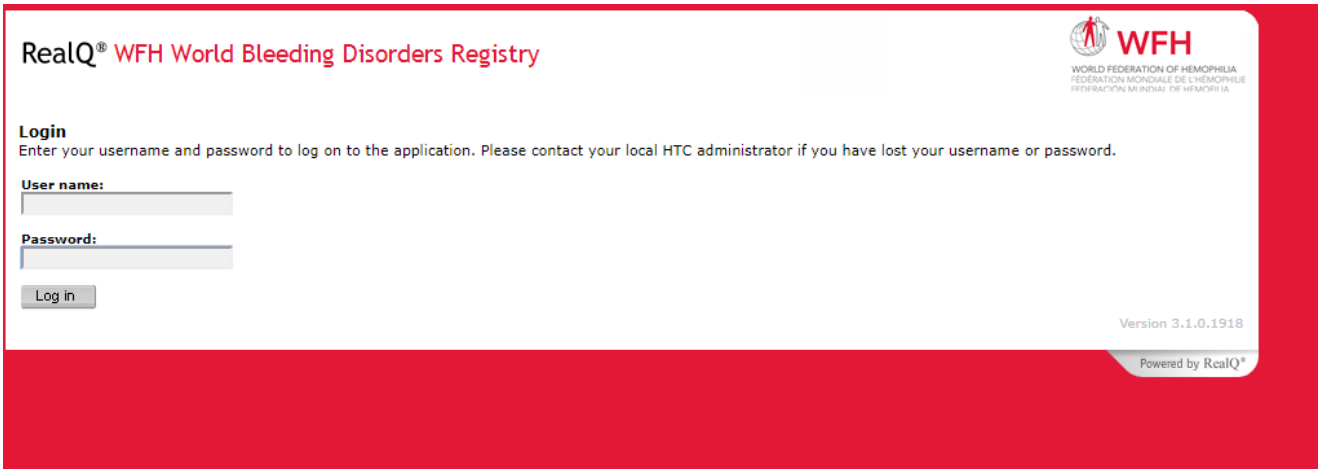
Below is an overview of the patient progress through the WBDR. At baseline visit, data is collected on all patient experienced for the previous 6-month period. At follow up visit #1, data is collected on all patient experiences since baseline visit. At all subsequent follow up visits, data is collected on all patient experiences since the previous follow up visit. This ensures that there are no gaps in data collection.



Logging into the WBDR

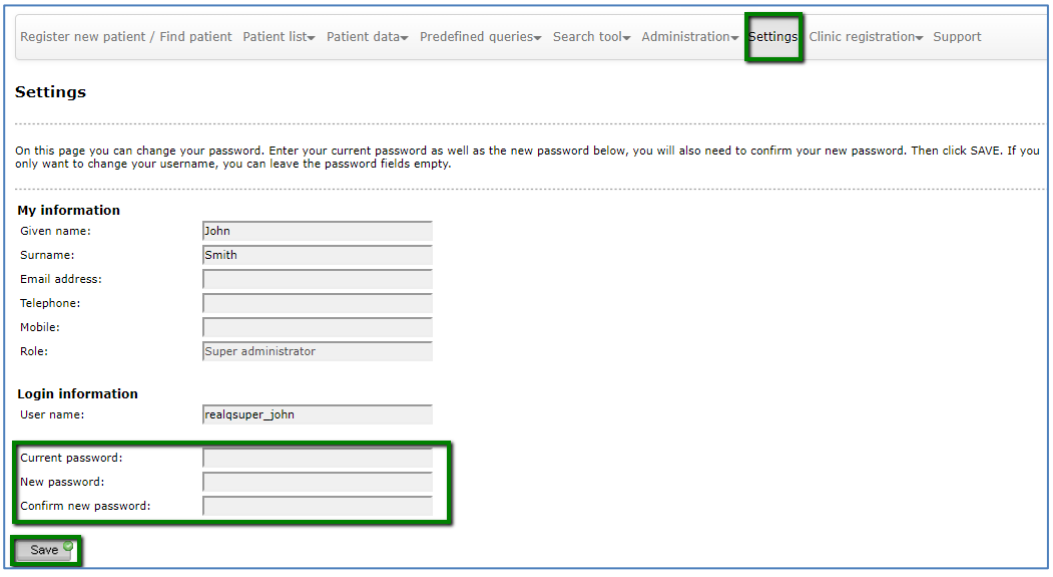
The WBDR database can be found at https://www.wfh.org/en/wbdr_access. The first page displayed when you enter the WBDR database is the Login page.

Username/Password: WFH will provide you with a username and password, that is for you only. Do not disclose your username and password to anyone. To enter the WBDR database, enter your username and password, and click Log in. You will automatically be directed to the Register New Patient / Find Patient page.



You can change the password that was provided to you:

1. Click on **Settings** in the main toolbar
2. Enter your current and new password
3. Press **SAVE**

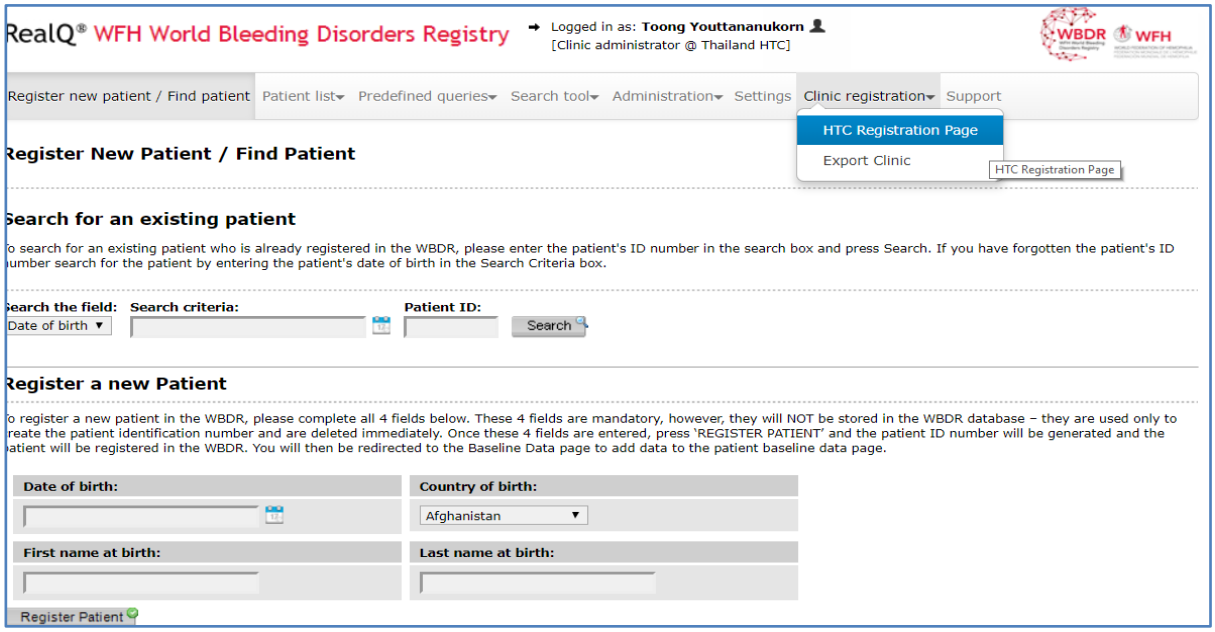


Clinic Registration Page

The Clinic Registration page captures information on all the patients at your centre and the type of care that your HTC provides. The Clinic Registration page should be completed before the first patient is enrolled at your HTC and once per year thereafter (in January). The Clinic Registration page can only be completed by the Clinic Administrator. Clinic Users do not have access to this page. When logging into the WBDR for the first time, **please complete this page first**. The WFH will send an email reminder each year in January, as a reminder to complete this page.

- When you complete this form for the first time when you receive your log in details for the WBDR, answer the questions on this form, based on the day you are completing the form.
- When you complete this form in January as part of the annual update, answer the questions on this form based on data available as of December 31st of the previous year.

Follow: Clinic registration > HTC Registration Page



Register New Patient / Find Patient

- Register New Patient

New patients enrolling in the WBDR need to be registered. If your patient has already been registered in the WBDR, go to the next section 'Find Patient' for instructions on how to find an existing patient in the WBDR.

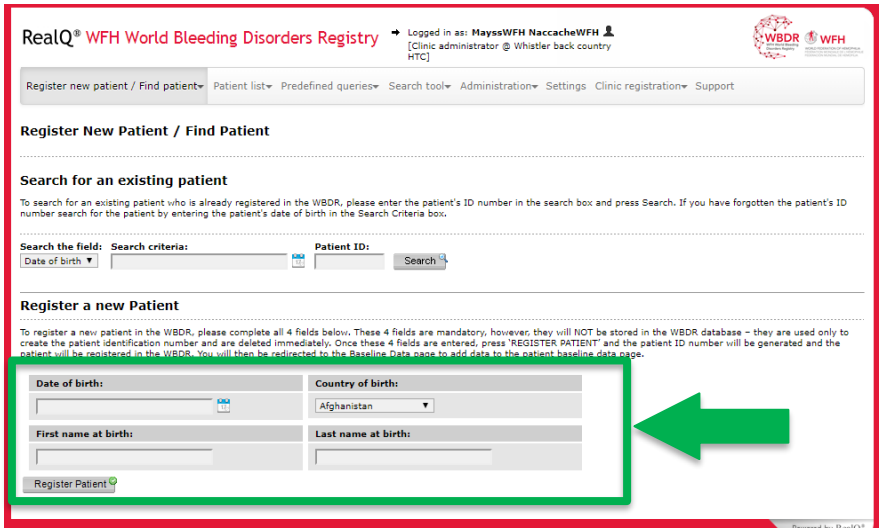
To register a new patient in the WBDR, please complete all 4 fields highlighted in green below. These 4 fields are used to generate a **Unique Patient Identifier (UPI)**.

The UPI is created based on 4 pieces of patient data which is entered in the database but NOT STORED in the computer. These 4 pieces of information are:

- Date of birth
- Country of birth
- First name of patient at birth
- Last name of patient at birth

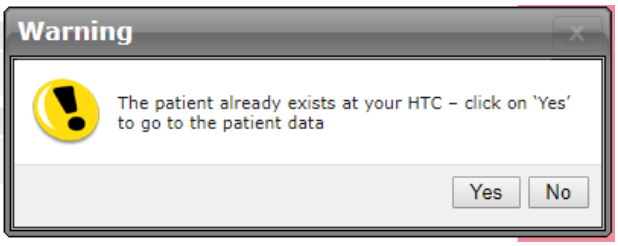
With these 4 pieces of information a UPI is generated, which is unique to the patient and will be used to detect duplicate patients.

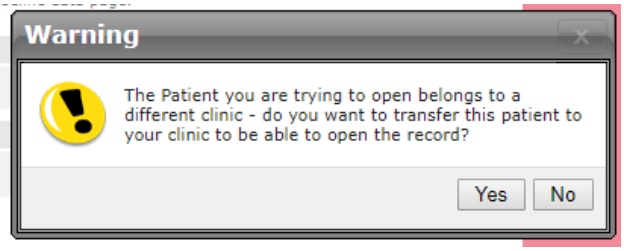
Once these 4 fields are entered, press **REGISTER PATIENT** and the patient ID number will be generated and the patient will be registered in the WBDR. You will then be redirected to the Baseline Data page to add data to the patient baseline data page. You will notice the Patient ID is displayed at the at the top of the Baseline Data page.



- Warning message for duplicate patient

If this patient has already been registered in the WBDR, a pop-up window will appear indicating that the patient already exists in the database. If the patient is at your clinic, you can go directly to this patient. If the patient belongs to another HTC, you have the option of requesting that the patient be transferred to your clinic.



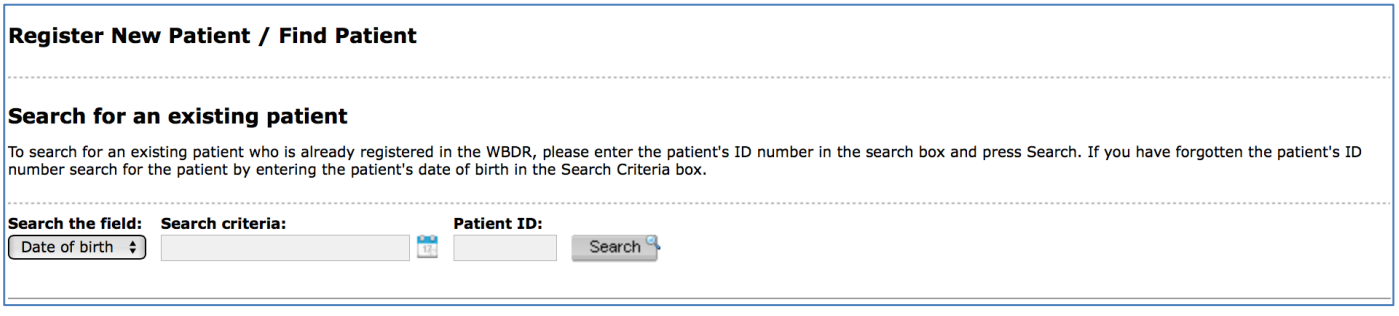


- Find Existing Patient

To search for an existing patient in the WBDR, enter the Patient ID in the search field under Patient ID, and press Search.

If you have forgotten the Patient ID, you can search for this patient by entered the patient's date of birth, in the field Search criteria. You can either click on the calendar and choose the date, or enter the date of birth in the format dd-mm-yy. For example, if your patient was born on February 8, 1963, you would enter 08-02-63 and press Search.

All patients registered at your HTC with this date of birth will appear. In almost all circumstances, only one patient will appear. Click on the Patient ID number of the patient. In the event that there are 2 patients with the exact same date of birth at your HTC, both will appear in the window. You may need to go into the patient's baseline data page to identify which of the 2 patients is the correct one.

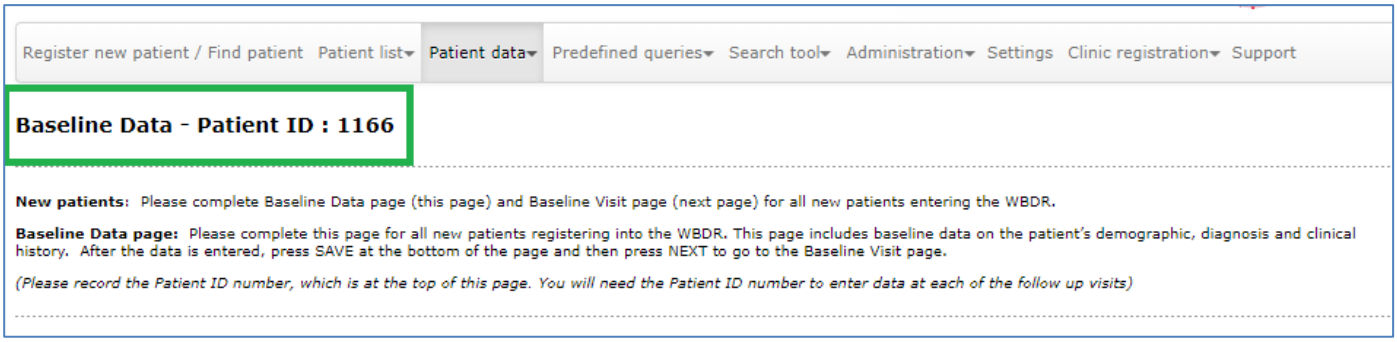


Patient Data Pages

- **Baseline Data**

Once you register a new patient, and click on REGISTER PATIENT, you will be automatically directed to the Baseline Data page. Data on this page should only be entered ONCE for a patient.

Important: The **Patient ID number** will appear at the top of this page. **Please record this number**, you will need the Patient ID number to enter data at each of the follow up visits. You can write it down on the WBDR Identification Card, provided by the WFH, and provide this to the patient. Ask the patient to keep this in his wallet and bring it with him to all clinic visits.



New patients: For all new patients entering the WBDR, 2 database pages need to be completed: The **Baseline Data page** and **Baseline Visit page**.

Baseline Data page: Please complete this page for all new patients registering into the WBDR. Fields identified with an asterisk (*) are part of the Minimal Dataset of the WBDR. These fields are mandatory for all patients. Fields that do not have an asterisk (*) are part of the Extended Dataset. These fields are recommended but not mandatory. The following data is collected on each patient on the Baseline Data page:

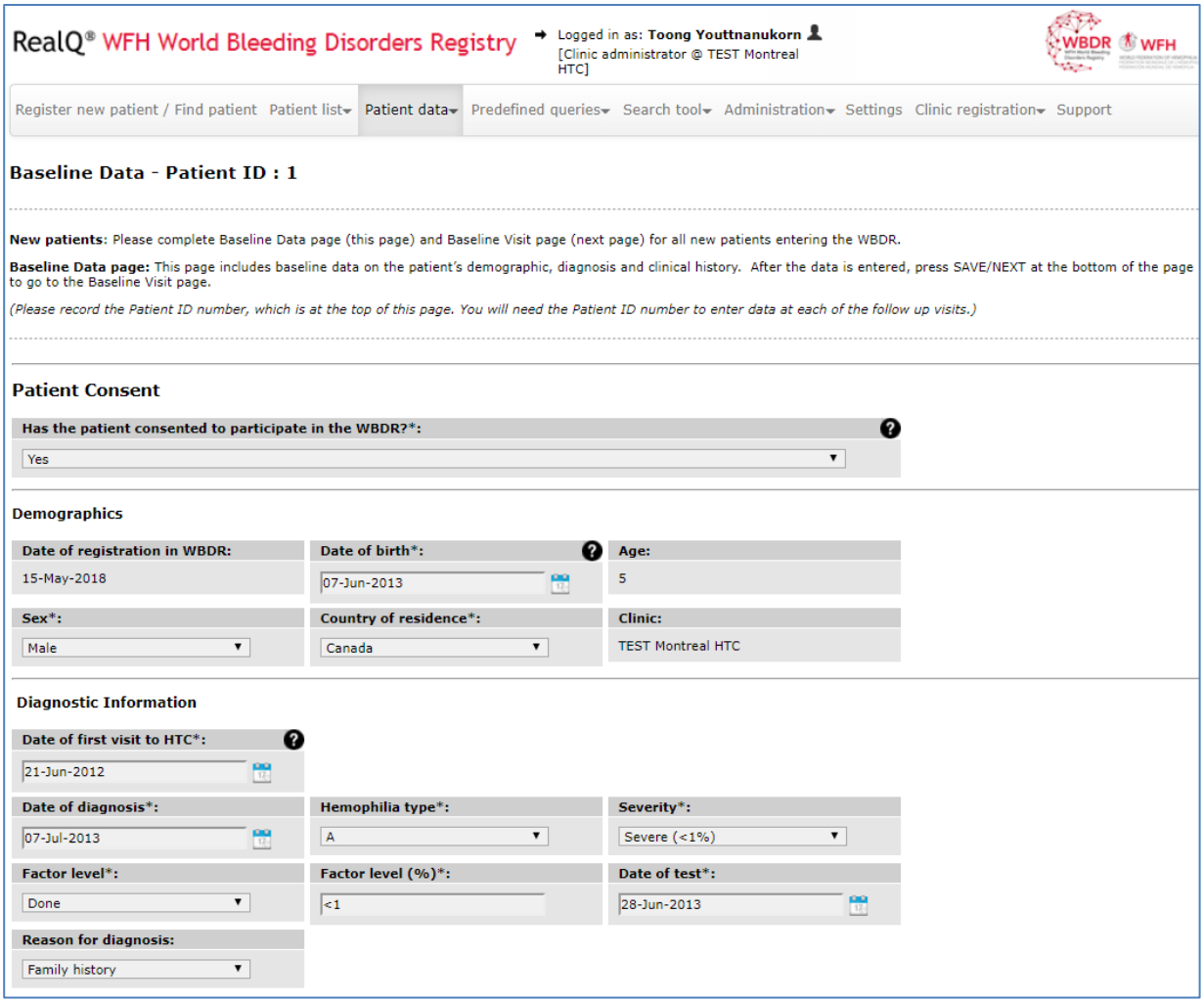
- Patient Consent
  - Has the patient consented to participate in the WBDR? *
- Demographics
  - Date of registration in the WBDR (date the patient had their baseline visit)
  - Date of birth*
  - Age (automatically calculated)
  - Sex*
  - Country of residence*
  - Clinic (your HTC name will automatically be displayed here)

- Diagnosis Information
  - Date of first visit to HTC*
  - Date of diagnosis*
  - Hemophilia type*
  - Hemophilia severity*
  - Factor level % and date of test*

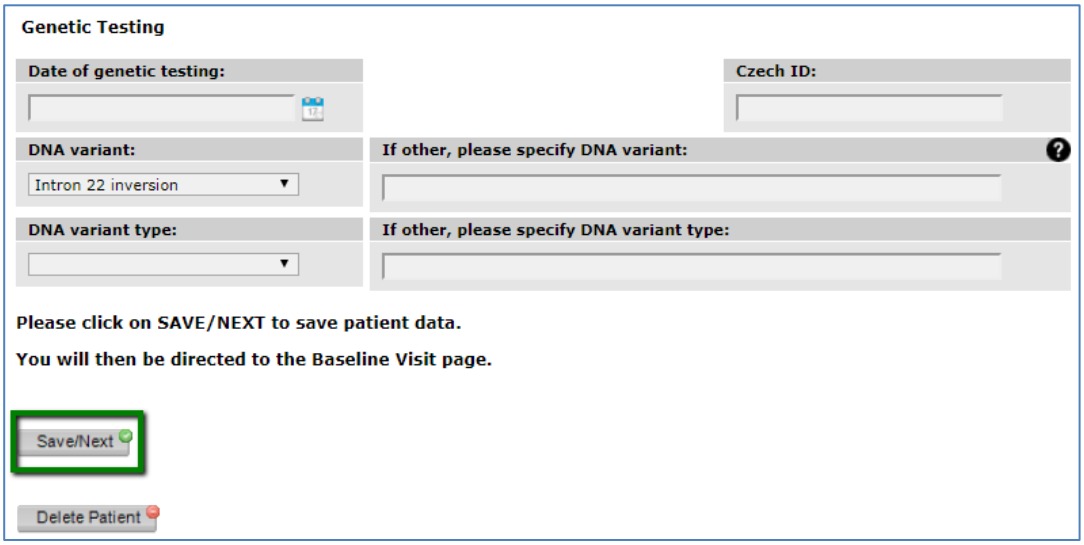
- Clinical History
  - Bleeding history*
  - Joint bleeding history*
  - Inhibitor history*
  - Treatment history*
  - Has any family member ever had an inhibitor?

- Blood Group
  - Blood group
  - Rh factor

- Genetic Testing
  - Date of genetic testing
  - DNA variant and DNA variant type



After the data is entered, press **SAVE/NEXT** at the bottom of the page. You will be automatically directed to the Baseline Visit page.



- ## Baseline Visit

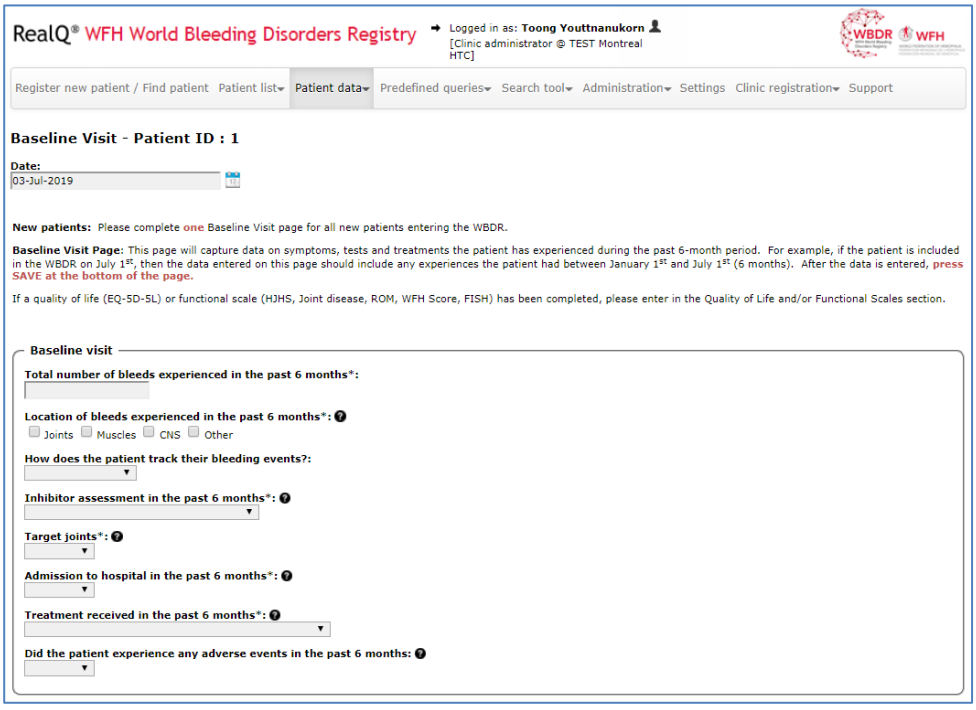
Baseline Visit Page: Please complete this page for all new patients registering into the WBDR. This page will capture data on symptoms, tests and treatments the patient has experienced during the **past 6-month period**. Data on this page should only be entered ONCE for a patient. For example, if the patient enters the WBDR on July 1st, then the data entered on this page should include all events the patient experienced between January 1st and July 1st (6 months).

The date that you are entering the data will be displayed in the Date field. If this date is not the date of the actual visit, please change it to the date the patient came to the clinic for his visit.

The following data is collected on each patient at the Baseline Visit:

- Total number of bleeds in the past 6 months*
- Location of bleeds experienced in the past 6 months*
- How does the patient track their bleeding events?
- Inhibitor assessment in the past 6 months*
- Target joints*
- Admission to hospital in the past 6 months*
- Treatment received in the past 6 months*
- Did the patient experience any adverse events in the past 6 months

After the data is entered, press **SAVE** at the bottom of the page. After saving the data on the baseline visit page, your patient's baseline visit is now complete. The next time you will enter data for this patient is at the patient's next follow up visit to your clinic.



- **Follow Up Visits**

A **Follow Up Visit** should be completed **each time** the patient comes to the clinic for a clinic visit. When you search for an existing patient in the WBDR database and click on your patient, you will be automatically directed to the Follow Up page.

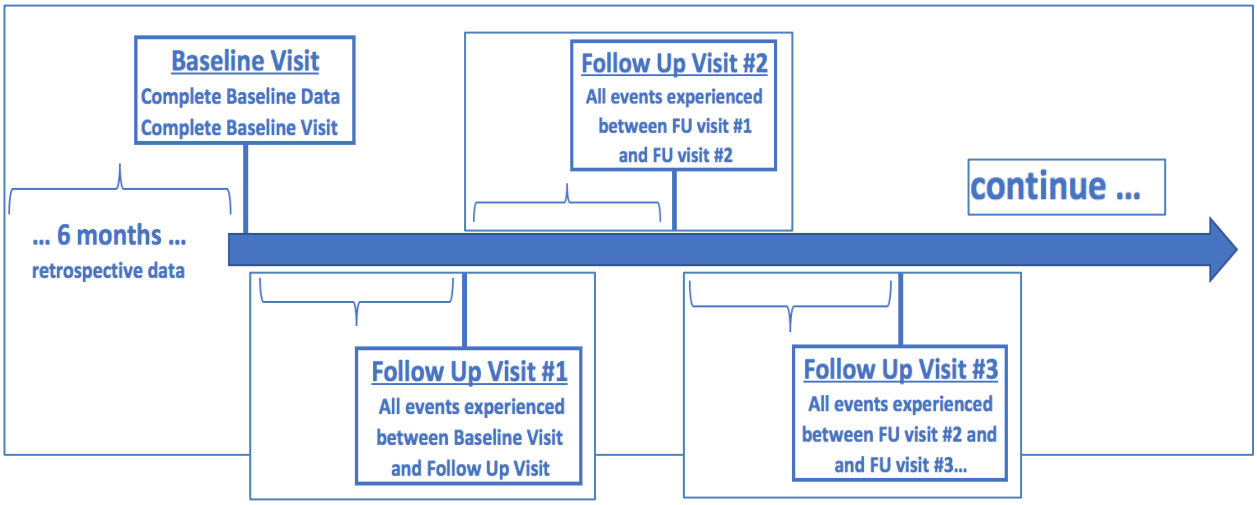
Follow Up Visit Page: This page will capture data on symptoms, tests and treatments the patient has experienced since the last visit entered into the database.

The date that you are entering the data will be displayed in the Date field. If this date is not the date of the actual visit, please change it to the date the patient came to the clinic for his visit.

At each Follow Up visit, data is collected on all events that the patient experienced between the previous visit (either the Baseline visit or the previous Follow Up visit) and this Follow Up visit. Using this design allows us to capture all events that the patient experienced with no gaps in data collection. (See Schematic Diagram of the WBDR below)

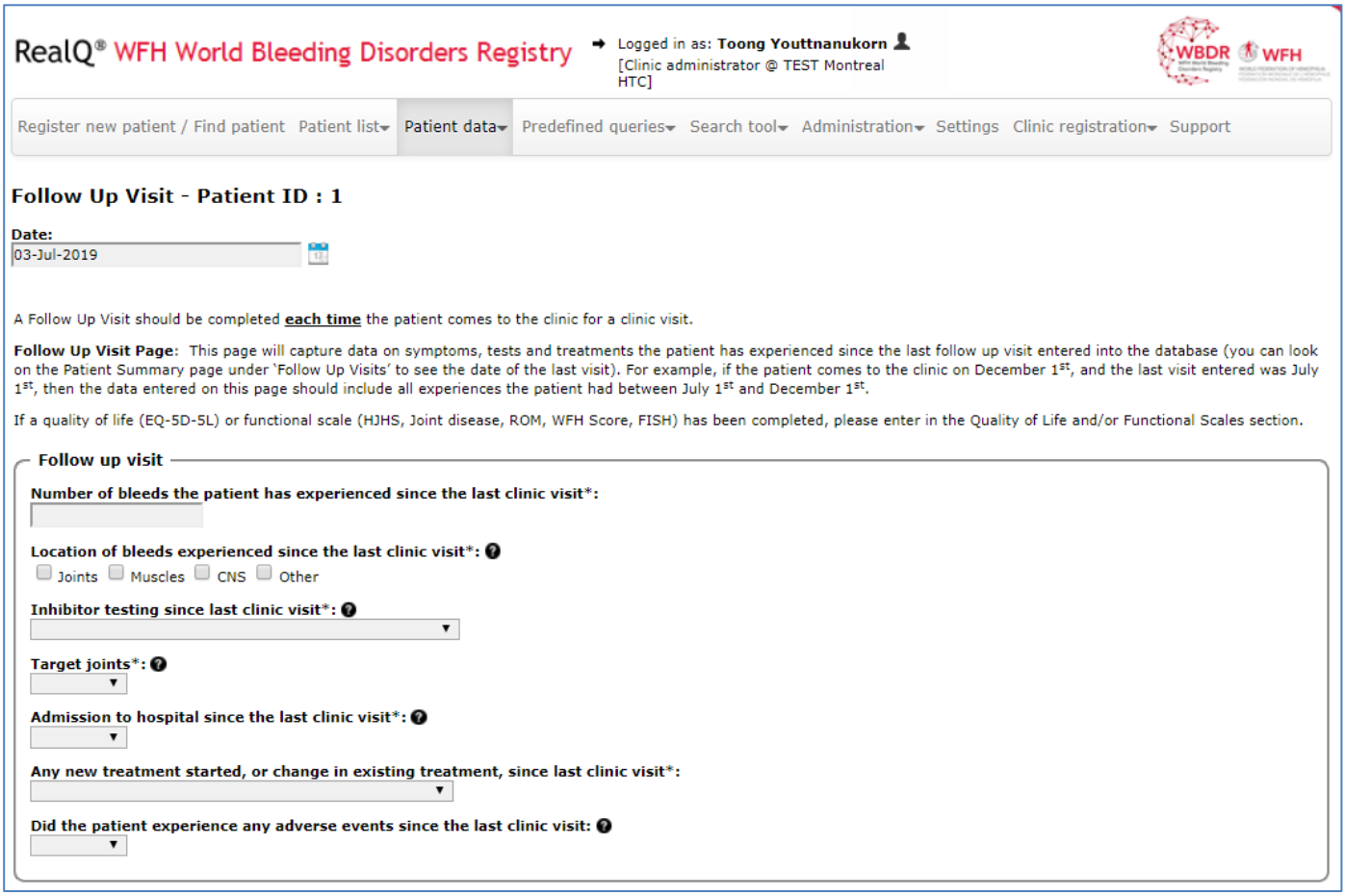
For example, if the patient comes to the clinic on December 1st for a Follow Up Visit, and the last visit entered was July 1st, then the data entered on this page should include all experiences the patient had between July 1st and December 1st.

Schematic Diagram of the WBDR



The following data is collected on each patient at the Follow Up Visits:

- Number of bleeds the patient has experienced since the last clinic visit*
- Location of bleeds experienced since the last clinic visit*
- Inhibitor testing since last clinic visit*
- Target joints*
- Admission to hospital since the last clinic visit*
- Any new treatment started, or change in existing treatment, since the last clinic visit*
- Did the patient experience any adverse events since the last clinic visit?


RealQ® WFH World Bleeding Disorders Registry
Logged in as: Toong Youttnanukorn
[Clinic administrator @ TEST Montreal HTC]
Register new patient / Find patient
Patient list
Patient data
Predefined queries
Search tool
Administration
Settings
Clinic registration
Support
Follow Up Visit - Patient ID : 1
Date:
03-Jul-2019
A Follow Up Visit should be completed each time the patient comes to the clinic for a clinic visit.
Follow Up Visit Page: This page will capture data on symptoms, tests and treatments the patient has experienced since the last follow up visit entered into the database (you can look on the Patient Summary page under 'Follow Up Visits' to see the date of the last visit). For example, if the patient comes to the clinic on December 1st, and the last visit entered was July 1st, then the data entered on this page should include all experiences the patient had between July 1st and December 1st.
If a quality of life (EQ-5D-5L) or functional scale (HJHS, Joint disease, ROM, WFH Score, FISH) has been completed, please enter in the Quality of Life and/or Functional Scales section.
Follow up visit
Number of bleeds the patient has experienced since the last clinic visit*:
Location of bleeds experienced since the last clinic visit*:
Joints
Muscles
CNS
Other
Inhibitor testing since last clinic visit*:
Target joints*:
Admission to hospital since the last clinic visit*:
Any new treatment started, or change in existing treatment, since last clinic visit*:
Did the patient experience any adverse events since the last clinic visit:

• Inhibitor Assessments Module

The **Inhibitor Assessments** module is available at both baseline and follow up visits.

Baseline Visit

If Yes, inhibitor testing done was answered to the question 'Inhibitor assessment in the past 6 months' at baseline, please complete the 'Inhibitor assessments' module, found at the bottom of the screen.

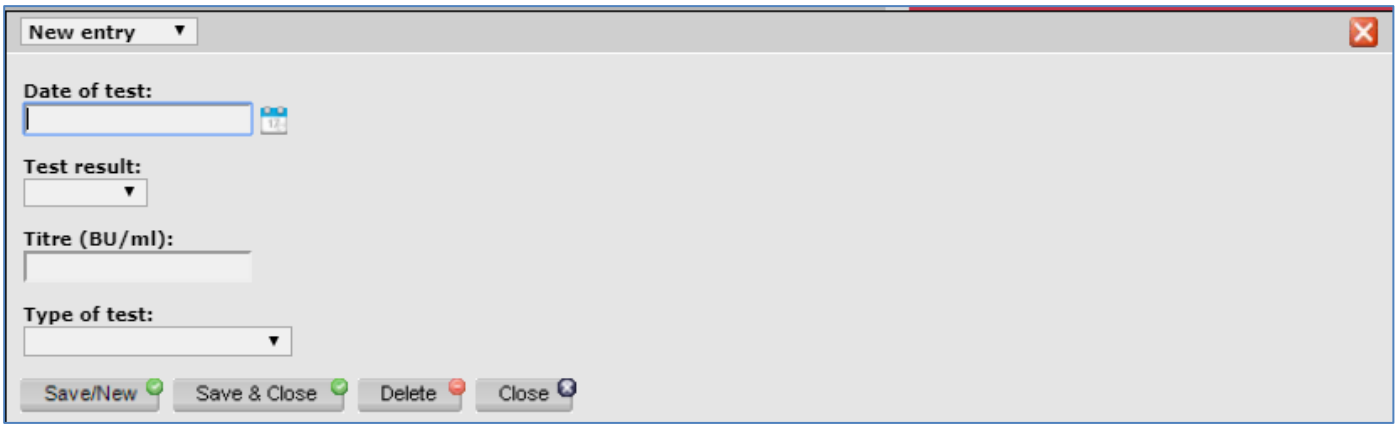
Follow Up Visit

If Yes, inhibitor testing done was answered to the question 'Inhibitor testing since last clinic visit' at a follow up visit, please complete the 'Inhibitor assessments' module, found at the bottom of the screen.

The following data is collected on each patient in the 'Inhibitor assessments' Module:

- Date of test (the date of inhibitor testing)
- Test result (positive or negative)
- Titer (BU/ml)
- Type of test (Bethesda, Nijmegen-Bethesda, Mixing study (aPPT test), Other or Unknown)

Press Save/New, to save your data and add another treatment.
Press Save/Close, to save your data and close the module.
Press Delete, to delete all of the data in this module and not save it.
Press Close, to close the module, and not save your data.



• Hospitalization Module

The **Hospital Admissions** module is available at both baseline and follow up visits.

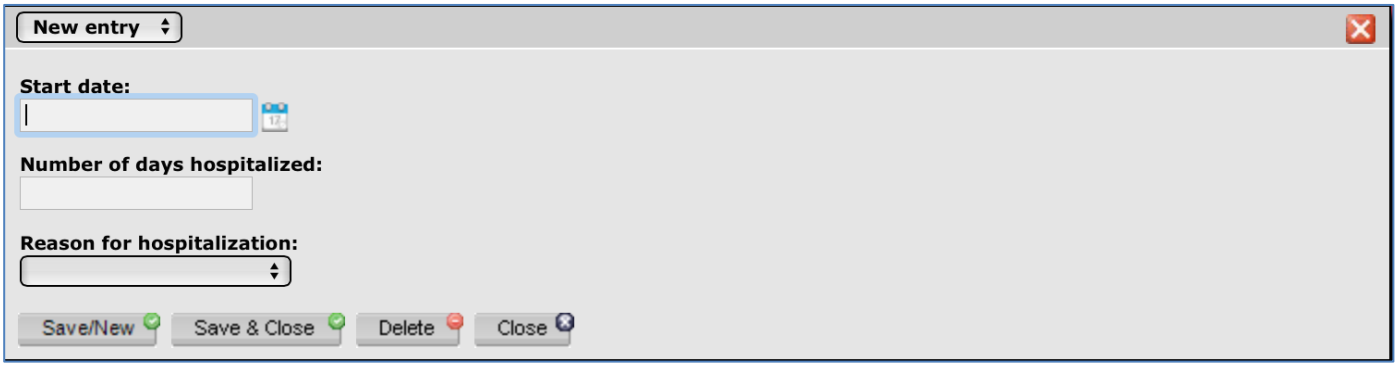
Baseline Visit
If Yes was answered to the question 'Admission to hospital in the past 6 months' at baseline, please complete the 'Hospital Admissions' module, found at the bottom of the screen.

Follow Up Visit
If Yes was answered to the question 'Admission to hospital since the last clinic visit' at a follow up visit, please complete the 'Hospital Admissions' module, found at the bottom of the screen.

The following data is collected on each patient in the 'Hospital Admissions' Module:

- Start date of the hospitalization (the date the patient entered the hospital)
- Number of days hospitalized (calculated by the number of nights the patient slept at the hospital)
- Reason for hospitalization

Press Save/New, to save your data and add another hospital admission.
Press Save/Close, to save your data and close the module.
Press Delete, to delete all of the data in this module and not save it.
Press Close, to close the module, and not save your data.



• Treatments Module

The **Treatments** module is available on both baseline and follow up visit pages.

Baseline Visit
If Yes was answered to the question 'Treatment received in the past 6 months' at baseline, please complete the 'Treatments' module, found at the bottom of the screen.

Follow Up Visit
If Yes was answered to the question 'Any new treatment started, or change in existing treatment, since the last clinic visit' at a follow up visit, please complete the 'Treatments' module, found at the bottom of the screen.

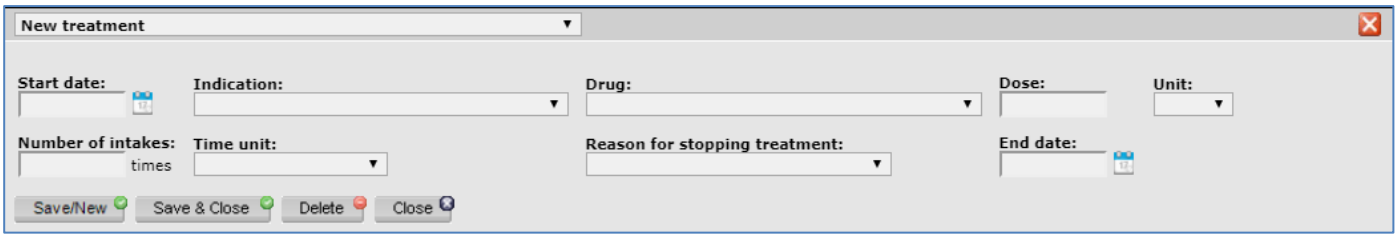
The following data is collected on each patient in the Treatments Module:

Start Date	First date the treatment/drug was taken
Indication	Choose from the drop-down menu: Prophylaxis, On demand, ITI, Surgery, Trauma with no known bleed, Selective bleed prevention (i.e. before activity), Other, Unknown
Drug	Choose from the drop-down menu. If the patient is receiving treatment through a clinical trial, select: Clinical Trial – Gene Therapy or Clinical Trial Product (not including Gene Therapy). If the product used is not in the list, choose Other – not listed.
Dose	Enter the total amount of product used per infusion or administration (e.g., 1000)
Unit	Enter the unit (e.g., IU)
Number of Intakes	Enter number of intakes (e.g., 4 times)
Time unit	Enter the time unit (e.g. daily)
Reason for stopping treatment	If the patient stopped a treatment during the follow up period, indicate the reason treatment was stopped and then the end date. If the treatment is ongoing, keep this field blank.
End date	Enter the date treatment was stopped. If the treatment was not stopped during the period, leave the end date blank and the reason for stopping treatment blank. When the treatment is stopped, return to this module to add the stop date and reason.

NOTES:
- If the patient had more than 1 treatment episode during the visit period, each treatment episode should be a separate entry with different start and stop dates.
- If the exact start date of a treatment is not known: if the month and year is known, enter the first day (01) of the month and year; if the day and month are not known: enter the first day (01) and the first month (01) of the year; if the year is not known, add your best estimate.

- If treatment is ongoing at the time of the visit, do not enter an end date or reason for stopping treatment; when the patient does stop treatment, you can return to this module and enter the stop date and reason for stopping.
- Trauma with no known bleed = select if the patient experienced a trauma and received treatment even though there is no evidence of bleeding; enter start date and end date of treatment;
- If the patient took a drug that is not listed, enter Other - not listed and send an email to WFH asking to add this treatment;
- If the patient took Factor VIII or Factor IX but the exact product is not listed, enter Factor VIII - not listed or Factor IX - not listed;
- If the patient took gene therapy through a clinical trial, select Clinical Trial - Gene Therapy;
- If the patient took an unknown drug through a clinical trial other than gene therapy, enter Clinical Trial Product (not including Gene Therapy)

Press Save/New, to save your data and add another treatment.
Press Save/Close, to save your data and close the module.
Press Delete, to delete your data and not save it.
Press Close, to close the module, and not save your data.



- ## Adverse Events Module

The **Adverse events** module is available at both baseline and follow up visits.

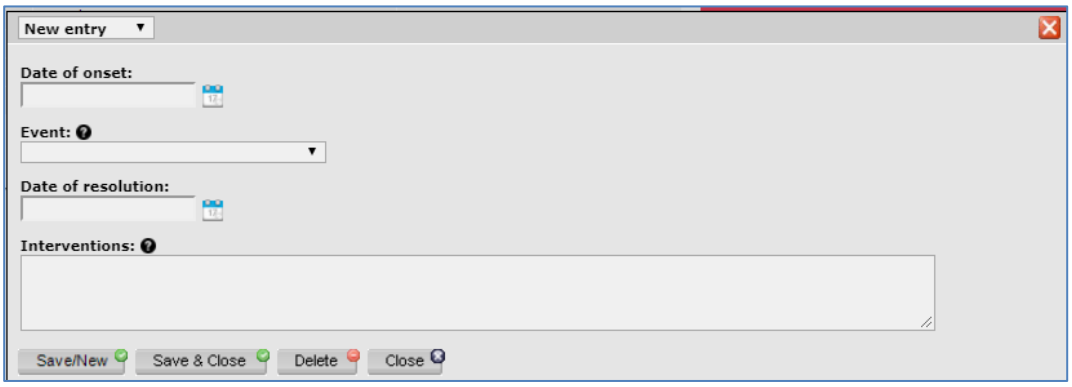
Baseline Visit
If Yes was answered to the question 'Did the patient experience any adverse events in the past 6 months' at baseline, please complete the 'Adverse events' module, found at the bottom of the screen.

Follow Up Visit
If Yes was answered to the question 'Did the patient experience any adverse events since the last clinic visit' at a follow up visit, please complete the 'Adverse events' module, found at the bottom of the screen.

The following data is collected on each patient in the 'Adverse events' Module:

- Start date of onset (the date the patient experience adverse events)
- Events (Infection, Allergic reaction including anaphylaxis, Thromboembolic event, Thrombotic microangiopathy, Lack of efficacy, Injection site reaction or Other)
- Date of resolution (the end date the patient experience adverse events)
- Interventions

Press Save/New, to save your data and add another treatment.
Press Save/Close, to save your data and close the module.
Press Delete, to delete all of the data in this module and not save it.
Press Close, to close the module, and not save your data.



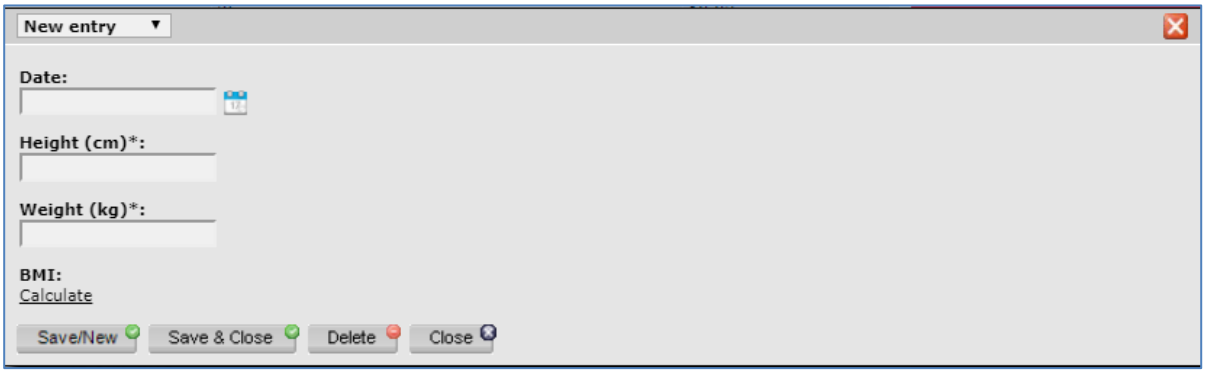
• Height & Weight

The **Height & Weight** module is available at both baseline and follow up visits.

The following data is collected on each patient in the 'Height & Weight' Module:

- Date of height and weight being recorded
- Height (cm)
- Weight (kg)

Press Save/New, to save your data and add another treatment.
Press Save/Close, to save your data and close the module.
Press Delete, to delete all of the data in this module and not save it.
Press Close, to close the module, and not save your data.



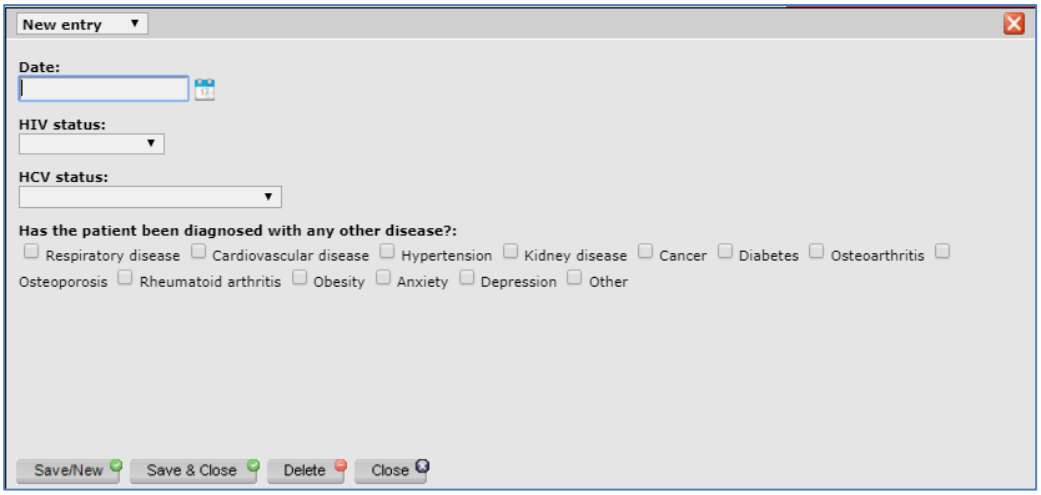
- **Co-morbidities Module**

The **Co-morbidities events** module is available at both baseline and follow up visits.

The following data is collected on each patient in the 'Co-morbidities Module:

- HIV Status
- HCV Status
- Has the patient been diagnosed with any other disease?

Press Save/New, to save your data and add another treatment.
Press Save/Close, to save your data and close the module.
Press Delete, to delete all of the data in this module and not save it.
Press Close, to close the module, and not save your data.



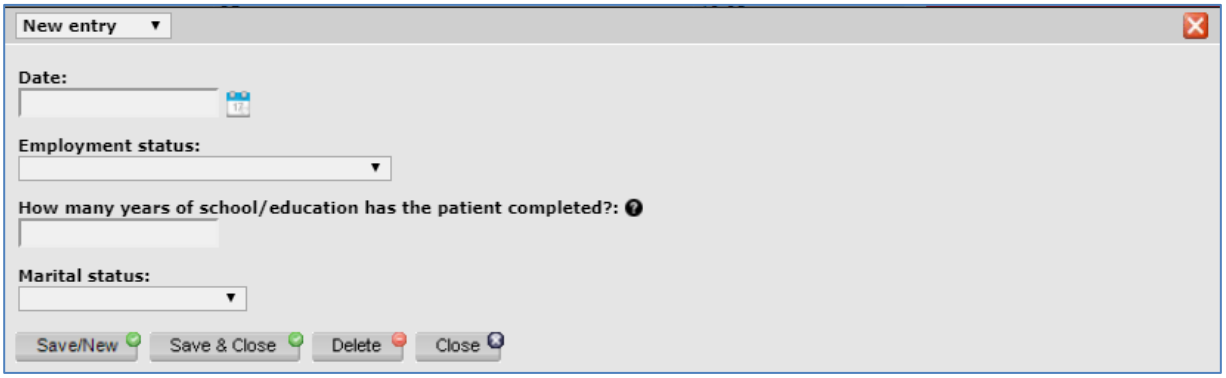
• Education/ Employment/ Marital Status Module

The **Education/ Employment/ Marital Status** module is available at both baseline and follow up visits.

The following data is collected on each patient in the 'Co-morbidities Module:

- Employment Status
- How many years of school/ education has the patient completed?
- Marital status

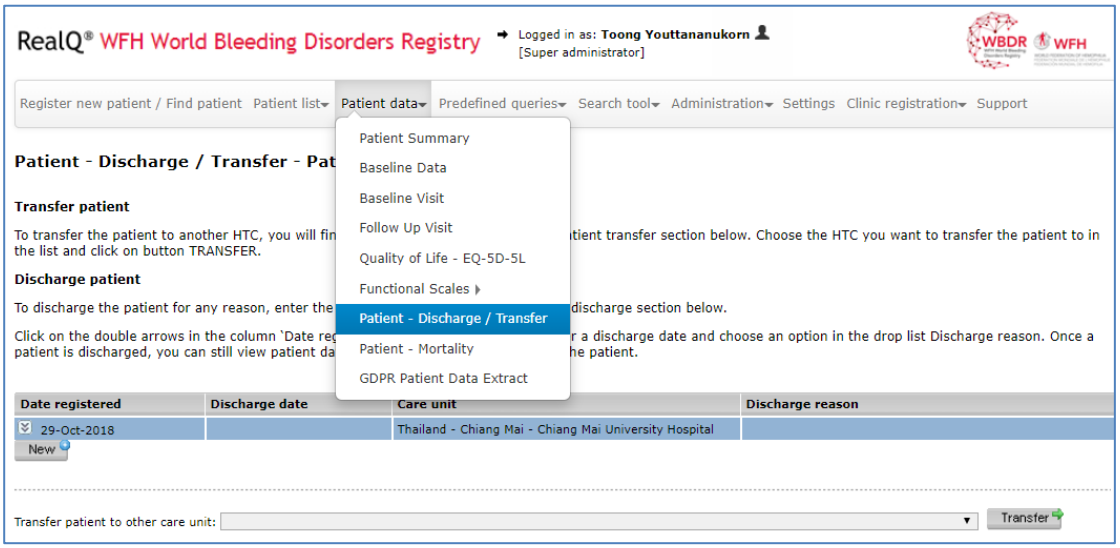
Press Save/New, to save your data and add another treatment.
Press Save/Close, to save your data and close the module.
Press Delete, to delete all of the data in this module and not save it.
Press Close, to close the module, and not save your data.



- **Patient Discharge / Transfer**
  - **Patient Discharge**

If one of your patients withdraws from the WBDR for any reason, please complete the Patient Discharge / Transfer page. Under the Patient data tab at the top of the screen, click on Patient - Discharge / Transfer.

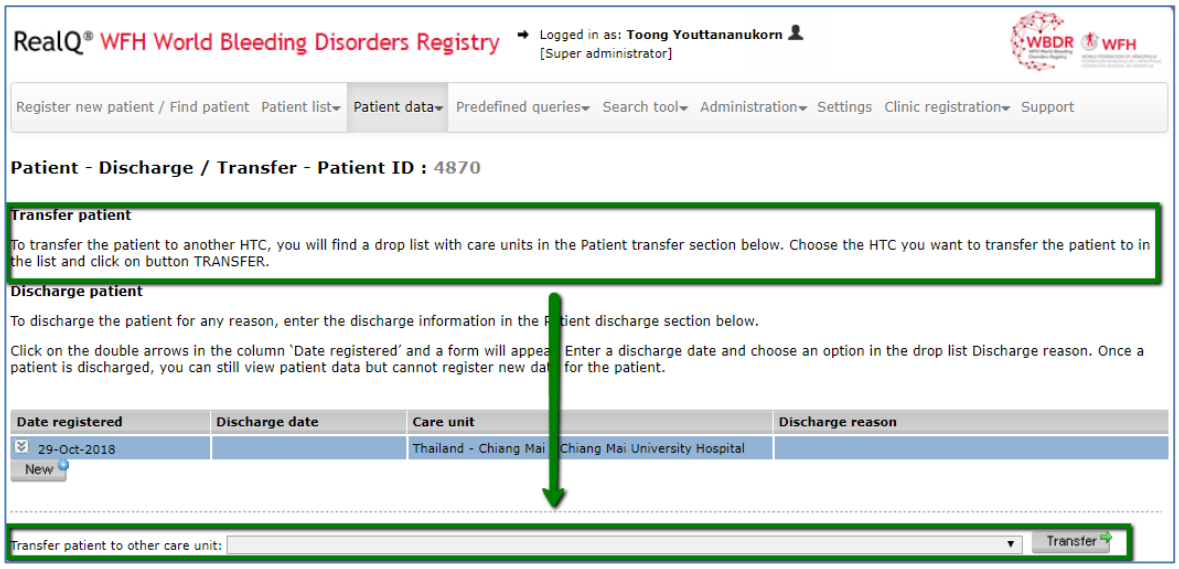
You will be prompted to add the date of discharge and the reason for discharge. If the reason for discharge was death, please complete a Patient – Mortality page as well.



- **Patient Transfer**

If one of your patients receives care at more than 1 HTC, you can transfer the patient between HTCs. Under the Patient data tab at the top of the screen, click on Patient - Discharge / Transfer.

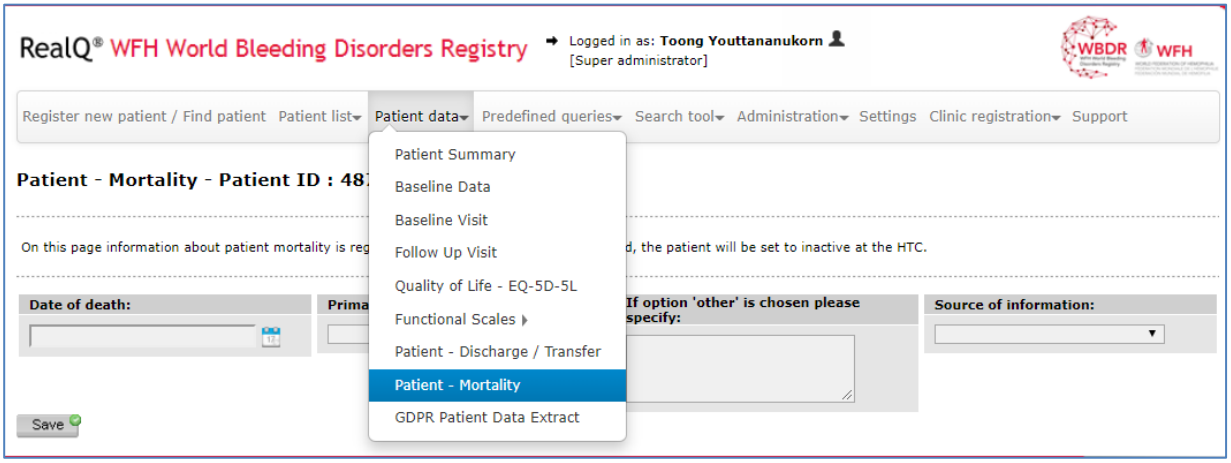
You will be prompted to select the HTC that you would like to transfer the patient to, and press Transfer. The patient is transferred to the new HTC once the HTC confirms that they accept the patient. The HTC can add data to the patient's WBDR file and transfer the patient back to the original HTC.



Patient Mortality

If one of your patients dies while enrolled in the WBDR, please complete the Patient Mortality page. Under the Patient data tab at the top of the screen, click on Patient – Mortality.

You will be prompted to add the date of death, cause of death and the source of the death information.

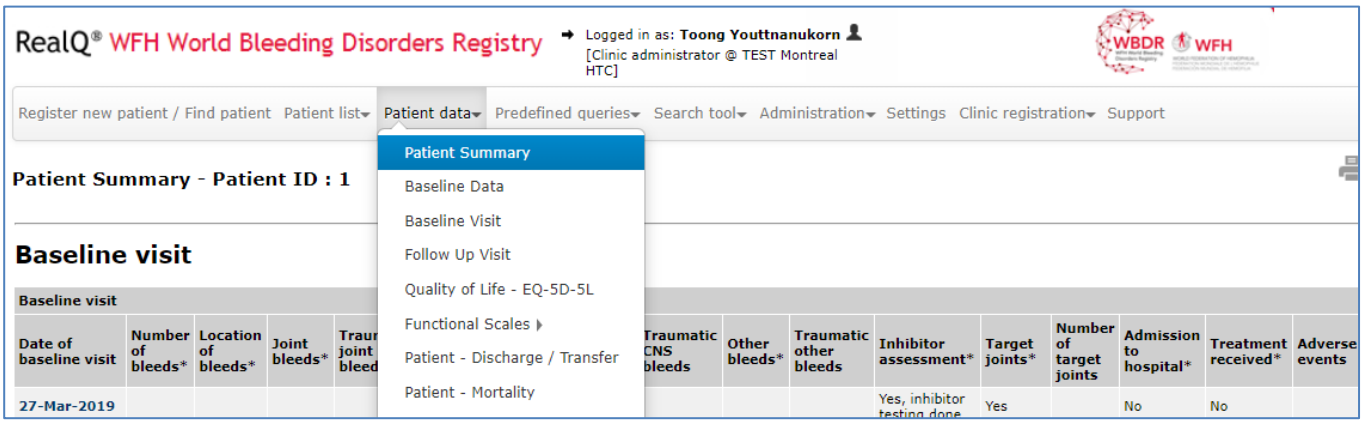


Patient Summary

To view a summary of all of the data entered for an individual patient, under the Patient data tab at the top of the screen, click on Patient Summary.

All of the data that has been entered for an individual patient since the patient was registered in the WBDR will be displayed: the Baseline Visit, all Follow Up Visits entered, all Inhibitor assessments, all Hospital admissions, all Treatments, all Adverse events, Height & Weight, all co-morbidities and Education/Employment/Marital Status.

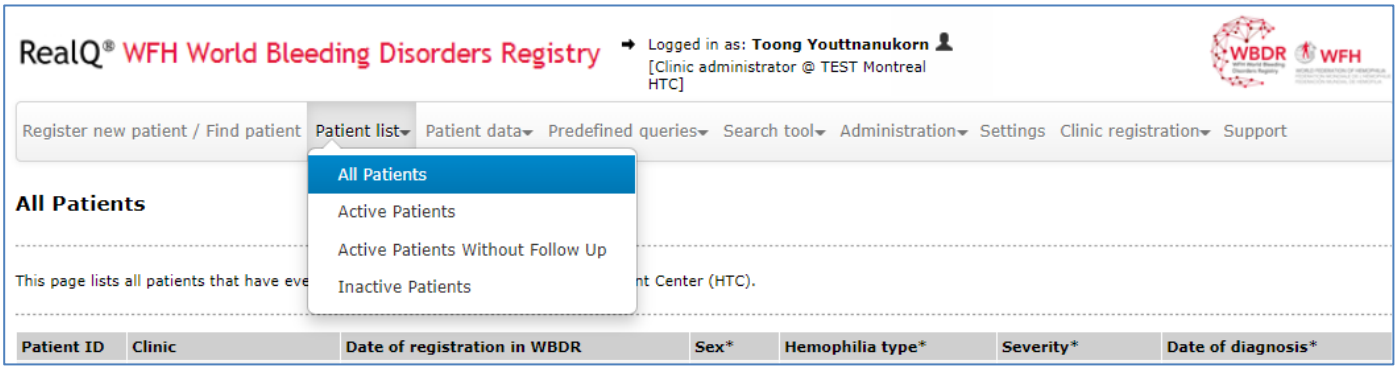
The Baseline Data page is not visible on this page. This data can be viewed by clicking on Baseline Data, under the Patient data tab.



Patient Lists

To view various lists of patients enrolled in the WBDR from your HTC, click on the Patient list tab in the top menu.

- All Patients: list of all patients ever enrolled at your HTC.
- Active Patients: a list of all patients enrolled at your HTC, have not been withdrawn for any reason, and have had at least one follow up visit in the past 36 months.
- Active Patients Without Follow Up: a list of patients enrolled at your HTC, who have not been withdrawn for any reason, but have not had at least one follow up visit in the past 36 months.
- Inactive Patients: a list of patients who have been enrolled at your HTC, but who have been withdrawn or transferred.



Setting up WBDR Clinic Administrators and Users

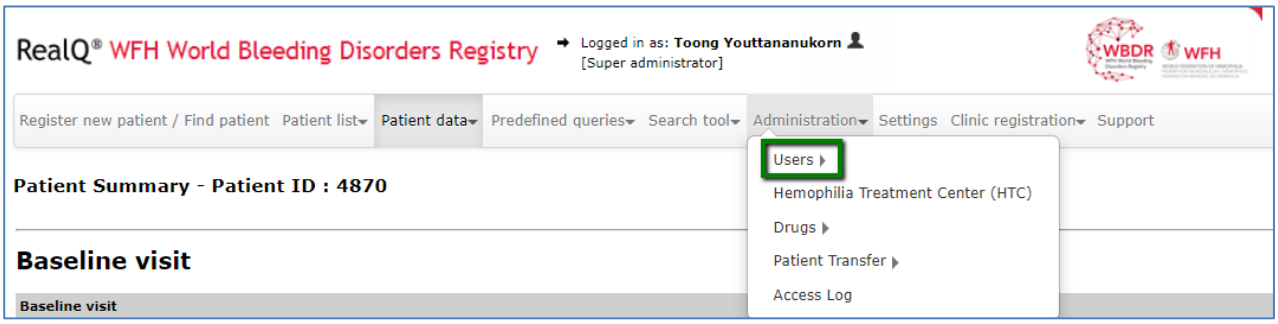
There are two types of users of the WBDR:

1. **Clinic Administrators**
2. **Clinic Users**

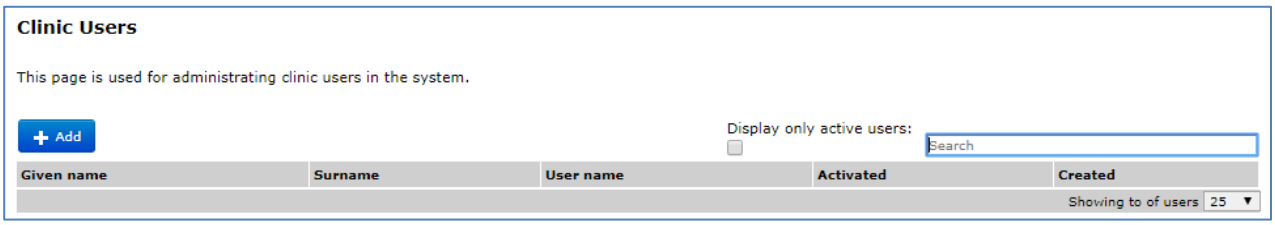
When the WFH sends login details to your HTC, the person's name that was provided to the WFH will be set up as the Clinic Administrator. Clinic Administrators have full access to the HTC's data, they can enter and view all patient data at the HTC. They can also complete the HTC Registration page. Clinic Administrators are the only ones who can create user accounts for team members who will be doing data entry. Remember to never disclose your username and password to anyone. The data in the WBDR is private.

Clinic Users have limited access to the HTC data. They can enter and view patient data but cannot view or enter data on the HTC Registration page. Clinic Users are typically reserved for individuals who will be doing the data entry.

To create accounts for the Clinic Users, the Clinical Administrators can click on the Administration tab in the Menu Bar and then click on the Users sub-tab:



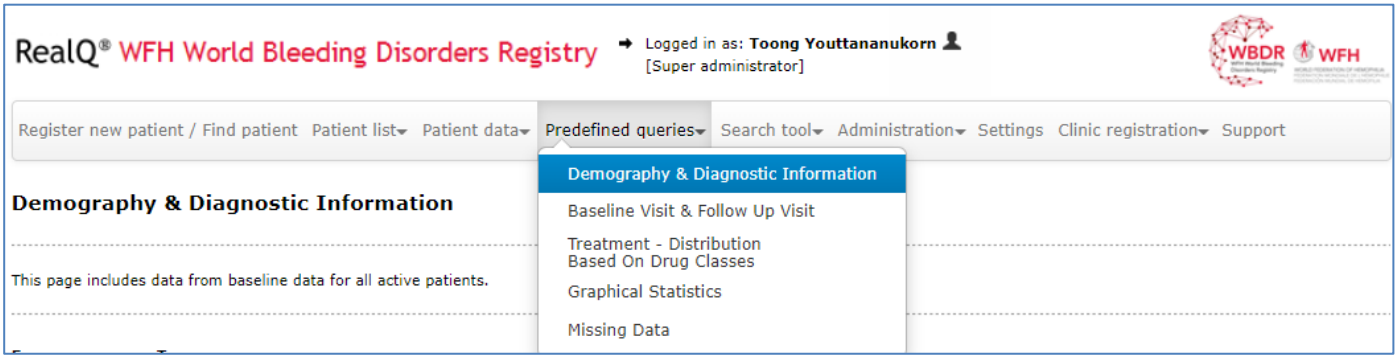
Clinic Users can be added by clicking on Add and entering the user name details.



Predefined Queries

Click on **Predefined queries** tab in the top menu to view the following data: Demography & Diagnostic information, Baseline Visit & Follow up Visit, Treatment – Distribution Based on Drug Classes, Graphical Statistics and Missing Data.

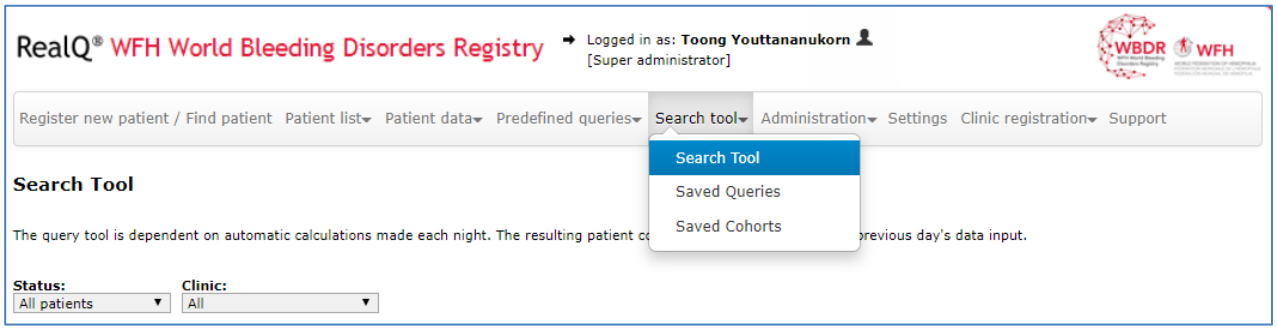
- **Demography & Diagnostic Information**: this page includes data from Baseline Data for all active patients.
- **Baseline Visit & Follow up Visit**: this page includes data from the 'Baseline Visit' and the 'Follow up Visit' pages for all active patients.
- **Treatment - Distribution Based on Drug Classes**: this page includes data that is registered in the treatment module for all active patients. This is one measurement for each part that shows number of patients with the treatment as on going and number of patients that has ever had the treatment registered.
- **Graphical Statistics**: this page presents graphical statistics of all patients or active patients. The use can choose to look at specific parameters, time periods and three different type of graphs (bar, pie, spline).
- **Missing Data**: this page represents aggregated data for fields where data is missing in Baseline Data, Baseline visit, and Follow Up Visit page for all active patients.



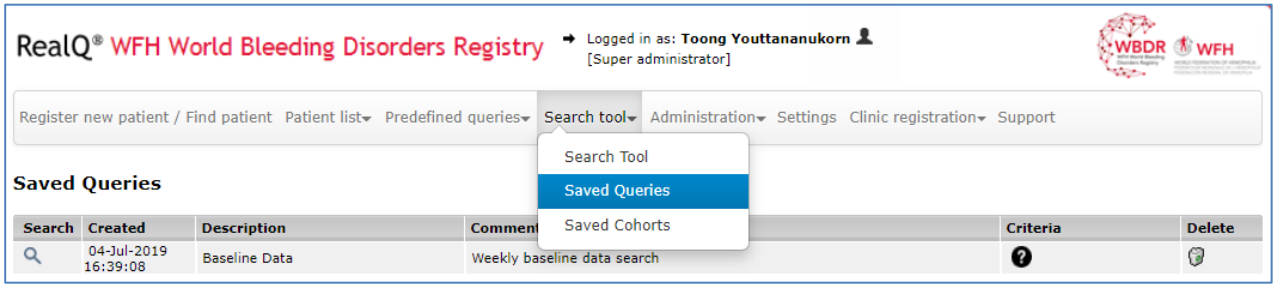
Search Tool

Click on **Search Tool** tab in the top menu to access the followings: Search Tool, Saved Queries and Saved Cohorts.

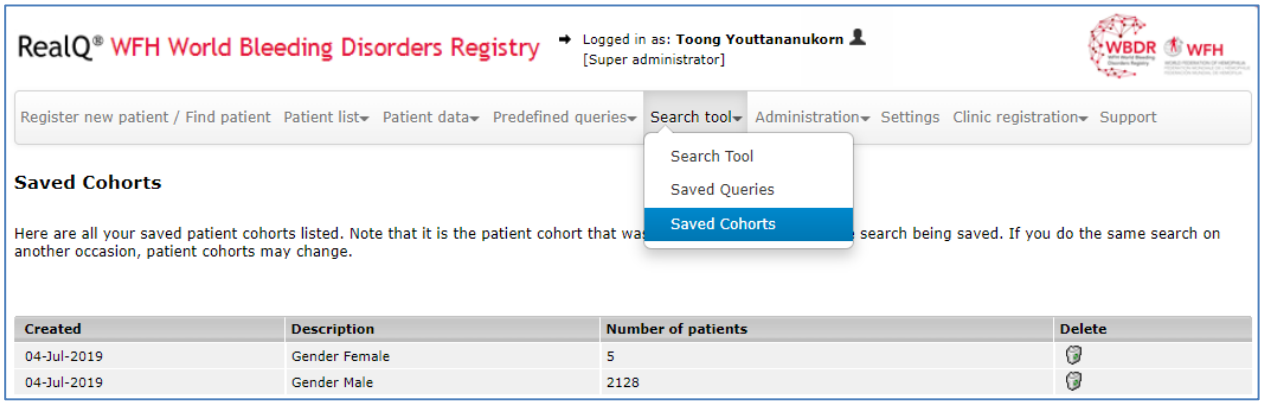
- **Search Tool**: The query tool is dependent on automatic calculations made each night. The resulting patient cohort is based on the previous day's data input. The user can also save all queries and all patient cohorts that they often search under this sub-tab.



- **Saved Queries**: All saved queries from 'Search Tool' sub-tab are shown here. The user can click on the saved queries to run search to save time.



- **Saved Cohorts**: All saved patient cohorts are shown here. This is the patient cohort that was the result at the time of the search being saved. Two cohorts can be combined and save as a new result under this sub-tab.



Support

REMINDER:
Please don't hesitate to contact us
wbdr@wfh.org
if you encounter any difficulties.

Thank you for your support and participation in the WBDR!