Registry eForm Data Entry Guidelines

Version 1.0 – 02 Apr 2014

Updated for eForm on 16 June 2016

Part 1

General recommendation for data entry in ProMISe and instructions of completion for the Registration Form and the Med-AB

PASS Protocol DF VOD-2013-03-REG

A multi-centre, multinational, prospective observational registry to collect safety and outcome data in patients diagnosed with severe hepatic VOD following hematopoietic stem cell transplantation (HSCT) and treated with Defitelio® or supportive care (control group)

Guideline for e-form completion of the VOD Registry is divided in 3 parts:

- **Part 1: general recommendation for data entry in ProMISe and instructions of completion for the Registration Form and the Med-AB**
- Part 2: instructions of completion for the Follow-up 100 days Form
- Part 3: instructions of completion for the Follow-up 6 & 12 months Form

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I/ MEANS TO ENTER PATIENTS INTO THE REGISTRY

- **Patients to be included**

1. Any patient in which you have made a diagnosis of severe VOD post-HSCT

    - *Note: It is important that you include also patients not treated with Defitelio® (for example patients in which Defitelio® is not used due to the presence of contraindications or patients considered unsuitable as a result of the special warnings and precautions listed in the Defitelio® SmPC)*
    - *Note: All consecutive and consenting patients with a diagnosis of severe VOD should be entered into the Registry*

2. Any patient receiving treatment with Defitelio® for any other condition

    - *Note: If in your clinical practice you treat conditions other than severe VOD with Defitelio® you should also enter these patients in the Registry (VOD-Project + EBMT Med-AB)*

- **Contacts**

If you have any questions on this Registry, regarding the means to enter patients into it or questions around Defitelio®, please contact:

- INFO ON REGISTRY:

jessica.lemaitre@upmc.fr & emmanuelle.polge@upmc.fr

- INFO ON DEFITELIO®:

medical-enquiries@gentium.it

- **Forms to be reported**

The registration form to enter patients into the Registry can be accessed via the EBMT website at: http://www.ebmt.org/Contents/Research/EBMTStudies/CurrentResearch/Pages/Study%20Pages/VOD-Project.aspx

EBMT CICs will be asked to report information for patients included in the VOD project via Internet and e-forms, at Registration, Day 100, 6 and 12 months after transplant as described below:

Once patient has given his/her consent,

- At sVOD diagnosis or start of Defitelio® (if Defitelio® is administered for other reason than treatment of the sVOD)
    - Fill in VOD-Project Registration Form :
- At 100 days post HSCT
    - Fill in Med-B and comorbidities Form (Med-AB project specific link)
    - Fill in VOD-Project 100 days Follow-up Form

- At 6 months post HSCT
  - Fill in VOD-Project 6 months Follow-up Form
- At 12months post HSCT
  - Fill in VOD-Project 12 months Follow-up Form

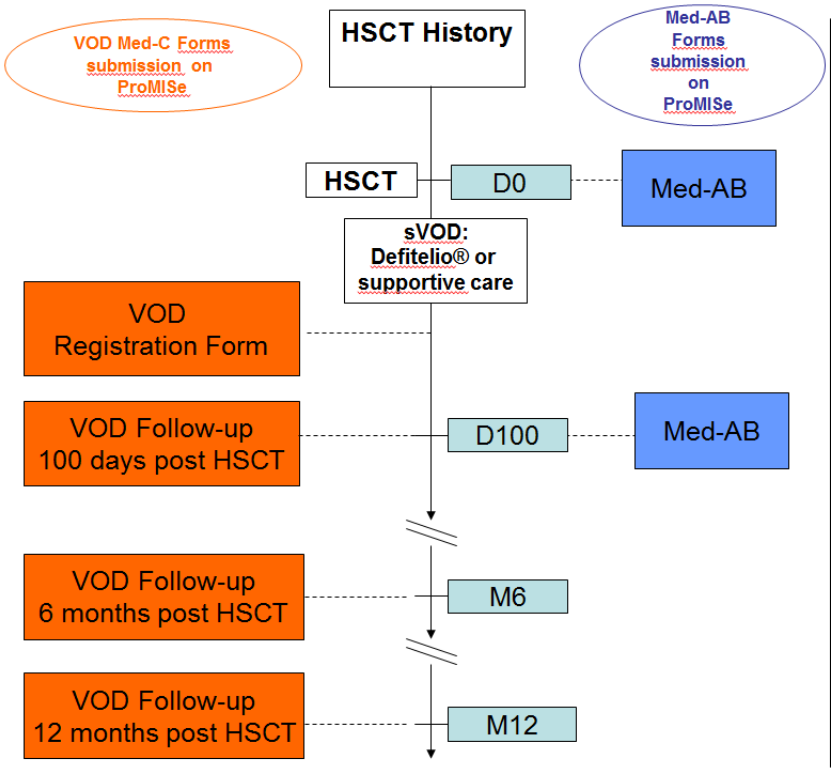


Figure 1 - Data Flow Chart

II/ Browser parameters verifications (at first use only)

Please find below a selection of points treated by the "ProMISe Manuel Data-Entry" that is not VOD-project specific.

Use of INTERNET EXPLORER is requested for data entry under ProMISe.

Start the application

ProMISe is an Internet Explorer-based application. It cannot be loaded in other browsers. You can access a ProMISe project via the project specific login page. You will usually receive the link to the login page with your account. It is often useful to store the login page in your Favorites. The login page location is not indexed, meaning that it cannot be found using Google (or a different search engine). For convenience, a link to the login page can be found on the EBMT Home page http://www.ebmt.org/

Configuration test

Proper functioning of the ProMISe application is dependent on several Internet Explorer settings. Therefore, if you are working with ProMISe for the first time, it is recommended to test (and adjust) the settings of your PC. To do this, click *on [How to make your PC ProMISe compatible and other important Tips and Tricks]* on the centre of the login page. In the expanded menu, click on *[Interactive browser configuration checker]*. The following page will appear:

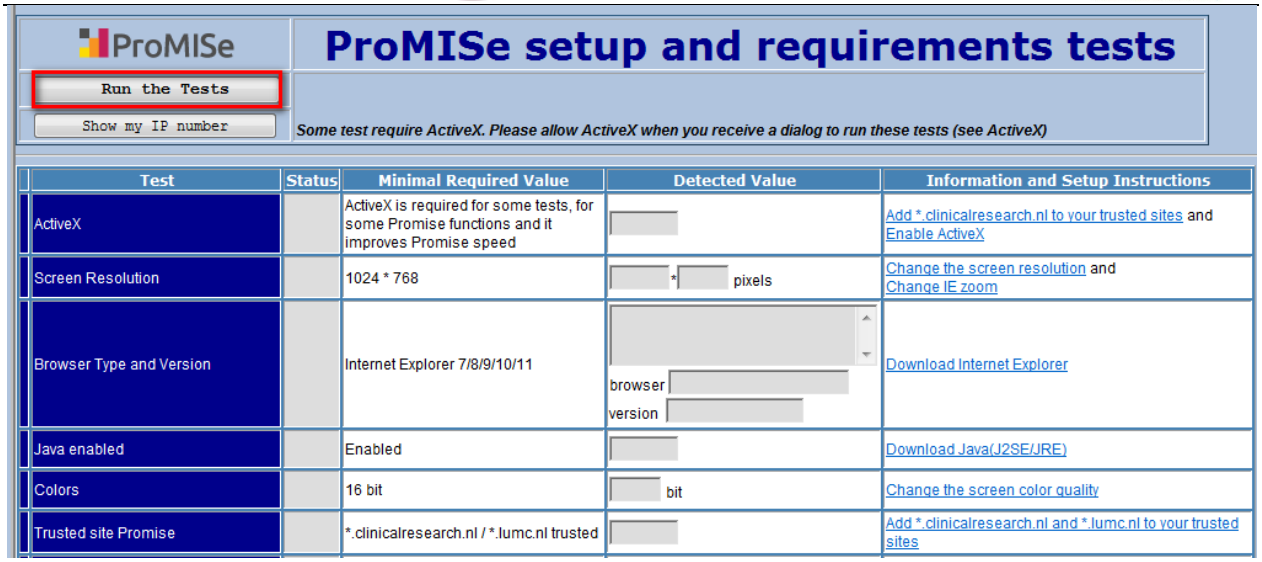


Figure 1 - The configuration test. Before you start with ProMISe, it is recommended to check the settings of your PC in the Interactive browser configuration checker.

Click on *[Run the Tests]*. You will get an overview of the settings of your browser, indicating possible problems and solutions (**Fig.2)**

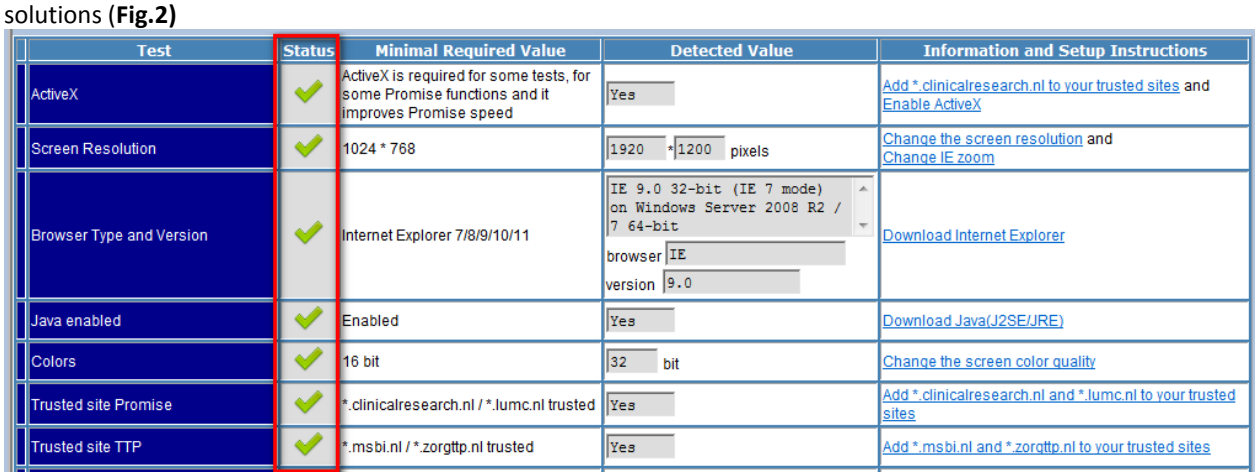


Figure 2 - Result of the configuration test. The column 'status' shows whether your computer settings are compatible with ProMISe or not.

The column 'Status' shows the status of that setting on your computer. The different figures and colors indicate whether the setting is properly configured (**Fig.3**).

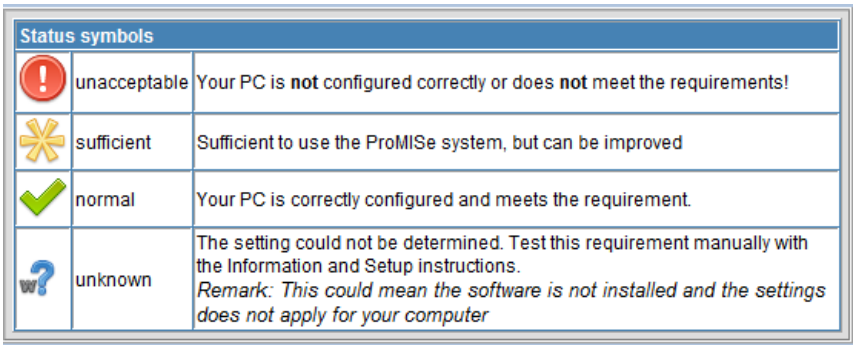


Figure 3 - Explanation status symbols.

What to do if ProMISe does not work:

If ProMISe does not start properly there are several things you can try to fix it:

- Use an up-to-date version of Internet Explorer.
- Add https://www.clinicalresearch.nl to the list of trusted websites.
- Allow pop-ups of www.clinicalresearch.nl.
- Allow use of ActiveX.
- Start ProMISe in XP/IE8 compatibility mode

In the column '*Information and Setup Instructions*' of the configuration checker, right side) links are provided to instructions on how to configure these options in Internet Explorer.

III/ e-Form Completion Instructions in ProMISe

III-1/ Connection to VOD Project (Med C)

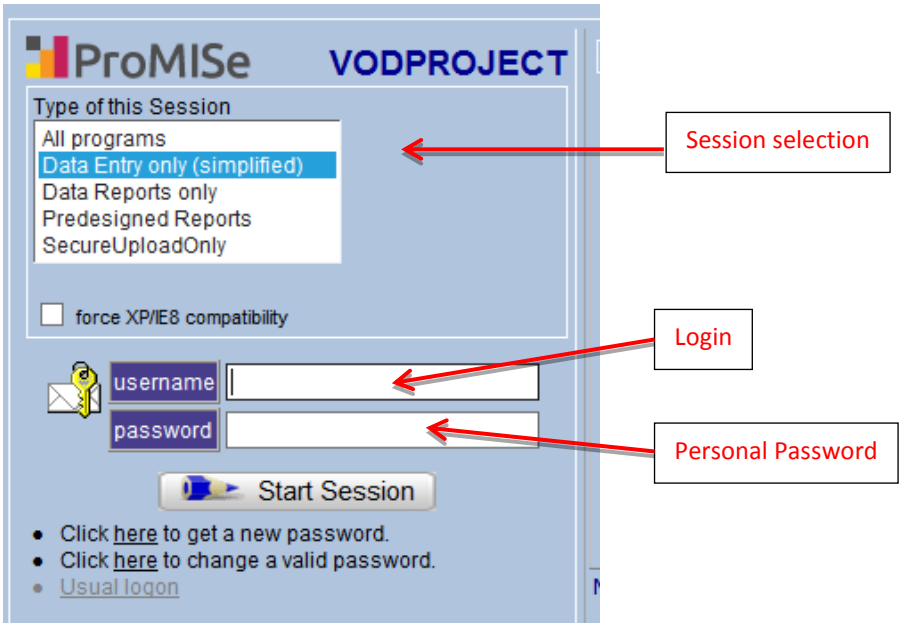
VOD-Project e-forms are available on Internet:

https://www.clinicalresearch.nl/PROMISE/S/HEIT/S_O_EBMT_C_NIS_VODPROJECT_/LOGON/INDEX.HEI

Before 1st use, please check the browser parameters (refer to chapter II page 4).

To connect for data entry:

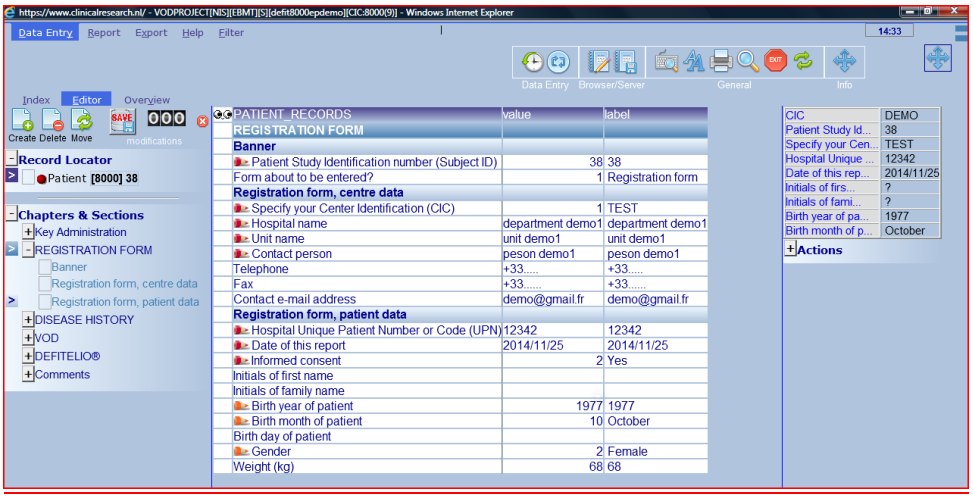
- 1st select either session "All programs" or session "Data entry only (simplified)"



- Then fill in the **username** and **password** fields then click on the "Start Session" button to enter the VOD Project.

Your password is personal. Please, keep it confidential. This personal password will be attributed and sent by email to the people in charge of the data entry after the training session. In case of lost or expiration or blocked account, please contact jessica.lemaitre@umpc.fr or emmanuelle.polge@upmc.fr

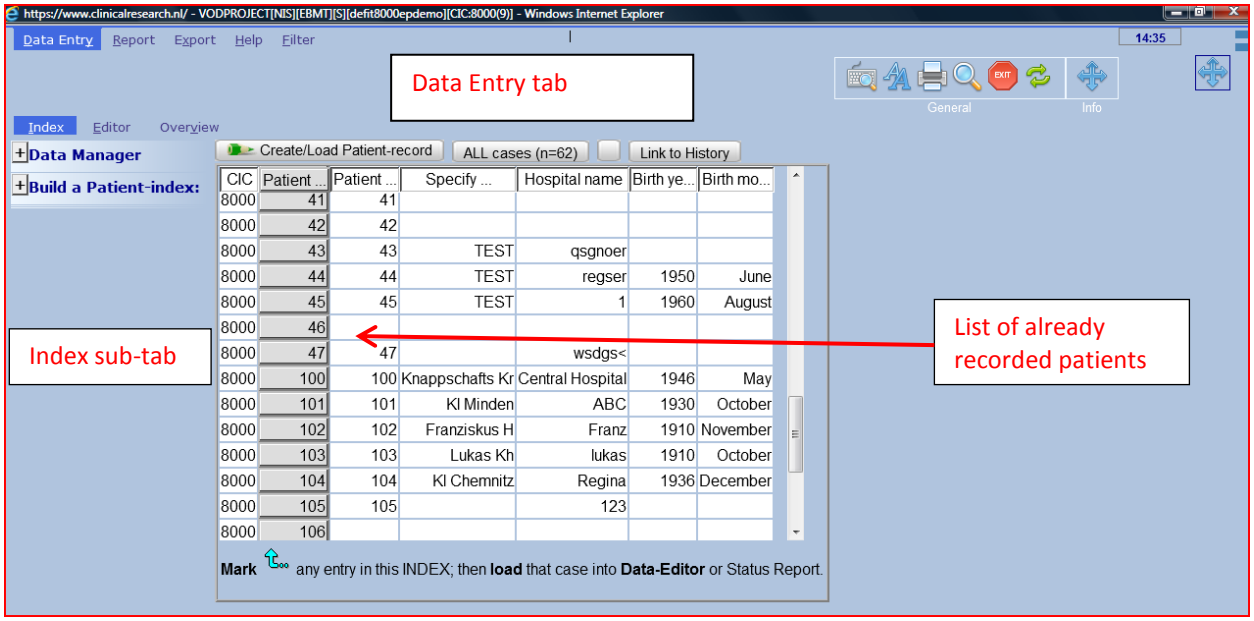
VOD Project opens on the Data Entry tab, and Editor sub-tab (screen copy below).



III-2/ List of patients already reported

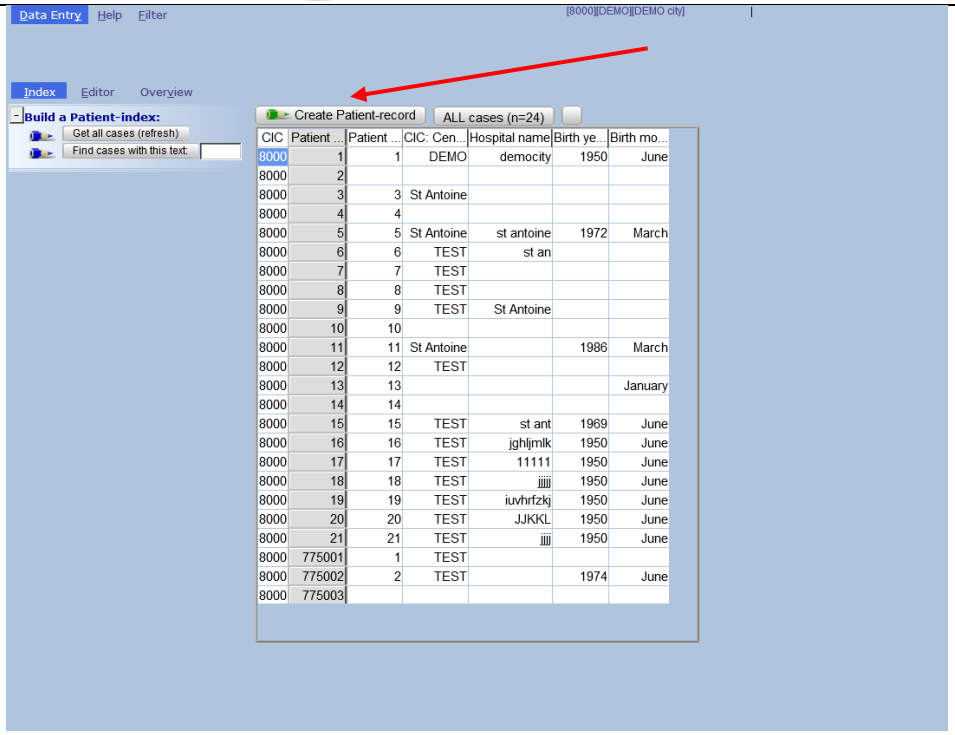
The list of patients already reported in the VOD project is available on:

Tab: **Data Entry**
Sub-tab: **Index**



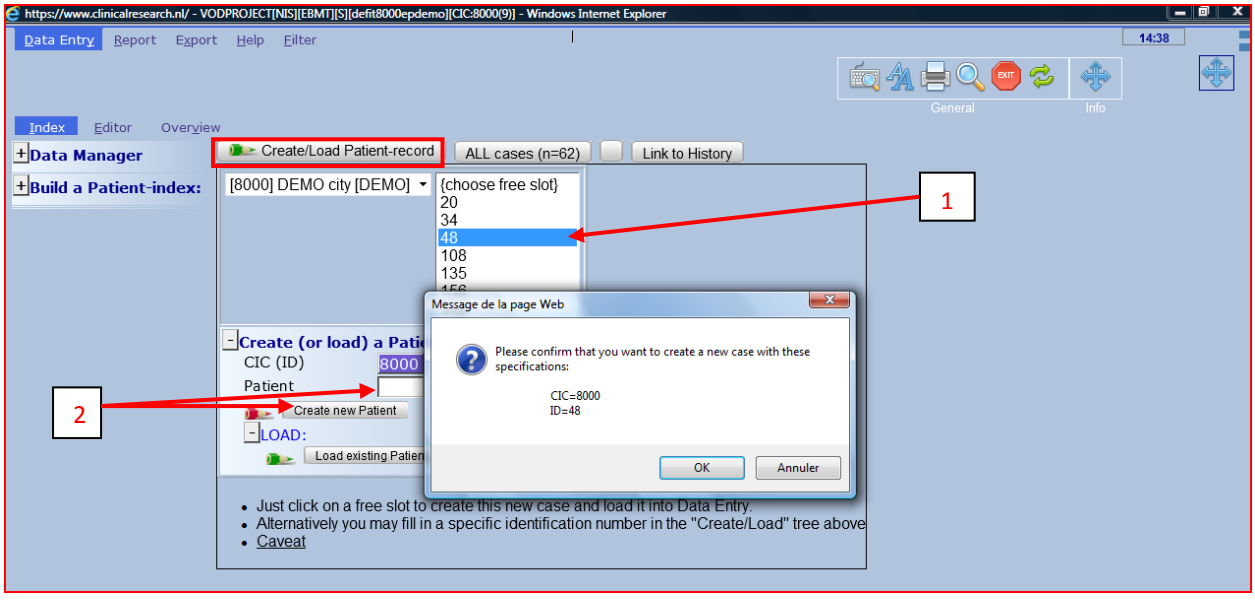
III-3/ Patient Record Creation & Selection of the Form to be entered

To record a new patient, please check that you are on the Tab Data Entry and the sub-tab Index.
Click on the button Create patient-Record.



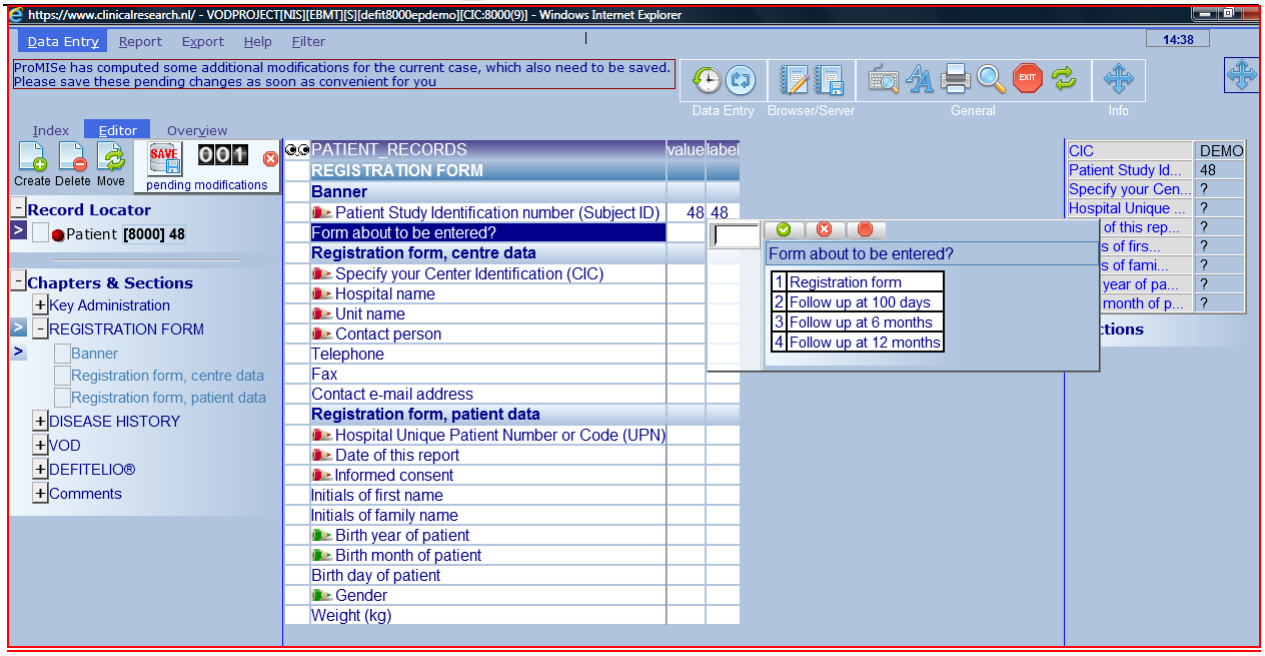
In the "create new case" menu, there are two options for creating a new case:

- 1/ select one of the free slot number,
- 2/ or enter a number you choose in the field Patient and click on **Create new Patient** button



Then, confirm by clicking on OK to generate the creation of the record for a new patient.
ProMISe will then check whether a case with the same value exists in the project. If so, the case creation is aborted, if not, the case is created. This option prevents duplicate cases to be (unknowingly) entered in the database.

After a patient has been created, ProMISe will open the Data Editor, you will obtain the following entry form:



III-4/ Data entry navigation

Data entry in ProMISe is interactive: it means that the programmed navigation will follow your form order, while skipping any irrelevant questions for that particular patient according to data already reported.

To allow a good navigation it is essential to complete the first variable: "**Form about to be entered**?"
and specify which form you are going to enter:

-the registration form
-the 100 days Follow-up form
-the 6 months Follow-up form
-the 12 months Follow-up form

IMPORTANT: To navigate within the eform from one item to the other, please use the Tabulation key.
Avoid using the mouse to go form one section to another, follow the cursor jump navigation.

III-5/ How to save or remove pending modifications

It is very important to note that the data entered in the browser are not automatically stored in the database on the server. In order to save the data on the server, you have to explicitly give the command to save the data, which is done by clicking the Save button above the record locator (**Erreur ! Source du renvoi introuvable.**) or by using the shortcut ctrl + s. If you wish to cancel all pending modifications, you can click on the cross button in the save dialog.
The save dialog also shows a counter with the number of pending modifications. The pending modifications count the number of items that have been modified, filled or erased since the last save. You can review the pending

modifications by using the function buttons shown in **Fig. 1**. These allow you to either view the pending modifications or view the original, unmodified data of the current case as stored on the server. The current case as on the server can also be viewed by selecting the Overview sub tab in Data Entry main tab and clicking Horizontal or Vertical.

Figure 1: Clicking the save button will save all pending modifications to the server. To cancel pending modifications, click the cross button on the right of the dialog.

Figure 2: Buttons for browser to server comparison. Clicking (1) will show a list of all pending (unsaved) modifications. Clicking (2) will show an overview of the current, unmodified data of the current case as on the server (without pending modifications).

III-6/ How to close ProMISe session

Finally, after a data entry session, you may wish to close the ProMISe application. To close the session, click the exit button in the upper right bar of the screen (**Erreur ! Source du renvoi introuvable.**1). ProMISe will warn you if there are unsaved changes and give an option to save these changes before closing. You can also use the "x"-button on the browser window to close ProMISe, but then ProMISe will not be able to give warning messages with regard to unsaved data.
There may arise situations in which you wish to restart the session. To restart the session, click the refresh session button next to the exit button (Fig**Erreur ! Source du renvoi introuvable.**1). This will close the current session and build a new session. This option is not available if there are unsaved changes; you must first save or discard all pending modifications.

Figure 1: The Exit and Refresh session buttons

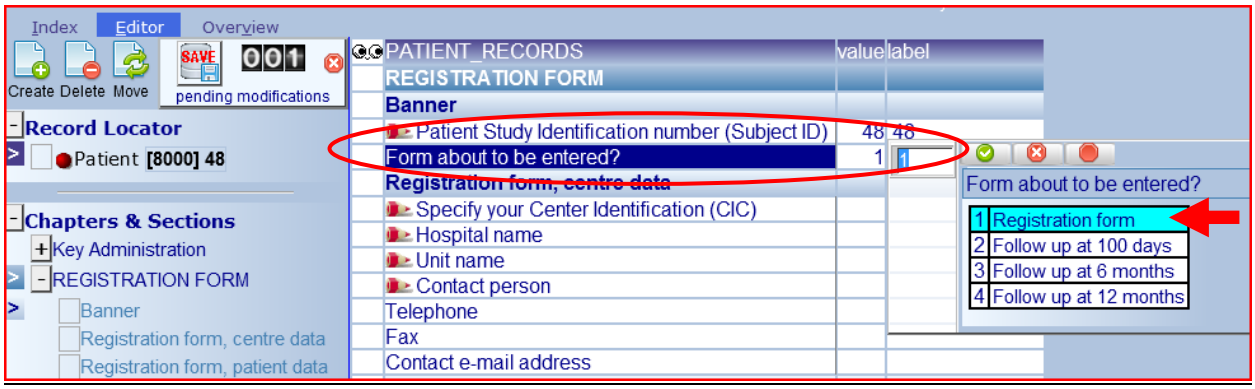
III-7/ READ ONLY status

In some rare case, you can see READ ONLY in watermark. This means that 2 persons are connected at the same time on the patient record. It can be 2 persons form the center if several persons have access (have personal password) to the VOD project data-base in you center, or it can be the data manager in charge of VOD Project at the EBMT Data Office in Paris.
In such cases, try to load the patient later or contact your colleague or the EBMT Data Office in Paris to disconnect the patient.

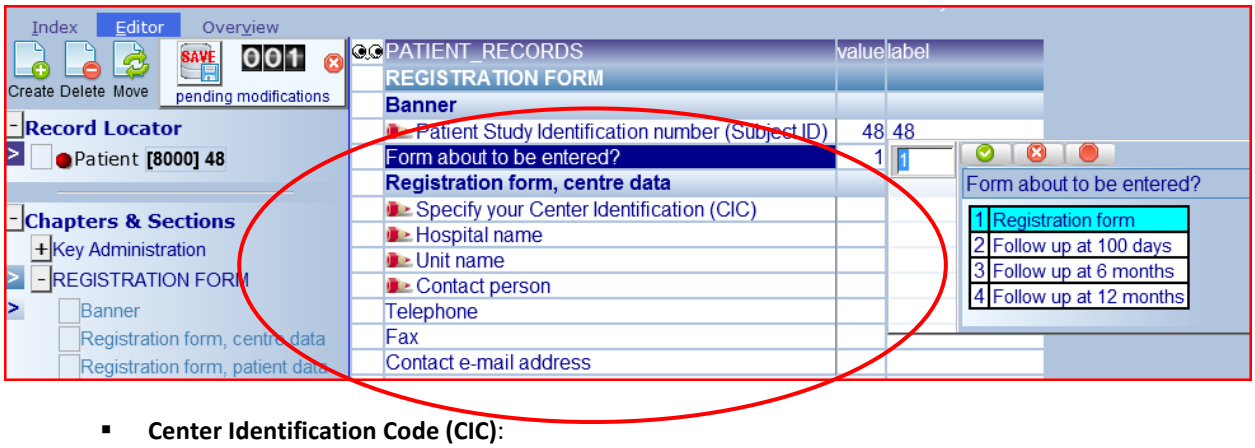
IV/ REGISTRATION FORM

Please complete the section REGISTRATION FORM, Subsection“ Banner”

To enter the 1st eform, please select the **Registration Form**.



Please complete the section REGISTRATION FORM, Subsection “Registration Form-Centre data”



- **Center Identification Code (CIC)**:
  Please record the EBMT assigned code (CIC) for your centre. If you don’t know your CIC, please look it up in the correspondence you have received from the EBMT Secretary or the Registry Office.
  If you still cannot find it, you can search for your centre in the EBMT website at:
  http://www.ebmt.org/Contents/Members-ponsors/Members/MembershipList/Pages/Membership-List.aspx
  If you still are not able to find your CIC, please contact the EBMT Barcelona Office at:
  membership@ebmt.org

- **Hospital name**: Please record the name in full of your hospital, by including also the city and country. Ensure that you always use the same name in the future.

- **Unit name**: Please record the name of your Unit (i.e. Paediatric Haematology, Haematology, Oncology, BMT Unit, etc.). Entering this information is particularly important if your centre has more than one unit reporting independently to the EBMT. Ensure that you always use the same name in the future.

- **Contact Person**: Please record first name and last name of the person who will be responsible for updating or correcting the data and who can be reached by the Clinical Research Associate, if any discrepancies need to be clarified.

- **Telephone**: Please record the international dialing code followed by the phone number at which the contact person (defined above) is most readily available.

- **Fax:** Please record the international dialing code followed by the fax number at which the contact person (defined above) is most readily available.

- **Contact e-mail:** Please record the e-mail address of the contact person (defined above).

Paper CRF screen shot template is reported below **for your reference only**:

CENTRE IDENTIFICATION

Med-AB code _____ _____
Centre Patient Number

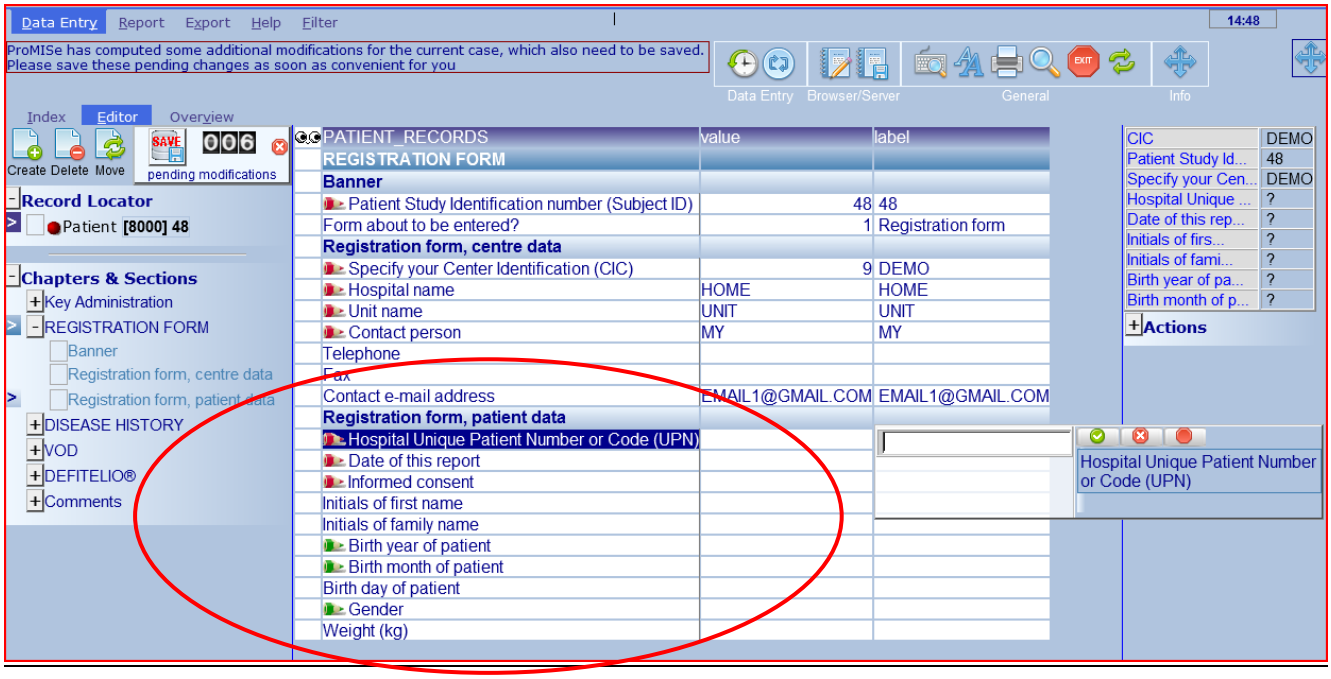
Hospital:.....Unit:.....

Contact person:..... .....

Phone:..... Fax:.....

e-mail:.....

Please complete the section REGISTRATION FORM, Subsection "Registration Form-Patient Data"



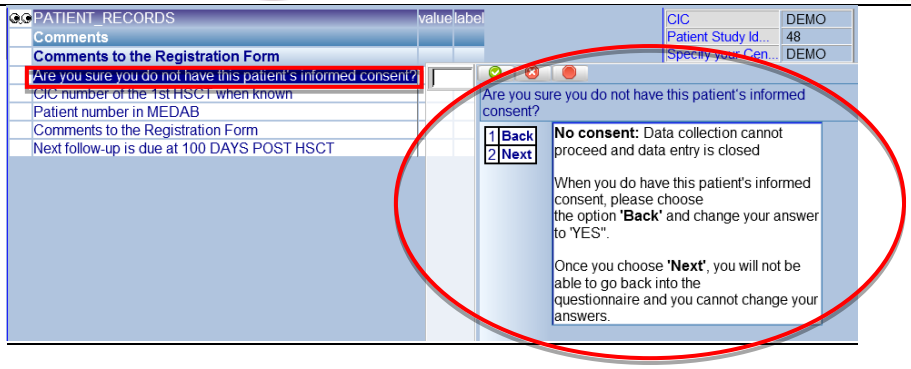
- **Hospital Unique Patient Number or Code:** Here, the system is not asking the registry patient code (EBMT site + enrollment sequential number), instead, please record here the number/code used by your transplant centre to uniquely identify this patient. This can be the UPN (unique patient number) used by the hospital, or a code given by the transplant unit. This item is compulsory. It must be unique, by itself should suffice to identify the patient and should not be liable to change. If a patient receives a second transplant, do not assign a new number: use the same unique number for this patient when registering subsequent transplants.
  Please note that when data will be exported for analysis the patient's initials will not be transferred.

- **Date of this report:** This is the date when you started recording the data of a single patient in the Registration form for the first time. The format for the date is YYYY/MM/DD (ei: 2014/03/05 for March 5th 2014)

- **Informed Consent: (Obtained at latest at the moment of registration**) Please record if the patient signed the informed consent form before his/her data were recorded in this e-form, by checking only one of the appropriate "Yes" or "No". Please be aware that if the patient didn't sign the informed consent form, his/her personal data cannot be collected in the e-Form.

  If "No" is selected, the cursor jumps to the end of the section Comments.
  You are asked to confirm by selecting "Back" or "Next"

  - **"Back" allows you to correct if "No" for consent was wrongly selected**
  - **"Next" allows you to confirm that patient didn't give consent and in this case the data entry cannot proceed. Cursor will jump to the beginning of the form for the registration of a new patient. Please save (see page 27).**



Please note that this is a prospective and not a retrospective study. This means that the Investigator should ask the patient to give his/her consent as soon as the Investigator identified him/her as a potential subject to be enrolled in the Registry. Please don't ask a patient to sign the consent when his/her course of treatment is already completed and he/she's going to be discharged: otherwise you will enter retrospectively data in the system, and this is not in the scope of this protocol.

Please note: For patients who signed the consent, and later decided to stop the study before completion, please record this information in comments at the end of registration form.

For patient who gave consent:

- **Initials of the first name and family name:** Please note that some countries or ethic committees don't allow the initials collection, for patient's privacy. If at your site/country your local laws or regulations don't allow to report this information, please leave this field blank. Please note that when data will be exported for analysis the patient's initials will not be transferred.

- **Date of Birth**: For all patients, please record:
  - Birth year of the patient
  - Birth month of the patient

  According to certain national laws, full birthdates cannot be recorded (ex: France)
  - Birth day of the patient may or may not be recorded according to the national law

- **Gender**: Please indicate the gender of the patient, by selecting Male or Female.

- **Weight (Kg)**: Please record the patient's body weight in Kg, defined as weight collected on the date of admission to the HSCT unit.

Paper CRF screen shot template is reported below **for your reference only**:

PATIENT DATA

Date of this report: _____/___/___

Informed consent obtained
☐ YES ☐ NO →If no, Data collection cannot proceed

Hospital Unique Patient Number or Code:_____

Patient study identification number: __ __ __ __ __ __

Initials*: ____//____(first name(s)//family name(s))

Date of birth**: _____/___/___

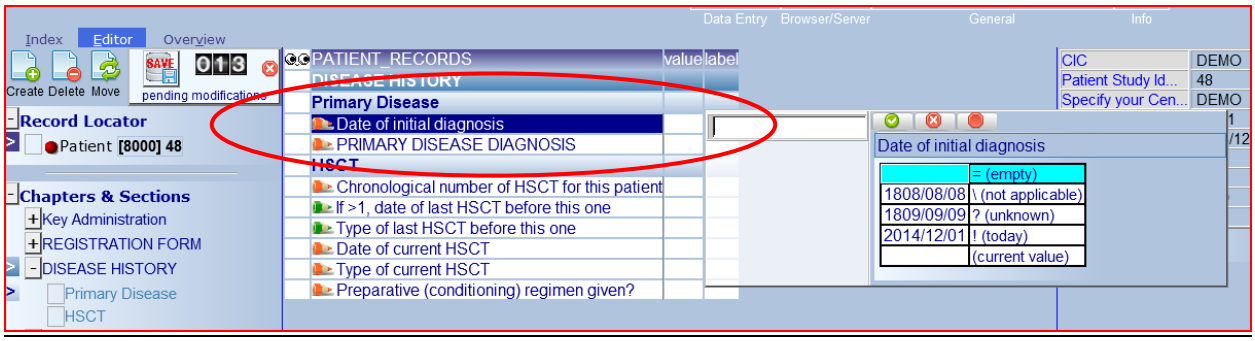
Gender: ☐ Male ☐ Female

Weight (kg): _____

*To be completed only if the local regulations allow to collect the patient's initials

**At least year and month; according to local regulation,, full birthdates cannot be recorded in some countries

Please complete the section DISEASE HISTORY, Subsection "Primary Disease"

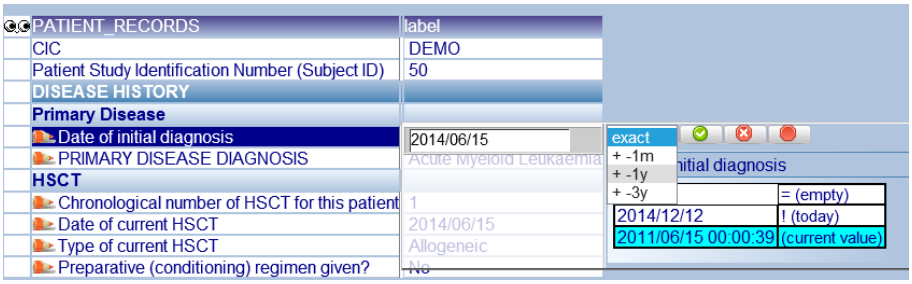


- **Date of initial diagnosis:** Please record the date of diagnosis of the disease for which the patient is being transplanted. If the disease is of secondary origin, write the date of diagnosis of the disease of secondary origin, not the date of diagnosis of the original disease.

  If the initial disease was diagnosed a long time ago and you don't have the exact date, please:
  -enter an approximate date, please enter 15 for the day if you don't know the exact day (ei 2014/03/15 for 2014/03/XX) and 06/15 for the month and the day if you know only the year (ei 2014/06/15 for 2014/XX/XX)

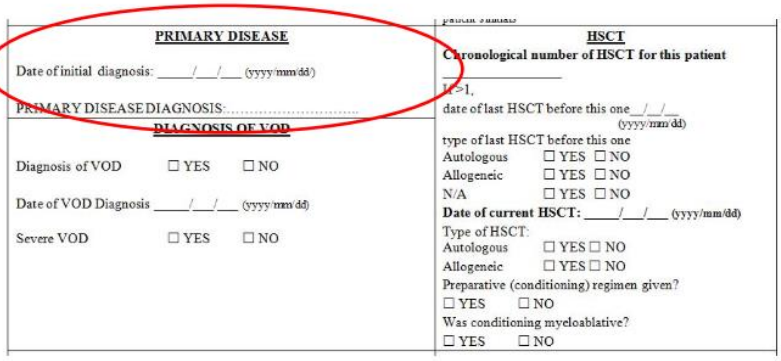
  -if you entered an approximate date, please try to record how much you think the approximation is close to the real date, by selecting one of the following on the scroll down menu:

  "+/-1m": more or less 1 month
  "+/-1y": more or less 1 year
  "+/-3y": more or less 3 years

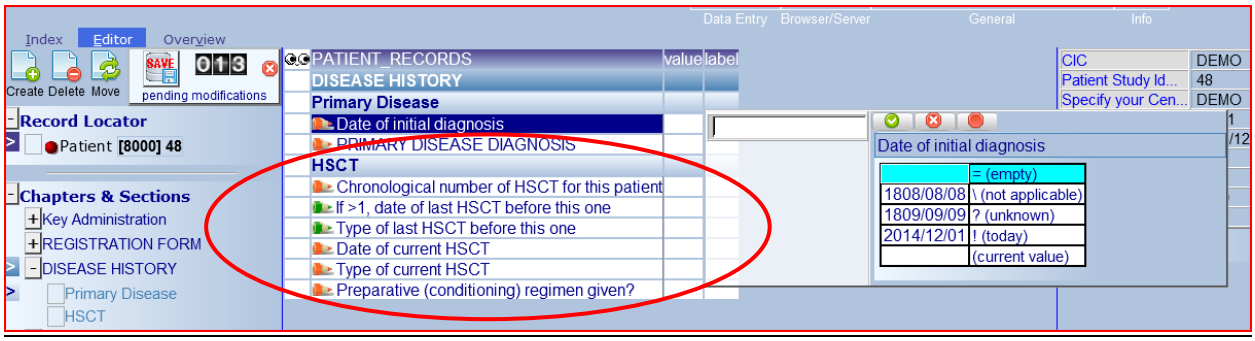


- **Primary Disease Diagnosis:** Please indicate the diagnosis of the disease for which the patient is being transplanted.

  Paper CRF screen shot template is reported below **for your reference only**:



Please complete the section DISEASE HISTORY, Subsection "HSCT"



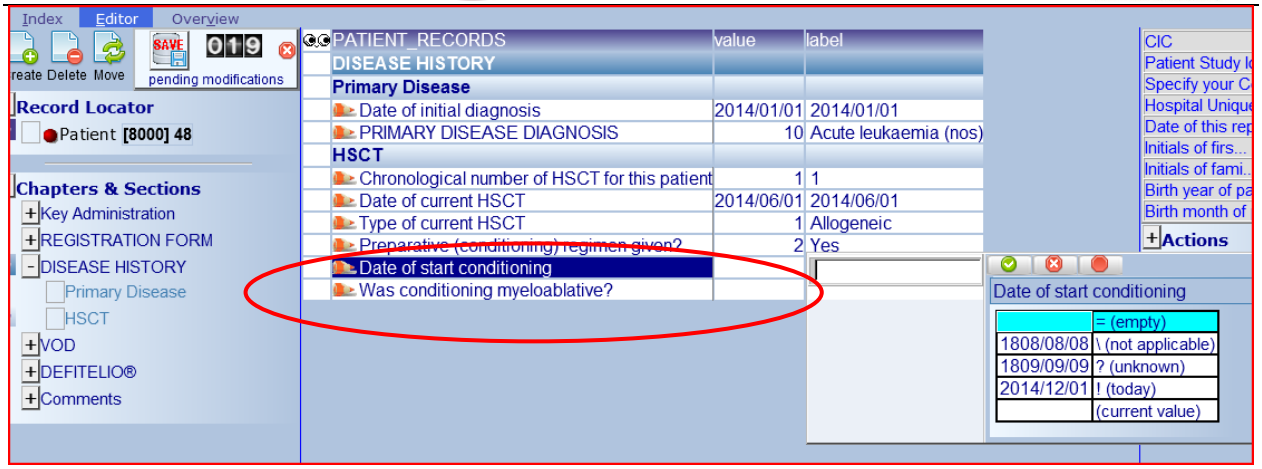
- **Chronological number of HSCT for this patient:** Please record the number of transplants that the patient had, including the current one. If the patient didn't undergo to any previous transplant, and this is the first one, please record "1".

    - **If > 1, date of last HSCT before this one:** If the above field "Chronological number of HSCT for this patient" is > 1, please record the date when the stem cell infusion for the previous most recent transplant occurred.

    - **Type of last HSCT before this one:** Please check the type of transplant performed and select the corresponding one. If the patient had more than one previous transplant, please refer to the previous most recent one.
      -Autologous: if the patient received his/her own stem cells back.
      -Allogeneic: if the patient received stem cells from a different donor.
      If the graft information is not available, please select Unknown

- **Date of current HSCT**: Please record the date when the stem cell infusion occurred for the current HSCT. If the patient died between conditioning start and HSCT infusion, and if she/he received Defitelio for another reason than treatment of sVOD, the date of transplant must be filed with the date of death. The follow-up at 100 days is due and will provide data on cause of death and on Defitelio administration status.

    - **Type of HSCT:** Check the type of transplant performed for the current HSCT that caused the VOD select.
      Autologous: if the patient received his/her own stem cells back.
      Allogeneic: if the patient received stem cells from a different donor.
    - **Preparative (conditioning) regimen given?** Please check Yes or No. Yes (most cases) usually chemotherapy with or without Total Body Irradiation. No, for instance for some inborn errors. This question is referring to the current HSCT.



- **Date of start conditioning?** Please enter the date when the conditioning started for the current HSCT

- **Was conditioning myeloablative?** Please check Yes or No.
  Please note that the myeloablative regimen is only applicable for the allo-HSCT.
  This question is referring to the current HSCT.

  The conventional HSCT was always myeloablative, understanding by this: ablation of the marrow with pancytopaenia which could last for over a month, required SCT for marrow recovery, and producing complete donor chimerism. If these conditions are met, answer “Yes”. Recently, several groups have tried to reduce the toxicity associated with transplants by reducing the doses of chemotherapy and/or radiotherapy given in the conditioning regimen. There are many different reduced intensity conditioning protocols and the intensity of the chemo-radiotherapy can vary from levels very close to conventional conditioning to regimens based only on immunosuppression. However, not all reduced intensity protocols are non myeloablative. The following guidelines should be followed to determine whether a regimen is truly non myeloablative in which case the answer to this question should be "No":

  1. Any regimen with 50% or less equivalence to a standard conditioning regimen is considered non myeloablative. This includes not only the 50% reduction of the total dose of a given drug (or TBI), but also the use of a single drug in a standard dose but without other drugs (or TBI) usually included in the standard protocol.

  2. The standard conditioning regimens vary according to the disease, so the non myeloablative regimens will also vary. The addition of ATG or any mono or polyclonal anti-lymphocyte antibody or the addition of purine analogues does not change the intensity category.

Paper CRF screen shot template is reported below **for your reference only**:

HSCT

Chronological number of HSCT for this patient

_____

If >1,

date of last HSCT before this one_____/___/___

(

type of last HSCT before this one

☐ Allo ☐ Auto ☐ Unknown

Date of current HSCT: _____/___/___

Type of current HSCT:

☐ Autologous ☐ Allogeneic

Preparative (conditioning) regimen given?

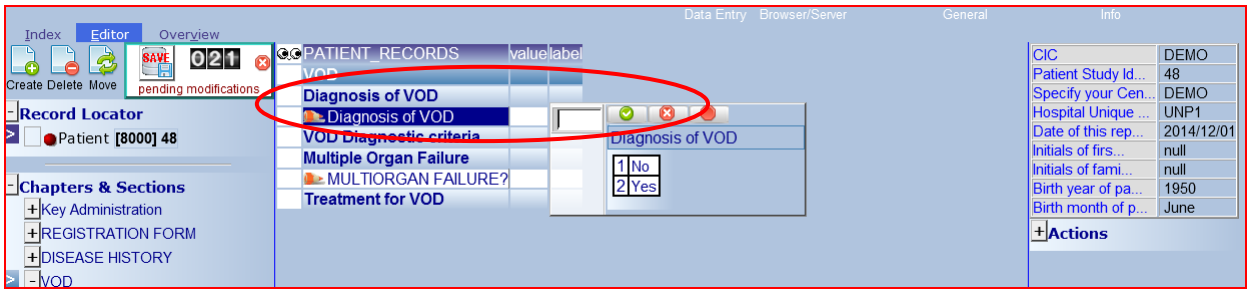
☐ YES ☐ NO

Conditioning start date: _____/___/___

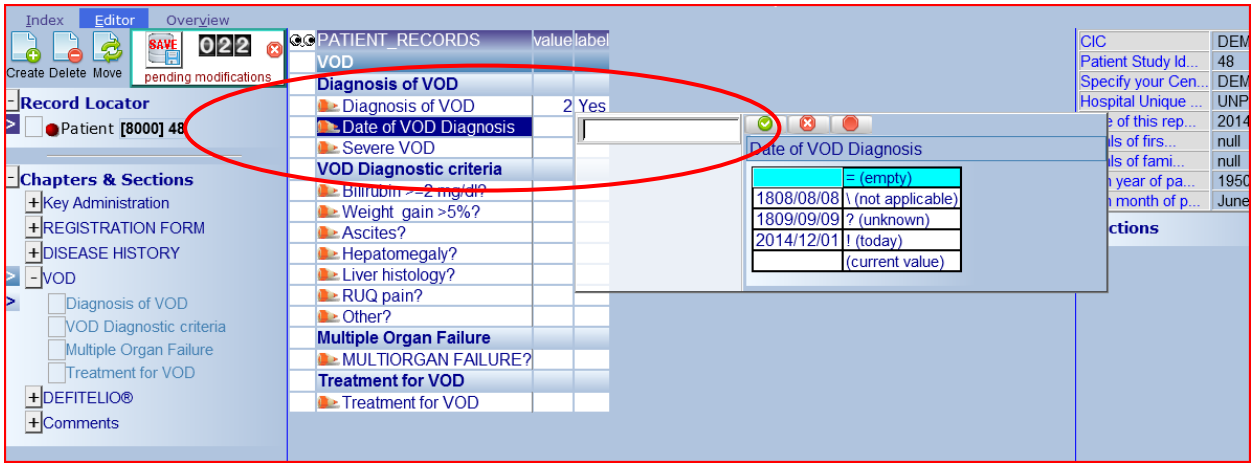
Was conditioning myeloablative?

☐ YES ☐ NO

Please complete the section VOD, Subsection "Diagnosis of VOD"



Please select if the patient suffered from VOD, by checking the appropriate "Yes" or "No".
If "Yes" is selected, please record the VOD diagnosis date.



Please select if the patient suffered from severe VOD (sVOD), by checking the appropriate "Yes" or "No". Please note that the sVOD diagnosis is established based on the physician's judgment and according to current clinical practice.

Paper CRF screen shot template is reported below **for your reference only**:

DIAGNOSIS OF VOD

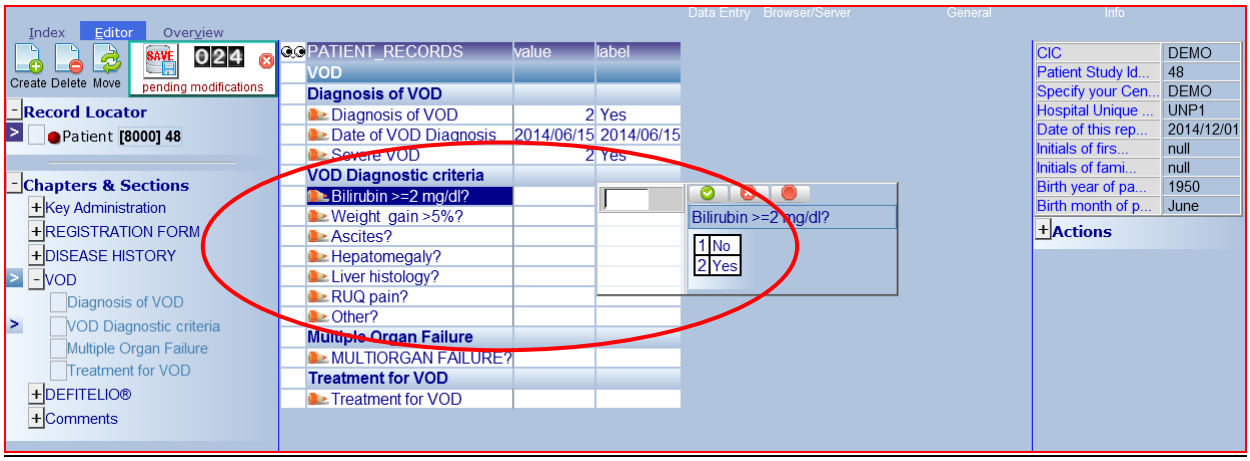
Diagnosis of VOD ☐ YES ☐ NO

Date of the Diagnosis _____/___/___(

Severe VOD ?

☐ YES ☐ NO

Please complete the section VOD, Subsection "VOD diagnostic Criteria"



Please check all the applicable criteria reported in the eForm, by selecting for each criteria "Yes" or "No": (Please note that if VOD = Yes has been selected, at least one of the following criteria should be checked)

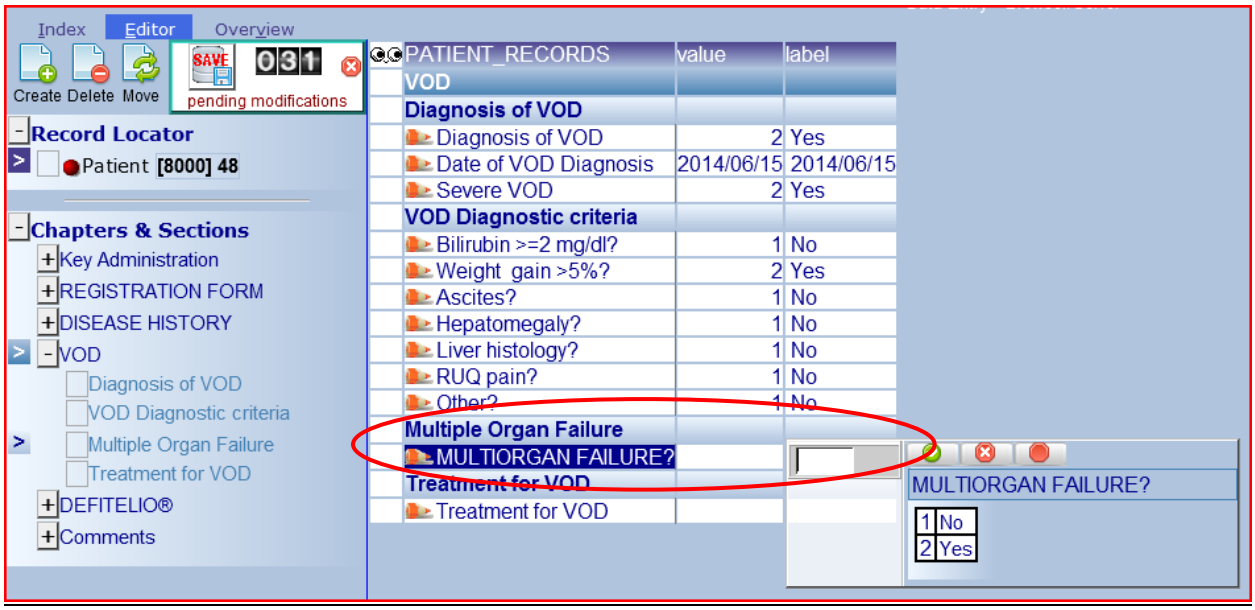
- **Bilirubin ≥ 2 mg/dL**
- **Weight gain > 5%:** Versus the weight collected on the date of admission to the HSCT unit. (Please see the patient data section).
- **Ascites:** Detected at physical or radiological exam.
- **Hepatomegaly:** Detected at physical or radiological exam.
- **Liver histology:** If liver biopsy has been performed and its histological exam is diagnostic of VOD.
- **RUQ (Right Upper Quadrant) Pain:** Detected during the physical examination.
- **Other:** If "Yes" is selected, please also specify

Paper CRF screen shot template is reported below **for your reference only**:

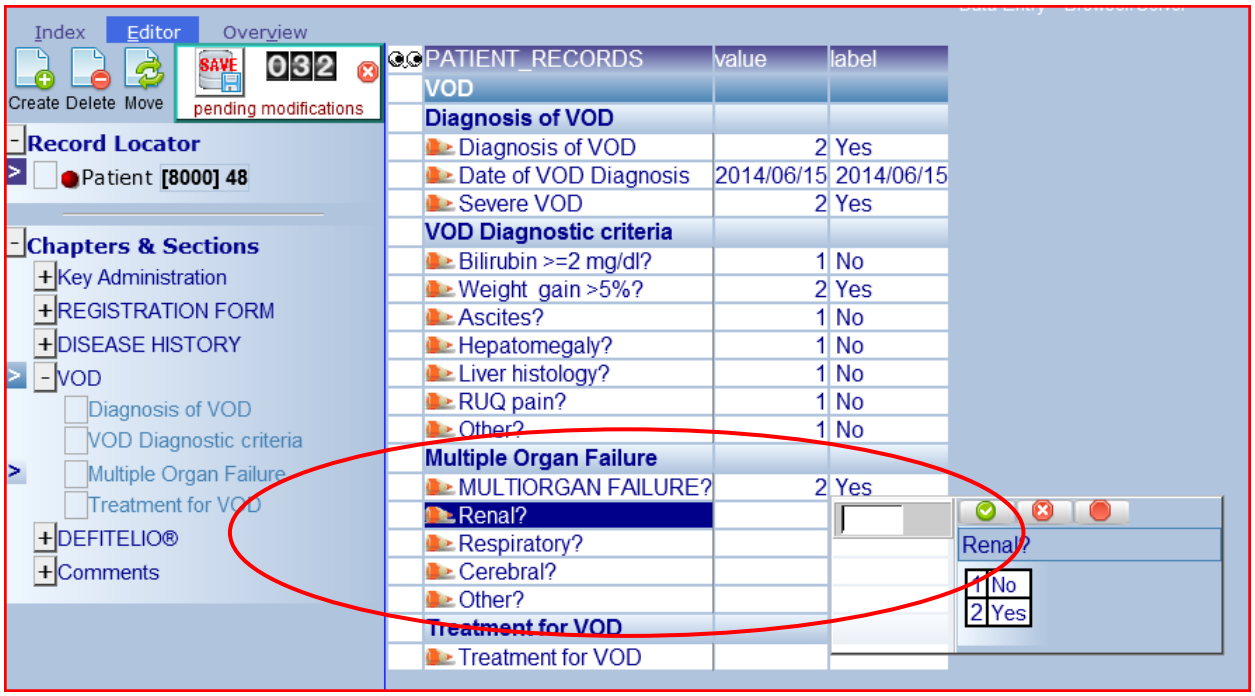
VOD DIAGNOSTIC CRITERIA

Bilirubin >2 mg/dl	☐ YES		☐ NO	
Weight gain >5%	☐ YES		☐ NO	
Ascites	☐ YES		☐ NO	
Hepatomegaly	☐ YES		☐ NO	
Liver histology	☐ YES		☐ NO	
RUQ pain	☐ YES		☐ NO	

Please complete the section VOD, Subsection "Multi-organ Failure"



Please record if the patient was suffering also from MOF (respiratory, renal, cerebral or other), by selecting "Yes" or "No".



If "Yes" is selected, please complete the MOF criteria by checking the appropriate option(s):

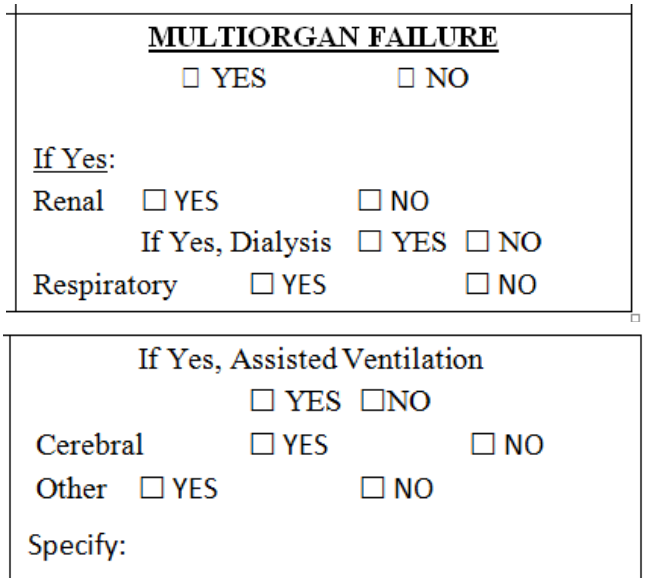
- **Renal:** If "Yes" is checked, please also specify if the patient is dialysis dependent, by selecting the appropriate: Dialysis "Yes" or "No". Please note that the dialysis may be intermittent or continuous (CVVH).

- **Respiratory:** Please check "Yes" only if the respiratory dysfunction is attributable to causes other than infectious. If "Yes" is checked, please also specify if the patient is ventilator dependent, by selecting the appropriate: Assisted Ventilator "Yes" or "No".
  Please note that patients requiring an oxygen supplementation with a nasal cannula, or blow-by mask are not considered on ventilator dependence.

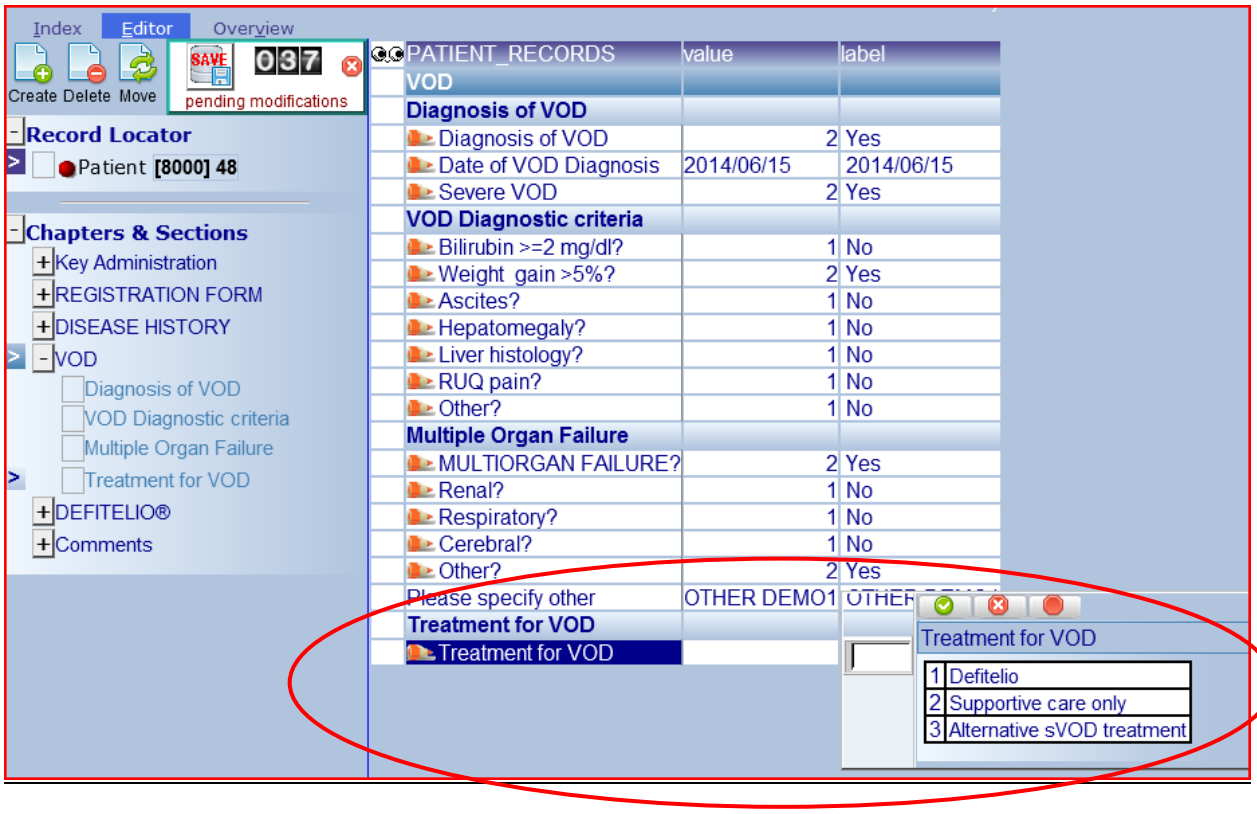
- **Cerebral:** Please record if the patient is suffering from any cerebral deficiencies due to VOD, by selecting "Yes" or "No"

- **Other:** If "Yes" is selected, please also specify

Paper CRF screen shot template is reported below **for your reference only**:



Please complete the section VOD, Subsection "Treatment for VOD"



- **Treatment for VOD:** Please specify the type of treatment for VOD the patient received, by selecting the appropriate option:
  - **Defitelio®**
  - **Supportive care only**
  - **Alternative sVOD treatment only:**
    If selected, please also specify the name of medical product (active principle)

Paper CRF screen shot template is reported below **for your reference only**:

TREATMENT FOR VOD

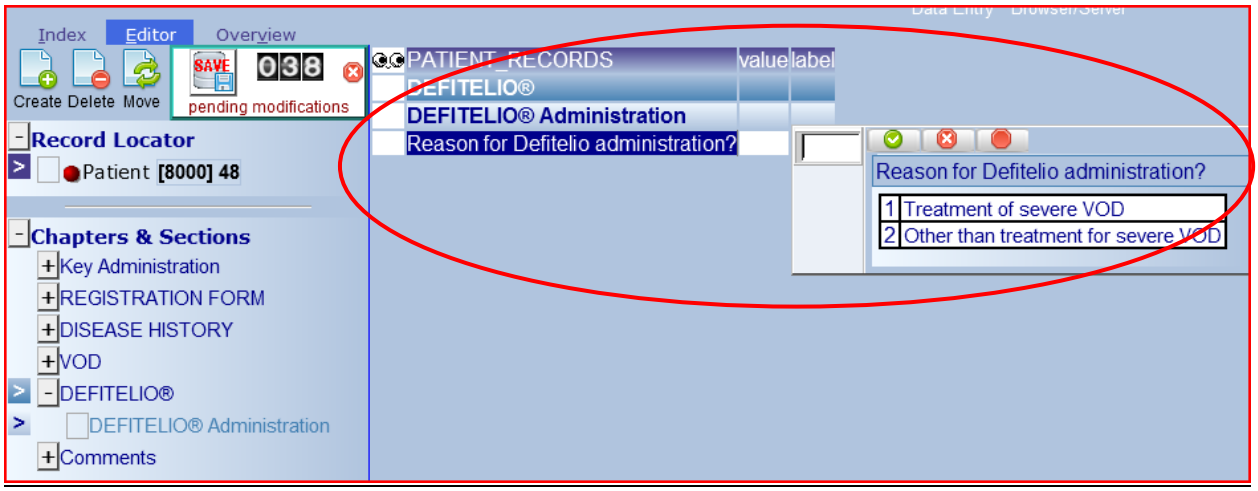
Defitelio® ☐

Supportive care only ☐

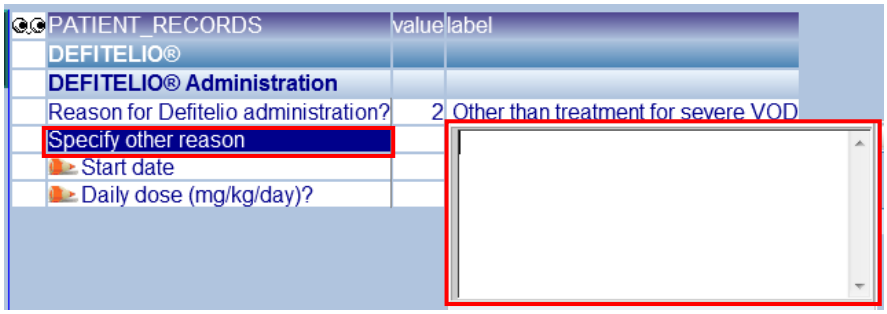
Alternative sVOD treatment ☐

→ *Specify* _____

Please complete the section DEFITELIO, Subsection "Reason for Defitelio® Administration" (for all the patients receiving Defitelio® at your centre, independently from the reason for treatment)



- **Reason for Defitelio administration:** Please select the appropriate reason:
  - **Treatment of severe VOD:** if Defitelio® was administered to treat the severe VOD.
  - **Other than treatment for severe VOD (specify):** if Defitelio® was administered for any other reason than treatment of severe VOD. If selected, please also specify the reason



Paper CRF screen shot template is reported below **for your reference only**:

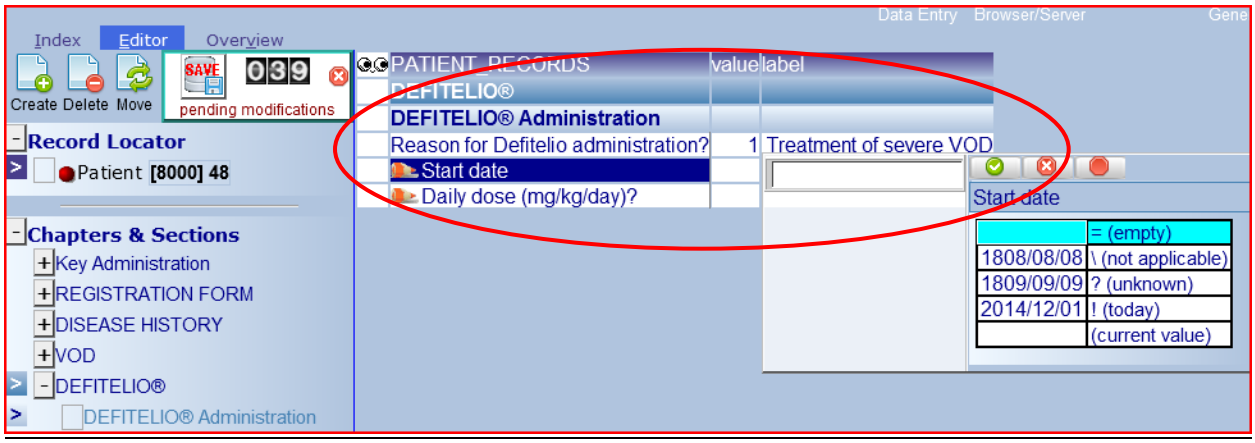
REASON for DEFITELIO® ADMINISTRATION

☐ Treatment of severe VOD

☐ Other than treatment for severe VOD

(specify)……

Please complete the section DEFITELIO, Subsection "Defitelio® Administration"



- **Start Date:** Please record the date when Defitelio® treatment started (date of first IV infusion).
- **Daily Dose (mg/Kg/day):** Please record the treatment daily dose of Defitelio® in mg/Kg/day. Please note that the approved dose for treatment of severe VOD is 25 mg/Kg/day.

Paper CRF screen shot template is reported below **for your reference only**:

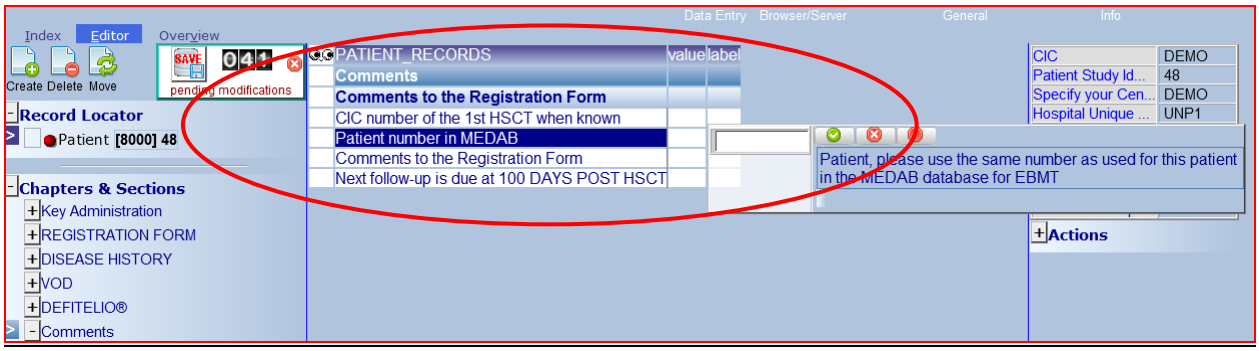
DEFITELIO® IV ADMINISTRATION FOR VOD

Start Date _____/___/___

Daily dose
(mg/kg/day)_____

Please remember to record Defibrotide treatment end date in the Follow-up forms

Please complete the section Comments



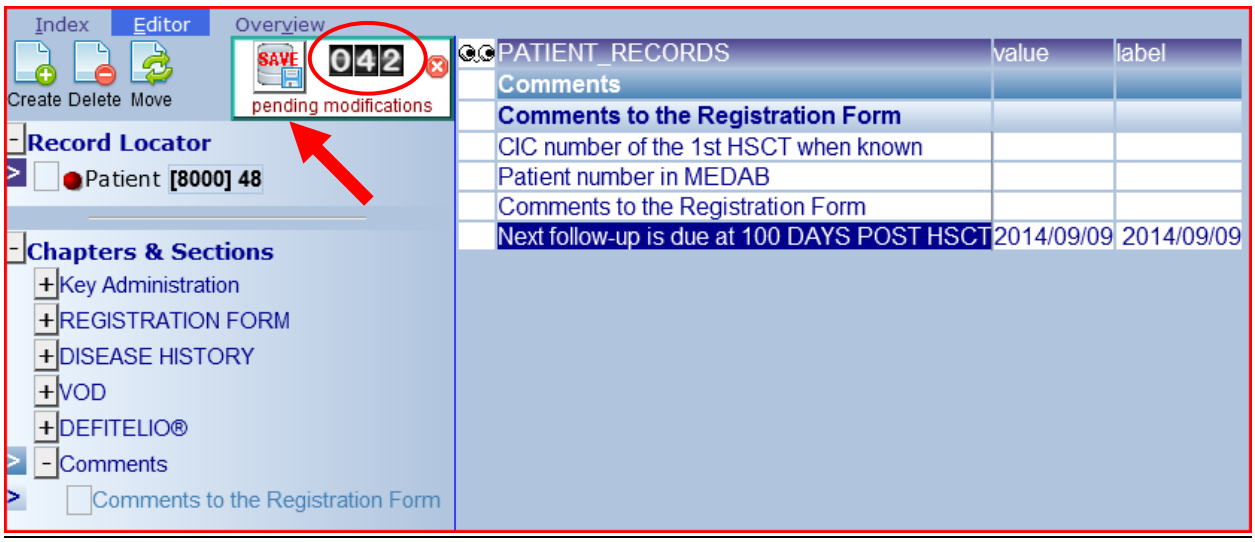
- **CIC number of the 1st HSCT when known:** If the patient is already recorded on the EBMT Med-AB project please enter here the code of this center. If the patient had a previous transplant in another center, the CIC number will be the one of the 1st Center.

- **Patient number in MEDAB:** If the patient is already recorded on the EBMT Med-AB project, please enter here the Patient Code used in the Med-AB project.

- **Comments to Registration Form:** Free text field

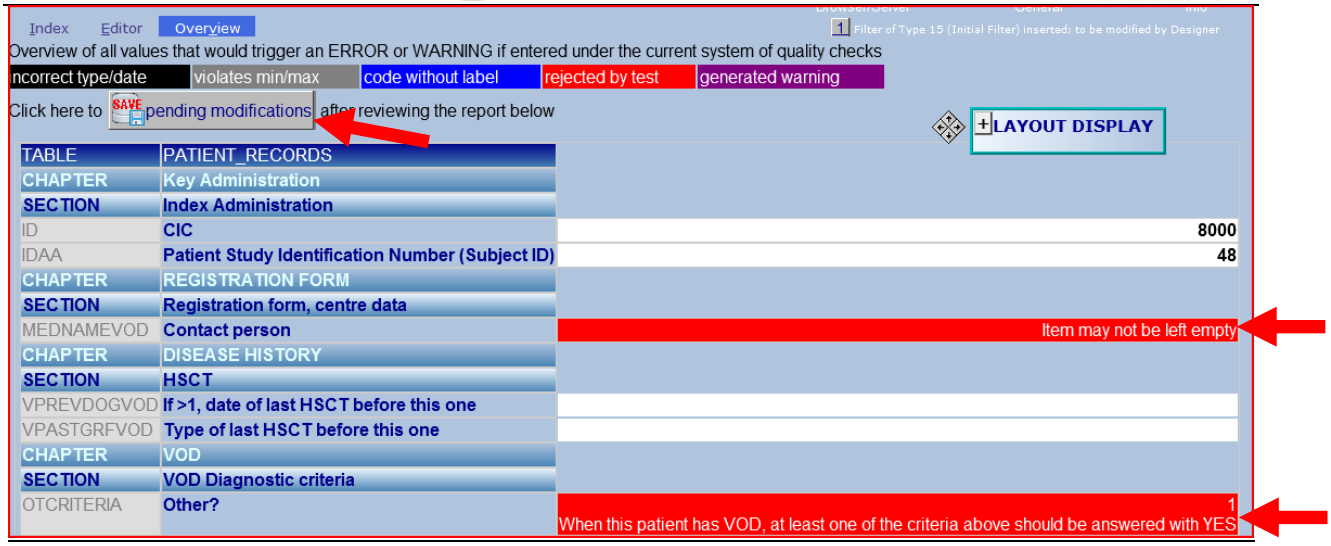
- **Next follow-up is due at 100 DAYS POST HSCT:** Automatic variable calculating and giving the date for the next form to be filled in: "MED-AB form" plus "VOD project days 100 Follow-up"

Please save the Registration Form



The total number of data entered since last saved, is written on the **pending modification counter.**
To save them, please click on the **Save Button** (floppy disk icon).

An overview of missing mandatory variables and rejected controls will appear.



Please complete missing or incorrect information by clicking on the corresponding red box cursor. This will jump directly to the variable to be corrected.

Please note that when you want to change the data already recorded, this is possible, but the system will ask you the reason why you've decided to make any change. Please be careful and record, for any changed data, the reason as:

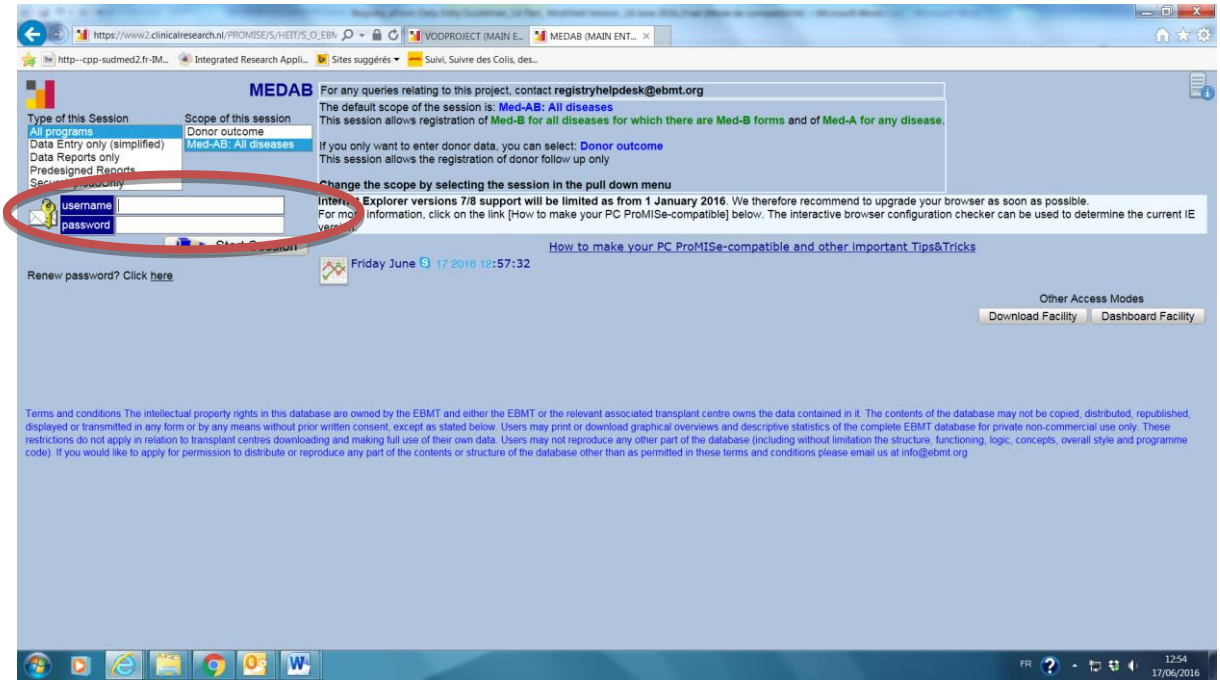
- Data Entry Error
- New data available
- Any other reason can be also specified here, as this is a free text field

And finalize the "Save action" by clicking on the pending modification button.

V/ MED-B RECOMMENDATIONS

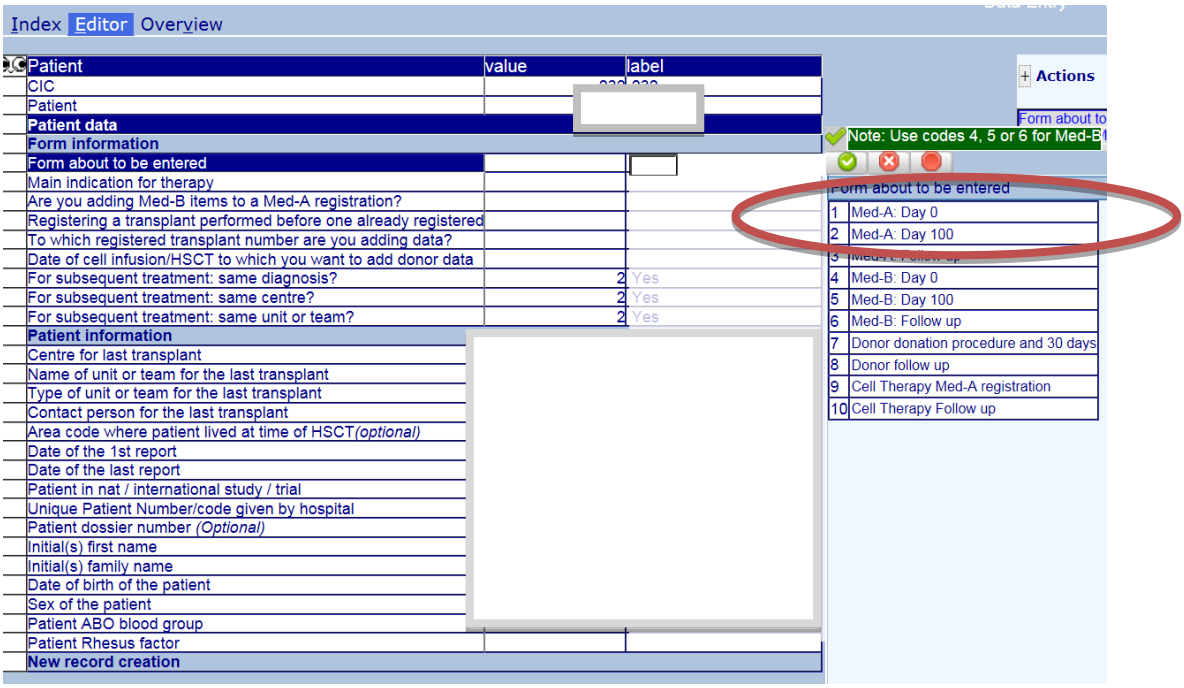
V-1/Logon:

At D0 and D100 after HSCT, the completion of Med-A is due, and data entry available on current EBMT portal: https://www2.clinicalresearch.nl/PROMISE/T/HEIT/T_O_EBMT_C_NEW_MEDAB_/LOGON/INDEX.HEI



V-2/ Navigation:

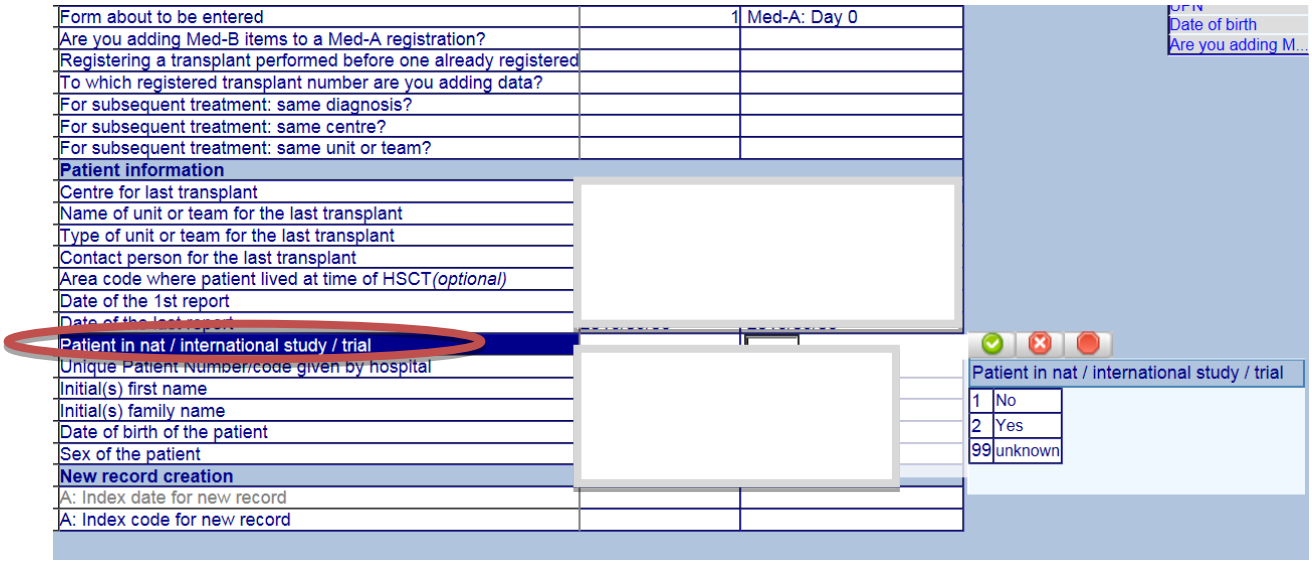
To fill in the Med-A, please select the form about to be entered = **HSCT MED-A D0 / MED A D100**



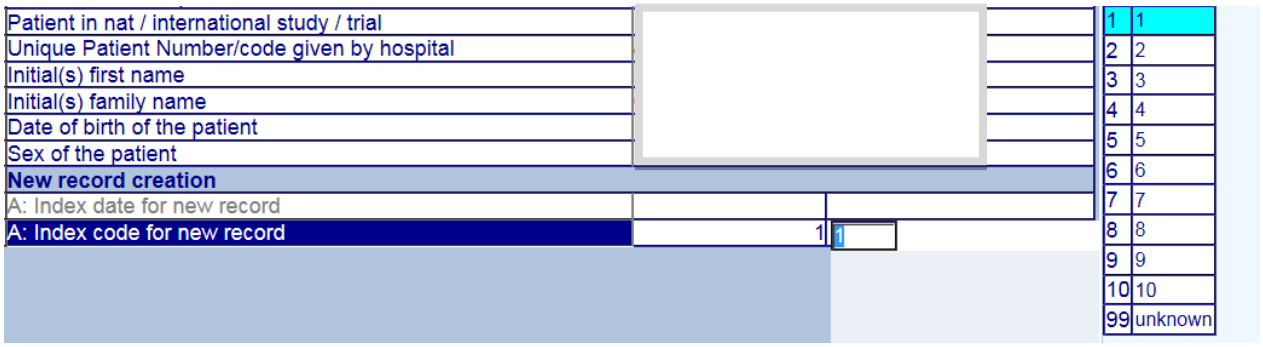
V-3/ Study number:

Please, in order to mark the patient:

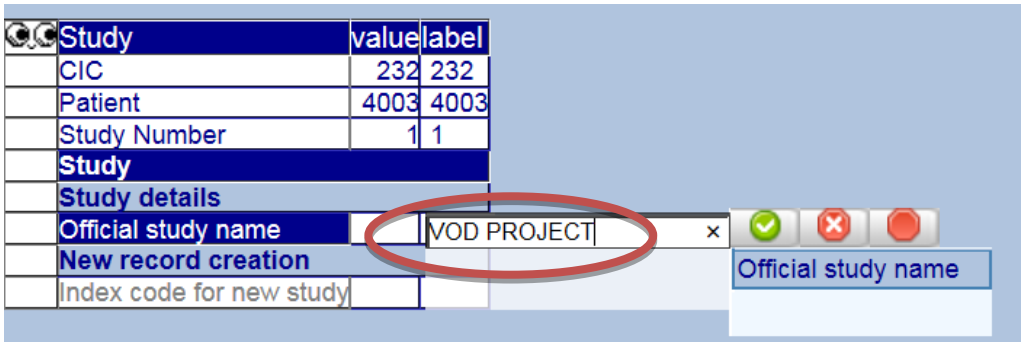
1/ Answer **Yes** to the question "**Patient in nat/international study/trial?** "



2/ Select the first free number to identify the study:



3/ Official study name is = **VOD PROJECT**



4/ To continue the Med-A, please leave the field « index code for new study" empty: