

## **Registry eForm Data Entry Guidelines**

Version 1.0 – 02 Apr 2014

Updated for eForm on 20 Jun 2016

### **Part 3**

General recommendation for data entry in ProMISe and instructions of completion  
for the Follow up Form 6 and 12 Months post HSCT

### **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 Form 100 days post HSCT
- **Part 3: instructions of completion for the Follow-up Forms 6 & 12 months post HSCT**

## Table of Contents

<b>I/ Means to Enter Patients into Registry</b>	<b>3</b>
<b>II/ e-Form Completion Instructions in ProMISe</b>	<b>4</b>
<u>II-1/ Connection to VOD Project (Med C)</u>	4
<u>II-2/ List of patients already reported</u>	5
<u>II-3/ Patient Record &amp; Selection of the Form to be entered</u>	6
<u>II-4/ Data navigation</u>	8
<u>II-5/ How to modify data in the form</u>	8
<u>II-6/ How to save or remove pending modifications</u>	9
<u>II-7/ How to close ProMISe session</u>	9
<u>II-8/ READ ONLY status</u>	9
<b>III/ FOLLOW UP FORM 6/12 Months post HSCT</b>	<b>10</b>
<u>III-1/ Section INFORMATION ON CRF</u>	10
<u>III-2/ Section PATIENT STATUS AT LAST CONTACT</u>	11
<u>III-3/ Section DEFITELIO ADMINISTRATION</u>	17
<u>III-4/ Section CLINICAL RESPONSE</u>	19
<u>III-5/ Section SAE</u>	22
<u>III-6/ Section OTHER EVENTS</u>	25
<u>III-7/ Save the Follow up Form</u>	28

## 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<sup>®</sup> (for example patients in which Defitelio<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> for any other condition
  - *Note: If in your clinical practice you treat conditions other than severe VOD with Defitelio<sup>®</sup> 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<sup>®</sup>, please contact:

- **INFO ON REGISTRY:**

[jessica.lemaitre@upmc.fr](mailto:jessica.lemaitre@upmc.fr) & [emmanuelle.polge@upmc.fr](mailto:emmanuelle.polge@upmc.fr)

- **INFO ON DEFITELIO<sup>®</sup>:**

[medical-enquiries@gentium.it](mailto: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<sup>®</sup> (if Defitelio<sup>®</sup> is administered for other reason than treatment of the sVOD)
  - Fill in VOD-Project Registration Form [\[link\]](#)
- 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

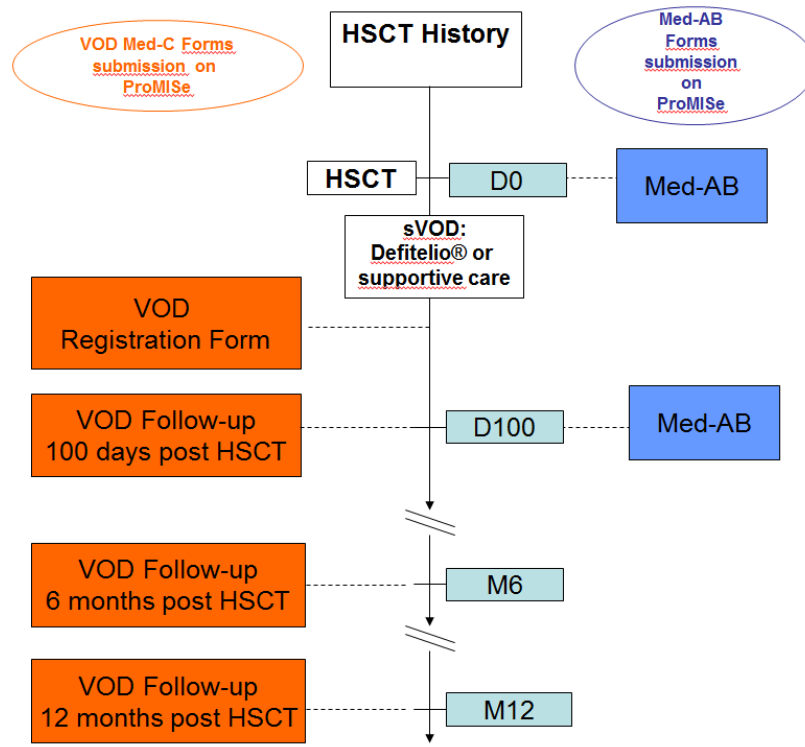


Figure 1 - Data Flow Chart

## II/ e-Form Completion Instructions in ProMISe

### II-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](https://www.clinicalresearch.nl/PROMISE/S/HEIT/S_O_EBMT_C_NIS_VODPROJECT_/LOGON/INDEX.HEI)

To connect for data entry:

- 1<sup>st</sup> 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 loss or expiration or blocked account, please contact [jessica.lemaitre@umpc.fr](mailto:jessica.lemaitre@umpc.fr) or [emmanuelle.polge@umpc.fr](mailto:emmanuelle.polge@umpc.fr)

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

## II-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**

CIC	Patient ID	Patient Name	Specify	Hospital name	Birth year	Birth month
8000	41	41				
8000	42	42				
8000	43	43	TEST	qsgnoer		
8000	44	44	TEST	regser	1950	June
8000	45	45	TEST	1	1960	August
8000	46	46				
8000	47	47		wsdgs<		
8000	100	100	Knappschafts Kr	Central Hospital	1946	May
8000	101	101	KI Minden	ABC	1930	October
8000	102	102	Franziskus H	Franz	1910	November
8000	103	103	Lukas Kh	lukas	1910	October
8000	104	104	KI Chemnitz	Regina	1936	December
8000	105	105				
8000	106	106				

### II-3/ Patient Record & Selection of the Form to be entered

1/ To load a patient already recorded, click on “Data Entry” Tab (1), then “Index” sub tab (2), followed by “All cases” list (3) and RIGHT click on the patient you want to report a follow up Form (4).

The screenshot shows a web application interface for clinical research. The top navigation bar includes 'Data Entry', 'Help', and 'Filter'. The 'Data Entry' tab is selected. Below it, the 'Index' sub-tab is active. On the left, there is a 'Build a Patient-index' section with buttons for 'Get all cases (refresh)' and 'Find cases with this text:'. The main area displays a table of patient records. The table has columns: 'CIC', 'Patient ...', 'Specify ...', 'Hospital name', 'Birth ye...', and 'Birth mo...'. The table is titled 'Create Patient-record' and 'ALL cases (n=127)'. A red box labeled '1' points to the 'Data Entry' tab. A red box labeled '2' points to the 'Index' sub-tab. A red box labeled '3' points to the 'ALL cases (n=127)' list. A red box labeled '4' points to a right-click action on a patient record in the table.

Or

In “Data entry” tab and “Index” sub-tab, click on “Create/Load Patient-record” button

The screenshot shows the same web application interface. The 'Data Entry' tab is selected. Below it, the 'Index' sub-tab is active. On the left, there is a 'Data Manager' section with a 'Build a Patient-index' button. The main area displays a table of patient records. The table has columns: 'CIC', 'Patient ...', 'Specify ...', 'Hospital name', 'Birth ye...', and 'Birth mo...'. The table is titled 'Create/Load Patient-record' and 'ALL cases (n=151)'. A red box labeled '1' points to the 'Create/Load Patient-record' button. A red box labeled '2' points to the 'Index' sub-tab. A red box labeled '3' points to the 'ALL cases (n=151)' list.

Enter the Study Number of the patient you want to complete the follow-up, and then click on “load existing patient”.

**Data Entry** | Report | Export | Help | Filter

**Index** | Editor | Overview

**+ Data Manager**

**+ Build a Patient-index:**

Create/Load Patient-record | ALL cases (n=151) | Link to History

[8000] DEMO city [DEMO] | {choose free slot}

140  
156  
202  
502  
1237  
1318  
455663  
2015003  
123456790

**- Create (or load) a Patient ...**

CIC (ID)

Patient

Create new Patient

**- LOAD:**

Load existing Patient

5

4

- Just click on a free slot to create this new case and load it into Data Entry.
- Alternatively you may fill in a specific identification number in the "Create/Load" tree above
- Caveat

2/ To create the Follow up Form 6 or 12 Months, click on the menu "Registration form" (1), then select in "Form about to be entered?" the appropriate form you wish to create (2). Choose the follow up form you wish to report (6 months or 12 months).

https://www.clinicalresearch.nl/ - VODPROJECT[NIS][EBMT][S][defit8000]demo[CIC:8000] DataE - Windows Internet Explorer

**Data Entry** | Help | Filter

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

**Index** | Editor | Overview

Create | Delete | Move/ Copy | Save | Print | Show | Cancel

**Record Locator**

Patient [8000] 58

followup Follow up at 100 days

**Chapters & Sections**

Key Administration

**REGISTRATION FORM**

DISEASE HISTORY

VOD

DEFITELUS

Comments

Registration Form

1

**PATIENT RECORDS**

**REGISTRATION FORM**

**Form about to be entered?**

1 Registration form

2 Follow up at 100 days

3 Follow up at 6 months

4 Follow up at 12 months

2

**Registration form, centre data**

Specify your Center Identification (CIC) DEMO

Hospital name dthhs

Unit name dthgfr

Contact person wdgg

Telephone rgze@jil.fr

Fax

Contact e-mail address

**Registration form, patient data**

Hospital Unique Patient Number or Code (UPN) 123

Date of this report 2015/01/28

Informed consent Yes

Initials of first name

Initials of family name

Birth year of patient 1950

Birth month of patient June

Birth day of patient 19

Gender Male

Weight (kg) 81

CIC DEMO

Patient Study Id ... 58

Specify your Cen. DEMO

Hospital Unique ... 123

Date of this rep. 2015/01/28

Initials of firs. ?

Birth year of pa. 1950

Birth month of p. June

You can see the follow up Form 6 months post HSCT is created below:

The screenshot shows the ProMISe data entry interface. The top navigation bar includes 'Data Entry', 'Help', and 'Filter'. The sidebar on the left has 'Record Locator' and 'Chapters & Sections'. The main area displays 'FOLLOWUP RECORDS' with a table of patient information. A red arrow points to the 'Date of follow-up' field.

Index	Administration	label
CIC	DEMO	
Patient	58	
Information on CRF		
Information on FollowUp moment		
For which follow-up moment are you entering data?	Follow up at 6 months	
Date of follow-up (last contact or date of death)		

CIC	DEMO
Patient Study Id	58
Specify your Cen	DEMO
Hospital Unique	123
Date of this rep	2015/01/28
Initials of firs	?
Initials of fami	?
Birth year of pa	1950
Birth month of p	June

As the form is created, you can now start the data entry for this patient.

## II-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.

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



## II-5/ How to modify data in a form

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 have 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.



## II-6/ 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 (Fig. 1) 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. 2. This allows 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).

## II-7/ 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 (Fig. 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. 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

## II-8/ 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 from the center if several persons have access (have personal password) to the VOD project data-base in your 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.

### III/ FOLLOW UP FORM 6 or 12 MONTHS POST HSCT

#### III-1/ Please complete the section INFORMATION ON CRF:

#### - Subsection Information on follow up moment:

- Date of the follow up (Last contact or date of death): If the patient at last contact at 6 or 12 Months post HSCT is alive, please record the date closest to 6 or 12 Months follow-up after transplant when the patient contact happened; If the patient died before 6 or 12 Months, please record the date of death.

**The data entry is dynamic; sections will appear if necessary**

and according to information previously reported (in registration or in follow-up forms)

### III-2/ Please complete the Section PATIENT STATUS AT LAST CONTACT:

The screenshot shows a web-based data entry application. The main window displays a form for 'PATIENT STATUS AT LAST CONTACT'. The form includes several checkboxes and text input fields. The 'PATIENT STATUS AT LAST CONTACT' section is highlighted. The form is titled 'FOLLOWUP RECORDS' and includes a table with columns for 'Index Administration' and 'label'. The table contains the following data:

Index Administration	label
CIC	8000
Patient	59

The form also includes a 'PATIENT STATUS AT LAST CONTACT' section with the following fields:

- ☐ Patient status at last contact
- ☐ Relapse?
- ☐ DLI (Donor Lymphocyte Infusion)?
- ☐ Survival Status?
- ☐ Acute Graft versus Host Disease
- ☐ Chronic Graft versus Host Disease

The interface also shows a 'Record Locator' section with a search bar and a 'Chapters & Sections' sidebar. The sidebar includes sections for 'Key Administration', 'Information on CRF', 'PATIENT STATUS AT LAST CONTACT', 'DEFIBROTIDE ADMINISTRATION', 'CLINICAL RESPONSE', 'SAE', and 'OTHER EVENTS'.

#### - Subsection Patient status at last contact:

- Relapse: Please record if the patient had a relapse of the underlying disease, by clicking the appropriate answer "No" or "Yes" or "Unknown". If "Yes" is selected, please also record the first relapse date.
- DLI (Donor lymphocyte infusion): Please record the date when the first DLI was performed, when known.
- Has VOD been diagnosed since last visit: If defibrotide was administered initially for another reason than treatment sVOD then sVOD appeared, please tick Yes otherwise tick No.
- Survival Status: Please provide the most recent information you have. The status must be the status at the date of last contact and the latter must be either the very last date the patient was known to be alive or the date of death if the patient is known to have died; so please choose the applicable answer "Alive", "Dead", "Died before HSCT and after start of conditioning" or "Lost to follow up" as applicable.

- **Subsection Main Cause of death:**

**Record Locator**

Patient [8000] 10400 FREE

followup Follow up at 100 days

followup Follow up at 6 months

**Chapters & Sections**

- Key Administration
- Information on CRF
- PATIENT STATUS AT LAST CONTACT**
  - Patient status at last contact
  - Main cause of death**
  - Acute Graft versus Host Disease
  - Chronic Graft versus Host Disease
- DEFITELIO ADMINISTRATION
- CLINICAL RESPONSE
- SAE
- OTHER EVENTS

**FOLLOWUP RECORDS**

Index Administration	label
CIC	DEMO
Patient	10400
<b>PATIENT STATUS AT LAST CONTACT</b>	
Patient status at last contact	
Relapse?	No
DLI (Donor Lymphocyte Infusion)?	No
Survival Status?	Dead
<b>Main cause of death</b>	
Main cause of death	

**Main cause of Death (check only one main cause)**

1 Relapse or progression of original disease
2 Secondary malignancy
3 HSCT related cause (check as many as appropriate)
4 Cell therapy (non HSCT) related
7 Other
9 Unknown

- Main cause of death (check only one main cause): If the patient status at 6 or 12 Months was “Dead”, please click only one major cause of death in the list to indicate the primary cause of death:
  - Relapse or progression of original disease
  - Secondary Malignancy
  - HSCT related cause: in this case, please also check all the applicable choices:
  - Cell therapy (non-HSCT related): please specify.
  - Other: please specify.
  - Unknown

**Please note: if the patient died, a SAE form needs to be filled and sent to the contact details specified on the SAE form, 24 hours from the event awareness.**

**Record Locator**

Patient [8000] 10308 FREE

followup Follow up at 100 days

followup Follow up at 6 months

**Chapters & Sections**

- Key Administration
- Information on CRF
- PATIENT STATUS AT LAST CONTACT**
  - Patient status at last contact
  - Main cause of death**
  - Acute Graft versus Host Disease
  - Chronic Graft versus Host Disease
- DEFITELIO ADMINISTRATION
- CLINICAL RESPONSE
- SAE
- OTHER EVENTS

**FOLLOWUP RECORDS**

Index Administration	label
CIC	DEMO
Patient	10308
<b>PATIENT STATUS AT LAST CONTACT</b>	
Patient status at last contact	
Survival Status?	Dead
<b>Main cause of death</b>	
Main cause of death	HSCT related
GvHD?	
Infection?	
VOD?	
Cardiac Toxicity?	
Pulmonary Toxicity?	
Renal toxicity?	
Rejection / poor graft function?	
Other transplant related cause of death?	

- If the death is HSCT related, check as many causes as are considered to have been contributing to the outcome:
  - GvHD
  - Infection
  - VOD
  - Cardiac Toxicity
  - Pulmonary Toxicity
  - Renal Toxicity
  - Rejection/poor graft function
  - Other transplant related cause of death: please also specify.
- Please check with your physician since this information is sometimes difficult to find in the patient's file. In the absence of clinical disease, a death caused by complications or infections after transplant is considered HSCT-related. In the presence of clinical disease, if the disease is progressing, the death will be considered as relapse or progression, even if there are complications or infections during the post-transplant period. However, if the disease was stable, or there had been an improvement after transplantation and the patient were to die of complications or infections, the death should be considered HSCT-related.

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

<b><u>PATIENT STATUS AT LAST CONTACT</u></b>			
Relapse <input type="checkbox"/> YES <input type="checkbox"/> NO Date of relapse _____			
DLI <input type="checkbox"/> YES <input type="checkbox"/> NO, If yes, date of 1 <sup>st</sup> DLI (Donor Lymphocyte Infusion) _____			
Has VOD been diagnosed since last visit? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>(for off label use or absent at previous follow-up)</i>			
Survival Status		Alive <input type="checkbox"/> Dead <input type="checkbox"/> Lost to Follow-up <input type="checkbox"/>	
Date of follow-up (last contact or Date of death):		____/____/____	
Main cause of Death <i>(check only one main cause)</i>			
Relapse or progression/persistent disease		<input type="checkbox"/>	
Secondary malignancy		<input type="checkbox"/>	
HSCT related cause <i>(check as many as appropriate)</i>		<input type="checkbox"/>	
<input type="checkbox"/>		<input type="checkbox"/>	
GvHD <input type="checkbox"/> YES <input type="checkbox"/> NO		Cardiac toxicity <input type="checkbox"/> YES <input type="checkbox"/> NO	
Infection <input type="checkbox"/> YES <input type="checkbox"/> NO		Pulmonary Toxicity <input type="checkbox"/> YES <input type="checkbox"/> NO	
VOD <input type="checkbox"/> YES <input type="checkbox"/> NO		Other: <input type="checkbox"/> YES <input type="checkbox"/> NO	
		Rejection/poor graft function <input type="checkbox"/> YES <input type="checkbox"/> NO	
		Renal Toxicity <input type="checkbox"/> YES <input type="checkbox"/> NO	
Specify: _____			
Cell therapy (non HSCT) related		<input type="checkbox"/>	
Unknown		<input type="checkbox"/>	
Other		<input type="checkbox"/>	
Specify: _____			

- **Subsection Acute graft versus host disease:**

https://www.clinicalresearch.nl/ - VODPROJECT[NIS][EBMT][S][defi8000]demo[CIC:8000/9] DataE - Windows Internet Explorer

Data Entry Help Filter

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index Editor Overview

014

Create Delete Move/ Copy Save pending modifications Show Cancel

Record Locator

Patient [8000] 59

Followup Follow up at 100 days

Followup 3

Chapters & Sections

- Key Administration
- Information on CRF
- PATIENT STATUS AT LAST CONTACT
  - Patient status at last contact
  - Main cause of death
  - Acute Graft versus Host Disease
  - Chronic Graft versus Host Disease
- DEFITELIO ADMINISTRATION
- CLINICAL RESPONSE
- SAE
- OTHER EVENTS

FOLLOWUP RECORDS

Index Administration

CIC 8000

Patient 59

PATIENT STATUS AT LAST CONTACT

Patient status at last contact

Relapse?

DLI (Donor Lymphocyte Infusion)?

Survival Status? Alive

Acute Graft versus Host Disease

Acute Graft versus Host Disease?

Chronic Graft versus Host Disease

Chronic Graft versus Host Disease?

Acute Graft versus Host Disease?

1 No

2 Yes

CIC DEMO

Patient Study Id 59

Specify your Cen DEMO

Hospital Unique 11111

Date of this rep 2015/01/28

Initials of firs ?

Initials of fami ?

Birth year of pa 1950

Birth month of p June

145%

FR 1203 29/03/2016

This section will appear ONLY IF the patient underwent an allogeneic HSCT (please double check eForm Registration Form – Section HSCT):

- Please tick if the patient suffered from acute GvHD or not, by selecting the corresponding answer “Yes” or “No”.
- Acute GvHD date of diagnosis: If “Yes” is selected, please add the diagnosis date. In a conventional transplant the onset of acute GvHD in T-cell depleted transplants or in non myeloablative transplants, the onset of GvHD may be later than D100.

https://www.clinicalresearch.nl/ - VODPROJECT[NIS][EBMT][S][defi8000]demo[CIC:8000/9] DataE - Windows Internet Explorer

Data Entry Help Filter

Resume with the **first** item in the **current** section by pressing **Tab** (or click on any other item)

Index Editor Overview

015

Create Delete Move/ Copy Save pending modifications Show Cancel

Record Locator

Patient [8000] 59

Followup Follow up at 100 days

Followup 3

Chapters & Sections

- Key Administration
- Information on CRF
- PATIENT STATUS AT LAST CONTACT
  - Patient status at last contact
  - Main cause of death
  - Acute Graft versus Host Disease
  - Chronic Graft versus Host Disease
- DEFITELIO ADMINISTRATION
- CLINICAL RESPONSE
- SAE
- OTHER EVENTS

FOLLOWUP RECORDS

Index Administration

CIC 8000

Patient 59

PATIENT STATUS AT LAST CONTACT

Patient status at last contact

Relapse?

DLI (Donor Lymphocyte Infusion)?

Survival Status? Alive

Acute Graft versus Host Disease

Acute Graft versus Host Disease?

Chronic Graft versus Host Disease

Chronic Graft versus Host Disease?

Acute Graft versus Host Disease?

1 Yes

2 No

If yes, date of aGvHD?

2016/03/28 (today)

[current value]

CIC DEMO

Patient Study Id 59

Specify your Cen DEMO

Hospital Unique 11111

Date of this rep 2015/01/28

Initials of firs ?

Initials of fami ?

Birth year of pa 1950

Birth month of p June

145%

FR 1205 29/03/2016



- Maximum grade of acute GvHD: Please record the maximum GvHD grade, by selecting only one of the following:
  - I
  - II
  - III
  - IV

The overall grade (or the grade of skin, liver and or gut) should be mentioned in the patients' file. The maximum grade for acute graft versus host disease (aGvHD) is defined according to the stage presented by the skin, liver and gut.

ORGAN	STAGE	
Skin	1	Skin rash < 25% body surface
	2	Skin rash 25-50% body surface
	3	Skin rash >50% body surface
	4	erythroderma
Liver	1	Bilirubin 34-50 micromol/L
	2	Bilirubin 51-102 micromol/L
	3	Bilirubin 103-255 micromol/L
	4	Bilirubin > 255 micromol/L
Gut	1	Diarrhoea volume 501 - 1000 ml/day
	2	Diarrhoea volume 1001 - 1500 ml/day
	3	Diarrhoea volume 1501 - 2000 ml/day
	4	Severe pain with or w/o ileus

grade 1: Skin stage 1 or 2	AND	Liver stage 0	AND	Gut stage 0
grade 2: Skin stage 3	OR	Liver stage 1	OR	Gut stage 1
grade 3:		Liver stage 2 or 3	OR	Gut stage 2, 3 or 4
grade 4: Skin stage 4	OR	Liver stage 4		

(Przepiorka et al, Bone Marrow Transplantation 1995;15: 825-828)

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

**ACUTE GRAFT-versus-HOST-DISEASE**

☐ YES    ☐ NO    →

If Yes, Date of diagnosis: \_\_\_\_/\_\_\_\_/\_\_\_\_ (yyyy/mm/dd)

Maximum grade of acute GvHD:

☐ I    ☐ II    ☐ III    ☐ IV

**- Subsection Chronic graft versus host disease:**

Please complete this section ONLY IF the patient underwent an allogeneic HSCT (please double check eForm Registration Form – Section HSCT):

- Please tick if the patient suffered from chronic GvHD or not, by selecting the corresponding check-box “Yes” or “No”.
- Date of GvHD of diagnosis: If “Yes” is selected, please add the diagnosis date.
- Organ(s) involved: Please list all the organs involved by the chronic GvHD by selecting Yes or No in the table.

PATIENT STATUS AT LAST CONTACT	
Patient status at last contact	
Relapse?	No
DLI (Donor Lymphocyte Infusion)?	No
Survival Status?	Alive
Acute Graft versus Host Disease	
Acute Graft versus Host Disease?	Yes
If yes, date of aGvHD?	
Maximum grade of acute GvHD?	
Chronic Graft versus Host Disease	
Chronic Graft versus Host Disease?	Yes
If yes, date of cGvHD?	2015/04/14
Organ(s) involved?	10001 Liver Skin

reason for change?	
<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Organ(s) involved?	
A Eyes	<input checked="" type="checkbox"/>
B Gastrointestinal tract	<input checked="" type="checkbox"/>
C Lungs	<input checked="" type="checkbox"/>
D Oral Cavity	<input checked="" type="checkbox"/>
E Liver	<input checked="" type="checkbox"/>
F Skin	<input checked="" type="checkbox"/>
G Other organ involved	<input checked="" type="checkbox"/>
* {all options}	yes no ???

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

**CHRONIC GRAFT-versus-HOST-DISEASE**

☐ NO ☐ YES

If Yes: Date of diagnosis: \_\_\_\_/\_\_\_\_/\_\_\_\_

Organ(s) involved:

Eyes ☐ Gastrointestinal tract ☐ Lungs ☐ Oral cavity ☐

Liver ☐ Skin ☐ Other ☐: \_\_\_\_\_



**III-3/ Please complete the section DEFITELIO ADMINISTRATION: this section is completed ONLY IF the patient was treated with Defitelio®**

- Defitelio® administration status: Check if Defitelio® treatment is ongoing or if it is completed. If it is completed, please also give the date when the last infusion was administered to the patient.

FOLLOWUP_RECORDS		label
Index Administration		
CIC		DEMO
Patient		10604
DEFITELIO ADMINISTRATION		
Defitelio administration		
Defitelio administration status?	2	reason for change?
If completed: Date of last infusion?		
Temporary withdrawal since last visit?	No	
Reason for withdrawing or stopping treatment		
Death?		
Hospital discharge?		
Untoward reaction to Defitelio?		
Other?		

Defitelio administration status?  
 1 Ongoing treatment  
 2 Completed treatment (permanent withdrawal)

- If treatment is completed:  
Temporary withdrawal since last visit form: Please indicate if Defitelio® treatment has been withdrawn or not and, if applicable, the number of days for which the treatment was withdrawn.

Index Editor Overview
DynFil:undefined

**Record Locator**

Patient [8000] 10306 FREE

followup Follow up at 100 days

followup Follow up at 6 months

**Chapters & Sections**

- Key Administration
- Information on CRF
- PATIENT STATUS AT LAST CONTACT
- DEFITELIO ADMINISTRATION
  - Defitelio administration
  - Reason for withdrawing or stoppi...
- CLINICAL RESPONSE
- SAE
- OTHER EVENTS

FOLLOWUP_RECORDS		label
Index Administration		
CIC		DEMO
Patient		10306
DEFITELIO ADMINISTRATION		
Defitelio administration		
Defitelio administration status?		Completed treatment
If completed: Date of last infusion?		{date unknown}
Temporary withdrawal since last visit?		Yes
If temporary withdrawal, total No. days of withdrawal?	2	
Reason for withdrawing or stopping treatment		
VOD resolution?		
No improvement?		
Death?		
Hospital discharge?		
Untoward reaction to Defitelio?		
Other?		

If the drug has been withdrawn or stopped, please check "Yes" for only one reason (if more than one reason is existing, please check only the main one):

- VOD resolution (if applicable)
- No improvement (If applicable)
- Death
- Hospital Discharge

- Untoward reaction to Defitelio® (in this case, please specify which reaction took place. If the event is serious, please also complete and submit the SAE form for the details, please refer to the last version of the “Registry SAE Completion Guidelines”)
- Other: please specify.

**IMPORTANT:** If a patient has been enrolled and treated with Defitelio® for another reason than sVOD and, in a second moment, developed sVOD after registration, for which a new Defitelio® treatment is planned.

In this case, you should consider the patient and his/her follow-up in the way outlined below:

- Defitelio Administration: please select Defitelio® Administration: Completed Treatment.
- Complete the date of last infusion when Defitelio® was administered for another reason than sVOD
- For Reason for withdrawing or stopping treatment: Select Other and specify sVOD diagnosed after registration. Please record the patient in a new Registration Form (please refer to the most recent Registry eForm Data Entry Guidelines Part 1) with a new patient ID and report the patient as enrolled in the sVOD arm. Please in comment section, indicate the previous Patient Id used in the first Registration form.
- If the patient is re-enrolled after a new HSCT, he/she needs to re-sign the Registry ICF, otherwise this is not necessary.

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

<p><b>DEFITELIO® ADMINISTRATION</b> (Fill this Section if Defitelio administration continued after Day+100 post-HSCT)</p> <p>Defitelio® administration status?</p> <p><input type="checkbox"/> Ongoing treatment <input type="checkbox"/> Completed (permanent withdrawal)</p>	<p>If completed: Date of last infusion? ____/____/____</p> <p>Temporary withdrawal since registration form?  <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>If temporary withdrawal, Total No. days of withdrawal? ____</p> <p>Reason for stopping treatment: *temporary or permanent VOD resolution <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>No improvement <input type="checkbox"/> YES <input type="checkbox"/> NO          Death <input type="checkbox"/> YES <input type="checkbox"/> NO          Hospital discharge <input type="checkbox"/> YES <input type="checkbox"/> NO          Untoward reaction to Defitelio® <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Specify: _____  <input type="checkbox"/> Other <input type="checkbox"/> YES <input type="checkbox"/> NO          Specify: _____</p>
--	---

### III-4/ Please complete the section **CLINICAL RESPONSE**:

The screenshot shows a web-based data entry application. The 'CLINICAL RESPONSE' section is active, and the 'VOD RESOLUTION?' field is highlighted with a red circle. A dropdown menu is open for this field, showing two options: '1 No' and '2 Yes'. The 'Record Locator' on the left shows patient information: Patient [8000] 5000 FREE, followup Follow up at 100 days, SAEs of interest 1 [Bleeding], and Concomitant Medication 1. The 'Chapters & Sections' on the left lists various sections, with 'CLINICAL RESPONSE' selected.

▪ VOD Resolution: If the patient suffered from VOD (please double check the Registration Form), please check the appropriate answer “Yes” or “No”, to record if the patient’s VOD resolved: “Yes” should be checked if the patient suffered from VOD at the registration or D100 follow up and resolved within the next visit follow-up; If the patient had a VOD response, please also record the date when VOD resolved.

“No” should be checked if the VOD previously declared, didn’t resolve within the current visit.

The screenshot shows the same web-based data entry application. The 'CLINICAL RESPONSE' section is active, and the 'VOD RESOLUTION?' field is highlighted with a red circle. A dropdown menu is open for this field, showing two options: '1 No' and '2 Yes'. The 'Date of VOD resolution' field is also highlighted with a red circle, and a dropdown menu is open for this field, showing two options: '2016/06/15' and '(today)'. The 'Record Locator' on the left shows patient information: Patient [8000] 5000 FREE, followup Follow up at 100 days, SAEs of interest 1 [Bleeding], and Concomitant Medication 1. The 'Chapters & Sections' on the left lists various sections, with 'CLINICAL RESPONSE' selected.

- Did the MOF developed after patient's last visit? Please check the appropriate answer "Yes" or "No".

"Yes" should be ONLY clicked if the patient didn't suffer from MOF previously, but he/she developed MOF after the previous visit.

"No" should be checked in all the other cases.

The screenshot shows a clinical trial data entry interface. The main table is titled 'FOLLOWUP RECORDS' and has columns for 'Index Administration', 'CIC', 'Patient', 'CLINICAL RESPONSE', 'VOD response', 'VOD RESOLUTION?', and 'MOF response'. The 'MOF response' row is highlighted, and a dropdown menu is open for the 'Multiple Organ Failure RESOLUTION?' field. The dropdown menu shows two options: '1 No' and '2 Yes'. A red circle highlights the dropdown menu and the 'MOF response' row in the table.

- MOF resolution: If the patient suffered from MOF at any time between the study entry and the current visit, please check the appropriate answer "Yes" or "No", to record if the patient's MOF resolved.

"Yes" should be checked if the patient suffered from MOF at any visit and resolved within the current visit; In this case, please specify the affected system(s) and the date when the MOF dysfunctions resolved:

- Renal: If selected, please add also the renal dysfunction resolution date
- Respiratory: If selected, please add also the respiratory dysfunction resolution date
- Cerebral: If selected, please add also the cerebral dysfunction resolution date
- Other: If selected, please add the date of resolution

"No" should be checked if the patient suffered from MOF at any time between the study entry and the current visit, but his/her MOF didn't resolve within the current visit.

Index Editor Overview DynFil:undefined

Create Delete Move/Copy Save pending modifications Show Cancel

**Record Locator**

Patient \$ [8000] 5000 FREE

followup Follow up at 100 days

SAEs of interest 1 [Bleeding]

Concomitant Medication 1

followup Follow up at 6 months

**Chapters & Sections**

- + Key Administration
- + Information on CRF
- + PATIENT STATUS AT LAST CONTACT
- + DEFITELIO ADMINISTRATION
- **CLINICAL RESPONSE**
  - VOD response
  - MOF response**
- + SAE
- + OTHER EVENTS

**FOLLOWUP RECORDS**

Index Administration	label
CIC	DEMO
Patient	5000
<b>CLINICAL RESPONSE</b>	
VOD response	
VOD RESOLUTION?	No
MOF response	
Multiple Organ Failure RESOLUTION?	Yes
Renal resolution?	
Respiratory resolution?	
Cerebral resolution?	
Other MOF resolution?	

Renal resolution?

1	No
2	Yes
9	Unknown

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

**CLINICAL RESPONSE**

☐ VOD RESOLUTION ☐ YES ☐ NO

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Did MOF developed after patient's last follow-up? ☐ YES ☐ NO

☐ MOF RESOLUTION ☐ YES ☐ NO

☐ Renal Date \_\_\_\_/\_\_\_\_/\_\_\_\_

☐ Respiratory Date \_\_\_\_/\_\_\_\_/\_\_\_\_

☐ Cerebral Date \_\_\_\_/\_\_\_\_/\_\_\_\_

☐ Other Date \_\_\_\_/\_\_\_\_/\_\_\_\_

### III-5/ Please complete the section SAE:

The screenshot shows a web-based clinical research form. The main section is titled 'FOLLOWUP RECORDS' and contains a table with columns 'value' and 'label'. The table has rows for 'Index Administration', 'Patient', 'SAE', and 'Serious Adverse Events'. A red circle highlights the 'SAE' row. To the right of the table, there is a pop-up message that reads: 'ANY NEW SERIOUS ADVERSE EVENTS (SAEs) (since last visit)? If Yes is selected, please be sure that a SAE form has been submitted to the contact details specified on the SAE form, within 24 hours from the event's awareness.' The form also includes a 'Record Locator' section on the left and a 'Chapters & Sections' list on the bottom left.

#### - Subsection Serious Adverse Event:

Please indicate if one or more SERIOUS adverse events occurred within 100 days follow-up. Please note that all the serious events need to be reported, irrespective of the relationship with Defitelio® and also for patients treated with supportive or alternative care and not only for patients treated with Defitelio®.

If any, “Yes” is selected, please be sure that a SAE form has been submitted to the contact details specified on the SAE form, within 24 hours from the event’s awareness.

For serious adverse event seriousness criteria and for SAE form completion guideline, please refer to the most current version of DF VOD-2013-03-REG SAE completion guideline.

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

The template is a rectangular box with a title 'ANY SERIOUS ADVERSE EVENTS since last visit (SAEs)'. Below the title, there are two checkboxes: 'NO' and 'YES'. A small question mark icon is positioned between the two checkboxes. Below the checkboxes, there is a bold instruction: 'if YES complete in details the SAE FORM and SEND A FAX OR A SCANNED COPY TO THE CONTACT INFORMATION LISTED ON THE SAE FORM'.

#### - Subsection Serious Adverse Event of Interest:

If “Yes” is selected, please indicate in “sequence number of the SAE of interest” a chronological number. So, please start numbering with “1” and if you need to declare another SAE of interest later on, please increment the number to “2” and “3”, etc

https://www.clinicalresearch.nl/ - VODPROJECT[NIS][EBMT][S][defi8000][demo][CIC8000/9] DataE - Windows Internet Explorer

Data Entry Help Filter

Resume with the first item in the current section by pressing Tab (or click on any other item)

Index Editor Overview

Browser/Server General Info

006 pending modifications

Record Locator

Patient [8000] 7512 FREE

Follow up Follow up at 100 days

SAEs of Interest 1 [Infection]

SAEs of Interest 2 [Infection]

Concomitant Medication 1

Concomitant Medication 2

Follow up Follow up at 6 months

SAEs of Interest 1

Chapters & Sections

Key Administration

Information on CRF

PATIENT STATUS AT LAST CONTACT

DEFITELIO ADMINISTRATION

CLINICAL RESPONSE

SAE

Serious Adverse Events

Serious Adverse Events of Interest

OTHER EVENTS

CIC FOLLOWUP RECORDS

label
Index Administration
CIC
Patient
7512
SAE
Serious Adverse Events
ANY NEW SERIOUS ADVERSE EVENTS (SAEs) (since last visit)?
Yes
Serious Adverse Events of Interest
Did any SAE of interest occur since last visit?
Yes
Sequence number of the SAE of interest
2

Sequence number of the SAE of interest

Overview

DynFil:43:SAE of interest

018

g modifications

1

SAEs_of_INTEREST	label
CIC	DEMO
Patient	155
SERIOUS ADVERSE EVENTS OF INTEREST	
Serious Adverse Events of Interest	
Sequence number of the SAE of interest	1
Date SAE of interest started	
Which type of SAE of interest occurred?	
Would you like to report another SAE of interest?	

Also record the onset date and the type of SAE of interest declared:

- Bleeding: If "Yes" is selected, please also specify the localization
- Hypotension
- Coagulopathy
- Allergic/Hypersensitivity reactions
- Injection site reaction
- Infection: If "Yes" is selected, please also specify the localization and the type of infection
- Thromboembolic events



Index Editor Overview DynFil: undefined

Create Delete Move/ Copy Save pending modifications Show Cancel

**Record Locator**

Patient [8000] 130

followup Follow up at 6 months

**SAEs of interest 1**

followup Follow up at 12 months

**Chapters & Sections**

Key Administration

**SERIOUS ADVERSE EVENTS OF INTEREST**

Serious Adverse Events of Interest

SAEs of INTEREST	label
Index Administration	
CIC	DEMO
Patient	130
<b>SERIOUS ADVERSE EVENTS OF INTEREST</b>	
<b>Serious Adverse Events of Interest</b>	
Sequence number of the SAE of interest	1
Date SAE of interest started	
Which type of SAE of interest occurred?	
Would you like to report another SAE of interest?	

Date SAE of interest started

Date SAE of interest started	
	= (empty)
1808/08/08	\ (not applicable)
1809/09/09	? (unknown)
2016/06/15	! (today)
	(current value)

If you have another SAE to declare, please do the same way again.

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

SERIOUS ADVERSE EVENTS OF INTEREST	
Did a SAE of interest occur since last visit?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Sequence number of the SAE of interest :	___
Date SAE of interest started?	___/___/___
Bleeding	<input type="checkbox"/> Site: _____
Hypotension	<input type="checkbox"/>
Coagulopathy	<input type="checkbox"/> Allergic/Hypersensitivity reactions <input type="checkbox"/>
Injection site reaction	<input type="checkbox"/>
Infection	<input type="checkbox"/>



### III-6/ Please complete the section **OTHER EVENTS**:

#### - **Subsection Pregnancy and Lactation:** (If the patient is a female)

The screenshot shows the 'OTHER EVENTS' section of the clinical trial web application. The 'PREGNANCY and Lactation' subsection is highlighted with a red circle. The form includes fields for 'PREGNANCY?' and 'LACTATION?' with dropdown menus. A 'Comments' section is also visible. A tooltip for 'PREGNANCY?' provides instructions: 'If Yes is selected, please also complete and submit the pregnancy form'.

- Please check if the patient was pregnant or not at the current visit and please complete and submit the pregnancy form within 24 hours since the awareness in case of positive answer.
- Please check if the patient was lactating or not at the current visit and please complete and submit the pregnancy form within 24 hours since the awareness in case of positive answer.

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

<u>PREGNANCY*</u>	<u>LACTATION</u>
<input type="checkbox"/> YES <input type="checkbox"/> NO *If Yes is selected, please also complete and submit the pregnancy form	<input type="checkbox"/> YES <input type="checkbox"/> NO

#### - **Subsection Concomitant medication:**

Please **only** report:

- **Thrombolytic therapy**
- **Anticoagulant therapy (including direct thrombin and Xa factors)**
- **Corticosteroids** that the patient is taking while VOD is under treatment (including supportive care) - or in general while the patient is enrolled in the study - until the current time.

FOLLOWUP_RECORDS		label
<b>Index Administration</b>		
CIC		DEMO
Patient		10308
<b>OTHER EVENTS</b>		
<b>Pregnancy and Lactation</b>		
PREGNANCY?		No
LACTATION?		
<b>Concomitant Medication</b>		
CONCOMITANT MEDICATION?	<input checked="" type="checkbox"/>	
Sequence number of concomitant medication	2	
<b>Comments</b>		
CIC number of the 1st HSCT when known		
Patient number in MEDAB		
Comments to the Follow Up Form at 6 months		
Next follow-up is due at 12 MONTHS POST HSCT		2015/06/15

reason for change?

☒ ☐ ☐

**CONCOMITANT MEDICATION?**

1 No Please only report:

2 Yes

- Thrombolytic therapy
- Anticoagulant therapy (including direct thrombin and Xa factors)
- Corticosteroids

If "Yes" is selected, please indicate in "sequence number of concomitant medication" a chronological number. So, start numbering with "1" and if you need to declare another concomitant later on, please increment the number to "2" and "3", etc

Index Administration

CIC 8000 DEMO

Patient 140 140

Concomitant medication given

Concomitant medication given

Sequence number of concomitant medication 1

Medicinal product

Medicinal product, daily dose

Medicinal product unit

Duration (in days) of medicin administration

Indication for medicinal product

Additional concomitant medication given?

**CONCOMITANT MEDICATION**

value label

1 1

Medicinal product

1 Antithrombotic agents (other)

B01AA Vit. K antagonists (other)

B01AA03 Warfarin

B01AB Heparin group (other)

B01AB01 Heparin

B01AB02 Antithrombin

B01AB04 Dalteparin

B01AB05 Enoxaparin

B01AD Enzymes (other)

B01AD02 tPA (Alteplase)

B01AD04 Urokinase

B01AE Direct thrombin inhibitors

B01AE01 Desirudin

B01AE07 Dabigatran

B01AF Direct factor Xa inhibitors (other)

B01AF01 Rivaroxaban

H02 Corticosteroids for systemic use (other)

H02AB Glucocorticoids (other)

Please record the following details:

- Drug Name
- Daily Dose
- Dose Unit
- Treatment Duration (in days)
- Indication

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

CONCOMITANT MEDICATIONS <input type="checkbox"/> YES <input type="checkbox"/> NO	
Sequence number of the concomitant medication :	___
Medicinal product	_____
Medicinal product daily dose?	_____
Medicinal product unit?	_____
Medicinal product duration (in days)?	___
Medicinal product indication	_____
<i>*if several please indicate each</i>	

- **Subsection Comments:**

The screenshot shows the EBMT Med-AB project web application. The 'FOLLOWUP RECORDS' section is active, displaying a table of follow-up records. A red circle highlights the 'CIC number of the 1st HSCT when known', 'Patient number in MEDAB', and 'Comments to the Follow Up Form at 6 months' fields. The 'Next follow-up is due at 12 MONTHS POST HSCT' field shows the date 2016/10/30. The 'Record Locator' section on the left shows the patient's status as 'FREE' and the follow-up status as 'Follow up at 6 months'.

- **CIC number of the 1<sup>st</sup> 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 the follow up 6 or 12 Months:** Free text field
- **Next follow-up is due at 12 Months post HSCT:** Automatic variable calculating and giving the date for the next form to be filled in: "VOD project 12 months post HSCT Follow-up"

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

Comments
CIC number of the 1 <sup>st</sup> HSCT when known : _____
Patient Number in MEDAB : _____
Comment to the Follow-up Forms at 6 or 12 months : _____

### III-7/ Please save the Follow up Form:

The screenshot shows a web-based data entry application. At the top, there are tabs for 'Data Entry', 'Help', and 'Filter'. Below the tabs, a message reads: 'Resume with the first item in the current section by pressing Tab (or click on any other item)'. On the left, there is a 'Record Locator' section showing 'Patient [8000] 155' and 'followup 2'. Below this is a 'Chapters & Sections' list with expandable items like 'Key Administration', 'Information on CRF', 'PATIENT STATUS AT LAST CONTACT', 'DEFITELIO ADMINISTRATION', 'CLINICAL RESPONSE', 'SAE', and 'OTHER EVENTS'. The 'OTHER EVENTS' section is currently expanded, showing 'Pregnancy and Lactation', 'Concomitant Medication', and 'Comments'. In the center, there is a 'FOLLOWUP\_RECORDS' table with columns 'CIC' and 'label'. The table contains one row with 'CIC' value 8000 and 'label' value 155. To the right of the table, there is a 'Comments' section with text: 'CIC number of the 1st HSCT when known', 'Patient number in MEDAB', 'Comments to the Follow Up Form at 100 days', and 'Next follow-up is due at 6 MONTHS POST HSCT'. At the bottom of the interface, there is a 'pending modifications' counter showing '019'. A red circle highlights the 'SAVE' button (floppy disk icon) and an arrow points to the counter.

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:

The screenshot shows a web-based data entry application. At the top, there are tabs for 'Data Entry', 'Help', and 'Filter'. Below the tabs, a message reads: 'PLEASE REVIEW THE REPORT(S) DISPLAYED FIRST. CLICK ON THE SAVE BUTTON AGAIN TO ACTUALLY SAVE THE MODIFICATIONS ON THE SERVER'. On the left, there is a 'Record Locator' section showing 'Patient [8000] 155' and 'followup 2'. Below this is a 'Chapters & Sections' list with expandable items like 'Key Administration', 'Information on CRF', 'PATIENT STATUS AT LAST CONTACT', 'DEFITELIO ADMINISTRATION', 'CLINICAL RESPONSE', 'SAE', and 'OTHER EVENTS'. The 'OTHER EVENTS' section is currently expanded, showing 'Pregnancy and Lactation', 'Concomitant Medication', and 'Comments'. In the center, there is a table titled 'Overview of all values that would trigger an ERROR or WARNING if entered under the current system of quality checks'. The table has columns for 'TABLE', 'CHAPTER', 'SECTION', 'ID', 'IDAA', 'MEDNAMEVOD', 'VODMLAD', 'UPN', 'CHAPTER', 'SECTION', 'VPREVDGVD', 'VPASTGRFVD', 'MYELOABRVOD', 'TABLE', 'CHAPTER', 'SECTION', 'ID', 'IDAA', and 'IDAABA'. The table contains several rows of data, including 'PATIENT\_RECORDS', 'FOLLOWUP\_RECORDS', and 'SAE'. Some rows have red boxes indicating errors or warnings, such as 'This is not an e-mail address, please use this field for e-mail address only' and 'Item may not be left empty'. A red arrow points to the 'SAVE' button (floppy disk icon) and another red arrow points to the table.

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

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