European Society for Blood and Marrow Transplantation



Instructions on how to enter minimal essential data for non-consenting patients in ProMISe



INTRODUCTION

This document explains how to add in ProMISe minimal essential data for patients who did not consent to sharing their data with EBMT.

This document should only be used for the purpose of adding minimal essential data. Turning the dynamic item filter off in ProMISe for any other purpose is strongly advised against.

If you have any queries or any issues with data entry, please contact the Registry Helpdesk at registryhelpdesk@ebmt.org

TURNING OFF THE DYNAMIC ITEM FILTER

Create a new patient record in ProMISe using the normal procedure for this.

At the top of the screen, in the menu where the 'Exit' button is, there is an icon of a sheet of paper with binoculars:



Click the icon. This will turn off the dynamic item filter, resulting in all items in ProMISe becoming visible. The number next to the binoculars will change from 8 to 0, and the table will expand:

Index Editor Overview		Enty BrowserServerf unders Central Info	*
	valuo labol 8001 8001 123 123	Actions Form about to be Actions A	how Can
Initially first name Initially first name Date of brith of the patient Sex Patient RBO blood group. Patient Results factor New record creation			



ENTERING THE DIAGNOSIS DATA

To add a diagnosis to the patient, select the paper icon with the +:



Upon clicking the item, a list of items that can be added to the patient record appears. Select the 'diagnosis':





Specify the year of the diagnosis. For month and date you can fill in 1 and 1 (first of January), and click 'click here to create the records':

E E contro a recentor haño urandoran	x				
Create (a) new Diagn record(s) in table Diagnosis	Î				
1. Specify the value of [Diagnosis date] 2010 1 1 year mm dd year approximate? today. If you are unsure about the exact date, give your best estimate above and indicate the precision. 2. click here to create the record(s) 5.					
To create multiple records in one action					
Check this box specify the number of records					
records will be generated by incrementing the start value with 1 unit(s) until the requested number of new records is reached) and proceed as indicated above.					
Click here to <u>cancel the operation</u>					

ProMISe will ask the precision of the date again. This field can be left blank. Instead, select 'Main diagnosis classification' from the list of items on the right:

Index Editor Overview			
Concords value tedo: Sequences value tedo: Sequences value tedo: Sequences value value value value Sequences value va	O read data O read data O read data O read data	eliters vivelating vivelating Const. Charge, Delete Grantadot to is ord const. Charge, Delete Const. Charge, Delete Const. Charge, Delete Const. Charge, Delete vivelating vivela	Caster de aligne data Caster data Ca

ProMISe will move to the diagnosis classification chapter. Select 'Diagnosis' and choose the appropriate classification from the list.

and the second sec	value	label		
CIC		1 8001 3 123	-	
		0 2010/01/01 {exact	1	
Diagnosis classification	2010/01/01 00.0	0 2010/01/01 {exact	<u>n</u>	
Diagnosis classification				
Diagnosis			0 8 0	
Age at this diagnosis				
Interval from last transplant to this diagnosis	-		-	
interval nom last dansplant to this diagnosis			Diagnosis	Personal Manufacture of Concernance
			1 Acute leukaemia	IMPORTANT
			2 Chronic leukaemia	You can obtain a file with a lis
			3 Lymphoma	of diagnoses by clicking on lin
			4 Plasma cell disorders	DISMCLFD.PDF at the botton of this notice
			5 Solid tumours	of this notice.
			6 Myelodysplastic/Myeloproliferative	If the diagnosis is not covered
			and a state of the	by any of the broad categories
			7 Bone marrow failure	that are shown, you may need
			8 Inherited disorders	to use code 88.
			9 Histiocytic disorders	support of the support of the
			10 Auto-immune diseases	Before doing so, contact the
			11 Hemoglobinopathies	registryhelpdesk@ebmt.org
			88 Uncoded (other)	to confirm that the disease ha not been categorised.
			99 unknown	not been categorised.
			o dimitioni	It is rare for a disease not to
				belong to one of the listed
				categories.
				Additional help in DISMCLFD

Final Registry 53: Instructions on how to enter minimal essential data for non-consenting patients in ProMISe v1.0 Page 4 of 8



After selecting the diagnosis classification, ProMISe will automatically move to the sub-classification of the selected disease. The sub-classification needs to be filled in as well.

ENTERING TREATMENT DATA

After the diagnosis is registered, the treatment needs to be reported. Once again, click the paper icon with the green + next to it. The list of items that can be added will become visible again. This time, select 'Treat':



The window to enter the date of the treatment will pop up. This window is identical to the diagnosis window. Fill in the year of the treatment. For year and month, January 1st can be used again.



The table will expand to show the following 2 items (Date precision and Context):

C Treatment	value	label	l i i i i i i i i i i i i i i i i i i i		
· ·					+ Actions
CIC		8001			
Patient	123				Form about to be
	2011/01/01 00:00	2011/01/01 {exact}			Med-B over Med-A
Treatment record qualifier (manual)					UPN
Date precision					Date of birth
Date precision (manual input, see note)	41	This year			Are you adding M.
Event					
Context (manual input, see note)					
			Context (manual input, see note)		
			2 Non graft treatment	IMPORTANT	
			4 Collection	You MUST use this field if you have	
			7 Hematopoietic stem cell transplant	created the record manually.	
			14 Support / Boosts	You can also use it to make a correction	n
			17 Donor lymphocyte infusion	to the context of this treatment a posterior	iori.
			18 Cell therapy (non HSCT/DLI)		

For 'Date precision (manual input, see note)' select 'This year' again.

For 'Context (manual input, see note)' choose the appropriate context. For autologous or allogeneic stem cell transplants, select 'Hematopoietic stem cell transplant'. For CAR-Ts, select 'Cell therapy (non HSCT/DLI)'.

Entering details for an HSCT

From the list of chapters and sections, select 'Transplant and cell source specifics':



A table will appear. In this table, only 2 items need to be filled in; the type of transplant, and the chronologic number of this transplant for this patient:

Treatment	value	label
CIC	8	001 8001
Patient		123 123
Treatment date	2011/01/01 00	0:00 2011/01/01 {exact
Transplant and cell source specifics		
Type of transplant		
Type of HSC transplant		-
Specity if HSC transplant unusual		
Multiple donors	1	
Number of donors		
Total number of products		
Tissue source		
Bone marrow (BM)		
Number of BM collections		
Peripheral blood (PB)		
Number of mobilisation courses		
First date of BM collection or unmobilised PB pheresis		
Cord blood (CB)		
Adipose tissue		
Endothelial cell progenitors		
Other tissue source		
Other tissue source: specify		
First date of BM collection or of PB apheresis		
Number of the transplant		
Chronologic number of this transplant for this patient		
Providuo tranoplant		
Donor the same as previous transplant		
Date previous transplant		
Type of previous transplant		

Final Registry 53: Instructions on how to enter minimal essential data for non-consenting patients in ProMISe v1.0 Page 6 of 8



Entering details for a CAR-T

From the list of chapters and sections, select 'Cellular therapy':



A table will appear. In this table, only 2 items need to be filled in; the source of cells used to manufacture the CAR-T, and the chronologic number of cell therapy for this patient:

Treatment	value	label
CIC	8001	8001
Patient	123	123
Treatment date	2011/01/01 00:00	2011/01/01 {exact
Cellular therapy (non HSCT)		
Cellular therapy (non HSCT)		
Other cell therapy (non HSCT)		
Allogeneic stem cells from the same donor (boost) in the presence of engraftment	t	
Autologous stem cells from the patient (boost) without conditioning		
Cell characteristics	<u></u>	
Date DLL or other cell infusion started		
Cell origin		
riouuci manufactureu from		
Donor lymphocyte infusion (DLI)		
Selected lymphocytes		
Type of DLI, specify		
Mononuclear cells		
CD34+		
Mesenchymal cells		
Unseparated bone marrow		
Fibroblast infusion		
Dendritic cell infusion		
NK cells		
Regulatory T-cells		
Gamma/delta cells		
Other type of cells		
Other cells: specify		
Infusion units count		
Were there more than 1 CIU administered during this treatment		
Indicate number of cell infusion units administered during this treatment		
Previous cell therapy treatment		
Chronological number of cell therapy treatment for this patient		
Cell musion unit same as for previous cell merapy treatment		
Date previous cell therapy treatment		



SAVING THE FILE

After filling in these items, all minimal essential data will have been entered. Save the data by pressing the 'save' button, next to the number of pending modifications:



TURNING THE DYNAMIC ITEM FILTER BACK ON

After the minimal essential data has been entered, turn the dynamic item filter back on by clicking on the paper with the binoculars again:



The number next to the binoculars will change from 0 to a higher number. The dynamic item filter is now turned on. This is the final step.