

***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

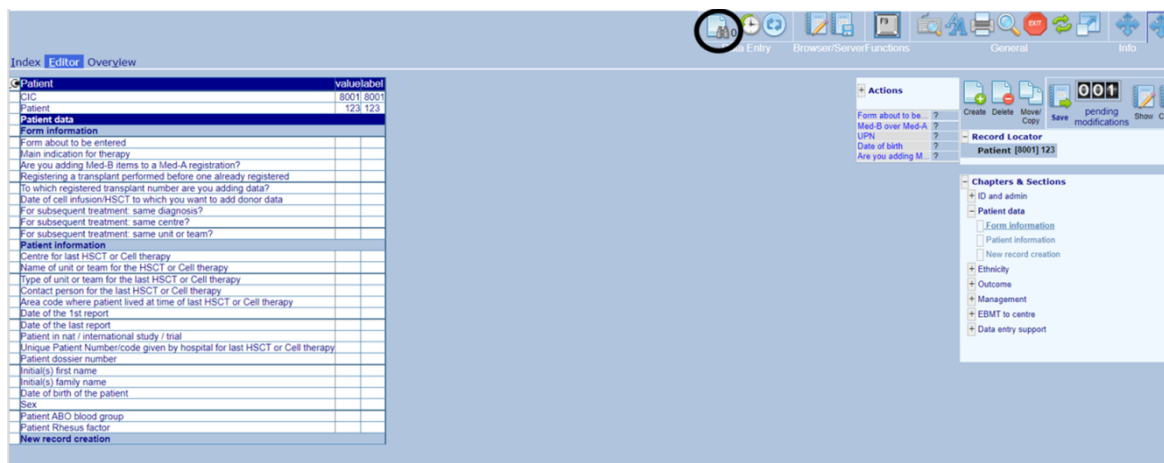
TURNING OFF THE DYNAMIC ITEM FILTER

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:

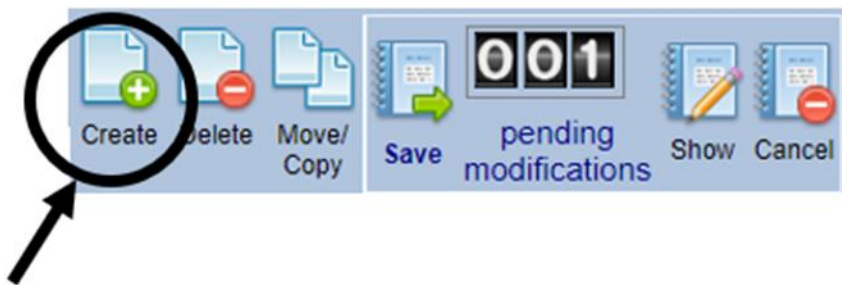


Click the icon. This will turn off the dynamic item filter, resulting in all items in ProMISe becoming visible. The number next to the binoculars will change from 8 to 0, and the table will expand:

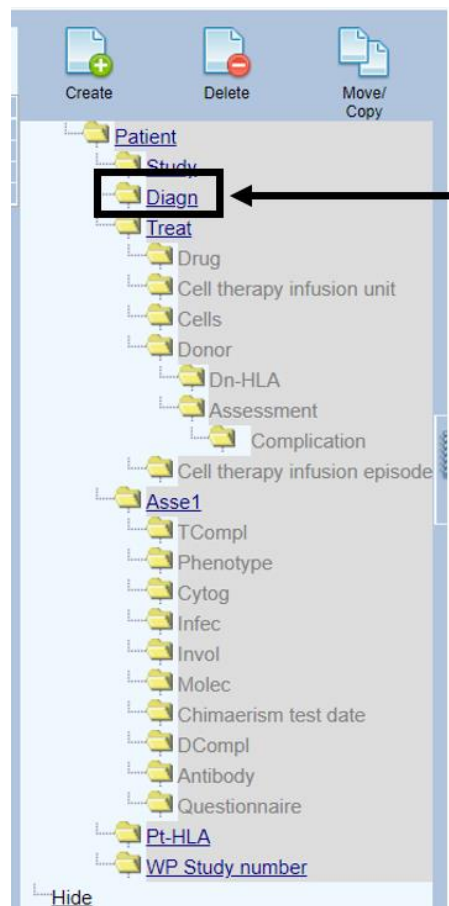


ENTERING THE DIAGNOSIS DATA

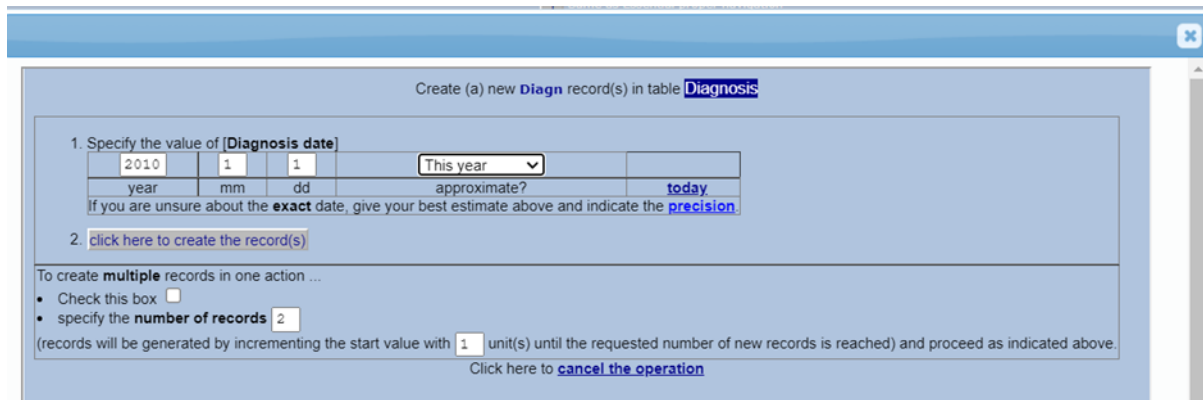
To add a diagnosis to the patient, select the paper icon with the +:



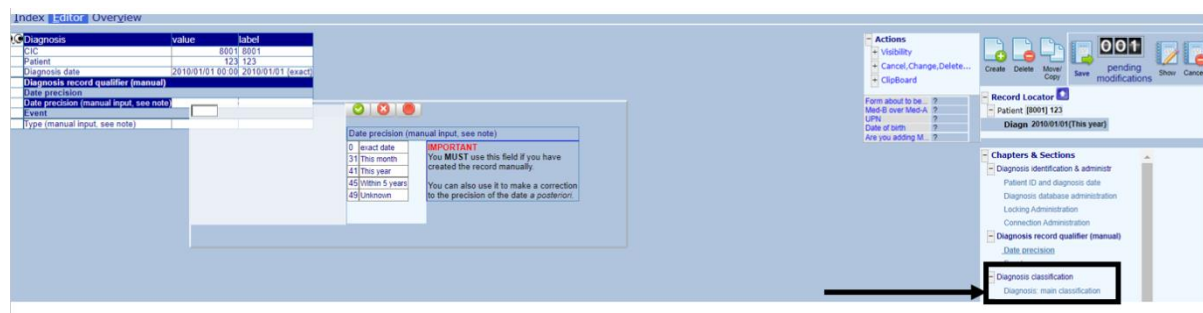
Upon clicking the item, a list of items that can be added to the patient record appears. Select the 'diagnosis':



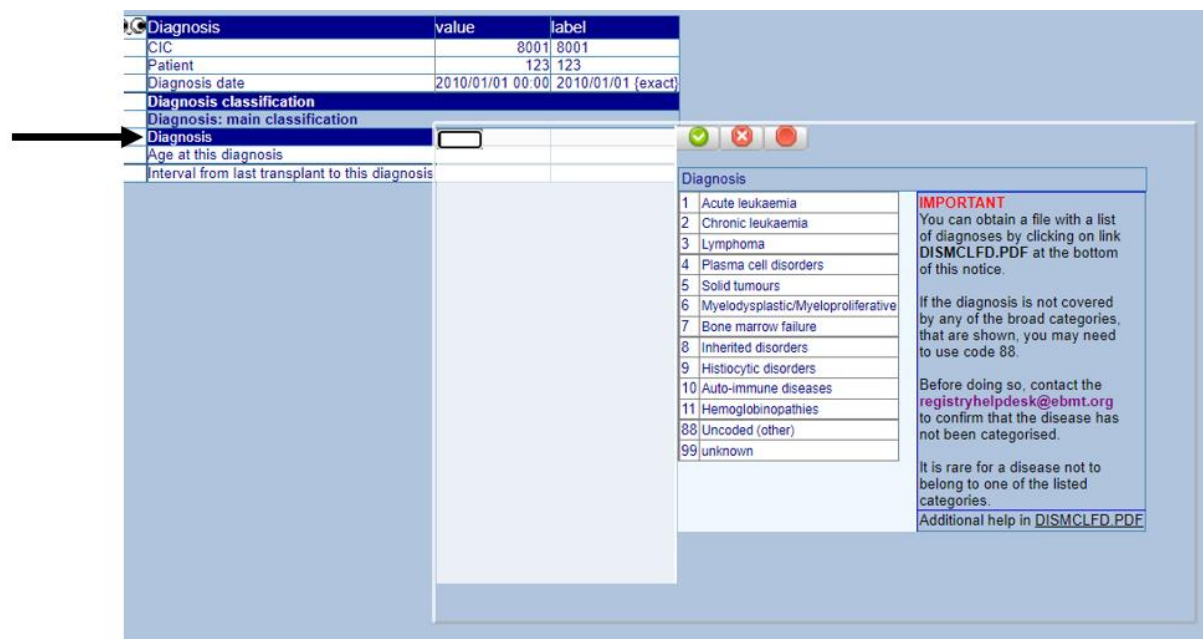
Specify the year of the diagnosis. For month and date you can fill in 1 and 1 (first of January), and click 'click here to create the records':



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:



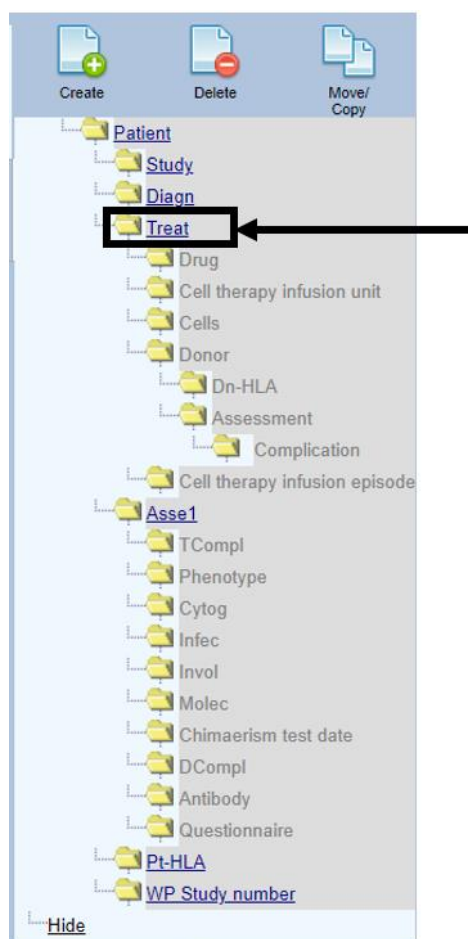
ProMISe will move to the diagnosis classification chapter. Select 'Diagnosis' and choose the appropriate classification from the list.



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):

Treatment	value	label
CIC	8001	8001
Patient	123	123
Treatment date	2011/01/01 00:00	2011/01/01 (exact)
Treatment record qualifier (manual)		
Date precision		
Date precision (manual input, see note)	41	This year
Event		
Context (manual input, see note)		

Context (manual input, see note)

- 2 Non graft treatment
- 4 Collection
- 7 Hematopoietic stem cell transplant
- 14 Support / Boosts
- 17 Donor lymphocyte infusion
- 18 Cell therapy (non HSCT/DLI)

IMPORTANT
You **MUST** use this field if you have created the record manually.
You can also use it to make a correction to the context of this treatment *a posteriori*.

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':

Treatment	value	label
CIC	8001	8001
Patient	123	123
Treatment date	2011/01/01 00:00	2011/01/01 (exact)
Treatment record qualifier (manual)		
Date precision		
Date precision (manual input, see note)		
Event		
Context (manual input, see note)		

Chapters & Sections

- Treatment identification & admin
- Treatment record qualifier (manual)
- Transplant and cell source specifics
- Transplant
- Tissue source
- Number of the transplant
- Previous transplant
- Graft program
- In-vivo graft manipulation

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	8001	8001
Patient	123	123
Treatment date	2011/01/01 00:00	2011/01/01 (exact)
Transplant and cell source specifics		
Type of transplant		
Specify if HSC transplant unusual		
Multiple donors		
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		
Donor the same as previous transplant		
Date previous transplant		
Type of previous transplant		

Entering details for a CAR-T

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

Treatment	value	label
CIC	8001	8001
Patient	123	123
Treatment date	2011/01/01 00:00	2011/01/01 {exact}
Treatment record qualifier (manual)		
Date precision		
Date precision (manual input, see note)		
Event		
Context (manual input, see note)		

Actions

Form about to be ... ?

Med-B over Med-A ?

UPN ?

Date of birth ?

Are you adding M ... ?

Record Locator

Patient [8001] 123

Treat 2011/01/01 (This year)

Chapters & Sections

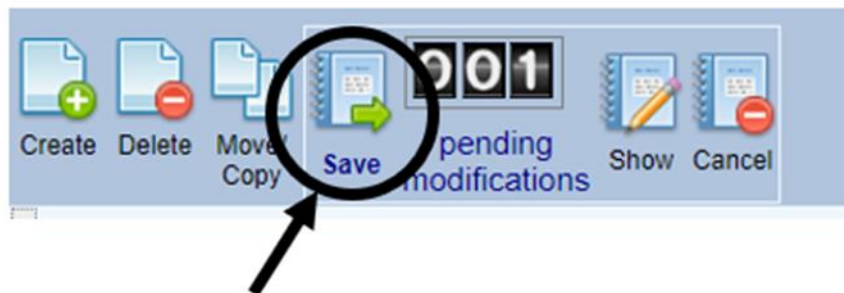
- Treatment Identification & administr
 - Patient ID and treatment date
 - Treatment database administration
 - Locking Administration
 - Connection Administration
- Treatment record qualifier (manual)
 - General
 - Transplant and cell source specifics
 - Ex-vivo graft manipulation
 - Main treatment
 - Hospital admin (STABMT)
 - Supportive treatment in the patient
 - Cellular therapy (non HSCT)**
 - Cellular therapy (non HSCT)
 - Cell characteristics
 - Infusion units count
 - Previous cell therapy treatment
 - Indication is the primary disease
 - Indications or previous treatment ...
 - Infusion episodes count
 - Infusion and dosing
 - Associated procedure

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		
Autologous stem cells from the patient (boost) without conditioning		
Cell characteristics		
Date DLI or other cell infusion started		
Cell origin		
Product manufactured 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 infusion unit same as for previous cell therapy treatment		
Date previous cell therapy treatment		
Type of 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.