European Society for Blood and Marrow Transplantation



Instructions on how to enter informed consent data for patients registered in ProMISe



## INTRODUCTION

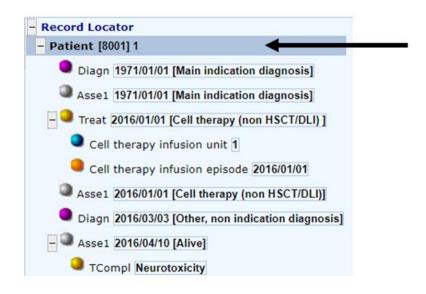
This document explains how to add informed consent data to patients who have already been registered in ProMISe. This document is not applicable for entering informed consent data for new patients.

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

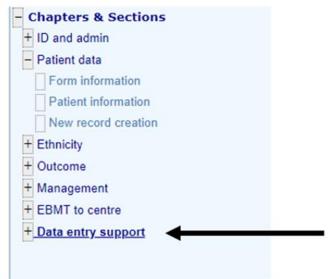
If you have any queries or any issues with data entry, please contact the Registry Helpdesk at registryhelpdesk@ebmt.org

## TURNING OFF THE DYNAMIC ITEM FILTER

Select the patient record that requires consent data to be added to in the ProMISe record locator. Open the patient record. It should look like this:



In the Chapters & Sections menu, select 'Data entry support':





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 16 to 0, and the table will expand:

Patient		abel	+ Actions	
	8001			
Patient	1	1	Form about to be Cell Therapy: 6 month or Annual	Create Delete Move/ Copy Save modifications Show C
Data entry support Section 0			Med-B over Med-A ?	- Record Locator
Exclusion from general analysis			UPN hgb1	- Patient [8001] 1
Reasons for exclusion from analysis			Date of birth 1970/01/01 Are you adding M 2	
Centre responsible for follow up			we loo sound at a	Diagn 1971/01/01 [Main indication diagno
Interval since last follow up if patient alive				Asse1 1971/01/01 [Main indication diagno
Date follow up requested				
Navigation items				- Treat 2016/01/01 [Cell therapy (non HSCT
Used to copy values during navigation				
Used to copy values during navigation				Cell therapy infusion unit 1
Used to copy values during navigation				Cell therapy infusion episode 2016/01/
s this a non-transplant registration?				
Copies the BOVERA1 into here. It is still in use!!! Last dated record created	2016/06/06	2010/02/02		Asse1 2016/01/01 [Cell therapy (non HSC]
Last dated record created	2010/06/08	2010/06/06		Diagn 2016/03/03 [Other, non indication d
Last coded record created	VPATSTAT	VPATSTAT		
Last ICD code record created	TRISIAI	TRISIAI		- Assel 2016/04/10 [Alive]
(Target when using 'alerts')				TCompl Neurotoxicity
[Copy of OUTQUERY]				
More items				- Chapters & Sections
Patient asked to consent to data submission?				+ ID and admin
s your centre using the EBMT Cellular Therapy informed consent form?	2			Patient data
Date of informed consent				
Consent to data sharing with health authorities/researchers?				Form information
Consent to data sharing with HTA?				Patient information
Consent to data sharing with MAH?				New record creation
Consent to review medical records?				+ Ethnicity
Used as target for pop up functions)				
(Test: Visibility to general users and managers)				+ Outcome
				+ Management
				+ EBMT to centre
				+ Data entry support

## **ENTERING THE CONSENT DATA**

The only question about informed consent that needs to be filled in, is the top one from the 'More items' section of the patient table:

More items	
Patient asked to consent to data submission?	
Is your centre using the EBMT Cellular Therapy informed consent form?	
Date of informed consent	
Consent to data sharing with health authorities/researchers?	
Consent to data sharing with HTA?	
Consent to data sharing with MAH?	
Consent to review medical records?	
{Used as target for pop up functions}	
{Test: Visibility to general users and managers}	

**Note:** The question 'Patient asked to consent to data submission?' should be interpreted as: '**Did the patient consent to having their data submitted to EBMT?**'



Upon clicking the question, a pop-up with answer options will appear. Please note that some of the answers seen below may not be visible to you:

Pa	tient asked to consent to da	ta submission?
1	No	
2	Yes	
3	Dead before law application	
4	Died before chance to request	
99	unknown	

- > If the patient did not give their consent to share their data with EBMT, click 'No' or type '1'.
- > If the patient consented to share their data with EBMT, click 'Yes' or type '2'.
- The option 'Dead before law application' is not applicable. Do not select this option, if it is visible.
- The option 'Died before chance to request' should not be used. Do not select this option, if it is visible. Instead 'No' should be selected.
- > The option 'unknown' should not be used. **Do not select this option, if it is visible.**

The navigation will automatically move to the next question. This question does not need to be answered. Save your updated consent data by clicking 'Save' next to the pending modifications:



## TURNING THE DYNAMIC ITEM FILTER BACK ON

After the informed consent information 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 go back from 0 to 16. The dynamic item filter is now turned on. This is the final step.