

***European Society for Blood and Marrow
Transplantation***



***Registry 62: Instructions on how to enter informed
consent data into ProMISe***

Version 1.0

Effective 23/05/2022

INTRODUCTION

This document explains how to complete the new informed consent items for new patients in ProMISe. These items are part of the dynamic item filter for day 0 forms since May 23rd, 2022.

This document is not applicable for entering informed consent data for already registered patients.

This document is divided into 2 sections:

The first section, 'Entering consent data', provides an overview of the new informed consent items in ProMISe and shows examples. The second section, 'Definitions of questions' provides a detailed explanation of each new question.

For any issues with data entry, please contact the Registry Helpdesk at registryhelpdesk@ebmt.org.

ENTERING CONSENT DATA

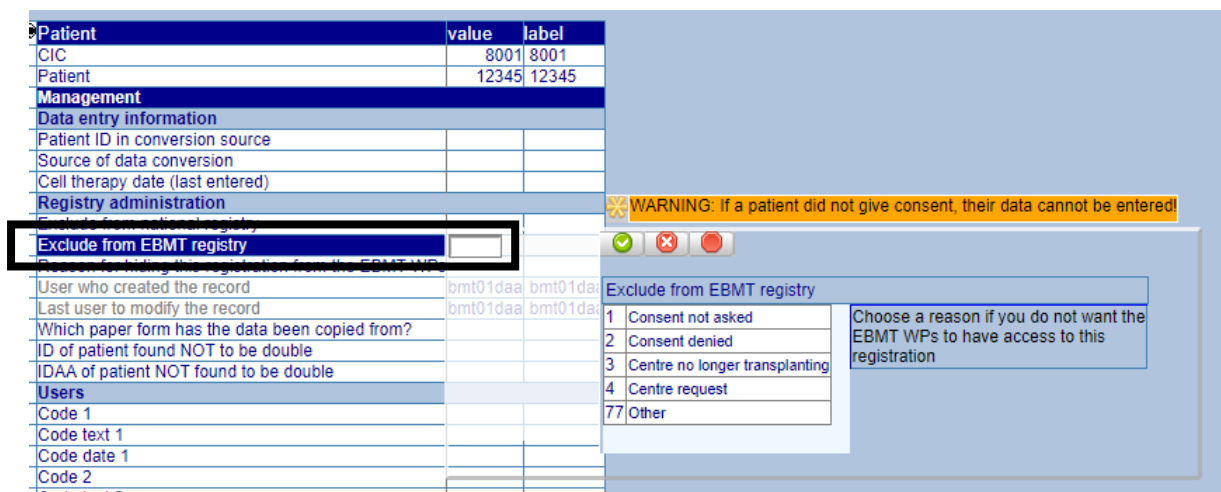
After creating a patient in ProMISe, the form about to be entered has to be selected. If any of the **Day 0** forms are selected (**MED-A**, **MED-B** or **CT**) the navigation will move to informed consent data. These items need to be filled in before further data entry can take place.

The new questions are part of the patient table, under *Data entry support*, as shown in figure 1:

Patient	value	label
CIC	8001	8001
Patient	12345	12345
Data entry support		
Section 0		
Navigation items		
More items		
Patient asked to consent to data submission?		
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?		

Figure 1 Informed consent items in ProMISe

The first question is 'Patient asked to consent to data submission?'. If the answer to this question is no, the navigation will move to the field to exclude this patient from the registry (figure 2). A reason for the missing consent must be given here. If the patient did not consent to sharing their data with EBMT, the patient's data cannot be entered.



Patient	value	label
CIC	8001	8001
Patient	12345	12345
Management		
Data entry information		
Patient ID in conversion source		
Source of data conversion		
Cell therapy date (last entered)		
Registry administration		
Exclude from EBMT registry	<input type="checkbox"/>	
User who created the record	bmt01daa	bmt01daa
Last user to modify the record	bmt01daa	bmt01daa
Which paper form has the data been copied from?		
ID of patient found NOT to be double		
IDAA of patient NOT found to be double		
Users		
Code 1		
Code text 1		
Code date 1		
Code 2		
Code text 2		

WARNING: If a patient did not give consent, their data cannot be entered

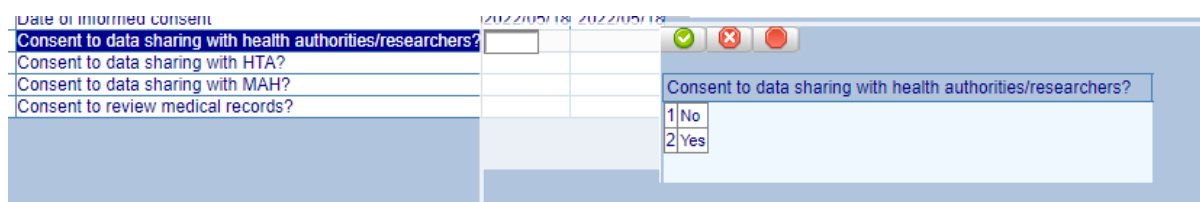
Exclude from EBMT registry

Choose a reason if you do not want the EBMT WPs to have access to this registration

- 1 Consent not asked
- 2 Consent denied
- 3 Centre no longer transplanting
- 4 Centre request
- 77 Other

Figure 2 Item for excluding patient from EBMT Registry

If the patient did consent to sharing their data with EBMT, the subsequent questions in the table need to be filled in. These do not affect the rest of the data entry, only the way the data will be used by EBMT. Except for the date item, all questions can only be answered with 'No' or 'Yes' as presented in figure 3:



Date of informed consent	12/22/2018	20/22/2018
Consent to data sharing with health authorities/researchers?	<input type="checkbox"/>	
Consent to data sharing with HTA?		
Consent to data sharing with MAH?		
Consent to review medical records?		

Consent to data sharing with health authorities/researchers?

- 1 No
- 2 Yes

Figure 3 Answer options to consent questions

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?**’.

Eventually, the section could look like this:

Patient	value	label
CIC	8001	8001
Patient	12345	12345
Data entry support		
Section 0		
Navigation items		
More items		
Patient asked to consent to data submission?	2	Yes
Date of informed consent	2022/05/18	2022/05/18
Consent to data sharing with health authorities/researchers?	2	Yes
Consent to data sharing with HTA?	2	Yes
Consent to data sharing with MAH?	1	No
Consent to review medical records?	1	No

After filling in the last item of the list, ‘Consent to review medical records?’ the navigation will continue as usual, starting from the *Name of unit or team for the HSCT or Cell therapy* in the *Patient information* chapter.

DEFINITIONS OF QUESTIONS

In this section, the new questions for informed consent are explained in detail as well as how to proceed with the data entry after each answer.

Was the patient asked to consent to data submission?

Indicate whether the patient or their legal guardians were asked if they consent to sharing their data with EBMT.

If the answer to this question is ‘no’, no further data entry can take place. If the answer is yes, the navigation will move on to the next question.

Date of informed consent

Indicate the date informed consent was given (by signing an informed consent form) by the patient or their legal guardians. Report the date as year/month/day.

If the date is partially known, use the following criteria to fill in the date field:

- If only the exact day is unknown, use the first day of the month to report the date, for example: 01-05-2020
- If both the day and month are unknown, use the first of January to report the date, for example: 01-01-2020

Consent to data sharing with health authorities/researchers?

Indicate whether the patient or their legal guardians consent to having their pseudonymized data shared with health authorities and/or researchers.

Consent to data sharing with HTA?

Indicate whether the patient or their legal guardians consent to having their pseudonymized data shared with Health Technology Assessment bodies (a public organisation that provides recommendations on medicines and other healthcare interventions that can be paid for or reimbursed).

Consent to data sharing with MAH?

Indicate whether the patient or their legal guardians consent to having their pseudonymized data shared with Market Authorization Holders (e.g.: Pharmaceutical Companies).

Consent to review medical records?

Indicate whether the patient or their legal guardians consented to allow monitors to review the patient's pseudonymized medical records.