

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



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

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.

These instructions are not applicable for entering informed consent data for already registered patients, as this is described in a separate document available at the EBMT website: <https://www.ebmt.org/registry/data-collection>.

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, please follow the instructions on how to enter minimal essential data for non-consenting patients in ProMISe available at the EBMT website: <https://www.ebmt.org/registry/data-collection>.

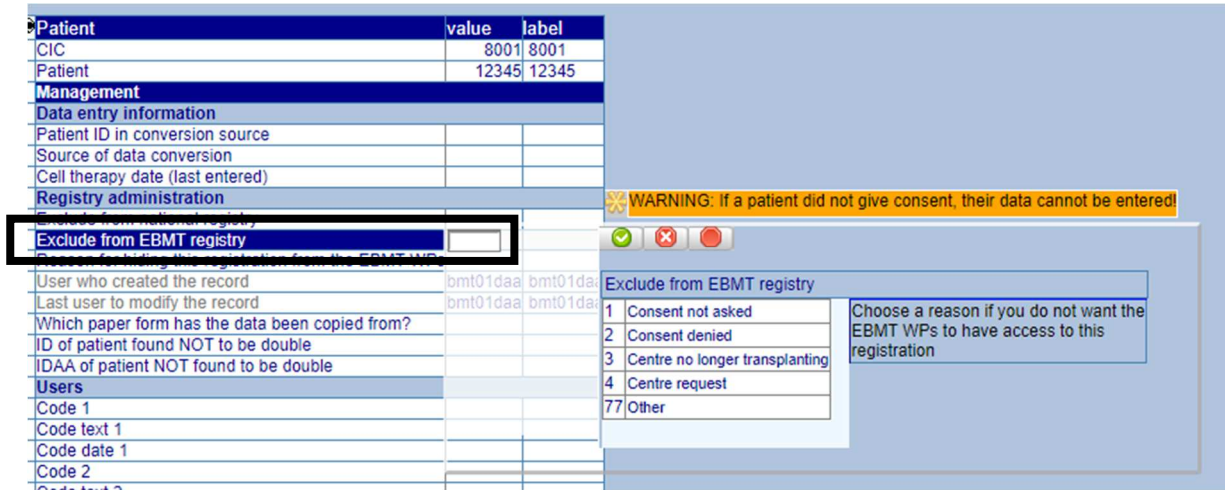


Figure 2 Item for excluding patient from EBMT Registry

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:

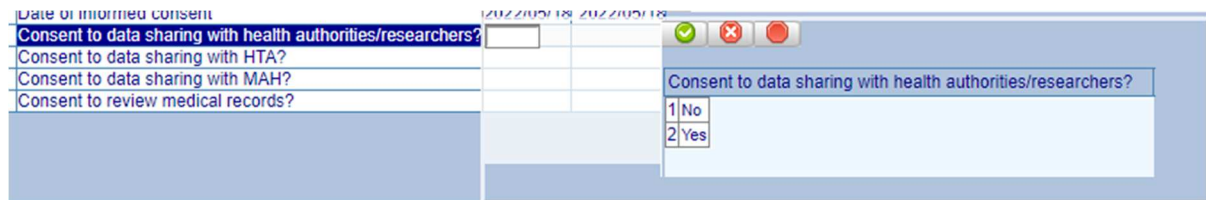


Figure 3 Answer options to consent questions

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', the centre may enter into ProMISe only minimal essential data.
- 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.