

EBMT

European Society for Blood and Marrow
Transplantation

Submitting data to the EBMT

*A guide to the submission of data to
the EBMT*



GETTING STARTED

How to submit your HCT data or other Cellular therapy (CT) data to the EBMT

The helpdesk team handles all data registration issues and you can contact us with any data submission queries. All data registration information and documents are located in “The Registry” section of our web site: <https://www.ebmt.org/ebmt-patient-registry>

Please apply to use ProMISe to access the EBMT data capture tool for data entry of HCT data or Castor EDC for data entry of Cellular Therapy data. If you belong to a National Registry that has a partnership with EBMT, please also contact them directly for further info on how to submit your data. You can view the list of affiliated registries [here](#).

Applying to use ProMISe

ProMISe (Project Manager Internet Server) is the central data management system used by the EBMT. Users are able to enter and retrieve data directly over a secure Internet connection. All users access the same copy of the entire project, but users have the option to download their own centre database for reference purposes. The only software necessary is a web browser such as Google Chrome or Microsoft Edge. When online, centres can access either the complete database for an overview of all EBMT data, or their centre database, to view and enter data for their own centre. You can access [ProMISe](#) online. It is possible to test your computer for compatibility using the [Interactive Browser Configuration checker](#).

You may need to update your Internet browser or change your screen settings. The [user manual](#) on our Data Submission web page has further instructions

There are 2 types of ProMISe access available:

- Data Entry (one password per person - full access to your centre data including data modification). Click here to download the [Data Entry application form](#)
- Download only (one password per person - full access to your centre data excluding data modification). *This option is recommended for team members who do not enter data but wish to view their centre's data.* Click here for the [Data Download application form](#)

If you are submitting data to your national HCT registry as well as the EBMT, do not forget to tick the box allowing your organisation to have access to your data.

The signed application form can be scanned and emailed to registryhelpdesk@ebmt.org

ProMISe Support & Training

When you apply to use ProMISe, we will send you instructions on how to access the Registry database, with the link to the user manual. The Helpdesk is available if you experience any problems or have any queries while using the database. ProMISe users receive news updates, and training sessions are organised in conjunction with EBMT meetings/national societies. Online training videos are available on <https://www.ebmt.org/registry/data-submission#guides>

Please email registryhelpdesk@ebmt.org for any further information.

Applying to use Castor EDC

Castor is a cloud-based clinical data collection management platform where the information related to Cellular Therapy studies is stored. Users are able to enter and retrieve data directly over a secure Internet connection. All users have the option to download their own centre data for reference purposes. The only software necessary is a web browser such as Google Chrome or Microsoft Edge and a two factor authentication application on the phone or the computer.

There is one access request document available for Castor EDC:

- Castor Personal Access Request for Data Entry: This document specifies the users authorised to access and edit the data of a particular centre and requires the signature of that centre P.I. Click here to download the [Access Request form](#).

If you are submitting data to your national registry as well as the EBMT, do not forget to tick the box allowing your organisation to have access to your data.

The signed application form can be scanned and emailed to cellulartherapyhelpdesk@ebmt.org.

Castor Support & Training

Before you can apply for access to Castor EDC, it is necessary to finish the Castor EDC Fundamentals course available at [EBMTs e-learning platform](#). The course, available for members as well as non-members will award the user a certificate upon completion. With this certificate, together with the Access Request form, users can request access to the platform via cellulartherapyhelpdesk@ebmt.org.

In addition to the e-course, a handbook that explores aspects of Cellular therapy data entry at Castor EDC is also available [here](#). Furthermore, Castor itself offers online free courses available for everybody at [Castor Academy](#).

Please email cellulartherapyhelpdesk@ebmt.org for any further information.

Data Collection forms

We have 2 sets of standard Data Collection Forms for HCT and you can choose to submit either MED-A, or MED-B.

The MED-A form contains the minimum essential data that must be submitted by members for every transplant performed since joining EBMT.

The MED-B forms are more detailed and provide more of the information that can be used in studies.

We request MED-A reports on day 0 (or within a week of day 0), then post transplant info at day 100, plus a follow up every year.

MED-A or MED-B forms are available to [download online](#). We have also compiled a [MED-AB manual](#), prepared by the Working Parties and revised by the Definitions Group. This document is available on the same web link and contains detailed notes and background information to help data managers who submit registrations.

Donor Outcome forms and a manual are also available [here](#). It is already mandatory to follow up donors in some countries.

For Cellular therapies we have three Data Collection Forms for the different time periods of the treatment. All of these are considered MED-A forms.

The Pre-Infusion Registration form contains the information relative to the diagnosis and pre-infusion stages of the treatment.

Day 0 form contains information about the day of the cell infusion.

Follow up forms that contain questions relative to the different follow ups after the cell infusion. In particular, the follow ups are divided into Day 100, 6 Months and Annual follow up.

These forms are available to [download online](#) under Cellular Therapy Forms. In addition to that, there is also a [Cellular Therapy Manual](#) which contains information to help data managers and data entry personnel to submit registrations and a [Data Entry handbook](#) that explains practical aspects of Data Entry in Castor from account creation to data modifications and export.

Please see over for more detailed information on the data collection forms. Should you have any queries relating to data reporting please do not hesitate to contact us.

We look forward to working with you.

The [EBMT Registry Office](#) team.

Data Sharing

We have agreements in place with a small number of organisations so that you only have to submit the data once if you have a commitment to also send them data. Please see the link below for more info and request forms. <https://www.ebmt.org/registry/data-sharing>

MED-AB DATA COLLECTION FORMS

Please read carefully before completing the forms

The MED-AB & Cellular therapy forms contain all items requested by the Working Parties. There is a MED-A (Minimum Essential Data) form: For hematopoietic stem cell transplantation (HCT).

This form should be entered on the day of transplant (or within a week of day 0), then the remainder at 100 days post-transplant or at time of death, whichever occurs first. Patients who die between conditioning and transplant should be reported.

It is also very important to update the follow up on a regular basis. Please see intervals below.

MED-A for HCT: Download form [here](#)

This is the essential set of variables used for registration of all hematopoietic stem cell transplants performed.

We ask that you enter data on the following:

- Day 0 registration for each transplant, including the disease specific section according to the indication for transplant
- Day 100 report
- Follow up form (see intervals below)

The EBMT requests follow up at the following intervals:

- Every year if the patient was transplanted less than 10 years ago
- Every 2 years if the patient was transplanted between 10 and 20 years ago

- Every 5 years if the patient was transplanted more than 20 years ago

Cell Therapy: Download from [Cellular Therapy Forms](#)

The Cellular therapy forms are divided in three documents:

- The Pre-Infusion Registration form contains the information relative to the diagnosis and pre-infusion stages of the treatment.
- Day 0 form contains information about the day of the cell infusion.
- Follow up forms that contain questions relative to the different follow ups after the cell infusion. In particular, the follow ups are divided into Day 100, 6 Months and Annual follow up.

MED-B for HCT: Download forms [here](#)

This larger set of specialised forms is used to provide detailed information on each transplant. It includes all the variables in the MED-A form for HCT. For this reason, if the MED-B forms are completed there is no need to also complete the MED-A form.

We ask that you enter the following for each transplant (At Day 0, then at Day 100):

- Disease Specific Form corresponding to the indication for transplant; this form is preceded by a page with General Information
- Transplant Specific Form corresponding to the type of transplant performed (Autograft or Allograft)
- Disease Specific Follow Up - Annual
- if applicable, the corresponding forms in the Forms Appendix (Cord Blood, TBI etc)

Form Completion Guides:

Manuals and Clinical Reference Documents (including a full [MED-AB manual](#)) are also available on the MED-AB forms web page