EBMT Registry

Immunosuppressive treatment (IST)

Day 0

Guide to the completion of the EBMT data collection form:

IST_Day0_v2.0

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EBMT Registry

EBMT Clinical Research & Registry Department

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Introduction

Please make sure you have already checked the **Introduction to the EBMT Registry Completion Guidelines** document latest version available under *Manuals and Reference Documents* section on EBMT website.

Immunosuppressive Treatment (IST) day 0

(For Bone Marrow Failure only)

IST Day 0 treatment form refers to immunosuppression and must be filled in for patients who either received immunosuppression only or immunosuppression regimen(s) before subsequent HCT. The immunosuppressive treatment (IST) day 0 form should be filled in for each individual IST episode at the start of the treatment.

Please also complete a **Status at HCT/CT/IST** form to report the status of the patient at the start of the IST.

An immunosuppressive treatment (IST) episode is defined as any treatment combination containing one of the following components:

- **Alemtuzumab**
- **Androgens**: Danazol, Etiocholanolone, Fluoxymesterone, Nandrolone, Norethandrolone, Oxandrolone, Oxymetholone, Testosterone
- **Anti-CD20 antibodies** (e.g. Rituximab)
- **ATG**
- **Corticosteroids**: Beclometasone, Budesonide, Dexamethasone, Methylprednisolone, Prednisolone
- **Cyclophosphamide**
- **Cyclosporin**
- **Growth factors**: Filgrastim, Lenograstim, Pegfilgrastim
- **Mycophenolate mofetil**

Date this IST episode started

Report the start date of the immunosuppressive treatment episode.

Centre where treatment took place (CIC)

Indicate CIC of the centre where the treatment took place.

Patient UPN for this treatment

Report the patient UPN (hospital unique patient number).

Team or unit where treatment took place (select all that apply)

Indicate whether the HCT took place in an adults or paediatrics unit under the supervision of the haematology or oncology team. Select if the patient received an allograft, autograft or other treatment.

Indication diagnosis for this IST episode

Specify what primary disease is the indication for this IST episode. Make sure that the respective **Indication diagnosis** form was filled before completing the IST Day 0 form.

Chronological number of this treatment

Indicate the chronological number of the current treatment among other treatments (HCT, CT, GT, IST) received by the patient throughout his/her lifetime, regardless of whether the previous treatments have been performed in your centre or other centres. It is NOT the serial number of the current treatment within all the treatments performed in your centre, and it is NOT the number of the treatments that this patient has received in your centre only.

The information about the chronological number can be obtained from the patient's medical history record.

Reason for this IST episode

Select the primary reason for the IST episode from the list:

- **First line treatment (for primary disease for which the reported treatment is being given)**
- **Failure of first line therapy;**
- **Relapse;**
- **PR to previous treatment;**

Otherwise select **Other** and specify the reason in the textbox.

Patients often receive more than one course of immunosuppression, and can have a complex treatment history. It is important to know the reason why each line of IST was given.

Select **Unknown** if the reason for the IST episode is not known.

Chronological number of this IST episode

The chronological (sequential) number of the treatment episode should be counted from the very first immunosuppressive treatment episode for the patient, which may have been already registered.

Transfusions

Complete this section only if this is the **first IST episode ever** for this patient.

Number of transfusions before the 1st IST episode

Red blood cells (RBC) transfusions given

Indicate if any RBC transfusions were given before the 1st IST episode by selecting **No** or **Yes**. Answer **Unknown** if it is not known whether or not RBC transfusions were given prior to the 1st IST episode.

Number of RBC transfusions given

Count and indicate the total number of red blood cells (RBC) units transfused before the start of IST by ticking an appropriate checkbox:

- **< 20 units;**
- **20 - 50 units;**
- **> 50 units.**

Answer **Unknown** if there is no information on RBC transfusions in the patient's medical records.

RBC irradiated

Indicate if RBC were irradiated (answer **Yes**), not irradiated (answer **No**) or if it is unknown (answer **Unknown**).

Platelets

Indicate if any platelets transfusions were given before the 1st IST episode by selecting **No** or **Yes**. Answer **Unknown** if it is not known whether or not platelets transfusions were given prior to the 1st IST episode.

Number of platelets transfusions given

Count and indicate the total number of platelets transfused before the start of IST by ticking an appropriate checkbox:

- **< 20 units;**
- **20 - 50 units;**
- **> 50 units.**

Answer **Unknown** if there is no information on platelet transfusions in the patient's medical records.

Platelets irradiated

Indicate if platelets were irradiated (answer **Yes**), not irradiated (answer **No**) or if it is unknown (answer **Unknown**).

Immunosuppression

Make sure you fill in the immunosuppression separately from the conditioning regimen (if the patient later received a transplant) even if the same drugs are mentioned for both treatments (e.g. ATG or cyclophosphamide may be used both for immunosuppression and conditioning). Supportive drugs given along with immunosuppression treatment in order to ameliorate side effects of treatment or improve response: e.g. corticosteroids and eltrombopag can be reported in this section too.

Drugs used for immunosuppression during this IST episode (check at least one)

The list contains the main drugs for immunosuppression and supportive therapy used. Check one or more of the drug options or check the box **Other** and specify the name of a drug.

Please consult the LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS on the EBMT website for drugs/regimens names.

Product name

For Anti-Thymocyte Globulin (ATG), indicate the name of the product.

Origin

For Anti-Thymocyte Globulin (ATG), indicate the animal the product originated from.

Start Date

Report the date this line of treatment was started.

Stop Date

Report the date this line of treatment ended.