EBMT Registry

Haematopoietic cell transplantation (HCT) day 100 follow-up

Guide to the completion of the EBMT data collection form: HCT_FU_D100_Core_Extended_v2.4

09 January 2026

EBMT Registry

EBMT Clinical Research & Registry Department

Co-funded by the European Union

Co-funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.

Table of Contents

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.

HCT Day 100 Follow-Up

The follow-up of HCT patients should be recorded using the HCT Day 100 form. The data on this assessment should reflect the patient's status on the day the patient was last seen, closest to 100 days post-HCT. If the patient died within 100 days, the data from the last date the patient was seen alive can be used.

Date of follow-up

Report the date that the HCT Day 100 follow-up occurred. If the patient died, enter the date of death. If the patient was lost to follow-up, enter the date the patient was last seen alive.

Survival status

Indicate if the patient is last known to be **Alive** or **Dead** on the date of follow-up previously noted. If the patient is lost to follow-up, tick the box for **Lost to follow-up**.

Main cause of death

Report only one main cause of death, even if it was considered to be a combination of various causes . If the cause of death is not known, select **Unknown**. Please select one of the following main causes of death:

- **Relapse or progression/persistent disease**
- **Secondary malignancy**
- **Cellular therapy-related** - death caused by complications or infections after cellular therapy)
- **HCT-related** - death caused by complications or infections after transplant
- **Gene therapy-related** - death caused by complications or infections after gene therapy
- **IST-related** - death caused by complications or infections after immunosuppressive treatment

If none of the suggested options fit, select **Other** and specify the cause of death in the textbox in English.

Select treatment related cause

In the case of treatment-related cause of death, select all the answer options that apply:

- **Graft versus host disease (GvHD);**
- **Non-infectious complication;**
- **Infectious complication.**

Infectious complication

In the case of an infectious complication, please specify the type of infection. In case of multiple infections with different pathogens. Select all the type of infection(s) that apply:

- **Bacterial infection**
- **Viral infection**
- **Fungal infection**
- **Parasitic infection**
- **Infection with an unknown pathogen**

Please note that the category “rejection/poor graft function or failure” as contributory cause of death (previously in MedAB (auto, allo and disease-specific forms)) does not exist since the cause of death following a graft failure is generally an infection.

Autopsy performed

Check **No**, if no autopsy has been performed. Check **Yes** if autopsy is performed. Check the box **Unknown** if it is unknown whether an autopsy was performed.

Best Response

The disease specific options for the best response can be found in Appendix 1 - Disease specific best response and disease status. This section is not applicable for patients receiving HCT for Inborn errors indication diagnosis.

Best clinical/biological response after HCT

Report the patient’s best response achieved after HCT but before any subsequent treatment, even if the patient got worse again afterwards. If the best response after the HCT has not been evaluated, select **Not evaluated**. If the best response after the HCT is unknown, select **Unknown.**

The best response is often achieved in the first 100 days. However, for some diseases the best response to HCT may take longer and shall be reported in the first annual follow-up form (e.g. PCM). For all indication diagnoses except for inherited disorders, report the best response achieved as per the date of follow-up. In case HCT was performed for inherited disorders, this section can be left blank.

If the patient had a relapse/progression post-HCT and received therapy for the disease relapse/progression, the response to that additional therapy should not be reported in this section. The best response prior to the relapse/progression should be reported here. The response should be captured before the start of unplanned treatment of underlying disease.

Date best response first observed

Report the date the best response was first observed. The response date is the date that the sample or image was taken for assessing the response. If the patient's best response was already achieved prior to HCT (eg. HCT in CR and best response CR) the first evaluation date after the HCT should be reported. If the date is unknown, select **Unknown**.

Recovery

Absolute neutrophil count (ANC) recovery (neutrophils ≥ $0.5x10^9$/L)

Absolute neutrophil count (ANC) recovery is considered to take place when the number of neutrophils in the patient's peripheral blood rises to at least $0.5x10^9$/L. Please note this is regardless of the use of growth factors and neutrophils level should be confirmed by three consecutive laboratory values obtained on different days.

Answer **No (**and proceed to Date of the last assessment) if ANC <$0.5x10^9$ cells/L

Answer **Yes** if the absolute count of neutrophils post-HCT is higher or equal to $0.5x10^9$ cells/L for 3 laboratory values (and proceed to Date of ANC recovery).

If the absolute count of the patient's neutrophils was never below $0.5x10^9$ cells/L, the answer **Never below** must be chosen instead of answer **Yes.** This may happen in non-myeloablative transplants.

Mark the ANC as **Unknown** if it was not assessed post-HCT.

Date of the last assessment

Indicate the date of the last assessment of the patient's neutrophils level.

Date of ANC recovery

The date to be entered is the first date out of the 3 consecutive neutrophil counts above $0.5x10^9$ cells/L were recorded on different days. This date must be at least 7 days after the last transfusion containing neutrophils.

Platelet reconstitution (platelets ≥$20x10^9$ cells/L)

Indicate whether or not there was platelet reconstitution achieved that is confirmed by 3 consecutive blood tests where absolute count of platelets is ≥$20x10^9$ cells/L. All dates should reflect no transfusions in the previous 7 days.

Answer **No** (and proceed to Date of the last assessment) if the platelet count was <$20x10^9$ cells/L or if platelet transfusions were administered in the previous 7 days.

Answer **Yes** (and proceed to Date of platelet reconstitution) if the platelet count ≥ $20x10^9$ cells/L was achieved and sustained for 3 consecutive laboratory values, obtained on different days without platelet transfusions administered in the previous 7 days.

Answer **Never below**, if the recipient's platelets never dropped below $20x10^9$ cells/L at any time post-HCT and a platelet transfusion was never required. If the recipient's platelet count drops below $20x10^9$ cells/L and/or the recipient received a platelet transfusion even once, do not use this option. This option is only applicable in the 100 day follow-up reporting period.

Answer **Unknown** if recipient's platelets were not assessed post-HCT.

Date of the last assessment

Indicate the date of the last assessment of the patient's platelets level, or if not known mark the date as **Unknown**.

Date of platelet reconstitution

The date to be entered is the first date out of the 3 consecutive platelets counts ≥ $20x10^9$ cells/L checked on different days and after 7 days without platelet transfusion. Mark as **Date unknown** if it is confirmed by medical record that patient achieved platelet reconstitution but the exact date of the first test with platelets counts ≥ $20x10^9$ cells/L is not known.

Date of the last platelet transfusion

Indicate the date when the patient received the latest platelet infusion within the 100 day follow-up period.

Graft function

Poor graft function

This question is only applicable if the follow-up is being reported for an allogeneic HCT.

Poor graft function is defined as frequent dependence on blood and/or platelet transfusions and/or growth factor support in the absence of other explanations, such as disease relapse, drugs, or infection. If poor graft function was observed - select **Yes**. If poor graft function was not observed, select **No**.

The definition for poor graft function assumes that donor chimaerism is within a desirable target level.

In contrast with graft failure, poor graft function requires some degree of allogeneic graft evidence. However, the "desirable" target level depends on the time point when it's measured, the indication for HCT (malignant versus non-malignant), intensity of the conditioning regimen, etc.

As an example, a patient with poor haematologic function but confirmation of donor source (proof of at least mixed/partial donor chimaerism), and in the absence of other explanations (disease relapse, drug toxicity, infections, GvHD, etc) represents a case of poor graft function. However, due to the dynamic nature of chimaerism, it is advisable to reassess donor chimaerism levels to confirm the results.

Note: please don't report graft failure in this section.

- If primary graft failure occurred, please report it in the Recovery section in Absolute neutrophil count (ANC) recovery (neutrophils ≥ 0.5x109/L).
- If secondary graft failure occurred, please report this through the Non-infectious complications section.

Date of poor graft function

Report the date when the patient started requiring frequent growth factor and/or packed RBC/platelets transfusions (at least weekly transfusions and/or growth factor support for at least 4 weeks) once other causes that could explain the poor graft function such as disease relapse, drugs, or infections have been ruled out.

Chimaerism

This section is only applicable for patients receiving an allogeneic HCT.

Complete this section for every chimaerism test performed within 100 days since HCT until complete donor chimaerism has been achieved (>95%). If the patient has mixed chimaerism (5%-95% for either one or both myeloid and lymphoid lineages), please, complete the section if the chimaerism results change at least 10% from the previous test.

Chimaerism test date

Report the chimaerism test date.

Source of cells tested

Indicate if **Peripheral blood** and/or **Bone marrow** was used as source of cells for the chimaerism test.

Cell types and test results

Select each cell type that was tested and indicate the percentage of donor cells. In case any other cell types were tested, please select Other and indicate the type of cells in the textbox in English.

Preventive Therapies

This section is only applicable for patients that received an allogeneic HCT.

Immunosuppression during this follow-up period?

This question is asked to know if the GvHD prevention initiated at transplant is still ongoing at this follow up.

Select **No** if the patient was not receiving preventive (immunosuppressive) therapy for GvHD post-transplant. Select **Yes** if the patient was receiving preventive therapy post-transplant. Report as **Unknown** if it is unknown if the patient was still receiving immunosuppressive GvHD preventive treatment.

Immunosuppression stopped?

If immunosuppression for GvHD prevention was stopped, please report **Yes** and provide the end date of the GvHD prevention. If the therapy is ongoing, select **No**. If it is not known if the patient is still on immunosuppressive treatment, select **Unknown**.

End date

Report the date the preventive treatment for GvHD was stopped. If the patient experiences a GvHD while receiving GvHD prevention, please report the date of onset of GvHD as the end date of GvHD prevention (as this becomes GvHD treatment rather than prevention). If the stop date was not known, select **Unknown**.

Letermovir used as CMV prophylaxis during this follow-up period?

Indicate whether the patient received letermovir as CMV prophylaxis during the follow-up period. Select **Unknown** if this information is unavailable.

Start date

If **Yes**, provide the start date of the letermovir regimen. Select **Unknown** if the start date is not known.

Letermovir treatment stopped

Indicate whether the letermovir regimen has stopped.

End date

If **Yes**, give the end date of the letermovir treatment. Select **Unknown** if the end date is not known.

Extended dataset

Antimicrobial prophylaxis

Did the patient receive prophylaxis for bacterial, viral or fungal infection?

Indicate if the patient received any type of prophylaxis.

If yes, what type of prophylaxis?

Check all types of prophylaxis the patient received.

Antibacterial

Antibiotic

Check all types of antibiotics that were administered as prophylaxis.

Phase

Select the phases (**pre-engraftment**, **post-engraftment**) during which the antibiotic was administered. If administered during the post-engraftment phase, indicate whether it was given only during post-engraftment, or whether it was a continuation from pre-engraftment into post-engraftment, or started and stopped during pre-engraftment and then restarted during post-engraftment. Select **unknown** if it is not known during what phase(s) the antibiotic was given.

Final date the antibacterial prophylaxis was discontinued

Report the date the patient last received any type of antibacterial prophylaxis, or select **unknown** if you do not know the final date antibacterial prophylaxis was administered, or select **ongoing** if the patient is still receiving antibacterial prophylaxis.

Antiviral

Did the patient receive CMV prophylaxis other than or in addition to letermovir ?

Choose **yes** if the patient received any type of CMV prophylaxis that is not letermovir. Choose **no** if the patient either received no CMV prophylaxis at all or received only letermovir. Letermovir is not included in this question as letermovir prophylaxis is a separate question in the core dataset.

Which drugs were used?

Check all types of drugs that have been administered as CMV prophylaxis. Please note that letermovir is not included here, as letermovir prophylaxis is a separate question in the core dataset. Please also do *not* include letermovir in the 'other drug' category.

Final date CMV prophylaxis was discontinued

Report the date the patient last received any type of CMV prophylaxis other than letermovir, or select **unknown** if you do not know the final date CMV prophylaxis other than letermovir was administered, or select **ongoing** if the patient is still receiving any type of CMV prophylaxis other than letermovir.

Only for allogeneic HCT: Did the patient receive prophylaxis for varicella-zoster virus (VZV) or herpes simplex virus (HSV) with either acyclovir or valacyclovir?

Indicate if either acyclovir or valacyclovir has been administered as VZV or HSV prophylaxis.

Final date VZV/HSV prophylaxis was discontinued

Report the date the patient last received either acyclovir or valacyclovir as VZV or HSV prophylaxis, or select **ongoing** if the patient is still receiving either acyclovir or valacyclovir as VZV or HSV prophylaxis, or select **unknown** if you do not know the final date either acyclovir or valacyclovir was last administered as VZV or HSV prophylaxis.

Only for allogeneic HCT: Did the patient receive rituximab or another anti-CD20 monoclonal drug as prophylaxis for Epstein-Barr virus (EBV) post-transplant lymphoproliferative disorder (EBV-PTLD)?

Indicate if any anti-CD20 monoclonal drug, including rituximab, has been administered as EBV-PTLD prophylaxis.

Did the patient receive prophylaxis for hepatitis B (HBV)?

Indicate if any type of HBV prophylaxis has been administered.

Which drugs were used?

Check all types of drugs that have been administered as HBV prophylaxis.

Final date HBV prophylaxis was discontinued

Report the date the patient last received any type of HBV prophylaxis, or select **ongoing** if the patient is still receiving any type of HBV prophylaxis, or select **unknown** if you do not know the final date HBV prophylaxis was administered.

Antifungal

Antifungal

Check all types of antifungals that have been administered as prophylaxis.

Phase

Select the phases (**pre-engraftment**, **post-engraftment**) during which the antifungal was administered. If administered during the post-engraftment phase, indicate whether it was given only during post-engraftment, or whether it was a continuation from pre-engraftment into post-engraftment, or stopped during pre-engraftment and then restarted during post-engraftment. Select **unknown** if it is not known during what phase(s) the antifungal was given.

Final date the antifungal prophylaxis was discontinued

Report the date the patient last received any type of antifungal prophylaxis, or select **unknown** if you do not know the final date antifungal prophylaxis was administered, or select **ongoing** if the patient is still receiving antifungal prophylaxis.

Did the patient receive prophylaxis for *Pneumocystis jirovecii* pneumonia (PJP)?

Indicate if any type of PJP prophylaxis has been administered.

Which drugs were used?

Check all types of drugs that have been administered as PJP prophylaxis.

Final date prophylaxis was discontinued

Report the date the patient last received any type of PJP prophylaxis, or select unknown if you do not know the final date PJP prophylaxis was administered, or select ongoing if the patient is still receiving PJP prophylaxis.

Pre-emptive viral therapy

Did the patient receive pre-emptive therapy for a viral infection?

Indicate if the patient received pre-emptive therapy for any virus.

If yes, for what virus?

Indicate whether the patient has received pre-emptive therapy for CMV and/or EBV.

Specify the pre-emptive therapy for each CMV episode that occurred

Repeat the questions below for each CMV episode to reflect all episodes that occurred.

CMV treatment start date

Report the date the patient first received any type of pre-emptive therapy for CMV, or select unknown if you do not know the date.

Antiviral(s) used

Check all types of antivirals that have been administered as pre-emptive therapy for CMV.

Was this episode of CMV infection due to a resistant CMV strain?

Indicate if the CMV strain causing this CMV episode was identified to be of a drug-resistant phenotype with viral genetic mutations decreasing susceptibility to one or more antiviral drugs, or select **unknown** if you do not know if it was a resistant CMV strain.

Specify the pre-emptive therapy for each EBV episode that occurred

Repeat the questions below for each EBV episode to reflect all episodes that occurred.

EBV treatment start date

Report the date the patient first received any type of pre-emptive therapy for EBV, or select unknown if you do not know the date.

Antiviral(s) used

Check all types of antivirals that have been administered as pre-emptive therapy for EBV.

Complications since the Last Report-GvHD

This section should only be completed if the patient received an allogeneic HCT.

Did graft versus host disease (GvHD) occur?

If **No** GvHD occurred or if this information is **Unknown**, select the appropriate answer and proceed to the next section: 'Complications since the last report - Non-infectious complications'. Select **Yes** if GvHD occurred and proceed to the next question.

GvHD refers to a clinical syndrome caused by the response of transplanted donor allogeneic cells to histocompatibility antigens expressed on tissues of the transplantation recipient. Acute GvHD (aGvHD) refers to the appearance of an allogeneic inflammatory response in exclusively three organs: the skin (inflammatory maculopapular erythematous skin rash), the liver (hyperbilirubinemia due to cholestatic jaundice), and the gastro-intestinal (GI) tract (upper and/or lower GI tract manifestations). The diagnosis must occur in the absence of manifestations of chronic GvHD (cGvHD) and should ideally be supported by positive histological findings. cGvHD is based on either the presence of specific diagnostic signs or distinctive signs accompanied by additional confirmation (e.g. biopsy or other objective diagnostic test) in

at least one target organ (skin & appendages, mouth, eyes, genitalia, oesophagus, lungs and muscles & fascia). Detailed definitions are described in the 2014 NIH Consensus (1) and 2018 EBMT—NIH—CIBMTR Task Force statement on standardised terminology (2).

Did the patient receive a systemic/immunosuppressive treatment for GvHD?

Indicate if the patient received a systemic immunosuppressive treatment including ECP (Extracorporeal Photopheresis) for GvHD. If the answer is **Yes**, specify:

Date treatment started

Report here the date the systemic immunosuppressive treatment for GvHD started**.** If immunosuppressive treatment was started before the GvHD (as prevention) and continued as GvHD treatment, please indicate the start date of immunosuppressive treatment before the GvHD.

Treatment stopped

Indicate whether systemic immunosuppressive treatment for GvHD is still ongoing and if not, report the stop date of this treatment. Mark as **Unknown** if this is not known.

Did acute GvHD occur?

Indicate if aGvHD occurred within 100 days post HCT. Mark as **Unknown** if this is not known.

Acute graft versus host disease (aGvHD) is a consequence of donor T-cells recognizing the patient's antigens as foreign. It usually consists of dermatitis, hepatitis, and gastroenteritis. Although it usually develops within the first 100 days, it can also appear later on.

Date of onset

If aGvHD occurred, report the date of onset. Mark as **Unknown** if this is not known.

Maximum observed organ severity score

Select for each organ listed in the table the observed severity score. If another site was also affected, answer **Yes** in **Other site affected** and specify this site in the text field in English.

The maximum grade for acute graft versus host disease (aGvHD) is defined according to the stages presented by the skin, liver, lower and upper GI tracts and can be found in table 1.

Organ	Stage	Description
Skin	0	No rash attributable to acute GVHD
	1	Skin rash < 25% body surface
	2	Skin rash 25-50% body surface
	3	Skin rash >50% body surface
	4	Generalised erythroderma (> 50% BSA) plus bullous formation and desquamation >5% of BSA

Organ	Stage	Description
Liver	0	Total serum bilirubin < 34 µmole/L (< 2 mg/dL)
	1	Total serum bilirubin 34–50 µmole/L (2 to 3 mg/dL)
	2	Total serum bilirubin 51–102µmole/L (3.1 to 6 mg/dL)
	3	Total serum bilirubin 103–255 µmole/L (6.1 to 15 mg/dL)
	4	Total serum bilirubin >255 µmole/L (> 15 mg/dL)
Lower gut	0	Diarrhoea < 500 mL/day or<3 episodes/day for adults or diarrhoea <10 mL/kg/day or <4 episodes/day for children
	1	Diarrhoea 500–999 mL/day or 3–4 episodes/day for adults or diarrhoea 10–19.9 mL/kg/day or 4–6 episodes/day for children
	2	Diarrhoea 1000–1500mL/day or 5–7 episodes/day for adults diarrhoea 20–30 mL/kg/day or 7–10 episodes/day for children
	3	Diarrhoea >1500 mL/day or >7 episodes/day for adults or diarrhoea > 30 mL/kg/day or >10 episodes/day for children
	4	Severe abdominal pain with or without ileus or grossly bloody stools (regardless of stool volume)
Upper gut	0	No or intermittent anorexia or nausea or vomiting
	1	Persistent anorexia or nausea or vomiting

Table 1. aGvHD grading system per organ (2) http://dx.doi.org/10.1038/s41409-018-0204-7.

Overall maximum grade observed

Select the overall maximum grade that was observed. If it is not known which overall maximum grade was observed, select **Unknown**.

The overall grade (or the stage of skin, liver and gut) should be mentioned in the patients' file. If not clearly stated, ask the treating physician. You should report the maximum grade seen during this follow-up period as calculated from table 2 according to the MAGIC consortium .

Grade							
1	Skin stage 1 or 2	AND	Liver stage 0	AND	Upper gut stage 0	AND	Lower gut stage 0
2	Skin stage 3	AND/ OR	Liver stage 1	AND/ OR	Upper Gut stage 1	AND/ OR	Lower gut stage 1
3	Not skin stage 4	AND	Liver stage 2 or 3	AND/ OR			Lower gut stage 2 or 3
4	Skin stage 4	OR	Liver stage 4	OR			Lower gut stage 4

Table 2. Overall maximum grade for aGvHD (2) http://dx.doi.org/10.1038/s41409-018-0204-7.

Steroid-refractory acute GvHD

Indicate if the patient experienced steroid-refractory acute GvHD or not. Steroid-refractory aGvHD is defined as failure to respond to standard steroid doses (defined as progression within 3–5 days of starting treatment or an incomplete response by 7–14 days) or recurrence after initial dose reduction (steroid dependence) as stated in the EBMT handbook (3). Mark as **Unknown** if this is not known.

Date of onset

If steroid-refractory acute GvHD is observed, report the date of onset. Mark as **Unknown** if this is not known.

aGvHD resolved?

Please indicate whether the aGvHD was resolved or not. Mark as **Unknown** if this is not known.

Date of aGvHD resolution

If the acute GvHD was resolved, please report the date on which it was thought to have resolved completely. Mark as **Unknown** if this is not known.

Extended dataset

aGvHD first line treatment

Did the patient receive steroids as first line treatment of aGvHD?

Please indicate here if steroids were used here for treatment of aGvHD in the first line. If steroids were used in prophylaxis only, but not in treatment of aGvHD, please report 'No' here.

Steroid details

Please report here the steroid used in treatment, start date, initial dose (in mg/kg/day), if the drug was stopped, and stop date if applicable. If you only have the drug in mg units, please divide by the patient weight in kg on the date of start of treatment to calculate in the correct units (mg/kg). If multiple steroids were given in the first line, please report all.

Were other systemic drugs/strategies used to treat aGvHD in the first line?

Please indicate if other systemic drugs/ strategies used to treat aGVHD in the first line during this follow-up period by answering **Yes** or **No**. Mark as **Unknown** if it is unknown.

Name of drug/strategy

Please report here all the drugs/strategies that were given in the first line treatment of aGvHD. Do not report drugs that were only given as GvHD prophylaxis.

How did aGvHD respond to steroids?

Please indicate the response of aGvHD to steroids based on the following definitions below:

Steroid sensitive (SS)

If a partial or complete response is achieved in aGvHD after undergoing steroid treatment, please report 'Yes' here.

Steroid refractory (SR)

Refractory: progression in any organ within 3, 4 or 5 days of therapy onset with >= 2 mg/Kg/day of prednisone equivalent, or failure to improve within 5 to 7 days of treatment initiation, or incomplete response after more than 28 days of immunosuppressive treatment including steroids.

Steroid dependent (SD)

Dependent: Inability to taper prednisone under 2 mg/Kg/day after an initially successful treatment of at least 7 days or as the recurrence of aGVHD activity during steroid tapering.

Date of onset of SD aGvHD

If steroid dependent, indicate the date of onset of steroid dependence. (Date of onset of steroid refractory aGvHD has already been reported in the Core data form). Please note that by definition, this cannot be the same date as onset of aGvHD. If the date is unavailable, select **Unknown**.

Steroid refractory/dependent aGvHD

Did the patient receive treatment for SR/SD aGvHD?

Indicate if the patient receives a treatment for SR/SD aGvHD.

Overall aGvHD grade at start of SR/SD aGvHD treatment

Please report the overall grade of the aGvHD on the date that SR/SD treatment started. This is the treatment that will be reported below (first line of SR/SD aGvHD, rather than the previously reported first line treatment of aGvHD). If treatment was started before SR/SD was established and continued as the first line treatment, please report the grade of aGvHD on the date that SR/SD was established.

Organs involved at start of SR/SD aGvHD treatment

As for regular GvHD, please report all involved organ stages according to the Glucksburg scale. The date of start of SR/SD aGvHD treatment applies, as above.

Drugs given in this line of treatment (after steroid refractoriness/dependence was established)

Please complete the table of drugs used to treat SR/SD aGvHD. Enter drugs line by line (first line for SR/SD aGvHD, then second line and any other subsequent lines). Please note that this is not first line treatment of aGvHD, but line treatment after SR/SD has been established. Enter all start dates, and stop dates, if relevant.

Organ involved during the course of treatment and response to the line of treatment

Please report if each organ was involved or not at the start of treatment, and if yes, please also report the response to this line of treatment. If organ specific responses are not available, please report the overall response. Responses to each line of treatment should be entered separately, starting with the first line and proceeding to subsequent lines, if applicable.

Note again, that this is the response to SR/SD aGvHD, so the response to treatment after SR/SD was established. This is not asking to report the response to first line steroid treatment of aGvHD (before SR/SD onset).

Did chronic GvHD occur?

Indicate if chronic GvHD occurred or not within 100 days post-HCT. Mark as **Unknown** if this is not known.

Date of onset

If cGvHD occurred, report the date of onset. Mark as **Unknown** if this is not known.

Maximum NIH score during this period

Indicate if the maximum NIH score during this period was **Mild**, **Moderate** or **Severe**. If the score is unknown, select **Unknown**.

The NIH scoring system was first published in 2005 and was updated in 2014 and 2022. As described in the 2014 Diagnosis and Staging Working Group report (1), eight classical organs or sites (skin, mouth, eyes, lungs, musculoskeletal system, gastrointestinal tract, genitourinary tract, and liver) are considered for calculating global score.

Elements included in the proposed global scoring include both the number of organs or sites involved and the severity score within each affected organ. Indicate the maximum NIH score during this period, as per the results of these measurements. Instructions for physicians on assessing the NIH score can be found in the EBMT handbook (1,4) or table 3.

Mild cGvHD	1 or 2 organs involved with no more than score 1 AND Lung score 0
Moderate cGvHD	3 or more organs involved with no more than score 1 OR At least 1 organ (not lung) with a score of 2 OR Lung score 1
Severe cGvHD	At least 1 organ with a score of 3 OR Lung score of 2 or 3

Table 3. Assessing the maximum NIH score (1).

In 2022 the NIH consensus (5) recognized atypical manifestations of chronic GvHD, which should be reported in the section '**Other site affected**' below the list of organs involved. Atypical manifestations do not contribute to the global severity score.

Date maximum NIH score

Report the date the maximum NIH score was observed.

Maximum observed organ severity score

Select for each organ in the table the observed severity score. If another site was affected, answer **Yes** in **Other site affected** and specify this site in the text field in English.

Use the NIH scoring system as described in 6.3.2.

Steroid-refractory chronic GvHD

Indicate if the patient experienced steroid-refractory chronic GvHD. Steroid refractory cGvHD is defined as progression of cGvHD while on prednisone at ≥1 mg/kg/day for 1 to 2 weeks or stable GvHD on ≥0.5 mg/kg/day (or 1 mg/kg every other day) of prednisone for 1 to 2 months (2).

Date of onset

If steroid-refractory chronic GvHD was observed, report the date of onset. Mark as **Unknown** if this is not known.

cGvHD resolved?

Please indicate whether the cGvHD was resolved or not. Mark as **Unknown** if this is not known.

Date of cGvHD resolution

If the chronic GvHD was resolved, please report the date on which this occurred. Mark as **Unknown** if this is not known.

Was overlap syndrome observed (features of both chronic and acute GvHD)

If overlap syndrome was observed, select **Yes**. If overlap syndrome was not observed, select **No**. Mark as **Unknown** if this is not known.

Extended dataset

cGvHD first line treatment

Did the patient receive steroids as first line treatment of cGvHD?

Please indicate here if steroids were used here for treatment of cGvHD in the first line. If steroids were used in prophylaxis only, but not in treatment of cGvHD, please report 'No' here. If steroids were given for aGvHD treatment only, but not for cGvHD treatment, please report 'No' here.

Steroid details

Please report here the steroid used in treatment of cGvHD, start date, initial dose (in mg/kg/day), if the drug was stopped, and stop date if applicable. If you only have the drug in mg units, please divide by the patient weight in kg on the date of start of treatment to calculate in the correct units (mg/kg). If multiple steroids were given in the first line, please report all.

Were other systemic drugs/strategies used to treat cGvHD in the first line?

Please report here all the drugs/strategies that were given in the first line treatment of cGvHD. Do not report drugs that were only given as GvHD prophylaxis.

How did cGvHD respond to steroids?

Please indicate the response of cGvHD to steroids based on the following definitions below:

Steroid sensitive (SS)

If a partial or complete response is achieved in aGvHD after undergoing steroid treatment, please report 'Yes' here.

Steroid refractory (SR)

Refractory: progression of GvHD while on prednisone at >= 1 mg/Kg/day for 1-2 weeks or stable GvHD while on >=0.5 mg/Kg/day (or 1 mg/Kg every other day) of prednisone for 1-2 months.

Steroid dependent (SD)

Dependent: inability to control GVHD symptoms while tapering prednisone below 0.25 mg/Kg/day (or 0.5 mg/Kg every other day) in at least two individual attempts, separated by at least 8 weeks.

Steroid intolerant (SI)

Intolerant: Includes avascular necrosis, severe myopathy, uncontrolled diabetes mellitus, systemic viral or fungal infections.

Date of onset of SD/SI cGvHD

If steroid dependent/intolerant, indicate the date of onset of steroid dependence/intolerance. (Date of onset of steroid refractory cGvHD has already been reported in the Core data form). Please note that by definition, this cannot be the same date as onset of cGvHD. If the date is unavailable, select **Unknown**.

Steroid refractory/dependent/intolerant cGvHD

Did the patient receive treatment for SR/SD/SI cGvHD?

Indicate if the patient receives a treatment for SR/SD cGvHD.

Overall cGvHD grade at start of SR/SD/SI treatment

Please report the overall grade of the cGvHD on the date that SR/SD/SI treatment started. This is the treatment that will be reported below (first line of SR/SD/SI cGvHD, rather than the previously reported first line treatment of cGvHD). If treatment was started before SR/SD/SI was established and continued as the first line treatment, please report the grade of cGvHD on the date that SR/SD/SI was established.

Organs involved at start of SR/SD/SI treatment

As for regular GvHD, please report all involved organ stages according to the NIH scoring system. The date of start of SR/SD/SI cGvHD treatment applies, as above.

Drugs given in this line of treatment (after steroid refractoriness/dependence/ intolerant was established)

Please complete the table of drugs used to treat SR/SD/SI cGvHD. Enter drugs line by line (first line for SR/SD/SI cGvHD, then second line and any other subsequent lines). Please note that this is not first line treatment of aGvHD, but lines of treatment after SR/SD/SI has been established. Enter all start dates and stop dates, if relevant.

Organ involvement during the course of treatment and response to the line of treatment

Please report if each organ was involved or not at the start of treatment, and if yes, please also report the response to this line of treatment. If organ specific responses are not available, please report the overall response. Responses to each line of treatment should be entered separately, starting with the first line and proceeding to subsequent lines, if applicable.

Note again, that this is the response to SR/SD/SI cGvHD, so the response to treatment after SR/SD/SI was established. This is not asking to report the response to first line steroid treatment of aGvHD (before SR/SD/SI onset).

Complications since the Last Report Non-infectious complications

Did non-infectious complications occur during the follow-up period?

If no other non-infectious complication than GvHD occurred during the follow-up period or if the complication was grade 1 or 2, select **No** and proceed to the next section. If non-infectious complications with a CTCAE grade of at least 3 occurred or graft failure, pure red cell aplasia, posterior reversible

encephalopathy syndrome or VOD of any grade occurred, select **Yes** and report in the table below. Mark **Unknown** if this information is not available.

For adverse events not listed in the table, specify them in the **Other** text field. Consult with Appendix 3 in the paper form which non-infectious complications should not be reported even for grades 3 and 4.

For secondary graft failure:-

Secondary graft failure is defined as a decline in hematopoietic function (may involve haemoglobin and/or platelets and/or neutrophils) necessitating blood products or growth factor support, after having met the standard definition of hematopoietic (neutrophils and platelets) recovery. Donor chimerism testing is also done to confirm the suspicion of graft failure.

Resolved is defined as three consecutive days with an absolute neutrophil count (ANC) ≥ 0.5×10^9/L, along with platelet recovery, defined as a platelet count ≥ 20×10^9/L without platelet transfusion for at least 7 consecutive days.

For the **'Stop date,'** report the first of the three consecutive days where the ANC reaches ≥ 0.5×10^9/L.

Adverse event observed

Specify for each adverse event listed whether it was observed or not. The CTCAE gradings (v5) can be found on the website of the NIH (6). Please note that if an event can be reported in more than one type of adverse event, it should be reported only once in the most precise category (eg. a cerebral thrombosis should be reported only as a cerebral thrombosis and not also as a vascular event).

If a grading is dependent on hospitalisation but the patient was an inpatient at the time of onset, the centre will make the interpretation. If the patient had been an out-patient and the severity was such that the patient would have been hospitalised, grading will be selected accordingly.

Maximum CTCAE grade observed

Select for each adverse event the maximum CTCAE grade that was observed. If the grade is unknown, select **unknown**.

Note, for the following complications there are different grading systems to be used:

- Graft failure (fatal/non-fatal)
- Pure red cell aplasia (fatal/non-fatal)
- Posterior reversible encephalopathy syndrome (considered severe if a patient was re-hospitalised,transferred to the ICU, experiences severe mental impairment or severe cerebral edema)

- Veno-occlusive disease (VOD)/ Sinusoidal obstruction syndrome (SOS) is diagnosed based on clinical criteria. The most recently proposed EBMT criteria can be found in table 4.

Adults	Children
Classical SOS/VOD *In the first 21 days after HSCT*: Bilirubin ≥2 mg/dL and two of the following criteria must be present: Painful hepatomegaly Weight gain >5% Ascites Late onset SOS/VOD >21 Days after HSCT: Classical VOD/SOS beyond day 21 Or Histologically proven SOS/VOD OR Two or more of the following criteria must be present: Bilirubin ≥2 mg/dL (or 34 µmol/L) Painful hepatomegaly Weight gain >5% Ascites AND Hemodynamic or/and ultrasound evidence of SOS/VOD	No limitation for time of onset of SOS/VOD The presence of two or more of the following: • Unexplained consumptive and transfusion-refractory thrombocytopenia • Otherwise unexplained weight gain on three consecutive days despite the use of diuretics or a weight gain >5% above baseline value • Hepatomegaly (best if confirmed by imaging) above baseline value • Ascites (best if confirmed by imaging) above baseline value • Rising bilirubin from a baseline value on 3 consecutive days or bilirubin ≥2 mg/dL within 72 h

Severity definition				
	Mild	Moderate	Severe	Very severe
Time since first clinical symptoms of SOS/VOD	>7 Days	5–7 Days	≤4 Days	Any time
Bilirubin (µmole/L)	≥34 and <51	≥51 and <85	≥85 and <136	≥136
Bilirubin kinetics			Doubling within 48 h	
Transaminases	≥2 × normal	> 2 and ≤5 × normal	>5 and ≤8 × normal	>8 × Normal
Weight increase	< 5%	≥5% and <10%	≥5% and <10%	≥10%
Renal function	<1.2 × baseline at transplant	≥1.2 and<1.5 × baseline at transplant	≥1.5 and <2 × baseline at transplant	≥2 × baseline at transplant or others signs of MOD/MOF

Table 4. Diagnostic criteria for SOS and VOD (8).

No grading needs to be marked for Pure red cell aplasia.

Onset date

Report the onset date when the adverse event was observed.

Resolved

Answer **Yes** if the non-infectious complication has been resolved within the follow-up period. If the complication was resolved in the observed period, report the date the complication was resolved/stopped.

Extended dataset

Treatment of early complications

Was TA-TMA treatment given?

Indicate if treatment was given.

Line of TA-TMA treatment given

Please complete the table of drugs used to treat TA-TMA. Enter drugs line by line, including the start date and the stop date if applicable. .

Other TA-TMA treatments given in this line of treatment

Please report any of the other requested procedures or therapies that were carried out as treatment of TA-TMA here, including renal replacement therapy, mechanical ventilation or exchange plasmapheresis. If applicable, please report the first date that each of these treatments was performed.

Response to this line of TA-TMA treatment

Did the patient achieve complete/partial response?

Please report whether the patient achieved a complete response (CR) or not per line of treatment for TA-TMA , and if so, please provide the date of this response. CR can be defined as normal LDH, no organ manifestations, high-risk TA-TMA harmonisation criteria not fulfilled anymore.

If the patient did not achieve a complete response, please report whether the patient achieved a partial response (PR) or not , and if so, please provide the date of this response. PR can be defined as LDH decreased, residual organ manifestations, high-risk TA-TMA harmonisation criteria not fulfilled anymore.

Was VOD treatment given?

Indicate if treatment was given.

Line of VOD treatment given

Please complete the table of drugs used to treat VOD . Enter drugs line by line, including the start date and the stop date if applicable.

Other VOD treatments given in this line of treatment

Please report any of the other requested procedures or therapies that were carried out as treatment of VOD here, including renal replacement therapy, mechanical ventilation or extracorporeal membrane oxygenation support. If applicable, please report the first date that each of these treatments was performed.

Response to this line of VOD treatment

Did the patient achieve complete/partial response?

Please report whether the patient achieved a complete response (CR) or not per line of treatment for VOD, and if so, please provide the date of this response. CR can be defined as serum bilirubin <2 mg/dL, no oxygen support, eGFR >50% from baseline before VOD and no renal replacement therapy.

If the patient did not achieve a complete response, please report whether the patient achieved a partial response (PR) or not , and if so, please provide the date of this response. PR can be defined as serum bilirubin increased, but >2 mg/dL, or pulmonary dysfunction, or eGFR <=50% from baseline before VOD.

Complications since the last report-Infectious complications

Did infectious complications occur during the follow-up period?

Answer **Yes** if any infectious complications occurred during this follow-up period. Select **No** if infectious complications have not occurred and proceed to the next section. Mark **Unknown** if this information is not available.

Infections that were resolved before the HCT do not need to be reported, unless a reactivation occurred after HCT.

Please note that the following infections do NOT need to be reported:

- Minor ophthalmologic bacterial infections (e.g. conjunctivitis treated topically; blepharitis treated topically; stye treated topically)
- External otitis treated topically
- Otitis media treated with oral antibiotics
- Isolated lip herpes simplex
- Bacterial tonsillitis or pharyngitis treated orally
- Laryngitis without viral identification managed at home by inhalations or without any intervention
- Upper respiratory tract infection (URTI) without viral/bacterial identification managed at home
- Bilateral cervical lymph node enlargement concurrent with URTI that resolved without specific treatment, together with the resolution of URTI
- Local superficial wound infection resolved under topical antibiotics (including impetigo)
- Minor skin bacterial infections (e.g. folliculitis; acne)
- Minor fungal skin infection (e.g. candidal intertrigo treated topically)
- Diaper rash treated with local antifungals
- Candidal balanitis treated topically
- Vaginal candidiasis treated topically or with a single oral dose
- Asymptomatic bacteriuria due to a pathogen not multi-resistant
- Single low urinary tract infection treated orally without need for hospitalisation
- Phlebitis following peripheral intravascular infusion that resolved after intravascular removal without treatment with antibiotics
- Any isolate that is considered part of the normal flora of the place (oral cavity, vagina, skin, stools) except if it carries an antimicrobial resistance that has clinical implications (induce isolation precautions or a pathogen-directed therapy)
- Positive culture without clinical implications (i.e. symptoms/signs of disease; administration of pathogen-directed therapy; isolation precautions or surveillance)

Bacterial infection

Indicate if the patient had a bacterial infection in the follow-up period after the treatment (after lymphodepleting/conditioning regimen) took place. Report here only bacterial infections with microbiological documentation, otherwise they shall be reported as infection with unknown pathogen.

Start date

Report the date a first positive blood or other relevant culture or diagnostic sample was obtained. In case a diagnostic sample was obtained with a delay since the symptoms of infection started – report here the date when symptoms attributable to this infection started (e.g. patient with pneumonia, urine test for legionella was sent after a few days and the test result was positive).

In case an infection was found for the first time at autopsy, use the date of death, unless you can identify the date when the symptoms attributable to this infection were reported for the first time.

Type of bacteria

Select the type of bacteria by marking if it is 'Gram-positive', 'Gram-negative' or 'Other' (see the list in Appendix 2 of the form or available in the database).

Pathogen

Select the bacterium that caused the infection from the list in Appendix 2 of the form or available in the database. Choose the most specific option. If the pathogen cannot be found, choose the 'Gram-positive bacteria other spp', 'Gram-negative bacteria other spp' or 'Bacteria other' option and enter its name in a textbox. Always report the full name of the bacterium.

Please note that some bacteria appear several times but with the emphasis on their resistance pattern. If relevant susceptibility data is unavailable, 'Gram-positive bacteria other spp' or 'Gram-negative bacteria other spp' can be selected (e.g. in case of *Pseudomonas* without information on carbapenem susceptibility (meropenem, imipenem or doripenem) choose 'Gram-negative bacteria other spp'). For *Staphylococcus aureus*: if vancomycin susceptibility is unavailable, but it is methicillin-susceptible (can appear as "oxacillin"), it should be reported as '*Staphylococcus aureus* MSSA (methicillin-susceptible)'. For '*Staphylococcus aureus* MRSA (methicillin-resistant)', indicate whether the vancomycin susceptibility was not tested, or whether it was VISA (vancomycin-intermediate) or VRSA (vancomycin-resistant) based on the minimum inhibitory concentration (MIC) for vancomycin falling within the range noted in the Appendix.

Common commensals (most commonly coagulase-negative Staphylococci, *Micrococcus* spp., *Bacillus* spp., *Propionibacterium* spp.) should be reported only if there are at least two positive blood cultures.

Infection with clinical implications

Indicate if the infection had clinical implications or not, or mark **Unknown** if it is not possible to identify. Infection with clinical implications is at least one of the following: symptomatic infection in the relevant organ/system, or infection that requires pathogen-directed therapy.

Infection with clinical implications, yes

Select all clinical implications of the infection that apply from suggested answer options:

- Symptoms/signs of disease;
- Administration of pathogen-directed therapy;

Localisation (adapted from CTCAE terms)

Select the localisation for the infection from the list in Appendix 3 of the form or available in the database.

In the appendix, we include both **general localisation** as part of the core dataset and **detailed localisation** as part of the extended dataset. If the more specific localisation is known, please report the **general localisation** and, if requested in the extended dataset, further specify by providing the **detailed localisation**. If only the higher-level localisation is known, report only the core dataset general localisation.

Please note that the impact of an infection can differ greatly depending on its localisation, and therefore, localisation is essential and at least 1 location involved during this follow-up period must be reported.

The localisations used in the current form are adapted from CTCAE version 5.0. Additional information on the CTCAE scoring can be found on the NIH website (6).

If the clinical information available does not specify the localisation of the infection, probably the infection was asymptomatic and will not have to be reported. Otherwise, the symptoms should guide the choice.

Intravascular catheter-related infection

Indicate if the infection was related to a central venous catheter (CVC). Please note that bacteraemia can be CVC-related or not CVC-related. The definition for the CVC-related bacteraemia requires one of the following:

- The same organism (genus, species and susceptibility pattern) growing from at least 1 percutaneous blood sample culture and from the catheter tip (e.g. two coagulase-negative Staphylococci, but different species, such as *Staphylococcus capitis* and *Staphylococcus epidermidis,* or two *Staphylococcus epidermidis* with completely different susceptibilities are not the same).
- 2 blood samples for culture are obtained (1 from a catheter hub and 1 from a peripheral vein) that meet CVC-related bacteraemia criteria for differential time to positivity (DTP): growth of microbes from blood obtained through the catheter hub being detected at least 2 hours before microbial growth is detected in blood samples obtained from a peripheral vein (9).

Specify

If the infection was related to an intravascular catheter, select the type of CVC infection from the list in Appendix 4 or available in the database.

Infection resolved

Indicate if the infection was resolved during the follow-up period. By resolved it is understood that the patient is free of symptoms/signs of this infection or symptoms/signs of this infection are under control,

and negative diagnostic tests were obtained in case the investigation was repeated, and the relevant imaging is compatible with expected improvement.

Contributory cause of death

In case the patient is deceased, indicate if the infection contributed to death.

If there was more than one bacterial infectious complication during the follow-up period, repeat these questions for the subsequent infection. Copy and fill-in the table as many times as necessary.

Viral infection

Indicate if the patient had a viral infection in the follow-up period after the treatment (after lymphodepleting/conditioning regimen) took place. Report here only infections with microbiological documentation, otherwise they shall be reported as infection with unknown pathogen.

Start date

Report the date a first positive viral test (usually PCR or antigen) was obtained. In case a diagnostic sample was obtained with a delay since the symptoms of infection started – report here the date when symptoms attributable to this infection started (e.g. patient with encephalitis, with a positive PCR in cerebrospinal fluid done 10 days after symptoms started).

In case an infection was found for the first time at autopsy, use the date of death, unless you can identify the date when the symptoms attributable to this infection were reported for the first time.

Pathogen

Select the virus that caused the infection from the list in Appendix 2 of the form or available in the database. Choose the most specific option. If the pathogen cannot be found, choose the 'Viruses other' option and enter its name in a textbox. Always report the full name of the virus.

If the pathogen was CMV/EBV: was this infection a reactivation?

Answer yes, if the patient's serology tests (CMV IgG, EBNA, EBV IgG) were positive before the treatment (start of lymphodepleting/conditioning regimen) took place or if the patient has been reported to have previously had an active CMV/EBV infection.

Infection with clinical implications

Indicate if the infection had clinical implications or not, or mark unknown if it is not possible to identify. Infection with clinical implications is at least one of the following: symptomatic infection in the relevant organ/system, or infection that requires pathogen-directed therapy.

Infection with clinical implications, yes:

Select all clinical implications of the infection that apply from suggested answer options:

- Symptoms/signs of disease;
- Administration of pathogen-directed therapy;

Localisation (adapted from CTCAE terms)

Select the localisation for the infection from the list in Appendix 3 of the form or available in the database.

In the appendix, we include both **general localisation** as part of the core dataset and **detailed localisation** as part of the extended dataset. If the more specific localisation is known, please report the **general localisation** and, if requested in the extended dataset, further specify by providing the **detailed localisation**. If only the higher-level localisation is known, report only the core dataset general localisation.

Please note that the impact of an infection can differ greatly depending on its localisation, and therefore, localisation is essential and at least 1 location involved during this follow-up period must be reported.

When EBV DNA is detected in the blood—which constitutes the vast majority of EBV detections—you can report the localization as viremia/DNAemia by selecting from the blood infections group.

The localisations used in the current form are adapted from CTCAE version 5.0. Additional information on the CTCAE scoring can be found on the NIH website (6).

If the clinical information available does not specify the localisation of the infection, probably the infection was asymptomatic and will not have to be reported. Otherwise, the symptoms should guide the choice.

Infection resolved

Indicate if the infection was resolved during the follow-up period. By resolved it is understood that the patient is free of symptoms/signs of this infection or symptoms/signs of this infection are under control, and negative diagnostic tests were obtained in case the investigation was repeated, and the relevant imaging is compatible with expected improvement.

Contributory cause of death

In case the patient is deceased, indicate if the infection contributed to death.

If there was more than one viral infectious complication during the follow-up period, repeat these questions for the subsequent infection. Copy and fill-in this table as many times as necessary.

Fungal infection

Indicate if the patient had a fungal infection in the follow-up period after the treatment (after lymphodepleting/conditioning regimen) took place. Report here only infections with microbiological documentation, otherwise they shall be reported as infection with unknown pathogen.

Start date

Report the date a first positive culture, PCR test or galactomannan test was obtained, or the pathogen was first identified by its typical appearance in the tissue/specimen material. In case a diagnostic sample was obtained with a delay since the symptoms of infection started – report here the date when symptoms attributable to this infection started, or when this is not known, the date of the first imaging (e.g. CNS, lungs, or liver/spleen imaging for instance in hepatosplenic candidiasis in a patient with persistent fever and negative blood cultures).

In case an infection was found for the first time at autopsy, use the date of death, unless you can identify the date when the symptoms attributable to this infection were reported for the first time.

Type of fungi

Select the type of fungal infection by marking if it is 'Yeasts' or 'Moulds'.

Pathogen

Select the fungus that caused the infection from the list in Appendix 2 of the form or available in the database. Choose the most specific option. If the pathogen cannot be found, choose the 'Yeasts other' or 'Moulds other spp' option and enter its name in a textbox. Always report the full name of the fungus. Please note that there is an option for mould infection diagnosed based on positive galactomannan only without additional microbiological confirmation.

Infection with clinical implications

Indicate if the infection had clinical implications or not, or mark unknown if it is not possible to identify. Infection with clinical implications is at least one of the following: symptomatic infection in the relevant organ/system, or infection that requires pathogen-directed therapy.

Infection with clinical implications, yes

Select all clinical implications of the infection that apply from suggested answer options:

- Symptoms/signs of disease;
- Administration of pathogen-directed therapy;

Localisation (adapted from CTCAE terms)

Select the localisation for the infection from the list in Appendix 3 of the form or available in the database.

In the appendix, we include both **general localisation** as part of the core dataset and **detailed localisation** as part of the extended dataset. If the more specific localisation is known, please report the **general localisation** and, if requested in the extended dataset, further specify by providing the **detailed localisation**. If only the higher-level localisation is known, report only the core dataset general localisation.

Please note that the impact of an infection can differ greatly depending on its localisation, and therefore, localisation is essential and at least 1 location involved during this follow-up period must be reported.

The localisations used in the current form are adapted from CTCAE version 5.0. Additional information on the CTCAE scoring can be found on the NIH website (6).

If the clinical information available does not specify the localisation of the infection, probably the infection was asymptomatic and will not have to be reported. Otherwise, the symptoms should guide the choice.

Intravascular catheter-related infection

Indicate if the infection was related to a central venous catheter (CVC). Please note that fungemia can be CVC-related or not CVC-related. The definition for the CVC-related fungemia requires one of the following:

- The same organism (genus, species and susceptibility pattern) growing from at least 1 percutaneous blood sample culture and from the catheter tip
- 2 blood samples for culture are obtained (1 from a catheter hub and 1 from a peripheral vein) that meet CVC-related fungemia criteria for differential time to positivity (DTP): growth of fungi from blood obtained through the catheter hub being detected at least 2 hours before fungal growth is detected in blood samples obtained from a peripheral vein (9).

Specify

If the infection was related to an intravascular catheter, select the type of CVC infection from the list in Appendix 4 or available in the database.

Infection resolved

Indicate if the infection was resolved during the follow-up period. By resolved it is understood that the patient is free of symptoms/signs of this infection or symptoms/signs of this infection are under control,

and negative diagnostic tests were obtained in case the investigation was repeated, and the relevant imaging is compatible with expected improvement.

Contributory cause of death

In case the patient is deceased, indicate if the infection contributed to death.

If there was more than one fungal infectious complication during the follow-up period, repeat these questions for the subsequent infection. Copy and fill-in this table as many times as necessary.

Parasitic infection

Indicate if the patient had a parasitic infection in the follow-up period after the treatment (after lymphodepleting/conditioning regimen) took place. Report here only infections with microbiological documentation, otherwise they shall be reported as infection with unknown pathogen.

Start date

Report the date a first positive antigen or DNA test was obtained or the first positive microscopic examination was performed. In case a diagnostic sample was obtained with a delay since the symptoms of infection started – report here the date when symptoms attributable to this infection started, or when this is not known, the date of the first imaging (e.g. CNS imaging for instance in Toxoplasmosis).

In case an infection was found for the first time at autopsy, use the date of death, unless you can identify the date when the symptoms attributable to this infection were reported for the first time.

Type of parasite

Select the type of parasitic infection by marking if it is ‘Protozoa’ or ‘Helminths’.

Pathogen

Select the parasite that caused the infection from the list in Appendix 2 of the form or available in the database. Choose the most specific option. If the pathogen cannot be found, choose the ‘Protozoa other spp’ or ‘Other helminths’ option and enter its name in a textbox. Always report the full name of the parasite.

Infection with clinical implications

Indicate if the infection had clinical implications or not, or mark unknown if it is not possible to identify. Infection with clinical implications is at least one of the following: symptomatic infection in the relevant organ/system, or infection that requires pathogen-directed therapy.

Infection with clinical implications, yes

Select all clinical implications of the infection that apply from suggested answer options:

- Symptoms/signs of disease;
- Administration of pathogen-directed therapy;

Localisation (adapted from CTCAE terms)

Select the localisation for the infection from the list in Appendix 3 of the form or available in the database.

In the appendix, we include both **general localisation** as part of the core dataset and **detailed localisation** as part of the extended dataset. If the more specific localisation is known, please report the **general localisation** and, if requested in the extended dataset, further specify by providing the **detailed localisation**. If only the higher-level localisation is known, report only the core dataset general localisation.

Please note that the impact of an infection can differ greatly depending on its localisation, and therefore, localisation is essential and at least 1 location involved during this follow-up period must be reported.

The localisations used in the current form are adapted from CTCAE version 5.0. Additional information on the CTCAE scoring can be found on the NIH website (6).

If the clinical information available does not specify the localisation of the infection, probably the infection was asymptomatic and will not have to be reported. Otherwise, the symptoms should guide the choice.

Infection resolved

Indicate if the infection was resolved during the follow-up period. By resolved it is understood that the patient is free of symptoms/signs of this infection or symptoms/signs of this infection are under control, and negative diagnostic tests were obtained in case the investigation was repeated, and the relevant imaging is compatible with expected improvement.

Contributory cause of death

In case the patient is deceased, indicate if the infection contributed to death.

If there was more than one parasitic infectious complication during the follow-up period, repeat these questions for the subsequent infection. Copy and fill-in the table as many times as necessary.

Infection with unknown pathogen

Indicate if the patient had an infection with unknown pathogen in the follow-up period after the treatment (after lymphodepleting/conditioning regimen) took place.

Use this section to report clinical infections without microbiological documentation, like pneumonia, cellulitis, typhlitis, etc.

Start date

Report the date the first signs or complaints were recorded or the first positive radiology was obtained. In case an infection was found for the first time at autopsy, use the date of death, unless you can identify the date when the symptoms attributable to this infection were reported for the first time.

Infection with clinical implications

Infection with clinical implications is at least one of the following: symptomatic infection in the relevant organ/system, or infection that requires pathogen-directed therapy. Since an infection with an unknown pathogen always has clinical implications to be reported, the 'Infection with clinical implications, yes' field always has to be filled in.

Infection with clinical implications, yes

Select all clinical implications of the infection that apply from suggested answer options:

- Symptoms/signs of disease;
- Administration of pathogen-directed therapy;

Localisation (adapted from CTCAE terms)

Select the localisation for the infection from the list in Appendix 3 of the form or available in the database.

In the appendix, we include both **general localisation** as part of the core dataset and **detailed localisation** as part of the extended dataset. If the more specific localisation is known, please report the **general localisation** and, if requested in the extended dataset, further specify by providing the **detailed localisation**. If only the higher-level localisation is known, report only the core dataset general localisation.

Please note that the impact of an infection can differ greatly depending on its localisation, and therefore, localisation is essential and at least 1 location involved during this follow-up period must be reported.

The localisations used in the current form are adapted from CTCAE version 5.0. Additional information on the CTCAE scoring can be found on the NIH website (6).

If the clinical information available does not specify the localisation of the infection, probably the infection was asymptomatic and will not have to be reported. Otherwise, the symptoms should guide the choice.

Intravascular catheter-related infection

Indicate if the infection was related to a central venous catheter (CVC). For example, a purulent infection of the exit site or tunnel, without isolation of pathogen.

Specify

If the infection was related to an intravascular catheter, select the type of CVC infection from the list in Appendix 4 or available in the database.

Infection resolved

Indicate if the infection was resolved during the follow-up period. By resolved it is understood that the patient is free of symptoms/signs of this infection or symptoms/signs of this infection are under control, and the relevant imaging is compatible with expected improvement.

Contributory cause of death

In case the patient is deceased, indicate if the infection contributed to death.

If there was more than one infectious complication with an unknown pathogen during the follow-up period, repeat these questions for the subsequent infection. Copy and fill-in the table as many times as necessary.

Extended dataset

SARS-CoV-2 related question

Did the patient receive a vaccination against SARS-CoV-2 during this period?

Indicate if the patient received a vaccination against SARS-CoV-2 in the follow-up period after the HCT treatment took place.

Number of doses

Report how many doses of the SARS-CoV-2 vaccine the patient has received.

Date of last dose

Report the date on which the patient received their last dose of the SARS-CoV-2 vaccine.

Secondary Malignancies and Autoimmune Disorders

Did a secondary malignancy or autoimmune disorder occur?

Answer **No** if neither secondary malignancy nor autoimmune disorder has been observed after this HCT. Mark as **Unknown** if this information is unavailable. Answer **Yes** if secondary malignancy or autoimmune disorder occurred and specify:

Was this disease an indication for a subsequent HCT/CT/IST/GT?

If the answer is **No**, complete the respective non-indication diagnosis form.

If the answer is **Yes**, complete the relevant indication diagnosis form.

Mark as **Unknown** if this is not known.

Additional treatments

Did the patient receive any additional disease treatment since the last follow-up?

If the patient received additional disease treatment (excluding additional cell infusions) since the last follow-up, select **Yes** and complete the Treatment - non-HCT/CT/GT/IST form. If the patient did not receive additional disease treatment, select **No**. Mark as **Unknown** if this is not known.

Additional cell infusions

Did the patient receive additional cell infusions?

If the patient received additional cell infusions, excluding a new HCT and/or CT treatment, select **Yes** and proceed to the next question. If the patient did not receive additional cell infusions, select **No**.Mark **Unknown** if this information is not available.

For this question, it does not matter if it was a boost or DLI. This can be clarified in the next questions.

If answered Yes, the following should be taken into account:

If the cells were infused with the aim of improving chimaerism, or preventing or treating relapses, it most likely was a DLI. The treating physician knows the aim of the infusion. In rare cases, the aim can be as for a boost and a DLI. In this case boost should be selected and the cell infusion sheet for DLI should be completed.

Is this cell infusion an allogeneic boost?

Indicate whether the cell infusion was an allogeneic boost or not.

An allogeneic boost is an infusion of cells from the same donor without conditioning, with no evidence of graft rejection. A boost is infused with the aim of providing enough hematopoietic cells to have an effect on engraftment.

If cells are not from the same donor OR there is conditioning (chemotherapy and/or TBI), then it is considered to be an HCT and not a boost.

Date of the allogeneic boost

If applicable, report the date the boost took place.

Is this cell infusion an autologous boost?

If the cell infusion was an autologous boost answer **Yes**. If it was not an autologous boost, select **No**.

An autologous boost is an infusion of pre-collected and stored autologous stem cells without conditioning.

Date of the autologous boost

If applicable, report here the date the boost took place.

Note: If this cell infusion is not a boost, attach the Cell Infusion (CI) sheet available in Appendix 6, completing as many sheets as episodes of cell infusion that took place during this follow-up period; then continue with questions below.

Did the patient receive subsequent HCT/CT?

If the patient received subsequent HCT/CT, either at your or another centre, select **Yes** and make sure that this subsequent treatment is registered using the appropriate HCT/CT form before proceeding.

If the patient did not receive subsequent HCT/CT, select **No**.

Relapse, Progression, Recurrence of disease or Significant Worsening

Was there a relapse, progression, recurrence of disease or significant worsening of organ function related to the primary disease after HCT?

Indicate if there was a relapse,progression, recurrence or significant worsening of organ function related to the primary disease after CT detected by any method. If multiple instances of relapse, progression, recurrence of disease or significant worsening took place in this follow-up period, report all instances. When filling this question in the EBMT registry, click the **add** button as many times as necessary for reporting all instances. ('+ Add' on the EBMT Registry.) If the answer is **No,** proceed to the next section.

Type

Report if a **relapse or recurrence of disease** is reported, or a **(continuous) progression or significant worsening**.

Date of relapse/progression/recurrence/significant worsening

Report the date of the relapse/progression/recurrence/significant worsening since HCT. If the date is not known, select **unknown**.

Extended dataset

In case of relapse or progression

Type of relapse (MPN and CML only)

Indicate if there was a relapse related to the primary disease after HCT.

Select from the list the worst disease status detected at this time point:

- Haematological
- Cytogenetic
- Molecular

If the disease status at relapse is not known, select **Unknown**.

What was the disease status? (CML only)

If haematological relapse occurred, also indicate the disease status:

- Chronic phase
- Accelerated phase
- Blast crisis

Disease status		
Chronic phase (CP)	**Accelerated phase (AP)**	**Blast crisis (BC)**
• None of the features of accelerated phase or blast crisis	• Bone marrow or peripheral blood blasts 10%-19% • Peripheral blood basophils ≥ 20% • Presence of additional clonal cytogenetic abnormality in Ph+ cells (ACA)[a]	• Bone marrow or peripheral blood blasts ≥ 20% • Extramedullary blast proliferation (myeloid sarcoma) • Presence of morphologically apparent lymphoblasts (>5%)

		warrants consideration of lymphoblastic crisis

Table 5. International Consensus Classification (ICC) criteria for Chronic Myeloid Leukaemias.

Medullary involvement

Indicate if the marrow or blood were affected by the disease. Please be aware that although the vast majority of acute leukaemias involve the invasion of the bone marrow by blasts, there are cases where blast invasion is only found in organs other than the bone marrow (e.g. choromas).

Medullary relapse is when malignant cells are only found in the bone marrow. In case of extramedullary relapse, malignant cells are found in sites other than the bone marrow, such as soft tissues or organs.

Extramedullary involvement

Extramedullary involvement (EMI) refers to disease cells found in organs or tissue outside the blood or bone marrow. The most common sites of extramedullary disease are the central nervous system (CNS), skin and ovaries/testes.

Involvement at time of relapse (If the relapse was extramedullary or both medullary and extramedullary)

Report if **Skin**, **CNS** (central nervous system) or **Testes/Ovaries** were involved at time of relapse. Also indicate if any other site was involved. If yes, please specify this in the textfield in English.

Disease status

Disease status at this follow-up or at time of death

Indicate the disease status at this follow-up or at time of death corresponding to indication diagnosis by selecting from the list provided in Appendix 1.

Appendix 1 - Disease specific best response and disease status

The disease status and best response are split into disease specific sections which can be found in appendix 1 of the follow-up form. This section is separated into disease status for:

- Acute leukaemias;
- Chronic leukemias;
- Plasma cell neoplasms;
- MPN, MDS, MDS/MPN overlap syndromes;
- Lymphomas;
- Solid tumours;
- Bone marrow failure syndromes (BMF) including aplastic anaemia (AA);
- Autoimmune disorders;
- Haemoglobinopathies;
- Other diagnoses;
- Inborn errors.

Please make sure to check the **Disease specific best response and disease status v1** document . latest version available under *Manuals and Reference Documents* section on EBMT website.

Acute leukaemias

This section is applicable to acute myeloid leukaemias (AML), precursor lymphoid neoplasms (PLN) and other acute leukaemias.

Acute leukaemias disease status or best response

Select the disease status or best response from the following list, refer from the criteria described in the **Disease specific best response and disease status v1** document.

- Complete remission (CR);
- Not in complete remission.

If the disease status or best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively. If reporting the disease status, also indicate the minimal residual disease (MRD) status.

Minimal residual disease (MRD)

Only for disease status section report the MRD status of acute leukaemia according to the guidelines provided below.

Chronic leukaemias

The chronic leukaemias section is split into chronic myeloid leukaemia (CML) and chronic lymphocytic leukaemia (CLL), prolymphocytic leukaemia (PLL) and other chronic leukaemias.

Chronic myeloid leukaemia disease status or best response

Select the disease status or best response from the list:

- Chronic phase (CP) and type of remission (haematological, cytogenetic, molecular)
- Accelerated phase
- Blast crisis

If the disease status or best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively.

Number

If the disease status or best response was chronic phase (CP), accelerated phase (AP) or blast crisis (BC), select the number of this status.

Number the different disease statuses chronologically. A patient can only be in the next chronic phase after he has experienced a blast crisis or accelerated phase.

If the disease status or best response was chronic phase (CP) also indicate:

Haematological remission

If the patient was in Chronic phase (CP), report if haematological remission was achieved (answer Yes), or not achieved (answer No) according to the criteria provided in the **Disease specific best response and disease status v1** document . Answer Not evaluated if it was not evaluated or Unknown if it cannot be verified if it was evaluated or not.

Cytogenetic remission

If the patient was in Chronic phase (CP), report if cytogenetic remission was achieved (answer Yes), or not achieved (answer No) according to the criteria provided in the **Disease specific best response and disease status v1** document .Answer Not evaluated if it was not evaluated or Unknown if it cannot be verified if it was evaluated or not.

Note: A patient in cytogenetic remission must be in haematological remission but could still present a molecular relapse. This is because the cytogenetic technique has a higher resolution than haematological measurements but lower resolution than molecular methods.

Extended dataset

Cytogenetic detection

Please answer these questions when the patient is in accelerated phase, blast crisis, or chronic phase without cytogenetic remission.

t(9;22) positive metaphases

Please report here the percentage (%) of the metaphases with the t(9;22) translocation. If the test was not done, select **not evaluated**. If the value is not known, select **unknown**.

t(9;22) positive cells detected by FISH

FISH (Fluorescent In Situ Hybridisation) is another cytogenetic technique that is frequently used. Where ''conventional'' cytogenetic investigation is performed on dividing cells (metaphases), FISH can also analyse non-dividing bone marrow cells (cells in interphase) and investigates about 400 cells, thus many more than the cells that are analysed with ''conventional'' cytogenetic analysis.

Molecular remission

If the patient was in Chronic phase (CP), report if molecular remission was achieved (answer Yes), or not achieved (answer No) according to the criteria provided in the **Disease specific best response and disease status v1** document . Answer Not evaluated if it was not evaluated or Unknown if it cannot be verified if it was evaluated or not.

Note: A patient in molecular remission must also be in cytogenetic and haematological remission. This is because molecular techniques have a higher resolution than both haematological and cytogenetic measurements.

Extended dataset

BCR::ABL1 variant allele frequency (VAF)

Please answer this question when the patient is in an accelerated phase, blast crisis, or chronic phase without molecular remission.

Please report the variant allele frequency of BCR::ABL1.

Minimal residual disease (MRD)

Only for disease status section report the MRD status of chronic myeloid leukaemia according to the guidelines provided below.

Chronic lymphocytic leukaemia (CLL), prolymphocytic leukaemia (PLL) and other chronic leukaemias disease status or best response

Select the disease status or best response from the list according to the criteria provided in the **Disease specific best response and disease status v1** document .

- Complete Remission (CR)
- Partial Remission (PR)
- Progression
- Stable Disease (SD)
- Relapse
    - Relapse is defined as evidence of disease progression in a patient who has previously achieved the criteria of a CR or PR for ≥6 months : see the **Disease specific best response and disease status v1** document.

If the disease status or best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively.

Progression sensitivity

If the disease status or best response was progression, indicate if the progression was **resistant** to the last chemotherapy regimen the patient received, or if it was **sensitive**. If this is not known, select **unknown**.

Minimal residual disease (MRD)

Only for disease status section report the MRD status of chronic lymphocytic leukaemia according to the guidelines provided below.

Plasma cell neoplasms

Disease status or best response

Select the disease status or best response from the list according to the criteria provided in the **Disease specific best response and disease status v1** document:

- Complete remission (CR)
- Stringent complete remission (sCR)
- Very good partial remission (VGPR)
- Partial remission (PR)
- Stable disease (no change, no response/loss of response)
- Progression
- Relapse

If the disease status or best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively.

Please check the**Disease specific best response and disease status v1** document with the criteria for each disease status or response category for plasma cell neoplasms and a criteria for Immunoglobulin-related (AL) Amyloidosis.

Number

Please report the number (if it is **1st, 2nd, 3rd or higher** or if it is **Unknown)** for the following disease statuses or responses**:**

- Complete remission (CR)
- Stringent complete remission (sCR)
- Very good partial remission (VGPR)
- Partial remission (PR)
- Relapse

Each different status/response has their own sequential count.

For example, a patient received a non-graft treatment and is in PR1 as response to this treatment. After that there is a progression, another treatment, and response to this treatment is CR1, relapse, another treatment, response CR2.

The count doesn't reflect the different disease statuses/responses (eg. in the example above it should not be PR1, CR2, CR3), but within that status/response the sequential count (so PR1, CR1, CR2).

Extended dataset

Immunoglobulin-related (AL) amyloidosis

Organ response

Please check the **Disease specific best response and disease status v1** document for definitions of organ response and progression.

Was the patient on dialysis during this follow-up period?

Report whether the patient was on dialysis during this follow-up period. Select **Unknown** if this information is unavailable.

Start date

If the answer to the previous question was **Yes**, report the start date of dialysis. If the start date is not known, select **Unknown.**

Did dialysis stop?

Report whether dialysis was stopped during this follow-up. Select **Unknown** if this information is unavailable.

End date

Report the dialysis end date. If the dialysis stopped but the end date is not known, select **Unknown**.

Minimal residual disease

Complete this section only if the patient disease status is reported for an AL, CLL diagnosis, or a plasma cell neoplasm.

If the patient is in haematologic CR, but has evidence of disease by more sensitive assessments including molecular, flow cytometry or cytogenetic methods, mark it as **Positive**. If the MRD assay cannot detect leukaemic cells mark it as **Negative**. Mark it as **Not evaluated** if MRD status evaluation was not carried out at initiation of HCT/CT/IST.

Indicate if there was a minimal residual disease by selecting positive, no minimal residual disease by selecting negative, or if the minimal residual disease was not evaluated or unknown.

Positive minimal residual disease

If there was positive minimal residual disease, indicate if this was **increasing**, **stable** or **decreasing**. If the level is not known, select **unknown**. A change in MRD should be confirmed within 4 weeks, in a second consecutive sample, preferably with a BM sample. The definitions are as follows:

- **Increasing** (>1 $\log_{10}$ increase between any 2 positive samples measured in the same tissue (PB or BM));
- **Stable** (<1$\log_{10}$ between any 2 positive samples measured in the same tissue (PB or BM));
- **Decreasing** (>1 $\log_{10}$ decrease between any 2 positive samples measured in the same tissue (PB or BM)).

Date MRD status evaluated

Report the date that the MRD status was evaluated. If the date is not known, select **unknown**.

Sensitivity of MRD assay

Select the appropriate sensitivity of the MRD assay from the list.

Method used

Select the most sensitive method that was used to assess the MRD status.

Myeloproliferative neoplasms (MPN), Myelodysplastic neoplasms (MDS), MDS/MPN overlap syndromes

Disease status or best response

Select the disease status or best response from the list according to the criteria provided in the **Disease specific best response and disease status v1** document:

- Complete remission (CR).
- Improvement but no CR
- Primary refractory phase (no change)
- Relapse
- Progression/worsening

If the disease status or best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively.

Number

If the disease status or best response was complete remission (CR) or relapse, please report the number (if it is **1st, 2nd, 3rd or higher** or if it is **Unknown).**

Each different status/response has their own sequential count.

For example, a patient received a non-graft treatment and is CR1 in response to this treatment, after that there is a (1st) relapse, another treatment, and response CR2.

The count doesn't reflect the different disease statuses/responses (eg. in the example above it should not be CR1, 2nd Relapse, CR3), but within that status/response the sequential count (so CR1, 1st Relapse, CR2).

Lymphomas

Disease status or best response

Select the disease status or best response from the list according to the criteria provided in the **Disease specific best response and disease status v1** document:

- Chemorefractory relapse or pression, including primary refractory disease
- Complete remission (CR)
- Partial remission
- Stable disease (no change, no response/loss of response)
- Untreated relapse (from a previous CR) or progression (from a previous PR)

If the disease status or best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively.

Complete remission: confirmed

Indicate if the complete remission was **confirmed** or **unconfirmed**. Unconfirmed means a complete response with persistent scan abnormalities of unknown significance. If it is not known if the complete remission was confirmed, select **unknown**.

Solid tumours

Disease status or best response

Select the disease status or best response from the list according to the criteria provided in the **Disease specific best response and disease status v1** document:

- Complete remission (CR)
- First partial remission
- Partial remission (PR)
- Progressive disease
- Relapse
- Stable disease (no change, no response/loss of response)

If the disease status or best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively.

Bone marrow failures (incl. AA)

Disease status or best response

Select the disease status or best response from the list according to the criteria provided in the **Disease specific best response and disease status v1** document:

- Complete remission (CR)
- Partial remission (PR)
- Haematological improvement (HI); NIH partial response
- Stable disease (no change, no response/loss of response)
- Relapse/Progression

If the disease status or best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively.

Did transfusions stop during the follow-up period?

If the disease status is reported for bone marrow failures, indicate if transfusions stopped since the last follow-up. If the patient was never transfusion dependent, select **patient was never transfusion dependent**.

If the transfusions are ongoing, select **no**. If the transfusions did stop, select **Yes** and complete the next questions. If the transfusion status is not known, select **unknown**.

Did the patient return to transfusion dependency afterwards?

If the patient was transfusion independent after HCT but is back to needing transfusions within this follow-up period, select **yes**. If they continue to be independent of transfusions after stopping in this follow-up period, select **no**. If it is not known if the patient went back to needing transfusions, select **unknown**.

First transfusion date

If the patient stopped transfusions during the follow-up period but went back to being transfusion dependent, report the first transfusion date after the transfusion free period. If the date is not known, select **unknown**.

Autoimmune disorders

Disease status or best response

Select the disease status or best response from the list:

- **No evidence of disease** - the patient has achieved complete absence of disease, there are no signs or symptoms of the original disease described.
- **Improved**
- **Unchanged** - Patients who have not demonstrated complete absence of disease, improvement in symptoms, or deterioration of symptoms will be classified as **Unchanged**.
- **Worse**

If the disease status or best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively.

Haemoglobinopathies

The haemoglobinopathies section is split into thalassemia and sickle cell disease.

Thalassemia best response

Select the best response that was achieved since the HCT:

- Transfusion independent
- Transfusions required

For clarification, transfusion independence is typically defined as going 8-12 weeks without needing transfusions, without a specific haemoglobin threshold.

If the best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively.

Date of last transfusion

If a patient reached transfusion independence, report the date of the last transfusion after main treatment the patient received. If the date is not known, select **unknown**.

Date of first transfusion

If a patient still requires transfusions, report the date of the first transfusion the patient received after main treatment due to Haemoglobin deficiency (recurrence of disease). If the date is not known, select **Unknown**.

Thalassemia disease status

Patient requires transfusions during follow-up period

Indicate if the patient requires transfusions during follow-up period after haematopoietic recovery by selecting **No** or **Yes**.

Date of first transfusion

If a patient has returned to transfusion dependence after main treatment, report the date of the first transfusion after main treatment. If the date is not known, select **Unknown**.

Number of units

Report the number of transfusion units patient received during this follow-up period. If the exact number is not known, select **unknown**.

Did transfusions stop?

Indicate if the patient stopped receiving the transfusions. If the patient stopped transfusions and did not require more during this follow-up period, select **yes.**

Date of last transfusion

If the patient stopped transfusions during the reporting period, provide the date when the last transfusion was administered. If it is not known, select **unknown**.

Sickle cell disease best response

Select the best response that was achieved since the main treatment:

- No return of sickling episodes. Patients are considered to have no return of sickling episodes when they have shown an absence of recurrent sickle cell crises.
- Return of sickling episodes. When recurrent sickle cell crises reoccur.

If the best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively.

Date of first episode

If a patient has returned to sickling episodes, report the date of the first episode after main treatment. If the date is not known, select **unknown**.

Sickle cell disease best response

Select the best response that was achieved since the main treatment:

- No return of sickling episodes. Patients are considered to have no return of sickling episodes when they have shown an absence of recurrent sickle cell crises.
- Return of sickling episodes. When recurrent sickle cell crises reoccur.

If the best response is not known or was not evaluated, select **Unknown** or **Not evaluated**, respectively.

Sickling episodes occur during follow-up period

This should only be completed when reporting the disease status. Indicate if there were no more recurrent sickle cell episodes after HCT by selecting **no**. If recurrent sickling episodes were present after HCT, select **yes**. If it is not known if the sickling episodes returned, select **Unknown**.

Sickling episodes occur during follow-up period, Yes

Indicate whether the sickling episodes first return after gene therapy or there was an ongoing presence of sickling episodes since last follow-up assessment.

Date of first episode

If the sickling episodes reoccurred for the first time since the main treatment, report the date of the first sickling episode. If the date is not known, select **Unknown**.

Number of SCD episodes (during follow-up)

If the sickling episodes first returned after main treatment, report the number of sickling episodes which occurred during this follow-up period. If the number is not known, select **Unknown**.

Other diagnosis

Disease status or best response

Select the disease status or best response from the list:

- **No evidence of disease-** the patient has achieved complete absence of disease, there are no signs or symptoms of the original disease described.
- **Improved**
- **Unchanged-** Patients who have not demonstrated complete absence of disease, improvement in symptoms, or deterioration of symptoms will be classified as **Unchanged**.
- **Worse**

If the disease status or best response is not known or was not evaluated, select **unknown** or **not evaluated**, respectively.

Extended dataset

Inborn errors

Patient height

Report the patient height within 100 days after HCT in centimetres.

Patient weight

Report the patient weight within 100 days after HCT in kilograms.

Patient is attending

Please select whether one of the situation below applies to the patient:

- **Regular school/work:** If the patient attending regular school or work;
- **Alternative school/adapted work:** If the patient attending school or working that is adapted to their inabilities;
- **Patient is not able to attend work/school:** if the patient does not attend school or work.

If the patient is not known whether he/she is attending school or working, please select **Unknown.**

Immune profiling

Indicate if immune profiling was done.

Test date

Report the date of the most recent immune reconstitution was tested

Cell type and test results

Please report the value of the cell types below from the most recent test performed. For Naive CD4 T-cells and CD8 T-cells please select the unit of measurements.

Cell type	Unit of measurement
T-cells (CD3)	Cells/µl
CD4 T-cells (CD4)	Cells/µl
CD4 T-cells (CD8)	Cells/µl
B-cells (CD19)	Cells/µl
NK-cells (CD16/CD56)	Cells/µl
Naive CD4 T-cells (CD4/CD45RA)	Please select the unit of measurement
Naive CD8 T-cells (CD8/CD45RA)	Please select the unit of measurement
IgG	Gram/l
IgA	Gram/l
IgM	Gram/l

Select the immunomodulatory treatments the patient received within 100 days post HCT

Only report treatments administered within 100 days post HCT for the underlying disease. Do not report treatments for GvHD or other HCT/CT related complications.

Comorbidities after HCT (Inborn errors of immunity only)

Indicate if the comorbidities de novo, resolved, improved, stabilised or worsened since the last treatment took place.

Was the patient admitted to ICU after HCT

Indicate if the patient was admitted to ICU after HCT. If the information is not available mark as **Unknown**.

Cell Infusion Sheet

The following completion guidelines refer to the completion of appendix 4 of the day 100 form, the cell infusion sheet.

Please report each cell infusion episode performed during the follow-up period in a separate cell infusion sheet, completing as many sheets as episodes of cell infusion that took place. Cell infusion treatment is often given as sequential cell infusions through a series of days or even weeks. In order to make the data comparable, one episode of cell infusion treatment (one "CI)" is defined as any number of cell infusions that take place for the same indication within 10 weeks from first to last infusion. If the indication for the treatment changes within the 10 weeks, that would be considered as 2 separate episodes of cell infusion (2 "CI"), with the 2nd episode starting on the 1st day infusions were given after the change in indication.

Do not use this cell infusion sheet for any boost. All boosts shall be registered inside the HCT follow-up form.

Chronological number of CI episode for this patient

Report the chronological number of this cell infusion episode for this patient.

Date of the first infusion

Report the date of the first infusion within this episode.

Number of infusions within this episode (10 weeks)

Report the number of infusions within 10 weeks. Count only infusions that are part of the same regimen and given for the same indication.

Source of cells

Indicate if the source of cells are **allogeneic** or **autologous**.

Type of cells

Select the type of cells:

- **Lymphocytes (DLI);**
- **Mesenchymal;**
- **Fibroblasts;**
- **Dendritic cells;**
- **NK cells;**
- **Regulatory T-cells;**
- **Gamma/delta cells;**
- **Virus-specific T-cells.**

If the type of cells is **virus specific T-cells,** also specify the virus the T-cells were directed against in the textbox in English.

If the type of cells is not listed, select **Other** and specify the type of cells in the text field in English.

Disease status at time of this cell infusion

Report the disease status at the time of this cell infusion. If the disease status has not been evaluated, select **Not evaluated**. Select **Unknown** if the disease status at the time of this cell infusion is not known.

Indication

Select all the indications for this cell infusion episode that apply:

- **Planned/protocol;**
- **Prophylactic;**
- **Treatment of acute GvHD;**
- **Treatment of chronic GvHD;**
- **Treatment PTLD, EBV lymphoma;**
- **Treatment for primary disease;**
- **Mixed chimaerism;**
- **Loss/decreased donor chimaerism;**
- **Treatment of viral infection other than EBV;**
- **Poor graft function;**
- **Infection prophylaxis.**

If the indication is not listed, select **Other** and specify it in the text field in English.

Acute GvHD - maximum grade *(after this infusion episode but before any subsequent cell infusion/HCT/CT)*

Indicate the maximum grade (Grade scale 0 - 4) of acute GvHD. If the grade is unknown but aGvHD is present, select **Present but grade unknown**. The grades are as in question Maximum observed organ severity score of the main questions.

Date Acute GvHD onset after cell infusion

Report the aGvHD onset date after the cell infusion. If the date is not known, select **unknown**.

Bibliography

1. Jagasia MH, Greinix HT, Arora M, Williams KM, Wolff D, Cowen EW, et al. National Institutes of Health Consensus Development Project on Criteria for Clinical Trials in Chronic Graft-versus-Host Disease: I. The 2014 Diagnosis and Staging Working Group report. Biol Blood Marrow Transplant [Internet]. 2015 Mar;21(3):389–401.e1. Available from: http://dx.doi.org/10.1016/j.bbmt.2014.12.001
2. Schoemans HM, Lee SJ, Ferrara JL, Wolff D, Levine JE, Schultz KR, et al. EBMT-NIH-CIBMTR Task Force position statement on standardized terminology & guidance for graft-versus-host disease assessment. Bone Marrow Transplant [Internet]. 2018 Nov;53(11):1401–15. Available from: http://dx.doi.org/10.1038/s41409-018-0204-7
3. Holler E, Greinix H, Zeiser R. Acute Graft-Versus-Host Disease. In: Carreras E, Dufour C, Mohty M, Kröger N, editors. The EBMT Handbook: Hematopoietic Stem Cell Transplantation and Cellular Therapies [Internet]. Cham (CH): Springer; Available from: http://dx.doi.org/10.1007/978-3-030-02278-5_43
4. Wolff D, Lawitschka A. Chronic Graft-Versus-Host Disease. In: Carreras E, Dufour C, Mohty M, Kröger N, editors. The EBMT Handbook: Hematopoietic Stem Cell Transplantation and Cellular Therapies [Internet]. Cham (CH): Springer; Available from: http://dx.doi.org/10.1007/978-3-030-02278-5_44
5. Cuvelier GDE, Schoettler M, Buxbaum NP, Pinal-Fernandez I, Schmalzing M, Distler JHW, et al. Toward a Better Understanding of the Atypical Features of Chronic Graft-Versus-Host Disease: A Report from the 2020 National Institutes of Health Consensus Project Task Force. Transplant Cell Ther [Internet]. 2022 Aug;28(8):426–45. Available from: http://dx.doi.org/10.1016/j.jtct.2022.05.038
6. National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE) [Internet]. 2021 [cited 2023 Mar 21]. Available from: https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm
7. Schoettler ML, Carreras E, Cho B, Dandoy CE, Ho VT, Jodele S, et al. Harmonizing Definitions for Diagnostic Criteria and Prognostic Assessment of Transplantation-Associated Thrombotic Microangiopathy: A Report on Behalf of the European Society for Blood and Marrow Transplantation, American Society for Transplantation and Cellular Therapy, Asia-Pacific Blood and Marrow Transplantation Group, and Center for International Blood and Marrow Transplant Research. Transplant Cell Ther [Internet]. 2023 Mar;29(3):151–63. Available from: http://dx.doi.org/10.1016/j.jtct.2022.11.015

8. Ruutu T, Carreras E. Hepatic Complications. In: Carreras E, Dufour C, Mohty M, Kröger N, editors. The EBMT Handbook: Hematopoietic Stem Cell Transplantation and Cellular Therapies [Internet]. Cham (CH): Springer; Available from: http://dx.doi.org/10.1007/978-3-030-02278-5_49
9. Mermel LA, Allon M, Bouza E, Craven DE, Flynn P, O'Grady NP, et al. Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 Update by the Infectious Diseases Society of America. Clin Infect Dis [Internet]. 2009 Jul 1;49(1):1–45. Available from: http://dx.doi.org/10.1086/599376
10. Kharfan-Dabaja MA, Kumar A, Ayala E, Aljurf M, Nishihori T, Marsh R, et al. Standardizing Definitions of Hematopoietic Recovery, Graft Rejection, Graft Failure, Poor Graft Function, and Donor Chimerism in Allogeneic Hematopoietic Cell Transplantation: A Report on Behalf of the American Society for Transplantation and Cellular Therapy. Transplant Cell Ther [Internet]. 2021 Aug;27(8):642–9. Available from: http://dx.doi.org/10.1016/j.jtct.2021.04.007
11. Comenzo RL, Reece D, Palladini G, et al. Consensus guidelines for the conduct and reporting of clinical trials in systemic light-chain amyloidosis. Leukemia 2012; 26:2317.