EBMT Registry

Haematopoietic cell transplantation (HCT) day 100 follow-up

Guide to the completion v2.7 of the EBMT data collection form: HCT_FU_D100_Core_Extended_v2.6

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EBMT Registry

EBMT Clinical Research & Registry Department

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Introduction

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

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.

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 cause of death** 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);**
  If the main cause of death was IST-related, graft versus host disease can not be selected.
- **Non-infectious complication;**

- **Infectious complication.**

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

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.

Extended dataset
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 or mark it as **Unknown**.

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. Mark as **Unknown**, if the first date is not known,

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 **Unknown** if it is confirmed by medical record that the 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 or mark it as **Unknown**. If the patient did not receive platelet infusions within the reported period, mark it as **Not applicable** (not transfused).

Primary graft failure?

Answer **Yes** if there occurred failure of initial engraftment of induced haematopoietic cells. Answer **No** if primary graft failure did not occur. Mark this field as **Unknown** if there is no information on the primary graft failure.

Primary Graft failure PBSC - lack of achievement of an ANC ≥500/µL by day +30 with associated pancytopenia. (Donor chimerism testing is also done to confirm the suspicion of graft failure).

Primary Graft failure Unstimulated BM - lack of achievement of an ANC ≥500/µL by day +30 with associated pancytopenia. (Donor chimerism testing is also done to confirm the suspicion of graft failure).

Primary Graft failure UCB - Lack of achievement of an ANC ≥ 500/µL by day +42 with associated pancytopenia (Donor chimerism testing is also done to confirm the suspicion of graft failure).

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

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 in the following cases:

- 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. Mark the date an **Unknown**, if the date is not known.

Chimaerism

This section is only applicable for patients receiving an allogeneic HCT and it is optional for malignant disorders.

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 or mark it as **Unknown**.

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, mark specific percentage as **Unknown** if this information is not known. In case any other cell types were tested, please select **Other cell type** and indicate the type of cells in the textbox in English and its percentage of donor cells or mark the percentage as **Unknown**.

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 primary CMV prophylaxis during this follow-up period?

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

Start date

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

Letermovir prophylaxis stopped

Indicate whether the letermovir regimen has stopped by answering **Yes**, **No** or **Unknown**.

End date

If letermovir regimen has stopped, give the end date of the letermovir prophylaxis. Select **Unknown** if the end date is not known.

Extended dataset

Was secondary letermovir prophylaxis given?

Indicate whether the patient received letermovir as secondary CMV prophylaxis during the follow-up period, meaning given after pre-emptive treatment of a CMV reactivation or treatment for CMV disease regardless of whether primary letermovir prophylaxis was given during the course of the most recent HCT. Select **Unknown** if this information is unavailable.

Start date secondary letermovir prophylaxis

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

Antimicrobial prophylaxis

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

Indicate if the patient received any type of prophylaxis by answering **Yes** or **No**.

If yes, what type of prophylaxis?

Check all types of prophylaxis the patient received: Antibacterial, Antifungal, Antiviral.

Antibacterial prophylaxis

Antibiotic

Select all types of antibiotics that were administered as antibacterial prophylaxis: Ciprofloxacin, Levofloxacin, Moxifloxacin, Penicillin/Amoxycilline, Ampicillin clavulonate, Non-absorbable antibiotic.

Phase

Select the phase (**Pre-engraftment**, **Post-engraftment**) during which the antibiotic was administered. Select **Unknown** if it is not known during what phase the antibiotic was given. If the antibiotic was given during both the pre-engraftment and post-engraftment phase, select **Post-engraftment and answer the follow-up question: Only post-engraftment, Started pre-engraftment and continued into post-engraftment or Started and stopped in pre-engraftment phase and restarted in post-engraftment phase.**

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 prophylaxis

Only for allogeneic HCT: 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 valaciclovir?

Indicate if either acyclovir or valaciclovir has been administered as VZV or HSV prophylaxis by answering **Yes** or **No**.

Final date VZV/HSV prophylaxis was discontinued

Report the date the patient last received either acyclovir or valaciclovir as VZV or HSV prophylaxis, or select **Ongoing** if the patient is still receiving either acyclovir or valaciclovir as VZV or HSV prophylaxis, or select **Unknown** if you do not know the final date either acyclovir or valaciclovir 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 by answering **Yes** or **No**.

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

Indicate if any type of HBV prophylaxis has been administered by answering **Yes** or **No**.

Which drugs were used?

Check all types of drugs that have been administered as HBV prophylaxis: Lamivudine, Entecavir, Tenofovir, HBV immunoglobulin, Other drug.

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 prophylaxis

Antifungal

Check all types of antifungals that have been administered as prophylaxis except for prophylaxis against Pneumocystis jirovecci.

Phase

Select the phase (**pre-engraftment**, **post-engraftment**) during which the antifungal was administered. Select **Unknown** if it is not known during what phase the antifungal was given. If the antifungal was given during both the pre-engraftment and post-engraftment phase, select **Post-engraftment and answer the follow-up question: Only post-engraftment, Started pre-engraftment and continued into post-engraftment or Started and stopped in pre-engraftment phase and restarted in post-engraftment phase.**

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 by answering **Yes, No** or **Unknown**.

Which drugs were used?

Check all types of drugs that have been administered as PJP prophylaxis: Trimethoprim-sulfamethoxazole, Dapsone, Atovaquone, Pentamidine inhaled, Pentamidine intravenous, Other drug.

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.

Complications post HCT treatment -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 by answering **Yes**, **No** or **Unknown**. If the answer is **Yes**, specify details in the following questions.

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. Mark the date as **Unknown** if this information is not known.

Treatment stopped

Indicate whether systemic immunosuppressive treatment for GvHD has stopped by answering **No**, **Yes** or **Unknown**. Report the stop date of this treatment or mark the date as **Unknown** if this is not known.

Did acute GvHD occur?

Indicate if aGvHD occurred within 100 days post HCT by answering **Yes** or **No**. 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

If aGvHD occurred, 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
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

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

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 aGvHD 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. Please note that by definition, this cannot be the same date as onset of aGvHD. Mark as **Unknown** if the date is not known.

Extended dataset

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 (resolution of symptoms), 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 by answering **Yes**, **No** or **Unknown**. 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 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

Date of onset of steroid refractory aGvHD has already been reported in the Core data field. Please note that by definition, this cannot be the same date as onset of aGvHD.

Steroid refractory/dependent aGvHD

Did the patient receive treatment for SR/SD aGvHD?

Indicate if the patient receives a treatment for SR/SD aGvHD by answering **No**, **Yes** or **Unknown**.

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. The overall grade of the aGvHD can be marked as **Unknown**, if it is not known, or as **Not evaluated** if it was not evaluated.

Organs involved at start of SR/SD aGvHD treatment

As for regular GvHD, please report all involved organ stages according to the MAGIC 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, or mark the date as Unknown.

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 or mark it as Unknown. 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, 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?

This question is reported only for allogeneic HCT. 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

If cGvHD occurred, 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 or mark the date as **Unknown**, if it is not known.

Maximum observed organ severity score

Select for each organ in the table the observed severity score or mark it as **Not evaluated** or **Unknown**. 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 by answering **No**, **Yes** or **Unknown**. 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 the date is not known. Please note that by definition, this cannot be the same date as onset of cGvHD.

Extended dataset

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 by answering **No**, **Yes** or **Unknown**. 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 name of 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 if other than steroids drugs/strategies were given in the first line treatment of cGvHD by answering **No**, **Yes** or **Unknown**. Do not report drugs that were only given as GvHD prophylaxis.

If answered Yes, select all the drugs/strategy that were used.

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 field). 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 after steroid refractoriness/dependence/intolerance was established by answering **No**, **Yes** or **Unknown**.

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?

Please only report here toxic events that are above Grade 2 and not linked to GvHD and/or infections). 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 the **Maximum grade observed** and **Onset date**. 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.

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.

Non-infectious complication 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:

- Secondary graft failure (fatal/non-fatal)
- Pure red cell aplasia (PRCA) (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).

Onset date

Report the onset date when the adverse event was observed.

Extended dataset

Resolved

Specify if specific non-infectious complication was resolved or not within the follow-up period by answering **No**, **Yes** or **Unknown**. If the complication was resolved in the observed period, report the date the complication was resolved/stopped inthe **Stop date** field or mark it as **Unknown**, if it is not known.

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.

Extended dataset

Treatment of early complications

Was TA-TMA treatment given?

Indicate if treatment was given by answering **No**, **Yes** or **Unknown**..

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 SOS/VOD treatment given?

Indicate if treatment was given by answering **No**, **Yes** or **Unknown**.

Line of SOS/VOD treatment given

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

Other SOS/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 SOS/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 SOS/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 SOS/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 (e.g. "Pseudomonas aeruginosa (PSA) (carbapenem-susceptible)" or "Pseudomonas aeruginosa (PSA) (carbapenem-resistant)" or "Pseudomonas aeruginosa (PSA) (carbapenem susceptibility not checked)".

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

Extended dataset

Carbapenem (any of imipenem, meropenem, doripenem) resistance/susceptibility

Only if pathogen *'Acinetobacter baumannii', 'Acinetobacter lwofii', 'Acinetobacter other', 'Citrobacter', 'Enterobacter', 'Escherichia coli', 'Klebsiella pneumoniae', 'Klebsiella* other*', 'Morganella', 'Proteus',*

'Providencia', 'Pseudomonas aeruginosa', 'Pseudomonas other', 'Raoultella' or *'Serratia'* is selected, indicate whether the pathogen is **Susceptible** or **Resistant** to carbapenem, or indicate that the susceptibility is unknown.

KPC

For carbapenem-resistant bacteria, indicate whether the result of the KPC test was **Negative** or **Positive**, or mark **Unknown** if this information is not available.

OXA-48

For carbapenem-resistant bacteria, indicate whether the result of the OXA-48 test was **Negative** or **Positive**, or mark **Unknown** if this information is not available.

New Delhi metallo-beta-lactamase (NDM)/VIM/IMP/Other metallo-beta-lactamase

For cabapenem-resistant bacteria, indicate whether any of the NDM, VIM, IMP or any other metallo-beta-lactamase test was **Negative** or **Positive**, or mark **Unknown** if this information is not available.

Ceftazidime avibactam (caz-avi, avycaz)/ceftazidime avibactam+aztreonam/meropenem vaborbactam/imipenem-cilastatin-relebactam/cefiderocol resistance/susceptibility

Only if pathogen *'Citrobacter', 'Enterobacter', 'Escherichia coli', 'Klebsiella pneumoniae', 'Klebsiella* other*', 'Morganella', 'Proteus', 'Providencia', 'Pseudomonas aeruginosa', 'Pseudomonas* other*', 'Raoultella'* or *'Serratia'* is selected and the pathogen is carbapenem-resistant, indicate whether the pathogen is **Susceptible** or **Resistant** to any of these antibiotics, or indicate that the **Susceptibility is unknown**.

Trimethoprim/sulfamethoxazole resistance/susceptibility

Only if pathogen '*Stenotrophomas maltophilia*' is selected, indicate whether the pathogen is **Susceptible** or **Resistant** to trimethoprim/sulfamethoxazole, or indicate that the **Susceptibility is unknown**.

Sulbactam/cefiderocol resistance/susceptibility

Only if pathogen *'Acinetobacter baumannii', 'Acinetobacter lwofii'* or *'Acinetobacter* other*'* is selected, indicate whether the pathogen is **Susceptible** or **Resistan**t to sulbactam or cefiderocol, or indicate that the **Susceptibility is unknown**.

Ceftolozane tazobactam (zerbaxa)/ceftazidime/cefepime/piperacillin tazobactam/ciprofloxacin or levofloxacin/amikacin resistance/susceptibility

Only if pathogen '*Pseudomonas aeruginosa*' is selected, indicate whether the pathogen is **Susceptible** or **Resistant** to any of these antibiotics, or indicate that the **Susceptibility is unknown**. Regarding Pseudomonas aeruginosa susceptibility to ciprofloxacin or levofloxacin: report **Resistant** if resistant to any of them and **Susceptible** if susceptible to both of them or mark that the **Susceptibility is unknown**.

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.

Extended dataset

Were abnormalities detected upon radiological assessment?

If CTCAE term 'Central nervous system infection', 'Sinusitis infective', 'Esophagus or gastric infection', 'Liver site infection', 'Lower gastrointestinal infection', 'Enteritis infective', 'Other intra-abdominal infection', 'Splenic infection' or 'Urinary tract infection' is selected, indicate whether abnormalities were detected upon radiological assessment by answering **No**, **Yes** or **Unknown**.

What diagnostic technique was used?

If abnormalities were detected upon radiological assessment, indicate by what diagnostic technique: MRI, CT, PET, PET CT, Ultrasound, Other (specify it in the textbox in English).

Radiology showing new or worsening pulmonary infiltrates

If CTCAE term 'Pneumonia' is selected, indicate whether new or worsening pulmonary infiltrates were visible upon radiology by answering **No**, **Yes** or **Unknown**.

What diagnostic technique was used?

If new or worsening pulmonary infiltrates were visible upon radiology, indicate by what diagnostic technique: CT, PET, Chest X-ray, MRI.

Was a biopsy performed?

If the CTCAE term was **not** 'Bacteremia', (i.e. a blood infection), indicate whether a biopsy was performed by answering **No**, **Yes** or **Unknown**.

Date of biopsy

If a biopsy was performed, indicate the date on which the biopsy was performed or mark it as **Unknown**.

Was this pathogen detected in biopsy?

If a biopsy was performed, indicate whether the pathogen for which you are filling out this field was detected in biopsy. Only answer **Yes** if this specific pathogen was detected, so not for other pathogens potentially detected in biopsy. If more than one pathogen is detected in biopsy - report each one separately.

By what technique was the pathogen detected in biopsy?

If the pathogen for which you are filling out this field was detected in biopsy, indicate by what technique: Culture, Histopathological or cytopathological demonstration, Immunohistochemistry, PCR, Stain.

Was bronchoalveolar lavage (BAL) performed?

If CTCAE term 'Pneumonia' or 'Tracheobronchitis infective' is selected, indicate whether BAL was performed by answering **No**, **Yes** or **Unknown**.

Date of BAL

If BAL was performed, indicate the date of BAL or mark it as **Unknown**.

Was this pathogen detected in BAL?

If BAL was performed, indicate whether the pathogen for which you are filling out this field was detected in BAL by answering **No**, **Yes** or **Unknown**. Only answer **Yes** if this specific pathogen was detected, so not for other pathogens potentially detected in BAL. If more than one pathogen is detected in BAL - report each one separately.

By what technique was the pathogen detected in BAL?

If the pathogen for which you are filling out this field was detected in BAL, indicate by what technique: Culture, PCR, Stain.

Was CSF obtained?

If CTCAE term 'Central nervous system infection' is selected, indicate whether CSF was obtained by answering **No**, **Yes** or **Unknown**.

Date of CSF

If CSF was obtained, indicate the date on which CSF was obtained or mark it as **Unknown.**

Was this pathogen detected in CSF?

If CSF was obtained, indicate whether the pathogen for which you are filling out this field was detected in CSF by answering **No**, **Yes** or **Unknown**. Only answer **Yes** if this specific pathogen was detected, so not for other pathogens potentially detected in CSF. If more than one pathogen is detected in CSF - report each one separately.

By what technique was the pathogen detected in CSF?

If the pathogen for which you are filling out this field was detected in CSF, indicate by what technique: Culture, PCR, Stain, Serology/antigen in CSF.

Were typical lesions seen on the eye examination?

If CTCAE term 'Other eye infection' is selected, indicate whether typical lesions were seen on the eye examination by answering **No**, **Yes** or **Unknown**.

Was the patient transferred to the ICU due to this infection?

Indicate whether the patient was transferred to the ICU due to this infection by answering **No**, **Yes** or **Unknown**. Only answer **Yes** if the infection for which you are filling out this field was the reason the patient was transferred to the ICU, so not if the patient was in the ICU for any other reason.

Contributory cause of death

In case the patient is deceased, indicate if the infection contributed to death by answering **No**, **Yes** or **Unknown**.

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 by answering **No**, **Yes** or **Unknown**. 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.

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 (including pre-emptive therapy of patients without symptoms);

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.

A special situation exists if the virus is detected in samples from the blood (whole blood, plasma, or serum), the localization should then be reported as viremia/DNAemia by selecting from the blood infections group. This is relevant for CMV, EBV, ADV (adenovirus), BKV, JCV and HHV-6, and frequently occurs in patients without symptoms. The treatment sections below are split between pre-emptive

treatment given to asymptomatic patients and the virus detected only in the blood and viral infections localized to an organ (for example lung, gastrointestinal tract or the CNS).

Extended dataset

Were abnormalities detected upon radiological assessment?

If CTCAE term 'Central nervous system infection', 'Esophagus or gastric infection', 'Liver site infection', 'Lower gastrointestinal infection', 'Enteritis infective', 'Other intra-abdominal infection' or 'Urinary tract infection' is selected, indicate whether abnormalities were detected upon radiological assessment by answering **No**, **Yes** or **Unknown**..

What diagnostic technique was used?

If abnormalities were detected upon radiological assessment, indicate by what diagnostic technique: MRI, CT, PET, PET CT, Ultrasound, Other (specify it in the textfield in English).

Radiology showing new or worsening pulmonary infiltrates

If CTCAE term 'Pneumonia' is selected, indicate whether new or worsening pulmonary infiltrates were visible upon radiology by answering **No**, **Yes** or **Unknown**..

What diagnostic technique was used?

If new or worsening pulmonary infiltrates were visible upon radiology, indicate by what diagnostic technique: CT, PET, Chest X-ray, MRI.

Was a biopsy performed?

If the CTCAE term was **not** 'Viremia including DNAemia' indicate whether a biopsy was performed by answering **No**, **Yes** or **Unknown**..

Date of biopsy

If a biopsy was performed, indicate the date on which the biopsy was performed. If the date in not known mark it as **Unknown**.

Was this pathogen detected in biopsy?

If a biopsy was performed, indicate whether the pathogen for which you are filling out this field was detected in biopsy by answering **No**, **Yes** or **Unknown**. Only answer **Yes** if this specific pathogen was detected, so not for other pathogens potentially detected in biopsy. If more than one pathogen is detected in biopsy - report each one separately.

By what technique was the pathogen detected in biopsy?

If the pathogen for which you are filling out this field was detected in biopsy, indicate by what technique: Histopathological or cytopathological demonstration, Immunohistochemistry, Quantitative PCR, DNA hybridization.

Was bronchoalveolar lavage (BAL) performed?

If CTCAE term 'Pneumonia' or 'Tracheobronchitis infective' is selected, indicate whether BAL was performed by answering **No**, **Yes** or **Unknown**..

Date of BAL

If BAL was performed, indicate the date of BAL. If the date in not known mark it as **Unknown**.

Was this pathogen detected in BAL?

If BAL was performed, indicate whether the pathogen for which you are filling out this field was detected in BAL by answering **No**, **Yes** or **Unknown**. Only answer **Yes** if this specific pathogen was detected, so not for other pathogens potentially detected in BAL. If more than one pathogen is detected in BAL - report each one separately.

By what technique was the pathogen detected in BAL?

If the pathogen for which you are filling out this field was detected in BAL, indicate by what technique: PCR or Cytology and immunofluorescence (IF).

Was CSF obtained?

If CTCAE term 'Central nervous system infection' is selected, indicate whether CSF was obtained by answering **No**, **Yes** or **Unknown**..

Date of CSF

If CSF was obtained, indicate the date on which CSF was obtained. If the date in not known mark it as **Unknown**.

Was this pathogen detected in CSF?

If CSF was obtained, indicate whether the pathogen for which you are filling out this field was detected in CSF by answering **No**, **Yes** or **Unknown**. Only answer **Yes** if this specific pathogen was detected, so not for other pathogens potentially detected in CSF. If more than one pathogen is detected in CSF - report each one separately.

By what technique was the pathogen detected in CSF?

If the pathogen for which you are filling out this field was detected in CSF, indicate by what technique: PCR, Cytology and immunofluorescence (IF), Serology/antigen in CSF.

Was an endoscopy performed?

IF CTCAE term 'Lower gastrointestinal infection' or 'esophagus or gastric infection' is selected, indicate whether an endoscopy was performed by answering **No**, **Yes** or **Unknown**.

Were gastrointestinal lesions documented?

If an endoscopy was performed, indicate whether gastrointestinal lesions were documented on this endoscopy by answering **No**, **Yes** or **Unknown**.

Were typical lesions seen on the eye examination?

If CTCAE term 'Retinitis infective' or 'Other eye infection' is selected, indicate whether typical lesions were seen on the eye examination by answering **No**, **Yes** or **Unknown**.

Was haemorrhagic cystitis diagnosed?

If CTCAE term 'Urinary tract infection' is selected, indicate whether haemorrhagic cystitis was diagnosed by answering **No**, **Yes** or **Unknown**.

Was HSV resistance to antiviral drugs documented?

If pathogen 'Herpes simplex virus (HSV)' is selected, indicate whether this virus was resistant to any antiviral drugs by answering **No**, **Yes** or **Unknown**.

Was the patient transferred to the ICU due to this infection?

Indicate whether the patient was transferred to the ICU due to this infection by answering **No**, **Yes** or **Unknown**. Only answer **Yes** if the infection for which you are filling out this field was the reason the patient was transferred to the ICU, so not if the patient was in the ICU for any other reason.

Contributory cause of death

In case the patient is deceased, indicate if the infection contributed to death by answering **No**, **Yes** or **Unknown**.

Extended dataset

Pre-emptive viral therapy

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

Indicate whether the patient received pre-emptive therapy, meaning administration of pathogen-directed therapy in patients without symptoms. Answer **No**, **Yes** or **Unknown.**

If yes, for what virus?

If pre-emptive therapy was given, select all viruses for which pre-emptive therapy was administered: CMV, EBV, BKV, ADV, JCV, HHV-6. Please make sure this viral infection has also been registered in the core dataset viral infection-part above and the CTCAEterm 'Viremia including DNAemia' was chosen.

Specify each pre-emptive therapy modality administered for each CMV treatment course

A new pre-emptive therapy course is defined either as a relapse of CMV after at least 2 weeks without antiviral therapy (success of previous treatment) or change of antiviral therapy due to failure of any reason (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy)).

If the virus 'CMV' is selected:

CMV pre-emptive therapy start date

Indicate the date on which the first pre-emptive therapy for CMV was given or mark it as **Unknown** if this information is not known.

Antiviral(s) used

Select the antiviral that was given as pre-emptive therapy for CMV, and add a new section for each antiviral: Valganciclovir, Ganciclovir intravenous, Foscarnet, Cidofovir, Maribavir, CMV-specific T-cells (VST), CMV hyperimmune immunoglobulin, Regular immunoglobulin, Leflunomide, Artesunate, Other drug. In case CMV-specific T-cells (VST) were given, also fill out the additional Cell Infusion Sheet in Appendix 6.

In case of refractory CMV, was a resistance test performed?

In case of refractory CMV, indicate whether a resistance test was performed by answering **No**, **Yes** or **Unknown**.

Which mutations were identified?

If a resistance test was performed, select all mutations that were identified in this resistance test: UL97, UL54, UL56, UL27, No mutation identified.

Response to pre-emptive therapy (address response to this specific treatment modality)

Indicate whether the pre-emptive therapy for CMV was a '**Success**' (stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks) or a '**Failure**' (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy), progression to disease (during treatment or in the 2 weeks after end of therapy), or unacceptable toxicity).

Viral load at the start (+/- 3 days) of pre-emptive therapy

Indicate the CMV viral load at the start of pre-emptive therapy for CMV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available. If you do not know the unit, please ask your virology laboratory.

Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy

Indicate the CMV viral load at the discontinuation of pre-emptive therapy for CMV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Date of discontinuation of pre-emptive therapy

Indicate the date on which the pre-emptive therapy for CMV was stopped or mark it as **Unknown** if the date is not known.

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

Specify each pre-emptive therapy modality administered for each EBV treatment course

A new pre-emptive therapy course is defined either as a relapse of EBV after at least 2 weeks without therapy (success of previous treatment) or change of therapy due to failure of any reason (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy)).

If the virus 'EBV' is selected:

EBV pre-emptive therapy start date

Indicate the date on which the first pre-emptive therapy for EBV was given or mark it as **Unknown** if the date is not known.

Therapy used (EBV)

Select the therapy that was given as pre-emptive therapy for EBV, and add a new section for each therapy that was given. In case EBV-specific T-cells (VST) were given, also fill out the additional Cell Infusion Sheet in Appendix 6.

Response to pre-emptive therapy (address response to this specific treatment modality)

Indicate whether the pre-emptive therapy for EBV was a '**Success**' (stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks) or a '**Failure**' (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy), progression to disease (during treatment or in the 2 weeks after end of therapy), or unacceptable toxicity).

Viral load at the start (+/- 3 days) of pre-emptive therapy

Indicate the EBV viral load at the start of pre-emptive therapy for EBV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy

Indicate the EBV viral load at the discontinuation of pre-emptive therapy for EBV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Date of discontinuation of pre-emptive therapy

Indicate the date on which the pre-emptive therapy for EBV was stopped.

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

Specify each pre-emptive therapy modality administered for each BKV treatment course

A new pre-emptive therapy course is defined either as a relapse of BKV after at least 2 weeks without antiviral therapy (success of previous treatment) or change of antiviral therapy due to failure of any reason (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy)).

If the virus 'BKV' is selected:

BKV pre-emptive therapy start date

Indicate the date on which the first pre-emptive therapy for BKV was given.

Antiviral(s) used

Select the antiviral that was given as pre-emptive therapy for BKV: if it is Cidofovir and/or BKV-specific T-cells (VST), and add a new section for each antiviral that was given. In case BKV-specific T-cells (VST) were given, also fill out the additional Cell Infusion Sheet in Appendix 6.

Response to pre-emptive therapy (address response to this specific treatment modality)

Indicate whether the pre-emptive therapy for BKV was a '**Success**' (stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks) or a '**Failure**' (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy), progression to disease (during treatment or in the 2 weeks after end of therapy), or unacceptable toxicity).

Viral load in blood at the start (+/- 3 days) of pre-emptive therapy

Indicate the BKV viral load at the start of pre-emptive therapy for BKV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Viral load in blood at the discontinuation (+/- 3 days) of pre-emptive therapy

Indicate the BKV viral load at the discontinuation of pre-emptive therapy for BKV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Date of discontinuation of pre-emptive therapy

Indicate the date on which the pre-emptive therapy for BKV was stopped.

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

Specify each pre-emptive therapy modality administered for each ADV treatment course

A new pre-emptive therapy course is defined either as a relapse of ADV after at least 2 weeks without antiviral therapy (success of previous treatment) or change of antiviral therapy due to failure of any

reason (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy)).

If the virus 'ADV' is selected:

ADV pre-emptive therapy start date

Indicate the date on which the first pre-emptive therapy for ADV was given.

Antiviral(s) used (ADV)

Select all the antiviral that was given as pre-emptive therapy for ADV: Cidofovir, Brincidofovir, Ribavirin, Immunoglobulin as treatment (not for replacement), ADV-specific T-cells (VST); and add a new section for each antival that was given. In case ADV-specific T-cells (VST) were given, also fill out the additional Cell Infusion Sheet in Appendix 6.

Response to pre-emptive therapy (address response to this specific treatment modality)

Indicate whether the pre-emptive therapy for ADV was a '**Success**' (stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks) or a '**Failure**' (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy), progression to disease (during treatment or in the 2 weeks after end of therapy), or unacceptable toxicity).

Viral load in stool at the start (+/- 3 days) of pre-emptive therapy

Indicate the ADV viral load in stool at the start of pre-emptive therapy for ADV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Viral load in blood at the start (+/- 3 days) of pre-emptive therapy

Indicate the ADV viral load in blood at the start of pre-emptive therapy for ADV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Viral load in stool at the discontinuation (+/- 3 days) of pre-emptive therapy

Stool can be an important sample for the detection of ADV especially in children and is used for monitoring at several centres. Indicate the ADV viral load in stool at the discontinuation of pre-emptive therapy for ADV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Viral load in blood at the discontinuation (+/- 3 days) of pre-emptive therapy

Indicate the ADV viral load in blood at the discontinuation of pre-emptive therapy for ADV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Date of discontinuation of pre-emptive therapy

Indicate the date on which the pre-emptive therapy for ADV was stopped.

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

Specify each pre-emptive therapy modality administered for each JCV treatment course

A new pre-emptive therapy course is defined either as a relapse of JCV after at least 2 weeks without antiviral therapy (success of previous treatment) or change of antiviral therapy due to failure of any reason (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy)).

If the virus 'JCV' is selected:

JCV pre-emptive therapy start date

Indicate the date on which the first pre-emptive therapy for JCV was given.

Antiviral(s) used (JCV)

Select the antiviral that was given as pre-emptive therapy for JCV: Cidofovir and/or JCV-specific T-cells (VST); and add a new section for each antiviral that was given. In case JCV-specific T-cells (VST) were given, also fill out the additional Cell Infusion Sheet in Appendix 6.

Response to pre-emptive therapy (address response to this specific treatment modality)

Indicate whether the pre-emptive therapy for JCV was a '**Success**' (stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks) or a '**Failure**' (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy), progression to disease (during treatment or in the 2 weeks after end of therapy), or unacceptable toxicity).

Viral load at the start (+/- 3 days) of pre-emptive therapy

Indicate the JCV viral load at the start of pre-emptive therapy for JCV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy

Indicate the JCV viral load at the discontinuation of pre-emptive therapy for JCV and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Date of discontinuation of pre-emptive therapy

Indicate the date on which the pre-emptive therapy for JCV was stopped.

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

Specify each pre-emptive therapy modality administered for each HHV-6 treatment course

A new pre-emptive therapy course is defined either as a relapse of HHV-6 after at least 2 weeks without antiviral therapy (success of previous treatment) or change of antiviral therapy due to failure of any reason (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy)).

If the virus 'HHV-6' is selected:

HHV-6 pre-emptive therapy start date

Indicate the date on which the first pre-emptive therapy for HHV-6 was given.

Antiviral(s) used (HHV-6)

Select all the antiviral(s) that was/were given as pre-emptive therapy for HHV-6: Cidofovir, HHV-6-specific T-cells (VST), Ganciclovir, Valganciclovir, Foscarnet; and add a new section for each antiviral that was given. In case HHV-6-specific T-cells (VST) were given, also fill out the additional Cell Infusion Sheet in Appendix 6.

Was HHV-6 subtyping done?

Indicate whether HHV-6 subtyping was done by answering **No**, **Yes**, **Unknown**.

What HHV-6 subtype was identified?

If HHV-6 subtyping was done, indicate what HHV-6 subtype (A or B) was identified.

Was testing for chromosomally integrated HHV-6 done?

Indicate whether testing for chromosomally integrated HHV-6 was done by answering **No**, **Yes**, **Unknown**.

Was chromosomally integrated HHV-6 present?

If testing for chromosomally integrated HHV-6 was done, indicate whether chromosomally integrated HHV-6 was present by answering **No**, **Yes**, **Unknown**.

Response to pre-emptive therapy (address response to this specific treatment modality)

Indicate whether the pre-emptive therapy for HHV-6 was a '**Success**' (stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks) or a '**Failure**' (progression of viremia or stable viral load requiring change or addition of therapy, response followed by rebound (during treatment or in the 2 weeks after end of therapy), progression to disease (during treatment or in the 2 weeks after end of therapy), or unacceptable toxicity).

Viral load at the start (+/- 3 days) of pre-emptive therapy

Indicate the HHV-6 viral load at the start of pre-emptive therapy for HHV-6 and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy

Indicate the HHV-6 viral load at the discontinuation of pre-emptive therapy for HHV-6 and indicate in what unit this viral load is reported, or indicate '**Unavailable**' if the viral load is not available.

Date of discontinuation of pre-emptive therapy

Indicate the date on which the pre-emptive therapy for HHV-6 was stopped.

If there was more than one HHV-6 episode during the follow-up period, repeat these questions for the subsequent HHV-6 episode. Copy and fill-in this table as many times as necessary.

Treatment of end-organ viral disease

Did the patient receive treatment for end-organ viral disease?

Indicate whether there was administration of pathogen-directed therapy for end-organ disease caused by any viral infection by answering **No** or **Yes**.

If yes, for what virus?

If treatment for end-organ viral disease was given, select all viruses for which it was given: CMV, EBV, BKV, ADV, JCV, HHV-6, CARVs .

Specify each treatment modality given for each occurrence of CMV disease or change in antiviral therapy due to failure (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)) that occurred

It is recommended that the definitions of CMV disease according to the paper by Ljungman et al (Clin Infect Dis 2024; 79(3):787–94) are used.

If the virus 'CMV' is selected:

CMV end-organ disease treatment start date

Indicate the start date of the first end-organ disease treatment given for CMV or mark it as **Unknown** if the date is not known.

Antiviral(s) used

Select all the antiviral(s) that were given as end-organ disease treatment for CMV: Valganciclovir, Ganciclovir intravenous, Foscarnet, Cidofovir, Maribavir, CMV-specific T-cells (VST), CMV hyperimmune immunoglobulin, Regular immunoglobulin, Leflunomide, Artesunate, Other drug.

More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart. Otherwise, add a new section for the new antiviral. In case CMV-specific T-cells (VST) were given, also fill in the additional Cell Infusion Sheet in Appendix 6.

In case of refractory CMV, was a resistance test performed?

In case of refractory CMV, indicate whether a resistance test was performed by answering **No, Yes** or **Unknown**.

Which mutation(s) were identified?

In case a resistance test was performed, select all mutations that were identified in this resistance test: UL97, UL54, UL56, UL27, No mutation identified.

Response to end-organ disease treatment (address response to this/these specific treatment modality/modalities)

Indicate whether the end-organ disease treatment for CMV was a '**Success**' (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment) or a

'**Failure**' (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)).

Date of discontinuation of end-organ disease treatment

Indicate the date on which end-organ disease treatment for CMV was stopped.

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

Specify each treatment modality given for each occurrence of EBV disease or change in therapy due to failure (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)) that occurred

If the virus 'EBV' is selected:

EBV end-organ disease treatment start date

Indicate the start date of the first end-organ disease treatment given for EBV.

Therapy used

Select the therapy/therapies that were given as end-organ disease treatment for EBV: Rituximab or anti-CD20 antibody, EBV-specific T-cells (VST), Reduction of immunosuppression (defined as a sustained decrease of at least 20% of the daily dose of immunosuppressive drugs with the exception of low-dose corticosteriod therapy), Other drug.

More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart. Otherwise, add a new section for the new therapy. In case EBV-specific T-cells (VST) were given, also fill in the additional Cell Infusion Sheet in Appendix 6.

Response to end-organ disease treatment (address response to this/these specific treatment modality/modalities)

Indicate whether the end-organ disease treatment for EBV was a '**Success**' (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment) or a '**Failure**' (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)).

Date of discontinuation of end-organ disease treatment

Indicate the date on which end-organ disease treatment for EBV was stopped.

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

Specify each treatment modality given for each occurrence of BKV disease or change in antiviral therapy due to failure (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)) that occurred

If the virus 'BKV' is selected:

BKV end-organ disease treatment start date

Indicate the start date of the first end-organ disease treatment given for BKV.

Antiviral(s) used (BKV)

Select all the antiviral(s) that were given as end-organ disease treatment for BKV: Cidofovir and/or BKV-specific T-cells (VST). More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart. Otherwise, add a new section for the new antiviral. In case BKV-specific T-cells (VST) were given, also fill in the additional Cell Infusion Sheet in Appendix 6.

Response to end-organ disease treatment (address response to this/these specific treatment modality/modalities)

Indicate whether the end-organ disease treatment for BKV was a '**Success**' (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment) or a '**Failure**' (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)).

Date of discontinuation of end-organ disease treatment

Indicate the date on which end-organ disease treatment for BKV was stopped.

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

Specify each treatment modality given for each occurrence of ADV disease or change in antiviral therapy due to failure (Defined as progression requiring change or addition of end-organ disease

treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)) that occurred

If the virus 'ADV' is selected:

ADV end-organ disease treatment start date

Indicate the start date of the first end-organ disease treatment given for ADV.

Antiviral(s) used (ADV)

Select the antiviral(s) that were given as end-organ disease treatment for ADV: Cidofovir, Brincidofovir, Ribavirin, Immunoglobulin as treatment (not for replacement), ADV-specific T-cells (VST). More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart. Otherwise, add a new section for the new antiviral. In case ADV-specific T-cells (VST) were given, also fill in the additional Cell Infusion Sheet in Appendix 6.

Response to end-organ disease treatment (address response to this/these specific treatment modality/modalities)

Indicate whether the end-organ disease treatment for ADV was a '**Success**' (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment) or a '**Failure**' (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)).

Date of discontinuation of end-organ disease treatment

Indicate the date on which end-organ disease treatment for ADV was stopped.

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

Specify each treatment modality given for each occurrence of JCV disease or change in therapy due to failure (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)) that occurred

If the virus 'JCV' is selected:

JCV end-organ disease treatment start date

Indicate the start date of the first end-organ disease treatment given for JCV.

Antiviral(s) used (JCV)

Select all the antiviral(s) that were given as end-organ disease treatment for JCV: Cidofovir, JCV-specific T-cells (VST), Mirtazapine, Checkpoint inhibitors. More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart. Otherwise, add a new section for the new therapy. In case JCV-specific T-cells (VST) were given, also fill in the additional Cell Infusion Sheet in Appendix 6.

Response to end-organ disease treatment (address response to this/these specific treatment modality/modalities)

Indicate whether the end-organ disease treatment for JCV was a '**Success**' (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment) or a '**Failure**' (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)).

Date of discontinuation of end-organ disease treatment

Indicate the date on which end-organ disease treatment for JCV was stopped.

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

Specify each treatment modality given for each occurrence of HHV-6 disease or change in antiviral therapy due to failure (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)) that occurred

If the virus 'HHV-6' is selected:

HHV-6 end-organ disease treatment start date

Indicate the start date of the first end-organ disease treatment given for HHV-6.

Antiviral(s) used (HHV-6)

Select the antiviral(s) that were given as end-organ disease treatment for HHV-6: Cidofovir, HHV-6-specific T-cells (VST), Ganciclovir, Valganciclovir, Foscarnet. More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart. Otherwise, add a new section for the new antiviral. In case HHV-6-specific T-cells (VST) were given, also fill in the additional Cell Infusion Sheet in Appendix 6.

Was HHV-6 subtyping done?

Indicate whether HHV-6 subtyping was done by answering **No**, **Yes** or **Unknown**.

What HHV-6 subtype was identified?

If HHV-6 subtyping was done, indicate what HHV-6 subtype (A or B) was identified.

Was testing for chromosomally integrated HHV-6 done?

Indicate whether testing for chromosomally integrated HHV-6 was done by answering **No**, **Yes** or **Unknown**.

Was chromosomally integrated HHV-6 present?

If testing for chromosomally integrated HHV-6 was done, indicate whether chromosomally integrated HHV-6 was present by answering **No**, **Yes** or **Unknown**.

Response to end-organ disease treatment (address response to this/these specific modality/modalities)

Indicate whether the end-organ disease treatment for HHV-6 was a '**Success**' (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment) or a '**Failure**' (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)).

Date of discontinuation of end-organ disease treatment

Indicate the date on which end-organ disease treatment for HHV-6 was stopped.

If there was more than one HHV-6 episode during the follow-up period, repeat these questions for the subsequent HHV-6 episode. Copy and fill-in this table as many times as necessary.

Specify each treatment modality given for each occurrence of community acquired respiratory virus (CARV) disease or change in antiviral therapy due to failure (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)) that occurred

As end-organ disease treatment for ADV is already asked separately, ADV is not included in the CARVs. CARVs include 'Human coronavirus (excluding SARS-CoV-2 or COVID-19)', 'Human metapneumovirus

(hMPV)', 'Influenza A virus (including birdflu)', 'Influenza B virus', 'Parainfluenza', 'Respiratory syncytial virus (RSV)' and 'SARS-CoV-2 virus (COVID-19)'.

If the virus 'Community-aquired respiratory virus (CARV)' is selected:

CARV end-organ disease treatment start date

Indicate the start date of the first end-organ disease treatment given for CARV.

Antiviral(s) used (CARV)

Select the antiviral(s) that were given as end-organ disease treatment for CARV: Oseltamvir, Zanamivir, Baloxavir, Peramivir, Ribavirin, Intravenous immunoglobulin (IVIG) for treatment, Remdesivir, Nirmatrel-Ritonavir. More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart. Otherwise, add a new section for the new antiviral.

Response to end-organ disease treatment (address response to this/these specific treatment modality/modalities)

Indicate whether the end-organ disease treatment for CARV was a '**Success**' (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment) or a '**Failure**' (Defined as progression requiring change or addition of end-organ disease treatment, response followed by rebound (worsening symptoms after initial improvement, death or unacceptable toxicity)).

Date of discontinuation of end-organ disease treatment

Indicate the date on which end-organ disease treatment for CARV was stopped.

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

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.

Invasive fungal infection

Indicate if the patient had a fungal infection in the follow-up period after the treatment (after lymphodepleting/conditioning regimen) took place by answering **No**, **Yes** or **Unknown**. 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 fungus

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' 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.

Extended dataset

Voriconazole resistance/susceptibility

Only if pathogen 'Aspergillus flavus', 'Aspergillus fumigatus', 'Aspergillus terreus' or 'Aspergillus other' is selected, indicate whether the pathogen is '**Susceptible**' or '**Resistant**' to voriconazole, or indicate that the susceptibility is unknown.

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.

Extended dataset

Were abnormalities detected upon radiological assessment?

If CTCAE term 'Central nervous system infection', 'Sinusitis infective', 'Esophagus or gastric infection', 'Liver site infection', 'Lower gastrointestinal infection', 'Enteritis infective', 'Other intra-abdominal infection', 'Splenic infection' or 'Urinary tract infection' is selected, indicate whether abnormalities were detected upon radiological assessment by answering **No**, **Yes** or **Unknown**.

What diagnostic technique was used?

If abnormalities were detected upon radiological assessment, indicate by what diagnostic technique: MRI, CT, PET, , PET CT, Ultrasound, Other (specify in the text field in English).

Radiology showing new or worsening pulmonary infiltrates

If CTCAE term 'Pneumonia' is selected, indicate whether new or worsening pulmonary infiltrates were visible upon radiology by answering **No**, **Yes** or **Unknown**.

What diagnostic technique was used?

If new or worsening pulmonary infiltrates were visible upon radiology, indicate by what diagnostic technique: CT, PET, Chest X-ray, MRI.

Were at least one of the following detected: Nodular lesion/Halo sign/Reverse halo sign/Cavity/Tree in bud/Ground glass/Wedge-shaped and segmental or lobal consolidation

If new or worsening pulmonary infiltrates were visible upon radiology, indicate whether any of nodular lesion, halo sign, reverse halo sign, cavity, three in bud, ground glass or wedge-shaped and segmental or global consolidation was detected by answering **No**, **Yes** or **Unknown**.

Was PCR in blood performed?

Indicate whether PCR in blood was performed, and if so, whether the result was negative or positive.

Date of PCR in blood

If PCR in blood was performed, indicate the date on which the PCR in blood was performed.

Was the result confirmed by a second test?

If PCR in blood was performed and positive, indicate whether this positive result was confirmed by a second test.

Was a biopsy performed?

If the CTCAE term was not 'Fungemia' (i.e. a blood infection), indicate whether a biopsy was performed by answering **No**, **Yes** or **Unknown**.

Date of biopsy

If a biopsy was performed, indicate the date on which the biopsy was performed.

Was this pathogen detected in biopsy?

If a biopsy was performed, indicate whether the pathogen for which you are filling out this field was detected in biopsy by answering **No**, **Yes** or **Unknown**. Only answer '**Yes**' if this specific pathogen was detected, so not for other pathogens potentially detected in biopsy. If more than one pathogen is detected in biopsy - report each one separately.

By what technique was the pathogen detected in biopsy?

If the pathogen for which you are filling out this field was detected in biopsy, indicate by what technique: Culture, Histopathological or cytopathological demonstration, Immunohistochemistry, PCR, Fungal stain.

Was bronchoalveolar lavage (BAL) performed?

If CTCAE term 'Pneumonia' or 'Tracheobronchitis infective' is selected, indicate whether BAL was performed by answering **No**, **Yes** or **Unknown**.

Date of BAL

If BAL was performed, indicate the date of BAL.

Was this pathogen detected in BAL?

If BAL was performed, indicate whether the pathogen for which you are filling out this field was detected in BAL by answering **No**, **Yes** or **Unknown**. Only answer '**Yes**' if this specific pathogen was detected, so not for other pathogens potentially detected in BAL. If more than one pathogen is detected in BAL - report each one separately.

By what technique was the pathogen detected in BAL?

If the pathogen for which you are filling out this field was detected in BAL, indicate by what technique: Culture, PCR, Stain, BAL Galactomannan assay.

Was CSF obtained?

If CTCAE term 'Central nervous system infection' is selected, indicate whether CSF was obtained by answering **No**, **Yes** or **Unknown**.

Date of CSF

If CSF was obtained, indicate the date on which CSF was obtained

Was this pathogen detected in CSF?

If CSF was obtained, indicate whether the pathogen for which you are filling out this field was detected in CSF by answering **No**, **Yes** or **Unknown**. Only answer '**Yes**' if this specific pathogen was detected, so not for other pathogens potentially detected in CSF. If more than one pathogen is detected in CSF - report each one separately.

By what technique was the pathogen detected in CSF?

If the pathogen for which you are filling out this field was detected in CSF, indicate by what technique: Culture, PCR, Beta D glucan galactomannan, Stain, Serology/antigen in CSF.

Was sinus fluid sampled?

If CTCAE term 'Sinusitis infective' is selected, indicate whether sinus fluid was sampled by answering **No**, **Yes** or **Unknown**.

Date of sinus fluid sampling

If sinus fluid was sampled, indicate the date of sinus fluid sampling or mark it Unknown if the date is not known.

Was this fungus detected in sinus fluid?

If sinus fluid was sampled, indicate whether this fungus was detected in sinus fluid for which you are filling out this field by answering **No**, **Yes** or **Unknown**. Only answer '**Yes**' if this specific fungus was detected, so not for other fungus potentially detected in sinus fluid. If more than one pathogen is detected in sinus fluid - report each one separately.

By what technique was the pathogen detected sinus fluid?

If the fungus for which you are filling out this field was detected in sinus fluid, indicate by what technique: Culture, PCR, Fungal stain.

Was an endoscopy performed?

IF CTCAE term 'Lower gastrointestinal infection' or 'esophagus or gastric infection' is selected, indicate whether an endoscopy was performed by answering **No**, **Yes** or **Unknown**.

Were gastrointestinal lesions documented?

If an endoscopy was performed, indicate whether gastrointestinal lesions were documented on this endoscopy by answering **No**, **Yes** or **Unknown**.

Were typical lesions seen on the eye examination?

If CTCAE term 'Retinitis infective' or 'Other eye infection' is selected, indicate whether typical lesions were seen on the eye examination by answering **No**, **Yes** or **Unknown**.

Was the patient transferred to the ICU due to this infection?

Indicate whether the patient was transferred to the ICU due to this infection by answering **No**, **Yes** or **Unknown**. Only answer '**Yes**' if the infection for which you are filling out this field was the reason the patient was transferred to the ICU, so not if the patient was in the ICU for any other reason.

Contributory cause of death

In case the patient is deceased, indicate if the infection contributed to death by answering **No**, **Yes** or **Unknown**.

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.

Extended dataset

Were abnormalities detected upon radiological assessment?

If CTCAE term ‘Central nervous system infection’, ‘Sinusitis infective’, ‘Esophagus or gastric infection’, ‘Liver site infection’, ‘Lower gastrointestinal infection’, ‘Enteritis infective’, ‘Other intra-abdominal infection’, ‘Splenic infection’ or ‘Urinary tract infection’ is selected, indicate whether abnormalities were detected upon radiological assessment by answering **No**, **Yes** or **Unknown**.

What diagnostic technique was used to detect abnormalities?

If abnormalities were detected upon radiological assessment, indicate by what diagnostic technique: MRI, CT, PET, PET CT, Ultrasound, Other (specify in the text field in English).

Radiology showing new or worsening pulmonary infiltrates

If CTCAE term 'Pneumonia' is selected, indicate whether new or worsening pulmonary infiltrates were visible upon radiology by answering **No**, **Yes** or **Unknown**.

What diagnostic technique was used?

If new or worsening pulmonary infiltrates were visible upon radiology, indicate by what diagnostic technique: CT, PET, Chest X-ray, MRI.

Was a biopsy performed?

If the CTCAE term was not 'Bacteremia', 'Fungemia', 'Viremia including DNAemia' or 'DNAemia for parasitic infection' (i.e. a blood infection), indicate whether a biopsy was performed by answering **No**, **Yes** or **Unknown**.

Date of biopsy

If a biopsy was performed, indicate the date on which the biopsy was performed.

Was this pathogen detected in biopsy?

If a biopsy was performed, indicate whether the pathogen for which you are filling out this field was detected in biopsy by answering **No**, **Yes** or **Unknown**. Only answer '**Yes**' if this specific pathogen was detected, so not for other pathogens potentially detected in biopsy. If more than one pathogen is detected in biopsy - report each one separately.

By what technique was the pathogen detected in biopsy?

If the pathogen for which you are filling out this field was detected in biopsy, indicate by what technique: Culture, Histopathological or cytopathological demonstration, Immunohistochemistry, PCR, Stain.

Was bronchoalveolar lavage (BAL) performed?

If CTCAE term 'Pneumonia' or 'Tracheobronchitis infective' is selected, indicate whether BAL was performed by answering **No**, **Yes** or **Unknown.**

Date of BAL

If BAL was performed, indicate the date of BAL.

Was this pathogen detected in BAL?

If BAL was performed, indicate whether the pathogen for which you are filling out this field was detected in BAL by answering **No**, **Yes** or **Unknown**. Only answer '**Yes**' if this specific pathogen was detected, so not for other pathogens potentially detected in BAL. If more than one pathogen is detected in BAL - report each one separately.

By what technique was the pathogen detected in BAL?

If the pathogen for which you are filling out this field was detected in BAL, indicate by what technique: Culture, PCR, Stain.

Was CSF obtained?

If CTCAE term 'Central nervous system infection' is selected, indicate whether CSF was obtained by answering **No**, **Yes** or **Unknown**.

Date of CSF

If CSF was obtained, indicate the date on which CSF was obtained

Was this pathogen detected in CSF?

If CSF was obtained, indicate whether the pathogen for which you are filling out this field was detected in CSF by answering **No**, **Yes** or **Unknown**. Only answer '**Yes**' if this specific pathogen was detected, so not for other pathogens potentially detected in CSF. If more than one pathogen is detected in CSF - report each one separately.

By what technique was the pathogen detected in CSF?

If the pathogen for which you are filling out this field was detected in CSF, indicate by what technique: Culture, PCR, Stain, Serology/antigen in CSF.

Were typical lesions seen on the eye examination?

If CTCAE term 'Retinitis infective' or 'Other eye infection' is selected, indicate whether typical lesions were seen on the eye examination by answering **No**, **Yes** or **Unknown**.

Was the patient transferred to the ICU due to this infection?

Indicate whether the patient was transferred to the ICU due to this infection by answering **No**, **Yes** or **Unknown**. Only answer '**Yes**' if the infection for which you are filling out this field was the reason the patient was transferred to the ICU, so not if the patient was in the ICU for any other reason.

Contributory cause of death

In case the patient is deceased, indicate if the infection contributed to death by answering **No**, **Yes** or **Unknown**.

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 by answering **No**, **Yes** or **Unknown**.

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.

Extended dataset

Were abnormalities detected upon radiological assessment?

If CTCAE term 'Central nervous system infection', 'Sinusitis infective', 'Esophagus or gastric infection', 'Liver site infection', 'Lower gastrointestinal infection', 'Enteritis infective', 'Other intra-abdominal infection', 'Splenic infection' or 'Urinary tract infection' is selected, indicate whether abnormalities were detected upon radiological assessment by answering **No**, **Yes** or **Unknown**.

What diagnostic technique was used?

If abnormalities were detected upon radiological assessment, indicate by what diagnostic technique: MRI, CT, PET, PET CT, Ultrasound, Other (specify in the text field in English).

Radiology showing new or worsening pulmonary infiltrates

If CTCAE term 'Pneumonia' is selected, indicate whether new or worsening pulmonary infiltrates were visible upon radiology by answering **No**, **Yes** or **Unknown**.

What diagnostic technique was used?

If new or worsening pulmonary infiltrates were visible upon radiology, indicate by what diagnostic technique: CT, PET, Chest X-ray, MRI.

Was the patient transferred to the ICU due to this infection?

Indicate whether the patient was transferred to the ICU due to this infection by answering **No**, **Yes** or **Unknown**. Only answer '**Yes**' if the infection for which you are filling out this field was the reason the patient was transferred to the ICU, so not if the patient was in the ICU for any other reason.

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

Vaccinations

Only if allogeneic HCT: Was the patient vaccinated with recombinant zoster vaccine (RZV; Shingrix® - GlaxoSmithKline (GSK)) during this follow-up period after the HCT treatment took place?

Indicate whether the patient has been vaccinated with the RZV (Shingrix®) during this follow-up period after the HCT treatment took place by answering **No**, **Yes** or **Unknown**.

Date of the first RZV (Shingrix®) vaccination

If the patient was vaccinated with RZV (Shingrix®), indicate on what date the patient received the first vaccination.

Date of the last RZV (Shingrix®) vaccination

If the patient was vaccinated with RZV (Shingrix®), indicate on what date the patient received the last vaccination.

Number of doses RZV (Shingrix®) vaccine

If the patient was vaccinated with RZV (Shingrix®), indicate how many doses in total the patient received.

Was the patient vaccinated against Respiratory syncytial virus (RSV) during this follow-up period after the HCT treatment took place?

Indicate whether the patient received a vaccination against the respiratory syncytial virus (RSV) during this follow-up period after the HCT treatment took place by answering **No**, **Yes** or **Unknown**.

What type of RSV vaccine did the patient receive?

If the patient was vaccinated against RSV, indicate what type of RSV vaccine the patient received.

Date of RSV vaccination

If the patient was vaccinated against RSV, indicate on what date the patient received this vaccination.

Did the patient receive monoclonal antibody against RSV during this follow-up period after the HCT treatment took place?

Indicate whether the patient received monoclonal antibody against RSV during this follow-up period after the HCT treatment took place by answering **No**, **Yes** or **Unknown**.

What type of RSV antibody did the patient receive?

If the patient received a monoclonal antibody against RSV, indicate what type of RSV antibody the patient received.

Date of monoclonal antibody given

If the patient received monoclonal antibody against RSV, indicate on what date the patient received this monoclonal antibody.

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 it a secondary malignancy or autoimmune disorder?

Indicate whether it is a secondary malignancy or autoimmune disorder.

Date of diagnosis

Indicate the date of diagnosis. In case the date is not known, report **Unknown**.

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 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

MRD detectable (with any method)

Only for Acute leukaemia, report if MRD detectable by answering No, Yes , Not evaluated or Unknown.

Date of first detectable MRD

Report the dat of the first detectable MRD or mark the date Unknown if it is not known.

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
- Unknown

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

- Unknown

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 (Malignant disorders only)

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 (Malignant disorders only)

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)

For malignant disorders only: 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.

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 detectails

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. If the test was not done, select **not evaluated**. If the value is not known, select **unknown**.

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** 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**.

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.

Extended dataset

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.

Technique used for disease assessment

Specify the technique used for disease assessment.

If the technique used is not listed, select **Other** and specify the technique used in the text field.

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.

Inborn errors

Patient height after HCT

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

Patient weight after HCT

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 done

Indicate if immune profiling was done by answering No, Yes or Unknown.

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**
CD3 T-cells (CD3)	Cells/µl
CD4 T-cells (CD4)	Cells/µl
CD8 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

Extended dataset

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

Only for Inborn errorrs of immunity: 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 after HCT in a separate cell infusion sheet, completing as many sheets as episodes of cell infusion that took place. It is important that cell infusions for the prevention or treatment of complications are reported here and not on the Cell Therapy forms. 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 (VST).**

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

Specificity of VST product

If the type of cells is '**Virus-specific T-cells (VST)**', indicate whether VST were '**Single-virus specific**' or '**Multi-virus specific**'.

If single-virus specific, to which virus?

If '**Single-virus specific**', check to which virus the VST are specific. Please register this virus in the Infectious complications - Viral infection part and fill in the VST in the 'Pre-emptive viral therapy' or 'Treatment of end-organ viral disease' section.

If multi-virus specific, to which viruses?

If '**Multi-virus specific**', check all viruses to which the VST are specific. Please register these viruses in the Infectious complications - Viral infection part and fill in the VST in the 'Pre-emptive viral therapy' or 'Treatment of end-organ viral disease' section.

Extended dataset

Product origin

If the type of cells is '**Virus-specific T-cells (VST)**', indicate whether the VST product was '**In-house manufactured**' or is a '**Commercial product**'.

If the VST product is a '**Commercial product**' check the box if this commercial product is '**Tabelecleucel**'.

Donor source

If the source of cells is '**Allogeneic**', indicate whether this source was the '**Stem cell donor**' or a '**Third-party donor**'.

If the source was a '**Third party donor**', indicate whether this donor was '**Related (family)**' or '**Unrelated**'.

Manufacturing method

Indicate the method by which the VST were manufactured.

Number of doses per infection episode

Indicate whether the patient received 1 VST dose or more than 1 VST dose per infection episode.

Total number of doses

If the patient received more than 1 VST dose per infection episode, indicate how many doses the patient received in total.

Dosing interval (in days)

If the patient received more than 1 VST dose per infection episode, indicate how many days were in between 2 consecutive doses.

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.

Only for Acute leukemia donor lymphocyte infusions: Response to DLI

Report the response to DLI or mark it as Unknown if it is not known.

MRD status:

If the response to DLI is reported as Complete remission (CR), report also the MRD status: if it is MRD negative or positive. Select **Not evaluated** if it was not evaluated or **Unknown** if it is not known.

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.