EBMT Registry

Cellular therapy (CT) follow-up

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

CT_FU_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.

Cellular therapies Day 100, 6 Months, Annual & Unscheduled Follow-Up

The Cellular Therapy (CT) follow-up form must be submitted online into the EBMT Registry database within 100 days, 6 months and annually post-CT or at time of patient death, whichever occurs first.

Some sections of this form are relevant and should be submitted on a particular follow-up only. If so, it is mentioned in the subtitle of the respective section. Otherwise (if no instruction as to what follow-up period the section covers), the questions of the section should be completed for every follow-up: Day 100, 6 Months, Annual and Unscheduled follow-up.

Subsequent HCT/CT

In case a patient proceeds to a subsequent HCT/CT between time points (Day 100, 6 Months, Annual), the data collection form (DCF) form sequence will start over again with another Day 0 form associated with the treatment (e.g. HCT, CT). Before starting over, a follow-up should be reported prior to the preparative regimen for the subsequent HCT/CT, to capture any events that occurred between the last reported follow-up post-CT and before the subsequent treatment.

Survival status

Date of follow-up

Report the date of this follow-up. If the patient died before the specific time point, enter the date of death. If the patient was lost to follow-up, enter the last contact date the patient was alive.

Survival status

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

Assessment period covered by this report

Indicate which assessment period covers this report based on the time period in relation to the CT infusion date. You can select between the following:

- **Day 100:** 100 days post-CT. The data on this assessment should reflect the patient's status on the day the patient was last seen, closest to 100 days post-CT. If the patient died within 100 days, the data from the last date the patient was seen alive can be used.
- **6 months:** 6 months post-CT. The data on this assessment should reflect the patient's status on the day the patient was last seen, closest to 6 months post-CT. If the patient died within 6 months, the data from the last date the patient was seen alive can be used.
- **Annual or unscheduled follow-up** post-CT.
    - Annual follow-up: In principle each CT patient should receive a yearly follow-up after the CT. When reporting the annual follow-up in the Registry the follow-up that falls closest to the anniversary (yearly interval) of the CT should be reported.
    - Unscheduled follow-up: This form can also be used to report a follow-up that occurred outside of the scheduled follow-ups for a CT patient. For example, due to a death of a patient after 6 months post-CT or patient proceeding to a subsequent CT/HCT. If a patient proceeds to a subsequent HCT/CT then a follow-up should be reported prior to the preparative regimen for the subsequent HCT/CT, to capture any events that occurred in between. If there are fluctuations in the disease status during the follow-up period and the centres deem it relevant, or if the patient is discharged from the centre and/or moves to another centre, an additional report may be provided between the standard reporting schedule.

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**.

The following main causes of death can be reported (check only one):

- **Relapse or progression/persistent disease**;
- **Secondary malignancy**;
- **Cellular therapy-related** - death caused by complications or infections after cellular therapy (specify details in the question ***Select treatment related cause***);
- **HCT-related** - death caused by complications or infections after transplant (specify details in the question ***Select treatment related cause***).
- **Gene therapy related** - death caused by complications after GT (specify details in the question ***Select treatment related cause)***.
- **IST-related** - death caused by complications or infections after IST, for patients with Bone Marrow Failure only. Specify details in the question ***Select treatment related cause.***

If none of the suggested answer options match, tick the box **Other cause of death** and specify the cause of death in the textbox in English .

Select treatment related cause

In case of Cellular therapy- or HCT-related or Gene-therapy or IST-related cause of death, specify if the cause of death was related to, select all that apply:

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

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

Infectious complication

If the cause of death was related to an infectious complication, select the type(s) of infections that apply:

- **Bacterial infection;**
- **Viral infection;**
- **Fungal infection;**
- **Parasitic infection;**
- **Infection with unknown pathogen.**

Please note that the new core Data Collection Forms (DCFs) do not have the category *"rejection/poor graft function or failure"* as contributory cause of death (previously in MEDs-A and B (auto, allo and disease-specific forms) since the cause of death following a graft failure is generally an infection.

Extended dataset

Was an autopsy performed

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

Best Response

This section should be reported for the 100 days, 6 months and first annual follow-up completed. This section is not applicable for patients receiving CT for Inborn errors indication diagnosis.

Best clinical/biological response after this CT

Report the patient's best response achieved after CT but before any subsequent treatment, even if the patient got worse again afterwards. Please refer to Appendix 1 on the form to select the best response

that is appropriate for the diagnosis of the patient. This includes the response observed before any subsequent treatment. If the best response after the CT has not been evaluated, select **Not evaluated**. If the best response after the HCT is unknown, select **Unknown.**

For Cell therapy given as treatment of a primary disease, the best response only has to be completed for the 100 days, 6 months and first annual follow-up. The disease specific options for the best response can be found in appendix 1 of the form.

The response must be assessed prior to additional non-planned disease treatment.

For the six-month form, copy the best response that was reported with the Day 100 form, unless a better disease response to CT is achieved during the six-month reporting period.

Example 1: A recipient with B-Cell Non Hodgkin Lymphomas is in *Chemorefractory relapse or progression, including primary refractory disease* at CT, achieves a CR during the first 100 days, and then progresses during the six-month reporting period. The best response to CT occurred in the 100 days reporting period and should be reported as "CR" on both Day 100 and 6 Months form. See table 1:

Assessment period	**Current disease status**	**Best clinical/biological response**	**Date response evaluated**
D0 form	Chemorefractory relapse or progression, including primary refractory disease	-	-
Day 100 form	CR	CR	Date of sample/image that first confirmed CR
6 Months form	Relapsed	CR	Date of sample/image that first confirmed CR (same as reported with d100 form)

Table 1. Example of reporting the best response 1.

Example 2: A recipient with B-cell acute lymphoblastic leukaemia is in CR at CT, maintains the response after transplant, and then relapses within the six-month reporting period. The best response to CT would be reported as "CCR" for all subsequent reporting periods. See table 2:

Assessment period	Current disease status	Q4.1 Best clinical/biological response	Q5. Date response evaluated
D0 form	CR	-	-
Day 100 form	CR	CCR	Date of sample/image that first confirmed a continued CR
6 Months form	Relapsed	CCR	Date of sample/image that first confirmed a continued CR (same as reported with d100 form)

Table 2. Example of reporting the best response 2.

Example 3: A recipient with multiple myeloma goes to CT having established a PR prior to CT and maintains the response throughout the 100-day reporting period. During the six-month reporting period, the recipient achieves a CR. The best response to CT occurred in the six-month reporting period. See table 3:

Assessment period	Current disease status	Q4.1 Best clinical/biological response	Q5 Date response evaluated
D0 form	Chemorefractory relapse or progression, including primary refractory disease	-	-
Day 100 form	PR	PR	Date of sample/image that first confirmed PR
6 Months form	CR	CR	Date of sample/image that first confirmed CR

Table 3. Example of reporting the best response 3.

Date best response first observed

Report the date the best response to the CT was first observed. The response date is the date that the sample or image was taken for assessing the response.

For the six-month form, copy the date reported with the Day 100 form, unless a better disease response to CT is achieved during the six-month reporting period. If the date is unknown, select **Unknown**.

Recovery

This section should be submitted for Day 100 follow up and 6 Months follow up. It will be disabled for all subsequent reporting periods in the EBMT Registry online data entry system. If the recovery occurred before 100 days and was reported at Day 100 follow-up, the section can be skipped at 6 Months follow-up.(For (ANC) recovery and Platelet reconstitution)

Absolute neutrophil count (ANC) recovery (neutrophils ≥ $0.5x10^9$ cells/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 $0.5x10^9$ cells/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** if:

- An autologous reconstitution has taken place.
- The ANC $<0.5x10^9$ cells/L

Answer **Yes** if the absolute count of neutrophils post-CT is higher or equal to $0.5x10^9$ cells/L for 3 laboratory values.

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.**

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

Date of the last assessment

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

Date of ANC recovery

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

Did the patient receive granulocyte colony-stimulating factor (G-CSF) or pegylated G-CSF during this follow-up period?

Answer **Yes** if the patient received granulocyte colony-stimulating factor (G-CSF) or pegulated G-CSF during the follow-up period. Answer **No** if the patient did not receive G-CSF or pegulated G-CSF during this period. If it is not known - select **Unknown**.

Start date

Indicate the start date of administration of G-CSF or pegylated G-CSF after CT. If the date is unknown, select **Unknown**.

Stop date

Indicate the stop date of administration of G-CSF or pegylated G-CSF after CT. If the therapy has not been stopped yet select Ongoing. If the therapy was discontinued but the date is unknown, select **Unknown**.

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 if the platelet count was <20x10^9 cells/L or if platelet transfusions were administered in the previous 7 days.
Answer Yes 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-CT.

Date of the last assessment

If platelet reconstitution was not achieved, indicate the date of the last assessment of the patient's platelets level.

Date of platelet reconstitution

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

Date of the last platelet transfusion

Indicate the date when the patient received the latest platelet infusion within the 100 day follow-up period; or mark it as **Not applicable** (not transfused) or **Date unknown.**

Was B-cell count monitored during this follow up period?

If B-cell count was not monitored after cellular therapy, select **No.** If it is not known if there was B-cell recovery, select **Unknown**. If B-cell count was monitored after cellular therapy, select **Yes.**

Generally CD19+ cells are monitored but other B-cell markers may be assessed.

Please provide the absolute total immune cell count:

If B-cell count was monitored during this follow-up period, report the **absolute total immune cell count** (lymphocytes). If multiple assessments were done, report the most recent cell count. And specify the correct measurement units.

Please provide the absolute B-cell cell count:

If B-cell count was monitored during this follow-up period, report the **absolute B-cell count**. If multiple assessments were done, report the most recent absolute B-cell count. And specify the correct measurement units.

Date of immune cell assessment:

If B-cell count was monitored during this follow-up period, report the most recent **date of the immune cell assessment,** which was used to report the absolute total immune cell count and absolute B-cell count.

Current haematological findings

Report results of haematological investigation in the follow up period. If haematological values were assessed multiple times in the current reporting period, report the most recent (closest to the date of this follow-up) value. Carefully check in which unit the data should be reported.

- **Hb (haemoglobin):** Report the haemoglobin (Hb) level in grams per decilitre (g/dL). If the level was not evaluated, Select **Not evaluated**. If the haemoglobin level is not known, select **Unknown**.
- **Platelets:** Report the count of platelets in 10^9 cells/L. If it was not evaluated, select **Not evaluated**. If the amount is unknown, select **Unknown**.
    - Also specify if p**latelets were transfused within 7 days before the blood count assessment** by answering **Yes** (if transfused), **No** (not transfused), or marking **Unknown**, if it is not known.
- **White blood cells:** Report the amount of white blood cells in 10^9 cells/L. If it was not evaluated, select **Not evaluated**. If the amount is unknown, select **Unknown**.
- **Lymphocytes:** Report the percentage (%) or absolute count of lymphocytes. If it was not evaluated, select **Not evaluated**. If the amount is unknown, select **Unknown**.
- **Neutrophils:** Report the percentage (%) or absolute count of neutrophils. If it was not evaluated, select **Not evaluated**. If the amount is unknown, select **Unknown**.

Extended dataset

Antimicrobial prophylaxis

Did the patient receive antimicrobial prophylaxis?

Indicate if the patient received any type of prophylaxis.

If yes, what type of prophylaxis?

Check all types of prophylaxis the patient received.

Antibacterial prophylaxis

Antibiotic

Check all types of antibiotics that were administered as prophylaxis.

Phase

Only for the Day 100 Follow-Up:

Select the phase (**Pre-ANC recovery**, **Post-ANC recovery**) during which the antibiotic was administered. Select **unknown** if you do not know during what phase the antibiotic was given. If the antibiotic was given during both the pre-ANC and post-ANC recovery phase, select **Post-ANC recovery** and answer the follow-up

question: **Only post-ANC recovery**, **Started pre-ANC recovery and continued into post-ANC recovery** or **Started and stopped pre-ANC recovery phase and restarted in post-ANC recovery phase**.

Response for Follow-Ups after Day 100:

Indicate whether the antibacterial prophylaxis was **started during this follow-up period**, or whether it is a **continuation from the previous follow-up period**. If started during this follow-up period, indicate the start date or select **unknown** if you do not know the start date.

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

Did the patient receive cytomegalovirus (CMV) prophylaxis during this follow-up period?

Indicate if any type of CMV prophylaxis has been administered.

Which drugs were used?

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

Final date CMV prophylaxis was discontinued

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

Did the patient receive prophylaxis for varicella-zoster virus (VZV) or herpes simplex virus (HSV) with either acyclovir or valaciclovir during this follow-up period?

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

Final date VZV or HSV prophylaxis was discontinued

Report the date the patient last received 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, or select **ongoing** if the patient is still receiving either acyclovir or valaciclovir as VZV or HSV prophylaxis.

Did the patient receive rituximab or another anti-CD20 monoclonal drug as prophylaxis for Epstein-Barr virus post-transplant lymphoproliferative disorder (EBV-PTLD) during this follow-up period?

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

Did the patient receive prophylaxis for hepatitis B (HBV) during this follow-up period?

Indicate if any type of HBV prophylaxis has been administered.

Which drugs were used?

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

Final date HBV prophylaxis was discontinued

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

Antifungal prophylaxis

Antifungal

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

Phase

Only for the Day 100 Follow-Up:

Select the phase (**pre-ANC recovery**, **post-ANC recovery**) during which the antifungal was administered. Select **unknown** if you do not know during what phase the antifungal was given. If the antifungal was given during both the pre-ANC and post-ANC recovery phase, enter the antifungal twice, once for the pre-ANC recovery phase and once for the post-ANC recovery phase.

Response for Follow-Ups after Day 100:

Indicate whether the antifungal prophylaxis was **started during this follow-up period**, or whether it is a **continuation from the previous follow-up period**. If started during this follow-up period, indicate the start date or select **unknown** if you do not know the start date.

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) during this follow-up period?

Indicate if any type of PJP prophylaxis has been administered.

Which drugs were used?

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

Final date prophylaxis was discontinued

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

Preventive therapies

Were any immunoglobulins administered during this follow-up period?

Answer **Yes** if immunoglobulins were administered during the follow-up period. Answer **No** if the patient did not receive immunoglobulins during this period.

Start date

Indicate the start date of administration of immunoglobulins.

Stop date

Indicate the stop date of administration of immunoglobulins.

Complications since the Last Report - GvHD

This section shall be completed only if the patient ever received an allogeneic HCT or a cell therapy of allogeneic origin prior to this CT. Do not report complications that were resolved before this cellular therapy. Do not report complications that were previously reported as resolved, unless they recurred.

Did graft versus host disease (GvHD) occur?

This question only needs to be answered if the patient ever received an allogeneic HCT or a cell therapy of allogeneic origin. Select **Yes** if GvHD occurred/were ongoing/resolved in this follow up period. If it did not occur select **No** and proceed to the next section. If this information is unavailable, select **Unknown**.

Graft-versus-host disease (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 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 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 during this follow-up period?

Indicate **Yes** if the patient received a systemic/immunosuppressive treatment including ECP (Extracorporeal Photopheresis) for GvHD in this follow up period, and indicate **No** if the patient did not receive a systemic/ immunosuppressive treatment for GvHD. If the information is unavailable, select **Unknown**. In case of No and Unknown, proceed to the next section: Complications since the last report - Non-infectious complications.

If the answer is **Yes**, specify also details in the subsequent questions:

Started in this follow-up period

Select this option if systemic/immunosuppressive treatment for GvHD starts during this follow-up. and report the **Date treatment started**: report here the date the systemic/immunosuppressive treatment for GvHD started**.** If the date is not known, select **Unknown.**

Ongoing since previous follow-up

Select this option if systemic/immunosuppressive treatment for GvHD started in a previous follow-up period and it was ongoing in this follow-up period. The details on whether the

systemic/immunosuppressive treatment for GvHD stopped or not in the current follow up period should be reported in the subsequent question.

Treatment stopped

Report if systemic/immunosuppressive treatment for GvHD stopped during this follow-up. Mark **Unknown** if this information is unavailable. If the answer is Yes, specify also the **Stop date of treatment (**during this follow-up) or mark the date as **Unknown** if this date is unavailable.

Did acute GvHD occur?

Indicate if aGvHD occurred/were ongoing/resolved in this follow up period (including ongoing aGvHD first reported in a previous FU).

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.

If the information is unavailable, select **Unknown**.

Started in this follow-up period

Select this option if aGvHD started during this follow-up and report the **date of onset** in the subsequent question. If the date is not known, select **Unknown.**

Ongoing since previous follow-up

Select this option if aGvHD started in a previous follow-up period and was ongoing in this follow-up period. The details on whether the aGvHD was resolved or not in the current follow up period should be reported in the subsequent question ***aGvHD resolved***.

Maximum observed organ severity score during this period

Select for each organ listed in the table the observed severity score during this follow up period. If another site was also affected, answer **Yes** in **Other site affected** and specify this site in the text field in English. Report **Unknown** if this information is unavailable. Select **Not evaluated** if aGvHD was not assessed.

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 4.

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	Generalized erythroderma (> 50% BSA) plus bullous formation and desquamation >5% of BSA

Organ	Stage	Description
Liver	0	Total serum bilirubin < 34 µmole/L (< 2 mg/dL)
	1	Total serum bilirubin 34–50 µmole/L (2 to 3 mg/dL)
	2	Total serum bilirubin 51–102µmole/L (3.1 to 6 mg/dL)
	3	Total serum bilirubin 103–255 µmole/L (6.1 to 15 mg/dL)
	4	Total serum bilirubin >255 µmole/L (> 15 mg/dL)
Lower GI tract (Lower gut)	0	Diarrhea < 500 mL/day or<3 episodes/day for adults or diarrhea <10 mL/kg/day or <4 episodes/day for children
	1	Diarrhea 500–999 mL/day or 3–4 episodes/day for adults or diarrhea 10–19.9 mL/kg/day or 4–6 episodes/day for children
	2	Diarrhea 1000–1500mL/day or 5–7 episodes/day for adults diarrhea 20–30 mL/kg/day or 7–10 episodes/day for children
	3	Diarrhea >1500 mL/day or >7 episodes/day for adults or diarrhea > 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 GI tract (Upper gut)	0	No or intermittent anorexia or nausea or vomiting
	1	Persistent anorexia or nausea or vomiting

Table 4. aGvHD grading system per organ (2).

Overall maximum grade observed during this period

Select the overall maximum grade that was observed during this follow up period. If it is not known which overall maximum grade was observed, select **Unknown**. Select **Not evaluated** if aGvHD was not assessed.

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 the relevant period being studied as calculated from table 5.

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	Any skin	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 5. Overall maximum grade for aGvHD (2).

Steroid-refractory acute GvHD

Indicate if the patient experienced steroid-refractory acute GvHD (answer **Yes** and provide details in subsequent questions) or not (answer **No**). Select **Unknown** if this information is not available.

Steroid refractory aGvHD is defined in the EBMT handbook (3) 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)".

Started in this follow-up period

Select this option if the patient experienced steroid-refractory acute GvHD and it started during this follow-up. Report also Date of onset (the date when steroid-refractory aGvHD started) or If the date is not known, select **Unknown.**

Ongoing since previous follow-up

Select this option if the patient experienced steroid-refractory acute GvHD that started in a previous follow-up period and was still ongoing in this follow-up period.

Extended dataset

aGvHD resolved

If acute GvHD was resolved in this follow-up period, answer **Yes** and specify the **Date of aGvHD resolution** (the date on which aGvHD resolved completely) in this follow-up period or mark the date as **Unknown**.

Answer No if acute GvHD was not resolved in this follow-up period. If it is unknown whether aGvHD resolved, mark **Unknown**.

Did chronic GvHD occur during this follow-up period?

Indicate if chronic GvHD occurred/were ongoing/resolved in this follow up period (including ongoing cGvHD first reported in a previous FU).

Answer **No** if the patient has never had an episode of cGvHD in this follow up period. If the information is unavailable, select **Unknown**.

If the answer is **Yes**, specify also:

Started in this follow-up period

Select this option if cGvHD started during this follow-up and report the **Date of onset (**the date when cGvHD started) or if the date is not known, select **Unknown.**

Ongoing since previous follow-up

Select this option if cGvHD started in a previous follow-up period and was ongoing during this follow-up period. The details on whether the cGvHD was resolved or not in the current follow up period should be reported in the subsequent question ***aGvHD resolved***.

Maximum NIH score during this period

Indicate if the maximum NIH score during this period was **Mild**, **Moderate** or **Severe**. If the score is unknown, select **Unknown**. Select **Not evaluated** if cGvHD was not assessed

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 6.

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 6. Assessing the maximum NIH score (1).

In 2022 the NIH consensus (5) recognized atypical manifestations of chronic GvHD, which should be placed in the section 'other' 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 in this follow-up period. If the date is not known, mark **Unknown**.

Maximum observed organ severity score

Select for each organ in the table the observed severity score. If another site was affected, answer **Yes** in **Other site affected** and specify this site in the text field. Select **Not evaluated** if cGvHD was not assessed.

Use the NIH scoring system as described in Chronic GvHD.

Steroid-refractory chronic GvHD

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

mg/kg/day (or 1 mg/kg every other day) of prednisone for 1 to 2 months" (2). Mark **Unknown** if this information is not available.

If the answer is **Yes**, specify details in the subsequent questions.

Started in this follow-up period

Select this option if steroid-refractory cGvHD started during this follow-up period and report the **Date of onset (**the date when steroid-refractory cGvHD started) or If the date is not known, select **Unknown.**

Ongoing since previous follow-up

Select this option if steroid-refractory cGvHD started in a previous follow-up period ans was ongoing in this follow-up period.

Extended dataset

cGvHD resolved

Report whether chronic GvHD was resolved in this follow up period or not. If it is unknown whether cGvHD resolved, mark **Unknown**.

If the answer is **Yes**, specify the **Date of cGvHD resolution** or if the date is unavailable, select **Unknown**.

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 **Unknown** if this information is unavailable.

Complications since the last report - Non-infectious complications

Do not report complications that were resolved before this cellular therapy.

Do not report complications that were previously reported as resolved, unless they recurred.

Did non-infectious complications occur or continue during this follow-up period?

If no other non-infectious complication than GvHD occurred during the follow-up period or if the complication was grade 1 or 2, select **No** and proceed to the next section (except for the complications CRS and ICANS; these should always be reported regardless of the grade). Mark **Unknown** if this information is not available.

If non-infectious complications (other than GvHD) occurred/were ongoing/resolved in this follow-up period answer **Yes** taking into account the complication grade (if applicable) as follows:

- The following complications should be reported if present regardless of the Maximum grade observed:
    - Cytokine release syndrome (CRS),
    - IEC-associated neurotoxicity syndrome (ICANS),
- The other complications listed in the table should be considered for reporting with a Common Terminology Criteria for Adverse Events (CTCAE) grade of at least 3 or up.

For adverse events not listed in the table but observed with CTCAE grade of at least 3, they should be considerate while answering this question and for reporting in the relevant **Other** text field. Consult with Appendix 4 'Non-infectious Complications CTCAE term - No Reporting Required' in the paper form which non-infectious complications should not be reported even for grades 3 and 4.

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.

Adverse event observed during this period

Specify for each adverse event listed whether it was observed or not in this follow-up period. Follow the instructions on the minimum grade to consider the complication for reporting. The CTCAE gradings (version 5) can be found on the website of the NIH (6), and for CRS and ICANS the ASTCT Consensus Grading scale (Lee 2019) is recommended. If the status of the adverse event is unknown, select **Unknown.** The list of adverse events includes the following:

- **Cytokine release syndrome (CRS);**
- **IEC-associated neurotoxicity syndrome (ICANS);**
- **Other neurotoxicity;**
- **Macrophage activation syndrome (MAS);**
- **Secondary haemophagocytic lymphohistiocytosis;**
- **Organ toxicity: skin;**
- **Organ toxicity: liver;**
- **Organ toxicity: lung;**
- **Organ toxicity: heart;**
- **Organ toxicity: kidney;**
- **Organ toxicity: gastrointestinal;**

- **Other organ toxicity;**
- **Tumour lysis syndrome;**
- **B-cell aplasia;**
- **Bone marrow aplasia;**
- **Hypogammaglobulinemia;**
- **Exacerbation of existing neurological disorder;**
- **Other complication.**

Example 1: A recipient with B-cell acute lymphoblastic leukaemia receives a CT on January 1st 2021 and develops a grade 1 CRS on January 3rd 2021. The patient is not treated during the reporting period and the CRS is not resolved at the moment of Day 100 assessment. The CRS develops to grade 2 within the six-month reporting period, the patient receives treatment and the CRS is resolved on May 12 2021, at the 6 months assessment. See table 7:

Reporting period	**Current adverse event**	**Complication observed during this follow-up period?**	**Newly developed or Ongoing since previous assessment**	**Maximum grade observed during this period + grading system**	**Onset date**	**Treated**	**Resolved + stop date**
Day 100 form	CRS – present grade 1	Yes	Newly developed	Grade 1 (ASTCT)	03-01-2021	No	No
6 Months form	CRS – present, develops into grade 2, resolved after 5 months	Yes	Ongoing since previous assessment	Grade 2 (ASTCT)	-	Yes	Yes, 12-05-2021
Annual FU	CRS – absent	No	-	-	-	-	-

Table 7. Example of reporting an observed CRS complication.

Event newly developed or ongoing since previous assessment

If you are reporting 6 months or annual follow-up, indicate if the observed adverse event **newly developed** in the follow-up period (i.e. started since the last follow-up event was reported and was not present at previous follow-up) or if it was **Ongoing since previous assessment** (i.e. the adverse event was reported at a previous follow-up and is still present at this follow-up).

Maximum grade observed

Select for each adverse event the maximum grade that was observed in the reporting period. If the grade is unknown, select **Unknown**. If not otherwise specified, CTCAE grading system is to be used (6).

For the following complications please use ASTCT Consensus Grading scale (Lee 2019) (https://www.astctjournal.org/article/S1083-8791(18)31691-4/fulltext):

- Cytokine release syndrome (CRS): is a non–antigen specific toxicity that occurs as a result of high-level immune activation;
- IEC-associated neurotoxicity syndrome (ICANS).

If for some reason it is not possible to use this grading system, please select the appropriate scale from the list (see Grading system question below).

There is no maximum grade to be indicated for bone marrow aplasia, hypogammaglobulinemia and B-cell aplasia.

Grading system

If Cytokine release syndrome (CRS) and/or IEC-associated neurotoxicity syndrome (ICANS) marked as observed during this follow-up period, specify the Grading system used for assessment by selecting one of the answer options:

- **ASTCT consensus** (Lee 2019)
- **Penn**
- **CTCAE**
- **Lee 2014**
- **MDACC**
- **Other**; specify it in the text field.

Onset date

For each adverse event occurred in this follow up period (only if newly developed), indicate the onset date of the event. Report the onset date when the adverse event was first observed during this follow-up period. If the complication has been reported in a previous follow-up form and was not resolved at that follow-up, leave this field empty.

Resolved

Report for each adverse event if the complication was resolved or not in this follow-up period.

- **Yes** - select this option if the complication was resolved during this follow-up period. In addition, specify the **Stop date** it was resolved (according to the physician's evaluation). If the date of resolution is not known, mark the date as **Unknown**).
    - For CRS/ICANS, this is usually from the day of starting withdrawal of the CRS/ICANS treatment.

- For the stop date of B-cell aplasia, report the day of presence of B lymphocytes (regardless the cutoff).

- No - select this option if the complication is still ongoing.
- Unknown - use the **u**nknown answer option if there is no information on whether the complication was resolved or not**.**

Additional questions for specific non-infectious complications:

Cytokine release syndrome (CRS)

If **Cytokine release syndrome (CRS)** is reported as observed during this follow up period**,** specify also the following details:

Was the CRS treated?

Indicate if the CRS complication was treated in the current reporting period. Answer **No,** if the patient did not receive treatment for CRS. Answer **Yes**, if the patient received therapy to treat the CRS and specify which treatments were given in the text field.

IEC-associated neurotoxicity syndrome (ICANS)

Was the ICANS treated?

If **IEC-associated neurotoxicity syndrome (ICANS)** is reported as observed during this follow up period, specify also if the ICANS was treated in the current reporting period. Answer **No,** if the patient did not receive treatment for ICANS. Answer **Yes**, if the patient received therapy to treat the ICANS and specify which treatments were given in the text field.

B-cell aplasia

If B-cell aplasia is reported as Complication observed during this follow-up period, specify also the following details:

% B-cells

B-cell aplasia is a condition characterised by extremely low B-cell counts. Testing may be performed multiple times during this follow-up period; please report the lowest percentage of **B-cells** observed since the complication started or mark it as **Not evaluated**. If the B-cell aplasia complication is ongoing since

previous submitted follow-up, continue to report the lowest B-cell percentage observed within each respective follow-up interval.

Hypogammaglobulinemia

Hypogammaglobulinemia is a condition with low antibody (IgG) levels in the blood. It is defined as **serum IgG < 400 mg/dL (4 g/L).** If **hypogammaglobulinemia** is reported as **Observed during this follow up period,** specify also the following details:

Was it also present at time of the cellular therapy?

Answer **No, occurred after the cellular therapy**, if the patient had no hypogammaglobulinemia at time of this cellular therapy.

Answer **Yes**, if the patient had hypogammaglobulinemia at time of this cellular therapy and report **Was it worsened by the cellular therapy** or not.

Exacerbation of existing neurological disorder or Other complication

If **Exacerbation of existing neurological disorder** or **Other complication** is reported as **Observed during this follow up period,** specify also the following details:

Specify (Indicate CTCAE term)

If **Exacerbation of existing neurological disorder** or **Other complication** is reported as **Observed during this follow up period, s**pecify the CTCAE term.

Consult with Appendix 4 in the paper form which non-infectious complications should not be reported even for grades 3 and 4.

Complications since the last report - Infectious complications

Do not report infections that were already reported as resolved on the previous assessment and did not reoccur.

Did infectious complications occur during the follow-up period?

Answer **Yes** if any infectious complications occurred/were ongoing/resolved in this follow up period (including any ongoing infectious complication first reported in a previous FU) during the follow-up

period, select **No** if infectious complications not occurred and proceed to the next section. Mark **Unknown** if this information is not available.

Infections already reported on the previous follow-up need to be taken into account while reporting since they continued into this follow-up period. In this case, please make sure to report the current state in the current follow up period (e.g. clinical implications/localization/resolution).

Infections already resolved at the previous follow-up do not need to be reported, unless a reactivation occurred.

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.

New or ongoing

Indicate if the patient had a **Newly developed** bacterial infection or if it was **Ongoing since previous assessment**.

Start date

Only if newly developed bacterial infection, 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.

If the start date was already reported on the previous follow-up form (with the **Ongoing since previous assessment** option selected), the start date does not need to be reported again and this field shall be left blank.

Type of bacteria

Select the type of bacteria by marking if it is '**Gram-positive**', '**Gram-negative**' or **'Other'** (see the list in Appendix 1 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 '**Resistant**' 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.

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 during this follow-up period 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.

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.

Was a biopsy performed?

If the CTCAE term was **not** 'Bacteremia', (i.e. a blood infection), indicate whether a biopsy was performed.

Date of biopsy

If a biopsy was performed, indicate the date on which the biopsy was performed. If the date is not known mark 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.

Was bronchoalveolar lavage (BAL) performed?

If CTCAE term 'Pneumonia' or 'Tracheobronchitis infective' is selected, indicate whether BAL was performed.

Date of BAL

If BAL was performed, indicate the date of BAL. If the date is not known mark 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.

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 is not known mark 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.

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.

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 possible.

Viral infection

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

New or ongoing

Indicate if the patient had a **Newly developed** viral infection or if it was **Ongoing since previous assessment**.

Start date

Only if newly developed infection, 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.

In case the start date was already reported on the previous follow-up form (with the **Ongoing since previous assessment** option selected), the start date does not need to be reported again and this field should be left blank.

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 during this follow-up period 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.

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.

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 is 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.

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 is 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.

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 is 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.

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

Contributory cause of death

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

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.

If yes, for what virus?

If pre-emptive therapy was given, select all viruses for which pre-emptive therapy was administered.

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. If the date is not known, mark as **Unknown**.

Antiviral(s) used

Select the antiviral that was given as pre-emptive therapy for CMV, and add a new section for each antiviral. 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.

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.

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. If the date is not known, mark as **Unknown**.

Therapy used

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 the date is not known, mark as **Unknown**.

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.

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.

Extended dataset

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.

If yes, for what virus?

If treatment for end-organ viral disease was given, select all viruses for which it was given.

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. If the date is not known, mark as **Unknown**.

Antiviral(s) used

Select the antiviral(s) that were given as end-organ disease treatment for CMV. 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.

Which mutation(s) were identified?

In case a resistance test was performed, select all mutations that were identified in this resistance test.

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 the date is not known, mark as **Unknown**.

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. 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 the date is not known, mark as **Unknown**.

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

Select the antiviral(s) that were given as end-organ disease treatment for BKV. 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 the date is not known, mark as **Unknown**.

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

Select the antiviral(s) that were given as end-organ disease treatment for ADV. 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 the date is not known, mark as **Unknown**.

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. If the date is not known, mark as **Unknown**.

Therapy used

Select the therapy/therapies that were given as end-organ disease treatment for JCV. 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 the date is not known, mark as **Unknown**.

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. If the date is not known, mark as **Unknown**.

Antiviral(s) used

Select the antiviral(s) that were given as end-organ disease treatment for HHV-6. 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.

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.

Was chromosomally integrated HHV-6 present?

If testing for chromosomally integrated HHV-6 was done, indicate whether chromosomally integrated HHV-6 was present.

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 the date is not known, mark as **Unknown**.

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. If the date is not known, mark as **Unknown**.

Antiviral(s) used

Select the antiviral(s) that were given as end-organ disease treatment for CARV. 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 the date is not known, mark as **Unknown**.

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.

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. Report here only infections with microbiological documentation, otherwise they shall be reported as infection with unknown pathogen.

New or ongoing

Indicate if the patient had a **Newly developed** bacterial infection or if it was **Ongoing since previous assessment.**

Start date

Only if newly developed infection, 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.

In case the start date was already reported on the previous follow-up form (with the **Ongoing since previous assessment** option selected), the start date does not need to be reported again and this field should be left blank.

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 during this follow-up period 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.

What diagnostic technique was used?

If abnormalities were detected upon radiological assessment, indicate by what diagnostic technique.

Radiology showing new or worsening pulmonary infiltrates

If CTCAE term 'Pneumonia' is selected, indicate whether new or worsening pulmonary infiltrates were visible upon radiology.

What diagnostic technique was used?

If new or worsening pulmonary infiltrates were visible upon radiology, indicate by what diagnostic technique.

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.

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.

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. 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.

Was bronchoalveolar lavage (BAL) performed?

If CTCAE term 'Pneumonia' or 'Tracheobronchitis infective' is selected, indicate whether BAL was performed.

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. 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.

Was CSF obtained?

If CTCAE term 'Central nervous system infection' is selected, indicate whether CSF was obtained.

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. 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.

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 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 in 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.

Were gastrointestinal lesions documented?

If an endoscopy was performed, indicate whether gastrointestinal lesions were documented on this endoscopy.

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.

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

Indicate whether the patient was transferred to the ICU due to this infection. 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 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.

New or ongoing

Indicate if the patient had a **Newly developed** parasitic infection or if it was **Ongoing since previous assessment**.

Start date

Only if newly developed infection, 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.

In case the start date was already reported on the previous follow-up form (with the **Ongoing since previous assessment** option selected), the start date does not need to be reported again and this field should be left blank.

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 during this follow-up period 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.

What diagnostic technique was used?

If abnormalities were detected upon radiological assessment, indicate by what diagnostic technique.

Radiology showing new or worsening pulmonary infiltrates

If CTCAE term 'Pneumonia' is selected, indicate whether new or worsening pulmonary infiltrates were visible upon radiology.

What diagnostic technique was used?

If new or worsening pulmonary infiltrates were visible upon radiology, indicate by what diagnostic technique.

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.

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. 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.

Was bronchoalveolar lavage (BAL) performed?

If CTCAE term 'Pneumonia' or 'Tracheobronchitis infective' is selected, indicate whether BAL was performed.

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. 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.

Was CSF obtained?

If CTCAE term 'Central nervous system infection' is selected, indicate whether CSF was obtained.

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. 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.

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.

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

Indicate whether the patient was transferred to the ICU due to this infection. 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 parasitic 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.

Infection with unknown pathogen

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

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

New or ongoing

Indicate if the patient had a **Newly developed** infection with unknown pathogen or if it was **Ongoing since previous assessment**.

Start date

Only if newly developed infection, 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.

In case the start date was already reported on the previous follow-up form (with the **Ongoing since previous assessment** option selected), the start date does not need to be reported again and this field should be left blank.

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 doesn't 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.

What diagnostic technique was used?

If abnormalities were detected upon radiological assessment, indicate by what diagnostic technique.

Radiology showing new or worsening pulmonary infiltrates

If CTCAE term 'Pneumonia' is selected, indicate whether new or worsening pulmonary infiltrates were visible upon radiology.

What diagnostic technique was used?

If new or worsening pulmonary infiltrates were visible upon radiology, indicate by what diagnostic technique.

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

Indicate whether the patient was transferred to the ICU due to this infection. 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 this table as many times as necessary.

Extended dataset

Vaccinations

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

Indicate whether the patient has been vaccinated with the RZV (Shingrix®) during this follow-up period after the CT treatment took place.

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 RSV during this follow-up period after the CT treatment took place?

Indicate whether the patient received a vaccination against the respiratory syncytial virus (RSV) during this follow-up period after the CT treatment took place.

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 CT treatment took place?

Indicate whether the patient received monoclonal antibody against RSV during this follow-up period after the CT treatment took place.

What type of RSV antibody did the patient receive?

If the patient received 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 no secondary malignancy or autoimmune disorder occurred in the current reporting period (post-infusion), or if the secondary malignancy or autoimmune disorder was already reported in the previous CT follow-up form.

Answer **Yes** if secondary malignancy or autoimmune disorder occurred and it has not been reported with a CT follow-up form yet. The secondary malignancy can be any disease for which the patient had not been diagnosed before the CT. Do not include relapse, progression or transformation of the recipient's same disease subtype (disease for which the CT was performed) as these should be reported as relapse or disease progression). Do not report any autoimmune disorders that were diagnosed pre-CT infusion and persisted post-CT infusion.

Answer **Unknown** if there is no information on whether secondary malignancy or autoimmune disorder occurred or not.

Was it a secondary malignancy or autoimmune disorder?

If answered yes in the previous question, indicate whether it is a **secondary malignancy** or **autoimmune disorder**.

Date of diagnosis

Report the date of diagnosis of secondary malignancy/autoimmune disorder.

Further details on secondary malignancy or autoimmune disorder

Report, if applicable, the further details on secondary malignancy or autoimmune disorder.

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

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

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

Secondary malignancies only:

Complete this section only if a secondary malignancy occurred after CT.

Histologic type

If applicable, report the histological type of the secondary malignancy, for instance acute myeloid leukemia, myelodysplastic syndromes.

Location

If applicable, report the anatomical location(s) of the secondary malignancy.

Secondary malignancy material preserved

Answer **Yes** if secondary malignancy material was preserved. Answer **No** if secondary malignancy material was not preserved. If it is not known if secondary malignancy material was preserved or not, select **Unknown**.

Concomitant PBMCs preserved

Answer **Yes** if concomitant peripheral blood mononuclear cells (PBMCs) were preserved. Answer **No** if concomitant PBMCs were not preserved. If it is not known if concomitant PBMCs were preserved or not, select **Unknown**.

Was a test on the secondary malignancy material performed?

Answer **Yes** if the test (PCR, flow cytometry or other) on the secondary malignancy material performed. Answer **No** if test on the secondary malignancy material was not performed. If it is not known if the test was performed or not, select **Unknown**.

Specify performed test

Select the test which was performed on the secondary malignancy material: **PCR**, **flow cytometry** or **other**. If **Other** was selected specify the performed test in the text field.

What was the outcome of the test?

In case a test was performed on the secondary malignancy material, indicate the outcome of the test:

- **CAR not detected: choose if CAR transgene was not detected in the malignancy sample.**
- **CAR detected: choose if CAR transgene** was detected in the malignancy sample.
- **Other specify**: choose if the outcome of the test was different, and specify the outcome in the text field.
- **Unknown**: choose if the outcome of the test is not known**.**

Is the secondary malignancy of T-cell origin?

Answer **Yes** if the secondary malignancy is of T-cell origin (e.g. T-cell lymphoma) and specify the details. If the secondary malignancy is not of T-cell origin select **No**. If it is not known if the secondary malignancy is of T-cell origin or not, select **Unknown**.

For CAR-T cells: In November 2023 the Food and Drug Administration (FDA) disseminated a warning regarding T-cell lymphomas in patients undergoing Chimeric Antigen Receptor T-cell (CART) therapy. Specifically, the FDA warning highlights the potential risks associated with CAR T-cell therapies regarding the development of T-cell lymphomas secondary to a mechanism of CART transgene insertional mutagenesis (FDA Investigating Serious Risk of T-cell Malignancy Following BCMA-Directed or CD19-Directed Autologous Chimeric Antigen Receptor (CAR) T cell Immunotherapies. 2023; Available from: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-investigating-serious-risk-t-cell-malignancy-following-bcma-directed-or-cd19-directed-autologous). The EBMT-EHA-GoCART Coalition published a statement supporting the FDA statement that the therapeutic benefits of CAR T-cell therapies outweigh their potential risks for the approved settings (FDA Reports of Secondary Malignancies Following Chimeric Antigen Receptor (CAR) T Cell Therapies and Relative Risk: an EBMT-EHA-GoCART Coalition Statement. 2023; available from: https://www.ebmt.org/ebmt/news/fda-reports-secondary-malignancies-following-chimeric-antigen-receptor-car-t-cell).

Please specify the type of secondary malignancy

- Iatrogenic disease in relation with treatments administered prior to cellular therapy cells indication and administration (i.e. cytotoxic agents, targeted therapies, immunotherapies, radiation therapy, etc.);
- Transformation of engineered immune effector cells through insertional mutagenesis or other mechanisms.

Has an investigation to assess the detection of replication competent retrovirus (RCR) in samples of secondary malignancy been conducted?

If PCR test was performed indicate whether testing for replication-competent retrovirus (RCR) was performed on samples obtained from a secondary malignancy. Select **Yes** only when a laboratory investigation specifically assessing RCR (e.g., **PCR-based testing**) has been carried out on the malignancy

sample. If no such investigation was performed, select **No**. If it is unknown whether RCR testing was conducted, select **Unknown**.

What was the outcome?

Select the outcome of the **RCR investigation**:

- **RCR undetected** – choose if the test showed no replication-competent retrovirus.
- **RCR detected: please specify RCR details** – choose if RCR was found, and provide relevant details
- **Other: please specify** – choose if the outcome does not fit the above categories, and describe the result.

Persistence of the infused cells

Was persistence of the infused cellular products assessed since the last follow-up?

Answer **No** if persistence of the infused cellular products has not been assessed since the last reported follow-up and proceed with the next section. Answer **Yes** if tests to detect the persistence of the infused cells have been performed since the last reported follow-up and provide details in subsequent questions. If it is not known, select **Unknown**.

Date of the last assessment

If a test was performed, indicate the date of the last test before the follow-up assessment that is being reported. If it is not known, select **Unknown**.

Source of cells used for testing

Report the source of cells that was used to assess the persistence of the infused cellular product:

- **Bone marrow,**
- **Peripheral blood,**
- **Tumour**.

If another source of cells was used for testing, select **Other** and specify the source of cells in the text field.

Technique used for testing

Indicate the technique that was used to assess the persistence of the infused cellular product:

- **Molecular (PCR),**
- **Flow Cytometry,**
- **Chimerism,**

- **Imaging,**
- **Immunohistochemistry**.

If another technique was used for testing, select **Other** and specify technique used in the text field.

Were immune effector cells (IEC) detected

Select **Yes** if immune effector cells (IEC) were detected. Select **No** if immune effector cells were not detected.

Last Disease Status – Additional Assessments

Disease burden

LDH level

Indicate if the LDH level was **Normal, Elevated**, or if it was **Not evaluated**. If the LDH was assessed multiple times in the current reporting period, report the most recent value. If the LDH level is not known, select **Unknown**.

Inflammatory state (C-reactive protein [CRP] concentration)

Indicate if the C-reactive protein [CRP] concentration was **Normal, Elevated**, or if it was **Not evaluated**. If the CRP was assessed multiple times in the current reporting period, report the most recent value. If the CRP level is not known, select **Unknown**.

Maximum CRP concentration:

If C-reactive protein [CRP] concentration was Elevated, report the **maximum CRP concentration** and specify the units used: if it is **mg/dL** or **mg/L**.

Date of C-reactive protein level assessment

- Report the date of C-reactive protein level assessment.

Additional treatments

Include only systemic treatments designed to consolidate the anti-tumour activity of CT cells, prevent relapse (i.e. administration of immune checkpoint inhibitors). Do not include supportive care, including anti-infectious agents.

Indicate only treatments that have not been reported at previous CT follow-up(s).

Did the patient undergo additional treatment during this follow-up period?

Select **No** if the patient did not undergo additional treatment during or after this cellular therapy since the last follow-up.

Select **Yes** if the patient did undergo additional treatment and newly started in this follow-up period complete the **"Treatment non-HCT/CT/GT/IST"** form and/or cell infusion sheet.

Select **Unknown** if it is unknown if the patient underwent additional treatment.

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**.Select **Unknown** if it is unknown if the patient received additional cell infusions.

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?

If the cell infusion was an allogeneic boost, select **Yes**. Otherwise select **No**.

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 (in the case of inborn errors) OR there is conditioning (chemo and/or TBI), then it is considered to be a genuine transplant.

Date of the allogeneic boost

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

Is this cell infusion an autologous boost?

If the cell infusion was an autologous boost answer **Yes** and proceed to the question below. If it was not an autologous boost, select **No**.

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

Date of the autologous boost

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

Note: If this cell infusion is not a boost, attach the Cell Infusion (CI) sheet available in Appendix 4, 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 (either at your or another centre)?

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

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

Did the patient receive subsequent CT (either at your or another centre)?

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

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

Reason for subsequent CT

If the patient received subsequent CT, select the reason a subsequent CT was required by choosing among the following answer options:

- Primary failure;
- Consolidation;
- Mitigation of side effects.

Hospital Admission

This section should be submitted only for the Day 100 and 6 Months follow-ups.

Was inpatient admission and care needed since the last follow-up?

If the patient did not require inpatient admission or care since the last follow-up, select No and proceed to the next question.

If inpatient admission and care was needed since the last follow-up, select **Yes** and report the **number of days** the patient was admitted in the hospital. This question concerns readmission after the patient was already discharged from hospital after conditioning therapy and cell infusion. If it is a planned admission for the procedure itself, it shall not be reported.

If it is unknown if inpatient admission and care was needed since the last follow up, select **Unknown**.

Was the patient transferred to the intensive care unit (ICU) since the last follow-up?

If the patient was not transferred to the ICU since the last follow-up, select **No**. If the patient was transferred to the ICU after the last follow-up, select **Yes** and report the **number of days the patient spent in the ICU.** If the patient was transferred to the ICU within the admission of conditioning and cell infusion, the answer should be **Yes**.

If it is not known whether the patient was transferred to ICU or not since the last follow-up, select **Unknown**.

Relapse, Progression, Recurrence of disease or Significant Worsening

This section is not relevant if CT was for Inborn Errors indication diagnosis.

MRD detectable (with any method)

Only for Acute leukaemia, report if MRD detectable by answering No, Yes 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 since last follow-up?

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/worsening

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

Malignant disorders only

Type of relapse/progression

For malignant disorders only report the type of relapse/progression: answer **Yes** next to Medullary and/or Extramedullary to report that there was this type of relapse/progression observed; answer **No** next to indicated involvement types to mark that it was not observed. Use **Unknown** answer option to indicate that there is no information for this involvement type.

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

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

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

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

If the relapse/progression was extramedullary or both medullary and extramedullary, report per each of the site listed, 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, specify this in the text field in English.

Target expression at relapse after CT

For CTs targeting a specific tumour antigen expressed on tumour cells (e.g. CD19-directed CAR-T cells such as Kymriah or Yescarta), target loss of the tumour antigen can occur (tumour escape). This is a phenomenon that typically occurs after T cell-based therapies such as CAR-T and it is a major cause of therapy resistance, preventing effective tumour recognition and destruction (The EU CAR-T Handbook, 12 - Tumour Escape from CAR-T Cells, 2025). Target expression can be assessed by blood or bone marrow testing.

In case the infused CT targets a tumour antigen, indicate if target antigen expression (usually CD19 or another relevant antigen) was **Absent** or **Present** at the time of relapse. Select **Unknown** if the target expression at relapse was not tested, not reported, or results are unavailable.

Patient status

Performance status at the last assessment

Select one answer to indicate the performance score system used to calculate the performance status at CT follow-up:

- Karnofsky;
- Lansky;
- ECOG.

If the performance status at cellular therapy follow-up is not known or was not evaluated, select **unknown** or **not evaluated**, respectively. Report the score that reflects the performance status at the current follow-up. It is not necessary to fill in both the Karnofsky/Lansky and ECOG score, one is sufficient. Descriptions of the Karnofsky score system can be found in table 8, Lansky in table 9 and the ECOG score system can be found in table 10.

Karnofsky scale

Score	Performance Status
100	Normal, no complaints or evidence of disease
90	Able to perform normal activity; minor signs and symptoms of disease
80	Able to perform normal activity with effort; some signs and symptoms of disease
70	Cares for self, unable to perform normal activity or to do active work
60	Requires occasional assistance but is able to care for most of own needs
50	Requires considerable assistance and frequent medical care
40	Requires special care and assistance; disabled
30	Hospitalisation indicated, although death not imminent; severely disabled
20	Hospitalisation necessary; active supportive treatment required, very sick
10	Fatal processes progressing rapidly; moribund

Score	Performance Status
0	Dead

Table 8. Karnofsky scoring system for adult patients.

Lansky scale

Score	Performance Status
100	Fully active, normal
90	Minor restrictions in physically strenuous activity
80	Active, but tires more quickly
70	Both greater restriction of and less time spent in play activity
60	Up and around, but minimal active play; keeps busy with quieter activities
50	Gets dressed but lies around much of the day, no active play but able to participate in all quiet play and activities
40	Mostly in bed; participates in quiet activities
30	In bed; needs assistance even for quiet play
20	Often sleeping; play entirely limited to very passive activities
10	No play; does not get out of bed
0	Unresponsive

Table 9. Lansky scoring system for paediatric patients.

ECOG scale

Grade	Performance Status
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair

5	Dead

Table 10. ECOG scoring system.

Pregnancy after cellular therapy

Complete only for 6 Months and Annual/Unscheduled Follow-Up.

Has a patient become pregnant or impregnated another person since the last follow-up?

If the patient has not become pregnant or has not impregnated another person 6 months post CT or since the last follow-up, select **No** and proceed to the next section.

Extended dataset

Was there an attempted pregnancy since the last follow-up?
Indicate if there was an attempted pregnancy since the last follow-up select **Yes, No or Unknown.**

If the patient has become pregnant or has impregnated another person 6 months post CT or since the last follow-up select **Yes** and provide details in the question below. Select Unknown if it is not known.

Did the pregnancy result in a live birth?

If the patient has become pregnant or has impregnated another person since the last follow-up, answer **Yes**. If the pregnancy resulted in a live birth, indicate the **Year of birth** and **Month of birth** of the child, or mark the date **Unknown** if the date is not available.

Answer **No** if pregnancy did not result in a live birth and indicate the **Date of spontaneous or induced termination** (YYYY/MM/DD) or mark the date as **Unknown**. In case of multiple spontaneous or induced terminations, report the date of the first such event.

Select **Still pregnant at time of follow-up** if the patient/the person they impregnated was still pregnant at the time of the follow-up.

If there is no detailed information about the pregnancy and whether or not it resulted in a live birth, select **Unknown**.

If multiple pregnancies occurred in the follow-up period, the live birth should be prioritised in reporting, in the absence of the live birth, ongoing pregnancy should be prioritised: if one pregnancy resulted in live birth and another not, report the live birth only; if there occurred any terminated pregnancy and the other pregnancy is ongoing as of this follow-up date, select *Still pregnant at time of follow-up* answer option.

Extended dataset

Conception method

Indicate which conception method was used for the pregnancy that resulted in live birth. Select **Natural, Assisted** or **Unknown**

Disease Status (Disease specific)

This section is not applicable for patients with Inborn Errors indication diagnosis.

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 the indication diagnosis, by selecting from the list provided in Appendix 1 'Best Response and Disease Status (Disease Specific)'.

The disease status is split into disease specific sections:

- Acute Leukaemias
- Chronic Leukaemias
- Plasma Cell Neoplasms (Pcn)
- Mpn, Mds, Mds / Mpn Overlap Syndromes
- Lymphomas
- Solid Tumours
- Bone Marrow Failure Syndromes (Bmf) Including Aplastic Anaemia (Aa)
- Autoimmune Disorders
- Haemoglobinopathies
- Other Diagnosis.

The instructions for completing appendix 1 'Best Response and Disease Status (Disease Specific)' can be found in appendix 1 of this document.

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.

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, consult with criteria described in the **Disease specific best response and disease status v1** document.

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

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

Minimal residual disease (MRD)

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

Chronic leukaemias

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

Chronic myeloid leukaemia disease status or best response

Select the disease status or best response from the list:

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

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

Number

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

If the disease status or best response was chronic phase (CP) also indicate Haematological remission, Cytogenetic remission, Molecular remission below

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.

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.

Minimal residual disease (MRD)

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

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

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

- Complete Remission (CR)
- Partial Remission (PR)
- Progression
- Stable Disease (SD)

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

Progression sensitivity

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

Minimal residual disease (MRD)

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

Plasma cell neoplasms

Disease status or best response

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

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

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

Number

For patients in Complete remission (CR), Stringent complete remission (sCR), Very good partial remission (VGPR), Partial remission (PR) or Relapse, select the number of the status or mark it as Unknown.

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

for PCN Disease Status, report whether the patient was on dialysis during this follow-up period. Select **Unknown** if this information is unavailable. If the answer is Yes, provide details in sub-questions.

Started in this follow-up period

Select this option if dialysis started during this follow-up period. and specify the **Start date** of dialysis. If the start date is not known, select **Unknown.**

Ongoing since previous follow-up

Select this option if dialysis started during a previous follow-up period and was still ongoing during this follow-up.

Did dialysis stop?

Report whether dialysis was stopped during this follow-up. Select **Unknown** if this information is unavailable. If the answer is Yes, specify the **End date** of the dialysis. 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 patients with an AL, CLL or a plasma cell neoplasm diagnosis.

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 malignant cells mark it as **Negative**. Mark it as **Not evaluated** if MRD status evaluation was not carried out during the follow-up period.

Extended dataset

Date MRD status evaluated

Report the date 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, select the number of this status.

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 which technique was used to assess disease status or best response. If the technique is not known, select **unknown**.

If the technique was not listed, select **Other** and specify 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 patient is transfusion independent and was transfusion dependent at a previous follow-up, select **ongoing transfusion independence since last follow-up**. If the transfusion status is not known, select **unknown**.

Did the patient return to transfusion dependency afterwards?

If the patient became transfusion independent since the last follow-up, 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 main treatment:

- 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**.

Patient requires transfusions, Yes

If a patient is transfusion dependent indicate whether at this follow-up period the **Return to transfusion dependence after CT or transfusion free period** occurred or patient **Ongoing transfusion dependence since previous assessment.**

Date of first transfusion

If a patient has returned to transfusion dependence after main treatment or transfusion free period during this follow-up period, report the date of the first transfusion after main treatment or transfusion free period. If the date is not known, select **Unknown**. If a patient has ongoing transfusion dependence since the previous assessment and the date was reported at the previous follow-up form, do not report the date here, the question will be disabled.

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**.

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 since the last follow-up by selecting **no**. If recurrent sickling episodes were present since the last follow-up, select **yes**. If it is not known if the sickling episodes returned, select **unknown**.

First return of sickling episodes after cellular therapy

Select this option if it is the first return of sickling episodes after CT.

Date of first episode (after cellular therapy)

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**.

Ongoing presence of sickling episodes

Select this option if the sickling episodes have been ongoing since a previous follow-up period.

Number of SCD episodes (during follow-up)

If the sickling episodes first returned after main treatment or were ongoing from the previous follow-up, 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.

Cell Infusion Sheet

The following completion guidelines refers to the completion of appendix 6 of the form, the cell infusion sheet.

Please report each cell infusion episode performed during the follow-up period in a separate cell infusion sheet, completing as many sheets as episodes of cell infusion that took place. 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 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** and/or **autologous**, check all that apply.

Type of cells

Select the type of cells, check all that apply:

- **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.

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**'.

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.

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

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

Indicate the disease status at time of this cell infusion corresponding to indication diagnosis by selecting from the list provided in Appendix 1.

The disease status is split into disease specific sections:

- Acute leukemias;
- 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.

The instructions for completing appendix 1 can be found in appendix 1 of this document.

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.

Response to DLI:

Only for Acute leukemia donor lymphocyte infusions: specify 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.

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