

## HAEMATOPOIETIC CELL TRANSPLANTATION (HCT) --- Annual/Unscheduled Follow-Up ---

### SURVIVAL STATUS

**Date of follow-up:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  
 (if died: date of death, if lost to follow up: date last seen)

**Survival status:**

- Alive
- Dead
- Lost to follow-up

**Main cause of death:**  
 (check only one main cause)

<input type="checkbox"/> Relapse or progression/persistent disease	
<input type="checkbox"/> Secondary malignancy	
<input type="checkbox"/> CT-related	<b>Select treatment related cause:</b> <i>(select all that apply)</i> <input type="checkbox"/> Graft versus Host Disease <input type="checkbox"/> Non-infectious complication <input type="checkbox"/> Infectious complication: <i>(select all that apply)</i> <input type="checkbox"/> Bacterial infection <input type="checkbox"/> Viral infection <input type="checkbox"/> Fungal infection <input type="checkbox"/> Parasitic infection <input type="checkbox"/> Infection with unknown pathogen <input type="checkbox"/> Other treatment related cause of death; specify: _____
<input type="checkbox"/> HCT-related	
<input type="checkbox"/> GT-related	
<input type="checkbox"/> IST-related	
<input type="checkbox"/> Unknown	
<input type="checkbox"/> Other cause of death; specify: _____	

*Extended dataset*

**Autopsy performed:**

- No
- Yes
- Unknown

### BEST RESPONSE

*Complete only for the first annual follow-up  
 Not applicable for Inborn Errors*

**Best clinical/biological response after HCT\*** (observed before any subsequent treatment): \_\_\_\_\_

**Date best response first observed:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

\* Indicate the best clinical/biological response after HCT corresponding to indication diagnosis by selecting from the list provided in Appendix 1



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

### GRAFT FUNCTION

**Poor graft function** (defined as: frequent dependence on blood and/or platelet transfusions and/or growth factor support in the absence of other explanations, such as disease relapse, drugs, or infection):

- No  
 Yes: **Date of poor graft function:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Unknown

**Complete for every chimaerism test performed since last follow-up:**  
 (complete only if patient received an allogeneic HCT. This section is optional for malignant disorders)

**Chimaerism test date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Source of cells tested:**  Peripheral blood  
 Bone marrow

**Select cell type and complete relevant test results:**

- Global (%): \_\_\_\_\_ % donor  Unknown  
 Myeloid cells (i.e. CD33, CD15 or CD14) (%): \_\_\_\_\_ % donor  Unknown  
 T-cells (CD3) (%): \_\_\_\_\_ % donor  Unknown  
 B-cells (CD19 or CD20) (%): \_\_\_\_\_ % donor  Unknown  
 CD34+ cells (%): \_\_\_\_\_ % donor  Unknown  
 Other cell type; specify cells (%): \_\_\_\_\_ % donor  Unknown

*copy and fill-in this table as many times as necessary.*

### PREVENTIVE THERAPIES

*(Complete only if the patient received an allogeneic HCT)*

**Immunosuppression during this follow-up period:**

- No  
 Yes; **Immunosuppression stopped:**  
 No  
 Yes; **End date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Unknown  
 Unknown

*Extended dataset*

**PREVENTIVE THERAPIES continued**  
*(Complete only if the patient received an alloHCT)*

**Was secondary letermovir prophylaxis given (after CMV reactivation leading to treatment or CMV disease regardless of whether primary letermovir prophylaxis was previously given during the course of the most recent HCT)?**

- No  
 Yes: **Start date secondary letermovir prophylaxis:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Unknown

**Antimicrobial prophylaxis**

**Did the patient receive prophylaxis for bacterial, viral or fungal infection during this follow-up period?**  No  Yes

**If yes, what type of prophylaxis?**  Antibacterial  Antifungal  Antiviral  
(select all that apply and complete the relevant section)

**Antibacterial prophylaxis**

**Antibiotic**  
(select all that were administered)

- Ciprofloxacin:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Levofloxacin:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Moxifloxacin:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Penicillin/Amoxicilline:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Ampicillin clavulonate:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Non-absorbable antibiotic:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown

**Final date antibacterial prophylaxis was discontinued:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**Antimicrobial prophylaxis continued**

*Extended dataset*

**Antiviral prophylaxis**

**Did the patient receive CMV prophylaxis other than or in addition to letermovir during this follow-up period?** *(Only for allo-HCT, not auto-HCT)*

- No (i.e. no prophylaxis or only letermovir)
- Yes: **Which drugs were used?** *(select all that apply)*
- Note: letermovir is not included as this is requested on the core dataset. Do not consider letermovir for 'Other drug'.*
- High-dose acyclovir (≥500 mg/m<sup>2</sup>/8h (IV) with normal renal function or ≥ 800 mg/6h (oral) with normal renal function)
  - High-dose valaciclovir (2 grams Q8 hours with normal renal function)
  - Ganciclovir intravenous
  - Valganciclovir
  - Foscarnet
  - Maribavir
  - CMV immunoglobulin
  - Standard immunoglobulin
  - CMV-specific T-cells (VST)
  - Other drug

**Final date CMV prophylaxis was discontinued:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown

**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?** *(Only for allo-HCT, not auto-HCT)*

- No
- Yes: **Final date VZV or HSV prophylaxis was discontinued:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown

**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?** *(Only for allo-HCT, not auto-HCT)*

- No
- Yes

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

- No
- Yes: **Which drugs were used?** *(select all that apply)*
- Lamivudine
  - Entecavir
  - Tenofovir
  - HBV immunoglobulin
  - Other drug

**Final date HBV prophylaxis was discontinued:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown

### Antimicrobial prophylaxis

#### Extended dataset

### Antifungal prophylaxis

#### Antifungal

(select all that were administered)

- Fluconazole:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Voriconazole:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Posaconazole:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Itraconazole:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Isavuconazole:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Caspofungin:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Micafungin:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Anidulafungin:  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown
- Ambisome:  
(IV or inhalations)  Started in this follow-up period; **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Ongoing since previous follow-up  
 Unknown

**Final date antifungal prophylaxis was discontinued:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
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Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

### Antimicrobial prophylaxis continued

*Extended dataset*

### Antifungal prophylaxis

Did the patient receive prophylaxis for *Pneumocystis jirovecii* pneumonia (PJP) during this follow-up period?

No

Yes: **Which drugs were used?**  
(select all that apply)

Trimethoprim-sulfamethoxazole

Dapsone

Atovaquone

Pentamidine inhaled

Pentamidine intravenous

Other drug

Final date prophylaxis was discontinued: \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Ongoing  Unknown

Unknown



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**COMPLICATIONS SINCE THE LAST REPORT**

-- GvHD --  
*Allogeneic HCT only*

**Did graft versus host disease (GvHD) occur during this follow-up period?**

No (proceed to 'Complications since the last report - Non-infectious complications')

Yes: **Did the patient receive a systemic/immunosuppressive treatment for GvHD during this follow-up period?**

No

Yes:  Started in this follow-up period; **Date treatment started:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

Ongoing since previous follow-up

**Treatment stopped:**  No

Yes; **Stop date of treatment:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

Unknown

Unknown (proceed to 'Complications since the last report - Non-infectious complications')

**Did acute GvHD occur during this follow-up period?**

No

Yes:  Started in this follow-up period; **Date of onset:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

Ongoing since previous follow-up

**Maximum observed organ severity score during this period:**

Skin:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Liver:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Lower GI tract:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Upper GI tract:	<input type="checkbox"/> 0 (none)		<input type="checkbox"/> 1	<input type="checkbox"/> Not evaluated		<input type="checkbox"/> Unknown	
Other site affected:	<input type="checkbox"/> No		<input type="checkbox"/> Yes; specify: _____				

**Overall maximum grade observed:**  1  2  3  4  Unknown  Not evaluated

**Steroid-refractory acute GvHD:**  No

Yes:  Started in this follow-up period; **Date of onset:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

Ongoing since previous follow-up

Unknown

*Extended dataset*

**aGvHD resolved:**  No

(Resolution of symptoms)  Yes; **Date of aGvHD resolution:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

Unknown (Resolution of symptoms)

Unknown

### COMPLICATIONS SINCE THE LAST REPORT

-- GvHD --  
*Allogeneic HCT only*

*Extended dataset*

#### aGvHD first line treatment

**Did the patient receive steroids as first line treatment of aGvHD during this follow-up period?**     No     Yes     Unknown

**Steroid details during this follow-up period:**

Name of steroid	Treatment started / date (YYYY/MM/DD)	Initial dose (mg/kg/day)	Treatment stopped / date (YYYY/MM/DD)
<input type="checkbox"/> Prednisolone <input type="checkbox"/> Methylprednisolone <input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; _____/____/____ <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Prednisolone <input type="checkbox"/> Methylprednisolone <input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; _____/____/____ <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown

*Copy and print this table as many times as needed, or enter the data directly into the EBMT Registry*

**Were other systemic drugs/strategies used to treat aGvHD in the first line during this follow-up period: (other than steroids)**     No     Yes     Unknown

**If yes, select the drugs below:**  
*(select all that apply)*

Name of drug/strategy
<input type="checkbox"/> ECP <input type="checkbox"/> Ruxolitinib <input type="checkbox"/> MMF <input type="checkbox"/> Cyclosporin A <input type="checkbox"/> Tacrolimus <input type="checkbox"/> Sirolimus <input type="checkbox"/> Other; specify: _____

*Extended dataset*

**aGvHD first line treatment continued**

*Steroid refractory definition covers other subtypes, such as dependent and intolerant, but 'Steroid Refractory' (SR) will be used as an umbrella term in this form*

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

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

**How did aGvHD respond to steroids during this follow-up period?** (according to the definitions above)

**Steroid sensitive:**  No  Yes  Unknown

*If steroid sensitive, please continue at 'Complications since the last report'*

**Steroid refractory:**  No  Yes  Unknown

**Steroid dependent:**  No

Yes:  Started in this follow-up period: **Date of onset:** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 (YYYY/MM/DD)

Ongoing since previous follow-up

Unknown

**Steroid refractory/dependent aGvHD**

**Did the patient receive treatment for SR/SD aGvHD during this follow-up period?**  No  Yes:  Started in this follow-up period  Unknown

(after steroid refractoriness/dependence was established)

Ongoing since previous follow-up

*if SR/SD aGvHD treatment started in this follow-up period:*

**Overall aGvHD grade at start of SR/SD GvHD treatment:**  0  1  2  3  4  Not evaluated  Unknown

**Organ(s) involved at start of SR/SD GvHD treatment:**

Organ	Stage (MAGIC scale)
Skin	<input type="checkbox"/> Stage 0 <input type="checkbox"/> Stage 1 <input type="checkbox"/> Stage 2 <input type="checkbox"/> Stage 3 <input type="checkbox"/> Stage 4 <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
Liver	<input type="checkbox"/> Stage 0 <input type="checkbox"/> Stage 1 <input type="checkbox"/> Stage 2 <input type="checkbox"/> Stage 3 <input type="checkbox"/> Stage 4 <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
Lower GI tract	<input type="checkbox"/> Stage 0 <input type="checkbox"/> Stage 1 <input type="checkbox"/> Stage 2 <input type="checkbox"/> Stage 3 <input type="checkbox"/> Stage 4 <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
Upper GI tract	<input type="checkbox"/> Stage 0 <input type="checkbox"/> Stage 1 <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown

## Extended dataset

**Steroid refractory/dependent aGvHD  
continued**
**Drugs given in this line of treatment during this follow-up period**

Line of treatment, \_\_\_\_\_

Name of drug/ strategy (select all that applies)	Started / date (YYYY/MM/DD)	Stopped / date (YYYY/MM/DD)
<input type="checkbox"/> ECP	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Ruxolitinib	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> MMF	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Cyclosporin A	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Tacrolimus	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Sirolimus	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown

If there were more lines of treatment, copy the page as often as necessary or enter the data directly into the EBMT Registry

*Extended dataset*

**Steroid refractory/dependent aGvHD  
continued**

**Organ involved during the course of treatment and response to the line of treatment during this follow-up period:**

Organ involved during the course of treatment	Organ(s) involved during the course of treatment and Best response achieved	Date best response assessed (YYYY/MM/DD)
Skin	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Liver	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Lower GI tract	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Upper GI tract	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Overall (if organ specific is not available)	<input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown

*If there were more lines of treatment, copy the page as often as necessary or enter the data directly into the EBMT Registry*

**COMPLICATIONS SINCE THE LAST REPORT continued**

-- GvHD --

*Allogeneic HCT only*
**Did chronic GvHD occur during this follow-up period?**
 No

 Yes:  Started in this follow-up period; **Date of onset:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

 Ongoing since previous follow-up

**Maximum NIH score during this period:**  Mild  
 Moderate  
 Severe  
 Unknown  
 Not evaluated

**Date of maximum NIH score:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Maximum observed organ severity score during this period:**

Skin:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Oral:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Gastrointestinal:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Eyes:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Liver:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Joints and fascia:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Lungs:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Genitalia:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Other site affected:	<input type="checkbox"/> No	<input type="checkbox"/> Yes; specify: _____				

**Steroid-refractory chronic GvHD:**  No

 Yes:  Started in this follow-up period; **Date of onset:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

 Ongoing since previous follow-up

 Unknown

*Extended dataset*
**cGvHD resolved:**  No  
 (Resolution of symptoms)  Yes; **Date of cGvHD resolution:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Unknown (Resolution of symptoms)

**Was overlap syndrome observed:**  No  Yes  Unknown  
*(features of both chronic and acute GvHD)*
 Unknown

## Extended dataset

**cGvHD first line treatment**

 Did the patient receive steroids as first line treatment of cGvHD during this follow-up period?  No  Yes  Unknown

**Steroid details during this follow-up period:**

Name of steroid	Treatment started / date (YYYY/MM/DD)	Initial dose (mg/kg/day)	Treatment stopped / date (YYYY/MM/DD)
<input type="checkbox"/> Prednisolone <input type="checkbox"/> Methylprednisolone <input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Prednisolone <input type="checkbox"/> Methylprednisolone <input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown

Copy and print this table as many times as needed, or enter the data directly into the EBMT Registry

 Were other systemic drugs/strategies used to treat cGvHD in the first line during this follow-up period: (other than steroids)  No  Yes  Unknown

**If yes, select the drugs below:**

(select all that apply)

Name of drug/strategy
<input type="checkbox"/> ECP
<input type="checkbox"/> Ruxolitinib
<input type="checkbox"/> MMF
<input type="checkbox"/> Cyclosporin A
<input type="checkbox"/> Tacrolimus
<input type="checkbox"/> Sirolimus
<input type="checkbox"/> Other; specify: _____

Steroid refractory definition covers other subtypes, such as dependent and intolerant, but 'Steroid Refractory' (SR) will be used as an umbrella term in this form

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

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

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

**How did cGvHD respond to steroids during this follow-up period? (according to the definitions above)**
**Steroid sensitive:**  No  Yes  Unknown

If steroid sensitive, please continue at 'Complications since the last report'

**Steroid refractory:**  No  Yes  Unknown

**Steroid dependent:**  No

 Yes:  Started in this follow-up period; **Date of onset:** \_\_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown (YYYY/MM/DD)  
 Ongoing since previous follow-up  
 Unknown

**Steroid intolerant:**  No

 Yes:  Started in this follow-up period; **Date of onset:** \_\_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown (YYYY/MM/DD)  
 Ongoing since previous follow-up  
 Unknown

## Extended dataset

**Steroid refractory/dependent/intolerant cGvHD**

**Did the patient receive treatment for SR/SD/SI cGvHD during this follow-up period?**
 No
  Yes:
  Started in this follow-up period
  Unknown

(after steroid refractoriness/dependence/intolerance was established)

Ongoing since previous follow-up

*if SR/SD/SI cGvHD treatment started in this follow-up period:*

**Overall cGvHD grade at start of SR/SD/SI GvHD treatment:**
 Mild
  Moderate
  Severe
  Not evaluated
  Unknown

**Organ(s) involved at start of SR/SD/SI GvHD treatment:**

Skin:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Oral:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Gastrointestinal:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Eyes:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Liver:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Joints and fascia:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Lungs:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Genitalia:	<input type="checkbox"/> 0 (none)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Other site affected:	<input type="checkbox"/> No	<input type="checkbox"/> Yes; specify: _____				

## Extended dataset

**Steroid refractory/dependent/intolerant cGvHD**
**Drugs given in this line of treatment during this follow-up period**

Line of treatment \_\_\_\_\_

Name of drug/ strategy (select all that applies)	Started / date (YYYY/MM/DD)	Stopped / date (YYYY/MM/DD)
<input type="checkbox"/> ECP	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Ruxolitinib	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> MMF/CellCept	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Belumosudil	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Ibrutinib	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Everolimus	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Sirolimus	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Cyclosporin A	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Tacrolimus	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown

If there were more lines of treatment, copy the page as often as necessary or enter the data directly into the EBMT Registry

### Steroid refractory/dependent/intolerant cGvHD

*Extended dataset*

**Organ involved during the course of treatment and response to the line of treatment during this follow-up period:**

Organ involved during the course of treatment	Organ(s) involved during the course of treatment and Best response achieved	Date best response assessed (YYYY/MM/DD)
Skin	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Oral	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Gastrointestinal	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Eyes	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Liver	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Joints and fascia	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Lungs	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Genitalia	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown
Overall (if organ specific is not available)	<input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> Progression <input type="checkbox"/> Stable/no change <input type="checkbox"/> Unknown	____/____/____ <input type="checkbox"/> Unknown

*If there were more lines of treatment, copy the page as often as necessary or enter the data directly into the EBMT Registry*



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**COMPLICATIONS SINCE THE LAST REPORT**

-- Non-infectious complications --

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

*(Please only report toxic events here that are above Grade 2 and not linked to GvHD and/or infections)*

- No (proceed to 'Complications since the last report - Infectious complications')  
 Yes (report in the table below)  
 Unknown

**Secondary graft failure**

Complication observed during this follow-up period?  No  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

Maximum grade observed during this period:  Non-fatal  Fatal

Onset date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

Resolved:  No  
 Yes; Stop date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Cardiac event**

Complication observed during this follow-up period?  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

Maximum CTCAE grade observed during this period:  3  4  5 (fatal)  Unknown

Onset date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

Resolved:  No  
 Yes; Stop date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Central nervous system (CNS) toxicity**

Complication observed during this follow-up period?  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

Maximum CTCAE grade observed during this period:  3  4  5 (fatal)  Unknown

Onset date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

Resolved:  No  
 Yes; Stop date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Gastrointestinal (GI) Toxicity (non-GvHD and non-infectious related)**

Complication observed during this follow-up period?  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

Maximum CTCAE grade observed during this period:  3  4  5 (fatal)  Unknown

Onset date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

Resolved:  No  
 Yes; Stop date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

\* Grade 0-2



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**COMPLICATIONS SINCE THE LAST REPORT**

-- Non-infectious complications --

**Liver disorder**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Renal failure (chronic kidney disease, acute kidney injury)**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Respiratory disorders**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Skin Toxicity (non-GvHD and non-infectious related)**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

\* Grade 0-2



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**COMPLICATIONS SINCE THE LAST REPORT**

-- Non-infectious complications --

**Vascular event**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Avascular necrosis (AVN)**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Cerebral haemorrhage**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Haemorrhage (other than cerebral haemorrhage)**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

\* Grade 0-2



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**COMPLICATIONS SINCE THE LAST REPORT**

-- Non-infectious complications --

**Cerebral thrombosis**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Cytokine release syndrome (CRS)**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Haemophagocytic lymphohistiocytosis (HLH)**

**Complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum CTCAE grade observed during this period:**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**Pure red cell aplasia (PRCA)**

**Complication observed during this follow-up period?**  No  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum grade observed during this period:**  Non-fatal  Fatal

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

\* Grade 0-2



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

### COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

#### Posterior reversible encephalopathy syndrome (PRES)

Complication observed during this follow-up period?  No  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

Maximum grade observed during this period:  Non-severe  Severe  Fatal  Unknown

Onset date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

Resolved:  No  
 Yes; Stop date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

#### Transplant-associated microangiopathy (TMA)

Complication observed during this follow-up period?  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

Maximum grade observed during this period:  Non-severe  Severe  Unknown

Onset date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

#### Extended dataset

Resolved:  No  
 Yes; Stop date (YYYY/MM/DD): \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

Was TA-TMA treatment given during this follow-up period:  No  Yes  Unknown

#### TA-TMA treatment given during this follow-up period

Line of treatment \_\_\_\_\_

Name of drug	Start date (YYYY/MM/DD)	Stopped / date (YYYY/MM/DD)
<input type="checkbox"/> Defibrotide	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Eculizumab	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Narsoplimab	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown

\* Grade 0-2



**COMPLICATIONS SINCE THE LAST REPORT**  
 -- Non-infectious complications --

**Sinusoidal obstruction syndrome/Veno-occlusive disease (SOS/VOD)**

**Complication observed during this follow-up period?**  No  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Maximum grade observed during this period:**  Mild  Moderate  Severe  Very severe  Fatal  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

*Extended dataset*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

**SOS/VOD treatment given during this follow-up period:**  No  Yes  Unknown

**SOS/VOD treatment given during this follow-up period**

**Line of treatment** \_\_\_\_\_

Name of drug	Start date (YYYY/MM/DD)	Stopped / date (YYYY/MM/DD)
<input type="checkbox"/> Defibrotide	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown

**Other SOS/VOD treatment given in this line of treatment during this follow-up period:**

<b>Renal replacement therapy performed:</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown
<b>Mechanical ventilation performed:</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown
<b>Extracorporeal membrane oxygenation performed:</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up <input type="checkbox"/> Unknown

**Response to this line of SOS/VOD treatment during this follow-up period**

**Did the patient achieve complete response?**  No  Yes  Unknown  
*Defined as serum bilirubin <2 mg/dL, no oxygen support, eGFR >50% from baseline before SOS/VOD and no renal replacement therapy*

**If yes, date of complete response:** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown

**If no, did the patient achieve partial response?**  No  Yes  Unknown  
*Defined as serum bilirubin increased, but >2 mg/dL, or pulmonary dysfunction, or eGFR ≤50% from baseline before SOS/VOD*

**If yes, date of partial response:** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown

Copy and print this table as many times as needed, or enter the data directly into the EBMT Registry



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**COMPLICATIONS SINCE THE LAST REPORT**  
 -- Non-infectious complications --

**Other complication observed during this follow-up period?**  No\*  
 Yes:  Newly developed  Ongoing since previous assessment  
 Unknown

**Specify:** \_\_\_\_\_ *Consult appendix 4 for a list of complications that should not be reported*  
 (Indicate CTCAE term)

**Maximum CTCAE grade observed**  3  4  5 (fatal)  Unknown

**Onset date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown *Only if newly developed*

**Resolved:**  No  
 Yes; **Stop date (YYYY/MM/DD):** \_\_\_\_/\_\_\_\_/\_\_\_\_  Unknown  
 Unknown

*If more other complications occurred, copy and fill-in this table as many times as necessary.*

\* Grade 0-2



**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?**

- No *Consult appendix 4 for a list of complications that should not be reported*  
 Yes (report all infection-related complications below)  
 Unknown

**Bacterial infection:**  No  Yes  Unknown

**New or ongoing:**  Newly developed  Ongoing since previous assessment

**Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD) only if newly developed  Unknown

Gram-positive  Gram-negative  Other

**Pathogen\*:** \_\_\_\_\_

*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)*

- Susceptible  
 Resistant; **KPC:**  Negative  Positive  Unknown  
**OXA-48:**  Negative  Positive  Unknown

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

- Negative  Positive  Unknown

*Only if pathogen 'Citrobacter', 'Enterobacter', 'Escherichia coli', 'Klebsiella pneumoniae', 'Klebsiella other', 'Morganella', 'Proteus', 'Providencia', 'Pseudomonas aeruginosa', 'Pseudomonas other', 'Raoultella' or 'Serratia' is selected*

**Ceftazidime avibactam (caz-avi, avycaz) resistance/susceptibility:**

- Susceptible  Resistant  Susceptibility unknown

**Ceftazidime avibactam+aztreonam resistance/susceptibility:**

- Susceptible  Resistant  Susceptibility unknown

**Meropenem vaborbactam resistance/susceptibility:**

- Susceptible  Resistant  Susceptibility unknown

**Imipenem-cilastatin-relebactam resistance/susceptibility:**

- Susceptible  Resistant  Susceptibility unknown

**Cefiderocol resistance/susceptibility:**

- Susceptible  Resistant  Susceptibility unknown

- Susceptibility unknown

**Trimethoprim/sulfamethoxazole resistance/susceptibility:** *(Only if pathogen 'Stenotrophomas maltophilia' is selected)*

- Susceptible  Resistant  Susceptibility unknown

**Sulbactam resistance/susceptibility:** *(Only if pathogen 'Acinetobacter baumannii', 'Acinetobacter lwofii' or 'Acinetobacter other' is selected)*

- Susceptible  Resistant  Susceptibility unknown

**Cefiderocol resistance/susceptibility:** *(Only if pathogen 'Acinetobacter baumannii', 'Acinetobacter lwofii' or 'Acinetobacter other' is selected)*

- Susceptible  Resistant  Susceptibility unknown

*Only if pathogen 'Pseudomonas aeruginosa' is selected*

**Ceftolozane tazobactam (zerbaxa) resistance/susceptibility:**  Susceptible  Resistant  Susceptibility unknown

**Ceftazidime resistance/susceptibility:**  Susceptible  Resistant  Susceptibility unknown

**Cefepime resistance/susceptibility:**  Susceptible  Resistant  Susceptibility unknown

**Piperacillin tazobactam resistance/susceptibility:**  Susceptible  Resistant  Susceptibility unknown

**Amikacin resistance/susceptibility:**  Susceptible  Resistant  Susceptibility unknown

**Ciprofloxacin/levofloxacin resistance/susceptibility:**  Susceptible  Resistant (if resistant to any of them)  Susceptibility unknown

*If more than 1 bacterial infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

\*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

## COMPLICATIONS SINCE THE LAST REPORT

### -- Infectious complications --

- Infection with clinical implications:**  No  
 Yes: *(select all that apply during this period)*  
 Symptoms/signs of disease  
 Administration of pathogen-directed therapy  
 Unknown

Indicate at least 1 location involved during this period:

**Localisation 1 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 2 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 3 (CTCAE term)\*\*:** \_\_\_\_\_

#### Extended dataset

**Were abnormalities detected upon radiological assessment?**

- No  
 Yes; **What diagnostic technique was used to detect abnormalities?**  
 Unknown
- MRI  
 CT  
 PET  
 PET CT  
 Ultrasound  
 Other; Specify: \_\_\_\_\_

*(Only if CTCAE term 'Central nervous system infection', 'Sinusitis infective', 'Liver site infection', 'Esophagus or gastric infection', 'Lower gastrointestinal infection', 'Enteritis infective', 'Other intra-abdominal infection', 'Splenic infection' or 'Urinary tract infection' is selected)*

**Radiology showing new or worsening pulmonary infiltrates:** *(Only if CTCAE term 'Pneumonia' is selected)*

- No  
 Yes; **What diagnostic technique was used to show pulmonary infiltration?**  
 Unknown
- CT  
 PET  
 Chest X-ray  
 MRI

**Was a biopsy performed?** *(Not applicable if CTCAE term 'Bacteremia' is selected)*

- No  
 Yes; **Date of biopsy:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Was this pathogen detected in biopsy?**  No  
 Yes; **By what technique was the pathogen detected in biopsy?**  
 Unknown
- Culture  
 Histopathological or cytopathological demonstration  
 Immunohistochemistry  
 PCR  
 Stain

**Was bronchoalveolar lavage (BAL) performed?** *(Only if CTCAE term 'Pneumonia' or 'Tracheobronchitis infective' is selected)*

- No  
 Yes; **Date of BAL:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Was this pathogen detected in BAL?**  No  
 Yes; **By what technique was the pathogen detected in BAL?**  
 Unknown
- Culture  
 PCR  
 Stain

**Was CSF obtained?** *(Only if CTCAE term 'Central nervous system infection' is selected)*

- No  
 Yes; **Date of CSF:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Was this pathogen detected in CSF?**  No  
 Yes; **By what technique was the pathogen detected in CSF?**  
 Unknown
- Culture  
 PCR  
 Stain  
 Serology/antigen in CSF

*If more than 1 bacterial infections, copy and fill-in this table as many times as necessary.*



EBMT Centre Identification Code (CIC): \_\_\_\_\_

Treatment Type  HCT

Hospital Unique Patient Number (UPN): \_\_\_\_\_

Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**COMPLICATIONS SINCE THE LAST REPORT**

-- Infectious complications --

*Extended dataset*

**Were typical lesions seen on the eye examination?** *(Only if CTCAE term 'Other eye infection' is selected)*

No     Yes     Unknown

**Was the patient transferred to the ICU due to this infection?**     No     Yes     Unknown

*(if patient died)*

**Contributory cause of death:**     No     Yes     Unknown

*If more than 1 bacterial infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

\*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

**COMPLICATIONS SINCE THE LAST REPORT**

-- Infectious complications -- continued

**Viral infection:**  No  Yes  Unknown

**New or ongoing:**  Newly developed  Ongoing since previous assessment

**Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD) *only if newly developed*  Unknown

**Pathogen\*:** \_\_\_\_\_

**Infection with clinical implications:**  No

Yes\*\*\*: (select all that apply during this period)

Symptoms/signs of disease

Administration of pathogen-directed therapy (including pre-emptive therapy)

Unknown

Indicate at least 1 location involved during this period:

**Localisation 1 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 2 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 3 (CTCAE term)\*\*:** \_\_\_\_\_

*Extended dataset*

**Were abnormalities detected upon radiological assessment?** (Only if CTCAE term 'Central nervous system infection', 'Liver site infection', 'Esophagus or gastric infection', 'Lower gastrointestinal infection', 'Enteritis infective', 'Other intra-abdominal infection' or 'Urinary tract infection' is selected)

No

Yes; **What diagnostic technique was used to detect abnormalities?**

Unknown

MRI

CT

PET

PET CT

Ultrasound

Other; Specify: \_\_\_\_\_

**Radiology showing new or worsening pulmonary infiltrates:** (Only if CTCAE term 'Pneumonia' is selected)

No

Yes; **What diagnostic technique was used to show pulmonary infiltration?**

Unknown

CT

PET

Chest X-ray

MRI

**Was a biopsy performed?** (Not applicable if CTCAE term 'Viremia including DNAemia' is selected)

No

Yes; **Date of biopsy:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Was this pathogen detected in biopsy?**  No

Yes; **By what technique was the pathogen detected in biopsy?**

Histopathological or cytopathological demonstration

Immunohistochemistry

Quantitative PCR

DNA hybridization

Unknown

Unknown

**Was bronchoalveolar lavage (BAL) performed?** (Only if CTCAE term 'Pneumonia' or 'Tracheobronchitis infective' is selected)

No

Yes; **Date of BAL:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Was this pathogen detected in BAL?**  No

Yes; **By what technique was the pathogen detected in BAL?**

PCR

Cytology and immunofluorescence (IF)

Unknown

Unknown

*If more than 1 viral infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

\*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

\*\*\* Also answer 'Yes' in case of pre-emptive therapy

**COMPLICATIONS SINCE THE LAST REPORT**

-- Infectious complications -- continued

*Extended dataset*

**Was CSF obtained?** *(Only if CTCAE term 'Central nervous system infection' is selected)*

- No  
 Yes; **Date of CSF:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Was this pathogen detected in CSF?**  No

Yes; **By what technique was the pathogen detected in CSF?**

- PCR  
 Cytology and immunofluorescence (IF)  
 Serology/antigen in CSF

Unknown

Unknown

**Was an endoscopy performed?** *(Only if CTCAE term 'Lower gastrointestinal infection' or 'Esophagus or gastric infection' is selected)*

- No  
 Yes; **Were gastrointestinal lesions documented?**  No  Yes  Unknown  
 Unknown

**Were typical lesions seen on the eye examination?** *(Only if CTCAE term 'Retinitis infective' or 'Other eye infection' is selected)*

- No  Yes  Unknown

**Was haemorrhagic cystitis diagnosed?** *(Only if CTCAE term 'Urinary tract infection' is selected)*

- No  Yes  Unknown

**Was HSV resistance to antiviral drugs documented?** *(Only if pathogen 'Herpes simplex virus (HSV)' is selected)*

- No  Yes  Unknown

**Was the patient transferred to the ICU due to this infection?**  No  Yes  Unknown

*(if patient died)*

**Contributory cause of death:**  No  Yes  Unknown

*If more than 1 viral infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

\*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

### Pre-emptive viral therapy

*Extended dataset*

*(If 'Viral infection' is 'Yes')*

**Did the patient receive pre-emptive therapy for a viral infection during this follow-up period?**  No  Yes

**If yes, for what virus?** *(Please make sure this viral infection has also been registered in the core dataset viral infection-part above (select all that apply) and the CTCAE term 'Viremia including DNAemia' was chosen)*

- CMV
- EBV
- BKV
- ADV
- JCV
- HHV-6

**Specify each pre-emptive therapy modality administered during this follow-up period 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 (see definition at 'Response'-question below))*

**CMV pre-emptive therapy start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used:**

*(Select all that apply)*

- Valganciclovir
- Ganciclovir intravenous
- Foscarnet
- Cidofovir
- Maribavir
- CMV-specific T-cells (VST) *(Please fill in the additional Cell Infusion Sheet in the appendix)*
- CMV hyperimmune immunoglobulin
- Regular immunoglobulin
- Leflunomide
- Artesunate
- Other drug

**In case of refractory CMV, was a resistance test performed?** *(please see definition in the completion guidelines)*

- No
- Yes: **Which mutation(s) were identified?**
  - UL97
  - UL54
  - UL56
  - UL27
  - No mutation identified
- Unknown

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

- Success: *(stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks)*
- 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)*

<b>Viral load at the start (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL <input type="checkbox"/> copies/mL <input type="checkbox"/> Not evaluated

<b>Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL <input type="checkbox"/> copies/mL <input type="checkbox"/> Not evaluated

**Date of discontinuation of pre-emptive therapy:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

*Copy as often as necessary to reflect all episodes that occurred*

**Pre-emptive viral therapy continued**

*Extended dataset*

**Specify each pre-emptive therapy modality administered during this follow-up period 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 (see definition at 'Response'-question below))*

**EBV pre-emptive therapy start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Therapy used: (EBV)**

*(Select all that apply)*

- Rituximab or anti-CD20 antibody
- EBV-specific T-cells (VST) *(Please fill in the additional Cell Infusion Sheet in the appendix)*
- Reduction of immunosuppression (defined as a sustained decrease of at least 20% of the daily dose of immunosuppressive drugs with the exception of low-dose corticosteroid therapy)
- Other drug

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

- Success:** (stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks)
- 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)

<b>Viral load at the start (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL <input type="checkbox"/> copies/mL	<input type="checkbox"/> Not evaluated

<b>Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL <input type="checkbox"/> copies/mL	<input type="checkbox"/> Not evaluated

**Date of discontinuation of pre-emptive therapy:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Specify each pre-emptive therapy modality administered during this follow-up period for each BKV treatment course**

*(a new pre-emptive therapy course is defined either as a relapse of BKV after at least 2 weeks without antiviral therapy (success of previous treatment) or change of antiviral therapy due to failure of any reason (see definition at 'Response'-question below))*

**BKV pre-emptive therapy start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used: (BKV)**

*(Select all that apply)*

- Cidofovir
- BKV-specific T-cells (VST) *(please fill in the additional Cell Infusion Sheet in the appendix)*

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

- Success:** (stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks)
- 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)

<b>Viral load in blood at the start (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL <input type="checkbox"/> copies/mL	<input type="checkbox"/> Not evaluated

<b>Viral load in blood at the discontinuation (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL <input type="checkbox"/> copies/mL	<input type="checkbox"/> Not evaluated

**Date of discontinuation of pre-emptive therapy:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

*Copy as often as necessary to reflect all episodes that occurred*

**Pre-emptive viral therapy continued**

*Extended dataset*

**Specify each pre-emptive therapy modality administered during this follow-up period for each ADV treatment course**  
 (a new pre-emptive therapy course is defined either as a relapse of ADV after at least 2 weeks without antiviral therapy (success of previous treatment) or change of antiviral therapy due to failure of any reason (see definition at 'Response'-question below))

**ADV pre-emptive therapy start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used: (ADV)**

(Select all that apply)

- Cidofovir
- Brincidofovir
- Ribavirin
- Immunoglobulin as treatment (not for replacement)
- ADV-specific T-cells (VST) (Please fill in the additional Cell Infusion Sheet in the appendix)

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

- Success: (stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks)
- 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)

<b>Viral load in stool at the start (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL	<input type="checkbox"/> copies/mL <input type="checkbox"/> Not evaluated

<b>Viral load in blood at the start (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL	<input type="checkbox"/> copies/mL <input type="checkbox"/> Not evaluated

<b>Viral load in stool at the discontinuation (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL	<input type="checkbox"/> copies/mL <input type="checkbox"/> Not evaluated

<b>Viral load in blood at the discontinuation (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL	<input type="checkbox"/> copies/mL <input type="checkbox"/> Not evaluated

**Date of discontinuation of pre-emptive therapy:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Specify each pre-emptive therapy modality administered during this follow-up period for each JCV treatment course**  
 (a new pre-emptive therapy course is defined either as a relapse of JCV after at least 2 weeks without antiviral therapy (success of previous treatment) or change of antiviral therapy due to failure of any reason (see definition at 'Response'-question below))

**JCV pre-emptive therapy start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used: (JCV)**

(Select all that apply)

- Cidofovir
- JCV-specific T-cells (VST) (Please fill in the additional Cell Infusion Sheet in the appendix)

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

- Success: (stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks)
- 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)

<b>Viral load at the start (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL	<input type="checkbox"/> copies/mL <input type="checkbox"/> Not evaluated

<b>Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL	<input type="checkbox"/> copies/mL <input type="checkbox"/> Not evaluated

**Date of discontinuation of pre-emptive therapy:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

*Copy as often as necessary to reflect all episodes that occurred*

### Pre-emptive viral therapy continued

*Extended dataset*

**Specify each pre-emptive therapy modality administered during this follow-up period for each HHV-6 treatment course**  
 (a new pre-emptive therapy course is defined either as a relapse of HHV-6 after at least 2 weeks without antiviral therapy (success of previous treatment) or change of antiviral therapy due to failure of any reason (see definition at 'Response'-question below))

**HHV-6 pre-emptive therapy treatment start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used: (HHV-6)**

(Select all that apply)

- Cidofovir
- HHV-6-specific T-cells (VST) (Please fill in the additional Cell Infusion Sheet in the appendix)
- Ganciclovir
- Valganciclovir
- Foscarnet

**Was HHV-6 subtyping done?**

- No
- Yes; **What HHV-6 subtype was identified?**  HHV-6A  HHV-6B  Unknown
- Unknown

**Was testing for chromosomally integrated HHV-6 done?**

- No
- Yes; **Was chromosomally integrated HHV-6 present?**  No  Yes  Unknown
- Unknown

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

- Success:** (stopping pre-emptive therapy without need for restarting therapeutic dose of the same or another antiviral agent within 2 weeks)
- 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)

<b>Viral load at the start (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL	<input type="checkbox"/> copies/mL <input type="checkbox"/> Not evaluated

<b>Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy:</b> _____	<b>Unit</b>	
	<input type="checkbox"/> log 10 IU/mL <input type="checkbox"/> IU/mL	<input type="checkbox"/> copies/mL <input type="checkbox"/> Not evaluated

**Date of discontinuation of pre-emptive therapy:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

*Copy as often as necessary to reflect all episodes that occurred*

### Treatment of end-organ viral disease

*Extended dataset*

*(If 'Viral infection' is 'Yes')*

**Did the patient receive treatment for end-organ viral disease during this follow-up period?**  No  Yes

**If yes, for what virus?** *(Please make sure this viral infection has also been registered in the core dataset viral infection-part above)*  
*(select all that apply)*

- CMV
- EBV
- BKV
- ADV
- JCV
- HHV-6
- CARVs (community acquired respiratory viruses)

**Specify each treatment modality given during this follow-up period for each occurrence of CMV disease or change in antiviral therapy due to failure (see definition at 'Response'-question below) that occurred**

**End-organ disease treatment start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used:**

*(Select all that apply (More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart))*

- Valganciclovir
- Ganciclovir intravenous
- Foscarnet
- Cidofovir
- Maribavir
- CMV-specific T-cells (VST) *(Please fill in the additional Cell Infusion Sheet in the appendix)*
- CMV hyperimmune immunoglobulin
- Regular immunoglobulin
- Leflunomide
- Artesunate
- Other drug

**In case of refractory CMV, was a resistance test performed?** *(please see definition in the completion guidelines)*

- No
- Yes: **Which mutation(s) were identified?**
  - UL97
  - UL54
  - UL56
  - UL27
  - No mutation identified
- Unknown

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

- Success: *(Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment)*
- 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:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Specify each treatment modality given during this follow-up period for each occurrence of EBV disease or change in therapy due to failure (see definition at 'Response'-question below) that occurred**

**EBV end-organ disease treatment start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Therapy used: (EBV)**

*(Select all that apply (More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart))*

- Rituximab or anti-CD20 antibody
- EBV-specific T-cells (VST) *(Please fill in the additional Cell Infusion Sheet in the appendix)*
- Reduction of immunosuppression *(defined as a sustained decrease of at least 20% of the daily dose of immunosuppressive drugs with the exception of low-dose corticosteroid therapy)*
- Other drug

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

- Success: *(Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment)*
- 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:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

### Treatment of end-organ viral disease continued

#### Extended dataset

Specify each treatment modality given during this follow-up period for each occurrence of BKV disease or change in antiviral therapy due to failure (see definition at 'Response'-question below) that occurred

**BKV end-organ disease treatment start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used: (BKV)**

(Select all that apply (More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart))

- Cidofovir
- BKV-specific T-cells (VST) (Please fill in the additional Cell Infusion Sheet in the appendix)

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

- Success:** (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment)
- 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:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

Specify each treatment modality given during this follow-up period for each occurrence of ADV disease or change in antiviral therapy due to failure (see definition at 'Response'-question below) that occurred

**ADV end-organ disease treatment start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used: (ADV)**

(Select all that apply (More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart))

- Cidofovir
- Brincidofovir
- Ribavirin
- Immunoglobulin as treatment (not for replacement)
- ADV-specific T-cells (VST) (Please fill in the additional Cell Infusion Sheet in the appendix)

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

- Success:** (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment)
- 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:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

Specify each treatment modality given during this follow-up period for each occurrence of JCV disease or change in therapy due to failure (see definition at 'Response'-question below) that occurred

**JCV end-organ disease treatment start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Therapy used: (JCV)**

(Select all that apply (More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart))

- Cidofovir
- JCV-specific T-cells (VST) (Please fill in the additional Cell Infusion Sheet in the appendix)
- Mirtazapine
- Checkpoint inhibitors

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

- Success:** (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment)
- 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:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

Copy as often as necessary to reflect all episodes that occurred

**Treatment of end-organ viral disease continued**

*Extended dataset*

**Specify each treatment modality given during this follow-up period for each occurrence of HHV-6 disease or change in antiviral therapy due to failure (see definition at 'Response'-question below) that occurred**

**HHV-6 end-organ disease treatment start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used: (HHV-6)**

*(Select all that apply (More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart))*

- Cidofovir
- HHV-6-specific T-cells (VST) (Please fill in the additional Cell Infusion Sheet in the appendix)
- Ganciclovir
- Valganciclovir
- Foscarnet

**Was HHV-6 subtyping done?**

- No
- Yes; **What HHV-6 subtype was identified?**  HHV-6A  HHV-6B  Unknown
- Unknown

**Was testing for chromosomally integrated HHV-6 done?**

- No
- Yes; **Was chromosomally integrated HHV-6 present?**  No  Yes  Unknown
- Unknown

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

- Success:** (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment)
- 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:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Specify each treatment modality given during this follow-up period for each occurrence of community acquired respiratory virus (CARV) disease or change in antiviral therapy due to failure (see definition at 'Response'-question below) that occurred**

**CARV end-organ disease treatment start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Antiviral(s) used: (CARV)**

*(Select all that apply (More than one modality can be added if the intention is combination therapy and the modalities are started no more than 48 hours apart))*

- Oseltamvir
- Zanamivir
- Baloxavir
- Peramivir
- Ribavirin
- Intravenous immunoglobulin (IVIG) for treatment
- Remdesivir
- Nirmatrel-Ritonavir

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

- Success:** (Defined as stopping end-organ disease treatment without the need for restarting the same or other treatment)
- 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:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

*Copy as often as necessary to reflect all episodes that occurred*

**COMPLICATIONS SINCE THE LAST REPORT**  
 -- Infectious complications -- continued

**Invasive fungal infection:**  No  Yes  Unknown

---

**New or ongoing:**  Newly developed  Ongoing since previous assessment

**Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD) *only if newly developed*  Unknown

Yeasts  Moulds

**Pathogen\*:** \_\_\_\_\_

*Extended dataset*

**Voriconazole resistance/susceptibility:**  Susceptible  Resistant  Susceptibility unknown  
*(Only if pathogen 'Aspergillus flavus', 'Aspergillus fumigatus', 'Aspergillus terreus' or 'Aspergillus other' is selected)*

**Infection with clinical implications:**  No  
 Yes: *(select all that apply during this period)*

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

*Indicate at least 1 location involved during this period:*

**Localisation 1 (CTCAE term)\*\*:** \_\_\_\_\_  
**Localisation 2 (CTCAE term)\*\*:** \_\_\_\_\_  
**Localisation 3 (CTCAE term)\*\*:** \_\_\_\_\_

*Extended dataset*

**Were abnormalities detected upon radiological assessment?** *(Only if CTCAE term 'Central nervous system infection', 'Sinusitis infective', 'Liver site infection', 'Esophagus or gastric infection', 'Lower gastrointestinal infection', 'Enteritis infective', 'Other intra-abdominal infection', 'Splenic infection' or 'Urinary tract infection' is selected)*

No  
 Yes; **What diagnostic technique was used to detect abnormalities?**  
 Unknown

MRI  
 CT  
 PET  
 PET CT  
 Ultrasound  
 Other; Specify: \_\_\_\_\_

**Radiology showing new or worsening pulmonary infiltrates:** *(Only if CTCAE term 'Pneumonia' is selected)*

No  
 Yes; **What diagnostic technique was used to show pulmonary infiltration?**

CT  
 PET  
 Chest X-ray  
 MRI

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

No  
 Yes  
 Unknown

Unknown

**Was PCR in blood performed?**  No  Yes, negative  Yes, positive  Unknown

*(If Yes, negative/Yes, positive)*  
**Date of PCR in blood performed:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  
*(If Yes, positive)*

**Was the result confirmed by a second test?**  No, second PCR in blood not taken  
 No, second PCR in blood taken and negative  
 Yes  
 Unknown

*If more than 1 fungal infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2  
 \*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

**COMPLICATIONS SINCE THE LAST REPORT**

-- Infectious complications -- continued

*Extended dataset*

**Was a biopsy performed?** *(Not applicable if CTCAE term 'Fungemia' is selected)*

- No  
 Yes; **Date of biopsy:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Was this pathogen detected in biopsy?**  No  
 Yes; **By what technique was the pathogen detected in biopsy?**
- Unknown
- Culture
  - Histopathological or cytopathological demonstration
  - Immunohistochemistry
  - PCR
  - Fungal stain
- Unknown

**Was bronchoalveolar lavage (BAL) performed?** *(Only if CTCAE term 'Pneumonia' or 'Tracheobronchitis infective' is selected)*

- No  
 Yes; **Date of BAL:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Was this pathogen detected in BAL?**  No  
 Yes; **By what technique was the pathogen detected in BAL?**
- Unknown
- Culture
  - PCR
  - Stain
  - BAL Galactomannan assay
- Unknown

**Was CSF obtained?** *(Only if CTCAE term 'Central nervous system infection' is selected)*

- No  
 Yes; **Date of CSF:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Was this pathogen detected in CSF?**  No  
 Yes; **By what technique was the pathogen detected in CSF?**
- Unknown
- Culture
  - PCR
  - Beta D glucan galactomannan
  - Stain
  - Serology/antigen in CSF
- Unknown

**Was sinus fluid sampled?** *(Only if CTCAE term 'Sinusitis infective' is selected)*

- No  
 Yes; **Date of sinus fluid sampling:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Was this fungus detected in sinus fluid?**  No  
 Yes; **By what technique was the fungus detected in sinus fluid?**
- Unknown
- Culture
  - PCR
  - Fungal stain
- Unknown

**Was an endoscopy performed?** *(Only if CTCAE term 'Lower gastrointestinal infection' or 'Esophagus or other gastric infection' is selected)*

- No  
 Yes; **Were gastrointestinal lesions documented?**  No  Yes  Unknown  
 Unknown

**Were typical lesions seen on the eye examination?** *(Only if CTCAE term 'Retinitis infective' or 'Other eye infection' is selected)*

- No  Yes  Unknown

**Was the patient transferred to the ICU due to this infection?**  No  Yes  Unknown

*(if patient died)*

**Contributory cause of death:**  No  Yes  Unknown

*If more than 1 fungal infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

\*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

### COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

**Parasitic infection:**  No  Yes  Unknown

**New or ongoing:**  Newly developed  Ongoing since previous assessment

**Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD) *only if newly developed*  Unknown

Protozoa  Helminths

**Pathogen\*:** \_\_\_\_\_

**Infection with clinical implications:**  No

Yes: *(select all that apply during this period)*

Symptoms/signs or disease

Administration of pathogen-directed therapy

Unknown

*Indicate at least 1 location involved during this period:*

**Localisation 1 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 2 (CTCAE term)\*\*:** \_\_\_\_\_

**Localisation 3 (CTCAE term)\*\*:** \_\_\_\_\_

#### Extended dataset

**Were abnormalities detected upon radiological assessment?**

- No  
 Yes; **What diagnostic technique was used to detect abnormalities?**  
 Unknown

- MRI  
 CT  
 PET  
 PET CT  
 Ultrasound  
 Other; Specify: \_\_\_\_\_

*(Only if CTCAE term 'Central nervous system infection', 'Sinusitis infective', 'Liver site infection', 'Esophagus or gastric infection', 'Lower gastrointestinal infection', 'Enteritis infective', 'Other intra-abdominal infection', 'Splenic infection' or 'Urinary tract infection' is selected)*

**Radiology showing new or worsening pulmonary infiltrates:** *(Only if CTCAE term 'Pneumonia' is selected)*

- No  
 Yes; **What diagnostic technique was used to show pulmonary infiltration?**  
 Unknown

- CT  
 PET  
 Chest X-ray  
 MRI

**Was a biopsy performed?** *(Not applicable if CTCAE term 'DNAemia for parasitic infection' is selected)*

- No  
 Yes; **Date of biopsy:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Was this pathogen detected in biopsy?**  No

Yes; **By what technique was the pathogen detected in biopsy?**

- Culture  
 Histopathological or cytopathological demonstration  
 Immunohistochemistry  
 PCR  
 Stain

Unknown

Unknown

*If more than 1 parasitic infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

\*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

### COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

#### Extended dataset

**Was bronchoalveolar lavage (BAL) performed?** *(Only if CTCAE term 'Pneumonia' or 'Tracheobronchitis infective' is selected)*

- No  
 Yes; **Date of BAL:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Was this pathogen detected in BAL?**  No

- Yes; **By what technique was the pathogen detected in BAL?**  
 Culture  
 PCR  
 Stain  
 Unknown

Unknown

**Was CSF obtained?** *(Only if CTCAE term 'Central nervous system infection' is selected)*

- No  
 Yes; **Date of CSF:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Was this pathogen detected in CSF?**  No

- Yes; **By what technique was the pathogen detected in CSF?**  
 Culture  
 PCR  
 Stain  
 Serology/antigen in CSF

Unknown

Unknown

**Were typical lesions seen on the eye examination?** *(Only if CTCAE term 'Retinitis infective' or 'Other eye infection' is selected)*

- No  Yes  Unknown

**Was the patient transferred to the ICU due to this infection?**  No  Yes  Unknown

*(if patient died)*

**Contributory cause of death:**  No  Yes  Unknown

*If more than 1 parasitic infections, copy and fill-in this table as many times as necessary.*

\* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

\*\* Indicate CTCAE term by choosing from the list provided in Appendix 3

**COMPLICATIONS SINCE THE LAST REPORT**

-- Infectious complications -- continued

**Infection with unknown pathogen:**  No  Yes  Unknown

(for clinical infections without microbiological documentation, like pneumonia, cellulitis, etc.)

**New or ongoing:**  Newly developed  Ongoing since previous assessment

**Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD) *only if newly developed*  Unknown

**Infection with clinical implications:**  No

Yes: (select all that apply)

Symptoms/signs or disease

Administration of pathogen-directed therapy

Unknown

Indicate at least 1 location:

**Localisation 1 (CTCAE term)\*:** \_\_\_\_\_

**Localisation 2 (CTCAE term)\*:** \_\_\_\_\_

**Localisation 3 (CTCAE term)\*:** \_\_\_\_\_

*Extended dataset*

**Were abnormalities detected upon radiological assessment?** *(Only if CTCAE term 'Central nervous system infection', 'Sinusitis infective', 'Liver site infection', 'Esophagus or gastric infection', 'Lower gastrointestinal infection', 'Enteritis infective', 'Other intra-abdominal infection', 'Splenic infection' or 'Urinary tract infection' is selected)*

No

Yes; **What diagnostic technique was used to detect abnormalities?**

Unknown

MRI

CT

PET

PET CT

Ultrasound

Other; Specify: \_\_\_\_\_

**Radiology showing new or worsening pulmonary infiltrates:** *(Only if CTCAE term 'Pneumonia' is selected)*

No

Yes; **What diagnostic technique was used to show pulmonary infiltration?**

Unknown

CT

PET

Chest X-ray

MRI

**Was the patient transferred to the ICU due to this infection?**  No

Yes

Unknown

*(if patient died)*

**Contributory cause of death:**  No  Yes  Unknown

*If more than 1 infections with unknown pathogen, copy and fill-in this table as many times as necessary.*

\* Indicate CTCAE term by choosing from the list provided in Appendix 3 at page 25

### VACCINATIONS

*Extended dataset*

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

- No
- Yes; **Date of first RZV (Shingrix®) vaccination:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Date of last RZV (Shingrix®) vaccination:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Number of doses RZV (Shingrix®) vaccine:** \_\_\_\_\_
- Unknown

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

- No
- Yes; **What type of RSV vaccine did the patient receive?**
- Adjuvant subunit vaccine (Arexvy® - GlaxoSmithKline (GSK))
  - Unadjuvanted bivalent recombinant RSV vaccine (Abrysvo® - Pfizer)
  - mRNA-based vaccine (mResvia® - Moderna)
- Date of RSV vaccination :** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Unknown

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

- No
- Yes; **What type of RSV antibody did the patient receive?**
- Clesrovimab (Enflonsia® - Merck)
  - Palivizumab (Synagis® - AstraZeneca)
  - Nirsevimab (Beyfortus® - Sanofi)
  - Unknown
- Date of monoclonal antibody given:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Unknown

### SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS

**Did secondary malignancy or autoimmune disorder occur since the last follow-up?**

- No
- Yes; **Was it a secondary malignancy or autoimmune disorder?**
- Secondary malignancy
  - Autoimmune disorder

**Date of diagnosis:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

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

- No (complete the non-indication diagnosis form)
  - Yes (complete the relevant indication diagnosis form)
- Unknown

### ADDITIONAL TREATMENTS

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

- No
- Yes;  Started in this follow-up period;  
 Ongoing since previous follow-up
- Unknown

**complete the "Treatment — non-HCT/CT/GT/IST form and /or the Cell infusion sheet"**

### ADDITIONAL CELL INFUSIONS

**Did the patient receive additional cell infusions (excluding a new HCT and CT) since the last follow-up?**

No

Yes: **Is this cell infusion an allogeneic boost\* ?**  No  Yes

*\* An allogeneic boost is an infusion of cells from the same donor without conditioning, with no evidence of graft rejection.*

**Date of the allogeneic boost:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**Is this cell infusion an autologous boost?**  No  Yes

**Date of the autologous boost:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

Unknown

*If this cell infusion is not a boost, attach the Cell Infusion (CI) sheet available in Appendix 6, completing as many sheets as episodes of cell infusion that took place during this interval; then continue below.*

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

No

Yes

*If the patient had a subsequent HCT/CT, please, make sure that this subsequent treatment is registered using the appropriate treatment form before proceeding.*

**RELAPSE, PROGRESSION, RECURRENCE OF DISEASE OR SIGNIFICANT WORSENING**

*(not relevant for Inborn errors)*

**MRD detectable (with any method):** (only for Acute leukaemia)

- No  
 Yes: **Date of first detectable MRD:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Not evaluated  
 Unknown

**Was there a relapse, progression, recurrence of disease or significant worsening of organ function related to the primary disease since last follow-up?** *(detected by any method)*

- No  
 Yes: *for every relapse, progression, recurrence, significant worsening complete the questions below*

**Type:**  Relapse / Recurrence of disease

(Continuous) progression / Significant worsening

**Date of relapse/progression/recurrence/worsening:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

*Extended dataset*

**In case of relapse or progression (CML only)**

**Type of relapse:**

*(select worst detected at this time point)*

- Haematological; **Disease status at relapse:**  Chronic phase  
 Accelerated phase  
 Blast crisis  
 Unknown
- Cytogenetic  
 Molecular  
 Unknown

**In case of relapse or progression (MPN only)**

**Type of relapse:**

*(select worst detected at this time point)*

- Haematological  
 Molecular  
 Unknown

**Malignant disorders only:**

**Type of relapse/progression:**

**Medullary:**  No  Yes  Unknown

**Extramedullary:**  No  Yes  Unknown

*If the relapse/progression was extramedullary or both medullary and extramedullary:*

**Involvement at time of relapse/progression:**

**Skin:**  No  Yes  Not evaluated

**CNS:**  No  Yes  Not evaluated

**Testes/Ovaries:**  No  Yes  Not evaluated

**Other:**  No  Yes; specify: \_\_\_\_\_

*copy and fill-in this table as many times as necessary.*

Unknown

### DISEASE STATUS

*Disease specific*

Disease status at this follow-up or at time of death\*: \_\_\_\_\_

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

### PREGNANCY AFTER HCT

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

No;

*Extended dataset*

Was there an attempted pregnancy since last follow-up?  No  Yes  Unknown

Yes: Did the pregnancy result in a live birth?

No; Date of spontaneous or induced termination: \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

Yes; Year of birth: \_\_\_\_ (YYYY) Month of birth: \_\_ (MM)  Unknown

Still pregnant at time of follow-up

Unknown

*Extended dataset*

Conception method:  Natural  Assisted  Unknown

Unknown

**Appendix 1**  
Best Response and Disease Status (Disease Specific)

*Complete only one section with the main indication diagnosis for which HCT was given.*

ACUTE LEUKAEMIAS	<i>Go to page 48</i>
CHRONIC LEUKAEMIAS	<i>Go to page 48</i>
PLASMA CELL NEOPLASMS (PCN)	<i>Go to page 49</i>
MPN, MDS, MDS / MPN OVERLAP SYNDROMES	<i>Go to page 51</i>
AUTOIMMUNE DISORDERS	<i>Go to page 52</i>
HAEMOGLOBINOPATHIES	<i>Go to page 52</i>
LYMPHOMAS	<i>Go to page 53</i>
SOLID TUMOURS	<i>Go to page 53</i>
BONE MARROW FAILURE SYNDROMES (BMF) including APLASTIC ANAEMIA (AA)	<i>Go to page 53</i>
OTHER DIAGNOSIS	<i>Go to page 54</i>
Inborn Errors	<i>Go to page 55</i>

**Appendix 1**  
 Best Response and Disease Status (Disease Specific)

**Acute leukaemias (AML, PLN, Other)**

<input type="checkbox"/> Complete remission (CR)
<input type="checkbox"/> Not in complete remission
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

*Proceed to next page for Diseases Status section*

**Chronic leukaemias (CML, CLL, PLL, Other)**
Chronic Myeloid Leukaemia (CML):

<input type="checkbox"/> Chronic phase (CP); <b>Number:</b> <input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher <input type="checkbox"/> Unknown <b>Haematological remission:</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown <b>Cytogenetic remission:</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
--

*Extended dataset*
**In case of NO cytogenetic remission**

<b>Cytogenetic details :</b> t(9;22) positive metaphases: _____ (%)	<input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
t(9;22) positive cells detected by FISH: _____ (%)	<input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown

**Molecular remission:**  No  Yes  Not evaluated  Unknown

*Extended dataset*
**In case of NO molecular remission**

**BCR::ABL1 variant allele frequency (VAF):** \_\_\_\_\_%  Unknown

<input type="checkbox"/> Accelerated phase; <b>Number:</b> <input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher <input type="checkbox"/> Unknown
--

*Extended dataset*

<b>Cytogenetic details:</b> t(9;22) positive metaphases: _____ (%)	<input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
t(9;22) positive cells detected by FISH: _____ (%)	<input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown

**BCR::ABL1 variant allele frequency (VAF):** \_\_\_\_\_%  Unknown

<input type="checkbox"/> Blast crisis; <b>Number:</b> <input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> or higher <input type="checkbox"/> Unknown
---

*Extended dataset*

<b>Cytogenetic details:</b> t(9;22) positive metaphases: _____ (%)	<input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
t(9;22) positive cells detected by FISH: _____ (%)	<input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown

**BCR::ABL1 variant allele frequency (VAF):** \_\_\_\_\_%  Unknown

<input type="checkbox"/> Not evaluated
--

<input type="checkbox"/> Unknown
----------------------------------

*Proceed to next page for Diseases Status section*

## Appendix 1

### Best Response and Disease Status (Disease Specific)

Chronic Lymphocytic Leukaemia (CLL), Prolymphocytic Leukaemia (PLL) and other chronic leukaemias:

<input type="checkbox"/> Complete remission (CR)
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Progression: <input type="checkbox"/> Resistant to last regimen <input type="checkbox"/> Sensitive to last regimen <input type="checkbox"/> Unknown
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Relapse
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

*Proceed to next page for Diseases Status section*

#### Plasma cell neoplasms (PCN)

<input type="checkbox"/> Complete remission (CR)	<b>Number:</b> <input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Stringent complete remission (sCR)	
<input type="checkbox"/> Very good partial remission (VGPR)	
<input type="checkbox"/> Partial remission (PR)	
<input type="checkbox"/> Relapse	
<input type="checkbox"/> Progression	
<input type="checkbox"/> Stable disease (no change, no response/loss of response)	
<input type="checkbox"/> Not evaluated	
<input type="checkbox"/> Unknown	

#### Extended dataset

Immunoglobulin-related (AL) Amyloidosis only

#### Organ response during this follow-up period:

Heart	<input type="checkbox"/> Response <input type="checkbox"/> No change <input type="checkbox"/> Progression <input type="checkbox"/> Not involved <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
Kidney	<input type="checkbox"/> Response <input type="checkbox"/> No change <input type="checkbox"/> Progression <input type="checkbox"/> Not involved <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
Liver	<input type="checkbox"/> Response <input type="checkbox"/> No change <input type="checkbox"/> Progression <input type="checkbox"/> Not involved <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
Peripheral nervous system	<input type="checkbox"/> Response <input type="checkbox"/> No change <input type="checkbox"/> Progression <input type="checkbox"/> Not involved <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown

*Proceed to next page for Diseases Status section*

**Appendix 1**  
Best Response and Disease Status (Disease Specific)  
**continued**

Complete only for PCN Disease Status

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

- No
- Yes;  Started in this follow-up period: **Start date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Ongoing since previous follow-up
- Did dialysis stop?**  No
- Yes; **End date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown
- Unknown

Complete only for AL, CLL and PCN Disease Status

**Leukaemias (AL, CLL) and PCN** (complete only for patient in CR or sCR)

**Minimal residual disease (MRD):**

- Positive
- Negative
- Not evaluated
- Unknown

*Extended dataset*

**Date MRD status evaluated:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

**Sensitivity of MRD assay:**

- $\leq 10^{-6}$
- $\leq 10^{-5}$
- $\leq 10^{-4}$
- $\leq 10^{-3}$
- Other; specify: \_\_\_\_\_
- Unknown

**Method used:**

*(select the most sensitive method used)*

- PCR
- Flow cytometry
- NGS
- Other; specify: \_\_\_\_\_
- Unknown



EBMT Centre Identification Code (CIC): \_\_\_\_\_

Treatment Type  HCT

Hospital Unique Patient Number (UPN): \_\_\_\_\_

Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**Appendix 1****Best Response and Disease Status (Disease Specific)  
continued****Myeloproliferative neoplasms (MPN), Myelodysplastic neoplasms (MDS), MDS/MPN overlap syndromes**

<input type="checkbox"/> Complete remission (CR)	<u>Number:</u> <input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Improvement but no CR	
<input type="checkbox"/> Primary refractory phase (no change)	
<input type="checkbox"/> Relapse	<u>Number:</u> <input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Progression/Worsening	
<input type="checkbox"/> Not evaluated	
<input type="checkbox"/> Unknown	

**Appendix 1**  
**Best Response and Disease Status (Disease Specific)**  
**continued**

**Autoimmune disorders**

<input type="checkbox"/> No evidence of disease
<input type="checkbox"/> Improved
<input type="checkbox"/> Unchanged
<input type="checkbox"/> Worse
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

**Haemoglobinopathies**

Thalassaemia:

**Complete only for Thalassemia Best Response**

<input type="checkbox"/> Transfusion independent	<b>Date of last transfusion:</b> ____/____/____ (YYYY/MM/DD)	<input type="checkbox"/> Unknown
<i>(after HCT)</i>		
<input type="checkbox"/> Transfusions required;	<b>Date of first transfusion:</b> ____/____/____ (YYYY/MM/DD)	<input type="checkbox"/> Unknown
<i>(after HCT)</i>		
<input type="checkbox"/> Not evaluated		
<input type="checkbox"/> Unknown		

**Complete only for Thalassemia Disease Status**

**Patient requires transfusions during follow-up period:**

No

Yes;  Return to transfusion dependence after HCT or transfusion free period; **Date of first transfusion:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
*(after HCT or transfusion free period)*

Ongoing transfusion dependence since previous assessment

**Number of units:** \_\_\_\_  Unknown  
*(during follow-up period)*

**Did transfusions stop?**  No  
 Yes; **Date of last transfusion:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
 Unknown

Unknown

Sickle cell disease:

**Complete only for Sickle cell disease Best Response**

<input type="checkbox"/> No return of sickling episodes		
<input type="checkbox"/> Return of sickling episodes;	<b>Date of first episode:</b> ____/____/____ (YYYY/MM/DD)	<input type="checkbox"/> Unknown
<i>(after HCT)</i>		
<input type="checkbox"/> Not evaluated		
<input type="checkbox"/> Unknown		

**Complete only for Sickle cell disease Disease Status**

**Sickling episodes occur during follow-up period:**

No

Yes;  First return of sickling episodes after HCT **Date of first episode :** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
*(after HCT)*

Ongoing presence of sickling episodes

**Number of SCD episodes:** \_\_\_\_  Unknown  
*(during follow-up)*

Unknown

**Appendix 1**  
**Best Response and Disease Status (Disease Specific)**  
**continued**
**Lymphomas**

<input type="checkbox"/> Chemorefractory relapse or progression, including primary refractory disease
<input type="checkbox"/> Complete remission (CR)
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Untreated relapse (from a previous CR) or progression (from a previous PR)
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

**Technique used for disease assessment:**

CT scan  
 PET-CT  
 MRI  
 Clinical assessment (for continuous CR)  
 Other; specify: \_\_\_\_\_  
 Unknown

**Solid tumours**

<input type="checkbox"/> Complete remission (CR): <input type="checkbox"/> Confirmed <input type="checkbox"/> Unconfirmed <input type="checkbox"/> Unknown
<input type="checkbox"/> First partial remission
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Progressive disease
<input type="checkbox"/> Relapse: <input type="checkbox"/> Resistant <input type="checkbox"/> Sensitive <input type="checkbox"/> Unknown
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

**Bone marrow failures (incl. AA)**

<input type="checkbox"/> Complete remission (CR)
<input type="checkbox"/> Partial remission (PR)
<input type="checkbox"/> Haematological improvement (HI); <i>NIH partial response</i>
<input type="checkbox"/> Stable disease (no change, no response/loss of response)
<input type="checkbox"/> Relapse / Progression
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

Complete only for Bone marrow failures (incl. AA) Disease Status

**Did transfusions stop during the follow-up period?**

Patient was never transfusion dependent  
 No  
 Yes; **Did the patient return to transfusion dependency afterwards?**  
      No  
      Yes; **First transfusion date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown  
         (after transfusion free period)  
      Unknown  
 Unknown



EBMT Centre Identification Code (CIC): \_\_\_\_\_

Hospital Unique Patient Number (UPN): \_\_\_\_\_

Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT

Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**Appendix 1**  
Best Response and Disease Status (Disease Specific)  
**continued**

**Other diagnosis**

<input type="checkbox"/> No evidence of disease
<input type="checkbox"/> Improved
<input type="checkbox"/> No response
<input type="checkbox"/> Worse
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

**Appendix 1**  
**Disease Status**  
*Inborn errors only*

**Patient height at this follow-up:** \_\_\_\_\_ cm  Not evaluated  Unknown

**Patient weight at this follow-up:** \_\_\_\_\_ kg  Not evaluated  Unknown

- Patient is attending:**
- Regular school/work
  - Alternative school/adapted work
  - Patient is not able to attend work/school
  - Unknown

*(Only for Inborn errors of Immunity)*

**Immune profiling done during this follow-up period:**  No  Yes  Unknown

**Test date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)  Unknown

Cell type and test results	Units (for CD4 and CD8, select unit)
CD3 T-cells: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Cells/ $\mu$ l
CD4 T-cells: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Cells/ $\mu$ l
CD8 T-cells: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Cells/ $\mu$ l
B-cells (i.e. CD19): _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Cells/ $\mu$ l
NK-cells (CD16/CD56): _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Cells/ $\mu$ l
Naive CD4 T-cells (CD4/CD45RA): _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	<input type="checkbox"/> % of CD4 <input type="checkbox"/> Cells/ $\mu$ l
Naive CD8 T-cells (CD8/CD45RA): _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	<input type="checkbox"/> % of CD8 <input type="checkbox"/> Cells/ $\mu$ l
IgG: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Gram/l
IgA: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Gram/l
IgM: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Gram/l

**Appendix 1**  
**Disease Status**  
*( Only for Inborn errors of immunity )*

*Extended dataset*

**Select the immunomodulatory treatments the patient received in the 3 months before the follow-up.**

*Only report treatments administered in the 3 months before this follow-up. Do not report treatments for GvHD or other HCT/CT related complications, only for the underlying disease*

- No treatment given
- IVIG
- SCIG
- Steroids (>0.5 mg/kg/day prednison equivalent)
- Cyclosporine A
- Tacrolimus
- Sirolimus
- Ruxolitinib
- Baricitinib
- Other JAK-inhibitor, specify: \_\_\_\_\_
- Leniolisib
- Abatacept
- Anakinra
- Canakinumab
- Etoposide
- Interferon gamma
- Etanercept
- Infliximab
- Vedolizumab
- Dupilumab
- Emapalumab
- PEG-ADA
- Other drug; specify: \_\_\_\_\_
- Unknown

**Appendix 1**  
**Disease Status**  
*Inborn errors of Immunity only*

*Extended dataset*

**Comorbidities during this follow-up period**  
*Only for Inborn Errors of Immunity*

Indicate in the table below if the comorbidities de novo, resolved, improved, stabilised or worsened during this follow-up period.

Inflammatory bowel disease	Crohn's disease or ulcerative colitis	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Stabilised <input type="checkbox"/> Worsened <input type="checkbox"/> De novo <input type="checkbox"/> Not evaluated
Rheumatologic	SLE, RA, polymyositis, mixed CTD or polymyalgia rheumatica	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Stabilised <input type="checkbox"/> Worsened <input type="checkbox"/> De novo <input type="checkbox"/> Not evaluated
Renal: moderate/severe	Serum creatinine > 2 mg/dL or >177 µmol/L, on dialysis, or prior renal transplantation	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Stabilised <input type="checkbox"/> Worsened <input type="checkbox"/> De novo <input type="checkbox"/> Not evaluated
Hepatic: mild	Chronic hepatitis, bilirubin between Upper Limit Normal (ULN) and 1.5 x ULN, or AST/ALT between ULN and 2.5 x ULN	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Stabilised <input type="checkbox"/> Worsened <input type="checkbox"/> De novo <input type="checkbox"/> Not evaluated
Hepatic: moderate/severe	Liver cirrhosis, bilirubin greater than 1.5 x ULN, or AST/ALT greater than 2.5 x ULN	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Stabilised <input type="checkbox"/> Worsened <input type="checkbox"/> De novo <input type="checkbox"/> Not evaluated
Chronic lung disease	Bronchiectasis, interstitial pneumonitis, GLILD, oxygen dependency, structural lung disease (e.g. pneumatoceles)	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Stabilised <input type="checkbox"/> Worsened <input type="checkbox"/> De novo <input type="checkbox"/> Not evaluated
Pre-HCT malignancy	Leukaemia, lymphoma, myelodysplastic syndrome (MDS)	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> In remission <input type="checkbox"/> Stable disease <input type="checkbox"/> Relapsed <input type="checkbox"/> Not evaluated <input type="checkbox"/> Not evaluated
Failure to thrive	Weight <3 <sup>rd</sup> percentile or requirement for (par)enteral feeding	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Stabilised <input type="checkbox"/> Worsened <input type="checkbox"/> De novo <input type="checkbox"/> Not evaluated
Active infection at HCT	Any infection requiring therapy in the immediate pre HCT period	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Stabilised <input type="checkbox"/> Worsened <input type="checkbox"/> Not evaluated
Lymphoproliferation	I.e. splenomegaly, organ specific lymphoproliferation	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Stabilised <input type="checkbox"/> Worsened <input type="checkbox"/> De novo <input type="checkbox"/> Not evaluated



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**Appendix 1**  
**Disease Status**  
*Inborn errors only*

*Extended dataset*

**Comorbidities during this follow-up period**  
*Only for Inborn Errors of Immunity*

**Indicate in the table below if the comorbidities de novo, resolved, improved, stabilised or worsened during this follow-up period.**

Pre-HCT organ impairment	Infectious or non-infectious (including neurologic)	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Stabilised <input type="checkbox"/> Worsened <input type="checkbox"/> Not evaluated
Autoimmunity/ autoinflammation	Pre HCT/CT (includes patients in remission but on immunomodulatory treatment within 3 months before HCT/CT)	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Stabilised <input type="checkbox"/> Worsened <input type="checkbox"/> Not evaluated

**Was the patient admitted to ICU during this follow-up period?**  No     Yes     Unknown

**Appendix 2**  
 -- Pathogens as per EBMT Registry database --

*\*As defined by the IDSA (Mermel LA, Allon M, Bouza E, Craven DE, Flynn P, O'Grady NP, et al. Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 Update by the Infectious Diseases Society of America. Clin Infect Dis. 2009;49(1):1-45)*

**Bacterial infections**

**Gram-positive:**

- . Bacillus (in blood: report only if ≥2 positive separately taken cultures)
- . Clostridioides difficile (c difficile/CDT/CDI)
- . Clostridium other (NOT difficile)
- . Corynebacterium jeikeium
- . Corynebacterium other (NOT jeikeium) (in blood: report only if ≥2 positive separately taken cultures)
- . Enterococcus faecalis (vancomycin-susceptible)
- . Enterococcus faecalis (vancomycin-resistant)
- . Enterococcus faecium (vancomycin-susceptible)
- . Enterococcus faecium (vancomycin-resistant)
- . Listeria monocytogenes
- . Nocardia (specify)
- . Propionibacterium (in blood: report only if ≥2 positive separately taken cultures)
- . Rothia
- . Staphylococcus aureus (s aureus/staph aureus) MSSA (methicillin-susceptible)
- . Staphylococcus aureus (s aureus/staph aureus) MRSA (methicillin-resistant vancomycin-susceptible)
- . Staphylococcus coagulase-negative (in blood: report only if ≥2 positive separately taken cultures)
- . Staphylococcus lugdunensis
- . Streptococcus pneumoniae (pneumococcus)
- . Streptococcus viridans
- . Streptococcus other (specify)
- . Gram-positive bacteria other (specify)

**Gram-negative:**

- . Acinetobacter baumannii
- . Acinetobacter Iwoffii (in blood: report only if ≥2 positive separately taken cultures)
- . Acinetobacter other (NOT baumannii, NOT Iwoffii)
- . Bacteroides fragilis
- . Bordetella pertussis
- . Borrelia
- . Brucella
- . Campylobacter jejuni
- . Citrobacter freundii
- . Coxiella burnetii (Q fever)
- . Enterobacter cloacae
- . Enterobacter other
- . Escherichia coli (e coli)
- . Fusobacterium
- . Haemophilus influenzae (haemophilus influenzae type B/Hib/hemophilus influenzae)
- . Haemophilus other (hemophilus)
- . Helicobacter pylori
- . Klebsiella pneumoniae (carbapenem-susceptible)
- . Klebsiella other (NOT pneumoniae) (carbapenem-susceptible)
- . Klebsiella (any species) (carbapenem-resistant)
- . Klebsiella (any species) (carbapenem-susceptibility not checked)
- . Legionella pneumophila
- . Morganella morganii
- . Micrococcus (in blood: report only if ≥2 positive separately taken cultures)
- . Moraxella catarrhalis
- . Neisseria gonorrhoeae (gonococcus)
- . Neisseria meningitidis (meningococcus)
- . Proteus vulgaris
- . Providencia
- . Pseudomonas aeruginosa (PSA) (carbapenem-susceptible)
- . Pseudomonas aeruginosa (PSA) (carbapenem-resistant)
- . Pseudomonas aeruginosa (PSA) (carbapenem-susceptibility not checked)
- . Pseudomonas other (NOT aeruginosa)
- . Raoultella
- . Salmonella (specify)
- . Serratia marcescens
- . Shigella
- . Stenotrophomonas maltophilia
- . Treponema pallidum (syphilis/lues)
- . Yersinia
- . Gram-negative bacteria other (specify)

**Other bacteria:**

- . Chlamydia
- . Chlamydoxiphila
- . Mycobacterium other (specify)
- . Mycobacterium tuberculosis (TB)
- . Mycoplasma pneumoniae
- . Rickettsia
- . Ureoplasma
- . Bacteria other (specify)

**Viral infections:**

- . Adenovirus (ADV)
- . Chikungunya virus
- . Crimean-Congo haemorrhagic fever virus (CCHFV)
- . Dengue virus
- . Gastrointestinal viruses:
  - o Norovirus
  - o Rotavirus
  - o Sapovirus
  - o Astrovirus
- . Hepatotropic viruses:
  - o Hepatitis A virus (HAV)
  - o Hepatitis B virus (HBV)
  - o Hepatitis C virus (HCV)
  - o Hepatitis D virus (HDV)
  - o Hepatitis E virus (HEV)
- . Herpes group:
  - o Cytomegalovirus (CMV)
  - o Epstein-Barr virus (EBV)
  - o Herpes simplex virus (HS/HSV)
  - o Herpesvirus 6 (HHV6)
  - o Herpesvirus 7 (HHV7)
  - o Herpesvirus 8 (HHV8/Kaposi's sarcoma-associated herpesvirus/KSHV/Kaposi)
  - o Varicella zoster virus (VZV/VZV/HSV/shingles/zoster/chickenpox)
- . Human immunodeficiency virus (HIV)
- . Human papilloma viruses (HPV)
- . Human T-lymphotropic virus 1 (HTLV-1)
- . Human T-lymphotropic virus 2 (HTLV-2)
- . Measles virus
- . Mumps virus
- . Parechovirus
- . Parvovirus (parvovirus B-19/B-19)
- . Poliovirus
- . Polyomaviruses:
  - o BK polyomavirus (BKV)
  - o JC virus (JCV)
  - o Merkel cell virus
- . Respiratory viruses:
  - o Bocavirus
  - o Enterovirus
  - o Human coronavirus (excluding SARS-CoV-2 or COVID-19)
  - o Influenza A virus (including birdflu)
  - o Influenza B virus
  - o Human metapneumovirus (hMPV)
  - o Parainfluenza
  - o Rhinovirus
  - o Respiratory syncytial virus (RSV)
  - o SARS-CoV-2 virus (COVID-19)
- . Rubella virus
- . Sandfly viruses (Naples virus/Sicilian virus/Toscana virus/Cyprus virus/Turkey virus/Tehran virus/phlebovirus)
- . Tick-borne encephalitis virus (TBE)
- . West Nile virus (WNV)
- . Yellow fever virus
- . Zika virus (ZIKV)
- . Viruses other (specify)

**Appendix 2**

-- Pathogens as per EBMT Registry database -- continued

*\*As defined by the IDSA (Mermel LA, Allon M, Bouza E, Craven DE, Flynn P, O'Grady NP, et al. Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 Update by the Infectious Diseases Society of America. Clin Infect Dis. 2009;49(1):1-45)*

**Fungal infections:****Yeasts:**

- Candida albicans
- Candida auris
- Candida other (specify)
- Cryptococcus neoformans
- Geotrichum
- Magnusiomyces
- Pneumocystis jirovecii
- Saccharomyces
- Saprochaete
- Trichosporon
- Yeasts other (specify)

**Moulds:**

- Aspergillus flavus
- Aspergillus fumigatus
- Aspergillus other (NOT flavus, NOT fumigatus, NOT terreus)
- Aspergillus terreus
- Blastomyces
- Coccidioides
- Dematiaceous fungi / phaeohyphomycosis (specify)
- Fusarium solani
- Fusarium other (NOT solani)
- Galactomannan positive in blood or BAL, without microbiological confirmation of fungal infection
- Histoplasma
- Lomentospora prolificans / scedosporium prolificans
- Mucorales (mucor/rhizomucor/rhizopus/lichteinia) (specify)
- Paracoccidioides
- Scedosporium other (NOT prolificans) (specify)
- Moulds other (specify)

**Parasitic infections:****Protozoa:**

- Amoeba
- Babesia
- Cryptosporidium
- Giardia
- Leishmania
- Plasmodium (malaria)
- Toxoplasma gondii
- Trypanosoma cruzi
- Protozoa other

**Helminths:**

- Schistosoma
- Strongyloides stercoralis
- Helminths other

**Appendix 3**  
 -- CTCAE term --

CTCAE terms related to infections and infestations (version 5.0.)  
[https://ctep.cancer.gov/protocoldevelopment/electronic\\_applications/ctc.htm#ctc\\_50](https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm#ctc_50)

**Respiratory tract infections**

- Pneumonia
- Other respiratory tract infections, please specify:

- Upper respiratory tract infection
- Tracheobronchitis infective
- Pleural infection

**Intra-abdominal infections**

- Esophagus or gastric infection
- Liver site infection (including biliary tract and gallbladder), please specify:

- Biliary tract or gallbladder infection
- Liver infection

- Lower gastrointestinal infection, please specify:

- Anorectal infection
- Appendicitis infective
- Typhlitis infective

- Enteritis infective, please specify:

- Duodenal infection
- Enterocolitis infective
- Small intestine infection

- Other intra-abdominal infection, please specify:

- Pancreas infection
- Peritoneal infection
- Splenic infection

**Skin, soft tissue and muscle infections**

- Lymph gland infection
- Skin, soft tissue or muscle infection, please specify:

- Breast infection
- Papulo/pustular rash
- Periorbital infection
- Skin infection (other than periorbital)
- Soft tissue infection (other than periorbital) and muscle infection

**Blood infections**

- Bacteremia
- Fungemia
- Viremia (including DNAemia)
- DNAemia for parasitic infection

**Other infections**

- Device-related infection (other than intravascular catheter)
- Post-transplant lymphoproliferative disorder (PTLD)\*\*

**Uro-genital tract infections**

- Genital infection, please specify:

- Deep genital infection( including cervicitis infective, ovarian/ pelvic/ prostate/ uterine infection)
- Superficial genital infection( including penile/ scrotal / vaginal / vulval infection)

- Urinary tract infection, please specify:

- Cystitis or urethritis infective
- Upper urinary tract infection (e.g. kidney infection)

**Nervous system infection**

- Central nervous system infection, please specify:

- Encephalitis infective (including abscess)
- Isolated meningitis infective
- Progressive multifocal leukoencephalopathy (PML)\*
- Myelitis infective

- Other nervous system infection, please specify:

- Cranial nerve infection
- Other nervous system infection

**Cardiovascular infections**

- Endocarditis infective
- Other cardiovascular infection, please specify:

- Arteritis infective
- Mediastinal infection
- Myocarditis infective

**Head and neck infections (excluding lymph gland)**

- Ear infection
- Oral cavity infection, please specify:

- Salivary gland infection
- Other oral cavity structure infection

- Retinitis infective
- Sinusitis infective

- Other eye infection, please specify:

- Conjunctivitis infective
- Corneal infection
- Endophthalmitis infective

**Osteoarticular infections**

- Joint infection
- Bone infection

\* Only if pathogen 'JC virus' is selected

\*\* Only if pathogen 'Epstein-Barr virus' is selected

Appendix 4

-- Non-infectious and infectious Complications CTCAE term -- **No Reporting Required**

**Non-infectious complications**

**Infectious complications**

- Allergic reaction
- All laboratory abnormalities
- All types of pain
- Alopecia
- Blurred vision
- Diarrhoea (enteropathy)
- Dry mouth
- Dyspepsia
- Dysphagia
- Edema
- Esophageal stenosis
- Fatigue
- Flashes
- Gastritis
- Hematologic toxicities
- Hematoma
- Hypertension
- Injection site reaction
- Malaise
- Mucositis
- Sore throat
- Tinnitus
- Vertigo
- Weight loss

- Minor ophthalmologic bacterial infections
- 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
- 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 (incl. impetigo)
- Minor skin bacterial infections
- Minor fungal skin infection
- 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
- Neutropenic fever and sepsis of unknown origin

## Appendix 6 Cell Infusion Sheet

**Chronological number of CI episode for this patient:** \_\_\_\_\_

**Date of the first infusion (within this episode):** \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**Number of infusions within this episode (10 weeks):** \_\_\_\_\_  
*(Count only infusions that are part of the same regimen and given for the same indication)*

**Source of cells:**

- Allogeneic
- Autologous

**Type of cells:**

- Lymphocytes (DLI)
- Mesenchymal
- Fibroblasts
- Dendritic cells
- NK cells
- Regulatory T-cells
- Gamma/delta cells
- Virus-specific T-cells (VST)
- Other; specify: \_\_\_\_\_

*(Only if 'Type of cells: = Virus-specific T-cells (VST))'*

**Specificity of VST product:**  Single-virus specific  Multi-virus specific

**If single-virus specific, to which virus?** *(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)*

- EBV
- CMV
- ADV
- BKV or JCV
- HHV-6

**If multi-virus specific, to which viruses?** *(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)*

- (Select all that apply)**
- EBV
  - CMV
  - ADV
  - BKV or JCV
  - HHV-6

*Extended dataset*

**Product origin:**  In-house manufactured

Commercial product;

Tabelecleucel

**Donor source:** *(Only if 'Source of cells: = Allogeneic')*

Stem cell donor

Third-party donor;

Related (family)

Unrelated

**Manufacturing method:**  In vitro expansion

Cytokine capture system (CCS)

Multimer sorting

**Number of doses per infection episode:**  1 dose

>1 dose; **Total number of doses:** \_\_\_\_\_

**Dosing interval (in days):** \_\_\_\_\_



EBMT Centre Identification Code (CIC): \_\_\_\_\_  
 Hospital Unique Patient Number (UPN): \_\_\_\_\_  
 Patient Number in EBMT Registry: \_\_\_\_\_

Treatment Type  HCT  
 Treatment Date \_\_\_\_/\_\_\_\_/\_\_\_\_ (YYYY/MM/DD)

**Appendix 6**  
 Cell Infusion Sheet continued

*Not applicable for Inborn Errors*

**Disease status at time of this cell infusion\*:** \_\_\_\_\_

\* Indicate the disease status corresponding to indication diagnosis by selecting from the list provided in Appendix 1

**Indication:**

*(check all that apply)*

- |  |  |
|--|--|
| <input type="checkbox"/> Planned/protocol<br><input type="checkbox"/> Prophylactic<br><input type="checkbox"/> Treatment of acute GvHD<br><input type="checkbox"/> Treatment of chronic GvHD<br><input type="checkbox"/> Treatment PTLD, EBV lymphoma<br><input type="checkbox"/> Treatment for primary disease<br><input type="checkbox"/> Mixed chimaerism<br><input type="checkbox"/> Loss/decreased donor chimaerism<br><input type="checkbox"/> Treatment of viral infection other than EBV | <input type="checkbox"/> Poor graft function<br><input type="checkbox"/> Infection prophylaxis<br><input type="checkbox"/> Other; specify: _____ |
|--|--|

*Only for Acute leukemia donor lymphocyte infusions:*

**Response to DLI:**

- Complete remission (CR)    **MRD status:**  MRD negative    MRD positive    Not evaluated    Unknown  
 Not in CR  
 Not evaluated  
 Unknown