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

Treatment Type ☐ HCT

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

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)

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

GRAFT FUNCTION

Poor graft function *(defined as: frequent dependence on blood and/or platelet transfusions and/or growth factor support in the absense 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; **Immunosuppresion 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?
(select all that apply and complete the relevant section)

☐ Antibacterial ☐ Antifungal ☐ Antiviral

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
- ☐ Unkown

☐ Levofloxacin:
- ☐ Started in this follow-up period; **Start date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
- ☐ Ongoing since previous follow-up
- ☐ Unkown

☐ Moxifloxacin:
- ☐ Started in this follow-up period; **Start date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
- ☐ Ongoing since previous follow-up
- ☐ Unkown

☐ Penicillin/Amoxicillin:
- ☐ Started in this follow-up period; **Start date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
- ☐ Ongoing since previous follow-up
- ☐ Unkown

☐ Ampicillin clavulanate:
- ☐ Started in this follow-up period; **Start date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
- ☐ Ongoing since previous follow-up
- ☐ Unkown

☐ Non-absorbable antibiotic:
- ☐ Started in this follow-up period; **Start date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
- ☐ Ongoing since previous follow-up
- ☐ Unkown

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

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/m2/8h (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

☐ Rezafungin ☐ 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

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

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

☐ 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:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Liver:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Lower GI tract:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not evaluated	☐ Unknown
Upper GI tract:	☐ 0 *(none)*	☐ 1	☐ Not evaluated	☐ Unknown			
Other site affected:	☐ No	☐ 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: (Resolution of symptoms) ☐ No ☐ Yes; **Date of aGvHD resolution:** _ _ _ _ / _ _ / _ _ (YYYY/MM/DD) (Resolution of symptoms) ☐ Unknown ☐ Unknown

☐ 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)
☐ Prednisolone ☐ Methylprednisolone ☐ Other; specify: _____	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	_____ ☐ Unknown	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Prednisolone ☐ Methylprednisolone ☐ Other; specify: _____	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	_____ ☐ Unknown	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ 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
☐ ECP
☐ Ruxolitinib
☐ MMF
☐ Cyclosporin A
☐ Tacrolimus
☐ Sirolimus
☐ 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 >= 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:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

☐ Ongoing since previous follow-up

☐ Unknown

Steroid refractory/dependent aGvHD

Did the patient receive treatment for SR/SD aGvHD during this follow-up period?
(after steroid refractoriness/dependence was established)

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

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	☐ Stage 0 ☐ Stage 1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4 ☐ Not evaluated ☐ Unknown
Liver	☐ Stage 0 ☐ Stage 1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4 ☐ Not evaluated ☐ Unknown
Lower GI tract	☐ Stage 0 ☐ Stage 1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4 ☐ Not evaluated ☐ Unknown
Upper GI tract	☐ Stage 0 ☐ Stage 1 ☐ Not evaluated ☐ 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)
☐ ECP	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Ruxolitinib	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ MMF	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Cyclosporin A	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Tacrolimus	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Sirolimus	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Other; specify: ____	☐ Started in this follow-up period;_ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ 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	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Liver	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Lower GI tract	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Upper GI tract	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Overall (if organ specific is not available)	☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ 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 <u>this period</u>: ☐ Mild ☐ Moderate ☐ Severe ☐ Unknown ☐ Not evaluated

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

Maximum observed organ severity score during <u>this period</u>:

Skin:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluared	☐ Unknown
Oral:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Gastrointestinal:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Eyes:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Liver:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Joints and fascia:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Lungs:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Genitalia:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Other site affected:	☐ No	☐ Yes; specify: _____				

Steroid-refractory chronic GvHD: ☐ No
☐ Yes: ☐ Started in this follow-up period; **Date of onset:** _ _ _ _ / _ _ / _ _ ☐ Unknown *(YYYY/MM/DD)*
☐ Ongoing since previous follow-up
☐ Unknown

Extended dataset

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

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

☐ 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)
☐ Prednisolone ☐ Methylprednisolone ☐ Other; specify: _____	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	_____ ☐ Unknown	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Prednisolone ☐ Methylprednisolone ☐ Other; specify: _____	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	_____ ☐ Unknown	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ 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
☐ ECP
☐ Ruxolitinib
☐ MMF
☐ Cyclosporin A
☐ Tacrolimus
☐ Sirolimus
☐ ATG (antithymocyte globulin)
☐ Alemtuzumab
☐ 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 >= 1 mg/Kg/day for 1-2 weeks or stable GvHD while on >=0.5 mg/Kg/day (or 1 mg/Kg every other day) of prednisone for 1-2 months.*
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 ☐ Ongoing since previous follow-up ☐ Unknown
(after steroid refractoriness/dependence/intolerance was established)

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:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluared	☐ Unknown
Oral:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Gastrointestinal:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Eyes:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Liver:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Joints and fascia:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Lungs:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Genitalia:	☐ 0 *(none)*	☐ 1	☐ 2	☐ 3	☐ Not evaluated	☐ Unknown
Other site affected:	☐ No	☐ 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)
☐ ECP	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Ruxolitinib	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ MMF/CellCept	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Belumosudil	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Ibrutinib	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Everolimus	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Sirolimus	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Cyclosporin A	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Tacrolimus	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ ATG (antithymocyte globulin)	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Alemtuzumab	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Other; specify: ____	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ 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	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Oral	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Gastrointestinal	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Eyes	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Liver	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Joints and fascia	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Lungs	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Genitalia	☐ No ☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown ☐ Not evaluated ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ Unknown
Overall (*if organ specific is not available*)	☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown	_ _ _ _ / _ _ / _ _ ☐ 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
-- 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 <u>this period</u>: ☐ 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 <u>this period</u>: ☐ 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 <u>this period</u>: ☐ 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 <u>this period</u>: ☐ 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

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 <u>this period</u>: ☐ 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 <u>this period</u>: ☐ 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 <u>this period</u>: ☐ 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 <u>this period</u>: ☐ 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

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 <u>this period</u>: ☐ 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 <u>this period</u>: ☐ 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 <u>this period</u>: ☐ 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 <u>this period</u>: ☐ 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

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

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 <u>this period</u>: ☐ 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 <u>this period</u>: ☐ 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)
☐ Defibrotide	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Eculizumab	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Narsoplimab	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown

* Grade 0-2

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

Extended dataset

Name of drug	Start date (YYYY/MM/DD)	Stopped / date (YYYY/MM/DD)
☐ Pegcetacoplan	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Iptacopan	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Danicopan	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Ravulizumab	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Other; specify: ____	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown

Other TA-TMA treatment given in this line of treatment during this follow-up period:

Renal replacement therapy performed:	☐ No ☐ Yes: ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up ☐ Unknown
Mechanical ventilation performed:	☐ No ☐ Yes: ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up ☐ Unknown
Exchange plasmapheresis performed:	☐ No ☐ Yes: ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up ☐ Unknown

Response to this line of TA-TMA treatment during this follow-up period

Did the patient achieve complete response? ☐ No ☐ Yes ☐ Unknown

Defined as normal LDH, no organ manifestations, high-risk TA-TMA harmonisation criteria not fulfilled anymore

If yes, date of complete response: _ _ _ _ / _ _ / _ _ ☐ Unknown

If no, did the patient achieve partial response? ☐ No ☐ Yes ☐ Unknown

Defined as LDH decreased, residual organ manifestations, high-risk TA-TMA harmonisation criteria not fulfilled anymore

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

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

Sinusoidal obstruction syndrome/Veno-occulive disease (SOS/VOD)

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

Maximum grade observed during <u>this period</u>: ☐ 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)
☐ Defibrotide	☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Other; specify: _____	☐ Started in this follow-up period;_ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown

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

Renal replacement therapy performed:	☐ No ☐ Yes: ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up ☐ Unknown
Mechanical ventilation performed:	☐ No ☐ Yes: ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up ☐ Unknown
Extracoporeal membrane oxygenation performed:	☐ No ☐ Yes: ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Ongoing since previous follow-up ☐ 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

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

Extended dataset

Additional late complications

Indicate if any of the following complications occurred during follow-up period:

Cataract diagnosis:
☐ No
☐ Yes; **Date first reported:** _ _ _ _ / _ _ / _ _ ☐ Unknown
Did the patient undergo cataract surgery? ☐ No ☐ Yes ☐ Unknown
Date of cataract operation: _ _ _ _ / _ _ / _ _ ☐ Unknown
☐ Unknown

Thyroid disorder requiring treatment:
☐ No
☐ Yes; **Type of thyroid disorder:** ☐ Hyperthyroidism
☐ Hypothyroidism
☐ Goiter
☐ Other; specify: _____
Start date of treatment: _ _ _ _ / _ _ / _ _ ☐ Unknown
☐ Unknown

Osteoporosis requiring treatment:
☐ No
☐ Yes; **Start date of treatment:** _ _ _ _ / _ _ / _ _ ☐ Unknown
☐ Unknown

Bone fracture:
☐ No
☐ Yes; **Bone involved:** _____
Date of fracture: _ _ _ _ / _ _ / _ _ ☐ Unknown
☐ Unknown

Iron overload requiring treatment:
☐ No
☐ Yes; **Start date of treatment:** _ _ _ _ / _ _ / _ _ ☐ Unknown
☐ Unknown

Dyslipidemia requiring treatment:
☐ No
☐ Yes; **Start date of treatment:** _ _ _ _ / _ _ / _ _ ☐ Unknown
☐ Unknown

Arterial hypertension requiring treatment:
☐ No
☐ Yes; **Start date of treatment:** _ _ _ _ / _ _ / _ _ ☐ Unknown
☐ Unknown

Morbid obesity requiring treatment:
☐ No
☐ Yes; **Start date of treatment:** _ _ _ _ / _ _ / _ _ ☐ Unknown
☐ Unknown

Mental health disorder requiring treatment:
☐ No
☐ Yes; **Diagnosis:** _____
Start date of treatment: _ _ _ _ / _ _ / _ _ ☐ Unknown
☐ Unknown

Cognitive function disorder requiring treatment:
☐ No
☐ Yes; **Diagnosis:** _____
Start date of treatment: _ _ _ _ / _ _ / _ _ ☐ Unknown
☐ Unknown

Return to work/school:
☐ No
☐ Yes; **Involvement:** ☐ Parttime
☐ Fulltime
☐ Unknown
Date of return to work/school: _ _ _ _ / _ _ / _ _ ☐ Unknown
☐ Unknown

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? *(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?**
- ☐ MRI
- ☐ CT
- ☐ PET
- ☐ PET CT
- ☐ Ultrasound
- ☐ Other; Specify:_____

☐ Unknown

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

☐ Unknown

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?**
- ☐ Culture
- ☐ Histopathological or cytopathological demonstration
- ☐ Immunohistochemistry
- ☐ PCR
- ☐ Stain

☐ 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?**
- ☐ 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

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

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

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?**
☐ Unknown

- ☐ Histopathological or cytopathological demonstration
- ☐ Immunohistochemistry
- ☐ Quantitative PCR
- ☐ DNA hybridization

☐ 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

- ☐ PCR
- ☐ Cytology and immunofluorescence (IF)

☐ 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 gastrointenstinal 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? *(select all that apply)* *(Please make sure this viral infection has also been registered in the core dataset viral infection-part above 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)

	Unit	
Viral load at the start (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ Not evaluated
Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ 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 corticosteriod 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)

	Unit	
Viral load at the start (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ Not evaluated
Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ 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)

	Unit	
Viral load in blood at the start (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ Not evaluated
Viral load in blood at the discontinuation (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ 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)

	Unit	
Viral load in stool at the start (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ Not evaluated
Viral load in blood at the start (+/- 3 days) of pre-emptive therapy:_____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ Not evaluated
Viral load in stool at the discontinuation (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ Not evaluated
Viral load in blood at the discontinuation (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ 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)

	Unit	
Viral load at the start (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ Not evaluated
Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ 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)

	Unit	
Viral load at the start (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ Not evaluated
Viral load at the discontinuation (+/- 3 days) of pre-emptive therapy: _____	☐ log 10 IU/mL ☐ IU/mL ☐ copies/mL	☐ 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 corticosteriod 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

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 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))

- ☐ Oseltamivir
- ☐ 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)* ☐ Unknown

(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?**
☐ Culture
☐ Histopathological or cytopathological demonstration
☐ Immunohistochemistry
☐ PCR
☐ Fungal stain
☐ 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?**
☐ Culture
☐ PCR
☐ Stain
☐ BAL Galactomannan assay
☐ 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
☐ Beta D glucan galactomannan
☐ Stain
☐ Serology/antigen in CSF
☐ Unknown
☐ 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?**
☐ Culture
☐ PCR
☐ Fungal stain
☐ Unknown
☐ Unknown

Was an endoscopy performed? *(Only if CTCAE term 'Lower gastrointestinal infection' or 'Esophagus or other gastric infection' is selected)*
☐ No
☐ Yes; **Were gastrointenstinal 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? *(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?**
☐ MRI
☐ CT
☐ PET
☐ PET CT
☐ Ultrasound
☐ Other; Specify:_____
☐ Unknown

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
☐ Unknown

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)*: _____ ☐ Unknown

Localisation 2 (CTCAE term)*: _____ ☐ Unknown

Localisation 3 (CTCAE term)*: _____ ☐ Unknown

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

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

☐ Unknown

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.

Appendix 1
Best Response and Disease Status (Disease Specific)

Acute leukaemias (AML, PLN, Other)

- ☐ Complete remission (CR)
- ☐ Not in complete remission
- ☐ Not evaluated
- ☐ Unknown

Proceed to next page for Diseases Status section

Chronic leukaemias (CML, CLL, PLL, Other)

Chronic Myeloid Leukaemia (CML):

☐ Chronic phase (CP); **Number**: ☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown

Haematological remission: ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Cytogenetic remission: ☐ No ☐ Yes ☐ Not evaluated ☐ Unknown

Extended dataset

In case of NO cytogenetic remission

Cytogenetic details : t(9;22) positive metaphases: _____ (%) ☐ Not evaluated ☐ Unknown

t(9;22) positive cells detected by FISH: _____ (%) ☐ Not evaluated ☐ Unknown

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

Extended dataset

In case of NO molecular remission

BCR::ABL1 variant allele frequency (VAF): _____% ☐ Unknown

☐ Accelerated phase; **Number**: ☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown

Extended dataset

Cytogenetic details: t(9;22) positive metaphases: _____ (%) ☐ Not evaluated ☐ Unknown

t(9;22) positive cells detected by FISH: _____ (%) ☐ Not evaluated ☐ Unknown

BCR::ABL1 variant allele frequency (VAF): _____% ☐ Unknown

☐ Blast crisis; **Number**: ☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown

Extended dataset

Cytogenetic details: t(9;22) positive metaphases: _____ (%) ☐ Not evaluated ☐ Unknown

t(9;22) positive cells detected by FISH: _____ (%) ☐ Not evaluated ☐ Unknown

BCR::ABL1 variant allele frequency (VAF): _____% ☐ Unknown

- ☐ Not evaluated
- ☐ 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:

☐ Complete remission (CR)
☐ Partial remission (PR)
☐ Progression: ☐ Resistant to last regimen ☐ Sensitive to last regimen ☐ Unknown
☐ Stable disease (no change, no response/loss of response)
☐ Relapse
☐ Not evaluated
☐ Unknown

Proceed to next page for Diseases Status section

Plasma cell neoplasms (PCN)

☐ Complete remission (CR)	**Number:** ☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown
☐ Stringent complete remission (sCR)	
☐ Very good partial remission (VGPR)	
☐ Partial remission (PR)	
☐ Relapse	
☐ Progression	
☐ Stable disease (no change, no response/loss of response)	
☐ Not evaluated	
☐ Unknown	

Extended dataset

Immunoglobulin-related (AL) Amyloidosis only

Organ response during this follow-up period:

Heart	☐ Response ☐ No change ☐ Progression ☐ Not involved ☐ Not evaluated ☐ Unknown
Kidney	☐ Response ☐ No change ☐ Progression ☐ Not involved ☐ Not evaluated ☐ Unknown
Liver	☐ Response ☐ No change ☐ Progression ☐ Not involved ☐ Not evaluated ☐ Unknown
Peripheral nervous system	☐ Response ☐ No change ☐ Progression ☐ Not involved ☐ Not evaluated ☐ 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

☐ 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

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

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

☐ Complete remission (CR)	Number:	☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown
☐ Improvement but no CR		
☐ Primary refractory phase (no change)		
☐ Relapse	Number:	☐ 1st ☐ 2nd ☐ 3rd or higher ☐ Unknown
☐ Progression/Worsening		
☐ Not evaluated		
☐ Unknown		

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

Autoimmune disorders

- ☐ No evidence of disease
- ☐ Improved
- ☐ Unchanged
- ☐ Worse
- ☐ Not evaluated
- ☐ Unknown

Haemoglobinopathies

Thalassaemia:
Complete only for Thalassemia Best Response

- ☐ Transfusion independent — **Date of last transfusion:** _ _ _ _ / _ _ / _ _ (YYYY/MM/DD) ☐ Unknown (after HCT)
- ☐ Transfusions required; — **Date of first transfusion:** _ _ _ _ / _ _ / _ _ (YYYY/MM/DD) ☐ Unknown (after HCT)
- ☐ Not evaluated
- ☐ 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

- ☐ No return of sickling episodes
- ☐ Return of sickling episodes; — **Date of first episode:** _ _ _ _ / _ _ / _ _ (YYYY/MM/DD) ☐ Unknown (after HCT)
- ☐ Not evaluated
- ☐ 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

- ☐ Chemorefractory relapse or progression, including primary refractory disease
- ☐ Complete remission (CR)
- ☐ Partial remission (PR)
- ☐ Stable disease (no change, no response/loss of response)
- ☐ Untreated relapse (from a previous CR) or progression (from a previous PR)
- ☐ Not evaluated
- ☐ Unknown

Technique used for disease assessment:
- ☐ CT scan
- ☐ PET-CT
- ☐ MRI
- ☐ Clinical assessment (for continuous CR)
- ☐ Other; specify: _____
- ☐ Unknown

Solid tumours

- ☐ Complete remission (CR): ☐ Confirmed ☐ Unconfirmed ☐ Unknown
- ☐ First partial remission
- ☐ Partial remission (PR)
- ☐ Progressive disease
- ☐ Relapse: ☐ Resistant ☐ Sensitive ☐ Unknown
- ☐ Stable disease (no change, no response/loss of response)
- ☐ Not evaluated
- ☐ Unknown

Bone marrow failures (incl. AA)

- ☐ Complete remission (CR)
- ☐ Partial remission (PR)
- ☐ Haematological improvement (HI); *NIH partial response*
- ☐ Stable disease (no change, no response/loss of response)
- ☐ Relapse / Progression
- ☐ Not evaluated
- ☐ 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)* (after transfusion free period) ☐ Unknown
  - ☐ Unknown
- ☐ Unknown

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

Other diagnosis

☐ No evidence of disease
☐ Improved
☐ No response
☐ Worse
☐ Not evaluated
☐ 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: _____	☐ Not evaluated ☐ Unknown	Cells/µl
CD4 T-cells: _____	☐ Not evaluated ☐ Unknown	Cells/µl
CD8 T-cells: _____	☐ Not evaluated ☐ Unknown	Cells/µl
B-cells (i.e. CD19): _____	☐ Not evaluated ☐ Unknown	Cells/µl
NK-cells (CD16/CD56): _____	☐ Not evaluated ☐ Unknown	Cells/µl
Naive CD4 T-cells (CD4/CD45RA): _____	☐ Not evaluated ☐ Unknown	☐ % of CD4 ☐ Cells/µl
Naive CD8 T-cells (CD8/CD45RA): _____	☐ Not evaluated ☐ Unknown	☐ % of CD8 ☐ Cells/µl
IgG: _____	☐ Not evaluated ☐ Unknown	Gram/l
IgA: _____	☐ Not evaluated ☐ Unknown	Gram/l
IgM: _____	☐ Not evaluated ☐ Unkown	Gram/l

Appendix 1
Disease Status
(Only for Inborn errorrs 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	☐ No ☐ Yes: ☐ Resolved ☐ Improved ☐ Stabilised ☐ Worsened ☐ De novo ☐ Not evaluated
Rheumatologic	SLE, RA, polymyositis, mixed CTD or polymyalgia rheumatica	☐ No ☐ Yes: ☐ Resolved ☐ Improved ☐ Stabilised ☐ Worsened ☐ De novo ☐ Not evaluated
Renal: moderate/severe	Serum creatinine > 2 mg/dL or >177 µmol/L, on dialysis, or prior renal transplantation	☐ No ☐ Yes: ☐ Resolved ☐ Improved ☐ Stabilised ☐ Worsened ☐ De novo ☐ 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 × ULN	☐ No ☐ Yes: ☐ Resolved ☐ Improved ☐ Stabilised ☐ Worsened ☐ De novo ☐ Not evaluated
Hepatic: moderate/severe	Liver cirrhosis, bilirubin greater than 1.5 × ULN, or AST/ALT greater than 2.5 × ULN	☐ No ☐ Yes: ☐ Resolved ☐ Improved ☐ Stabilised ☐ Worsened ☐ De novo ☐ Not evaluated
Chronic lung disease	Bronchiectasis, interstitial pneumonitis, GLILD, oxygen dependency, structural lung disease (e.g. pneumatoceles)	☐ No ☐ Yes: ☐ Resolved ☐ Improved ☐ Stabilised ☐ Worsened ☐ De novo ☐ Not evaluated
Pre-HCT malignancy	Leukaemia, lymphoma, myelodysplastic syndrome (MDS)	☐ No ☐ Yes: ☐ In remission ☐ Stable disease ☐ Relapsed ☐ Not evaluated ☐ Not evaluated
Failure to thrive	Weight <3rd percentile or requirement for (par)enteral feeding	☐ No ☐ Yes: ☐ Resolved ☐ Improved ☐ Stabilised ☐ Worsened ☐ De novo ☐ Not evaluated
Active infection at HCT	Any infection requiring therapy in the immediate pre HCT period	☐ No ☐ Yes: ☐ Resolved ☐ Improved ☐ Stabilised ☐ Worsened ☐ Not evaluated
Lymphoproliferation	I.e. splenomegaly, organ specific lymphoproliferation	☐ No ☐ Yes: ☐ Resolved ☐ Improved ☐ Stabilised ☐ Worsened ☐ De novo ☐ Not evaluated

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)	☐ No ☐ Yes: ☐ Resolved ☐ Improved ☐ Stabilised ☐ Worsened ☐ Not evaluated
Autoimmunity/ autoinflammation	Pre HCT/CT (includes patients in remission but on immunomodulatory treatment within 3 months before HCT/CT)	☐ No ☐ Yes: ☐ Resolved ☐ Improved ☐ Stabilised ☐ Worsened ☐ 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 lwoffi (in blood: report only if ≥2 positive separately taken cultures)
. Acinetobacter other (NOT baumannii, NOT lwoffi)
. Bacteroides fragilis
. Bordetella pertussis
. Borrelia
. Brucella
· Campylobacter jejuni
· Citrobacter freundii
. Coxiella burnetti (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
· Chlamydophila
· Mycobacterium other (specify)
· Mycobacterium tuberculosis (TB)
· Mycoplasma pneumoniae
· Rickettsia
. Ureoplasma
· Bacteria other (specify)

Viral infections:

· Adenovirus (ADV)
. Chikungunya virus
. Crimean-Congo haemorrhagic fever virus (CCHV)
. 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 (VZ/VZV/HZV/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

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

- 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

Infectious complications

- 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): _____

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)

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