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
☐ HCT-related	
☐ GT-related	
☐ IST-related	
☐ Unknown	
☐ Other; specify: _____	

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)

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

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

☐ No

☐ Yes; ☐ Started in this follow-up period; **Start date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

☐ Ongoing since previous follow-up

Letermovir treatment stop? ☐ No
☐ Yes; **End date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
☐ Unknown

☐ Unknown

Extended dataset

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

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: ☐ 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

Did the patient receive CMV prophylaxis other than or in addition to letermovir during this follow-up period?

☐ 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
- ☐ High-dose valacyclovir
- ☐ Gancyclovir intravenous
- ☐ Valgancyclovir
- ☐ Foscarnet
- ☐ 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 valacyclovir 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
- ☐ Other drug

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

Antimicrobial prophylaxis

Extended dataset

Antifungal

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

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

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

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

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

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

Antimicrobial prophylaxis continued

Extended dataset

Antifungal

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

Extended dataset

Pre-emptive viral therapy

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)* ☐ CMV ☐ EBV

Specify the pre-emptive therapy for each CMV episode that occurred during this follow-up period

CMV treatment start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

Antiviral(s) used:
(Select all that apply)

- ☐ Valgancyclovir
- ☐ Gancyclovir intravenous
- ☐ Foscarnet
- ☐ Cidofovir
- ☐ Maribavir
- ☐ Specific CMV T-cell
- ☐ Other drug

Was this episode of CMV infection due to a resistant CMV strain?
☐ No ☐ Yes ☐ Unknown

Copy as often as necessary to reflect all episodes that occurred

Specify the pre-emptive therapy for each EBV episode that occurred during this follow-up period

EBV treatment start date: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

Antiviral(s) used:
(Select all that apply)

- ☐ Rituximab
- ☐ Specific EBV T-cells
- ☐ Other drug

Copy as often as necessary to reflect all episodes that occurred

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 <u>this period</u>:

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

aGvHD resolved: ☐ No
- ☐ Yes; **Date of aGvHD resolution:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ 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 (Glucksberg 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:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
☐ Ongoing since previous follow-up
☐ Unknown

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

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

☐ Unknown

Extended dataset

cGvHD first line treatment

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

Steroid details during this follow-up period:

Name of steroid	**Treatment started / date** (YYYY/MM/DD)	**Initial dose** (mg/kg/day)	**Treatment stopped / date** (YYYY/MM/DD)
☐ 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
☐ 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?
(after steroid refractoriness/dependence/intolerance was established)

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

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
☐ 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 <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

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 <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

Haemophagocytic lymphohistiocytosis (HLH)

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

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 <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

* 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*

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

Extended dataset

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 --

Veno-occlusive disease (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*

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

Extended dataset

VOD treatment given during this follow-up period: ☐ No ☐ Yes ☐ Unknown

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 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 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 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 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

1) **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*: _____

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):** _____

Intravascular catheter-related infection: ☐ No ☐ Yes; specify***: _____ ☐ Unknown

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)

Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

2) **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*: _____

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):** _____

Intravascular catheter-related infection: ☐ No ☐ Yes; specify***: _____ ☐ Unknown

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)

Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

If more than 2 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

*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

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

Viral infection: ☐ No ☐ Yes ☐ Unknown

1) **New or ongoing:** ☐ Newly developed ☐ Ongoing since previous assessment

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

Pathogen*: _____

If the pathogen was CMV/EBV: **Was this infection a reactivation?** ☐ No ☐ Yes

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):** _____

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)
Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

2) **New or ongoing:** ☐ Newly developed ☐ Ongoing since previous assessment

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

Pathogen*: _____

If the pathogen was CMV/EBV: **Was this infection a reactivation?** ☐ No ☐ Yes

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):** _____

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)
Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

If more than 2 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
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

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

Fungal infection: ☐ No ☐ Yes ☐ Unknown

1) **New or ongoing:** ☐ Newly developed ☐ Ongoing since previous assessment

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

☐ Yeasts ☐ Moulds

Pathogen*: _____

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)**: _____

Intravascular catheter-related infection: ☐ No ☐ Yes; specify***: _____ ☐ Unknown

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)

Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

2) **New or ongoing:** ☐ Newly developed ☐ Ongoing since previous assessment

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

☐ Yeasts ☐ Moulds

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)**: _____

Intravascular catheter-related infection: ☐ No ☐ Yes; specify***: _____ ☐ Unknown

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)

Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

If more than 2 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
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

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

Parasitic infection: ☐ No ☐ Yes ☐ Unknown

1) **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):** _____

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)

Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

2) **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):** _____

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)

Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

If more than 2 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
*** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

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.)

1) **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 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)*: _____

Intravascular catheter-related infection: ☐ No
☐ Yes; specify**: _____
☐ Unknown

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)
Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

2) **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 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)*: _____

Intravascular catheter-related infection: ☐ No
☐ Yes; specify**: _____
☐ Unknown

Resolved: ☐ No ☐ Yes ☐ Unknown

(if patient died)
Contributory cause of death: ☐ No ☐ Yes ☐ Unknown

If more than 2 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
** If intravascular catheter-related infection, specify it by choosing from the list provided in Appendix 5

Extended dataset

SARS-CoV-2 RELATED QUESTION

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

☐ No

☐ Yes: **Number of doses:** _____ ☐ Unknown

Date of the last dose: _ _ _ _ / _ _ / _ _ *(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 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)

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
☐ Increasing (>1log10 change) ☐ Stable (<1log10 change) ☐ Decreasing (>1log10 change) ☐ Unknown

☐ Negative

☐ Not evaluated

☐ Unknown

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

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

Lymphomas

- ☐ Chemorefractory relapse or progression, including primary refractory disease
- ☐ Complete remission (CR): ☐ Confirmed ☐ Unconfirmed (CRU*) ☐ Unknown
- ☐ 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

** CRU: Complete response with persistent scan abnormalities of unknown significance*

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

Haemoglobinopathies

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

Other diagnosis

☐ No evidence of disease
☐ Improved
☐ No response
☐ Worse
☐ Not evaluated
☐ Unknown

Appendix 1
Disease Status
Inborn errors only

Extended dataset

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:
- · Clostridioides difficile
- · Enterococcus faecalis (vancomycin-susceptible)
- · Enterococcus faecalis (vancomycin-resistant)
- · Enterococcus faecium (vancomycin-susceptible)
- · Enterococcus faecium (vancomycin-resistant)
- · Listeria monocytogenes
- · Nocardia spp (specify)
- · Staphylococcus aureus MSSA (methicillin-susceptible)
- · Staphylococcus aureus MRSA (methicillin-resistant) vancomycin-susceptible
- · Staphylococcus aureus MRSA (methicillin-resistant) vancomycin not tested
- · Staphylococcus aureus MRSA and VISA (vancomycin-intermediate, MIC 4-8 µg/ml)
- · Staphylococcus aureus MRSA and VRSA (vancomycin-resistant, MIC ≥ 16 µg/ml)
- · Staphylococcus coagulase-negative spp (at least two positive blood cultures)
- · Streptococcus pneumoniae
- · Streptococcus viridans
- · Streptococcus other spp (specify)
- · Gram-positive bacteria other spp (specify)

Gram-negative:
- · Acinetobacter baumannii
- · Campylobacter jejuni
- · Citrobacter freundii
- · Enterobacter cloacae
- · Enterobacter other spp (specify)
- · Escherichia coli
- · Haemophilus influenzae
- · Helicobacter pylori
- · Klebsiella aerogenes (carbapenem-susceptible)
- · Klebsiella pneumoniae (carbapenem-susceptible)
- · Klebsiella (any species) (carbapenem-resistant) (specify)
- · Legionella pneumophila
- · Morganella morganii
- · Neisseria gonorrhoeae
- · Neisseria meningitidis
- · Proteus vulgaris
- · Providencia spp
- · Pseudomonas aeruginosa (carbapenem-susceptible)
- · Pseudomonas aeruginosa (carbapenem-resistant)
- · Salmonella spp (specify)
- · Serratia marcescens
- · Shigella spp
- · Stenotrophomonas maltophilia
- · Treponema pallidum
- · Gram-negative bacteria other spp (specify)

Other bacteria:
- · Chlamydia spp
- · Chlamydophila
- · Mycobacterium other spp (specify)
- · Mycobacterium tuberculosis
- · Mycoplasma pneumoniae
- · Rickettsia spp
- · Bacteria other (specify)

Viral infections:

- · Adenovirus
- · Gastrointestinal viruses:
  - o Norovirus
  - o Rotavirus
- · Hepatotropic viruses:
  - o HAV
  - o HBV
  - o HCV
  - o HEV
- · Herpes group:
  - o CMV
  - o EBV
  - o HHV6
  - o HHV7
  - o HHV8
  - o HS
  - o VZ
- · HIV
- · Human papilloma viruses (HPV)
- · Parvovirus
- · Polyomaviruses:
  - o BK
  - o JC
  - o Merkel cell
  - o Other polyomavirus (specify)
- · Respiratory viruses:
  - o Enterovirus
  - o Human coronavirus
  - o Influenza A
  - o Influenza B
  - o Metapneumovirus
  - o Parainfluenza
  - o Rhinovirus
  - o RSV
  - o SARS-CoV-2
  - o Respiratory virus other (specify)
- · 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
· Trichosporon (specify)
· Pneumocytis jiroveci
· Yeasts other (specify)

Moulds:
· Aspergillus flavus
· Aspergillus fumigatus
· Aspergillus other spp (specify)
· Aspergillus terreus
· Fusarium other spp (specify)
· Fusarium solani
· Lomentospora prolificans (formerly Scedosporium prolificans)
· Order Mucorales (specify)
· Dematiaceous fungi (Phaeohyphomycosis) (specify)
· Scedosporium spp (specify)
· Moulds other spp (specify)
· Mould infection diagnosed based on positive galactomannan only, without microbiological confirmation
· Blastomyces spp
· Histoplasma spp (specify)
· Coccidioides spp
· Paracoccidioides spp

Parasitic infections:

Protozoa:
· Babesia spp (specify)
· Cryptosporidium
· Giardia spp
· Leishmania spp (specify)
· Plasmodium spp (specify)
· Toxoplasma gondii
· Trypanosoma cruzi
· Protozoa other spp (specify)

Helminths:
· Strongyloides stercoralis
· Other helminths

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
.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
· Duodenal infection
· Enterocolitis infective
· Small intestine infection
.Typhlitis infective

· 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
· Muscle infection
· Papulo/pustular rash
· Periorbital infection
. Skin infection (other than periorbital)
. Soft tissue infection (other than periorbital)

Blood infections
· Bacteremia
· Fungemia
· Viremia (including DNAemia)
. DNAemia for parasitic infection

Other infections
. Device-related infection (other than intravascular catheter)

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 / vulvai 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

· Other nervous system infection, please specify:

· Cranial nerve infection
. Myelitis infective

Cardiovascular infections
. Endocarditis infective
. Other cardiovascular infection, please specify:

· Arteritis infective
. Mediastinal infection

Head and neck infections (excluding lymph gland)
· Conjunctivitis infective
· Corneal infection
. Ear infection
· Endophthalmitis infective
· Oral cavity infection, please specify:

· Salivary gland infection
. Other oral cavity structure infection

· Retinitis infective
· Sinusitis infective

Osteoarticular infections
· Joint infection
· Bone infection

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 5

-- Intravascular catheter-related infections --

CVC infections:

- Catheter colonization
- Phlebitis
- Exit site infection
- Tunnel infection
- Pocket infection
- Bloodstream infection

Appendix 6
Cell Infusion Sheet

Chronological number of CI episode for this patient: _____

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

Not applicable for Inborn Errors

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-specifc T-cells; specify virus: _____
- ☐ Other; specify: _____

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: _____

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

- ☐ 0 (none)
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ Present but grade unknown

Date Acute GvHD onset after cell infusion: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Unknown