

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

SURVIVAL STATUS

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

Survival status:

- Alive
- Dead
- Lost to follow-up

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

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

Was an 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 absence of other explanations, such as disease relapse, drugs, or infection):

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

Complete for every chimaerism test performed since last follow-up:
(complete only if patient received an allogeneic HCT)

Chimaerism test date: ____/____/____ (YYYY/MM/DD) Unknown

Source of cells tested: Peripheral blood
 Bone marrow

Select cell type and complete relevant test results:

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

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

PREVENTIVE THERAPIES

(Complete only if the patient received an allogeneic HCT)

Immunosuppression during this follow-up period:

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

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? Antibacterial Antifungal Antiviral
(select all that apply and complete the relevant section)

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?** High-dose acyclovir
(select all that apply) High-dose valacyclovir
- Note: letermovir is not included as this is requested on the core dataset. Do not consider letermovir for 'Other drug'.*
- 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?** Lamivudine
(select all that apply) 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
- Final date antifungal prophylaxis was discontinued:** ____/____/____ (YYYY/MM/DD) Ongoing Unknown



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

Treatment Type HCT
Treatment Date ____/____/____ (YYYY/MM/DD)

Antimicrobial prophylaxis continued

Extended dataset

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? CMV EBV
(select all that apply)

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 this period:

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

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

Steroid-refractory acute GvHD: No

Yes: Started in this follow-up period;

Date of onset: ____/____/____ (YYYY/MM/DD)

Unknown

Ongoing since previous follow-up

Unknown

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)
<input type="checkbox"/> Prednisolone <input type="checkbox"/> Methylprednisolone <input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Prednisolone <input type="checkbox"/> Methylprednisolone <input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown

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

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

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

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

Extended dataset

aGvHD first line treatment continued

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

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

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

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

Steroid sensitive: No Yes Unknown

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

Steroid refractory: No Yes Unknown

Steroid dependent: No

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

Ongoing since previous follow-up

Unknown

Steroid refractory/dependent aGvHD

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

(after steroid refractoriness/dependence was established)

Ongoing since previous follow-up

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

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

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

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

Extended dataset

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

Line of treatment _____

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

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

Extended dataset

**Steroid refractory/dependent aGvHD
continued**

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

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

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

COMPLICATIONS SINCE THE LAST REPORT continued

-- GvHD --

Allogeneic HCT only

Did chronic GvHD occur during this follow-up period?

- No
- Yes: Started in this follow-up period; **Date of onset:** ____/____/____ (YYYY/MM/DD) Unknown
- Ongoing since previous follow-up
- Maximum NIH score during this period:** Mild
 Moderate
 Severe
 Unknown
 Not evaluated
- Date of maximum NIH score:** ____/____/____ (YYYY/MM/DD) Unknown

Maximum observed organ severity score during this period:

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

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

- 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)
<input type="checkbox"/> Prednisolone <input type="checkbox"/> Methylprednisolone <input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Prednisolone <input type="checkbox"/> Methylprednisolone <input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: _____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown

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

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

If yes, select the drugs below:

(select all that apply)

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

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

Refractory: progression of GvHD while on prednisone at ≥ 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 Unknown

(after steroid refractoriness/dependence/intolerance was established)

Ongoing since previous follow-up

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

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

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

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

Extended dataset

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

Line of treatment, _____

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

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

Steroid refractory/dependent/intolerant cGvHD

Extended dataset

Organ involvement and response to the line of treatment during this follow-up period:

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

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



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)

Secondary graft failure

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

Maximum grade observed during this period: Non-fatal Fatal

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

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

Cardiac event

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

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

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

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

Central nervous system (CNS) toxicity

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

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

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

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

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

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

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

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

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

* Grade 0-2



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

Treatment Type HCT
 Treatment Date ____/____/____ (YYYY/MM/DD)

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

Liver disorder

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

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

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

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

Renal failure (chronic kidney disease, acute kidney injury)

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

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

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

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

Respiratory disorders

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

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

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

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

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

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

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

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

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

* Grade 0-2

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

Vascular event

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

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

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

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

Avascular necrosis (AVN)

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

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

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

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

Cerebral haemorrhage

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

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

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

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

Haemorrhage (other than cerebral haemorrhage)

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

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

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

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

* Grade 0-2



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 this period: Non-severe Severe Fatal Unknown

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

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

Transplant-associated microangiopathy (TMA)

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

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

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

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)
<input type="checkbox"/> Defibrotide	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Eculizumab	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Narsoplimab	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown

* Grade 0-2

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

Extended dataset

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

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

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

Response to this line of 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 this period: 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)
<input type="checkbox"/> Defibrotide	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Other; specify: _____	<input type="checkbox"/> Started in this follow-up period; ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Ongoing since previous follow-up	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown

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

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

Response to this line of 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



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

Treatment Type HCT
 Treatment Date ____/____/____ (YYYY/MM/DD)

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

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

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

Maximum CTCAE grade observed 3 4 5 (fatal) Unknown

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

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

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

* Grade 0-2

Extended dataset

Additional late complications

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

Cataract diagnosis:	<input type="checkbox"/> No <input type="checkbox"/> Yes; Date first reported: ____/____/____ <input type="checkbox"/> Unknown <p style="text-align: center;">Did the patient undergo cataract surgery? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown</p> <p style="text-align: center;">Date of cataract operation: ____/____/____ <input type="checkbox"/> Unknown</p> <input type="checkbox"/> Unknown
Thyroid disorder requiring treatment:	<input type="checkbox"/> No <input type="checkbox"/> Yes; Type of thyroid disorder: <input type="checkbox"/> Hyperthyroidism <input type="checkbox"/> Hypothyroidism <input type="checkbox"/> Goiter <input type="checkbox"/> Other; specify: _____ <p style="text-align: center;">Start date of treatment: ____/____/____ <input type="checkbox"/> Unknown</p> <input type="checkbox"/> Unknown
Osteoporosis requiring treatment:	<input type="checkbox"/> No <input type="checkbox"/> Yes; Start date of treatment: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
Bone fracture:	<input type="checkbox"/> No <input type="checkbox"/> Yes; Bone involved: _____ <p style="text-align: center;">Date of fracture: ____/____/____ <input type="checkbox"/> Unknown</p> <input type="checkbox"/> Unknown
Iron overload requiring treatment:	<input type="checkbox"/> No <input type="checkbox"/> Yes; Start date of treatment: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
Dyslipidemia requiring treatment:	<input type="checkbox"/> No <input type="checkbox"/> Yes; Start date of treatment: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
Arterial hypertension requiring treatment:	<input type="checkbox"/> No <input type="checkbox"/> Yes; Start date of treatment: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
Morbid obesity requiring treatment:	<input type="checkbox"/> No <input type="checkbox"/> Yes; Start date of treatment: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
Mental health disorder requiring treatment:	<input type="checkbox"/> No <input type="checkbox"/> Yes; Diagnosis: _____ <p style="text-align: center;">Start date of treatment: ____/____/____ <input type="checkbox"/> Unknown</p> <input type="checkbox"/> Unknown
Cognitive function disorder requiring treatment:	<input type="checkbox"/> No <input type="checkbox"/> Yes; Diagnosis: _____ <p style="text-align: center;">Start date of treatment: ____/____/____ <input type="checkbox"/> Unknown</p> <input type="checkbox"/> Unknown
Return to work/school:	<input type="checkbox"/> No <input type="checkbox"/> Yes; Involvement: <input type="checkbox"/> Parttime <input type="checkbox"/> Fulltime <input type="checkbox"/> Unknown <p style="text-align: center;">Date of return to work/school: ____/____/____ <input type="checkbox"/> Unknown</p> <input type="checkbox"/> 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)

Bacterial infection: No Yes

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

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

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

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:
 (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



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

Treatment Type HCT
 Treatment Date ____/____/____ (YYYY/MM/DD)

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: complete the "Treatment — non-HCT/CT/GT/IST" form
- 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)

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.

DISEASE STATUS
Only for malignancies

Disease detected during this follow-up period?

- No
- Yes; **Date last assessed:** ____/____/____ (YYYY/MM/DD) Unknown
- Method; specify:** Haematological
(select all that apply) Radiological
 Molecular
 Cytogenetic
 Other; specify _____
- Unknown

DISEASE STATUS
Disease specific
Not applicable for Inborn Errors

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

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

PREGNANCY AFTER HCT

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

No; *Extended dataset*
Was there an attempted pregnancy since last follow-up? No Yes Unknown

- Yes: **Did the pregnancy result in a live birth?**
- No; **Date of spontaneous or induced termination:** ____/____/____ (YYYY/MM/DD) Unknown
- Yes; **Year of birth:** ____ (YYYY) **Month of birth:** __ (MM) Unknown
- Still pregnant at time of follow-up
- Unknown

Extended dataset
Conception method: Natural Assisted Unknown

Unknown

Appendix 1
Best Response and Disease Status (Disease Specific)

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

ACUTE LEUKAEMIAS	<i>Go to page 37</i>
CHRONIC LEUKAEMIAS	<i>Go to page 37</i>
PLASMA CELL NEOPLASMS (PCN)	<i>Go to page 38</i>
MPN, MDS, MDS / MPN OVERLAP SYNDROMES	<i>Go to page 40</i>
AUTOIMMUNE DISORDERS	<i>Go to page 41</i>
HAEMOGLOBINOPATHIES	<i>Go to page 41</i>
LYMPHOMAS	<i>Go to page 42</i>
SOLID TUMOURS	<i>Go to page 42</i>
BONE MARROW FAILURE SYNDROMES (BMF) including APLASTIC ANAEMIA (AA)	<i>Go to page 42</i>
OTHER DIAGNOSIS	<i>Go to page 43</i>

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:

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

Proceed to next page for Diseases Status section

Plasma cell neoplasms (PCN)

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

Extended dataset

Immunoglobulin-related (AL) Amyloidosis only

Organ response during this follow-up period:

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

Proceed to next page for Diseases Status section

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

Complete only for PCN Disease Status

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

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

Complete only for AL, CLL and PCN Disease Status

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

Minimal residual disease (MRD):

- Positive
 - 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

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

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

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

Haemoglobinopathies
Thalassaemia:
Complete only for Thalassemia Best Response

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

Complete only for Thalassemia Disease Status
Patient requires transfusions during follow-up period:

No

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

Ongoing transfusion dependence since previous assessment

Number of units: ____ Unknown
(during follow-up period)

Did transfusions stop? No

Yes; **Date of last transfusion:** ____/____/____ (YYYY/MM/DD) Unknown

Unknown

Unknown

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

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

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

Solid tumours

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

Bone marrow failures (incl. AA)

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

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

Did transfusions stop during the follow-up period? Patient was never transfusion dependent

No

Yes; **Did the patient return to transfusion dependency afterwards?**

No

Yes; **First transfusion date:** ____/____/____ (YYYY/MM/DD) Unknown
(after transfusion free period)

Unknown

Unknown

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

Haemoglobinopathies

Sickle cell disease:

Complete only for Sickle cell disease Best Response

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

Complete only for Sickle cell disease Disease Status

Sickling episodes occur during follow-up period:

<input type="checkbox"/> No	
<input type="checkbox"/> Yes; <input type="checkbox"/> First return of sickling episodes after HCT	Date of first episode : ____/____/____ (YYYY/MM/DD) <input type="checkbox"/> Unknown (after HCT)
<input type="checkbox"/> Ongoing presence of sickling episodes	
Number of SCD episodes: ____ <input type="checkbox"/> Unknown (during follow-up)	
<input type="checkbox"/> Unknown	

Other diagnosis

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

Appendix 1
Disease Status
Inborn errors only

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

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

Test date: ____/____/____ (YYYY/MM/DD) Unknown

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

Appendix 1
Disease Status
Inborn errors only

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: _____

Appendix 1
Disease Status
Inborn errors of Immunity only

Extended dataset

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

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

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



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

Treatment Type HCT
 Treatment Date ____/____/____ (YYYY/MM/DD)

Appendix 1
 Disease Status
Inborn errors only

Extended dataset

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

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

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

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

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

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

Bacterial infections

Gram-positive:

- 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 other spp (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
- Chlamydomphila
- 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

- Bronchial infection
- Lung infection
- Laryngitis infective
- Pleural infection
- Tracheitis infective
- Upper respiratory infection

Intra-abdominal infections

- Anorectal infection
- Appendicitis infective
- Appendicitis with perforation infective
- Biliary tract infection
- Cecal infection
- Duodenal infection
- Enterocolitis infective
- Esophageal infection
- Gallbladder infection
- Gastritis infective
- Hepatic infection
- Pancreas infection
- Pelvic infection
- Peritoneal infection
- Splenic infection
- Stoma site infection
- Small intestine infection
- Typhlitis infective

Blood

- Bacteremia
- Fungemia
- Viremia

Uro-genital tract infections

- Cystitis infective
- Cervicitis infective
- Kidney infection
- Ovarian infection
- Scrotal infection
- Penile infection
- Prostate infection
- Urethral infection
- Urinary tract infection
- Uterine infection
- Vaginal infection
- Vulval infection

Muscles and bones

- Bone infection
- Myositis infective
- Joint infection

Nervous system infection

- Cranial nerve infection
- Encephalitis infective
- Encephalomyelitis infective
- Meningitis infective
- Myelitis infective
- Peripheral nerve infection

Cardiovascular infections

- Arteritis infective
- Endocarditis infective
- Mediastinal infection
- Phlebitis infective

Skin, soft tissue and mucosal surfaces

- Breast infection
- Folliculitis infective
- Lymph gland infection
- Nail infection
- Mucosal infection
- Papulo/pustular rash
- Paronychia
- Skin infection
- Soft tissue infection
- Wound infection

Head and neck

- Conjunctivitis infective
- Corneal infection
- Endophthalmitis infective
- Retinitis
- Gum infection
- Lip infection
- Oral cavity infection
- Otitis externa infective
- Otitis media infective
- Periorbital infection
- Salivary gland infection
- Sinusitis infective
- Tooth infection

Others

- Device related infection (other than Intravascular catheter)
- Febrile Neutropenia
- Fever of unknown origin (FUO)
- Sepsis

Appendix 4

-- Non-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

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-specific 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