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

Treatment Type ☐ HCT

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

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

## SURVIVAL STATUS

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

**Survival status:**

☐ Alive
☐ Dead
☐ Lost to follow-up

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

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

**Autopsy performed:**

☐ No
☐ Yes
☐ Unknown

## BEST RESPONSE

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

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

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

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

## GRAFT FUNCTION

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

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

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

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

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

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

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

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

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

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

☐ No
☐ Yes; **Immunosuppresion stopped:**
  ☐ No
  ☐ Yes; **End date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
  ☐ Unknown
☐ Unknown

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

☐ No
☐ Yes; ☐ Started in this follow-up period; **Start date:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
  ☐ Ongoing since previous follow-up

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

☐ Unknown

*Extended dataset*

## Antimicrobial prophylaxis

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

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

## Antibacterial

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

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

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

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

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

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

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

## Antimicrobial prophylaxis continued

*Extended dataset*

### Antiviral

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

☐ No (i.e. no prophylaxis or only letermovir)

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

*Note: letermovir is not included as this is requested on the core dataset.*
*Do not consider letermovir for 'Other drug'.*

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

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

**Did the patient receive prophylaxis for varicella-zoster virus (VZV) or herpes simplex virus (HSV) with either acyclovir or valacyclovir during this follow-up period?** *(Only for allo-HCT, not auto-HCT)*

☐ No

☐ Yes: **Final date VZV or HSV prophylaxis was discontinued:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Ongoing ☐ Unknown

**Did the patient receive rituximab or another anti-CD20 monoclonal drug as prophylaxis for Epstein-Barr virus post-transplant lymphoproliferative disorder (EBV-PTLD) during this follow-up period?** *(Only for allo-HCT, not auto-HCT*

☐ No

☐ Yes

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

☐ No

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

- ☐ Lamivudine
- ☐ Entecavir
- ☐ Tenofovir
- ☐ Other drug

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

# Antimicrobial prophylaxis

*Extended dataset*

## Antifungal

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

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

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

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

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

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

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

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

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

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

## Antimicrobial prophylaxis continued

*Extended dataset*

### Antifungal

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

☐ No

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

- ☐ Trimethoprim-sulfamethoxazole
- ☐ Dapsone
- ☐ Atovaquone
- ☐ Pentamidine inhaled
- ☐ Pentamidine intravenous
- ☐ Other drug

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

☐ Unknown

*Extended dataset*

## Pre-emptive viral therapy

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

**If yes, for what virus?** *(select all that apply)* ☐ CMV ☐ EBV

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

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

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

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

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

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

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

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

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

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

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

## COMPLICATIONS SINCE THE LAST REPORT
-- GvHD --
*Allogeneic HCT only*

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

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

☐ Yes: **Did the patient receive a systemic/immunosuppressive treatment for GvHD during this follow-up period?**
- ☐ No
- ☐ Yes: ☐ Started in this follow-up period; **Date treatment started:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
  - ☐ Ongoing since previous follow-up
  - **Treatment stopped:** ☐ No
    - ☐ Yes; **Stop date of treatment:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
    - ☐ Unknown
- ☐ Unknown

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

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

☐ No

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

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Skin: | ☐ 0 *(none)* | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ Not evaluated | ☐ Unknown |
| Liver: | ☐ 0 *(none)* | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ Not evaluated | ☐ Unknown |
| Lower GI tract: | ☐ 0 *(none)* | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ Not evaluated | ☐ Unknown |
| Upper GI tract: | ☐ 0 *(none)* | ☐ 1 | ☐ Not evaluated | ☐ Unknown | | | |
| Other site affected: | ☐ No | ☐ Yes; specify: _____ | | | | | |

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

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

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

☐ Unknown

## COMPLICATIONS SINCE THE LAST REPORT
-- GvHD --
*Allogeneic HCT only*

*Extended dataset*

### aGvHD first line treatment

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

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

| **Name of steroid** | **Treatment started / date** (YYYY/MM/DD) | **Initial dose** (mg/kg/day) | **Treatment stopped / date** (YYYY/MM/DD) |
|---|---|---|---|
| ☐ Prednisolone<br>☐ Methylprednisolone<br>☐ Other; specify: _____ | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | _____<br>☐ Unknown | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |
| ☐ Prednisolone<br>☐ Methylprednisolone<br>☐ Other; specify: _____ | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | _____<br>☐ Unknown | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |

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

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

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

| **Name of drug/strategy** |
|---|
| ☐ ECP |
| ☐ Ruxolitinib |
| ☐ MMF |
| ☐ Cyclosporin A |
| ☐ Tacrolimus |
| ☐ Sirolimus |
| ☐ Other; specify: _____ |

*Extended dataset*

## aGvHD first line treatment continued

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

***Refractory:*** *progression in any organ within 3, 4 or 5 days of therapy onset with >= 2 mg/Kg/day of prednisone equivalent, or failure to improve within 5 to 7 days of treatment initiation, or incomplete response after more than 28 days of immunosuppressive treatment including steroids.*
***Dependent:*** *Inability to taper prednisone under 2 mg/Kg/day after an initially successful treatment of at least 7 days or as the recurrence of aGVHD activity during steroid tapering.*

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

**Steroid sensitive:** ☐ No ☐ Yes ☐ Unknown

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

**Steroid refractory:** ☐ No ☐ Yes ☐ Unknown

**Steroid dependent:** ☐ No

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

☐ Ongoing since previous follow-up

☐ Unknown

## Steroid refractory/dependent aGvHD

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

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

☐ 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 | ☐ Stage 0 ☐ Stage 1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4 ☐ Not evaluated ☐ Unknown |
| Liver | ☐ Stage 0 ☐ Stage 1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4 ☐ Not evaluated ☐ Unknown |
| Lower GI tract | ☐ Stage 0 ☐ Stage 1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4 ☐ Not evaluated ☐ Unknown |
| Upper GI tract | ☐ Stage 0 ☐ Stage 1 ☐ Not evaluated ☐ Unknown |

*Extended dataset*

## Steroid refractory/dependent aGvHD continued

**Drugs given in this line of treatment during this follow-up period**

**Line of treatment** : _____

| **Name of drug/ strategy** (select all that applies) | **Started / date** (YYYY/MM/DD) | **Stopped / date** (YYYY/MM/DD) |
|---|---|---|
| ☐ ECP | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |
| ☐ Ruxolitinib | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |
| ☐ MMF | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |
| ☐ Cyclosporin A | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |
| ☐ Tacrolimus | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |
| ☐ Sirolimus | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |
| ☐ Other; specify: ____ | ☐ Started in this follow-up period;_ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |

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

*Extended dataset*

## Steroid refractory/dependent aGvHD continued

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

| **Organ involved during the course of treatment** | **Organ(s) involved during the course of treatment and Best response achieved** | **Date best response assessed** *(YYYY/MM/DD)* |
|---|---|---|
| Skin | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Liver | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Lower GI tract | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Upper GI tract | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Overall (if organ specific is not available) | ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ 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: | ☐ 0 *(none)* | ☐ 1 | ☐ 2 | ☐ 3 | ☐ Not evaluared | ☐ Unknown |
| Oral: | ☐ 0 *(none)* | ☐ 1 | ☐ 2 | ☐ 3 | ☐ Not evaluated | ☐ Unknown |
| Gastrointestinal: | ☐ 0 *(none)* | ☐ 1 | ☐ 2 | ☐ 3 | ☐ Not evaluated | ☐ Unknown |
| Eyes: | ☐ 0 *(none)* | ☐ 1 | ☐ 2 | ☐ 3 | ☐ Not evaluated | ☐ Unknown |
| Liver: | ☐ 0 *(none)* | ☐ 1 | ☐ 2 | ☐ 3 | ☐ Not evaluated | ☐ Unknown |
| Joints and fascia: | ☐ 0 *(none)* | ☐ 1 | ☐ 2 | ☐ 3 | ☐ Not evaluated | ☐ Unknown |
| Lungs: | ☐ 0 *(none)* | ☐ 1 | ☐ 2 | ☐ 3 | ☐ Not evaluated | ☐ Unknown |
| Genitalia: | ☐ 0 *(none)* | ☐ 1 | ☐ 2 | ☐ 3 | ☐ Not evaluated | ☐ Unknown |
| Other site affected: | ☐ No | ☐ Yes; specify: _____ | | | | |

**Steroid-refractory chronic GvHD:** ☐ No

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

☐ Ongoing since previous follow-up

☐ Unknown

**cGvHD resolved:** ☐ No

☐ Yes; **Date of cGvHD resolution:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

☐ Unknown

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

☐ Unknown

*Extended dataset*

## cGvHD first line treatment

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

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

| **Name of steroid** | **Treatment started / date** (YYYY/MM/DD) | **Initial dose** (mg/kg/day) | **Treatment stopped / date** (YYYY/MM/DD) |
|---|---|---|---|
| ☐ Prednisolone<br>☐ Methylprednisolone<br>☐ Other; specify: _____ | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | _____<br>☐ Unknown | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |
| ☐ Prednisolone<br>☐ Methylprednisolone<br>☐ Other; specify: _____ | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | _____<br>☐ Unknown | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |

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

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

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

| **Name of drug/strategy** |
|---|
| ☐ ECP |
| ☐ Ruxolitinib |
| ☐ MMF |
| ☐ Cyclosporin A |
| ☐ Tacrolimus |
| ☐ Sirolimus |
| ☐ Other; specify: _____ |

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

***Refractory:*** *progression of GvHD while on prednisone at >= 1 mg/Kg/day for 1-2 weeks or stable GvHD while on >=0.5 mg/Kg/day (or 1 mg/Kg every other day) of prednisone for 1-2 months.*
***Dependent:*** *inability to control GVHD symptoms while tapering prednisone below 0.25 mg/Kg/day (or 0.5 mg/Kg every other day) in at least two individual attempts, separated by at least 8 weeks.*
***Intolerant:*** *Includes avascular necrosis, severe myopathy, uncontrolled diabetes mellitus, systemic viral or fungal infections.*

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

**Steroid sensitive:** ☐ No ☐ Yes ☐ Unknown

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

**Steroid refractory:** ☐ No ☐ Yes ☐ Unknown

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

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

*Extended dataset*

## Steroid refractory/dependent/intolerant cGvHD

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

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

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

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

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

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

*Extended dataset*

## Steroid refractory/dependent/intolerant cGvHD

**Drugs given in this line of treatment during this follow-up period**

**Line of treatment** _____

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

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

## Steroid refractory/dependent/intolerant cGvHD

*Extended dataset*

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

| Organ involved during the course of treatment | Organ(s) involved during the course of treatment and Best response achieved | Date best response assessed *(YYYY/MM/DD)* |
|---|---|---|
| Skin | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Oral | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Gastrointestinal | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Eyes | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Liver | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Joints and fascia | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Lungs | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Genitalia | ☐ No<br>☐ Yes: ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown<br>☐ Not evaluated<br>☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ Unknown |
| Overall (*if organ specific is not available*) | ☐ CR ☐ PR ☐ Progression ☐ Stable/no change ☐ Unknown | _ _ _ _ / _ _ / _ _<br>☐ 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 <u>this period</u>:** ☐ Non-fatal ☐ Fatal

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

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

**Cardiac event**

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

**Maximum CTCAE grade observed during <u>this period</u>:** ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

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

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

**Central nervous system (CNS) toxicity**

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

**Maximum CTCAE grade observed during <u>this period</u>:** ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

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

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

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

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

**Maximum CTCAE grade observed during <u>this period</u>:** ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

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

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

* Grade 0-2

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

**Liver disorder**

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

**Maximum CTCAE grade observed during <u>this period</u>:** ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

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

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

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

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

**Maximum CTCAE grade observed during <u>this period</u>:** ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

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

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

**Respiratory disorders**

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

**Maximum CTCAE grade observed during <u>this period</u>:** ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

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

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

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

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

**Maximum CTCAE grade observed during <u>this period</u>:** ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

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

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

* Grade 0-2

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

**Vascular event**

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

**Maximum CTCAE grade observed during <u>this period</u>:** ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

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

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

**Avascular necrosis (AVN)**

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

**Maximum CTCAE grade observed during <u>this period</u>:** ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

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

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

**Cerebral haemorrhage**

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

**Maximum CTCAE grade observed during <u>this period</u>:** ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

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

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

**Haemorrhage (other than cerebral haemorrhage)**

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

**Maximum CTCAE grade observed during <u>this period</u>:** ☐ 3 ☐ 4 ☐ 5 (fatal) ☐ Unknown

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

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

* Grade 0-2

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

**Cerebral thrombosis**

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

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

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

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

**Cytokine release syndrome (CRS)**

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

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

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

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

**Haemophagocytic lymphohistiocytosis (HLH)**

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

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

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

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

**Pure red cell aplasia (PRCA)**

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

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

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

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

* Grade 0-2

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

**Posterior reversible encephalopathy syndrome (PRES)**

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

**Maximum grade observed during <u>this period</u>:** ☐ Non-severe ☐ Severe ☐ Fatal ☐ Unknown

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

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

**Transplant-associated microangiopathy (TMA)**

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

**Maximum grade observed during <u>this period</u>:** ☐ Non-severe ☐ Severe ☐ Unknown

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

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

*Extended dataset*

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

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

**Line of treatment** _____

| **Name of drug** | **Start date** (YYYY/MM/DD) | **Stopped / date** (YYYY/MM/DD) |
|---|---|---|
| ☐ Defibrotide | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |
| ☐ Eculizumab | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |
| ☐ Narsoplimab | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |

* Grade 0-2

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

*Extended dataset*

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

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

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

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

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

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

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

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

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

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

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

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

**Veno-occlusive disease (VOD)**

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

**Maximum grade observed during <u>this period</u>:** ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe ☐ Fatal ☐ Unknown

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

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

*Extended dataset*

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

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

**Line of treatment** _____

| **Name of drug** | **Start date** (YYYY/MM/DD) | **Stopped / date** (YYYY/MM/DD) |
|---|---|---|
| ☐ Defibrotide | ☐ Started in this follow-up period; _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |
| ☐ Other; specify: _____ | ☐ Started in this follow-up period;_ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Ongoing since previous follow-up | ☐ No<br>☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown<br>☐ Unknown |

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

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

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

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

*Defined as serum bilirubin <2 mg/dL, no oxygen support, eGFR >50% from baseline before VOD and no renal replacement therapy*

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

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

*Defined as serum bilirubin increased, but >2 mg/dL, or pulmonary dysfunction, or eGFR ≤50% from baseline before VOD*

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

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

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

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

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

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

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

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

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

* Grade 0-2

*Extended dataset*

## Additional late complications

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

☐ No *Consult appendix 4 for a list of complications that should not be reported*

☐ Yes (*report all infection-related complications below*)

**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

*Extended dataset*

## SARS-CoV-2 RELATED QUESTION

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

☐ No

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

**Date of the last dose**: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

☐ Unknown

## SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS

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

☐ No

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

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

☐ Unknown

## ADDITIONAL TREATMENTS

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

☐ No

☐ Yes; ☐ Started in this follow-up period; **complete the "Treatment — non-HCT/CT/GT/IST" form**

☐ Ongoing since previous follow-up

☐ 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:** *(select all that apply)*
- ☐ Haematological
- ☐ Radiological
- ☐ Molecular
- ☐ Cytogenetic
- ☐ Other; specify _____

☐ Unknown

## DISEASE STATUS
*Disease specific*

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

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

## PREGNANCY AFTER HCT

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

☐ No;

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

☐ Yes: **Did the pregnancy result in a live birth?**

- ☐ No; **Date of spontaneous or induced termination**: _ _ _ _ / _ _ / _ _ (YYYY/MM/DD) ☐ Unknown
- ☐ Yes; **Year of birth:** _ _ _ _ (YYYY) **Month of birth:** _ _ (MM) ☐ Unknown
- ☐ Still pregnant at time of follow-up
- ☐ Unknown

*Extended dataset*
**Conception method:** ☐ Natural ☐ Assisted ☐ Unknown

☐ Unknown

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

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

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

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

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

*Proceed to next page for Diseases Status section*

**Chronic leukaemias (CML, CLL, PLL, Other)**

Chronic Myeloid Leukaemia (CML):

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

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

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

*Extended dataset*

In case of NO cytogenetic remission

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

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

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

*Extended dataset*

In case of NO molecular remission

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

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

*Extended dataset*

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

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

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

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

*Extended dataset*

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

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

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

- ☐ Not evaluated
- ☐ Unknown

*Proceed to next page for Diseases Status section*

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

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

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

*Proceed to next page for Diseases Status section*

**Plasma cell neoplasms (PCN)**

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

*Extended dataset*

Immunoglobulin-related (AL) Amyloidosis only

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

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

*Proceed to next page for Diseases Status section*

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

Complete only for PCN Disease Status

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

☐ No

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

☐ Ongoing since previous follow-up

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

☐ Unknown

Complete only for AL, CLL and PCN Disease Status

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

**Minimal residual disease (MRD):**

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

☐ Negative

☐ Not evaluated

☐ Unknown

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

**Sensitivity of MRD assay:**
- ☐ $\leq 10^{-6}$
- ☐ $\leq 10^{-5}$
- ☐ $\leq 10^{-4}$
- ☐ $\leq 10^{-3}$
- ☐ Other; specify: _____
- ☐ Unknown

**Method used:**
*(select the most sensitive method used)*
- ☐ PCR
- ☐ Flow cytometry
- ☐ NGS
- ☐ Other; specify: _____
- ☐ Unknown

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

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

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

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

**Autoimmune disorders**

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

**Haemoglobinopathies**

Thalassaemia:

Complete only for Thalassemia Best Response

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

Complete only for Thalassemia Disease Status

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

☐ No

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

☐ Ongoing transfusion dependence since previous assessment

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

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

☐ Unknown

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

### Lymphomas

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

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

### Solid tumours

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

### Bone marrow failures (incl. AA)

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

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

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

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

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

### Haemoglobinopathies

Sickle cell disease:

Complete only for Sickle cell disease Best Response

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

Complete only for Sickle cell disease Disease Status

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

| |
|---|
| ☐ No |
| ☐ Yes; ☐ First return of sickling episodes after HCT **Date of first episode :** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown (after HCT)<br>☐ Ongoing presence of sickling episodes<br>**Number of SCD episodes**: ____ ☐ Unknown (during follow-up) |
| ☐ Unknown |

### Other diagnosis

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

## Appendix 1
Disease Status
*Inborn errors only*

*Extended dataset*

**Patient height at this follow-up:** _____ cm ☐ Not evaluated ☐ Unknown

**Patient weight at this follow-up:** _____ kg ☐ Not evaluated ☐ Unknown

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

*(Only for Inborn errors of Immunity)*

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

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

| **Cell type and test results** | | **Units** *(for CD4 and CD8, select unit)* |
|---|---|---|
| CD3 T-cells: _____ | ☐ Not evaluated ☐ Unknown | Cells/µl |
| CD4 T-cells: _____ | ☐ Not evaluated ☐ Unknown | Cells/µl |
| CD8 T-cells: _____ | ☐ Not evaluated ☐ Unknown | Cells/µl |
| B-cells (i.e. CD19): _____ | ☐ Not evaluated ☐ Unknown | Cells/µl |
| NK-cells (CD16/CD56): _____ | ☐ Not evaluated ☐ Unknown | Cells/µl |
| Naive CD4 T-cells (CD4/CD45RA): _____ | ☐ Not evaluated ☐ Unknown | ☐ % of CD4 ☐ Cells/µl |
| Naive CD8 T-cells (CD8/CD45RA): _____ | ☐ Not evaluated ☐ Unknown | ☐ % of CD8 ☐ Cells/µl |
| IgG: _____ | ☐ Not evaluated ☐ Unknown | Gram/l |
| IgA: _____ | ☐ Not evaluated ☐ Unknown | Gram/l |
| IgM: _____ | ☐ Not evaluated ☐ Unkown | Gram/l |

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

*Extended dataset*

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

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

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

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

*Extended dataset*

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

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

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

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

*Extended dataset*

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

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

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

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

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

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

### Bacterial infections

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

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

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

### Viral infections:

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

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

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

### Fungal infections:

**Yeasts:**
· Candida albicans
· Candida auris
· Candida other (specify)
· Cryptococcus neoformans
· Trichosporon (specify)
· Pneumocytis jiroveci
· Yeasts other (specify)

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

### Parasitic infections:

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

**Helminths:**
· Strongyloides stercoralis
· Other helminths

# Appendix 3
## -- CTCAE term --

*CTCAE terms related to infections and infestations (version 5.0.)*
*https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm#ctc_50*

**Respiratory tract infections**
· Pneumonia
· Other respiratory tract infections, please specify:

· Upper respiratory tract infection
·Tracheobronchitis
.Pleural infection

**Intra-abdominal infections**
· Esophagus or gastric infection
· Liver site infection (including biliary tract and gallbladder), please specify:

· Biliary tract or gallbladder infection
· Liver infection

· Lower gastrointestinal infection, please specify:

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

· Other intra-abdominal infection, please specify:

.Pancreas infection
.Peritoneal infection
.Splenic infection

**Skin, soft tissue and muscle infections**
. Lymph gland infection
. Skin, soft tissue or muscle infection, please specify:

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

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

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

**Uro-genital tract infections**
· Genital infection, please specify:

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

· Urinary tract infection, please specify:

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

**Nervous system infection**
· Central nervous system infection, please specify:

· Encephalitis infective (including abscess)
. Isolated meningitis infective

· Other nervous system infection, please specify:

· Cranial nerve infection
. Myelitis infective

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

· Arteritis infective
. Mediastinal infection

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

· Salivary gland infection
. Other oral cavity structure infection

· Retinitis infective
· Sinusitis infective

**Osteoarticular infections**
· Joint infection
· Bone infection

Appendix 4

## -- Non-infectious 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-specifc T-cells; specify virus: _____
- ☐ Other; specify: _____

*Not applicable for Inborn Errors*

**Disease status at time of this cell infusion*:** _____

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

**Indication:**
*(check all that apply)*

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

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

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

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

- ☐ Unknown