



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

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

AUTOLOGOUS HEMATOPOIETIC GENE THERAPY

--- Day 100, 6 Months, 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	Select treatment related cause: <i>(select all that apply)</i> <input type="checkbox"/> Graft versus Host Disease <input type="checkbox"/> Non-infectious complication <input type="checkbox"/> Infectious complication:
<input type="checkbox"/> HCT-related	<i>(select all that apply)</i> <input type="checkbox"/> Bacterial infection <input type="checkbox"/> Viral infection <input type="checkbox"/> Fungal infection <input type="checkbox"/> Parasitic infection <input type="checkbox"/> Infection with unknown pathogen
<input type="checkbox"/> GT-related	<input type="checkbox"/> Other treatment related cause of death; specify: _____
<input type="checkbox"/> IST-related	
<input type="checkbox"/> Unknown	
<input type="checkbox"/> Other cause of death; specify: _____	

Assessment period covered by this report:

- Day 100
- 6 months
- 12 months (1 year)
- 18 months
- 24 months (2 years)
- Annual or unscheduled Follow-Up *(up to 15 years)*



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BEST RESPONSE

*Complete only for Day 100 and 6 Months Follow-Up
 Only for Sickle cell disease*

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

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

RECOVERY

Complete only for Day 100 and 6 Months Follow-Up

Absolute neutrophil count (ANC) recovery (neutrophils $\geq 0.5 \times 10^9/L$):

- No: **Date of the last assessment:** ____/____/____ (YYYY/MM/DD) Unknown
- Yes: **Date of ANC recovery:** ____/____/____ (YYYY/MM/DD) Unknown
 (first of 3 consecutive values after 7 days without transfusion containing neutrophils)
- Never below
- Not evaluated
- Unknown

Platelet reconstitution (platelets $\geq 20 \times 10^9/L$):

- No: **Date of the last assessment:** ____/____/____ (YYYY/MM/DD) Unknown
- Yes: **Date of platelet reconstitution:** ____/____/____ (YYYY/MM/DD) Unknown
 (first of 3 consecutive values after 7 days without platelet transfusion)
- Never below
- Not evaluated
- Unknown

Date of the last platelet transfusion: ____/____/____ (YYYY/MM/DD) Not applicable (not transfused) Unknown

THERAPY SUCCESS
only for Primary Immunodeficiencies
Engraftment of the modified stem cells assessed?

- No
 Yes: **Date evaluated:** ____/____/____ (YYYY/MM/DD) Unknown

For gene transfer Gene Therapy only
For gene editing Gene Therapy only

T cells	VCN: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Gene editing efficiency: _____% <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
B cells	VCN: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Gene editing efficiency: _____% <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
NK cells	VCN: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Gene editing efficiency: _____% <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
PMN	VCN: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Gene editing efficiency: _____% <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
Monocytes	VCN: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Gene editing efficiency: _____% <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
Other; specify: _____	VCN: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Gene editing efficiency: _____% <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown

 Not evaluated

THERAPY SUCCESS
only for Haemoglobinopathies
For gene transfer Gene Therapy only
Vector copy number (VCN): _____ Not evaluated Unknown

For gene editing Gene Therapy only
Gene-edited cells: _____% Not evaluated Unknown

HbF _____% Not evaluated Unknown

For Sickle Cell Disease only
HbS _____% Not evaluated Unknown

For Bluebird Bio product only
H87q _____% Not evaluated Unknown

Other therapy specific recovery; specify: _____

CURRENT HAEMATOLOGICAL FINDINGS

Haemoglobin (g/dL) _____	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Ferritin (ng/mL) _____	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

Do not report complications that were resolved before the Gene Therapy

Do not report complications that were previously reported as resolved, unless they recurred

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

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

Macrophage activation syndrome (MAS)

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*

Secondary 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*

Organ toxicity: skin

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*

*Grade 0-2



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COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

Organ toxicity: liver**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***Organ toxicity: lung****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***Organ toxicity: heart****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***Organ toxicity: kidney****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*

* Grade 0-2

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

Organ toxicity: gastrointestinal**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***Other organ toxicity observed during this follow-up period?** No* Yes: Newly developed Ongoing since previous assessment Unknown**Organ specify:** _____**Maximum CTCAE grade observed during this period:** 3 4 5 (fatal) Unknown**Onset date (YYYY/MM/DD):** ____/____/____ Unknown*Only if newly developed***Tumour lysis syndrome (TLS)****Complication observed during this follow-up period?** No* Yes: Newly developed Ongoing since previous assessment Unknown**Maximum CTCAE grade observed** 3 4 5 (fatal) Unknown**Onset date (YYYY/MM/DD):** ____/____/____ Unknown*Only if newly developed*

* Grade 0-2

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

Cytopenia

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*

Idiopathic pneumonia syndrome

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*

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 during this period: 3 4 5 (fatal) Unknown

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

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

* Grade 0-2

COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications --

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

Did infectious complications occur during the follow-up period?

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

Bacterial infection: No Yes Unknown

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

Start date: ____/____/____ (YYYY/MM/DD) *only if newly developed*

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):** _____

(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*

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):** _____

(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

COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

Viral infection: No Yes Unknown

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

Start date: ____/____/____ (YYYY/MM/DD) *only if newly developed*

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):** _____

(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*

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):** _____

(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

COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

Parasitic infection: No Yes Unknown

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

Start date: ____/____/____ (YYYY/MM/DD) *only if newly developed*

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):** _____

(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*

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):** _____

(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

COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

Infection with unknown pathogen: No Yes: Unknown
(for clinical infections without microbiological documentation, like pneumonia, cellulitis, etc.)

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

Start date: ____/____/____ (YYYY/MM/DD) *only if newly developed*

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)*: _____

(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*

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)*: _____

(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

SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS

Did a secondary malignancy or autoimmune disorder occur during this follow-up period?

- No
 Yes:

Diagnosis: _____
Date of diagnosis: ____/____/____ (YYYY/MM/DD)
Histologic type (if applicable): _____
Location (if applicable): _____

Secondary malignancy material preserved:

- No
 Yes
 Unknown

Concomitant PBMCs preserved:

- No
 Yes
 Unknown

Unknown

Viral vectors: *For gene transfer Gene Therapy only*

Did insertional mutagenesis occur?	
<input type="checkbox"/> No	
<input type="checkbox"/> Yes:	
Integration site; specify _____	<input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
Integration site clonal diversity: <i>(Shannon diversity index)</i>	<input type="checkbox"/> Very High <input type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Low <input type="checkbox"/> Very Low <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
<input type="checkbox"/> Not evaluated	
<input type="checkbox"/> Unknown	

ADDITIONAL CELL INFUSIONS

Did the patient receive an (salvage infusion) autologous boost?

- No
 Yes: **Date of the (salvage infusion) autologous boost:** ____/____/____ (YYYY/MM/DD) Unknown
 Unknown

RECURRENCE OF DISEASE

only for Haemoglobinopathies

Was there a recurrence of disease since last follow-up? *(detected by any method)*

- No
- Yes; *for every recurrence complete the question below*

Date of recurrence: ____/____/____ (YYYY/MM/DD) Unknown

- Unknown

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

HOSPITAL ADMISSION

Complete only for Day 100 and 6 Months Follow-Up.

Was inpatient admission and care needed since the last follow-up?

- No
- Yes: **Number of days in hospital:** _____
- Unknown

Was the patient transferred to the intensive care unit (ICU) since the last follow-up?

- No
- Yes: **Number of days in ICU:** _____
- Unknown

PATIENT STATUS

Performance status at the last assessment *(choose only one):*

Type of scale used: _____ Score: _____

Karnofsky/Lansky	<input type="checkbox"/> 10 <input type="checkbox"/> 20 <input type="checkbox"/> 30 <input type="checkbox"/> 40 <input type="checkbox"/> 50 <input type="checkbox"/> 60 <input type="checkbox"/> 70 <input type="checkbox"/> 80 <input type="checkbox"/> 90 <input type="checkbox"/> 100 <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
ECOG	<input type="checkbox"/> 0 <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



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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 GENE THERAPY

Complete only after 6 Months

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

No;

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

Unknown

END OF GENERAL FOLLOW-UP REPORTING

TO COMPLETE FOLLOW-UP REPORTING, PLEASE FILL IN THE APPLICABLE
 DIAGNOSE-SPECIFIC QUESTIONS ATTACHED TO THIS FORM



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Appendix 1
Disease Status

Patient status post GT
Inborn errors only

Patient height: _____ **cm** Not evaluated Unknown

Patient weight: _____ **kg** Not evaluated Unknown

Patient is attending:

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

(Only for Inborn errors of Immunity)

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

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

Cell type and test results	Units (for CD4 and CD8, select unit)
CD3 T-cells: _____ <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown	Cells/ 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



EBMT Centre Identification Code (CIC): ___

Treatment Type GT

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Patient Number in EBMT Registry: _____

Treatment Date ___/___/___ (YYYY/MM/DD)

Appendix 1

Best Response and Disease Status (Disease Specific)

Haemoglobinopathies

Complete only for Thalassemia Disease Status

Patient requires regular transfusions during follow-up period:

<input type="checkbox"/> No;	Occasional transfusions during follow-up period:
	<input type="checkbox"/> No <input type="checkbox"/> Yes; Number of units: ____ <input type="checkbox"/> Unknown Reason: _____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown

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

Ongoing transfusion dependence since previous assessment

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

Did transfusions stop? No

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

Unknown

Sickle cell disease:

Complete only for Sickle cell disease Best Response

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



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

Other diagnosis

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

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

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

Bacterial infections

Gram-positive:

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

Gram-negative:

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

Other bacteria:

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

Viral infections:

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

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

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

Fungal infections:**Yeasts:**

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

Moulds:

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

Parasitic infections:**Protozoa:**

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

Helminths:

- Schistosoma
- Strongyloides stercoralis
- Helminths other

Appendix 3
-- CTCAE term --

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

Respiratory tract infections

- Pneumonia
- Other respiratory tract infections, please specify:

Intra-abdominal infections

- Esophagus or gastric infection
- Liver site infection (including biliary tract and gallbladder), please specify:
- Lower gastrointestinal infection, please specify:
 - . Enteritis infective, please specify:
- Other intra-abdominal infection, please specify:

Skin, soft tissue and muscle infections

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

Blood infections

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

Other infections

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

Uro-genital tract infections

- Genital infection, please specify:
- Urinary tract infection, please specify:

Nervous system infection

- Central nervous system infection, please specify:
- Other nervous system infection, please specify:

Cardiovascular infections

- . Endocarditis infective
- . Other cardiovascular infection, please specify:

Head and neck infections (excluding lymph gland)

- . Ear infection
- Oral cavity infection, please specify:
- Retinitis infective
- Sinusitis infective
- Other eye infection, please specify:

Osteoarticular infections

- Joint infection
- Bone infection

* Only if pathogen 'JC virus' is selected

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



EBMT Centre Identification Code (CIC): ____

Treatment Type GT

Hospital Unique Patient Number (UPN): _____

Patient Number in EBMT Registry: _____

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

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