

HAEMATOPOIETIC CELL TRANSPLANTATION (HCT) --- Day 100 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

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: <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"/> Other treatment related cause of death; specify: _____
<input type="checkbox"/> HCT-related	
<input type="checkbox"/> GT-related	
<input type="checkbox"/> IST-related	
<input type="checkbox"/> Unknown	
<input type="checkbox"/> Other cause of death; specify: _____	

BEST RESPONSE

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

RECOVERY

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
- 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
- Unknown

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

Primary graft failure?

- No
- Yes
- Unknown



EBMT Centre Identification Code (CIC): _____
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Treatment Type HCT
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GRAFT FUNCTION

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

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

Complete for every chimaerism test performed:

(complete only if patient received an allogeneic HCT. This section is optional for malignant disorders)

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

Source of cells tested: Peripheral blood
 Bone marrow

Select cell type and complete relevant test results:

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

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

PREVENTIVE THERAPIES

(Complete only if the patient received an alloHCT)

Immunosuppression:

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

Letermovir used as primary CMV prophylaxis:

- No
 Yes; **Start date:** ____/____/____ (YYYY/MM/DD) Unknown
Letermovir prophylaxis stopped? No
 Yes; **End date:** ____/____/____ (YYYY/MM/DD) Unknown
 Unknown



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Treatment Type HCT

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

COMPLICATIONS POST HCT TREATMENT

-- GvHD --

*Allogeneic HCT only***Did graft versus host disease (GvHD) occur?** No (proceed to 'Complications since the last report - Non-infectious complications') Yes: **Did the patient receive a systemic/immunosuppressive treatment for GvHD?** No Yes: **Date treatment started:** ____/____/____ (YYYY/MM/DD) Unknown**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: **Date of onset:** ____/____/____ (YYYY/MM/DD) Unknown**Maximum observed organ severity score:**

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

Overall maximum grade observed: 1 2 3 4 Unknown Not evaluated**Steroid-refractory acute GvHD:** No Yes: **Date of onset:** ____/____/____ (YYYY/MM/DD) Unknown Unknown Unknown



EBMT Centre Identification Code (CIC): _____

Hospital Unique Patient Number (UPN): _____

Patient Number in EBMT Registry: _____

Treatment Type HCT

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

COMPLICATIONS SINCE THE LAST REPORT

-- GvHD --

*Allogeneic HCT only***Did chronic GvHD occur during this follow-up period?** No Yes: **Date of onset:** ____/____/____ (YYYY/MM/DD) Unknown**Maximum NIH score:**

- Mild
 Moderate
 Severe
 Unknown
 Not evaluated

Date of maximum NIH score: ____/____/____ (YYYY/MM/DD) Unknown**Maximum observed organ severity score:**

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

Steroid-refractory chronic GvHD: No Yes: **Date of onset:** ____/____/____ (YYYY/MM/DD) Unknown Unknown**Was overlap syndrome observed:** No Yes Unknown*(features of both chronic and acute GvHD)* Unknown

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --

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

(Please only report toxic events here that are above Grade 2 and not linked to GvHD and/or infections)

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

Secondary graft failure

Complication observed? No
 Yes
 Unknown

Maximum grade observed during this period: Non-fatal Fatal

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

Cardiac event

Complication observed? No*
 Yes:
 Unknown

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

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

Central nervous system (CNS) toxicity

Complication observed? No*
 Yes:
 Unknown

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

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

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

Complication observed? No*
 Yes:
 Unknown

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

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



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

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

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --
 continued

Liver disorder

Complication observed? No*
 Yes:
 Unknown

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

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

Renal failure (chronic kidney disease, acute kidney injury)

Complication observed? No*
 Yes:
 Unknown

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

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

Respiratory disorders

Complication observed? No*
 Yes:
 Unknown

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

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

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

Complication observed? No*
 Yes:
 Unknown

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

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

* Grade 0-2

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --
continued

Vascular event

Complication observed? No*

Yes:

Unknown

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

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

Avascular necrosis (AVN)

Complication observed? No*

Yes:

Unknown

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

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

Cerebral haemorrhage

Complication observed? No*

Yes:

Unknown

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

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

Haemorrhage (other than cerebral haemorrhage)

Complication observed? No*

Yes:

Unknown

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

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

* Grade 0-2



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

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --
 continued

Cerebral thrombosis

Complication observed? No*

Yes:

Unknown

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

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

Cytokine release syndrome (CRS)

Complication observed? No*

Yes:

Unknown

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

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

Haemophagocytic lymphohistiocytosis (HLH)

Complication observed? No*

Yes:

Unknown

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

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

Pure red cell aplasia (PRCA)

Complication observed? No

Yes:

Unknown

Maximum grade observed: Non-fatal Fatal

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

* Grade 0-2

COMPLICATIONS SINCE THE LAST REPORT

-- Non-infectious complications --
 continued

Posterior reversible encephalopathy syndrome (PRES)

Complication observed? No
 Yes:
 Unknown

Maximum grade observed: Non-severe Severe Fatal Unknown

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

Transplant-associated microangiopathy (TMA)

Complication observed? No*
 Yes:
 Unknown

Maximum grade observed: Non-severe Severe Unknown

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

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

Complication observed? No* Yes Unknown

Maximum CTCAE grade observed Mild Moderate Severe Very severe Fatal Unknown

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

Other complication observed? No* Yes 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

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 infection-related complications below)
 Unknown

Bacterial infection: No Yes Unknown

1) **Start date:** ____/____/____ (YYYY/MM/DD)

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

* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

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

COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

Viral infection: No Yes Unknown

Start date: ____/____/____ (YYYY/MM/DD)

Pathogen*: _____

Infection with clinical implications: No

Yes***: (select all that apply during this period)

Symptoms/signs of disease

Administration of pathogen-directed therapy (including pre-emptive therapy)

Unknown

Indicate at least 1 location involved during this period:

Localisation 1 (CTCAE term)**: _____

Localisation 2 (CTCAE term)**: _____

Localisation 3 (CTCAE term)**: _____

(if patient died)

Contributory cause of death: No Yes Unknown

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

* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

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

*** Also answer 'Yes' in case of pre-emptive therapy

COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

Invasive fungal infection: No Yes Unknown

Start date: ____/____/____ (YYYY/MM/DD)

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)**: _____

(if patient died)

Contributory cause of death: No Yes Unknown

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

* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

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



EBMT Centre Identification Code (CIC): _____

Treatment Type HCT

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Patient Number in EBMT Registry: _____

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

COMPLICATIONS SINCE THE LAST REPORT

-- Infectious complications -- continued

Parasitic infection: No Yes Unknown

1) **Start date:** ____/____/____ (YYYY/MM/DD)

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 1 parasitic infections, copy and fill-in this table as many times as necessary.

* Indicate the pathogen and sub-type (if applicable) by choosing from the list of pathogens provided in Appendix 2

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



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

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

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) **Start date:** ____/____/____ (YYYY/MM/DD)

Infection with clinical implications: No Yes: (select all that apply)
 Symptoms/signs or disease
 Administration of pathogen-directed therapy
 Unknown

Indicate at least 1 location:

Localisation 1 (CTCAE term)*: _____

Localisation 2 (CTCAE term)*: _____

Localisation 3 (CTCAE term)*: _____

(if patient died)

Contributory cause of death: No Yes Unknown

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

* Indicate CTCAE term by choosing from the list provided in Appendix 3 at page 25



EBMT Centre Identification Code (CIC): _____

Hospital Unique Patient Number (UPN): _____

Patient Number in EBMT Registry: _____

Treatment Type HCT

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

SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS

Did a secondary malignancy or autoimmune disorder occur after HCT?

No

Yes: **Was it a secondary malignancy or autoimmune disorder?**

Secondary malignancy

Autoimmune disorder

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

Was this disease an indication for a subsequent HCT/CT/IST/GT?

No (*complete the non-indication diagnosis form*)

Yes (*complete the relevant indication diagnosis form*)

Unknown



EBMT Centre Identification Code (CIC): _____

Treatment Type HCT

Hospital Unique Patient Number (UPN): _____

Patient Number in EBMT Registry: _____

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

ADDITIONAL TREATMENTS

Did the patient receive any additional disease treatment?

No

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

Unknown

ADDITIONAL CELL INFUSIONS

Did the patient receive additional cell infusions during this period?

(excluding a new HCT and CT)

No

Yes; **Is this cell infusion an allogeneic boost* ?** No Yes

** An allogeneic boost is an infusion of cells from the same donor without conditioning, with no evidence of graft rejection.*

Date of the allogeneic boost: ____/____/____ (YYYY/MM/DD)

Is this cell infusion an autologous boost? No Yes

Date of the autologous boost: ____/____/____ (YYYY/MM/DD)

Unknown

If this cell infusion is not a boost, attach the Cell Infusion (CI) sheet available in Appendix 6, completing as many sheets as episodes of cell infusion that took place during this interval; then continue below.

Did the patient receive subsequent HCT/CT (either at your or another centre)?

No

Yes

If the patient had a subsequent HCT/CT, please, make sure that this subsequent treatment is registered using the appropriate treatment form before proceeding.

RELAPSE, PROGRESSION, RECURRENCE OF DISEASE OR SIGNIFICANT WORSENING
(not relevant for Inborn errors)

MRD detectable (with any method): (only for Acute leukaemia)

- No
 Yes: **Date of first detectable MRD:** ____/____/____ (YYYY/MM/DD) Unknown
 Unknown

Was there a relapse, progression, recurrence of disease or significant worsening of organ function related to the primary disease after HCT? *(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

Malignant disorders only:

Type of relapse/progression:

- Medullary:** No Yes Unknown
Extramedullary: No Yes Unknown

If the relapse/progression was extramedullary or both medullary and extramedullary:

Involvement at time of relapse/progression:

- Skin:** No Yes Not evaluated
CNS: No Yes Not evaluated
Testes/Ovaries: No Yes Not evaluated
Other: No Yes; specify: _____

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

Unknown



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

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

DISEASE STATUS

Disease status after HCT 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

Appendix 1 Best Response and Disease Status (Disease Specific)

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

ACUTE LEUKAEMIAS	<i>Go to page 20</i>
CHRONIC LEUKAEMIAS	<i>Go to page 20</i>
PLASMA CELL NEOPLASMS (PCN)	<i>Go to page 21</i>
MPN, MDS, MDS / MPN OVERLAP SYNDROMES	<i>Go to page 23</i>
LYMPHOMAS	<i>Go to page 24</i>
SOLID TUMOURS	<i>Go to page 24</i>
BONE MARROW FAILURE SYNDROMES (BMF) including APLASTIC ANAEMIA (AA)	<i>Go to page 24</i>
AUTOIMMUNE DISORDERS	<i>Go to page 25</i>
HAEMOGLOBINOPATHIES	<i>Go to page 25</i>
OTHER DIAGNOSIS	<i>Go to page 26</i>



EBMT Centre Identification Code (CIC): _____

Treatment Type HCT

Hospital Unique Patient Number (UPN): _____

Patient Number in EBMT Registry: _____

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

Appendix 1
Best Response and Disease Status (Disease Specific)

Acute leukaemias (AML, PLN, Other)

<input type="checkbox"/> Complete remission (CR)
<input type="checkbox"/> Not in complete remission
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

Proceed to next page for Diseases Status section

Chronic leukaemias (CML, CLL, PLL, Other)

Chronic Myeloid Leukaemia (CML):

<input type="checkbox"/> Chronic phase (CP); Number: <input type="checkbox"/> 1 st <input type="checkbox"/> 2 nd <input type="checkbox"/> 3 rd or higher <input type="checkbox"/> Unknown Haematological remission: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown Cytogenetic remission: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown Molecular remission: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not evaluated <input type="checkbox"/> Unknown
<input type="checkbox"/> Accelerated phase; Number: <input type="checkbox"/> 1 st <input type="checkbox"/> 2 nd <input type="checkbox"/> 3 rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Blast crisis; Number: <input type="checkbox"/> 1 st <input type="checkbox"/> 2 nd <input type="checkbox"/> 3 rd or higher <input type="checkbox"/> Unknown
<input type="checkbox"/> Not evaluated
<input type="checkbox"/> Unknown

Proceed to next page for Diseases Status section



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

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

Appendix 1
Best Response and Disease Status (Disease Specific)

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

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

Proceed to next page for Diseases Status section

Plasma cell neoplasms (PCN)

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

Proceed to next page for Diseases Status section



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

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

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

Complete only for PCN Disease Status

Was the patient on dialysis after HCT?

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

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

Complete only for leukaemias (AL, CLL) and PCN Disease Status

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

Minimal residual disease (MRD):

- Negative
- Positive
- Not evaluated
- Unknown

Date MRD status evaluated: ____/____/____ (YYYY/MM/DD) Unknown



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

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

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

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

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

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

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

Technique used for disease assessment: CT scan
 PET
 MRI
 Unknown

Solid tumours

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

Bone marrow failures (incl. AA)

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

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

Did transfusions stop during the follow-up period? Patient was never transfusion dependent
 No
 Yes; **Did the patient return to transfusion dependency afterwards?**
 No
 Yes; **First transfusion date:** ____/____/____ (YYYY/MM/DD) Unknown
 (after transfusion free period)
 Unknown
 Unknown



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

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

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

Autoimmune disorders

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

Haemoglobinopathies

Thalassaemia:

Complete only for Thalassaemia Best Response

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

Complete only for Thalassaemia Disease Status

Patient requires transfusions during follow-up period:

No

Yes; **Date of first transfusion:** ____/____/____ (YYYY/MM/DD) Unknown
(after HCT)

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

Did transfusions stop? No

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

Unknown

Unknown



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

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

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

Haemoglobinopathies

Sickle cell disease:

Complete only for Sickle cell disease Best Response

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

Complete only for Sickle cell disease Disease Status

Sickling episodes occur during follow-up period:

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

Other diagnosis

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

Appendix 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
- . Chlamydomphila
- . 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/HSVV/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



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

Treatment Type HCT

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

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

Appendix 4
 -- Non-infectious and infectious Complications CTCAE term -- **No Reporting Required**

Non-infectious complications

Infectious complications

- Allergic reaction
- All laboratory abnormalities
- All types of pain
- Alopecia
- Blurred vision
- 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

- Minor ophthalmologic bacterial infections
- External otitis treated topically
- Otitis media treated with oral antibiotics
- Isolated lip herpes simplex
- Bacterial tonsillitis or pharyngitis treated orally
- Laryngitis without viral identification managed at home by inhalations or without any intervention
- URTI without viral/bacterial identification managed at home
- Bilateral cervical lymph node enlargement concurrent with URTI that resolved without specific treatment, together with the resolution of URTI
- Local superficial wound infection resolved under topical antibiotics (incl. impetigo)
- Minor skin bacterial infections
- Minor fungal skin infection
- Diaper rash treated with local antifungals
- Candidal balanitis treated topically

- Vaginal candidiasis treated topically or with a single oral dose
- Asymptomatic bacteriuria due to a pathogen not multi-resistant
- Single low urinary tract infection treated orally without need for hospitalisation
- Phlebitis following peripheral intravascular infusion that resolved after intravascular removal without treatment with antibiotics
- Any isolate that is considered part of the normal flora of the place (oral cavity, vagina, skin, stools) except if it carries an antimicrobial resistance that has clinical implications (induce isolation precautions or a pathogen-directed therapy)
- Positive culture without clinical implications
- Neutropenic fever and sepsis of unknown origin

Appendix 5
 -- Intravascular catheter-related infections --

CVC infections:

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

Number of infusions within this episode (10 weeks): _____
 (Count only infusions that are part of the same regimen and given for the same indication)

Source of cells:

- Allogeneic
- Autologous

Type of cells:

- Lymphocytes (DLI)
- Mesenchymal
- Fibroblasts
- Dendritic cells
- NK cells
- Regulatory T-cells
- Gamma/delta cells
- Virus-specific T-cells (VST)
- Other; specify: _____

(Only if 'Type of cells: = Virus-specific T-cells (VST))'

Specificity of VST product: Single-virus specific Multi-virus specific

If single-virus specific, to which virus? *(Please register this virus in the Infectious complications - Viral infection part and fill in the VST in the 'Pre-emptive viral therapy' or 'Treatment of end-organ viral disease' section)*

- EBV
- CMV
- ADV
- BKV or JCV
- HHV-6

If multi-virus specific, to which viruses? *(Please register these viruses in the Infectious complications - Viral infection part and fill in the VST in the 'Pre-emptive viral therapy' or 'Treatment of end-organ viral disease' section)*

- (Select all that apply)**
- EBV
 - CMV
 - ADV
 - BKV or JCV
 - HHV-6

Appendix 6
Cell Infusion Sheet continued

Not applicable for Inborn Errors

Disease status at time of this cell infusion*: _____

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

Indication:

(check all that apply)

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

Only for Acute leukemia donor lymphocyte infusions:

Response to DLI:

- Complete remission (CR) **MRD status:** MRD negative MRD positive Not evaluated Unknown
- Not in CR
- Not evaluated
- Unknown