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

Treatment Type ☐ IST

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

IMMUNOSUPPRESSIVE TREATMENT (IST)
--- Annual/Unscheduled Follow-Up ---

SURVIVAL STATUS

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

Survival status:

☐ Alive
☐ Dead
☐ Lost to follow-up

Date of the last IST for this patient: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

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

☐ Relapse or progression/persistent disease

☐ Secondary malignancy

☐ IST-related

☐ HCT-related

Select treatment related cause: *(select all that apply)*
- ☐ Graft versus Host Disease*(Not applicable for IST-related)*
- ☐ Non-infectious complication
- ☐ Infectious complication
  (select all that apply)
  - ☐ Bacterial infection
  - ☐ Viral infection
  - ☐ Fungal infection
  - ☐ Parasitic infection
  - ☐ Infection with unknown pathogen
- ☐ Other treatment related cause of death; specify: _____

☐ Other cause of death; specify: _____

☐ Unknown

Extended dataset

Was an autopsy performed?

☐ No
☐ Yes
☐ Unknown

BEST RESPONSE

Best response after this IST:

☐ Complete remission (CR):

Is the date that the PR was achieved/first observed known? (*This question can be skipped if reported on the 100 days follow-up)*

☐ No

☐ Yes: **Date PR was achieved/first observed:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*

☐ Partial remission (PR)

☐ Haematological improvement (HI); *NIH partial response*

☐ Stable disease (no change, no response/loss of response)

☐ Relapse / Progression

☐ Not evaluated

☐ Unknown

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

TRANSFUSIONS

RBC transfusions given since last IST episode: ☐ No ☐ Yes ☐ Unknown

If yes:

RBC: ☐ < 20 units
☐ 20 - 50 units
☐ > 50 units
☐ Unknown

RBC irradiated: ☐ No
☐ Yes
☐ Unknown

Platelet transfusions given since last IST episode: ☐ No ☐ Yes ☐ Unknown

If yes:

Platelets: ☐ < 20 units
☐ 20 - 50 units
☐ > 50 units
☐ Unknown

Platelets irradiated: ☐ No
☐ Yes
☐ Unknown

Extended dataset

Haematological tests

Date tests performed: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

Haemoglobin (g/dL)	_____	☐ Not evaluated	☐ Unknown
Was haemoglobin transfused within 4 weeks before assessment?	☐ No	☐ Yes	☐ Unknown
Platelets (10^9 cells/L)	_____	☐ Not evaluated	☐ Unknown
Were platelets transfused within 7 days before assessment?	☐ No	☐ Yes	☐ Unknown
Neutrophils (10^9 cells/L)	_____	☐ Not evaluated	☐ Unknown
Reticulocytes (10^9 cells/L)	_____	☐ Not evaluated	☐ Unknown
Ferritin (ng/mL)	_____	☐ Not evaluated	☐ Unknown

FIRST RELAPSE AFTER IST

Complete this section only for the first relapse after this IST.

First relapse/progression of Aplastic Anaemia *(detected by any method):*

☐ No

☐ Yes: **Date of relapse/progression:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

DISEASE STATUS AT THIS FOLLOW-UP

Disease status this follow-up:

☐ 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

COMPLICATIONS SINCE LAST FOLLOW-UP

Adverse events/non-infectious complications grade 3-5 observed *(based on CTCAE grades)*:

☐ No
☐ Yes (provide details in the table on the next page)
☐ Unknown

COMPLICATIONS SINCE LAST FOLLOW-UP

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*

Extended dataset

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

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

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

Maximum CTCAE grade observed during this period: ☐ Mild ☐ Moderate ☐ Fatal
☐ Severe ☐ Very severe ☐ Unknown

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

Extended dataset

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

Cataract

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*

Extended dataset

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

Haemorrhagic cystitis, non-infectious

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*

Extended dataset

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

* Grade 0-2

COMPLICATIONS SINCE LAST FOLLOW-UP

ARDS, non-infectious

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*

Extended dataset

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

Multiorgan failure, non-infectious

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*

Extended dataset

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

Renal failure (chronic kidney disease, acute kidney injury)

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

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

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

Extended dataset

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

Haemolytic anaemia due to blood group

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*

Extended dataset

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

* Grade 0-2

COMPLICATIONS SINCE LAST FOLLOW-UP

Aseptic bone necrosis

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*

Extended dataset

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

Liver disorder

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

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

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

Extended dataset

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

Cardiovascular event

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

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

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

Extended dataset

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

Stroke

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*

Extended dataset

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

* Grade 0-2

COMPLICATIONS SINCE LAST FOLLOW-UP

Central nervous system (CNS) toxicity

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

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

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

Extended dataset

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

Endocrine event

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

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

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

Extended dataset

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

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

Specify: _____ *Consult appendix 1 for a list of complications that should not be reported*

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

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

Extended dataset

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

* Grade 0-2

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

SECONDARY MALIGNANCIES AND AUTOIMMUNE DISORDERS

Did a secondary malignancy or autoimmune disorder occur?

☐ 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?

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

☐ Unknown

BONE MARROW INVESTIGATION

Bone Marrow Investigation:

☐ No

☐ Yes: **Date of bone marrow investigation:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

Type of bone marrow investigation:

- ☐ Cytology
- ☐ Histology
- ☐ Both

Type of dysplasia:

Erythroid dysplasia	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown
Granulocyte dysplasia	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown
Megakaryocyte dysplasia	☐ No	☐ Yes	☐ Not evaluated	☐ Unknown

Bone marrow assessments:

Cellularity in the bone marrow aspirate	☐ Acellular ☐ Hypocellular ☐ Normocellular ☐ Hypercellular	☐ Focal cellularity ☐ Not evaluated ☐ Unknown
Cellularity in the bone marrow trephine	☐ Acellular ☐ Hypocellular ☐ Normocellular ☐ Hypercellular	☐ Focal cellularity ☐ Not evaluated ☐ Unknown
Fibrosis on bone marrow biopsy	☐ No ☐ Mild ☐ Moderate ☐ Severe	☐ Not evaluable ☐ Not evaluated ☐ Unknown
CD34+ cell count percentage (%)	_____ %	☐ Not evaluated ☐ Unknown
Blast count percentage (%)	_____ % **If the precise blast count is not available, please indicate whether it is:** ☐ ≤ 5% ☐ > 5%	☐ Not evaluated ☐ Unknown ☐ Not evaluated ☐ Unknown

CHROMOSOME ANALYSIS

Chromosome analysis done at follow-up:
(Describe results of the most recent complete analysis)

☐ No
☐ Yes: **Output of analysis:** ☐ Separate abnormalities ☐ Full karyotype
☐ Unknown

If chromosome analysis was done:

What were the results?

☐ Normal
☐ Abnormal: number of abnormalities present: _____
☐ Failed

Date of chromosome analysis: _ _ _ _ **/** _ _ **/** _ _ *(YYYY/MM/DD)* ☐ Unknown

For abnormal results, indicate below whether the abnormalities were absent, present or not evaluated.

abn 3	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
del(13q)	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Monosomy 7	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Trisomy 8	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Other; specify: _______________	☐ Absent	☐ Present		

OR

Transcribe the complete karyotype: ____

MOLECULAR MARKER ANALYSIS

Molecular marker analysis done at follow-up:

☐ No
☐ Yes
☐ Unknown

Date of molecular marker analysis *(if applicable)*: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

Indicate below whether the markers were absent, present or not evaluated.

ASXL1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
BCOR	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
BCORL1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
CBL	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
CSMD1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
DNMT3A	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
ETV6	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
EZH2	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
FLT3	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
GNAS	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
IDH1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
IDH2	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
JAK2	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
KRAS	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
MPL	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
NPM1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
NRAS	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
PHF6	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
PIGA	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
PPM1D	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
PTPN11	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
RAD21	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
RUNX1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
SETBP1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
SF3B1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
SRSF2	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
STAG2	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
TET2	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
TP53	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
	TP53 mutation type: ☐ Single hit ☐ Multi hit ☐ Unknown			
U2AF1	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
ZRSR2	☐ Absent	☐ Present	☐ Not evaluated	☐ Unknown
Other; specify: _____	☐ Absent	☐ Present		

PNH TESTS SINCE LAST FOLLOW-UP

PNH test done:

☐ No
☐ Yes: **Date of PNH test:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown
☐ Unknown

PNH diagnostics by flow cytometry:

☐ Clone absent
☐ Clone present: **Size of PNH clone in percentage (%):** _____
☐ Unknown

Flow cytometry assessment done on:

☐ Granulocytes
☐ RBC
☐ Both
☐ Other; specify: _____

PNH TESTS SINCE LAST FOLLOW-UP continued

Clinical manifestation of PNH:

☐ No

☐ Yes: **Date of clinical manifestation:** _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)* ☐ Unknown

Anti-complement treatment given?

☐ No

☐ Yes, complete the table:

Drug	**New or ongoing**	**Start date** (YYYY/MM/DD) *(only if new drug administered)*	**Treatment stopped/date** (YYYY/MM/DD)
☐ Eculizumab	☐ New drug administration ☐ Ongoing since previous assessment	_ _ _ _ / _ _ / _ _ ☐ Unknown	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Ravalizumab	☐ New drug administration ☐ Ongoing since previous assessment	_ _ _ _ / _ _ / _ _ ☐ Unknown	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Pegcetacoplan	☐ New drug administration ☐ Ongoing since previous assessment	_ _ _ _ / _ _ / _ _ ☐ Unknown	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown
☐ Other; specify*: _____	☐ New drug administration ☐ Ongoing since previous assessment	_ _ _ _ / _ _ / _ _ ☐ Unknown	☐ No ☐ Yes: _ _ _ _ / _ _ / _ _ ☐ Unknown ☐ Unknown

*Please consult the **LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS** on the EBMT website for drugs/regimens names

If there were more drugs given during one line of treatment add more copies of this page.

Appendix 1

-- Non-infectious Complications CTCAE term --

No Reporting Required

- 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