



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
☐ Non-infectious complication
☐ Infectious complication

(select all that apply)

- ☐ Bacterial infection
☐ Viral infection
☐ Fungal infection
☐ Parasitic infection
☐ Infection with unknown pathogen

☐ Other; specify: _____

☐ Unknown

Was an autopsy performed?

- ☐ No
☐ Yes
☐ Unknown

BEST RESPONSE

(Complete only for the first annual follow-up)

Best response after this IST (even if the response got worse again afterwards):

- ☐ 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

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

TRANSFUSIONS

RBC transfusions given since last follow-up: ☐ No ☐ Yes ☐ Unknown

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

- RBC irradiated: ☐ No
☐ Yes
☐ Unknown

Platelet transfusions given since last follow-up: ☐ No ☐ Yes ☐ Unknown

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

- Platelets irradiated: ☐ No
☐ Yes
☐ 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*

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

Veno-occlusive disease (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*

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*

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*

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*

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

Multorgan 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*

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

Renal failure (chronic kidney disease, acute kidney injury)

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

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

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

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

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*

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*

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*

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*

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*

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*

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*

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*

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 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



EBMT Centre Identification Code (CIC): _____

Hospital Unique Patient Number (UPN): _____

Patient Number in EBMT Registry: _____

Treatment Type ☐ IST

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

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		



EBMT Centre Identification Code (CIC): ____

Hospital Unique Patient Number (UPN): _____

Patient Number in EBMT Registry: _____

Treatment Type ☐ IST

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

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.



EBMT Centre Identification Code (CIC): _ _ _ _

Hospital Unique Patient Number (UPN): _ _ _ _ _

Patient Number in EBMT Registry: _ _ _ _ _

Treatment Type ☐ IST

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

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