

Treatment Date \_ \_ \_ / \_ / \_ \_ (YYY/MM/DD)

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

รเ	JR	VIV	AL	ST	ΤA	US
----	----	-----	----	----	----	----

**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	Select treatment related cause: (select all that apply) Graft versus Host Disease Non-infectious complication Infectious complication
HCT-related	(select all that apply) Bacterial infection Viral infection Fungal infection Parasitic infection Infection with unknown pathogen
Other; specify:	

#### Was an autopsy performed?

🗌 No

Yes

Unknown

□ 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:1 (YYYY/MM/DD)   □ Unknown     RBC transfusions given since last follow-up:   □ 20 - 50 units   □ Unknown   Platelet transfusions given since last follow-up:   No   □ Yes   □ Unknown   Platelet transfusions given since last follow-up: Unknown Unknown Unknown Ves	EBMT       Hospital Unique Patient Number (UPN):          Patient Number in EBMT Registry:        Treatment Date          Vertication
□ Complete remission (CR)         □ Partial remission (PR)         □ Haematological improvement (H)): N/H partial response         □ Stable disease (no change, no response/loss of response)         □ Releipes / Progression         □ Not evaluated         □ Unknown         Date best response first observed:I (YYYY/MM/DD)       □ Unknown         RBC:	
RBC: transfusions given since last follow-up: No   RBC: 20 units   RBC: 20 units   RBC: No   Yes Unknown   Platelet transfusions given since last follow-up: No Platelets: 20 units Platelets: 20 units Platelets irradiated: No No No Platelet transfusions given since last follow-up: No Platelets (10 <sup>o</sup> cells/L) Platelets transfused within 7 days before assessment? No No Platelets (10 <sup>o</sup> cells/L) No No No No Platelets (10 <sup>o</sup> cells/L) No No No No Platelets (10 <sup>o</sup> cells/L) No	<ul> <li>Partial remission (PR)</li> <li>Haematological improvement (HI); <i>NIH partial response</i></li> <li>Stable disease (no change, no response/loss of response)</li> <li>Relapse / Progression</li> <li>Not evaluated</li> <li>Unknown</li> </ul>
RBC: 20 - 50 units   20 - 50 units   20 - 50 units   Unknown    Platelet transfusions given since last follow-up: No   Yes   Unknown    Platelets: 20 units   20 - 50 units   Unknown    Platelets: (YYYY/MM/DD) Unknown  Haemoglobin (g/dL)   Haemoglobin (g/dL)   Materets    Platelets (10° cells/L) (No evaluated Unknown)  Were platelets transfused within 7 days before assessment?   No   No   No   Vere platelets transfused within 7 days before assessment?   No   Not evaluated   Unknown    No evaluated Unknown  No evaluated Unknown  No evaluated Unknown	TRANSFUSIONS
Haematological tests         ate 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 <sup>9</sup> cells/L) Not evaluated Unknown         Were platelets transfused within 7 days before assessment? No Yes Unknown         Neutrophils (10 <sup>9</sup> cells/L) Not evaluated Unknown         Reticulocytes (10 <sup>9</sup> cells/L) Not evaluated Unknown	RBC: < 20 units
ate tests performed://(YYY/IMM/DD)   Haemoglobin (g/dL)   Was haemoglobin transfused within 4 weeks before assessment? No   No Yes   Unknown   Platelets (10° cells/L)   Were platelets transfused within 7 days before assessment? No   No Yes   Unknown   Neutrophils (10° cells/L)   Not evaluated   Not evaluated   Unknown   Neutrophils (10° cells/L)   Not evaluated   Not evaluated	Extended dataset
Haemoglobin (g/dL)       Image: Not evaluated image:	Haematological tests
Was haemoglobin transfused within 4 weeks before assessment? No Yes Unknown   Platelets (10 <sup>9</sup> cells/L) Not evaluated Unknown   Were platelets transfused within 7 days before assessment? No Yes Unknown   Neutrophils (10 <sup>9</sup> cells/L) Not evaluated Unknown   Reticulocytes (10 <sup>9</sup> cells/L) Not evaluated Unknown	Date tests performed: / _ / _ / _ (YYYY/MM/DD)  Unknown
Platelets (10 <sup>9</sup> cells/L)   Were platelets transfused within 7 days before assessment?   No   Yes   Unknown   Neutrophils (10 <sup>9</sup> cells/L)   Reticulocytes (10 <sup>9</sup> cells/L)	Haemoglobin (g/dL)
Were platelets transfused within 7 days before assessment? No Yes Unknown   Neutrophils (10 <sup>9</sup> cells/L) Not evaluated Unknown   Reticulocytes (10 <sup>9</sup> cells/L) Not evaluated Unknown	Was haemoglobin transfused within 4 weeks before assessment? No Yes Unknown
Neutrophils (10 <sup>9</sup> cells/L)     Image: Constraint of the second sec	Platelets (10 <sup>9</sup> cells/L)
Reticulocytes (10 <sup>9</sup> cells/L)     Image: Content of the second seco	Were platelets transfused within 7 days before assessment?
	Neutrophils (10 <sup>9</sup> cells/L)
Ferritin (ng/mL)             Image: Constraint of the second	Reticulocytes (10 <sup>9</sup> cells/L)
	Ferritin (ng/mL)

Treatment Type

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

ſ

l



Treatment Type	🗌 IST
----------------	-------

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

### 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):

Yes: Date of relapse/progression: \_ \_ / \_ / \_ (YYYY/MM/DD)

### 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):

|--|--|

 $\Box$  Yes (provide details in the table on the next page)



Treatment Type	IST
rieument type	 101

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

## COMPLICATIONS SINCE LAST FOLLOW-UP

Idiopathic pneumonia syndrome
Complication observed during this follow-up period? 🔲 No*
Yes: Newly developed Ongoing since previous assessment
Maximum CTCAE grade observed during this period:       3       4       5 (fatal)       Unknown
<b>Onset date (</b> <i>YYYY/MM/DD</i> ):// Unknown only if newly developed
Resolved: No
Yes; Stop date (YYYY/MM/DD): / _ / _ Unknown
Veno-occlusive disease (VOD)
Complication observed during this follow-up period?
<ul> <li>Yes: Newly developed Ongoing since previous assessment</li> <li>Unknown</li> </ul>
Maximum CTCAE grade observed during this period: Mild Moderate Fatal
Severe Very severe Unknown
<b>Onset date (</b> YYYY/MM/DD):/ / Unknown Only if newly developed
Resolved: No
Yes; Stop date (YYYY/MM/DD):/ Unknown
Cataract
Complication observed during this follow-up period?
Yes: Newly developed Ongoing since previous assessment
Unknown Maximum CTCAE grade observed during <u>this period:</u> 3 4 5 (fatal) Unknown
Onset date (YYYY/MM/DD):/ Unknown Only if newly developed  Resolved: No
Yes; Stop date (YYYY/MM/DD): / _ / _ Unknown
Haemorrhagic cystitis, non-infectious
Complication observed during this follow-up period? No*
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

<sup>\*</sup> Grade 0-2



Treatment Type	П	IST
freddinent rype		101

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

## COMPLICATIONS SINCE LAST FOLLOW-UP

ARDS, non-infectious
Complication observed during this follow-up period?  No*
Yes: Newly developed Ongoing since previous assessment
Maximum CTCAE grade observed during this period: 3 4 5 (fatal) Unknown
<b>Onset date (</b> <i>YYYY/MM/DD</i> ):// Unknown only if newly developed
Resolved: No
Yes; Stop date (YYY/MM/DD): / _ / _ Unknown
Unknown
Multiorgan failure, non-infectious
Complication observed during this follow-up period? 🔲 No*
Yes: 🗌 Newly developed 🔲 Ongoing since previous assessment
Maximum CTCAE grade observed during this period: 3 4 5 (fatal) Unknown
<b>Onset date (</b> YYYY/MM/DD):/ Unknown Only if newly developed
Resolved: No
Yes; Stop date (YYYY/MM/DD): / _ / _ Unknown
Renal failure (chronic kidney disease, acute kidney injury)
Complication observed during this follow-up period? 🔲 No*
☐ Yes: ☐ Newly developed ☐ Ongoing since previous assessment
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
Haemolytic anaemia due to blood group
Complication observed during this follow-up period? 🔲 No*
Yes: Newly developed Ongoing since previous assessment
Maximum CTCAE grade observed during this period: 3 4 5 (fatal) Unknown
Onset date (YYYY/MM/DD):/ Unknown Only if newly developed
Yes; Stop date (YYYY/MM/DD):/ Unknown



Treatment Type	П	IST
freddinent rype		101

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

## COMPLICATIONS SINCE LAST FOLLOW-UP

Aseptic bone necrosis
Complication observed during this follow-up period? 🔲 No*
🗌 Yes: 🔲 Newly developed 🔲 Ongoing since previous assessment
Maximum CTCAE grade observed during this period: 3 4 5 (fatal) Unknown
<b>Onset date (</b> YYYY/MM/DD):// Unknown only if newly developed
Resolved: No
☐ Yes; <b>Stop date (</b> <i>YYYY/MM/DD):</i> / / Unknown
Liver disorder
Complication observed during this follow-up period? 🔲 No*
☐ Yes: ☐ Newly developed ☐ Ongoing since previous assessment
Maximum CTCAE grade observed during this period: 3 4 5 (fatal) Unknown
<b>Onset date (</b> YYYY/MM/DD): / _ / _ Unknown Only if newly developed
Resolved: 🔲 No
Yes; Stop date (YYYY/MM/DD): / _ / _ Unknown
Cardiovascular event
Complication observed during this follow-up period? 🔲 No*
☐ Yes: ☐ Newly developed ☐ Ongoing since previous assessment
Maximum CTCAE grade observed during this period: 3 4 5 (fatal) Unknown
<b>Onset date (</b> YYYY/MM/DD): / _ / _ Unknown Only if newly developed
Resolved: No
Yes; Stop date (YYYY/MM/DD): / _ / _ Unknown
$\Box$ Unknown
Stroke
Complication observed during this follow-up period?
Yes: Newly developed Ongoing since previous assessment Unknown
Maximum CTCAE grade observed during <u>this period:</u> 3 4 5 (fatal) Unknown
Onset date (YYYY/MM/DD): / _ / _ □ Unknown Only if newly developed Resolved: □ No
 ☐ Yes; Stop date (YYYY/MM/DD): / / ☐ Unknown



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

# 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
Maximum CTCAE grade observed during this period: 3 4 5 (fatal) Unknown
<b>Onset date (</b> YYYY/MM/DD): / / Unknown <i>only if newly developed</i>
Resolved: No
Yes; Stop date (YYY/MM/DD): / _ / _ Unknown
Endocrine event
Complication observed during this follow-up period? 🔲 No*
🗌 Yes: 🔲 Newly developed 🔲 Ongoing since previous assessment
Maximum CTCAE grade observed during this period: 3 4 5 (fatal) Unknown
<b>Onset date (</b> YYYY/MM/DD): / _ / _ Unknown Only if newly developed
Resolved: No
Yes; Stop date (YYYY/MM/DD):/ Unknown
Other complication observed during this follow-up period? $\square$ No*
☐ Yes: ☐ Newly developed ☐ Ongoing since previous assessment
These therefore the 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
<b>Onset date (</b> YYYY/MM/DD):/ / Unknown Only if newly developed
Resolved: No
—

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



Treatment Type	🗌 IST
freatment type	

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

<b>Did a secondary malignancy or autoimn</b> No	nune disorder occur?		
☐ Yes: Was this disease an indication f	or a subsequent HCT/CT/IST?	2	
$\square$ No (complete the non-indication	-		
Yes (complete the relevant ind	ication diagnosis form)		
Unknown			
	BONE MARROW INVESTIG	GATION	
Bone Marrow Investigation:			
 Yes: Date of bone marrow investigati	on:// (YYYY/M/	M/DD) 🔲 Unknown	
Type of bone marrow investigat	ion:		
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:			
	Acellular	Focal cellularity	
	☐ Hypocellular	☐ Not evaluated	
Cellularity in the bone marrow aspirate	☐ Normocellular	☐ Unknown	
	☐ Hypercellular		
	🗌 Acellular	Focal cellularity	
Collularity in the hone marrow tranking	Hypocellular	☐ Not evaluated	
Cellularity in the bone marrow trephine	☐ Normocellular	 ☐ Unknown	
	 □ Hypercellular	—	
	□ No	Not evaluable	
Fibracia on bono marrow bioney	Mild	 □ Not evaluated	
Fibrosis on bone marrow biopsy	 ☐ Moderate	 ☐ Unknown	
	 ☐ Severe	_	
CD34+ cell count percentage (%)	%	🗌 Not evaluated 🛛 Unknown	
	%		
		🗌 Not evaluated 🛛 Unknown	
Blast count percentage (%) If the precise blast count is not available, please indicate whether it is:			
	□ ≤ 5% □ > 5	5% 🔲 Not evaluated 🔄 Unknown	

EBMT	EBMT Centre Identification Code (CIC):          Hospital Unique Patient Number (UPN):          Patient Number in EBMT Registry:	Treatment Type IST Treatment Date// ( <i>YYYY/MM/DD</i> )
	CHROMOSOME ANALY	(SIS
	ome analysis done at follow-up: results of the most recent complete analysis)	
☐ Yes: ☐ Unkn	Output of analysis: 🔲 Separate abnormalities own	Full karyotype
	osome analysis was done: ere the results?	
☐ Norm ☐ Abnoi ☐ Failec	rmal: number of abnormalities present:	
Date of o	chromosome analysis: I I (YYYY/MM/DD) [	] Unknown

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

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

OR

Transcribe the complete karyotype: \_\_\_\_\_



Treatment Type IS
-------------------

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

## **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
	Absent	Present	Not evaluated	Unknown
ТР53	TP53 mutation			
		Multi hit		
U2AF1	Absent		☐ Not evaluated	Unknown
ZRSR2	Absent	□ Present	□ Not evaluated	
Other; specify:	Absent	Present		



Treatment Date \_ \_ \_ / \_ / \_ (YYY/MM/DD)

### PNH TESTS SINCE LAST FOLLOW-UP

PNH test done:          No         Yes: Date of PNH test:// (YYYY/MM/DD)         Unknown
PNH diagnostics by flow cytometry:
Clone absent
Clone present: Size of PNH clone in percentage (%):
Flow cytometry assessment done on:
Both
Other; specify:

(	EBN	ИΤ

# PNH TESTS SINCE LAST FOLLOW-UP continued

### **Clinical manifestation of PNH:**

🗌 No

Yes: Date of clinical manifestation: \_ \_ / \_ / \_ (YYYY/MM/DD)

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	<ul> <li>New drug administration</li> <li>Ongoing since previous assessment</li> </ul>	// Unknown	☐ No ☐ Yes: / / ☐ Unknown ☐ Unknown
🔲 Ravalizumab	<ul> <li>New drug administration</li> <li>Ongoing since previous assessment</li> </ul>	// Unknown	No     Yes://      Unknown     Unknown
Pegcetacoplan	<ul> <li>New drug administration</li> <li>Ongoing since previous assessment</li> </ul>	// Unknown	No     Yes:// Unknown     Unknown
Other; specify*:	<ul> <li>New drug administration</li> <li>Ongoing since previous assessment</li> </ul>	// 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.



Treatment Type	П	IST

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

# Appendix 1

-- Non-infectious Complications CTCAE term --

### No Reporting Required

- · Allergic reaction
- Gastritis
   ities
   · Hematologic toxicities

· Malaise

Tinnitus

Vertigo

· Mucositis

· Sore throat

Weight loss

· Hypertension

· Injection site reaction

- All laboratory abnormalities
   Hematologi
   All types of pain
   Hematoma
- · Alopecia
- · Blurred vision
- · Diarrhoea (enteropathy)
- · Dry mouth
- · Dyspepsia
- · Dysphagia
- · Edema
- $\cdot$  Esophageal stenosis
- Fatigue
- Flashes