



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)

<input type="checkbox"/> Relapse or progression/persistent disease	
<input type="checkbox"/> Secondary malignancy	
<input type="checkbox"/> IST-related	Select treatment related cause: <i>(select all that apply)</i> <input type="checkbox"/> Graft versus Host Disease <i>(Not applicable for IST-related)</i> <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"/> Other cause of death; specify: _____	
<input type="checkbox"/> Unknown	

Extended dataset

Was an autopsy performed?

- No
- Yes
- Unknown



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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 follow up: No Yes Unknown

If yes:

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

RBC irradiated: No
 Yes
 Unknown

Platelet transfusions given since last follow up: 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) _____	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Was haemoglobin transfused within 4 weeks before assessment?	<input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown
Platelets (10 ⁹ cells/L) _____	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Were platelets transfused within 7 days before assessment?	<input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown
Neutrophils (10 ⁹ cells/L) _____	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Reticulocytes (10 ⁹ cells/L) _____	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Ferritin (ng/mL) _____	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> 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-occlusive 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 | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Not evaluated | <input type="checkbox"/> Unknown |
| Granulocyte dysplasia | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Not evaluated | <input type="checkbox"/> Unknown |
| Megakaryocyte dysplasia | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Not evaluated | <input type="checkbox"/> Unknown |

Bone marrow assessments:

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



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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	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
del(13q)	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Monosomy 7	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Trisomy 8	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated	<input type="checkbox"/> Unknown
Other; specify: _____	<input type="checkbox"/> Absent	<input type="checkbox"/> Present		

OR

Transcribe the complete karyotype: _____



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



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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)
<input type="checkbox"/> Eculizumab	<input type="checkbox"/> New drug administration <input type="checkbox"/> Ongoing since previous assessment	____/____/____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Ravalizumab	<input type="checkbox"/> New drug administration <input type="checkbox"/> Ongoing since previous assessment	____/____/____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Pegcetacoplan	<input type="checkbox"/> New drug administration <input type="checkbox"/> Ongoing since previous assessment	____/____/____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
<input type="checkbox"/> Other; specify*: _____	<input type="checkbox"/> New drug administration <input type="checkbox"/> Ongoing since previous assessment	____/____/____ <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes: ____/____/____ <input type="checkbox"/> Unknown <input type="checkbox"/> 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.



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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