Core dataset updates 2024 summary

The current document lists a summary of major updates and changes between the v.1 and v.2 of the Data collection forms (DCFs) included into the EBMT core dataset.

Patient registration

Version	Change	Details
2.0	Change	Rephrased 'Date of informed consent' to first informed consent date
2.0	Add	Added 'Most recent consent date'

Diagnosis forms

Acute leukaemias

Version	Change	Details
2.0	Add	Added 'white blood cell count', '% blasts' in peripheral blood, added '% blasts' in bone marrow
2.0	Change	Re-structured chromosome analysis section to differentiate analysis output, added question about multiple trisomies
2.0	Change	Pre-set chromosome abnormalities required for data entry in EBMT Registry
2.0	Add	Added date of molecular marker analysis, updated list of molecular markers to be entered
2.0	Add	Added question if next generation sequencing was performed

Autoimmune disorders

No changes.

Bone marrow failures including aplastic anaemia

Version	Change	Details
2.0	Add	Updated mutated genes list for Fanconi anaemia
2.0	Add	Added 'Congenital sideroblastic anaemia (CSA) '
2.0	Change	Re-structured chromosome analysis section to differentiate analysis output
2.0	Change	Pre-set chromosome abnormalities required for data entry in EBMT Registry
2.0	Add	Added molecular marker analysis questions
2.0	Add	Added option to report blast count bone marrow percentage less precise if exact results not available

Chronic leukaemia

Version	Change	Details
2.0	Change	Updated classification to 2022 WHO classification
2.0	Change	Re-structured chromosome analysis section to differentiate analysis output
2.0	Change	Pre-set chromosome abnormalities and molecular markers required for data entry in EBMT Registry
2.0	Change	Changed previous therapies section to refer to 'Treatment - non-HCT/CT/GT/IST' form

MDS/MPN overlap syndromes

Version	Change	Details
2.0	Change	Updated classification to 2022 WHO classification
2.0	Add	Added CPSS and CPSS-Mol for CMML
2.0	Change	Re-structured chromosome analysis section to differentiate analysis output
2.0	Change	Pre-set chromosome abnormalities and molecular markers required for data entry in EBMT Registry
2.0	Add	Added question to specify TP53 mutation type

Haemoglobinopathies

Version	Change	Details
2.0	Change	Updated Thalassaemia types
2.0	Remove	Removed % sickle cell question and thalassaemia genotype question

Inborn errors

Version	Change	Details
2.0	Add	Added questions if patient is registered in another registry
2.0	Add	Added option for other inborn errors

Lymphomas

Version	Change	Details
2.0	Change	Updated classification to 5th edition WHO classification

2.0	Remove	Removed follicular lymphoma and mantle cell lymphoma grading, removed KI-67%
2.0	Change	Changed parameters for prognostic indices, added option to only report final score
2.0	Change	Re-structured chromosome analysis section to differentiate analysis output
2.0	Change	Pre-set chromosome abnormalities and molecular markers required for data entry in EBMT Registry

Myelodysplastic syndromes

Version	**Change**	**Details**
2.0	Change	Updated classification to 2022 WHO classification
2.0	Add	Added IPSS-R and IPSS-M
2.0	Change	Re-structured chromosome analysis section to differentiate analysis output
2.0	Change	Pre-set chromosome abnormalities and molecular markers required for data entry in EBMT Registry
2.0	Add	Added question to specify TP53 mutation type

Myeloproliferative neoplasms

Version	**Change**	**Details**
2.0	Change	Updated classification to 2022 WHO classification
2.0	Change	Re-structured chromosome analysis section to differentiate analysis output
2.0	Change	Pre-set chromosome abnormalities and molecular

		markers required for data entry in EBMT Registry
2.0	Add	Added question to specify TP53 mutation type

Other indication diagnosis

No changes.

Non-indication diagnosis

Version	Change	Details
2.0	Change	Updated classifications to reflect changes on diagnosis specific forms

Plasma cell neoplasms

The form name was updated, it was previously called Plasma Cell Disorders (PCD) inc. Multiple Myeloma (MM).

Version	Change	Details
2.0	Change	Updated classification to 2022 WHO classification
2.0	Change	Re-structured chromosome analysis section to differentiate analysis output
2.0	Change	Pre-set chromosome abnormalities required for data entry in EBMT Registry

Solid tumours

No changes.

Treatment forms

Disease status at HCT/CT/GT/IST

Version	Change	Details
2.0	Add	Added question if autopsy was performed
2.0	Add	Added patient EBV/CMV status
2.0	Change	Acute leukaemias: Updated status options, updated bone marrow burden % blast options
2.0	Add	Chronic lymphocytic leukaemias: added sensitivity to last regimen question, added specifications for MRD if patient was in CR
2.0	Add	Prolymphocytic (PLL) and other chronic leukaemias: added sensitivity to last regimen question
2.0	Change	Lymphomas: updated statuses, updated parameters for prognostic indices, added option to only report final score
2.0	Change	MDS: updated classification at treatment to WHO 2022, added IPSS-R and IPSS-M questions
2.0	Change	MDS/MPN: updated classification at treatment to WHO 2022, added CPSS and CPSS-Mol for CMML
2.0	Change	MPN: updated classification at treatment to WHO 2022
2.0	Add	PCN: updated disease status options, added MRD questions for patients in CR or sCR, added dialysis questions
2.0	Change	Solid tumours: updated status questions
2.0	Change	Haemoglobinopathies: restructured section, added question about chelation

2.0	Add	Inborn errors: added immune profiling, added immunomodulatory treatments,
2.0	Add	Bone marrow failures: added ferritin level

Allogeneic HCT

Version	Change	Details
2.0	Add	Added UPN for this treatment, team type and unit number questions
2.0	Add	Added donor blood group and rhesus factor questions
2.0	Add	For inborn errors: added question if donor is a carrier for X-linked diseases
2.0	Add	Added question for donor product if product was cryopreserved prior to infusion
2.0	Change	Changed mismatch question to number of mismatches per locus
2.0	Remove	Removed patient EBV and CMV status questions (moved to 'Status at HCT/CT/GT/IST' form)
2.0	Add	Added questions about TLI and TAI
2.0	Remove	Removed ECP from GvHD preventive treatment
2.0	Add	Added questions about PTCY

Autologous HCT

Version	Change	Details
2.0	Add	Added UPN for this treatment, team type and unit number questions
2.0	Add	Added question about product cryopreservation

Cellular therapy

Version	Change	Details
2.0	Add	Added UPN for this treatment, team type and unit number questions
2.0	Remove	Removed previous therapies section (now to be entered in 'Treatment - non HCT/CT/GT/IST' form)
2.0	Remove	Removed gene editing questions

Immunosuppressive treatment (IST)

Version	Change	Details
2.0	Add	Added UPN for this treatment, team type and unit number questions
2.0	Remove	Removed ferritin level question (moved to 'Status at HCT/CT/GT/IST' form)
2.0	Change	Updated list of immunosuppressive treatment drugs

Autologous Hematopoietic Gene Therapy (GT)

This is a newly introduced form.

Treatment non HCT/CT/GT/IST

This is a newly introduced form.

Follow-up

HCT Day 100

Version	Change	Details
2.0	Add	Added autopsy performed

		question
2.0	Change	Restructured best response section to be diagnosis specific
2.0	Change	Updated graft function section to latest definitions
2.0	Change	Added option to report multiple chimaerism tests and cell-specific chimaerism tests
2.0	Add	Added question if letermovir was used as CMV prophylaxis
2.0	Change	Updated non-infectious complications list, restructured layout, added list of complications that do not need to be reported
2.0	Change	Added option to allow multiple locations (CTCAE) for infectious complications, added if infection was a contributory cause of death, updated pathogen list
2.0	Remove	Removed SARS-CoV-2 questions
2.0	Remove	Removed additional chemotherapy/drugs questions (moved to 'Treatment-non HCT/CT/GT/IST' form)
2.0	Change	Updated disease status section to be diagnosis specific
2.0	Add	Added questions for diagnosis specific best response/last disease status
2.0	Change	Added virus-specific T-cells to type of cells for cell infusion, added diagnosis specific disease status, added date of aGvHD onset after cell infusion

HCT annual/unscheduled

Version	**Change**	**Details**
2.0	Add	Added autopsy performed question

2.0	Change	Restructured best response section to be diagnosis specific
2.0	Change	Updated graft function section to latest definitions
2.0	Change	Added option to report multiple chimaerism tests and cell-specific chimaerism tests
2.0	Add	Added question if letermovir was used as CMV prophylaxis
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2.0	Remove	Removed SARS-CoV-2 questions
2.0	Remove	Removed additional chemotherapy/drugs questions (moved to 'Treatment-non HCT/CT/GT/IST' form)
2.0	Change	Updated disease status section to be diagnosis specific
2.0	Add	Added questions for diagnosis specific best response/last disease status
2.0	Add	Added date questions in pregnancy section
2.0	Change	Added virus-specific T-cells to type of cells for cell infusion, added diagnosis specific disease status, added date of aGvHD onset after cell infusion

Cellular therapy day 100, 6 months, annual & unscheduled

Version	**Change**	**Details**
2.0	Add	Added autopsy performed

		question
2.0	Change	Restructured best response section to be diagnosis specific
2.0	Change	Updated non-infectious complications list, restructured layout, added list of complications that do not need to be reported
2.0	Change	Added option to allow multiple locations (CTCAE) for infectious complications, added if infection was a contributory cause of death, updated pathogen list
2.0	Remove	Removed SARS-CoV-2 questions
2.0	Remove	Removed additional chemotherapy/drugs questions (moved to 'Treatment-non HCT/CT/GT/IST' form)
2.0	Change	Updated disease status section to be diagnosis specific
2.0	Add	Added questions for diagnosis specific best response/last disease status
2.0	Add	Added date questions in pregnancy section
2.0	Change	Added virus-specific T-cells to type of cells for cell infusion, added diagnosis specific disease status, added date of aGvHD onset after cell infusion

IST day 100

Version	**Change**	**Details**
2.0	Add	Added autopsy performed question

IST annual/unscheduled

Version	**Change**	**Details**

2.0	Add	Added autopsy performed question
2.0	Change	Updated non-infectious complications list, restructured layout, added list of complications that do not need to be reported
2.0	Change	Re-structured chromosome analysis section to differentiate analysis output
2.0	Change	Pre-set chromosome abnormalities and molecular markers required for data entry in EBMT Registry

Gene therapy

This is a newly introduced form.

Anonymous events

Version	**Change**	**Details**
2.0	Add	Updated disease classifications to align with core forms where applicable
2.0	Change	Added ‘gene therapy’ to list of treatments