DCF updates summary

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

Patient registration

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Change	Rephrased 'Date of informed consent' to first informed consent date
		Add	Added 'Most recent consent date'

Diagnosis forms

Acute leukaemias

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added 'white blood cell count', '% blasts' in peripheral blood, added '% blasts' in bone marrow
		Change	Re-structured chromosome analysis section to differentiate analysis output, added question about multiple trisomies
		Change	Pre-set chromosome abnormalities required for data entry in EBMT Registry
		Add	Added date of molecular marker analysis, updated list of molecular markers to be entered
		Add	Added question if next generation sequencing was performed
2.1	12.11.2024	Add	Extended dataset
		Add	Added lower and upper limit question for % blast in peripheral blood

Autoimmune disorders

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Change	Updated Previous therapy lines before the HCT/CT list.
		Add	Unknown answer option is added in some fields.

Bone marrow failures including aplastic anaemia

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Updated mutated genes list for Fanconi anaemia
		Add	Added 'Congenital sideroblastic anaemia (CSA) '
		Change	Re-structured chromosome analysis section to differentiate analysis output
		Change	Pre-set chromosome abnormalities required for data entry in EBMT Registry
		Add	Added molecular marker analysis questions
		Add	Added option to report blast count bone marrow percentage less precise if exact results not available
2.1	12.11.2024	Add	Extended dataset

Chronic leukaemia

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Change	Updated classification to 2022 WHO classification
		Change	Re-structured chromosome analysis section to differentiate analysis output
		Change	Pre-set chromosome abnormalities and molecular markers required for data entry in EBMT Registry
		Change	Changed previous therapies section to refer to 'Treatment - non-HCT/CT/GT/IST' form
2.1	12.11.2024	Add	Extended dataset

MDS/MPN overlap syndromes

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Change	Updated classification to 2022 WHO classification
		Add	Added CPSS and CPSS-Mol for CMML
		Change	Re-structured chromosome analysis section to differentiate analysis output
		Change	Pre-set chromosome abnormalities and molecular markers required for data entry in EBMT Registry
		Add	Added question to specify TP53 mutation type
2.1	12.11.2024	Add	Extended dataset

Haemoglobinopathies

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Change	Updated Thalassaemia types
		Remove	Removed % sickle cell question and thalassaemia genotype question

Inborn errors

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added questions if patient is registered in another registry
		Add	Added option for other inborn errors
2.1	12.11.2024	Add	Extended dataset

Lymphomas

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Change	Updated classification to 5th edition WHO classification
		Remove	Removed follicular lymphoma and mantle cell lymphoma grading, removed KI-67%
		Change	Changed parameters for prognostic indices, added option to only report final score
		Change	Re-structured chromosome analysis section to differentiate analysis output
		Change	Pre-set chromosome abnormalities and molecular markers required for data entry in EBMT Registry
2.1	12.11.2024	Add	Extended dataset
		Change	Excluded T-PLL from classification. It is a Chronic Leukaemia

Myelodysplastic syndromes (MDS)

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Change	Updated classification to 2022 WHO classification
		Add	Added IPSS-R and IPSS-M
		Change	Re-structured chromosome analysis section to differentiate analysis output
		Change	Pre-set chromosome abnormalities and molecular markers required for data entry in EBMT Registry
		Add	Added question to specify TP53 mutation type
2.1	12.11.2024	Add	Extended dataset

Myeloproliferative neoplasms (MPN)

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Change	Updated classification to 2022 WHO classification
		Change	Re-structured chromosome analysis section to differentiate analysis output
		Change	Pre-set chromosome abnormalities and molecular markers required for data entry in EBMT Registry
		Add	Added question to specify TP53 mutation type
2.1	12.11.2024	Add	Extended dataset

Other indication diagnosis

Version	Release	Change	Details
1	05.06.2024		

Non-indication diagnosis

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Change	Updated classifications to reflect changes on diagnosis specific forms

Plasma cell neoplasms

The form name was updated in v2.0, it was previously called Plasma Cell Disorders (PCD) inc. Multiple Myeloma (MM).

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Change	Updated classification to 2022 WHO classification
		Change	Re-structured chromosome analysis section to differentiate analysis output
		Change	Pre-set chromosome abnormalities required for data entry in EBMT Registry
2.1	12.11.2024	Add	Extended dataset

Solid tumours

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Change	Removed 'unknown' option for 'Inflammatory breast cancer:' in Breast carcinoma risk factors and staging at diagnosis section

Treatment forms

Disease status at HCT/CT/GT/IST

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added question if autopsy was performed
		Add	Added patient EBV/CMV status
		Change	Acute leukaemias: Updated status options, updated bone marrow burden % blast options
		Add	Chronic lymphocytic leukaemias: added sensitivity to last regimen question, added specifications for MRD if patient was in CR
		Add	Prolymphocytic (PLL) and other chronic leukaemias: added sensitivity to last regimen question
		Change	Lymphomas: updated statuses, updated parameters for prognostic indices, added option to only report final score
		Change	MDS: updated classification at treatment to WHO 2022, added IPSS-R and IPSS-M questions
		Change	MDS/MPN: updated classification at treatment to WHO 2022, added CPSS and CPSS-Mol for CMML
		Change	MPN: updated classification at treatment to WHO 2022
		Add	PCN: updated disease status options, added MRD questions for patients in CR or sCR, added dialysis questions
		Change	Solid tumours: updated status questions
		Change	Haemoglobinopathies: restructured section, added question about chelation
		Add	Inborn errors: added immune profiling, added immunomodulatory treatments,
		Add	Bone marrow failures: added ferritin level
2.1	12.11.2024	Add	Extended dataset
		Change	Moved comorbidities index for Inborn Errors section after the generic comorbidity index questions.

Allogeneic HCT

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added UPN for this treatment, team type and unit number questions
		Add	Added donor blood group and rhesus factor questions
		Add	For inborn errors: added question if donor is a carrier for X-linked diseases
		Add	Added question for donor product if product was cryopreserved prior to infusion
		Change	Changed mismatch question to number of mismatches per locus
		Remove	Removed patient EBV and CMV status questions (moved to 'Status at HCT/CT/GT/IST' form)
		Add	Added questions about TLI and TAI
		Remove	Removed ECP from GvHD preventive treatment
		Add	Added questions about PTCY
2.1	12.11.2024	Add	Extended dataset

Autologous HCT

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added UPN for this treatment, team type and unit number questions
		Add	Added question about product cryopreservation
2.1	12.11.2024	Add	Extended dataset
		Remove	Removed question 'Date of cryopreservation'

Cellular therapy

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added UPN for this treatment, team type and unit number questions
		Remove	Removed previous therapies section (now to be entered in 'Treatment - non HCT/CT/GT/IST' form)
		Remove	Removed gene editing questions

Immunosuppressive treatment (IST)

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added UPN for this treatment, team type and unit number questions
		Remove	Removed ferritin level question (moved to 'Status at HCT/CT/GT/IST' form)
		Change	Updated list of immunosuppressive treatment drugs
2.1	12.11.2024	Add	Extended dataset
		Remove	Removed text in transfusion section 'Number of transfusions before the 1st IST episode:'

Autologous Hematopoietic Gene Therapy (GT)

Version	Release	Change	Details
1	05.06.2024		

Treatment non HCT/CT/GT/IST

Version	Release	Change	Details
1	05.06.2024		
1.1	12.11.2024	Add	Extended dataset
		Change	Added 'progression' to answer option relapse, for question reason for treatment
		Change	The form is both for Malignant disorders and Immunoglobulin-related amyloidosis(AL)

Follow-up

HCT Day 100

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added autopsy performed question
		Change	Restructured best response section to be diagnosis specific
		Change	Updated graft function section to latest definitions
		Change	Added option to report multiple chimaerism tests and cell-specific chimaerism tests
		Add	Added question if letermovir was used as CMV prophylaxis
		Change	Updated non-infectious complications list, restructured layout, added list of complications that do not need to be reported
		Change	Added option to allow multiple locations (CTCAE) for infectious complications, added if infection was a contributory cause of death, updated pathogen list
		Remove	Removed SARS-CoV-2 questions
		Remove	Removed additional chemotherapy/drugs questions (moved to 'Treatment-non HCT/CT/GT/IST' form)
		Change	Updated disease status section to be diagnosis specific
		Add	Added questions for diagnosis specific best response/last disease status
		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
2.1	12.11.2024	Add	Extended dataset
		Remove	Removed option 'isolation / surveillance' from question Infections with clinical implications
		Change	Transplant-associated microangiopathy (TMA) grade observed changed from CTCAE grade to Non-severe, Severe

HCT annual/unscheduled

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added autopsy performed question
		Change	Restructured best response section to be diagnosis specific
		Change	Updated graft function section to latest definitions
		Change	Added option to report multiple chimaerism tests and cell-specific chimaerism tests
		Add	Added question if letermovir was used as CMV prophylaxis
		Change	Updated non-infectious complications list, restructured layout, added list of complications that do not need to be reported
		Change	Added option to allow multiple locations (CTCAE) for infectious complications, added if infection was a contributory cause of death, updated pathogen list
		Remove	Removed SARS-CoV-2 questions
		Remove	Removed additional chemotherapy/drugs questions (moved to 'Treatment-non HCT/CT/GT/IST' form)
		Change	Updated disease status section to be diagnosis specific
		Add	Added questions for diagnosis specific best response/last disease status
		Add	Added date questions in pregnancy section
		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
2.1	12.11.2024	Add	Extended dataset
		Remove	Removed option 'isolation / surveillance' from question Infections with clinical implications
		Change	Transplant-associated microangiopathy (TMA) grade observed changed from CTCAE grade to Non-severe, Severe

Cellular therapy day 100, 6 months, annual & unscheduled

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added autopsy performed question
		Change	Restructured best response section to be diagnosis specific
		Change	Updated non-infectious complications list, restructured layout, added list of complications that do not need to be reported
		Change	Added option to allow multiple locations (CTCAE) for infectious complications, added if infection was a contributory cause of death, updated pathogen list
		Remove	Removed SARS-CoV-2 questions
		Remove	Removed additional chemotherapy/drugs questions (moved to 'Treatment-non HCT/CT/GT/IST' form)
		Change	Updated disease status section to be diagnosis specific
		Add	Added questions for diagnosis specific best response/last disease status
		Add	Added date questions in pregnancy section
		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
2.1	12.11.2024	Add	Extended dataset
		Change	B-cell count monitored after CT should be asked at every follow-up
		Remove	Removed option 'isolation / surveillance' from question Infections with clinical implications

IST day 100

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added autopsy performed question
2.1	12.11.2024	Add	Extended dataset

IST annual/unscheduled

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Added autopsy performed question
		Change	Updated non-infectious complications list, restructured layout, added list of complications that do not need to be reported
		Change	Re-structured chromosome analysis section to differentiate analysis output
		Change	Pre-set chromosome abnormalities and molecular markers required for data entry in EBMT Registry
2.1	12.11.2024	Add	Extended dataset
		Change	In the best response section added Complete only for the first annual follow-up.

Gene therapy day 100, 6 months, 1 year, 18 months,2 years, annual & unscheduled

Version	Release	Change	Details
1	05.06.2024		
1.1	12.11.2024	Add	Extended dataset
		Remove	Removed option 'isolation / surveillance' from question Infections with clinical implications

Anonymous events

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024	Add	Updated disease classifications to align with core forms where applicable
		Change	Added 'gene therapy' to the list of treatments

Anonymous events