

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
2.2	28.03.2025	Add	Added question about donor cell leukaemia
		Add	Added "(if applicable)" for the Other AML classification

		Add	Added "(Optional)" for the FAB classification
		Add	Added "(Not applicable in Ph+ ALL (BCR/ABL present))" for the Phi-like ALL question

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.
2.1	28.03.2025	Change	Vasculitis sub-classification / Other, specify changed to " Other vasculitis, specify"
		Change	Connective tissue / Systemic sclerosis (SSc) changed to "(SSc, scleroderma)"
		Change	Systemic sclerosis (SSc)/ SSc type / Other, specify changed to "Other SSc type, specify"

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
2.2	28.03.2025	Change	Gene list updated
		Change	Immune profiling section should be asked only for IEI, added hint

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
2.2	28.03.2025	Change	Classification updated for Cytogenetic questions

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
2.2	28.03.2025	Add	Added question about donor cell leukaemia
		Remove	Removed from options "Other abn(5q); specify, Other abn(7q); specify, Other abn(3q); specify"

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
2.1	28.03.2025	Add	Added question about donor cell leukemia (in AL and MDS section)
		Add	Added "AML with myelodysplasia related changes? and AML with myelodysplasia related changes? No Yes; Was there a previous diagnosis of MDS, MPN or MDS/MPN?"
		Change	Autoimmune disorders diagnosis classification / Connective tissue / Systemic sclerosis (SSc) changed to "(SSc, scleroderma)"
		Change	Autoimmune disorders diagnosis classification / Connective tissue / Systemic sclerosis (SSc)/ SSc type / Other, specify changed to "Other SSc type, specify"
		Change	Autoimmune disorders diagnosis classification / Vasculitis/ Other; specify changed to "Other vasculitis, specify"
		Change	Classification Other, specify changed to "Other solid tumour, specify"

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
2.2	28.03.2025	Change	Cytogenetic questions applicable for Immunoglobulin-related (AL) amyloidosis too

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
2.1	28.03.2025	Change	Classification Other, specify changed to "Other solid tumour, specify"
		Change	Breast carcinoma risk factors and staging at diagnosis / Carcinoma type / Other; specify changed to "other type, specify"

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.
2.2	28.03.2025	Add	Added "Untreated/ Upfront" option on Acute leukemia disease status

		Add	Added to comorbidities table definition for pediatric obesity
		Add	PCN: added question regarding EMD
		Add	Immune profiling and immunomodulatory treatment sections for IEI, added hint
		Add	For patients less than 2 years old added question, "Patient age at initiation in months"
		Change	Solid tumours/ Organ involvement at time of this treatment / Other; specify changed to "Other organ involvement, specify"
		Change	Autoimmune diseases / Systemic sclerosis only/ SSc subset/ Other: specify changed to "Other SSc type, specify"
		Change	Autoimmune diseases / Multiple sclerosis only/ Status at mobilisation/ Other: specify changed to " Other MS type, specify"

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
2.2	28.03.2025	Change	Renamed Donor & Graft Info section, it was duplicated on the forms. ("Donor & Graft information" the first section changed to

			“Donor & Graft” second section to “ Donor information”)
		Change	Changed text in brackets to be clearer. “Include all allogeneic HCTs this patient received in the past”
		Add	Added hint for donor age if source is cord blood

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'
2.2	28.03.2025	Change	Changed text in brackets to be clearer. “Include all allogeneic HCTs this patient received in the past”
		Change	Preparative regimen for Autoimmune diseases:Other; specify changed to “Other serotherapy, specify”

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
2.1	28.03.2025	Remove	Removed hide registration questions, replaced by embargo functionality
		Add	Added extra explanation on B-cell aplasia
		Add	Added hint for donor age if source is cord blood

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		
1.1	28.03.2025	Remove	Removed hide registration questions, replaced by embargo functionality
		Change	Shifted the specify question from 'Treosulfan' to 'Other' option in PREPARATIVE REGIMEN section

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)
1.2	28.03.2025	Change	"Type of relapse prevention" (MRD) rephrased to "MRD status at start of treatment" and updated the option to CR MRD negative / CR MRD positive / CR MRD unknown
		Add	Added question for consolidation into "MRD status at the start of treatment"

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
2.2	28.03.2025	Add	Appendix 1 best response and disease status , for CLL, PLL and other CL added option "relapse"
		Add	Added Ambisome (IV or inhalations) to the list of antifungal prophylaxis
		Add	Added simplified infectious complications CTCAE appendix, making

			detailed localisation for extended only
		Add	Immune profiling and immunomodulatory treatment sections for IEI, added hint
		Change	aGVHD and cGVHD section paraphrased the organ involved section to "Organ involved during the course of treatment."
		Change	In appendix 2 changed "Klebsiella other spp (carbapenem-resistant) (specify)" to "Klebsiella (any species) (carbapenem-resistant)"

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
2.2	28.03.2025	Add	Appendix 1 best response and disease status, for CLL, PLL and other CL added option "relapse"
		Add	Added Ambisome (IV or inhalations) to the list of antifungal prophylaxis
		Add	Added 'Ongoing' or 'Newly started' After the question Did the patient receive any additional disease treatment? if the answer is Yes
		Add	Added simplified infectious complications CTCAE appendix, making detailed localisation for extended only
		Add	Immune profiling and immunomodulatory treatment sections for IEI, added hint
		Change	aGVHD and cGVHD section paraphrased the organ involved section to "Organ involved during the course of treatment."
		Change	In appendix 2 changed "Klebsiella other spp (carbapenem-resistant) (specify)" to "Klebsiella (any species) (carbapenem-resistant)"

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
2.2	28.03.2025	Add	Added Ambisome (IV or inhalations) to the list of antifungal prophylaxis
		Add	Added 'Ongoing' or 'Newly started' After the question Did the patient receive any additional disease treatment? if the answer is Yes
		Add	Added simplified infectious complications CTCAE appendix, making detailed localisation for extended only
		Change	In appendix 2 changed "Klebsiella other spp (carbapenem-resistant) (specify)" to "Klebsiella (any species) (carbapenem-resistant)"
		Change	B-cell count questions structure updated accounting for repetitive nature of questions

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
1.2	28.03.2025	Add	Added Ambisome (IV or inhalations) to the list of antifungal prophylaxis
		Add	Added simplified infectious complications CTCAE appendix, making detailed localisation for extended only
		Add	Immune profiling and immunomodulatory treatment sections for IEI,

			added hint
		Change	In appendix 2 changed "Klebsiella other spp (carbapenem-resistant) (specify)" to "Klebsiella (any species) (carbapenem-resistant)"

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

EBMT List of disease classifications

Version	Release	Change	Details
1	21.08.2023		
2.0	05.06.2024		
2.1	12.11.2024		
2.2	28.03.2025	Add	Added more diagnoses classifications in Acute leukemia form