

Document Type		Form
Index Number	I	Registry 109
Version Number		1.0
Title		Disease status HCT CT IST Day 0
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Authorised By	I	Annelot van Amerongen
Authorised On	Ι	22-Aug-2023
Release Date:		22-Aug-2023



Treatment Type	🗌 нст 🔲 ст	🗌 IST	Other

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

DISEASE STATUS AT HCT/CT/IST Day 0

	PATIENT STATUS (All Diagnoses)										
Date of HCT/CT/IST: _ (or planned date of HC											
Survival status at HC	T/CT/IST:										
Alive											
Died after condition	ning but be	efore HCT/C	CT/IST								
Died after apheresi	is but befo	ore cell infus	sion								
Date of death:	/	/(YYYY	//MM/DD))							
Main cause of dea (check only one m)									
Relapse or prog	gression/p	ersistent dis	sease								
Secondary mali	gnancy										
Cellular therapy	/-related						Graft vers Non-infec	ent related sus host dis tious comp complicati Il that apply	ease lication		
HCT-related							Uira	terial infect l infection gal infectio asitic infecti ction with u	n ion	thogen	
☐ Other; specify: _	Other; specify:										
Performance statu Type of scale used:		tion of HC	T/CT/IST Score:	「 (choose c	only (one):					
☐ Karnofsky ☐ Lansky	10	20	□ 30	40] 50	□ 60	□ 70	80	09 🗌	100
	0 🗌	□ 1		2		3		4			
Patient weight at in Patient height at ir						kg cm					

Index: Registry 109 | Title: Disease status HCT CT IST Day 0 | Version: 1.0 | Effective Date: 2023-08-22 | THIS IS AN UNCONTOLLED COPY

 $Disease_status_HCT_CT_IST_Day0_v1.0$

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Definition:

Treatment Type	🗌 нст 🔲 ст	IST Other
Treatment Date _	// (YY	YY/MM/DD)

COMORBIDITY INDEX

Sorror et al., Blood, 2005 Oct 15; 106(8): 2912-2919: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1895304

Was there any <u>clinically significant</u> co-existing disease or organ impairment <u>as listed below</u> at time of patient assessment prior to the preparative regimen?

□ No

☐ Yes (indicate each comorbidity below)

Unknown

COMORBIDITY:

Solid tumour, previously present	Treated at any time point in the patient's past history, excluding non-melanoma skin cancer. Indicate type:	🗌 No	🗌 Yes	☐ Not evaluated
Inflammatory bowel disease	Crohn's disease or ulcerative colitis	🗌 No	🗌 Yes	☐ Not evaluated
Rheumatologic	SLE, RA, polymyositis, mixed CTD or polymyalgia rheumatica	🗌 No	🗌 Yes	Not evaluated
Infection	Requiring continuation of antimicrobial treatment after day 0	🗌 No	🗌 Yes	Not evaluated
Diabetes	Requiring treatment with insulin or oral hypoglycaemics but not diet alone	🗌 No	🗌 Yes	Not evaluated
Renal: moderate/severe	Serum creatinine > 2 mg/dL or >177 µmol/L, on dialysis, or prior renal transplantation	🗌 No	☐ Yes	☐ Not evaluated
Hepatic: mild	Chronic hepatitis, bilirubin between Upper Limit Normal (ULN) and 1.5 x ULN, or AST/ALT between ULN and 2.5 × ULN	🗌 No	🗌 Yes	Not evaluated
Hepatic: moderate/severe	Liver cirrhosis, bilirubin greater than 1.5 × ULN, or AST/ALT greater than 2.5 × ULN	🗌 No	🗌 Yes	Not evaluated
Arrhythmia	Atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias	🗌 No	🗌 Yes	Not evaluated
Cardiac	Coronary artery disease, congestive heart failure, myocardial infarction, $EF \le 50\%$, or shortening fraction in children (<28%)	□ No	☐ Yes	□ Not evaluated
Cerebrovascular disease	Transient ischaemic attack or cerebrovascular accident	🗌 No	🗌 Yes	Not evaluated
Heart valve disease	Except mitral valve prolapse	🗌 No	🗌 Yes	Not evaluated
Pulmonary: moderate	DLco and/or FEV1 66-80%, or dyspnoea on slight activity	🗌 No	🗌 Yes	Not evaluated
Pulmonary: severe	DLco and/or FEV1 \leq 65%, or dyspnoea at rest or requiring oxygen	🗌 No	🗌 Yes	☐ Not evaluated
Obesity	Patients with body mass index > 35 kg/m ²	🗌 No	🗌 Yes	Not evaluated
Peptic ulcer	Requiring treatment	🗌 No	🗌 Yes	Not evaluated
Psychiatric disturbance	Depression or anxiety requiring psychiatric consultation or treatment	🗌 No	🗌 Yes	Not evaluated

(EB	MT

Treatment Type	🗌 нст 🔲 ст	IST Other
Treatment Date _	//(YY	YY/MM/DD)

COMORBIDITY INDEX continued

Sorror et al., Blood, 2005 Oct 15; 106(8): 2912-2919: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1895304

Was there any additional <u>major</u> clinical abnormality not listed above and present prior to the preparative regimen?

 No

 Yes; specify:

 Were there any autoimmune diseases?

 No

 Yes; specify:

 Date:

 Date:

 YYYY/MM/DD

COMORBIDITY INDEX

Inborn Errors of Immunity only

COMORBIDITY:	Definition:			
Chronic lung disease	Bronchiectasis, interstitial pneumonitis, GLILD, oxygen dependency, structural lung disease (e.g. pneumatoceles)	□ No	🗌 Yes	Not evaluated
Previous haematological malignancy	Leukaemia, lymphoma, myelodysplastic syndrome (MDS)	🗌 No	Yes	☐ Not evaluated
Failure to thrive	Weight <3 rd percentile or requirement for (par)enteral feeding	🗌 No	Yes	Not evaluated
Active infection at HCT	Any infection requiring therapy in the immediate pre HCT period	🗌 No	☐ Yes	☐ Not evaluated
Lymphoproliferation	I.e. splenomegaly, organ specific lymphoproliferation	🗌 No	🗌 Yes	Not evaluated
Pre-HCT organ impairment	Infectious or non-infectious (including neurologic)	🗌 No	☐ Yes	□ Not evaluated
Autoimmunity/autoinflammation	Active at HCT (includes patients in remission but on immunomodulatory treatment within 3 months before HCT)	□ No	PYes	☐ Not evaluated



Treatment Type	🗌 нст 🔲 ст	IST Other
Treatment Date _	//(YY	YY/MM/DD)

SARS-CoV-2 RELATED QUESTIONS

Did the patient have a <u>symptomatic</u> SARS-CoV-2 infection (positive PCR or antigen test) in the 3 months prior to the day of treatment? Note: do not report here if the infection was asymptomatic.

🗌 No

□ Yes; Date: ____/ __/ __(*YYYY/MM/DD*)

Did the patient have an ongoing SARS-CoV-2 infection (positive PCR or antigen test) at the moment of the start of the conditioning regimen?

🗌 No

Yes

END OF GENERAL SECTION

TO COMPLETE DISEASE STATUS AT HCT/CT/IST REPORT, PLEASE FILL IN THE

APPLICABLE DIAGNOSE-SPECIFIC QUESTIONS ATTACHED



Treatment Type	🗌 нст 🔲 ст	IST	Other
Treatment Date _	// (YY	YY/MM/DE))

Status at treatment

Complete only for one main indication diagnosis for which this HCT/CT/IST is given.

ACUTE LEUKAEMIAS	Go to page 6
CHRONIC LEUKAEMIAS - Chronic Myelogenous Leukaemias (CML)	Go to page 7
CHRONIC LEUKAEMIAS - Chronic Lymphocytic Leukaemias (CLL)	Go to page 8
CHRONIC LEUKAEMIAS - Prolymphocytic (PLL) and Other Chronic Leukaemias	Go to page 9
LYMPHOMAS	Go to page 10
MYELODYSPLASTIC SYNDROMES (MDS)	Go to page 11
COMBINED MYELODYSPLASTIC SYNDROMES/MYELOPROLIFERATIVE NEOPLASMS (MDS/MPN)	Go to page 12
MYELOPROLIFERATIVE NEOPLASMS (MPN)	Go to page 13
PLASMA CELL DISORDERS (PCD) including MULTIPLE MYELOMA (MM)	Go to page 15
SOLID TUMOURS	Go to page 16
AUTOIMMUNE DISEASES	Go to page 17
HAEMOGLOBINOPATHIES	Go to page 18

(EBMT
	_

Treatment Type	🗌 нст 🔲 ст	🗌 IST	Other
Treatment Date _	//(YY	YY/MM/DE))

ACUTE LEUKAEMIAS
Status at treatment

Status:				
Primary induction failure				
1 st complete haematologi	cal remission (CR)		
☐ 1 st relapse				
☐ 2 nd complete haematologi	cal remission ((CR)		
\square 2 nd relapse				
\square 3 rd or higher complete ha	ematological re	emission (CR)		
\square 3 rd or higher relapse				
Number of induction cours				
Date of the last relapse bet (if applicable)	ore this treatr	ment: / _	_I _ (YYYY/MM/DD)	
CD19 expression at the las	t relapse: 🗌	Positive 🔲 Ne	gative 🔲 Not evaluated	
Bone marrow burden (% b	lasts): 0	% 🔲 Not evalua	ated 🔲 Unknown	
Involvement at time of tre	atment:			
Medullary only				
Extra-medullary only				
Both, medullary and ext	a-medullary			
Unknown				
Organs involved at time o	f treatment:			
Skin:	□ No	☐ Yes	☐ Not evaluated	
CNS:		☐ Yes	☐ Not evaluated	
		☐ Yes	☐ Not evaluated	
Testes/Ovary:		☐ Yes		
Other; specify:				
Complete this section only if				י ו ו
Minimal residual disease	(MRD) at initia	ation of treatme	nt:	i
Positive				1
Negative				
Not evaluated				ļ
Date MRD status evaluate	d /			
		_/(//////////////////////////////////		1
Sensitivity of MRD assay	1			1
$\square < 10^{-5}$ $\square < 10^{-4}$				
$\square < 10^{-3}$				į
Other; specify:				i
				I
Method used:				1
				1
Flow cytometry				
Other; specify: Index: Registry 109 Tif	le: Disease stati	us HCT CT IST Dav	0 Version: 1.0 Effective Date: 2023-08-22 THIS IS AN	



CHRONIC LEUKAEMIAS Chronic Myelogenous Leukaemias (CML) - Status at treatment

Status:			
Chronic phase (CP)			
Number:	Haematological remission:	Cytogenetic remission:	Molecular remission:
$\square 2^{nd}$	Yes		
☐ 3 rd or higher	Not evaluated	Not evaluated	□ Not evaluated
Unknown	Unknown	Unknown	Unknown
Accelerated phase			
<u>Number:</u>			
□ 1 st			
□ 2 nd			
☐ 3 rd or higher			
🔲 Unknown			
Blast crisis			
<u>Number:</u>			
□ 1 st			
□ 2 nd			
☐ 3 rd or higher			
🗌 Unknown			



Treatment Type	П нст П с.	T 🗌 IST	Other
freatment type			

CHRONIC LEUKAEMIAS Chronic Lymphocytic Leukaemias (CLL) - Status at treatment

Status:

Complete remission (CR) Partial remission (PR)	
☐ Stable disease (SD) ☐ Relapse (untreated)	
Progressive disease (PD)	
Never treated Unknown	
Complete this section only if the disease status is CR	
Minimal residual disease (MRD) at initiation of treatment: (by FACS or PCR)	
□ Negative □ Positive	
│ □ Not evaluated	1
	1



CHRONIC LEUKAEMIAS Prolymphocytic (PLL) and Other Chronic Leukaemias Status at treatment

Status:

- Complete remission (CR)
- Partial remission (PR)
- ☐ Stable disease (SD)
- □ Relapse (untreated)
- Progressive disease (PD)
- □ Never treated
- Unknown



Treatment Type	🗌 нст 🔲 ст	IST Other
Treatment Date _	// (YY	YY/MM/DD)

LYMPHOMAS Status at treatment

Status:						
Complete remission (CR)						
Unconfirmed (Cl	RU*) [] Confirmed				
* CRU: Complete r	esponse wi	ith persistent	scan abno	ormalities of u	unknown sig	gnificance
Partial response (PR) with o	r without pr	ior CR				
Stable disease						
Untreated relapse from previo	ous CR / unt	reated progre	ession from	n previous PR		
Histopathological ve	erification of	relapse:	🗌 No	🗌 Yes		
Chemorefractory relapse or	progressior	n, including p	orimary refr	actory diseas	se	
Histopathological ve	erification of	relapse:	🗌 No	🗌 Yes		
Disease status unknown						
CT scan PET MRI Parameters for international p	prognostic	indices:				
Age at diagnosis :	_years (this	s is automati	cally calcu	lated in the d	atabase)	
LDH levels elevated:	🗌 No	🗌 Yes	🗌 Not e	evaluated		
Ann Arbor staging:					🗌 Not e	valuated
ECOG performance status:	0	1	2	3	4	Not evaluated
> 1 extranodal site involved:	🗌 No	🗌 Yes	🗌 Not e	evaluated		
> 4 nodal sites involved:	🗌 No	🗌 Yes	🗌 Not e	evaluated		
Hemoglobin < 120g/L:	🗌 No	🗌 Yes	Not e	evaluated		
White Blood Cell count:		x 10 ⁹ cel	ls/L		🗌 Not e	valuated



Treatment Type	🗌 нст 🔲 ст	🗌 IST	Other

MYELODYSPLASTIC SYNDROMES (MDS) Status at treatment

Classification at treatment (WHO 2016):

MDS with single lineage dysplasia (MDS-SLD)

 $\hfill\square$ MDS with ring sideroblasts (MDS-RS)

Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality

☐ MDS with multilineage dysplasia (MDS-MLD)

MDS-RS with single lineage dysplasia (MDS-RS-SLD)

☐ MDS-RS with multilineage dysplasia (MDS-RS-MLD)

MDS with excess blasts (EB)-1

MDS with excess blasts (EB)-2

Refractory cytopenia of childhood

☐ MDS unclassifiable (MDS-U)

Status:

Complete remission (CR)	Number:	
	2 nd	
	3 rd or higher	
	Unknown	
Improvement but no CR		
Primary refractory phase (no change)		
☐ Relapse	Number:	
	2 nd	
	☐ 3 rd or higher	
	Unknown	
Progression/Worsening		
Never treated (supportive care or treatment without chemotherapy)		
🔲 Unknown		



COMBINED MYELODYSPLASTIC SYNDROMES/MYELOPROLIFERATIVE NEOPLASMS (MDS/MPN) - Status at treatment

Classification:

Chronic myelomonocytic leukaemia (CMMoL, CMML): CMML type:	Myelodysplastic
	Myeloproliferative
WHO subclassification (2016):	CMML-0
	CMML-1
	CMML-2
	Unknown
Juvenile myelomonocytic leukaemia (JCMMoL, JMML, JCML, JCMML)	
Atypical CML (t(9;22) negative and BCR-ABL1 negative)	
MDS/MPN with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)	
MDS/MPN unclassifiable	

Status:

Complete remission (CR)	Number:
	□ 2 nd
	☐ 3 rd or higher
	Unknown
Improvement but no CR	
Primary refractory phase (no change)	
🔲 Relapse	Number:
	2 nd
	3 rd or higher
	Unknown
Progression/Worsening	
☐ Never treated (supportive care or treated)	tment without chemotherapy)
🔲 Unknown	



MYELOPROLIFERATIVE NEOPLASMS (MPN) Status at treatment

Classification at treatment (WHO 2016):

Primary myelofibrosis (Chronic idiopathic myelofibrosis; fibrosis with myeloid metaplasia)
Secondary myelofibrosis (Transformed to myelofibrosis from PV/ET)
Polycythaemia vera (PV)
Essential or primary thrombocythaemia (ET)
Hyper eosinophilic syndrome (HES)
Chronic eosinophilic leukaemia (CEL)
Chronic neutrophilic leukaemia
Systemic mastocytosis
Mast cell leukaemia
Mast cell sarcoma
MPN not otherwise specified
Myeloid and lymphoid neoplasms with FGFR1 abnormalities (Stem cell leukaemia-lymphoma syndrome, 8p11 syndrome)
Myeloid and lymphoid neoplasms with PDGFRA rearrangement
Myeloid and lymphoid neoplasms with PDGFRB rearrangement
Myeloid and lymphoid neoplasms with PCM1-JAK2 rearrangement
Transformed to AML
Other; specify:

Status:

Complete remission (CR)	Number:
	□ 2 nd
	☐ 3 rd or higher
Improvement but no CR	
Primary refractory phase (no change)	
□ Relapse	Number:
	□ 2 nd
	☐ 3 rd or higher
Progression/Worsening	
Never treated (supportive care or treatment without chemotherapy)	
Unknown	



MYELOPROLIFERATIVE NEOPLASMS (MPN) Status at treatment				
Blast count (peripheral blood): % 🔲 Not evaluated 📋 Unknown				
Spleen size: cm (below costal margin)	□ Not evaluated □ Unknown			
Spleen span in ultrasound or CT scan:	cm (maximum diameter) 🛛 Not evaluated 🔲 Unknown			
JAK inhibitor exposure between diagnosis and tre	Yes			
Was a JAK inhibitor continued during conditionin	g?			
☐ Yes: Dose: mg/day				
Start date: / / (YYYY/MM/	DD)			
End date: / / (YYYY/MM/E	DD)			
Response status: Spleen response No response/loss of response Primary resistance Unknown				
Myelofibrosis only:				
DIPSS Risk score at treatment: Low risk Intermediate - 1 Intermediate - 2 High risk Not evaluated Unknown	MIPSS70 score at treatment: Low risk Intermediate High risk Not evaluated Unknown			
Secondary myelofibrosis only (post-ET MF, post-PV MF):				
MYSEC-PM score at time of secondary MF diagno Low risk Intermediate - 1 Intermediate - 2 High risk Not evaluated Unknown	osis:			



Treatment Type	🗌 нст 🔲 ст	🗌 IST	Other

PLASMA CELL DISORDERS (PCD) incl. MULTIPLE MYELOMA (MM) Status at treatment

Status:

MRD negative CR	
Stringent complete remission (sCR)	Number:
Complete remission (CR)	☐ 1 st
Ury good partial remission (VGPR)	$\square \stackrel{\bullet}{=} 2^{nd}$
Partial remission (PR)	☐ ² ☐ 3 rd or higher
Stable disease / No change	
Progression	
Never treated	
🔲 Unknown	



Treatment Type	🗌 нст 🔲 ст	🗌 IST	Other

SOLID TUMOURS Status at treatment

Status:			
Adjuvant			
Never treated (upfront)			
Stable disease/no response			
Complete remission (CR)			
Unconfirmed (UCR*)		Number:	
		1 st	
* UCR: complete response w	vith persistent scan	□ 2 nd	
abnormalities of unkn		☐ 3 rd or higher	
		Unknown	
1 st partial response (PR1)			
Relapse			
Number:	Sensitivity to chemotherapy:		
	Sensitive		
□ 2 nd	🗌 Resistant		
☐ 3 rd or higher	Untreated		
Unknown			
Progressive disease (PD)			
Unknown			
Complete this section only if the disease status <u>is not CR</u>			
Organ involvement at time of this treatmen			
Nodes below diaphragm			
¦ ☐ Nodes above diaphragm			
Liver			
Bone			
Lung			
Soft tissue			
Cher; specify:			
Germ cell tumours only:			
Risk category at disease recurrence (or platinum refractoriness) following first line chemotherapy: Note: according to International Prognostic Factors Study Group classification published in 2010.			

	Very low
	Low
	Intermediate
	High
	Very high
	Not evaluated gistry 109 Title: Disease status HCT CT IST Day 0 Version: 1.0 Effective Date: 2023-08-22 THIS IS AN
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Treatment Type	🗌 нст 🔲 ст	🗌 IST	Other

AUTOIMMUNE DISEASES
Status at Mobilisation

<u>.</u>	
Status	
Julius	

Systemic sclerosis only: SSc subset: Diffuse cutaneous Limited cutaneous
Sine scleroderma
Other; specify:
Assessments at time of mobilisation (within 3 months before mobilisation):
Creatinine Clearance (Cockroft formula): ml/min 🔲 Unknown Proteinuria: g/24hrs 🔲 Unknown
DLCO (corrected for Hb):% Unknown
Mean Pulmonary Arterial Systolic Pressure [PASP] (from right heart catheterisation): mm Hg
GI Involvement: 🗌 No 📄 Yes 📄 Not evaluated 📄 Unknown
Systemic lupus erythematosus only:
Assessments at time of mobilisation (within 3 months before mobilisation):
SLEDAI-2K Score: Not evaluated 🔲 Unknown
Multiple sclerosis only:
Status at time of mobilisation (within 3 months before mobilisation):
Secondary progressive
Relapsing/remitting Other; specify:
Assessments at time of mobilisation (within 3 months before mobilisation):
EDSS (1-10): Not evaluated
Number of gadolinium enhancing lesions present on MRI brain scan: 🔲 Unknown
Crohn's disease only:
Assessments at time of mobilisation (within 3 months before mobilisation):
CDAI (0-700): Not evaluated Duknown
Serum albumin: g/L 🔲 Unknown
Index: Registry 109 Title: Disease status HCT CT IST Day 0 Version: 1.0 Effective Date: 2023-08-22 THIS IS AN
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Treatment Type	🗌 нст 🔲 ст	🗌 IST	Other

HAEMOGLOBINOPATHIES Status at treatment			
Ferritin level : ng/mL	Not evaluated 🛛 Unknown		
Number of red blood cell transfusions:	□ <20 units		
	20 to 50 units		
	None		
	Unknown		
Liver iron concentration: mg/g d	dry weight		
Pre-existing liver disease?			
□ No			
Yes: Hepatitis: Absent Chronic persistent Chronic active hep	•		
Liver biopsy performed?)		
	es: Liver fibrosis (Ishak staging)	: 🔲 F0 (no fibrosis)	
		🔲 F1 (partial fibrosis)	
		☐ F2 (general fibrosis)	
		F3 (partial bridging in fibrosis)	
		 ☐ F4 (general bridging in fibrosis) ☐ F5 (near cirrhosis) 	
		\square F6 (cirrhosis)	
Pre-existing cardiac disease?			
No No			
Yes: Cardiac echography ejection	fraction: 🗌 No 📄 Yes		
Cardiovascular magnetic res	onance (CMR) T2:	mg/g dry weight	

ickle cell disease only Chronic transfusion program: 🔲 No	
☐ Yes	



Treatment Type	🗌 нст 🔲 ст	🗌 IST	Other

HAE	MOC	GLO	BINC	PAT	HIES
	_				

Status at treatment

<u>Pre-treatment complications (Sickle cell disease only):</u>				
(check all that apply)				
Cerebrovascular disease				
Abnormal Doppler	🗌 No	Yes	□ Not evaluated	
Stroke	🗌 No	🗌 Yes	□ Not evaluated	
Haemorrhage	🗌 No	🗌 Yes	□ Not evaluated	
Arteriopathy	🗌 No	🗌 Yes	□ Not evaluated	
Moyamoya disease	🗌 No	🗌 Yes	□ Not evaluated	
Silent infarcts	🗌 No	Yes	□ Not evaluated	
Renal involvement				
Microalbumin level	mg/g	Not evaluated	ł	
Glomerular filtration rate	Glomerular filtration rate mL/min/1.73m ² D Not evaluated			
Avascular necrosis	Avascular necrosis 🛛 No 🗋 Yes 🗋 Not evaluated			
Hyperhaemolysis or autoimmune No haemolytic anaemia: Yes: Hyperhaemolysis Autoimmune haemolytic anaemia Not evaluated				
Other SCD related complicat	ions			
Acute chest syndrome	🗌 No	🗌 Yes	□ Not evaluated	
Vaso-occlusive crisis	🗌 No	🗌 Yes	□ Not evaluated	
Priapism	🗌 No	🗌 Yes	□ Not evaluated	
Pulmonary artery pressure	🗌 No	Yes	☐ Not evaluated	
Chronic lung disease	🗌 No	Yes	☐ Not evaluated	
Endocrinopathies pre-existing to HCT (Thalassemia only):				
Hypothyroidism	No No	🗌 Yes	☐ Not evaluated	
Hypoparathyroidism	🗌 No	🗌 Yes	☐ Not evaluated	
Diabetes mellitus	🗌 No	🗌 Yes	☐ Not evaluated	
Osteoporosis	🗌 No	🗌 Yes	☐ Not evaluated	
Gonadal dysfunction	No No	🗌 Yes	☐ Not evaluated	

Index: Registry 109 | Title: Disease status HCT CT IST Day 0 | Version: 1.0 | Effective Date: 2023-08-22 | THIS IS AN UNCONTOLLED COPY

☐ Yes

No No

Growth impairment

☐ Not evaluated