Covall visite to another details and a line of the second se	1					
Scroll right to see the database codes for Disease status and Response						
Tor Disease status and Response		Diagnosis it refers t	0			
Disease status or response to treatment	_	-	ALL	CML	CLL	MDS or MD/MPN or acute leukaemia secondary to
						previous treatment of another disease
Chronic phase Accelerated phase				None of the features of accelerated phase or blast crisis At least one of the following:		
				blasts 10-19% of WBCs in peripheral blood and/or nucleated bone marrow cells;		
				• peripheral blood basophils >=20%;		
				 persistent thrombocytopenia (<100 x 10⁹)/L unrelated to therapy; 		
				 persistent thrombocytosis (>1000 x 10⁹/L) unresponsive to standard therapy; 		
				 increasing spleen size and increasing WBC count unresponsive to standard therapy; 		
				cytogenetic evidence of clonal evolution		
Blast crisis				At least one of the following:		
				 blasts >=20% of peripheral blood white cells or nucleated bone marrow cells; 		
				 extramedullary blast proliferation; large foci or clusters of blasts in the bone marrow biopsy 		
Progressive relapsing (malignant)						
Primary progressive						
Secondary progressive						
Relapsing/remitting	\rightarrow					
Primary induction failure / Primary refractory						
Primary induction failure / Primary refractory		Despite treatment pa	tient has never			Treatment with intent to achieve remission was given,
		achieved a complete				but no Complete remission was achieved
Stable disease (no change, no response)					Patients who have not achieved a CR or a PR, and who have	
					not exhibited progression, will be considered to have no change	
Stringent Complete remission (sCR)						
Complete register en regenere (CD)		Ess et la s	at 4			
Complete remission or response (CR)			st 4 weeks: the bone marrow		All of the following:	Response must persist for a minimum duration of four
			r rods (applies to AML		absence of clonal lymphocytes in the peripheral blood	weeks: Bone marrow with ≤5 percent myeloblasts with
			nly)		• absence of significant lymphadenopathy (e.g. lymph nodes	normal maturation of all cell lines. Dysplastic changes
			ation of all cellular	If unqualified, Complete remission is considered to be Haematological complete remission	greater than 1,5 cm in diameter)	may be seen, but should be considered within the
			the bone marrow		absence of hepatomegaly or splenomegaly	normal range of dysplastic changes. Peripheral blood
			y disease (e.g., CNS, e disease)		absence of constitutional symptoms	demonstrates hemoglobin \geq 11 g/dL, platelets \geq 100 x 109/L, neutrophils \geq 1 x 109/L, and no circulating blasts.
			n independent			Tog/L, fieutrophils 21 x Tog/L, and no circulating blasts.
Haematological CR			st 4 weeks:			
			the bone marrow	All of the following:		
			r rods (applies to AML			
			nly) Nion of all collular	• Hemoglobin>11.0gm/dL;		
			ation of all cellular the bone marrow	• platelet count<500X10 ⁹ /L;		
		components in t		 normal differential (<1%precursor cells); no palpable splenomegaly; 		
l II				no extramedullary disease:		
		No extramedullary soft tissues	/ disease (e.g., CNS, e disease)	• no extramedullary disease;		
		No extramedullary soft tissues	y disease (e.g., CNS, e disease) n independent			
Cytogenetic CR		No extramedullary soft tissues	y disease (e.g., CNS, e disease) n independent	All of the following:		
Cytogenetic CR		No extramedullary soft tissu • Transfusion Disappearance of cy	y disease (e.g., CNS, e disease) n independent	All of the following: • Haematological remission		
		No extramedullary soft tissu • Transfusion Disappearance of cy	y disease (e.g., CNS, e disease) n independent togenetic anomalies if	All of the following: • Haematological remission • 0% positive (t(9;22) metaphases		
Cytogenetic CR Molecular CR		No extramedullary soft tissu • Transfusion Disappearance of cy	y disease (e.g., CNS, e disease) n independent togenetic anomalies if	All of the following: • Haematological remission		
	_	No extramedullary soft tissu Transfusion Disappearance of cy previousl	y disease (e.g., CNS, e disease) n independent togenetic anomalies if y detected	All of the following: • Haematological remission • 0% positive (t(9;22) metaphases All of the following: • Haematological remission • Cytogenetic remission (if cytogenetics done)		
	_	No extramedullary soft tissu • Transfusion Disappearance of cy previousl	y disease (e.g., CNS, e disease) <u>n independent</u> togenetic anomalies if y detected	 All of the following: Haematological remission 0% positive (t(9;22) metaphases All of the following: Haematological remission Cytogenetic remission (if cytogenetics done) Cells with the BCR/ABL fusion protein are not detectable in the peripheral blood and /or the 		
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Disease status or response to treatment	AML	ALL	CML		MDS or MD/MPN or acute leukaemia secondary to previous treatment of another disease
First partial remission (PR1)					
Very good PR (VGPR)					
 Partial remission or response Note: The specification " (>1, never CR, Solid tum only)" only applies to 				At leat one of the following: • A decrease in the number of blood lymphocytes by below 50%	
 The specification (>1, never CR, Solid turn only) only applies to disease status in Solid Turnours For any other diagnosis, the disease status of PR can have been 				or more from the value prior to therapy; • A decrease in lymph node size by below 50% or more in the	
preceded by a relapsed CR				sum products of up to 6 lymph nodes, or in one lymph node diameter if only a single lymph node was present prior to thereasy without increases in any lymph node, and no new	
				 therapy, without increase in any lymph node, and no new enlarged lymph node; A decrease in the size of the liver and/or spleen by 50% or 	
				 The blood count should show one of the following results if 	
				abnormal prior to therapy: . Polymorphonuclear leukocytes at 1.500/µL or more or 50%	
				improvement over baseline without G-CSF support;	
Minimal respponse / Poor partial remission or response					
Response / improvement (no CR)					
Response / Improvement (no CR)					
Relapse					
	> 5% blasts in the bo				At least one Complete remission was achieved with a
	period of Complete		If unqualified, Relapse is considered to be Haematological relapse		previous treatment but the patient has relapsed since then
Haematological Relapse					
	> 5% blasts in the bo period of Complete i		Cytological and/or histological evidence of the disease in the marrow-blood and/or in extramedullary sites (CNS, testis, skin, etc.) in a patient considered to have been in		
			Haematological complete remission		
Out-and Bullion					
Cytogenetic Relapse	alata ata al a aultau in th	romosome anomalies			
	detected earlier in the disease. Cytogeneti	c relapse can only be	Presence of one or more t(9:22) positive metaphases with standard cytogenetics or hypermetaphase FISH and/or >2% cells with the BCR/ABL fusion gene by interphase FISH, in a		
	 been previously dem		patient lacking any evidence of the disease at haematological/clinical level.		

Disease status or response to treatment	AML	ALL	CML	CLL	MDS or MD/MPN or acute leukaemia secondary to previous treatment of another disease
Molecular Relapse	Reappearance of m detected earlier in th disease. Molecular determined if Molec been previously dem	he history of the relapse can only be cular remission has	Presence of one or more t(9:22) positive metaphases with standard cytogenetics or hypermetaphase FISH and/or >2% cells with the BCR/ABL fusion gene by interphase FISH, in a patient lacking any evidence of the disease at haematological/clinical level.		
untreated relapse					
sensitive (responding) relapse					
resistant relapse					
Progression [progression] resistant to chemotherapy [progression] sensitive to chemotherapy Untreated relapse (from a previous CR) or progression from a previous (PR)				 At least one of the following: Progression of lymphadenopathy, defined as the occurrence of at least one of the following eventsAppearance of any new lesion such as enlarged lymph nodes (> 1.5 cm), splenomegaly, hepatomegaly or other organ infiltratesAn increase by 50% or more in greatest determined diameter of any previous siteAn increase of 50% or more in the sum of the product of diameters of multiple nodes. An increase in the liver or spleen size by 50% or more or the de novo appearance of hepatomegaly or splenomegaly. An increase in the number of blood lymphocytes by 50% or more with at least 5,000 B-cells per μL. Transformation to a more aggressive histology (e.g. Richter's syndrome). Patient received another treatment following progression but no remission of any type was achieved Patient received another treatment after progression and achieved some kind of remission 	More blasts in bone marrow than before treatment or leukaemic transformation
Chemorefractory relapse or progression, including primary refractory disease	+				
Never in CR				1	use only if more precise evaluation is
Not in CR					use only if more precise evaluation is
Untreated/Upfront	Patient has never be disease	en treated for this		Patient has never been treated for this disease	Treatment is supportive or there has not been any treatment at all (blood transfusions are not considered as treatment in this context)
Adjuvant Not evaluable					if pat. died within 100 days after tran
unknown					if data cannot be obtained

Scroll right to see the database codes	1			
for Disease status and Response				
Disease status or response to treatment	Myelofibrosis (MPN)	Lymphoma	Plasma cell disorders; mainly Multiple myeloma	Solid Tumors
Chronic phase				
Accelerated phase				
Blast crisis				
Progressive relapsing (malignant)				
Primary progressive				
Secondary progressive				
Relapsing/remitting				
Primary induction failure / Primary refractory	Doest not present any of the features of any type of remission after treatment			The patient has not achieved any of the types of response described below until now with any type of therapy
Stable disease (no change, no response)			IDDAS NOT MARTINA COTADA TOL COMPLETE LEMISSION VELV DOOD DALLIAL LEMISSION	Less than 50% reduction in the disease
Stringent Complete remission (sCR)			 All of the following: Complete remission as defined below normal free light chain ratio absence of clonal cells in bone marrow by immunohistochemistry or immunofluorescence 	
		Complete absence of disease, no signs or symptoms of the original disease	chains in the urine by immunofixation. Detectable monoclonal immunoglobulin, even if	The patient has achieved complete absence of disease prior to HSCT and the HSCT is not part of any adjuvant therapy
Haematological CR				
Cytogenetic CR				
Molecular CR				
CR confirmed		 At least one of the following: no abnormalities detected in any scan a negative PET scan if there is previous history of a positive PET scan, even in the presence of abnormalities in the CT scan 		No abnormalities detected in scan
CR unconfirmed		Scan abnormalities of unknown significance in the absence of a negative PET scan		Persistent scan abnormalities of unknown significance

Disease status or response to treatment	Myelofibrosis (MPN)	Lymphoma
First partial remission (PR1)		
Very good PR (VGPR)		
Partial remission or response		Reduction in the disease of 50% or more
Note:		
• The specification " (>1, never CR, Solid tum only)" only applies to disease status in Solid Tumours		
 For any other diagnosis, the disease status of PR can have been preceded by a relapsed CR 		
Minimal respponse / Poor partial remission or response		
	At least one of the following in the phoenes of	
Response / improvement (no CR)	At least one of the following in the absence of progression:	
	• Haemoglobin increase of 2 g/dL or transfusion independence	
	Spleen reduction of 50%	
	• 100% increase in platelet count and an absolute platelet count of at least 50.000 x 10 ⁹ /L	
	 Platelet count of at least 50.000 x 10°/L 100% increase in ANC and an ANC of at least 0.5 x 	
Relapse		
	Loss of Complete remission	
Haematological Relapse		
Cytogenetic Relapse		
	1	1

	o
Plasma cell disorders; mainly Multiple myeloma	Solid Tumors
	Patient achieved a reduction in disease of 50% or more for the first time ever, but did not achieve Complete remission
At least one of the following: • Serum and urine M-protein detectable by immunofixation but not on electrophoresis • >90% reduction in serum M-protein plus urine M-protein level <0.1 g/ per 24h Plus no increase in size or number of lytic lesions if assessed (radiographic studies are not mandatory)	Disease burden is reduced by at least 90%
 All of the following: >50% reduction in serum M-protein plus reduction in 24h urinary M-protein by >90% or to <0.2g/ per 24h <p>In the absence of measurable serum and urine M-protein, the following criteria applies: A decrease in the difference between involved and uninvolved free light chain (FLC) of more than 50% If the FLC assay cannot be measured, the following criteria applies: >50% reduction in plasma cells provided baseline bone marrow plasma cell percentage was >30% • A reduction of more than 50% in the size of soft tissue plasmacytomas if present at pretreatment. • No increase in size or number of lytic lesions if assessed (radiographic studies are not mandatory)</p>	<u>Second</u> or <u>subsequent</u> time a reduction in the disease of 50% or more is achieved in patients who have <u>never</u> achieved a Complete remission
	Reappearance of disease in patients whose last disease status was Complete
At least one of the following for patients whose last disease status was Complete remission: - Reappearance of measurable monoclonal immunoglobulin in serum or urine by immunofixation or electrophoresis - Appearance of more than 5% plasma cells in the bone marrow - Increase of old/appearance of new osteolytic bone lesions on x-ray - Appearance of soft tissue plasmacytoma	remission

Disease status or response to treatment	Myelofibrosis (MPN)	Lymphoma	Plasma cell disorders; mainly Multiple myeloma	Solid Tumors
		Lymphonia		
Molecular Relapse				
untreated relapse				Patient has not been treated for this
sensitive (responding) relapse				relapse
Sensitive (responding) relapse				Patient achieves a reduction of >50% in the disease burden after treatment
				for this relapse
resistant relapse				
				Patient has not achieved a reduction of
				more than 50% in the disease burden
				after treatment for this relapse
Progression			At least one of the following:	
			- Increase of 25% or more in measurable monoclonal immunoglobulin in serum or	
			urine (absolute increase must be >0.5g/dL)	
			- Increase of 25% or more in urinary light chains (absolute increase must be >0.2g/ per	·
	At least one of the following		24h)	
	progressive splenomegaly		In the absence of measurable serum and urine M-protein, the following criteria	
	leukemic transformation		applies:	
	• an increase of peripheral blood blast percentage of at		An increase of 25% or more in the difference between involved and uninvolved free	
	least 20%		light chain (absolute increase must be >0.01g/dL)	
			- An increase of 25% or more in bone marrow plasma cells (absolute % must be >10%)	
			- Increase of old/appearance of new osteolytic bone lesions on x-ray	
			- Appearance of soft tissue plasmacytoma	
			- Development of hypercalcemia (corrected serum calcium >11.5 mg/dL or 2.65	
			mmol/L) that can be attributed solely to the plasma cell disorder	
[progression] resistant to chemotherapy				
[progression] sensitive to chemotherapy				
Untreated relapse (from a previous CR) or progression from a		Worsening of the disease status in patients in PR or	r	
previous (PR)		re-appearance of the Lymphoma in patients in CR,		
		such as:		
		Occurrence of new sites of the disease		
		• Re-occurence of disease or systemic symptoms		
		(B symptoms)		
		Patient remains untreated after the relapse or		
Chemorefractory relapse or progression, including primary		progression Does not present any of the features of any type of		
refractory disease		remission after treatment		
-	not possible		•	1
	not possible			
IIntreated/IInfront				Potiont has never been treated for this
	Treatment is supportive or there has not been any treatment at all (blood transfusions are not considered	Patient has never been treated for this disease	Patient has never been treated for this disease	Patient has never been treated for this disease and the high dose therapy is
	as treatment in this context)	ו מופות וומא וופיפו שכפוו נופמנכט וטו נוווא טואפמאפ	ו מופות וומס וובעבו גובמובע ועו נוווס עוספמספ	part of the overall treatment strategy
				part of the overall actuation strategy
Adjuvant				
				Patient has no residual disease and
				the HSCT is part of the consolidation
				treatment; metastatic patients can
				never be considered as adjuvant.
Not evaluable	plant		•	
unknown				

Scroll right to see the database codes	1				
for Disease status and Response					L
Disease status or response to treatment	Severe Aplastic anaemia (SAA)	non Severe Aplastic anaemia (nSAA)	Multiple sclerosis	Data base Disease status	codes Response
					nooponoo
Chronic phase Accelerated phase				1 2	
				2	
Blast crisis				3	
				U U	
Progressive relapsing (malignant)			Continuous disease progression	5	
			with clear acute disease exacerbation episodes		
Primary progressive			Continuous disease progression	6	
			without distinct acute disease exacerbation episodes		
Secondary progressive			Acute disease exacerbations	7	
			periods where there is disease		
			progression after the acute disease exacerbation		
Relapsing/remitting			Aguita diagona avagathation paris l	8	
			Acute disease exacerbation periods that resolve completely without		
Drimony induction failures / Drimony, references			worsening of neurologic functions	10	
Primary induction failure / Primary refractory				10	
Stable disease (no change, no response)	Still meeting criteria of severe aplastic anaemia	Not meeting criteria of partial or complete		20	50
	and transfusion	response		20	
Stringent Complete remission (sCR)	dependence			28	10
				20	
Complete remission or response (CR)	All of the fo	l pllowing:		30	20
	• haemoglobin n	ormal for age			(21)
	• neutrophils >= • platelets >= *				(22) (23)
	• platelets >=	130 x 10 /E			
Haematological CK	2	[
Cytogenetic Ck	2				
Molecular Ck	2				
CR confirmed	1				
			1		
CR unconfirmed	1				

Disease status or response to treatment	Severe Aplastic anaemia (SAA)	non Severe Aplastic anaemia (nSAA)	Multiple sclerosis	Disease status	Response
First partial remission (PR1)				40	
Very good PR (VGPR)				41	35 (36)
					(37) (38)
					()
Note:	All of the following transfusion independent 	At least one of the following: • transfusion independence (if previously		45	30 (31)
• The specification " (>1, never CR, Solid tum only)" only applies to disease status in Solid Tumours		required) • doubling or normalization of at least one			(32) (33)
• For any other diagnosis, the disease status of PR can have been preceded by a relapsed CR		cell line • increase above baseline* by			(00)
		. 3 g/dl hemoglobin and			
		. 0.5x10 ⁹ /L neutrophils and . 20x10 ⁹ /L platelets			
Minimal respponse / Poor partial remission or response	All of the following				40
	 transfusion independent levels of hemoglobin, neutrophils and 				
	platelets still meeting criteria for severe aplastic anaemia (see <i>MED-AB Manual</i>)				
Response / improvement (no CR)	· · · ·			46	44
Relapse				50	60
Haematological Relapse					
Codesenatia Delaura					
Cytogenetic Relapse					
			1		

Disease status or response to treatment	Severe Aplastic anaemia (SAA)	non Severe Aplastic anaemia (nSAA)	Multiple sclerosis	Disease status	Response
Molecular Relapse					
untreated relapse					
sensitive (responding) relapse					
resistant relapse					
resistant relapse					
Progression				60	60
[progression] resistant to chemotherapy					
[progression] sensitive to chemotherapy					
Untreated relapse (from a previous CR) or progression from a previous (PR)				51	
Chomorofractory relance or progranding including primero				<u>(1</u>	
Chemorefractory relapse or progression, including primary refractory disease				61	
Never in CR				65	70
Not in CR Untreated/Upfront				66 70	
				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Adjuvant				75	
Net evelophia					
Not evaluable unknown				80 99	80 99
L	0			55	