EBMT European Society for Blood and Marrow Transplantation

EBMT MED-B Allograft

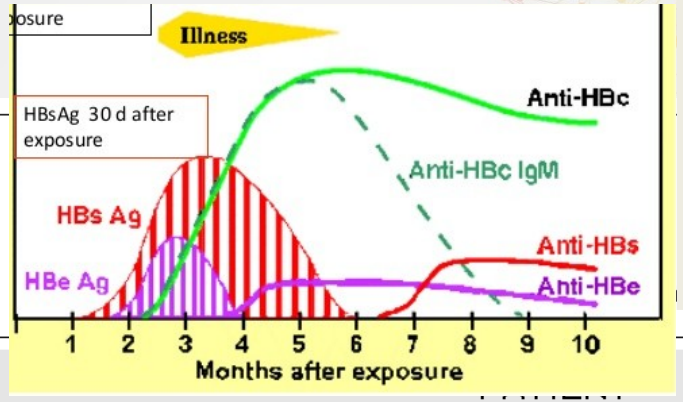
Jakob R Passweg

No conflicts of interest

Lisboa 20.3.18

Serology
Antibodies against an infectious agent

measures the defense mounted against this agent



Antigens
by antigen detection measures presence of immunologically detectable parts of the agent

by molecular biology = PCR = measures the presence of genes of the virus = viral replication

ANTIBODIES IN THE PATIENT (before transplantation)					ANTIGENS (if testing applicable)			
HIV	☐Negative	☐Positive	☐Not evaluated	☐Unknown	☐Negative	☐Positive	☐Not evaluated	☐Unknown
CMV	☐Negative	☐Positive	☐Not evaluated	☐Unknown				
EBV	☐Negative	☐Positive	☐Not evaluated	☐Unknown				
HBVs	☐Negative	☐Positive	☐Not evaluated	☐Unknown	☐Negative	☐Positive	☐Not evaluated	☐Unknown
HBVc	☐Negative	☐Positive	☐Not evaluated	☐Unknown				
HBVe	☐Negative	☐Positive	☐Not evaluated	☐Unknown	☐Negative	☐Positive	☐Not evaluated	☐Unknown
HCV	☐Negative	☐Positive	☐Not evaluated	☐Unknown	☐Negative	☐Positive	☐Not evaluated	☐Unknown
HTLV.I	☐Negative	☐Positive	☐Not evaluated	☐Unknown				
Toxoplasmosis	☐Negative	☐Positive	☐Not evaluated	☐Unknown				
Other	☐Negative	☐Positive	Specify… … … … … … … … … … … … … …					

Why do we want to know this?

Some viruses stay in the body forever
Even if they do not cause disease prior to HSCT
= latent viruses (herpes virus family)
These viruses may reactivate

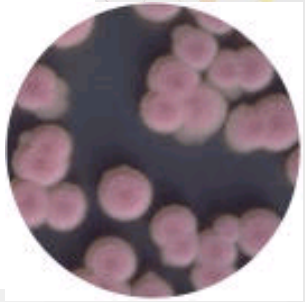
PRE-TRANSPLANT HISTORY OF DOCUMENTED INVASIVE FUNGAL INFECTION SINCE INITIAL DIAGNOSIS

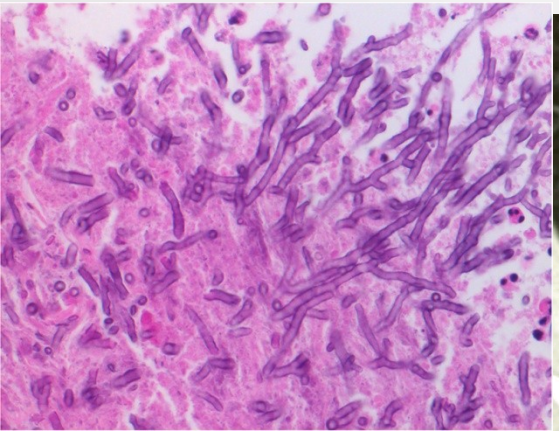
☐ No

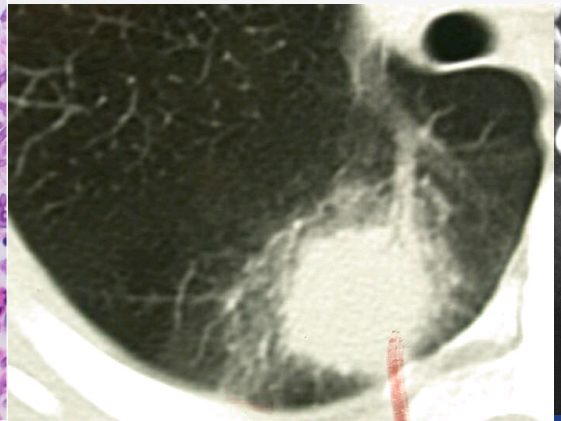
☐ Yes:

Candida	☐ Yes	☐ No	☐ Unknown
Aspergillus	☐ Yes	☐ No	☐ Unknown
Pneumocystis carinii	☐ Yes	☐ No	☐ Unknown
Other	☐ Yes	☐ No	If Yes, specify .....

☐ Unknown







PERFORMANCE SCORE

Type of score used ☐ Karnofsky ☐ Lansky

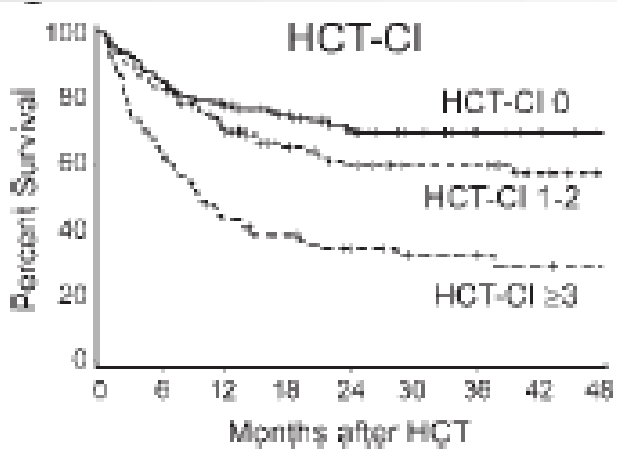
SCORE *(For more detailed description, see manual)*

☐ 100	Normal, NED	Normal, NED
☐ 90	Normal activity; minor signs and symptoms of disease	Minor restrictions in physically strenuous activity
☐ 80	Normal with effort	Active, but tires more quickly
☐ 70	Cares for self, unable to perform normal activity	Both greater restriction of and less time spent in play activity
☐ 60	Requires occasional assistance	Up and around, but minimal active play; keeps busy with quieter activities
☐ 50	Requires considerable assistance	Gets dressed but lies around much of the day, no active play but able to participate in all quiet play and activities
☐ 40	Requires special care; disabled	Mostly in bed; participates in quiet activities
☐ 30	Severely disabled	In bed; needs assistance even for quiet play
☐ 20	Very sick	Often sleeping; play entirely limited to very passive activities

EBMT

Comorbidity Index

= cumulative number of co-morbidities



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 ***clinically significant*** co-existing disease or organ impairment as listed below at time of patient assessment prior to the preparative regimen? ☐ No ☐ Yes, indicate each comorbidity below

Comorbidity	Definitions	No	Yes	Not evaluated
Solid tumour, previously present	Treated at any time point in the patient's past history, excluding non-melanoma skin cancer Indicate type ……	☐	☐	☐
Inflammatory bowel disease INBWDIS	Crohn's disease or ulcerative colitis	☐	☐	☐
Rheumatologic	SLE, RA, polymyositis, mixed CTD, or polymyalgia rheumatica	☐	☐	☐
Infection INFELPRE	Requiring continuation of antimicrobial treatment after day 0	☐	☐	☐
Diabetes	Requiring treatment with insulin or oral hypoglycaemics but not diet alone	☐	☐	☐
Renal: moderate/severe KIDNEYCO	Serum creatinine > 2 mg/dL or >177 µmol/L, on dialysis, or prior renal transplantation	☐	☐	☐
Hepatic: mild	Chronic hepatitis, bilirubin between Upper Limit Normal (ULN) and 1.5 x the ULN, or AST/ALT between ULN and 2.5 × ULN	☐	☐	☐
moderate/ severe	Liver cirrhosis, bilirubin greater than 1.5 × ULN, or AST/ALT greater than 2.5 × ULN	☐	☐	☐
Arrhythmia	Atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias	☐	☐	☐
Cardiac CARDIAC	Coronary artery disease, congestive heart failure, myocardial infarction, EF ≤ 50%, or shortening fraction in children (<28%)	☐	☐	☐
Cerebrovascular disease	Transient ischemic attack or cerebrovascular accident	☐	☐	☐
Heart valve disease VALVE	Except mitral valve prolapse	☐	☐	☐
Pulmonary: moderate	DLco and/or FEV1 66-80% or dyspnoea on slight activity	☐	☐	☐
severe	DLco and/or FEV1 ≤ 65% or dyspnoea at rest or requiring oxygen	☐	☐	☐
Obesity	Patients with a body mass index > 35 kg/m2	☐	☐	☐
Peptic ulcer PEPTICU	Requiring treatment	☐	☐	☐
Psychiatric disturbance	Depression or anxiety requiring psychiatric consultation or treatment	☐	☐	☐

COMORBIDITY INDEX

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Arrhythmia	Atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias	☐	☐	☐
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Obesity	Patients with a body mass index > 35 kg/m2	☐	☐	☐
Peptic ulcer PEPTICU	Requiring treatment	☐	☐	☐
Psychiatric disturbance	Depression or anxiety requiring psychiatric consultation or treatment	☐	☐	☐

DONOR 1

HLA MATCH TYPE *(DONOR RELATION WITH PATIENT)*

- ☐ HLA-identical sibling *(may include non-monozygotic twin)*
- ☐ Syngeneic *(monozygotic twin)*
- ☐ HLA-matched other relative
- ☐ HLA-mismatched relative: Degree of mismatch ☐ 1 HLA locus mismatch
  ☐ >=2 HLA loci mismatch

Donor ID given by the centre .....

HLA MISMATCHES BETWEEN DONOR AND PATIENT

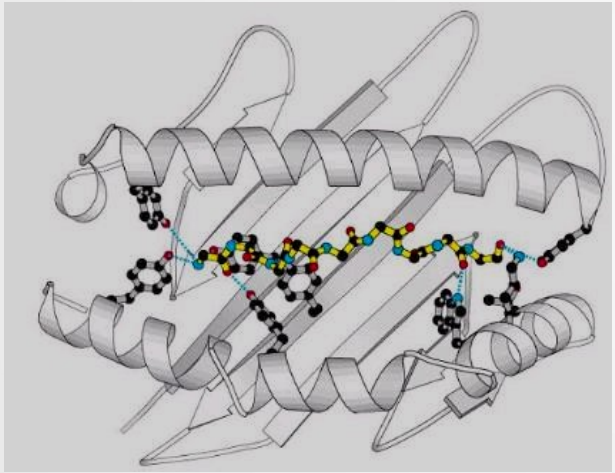
*(**Mismatched relatives only**. If you are submitting the HLA typing results, you can skip this item)*

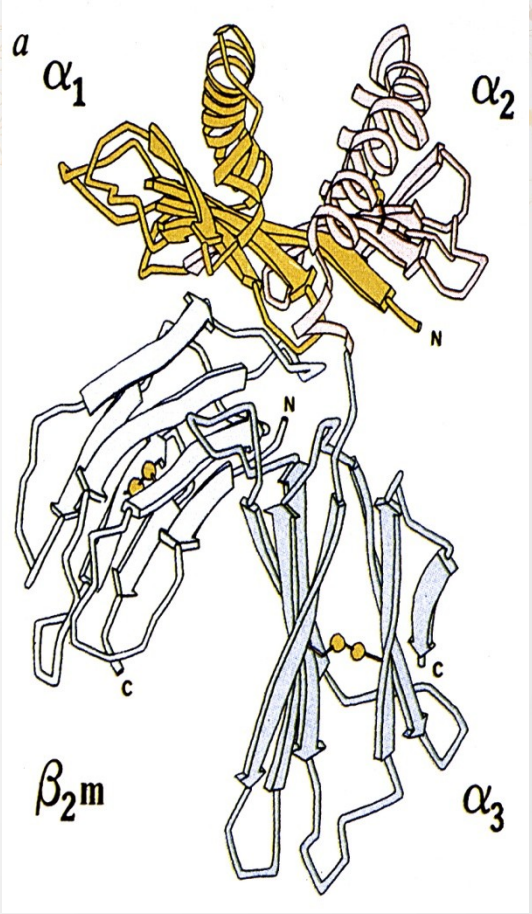
Complete number of mismatches inside each box

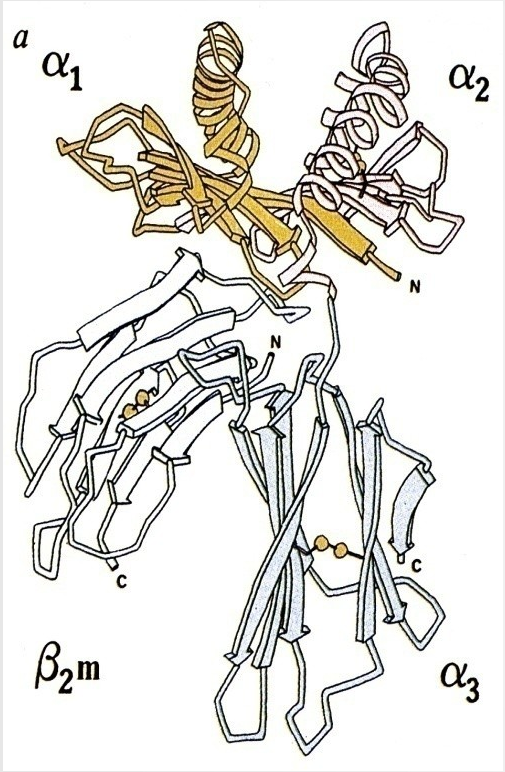
A	B	C	DRB1	DQB1	DPB1	
☐	☐	☐	☐	☐	☐	Antigenic (HLA code is 2 digits) *(if DNA box is filled, it is not necessary to fill Serology for that locus)*
☐	☐	☐	☐	☐	☐	Allelic (HLA code is 4 digits)

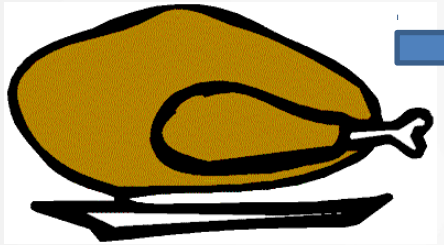
0=match; 1=one mismatch; 2=2 mismatches; N/E=not evaluated

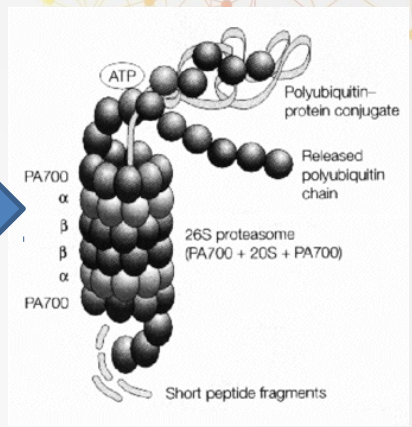
HLA-A2

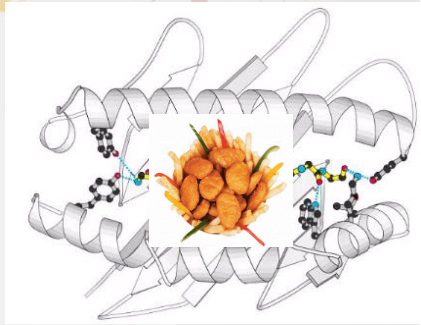


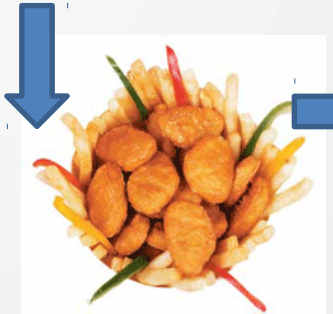


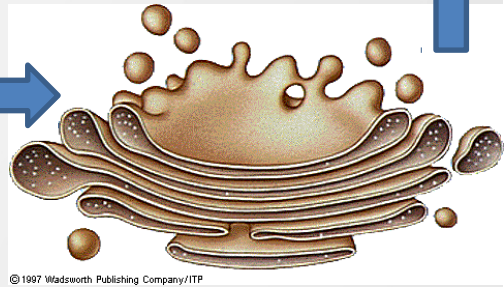

a
α1
α2
N
N
C
C
β2m
α3




ATP
Polyubiquitin–
protein conjugate
Released
polyubiquitin
chain
PA700
α
β
β
α
PA700
26S proteasome
(PA700 + 20S + PA700)
Short peptide fragments



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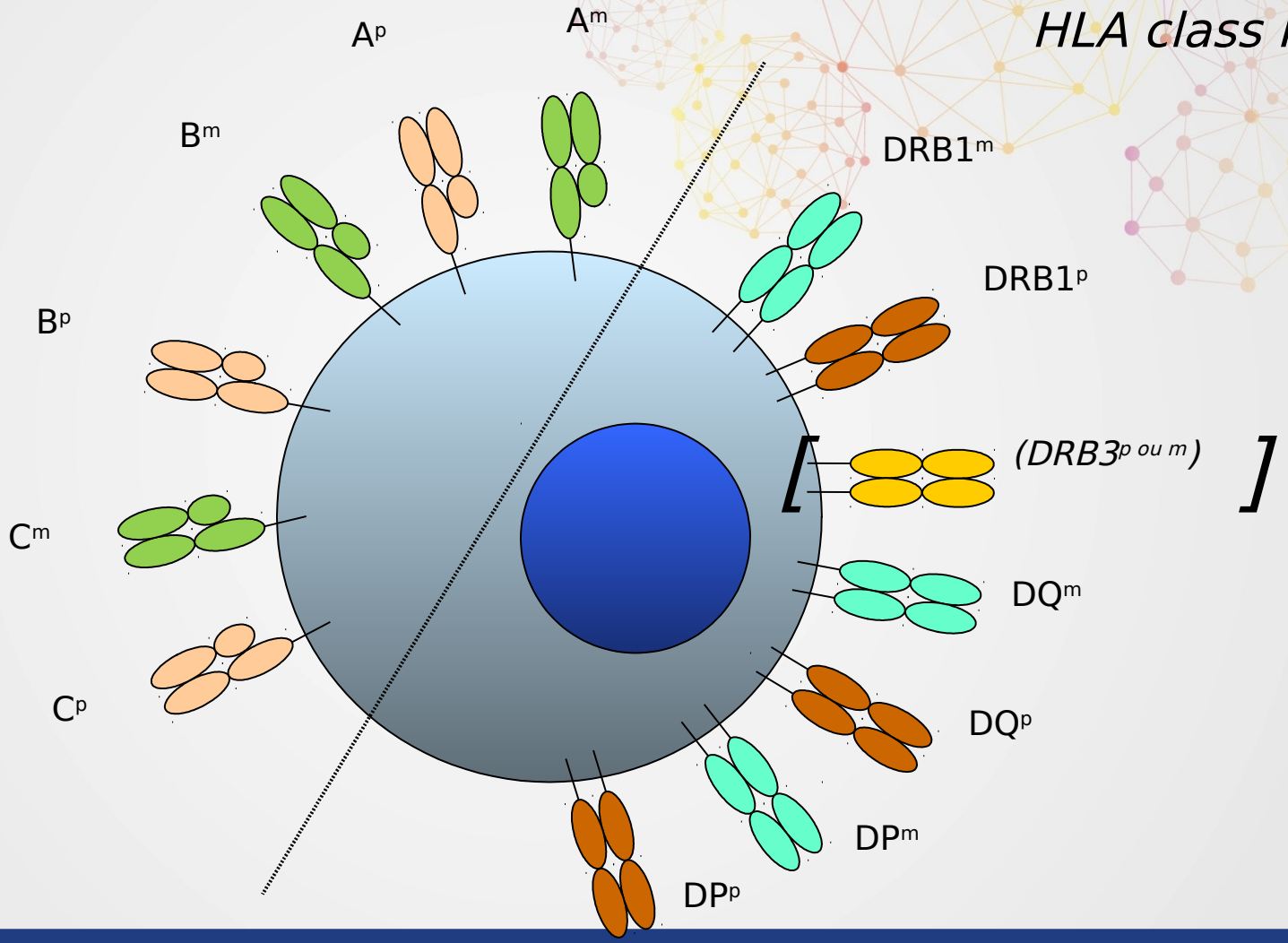
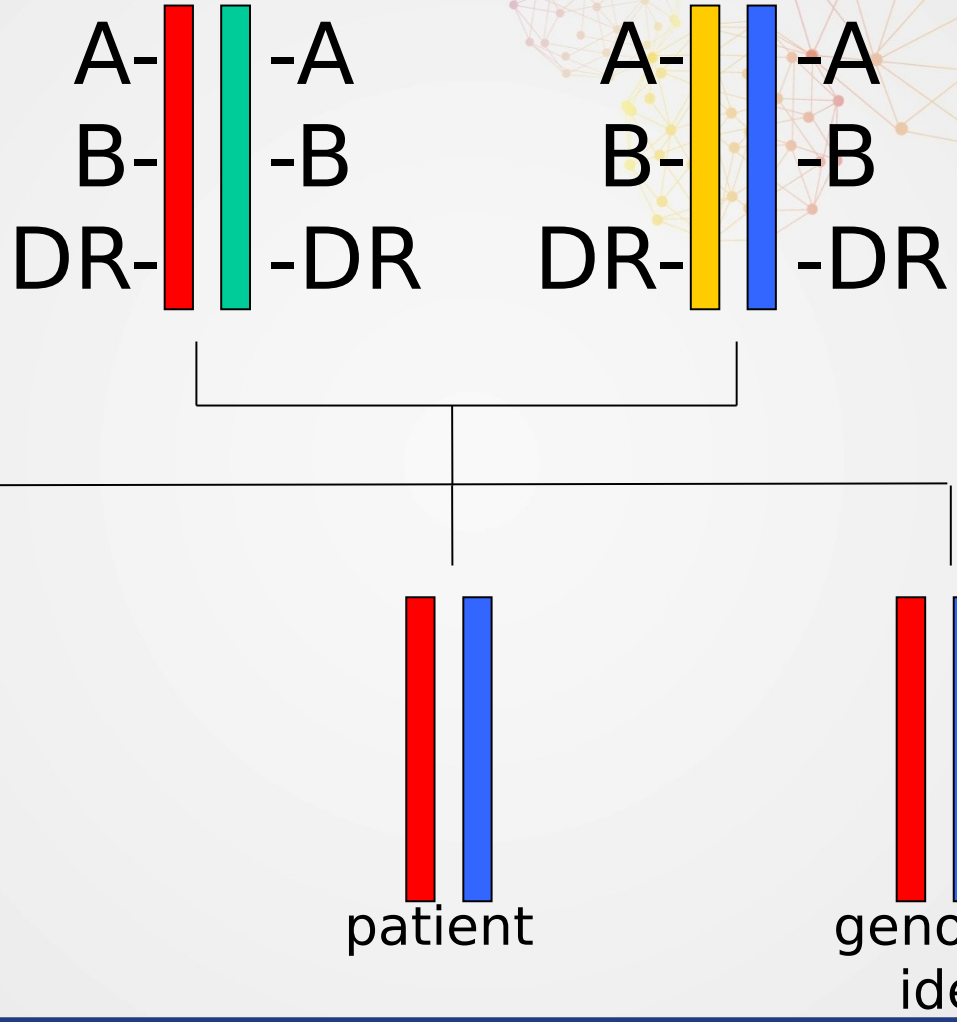
HLA class I

HLA class II

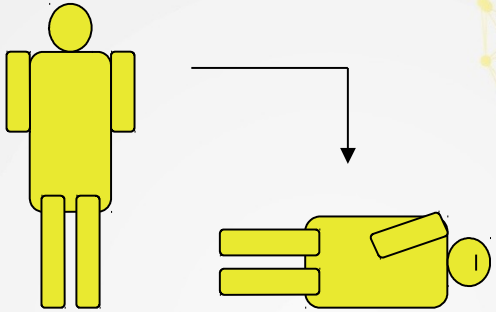




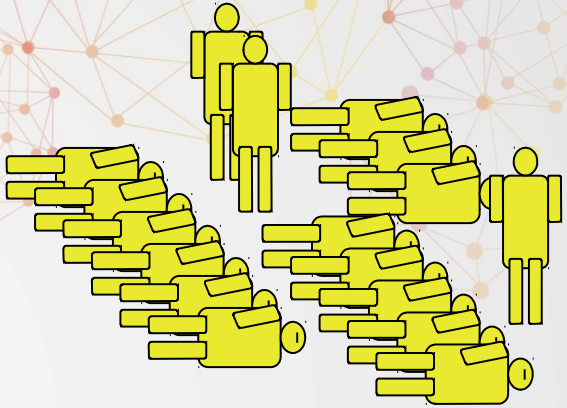
Sibs	Chance (%)
0	0
1	25
2	43
3	58
4	68
5	76
6	82

prob= 1 – (0.75 # sibs-

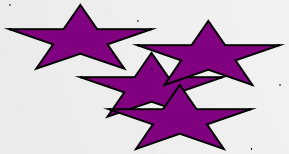
HLA a does not recognize the pathogen



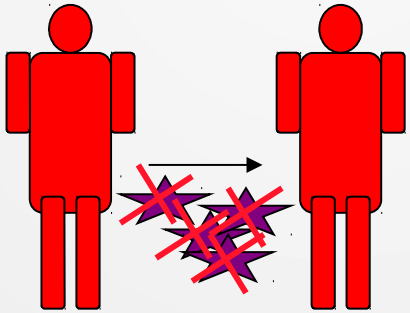
HLA a



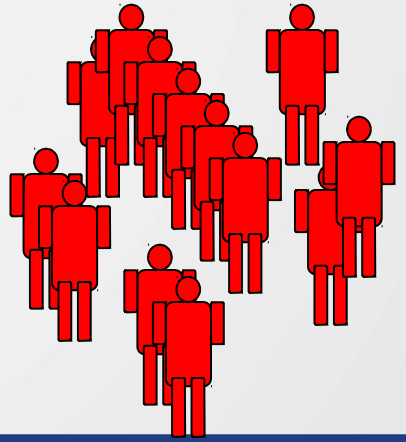
□□ population dies



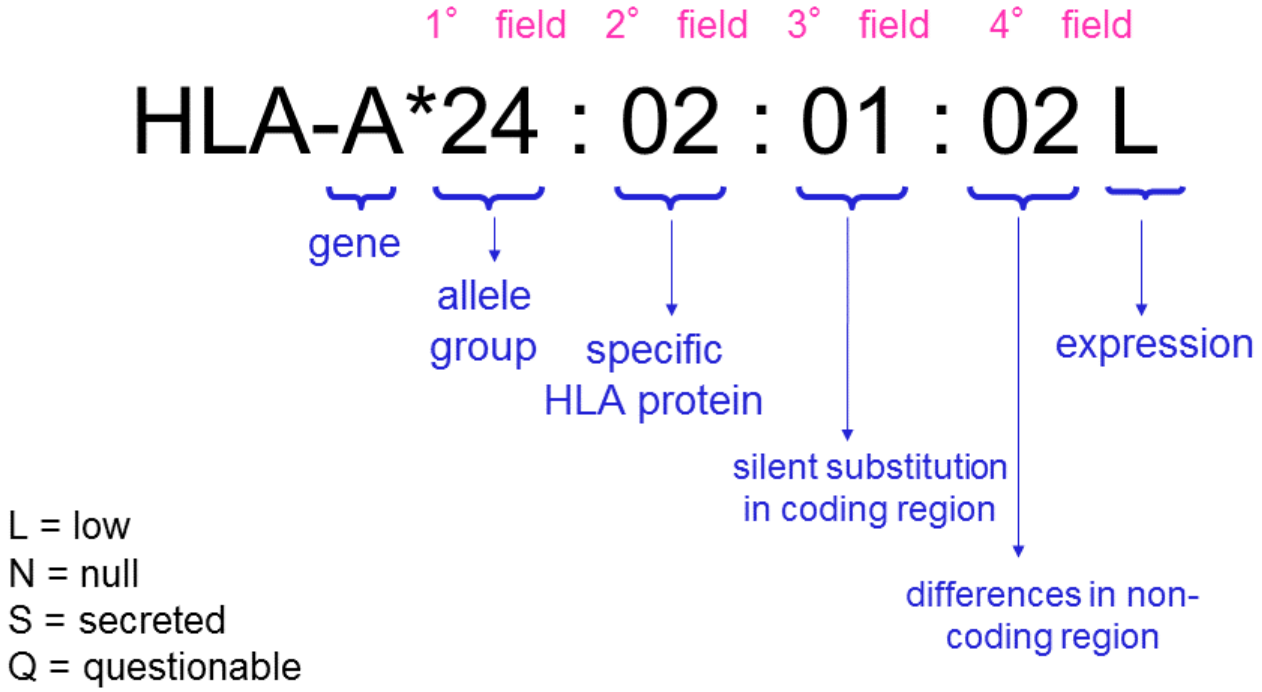
HLA b recognizes the pathogen



HLA b



HLA nomenclature



HLA MATCH TYPE *(DONOR RELATION WITH PATIENT)*

- ☐ HLA-identical sibling *(may include non-monozygotic twin)*
- ☐ Syngeneic *(monozygotic twin)*
- ☐ HLA-matched other relative
- ☐ HLA-mismatched relative:
  - Degree of allele mismatch
    - ☐ 1 HLA antigen mismatch
    - ☐ ≥ 2 HLA antigen mismatch *(full Haploidentical)*
- ☐ Unrelated donor
  - Donor registry/CB Bank name ....
  - WMDA code *(up to 4 characters)* …. …. …. ….

COMPLETE NUMBER OF MISMATCHES INSIDE EACH BOX FOR UNRELATED DONORS

A	B	C	DRB1	DQB1	DPB1	
☐	☐	☐	☐	☐	☐	Antigenic *(HLA code is 2 digits)*
☐	☐	☐	☐	☐	☐	Allelic *(HLA code is 4 digits)*

0=match; 1=one mismatch; 2=2 mismatches; N/E=not evaluated

Let‘s assume unrelated donor

patient:
A: 0101 0201
B: 1501 3502
DRB1: 0401 0302

donor:
A: 0101 0201
B: 1501 3502
DRB1: 0404 0302

Is this a haplo or not?

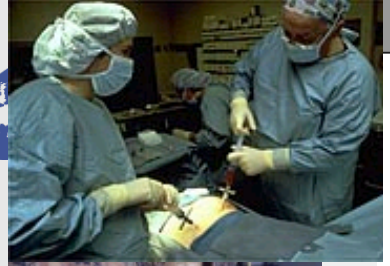
Patient	A	B	C	KIR-Liganden	DRB1	DRB3/4/5	DQB1	DPB1	Haplotyp
Erste Typisierung: 11.02.2015	A*11	B*07	C*07		DRB1*15	DRB5*	DQB1*06		n.b.
Notiz:	-	B*35	C*04		DRB1*01	-	DQB1*05		n.b.
Re-Typisierung: 21.07.2017	A*11:01	B*07:02	C*07:01	Bw6 C1	DRB1*15:01	DRB5*01:01	DQB1*06:02	DPB1*04:01	n.b.
Notiz: typisiert in Genf	-	B*35:01	C*04:01	Bw6 C2	DRB1*01:01	-	DQB1*05:01	-	n.b.

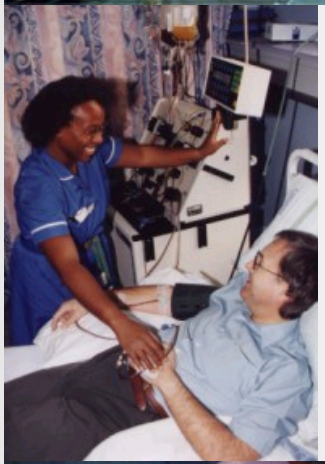
Spendergruppierung

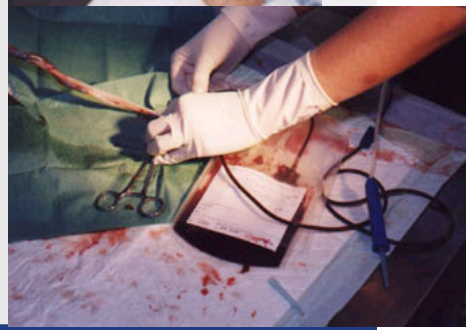
Spenderin: [redacted] 1964

Haploidentisch ohne KIR-L Mismatch

	A	B	C	KIR-Liganden	DRB1	DRB3/4/5	DQB1	DPB1	Haplotyp
Erste Typisierung: 14.04.2015	A*11	B*07	C*07	Bw6 C1	DRB1*15	DRB5*	DQB1*06		n.b.
Notiz: typisiert in Aachen	A*02	B*35	C*04	Bw6 C2	DRB1*01	-	DQB1*05		n.b.
Re-Typisierung: 24.01.2018	A*11	B*07	C*07:02	Bw6 C1!	DRB1*15	DRB5*	DQB1*06	DPB1*04:01	n.b.
Notiz: typisiert in Genf	A*02	B*35	C*04	Bw6 C2	DRB1*01	-	DQB1*05	-	n.b.







DONOR 1 – PRODUCT NUMBER 1

SOURCE OF STEM CELLS FOR THIS PRODUCT, SELECT ONLY ONE

- ☐ Bone Marrow
- ☐ Peripheral Blood
- ☐ Cord Blood
- ☐ Other: .....

Date of collection, including cord blood: .... - .... - ....
yyyy *mm* *dd*

Growth factors administered to the donor

☐ No ☐ Yes, specify: ..... ☐ Not appl

MANIPULATION FOR THIS PRODUCT

Graft manipulation *ex-vivo* including T-cell depletion *other than for RBC removal or volume reducti*

☐ No ☐ Yes:

Negative ☐ No ☐ Yes:

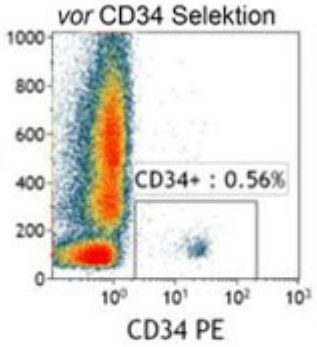
- ☐ T-cell (CD3+) depletion *(do not use for "Campath in*
- ☐ T-cell receptor αβ depletion
- ☐ B-cell depletion (CD19+) by MoAB
- ☐ NK cell depletion by MoAB
- ☐ Elutriation
- ☐ Other: .....

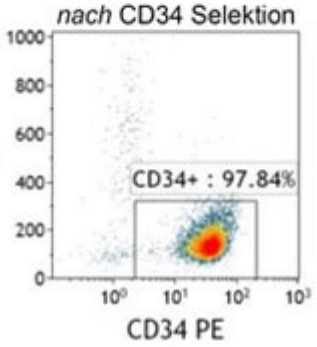
Positive ☐ No ☐ Yes:

- ☐ Monoclonal antibodies: CD34+ enrichment
  Other
- ☐ Other: .....

Expansion ☐ No ☐ Yes

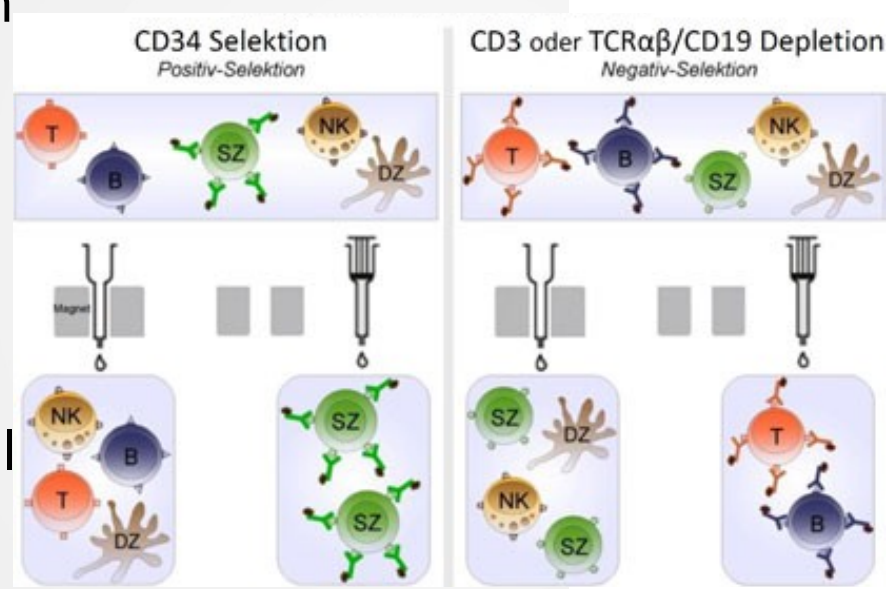
Genetic manipulation ☐ No ☐ Yes





Negative selection
Remove cells

Positive selection
Select for stem cel



MANIPULATION FOR THIS PRODUCT

Graft manipulation *ex-vivo* including T-cell deplet

☐ No ☐ Yes:

Negative

Positive

☐ C

Expansion ☐ No ☐ Y

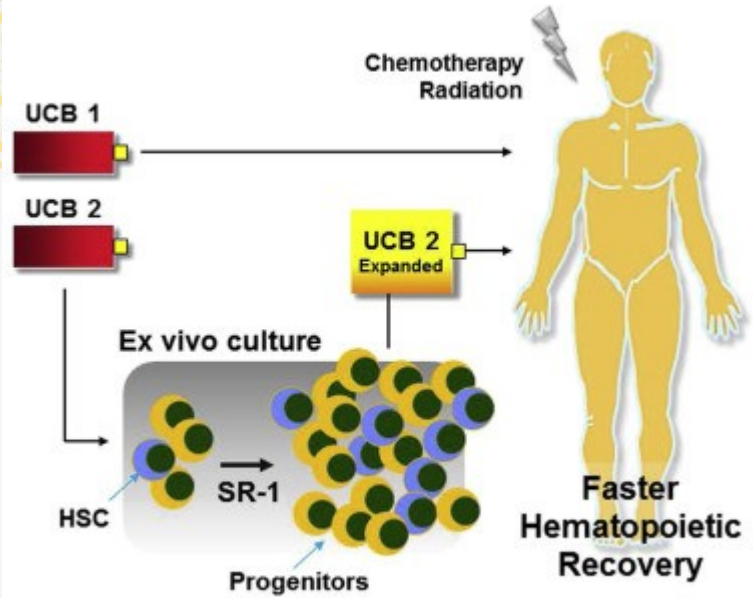
Genetic manipulation ☐ No ☐ Yes

☐ Elutriation
☐ Other: .....

Positive ☐ No ☐ Yes:
☐ Monoclonal antibodies: CD34+ enrichment
Other
☐ Other: .....

Expansion ☐ No ☐ Yes

Genetic manipulation ☐ No ☐ Yes



CELL COUNTS FOR THIS PRODUCT

Total number of Cells Infused (per kg of recipient body weight)

Type	Counts	x 10^5	x 10^6	x 10^7	X10^8
Nucleated cells (/kg)	3.0 ....-	☐	☐	☐	☒
CD 34+ (cells/kg)	4.0 ....-	☐	☒	☐	☐
T-cells (CD 3+) (cells/kg)	.... -	☐	☐	☐	☐

CORD BLOOD ONLY
CELL INFUSION METHOD FOR THIS PRODUCT

Route of infusion

☐ Intravenous (IV) ☐ intrabone / intramedullary
☐ Other, specify: ..... ☐ unknown

Infusion method

☐ DMSO ☐ Wash (Rubinstein/New York)
☐ Other, specify: .....

CELL VIABILITY RESULTS AT HSCT CENTRE FOR THIS PRODUCT

Tests performed after thawing of an aliquot on:

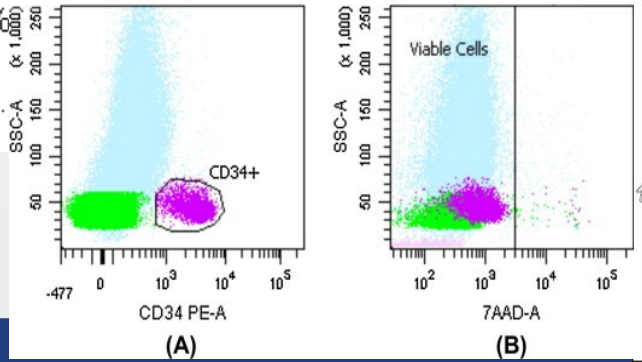
☐ Contiguous segment ☐ Reference bag ☐ **unknown**

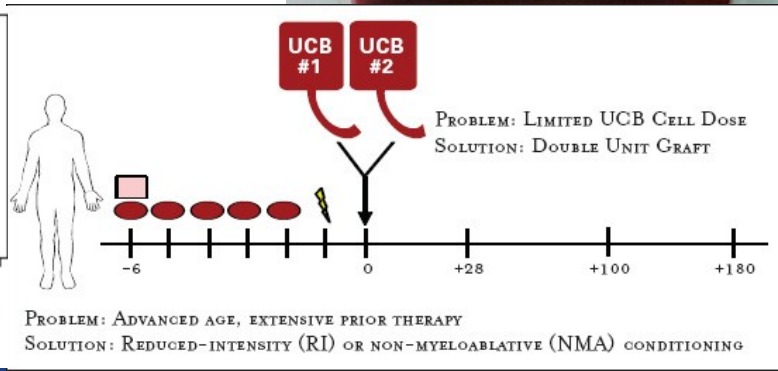
Method used

☐ 7-AAD ☐ Tryptan blue ☐ Acridine orange-ethidium iodide
☐ Acridine orange-ethidium bromide ☐ Other, specify ..... ☐ un

Viability of all cells ..... %

Viability of CD34+ cells .....





PREPARATIVE TREATMENT *(conditioning)*

PREPARATIVE (CONDITIONING) REGIMEN GIVEN

☐ No (*Usually Paediatric Inherited Disorders only*) *CONTINUE TO PAGE 14*

☐ Yes: **Was regimen intended to be myeloablative** ☐ No:

Reason not myeloablative	**Main reason** *(tick only one)*	**Additional reason** *(tick as many as necessary)*
Age of recipient	☐	☐
Comorbid conditions	☐	☐
Prior HSCT	☐	☐
Protocol driven	☐	☐
Other, specify	☐	☐

☐ Yes

☐ Unknown

Drugs ☐ No ☐ Yes ☐ Unknown

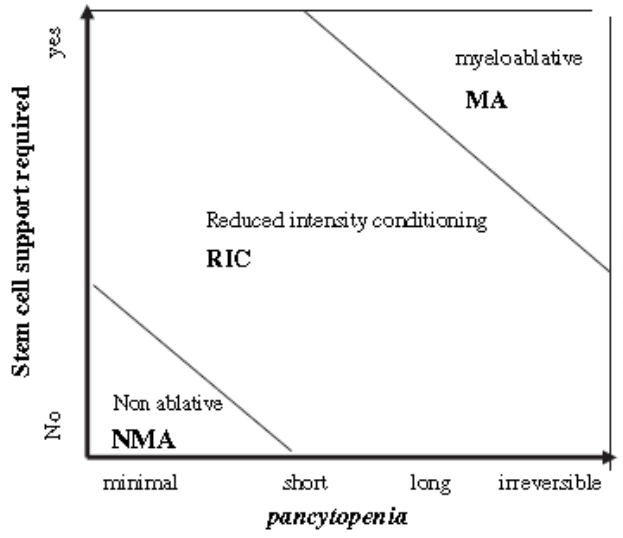
(include any active agent be it chemo, monoclonal antibody, polyclonal antibody, serotherapy, etc.)

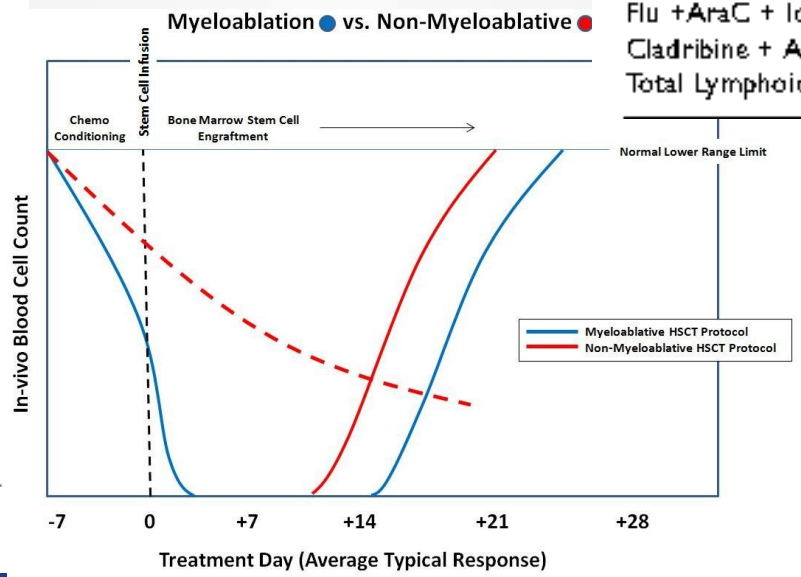
Defining the Intensity of Conditioning Regimens: Working Definitions

Andrea Bacigalupo, M.D.,[1] Karen Ballen, M.D.,[2] Doug Rizzo, M.D.,[3] Sergio Giralt, M.D.,[4] Hillard Lazarus, M.D.,[5] Vincent Ho, M.D.,[6] Jane Apperley, M.D.,[7] Shimon Slavin, M.D.,[8] Marcelo Pasquini, M.D.,[3] Brenda M. Sandmaier, M.D.,[9] John Barrett, M.D.,[10] Didier Blaise, M.D.,[11] Robert Lowski, M.D.,[12] Mary Horowitz, M.D.[3]

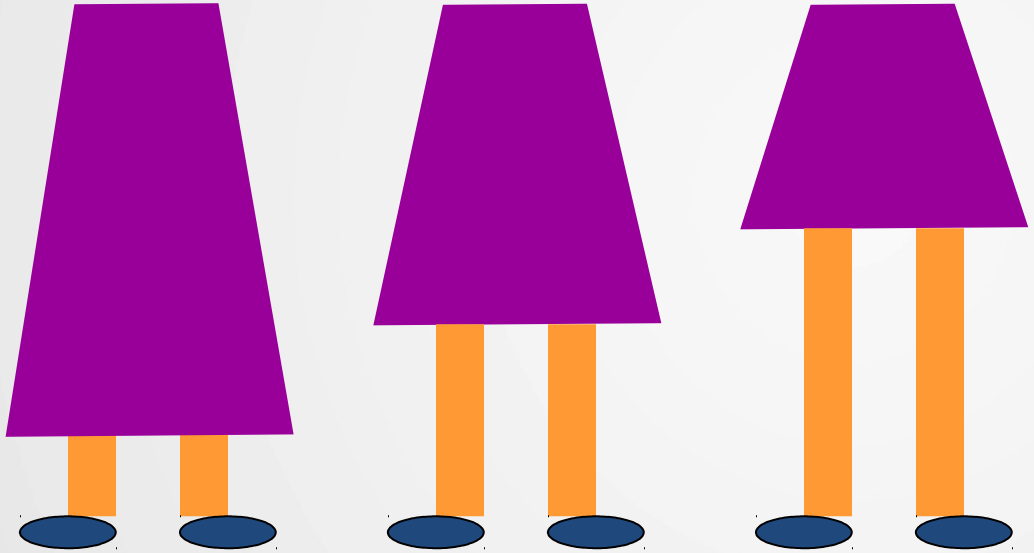
Table 1. Example of Myeloablative and Nonmyeloablative Regimens According to Commonly Used Combinations

Myeloablative (MA)*
TBI >5 Gy single dose or >8 Gy fractionated
Bu >8 mg/kg orally or intravenous equivalent
Nonmyeloablative (NMA)†
TBI <2 Gy± purine analog
Flu + Cy ± ATG
Flu +AraC + Ida
Cladribine + AraC
Total Lymphoid Irradiation + ATG



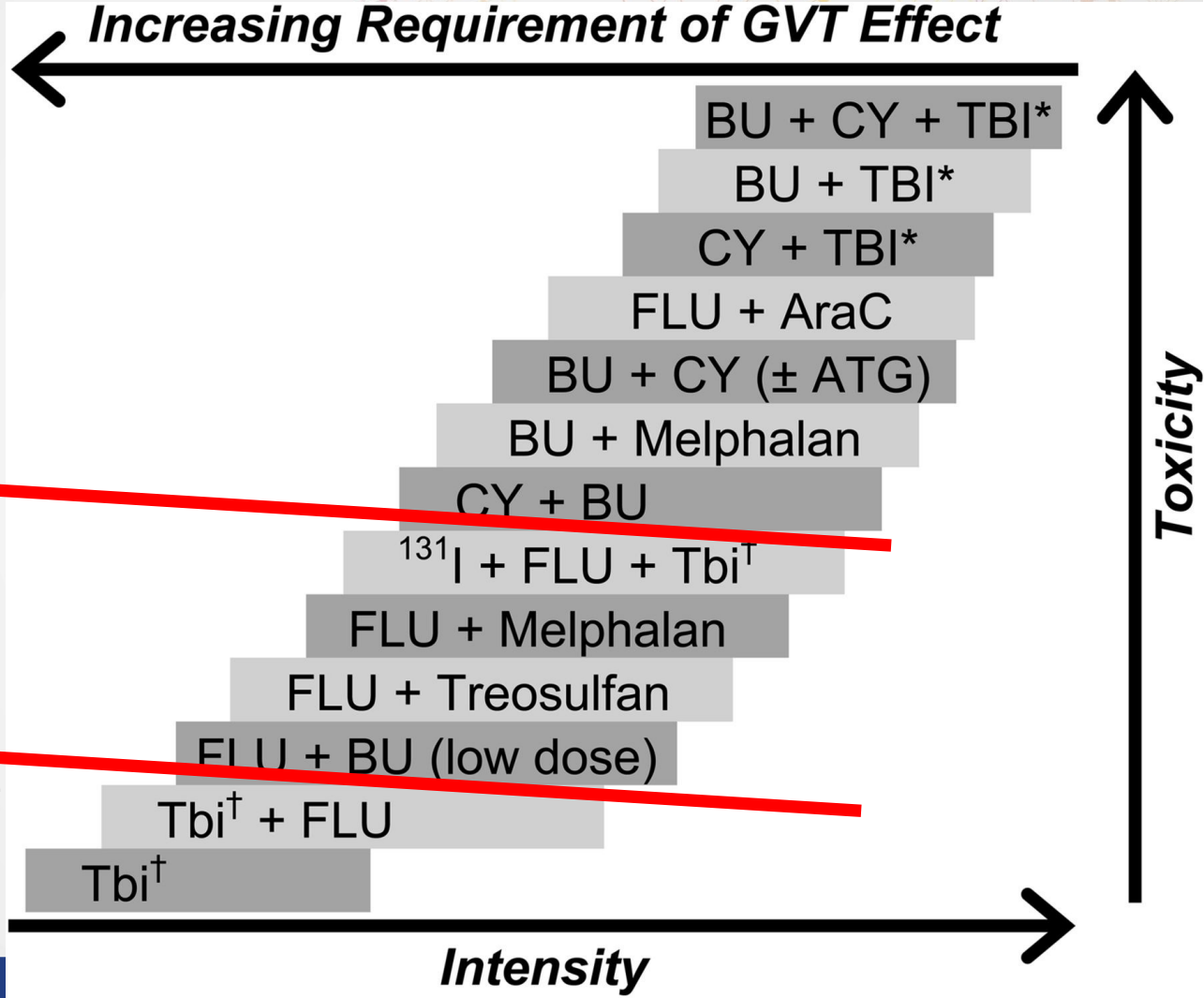


Conditioning Intensity



Maxi **Midi** **Mini**

- Myeloablative
- Reduced Intensity
- Non myeloablative



Conditioning

If you cannot agree on conditioning
Intensity:
List the drugs and the doses

TOTAL PRESCRIBED CUMULATIVE DOSE*

Multiply daily dose in mg/kg or mg/m² by the number of days; e.g. Busulfan given 4mg/kg daily for 4 days, total dose to report is 16mg/kg. NOTE: ONLY AGENTS GIVEN BEFORE THE DATE OF THE 1ST CELL INFUSION (DAY 0) SHOULD BE LISTED HERE

DRUG (given before day 0)	DOSE	UNITS		Area under the curve (AUC)
☐ Ara-C *(cytarabine)*		☐ mg/m²	☐ mg/kg	
☐ ALG, ATG Animal origin: ☐ Horse ☐ Rabbit ☐ Other, specify…. …… ..		☐ mg/m²	☐ mg/kg	
☐ Bleomycin		☐ mg/m²	☐ mg/kg	
☐ Busulfan ☐ Oral ☐ IV ☐ Both		☐ mg/m²	☐ mg/kg	☐ mg x h/L ☐ mbromol x min/L ☐ mg x min/mL
☐ BCNU		☐ mg/m²	☐ mg/kg	
☐ Bexxar *(radiolabelled MoAB)*		☐ mCi	☐ MBq	
☐ CCNU		☐ mg/m²	☐ mg/kg	
☐ Campath *(antiCD52)*		☐ mg/m²	☐ mg/kg	
☐ Carboplatin		☐ mg/m²	☐ mg/kg	☐ mg x h/L ☐ mbromol x min/L ☐ mg x min/mL
☐ Cisplatin		☐ mg/m²	☐ mg/kg	
☐ Clofarabine		☐ mg/m²	☐ mg/kg	
☐ Corticosteroids		☐ mg/m²	☐ mg/kg	
☐ Cyclophosphamide		☐ mg/m²	☐ mg/kg	
☐ Daunorubicin		☐ mg/m²	☐ mg/kg	
☐ Doxorubicin *(adriamycine)*		☐ mg/m²	☐ mg/kg	
☐ Epirubicin		☐ mg/m²	☐ mg/kg	
☐ Etoposide *(VP16)*		☐ mg/m²	☐ mg/kg	
☐ Fludarabine		☐ mg/m²	☐ mg/kg	
☐ Gemtuzumab		☐ mg/m²	☐ mg/kg	
☐ Idarubicin		☐ mg/m²	☐ mg/kg	
☐ Ifosfamide		☐ mg/m²	☐ mg/kg	
☐ Imatinib mesylate		☐ mg/m²	☐ mg/kg	
☐ Melphalan		☐ mg/m²	☐ mg/kg	
☐ Mitoxantrone		☐ mg/m²	☐ mg/kg	
☐ Paclitaxel		☐ mg/m²	☐ mg/kg	
☐ Rituximab *(mabthera, antiCD20)*		☐ mg/m²	☐ mg/kg	
☐ Teniposide		☐ mg/m²	☐ mg/kg	
☐ Thiotepa		☐ mg/m²	☐ mg/kg	
☐ Treosulphan		☐ mg/m²	☐ mg/kg	
☐ Zevalin *(radiolabelled MoAB)*		☐ mCi	☐ MBq	
☐ Other radiolabelled MoAB, specify		☐ mCi	☐ MBq	
☐ Other MoAB, specify ……		☐ mg/m²	☐ mg/kg	
☐ Other, specify ……		☐ mg/m²	☐ mg/kg	

TBI

TBI ☐ No ☐ Yes ☐ Unknown

Total dose (Gy): .... - ..... 12 Gy Number of fractions .... over .... radiation days 6 3

TLI / TNI / TAI ☐ No ☐ Yes: Total dose (Gy): .... - ..... ☐ Unknown

Local radiotherapy ☐ No ☐ Yes ☐ Unknown

GvHD PREVENTION IN THE RECIPIENT

☐ No

☐ Yes: ☐ Drugs *(Immunosuppressive chemo)*

☐ ALG, ALS, ATG, ATS *(given after day 0)*: Animal origin: ☐ Horse ☐ Rabbit ☐ Other, specify.... .....

☐ Anti CD25 *(MoAB in vivo)*

☐ Campath *(MoAB in vivo; can be "in the bag")*

☐ Systemic corticosteroids

☐ Cyclosporine

☐ Cyclophosphamide *(given after day 0)*

☐ Etanercept *(MoAB in vivo)*

☐ FK 506 (Tacrolimus, Prograf)

☐ Infliximab *(MoAB in vivo)*

☐ Methotrexate

☐ Mycophenolate (MMF)

☐ Sirolimus

☐ Other monoclonal antibody *(in vivo)*, specify .....

☐ Other agent *(in vivo)*, specify.....

Extra-corporeal photopheresis (ECP)

Other: .....

Standards:
CSA + MTX
CSA + MMF

TAC + MTX
TAC + MMF

+- ATG

posttransplant Cyclophosphamide

Main Cause of Death *(check only one main cause)*:

☐ Relapse or Progression/Persistent disease ☐ HSCT Related Cause

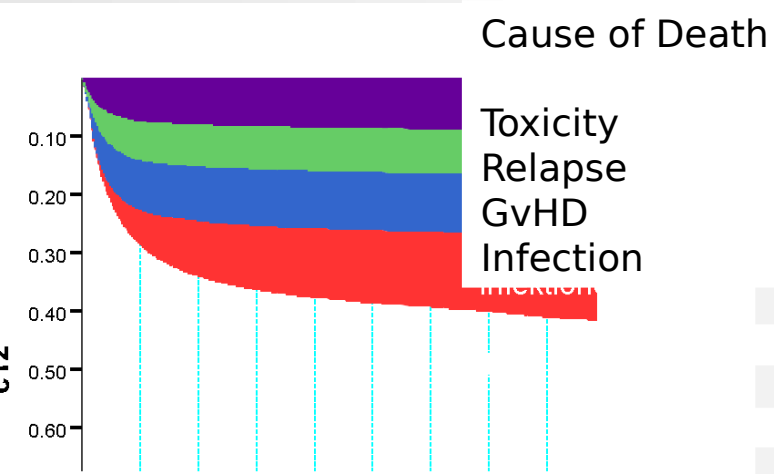
☐ Unknown

☐ Other: .....

Contributory Cause of Death *(check as many as appropriate)*:

(check as many as appropriate)	Yes	No	Unknown
GvHD *(if previous allograft)*	☐	☐	☐
Interstitial pneumonitis	☐	☐	☐
Pulmonary toxicity	☐	☐	☐
'nfection	☐	☐	☐
bacterial	☐	☐	☐
viral	☐	☐	☐
fungal	☐	☐	☐
parasitic	☐	☐	☐
ejection / poor graft function	☐	☐	☐
istory of severe Veno-Occlusive disorder (VOD)	☐	☐	☐
Haemorrhage	☐	☐	☐
Cardiac toxicity	☐	☐	☐
Central nervous system toxicity	☐	☐	☐
Gastro intestinal toxicity	☐	☐	☐
Skin toxicity	☐	☐	☐
Renal failure	☐	☐	☐
Multiple organ failure	☐	☐	☐

Other: .....



RECOVERY and GRAFT PERFORMANCE

Absolute neutrophil count (ANC) recovery *(Neutrophils ≥0.5X10⁹ /L)*

☐ No: Date of last assessment: ..... - ..... - .....
yyyy mm dd

☐ Yes: Date of ANC recovery: ..... - ..... - ..... *(first of 3 consecutive values after 7 days without transfusion)*
yyyy mm dd

☐ Never below

☐ Unknown

Platelet recovery

Platelets **≥20** x 10^9/l; *(first of 3 consecutive values after 7 days without transfusion)*

☐ No

☐ Yes: Date Platelets ≥ 20 x 10^9/l ..... - ..... - .....
yyyy mm dd

☐ Never below this level

☐ Date unknown: patient discharged before levels reached

☐ Date unknown: out-patient

☐ Unknown

Platelets **≥50** x 10^9/l; *(first of 3 consecutive values after 7 days without transfusion)*

☐ No

☐ Yes: Date Platelets ≥ 50 x 10^9/l ..... - ..... - .....
yyyy mm dd

☐ Never below this level

☐ Date unknown: patient discharged before levels reached

☐ Date unknown: out-patient

☐ Unknown

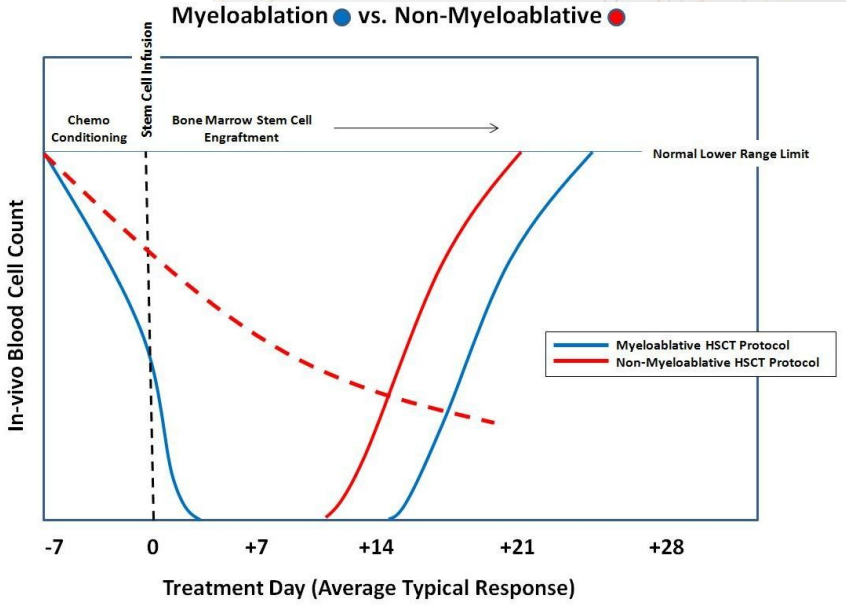
Date last platelet transfusion:..... - ..... - ..... ☐ Not applicable: not transfused
yyyy mm dd

Early graft loss *(Engraftment followed by loss of graft within the first 100 days)*

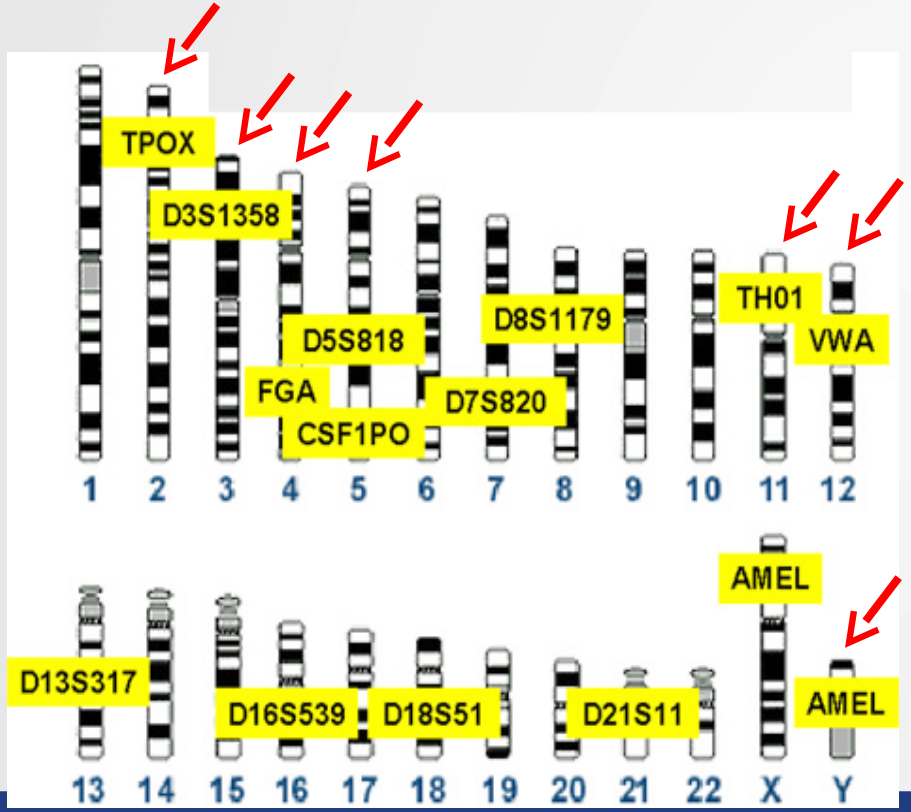
☐ No

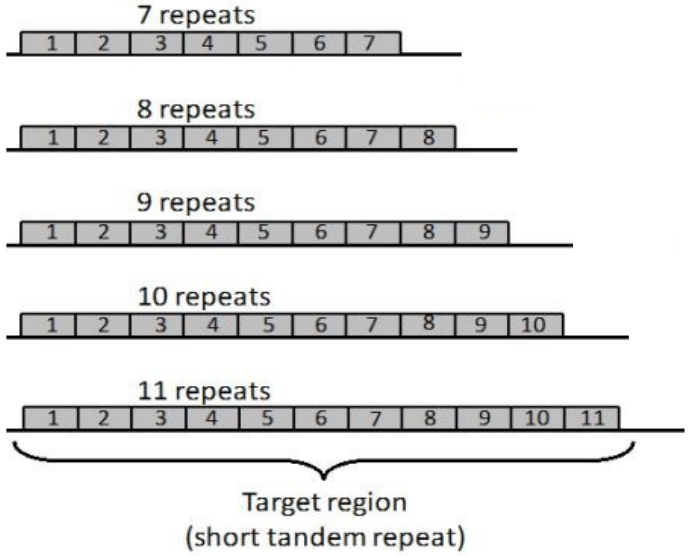
☐ Yes: date of graft failure ..... - ..... - .....
yyyy mm dd

☐ Unknown

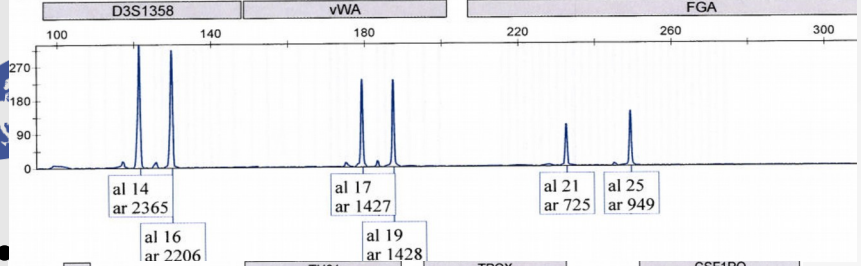


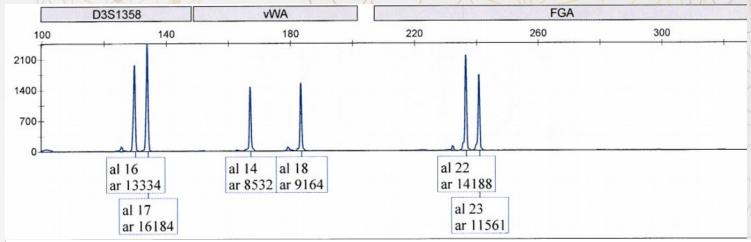
Variable number tandem repeats or short tandem repeats

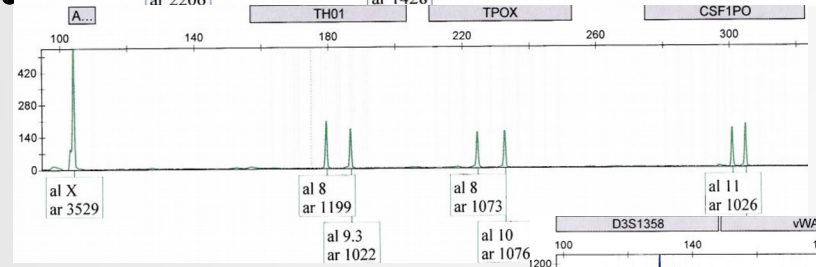


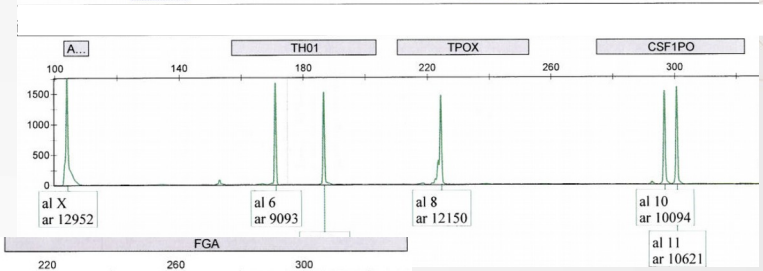


- 2-nucletotide repeat unit : (CA)(CA)(CA)····
- 3 -nucletotide repeat unit : (GCC)(GCC)(GCC) ····
- 4 -nucletotide repeat unit : (AATG)(AATG)(AATG) ····
- 5 -nucletotide repeat unit : (AGAAA)(AGAAA) ····

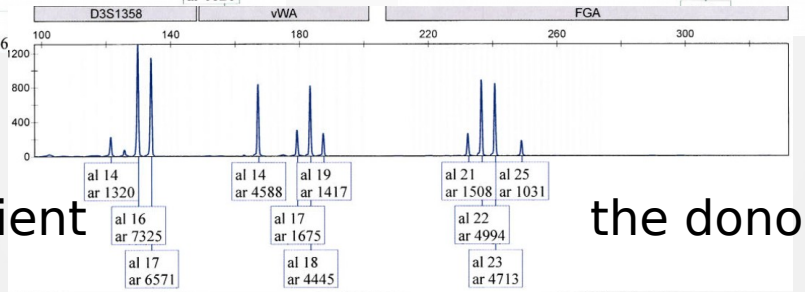






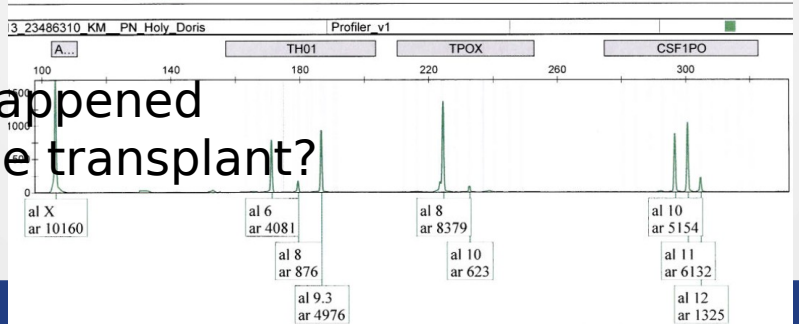


the patient



the donor

What happened
After the transplant?



HAEMOPOIETIC CHIMAERISM

Overall chimaerism

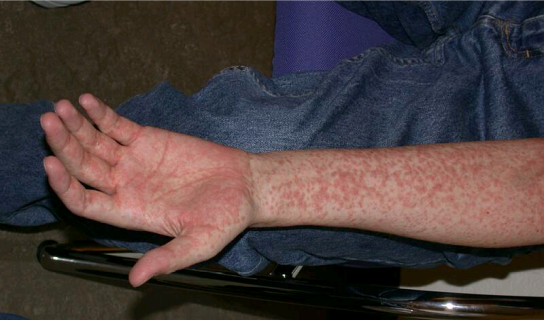
- ☐ Full *(donor ≥95 %)*
- ☐ Patient reconstitution *(recipient ≥95 %)*
- ☐ Not informative
- ☐ Mixed *(partial)*
- ☐ Aplasia
- ☐ Not evaluated

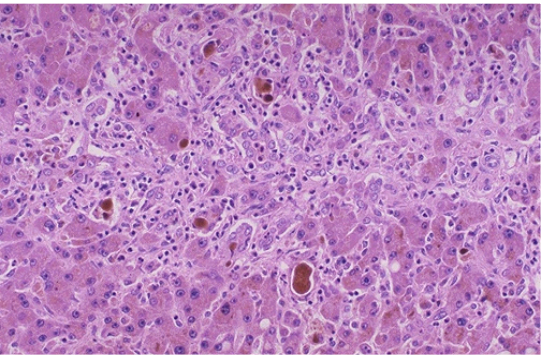
INDICATE THE DATE(S) AND RESULTS OF ALL TESTS DONE FOR ALL DONORS.

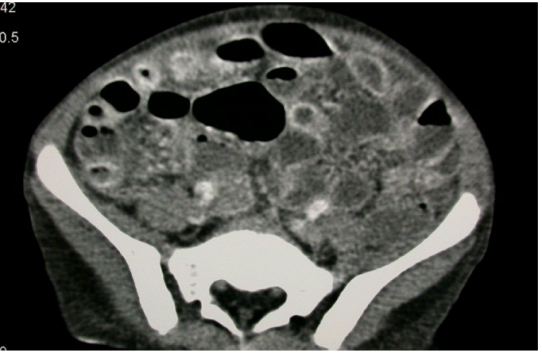
SPLIT THE RESULTS BY DONOR AND BY THE CELL TYPE ON WHICH THE TEST WAS PERFORMED IF APPLICABLE.

COPY THIS TABLE AS MANY TIMES AS NECESSARY.

Date of test	Identification of donor or Cord Blood Unit given by the centre	Number in the infusion order *(if applicable)*	Cell type on which test was performed	% Donor cells	Test used
.... - ..... - .... *yyyy* *mm* *dd*	.....	..... ☐ N/A	☐ BM ☐ PB mononuclear cells (PBMC) ☐ T-cell ☐ B-cells ☐ Red blood cells ☐ Monocytes ☐ PMNs (neutrophils) ☐ Lymphocytes, NOS ☐ Myeloid cells, NOS ☐ Other, specify:	..... % ....% ..... % ..... % ....% ..... % ..... % ....% ..... % ..... %	☐ FISH ☐ Molecular ☐ Cytogenetic ☐ ABO group ☐ Other: ..... ☐ unknown







GVHD

ACUTE GRAFT VERSUS HOST DISEASE (AGVHD)

Maximum grade ☐ 0 (none) ☐ grade I ☐ grade II ☐ grade III ☐ grade IV ☐ Not evaluated

Date of onset: ....- .... - ....
yyyy *mm* *dd*

Stage:

Skin	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Liver	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Lower GI tract	☐ 0 (none)	☐ 1	☐ 2	☐ 3	☐ 4
Upper GI tract	☐ 0 (none)	☐ 1			

Other site affected ☐ No ☐ Yes

Resolution

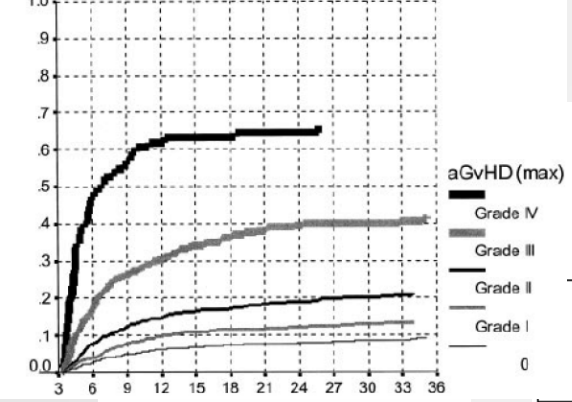
☐ No ☐ Yes: Date of resolution: ....- .... - ....
yyyy *mm* *dd*

Treatment

☐ No

☐ Yes
- ☐ Corticosteroids
- ☐ MoAB: .....
- ☐ ATG/ALG
- ☐ Extra-corporeal photopheresis (ECP)
- ☐ Other: .....

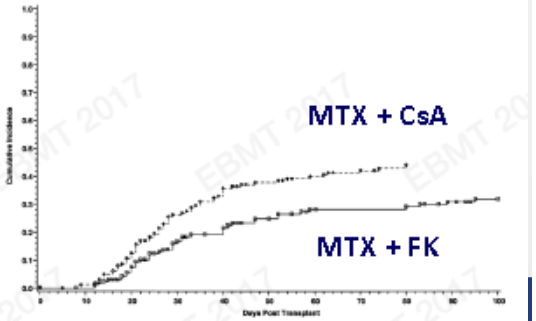
Acute GVHD: Clinical Stage



Time to GvHD Onset = Cumulative Incidence

	Skin	Liver	Gut
Stage	% BSA	Bilirubin (mg/dl)	Diarrhea (ml/day)
I	<25	2-3	500-1000
II	25-50	3.1-6	1000-15000
III	Generalized erythroderma	6.1-15	>1500
IV	Bullae	>15	Pain+/-ileus

Acute GvHD, Grade II-IV
HLA-Id. sibling transplant



Acute GVHD: Clinical Grade

Overall Grade	Skin	Liver	GI	Upper GI
1	1-2	0	0	0
II	1-3	1	1	1
III	2-3	2-4	2-3	
IV	4	-	4	

ADDITIONAL CELL INFUSIONS ***(excluding a new HSCT)***

☐ No

☐ Yes: Is this cell infusion an allogeneic boost? ☐ No ☐ Yes – *Skip Cell therapy table below*

An allo boost is an infusion of cells from the same donor without conditioning, with no evidence of graft rejection.

Is this cell infusion an autologous boost? ☐ No ☐ Yes – *Skip Cell therapy table below*

If the cell infusion is **not** a boost fill in the **Cell therapy** section below:

CELL THERAPY

First date of the cell therapy infusion..... - ..... - .....
yyyy mm dd

Source of cell(s): ☐ Allo ☐ Auto
(check all that apply)

Type of cell(s): *(check all that apply)*

☐ Lymphocyte *(DLI)* ☐ Mesenchymal ☐ Fibroblasts ☐ Dendritic cells
☐ NK cells ☐ Regulatory T-cells ☐ Gamma/delta cells ☐ Other, specify ....

Number of cells infused by type		
Nucleated cells (/kg*) *(DLI only)*	....- .... ☐ Not evaluated ☐ unknown	x 10^8
CD 34+ (cells/kg*) *(DLI only)*	....- .... ☐ Not evaluated ☐ unknown	x 10^6
CD 3+ (cells/kg*) *(DLI only)*	....- .... ☐ Not evaluated ☐ unknown	x 10^6
Total number of cells infused		
All cells (cells/kg*) *(non DLI only)*	....- .... ☐ Not evaluated ☐ unknown	x 10^6

Chronological number of the cell infusion episode for this patient .....

Indication: *(check all that apply)*

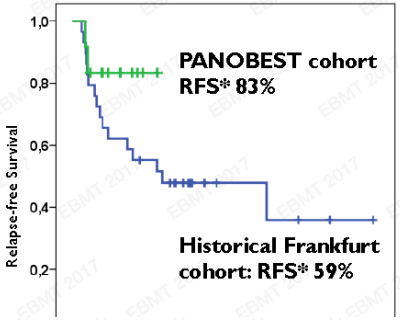
☐ Planned/protocol ☐ Treatment for disease
☐ Prophylactic ☐ Mixed chimaerism
☐ Treatment of GvHD ☐ Treatment viral infection
☐ Loss/decreased chimaerism
☐ Treatment PTLD, EBV lymphoma
☐ Other, specify ....

Number of infusions within 10 weeks .....
(count only infusions that are part of same regimen and given for the same indication)

Safety and Feasibility of Administration of High Doses of Ex Vivo Expanded NK Cells for Prevention of Disease Relapse after Transplantation for Patients with Myeloid Malignancies - Final Results of a Phase I Clinical Trial

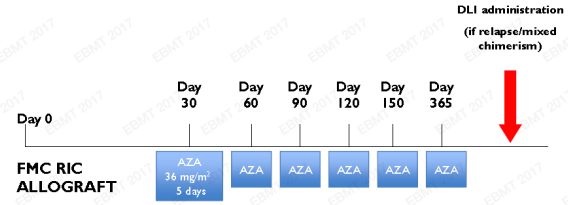
Stefan O. Ciurea, MD, The University of Texas MD Anderson Cancer Center

Relapse-free survival in PANOBEST study



	PANOBEST cohort (n=12)	Historical cohort (n=29)
Median age (years)	50	51
Diagnosis (AML/MDS)	11/1	29/0
Disease stage at HSCT (active/CR2)	11/1	29/0
BM blasts at HSCT (median, %)	25	31
Year of HSCT (median)	2012	2008
Median follow-up (years)	1,2	2,3

UK Phase I/II RICAZA trial of adjunctive AZA after RIC allogeneic SCT in AML/MDS



Commence AZA 36 mg/m² on Day +42 if ANC >0.5, Plt >50
AZA discontinued at 12/12 post-SCT

NEJM Original Article

Ipilimumab for Patients with Relapse after Allogeneic Transplantation

ADDITIONAL DISEASE TREATMENT

☐ No
☐ Yes: ☐ Pre-emptive / preventive *(planned before the transplant took place)*
☐ For relapse / progression or persistent disease *(not planned)*

Date started ..... - ..... - .....
yyyy *mm* *dd*

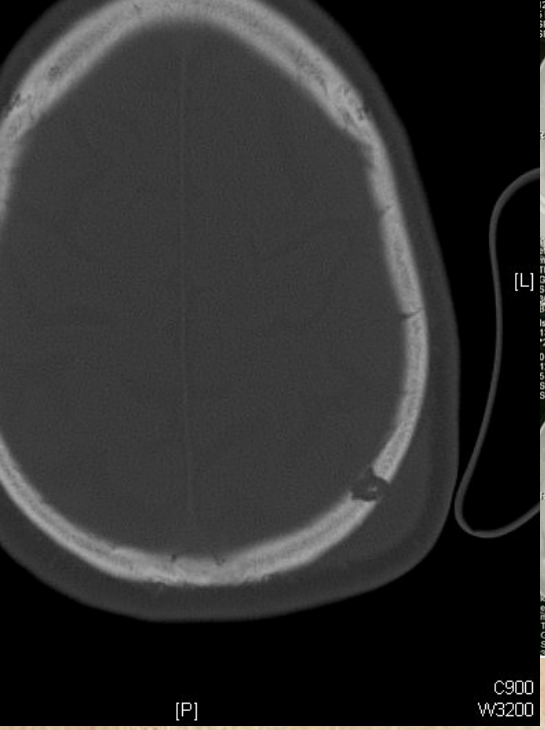
Chemo/drug
☐ No
☐ Yes:
- ☐ Anti-lymphocyte antibodies
- ☐ Azacytidine
- ☐ Azathioprine
- ☐ Bortezomib (Velcade)
- ☐ Cop-l
- ☐ Corticosteroids
- ☐ Crenolanib
- ☐ Cyclophosphamide
- ☐ Dasatinib (Sprycel)
- ☐ Decitabine
- ☐ Eculizumab (Soliris)
- ☐ Imatinib mesylate (Gleevec, Glivec)
- ☐ Interferon α
- ☐ Interferon β
- ☐ Kepivance (KGF, palifermin)
- ☐ Lenalidomide (Revlimid)
- ☐ Midostaurin
- ☐ Mitoxantrone
- ☐ Nilotinib (Tasigna)
- ☐ Panobinosta
- ☐ Quizartinib
- ☐ Rituximab (Rituxan, mabthera)
- ☐ Sorafenib
- ☐ Thalidomide
- ☐ Velafermin (FGF)

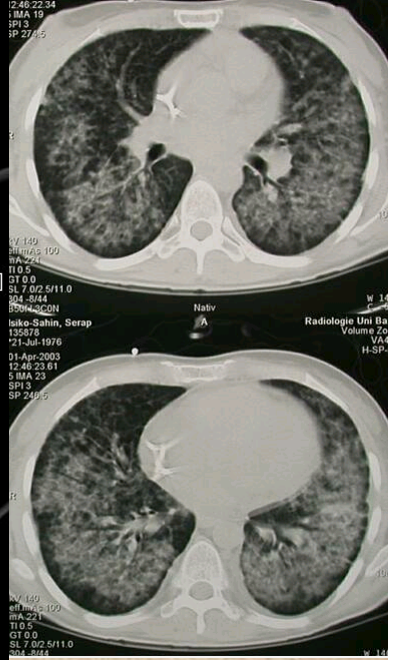
☐ Other HDAC inhibitor: .....
☐ Other TKI inhibitor: .....

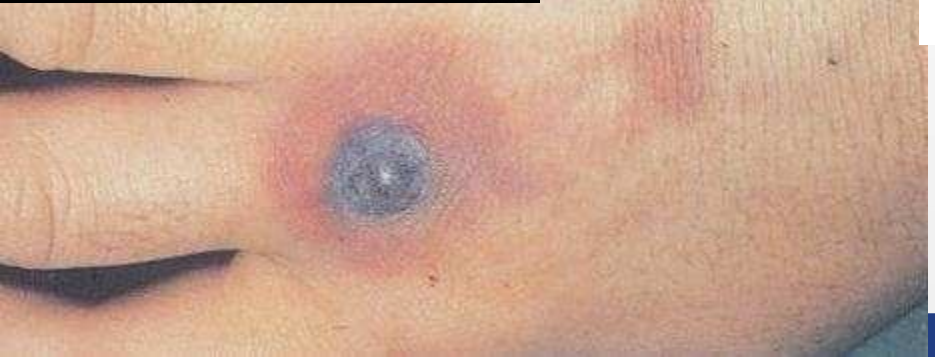
☐ Other drug/chemotherapy, specify ..... Intrathecal: ☐ No ☐ Yes

Radiotherapy ☐ No ☐ Yes ☐ Unknown

Other type ☐ No ☐ Yes, specify ..... ☐ Unknown







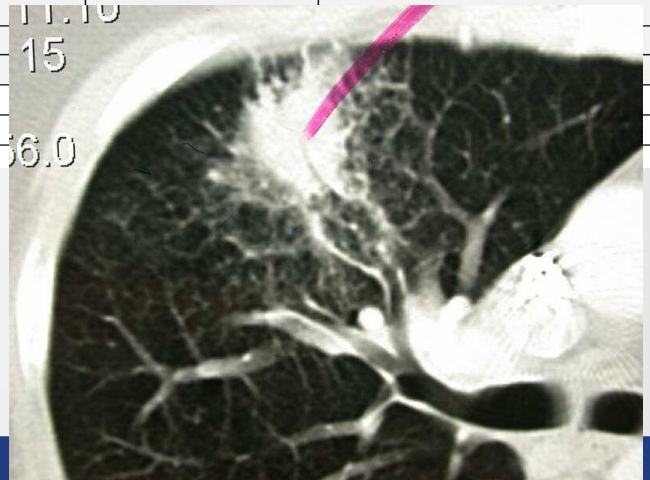
COMPLICATIONS WITHIN THE FIRST 100 DAYS.

PLEASE USE THE DOCUMENT "DEFINITIONS OF INFECTIOUS DISEASES AND COMPLICATIONS AFTER STEM CELL TRANSPLANTATION" TO FILL THESE ITEMS.

INFECTION RELATED COMPLICATIONS

☐ No complications
☐ Yes

Type	Pathogen *Use the list of pathogens listed after this table for guidance. Use "unknown" if necessary.*	Date *Provide different dates for different episodes of the same complication if applicable.*
Bacteraemia/ fungemia / viremia / parasites		
SYSTEMIC SYMPTOMS OF INFECTION		
Septic shock		
ARDS		
Multiorgan failure due to infection		



ENDORGAN DISEASES
Pneumonia
Hepatitis
CNS infection
Gut infection
Skin infection
Cystitis

DOCUMENTED PATHOGENS *(Use this table for guidance on the pathogens of interest)*

Type	Pathogen	Type	Pathogen
Bacteria		Viruses	
	S. pneumoniae		HSV
	Other gram positive *(i.e.: other streptococci, staphylococci, listeria ...)*		VZV
	Haemophilus influenzae		EBV
	Other gram negative *(i.e.: E. coli klebsiella, proteus, serratia, pseudomonas ...)*		CMV
	Legionella sp		HHV-6
	Mycobacteria sp		RSV
	Other:		Other respiratory virus *(influenza, parainfluenza, rhinovirus)*
Fungi			Adenovirus
	Candida sp		HBV
	Aspergillus sp		HCV
	Pneumocystis carinii		HIV
	Other:		Papovavirus
Parasites			Parvovirus
	Toxoplasma gondii		Other: .....
	Other:		

NON INFECTION RELATED COMPLICATIONS

☐ No complications
☐ Yes

Type *(Check all that are applicable for this period)*	**Yes**	**No**	**Unknown**	**Date**
Idiopathic pneumonia syndrome	☐	☐	☐	
VOD	☐	☐	☐	
Cataract	☐	☐	☐	
Haemorrhagic cystitis, non infectious	☐	☐	☐	
ARDS, non infectious	☐	☐	☐	
Multiorgan failure, non infectious	☐	☐	☐	
HSCT-associated microangiopathy	☐	☐	☐	
Renal failure requiring dialysis	☐	☐	☐	
Haemolytic anaemia due to blood group	☐	☐	☐	
Aseptic bone necrosis	☐	☐	☐	
Other: ..... VOTCOMPS	☐			
				yyyy *mm* *dd*

LAST CONTACT DATE FOR 100 DAY ASSESSMENT

*If patient has died **before** this date, enter date of death, otherwise enter Date of HSCT + 100 DAYS APPROX.*

Day 100 assessment: ..... - ..... - .....
yyyy *mm* *dd*

OR

Date of death (if before day 100): ..... - ..... - .....
yyyy *mm* *dd*

The many facets of cGvHD

CHRONIC GRAFT VERSUS HOST DISEASE (cGvHD)

Chronic Graft Versus Host Disease present between HSCT and 100 days or date of death

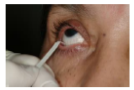
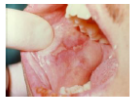
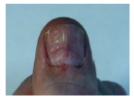
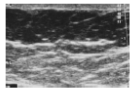
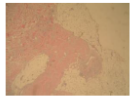
- ☐ No *(never)*
- ☐ Yes, first episode

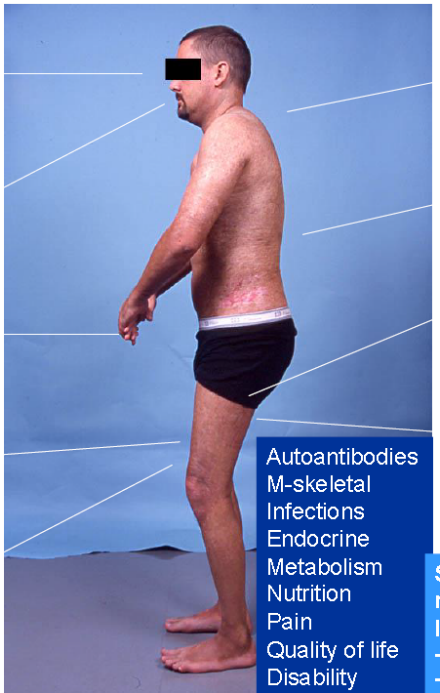
Date of onset ..... - ..... - .....
yyyy *mm* *dd*

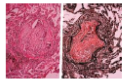
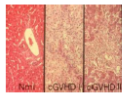
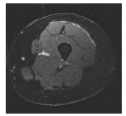
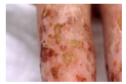
Maximum extent during this period ☐ Limited ☐ Extensive ☐ Not evaluated

Maximum NIH score during this period
☐ Mild ☐ Moderate ☐ Severe ☐ Not calculated

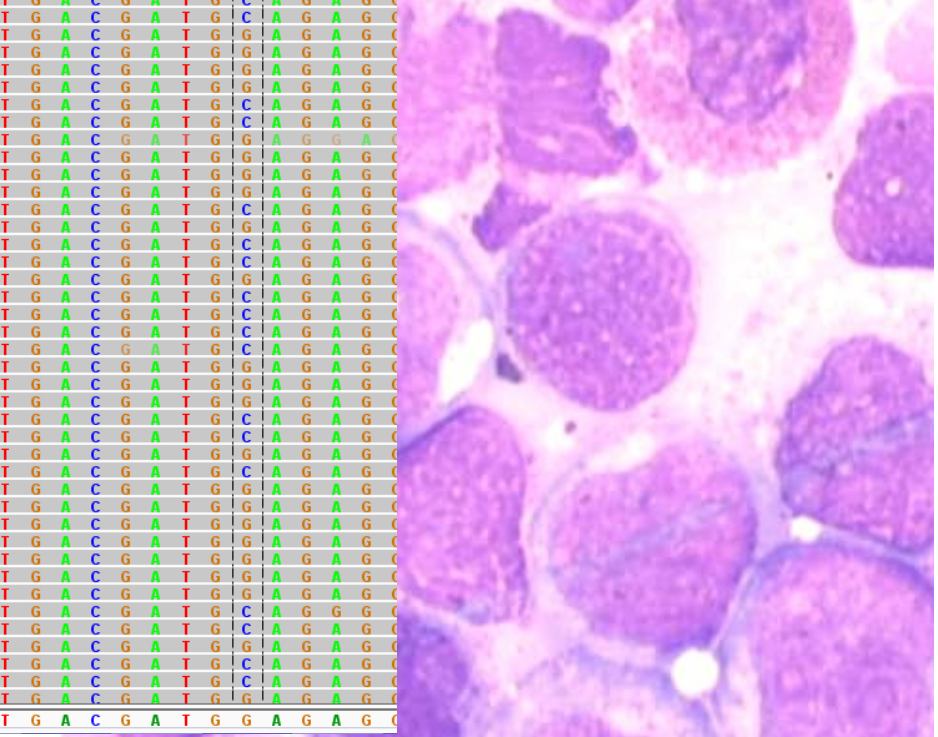
Organs affected ☐ Skin ☐ Liver ☐ Lower GI tract ☐ Upper GI tract
☐ Mouth ☐ Eyes ☐ Lung ☐ Other, specify
☐ Unknown

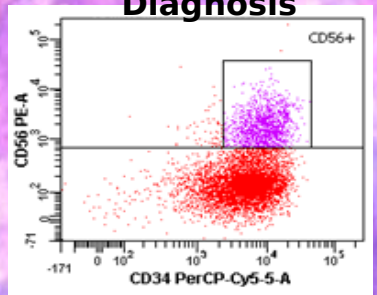






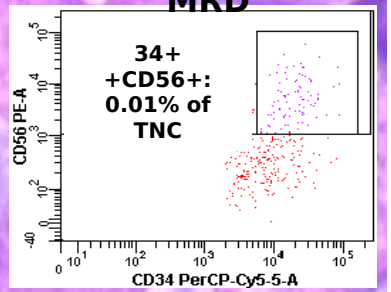


Spectrum of manifestations In cGVHD
- 50% Incidence
- 15% Life Threatening







FIRST RELAPSE OF PROGRESSION

- ☐ No
- ☐ Yes; date diagnosed: .... - .... - .... (yyyy mm dd)

FOR LEUKAEMIAS ONLY, IF RELAPSE OR PROGRESSION IS YES, FILL IN METHOD DETAILS:

Method of detection		Site
Clinical/haematological relapse or progression	☐ No: Date assessed ..... - ..... - ..... (yyyy mm dd) ☐ Yes: Date first seen ..... - ..... - ..... (yyyy mm dd) ☐ Not evaluated	☐ marrow – blood ☐ extramedullary
Cytogenetic relapse or progression	☐ No: Date assessed ..... - ..... - ..... (yyyy mm dd) ☐ Yes: Date first seen ..... - ..... - ..... (yyyy mm dd) ☐ Not evaluated	☐ marrow – blood ☐ extramedullary
Molecular relapse or progression	☐ No: Date assessed ..... - ..... - ..... (yyyy mm dd) ☐ Yes: Date first seen ..... - ..... - ..... (yyyy mm dd) ☐ Not evaluated	☐ marrow – blood ☐ extramedullary

- ☐ Continuous progression since transplant
- ☐ Unknown

DISEASE STATUS AT 100 DAYS *(record the most recent status and date for each method of assessment, depending on the disease)*

Method	Disease detected
Clinical/haematological	☐ No ☐ Yes Last date evaluated ..... - ..... - ..... (yyyy mm dd) ☐ Not evaluated
FILL IN ONLY FOR ACUTE AND CHRONIC LEUKAEMIAS Cytogenetic/FISH	☐ No ☐ Yes: Considered disease relapse/progression ☐ No ☐ Yes Last date assessed ..... - ..... - ..... (yyyy mm dd) ☐ Not evaluated
Molecular	☐ No ☐ Yes: Considered disease relapse/progression ☐ No ☐ Yes Last date assessed ..... - ..... - ..... (yyyy mm dd) ☐ Not evaluated

Thank you for your hard work