GPOH / DGHO – DBA

SCT day 100

Bitte senden an: DBA-Studienzentrale, Universitätsklinikum Freiburg, Kinder- und Jugendklinik, Klinik für Pädiatrische Hämatologie und Onkologie
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Patient Identification Number / Name
|_____|

Date of Birth
|__|__||__|__||__|__|__I__I
(dd/mm/yyyy)

Center
|_____|

UPN
|_____|

Date of SCT
|__|__||__|__||__|__|__I__I
(dd/mm/yyyy)

Number of SCT |_____|

Informed consent given for: PRST ☐ no ☐ yes EBMT ☐ no ☐ yes

DRST ☐ no ☐ yes CIBMTF ☐ no ☐ yes

Patient

Date of specimen collection |__|__||__|__||__|__|__I__I (dd/mm/yyyy)

Blood group ☐ A ☐ B ☐ AB ☐ 0

☐ Rh pos ☐ Rh neg

HLA Typing

|__|__|__|__| A |__|__|__|__| B |__|__|__|__| C |__|__|__|__| DRB1 |__|__|__|__| DQB1 |__|__|__|__| DPB1

|__|__|__|__| A |__|__|__|__| B |__|__|__|__| C |__|__|__|__| DRB1 |__|__|__|__| DQB1 |__|__|__|__| DPB1

Infection Markers prior to HSCT

CMV IgG	☐ positive	☐ negative	☐ unknown
CMV IgM	☐ positive	☐ negative	☐ unknown
EBV-VCA IgG	☐ positive	☐ negative	☐ unknown
EBV-VCA IgM	☐ positive	☐ negative	☐ unknown
Anti-HBc	☐ positive	☐ negative	☐ unknown
HBsAg	☐ positive	☐ negative	☐ unknown
Anti-HBs	☐ positive	☐ negative	☐ unknown
HCV IgG	☐ positive	☐ negative	☐ unknown
HIV IgG	☐ positive	☐ negative	☐ unknown
HSV IgG	☐ positive	☐ negative	☐ unknown
HTLV I IgG	☐ positive	☐ negative	☐ unknown
Toxoplasmosis IgG	☐ positive	☐ negative	☐ unknown
VZV	☐ positive	☐ negative	☐ unknown
HCV PCR	☐ positive	☐ negative	☐ unknown
HIV PCR	☐ positive	☐ negative	☐ unknown
HTLV PCR	☐ positive	☐ negative	☐ unknown

Body measurements Height (cm) : _____ Weight (kg) : _____ Body surface area (BSA): _____

Performance status Date of assessment: |__|__||__|__||__|__|__I__I (dd/mm/yyyy)

Karnofsky / Lansky score : _____ %

Pregnancy excluded ☐ no ☐ yes

DBA specific data at HSCT

Indication for SCT

transfusions ☐ no ☐ yes, number of transfusions prior to HSCT: ☐ < 20
☐ 20-50
☐ > 50, number |_____|

steroids ☐ no ☐ yes, last dose |_____|

steroid side effects ☐ no ☐ yes, please specify |_____|

clonal chromosomal aberration ☐ no ☐ yes, please specify |_____|

thrombocytopenia ☐ no ☐ yes, platelet transfusions ☐ no ☐ yes

other ☐ no ☐ yes |_____|

Hämosiderosis

Ferritin (Serum) |_____| (µg/l) Date |__|__||__|__||__|__|__|__| (dd/mm/yyyy)

SQUID |____| mg / g liver-dry weight Date |__|__||__|__||__|__|__|__| (dd/mm/yyyy)

Liver-biopsy |____| mg / g liver-dry weight Date |__|__||__|__||__|__|__|__| (dd/mm/yyyy)

Iron-MRI performed ☐ no ☐ yes, please enclose report Date |__|__||__|__||__|__|__|__| (dd/mm/yyyy)

Hepatopathy SGPT elevated > CTCAE grade 2 ☐ no ☐ yes ☐ CTCAE °3 ☐ CTCAE °4
(SGPT grade 3: > 5.0-20.0 x ULN, grade 4: SGPT > 20.0 x ULN, grades 1 and 2 are treated as not relevant)

hepatomegaly > 3 cm below costal margin ☐ no ☐ yes

Chelation ☐ no ☐ yes:

☐ Deferoxamin (Desferal), application: ☐ s.c. ☐ i.v.
Dose: |_____| mg/kg/day frequency: |_____| days/week
Date: |__|__||__|__||__|__|__|__| - |__|__||__|__||__|__|__|__| ❒ ongoing

☐ Deferasirox (Exjade)
Dose: |_____| mg/kg/day frequency: |_____| days/week
Date: |__|__||__|__||__|__|__|__| - |__|__||__|__||__|__|__|__| ❒ ongoing

☐ Deferipron (Ferriprox)
Dose: |_____| mg/kg/day frequency: |_____| days/week
Date: |__|__||__|__||__|__|__|__| - |__|__||__|__||__|__|__|__| ❒ ongoing

☐ other: |_____|
application: ☐ s.c. ☐ p.o. ☐ i.v.
Dose: |_____| mg/kg/day frequency: |_____| days/week
Date: |__|__||__|__||__|__|__|__| - |__|__||__|__||__|__|__|__| ☐ ongoing

Peripheral blood: Date |__|__||__|__||__|__|__I__I (dd/mm/yy yy)

Hb	_____	☐ g/dl
		☐ mmol/l
Hematocrit	_____	%
MCV	_____	fl
Erythrocytes	_____	x 10^6/µl
Reticulocytes	_____	‰
WBC	_____	x 10^3/µl
Platelets	_____	x 10^3/µl

Differential count (in %)	Peripheral blood
Blast	
Promyelocyte	
Myelocyte	
Metamyelocyte	
Band	
Segmented	
Eosinophil	
Basophil	
Lymphocyte	
Monocyte	
Normoblast	
	100 %

Donor

Age (YY) |__|__| **Sex** ☐ male ☐ female

Relation with the patient ☐ unrelated: donor ID (eg DKM): I_____I

☐ related: ☐ syngeneic ☐ other sibling ☐ other family member

Date of specimen collection Date |__|__||__|__||__|__|__I__I (dd/mm/yy yy)

ABO Group ☐ A ☐ B ☐ AB ☐ 0

☐ Rh pos ☐ Rh neg

HLA Typing

|__|__|__|__| A |__|__|__|__| B |__|__|__|__| C |__|__|__|__| DRB1 |__|__|__|__| DQB1 |__|__|__|__| DPB1

|__|__|__|__| A |__|__|__|__| B |__|__|__|__| C |__|__|__|__| DRB1 |__|__|__|__| DQB1 |__|__|__|__| DPB1

Serologic Status of the Donor

CMV IgG	☐ positive	☐ negative	☐ unknown
CMV IgM	☐ positive	☐ negative	☐ unknown
EBV-VCA IgG	☐ positive	☐ negative	☐ unknown
EBV-VCA IgM	☐ positive	☐ negative	☐ unknown
Anti-HBc	☐ positive	☐ negative	☐ unknown
HBsAg	☐ positive	☐ negative	☐ unknown
Anti-HBs	☐ positive	☐ negative	☐ unknown
HCV IgG	☐ positive	☐ negative	☐ unknown
HIV IgG	☐ positive	☐ negative	☐ unknown
HSV IgG	☐ positive	☐ negative	☐ unknown
HTLV I IgG	☐ positive	☐ negative	☐ unknown

Toxoplasmosis IgG	☐ positive	☐ negative	☐ unknown
VZV	☐ positive	☐ negative	☐ unknown
HCV PCR	☐ positive	☐ negative	☐ unknown
HIV PCR	☐ positive	☐ negative	☐ unknown
HTLV PCR	☐ positive	☐ negative	☐ unknown
Other	☐ positive	☐ negative	if positive, specify I_____I

Conditioning regimen

Drugs, ATG, mono AB

I_____I days of administration I__I I__I I__I I__I I__I I__I I__I I__I I__I (-7, -6, -5, ...)

dose each day I__I I__I I__I I__I I__I I__I I__I I__I I__I ☐ mg/m²/d ☐ mg/kg/d

I_____I days of administration I__I I__I I__I I__I I__I I__I I__I I__I I__I (-7, -6, -5, ...)

dose each day I__I I__I I__I I__I I__I I__I I__I I__I I__I ☐ mg/m²/d ☐ mg/kg/d

I_____I days of administration I__I I__I I__I I__I I__I I__I I__I I__I I__I (-7, -6, -5, ...)

dose each day I__I I__I I__I I__I I__I I__I I__I I__I I__I ☐ mg/m²/d ☐ mg/kg/d

I_____I days of administration I__I I__I I__I I__I I__I I__I I__I I__I I__I (-7, -6, -5, ...)

dose each day I__I I__I I__I I__I I__I I__I I__I I__I I__I ☐ mg/m²/d ☐ mg/kg/d

Modification of dosage ☐ no ☐ yes, reason I_____I

BSA used for drug calculation (m²): _____

TBI: ☐ no ☐ yes days of application I__I I__I I__I I__I I__I I__I I__I I__I I__I I__I (-7, -6, -5, ...)

number of fractions per day I__I I__I I__I I__I I__I I__I I__I I__I I__I

Gy per fraction I__I I__I I__I I__I I__I I__I I__I I__I I__I

Transplantation

Source of Stem Cells ☐ bone marrow ☐ peripheral blood ☐ cord blood

Manipulation of Graft ☐ no ☐ yes T-cell-depletion ☐ no ☐ yes

CD 34 positive selection ☐ no ☐ yes

other ☐ no ☐ yes, specify I_____I

Cells Infused number of nucleated cells infused (cells/kg of recipient body weight) _____ x10^8

number of CD34+ (cells/ kg of recipient body weight) _____ x10^6

number of CD3+ (cells/ kg of recipient body weight) _____ x10^4

Cytokines in the immediate Post-transplant Period (Excluding cytokines administered for engraftment failure)

☐ none ☐ G-CSF ☐ GM-CSF ☐ other, please specify _____

date of start |__|__||__|__||__|__|__|__I (dd/mm/yyyy)

date of last application |__|__||__|__||__|__|__|__I (dd/mm/yyyy)

GvHD Prophylaxis

Prophylaxis

Cyclosporin A (CSA) ☐ no ☐ yes starting dose (first 2 weeks i.v.) |_____| mg/kg/d

Date of first dose |__|__||__|__||__|__|__|__| (dd/mm/yyyy)

date of first tapering |__|__||__|__||__|__|__|__| (dd/mm/yyyy)

date of last dose |__|__||__|__||__|__|__|__| (dd/mm/yyyy)

Methotrexate ☐ no ☐ yes days |___| |___| |___| |___| after graft infusion

dose / day |___| |___| |___| |___| mg/m²

Leucovorin ☐ no ☐ yes

other ☐ no ☐ yes please specify |_____|

Engraftment

Engraftment ☐ no

☐ yes, hematopoietic reconstitution

leukocytes > $1x10^9$/l (dd/mm/yy) |__|__||__|__||__|__|__|__| (dd/mm/yyyy)
leukocytes never went below this level tick here ☐

neutrophils > $0.5x10^9$/l (dd/mm/yy |__|__||__|__||__|__|__|__| (dd/mm/yyyy)
if neutrophils never went below this level tick here ☐

platelets > $20x10^9$/l (dd/mm/yy) |__|__||__|__||__|__|__|__| (dd/mm/yyyy) ☐ not reached
if platelets never went below this level tick here ☐

platelets > $50x10^9$/l (dd/mm/yy) |__|__||__|__||__|__|__|__| (dd/mm/yyyy) ☐ not reached
if platelets never went below this level tick here ☐

transfusion dependent for red blood cells at day 100 ☐ no ☐ yes

Graft failure occured ☐ no ☐ yes,

☐ rejection

☐ late loss of graft

date |__|__||__|__||__|__|__|__| (dd/mm/yyyy)

Chimerism

PB/BM	Date	% of donor cells	Method
|_____|	|__|__||__|__||__|__|	|_____|	|_____|
|_____|	|__|__||__|__||__|__|	|_____|	|_____|
|_____|	|__|__||__|__||__|__|	|_____|	|_____|
|_____|	|__|__||__|__||__|__|	|_____|	|_____|
|_____|	|__|__||__|__||__|__|	|_____|	|_____|

Manifestation of GvHD

aGvHD ☐ no ☐ yes, date of onset |__|__||__|__||__|__|__|__| (dd/mm/yyyy)

based on ☐ clinical evidence ☐ histology

maximum (overall) grade ☐ grade 1 ☐ grade 2 ☐ grade 3 ☐ grade 4

stage skin I___I stage liver I___I stage gut I___I

Resolution ☐ no ☐ yes, date (dd/mm/yyyy) I__I__II__I__II__I__I

Treatment of aGvHD ☐ no ☐ yes,

☐ CSA dose(mg/kg/day)I____I for I____I days

☐ Prednison dose(mg/kg/day)I____I for I____I days

☐ MMF dose(mg/kg/day)I____I
date of last dose I__I__II__I__II__I__I (dd/mm/yyyy)

☐ ECP Starting date I__I__II__I__II__I__I (dd/mm/yyyy)
Last date I__I__II__I__II__I__I (dd/mm/yyyy)

☐ Other drug specify I_____I

cGvHD ☐ no ☐ yes, date of onset |__|__||__|__||__|__|__|__| (dd/mm/yyyy)

Score	
☐ skin	☐ 1 ☐ 2 ☐ 3
☐ mouth	☐ 1 ☐ 2 ☐ 3
☐ eyes	☐ 1 ☐ 2 ☐ 3
☐ GI tract	☐ 1 ☐ 2 ☐ 3
☐ lungs	☐ 1 ☐ 2 ☐ 3
☐ liver	☐ 1 ☐ 2 ☐ 3
☐ joints and fascia	☐ 1 ☐ 2 ☐ 3
☐ genital tract	☐ 1 ☐ 2 ☐ 3
☐ performance score	☐ 1 ☐ 2 ☐ 3
☐ other, specify I_____I	

maximum (overall) grade ☐ mild ☐ moderate ☐ severe

Treatment of cGvHD ☐ no ☐ yes

☐ CSA dose(mg/kg/day)I____I for I____I days

☐ Prednison dose(mg/kg/day)I____I for I____I days

☐ MMF dose(mg/kg/day)I____I for I____I days

☐ ECP Starting date I__I__II__I__II__I__I (dd/mm/yyyy)
Last date I__I__II__I__II__I__I (dd/mm/yyyy)

☐ Other drug specify I_____I

Complications within the first 100 days

Infections	date	localisation systemic	localisation localized	pathogen, please specify
Bacterial	|__|__||__|__||__|__|__|__| (dd/mm/yyyy)	☐	☐	|_____|
Fungal	|__|__||__|__||__|__|__|__| (dd/mm/yyyy)	☐	☐	|_____|
Parasitic	|__|__||__|__||__|__|__|__| (dd/mm/yyyy)	☐	☐	|_____|
Viral	|__|__||__|__||__|__|__|__| (dd/mm/yyyy)	☐	☐	

☐ CMV infection ☐ CMV disease

☐ EBV infection ☐ EBV PTLD

☐ other, please specify \|_____\|

Pulmonary toxicity	☐ no	☐ yes
Radiologic changes and/or oxygen support	☐ no	☐ yes
Mechanical ventilation	☐ no	☐ yes
Severe cardio-vascular complications	☐ no	☐ yes
Shortening fraction < 25%	☐ no	☐ yes
Inotropic support with catecholamines	☐ no	☐ yes
Anti-arrhythmic therapy	☐ no	☐ yes
Severe renal complications	☐ no	☐ yes
Relevant creatinine elevation > CTCAE grade 2 (CTCAE grade 3: > 3.0 - 6.0 x ULN, CTCAE grade 4: > 6.0 x ULN, CTCAE grades 1 and 2 are treated as not relevant)	☐ no	☐ yes
Hemodialysis or hemofiltration	☐ no	☐ yes
Fanconi syndrome (Renal Fanconi syndrome: glucosuria, aminoaciduria, phosphaturia and/or tubular acidosis)	☐ no	☐ yes
Nephrotic syndrome (Nephrotic syndrome: hyperlipidemia, proteinuria, edema)	☐ no	☐ yes
Severe hepatic complications	☐ no	☐ yes
Relevant bilirubin elevation > CTCAE grade 2 (CTCAE grade 3: > 3.0 - 10.0 x ULN, CTCAE grade 4: > 10.0 x ULN, CTCAE grades 1 and 2 are treated as not relevant)	☐ no	☐ yes
VOD	☐ no	☐ yes
Severe neurological complications	☐ no	☐ yes
Leukencephalopathy (Only if positive in MRI finding)	☐ no	☐ yes
CNS haemorrhage	☐ no	☐ yes
Seizures	☐ no	☐ yes
Severe gastrointestinal complications	☐ no	☐ yes
Ileus	☐ no	☐ yes
Other severe complications	☐ no	☐ yes, please specify |_____|

Additional treatment post transplant

Any other treatment

☐ none

☐ DLI |__|__||__|__||__|__|__|__I (dd/mm/yyyy) please complete Cell Therapy Form

☐ Subsequent SCT |__|__||__|__||__|__|__|__I (dd/mm/yyyy) please complete another SCT Form

☐ other, please specify I_____I

Status at day 100

Disease status:

☐ CR ☐ Autologous reconstitution

Survival status:

☐ Alive date of last examination (dd/mm/yyyy) I__I__II__I__II__I__I__I__I Karnofsky / Lansky score I_____I %

☐ Dead date of death (dd/mm/yyyy) I__I__II__I__II__I__I__I__I Autopsy ☐ no ☐ yes

Cause of death: (check as many as appropriate)

	no	yes
☐ Rejection / poor graft function	☐	☐
☐ GvHD	☐	☐
☐ Veno-Occlusive disease (VOD)	☐	☐
☐ Infection	☐	☐
☐ Hemorrhage	☐	☐
☐ EBV lymphoprolif. disease (LPD)	☐	☐
☐ Pulmonary toxicity	☐	☐
☐ Liver failure	☐	☐

☐ Other, specify I_____

Further comments: _____I

Date: I__I__II__I__II__I__I__I__I Stamp Signature _____