Fanconi Anemia Registry 01
FAR01 HSCT (day 100)

Patient initials |__|__|
(first name / last name)

Quarter and year of birth (q/yyyy) |__| / |__|__|__|__|

Sex: ☐ male ☐ female

Patient Identification Number |____________________________________|

Transplantation Center |____|

Date of SCT |__|__||__|__||__|__| (dd/mm/yy)

Number of SCT |________| Type of SCT ☐ autologous ☐allogeneic

Reason for HSCT

Reason for HSCT:
- ☐ Bone Marrow Failure
- ☐ mod AA ☐ sev AA
- ☐ MDS ☐ AML
- ☐ other, specify l____
- ☐ presence of clones/chromosomal abnormalities/MDS/AML (include cytogenetic result, provide to study centre), specify l____

Disease status at HSCT
- ☐ Bone Marrow Failure
- ☐ AML BM Blast (%) l______l
- ☐ MDS BM Blast (%) l______l
- ☐ other, specify l____

Patient

Performance status at HSCT Date of examination: |__|__||__|__||__|__| (dd/mm/yy)

Karnofsky/ Lansky: ________

Weight (kg) : ________ Height (cm) : ______ Body surface area (BSA): ______m²

Pregnancy excluded ☐ no ☐ yes

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

☐ A ☐ B ☐ AB ☐ 0

☐ Rh neg ☐ Rh pos

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

Method class I typing ☐ molecularbiological ☐ serological

Method class II typing ☐ molecularbiological ☐ serological

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

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

Infection Markers (before SCT)

CMV IgG	☐ negative	☐ positive	☐ unknown
CMV IgM	☐ negative	☐ positive	☐ unknown
EBV IgG	☐ negative	☐ positive	☐ unknown
EBV IgM	☐ negative	☐ positive	☐ unknown
Anti HBc	☐ negative	☐ positive	☐ unknown
HBs Ag	☐ negative	☐ positive	☐ unknown
Anti HBs	☐ negative	☐ positive	☐ unknown
HCV IgG	☐ negative	☐ positive	☐ unknown
HIV IgG	☐ negative	☐ positive	☐ unknown
HSV IgG	☐ negative	☐ positive	☐ unknown
HTLV I IgG	☐ negative	☐ positive	☐ unknown
Toxoplasmosis IgG	☐ negative	☐ positive	☐ unknown
VZV IgG	☐ negative	☐ positive	☐ unknown
HCV PCR	☐ negative	☐ positive	☐ unknown
HIV PCR	☐ negative	☐ positive	☐ unknown
HTLV PCR	☐ negative	☐ positive	☐ unknown
Other	☐ negative	☐ positive, specify I__________________________________I	

Donor

Relation with the Patient ☐ unrelated: donor ID (eg DKMS): ___________________________________

WMDA-Code: ___________________________________

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

Age |__|__| Years **Sex** ☐ male ☐ female

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

☐ A ☐ B ☐ AB ☐ 0

☐ Rh neg ☐ Rh pos

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

Method class I typing ☐ molecularbiological ☐ serological

Method class II typing ☐ molecularbiological ☐ serological

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

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

If mismatched, complete number inside each box

A	B	C	DRB1	DQB1	DPB1
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

Infection Markers (before SCT)

CMV IgG	☐ negative	☐ positive	☐ unknown
CMV IgM	☐ negative	☐ positive	☐ unknown
EBV IgG	☐ negative	☐ positive	☐ unknown
EBV IgM	☐ negative	☐ positive	☐ unknown
Anti HBc	☐ negative	☐ positive	☐ unknown
HBs Ag	☐ negative	☐ positive	☐ unknown
Anti HBs	☐ negative	☐ positive	☐ unknown
HCV IgG	☐ negative	☐ positive	☐ unknown
HIV IgG	☐ negative	☐ positive	☐ unknown
HSV IgG	☐ negative	☐ positive	☐ unknown
HTLV I IgG	☐ negative	☐ positive	☐ unknown
Toxoplasmosis IgG	☐ negative	☐ positive	☐ unknown
VZV IgG	☐ negative	☐ positive	☐ unknown
HCV PCR	☐ negative	☐ positive	☐ unknown
HIV PCR	☐ negative	☐ positive	☐ unknown
HTLV PCR	☐ negative	☐ positive	☐ unknown
Other	☐ negative	☐ positive, specify I___________________________________I	

Conditioning regimen

Type of Treatment

Drugs, ATG, mono AB (product name)	type of application	daily dose given	mg/m²/d	mg/kg/d	days of administration	dosage modification no	yes
Example: IBusulfan I	I i.v. I	I 20 I	☐	☐	I -7 II -6 II -5 II__II__II__I	x	☐
I______I	I______I	I______I	☐	☐	I__II__II__II__II__II__I	☐	☐
I______I	I______I	I______I	☐	☐	I__II__II__II__II__II__I	☐	☐
I______I	I______I	I______I	☐	☐	I__II__II__II__II__II__I	☐	☐
I______I	I______I	I______I	☐	☐	I__II__II__II__II__II__I	☐	☐
I______I	I______I	I______I	☐	☐	I__II__II__II__II__II__I	☐	☐
I______I	I______I	I______I	☐	☐	I__II__II__II__II__II__I	☐	☐

If dose modification, specify: I______________________________

Radiotherapy

	no	yes	number of fractions/d	Dose per fraction	day of administration
TBI	☐	☐	|__|__|	|_|_|_|,|_| Gy	|__|__|__|__|__|__|
TLI	☐	☐	|__|__|	|_|_|_|,|_| Gy	|__|__|__|__|__|__|
TAI	☐	☐	|__|__|	|_|_|_|,|_| Gy	|__|__|__|__|__|__|
TNI	☐	☐	|__|__|	|_|_|_|,|_| Gy	|__|__|__|__|__|__|
Cranial boost	☐	☐	|__|__|	|_|_|_|,|_| Gy	|__|__|__|__|__|__|
Testes boost	☐	☐	|__|__|	|_|_|_|,|_| Gy	|__|__|__|__|__|__|

Radionuklid Therapy

	no	yes	dose in Bq/kg	start of therapy
MIBG	☐	☐	|__|__||__|__|	|__|__|__|__|__|__|
Samarium	☐	☐	|__|__||__|__|	|__|__|__|__|__|__|
Yttrium	☐	☐	|__|__||__|__|	|__|__|__|__|__|__|

Transplantation

Date of stem cell collection |__|__||__|__||__|__| (dd/mm/yy)

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

Manipulation of Graft ☐ no ☐ yes

CD 34+ Selection	☐ no	☐ yes, method:	|____________|
T-cell-depletion	☐ no	☐ yes, method:	|____________|
CD 3/CD19 Depletion	☐ no	☐ yes, method:	|____________|
other	☐ no	☐ yes, specify	I____________I

Cells Infused

number of nucleated cells	__________	$x10^{8/}$kg
number of CD34+	__________	$x10^{6}$ kg
number of CD3+	__________	$x10^{4}$ kg

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

☐ No ☐Yes, specify:

☐ G-CSF

starting day (dd/mm/yy) |__|__| |__|__| |__|__|

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

☐ other: |_______________________________|

starting day (dd/mm/yy) |__|__| |__|__| |__|__|

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

Engraftment

Evidence of hematopoietic reconstitution: (dd/mm/yy)

Leucocytes >1.000/µl: |__|__| |__|__| |__|__| ☐ not reached

[**Definition:** first of three consecutive days with more than 1.000 leucocytes/µl]

Neutrophils >500/µl: |__|__| |__|__| |__|__| ☐ not reached

[**Definition:** first of three consecutive days with more than 500 neutrophils/µl]

Platelets >20.000/µl: |__|__| |__|__| |__|__| ☐ not reached

[**Definition:** first of three consecutive days with more than 20.000 platelets/µl, no platelet transfusions in the past seven days]

Platelets >50.000/µl: |__|__| |__|__| |__|__| ☐ not reached

[**Definition:** first of three consecutive days with more than 50.000 platelets/µl, no platelet transfusions in the past seven days]

Lymphocytes >100/µl: |__|__| |__|__| |__|__| ☐ not reached

[**Definition:** first of three consecutive days with more than 100 lymphocytes/µl]

Last platelet transfusion: |__|__| |__|__| |__|__| ☐ transfusions ongoing

Last red cell transfusion: |__|__| |__|__| |__|__| ☐ transfusions ongoing

Graft Failure:

☐ No ☐ Yes, date of diagnosis |__|__| |__|__| |__|__| (dd/mm/yy)

Kind of graft failure:

☐ non-engraftment (=neutrophils never >500/µl on d+40)

☐ late graft loss

GVHD Prophylaxis (pharmaceutical – NOT: T-Cell Depletion, Antibodies)

GVHD prophylaxis ☐ none

☐ Cyclosporine A i. v.**:** starting dose CSA i. v.: |_____| mg/kg/day

date of CSA start i. v.: |__|__| |__|__| |__|__| (dd/mm/yy)

date of CSA stop i. v.: |__|__| |__|__| |__|__| (dd/mm/yy)

date of last dose CSA |__|__| |__|__| |__|__| (dd/mm/yy)

☐ MTX days: +|___| +|___| +|___| +|___|

☐ Leukovorin days: +|___| +|___| +|___| +|___|

☐ Other (e.g. MMF) specify____

☐continued ☐ new started

dose ☐ mg/kg/day ☐ $mg/m^2/day$ ☐ other:_________

starting date: |__|__| |__|__| |__|__| (dd/mm/yy)

stopping date: |__|__| |__|__| |__|__| (dd/mm/yy)

☐ Other (e.g. MMF) specify____

☐continued ☐ new started

dose ☐ mg/kg/day ☐ $mg/m^2/day$ ☐ other:_________

starting date: |__|__| |__|__| |__|__| (dd/mm/yy)

stopping date: |__|__| |__|__| |__|__| (dd/mm/yy)

☐ Other (e.g. MMF) specify____
☐continued ☐ new started
dose ☐ mg/kg/day ☐ mg/m^2/day ☐ other:__________
starting date: |__|__| |__|__| |__|__| (dd/mm/yy)
stopping date: |__|__| |__|__| |__|__| (dd/mm/yy)

Acute GVHD

☐ No ☐ Yes, date of onset: |__|__| |__|__| |__|__| (dd/mm/yy)
histological confirmation ☐ No ☐ yes
overall grade ☐ 0 ☐ I ☐ II ☐ III ☐ IV

skin: stage: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
liver: stage: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
gut: stage: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

aGVHD resolved ☐ No ☐ Yes, date |__|__| |__|__| |__|__| (dd/mm/yy)

Acute GVHD Treatment

☐ No ☐ Yes, specify:

Medication	**Continued**	**New started**	**product name**	**Date of first dose**	**Date of last dose**	**ongoing**
Increase of CSA	☐	☐				☐
Prednison	☐	☐				☐
Mycophenolate-Mofetile	☐	☐				☐
Tacrolimus	☐	☐				☐
ALG/ATG	☐	☐	|____________________|			☐
Monoclonal AB	☐	☐	|____________________|			☐
ECP	☐	☐				☐
Other	☐	☐	|____________________|			☐

Chimerism

Best Chimerism until day +100:

	PB/BM	Date	% of Donor cells	Method	Immunosuppressive Therapy: none	unchanged	reduced	stopped
	I_____I	I__I__II__I__II__I__I	I______I	I___________I	☐	☐	☐	☐
Chimerism at								
d30	I_____I	I__I__II__I__II__I__I	I______I	I___________I	☐	☐	☐	☐
d60	I_____I	I__I__II__I__II__I__I	I______I	I___________I	☐	☐	☐	☐
d100	I_____I	I__I__II__I__II__I__I	I______I	I___________I	☐	☐	☐	☐

Complications < day 100 or date of death respectively

Severe complications:		no yes
pulmonary	radiologic changes and/or oxygen support	☐ ☐
	mechanical ventilation	☐ ☐
cardio vascular	shortening fraction < 25%	☐ ☐
	inotropic support with catecholamines	☐ ☐
	anti-arrhythmic therapy	☐ ☐
renal	relevant creatinine elevation (>CTCAE grade 2)	☐ ☐
	hemodialysis or hemofiltration	☐ ☐
	Fanconi syndrom	☐ ☐
	nephrotic syndrom	☐ ☐
hepatic	relevant bilirubine elevation (>CTCAE grade 2)	☐ ☐
neurological	leukencephalopathy	☐ ☐
	CNS hemorrhage	☐ ☐
	seizures	☐ ☐
gastrointestinal	Ileus	☐ ☐
	gastrointestinal hemorrhage	☐ ☐

Infectious Toxicity

Date of infection: |__|__| |__|__| |__|__| (dd/mm/yy)

Clinical type of infection:
☐ viral
☐ bacterial
☐ fungal
☐ parasitic

Site
☐ systemic
☐ localized: ☐ respiratory tract ☐ GI tract ☐ CNS
☐ urogenital tract ☐ other, specify:
|____________________________|

Pathogen identified

☐ No ☐ Yes

Viral infection pathogen
☐ CMV
☐ EBV
☐ Adenovirus
☐ other, specify:|____________________________|

Status CMV infection
☐ infection
☐ disease

Status EBV infection
☐ infection
☐ PTLD

Fungal infection pathogen
☐ Aspergillus
☐ Candida
☐ other, specify:|____________________________|

Other clinically significant coexisting disease or organ impairment:

☐ No ☐ Yes, please specify:

- ☐ severe bleeding
- ☐ infarction or thrombosis
- ☐ ^VOD
- ☐ ARDS
- ☐ acute vascular leak syndrome

Intensive care measures:

☐ No ☐ Yes, please state indication:

- ☐ assisted ventilation
- ☐ hemodialysis
- ☐ hemofiltration
- ☐ other: |____|

Admittance to ICU?

☐ No ☐ Yes

Treatment after SCT

☐ No ☐ Yes, please specify indication:

- ☐ relapse
- ☐ no remission
- ☐ mixed chimerism
- ☐ graft failure
- ☐ GVHD
- ☐ Viral infection
- ☐ EBV induced lymphproliferation
- ☐ prophylactic treatment
- ☐ other: |____|

If yes, kind of treatment:

- ☐ reduction or discontinuation of immunosuppression
- ☐ chemotherapy
- ☐ donor leukocyte infusion

1.DLI: no. of CD3 or CD|__| cells: |___| /kg x10E |__| |__|__||__|__||__|__| (dd/mm/yy)
2.DLI: no. of CD3 or CD|__| cells: |___| /kg x10E |__| |__|__||__|__||__|__| (dd/mm/yy)
3.DLI: no. of CD3 or CD|__| cells: |___| /kg x10E |__| |__|__||__|__||__|__| (dd/mm/yy)
4.DLI: no. of CD3 or CD|__| cells: |___| /kg x10E |__| |__|__||__|__||__|__| (dd/mm/yy)

other type of infusion:

☐ MNC cells:	number: |__|__|	☐ dentritic cells:	number: |__|__|
☐ mesenchymal cells:	number: |__|__|	☐ NK cells:	number: |__|__|
☐ antigen specific T-cells:	number: |__|__|	☐ fibroblasts:	number: |__|__|

☐ stem cell boost (CD 34+ pos.selec.) number: |__________| /10^6kg
Date : |__|__| |__|__| |__|__| (dd/mm/yy)

☐ subsequent SCT Date of SCT:|__|__| |__|__| |__|__| (dd/mm/yy)
type of transplant: ☐ auto ☐ allo

Status at day 100

Disease status:

☐ CR ☐ Autologous reconstitution

☐ Relapse in the case of AML/MDS (date) I__I__II__I__II__I__I

site: ☐ BM ☐ PB ☐ other, specify_________________________________

☐ Secondary malignancy ☐ No ☐ Yes, date of diagnosis |__|__| |__|__| |__|__| (dd/mm/yy)
specified:|_________________________________|

Survival status:

☐ Alive date last examination (dd/mm/yy) I__I__II__I__II__I__I Karnofsky/ Lansky score I_____I %

☐ Dead date of death (dd/mm/yy) I__I__II__I__II__I__I Autopsie ☐ no ☐ yes

Main cause of death: ☐ Underlying disease: Relapse, progression or persistence

☐ Transplant related cause (tick all that apply):

☐ GVHD

☐ graft failure

☐ pulmonary toxicity

☐ cardiac toxicity

☐ infection

☐ VOD

☐ post transplant lymphoproliferative disorder

☐ other: |____|

☐ other: |____|

Further comments: ____

Referring physician name and institution I____I

Address I____I

Telephone and fax I____I

email I____I

Date I__I__II__I__II__I__I Signature ___________________________________