



Marrow Donor Program Belgium - Registry
Motstraat 40 2800 Mechelen
Tel: (32) - 15 44 33 96 Fax: (32) - 15 44 36 56
Email : MDPB-registry@rodekruis.be

INCIDENT REPORT FOR TRANSPLANT CENTERS

Donor centers, collection centers and cord blood banks use the WMDA SEAR (serious events and adverse reactions) and SPEAR (serious product events and adverse effects) forms to report incidents.

TO BE COMPLETED BY TRANSPLANT CENTER:

Date of incident :	
Transplant center: Address:	Person completing the form : Date:

PATIENT INFORMATION	DONOR INFORMATION
Patient ID:	Donor ID:
TYPE OF STEM CELLS COLLECTED: <input type="checkbox"/> HPC, APHERESIS <input type="checkbox"/> HPC, MARROW <input type="checkbox"/> HPC, CORD <input type="checkbox"/> TC, APHERESIS	Donor center :
Transplant Date: (Day/Month/Year)	Collection Date(s): (Day/Month/Year)

Apheresis collection	
01	When did this Serious Event / Adverse effect occur?
	<input type="checkbox"/> During HPC, M harvest <input type="checkbox"/> During HPC, A collection <input type="checkbox"/> During HPC, CORD collection <input type="checkbox"/> During HPC, M / HPC, A / HPC, cord processing <input type="checkbox"/> During HPC, M / HPC, A / HPC, cord storage <input type="checkbox"/> During HPC, M / HPC, A / HPC, cord transplantation
02	DID THE EVENT/ADVERSE REACTION RESULT FOR THE RECIPIENT IN: <input type="checkbox"/> DEATH OF THE RECIPIENT <input type="checkbox"/> LIFE-THREATENING DISEASE <input type="checkbox"/> PROLONGATION OF HOSPITALIZATION OF PATIENT <input type="checkbox"/> PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY NUMBER OF EXTRA INPATIENT DAYS (IF APPLICABLE).....



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03	Please give a brief description of the Serious Event / Adverse effect:
04	Inadequate cell dose Was the cell dose harvested inadequate (defined as total nucleated cells < 0.5 x 10 ⁸ /kg and/or CD34+ cells < 0.5 x 10 ⁶ /kg) <input type="checkbox"/> Please state the cell number: <input type="checkbox"/> Did engraftment occur? <input type="checkbox"/> Yes <input type="checkbox"/> No
05	Was there another serious deficit in the stem cell product? <input type="checkbox"/> Please specify:
06	Did serious problems arise during transportation of the product? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Please specify:
07	Was the wrong stem cell product transfused? <input type="checkbox"/> Yes <input type="checkbox"/> No
08	Was there a transmission of severe unpredicted infection? <input type="checkbox"/> HIV <input type="checkbox"/> HCV <input type="checkbox"/> HBV <input type="checkbox"/> Bacterial infection <input type="checkbox"/> Other infection (please specify).....
09	Was there a severe unpredicted transmission of a non-infectious disease originating in the donor? <input type="checkbox"/> Please specify:
10	Was the adverse event related to the donation? <input type="checkbox"/> Definitely <input type="checkbox"/> Probably <input type="checkbox"/> Possibly <input type="checkbox"/> Probably Not <input type="checkbox"/> Definitely Not



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11	LABELING
	<input type="checkbox"/> Missing mandatory requirements Please specify:
12	PACKAGING
	<input type="checkbox"/> Missing mandatory requirements Please specify:
13.	OTHER

PLEASE INCLUDE A COPY OF TRANSPORT AUDIT FORM

To be completed by Registry:

Incident number :