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MARROW DONOR PROGRAM BELGIUM
STANDARDS
CORD BLOOD (HPC, Cord Blood or HPC, CB)

APPROVAL

Governing Board of the MDPB-R	Function	Approval date + Signature
Prof. dr. Philippe Vandekerckhove	Director General Rode Kruis – Vlaanderen MDPB-R Governing Board	Digitally signed by Philippe Vandekerckhove (Signature) Date: 14/10/2022 20:46:43
Prof. dr. Pierre Zachée	Chair BHS-MDP-B Committee	Digitally signed by ZACHEE PIERRE GABRIELLE Date: 16/10/2022 21:53:01

DISTRIBUTION

Function	Department - Institution
Contact person	Belgian Cord Blood Bank
Members	MDPB-R Governing Board
Members	BHS-MDP-B Committee
Registry staff	MDPB-R
Contact person	WMDA
Contact person	Supporting services RKVL

VERSION CONTROL

Effective date	Version	Comment
1/11/2022	v5	Update to WMDA standards
01/11/2021	v4	GDPR update
01/03/2017	v3	Update Quality Assurance Program, Clinical outcome data.
25/06/2016	v2	New logo + address + fax number
01/09/2015	v1	Update to WMDA standards, update WMDA forms, Governing Board: details in summary of changes.
25/06/2012	v03/2012	SOP
01/02/2012	v02/2011	SOP and forms
01/09/2010	v01/2010	SOP and forms

SUMMARY OF MAJOR CHANGES

Version	Comment
v5	- Changed “should” and “may” to “must” according to the latest WMDA standards - Notify key changes
v4	- Changes to comply with GDPR
v3	- 3.11 Clinical outcome data
v2	- New logo + address + fax number
v1	- MDPB “SOP”: changed into MDPB “Standards”. - MDPB VZW: replaced by “BHS-MDP-B Committee”. - “Board” replaced by “Governing Board MDPB-R”. - Software “ Syrenad” replaced by “Prometheus”. - Update to WMDA forms where applicable. - Parts described in the MDPB Donor Standards are not repeated in the MDPB Cord Standards. - Part 3.2: eligibility requirements: refer to FACT NETCORD. - Transport audit form: registry keeps record of all exchanged documentation. Confirmation of receipt of required documents. - New document numbering (document management system)
v03/2012	- Infectious disease markers on maternal sample : option 2 after 6 months. - Addition of syphilis serology (cf. KB/AR 28/09/2009. Annexe VI,2.5).

REVIEW AND UPDATE

Every 3 years, a profound review of the MDPB Standards is necessary: the medical and scientific regulations will be reviewed by the BHS-MDP-B Committee, the operational and procedural review by MDPB-R. WMDA recommendations must be cross-checked with the MDPB policy and procedures.

If there are no major changes, the MDPB Standards are prolonged annually. New and revised policies and procedures will be approved by the BHS- MDP-B Committee and the MDPB-R Governing Board, the review must be documented. Final voting will be done by email and requires a 2/3's majority for approval.

Update requests must be sent to the MDPB-registry@rodekruis.be using the *MDPB FRM017 Update request MDPB Standards and forms*.

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1 INTRODUCTION

The Marrow Donor Program Belgium (MDPB) consists of the MDPB-Registry (MDPB-R) within the Belgian Red Cross and the BHS-MDP-B Committee.

The MDPB-R is responsible for the administrative, financial and operational management of the MDPB. The BHS-MDP-B Committee is responsible for the medical and scientific matters (issues). The Medical Advisory Committee of the BHS-MDP-B Committee must be consulted for any medical question/procedure not covered by the MDPB Standards.

The Marrow Donor Program Belgium Standards, Cord Blood covers all procedures involving HPC, Cord Blood products. (All procedures involving unrelated volunteer donors, criteria for Donor Centers, Collection Centers, Transplant Centers and Hematopoietic Stem Cell Banks and related procedures are covered in the Marrow Donor Program Belgium Standards, current version). These Standards intend to provide practical information to all MDPB users or coworkers. Deviation of procedures from these Standards must be submitted in advance to the Governing Board of the MDPB-R.

The Medical Director of the participating Cord Blood Bank is responsible for ensuring the center's compliance with these Standards.

The term “must” means that the Standard is to be complied with at all times. The term “should” indicates an activity that is recommended or advised, but for which there may be effective alternatives. The term may or might is permissive, indicating that the practice is acceptable, but not necessarily recommended.

After the WMDA qualification period is completed, the word “must” indicates that deviations are not acceptable. There will be no difference between WMDA bolded benchmark standards and non-bolded standards containing the words “must”. The words “should”, “might”, and “may” are used for recommendations that are not mandatory.

A separate Collaboration agreement covers the procedures to assure the proper functioning of (the software application) “Prometheus”, facilitating the search process for unrelated donors and cord blood units and sets outs rights and obligations as regards to the processing of personal data in the scope of the MDPB.

Each institution must be GDPR compliant and appoint a Data protection officer.

2 CORD BLOOD BANK ACCREDITATION CRITERIA

2.1 CB banks affiliated to MDPB must fulfil the following criteria

2.1.1 The Cord Blood Bank (CBB) must have a valid FAGG/AFMPS certification (the certificate must be provided to MDPB-R in due time).

2.1.2 The CBB has a valid FACT - NETCORD certificate.

2.1.3 The CBB shall be in good order with NMDP regarding its obligations concerning the CB IND requirements.

2.1.4 All typings must be performed at an ASHI or EFI accredited lab.

2.1.5 If a bank loses FACT or FAGG/AFMPS accreditation, this must be notified to the Registry.

2.2 Requirements regarding the inventory

2.2.1 The CBB must an inventory of at least 500 HLA-A, B and DR typed CBUs (for existing banks at least 1000 units).

2.2.2 Informed consent forms and medical questionnaires must submitted to the MDPB-R on request for compliance to all relevant national and international (including, but not limited to FAGG/AFMPS, NMDP-USA, FACT-NETCORD, WMDA) standards and regulations (for medical history questionnaire).

2.2.3 The CBB must have an inventory of validated CBUs and comply with the Prometheus data structure requirements (Final BE CBU import - current version) and with the EMDIS data dictionary requirements : https://share.wmda.info

Units stored after 2002 shall be typed with molecular methods.

Testing requirements must apply to comply with FACT-NETCORD Standards-appendix 3 and National law.

2.2.4 For every unit in stock the bank needs to have a report following the latest version of the EMDIS_Data Dictionary.

2.2.5. Each center must have the necessary agreements in place with its data processors or third parties with whom it exchanges personal data in order to be compliant with GDPR.

2.2.6. Each center must have the following procedures, technical and organizational measures in place in order to be compliant with GDPR:

- There must be continuity in the performance of the role “DPO’ by the person designated by the organization. The DPO must have a backup with the required knowledge about GDPR legislation.
- The institution must have a register of processing activities.
- The institution must have a security policy and internal policies related to the retention of personal data, access control, permitted use, measures to be observed when using personal data.

These procedures must be documented in a “WISP”: Written information security policy:

- physical access control: to prevent unlawful or unauthorized processing of personal data, as well as to prevent accidental loss, destruction or damage to them or unauthorized disclosure or access to them.

- electronic data protection, pass word management, access rights management.

- infringement procedure, documentation of all infringements.

- a communication security policy: the institution must have a policy to ensure that all communication and records about cords are stored to ensure confidentiality.

- the institution must have a procedure to deal with questions form a data subject.

3 PROCEDURES

3.1 Recruitment of maternal donors and informed consent

Criteria complying with FACT-NETCORD, WMDA Standards and national law must apply.

3.1.1 Informed consent forms (ICF) shall meet criteria established based at a minimum on WMDA guidelines. In addition to information on the process, risks, and benefits, documents must include information on the collection and protection of donor data and the right of the donor to medical confidentiality and to receive medical information. ICFs must be written clearly, in terms that are understandable by the mother, must be understood and signed by the mother and must contain following information:

- The right of the mother to refuse the collection without prejudice at any time.
- The overall purpose and participation of the mother and infant donor.
- An explanation of the processing procedure and activities in terms the mother can understand.
- The possible risks and benefits to the mother and/or infant donor.
- The possible alternatives to participation.
- The intent of the donation for unrelated use.
    - If the CBU is intended for unrelated allogeneic use, the mother must be informed that the CBU is a donation that will be made available to other individuals and will not necessarily be available to the infant donor or the infant donor's family at a later date.

3.1.2 The maternal donors must sign ICF prior to active labor.

3.1.3 The maternal donor does not receive payment for the donation.

3.1.4 Informed consent must be obtained and documented from the mother, while she is able to concentrate on the information and is not distracted by aspects of labor.

3.1.5 All aspects of participation in CB donation must be discussed with the mother in a language and with terms that she understands.

3.1.6 The mother must have an opportunity to ask questions.

3.1.7 The mother will be asked to provide personal and family medical history.

3.1.8 Personnel will be permitted to review the medical records of the mother and infant donor.

3.1.9 Reference Cord Blood samples and maternal samples will be collected and stored for future testing.

3.1.10 The CBB will maintain linkage for the purpose of notifying the infant donor's mother or family and/or her physician of communicable or genetic diseases, whenever possible.

- The CBB retains the right to follow up with the mother or her primary physician at a future date.
- Information related to the infant donor and the infant donor's family must remain confidential and is only available for review by individuals designated by the CBB or by national authorities to evaluate the CBB.

- Linkage between the infant donor and mother with the CBU must be maintained indefinitely.

3.1.11 Possible uses of the CBU for purposes other than clinical transplantation and the CBB's policies for disposal of CBUs must be mentioned in the informed consent.

3.2 Eligibility

3.2.1 Requirements for donor health affecting the eligibility of donors must be established.

3.2.2 The health screening and medical evaluation guidelines must comply with FACT NETCORD requirements.

3.2.3 Eligibility forms are required for all CB's collected on or after May 25, 2005 to be in compliance with U.S. Food and Drug Administration (FDA) eligibility requirements.

3.2.4 The HLA matching between CBU and patient is the responsibility of the Transplant Center.

3.3 Initial search request

3.3.1 Cord searches can be requested by a Belgian accredited Transplant Center (TC), any International Registry (HUB) or any Transplant Center accredited by a competent authority (if no HUB available in that country). The request is free of charge for the partner HUB/Transplant Center.

Fee discount or reduction can be looked at case by case by the CBB and MDPB-R. Fee for CBB and MDPB-R are proportionally reduced.

3.3.2 Each initial search request has to be sent on a specific form *MDPB FRM001 Preliminary search request* except for requests from Belgian Transplant Centers or International Registries sent through EMDIS.

The search request must include the following information on the patient:

- Date of request,
- Last and first name,
- Date of birth,
- Body weight,
- ABO and Rh blood group,
- Diagnosis,
- Disease status,
- HLA A, B, C, DRB1 and DQB1 typing: performed preferably by molecular typing.

And the following administrative information:

- Identity of requesting institution,
- name of transplant physician and institution,
- contact person.

3.3.3 Upon the submission of an initial search request for a Belgian or international patient at the MDPB-R, a search report on CBUs of the Belgian CBBs is sent to the

requesting Transplant Center by MDPB-R. Cord search results for Belgian patients and international patients of EMDIS connected countries will be sent via Prometheus, cord search results for international patients not connected via EMDIS will be sent via email (via TLS encryption).
Search results will be sent the same working day after receiving the request or at the latest the next working day.

On the report appear (depending on the selected parameters):

6/6 allele Matched donors (and Cord Bloods)
6/6 Potential (Allele) Matched donors (and Cord Bloods)
6/6 Antigen Match (Allele Mismatch)
5/6 Antigen Match donors (and Cord Bloods)
4/6 Antigen Match donors (and Cord Bloods)
4/4 AB Antigen Match donors (and Cord Bloods)
3/4 AB Antigen Match donors (and Cord Bloods)

With the following information:

- CB ID = BECB followed by the local bank identifier.
- HLA typing.
- Birth date.
- Availability status.
- Collected volume in ml.
- Total nucleated cells (x10E8) post processing.
- Total viable CD34+ cells post processing when available.
- Method of volume reduction.
- Patient ID.

3.4 Dispatch of complementary information: full unit report

Upon request the complementary CB information can be provided by the CBB following FACT-NETCORD requirements.
The registry keeps record of all exchanged documentation.

3.5 Further tests when a potential CB has been identified

The partner HUB/Transplant Center may require additional tests or typings to be done on the unit:

3.5.1 Request for additional typing

Cord Blood high resolution typing requests can be requested via EMDIS (Prometheus) by Belgian and international EMDIS connected registries. Other countries must complete the form *MDPB FRM003 Request for further DNA based cord typing*.
The Cord Blood Banks will receive all typing requests via Prometheus and must report the results via Prometheus. After having received a typing request via Prometheus, the Cord Blood must be reserved for 60 days. When the unavailability date expires, the Cord Blood Unit's status will be automatically changed to 'available'. When entering the typing results, the Cord Blood Unit must be again reserved for a renewed period of 60 days.

MDPB-R coordinates the invoicing to the International Registry. MDPB-R will pay fees to the HLA labs after having received the funds, and after having received invoices from the HLA labs (order forms will be sent to the labs listing all typings performed).

3.5.2 Various tests

For tests that are not listed in the MDPB fee list, specific agreement on fees to be charged must be made in advance between the partner HUB/Transplant Center, the Cord Blood Bank and the MDPB-R.

The following tests are done at the bank level depending on agreement with laboratories accredited or licensed in accordance with applicable laws – regulations approved by the governmental authority:

- Additional IDMs,
- Hemoglobinopathy screening,
- Specific tests as needed.

3.6 Samples prior to shipment

The Transplant Center may need reference samples from the CBU or from the mother.
The Transplant Center, if connected via EMDIS, must activate the DNA sample, material suitable for DNA extraction or maternal sample request via Prometheus or in case of a non EMDIS country, the samples can be requested via the form *MDPB FRM004 Cord Blood sample request*.

The following samples can be requested:

- Cord Blood plasma (stored at -70° C or below).
- Cord Blood cells (stored in liquid nitrogen).
- Cord Blood DNA (stored at -70° C or below) or material suitable for DNA extraction.
- Maternal serum or plasma (stored at -70° C or below).
- Maternal cells (stored in liquid nitrogen or -70° C or below).
- Maternal DNA (stored at -70° C or below) or material suitable for DNA extraction.
- Other.

The CBB must inform the shipment of the sample via Prometheus or using the Cord Blood sample procurement form *MDPB FRM005 Cord Blood sample procurement*.
After having received a blood sample request via the application Prometheus, the CBU must be reserved for 60 days. When the unavailability date expires, the CBU's status will be automatically changed to 'available'. When entering the blood sample arrival date, the CBU must be reserved again for a period of 60 days.

Invoices for DNA samples and maternal samples for IDM testing prior to transplantation are invoiced by the Cord Blood Banks to the MDPB-R, the form *MDPB FRM011 Additional info invoice Cord Blood transport* must be attached. Billing should occur within 40 days of service completion. The MDPB-R will re-bill to destination of the International Registry and follow up settlement of payments by sending regular statements of account.

3.7 CBU reservation

To reserve a CBU the Transplant Center must complete the *MDPB FRM006 Cord Blood Unit reservation* form. Upon reception of this form the Cord Blood must be marked as "reserved"

for 60 days in Prometheus. To extend the reservation, the TC should resend the Cord Blood Unit reservation form or confirm by e-mail.
The Cord Blood Bank must change in Prometheus the availability status of the CBU to "reserved" indicating the "end of reservation date". After this date, the CBU will automatically be made available again.

3.8 CBU request for transplantation

3.8.1 The CBB and MDPB-R must retain indefinitely documentation of requests for CBUs, requests for reference samples and maternal samples, requests for and results of testing, and transportation and shipping of CBUs and samples between facilities.

3.8.2 Before a CBU is released, a sample obtained from a contiguous segment of that CBU must be tested.

3.8.3 Any histocompatibility discrepancy must be resolved and communicated to the MDPB-R.
Discrepancies must be reported using the *S70 Discrepant typing report*. The Transplant Center finding the discrepant typing must complete section A, the CBB must complete section B and return via the Registry to the Transplant Center, specifying the type of error: clerical error or technical error.
The CBB checks the Cord Blood Unit for fulfillment of all criteria for release and transplantation (according FACT-NETCORD).

3.8.4 When requesting a CBU for transplantation the Transplant Center must complete the form *MDPB FRM007 Cord Blood Unit request for transplantation (HPC, CB)* or the WMDA *CB30 Cord Blood Unit shipment request*.

3.9 Transportation and shipping of cryopreserved Cord Blood Units

3.9.1 Procedures for transportation and shipping of cryopreserved CBUs must be designed to protect the integrity of the CBU and the health and safety of personnel in accordance with applicable laws (FDA, IATA, FACT, NETCORD, WMDA).

3.9.2 The CBB organizes the transport with a certified, validated courier of his choice. If the TC wants to organize the transport, the CBB is no longer responsible.

3.9.3 Once an unrelated CBU has left the CBB premises, it must not be returned to the general CBB inventory.

3.9.4 Transportation and shipping records must be maintained by the bank according to standards and requirements.
The form *MDPB FRM009 Transport of Cord Blood Unit audit (HPC, CB)* must be completed and will accompany the CBU shipment.

Section A: To be completed by the CBB.

Section B: To be completed by the courier.

Section C: To be completed by the TC and faxed back to the MDPB-R.

The data regarding the transfer of the Cord Blood Unit must be informed prior to shipment with the form *MDPB FRM008 Cord Blood Unit transfer plan (HPC, CB)*:

Section A: to be completed by the Cord Blood Bank.

The CBB will confirm the transfer arrangements:

- a courier from the TC will pick up the unit with their own shipment equipment or equipment of the CBB, the CBB specifies the pickup details.
- the CBB will ship the unit in a dry-shipper.

Section B: To be completed by the center who organizes the transport.

Here the details of the shipment are listed: date and time of delivery to the transport company, the Job number or Airway bill number, the date and time of arrival at the Transplant Center and the shipment address.

Section C: To be completed by the Transplant Center and to be faxed to the MDPB-R.

The TC must agree with the transfer plan and accept to pay the CB release fees (according to MDPB-R fees) plus transport fees if applicable.

3.9.5 The CBB must have a written policy to obtain the following data from the receiving facility about the CBU upon receipt:

- Date and time of receipt.
- Integrity of the dry shipper.
- Internal temperature of the dry shipper.
- Integrity of the CBU.

3.10 Import

CB from a CBB located outside the EU must be imported by a registered Belgian Hematopoietic Stem Cell Bank. Procedures must be in place accordingly at the TC (as required by applicable law.

3.11 Clinical outcome data

Clinical outcome data of the CBUs delivered by the Belgian Cord Blood Banks are available via the Eurocord Registry and can be shared with the MDPB-Registry.

The outcome analysis for the MDPB Quality Assurance will be prepared by the Belgian Cancer Registry based on the EBMT reporting by Transplant Centers.

4 TASKS/RESPONSIBILITIES OF THE CORD BLOOD BANK AND THE MDPB-R

4.1 MDPB-R

4.1.1 Criteria

The criteria are covered in the Marrow Donor Program Belgium Standards.

The MDPB-R must maintain records of its activities and must maintain a database of volunteer donor information and Cord Blood information. All patient and donor/Cord Blood records must be stored to ensure confidentiality according to WMDA Standards: Cord Blood and patient identity must remain confidential during the search process. The access to Cord Blood and patient data information as well as the transmission must be organized so that unauthorized access is prevented – confidentiality is guaranteed.

4.1.2 Tasks

Administrative and financial management of the Belgian Cord Program.

4.1.2.1 Management of the Cord Blood database. The Governing Board of the MDPB-R defines which equipment to be used in line with the international procedures. The coordinators act as the Belgian representatives at international meetings of the registries.

4.1.2.2 Searches for patients from Belgium and abroad: consultation of the cord database of the MDPB-R (incl. Belgian Cord Blood Bank) and all registries connected through EMDIS, via internet (via TLS encryption) or by fax.

4.1.2.3 Transmission of requests from Belgian Transplant Centers or Transplant Centers abroad.

4.1.2.4 Once a CBU has been selected by the Transplant Center, the Registry is coordinating the communication between the Transplant Center and the CBB.

4.1.2.5 The MDPB-R must keep complete and accurate financial records for all services provided and requested according to national laws and regulations as well as international standards.

4.1.2.6 The MDPB-R must have sufficient staff dedicated to perform all accounting duties.

4.1.2.7 Fee structure

4.1.2.7.1 A clear fee schedule detailing payment terms must be available upon request. Changes in the fee schedule (*MDPB LST007 Fee schedule Cord Blood*) should be provided to interested parties 60 days prior to implementation.

4.1.2.7.2 Any cost not standardized or, for any reason, not accessible through such a schedule (excluding courier charges) must be estimated and communicated in advance to the requesting Registry and/or the Transplant Center.

4.1.2.7.3 Cancellation fee: After the CBB receives the formal request for delivery of a Cord Blood Unit, the tests for Quality Assurance will be performed, including viability and GFU-GM.
As the samples stored for these QA tests will be used, the tests cannot be repeated and therefore the unit cannot be returned to the file of available CBUs (however in some cases QA tests can be performed with the CBU remaining available).

4.1.2.8 Invoices for international patients are made by the Registry and sent to the requesting center for

- Typing requests.
- Cord Blood Units.
- Cancellation of shipments.

Prices are defined by the Governing Board of the Registry. Payments are made to the Registry. The Registry will distribute a fee as agreed between the different parties involved after receiving an invoice from the Cord Blood Bank. (The Registry will send order forms to the involved centers for all services rendered.)

DNA/maternal samples including shipment, and shipments of Cord Blood Units are invoiced by the CBB to the MDPB-R. The CBB must attach the form *MDPB FRM011 Additional info invoice Cord Blood transport*.
Billing to the MDPB-R should occur within 40 days of service completion. The MDPB-R will re-bill to destination of the International Registry or TC and follow up settlement of payments by regular statements of account.

4.1.2.9 Statistics: the Registry collects monthly updates on the activities of the Registry.

4.1.2.10 The MDPB-R must maintain an updated list of participating Cord Blood Banks and HLA Typing Centers. Posting of Standards, forms, user documentation and other relevant information on the MDPB website (https://www.stemcelldonor.be).

4.1.2.11 Day to day contact with the Belgian and foreign centers in accordance to the national standards, guidelines defined by the Governing Board and the BHS-MDP-B Committee and the international guidelines. Consults with the BHS-MDP-B Committee for any medical/scientific question for which no procedures have been defined during previous board meetings to obtain a consensus.

4.1.2.12 The MDPB-R is not responsible for the operational management of Cord Blood Banks. It won't bear responsibility for Quality Assurance as to the Cord Blood collection, banking, release and shipment.

4.2 Cord Blood Bank

4.2.1 Criteria

The criteria for Cord Blood Banks is to be accredited by FACT-NETCORD and FAGG/AFMPS.

4.3 Cord Blood Bank - MDPB-R interactions and communications

All communication must be shared with all three parties: TC, MDPB-R and CBB.

4.4 Service level agreement between MDPB-R and its Cooperative Centers

A service level agreement will be signed between the MDPB-R and the Cord Blood Bank to delineate their respective medical, operational, GDPR and financial responsibilities. Each CBB will keep its own name and will retain visibility towards its donors, participating donor centers and sponsors.
This agreement will be signed by a delegate of the Governing Board of the MDPB-R on one hand and by the General or Medical Director and the Financial Director of the Cord Blood Bank on the other hand.

4.5 Quality Assurance Program

4.5.1 The MDPB must have a regularly updated Quality Assurance Program.

This program must include formal accreditation of the CBB by the BHS-MDP-B Committee and Governing Board of the MDPB-R on a regular basis.

- The criteria for accreditation of CBBs are listed in the MDPB Standards.
- The accreditation must be granted for a minimum of 1 year and a maximum of 3 years.
- Towards the end of the current accreditation period, the BHS-MDP-B Committee and the Governing Board of the MDPB-R must decide the duration of the next accreditation period.
- The MDPB-R must review the status of CBB before expiration of the current period of accreditation. This review must include compliance with the MDPB Standards and verification of all accreditation criteria as listed in the MDPB Standards. If necessary, the BHS-MDP-B Committee and Governing Board of the MDPB-R may perform on-site visits.
- The MDPB-R then prepares a list of centers proposed for accreditation approved by the BHS-MDP-B Committee, the Governing Board of the MDPB-R takes the final decision on that list of accredited centers.

4.5.2 The Quality Assurance Program must include a formal annual review of the clinical outcome of CB. This review must be performed by the Quality Assurance Committee (QAC) of the BHS-MDP-B Committee. The annual report of the QAC must be reviewed and approved by the BHS-MDP-B Committee.

4.5.3 Reporting Serious product events and adverse reactions to the WMDA

The Incident reporting is explained in chapter 4.12.3 of the MDPB Standards.

4.5.4 Incident reporting, quality deviations

Incidents not to be reported by the WMDA online tool and any other quality issues, have to reported by the *MDPB FRM013 Quality incident report* and will be logged in the MDPB-R QMS reporting database by the Registry staff.

Each incident or quality deviation must be investigated and closed with corrective actions taken if applicable.

4.5.5 Missing status report

If any report of the above chapters has not been provided after 3 reminders by the staff of the MDPB-R, the file will be closed. In case the information cannot be

provided, the form *MDPB FRM037 Notification of missing status report* must be completed.
The form will be evaluated by the Quality Assurance Committee.

4.5.6 Contact info

The CBB must have a procedure to notify the Marrow Donor Program Registry about key changes: address and contact information, change of staff, accreditation status, changes in affiliated facilities.

5 INFORMATION TECHNOLOGY AND INFORMATION MANAGEMENT

The software application Prometheus facilitates the search process for unrelated donors and Cord Blood Units for the benefit of patients in need of a stem cell transplantation. Prometheus provides a link with International Registries (connected to the EMDIS network) and operates in accordance with international procedures and in compliance with the MDPB Standards.

The information technology and information management standards including system administration, essential functionality of IT systems, security management and management of changes are described in Chapter 6 of the Marrow Donor Program Belgium Standards.

The Cord Blood Bank and MDPB-R work in close collaboration on future projects to be implemented in new EMDIS releases.

6 ABBREVIATIONS AND TERMINOLOGY

The following abbreviations cover terms used in these Standards:

Adverse event, Adverse reaction	Any unintended and unfavorable sign, symptom, abnormality, or condition temporally associated with an intervention, medical treatment, or procedure that may or may not have a causal relationship with the intervention, medical treatment, or procedure. Adverse reaction is a type of adverse event.
CD34	The 115 kD glycoprotein antigen, expressed by a small portion of Cord Blood cells, that is defined by a specific monoclonal antibody (anti-CD34) using the standardized cluster of differentiation (CD) terminology. Hematopoietic progenitor cells are largely contained within the CD34 cell population of Cord Blood Units.
Colony forming unit (CFU)	A clonogeneic cell able to produce hematopoietic colonies in vitro under specific conditions in the presence of appropriate colony stimulating factors and defined by the type of mature progeny that develop.
Collection	Any procedure for procuring and labeling cellular therapy products, regardless of technique.
Communicable disease	A disease or disease agent for which there may be a risk of transmission by a CBU either to a recipient or to the people who may handle or otherwise come in contact with the CBU.
Cord Blood (CB)	The infant's blood remaining in the placenta and umbilical cord after the umbilical cord has been clamped.
Cord Blood Bank (CBB)	An integrated team under a single Cord Blood Bank Director responsible for donor management and the collection, processing, testing, cryopreservation, storage, listing, search, selection, reservation, release, and distribution of Cord Blood Units.
Cord Blood banking (CB banking)	The processing, testing, cryopreservation, storage, listing, search, selection, reservation, release, and distribution of Cord Blood Units intended for administration.
Cord Blood collection	The procurement of Cord Blood for banking and administration before and/or after the placenta is delivered. Ex utero: The collection of Cord Blood cells from the placental and/or umbilical cord vessels after the placenta has been delivered. In utero: The collection of Cord Blood cells from the placental and/or umbilical cord vessels after the infant donor has been delivered and separated from the umbilical cord, but before the placenta has been delivered.
Cord Blood Unit (CBU)	The nucleated cells including stem and hematopoietic progenitor cells harvested from placental and umbilical Cord Blood vessels from a single placenta after the umbilical cord has been clamped. HPC, Cord Blood is the proper name of a Cord Blood Unit.

	Unless otherwise specified, the term CBU in this document refers to any CBU regardless of method of collection or intended use.
Cryopreservation	The processing of viable cells or tissues that consists of cooling the product to a very low temperature where viability is maintained.
DPO	Data protection officer
Eligible	An infant donor and/or mother who meet(s) all donor screening and testing requirements related to transmission of communicable disease as defined by applicable law.
Engraftment:	The reconstitution of hematopoiesis or other cellular functions with cells from a donor.
GDPR	General Data Protection Regulation (GDPR)
Hematopoietic Progenitor Cells (HPC)	Self-renewing and/or multi-potent stem cells capable of maturation into any of the hematopoietic lineages, lineage-restricted pluri-potent progenitor cells, and committed progenitor cells, regardless of tissue source (bone marrow, umbilical cord blood, peripheral blood, or other tissue source).
HPC, CB	HPC, Cord Blood
HUB	Stem cell registry, coordinating center for each country.
IMS	Intermediate structure
Ineligible	An infant donor and/or mother who does not meet all donor screening and testing requirements related to transmission of communicable disease as defined by applicable law.
Labeling	Steps taken to identify the original CBU collection and any products or product modifiers, to complete the required reviews, and to attach the appropriate labels.
Mother: Any of the following:	The woman who carries the infant donor to its delivery; may be the genetic mother or a surrogate mother. Genetic mother: The woman from whose egg the infant donor develops; the egg donor. Mother: When used unmodified, the term mother refers to the mother who is both the genetic and birth mother. Surrogate mother: The woman who carries an infant donor not genetically her own from an embryo to delivery. Under circumstances of a surrogate mother carrying the infant donor to term and the CBU being collected, both the surrogate and the genetic mother must be considered for purposes of communicable disease screening and testing; the genetic mother must be considered for purposes of genetic information.

Nonconforming Cord Blood Unit	Any CBU that does not completely meet the requirements specified by these Standards, the Cord Blood Bank, and/or the requirements for donor eligibility as defined by applicable law.
Outcome analysis	The process by which the results of a therapeutic procedure are formally assessed.
Prometheus	Prometheus is the information system for stem cell donor registries. It covers all key business processes of the registry's daily work, including donor management, upload to the WMDA submission platform, patient management and search management.
Reference samples	Aliquots of cells, plasma, serum, or cellular material from the CBU, the umbilical cord, or the placenta that can be used to confirm the identity, HLA typing, or genetic or communicable disease information associated with a single Cord Blood Unit. Such samples may or may not be contiguous segments.
Release	Removal of a CBU from quarantine or in-process status when it meets specified criteria.
Reservation	Temporary allocation of a CBU to a specific recipient to prevent consideration of that CBU for another recipient.
Rh	Abbreviation for the Rhesus system of human red cell antigens; used in this document to refer to the Rh (D) antigen only unless otherwise specified.
Sterility testing	The processes used to screen for the presence of microbial agents.
Storage	Holding CBU for future processing and/or distribution.
Time of collection	The time of day that the Cord Blood collection is completed.
TLS encryption	Transport layer Security: secure tunnel over the internet between the sender and the recipient, the message is protected in transit.
Total Nucleated Cells (TNC)	The total nucleated cells (red and white) in the graft portion of the collection (without aliquots). Using the NETCORD Standards the number of cells required are total nucleated cells including erythroblasts, and obtained directly from the automatic counter.
TC	Transplant Center
Unique Identifier	A numeric or alphanumeric sequence used to designate a specific CBU with reasonable confidence that the identifier will not be used for another purpose, including for another Cord Blood Unit.
Viability	Living cells as defined by dye exclusion, flow cytometry, or progenitor cell culture.

7 REFERENCE DOCUMENTS

Report of Serious (Product) Events and Adverse Reactions	www.wmda.info

8 STANDARDS

The centers must agree to abide by the standards, policies, and procedures of the (current version):

FAGG/ AFMPS	Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten - Agence Fédérale des Medicament et des Produits de Santé www.fagg-afmps.be
ASHI	American Society for Histocompatibility and Immunogenetics. www.ashi-hla.org
BELGIAN STANDARDS	HGR/CSS standards Nr 8271 (Hoge Gezondheidsraad / Conseil supérieur de la Santé) (2 July 2008) www.portal.health.fgov.be/portal Belgian law and subordinate decrees
EBMT	European Group for Blood and Marrow Transplantation Operational Manual (2004 Revised Edition) EBMT Transplant guidelines and accreditation Indications for unrelated HSCT transplantation : “Bone Marrow Transplantation : special report 2006, 37, 439-449 : allogeneic and autologous transplantation for haematological diseases, solid tumours and immune disorders: definitions and current practice in Europe”. P.Ljungman et al.” www.ebmt.org
EFI	European Federation for Immunogenetics www.efiweb.eu
EMDIS	European Marrow Donor Information System www.emdis.net
EUROPEAN DIRECTIVES	2004/23/EC of 31 March 2004 (standards of quality, safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.) 2006/17/EC of 8 February 2006 (Technical requirements for the donation, procurement and testing of human tissues and cells.)

	2008/86/EC of 24 October 2008 (Implementation of 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells. http://ec.europa.eu/health/ph_threats/human_substance/legal_tissues_cells_en.htm
FACT-NETCORD	The international Netcord foundation https://office.de.netcord.org/index.html http://www.factwebsite.org/main.aspx?id=102
FDA	US Food and Drug Administration www.fda.gov
NMDP	National Marrow Donor Program www.marrow.org
MDPB Standards	Marrow Donor Program Belgium Standards
MDPB cord Standards	Marrow Donor Program Belgium Cord Blood Standards
WMDA Standards	World Marrow Donor Association International Standards for unrelated hematopoietic stem cell donor registries. https://wmda.info
EUROCORD	International Registry on Cord Blood Transplantation. Eurocord registry operates on behalf of the European Group for Blood and Marrow Transplantation (EBMT). www.eurocord.org

9 ADDENDUM

See MDPB LST008 Addendum standards.