MDPB

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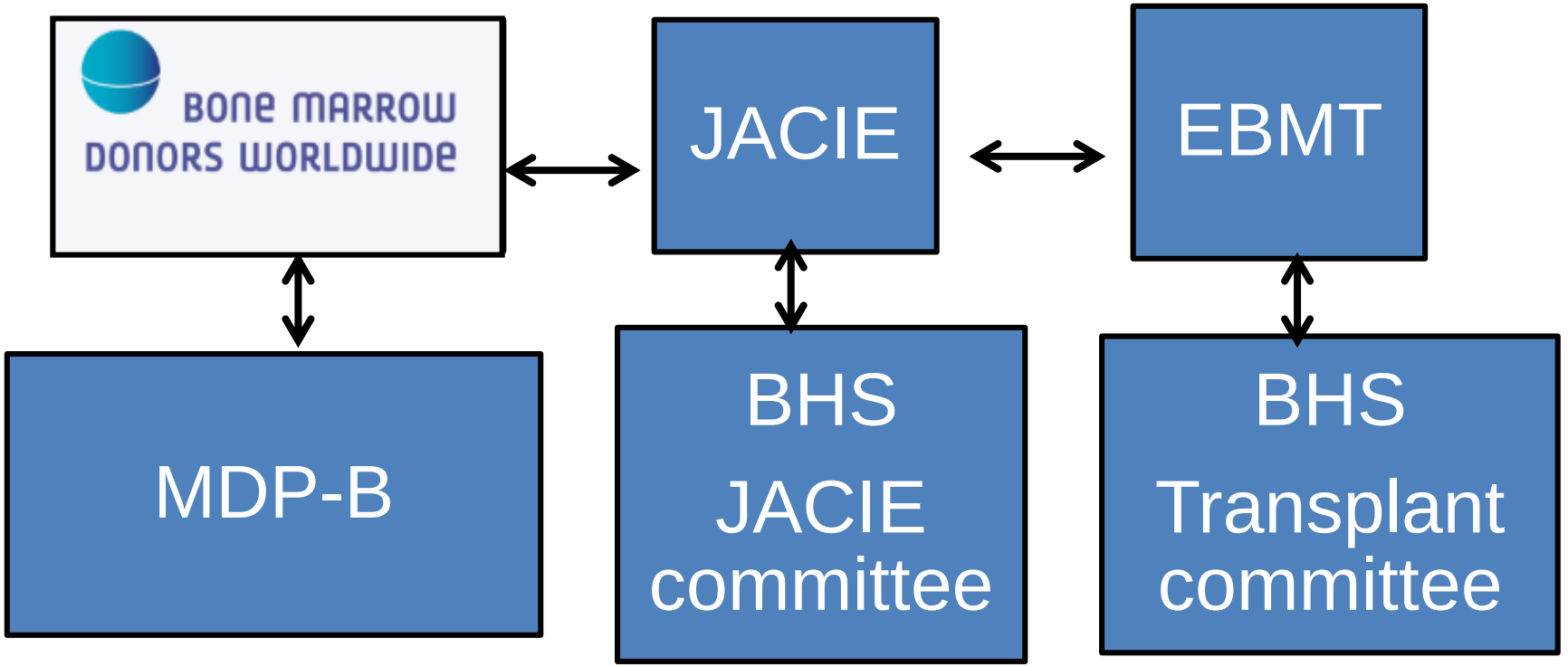
Marrow Donor
Program Belgium
Registry

Agenda

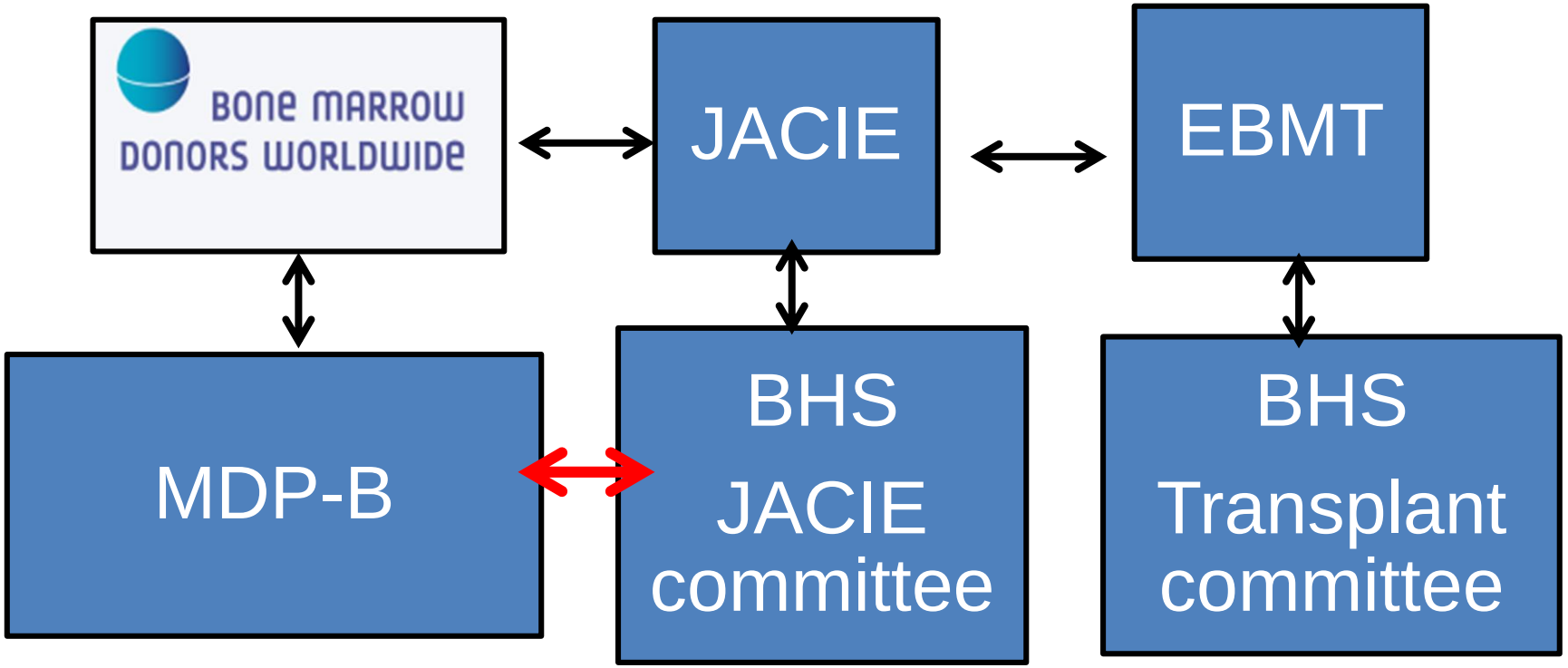
- 1. Opening
- 2. Donor - CBU activity overview
- 3. Donor recruitment action
- 4. Communication campaign
- 5. IT & GRID
- 6. WMDA qualification
- 7. Quality assurance
- 8. Varia
  - Education session MDPB 25 November 2016

TRANSPLANT RELATED committee's



Marrow Donor Program Belgium Registry

TRANSPLANT RELATED committee's



2. Donor – CBU activity overview:

	DONORS	CORD BLOOD
2006	46.197	5.994
2007	44.964	6.094
2008	47.477	6.705
2009	47.518	7.011
2010	49.709	7.709
2011	56.972	8.275
2012	62.732	16.960
2013	65.956	17.418
2014	72.775	18.662
2015	77.051	19.516
14-06-2016	**77.150**	**20.000**

Current number of donors and cord blood units listed in the BMDW database : donors: **27.810.532** and cord bloods: **690.799**

3. Donor recruitment action

Status

- Contract RIZIV-INAMI : convention 2014-2018 for 10.000 donors / financement of 140,- € per donor.
- Approval of RIZIV-INAMI for 7.143 donors to be financed by savings MDPB-R (140,- € per donor).
- Number of new registered donors since 2008: 42.881 (database of 78.931 donors).
- 66% of the new registered donors are female donors.

4. Communication project

Communication campaign + new website

Goals: Campaign, across Belgium

Primary

- Ineffectiveness of spontaneous individual campaigns for one patient in need of a stem cell transplantation

Secundary

- Clarify entire process from registration until stem cell donation.
- Insights and understanding in HLA matching, number and variety of donors needed in the Belgian database.

Timing:

- Target : Q1 2017

5. IT

Future projects : GRID

- **GRID**: Global Registration Identifier for donors.
- The GRID assures that every donor and cord blood unit is assigned a globally unique identifier.
- WMDA worked with the ICCBBA to develop and implement the GRID.
- WMDA, BMDW, EMDIS and all registries participating will adopt the GRID standard.
- GRID will start off as optional, but will then become a required field: **DEADLINE 2018.**

5. IT

Grid presentation

Figure 1. Eye-Readable GRID Format

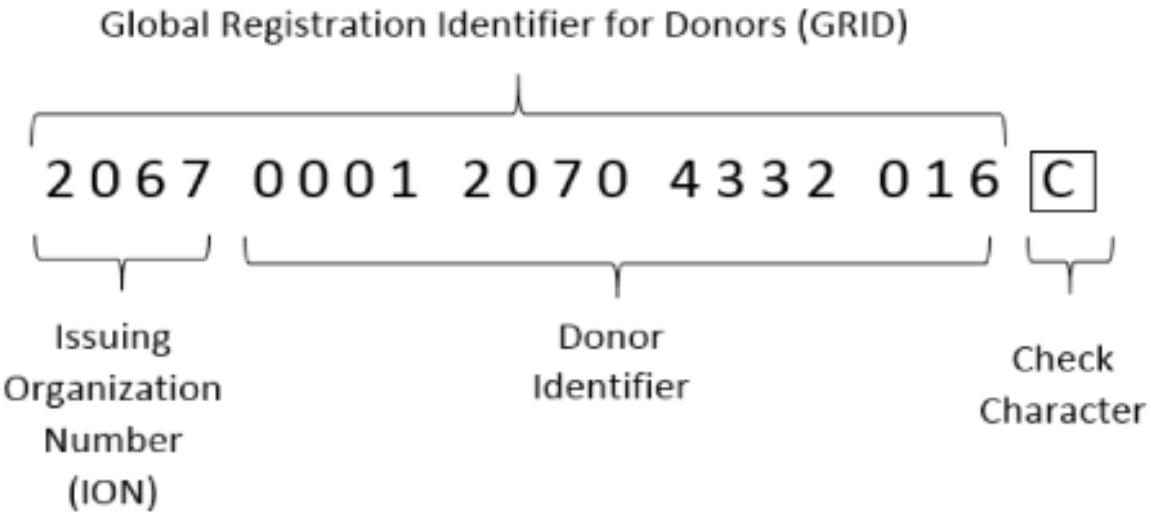


Figure 2. Machine-Readable GRID Format: Linear Bar Code (using Code 128)

6. WMDA accreditation

WMDA qualification

Phase	Target date
Coordinator: Lisa Verhaegen	
Donor/Collection working groups with quality coordinators/contact persons of donor and collection centers	February 2016
Collect information and documentation for application package (Registry, transplant centres,…)	Second half 2016
Send out application for qualification	When information collected
WMDA qualified (Bold section)	2017
WMDA accredited	2022

6. WMDA accreditation

Donor / collection working groups January 2016

Working groups	Dates	Participants
1. Informed consent + information letters	25 Jan 2016 14u00-17u00	Natalie Bogaard Philippe Lewalle Registry staff Wesley Rosseel Pascale Van Muylder
Donor reimbursement		
2. Donor criteria policy	27 Jan 2016 14u00-17u00	Lucien Noens Ineke Vanlaere Pascale Van Muylder Pierre Zachée Registry staff
Criteria donor for international patients		
Medical exam (search and workup)		
3. Confidentiality - retention	28 Jan 2016 14u00-17u00	Pascale Van Muylder Registry staff

6. WMDA accreditation

Donor / collection working groups

- MDPB Standards update and implementation done in 2015.
- The cross checking of WMDA standards & JACIE standards and application templates revealed shortcoming sections (gaps) in donor related chapters.
- Those sections have to be elaborated in additional MDPB policies.
- In January, working groups discussed these topics.

WORK FLOW

WMDA	Description	Guidance:	Bemerkingen Inneke Noens	Uit te voeren acties	Nodige documenten	Verantwoordelijke	Nodige documenten	
		▪ The registry must provide a standard operating procedure or policy documents that give details of the communications with transplant centres, collection centres, cord blood banks, and processing facilities.	same comment	operational procedure search workup	Standards JACIE	Lisa		
		▪ The registry must indicate the procedures for review of the requests for collections from transplant centres.	requirements in the rules of operation for			Lisa		
		▪ The registry must provide an example of forms/documents used to provide a request to the collection centres. The registry must provide a	ok		Forms			
		▪ Provide a procedure describing how the collection centre communicates back to the registry the feasibility to collect the requested amount of cells and any anticipated problems (such as inability to provide requested additives) and how this information is communicated back to the	verification form ok	info via mail (explained in the operational procedure).	Standards SOP Forms	Lisa		
8.07	**Written documentation of the characteristics of the collected product important in facilitating transplantation must be provided with the cells according to applicable guidelines. The documentation and/or label, at a minimum, must include information on the name of the product, the number of cells collected, the donor's unique**	Forms may either originate from the registry or may be from the collection centre or cord blood bank. They must comply with national legislation and accreditation requirements. See the following for requirements: http://www.worldmarrow.org/fileadmin/committees/RLAC/20110401-RLAC-INFO-LABEL.pdf. The registry should send a traceability form to the transplant centre to confirm the identity of the product, and to capture information related to the date and the time product was received and infused, processing, counts, amount used/cryopreservation of surplus, engraftment data, adverse events, etc. Records documenting the	C7.4 beschrijft de label content. "The number of cells" moet niet noodzakelijk op het label. IS INDICATED ON THE FORMS accompanying the transport.	MDPB FORMS.				p
		▪ The registry must provide forms/documentation that the collection centre uses as distribution records that contains a minimum data set as	Collection form		Standards			
		▪ An example of product labelling must be provided and this must conform to international standards.	cooperative center level: in checklist		Standards			à
		▪ Provide any form completed by the transplant centre upon receipt of the	Transport audit		Standards			

6. WMDA accreditation

Donor / collection working groups planning

Overview of major changes:

- Donor recruitment criteria
- Donor patient – contact 4.4.13.
- Ethnicity
- Explanation donation procedures
- Changes quality assurance program
- Rules of operation for international patients

6. WMDA accreditation

Donor / collection working groups planning

Overview of major changes:

- Update donor information letters and informed consents
- New medical questionnaires
- New forms:
  - Results health screening: C20 – C30 WMDA forms
  - Medical evaluation: F50 IDM testing performed at WU
- Donor reimbursement policy and communication policy
- New logo

7. Quality assurance

Patient follow up

Chapter 9.06 WMDA accreditation

> ***WMDA qualified/accredited registries*** *should require their national transplant centers to submit data to a regional or international patient outcome databases in order to collect clinical outcome data of the transplanted patients.*

• This standard is not required, it is important, however, that patient follow up information be collected and provided to a database so that outcomes can be evaluated. For example, the registry might require submission of specific data to the **EBMT** or the CIBMTR or a regional database.

7. Quality assurance

Patient follow up

PATIENT FOLLOW UP - DONORS + CORDS	Data analysis EBMT lifelong	Follow up of EBMT reporting	QAC
Belgian patients	Belgian Cancer Registry	Cross check MDPB Registry / Cancer Registry	MUD + CORD TRANSPLANT REPORT BY BELGIAN CANCER REGISTRY
		Registry will send reminders for missing EBMT reporting	Follow up of adequate EBMT reporting (requirement MDPB accreditation for TC's)
International patients	Registry	Registry	Database MDPB (Follow up reporting TC's)

8. Varia

10.1. Education session coordinators

- Fourth education session **25 November 2016, 14u00 – 17u00 Mechelen**
  (Zaal Plaza)

- Invited speakers:

  1. Dr Verfaille: “Regenerative medicine”

  2. Prof. MP Emonds: “Immunology”.