

Ministerul Sănătății

Registrul Național
al Donatorilor Voluntari
de Celule Stem Hematopoietice

Registry of Hematopoietic Stem Cell Donors present and perspectives

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Vision & Mission

- **The Vision** of NRHSCVD is that all Romanian patients in need of unrelated HSC allotransplant to undertake this intervention in one of the Transplant Centers in the country.
- **The Mission** of NRHSCVD is to identify and ensure, at international standards, compatible HSC donors to all patients from Romania in need of HSC transplant for whom there are no related compatible donors.

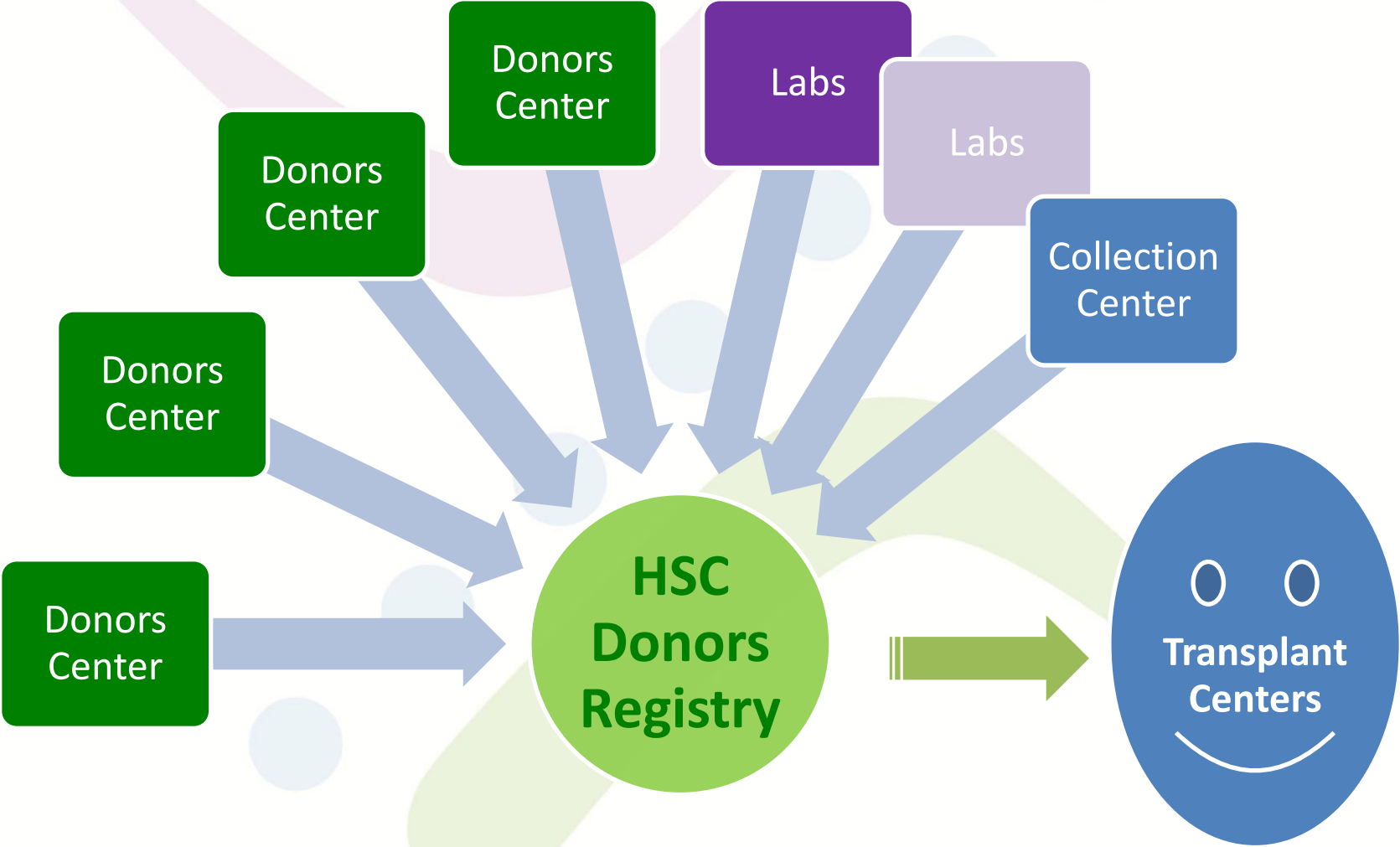
Organisation Overview

- 1 July 2009: the Government approved establishment of NRHSCVD (GD 760/ 2009) - inapplicable
- July 2009 – May 2011: efforts of HLA Labs from Fundeni Clinical Institute and National Institute of Hematology, to organize specific activities (the record the HLA typed related donors to express their willing to become donor for unrelated patient)
- 18 May 2011 has established the NRHSCVD (after modifying the GD 760/ 2009 in 23 April 2011)
- September 2011 – started the organization of NRHSCVD

The main goals of NRHSCVD

- **Co-ordination** the recruitment of HSC donors, HLA testing and collection from the unrelated HSC donors
- **Set-up a database** and to provide centralized information on the HLA phenotypes and other relevant data of unrelated stem cell donors from Romania
- **Search for compatible unrelated stem cells donors**
- **Interconnection with similar international bodies** – for maximizing the chance of finding a stem cell donor for Romanian patient
- **Research in the field of HSC transplant**
- **Adhere to the Standards** of the World Marrow Donor Association

Organization of NRHSCVD



For interconnection with similar bodies is mandatory the qualification / accreditation by the World Marrow Donors Association

WMDA Standards 1.06 A

- Registry that intends to request WMDA qualification must be a WMDA organizational member.
- The Registry must complete the WMDA Annual Report Questionnaire.

ACCREDITATION



QUALIFICATION

WMDA qualification criteria

general administration standards



Quality management

Data security management

Traceability

Training of personnel involved

Communication policies

Where we are?

- **Quality Management** – The Romanian Donors Registry is a ISO 9001: 2000 certified
- **Data security management** – The Romanian Donors Registry is a ISO/IEC 27001:2005 certified
- **Romanian Registry's Standards relate to WMDA Standards** are developed and will be endorsed through ministerial order
 - are defined - the donor and patient flows, and the Forms
 - Training of personal involved for using the Registry's software Prometeus and other software use
 - Equipped with IT and specific softwares
 - Space is secured and protected (intrusion, control access and fire systems)

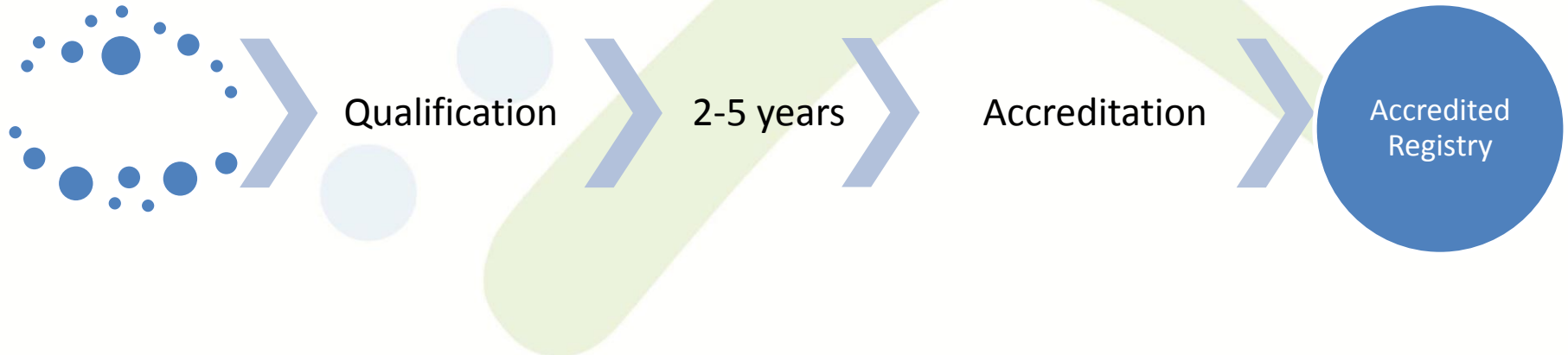
Where we are?

- **Traceability** - license for coding system of ISBT 128 (registration and assignment of unique codes of facilities network coordinated by the Registry) - ongoing process.
- **Staff training** - standardized training curricula for staff involved in the recruitment, the search and the donors provide and the donation testing - ongoing process.
- **Communication**
 - package information for donors
 - informed consent forms and health self-assessment
 - qualitative research on awareness, attitudes and perceptions of people on voluntary donation and transplantation CSH
 - communication platform - call center, toll free call center, web application communication records
 - preparing for a communication campaign strategy

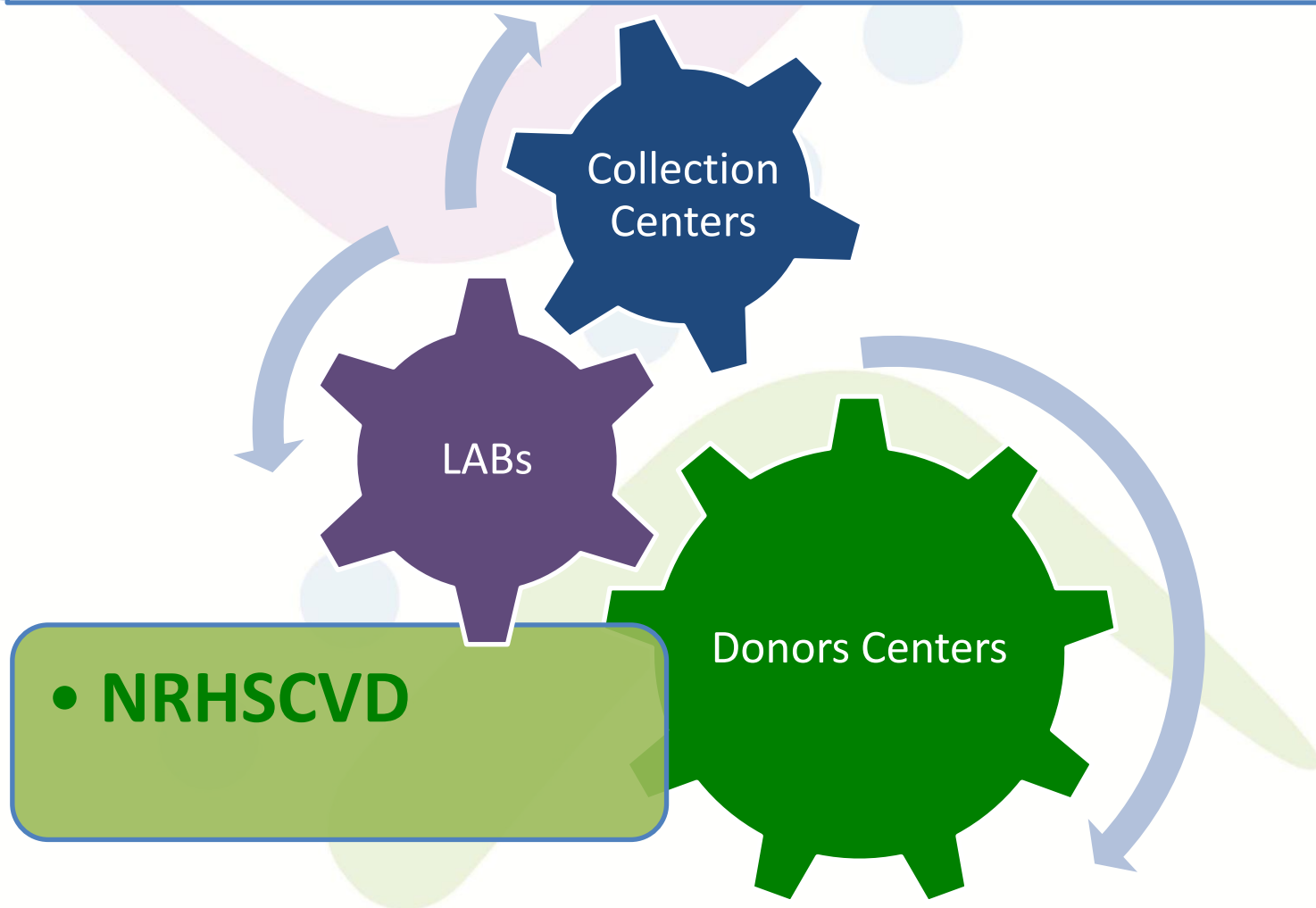
WMDA qualification criteria

minimum activities

1. **Searchable donor file:** minimum of 500 donors
2. **Access to donors/cord blood units for further testing:**
 - search requests received for international patients
 - at the request of international Registries/TCs, additional HLA testing has been performed
 - donor samples have been shipped
3. **Access to donors/units for transplantation:**
 - minimum of 6 donations shipments
 - 2 of the 6 for international patients



NRHSCVD and each facilities involved in the unrelated hematopoietic stem cells donation and transplantation program **must follow and maintain the NRHSCVD applicable standards**



Where we are?

NRHSCVD fulfill the minimum criteria for to be mentioned as a future **registry in Bone Marrow Donors Worldwide (BMDW)**:

- We have over 1000 HLA typed unrelated stem cell donors
- NRHSCVD is operational
- We are ready to start working on entering our donors in BMDW
- NRHSCVD is willing and able to provide HSC products from unrelated donors to registries/transplant centers abroad

Difficulties...

- **Due to frequently political changes**, delays the need of actual legislative framework for:
 - Compliance with standards WMDA (coding system, import/ export activities, audit)
 - Fees for access to BMDW, membership to WMDA , EBMT and EFI
 - Set up HSC donor centers in the districts
- **Insufficient medical staff** (migration of doctors and nurses)
- **Insufficient funding** generate difficulties to have necessary infrastructure (computers, ISBT 128 etc..)
- **Conduct the standard training of healthcare professionals** involved in recruitment, testing and stem cell donation

Perspectives

- The main objective of Romanian Registry is to become operational and to fulfill the minimum requests of WMDA standards, till the end of 2012
- Communication campaign
- Interconnection to international registers (BMDW, Czech Republic, Poland, Germany, etc.)
- Search and find unrelated donors for Romanian patients
- Provision of unrelated HSC donors for Romanian transplants centers
- Development of partnerships with similar institutions in Europe (networking / exchange of experience / training)



**Thank you for
your attention!**