

Ministerul Sănătății

Registrul Național  
al Donatorilor Voluntari  
de Celule Stem Hematopoietice

# Accreditation, Standards implementation and Audit in Donor Centers, Laboratories, Collection Centers and Transplant Centers

RNDVCSH

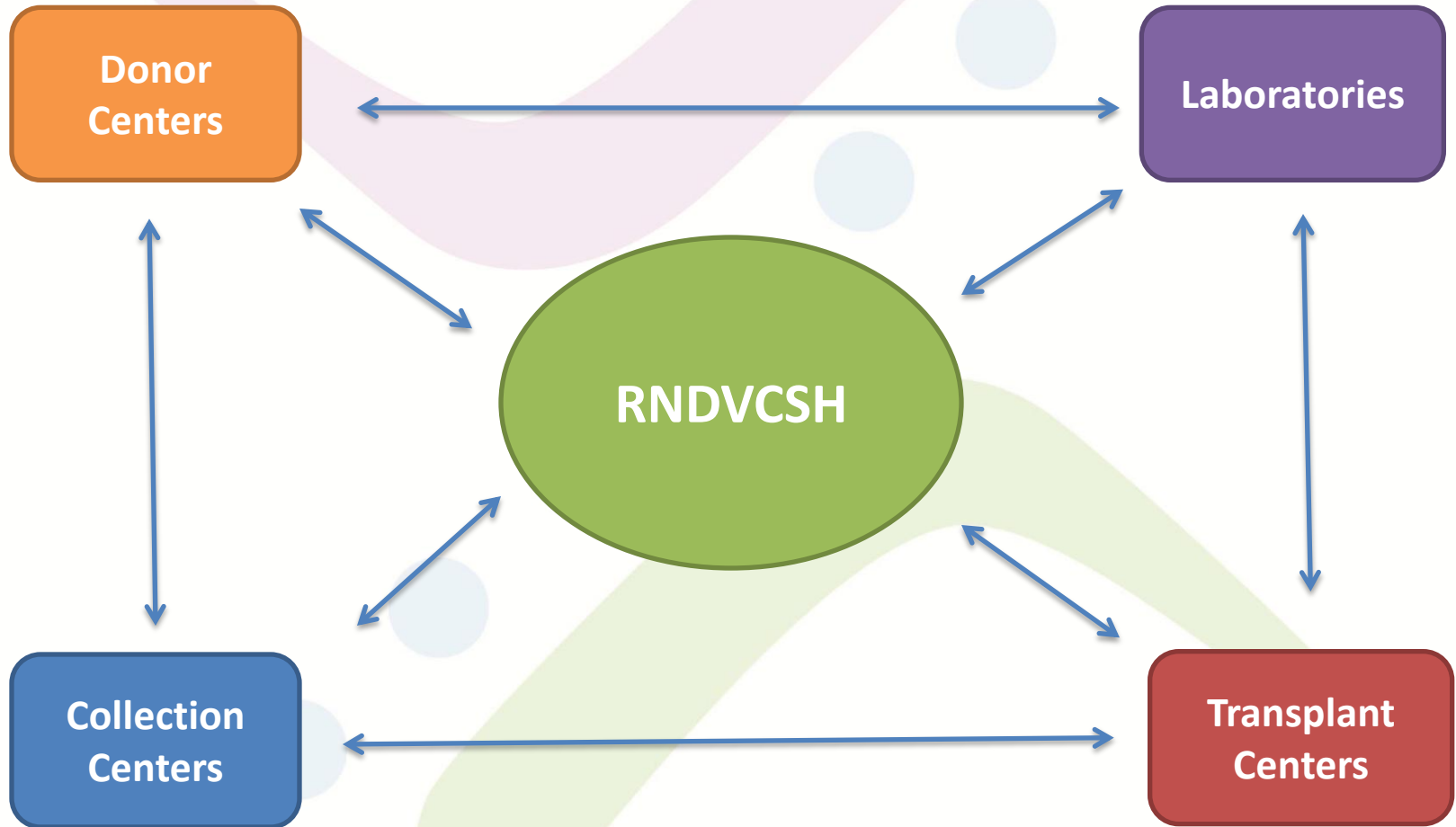
Bucharest, 30 April 2012

# WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries - January 1, 2011

## **Specific objectives of WMDA :**

- ``These standards are aimed at enhancing the quality of Stem Cell Donor Registries``
- ``...promote the quality of procedures...``
- ``...set forth only minimum guidelines for Registries working through the WMDA to facilitate hematopoietic stem cell transplants.``
- ``1.04 If a Registry relies on other entities to perform some of the duties described in these standards, it is the responsibility of the Registry to ensure that these entities comply with WMDA standards.

# RNDVCSH network



# Donor Centers (DCs)

- **Organized in: Blood transfusion centers**  
**Medical care institutions**

**Registry establish the standards which apply to the DCs**

(WMDA 1.04.1; 3.01-3.05; 3.06.2.2; 3.07; 4.05; 6.03; 8.02; 9.01-9.04)

- **Implementation of quality standards and procedures**

**Quality assurance schemes for IDM tests**

- **BIODEV**
- **NEQAS**

- **Written agreement with the Registry**

# HLA Laboratories in Romania - 7

- \* Bucharest – 2 labs
- \* Cluj
- \* Iasi
- \* Timisoara
- \* Tg. Mures
- \* Constanta

➤ **Ministry of Health Accreditation**

➤ **2 labs - EFI Accredited**

**National Institute of Hematology and Blood Transfusion  
Clinical Institute Fundeni, Bucharest**

# Techniques used in Romanian laboratories

## HLA typing methods:

- SSP 2 digits – 7
- SSO 2 digits – 5
- SSP – 4 digits – 2
- Sequencing – 1
- Serology – 3

# Participation of Romanian Laboratories in European - EFI schemes for HLA Typing

- **BEPT - ISTANBUL UNIVERSITY- MEDICAL FACULTY**
    - 5 labs -> molecular biology typing 2 digits : ABCDRDQ – 3  
ABDR – 2
  - **UK NEQAS** – 1 lab -> molecular biology typing 4 digits
  - **CET - Vienna Medical University** – 3 labs -> molecular biology typing 2 digits
  - **Instand ev** – 2 labs -> CDC typing
  - **HLA EPT for Central and East Europe** – Wroclaw Medical University
    - 1 lab -> molecular biology typing 4 digits
- No participation in any EPT scheme  
\* 2 labs

# Collection Centers & Transplant Centers

**National Transplant Agency**

-> accreditation criteria

-> inspection

-> **Ministry of Health Decision**



# Audit organization

## Organized by RNDVCSH

- **Periodical**
- **For all institutions from Registry network**
- **Audit plan are based on the SOP developed by Registry (compliant with WMDA Standards)**



Thank you!