

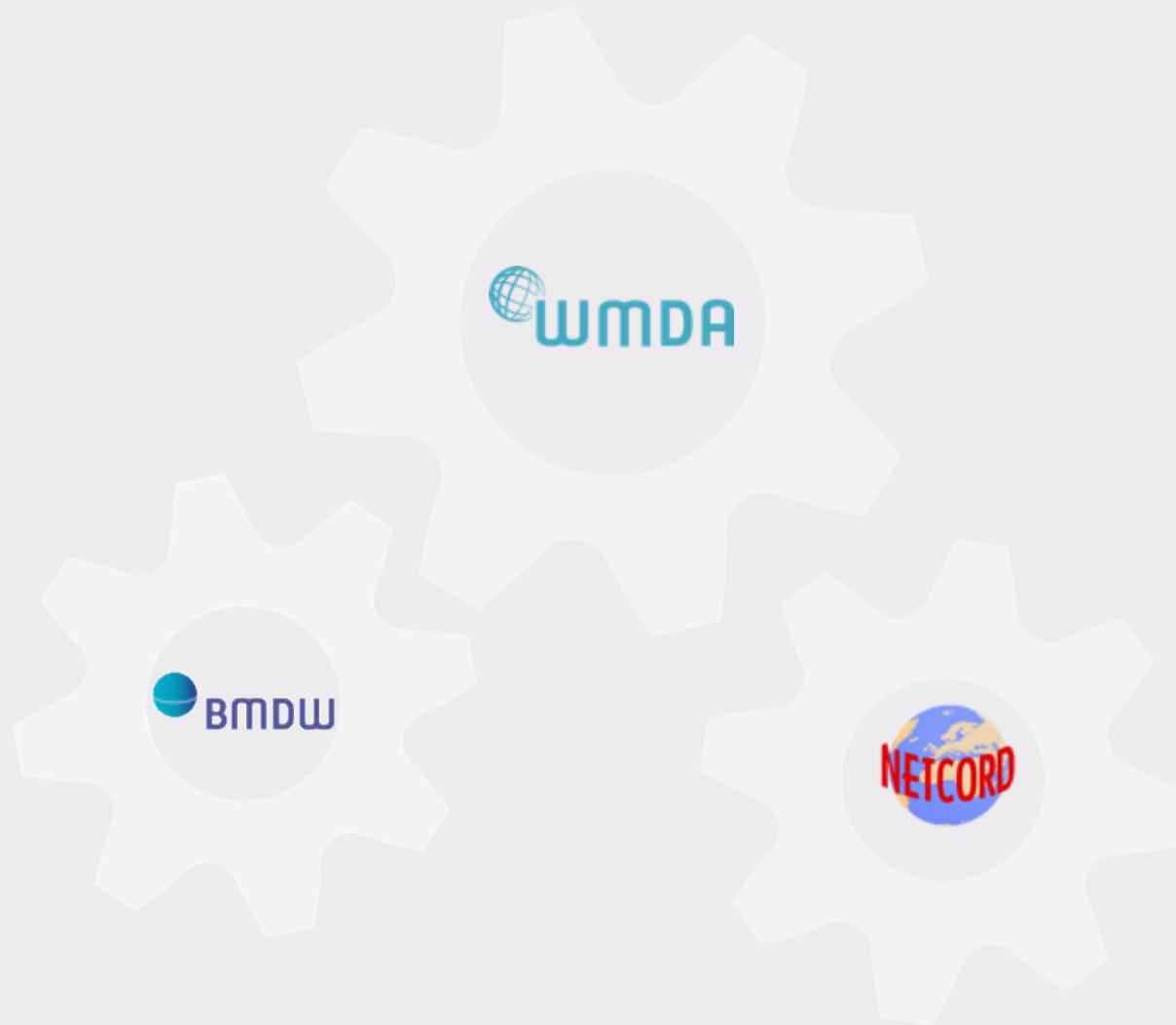


# **Marrow Donor Program Belgium Symposium**

**November 30, 2017**

**World Marrow Donor Association, who we are**

# Moving to One United Organisation

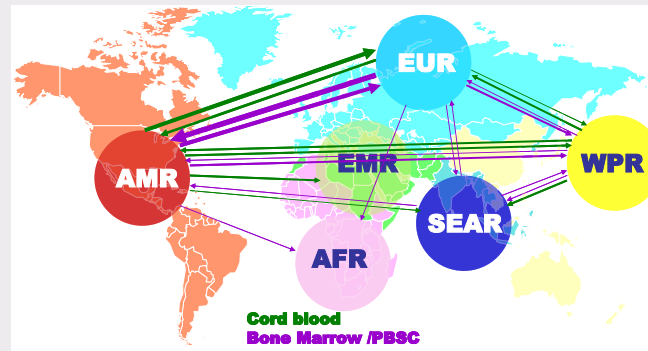


**WMDA is owned and driven by members**

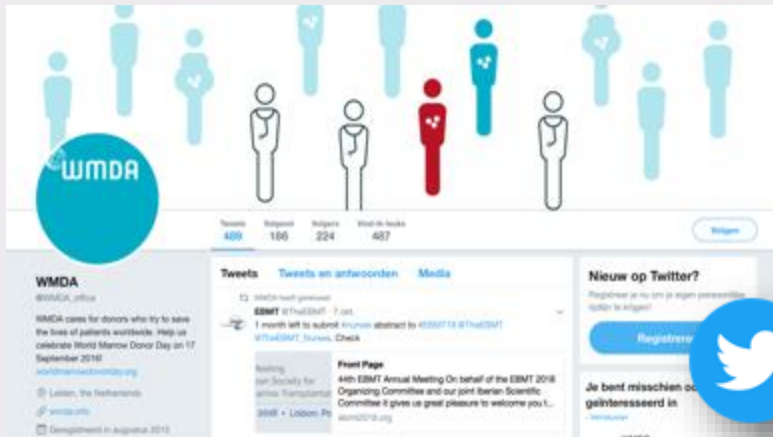
# A changing world



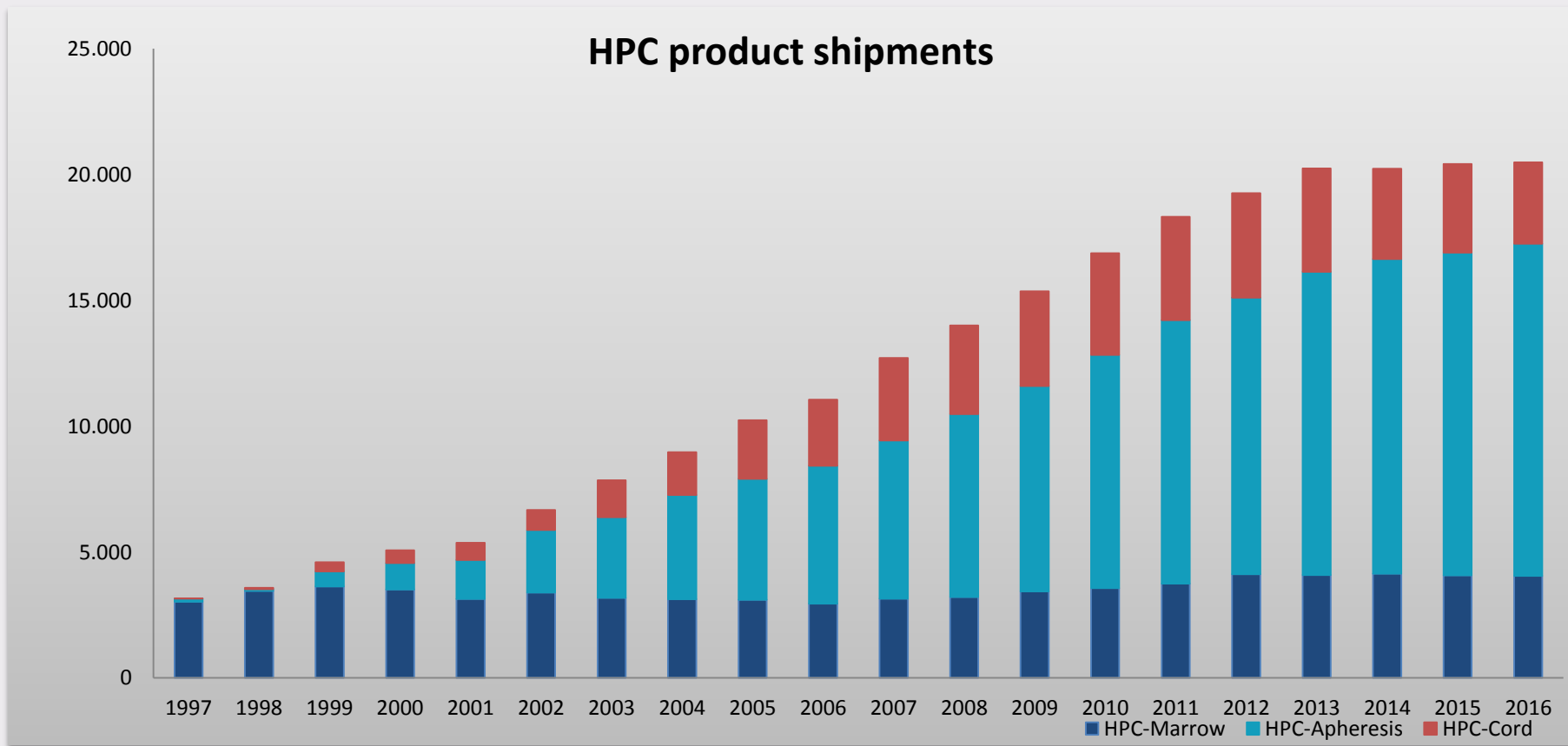
# A changing world



# A changing world



# A changing world



# WMDA

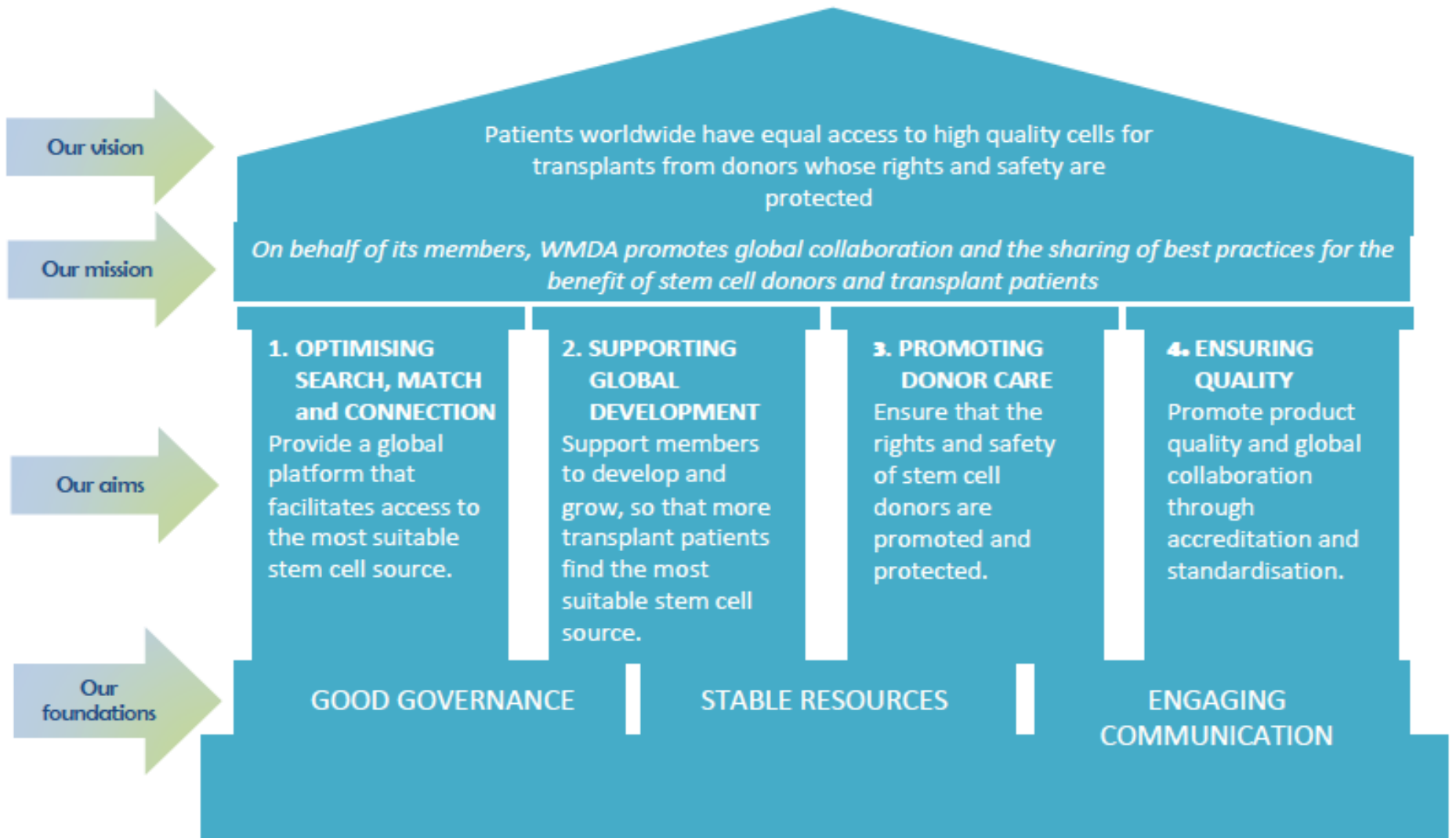
## Our Vision

Patients worldwide have equal access to high quality cells for transplants from donors whose rights and safety are protected.

## Our Mission

On behalf of its members, WMDA promotes global collaboration and the sharing of best practices for the benefit of stem cell donors and transplant patients.

# Strategy Overview





# Pillar 1: Optimising Search, Match & Connection



**A global search platform** that facilitates the best possible match between stem cell donors and transplant patients.



**User friendly** with automation to improve & simplify searches and improved training to support users.



**Privacy & data security** are safeguarded through the implementation of GRID & data agreements

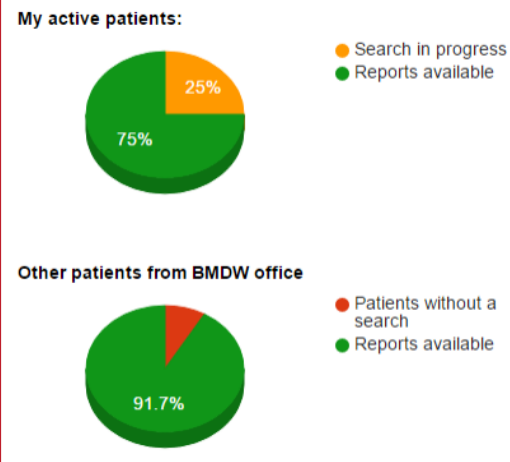
Navigation bar

## BMDW Search & Match Service

Welcome, Jorine Koenderman

### Your personalised dashboard

<b>My active patients</b>	<b>4</b>
Patients with errors	0
Patients without a search	0
Search in progress	1
Reports available	3
<b>Other patients from BMDW office</b>	<b>12</b>
Patients with errors	0
Patients without a search	1
Search in progress	0
Reports available	11



- Personalized Dashboard
- Simple to use interface

# Add patient

### Patient consent ✕

I declare that the patient has been informed about the transmission of their information to BMDW.

Without patient consent, you won't be able to enter your own Patient ID and comments.

## HLA details

\* Required fields

**Patient ID \***

[DNA Type Lookup tool](#)

### Class I

HLA-A *	<input type="text"/>	<input type="text"/>
HLA-B *	<input type="text"/>	<input type="text"/>
HLA-C	<input type="text"/>	<input type="text"/>

### Class II

HLA-DRB1 *	<input type="text"/>	<input type="text"/>
HLA-DQB1	<input type="text"/>	<input type="text"/>
HLA-DPB1	<input type="text"/>	<input type="text"/>

## Add patient

**HLA details**

\* Required fields

Patient ID \*  DNA Type Lookup tool

Class I		Class II	
HLA-A *	<input type="text"/>	HLA-DRB1 *	<input type="text"/>
HLA-B *	<input type="text"/>	HLA-DQB1	<input type="text"/>
HLA-C	<input type="text"/>	HLA-DPB1	<input type="text"/>

Extra Class II loci

**Medical details**

CMV status:  Blood group:  Rh:

Ethnicity\*:  Weight:  kg

Birth date:  Gender:

Diagnosis:  Diagnosis date:

Urgent:  Yes  No

**Search type**

Run an A, B, DR donor search  Run a cord search  Run an A, B donor search

**Additional information**

Comments:

**Legal terms**

I declare that the patient has been informed about the transmission of their information to BMDW.

Add patient and run match

## Update patient

**Match results**

- A, B, DR Donors:** 608 donors at 10/10 search (at HLA-A, B, C, DRB1, DQB1), using haplotype frequencies algorithm.
- Cord:** 4,896 cards at n/10 search (at HLA-A, B, C, DRB1, DQB1) allele matched, two mismatches on any locus, using haplotype frequencies algorithm.

**HLA details**

\* Required fields

Patient ID \*  DNA Type Lookup tool

Class I		Class II	
HLA-A *	<input type="text" value="02:01"/> <input type="text" value="11:01"/>	HLA-DRB1 *	<input type="text" value="04:01"/> <input type="text" value="04:07"/>
HLA-B *	<input type="text" value="15:01"/> <input type="text" value="35:01"/>	HLA-DQB1	<input type="text" value="03:02"/> <input type="text" value="03:01"/>
HLA-C	<input type="text" value="03:CD"/> <input type="text" value="04:01"/>	HLA-DPB1	<input type="text"/> <input type="text"/>

Extra Class II loci

**Medical details**

CMV status:  Blood group:  Rh:

Ethnicity\*:  Weight:  kg

Birth date:  Gender:

Diagnosis:  Diagnosis date:

Urgent:  Yes  No

**Search type**

Run an A, B, DR donor search  Run a cord search  Run an A, B donor search

**Additional information**

Comments:

**Legal terms**

I declare that the patient has been informed about the transmission of their information to BMDW.

Update patient and re-run match
Request Search Advisory
Deactivate patient

## Patient list for Jorine Koenderman

Active patients (3)

Inactive patients (19)

View:  Just my patients  All patients from BMDW office

Search by patient ID

Click on a column heading to sort

Urgent	Patient ID	Date of birth	Ethnicity	Patient last updated	Results ⓘ	Last viewed ⓘ ⚙
	JK-test0011	2000-03-13	UK	2017-03-21 11:19:49	<b>A, B, DR Donors:</b> 0 Match run in progress... <b>Cords:</b> 0 Match run in progress...	2017-03-21 11:19:49
	JK-test0003_2		UK	2017-01-06 11:58:37	<b>A, B, DR Donors:</b> 0 donors at 10/10 search (at HLA-A, B, C, DRB1, DQB1), using haplotype frequencies algorithm. <b>Cords:</b> 333 cords at n/10 search (at HLA-A, B, C, DRB1, DQB1) allele matched, two mismatches on any locus, using haplotype frequencies algorithm.	2017-03-21 09:44:28
	Test0001	1906-05-05	CAEU	2017-01-06 12:08:55	<b>A, B, DR Donors:</b> 623 donors at 10/10 search (at HLA-A, B, C, DRB1, DQB1), using haplotype frequencies algorithm. <b>Cords:</b> 4,917 cords at n/10 search (at HLA-A, B, C, DRB1, DQB1) allele matched, two mismatches on any locus, using haplotype frequencies algorithm.	2017-02-09 12:24:35

- Allowing multiple users to run multiple patient searches

## Donor match results for patient Test0001

### Summary of results

- 623 donors at 10/10 search (at HLA-A, B, C, DRB1, DQB1), using haplotype frequencies algorithm.
- Showing first 250 results
- Search date: 2017-03-21 00:13:43

Print results

Print selected results

### Search settings

#### Match type and algorithm ⓘ

Matching algorithm:  Allele frequencies  Haplotype frequencies

Loci to consider:\* 10/10 search (at HLA-A, B, C, DRB1, DQB1) ▼

Run a mismatch search ⓘ

#### Filter

##### Filter by gender:

- No filter
- Male  Male or unknown
- Female  Female or unknown

##### Filter by CMV status:

- No filter
- Positive  Positive or unknown
- Negative  Negative or unknown

Maximum number of donors to be retrieved:\* 250 ▼

Get search results

### Patient details

- Gender: Female
- Blood group: A -
- Weight: 80kg
- Birth date: 1906-05-05
- Diagnosis: Hodgkin's Lymphoma [HL]
- Diagnosis date: 2016-11-01
- CMV status: N
- Ethnicity: Caucasian: Mainland Europe, Greenland, Iceland, Western Russia [CAEU]

Edit patient

Match results for **test0001**.

Mismatches are shown in brackets. (**Bold**) are antigen mismatches, (underlined) are allele mismatches and italics indicate uncertainty.

+	Probability of mismatches 0, 1, 2 ⓘ	A 02:01 11:01	B 15:01 35:01	C 03:CD 04:01	DRB1 04:01 04:07	DQB1 03:02 03:01	DPB1 04:AB	DRB3/4/5	Registry ▼ Reg Abbr	Age M/F	Blood Gr ▼ CMV status	TNC (10 <sup>7</sup> ) ▼ CD34+ (10 <sup>6</sup> ) ▼	Select ⓘ
10/10 (potential) allele matches													
1	<b>P P P A P</b> 53% , 38% , 9%	02:XX 11:XX 99%	15:AEECY 35:XX 99%	03:XX 04:XX 58%	04:01 04:07:01G 100%				7748 AU-ABMDR	2 Female	O +	283 6.2	★
Cord details:		Cord ID: 390145432 Volume: 215ml			Status: MN:		Ethnicity: Viability:		CCR5: No. of attached segments:				
2	<b>A A P A P</b> 70% , 28% , 2%	02:01:01G 11:01	15:01:01G 35:01:01G	04:01:01G 03:04	04:07:01G 04:01		4*01:FVUU	3553 US-NMDP	6 Male	O +	208 16	☆	
3	<b>P P P P P</b> 1% , 1% , 2%	2 11	62 35		4			8405 KR-KONOS				176.2	☆
4	<b>P P P A P</b> 74% , 25% , 1%	02:XX 11:XX	15:DPUU 35:XX	03:DPVD 04:XX	04:01 04:07			7748 AU-ABMDR	8 Female			148 4.5	☆
5	<b>A A P A P</b> 70% , 28% , 2%	02:01:01G 11:01	15:01:01G 35:01:01G	04:01:01G 03:04	04:07 04:01			3553 US-NMDP	7 Male	A +	136 6.4	☆	
6	<b>P P P P P</b> 1% , 1% , 2%	2 11	35 62		4			8405 KR-KONOS				126.6	☆
6	<b>A A P A A</b> 79% , 21% , 0%	02:01 11:01	15:01 35:01	03:04 04:01	04:01 04:07	03:01:01 03:02:01	04:01:01 <b>P</b>		6939 DE-ZKRD	19 Male	O + N (2017-03-24) }		☆

## Donor search results   Cord blood unit search results

Better reporting capability by providing

- Probability matching based on new haplotype frequency sets
- Greater flexibility for filtering and sorting donor and cord results
- Additional fields, DPB1 TCE3 grading, accreditation status



# Haplotype frequency sets

Previously, OptiMatch used 1 global haplotype frequency set

- Not accurate for some populations
- Ethnicity information available for only small number of donors.

Haplotype frequency sets based upon geographical and available data of the donors of an organisation.

- Most sets based on geographical data
- Some subsets, like USA-AS



# Optional grouping/sorting

- **Standard:** search results are grouped/sorted by number of matching values on allele level and within the groups sorted by probability.

Problem: Users cannot see potentially 9/10 mismatched donors because of many potentially 10/10 matched donors with low probability

## Grouping/Sorting

- Standard (grouping by number of matches/sorted by probability)
- Sort by sum of probabilities - include 0 and 1 mismatches

- **Optional:** sorted by sum of probabilities, including 0 and 1 (1 mismatch selected), or 0,1 and 2 mismatches (2 mismatches selected)

# Optional grouping/sorting: Example

*haplotype frequencies, n/10, single A-mismatch, standard grouping/sorting*

*Results: 22,149 9/10 donors (pot 10/10 donors (12,135) on top)*

+	Probability of mismatches 0, 1, 2 ⓘ	A 01:01:01:01 02:01:01:01	B 08:01:01 44:02:01:01	C 07:01:01:01 16:01:01:01	DRB1 03:01:01 04:01:01	DQB1 02:01:01 03:01:01:01	DPB1 ▾	DRB3/4/5	Registry ▾ Reg Abbr	Age ▾ M/F	Blood Gr ▾ CMV status	Select ⓘ
10/10 (potential) allele matches												
+	<b>P P P A A</b> 1% , 99% , 1%	02:ACBKU 01:ACBKA	44:ABRMC 08:AAWXH	07:AAHFW 16:ZHNV	04:01 03:01	02:01:01G 03:01:01G	04:01:01G	3*01:01 4*01:01:01G	3553 US-NMDP	39 Female	A +	☆
+	<b>P P P P P</b> 1% , 99% , 1%	02:UXUA 01:UXSE	44:TKUB 08:TKPJ	07:NFCT 16:KMYE	04:UZPN 03:UXPE	02:SY 03:VVCC		3*01:UBX 4*01:FVUU	3553 US-NMDP	45 Male		☆

*haplotype frequencies, n/10, single A-mismatch, sorted by sum of probabilities - include 0 and 1 mismatches*

+	Probability of mismatches 0, 1, 2 ⓘ	A 01:01:01:01 02:01:01:01	B 08:01:01 44:02:01:01	C 07:01:01:01 16:01:01:01	DRB1 03:01:01 04:01:01	DQB1 02:01:01 03:01:01:01	DPB1 ▾	DRB3/4/5	Registry ▾ Reg Abbr	Age ▾ M/F	Blood Gr ▾ CMV status	Select ⓘ
+9/10 (potential) allele matches												
+	<b>M A A A A</b> 0% , 100% , 0%	<b>(68:01)</b> 01:01	44:02 08:01	07:01 16:01	04:01 03:01	02:01 03:ASXKF	04:ASXKD 06:01	3*01:01 4*01:01:01G	3553 US-NMDP	19 Female	A +	☆
+	<b>M A A A A</b> 0% , 100% , 0%	<b>(68:01:02G)</b> 01:01:01G	44:02:01G 08:01:01G	07:01:01G 16:01:01G	04:01 03:01	02:01 03:01	06:01 17:01		3553 US-NMDP	22 Male	A +	☆

# DPB1 TCE3 grading model

- Various studies have shown a potential beneficial effect if the HLA-DPB1 classification based on T-Cell Epitopes (TCE) is considered in donor selection.
- Among the 9/10 and 10/10 donor candidates, those with a permissive DPB1 constellation are preferred over those showing a non-permissive DPB1 constellation.
- DPB1 TCE3 grading in OptiMatch is based on the new score based algorithm that was realized with 3 TCE groups.

*Zino E et al. Blood (2004) 103:1417-24. June 2, 2016 56.*

*Zino E et al. Biol Blood Marrow Transplant (2007) 13:1031-40.*

*Crivello P et al. Biol Blood Marrow Transplant (2015) 21:233-41.*

# DPB1 TCE3 grading model

DPB1 TCE3 evaluation is performed and displayed for A, B, DR typed donors under the following conditions:

- Patient and donor DPB1 values must be present. Ambiguities (multiple alleles codes, G- codes) allowed
- Only available for 10/10 and 9/10 donor searches.

- P Permissive
- G Non-permissive in GvH direction
- H Non-permissive in HvG direction
- A Ambiguous

Match results for Test0001\_TCE3.

	Probability of mismatches 0, 1, 2 ⓘ	A 02:01 25:01	B 18:01 27:02	C 02:02 12:03	DRB1 04:04 16:01	DQB1 03:02 05:02	DPB1 03:EMS	DRB3/4/5	Registry Reg Abbr	Age M/F	Blood Gr CMV status
<b>10/10 (potential) allele matches</b>											
1	<span style="color: green;">A A A A A</span> 100% , 0% , 0%	02:01 25:01	18:01 27:02:01					4*01:03 5*02:02	7414 PL-DKMS	28 Male	O + N (2017-06-09) }
2	<span style="color: green;">A A A A A</span> 100% , 0% , 0%	02:01 25:01	18:01 27:02					4*01:03 5*02:02	7414 PL-DKMS	43 Female	B + G (2017-07-31) }
3	<span style="color: green;">A A A A A</span> 100% , 0% , 0%	02:01 25:01	18:01 27:02					4*01:03 5*02:02	7414 PL-DKMS	53 Female	A - G (2017-07-28) }
4	<span style="color: green;">A A P A A</span> 99% , 1% , 0%	02:DFKP 25:AH	18:RRG 27:02					4*01:XX 5*02:XX	7414 PL-DKMS	40 Male	
5	<span style="color: blue;">P P P A P</span> 38% , 50% , 11%	25:XX 02:XX	27:XX 18:XX					4*01:FVUU 5*01:ZCSF	3553 US-NMDP	52 Male	

**TCE3 match grade - Ambiguous**

Permissive: 87%

Non-permissive in HvG: 0%

Non-permissive in GvH: 13%

# Upcoming enhancements

- Show accreditation status CB banks
- More information in donor and CBU reports

-> Dependent on the current XML transition project

**GOAL:** Receive more data from organisations to accelerate donor or CBU selection procedures that might save more patients

## Benefits:

- Secure and user-friendly web-based data submission
- More robust and sophisticated validation to ensure data quality
- Enhanced processing reports

# Pillar 2: Supporting Global Development



WMDA supports its members to **develop and grow**, so that more transplant patients find the most suitable match.



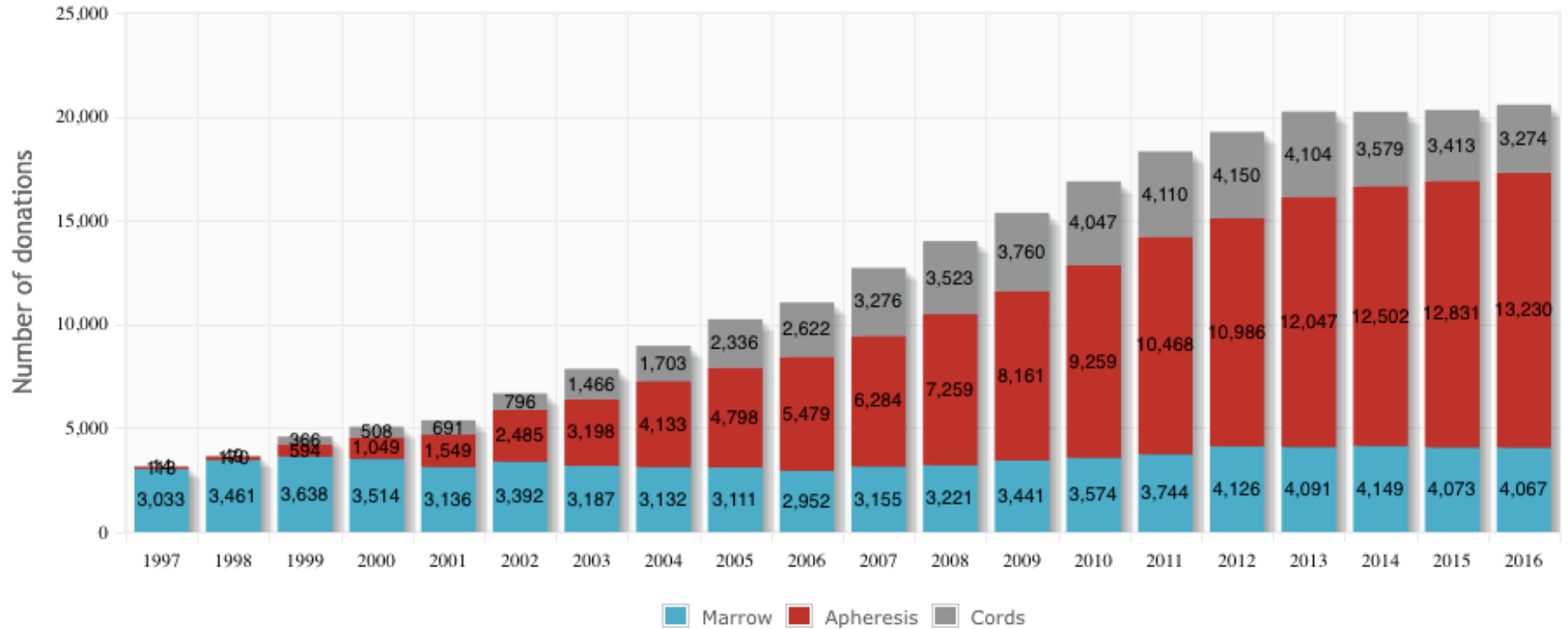
The **number and availability of stem cell donors increases** in areas where patient need is growing: through data collection, sharing global trends and tailored support in growth areas.



WMDA becomes a '**one-stop shop**' for support & advice through expanded & improved online training.

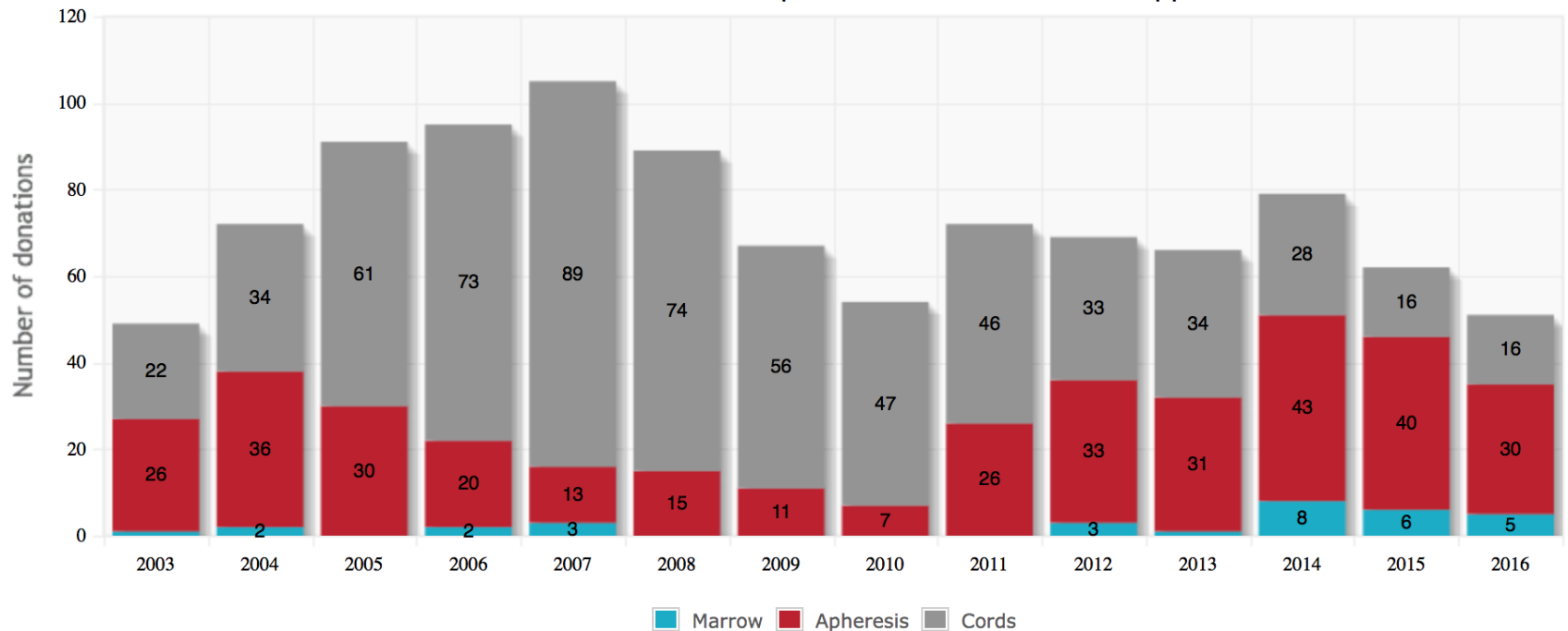
# Worldwide

## Unrelated HPC Marrow, HPC Apheresis and HPC Cords shipped



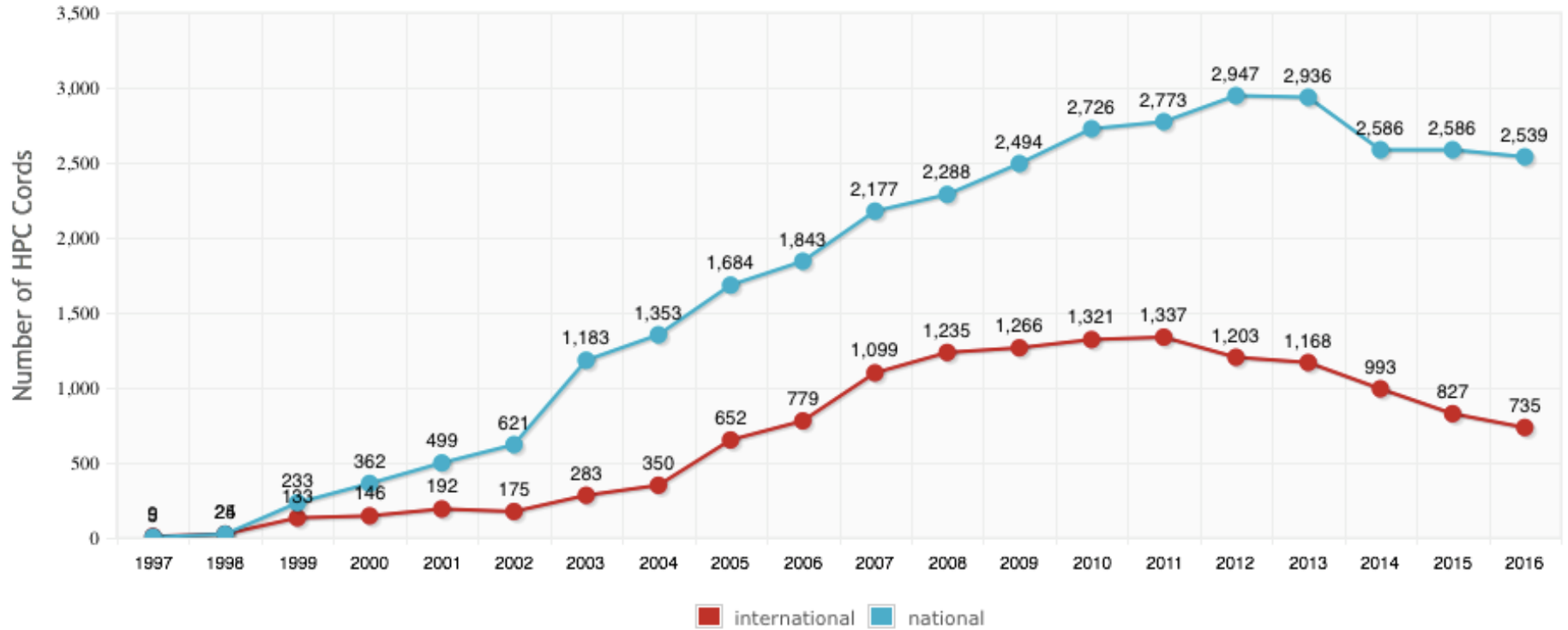
# Belgium

Unrelated HPC Marrow, HPC Apheresis and HPC Cords shipped

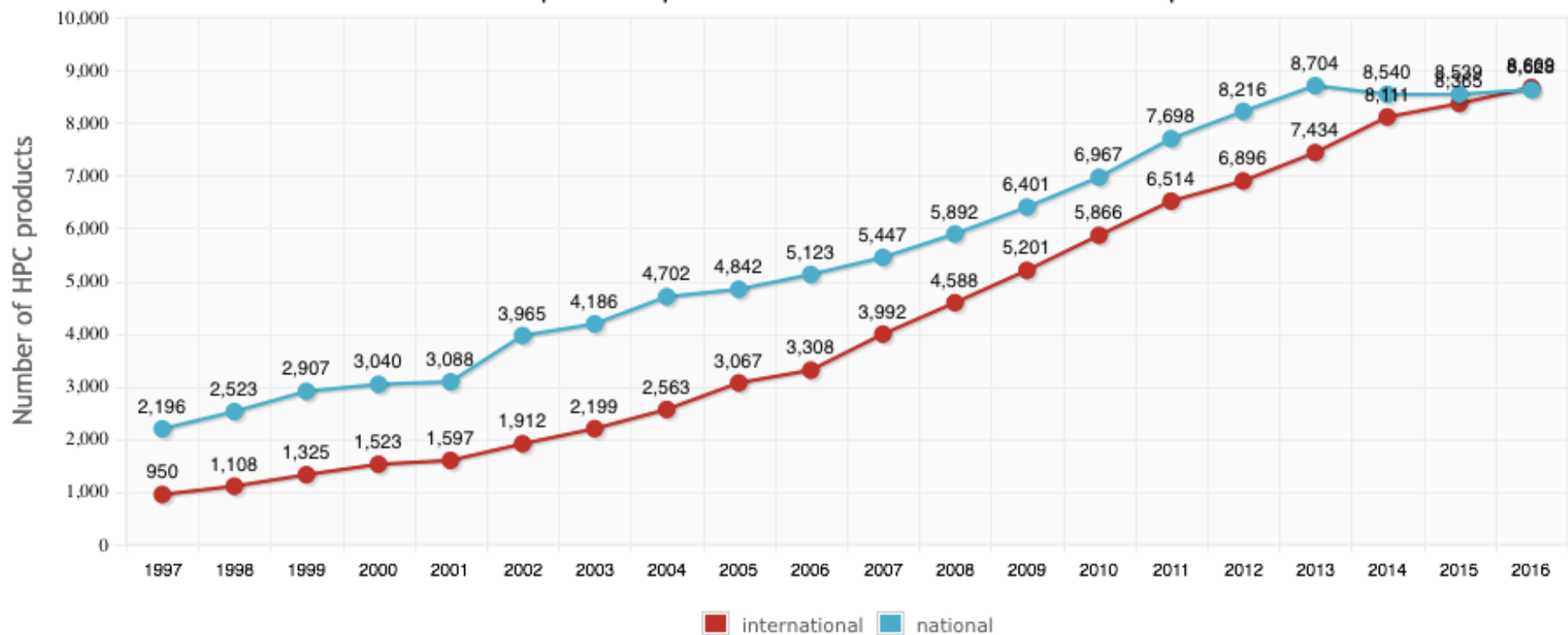




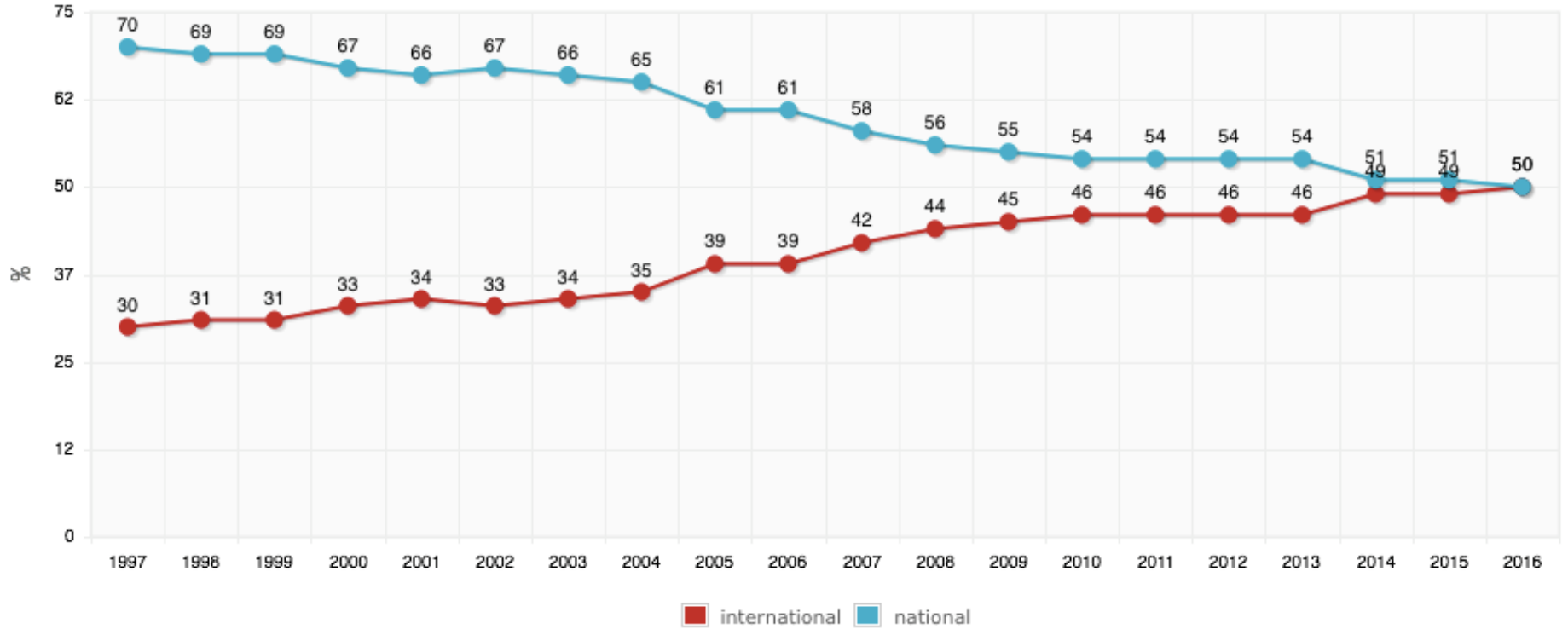
### Number of HPC Cords provided for national and international patients



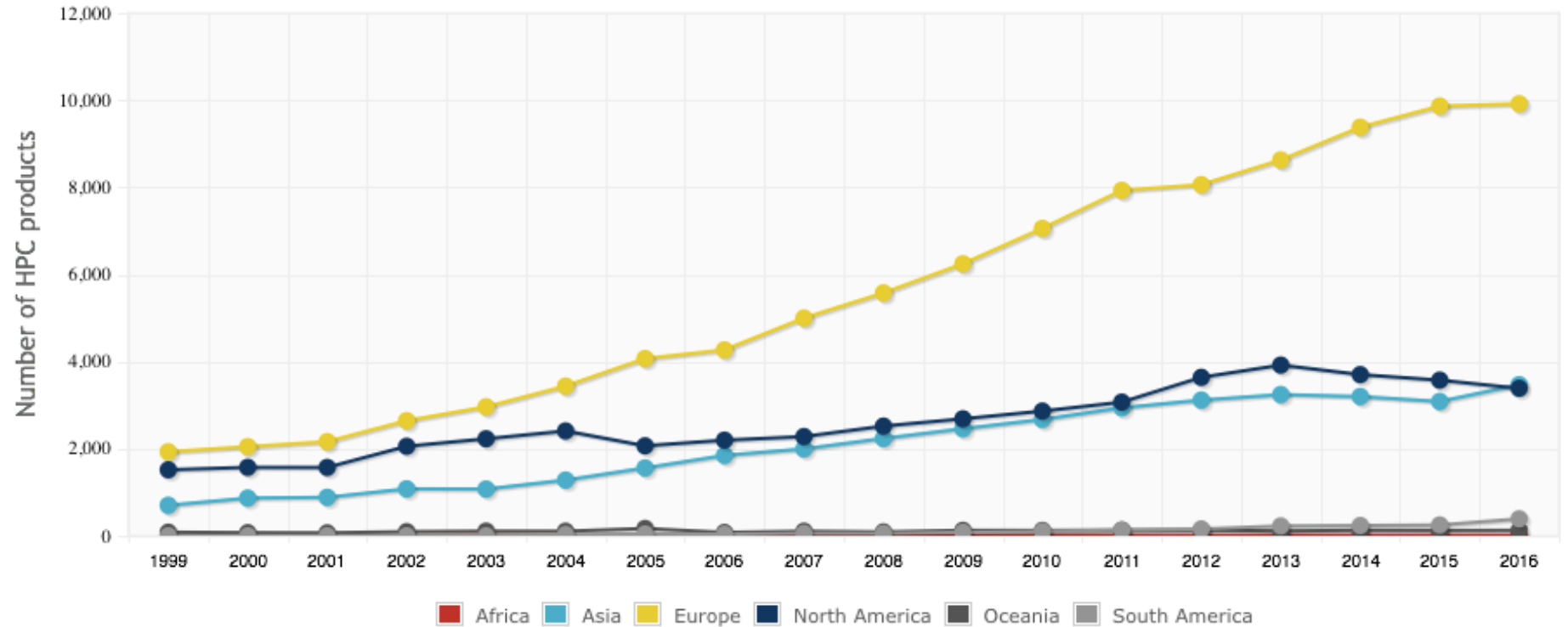
### Number of HPC products provided for national and international patients



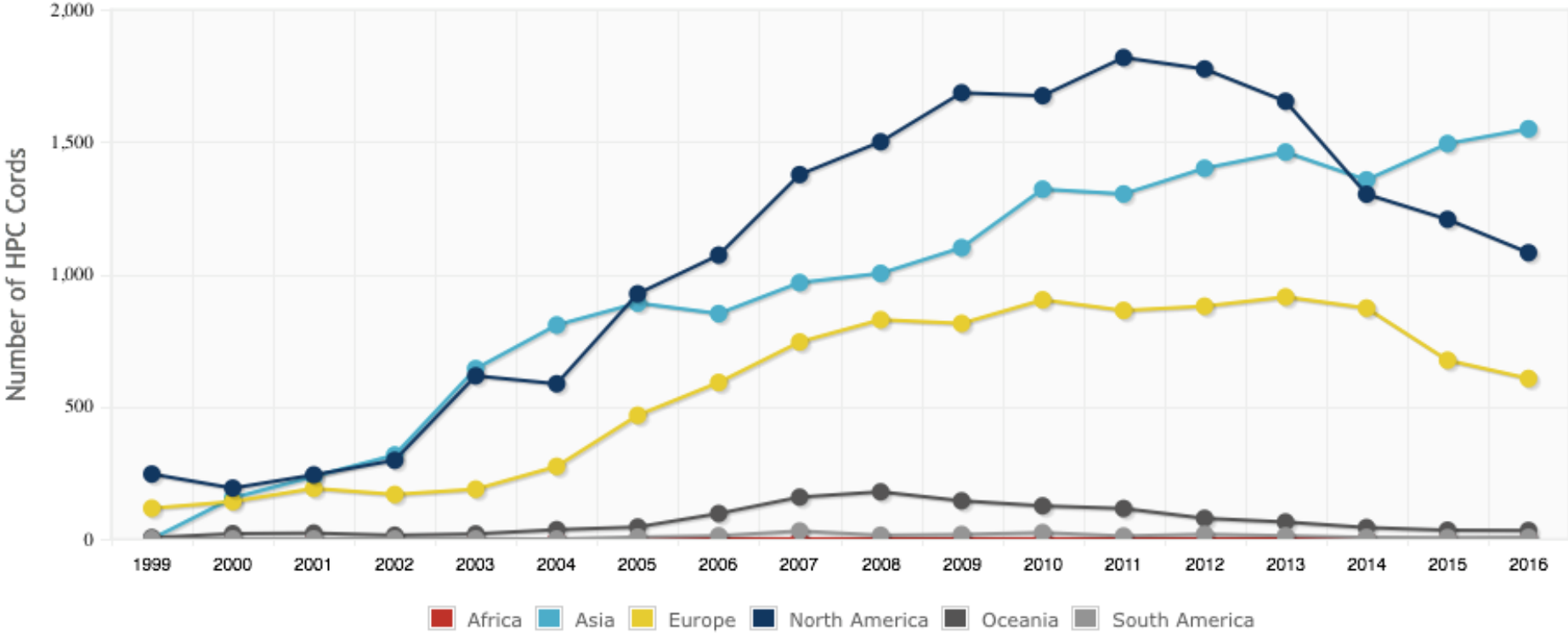
% of HPC products provided for national and international patients



Number of HPC products provided by the continents



Number of HPC Cords provided by the continents



HPC Apheresis			HPC Marrow		
	Provided Shipping %	rate %		Provided Shipping %	rate %
ZKRD Germany	42.23	0.08	ZKRD Germany	30.24	0.02
NMDP USA	17.58	0.03	JMDP Japan	27.34	0.24
DKMS Poland	6.85	0.10	NMDP USA	20.31	0.01
CMDP China	6.11	0.03	REDOME Brazil	5.26	0.01
Anthony Nolan UK	2.77	0.06	DKMS Poland	4.92	0.02

<b>HPC Cord</b>		
<b>Registry</b>	<b>Provided %</b>	<b>Shipping rate %</b>
JMDP Japan	42.03	12.41
NMDP USA	27.18	0.47
REDMO Spain	6.29	0.32
France Registry	4.73	0.44
NYBC USA	4.70	0.25

# Pillar 3: Promoting Donor Care



Ensure rights and safety of donors are **promoted and protected**.



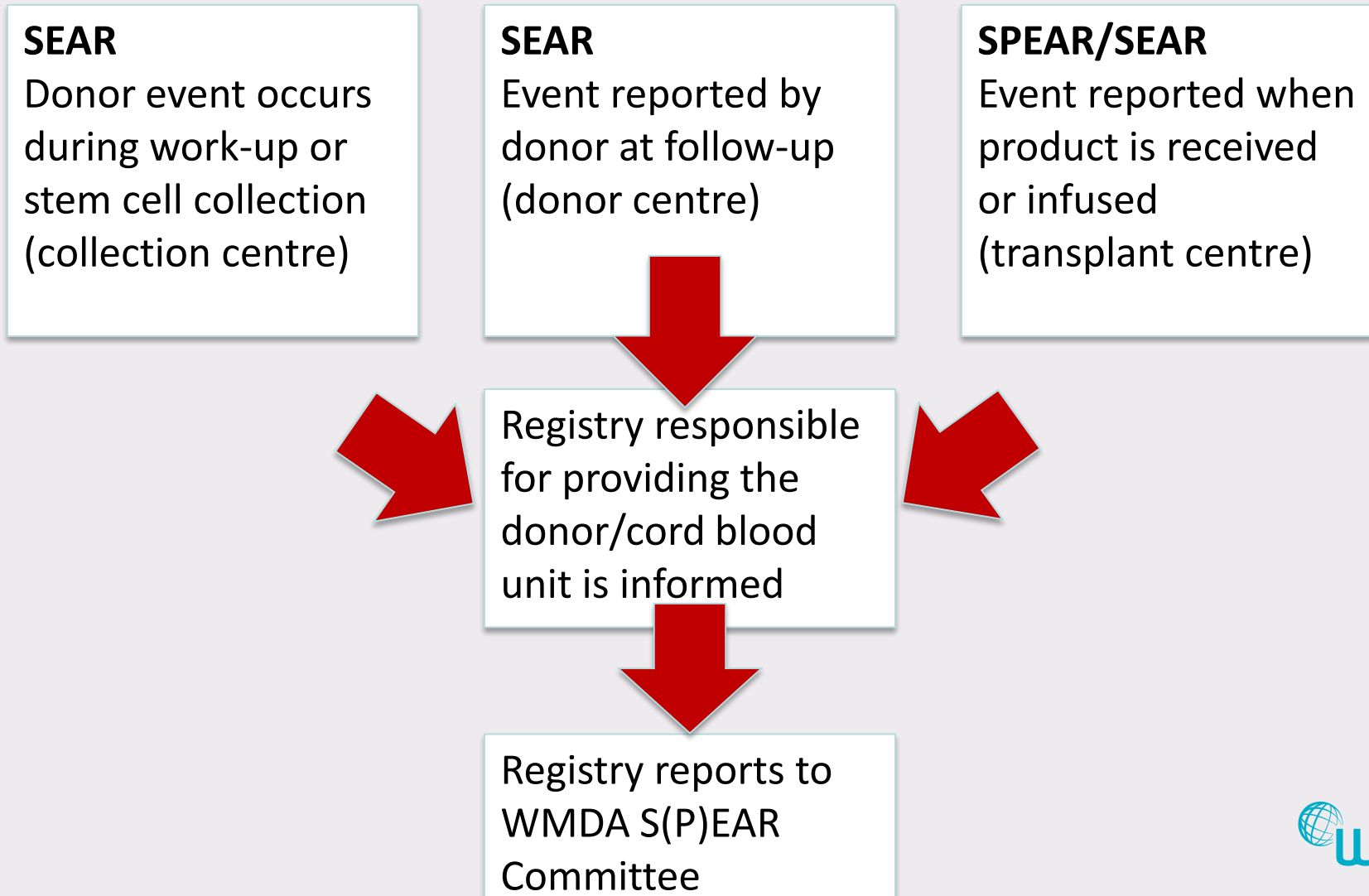
Inform donor care standards & practices through new and improved online **SEAR/SPEAR reporting system** for related & unrelated donors.



Introduce **professional training programme** for those working with donors.



# Serious Adverse Events and Reactions Reporting



# Investigating SAEs

## Root Cause Analysis (RCA):

1. Gathering Data: to include full details of what happened, as well as relevant policies and procedures
2. Mapping the Information – timelines, flowcharts
3. Identification of the problem(s) that contributed to the occurrence – review meeting with all personnel involved
4. Analysis of the contributing factors - with prioritization
5. Identification and agreement in the root causes
6. Reporting



It is easy to conclude that mistakes are caused by “human error’ but this error often has an underlying cause that must be identified.

# Investigating SAEs: “Five Whys”

Question	Answer
Why was the wrong virology report recorded?	It was a human error – the technician saw the reactive result but ticked the ‘non-reactive’ box on the results form.
Why did the technician make a mistake like this?	He was not used to manually recording results and was carrying out a number of tests simultaneously.
Why was he manually recording results if he was not used to doing that?	Automated testing system is used during normal busy day but not at night when the number of tests required is too low to justify the cost.
Why was he not familiar with the night time procedure?	It was his first time working alone at nights and he has not used the manual procedure for a number of years.
Why was he carrying out a procedure for which his competence had not been checked?	The person who normally worked at nights was ill.
<b>ROOT CAUSE</b>	<b>The technician was carrying out a task for which he had not been adequately trained and supervised.</b>

# Communication is important – three examples

## Example 1

### What happened?

PBSC collection was performed on **2015-10-29**, even though that collection was cancelled **2015-10-19**. The cancellation was sent on 2015-10-19, 14:47 to a wrong email address, which is a common address, where a lot of SPAM mails were received during the weekend.

The right email address for workup is [workup@orgx.org](mailto:workup@orgx.org), which was used for the correspondence during the whole workup. So the WU coordinator did not receive the cancellation request and the TC didn't get a confirmation of receipt.

# Communication is important – three examples

## Example 2

### What happened?

The DLI collection for one of our patients scheduled for **Monday December 12th** has been cancelled by the clinician on **Friday December 9th** in the afternoon.

The clinician informed the coordinator only by mail. As the coordinator was absent on Friday afternoon, the mail was unread up till **Monday December 12<sup>th</sup>** morning and the collection centre was informed of the cancellation at the same time.

DLI Collection started, product was not used.

# Communication can be important

The PBSC product was stolen during the transport in the train by "train thieves" in an European country. The courier noticed quickly the graft was missing. The police was warned and announcements were made on radio and on TV. Finally, the container with the graft was found in another train in another city. The container was unbroken and his external aspect was good. The inside temperature monitoring showed that the container had not been opened until it had been checked-out by the courier. The TC decided to proceed with quality controls and these results were good (viability 7AAD 96.73%) then they decided to infuse the graft.

# Pillar 4: Ensuring Quality



Promote **product quality and global collaboration** through accreditation and standardisation.



All organisations listing donors/cord blood units are making demonstrable progress towards accreditation through a **tailored support package and peer support**.



WMDA & FACT accreditation are seen as the **global Gold Standard** through awareness raising amongst members; clinicians and authorities.

# Why WMDA Accreditation?



To Overcome One Barrier to International Exchange



Trust to our customers:

- Donors
- Patients
- Transplant centres



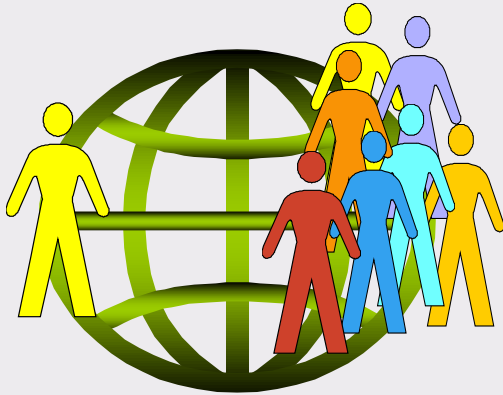
# Why WMDA Accreditation?

	Probability of mismatches 0, 1, 2 ⓘ	A 02:01 11:01	B 15:01 35:01	C 03:CD 04:01	DRB1 04:01 04:07	DQB1 03:02 03:01	DPB1	DRB3/4/5	Registry Reg Abbr	Age Gender	Blood group CMV status	Select ⓘ
10/10 (potential) allele matches												
+	A A P A A	02:01:01G 11:01:01G 100%	15:01:01G 35:01:01G 100%	03:04:01G 04:01:01G 79%	04:01:01 04:07:01G 100%	03:01:01G 03:02:01G 100%	02:01:02G 13:01:01G	4*01:01:01G	5103 CA-One Match	18 Male		★
Donor details:		Donor ID: CAR1001444869						Ethnicity:		CCR5:		
+	A P P A P	02:ZAKP 11:ZAKW	15:TFGP 35:XSTR	03:ZAMJ 04:YGKF	04:01:01 04:HTWY			6354 GB-Anthony	18 Female			☆
+	A A P A A	02:01:01G 11:01:01G 79% , 21% , 0%	15:01:01G 35:01:01G	03:04:01G 04:01:01G	04:01:01 04:07:01G	03:01:01 03:02:01	03:FYKD 04:ADCGE	6939 DE-ZKRD	19 Female	A +		☆
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+	A A P A A	02:01 11:01 79% , 21% , 0%	15:01 35:01	03:04 04:01	04:01:01 04:07	03:01:01 03:02:01	04:01:01	6939 DE-ZKRD	19 Female	O + N (2016-11-16)		☆

Visible in Search & Match Service



# Why WMDA Accreditation?



Friends are the best advisors.

A method to cross-check that your organisation complies with EU Regulation

## **EUROPEAN DIRECTIVE 2004/23/EC; article 9**

### Import/export of human tissues and cells

Member States and tissue establishments that receive such imports from third countries shall ensure that they meet standards of quality and safety.

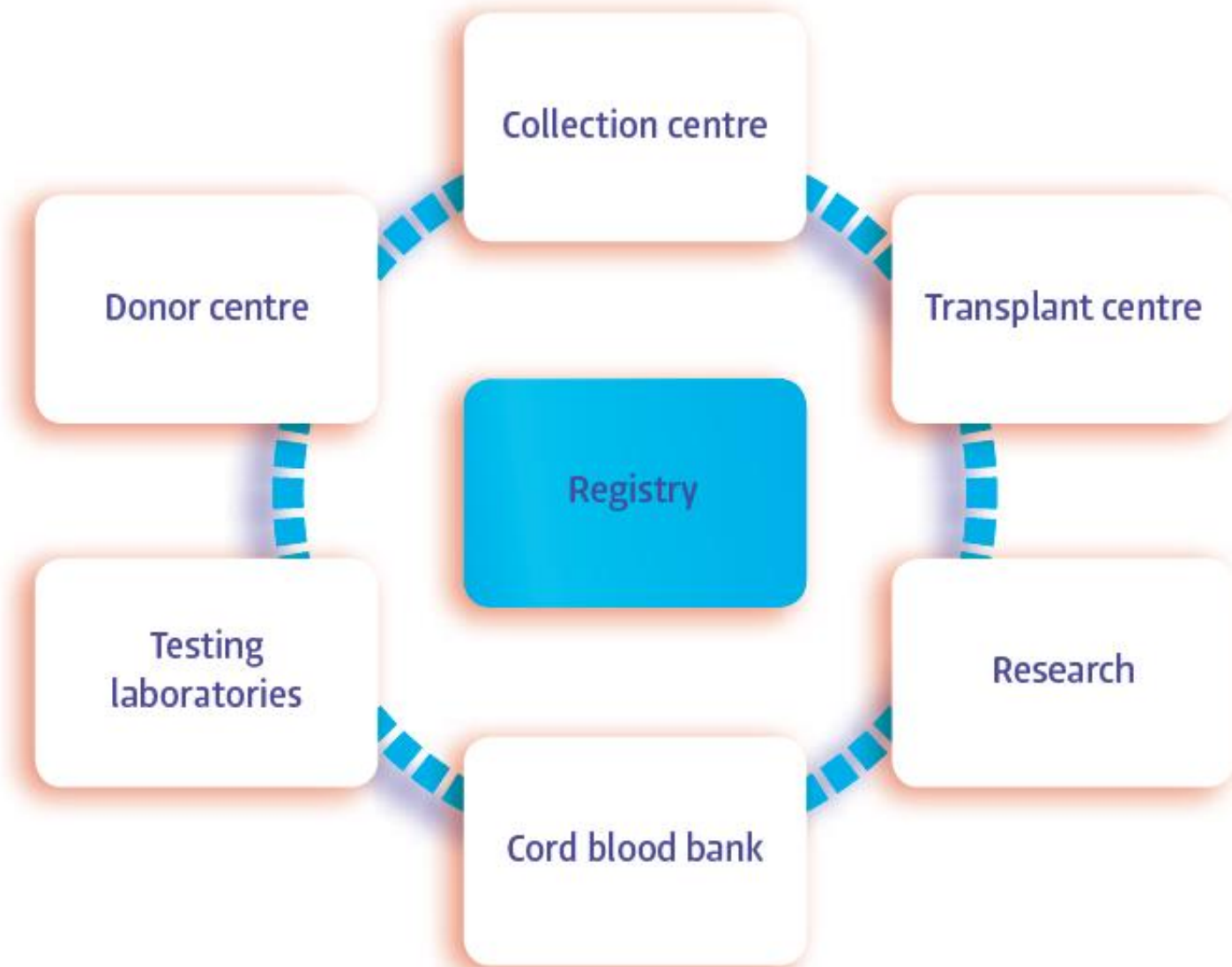
# How to prepare your organisation?

## Scope of the WMDA Standards

1. General
2. General organisation of the registry
3. Donor recruitment, consenting, screening and testing
4. Cord blood and maternal donor recruitment, consenting, screening, testing and review/release of cord blood units
5. Information technology and information management
6. Facilitation of search requests
7. Second / subsequent donations
8. Collection / processing / transport stem cells
9. Follow-up of patient / donor
10. Financial / legal liabilities

# Chapter 1: General

- Organisational structure
- Participation WMDA Annual Questionnaire
- Transplant centres requesting a donor only ask donations for a patient for whom transplantation is a medically accepted procedure
- Donor centres, cord blood banks and collection centres ensure that they comply with WMDA standards
- Keep up to date with WMDA recommendations and WMDA Standards



## Chapter 2: General organisation of a registry

- Registry is legal entity
- Expert & trained staff
- Physical location
- Communication links
- Written standard operating policies and procedures

# Train search coordinators – WMDA SCCP

Online Search Coordinator Certificate Programme (9 modules) for laboratory technicians, search coordinators, nurses, physicians or people with interest in unrelated donor search:

1. Cells and Hematopoietic System
2. Basic concepts in Immunology
3. Medical Basics of Hematopoietic Stem Cell Transplantation
4. Basic Genetics of HLA
5. Human Leukocyte Antigens (HLA)
6. HLA Matching
7. Registries and Cord Blood Banks
8. Search Strategy
9. The Donor Experience



<https://education.wmda.info/>



## Chapter 3: Donor recruitment, consenting, screening and testing

- Volunteer, not paid for donation
- Donation is anonymous
- Risks of donation discussed
- Donor written consent
- Health screening of donor
- Age limits





# Chapter 4: Cord Blood



# Chapter 5: Information Technology and Information Management

IT system in a registry:  
how to store records,  
database management,  
security,  
network,  
back-up,  
search algorithms



# Environmental Climate Change

- ↑ Monetization of medical records
- ↑ Attack methods (ransomware), sophistication
- ↑ Disruptive technologies (social, mobile, analytics, cloud)
- ↑ Accountability and regulatory changes (Global Data Privacy Regulation)
- ↑ Health sector breaches
- ↑ Business impact and consequences (breach costs, sanctions)



WMDA registries must be united in our response to be effective at cyber risk management - for the benefit our own registry and for the global community at large.

# Recent Non-Profit Example

## Red Cross Blood Service admits to personal data breach affecting half a million donors

Updated 28 Oct 2016, 1:41am

The personal data of 550,000 blood donors that includes information about "at-risk sexual behaviour" has been leaked from the Red Cross Blood Service in what has been described as Australia's largest security breach.

The organisation said it was told on Wednesday that a file containing donor information was placed on an "insecure computer environment" and "accessed by an unauthorised person".

The file contained the information of blood donors from between 2010 and 2016.

The data came from an online application form and included "personal details" and identifying information including names, gender, addresses and dates of birth, a Red Cross statement said.

Red Cross Blood Service chief executive Shelly Park said "due to human error" the unsecured data had been posted on a website by a contractor who maintains and develops the Red Cross website.



PHOTO: The file contained the information of blood donors from between 2010 and 2016. (ABC Adelaide: Brett Williamson)

MAP: Melbourne 3000

### Key points:

- Data from blood donor registration form posted insecurely online
- Leak included identifying information and "personal details" of 550,000 donors
- All copies of the data believed to be destroyed

Size: 1.3M medical records / 550k volunteer blood donors. 2<sup>nd</sup> largest healthcare breach in 2016.

System: Donor's online registration application

Root Cause: Negligent exposure of backup database by IT contract developer; basic hack

Control: Easily detectable weakness through ongoing vulnerability scanning

Impact: Estimated direct breach expenses at \$5.8M USD (652M €), plus donor trust

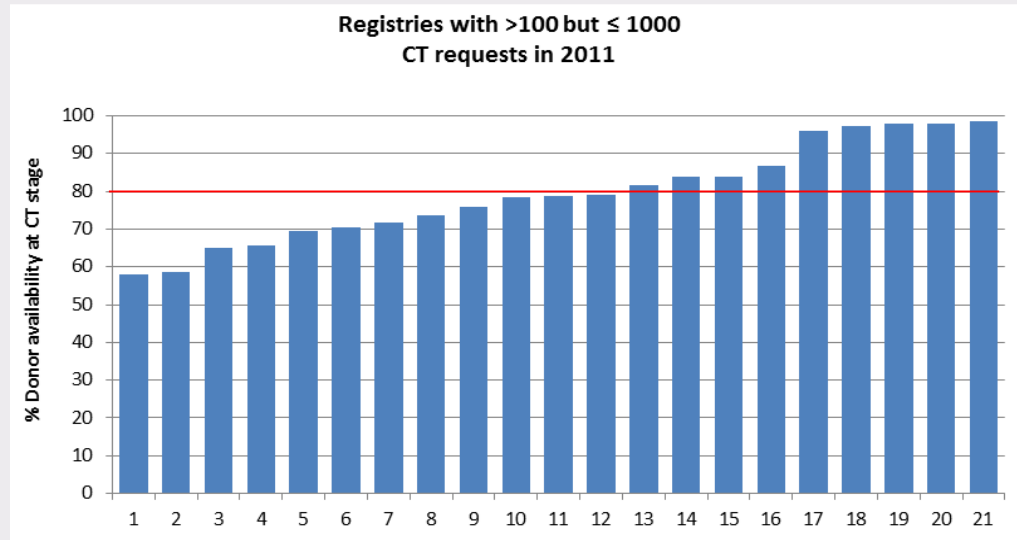
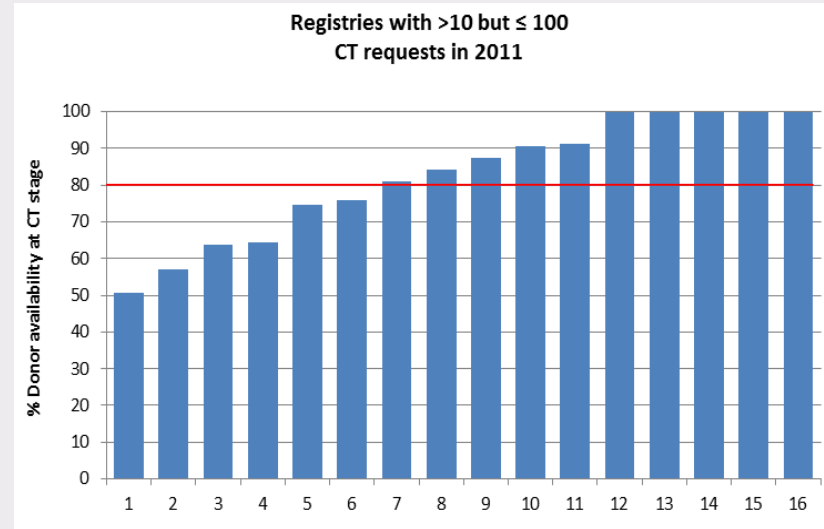
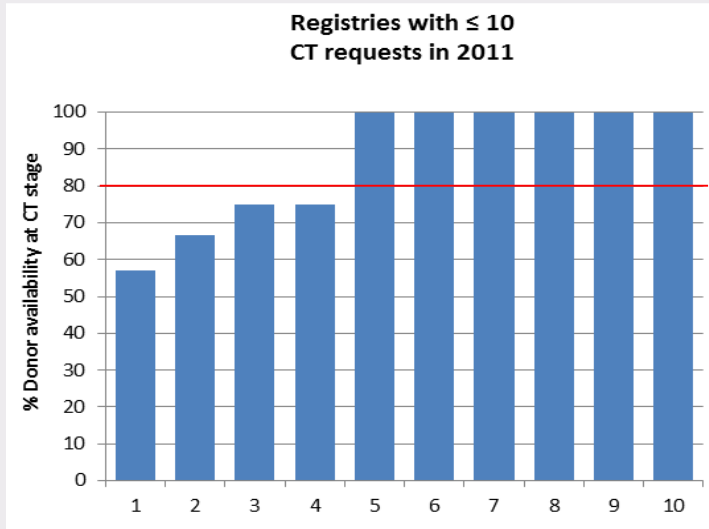


## Chapter 6: Facilitation of search requests

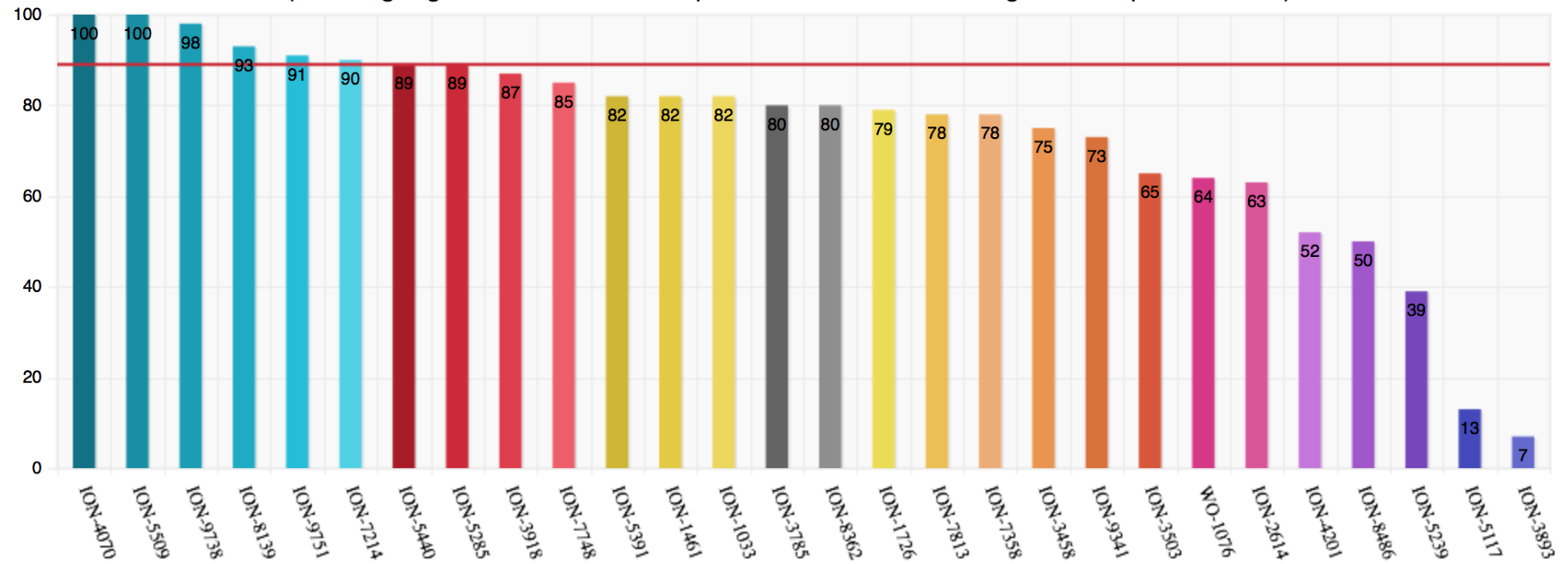
- Critical communication in writing
- Timelines to respond
- Communicating donor's preference
- Donor and patient identity remains confidential

# KPI #3: % donor availability at CT (verification) stage

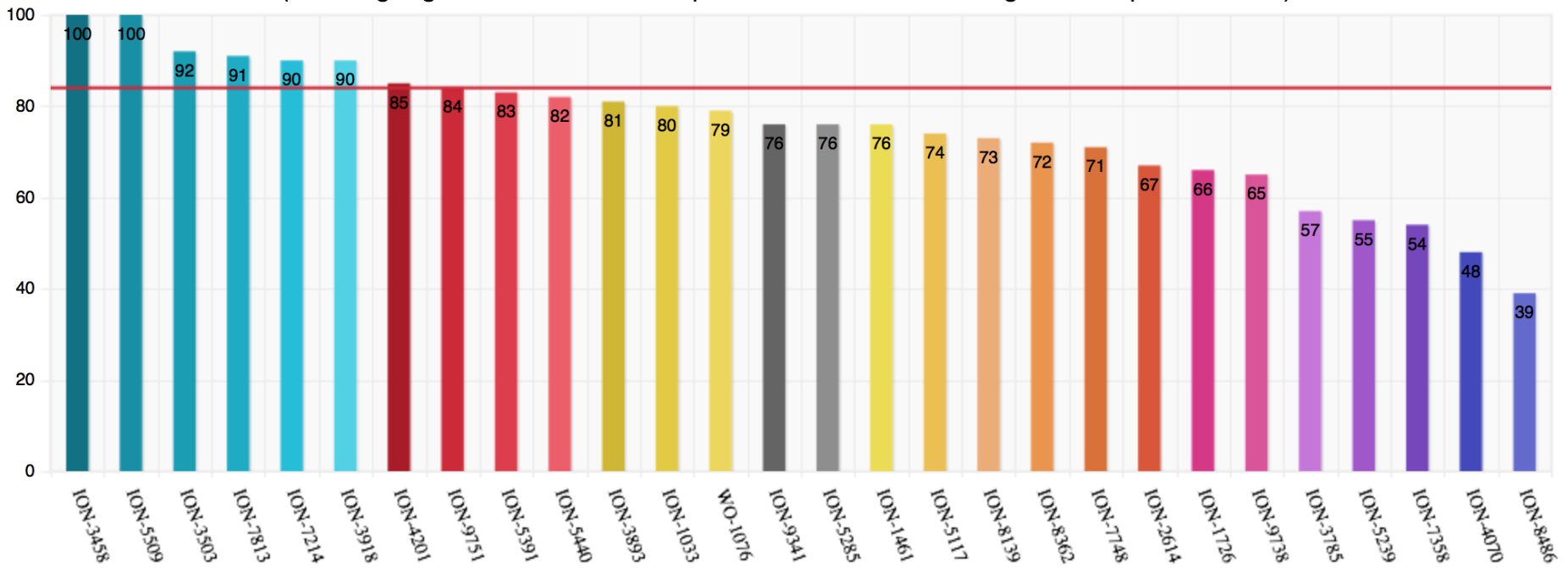
The proposed target value for this KPI is **80%** (or higher).



KPI 2: % of blood samples shipped for CT  $\leq$  14 days based on effectively shipped samples only  
 (Showing organisations with CT requests  $100 < N \leq 1,000$ ; target is 3rd quartile - 89%)



KPI 3: % donor availability at CT stage  
 (Showing organisations with CT requests 100 < N ≤ 1,000; target is 3rd quartile - 84%)





## Chapter 7: Subsequent donations

- Be sure that you know if the donor is willing to donate a second time for the same patient

## Chapter 8: Collection, transport

- Collection center must meet national guidelines
- Policies & procedures to ensure quality & quantity of product
- Labeling of collected product
- Guidelines for safe transport of cells



# Entities involved in international search and work-up of an unrelated donor



## Example of an adverse event (SPEAR)

- Registry in **Country A** request confirmation typing from Registry in **Country B**
- Registry in **Country B** sends report on 10/10 matched female donor to Registry in **Country A** (donor-ID: A-xxxx)
- Transplant centre in **Country A** sends work-up request to Donor Centre in **Country B** (number correct but truncated, instead of A-xxxx the number used was: xxxx)
- Donor Centre in **Country B** performs clearance and send cells on donor B-xxxx, which is a complete mismatch with the patient and a male donor

See for more info:

<http://www.nature.com/bmt/journal/vaop/ncurrent/full/bmt201659a.html>

## Example on adverse event (SPEAR) - continued

- Patient transplanted (engrafted, no GVHD)
- Error discovered when a request was sent to the transplant centre to find out if they still want the correct donor (A-xxxx) to be reserved
- Patient: 100% donor chimerism at 1 month post transplant
- Since then the patient has been re-transplanted with correct cells

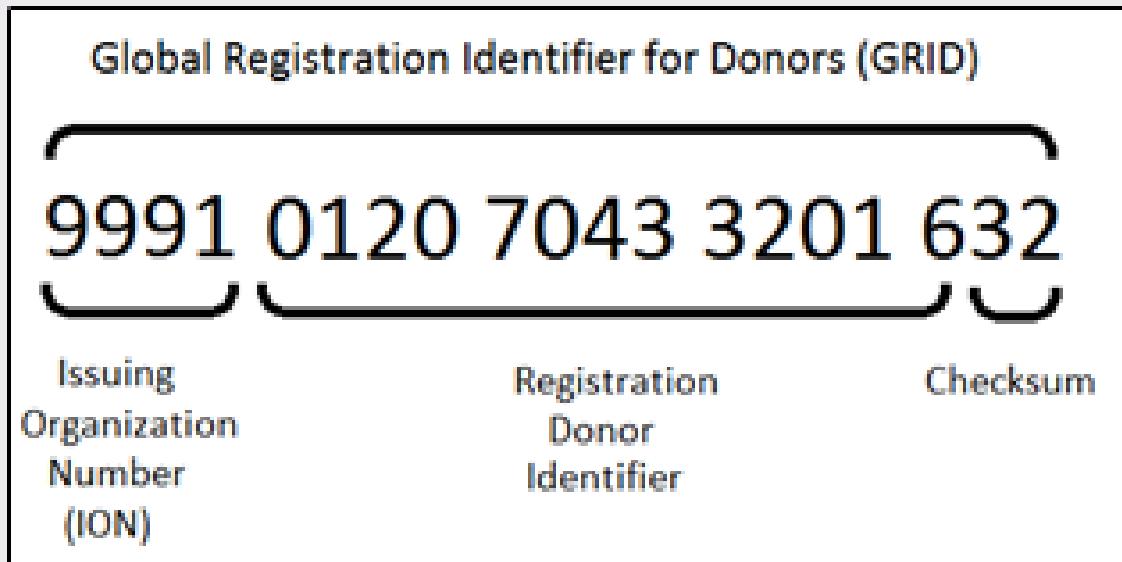
## Lessons learnt

- Multiple donor identifiers must be checked early in the workup process
- WMDA recommends that workup communication takes place between registries
- WMDA recommends that all donor centers and registries examine their numbering systems to ensure that numbers can not be duplicated
- A system to uniquely identify potential donors on a global scale is needed to facilitate communication and prevent errors in identification of donors.

# Introducing GRID: a new and better way to identify potential donors and listed cord blood units

- The GRID provides a standard format to be used by donor registries, donor centers and cord blood banks that issue donor identifiers, hereafter referred to as “issuing organizations” (IO).
- The GRID assures that every donor and listed cord blood unit is assigned a globally unique identifier; thus reducing the risk of misidentification.
- Pursuant to upcoming revised WMDA Standards, IOs must plan and prepare for full implementation in accordance with established phases and timelines.

**Moving to GRID:** GRID will be used as the key donor identifier on search reports and is integrated in forms for donor request and outcome reporting. GRID is used on label of products from adult donors when a donor identifier is required



<https://share.wmda.info/display/GRID/GRID%3A+moving+to+unique+donor+identifier>



## Chapter 9: Follow-up

- Short term follow up
- Long term follow up
- Reporting Serious Events

# Chapter 10: Finance

- How to organize the finance administration
- Billing
- Payment
- Legal liability
- Donor expenses



**Fast Facts: Donors make a WORLD of difference!**

Different countries. Different languages. Different traditions. But we share a common humanity — and a commitment to help one another. Your compassion helps unite the world.

- ▶ 30 million individuals have registered worldwide.
- ▶ 20,500 transplants took place worldwide in 2016
- ▶ 50% of all transplants are international

**> A Selfless Donor Saved My Son!**  
 Thank YOU for being part of the global movement to provide life and hope for patients everywhere.



# Highlights - events



# WMDD 2017 After Movie



# World Marrow Donor Day 2017



JOIN AGAIN  
NEXT YEAR

SEPT  
15<sup>TH</sup>  
2018

# WMDA office team



Serving blood stem cell organisations worldwide