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WORLD MARROW DONOR ASSOCIATION (WMDA)

Strategic Directions 2018-2022

www.wmda.info

*An association of members who share a
passion for donor care and strive to find the
best possible matches for blood cancer patients*

Table of Contents

Page

1.	<i>Mission & Vision of WMDA</i>	3
1.1.	Our vision	3
1.2.	Our mission	3
2.	<i>Content of WMDA's Strategic Plan</i>	4
2.1.	WMDA's strategic aims	4
2.2.	Strategic directions in detail:	4
3.	<i>WMDA Funding</i>	9
4.	<i>Organisation</i>	10
4.1.	General information	10
4.2.	Board and volunteers	10

1. MISSION & VISION OF WMDA

1.1. Our vision

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

1.2. Our mission

WMDA promotes global collaboration and the sharing of best practices between its members for the benefit of stem cell donors and patients.

In pursuing this mission, WMDA acts exclusively in the interest of donors voluntarily donating their haematopoietic (blood-forming) stem cells to patients in need of a transplant. WMDA is bound by core values of independence, integrity and transparency. To ensure these interests, WMDA has several instruments in place:

- Statutes: The association's independence is assured through its bylaws which state that its members are registries, responsible for the international provision of hematopoietic stem cells and healthcare professionals with an active interest in hematopoietic stem cell donation.
- Disclosure policy: Members of the Board, committees, working groups, and the staff of WMDA are obliged to declare any conflict of interest that they may have.
- Impartiality Oversight: Impartiality Officers provide a mechanism to minimize the risk of conflict between the interests of WMDA and other interests (e.g., commercial interests).
- Congress and education: For all WMDA congresses and education programmes, WMDA ensures the independence of the organiser, the topic selection, the speaker selection, and the educational materials. This is assured by having installed autonomous working groups and committees that ensure that all educational content is original, up-to-date, and relevant for participants of the meeting or students of the programme
- Transparency: WMDA publishes an annual report annually.
- The WMDA activities are clearly distinguished from commercially organised activities. Commercial companies are only allowed to provide unrestricted grants for a WMDA activity. These and accompanying social events will not compete with, nor take priority over, the WMDA sessions. Educational sessions will be held apart from commercially organised activities or sessions.

2. CONTENT OF WMDA'S STRATEGIC PLAN

The WMDA has implemented a strategic plan that conveys its ambition and priorities for the years 2018-2022. As an organisation that exists to achieve the best for stem cell donors and transplant patients, the strategy has been co-created with affiliate organisations so that it will support them to harness opportunities and mitigate risks in the medium-term. WMDA is serving the transplant community and has no intent to make any profit.

2.1. WMDA's strategic aims

Our strategy aims to deliver impact in the following areas:

A. Optimising 'search, match and connect'

Provide a global platform that facilitates access to the most suitable stem cell source for a transplant patient

IMPACT: facilitation of the best possible stem cell source for transplant patients.

B. Supporting global development

IMPACT: member organisations develop and grow allowing more transplant patients to find the best possible stem cell source.

C. Promoting donor care

IMPACT: Assuring that the rights and safety of stem cell donors are promoted and protected.

D. Ensuring quality

IMPACT: Product quality and global collaboration are promoted through accreditation and standardisation.

This strategy has been informed by the objectives of the EU Third Health Programme; EU's analysis of the economic landscape; results of the joint action ARTHIQS; European data protection regulations (GDPR) and analysis of key drivers in the operating environment.

2.2. Strategic directions in detail:

A. Optimising Search and select

In 2017 three professional organisations merged: World Marrow Donor Association (abbreviated as WMDA), Bone Marrow Donors Worldwide and NetCord Foundation. WMDA expanded its activities and took over the global database where the HLA-typings of potential donors and cryopreserved cord blood products are made visible for healthcare professionals in transplant centres. The database was operating in a legacy environment, which was not supported anymore by commercial software suppliers.

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In 2018 WMDA started to upgrade the first module of the ICT infrastructure in order to replace the legacy environment with a robust infrastructure. All efforts were focused on the upgrade of the legacy environment for accepting donor files and cord blood files from the participating countries. The infrastructure for accepting files from donors and cord blood products has been replaced and has been prepared to process larger data sets and to transition to real time updates. One-by-one organisations have been contacted and supported in understanding the new way of submitting files to the global database.

In the period 2018-2022 the focus of this strategic aim will be on two areas, *improving Data Quality* and *modernising the next module of Legacy software*.

A.1 Improving data quality

The first focus area is to expand the validation tools and to collaborate with organisations in receiving the best quality data on a regular base. The launch of the new infrastructure, allowing the processing of larger datasets from organisations, made it clear that data quality is crucial for selecting the best stem cell source. The following topics are identified to work on.

A.1.2 Determine which data is crucial for selecting the best stem cell source

The Preliminary search is the first step a transplant physician or search coordinator performs in finding the best stem cell source. If accurate and complete information is available, a decision to select the best stem cell source can be made quicker.

At recruitment, a potential stem cell donor can be typed for the targeted HLA loci (HLA-A, -B, -C, -DRB1, -DQB1 and -DPB1) at high resolution, or better, such as Next Generation Sequencing (NGS) typing.

In addition to the HLA, additional information can be made available. For example: blood group of the donor or the last contact date. This information might be valuable for a transplant physician or search coordinator when selecting a potential donor. Not only for volunteer donors, but also for cryopreserved cord blood products, transparent information is important and live saving. After collection, the cord blood bank has detailed information about the cryopreserved cord blood product available. This information is made available through a cord blood unit report, which is available on request.

WMDA strives to create an infrastructure where crucial data is visible when a preliminary search is done.

WMDA aims to define which data needs to be available to be able to select a potential stem cell source quickly.

The aim is to avoid the sharing of unnecessary privacy data, to meet global privacy regulations.

A.1.3 Moving to better data quality

Despite of the 40 million registered potential unrelated donors worldwide, for patients in need of allogenic hematopoietic stem cell transplant, <https://statistics.wmda.info/> finding suitable matched donors can be severely hampered by the heterogeneous quality of the available HLA typing information. Stem cell donor registries have utilised different serological and DNA-based HLA typing methods with variable resolutions. Since 2013 next generation sequencing (NGS)-based HLA typing methods made it possible to make precise and cost-effective HLA-typing's possible. An increasing percentage of the donors are typed based on this new typing technology. It will take time, funding and education to get all donors typed according to this new technology.

WMDA aims to prepare tools for participating countries, to compare the quality of their data with other participating organisations and to provide advice on how the quality of a donor or cord blood file can be improved.

A.1.4 Providing ethnic information about donors listed

The matching algorithm was improved in order to ensure better quality matching for patients from non-north-western European descent. To achieve a good prediction of the match the ethnic background of the donor or cord blood product will have to be provided by the organisation that is listing the donor. For example, if a donor with a non-north-western European descent is recruited by the Finnish Registry, a different calculation needs to be used than if the donor has a Finnish background. If a Finnish organisation does not provide the ethnic background of the non-north-western European donors, the Finnish calculation set will be used, instead of the calculation set of the population group the donor is originating from.

WMDA aims to prepare educational materials about the importance of providing ethnic background information.

A.1.5 Global registration identifier donors (GRID)

In 2010, World Health Assembly Resolution (WHA63.22) called on member states to 'encourage the implementation of globally consistent coding systems for human cells, tissues, and organs as such' as in order to facilitate the national and international traceability of materials of human origin for transplantation. In order to achieve this objective ISBT-128 and Single European Code (SEC) have been developed as a common format representing the information required on products.

There are steps defined before selecting the best stem cell source and before a product is collected from a healthy volunteer donor. During these steps of the search process, international communication takes place. This international communication is rather complicated. In table 1 is shown that there are plenty of formats using different lengths, numeric or alphanumeric coding, added characters, miscellaneous delimiters, or even multiple variations within some countries.

Exemplary part of a long list of compiled plausibilities to revise ID formats of different countries. Dedicated to each of the centers, that exhibit a self-defined structure of their IDs, is the regular expression (Regex) of plausibility control. (Z defines a number; B defines a character; n/a means not available)

#	Structure	Examples	Regex
1	ZZZZZZ	1001764, 1036396	$\wedge d\{7\} \$$
2	AR-ZZZZZ	AR-000181, AR-030194	$\wedge AR\d\{6\} \$$
3	ATZ ...	AT609, AT38668	$\wedge AAT[1-9]\d* \$$
4	AUZZZZ-ZZZZ-Z	AU4023-1671-5, AU2003-1470-6	$\wedge AAU\d\{4\}\d\{4\}\d \$$
5	SDZ ... D	S16465D, S11650D	$\wedge ASI[1-9]\d*DS \$$
6	Z ...	103922, 1698478	$\wedge A[1-9]\d+ \$$
7	n/a	n/a	$\wedge \$$
8	CHBB-Z ... or CHSBS-Z ... or CHCBS-Z ... or CHCGE-Z ...	CHZL-3086, CHSBS-205882, CHCBS-213	$\wedge CH([A-Z]\{2\})SBS(CBS(CGE)-[1-9])\d* \$$
9	MZ ... or DZ ...	M10032, M05061, D27634	$\wedge [MD]\d+ \$$
10	FRBBBZZZZ or FRCB ...	FRFAN00929, FRCBBE2803422, FR-CBBE6415060580-, FRCBBE-2703700679	$\wedge FR([A-Z]\{3\})\d\{5\}CB[-A-Z0-9]+ \$$
11	GR20-D-ZZZZZZZ	GR20-D-00007059, GR20-D-00189011	$\wedge GR20-D\d\{8\} \$$
12	Z ... or SHDZZZZZZ	288876 or SHD120256	$\wedge ([1-9]\d+SHD)\d\{6\} \$$
13	INBMSTZZBZZZZZZ	INBMST12A003456, INBMST45K648521	$\wedge INBMST\d\{2\}[A-Z]\d\{6\} \$$

Table 1: An exemplary part of the list of German National Bone Marrow donor Registry's (Zentrales Knochenmarkspender-Register für die Bundesrepublik Deutschland; ZKRD)

By implementing a global registration donor identifier, WMDA strives to reduce the error rate towards a minimum, thus improving safety of patients and donors.

WMDA aims to increase the percentage of donors that have a unified donor-ID number and to establish educational programmes as to how this GRID donor ID number can be implemented in the daily operations of an organisation that is providing stem cells internationally.

A.2 Modernise the next module of legacy software

The second focus area is to modernise the second module of the legacy software. This includes the request of detailed information of a potential stem cell source and to request blood samples for further testing. The goal is to determine which steps are required for the replacement of the legacy software to request blood samples. The experience gathered in 2018, when WMDA migrated to the new environment for data submission, showed that WMDA is collaborating with different types of organisations. Some of them have extended IT knowledge and others have limited IT resources. In order to make the project successful consensus is required, which is achieved by building relations in the community and organising educational events. One of the goals is to create a pathway to modernize the registry-to-registry communication, with defined milestones for the years to come.

A.2.1 Modernise the search process

WMDA's main focus in this area is to modernise the search process. The search process is defined in three main areas:

- Search
- Request blood sample
- Collect

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In order to perform the search, a good dataset is required to make the best selection for a potential stem cell source. When a donor is identified the next steps are: request blood sample followed by a collection of hematopoietic stem cells.

The infrastructure that has been developed is a viable product, and requires more development and testing in order to make it possible to accommodate a second matching algorithm.

To perform the next step in the search process, requesting a blood sample, a single virtual electronic tool – European Marrow Donor Information System (EMDIS) – enables efficient communication. EMDIS is used throughout the search, match and exchange process and is used by some organisations. The tool is based on old technology and needs to be updated to comply with the privacy legislations.

WMDA's resources will be allocated to prepare the infrastructure in a way that requests can be processed. As it is a complicated IT development process, with different skill sets among the member organisations, the roll-out of the infrastructure will be phased in steps. A request facilitation needs to be managed by both small and larger organisations. In order to finish this project successfully, consensus from the community is crucial. To achieve consensus of the community, a robust and secure IT governance infrastructure is one of the key points for achieving a successful outcome of the project.

B. Supporting Global Development

Unrelated stem cell transplantation is a last-resort treatment for an increasing number of patients. Europe imported 1,068 hematopoietic stem cell products from third countries in 2017. Based on the regulatory survey, defined in 2018, the WMDA aims to create a web environment. The website is available for WMDA member organisations and regulatory bodies where information is shared about the organisations in third countries that export products to European Member States.

Another area of the WMDA is to gather and share knowledge, insight and best practice. Therefore, WMDA is planning to share information on the current cord blood banking operations of public cord blood banks. This allows cord blood banks to adopt their strategies and improve their banking operations in accordance with the global standard.

WMDA initiated a World Marrow Donor Day campaign, which was targeted on #thankyoudonor and mixed races. WMDA collected HLA-typings of patients who are not able to find a match. These HLA-typings have been analysed to get an understanding for which population group need encouragement to become a stem cell donor. World Marrow Donor Day will focus on global recruitment for patients where the demand is high. In addition, educational workshops will be scheduled for WMDA members in which they can analyse their own patient searches.

Search coordinators and transplant centre physicians are the persons searching for (and finding) the best stem cell source for their patients. WMDA will be developing education opportunities to reflect the scientific and technological advance.

C. Promoting donor care

WMDA has a pivotal role in promoting donor care and ensuring that the safety of donors is protected. Stem cell donations can be accompanied by side effects, adverse events and substantial psychological discomfort with the donor. For example, stem cell donations often cause bone and muscle pain due to granulocyte colony stimulating factor (G-CSF) treatment. The main focus of WMDA will be education for healthcare professionals, who are reporting incidents occurring after unrelated stem cell donation to the WMDA.

D. Ensuring quality

EU Directive 2004/23/EC regulates quality and safety of the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Despite the EU's robust regulatory regime, the varying interpretations and implementations of regulations and directives, has resulted in divergent exchange procedures for stem cells.

WMDA surveyed the organisations in EU member states that are importing haematopoietic stem cells from third countries about the administrative work that is required.

In order to streamline the process of importing and exporting stem cells between Member States and between Third Countries and Member States, it is necessary to establish an operating environment incorporating centralised information. This will mitigate the risk of unnecessary delays and will reduce the administrative burden.

WMDA operates an accreditation programme that aims to provide assurance that standards and regulations are being met. WMDA aims for this accreditation to be recognised as the global Gold Standard by its members, and by national and international authorities, and for it to be reflected in regulatory frameworks. By supporting more members globally to embark on the journey towards formal accreditation, more donors and patients both within the EU and beyond, will benefit from evidence-based standards, policies and protocols.

3. WMDA FUNDING

WMDA is trying to achieve its aims by funding through:

- 1) Membership fees
- 2) Providing educational seminars
- 3) EU funding
- 4) Support from corporate partners

A copy of the WMDA Finance & Activities Report can be found in appendix 1.

4. ORGANISATION

The WMDA will be implementing an organisational structure which corresponds well with the aims and the goals defined – it is built to allow the projects to fully capitalise on the expertise from the community. As WMDA is a voluntary organisation it is crucial that volunteers are supported by professional staff. Each area is led by an operational lead, who is supported by expert groups of volunteers and professional office staff. Each WMDA Board member is responsible for an area, which ensures good communication between the expert groups and the WMDA Board. The WMDA Board meets on a monthly base and is responsible for the budget and the long-term strategic decisions.

The support office is a central day-to-day management office, consisting of a team with different skill sets. If necessary, the support office can be expanded with the support of larger member organisations. All projects are overseen by the executive director and supported by pillar coordinators and an operational coordinator.

4.1. General information

Statutory name:	World Marrow Donor Association (WMDA)
Organisation type	Association
Founded:	October 4, 1994
Chamber of Commerce	40448326
Bank account (IBAN):	NL61ABNA0421708514
VAT number (RSIN):	NL803 974 917 B02
Phone number	+31 88 505 7900
Website	www.wmda.info
E-mail	mail@wmda.info

4.2. Board and volunteers

The association has an unremunerated Board existing of 8 members (July 1, 2022). Each Board member has complimentary competences and networks.

The Board is led by Mrs. Bronwen Shaw.

Matthew Seftel, Board member: President Elect

Oliver Kürsteiner, Board member: Treasurer

Matti Korhonen, Board member: pillar 1 - Search, Match & Connect

Mike McCullough, Board member: pillar 1 - Search, Match & Connect

Dunia Jawdat, Board member: pillar 2 - Global Development

Thilo Mengling, Board member: pillar 3 - Donor Care

Garth Healey, Board member: pillar 4 - Ensuring Quality