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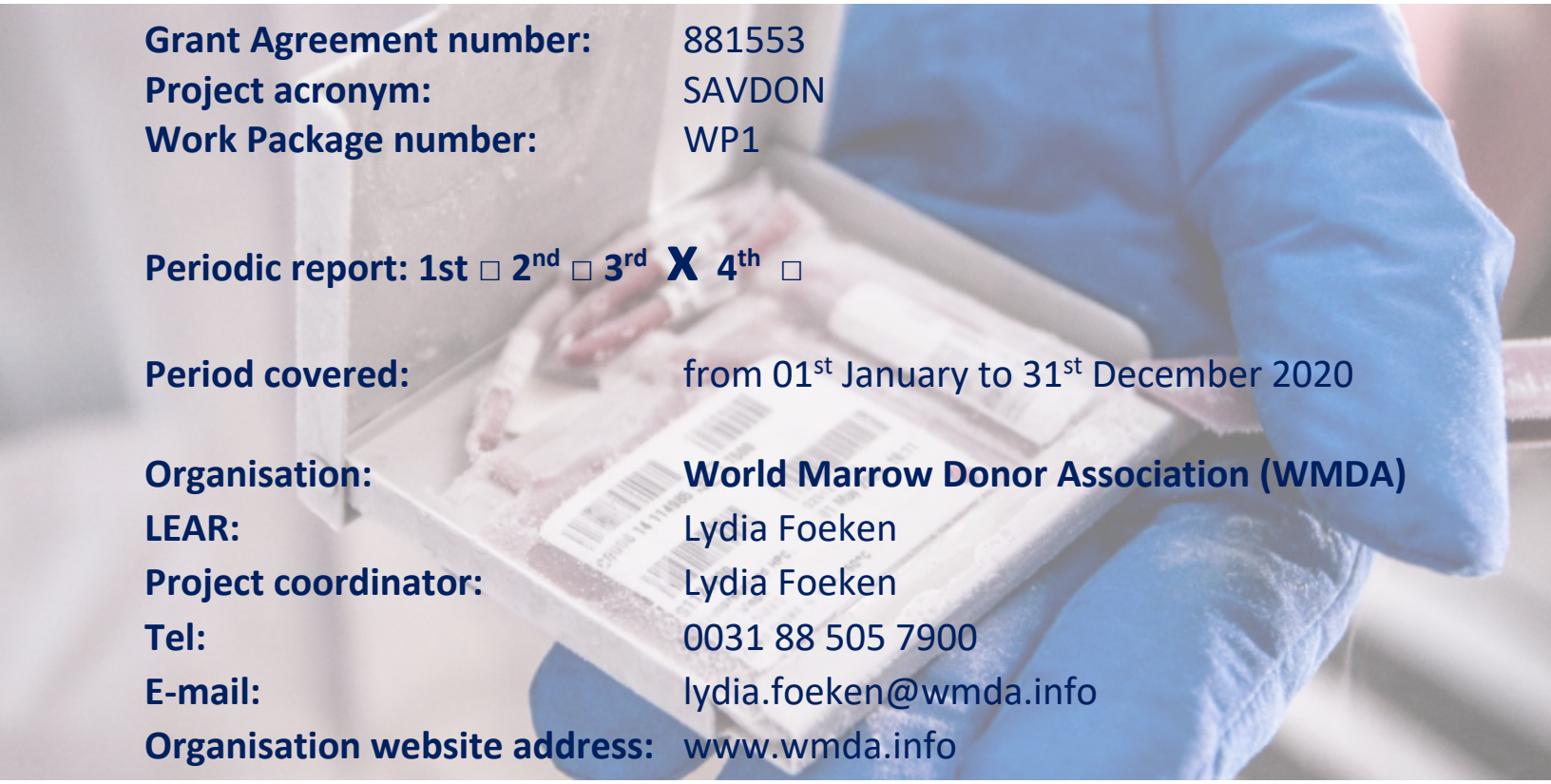
D4.3 Progress report on if it is feasible that WMDA will apply for ISO Certification



Grant Agreement number: 881553
Project acronym: SAVDON
Work Package number: WP1

Periodic report: 1st □ 2nd □ 3rd X 4th □

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Description:

Contents

I. INTRODUCTION

In a blood stem cell transplantation, a patient's defective stem cells are replaced with healthy ones. Blood stem cells are mostly found in the bone marrow, a spongy tissue inside the bones. Small numbers of stem cells also are found in the blood and in the umbilical cord (the cord that connects a foetus to the mother's placenta).

Stem cells develop into the three types of blood cells that the body needs:

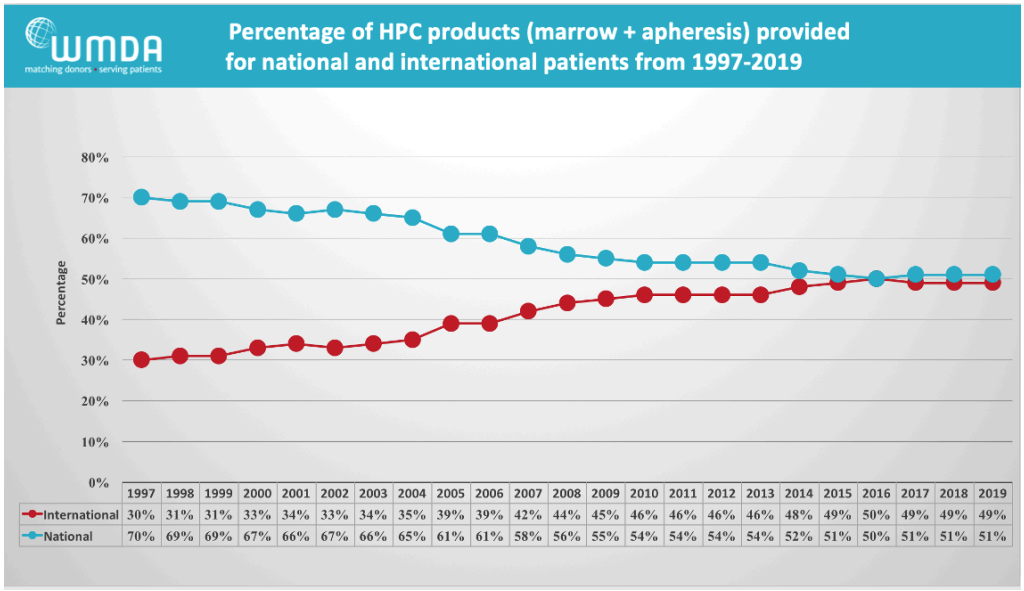
- red blood cells that carry oxygen throughout the body;
- white blood cells that fight infections; and
- platelets that help the blood to clot.

Patients receiving blood stem cell transplants are matched with a volunteer donor through a test called HLA tissue typing. Transplant physicians start looking for a matching donor in the patient's family and will extend the search to an unrelated donor when no matching family donor is available. About 70% of patients do not have a match in the family.

Alternatives for a matching family donor may be:

- family members who are not a complete HLA match;
- unrelated adult volunteers who are a complete HLA match;
- umbilical cord blood units that are a complete HLA match; or
- unrelated volunteers or umbilical cord blood units that are not a complete HLA match.

In order to find a match, almost 50% of the unrelated stem cell transplants involve a donor in a country different from that of the patient. International collaboration is crucial.

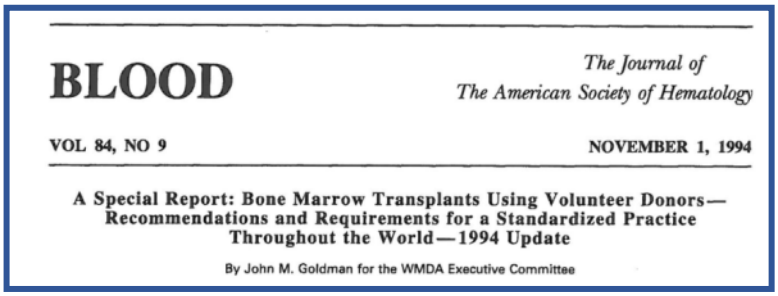


	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
International	30%	31%	31%	33%	34%	33%	34%	35%	39%	39%	42%	44%	45%	46%	46%	46%	46%	48%	49%	50%	49%	49%	49%
National	70%	69%	69%	67%	66%	67%	66%	65%	61%	61%	58%	56%	55%	54%	54%	54%	54%	52%	51%	50%	51%	51%	51%

Figure 1- WMDA Global Trends Report 2019

II. WMDA Goals: to Standardize practice Worldwide.

Between 1988 and 1994, WMDA was founded with the goal to Standardize Practice Worldwide. In 1994, WMDA stablished the first recommendations and requirements for a standardized practice throughout the world for bone marrow transplants. These recommendations and requirements were the seed of WMDA Accreditation Programme.



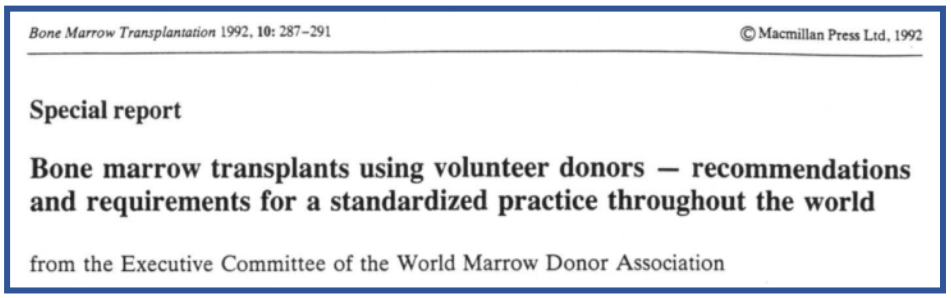
BLOOD

The Journal of The American Society of Hematology

VOL 84, NO 9 NOVEMBER 1, 1994

A Special Report: Bone Marrow Transplants Using Volunteer Donors— Recommendations and Requirements for a Standardized Practice Throughout the World—1994 Update

By John M. Goldman for the WMDA Executive Committee



Bone Marrow Transplantation 1992, 10: 287–291 © Macmillan Press Ltd, 1992

Special report

Bone marrow transplants using volunteer donors — recommendations and requirements for a standardized practice throughout the world

from the Executive Committee of the World Marrow Donor Association

Nowadays WMDA is organized in four Pillars:

- **Optimising Search, Match & Connect**: Provide a global platform that facilitates access to the most suitable stem cell source for a transplant patient;
- **Supporting global development**: Support members to develop and grow, so that more transplant patients find the most suitable match;
- **Promoting donor care**: Ensure that the rights and safety of blood stem cell donors are promoted and protected;
- **Ensuring quality**: Promote product quality and global collaboration through accreditation and standardization.

Pillar 4- Ensuring quality- is the responsible for WMDA Accreditation Programme. WMDA Accredited first registries in 2004:

- Registre France Greffe de Moelle, France
- Welsh Bone Marrow Donor Registry, Wales

Registries Qualified/Accredited Today list **84% of donors and cord blood units**

Bold marked are EU Member States

Australia	**Germany**	Switzerland
Austria	**Greece-Hellenic CBB**	**Sweden**
Belgium	**Ireland**	Taiwan-Tzu
Brazil	Israel-Ezer Mizion	Thailand
Canada-Hema Quebec	Israel Hadassah	**UK-Bristol**
Canada-One Match	**Italy**	**UK-Nolan**
China	Japan	**UK-Wales**
Cyprus	**Netherlands**	USA-Gift of Life
Czech National	New Zealand	USA-Be The Match
Czech-SCR	Norway	
Denmark	Russia-HPC	
Finland	Singapore	
France	South Africa	

WMDA Accreditation Programme is accepted by **National Authorities** like:

- Italy: National Competent Authorities for Donation and Transplant - CNT, CNS
- Switzerland: Federal Office of Public Health
- The Netherlands: Inspectie Gezondheidszorg (IGZ)
- Singapore
- Israel
- Denmark
- Czech Republic
- United Kingdom
- EU tissue directive

The WMDA Standards has been crosschecked with the EU Directives for Tissues and Cells to ensure compliancy with the EU legislation. An increasing number of countries have implemented the WMDA accreditation as a way to ensure that hematopoietic stem cells that are imported to their country are compliant with the regulation.

WMDA strives that an increasing EU Member States accept WMDA accreditation as an import requirement for their country. Therefore, the WMDA has start up the process to professionalise its accreditation programme and to make it compliant with ISO-17065.

III. ISO Accreditation

www.iso.org

ISO, the **International Organization for Standardization**, has developed different international standards required by business, governments and society to **build trust** in products and services.

ISO standards are widely respected and accepted by public and private sectors internationally.

ISO has today 165 members (there is one member per country) and has developed 23.512 Standards covering almost all aspects of technology and manufacturing.

Its **Committee on Conformity Assessment (CASCO)** covers topics such as the operating of **certification bodies**, testing laboratories, marks of conformity, accreditation and mutual recognition of conformity assessment results.

There are two key aspects in Conformity Assessment:

- **Provide Trust:** it gives all of us confidence and certainty about the environment in which we live.
- **Minimizing risks: supporting public policies**

Regulatory authorities can find it useful to introduce specific conformity assessment arrangements in order to provide assurance that legal requirements are being met.

The authorities will consider the dangers to workers, consumers, the environment and the economy posed by deficient goods, services or processes. The measures which they adopt will need to be proportional to the risks involved, with statutory inspection or **certification schemes** being introduced where the risks are highest.

Those two key aspects of **Conformity Assessment**

match perfectly the **WMDA aims**:

- **Provide trust** to the community
- **Minimize risks** through the development and operation of a Certification Scheme

We see ISO certification as a step forward in providing trust in WMDA Accreditation programme and in the future maybe it could be **worldwide** recognized by regulatory authorities.

WMDA is already recognised by regulatory authorities in some countries.

IV. Identification of the applicable ISO Standards.

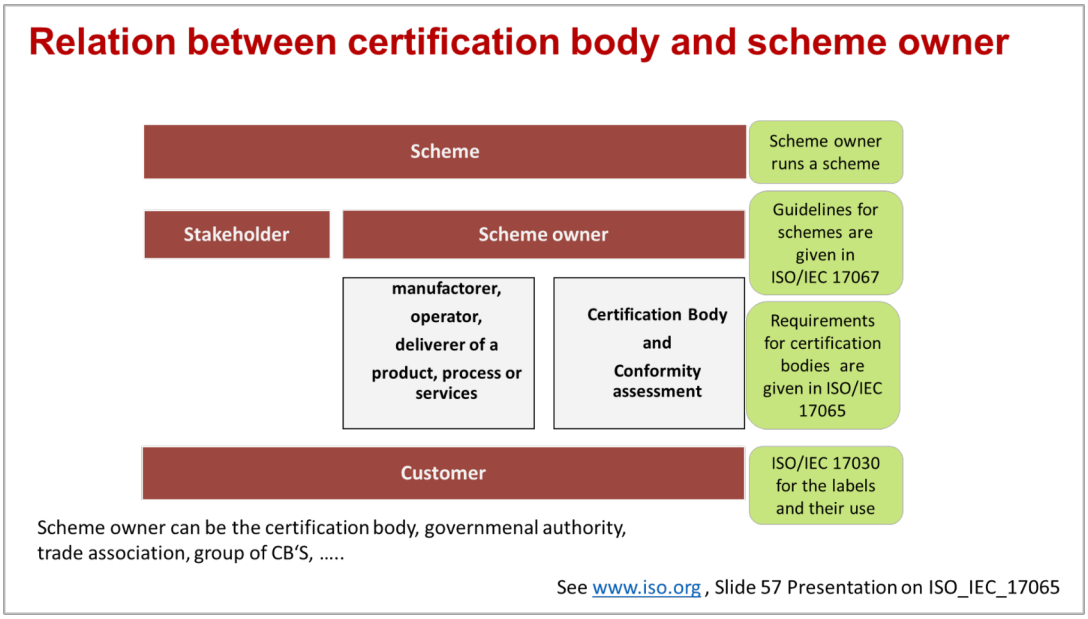
WMDA is a **Certification Body** which has developed a **Certification Scheme**

For the development of the Certification Scheme

> WMDA must comply with ISO 17067- *Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes*

For Certifying products, processes and services

> WMDA must comply with ISO 17065 - *Conformity assessment — Requirements for bodies certifying products, processes and services*



V. Gap analysis

To study the feasibility of ISO Accreditation, WMDA has performed a GAP Analysis between ISO 17065 and WMDA Accreditation Programme:

ISO/IEC 17065: 2012 (used Spanish version): Conformity assessment, requirements for bodies certifying products, processes, services

This gap analysis has been prepared based on **ISO/IEC 17065: 2012 Conformity assessment, requirements for bodies certifying products, processes, services**

- Focuses on WMDA Accreditation Programme, not individual registry
- 17065 document includes coverage of other conformity assessment docs: ISO 17000 (vocabulary), 17020 requirements for operation of bodies performing inspections, 17021 performing audit and inspection of management systems, 17025 competence of testing and calibration laboratories. Note that 17065 requires standards in other specific other ISO documents to be met
- Overlap with 17021 noted; 17021 more detailed in some topics having more standards but doesn't cover actual evaluation process

	17065 General Topic	Specifics	To Do	17021 Overlap
4	GENERAL REQUIREMENTS			
4.1	Legal and contractual matters			
4.1.1	Legal entity			Yes
4.1.2	Certification agreement with client	Legally enforceable, Covers responsibilities, lists client requirements—use in advertisement, communicating changes, allowing evaluation/audit, records complaints	Certification agreement with all the requirements of 4.1.2.2 Certification Agreement Between WMDA and Client-ns rev 02132019.docx	Yes
4.1.3	Use of license, certificates and marks of conformity (Ownership of marks/certificates)	Signs of qualification/accreditation under control of WMDA	Doc for the use of the license, certificates or mark. https://share.wmda.info/display/BCAS/ISO+Regulations Check Guides in Share and https://share.wmda.info/display/BCAS/PoliciesProceduresAccreditation	
4.2	Management of impartiality			
	Impartiality in evaluation	~10 standards , ISO 17021	Doc showing how impartiality is granted and risk analysis on an ongoing process. (There is a risk analysis for the Qualification & Accreditation process that contains information about impartiality, check https://share.wmda.info/display/BCAS/Accreditation+Program+Strategic+Planning Search& Match may be issue, see Clarification Process on ISO website https://isotc.iso.org/livelink/livelink?func=ll&objId=17864584&objAction=browse&viewType=1 (can be consider outside the Scope ???)	Yes

Figure 2- View of GAP analysis between ISO 17065 and WMDA Accreditation Programme

In the GAP analysis, WMDA has identified the following main issues:

ISO requirement	Changes because of gaps
4.1	Certification Agreement is not implemented within WMDA; WMDA has a process with a letter of intent.
4.4	Non-discriminatory conditions. WMDA accreditation programme is only available for member organisation. According to ISO standards it should be open for any organisation. A change in WMDA Std 1.01 is required.
5.2	Mechanism need to be implemented for safeguarding impartiality
6.1.3	Contract with personnel involved in the certification process (WMDA Board, WMDA office staff and members of the Accreditation Committee)

V.I. Certification Agreement:

Requirement 4.1 asks for a Certification Agreement: establish the responsibilities of WMDA and the registries regarding the Certification process. All registries that will go through WMDA Accreditation will need to sign this contract with WMDA before starting the process.

V.II. Non-discriminatory conditions:

Second gap is related to requirement 4.4. Non-discriminatory conditions: Access to certification shall not be conditional upon the size of the client or membership of any association or group. A change in WMDA Standard 1.01 is needed. This standard requires membership to registries applying for Certification, Qualification or Accreditation.

V.III. Mechanism for safeguarding Impartiality:

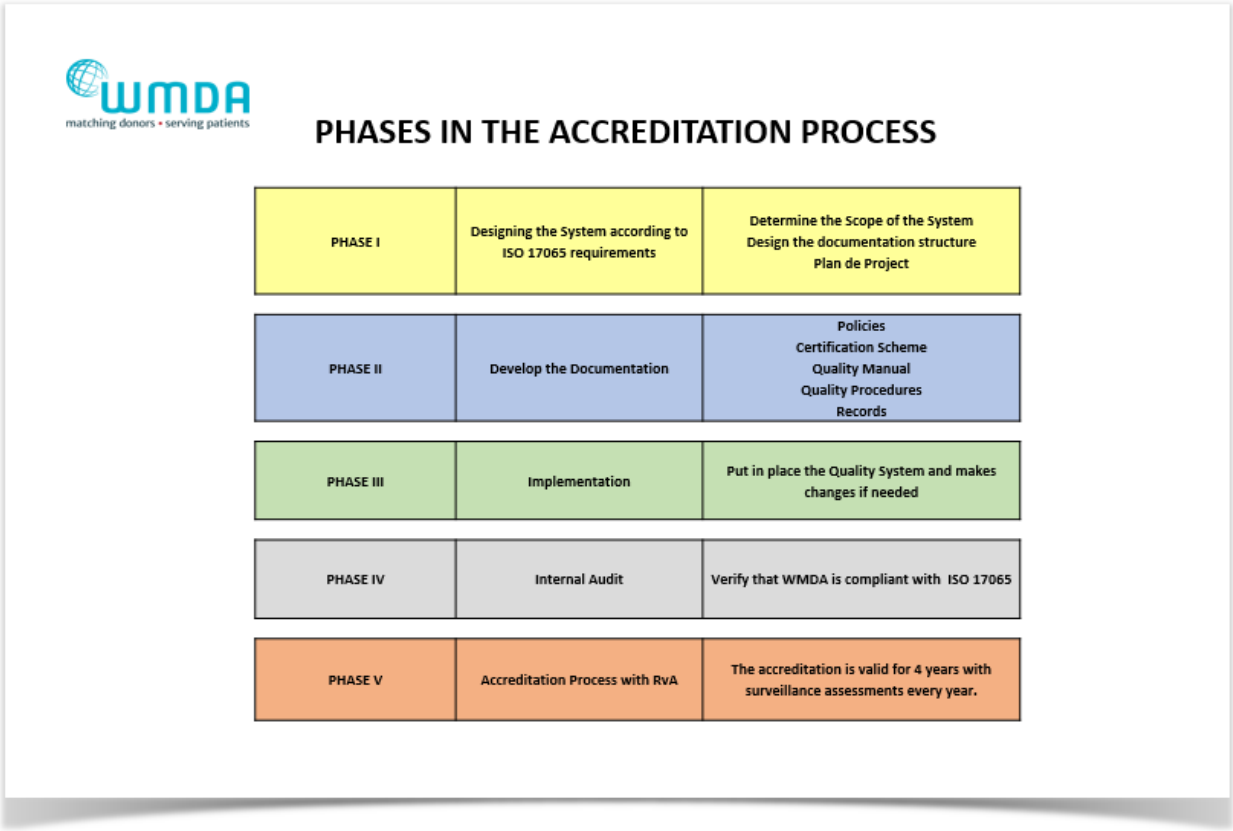
Requirement 5.2 Mechanism for safeguarding impartiality: WMDA needs to set up an Impartiality Committee that verifies, on a yearly basis, the impartiality of WMDA as a Certification body. That means that WMDA needs to formally review the measures we put in place to safeguard impartiality, like the Conflict of Interest forms (COI), that the members of the Accreditation Committees and Reviewers need to sign before they start performing their tasks.

V.I.V Contract with personnel involved in the certification process:

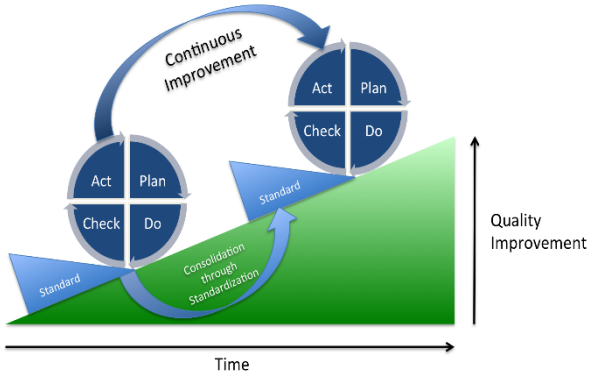
The Contract need to reflect commitment to comply with the rules defined by WMDA and with the Confidentiality and Conflict of Interest requirements.

V.I. Phases in the project

WMDA has identified the following phases in the project:



This project is designed to follow a continuos improvement cycle or **plan-do-check-act (PDCA) cycle**:



- **Plan:** Plan de change.
- **Do:** Perform
- **Check:** Monitor
- **Act:** Improve

Based on the feedback from both registries and reviewers, the WMDA is monitoring the quality of the accreditation programme. In 2020, major improvements were implemented based on feedback of WMDA members.

WMDA has identify the following improvements in the Accrediation Process that have already been implemented or are planned:

Improvements	
Registries	Accreditation templates: - More user friendly - WMDA office provides information that before had to be provided by the registry - Timeline for the accreditation process is now included in the template - Exploring the possibility to provide registries with a working copy of the applications
Reviewers	- Improvements in Share to make reviewers' work easier - Update or create some procedures e.g.: Remote assessments (due to pandemic) Scoring system for non-conformities
General improvements	- Improve WMDA Document Control System - Accreditation data traceability to WACC number - Improvements in WMDA software application, CRM - Improvements in WMDA membership website, WMDA Share - Improvements in WMDA Educational platform, Moodle

In het next paragraphs the status is described how WMDA will work through the five pahses described as the WMDA accreditation process outlined on the previous page.

a) Phase I – Designing the system according to ISO 17065 requirements

I. Determine the scope of the system

WMDA Accreditation Programme scope is the following:

Activities or services of coordination of the search for haematopoietic progenitor cells from donors (including cord blood) unrelated to the potential recipient in another country provided by Registries.

This activities or service includes the following

- Recruiting Donors
- Recruiting Cord Blood Units
- Identify potential donors/CBU
- Facilitate selected donor and/or umbilical cord blood donor education, consent, further testing, and medical evaluation; coordination with transplant centre activities regarding the patient
- Facilitate collection, labelling and shipment of viable hematopoietic stem or other cells to transplant centre of patient
- Support and care for the volunteer donor post-donation for issues related to the donation

ii. Organizing Policies and Procedures for ISO

WMDA has documented Policies and Procedures that covers all activities in the WMDA Accreditation process. The policies and procedure have been and are in the process of modification to ensure compliance with ISO requirements. According to the new proposed structure, WMDA will review, adapt and include all information needed to comply with ISO requirements.

Proposed Structure for the documentation (ISO 17067 + ISO 17065)

		Registries	Reviewers	BCAS + WMDA Pillar 4 office	ISO 17065	ISO 17067
1. Planning	1.1 Objectives		x	x		6.3.9
	1.2 Risks			x	4.2	6.3.10
	1.3 Planning of changes			x		6.6.2, 6.6.3
2. General	Legal entity	x	x	x	4.1.1	6.3.3
	2.1 Certification agreement	x	x	x	4.1.2	6.5.1 l)
	2.2 Use of license, certificate and marks of conformity	x	x	x	4.1.3	6.5.1 j), 6.5.1 k), 6.5.6, 6.5.12
	2.3 Impartiality Policy	x	x	x	4.2, 6.1	
	2.4 Financing and liability	x	x	x	4.3	6.3.11, 6.3.12
	2.5 Establishing certification Scheme: Develop, maintenance and improvement of the Scheme	x	x	x	6.2	6.3.1, 6.3.4, 6.3.5, 6.3.6, 6.3.7, 6.3,6.4, 6.5.1c),6.5.1d), 6.5.1e). 5.6.1 g), 6.5.7, 6.5.8, 6.6.2, 6.6.3
	2.6 Non-discriminatory conditions	x	x	x		
	2.7 Information confidentiality	x	x	x	4.5	6.3.9
	2.8 Publicly available information	x	x	x	4.6	6.5.1 u)
Structural requirements	Organizational chart		x	x	5.1	6.3.6
	Duties and responsibilities		x	x	5.1	6.3.6
Resources requirement	Competence of personnel		x	x	6.1 , 6.2	6.3.8, 6.5.1 l)
Process requirement	Certification workflows	x	x	x		
	WMDA Standards and guidance	x	x	x		6,5,1 a), b)
	Recognizing other certificates (NetCord/FACT)	x	x	x		6.5.3
	Certification Policy	x	x	x	4.4, 7	6.5.1 m), 6.5.1 n), 6.5.1 o), 6.5.1 p)
	Complaints and Appeals Policy	x	x	x		6.5.5
	Tariff	x		x		
	SOP Certification		x	x		6.5.1 h), 6.5.1 i), 6.5.2, 6.5.7
Management system	Document control			x	8	6.5.1 v), 6.6, 6.7
	Record control			x	8	6.5.1 v), 6.6, 6.7
	Non- conformity			x	8	6.6.1, 6.5.8
	Corrective actions			x	8	6.6.1
	Improvement			x	8	6.6.1
	Internal audit			x	8	6.6.1
	Feedback of interested parties			x	8	6.6.1
	Mechanism for safeguarding impartiality			x	5.2	6.6.1
	Management reviews			x	8	6.6.1
	Analysis and evaluation (KPI's CAB processes)			x	8	6.6.1

Figure 2 – Proposed structure for the WMDA documentation to comply with ISO 17067 and ISO 1765. The figure also shows the visibility of this documentation for stakeholders in the WMDA Accreditation Programme.

iii. Project plan

According to the gaps WMDA has identified, the structure of the documentation and the resources in the Accreditation Programme, a list of actions have been put together which will be worked on in 2021.

b) Phase II – Develop the documentation

WMDA will use ISO 9001:2015 requirements to do the document control for all documented information of the WMDA Accreditation Process.

- Approve documents
- Review, update, and submit documents for re-approval
- Identify changes
- Make documents available
- Ensure documents are legible and identifiable
- Identify and control external documents
- Keep obsolete documents out of circulation
- Identify obsolete documents as necessary if retained
- Identifying records
- Storing records
- Protecting records (including keeping them identifiable and legible)
- Retrieving records
- Retaining records
- Disposing of records

c) Phase III – Implementation

All certified management systems are based on evidence of fulfilment of the requirement. In this phase WMDA will put in place all the processes documented in the previous phase. That way, WMDA will have the objective evidences needed to demonstrate compliance with ISO 17065 to Dutch Council for Accreditation, Raad van Accreditatie.

d) Phase IV – Internal Audit

Collaboration with European Society for Blood and Marrow Transplantation (EBMT)

European Society for Blood and Marrow Transplantation

The EBMT is a not-for profit medical and scientific organisation established in 1974. It is dedicated to fighting life-threatening blood cancers and diseases and improving patients' lives.

EBMT members–more than 5,000 physicians, nurses, scientists and other healthcare professionals–participate in a unique collaborative network of peers involved in haematopoietic stem cell transplantation (HSCT) and cellular therapy research. Membership encompasses more than 550 centres from over 70 countries, that perform or are involved in HSCT.

The EBMT holds a central role in performing co-operative studies and disseminating state of-the-art knowledge: the aim is to increase survival rates and enhance the quality of life of patients with life-threatening blood cancers and diseases.

The Joint Accreditation Committee ISCT-Europe & EBMT (JACIE) is working on the accreditation under ISO 17065. For that reason, EBMT and WMDA are collaborating in this important project.

Aim of Internal Audits:

Verify that WMDA fulfils the requirements of ISO 17065 and that the management system is effectively implemented and maintained.

Internal Audit is a very important step before WMDA applies for ISO Accreditation. It will determine if WMDA management system is ready for the external audit that Raad voor Accreditatie needs to perform.

Among other, there are two requirements for Internal Audit that all organisations need to meet:

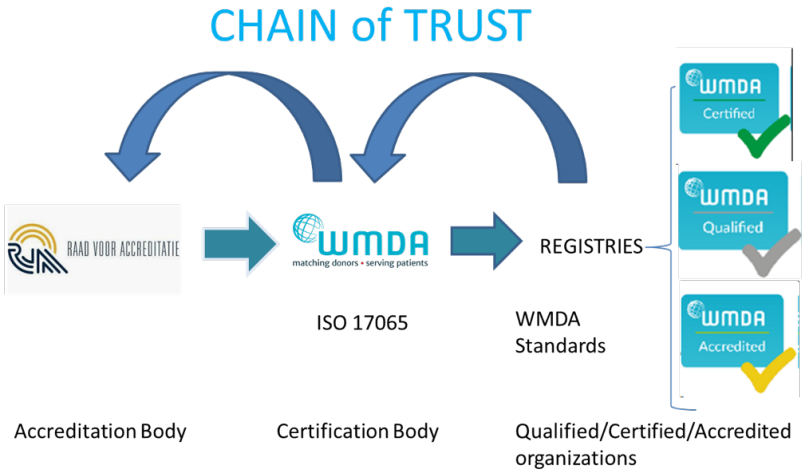
a) The internal auditors are knowledgeable in certification, auditing and the requirements of ISO 17065;
b) Auditors do not audit their own work

To comply with these requirements, WMDA has established a collaboration of EBMT. Both professional societies are working towards ISO17065 accreditation. It has been agreed to share knowledge and to perform internal audits.

e) Phase V – Accreditation process with Raad voor Accrediatatie (Dutch Accreditation Body)

Most countries have a national accreditation body. Because WMDA is registered as a legal entity in The Netherlands, WMDA will need to follow the Accreditation process with the Dutch Accreditation Body. It is called “Raad voor Accreditatie”

That way, WMDA grants Certification/Qualification or Accreditation to registries that demonstrate compliance with WMDA Standards and Dutch Accreditation Body will grant Accreditation to WMDA when WMDA is compliant with ISO 17065.

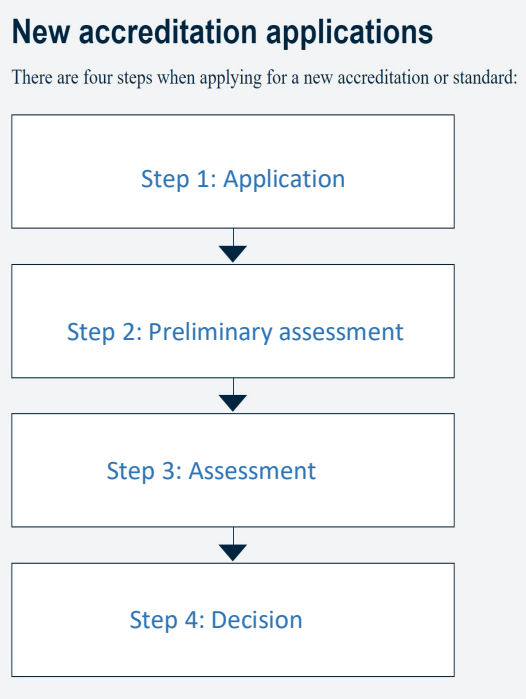


The Accreditation process with RvA has 4 steps:

1) In the first step WMDA must send an Application containing the scope of accreditation, WMDA Standards, policies and procedures.
2) Then there is a Preliminary Assessment where RvA informs WMDA whether or not we are ready to undergo the assessment. If WMDA is not ready, RvA provide a report with non-conformities that WMDA will need to address and if ready, then next steps are:
3) Audit
4) Final decision

If final decision is positive WMDA will obtain the accreditation and it will be valid for 4 years. During those 4 years we will have to undergo a number of surveillance audits.

Accreditation process with RvA



DUTCH ACCREDITATION COUNCIL