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D4.2 Progress report on the steps WMDA has taken to enhance the WMDA accreditation programme including the strategy on how to address organizations with low activity and how to certify the accreditation programme

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Description:

This document provides a comprehensive report setting out findings resulting from engagement with member registries in relation to the WMDA Accreditation Programme, the improvements, efforts, support and accreditation activities performed by WMDA as well as a synthesis of the achievements made in 2020.

WMDA is in continuous contact with its members and other stakeholders through different channels. WMDA gathers information in meetings, webinars, through the WMDA membership website (WMDA Share), surveys and of course WMDA office is accessible and open to questions, suggestions and comments.

Considering all the information, WMDA has established the following actions to improve WMDA Accreditation Programme:



I. New WMDA 2020 Standards – Certification Level

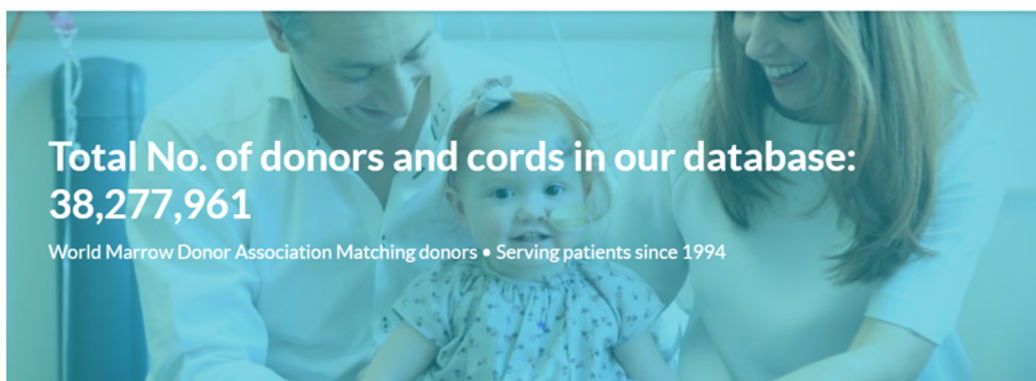
Justification: the WMDA Accreditation Programme based on 2017 WMDA Standards had a minimum level of activity to make a registry eligible to apply for Qualification and Accreditation:

WMDA 2017 Standards

*To be eligible to apply for WMDA qualification/accreditation, a registry must provide evidence that they are providing haematopoietic stem cells from volunteer unrelated donors or banked umbilical cord blood units to patients in another country. **A minimum of six (6) donations** within the last three years with 2 of the 6 for international patients is required to be eligible **for WMDA qualification/accreditation** for volunteer donors as a stem cell source. **A minimum of 6 cord blood unit shipments** within the last three years with 2 of the 6 for international patients is required to be eligible for WMDA qualification/accreditation for cord blood as a stem cell source. The remaining 4 donations/stem cell shipments may be for national patients. A registry applying for both unrelated donors and cord blood units must meet the criteria for both stem cell sources.*

This minimum level of activity was a barrier for small registries and emerging registries or registries starting to operate internationally.

In awareness of the importance of including these registries in the global collaboration network, and to be coherent with WMDA Mission, Vision and Aims:



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

MISSION - To promote global collaboration and the sharing of best practices between its members for the benefit of stem cell donors and patients.

AIMS - Optimising 'Search, Match & Connect', supporting global development, promoting donor care and ensuring quality.

WMDA has implemented a new category open for those registries that do not achieve the minimum level of activity.

This change has come into force in July 2020, when the 2020 WMDA Standards became effective.

WMDA 2020 Standards

To be eligible to apply for WMDA certification/qualification/accreditation, a registry must provide evidence that they are providing hematopoietic stem cells from volunteer unrelated donors or banked umbilical cord blood units to patients in another country.

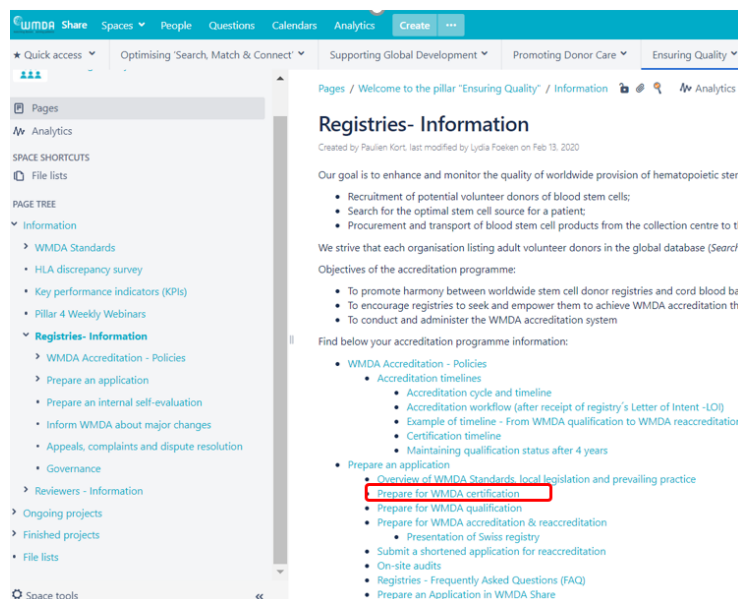
A minimum of six (6) donations within the last three years with 2 of the 6 for international patients is required to be eligible for WMDA qualification/accreditation for volunteer donors as a stem cell source. The remaining 4 donations may be for national patients.

A minimum of 6 cord blood unit shipments within the last three years with 2 of the 6 for international patients is required to be eligible for WMDA qualification / accreditation for cord blood as a stem cell source. The remaining 4 stem cell shipments may be for national patients.

If the minimum activity is not reached by the registry, the registry can apply for WMDA certification (instead of WMDA qualification).

To include this new category in the Accreditation programme, we have needed to adapt our processes:

- Review and update of WMDA Share (Confluence tool), including the Certification process.



The screenshot shows a Confluence page titled "Registries- Information" within the "WMDA Share" space. The page content includes:

- Our goal is to enhance and monitor the quality of worldwide provision of hematopoietic stem cells.
- Recruitment of potential volunteer donors of blood stem cells;
- Search for the optimal stem cell source for a patient;
- Procurement and transport of blood stem cell products from the collection centre to the patient.

We strive that each organisation listing adult volunteer donors in the global database (Search for Donors) is able to find a suitable donor for their patient.

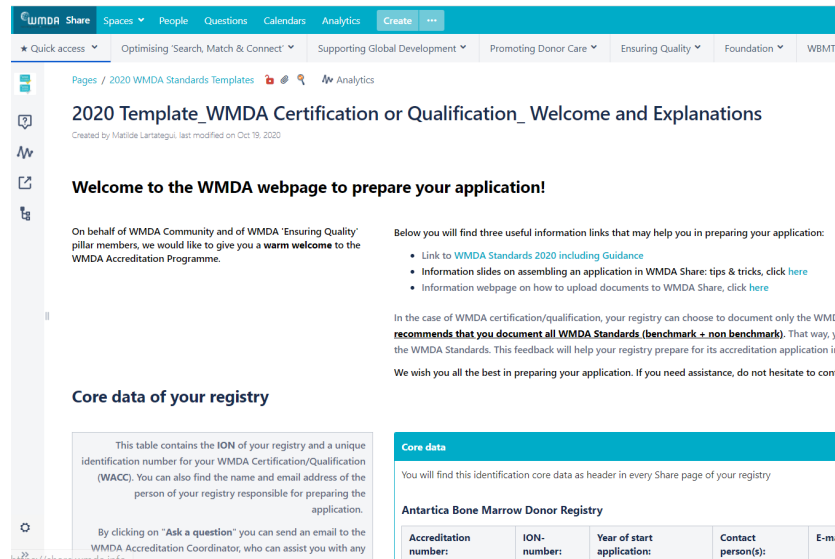
Objectives of the accreditation programme:

- To promote harmony between worldwide stem cell donor registries and cord blood banks
- To encourage registries to seek and empower them to achieve WMDA accreditation through the accreditation process
- To conduct and administer the WMDA accreditation system

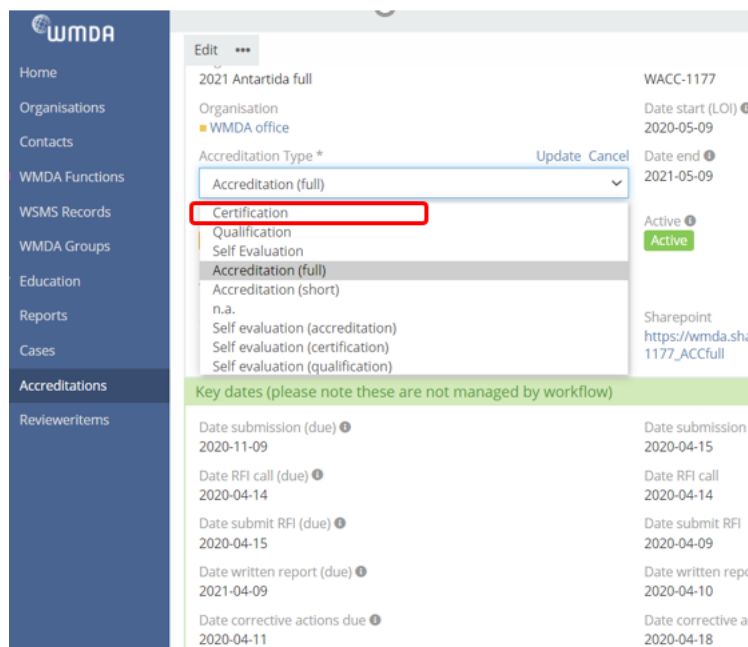
Find below your accreditation programme information:


- WMDA Accreditation - Policies
 - Accreditation timelines
 - Accreditation cycle and timeline
 - Accreditation workflow (after receipt of registry's Letter of Intent -LOI)
 - Example of timeline - From WMDA qualification to WMDA reaccreditation
 - Certification timeline
 - Maintaining qualification status after 4 years
- Prepare an application
 - Overview of WMDA Standards, local legislation and prevailing practice
 - Prepare for WMDA certification**
 - Prepare for WMDA qualification
 - Prepare for WMDA accreditation & reaccreditation
 - Presentation of Swiss registry
 - Submit a shortened application for reaccreditation
 - On-site audits
 - Registries - Frequently Asked Questions (FAQ)
 - Prepare an Application in WMDA Share

- Create a WMDA Share template to allow the registries to submit the information regarding the Certification process



- Include in WMDA CRM (data base) the Certification workflow and all related requirements.



	World Marrow Donor Association International Standards for Unrelated Hematopoietic Stem Cell Donor Registries			
	Document type	WMDA Standards	Approved by	WBRD
	Document reference	WMDA Standards 2020	Approval date	20190624
	Version	2020	Pages	Page 1 of 26
	Pillar	Pillar 4-EQ – Certification Body	Status	Public

WORLD MARROW DONOR ASSOCIATION
WMDA
INTERNATIONAL STANDARDS
UNRELATED HEMATOPOIETIC STEM CELL DONOR REGISTRIES

WMDA Standards 2020 COPYRIGHT © 2019 1 of 26 pages
 WORLD MARROW DONOR ASSOCIATION (WMDA)




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WMDA Standards 2020 COPYRIGHT © 2019 2 of 26 pages
 WORLD MARROW DONOR ASSOCIATION (WMDA)

Figure 1 WMDA 2020 Intl. Standards including Certification Level

The new category in the accreditation programme allows small organisation with limited number of donations provided to comply with internationally accepted standards and provide evidence that they comply with the EU Directive.

II. Improvements in WMDA Confluence tool (WMDA Share)

One of our most important tools to improve the Accreditation Programme is the feedback from stakeholders. According to the surveys we performed on 2019, WMDA has identified the following improvement actions related with WMDA Share tool.





Improvements	Priority level	Progress	Remarks
<p>WMDA Accreditation Confluence Tool</p> <p>Aims:</p> <ul style="list-style-type: none"> - Provide clear instructions and information about the process - Make the tool more user friendly - State the timeline for the whole process - Minimize workload for registries: Provide all the information WMDA already has about the Registry 	1		<p>The new improved WMDA Share space for applicant registries is finished and implemented.</p> <p><i>(See information below for more details)</i></p>
<p>Provide a working copy of the Share application</p> <p>Aims:</p> <ul style="list-style-type: none"> - Each registry can have a Confluence space where they can keep up to date all the policies and procedures needed to comply with WMDA Standards. It will save time when the registry needs to submit the application to WMDA. 	2		<p>Because of the change to the new 2020 WMDA Standards, each time a registry applies for first time certification/qualification or accreditation, we provide a working copy of their Share application, while retaining the original application.</p>
<p>Enhance the knowledge about WMDA Share</p> <p>Aims:</p> <ul style="list-style-type: none"> - Facilitate the preparation of the certification/qualification/accreditation applications. - Minimize workload for registries: bulk upload of documents 	3		<p>In progress:</p> <ul style="list-style-type: none"> - Video tutorials on "How to prepare your WMDA application" - Arrange training sessions for new applicants.

Improvements in WMDA Accreditation Confluence Tool

- Provide clear instructions and information about the process

First Share page which registries see is a welcome page that contains all the information to prepare the application (this page did not exist in previous version).

- Make the tool more user friendly: better layout, structure and easier navigation
- State the timeline for the whole process: overview of the new process with all due dates for each step.
- Minimize workload for registries: Provide all the information WMDA already has about the Registry

Pages / 2020 WMDA Standards Templates    

2020 Template_WMDA Certification or Qualification_ Welcome and Explanations

Created by Marlene Laruega, last modified on 13/10/2020

Welcome to the WMDA webpage to prepare your application!

On behalf of WMDA Community and of WMDA "Ensuring Quality" pillar members, we would like to give you a warm welcome to the WMDA Accreditation Programme.

Below you will find three useful information links that may help you in preparing your application:

- Link to WMDA Standards 2020 including Guidance
- Information slides on assembling an application in WMDA Share: tips & tricks, click here
- Information webpage on how to upload documents to WMDA Share, click here

In the case of WMDA certification/qualification, your registry can choose to document only the WMDA benchmark Standards. This is acceptable **BUT WMDA strongly recommends that you document all WMDA Standards (benchmark + non benchmark)**. That way, your registry will seize the opportunity to obtain feedback on all the WMDA Standards. This feedback will help your registry prepare for its accreditation application in the future.

We wish you all the best in preparing your application. If you need assistance, do not hesitate to contact WMDA staff members, we will be happy to help you.

Core data of your registry

This table contains the ION of your registry and a unique identification number for your WMDA Certification/Qualification (WACC). You can also find the name and email address of the person of your registry responsible for preparing the application.

By clicking on "Ask a question" you can send an email to the WMDA Accreditation Coordinator, who can assist you with any questions you might have.

Once you have uploaded all the information to demonstrate compliance with WMDA Standards, you can click on "Submit application". You will receive an automatic confirmation from the system and a confirmation email from the WMDA office. Once the application is submitted, you will not be able to make any changes so do not click submit until you are completely finished with the application.

Accreditation number:	ION-number:	Year of start application:	Contact person(s):	E-mail address(es):	Contact WMDA: (registry only)	Submit final application: (registry only)
WACC 9999	ION 0921	2020	template	template@wmda.info	Ask a question	Submit Application

Timeline of the WMDA Certification/Qualification process

Here you can find the different steps of the WMDA Certification/Qualification process and the timeline. By clicking on "Watching" in the upper right corner of the page, you will receive an automatic notification on any updates.

0. Unstarted	1. Preparation	2. Submission	3. Review and RFI	4. RFI response	5. On site audit	6. Report	7. Final steps	8. Finished
date start: 01 Jan 2021	date start: 01 Jun 2021	date start: 19 Jul 2021	date start: 13 Oct 2021			date start: 13 Nov 2021		date end: 01 Jan 2022

Application and response pages used in the WMDA Certification/Qualification process

Inside the Share spaces, you may find different pages:

- Application WACC 9999
- Request for Information WACC 9999
- Request for Translation WACC 9999 (only if needed)
- On site Visit WACC 9999 (only for (re)-accreditations)
- Corrective Action Plan WACC 9999 (only if needed)

Associated certification/qualification pages

- Certification/Qualification submission page
- Request for information
- Request for translation

Activity and overview documents

WMDA has uploaded your letter of intent (LOI) and other information below and, at the end of the process, we will upload the Witten Report.

Important documents	Find here the link to the documents
Signed Letter of Intent (LOI)	
Confirmation by WMDA that organization is a regular WMDA member organization	
Global Trend Report Submission - last edition	
Global Trends Report Submission - previous edition	
Key Performance Indicators of the last three years	
HLA discrepancy survey report	
Link to operational information of the registry on Share	
Link to regulatory information of the registry on Share	
Registered emergency number of the registry	
Number of submitted SEAR and SPEAR reports to WMDA in the previous calendar year	
Formal communication from WMDA with regard to the accreditation process (e.g., written reports, formal letters, self-evaluation reports, major changes in the registry) in the	

Links to WMDA Standards and Guidance.

Link to educational resources on how to prepare an application

Identification needed for traceability.

Submit button.

Timeline of the whole process, indicating the current step

Structure of the space with all the pages to facilitate navigation

Documents that WMDA provides (previously provided by the registry).

Certification/Qualification submission page

Created by Mariola Laranegui, last modified on Oct 19, 2020

WMDA 2020 Standards version

Core data						
Antartica Bone Marrow Donor Registry						
Accreditation number:	ION-number:	Year of start application:	Contact person(s):	E-mail address(es):	Contact WMDA: (registry only)	Submit final application: (registry only)
WACC-9999	ION-0921	2020	template	template@wmda.info	Ask a question	Submit Application

Important documents to provide with your application	
Information provided by registry	Please insert link to the document or the information here
Contact information for the registry	
Short description of the registry	
Organizational chart	
Documentation on how the registry meets key performance indicators (KPIs) (Note: this can be included for the relevant standards and not submitted here)	
Any unreported significant changes that have taken place since the last review and accompanying documentation to comply with Standard 1.05	
Information the registry would like to share with review team (in addition to documents/information provided in the application below)	

Table of contents:
<ul style="list-style-type: none"> WMDA 2020 Standards version Example 1. General 2. General organisation of the registry 3. Donor recruitment, consenting, screening and testing of donors 4. Umbilical 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 and subsequent donations of hematopoietic stem cells and/or cell products for the same patient 8. Collection, processing and transport of hematopoietic stem cells 9. Follow-up of patient and donor 10. Financial and legal liabilities

Table of contents added to facilitate navigation to specific parts of the application

Example		
Example WMDA Standard 3.1A	Prospective donors selected for hematopoietic stem cell collection must have passed a minimum age established by applicable law or their 18th birthday if no local regulations exist.	Find here the link to the registry procedure about donor recruitment, in paragraph 4a you can read that the donors must be between 18-60 years old.

Example to present expected results

1	Benchmark Standard (B)	New/KPI change	1- General	Please describe here how your registry complies with this WMDA Standard and upload one or more documents as "proof". The guidance to each Standard will recommend documents that will best demonstrate compliance. Label the sections of the documents that apply to the standard so the reviewers can easily find the information. Find an example above.
1.01			A WMDA regular member organisation is eligible for WMDA certification or WMDA qualification as a first step, followed by WMDA accreditation as a second step.	
1.02	B		If a registry is accredited for international exchange of hematopoietic stem cells by an international organisation with standards that meet or exceed WMDA Standards, that registry may be given WMDA certification/qualification following submission and evaluation of material documenting that accreditation.	

Ability to filter only benchmark standards or a specific standard

Clear differentiation between benchmark standards (marked in bold and with blue background) and the rest of the standards

These improvements will mainly benefit small registries that do not have an IT department, and/or are not familiar with IT tools, and/or do not have so many resources and cannot accommodate administrative burden.

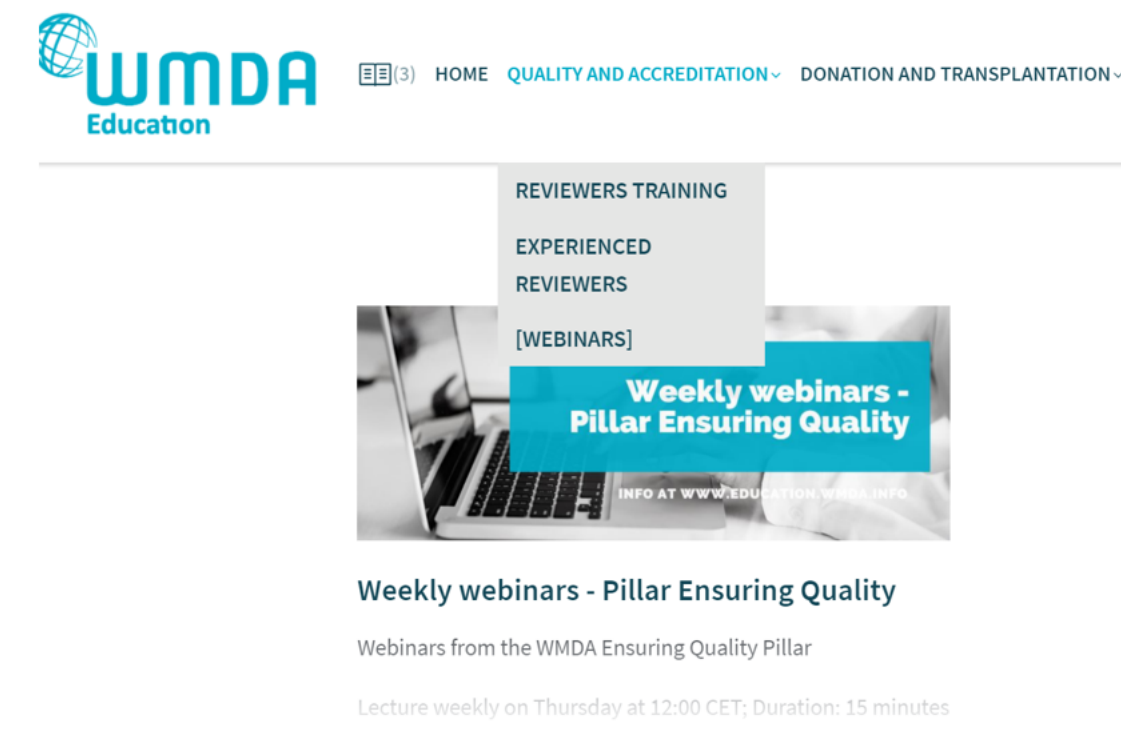
III. Weekly Pillar 4 Webinars

WMDA has made a big effort in 2020, during the COVID-19 Pandemic, to look for spaces for dialogue, exchange of ideas, experiences and knowledge and enrichment of our community, related to the WMDA Accreditation Programme. With this aim, WMDA prepared a set of webinars that covered the most interesting topics of WMDA Accreditation.

Target audience: open to the whole community, especially for certified/qualified/accredited registries or willing to apply.

Lecture weekly on Thursday at 12:00 CET, Duration: 15 minutes

All Webinars were taped and made available at WMDA Share collaboration tool, WMDA Educational Platform and WMDA YouTube channel.



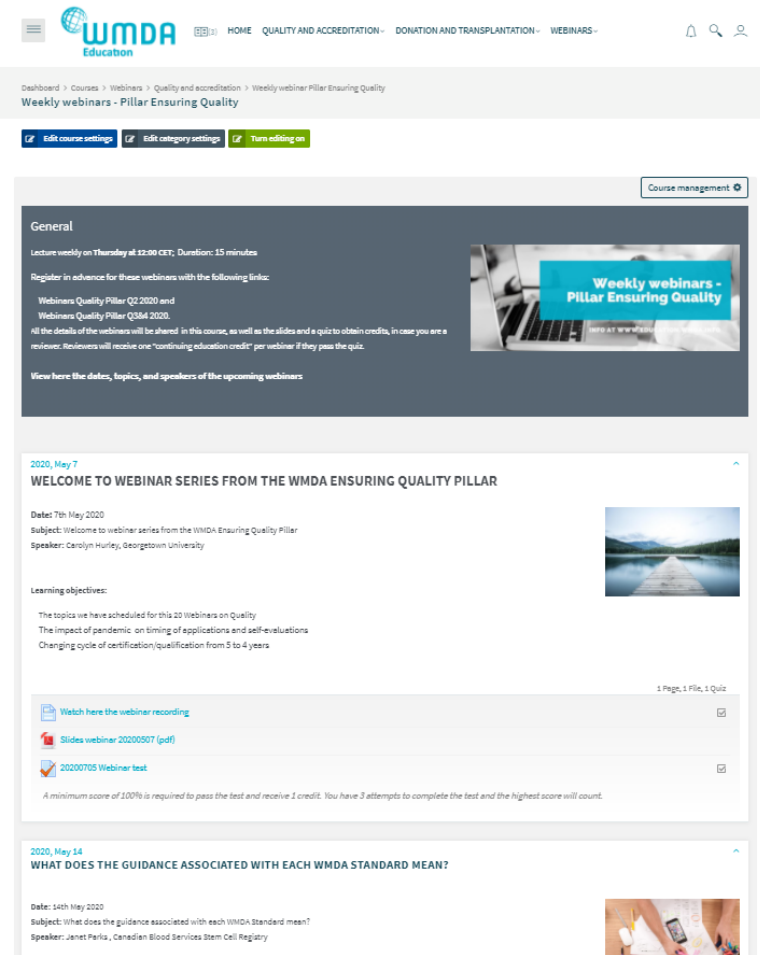
The screenshot shows the WMDA Education website. The logo is on the left. The navigation menu includes: (3) HOME, QUALITY AND ACCREDITATION (with a dropdown arrow), and DONATION AND TRANSPLANTATION (with a dropdown arrow). A dropdown menu is open under 'QUALITY AND ACCREDITATION', listing: REVIEWERS TRAINING, EXPERIENCED REVIEWERS, and [WEBINARS]. Below the menu is a banner for 'Weekly webinars - Pillar Ensuring Quality' with the text 'INFO AT WWW.EDUCATION.WMDA.INFO'. Under the banner, the text reads: 'Weekly webinars - Pillar Ensuring Quality', 'Webinars from the WMDA Ensuring Quality Pillar', and 'Lecture weekly on Thursday at 12:00 CET; Duration: 15 minutes'.

Figure 2 WMDA Educational Platform showing Weekly Quality Webinars.

List of topics that we have covered in the Webinars:

Date	Topic	Speaker
May 7	<u>Welcome to webinar series from the WMDA Quality Pillar</u> <u>Slides</u> of the presentation (opt 'download' for a good representation of the slides)	Carolyn Hurley Georgetown University
May 14	<u>What does the guidance associated with each WMDA Standard mean?</u> <u>Slides</u> of the presentation (opt 'download' for a good representation of the slides)	Janet Parks Canadian Blood Services Stem Cell Registry
May 28	<u>Documents helpful to support compliance with 2020 IT Standards</u> <u>Slides</u> of the presentation (opt 'download' for a good representation of the slides)	Ian Britton NHS Blood and Transplant - BBMR
June 4	<u>How to demonstrate compliance with documents written in your native language</u> <u>Slides</u> of the presentation (opt 'download' for a good representation of the slides)	Irene Andersen Norwegian Bone Marrow Donor Registry
June 11	<u>Accreditation challenges of hosting international donor centres</u> <u>Slides</u> to the presentation (opt 'download' for a good representation of the slides)	Carolyn Hurley Georgetown University
June 18	<u>Scoring on-site situations during a review—S(P)EAR reporting and SLAs</u> <u>Slides</u> to the presentation (opt 'download' for a good representation of the slides)	Pam Robinett - NMDP-BeTheMatch Felix Bussmann - Swiss Stem Cell Registry
June 25	<u>Internal self-evaluations –what reviewers expect to see</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Ingrid Tistl ZKRD - Zentrales Knochenmarkspender-Register Deutschland
July 2	<u>Auditing affiliated collection centres</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Nicoletta Sacchi Italian Bone Marrow Donor Registry
Sep 10	<u>The new WMDA KPIs</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Salmah Ahmed Anthony Nolan London
Sept 17	<u>Scoring on-site situations during a review—laboratory accreditation and IT security</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Terry Schlapphoff, SABMR Garth Healey, ABMDR
Sept 24	<u>Applying for WMDA accreditation while maintaining NetCord/FACT accreditation</u>	Dena Mercer

Date	Topic	Speaker
	<u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Canadian Blood Services Stem Cell Registry
Oct 1	<u>Problem management</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Sigal Manor Ezer Mizion
Oct 8	<u>Scoring on-site situations during a review—informing donors and labelling</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Janet Parks/Ingrid Tistl Canadian Blood Services Stem Cell Registry / ZKRD
Oct 15	<u>Auditing affiliated donor centres</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Maren Weber DKMS
Oct 22	<u>WMDA consultation hour for registries preparing for WMDA qualification</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Carolyn Hurley Georgetown University
Oct 29	<u>Risk management</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Sigal Manor Ezer Mizion
Nov 5	<u>Auditing affiliated transplant centres</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Hirasine Sngomona Anthony Nolan
Nov 12	<u>The advantages of being a WMDA reviewer</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Marie Kurikova Czech Stem Cells Registry Prague (CSCR)
Nov 19	<u>Auditing hematopoietic stem cell couriers</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Susie Joron Hema-Quebec Stem Cell Donor Registry
Nov 26	<u>What does ISO certification mean for WMDA?</u> <u>Slides</u> to the presentation (opt 'download for a good representation of the slides)	Matilde Lartategui WMDA Office



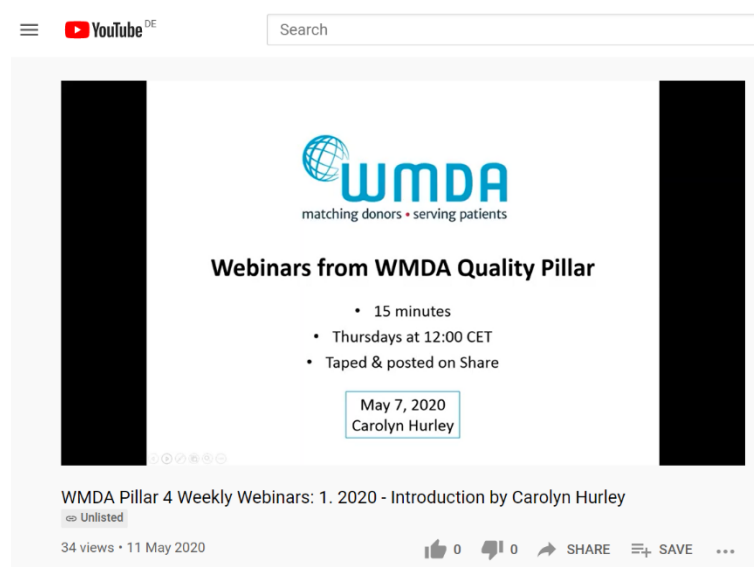
The screenshot shows the WMDA Educational Platform interface. At the top, there is a navigation bar with the WMDA logo and menu items: HOME, QUALITY AND ACCREDITATION, DONATION AND TRANSPLANTATION, and WEBINARS. Below the navigation bar, there is a breadcrumb trail: Dashboard > Courses > Webinars > Quality and accreditation > Weekly webinar Pillar Ensuring Quality. The main content area is titled "Weekly webinars - Pillar Ensuring Quality" and includes three action buttons: "Edit course settings", "Edit category settings", and "Turn editing on".

The "General" section provides details for a lecture webinar on Thursday at 12:00 CET, lasting 15 minutes. It includes a registration link and a list of webinars: "Webinars Quality Pillar Q2 2020 and Webinars Quality Pillar Q3&4 2020". A note states that details of the webinars will be shared in the course, along with slides and a quiz to obtain credits. It also mentions that reviewers will receive one "continuing education credit" per webinar if they pass the quiz. A link is provided to view dates, topics, and speakers of upcoming webinars.

The "2020, May 7" section is titled "WELCOME TO WEBINAR SERIES FROM THE WMDA ENSURING QUALITY PILLAR". It lists the date as 7th May 2020, the subject as "Welcome to webinar series from the WMDA Ensuring Quality Pillar", and the speaker as Carolyn Hurley, Georgetown University. Learning objectives include topics on pandemic impact, applications and self-evaluations, and certification cycles. Below the objectives, there is a list of resources: "Watch here the webinar recording", "Slides webinar 20200507 (pdf)", and "20200705 Webinar test". A note indicates that a minimum score of 100% is required to pass the test and receive 1 credit, with 3 attempts allowed.

The "2020, May 14" section is titled "WHAT DOES THE GUIDANCE ASSOCIATED WITH EACH WMDA STANDARD MEAN?". It lists the date as 14th May 2020, the subject as "What does the guidance associated with each WMDA Standard mean?", and the speaker as Janet Paris, Canadian Blood Services Stem Cell Registry.

Figure 3 WMDA Educational Platform showing access to recording, slides and test for each Webinar.



The screenshot shows a YouTube video player interface. The video title is "WMDA Pillar 4 Weekly Webinars: 1. 2020 - Introduction by Carolyn Hurley". The video content displays the WMDA logo and the text "matching donors • serving patients". Below the logo, the title "Webinars from WMDA Quality Pillar" is shown, followed by a list of details: "15 minutes", "Thursdays at 12:00 CET", and "Taped & posted on Share". A date and speaker box indicates "May 7, 2020" and "Carolyn Hurley". The video player shows 34 views and a date of 11 May 2020. The interface includes standard YouTube controls like like, dislike, share, and save.

Figure 4 WMDA YouTube channel- view of the Welcome Webinar.

Impact of the Webinars Programme:

Lecturers:

WMDA has had the honour of having lecturers who are best known authorities in the field of bone marrow transplantation from twelve different countries around the world. This is a great example of how WMDA is committed to its principles of promoting global collaboration and the sharing of best practices between its members for the benefit of stem cell donors and patients.

This global collaboration is particularly important for emerging registries, small registries or registries with less resources.

Average participants/webinar: 23

View of recordings: average of 20 views.

Survey about Webinars 2020 (See Annex X for report)

100% of respondents would like that the Webinars will continue in 2021.

100% of respondents agreed that the topics were interesting and useful.

Plans for 2021:

Given the success of Quality Webinars, WMDA wants to maintain this Programme reconsidering the following aspects:

- Frequency: 64.3% of respondents to the survey prefers to have the Webinars with less frequency (in 2020, the Webinars took place once a week).
- Enhance interaction: Add more sessions for consultation and open discussions about a specific topic.

IV. Support to registries preparing for Accreditation:

a. WMDA support to apply for Accreditation

Justification: The results from 2019 surveys to registries who have had an accreditation process during that year shown that an improvement was needed to:

- **Promote and encourage a climate of closeness and confidence for those registries in the process of Certification/Qualification/Accreditation, and especially for those who are working on the preparation of first time Certification and Qualification.**
- **Improve the response time.**

During 2020, WMDA has made an effort to provide support to registries in all stages of the Accreditation process.

WMDA has in place the following support channels:

- General email account: mail@wmda.info
- Accreditation email account: accreditation@wmda.info
- WMDA CEO and Accreditation coordination email account
- General WMDA phone
- On-line meeting with specific registries

WMDA has held on-line meetings with the following registries:

Registry	Status
China Marrow Donor Program	Applying for Qualification
Bone Marrow and Cord Blood Bank Registry Hadassah University Hospital	Applying for Accreditation
Dirección General de Donaciones, Transplantes y Banco de Sangre – Ministerio de Salud	Preparing for Qualification
Argentine HSC Donors Registry	Preparing for Qualification
Irish Unrelated Bone Marrow Registry	Applying for Accreditation
DKMS UK	Applying for Qualification

As part of our commitment with closeness and confidence, and thanks to the WMDA multicultural team, some parts of the communications/meeting have taken place in the native language of the registry.

Unfortunately, at the time of writing this document, we do not have yet the results from the WMDA 2020 survey but given the congratulatory messages WMDA has received from registries, we expect a significant improvement in our Key Performance Indicators for this service.

b. "Ask WMDA" session during WMDA Virtual meeting 2020

Justification: WMDA has been forced, as many organizations, to cancel face to face meetings during the COVID-19 pandemic. Our aims, from the beginning of this unprecedented circumstances, have been to keep the contact with WMDA community. For that reason, we switched our annual meeting that was going to take place in Quebec, Canada, to a Virtual meeting. WMDA also wants to maintain interaction between different organizations during this virtual meeting. Therefore, we held a session to answer questions from registries. Questions from one registry might be helpful for other registries.

Organization of the session:

During this session the following members of WMDA have been available for questions:

- Carolyn Hurley: Chair of Accreditation Steering Committee
- Felix Bussmann: Chair of Accreditation Committee and member of Accreditation Steering Committee
- Lydia Foeken: WMDA CEO
- Matilde Lartategui: WMDA Accreditation coordinator

"Ask WMDA Accreditation"



WMDA Virtual Meetings June 2020
Created by Martine Schuit, last modified by Lydia Foeken on Jun 26, 2020

Find your local time via this website: https://www.timeanddate.com/worldclock/converter.html?iso=20200615T100000&p1=tz_cest

Pillar 1: Search, Match & Connect	Pillar 2: Global Development	Pillar 3: Donor Care	Pillar 4: Quality	Foundation
June 22	June 23	June 24	June 25	June 26
Newcomers coffee: Your first time at WMDA? Start the conference with a new set of friends to make you feel at home right away! Link to recording Link to slides	GEMS (Group Medium Sized Registries) Link to recording Link to slides		Ask WMDA: Is it a challenge to prepare your application for Certification, Qualification or Accreditation? Our accreditation coordinator welcomes you to address all your questions. Link to the recording Slides of the meeting	Ask WMDA: WMDA staff members are ready to welcome you and answer your questions about WMDA. Link to the recording
			Weekly 15-minute webinar Pillar 4: Internal self-evaluations –what reviewers expect to see - by Ingrid Tistl Link to recording Slides of the meeting	
EMDIS User Group & Technical Group Link to recording Link to slides	Global Development Board Committee: registry and cord blood bank challenges during COVID-19 <ul style="list-style-type: none"> • 12:30-12:35: Welcome - Dunia Jawdat • 12:35-12:55: COVID-survey - responses of the registries - Ann O'Leary • 12:55-13:25: Cryopreservation - future or not - the registry 	SEAR Annual Report 2019 - lessons learnt Thilo Mengling and Mirjam Fechter will provide an update and share the results and takeaways from the SEAR Annual Report 2019. Link to recording Link to slides	Quality Pillar - quality in registry operations <ul style="list-style-type: none"> • 12:30-12:35: Welcome - Nicoletta Sacchi • 12:35-12:50: Standards Committee - Dena Mercer <ul style="list-style-type: none"> • WMDA Standards 2020 • Crosswalk NetCord-FACT Standards and WMDA Standards • Cycle for new version 	WMDA General Membership Meeting Agenda Minutes of the last meeting Link to the recording Slides of the meeting WMDA award ceremony Accreditation award ceremony Honorary membership



Figure 5 Recording of “Ask WMDA Accreditation” session

We have received questions from the following organizations:

Organization	Accreditation Status
Dirección General de Donaciones, Trasplantes y Banco de Sangre - Ministerio de Salud (Peru)	None
Fundación de Beneficencia Pública DKMS by intermediary of DKMS Registry (Chile)	None
China Marrow Donor Program	Applying for Qualification
Danish Stem Cell Donors - East (DSDE)	None
Armenian Bone Marrow Donor Registry Charitable Trust	None
Thai National Stem Cell Donor Registry	Qualified D since 2018
REDOME - Registro Nacional de Doadores Voluntarios de Medula Ossea (Brasil)	Qualified D/C since 2017
Irish Unrelated Bone Marrow Registry	Accredited D since 2016
Caribbean Bone Marrow Registry	None
DKMS BMST Foundation India	None
South African Bone Marrow Registry	Accredited D since 2018
Welsh Bone Marrow Donor Registry	Accredited D since 2016
National Registry of Hematopoietic Stem Cells Voluntary Donors (Romania)	None
Tobias Registry	Accredited D/C since 2019

Three out of seven organizations that at the moment of the WMDA Virtual Meeting (June 2020) were not yet Certified or Qualified, are now in the process to obtain WMDA Certification/Qualification.

c. Asia-Pacific conference

Justification:

WMDA has 69 organisation members (ranging from donor registries, cord blood banks to donor registries with cord blood units) in Asia-Pacific. Only 8 of these organizations are WMDA Qualified or Accredited.

To promote WMDA Accreditation Programme, our Association has participated in the 25th Congress of Asia Pacific Blood and Marrow Transplantation Group



The screenshot shows the website for the 25th Congress of Asia Pacific Blood and Marrow Transplantation Group (APBMT-2020) Virtual Conference. The page features a navigation menu with links for HOME, ABOUT, ABSTRACT, SPEAKERS, SCIENTIFIC PROGRAM, REGISTRATION, and CONTACT US. The main content area is a large banner with a dark red background and white text. The banner text reads: "25th Congress of Asia Pacific Blood and Marrow Transplantation Group", "APBMT 2020 - VIRTUAL", "October 09 - 11, 2020", and "The APBMT and the ISBMT have together decided to hold the 25th Annual Meeting of the APBMT as a Virtual Conference." The logos for APBMT and ISBMT are visible in the top right corner of the banner.

The Asia-Pacific Blood and Marrow Transplantation Group (APBMT) was initiated by transplant physicians from Australia, China, Hong Kong, India, Japan, Republic of Korea, Malaysia and Taiwan in 1990 to share the information regarding hematopoietic stem cell transplantation (HSCT) and promote collaborative basic and clinical studies.

As a first result of this conference, Jeevan Stem Cell Foundation, a Cord Blood Bank from India has shown its interest to apply for WMDA Certification/Qualification in 2021. They contacted the WMDA on more information. Jeevan is one of the six registries in India. They are already accredited by the European Federation of Immunogenetics (EFI) and looking forward to meeting the next step in 2021.

d. Project groups

WMDA has different project groups that provide guidance to registries in the implementation of WMDA Standards through the adoption of best practices.

i. Crosscheck with Net-Cord FACT Standards

WMDA 2020 Standards contain requirements for Donor Registries and Cord Blood Banks.

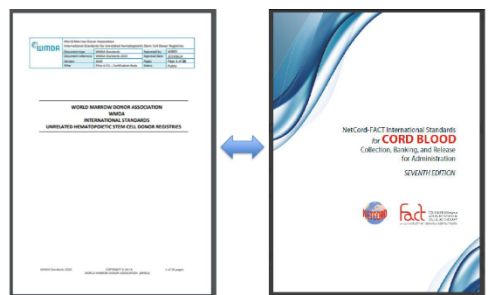
FACT – Foundation for the Accreditation of Cellular Therapy at the University of Nebraska Medical Center. Founded in 1996, FACT establishes **standards for high quality medical and laboratory practice in cellular therapies**. FACT is a non-profit corporation co-founded by the International Society for Cell and Gene Therapy (ISCT) and the American Society for Transplantation and Cellular Therapy (ASTCT) for the purposes of voluntary inspection and accreditation in the field of cellular therapy.

Over 90% of all eligible US facilities and programs are FACT accredited.

NetCord- FACT accreditation programme is internationally accepted.

Justification: Requirements for Cord Blood Banks in WMDA 2020 Standards overlap with some of the requirements in the NetCord-FACT Standards.

The aim of this project group is to perform a cross walk between WMDA and NetCord-FACT Standards. When an organization that has a Cord Blood Bank Accredited by NetCord-FACT applies to WMDA Accreditation, they will need to submit an abbreviated application. The abbreviated application will include the WMDA Standards that are not covered by NetCord-FACT standards. To complete the application, the organization will need to provide a copy of the accreditation by NetCord-FACT.



There are **41** WMDA Standards not covered by NetCord-FACT Standards:

Section	Title	# of Standards not covered by NetCord-FACT
1	General	7
2	General organization of the registry	4 (2 new)
3	Donor recruitment, consenting, screening and testing of donors	Not applicable
4	Umbilical cord blood and maternal donor recruitment, consenting, screening, testing and review/release of cord blood units	1
5	Information technology and information management	15 (8 new)
6	Facilitation of search requests	2
7	Second and subsequent donations of HSC and/or cell products for the same patient	Not applicable
8	Collection, processing and transport of hematopoietic stem cells	No gaps
9	Follow-up of patient and donor	No gaps
10	Financial and legal liabilities	12 (not covered by NetCord-FACT)

According to this crosscheck, WMDA is preparing a specification for those organizations that wish to apply for WMDA Accreditation and are already NetCord-FACT Accredited. Once the specification is approved by WMDA Board, WMDA will incorporate it to its Accreditation Programme.

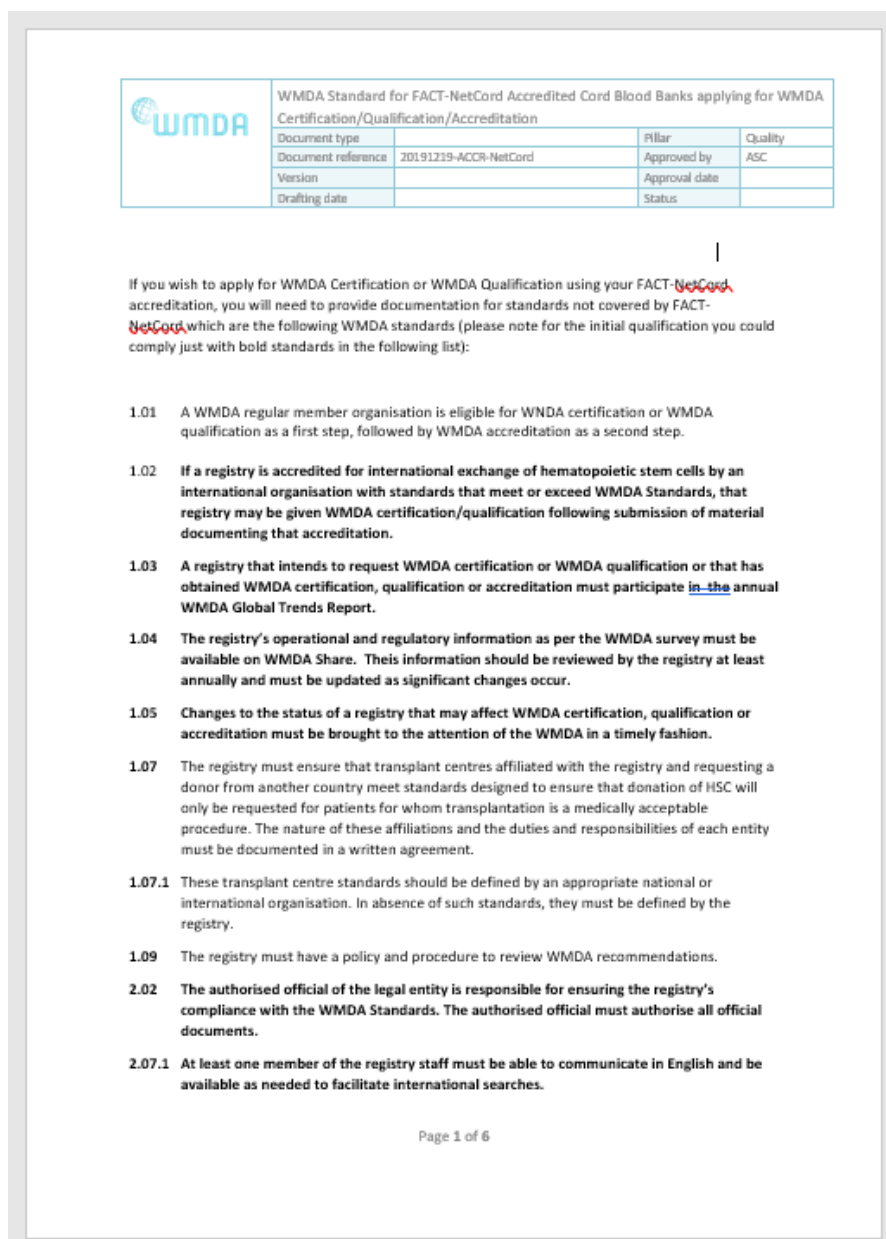


Figure 6 Final draft of WMDA Specification for organizations NetCord-FACT accredited applying for WMDA Certification/Qualification/Accreditation.

ii. Report registry to registry

Justification: There are some WMDA Standards (standards 8.09, 8.10, 8.10.1, 9.03, 9.04 and 9.05) that require a standardized procedure/policy for problem management and its reporting. This procedure/policy should describe how problems are reported from one registry to other registries.

Project: Problem management

Created by Paulien Kort, last modified by Marijke Larraeque on Sep 30, 2020

Summary

Project details:

Project group: Best Practices for Problem Management

Project group chair: [@Sigal Manor](#)

Project group members: Group: not? (List of members with blurred names)

Project office supporter: [@Lydia Poeken](#)

Project description: Develop educational resources (such as case studies, educational presentations, best practices) to assist registries in implementation and/or improvement of their processes to identify, capture, investigate and resolve quality-related problems.
*Resources to build upon Chapter 6-Problem Management of the WMDA Quality Manual Templates.

Working space

Click on the button to go to the **restricted working space**, this space is **only accessible for project members**.

[Project Working space](#)

Do you want to become a project group member?

Send an email to share@wmda.info or to the project chair.

Figure 7 WMDA confluence tool (WMDA Share) for the Project group “Problem management”.

Note: To comply with GDPR, personal data from the group members have been blurred.

In July 2020, the Problem management group published the final draft of the form. The document was open for comments and as a result some modifications were done.

Figure 8 F-WG-PM-001
 Notification and request for information regarding problem between registries V0 202009:

WMDA			
Document type	Form-Notification	WG/Committee	Board
Document reference	F-WG-PM-001	Approval date	20200915
Version	0	Pages	Page 3 of 2
Pillar	Pillar 4-EQ – Certification Body	Status	Confidential

Registry to Registry problem management communication
 Notification and request for information regarding a problem arising

Purpose:
 The purpose of this form is to notify the Receiving Registry (registry that receives the report) of an incident /problem /deviation /non-conformity that has arisen at the Reporting Registry (registry that initiates the report) and affects the Receiving Registry or vice versa. Full response of the Receiving Registry and any further communications should be given via email correspondence and reasonably be expected within 4-6 weeks of the notification.

How to complete each stage:

- Reporting Registry: Provide relevant contact details of your Quality Manager or person to whom the Receiving Registry should send information / investigation report.
- Receiving Registry: Indicate name and ION of the Receiving Registry.
- Problem Summary: Give a summary of the problem that has occurred, product or process affected.
- Immediate actions taken by the Reporting Registry: State any immediate actions you have taken that should be notified to the Receiving Registry.
- Further information: Use this space to request any further information that is not possible on the rest of the form. Indicate date by which the Receiving Registry should send its initial acknowledgment of the report (within 1 week).

1. Reporting Registry (registry that initiates the report):

Registry name: [blurred]

ION number: [blurred]

Name of person completing the notification: [blurred]

Job title: [blurred]

Phone: [blurred]

Email: [blurred]

Date of notification form completion: YYYY/MM/DD [blurred]

2. Receiving Registry (registry that receives the report):

Registry name: [blurred]

ION number: [blurred]

3. Problem Summary

Date of incident/problem occurrence: YYYY/MM/DD [blurred]

Date incident/problem detected: YYYY/MM/DD [blurred]

Indicate at which stage the incident/problem occurred: Search Typing VT WU Transport

Product (if relevant): pssc BM DU CBU

GRD: [blurred]

Patient ID (if relevant): [blurred]

Date of collection (if relevant): [blurred]

Collection Centre (if relevant): [blurred]

Transplant Centre: [blurred]

Other parties involved (if relevant): [blurred]

Other products concerned (if relevant): [blurred]

WMDA			
Document type	Form-Notification	WG/Committee	Board
Document reference	F-WG-PM-001	Approval date	20200915
Version	0	Pages	Page 2 of 2
Pillar	Pillar 4-EQ – Certification Body	Status	Confidential

Details of the incident/problem:

[blurred]

Who originally reported the problem?

Transplant Centre
 Collection centre
 Courier
 Laboratory
 Registry
 Other: [blurred]

Is the problem to be reported to WMDA?

No
 Intends to report
 Yes, S(P)EAR reference / Date of report: [blurred]

Is the problem to be / has been reported to another authority (e.g. competent / regulatory authority)?

No
 Intends to report
 Yes, name of authority: [blurred]
 Relevant reference/ Date of report: [blurred]

4. Immediate actions taken by the Reporting Registry

Are there immediate actions taken by the reporting registry? No Yes

If yes, please indicate below:
 [blurred]

5. Further information:

For incident investigation please assist with the following questions:

Please provide your acknowledgment of report recipient within 1 week by: YYYY/MM/DD [blurred]

Any further information:
 [blurred]

In September 2020, the final document was approved by WMDA Board and published in WMDA Share tool in **“WMDA Scientific Publications and Recommendations”**:

WMDA Scientific Publications and Recommendations

Created by Riny Heijndael, last modified by Matilde Lartategui on Oct 06, 2020

This webpage is based on the chapters of the WMDA handbook with the title 'A Gift for Life'

More information about the WMDA handbook:

- for non-members.
- for members.

Table of contents

- Recruitment and evaluation of volunteer donors
- Donor search request
- Collection and transportation
- Post-donation
- Cord blood banking
- Information technology and data management
- Archived Publications

WMDA Scientific Publications and Recommendations by subject

General Organisation of a Registry

WMDA Standard	Title and link to document	Explanation	Status
1.03	Global Trends Report of WMDA	Annual publication presenting the unrelated stem cell donor activity on a global scale.	Current (2019)
10.11	Donor and liability of donor registries, donor centres and collection centres-recommendations <i>Bone Marrow Transplantation (2004), 33: 467-470</i>	The paper outlines the ethical aspects of liability of involved parties and the need for insurance coverage. The article has shortcoming with the respect to legal advices.	Under review (2020)
2.10	WMDA Quality Manual	A template for a quality manual for registries and cord blood banks.	Current(2020)
2.10.1	Notification and request for information regarding problems between registries	A template for registry to registry problem management communication. Notification and request for information regarding a problem arising	Current (2020)

V. ISO 17065 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 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.

WMDA is a **Certification Body** that certifies registries which comply with [WMDA Standards](#).

ISO/IEC 17065:2012- specifies requirements, the observance of which is intended to ensure that certification bodies operate certification schemes in a **competent, consistent and impartial manner**, thereby facilitating the recognition of such bodies and the acceptance of certified services on a national and international basis and so furthering international trade.

WMDA is studying the feasibility of ISO 17065 Accreditation for the WMDA Accreditation Programme.

All the details and the progress made can be found in document [D4.3 Progress report on if it is feasible that WMDA will apply for ISO 17065 Accreditation](#)

Achievements

Qualitative and quantitative achievements.

Quantitative achievements in number of organizations Certified/Qualified or Accredited.

WMDA has listed 134 sources of donors and cord blood units from 98 different organizations (IONs) in 54 different countries.

At the time of writing this report, 84% of the donors and cord blood units are from WMDA Qualified or Accredited organizations.

2020	
Total number of Donors and Cord blood units	38,296,985 from 134 sources
Total number of Donors and Cord blood units from WMDA Qualified or Accredited organizations	32,186,426 from 55 sources

During 2020 we have incorporated:

Number of Donors and Cord blood units incorporated in 2020	993,145 from 1 source
------------------------------------------------------------	------------------------------

NOTE: These 993,145 Donors and Cord blood units are included in the Total number of Donors and Cord Blood units given in Table 1.

In the process to be incorporated:

From organizations that have already started the process to apply for WMDA Certification/Qualification or Accreditation:

Number of Donors and Cord blood units that will be incorporated when they successfully finalize the process	2,664,816 from 7 sources
-------------------------------------------------------------------------------------------------------------	---------------------------------

Qualitative achievements to be quantified after WMDA 2020 surveys

To measure all the improvements, we have done during 2020, WMDA has deployed several surveys. These surveys give WMDA a quantitative measurement for the qualitative aspects of the work done. These surveys will also provide WMDA with new inputs for its commitment to continuous improvement.

WMDA expects this information to be available for analysis during the first quarter of 2021. At that moment, we will need to consider the big disruption caused by the COVID-19 pandemic, and the impact it might have had on the WMDA data and results.

The pandemic caused that healthcare professionals were less available and not able to work on quality management in their organisation (by preparing an application for WMDA qualification) or performing a review for an applicant organisation.