

D5.1 Report on finding from engagement with EU Member States and recommendations from enhancement of the WMDA Accreditation Programme

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WMDA

Accredited

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Abbreviations

BCAS	=	Board Committee Accreditation (Steering)
BCAC	=	Board Committee Accreditation
RFI	=	Request For Information
SCCP	=	Search Coordinator Certificate Programme
WMDA	=	World Marrow Donor Association

1. Introduction to the WMDA Accreditation Programme

One of the WMDA pillars is Ensuring Quality. To this end, WMDA set up an Accreditation Programme for promoting product quality and global collaboration through Accreditation and Standardisation. The most important goal is that accreditation provides assurance that donors are eligible and that their care is protected. This also leads to better patient care. The WMDA Standards and Accreditation Programme are seen as the global standard by members, national and international authorities, and is reflected in regulatory frameworks. The accreditation process provides opportunities for evaluation and feedback and stimulates continuous improvement and collaboration. All WMDA members receive the right support and tools to guide them through the WMDA qualification and accreditation process. In addition, as a result of the WMDA Search Coordinator Certificate Programme (SCCP) there are more Search Coordinators certified to practice according to the agreed standards.

1.1 WMDA Accreditation programme objectives

The overall objectives of the WMDA accreditation programme are as follows:

- To promote harmony between worldwide progenitor cell donor registries and cord blood banks and encourage uniformity of the best practice based on WMDA Standards.
- To encourage registries to seek and empower them to achieve WMDA accreditation through the adoption of and adherence to WMDA Standards.
- To conduct and administer the WMDA accreditation system.

1.2 WMDA Standards

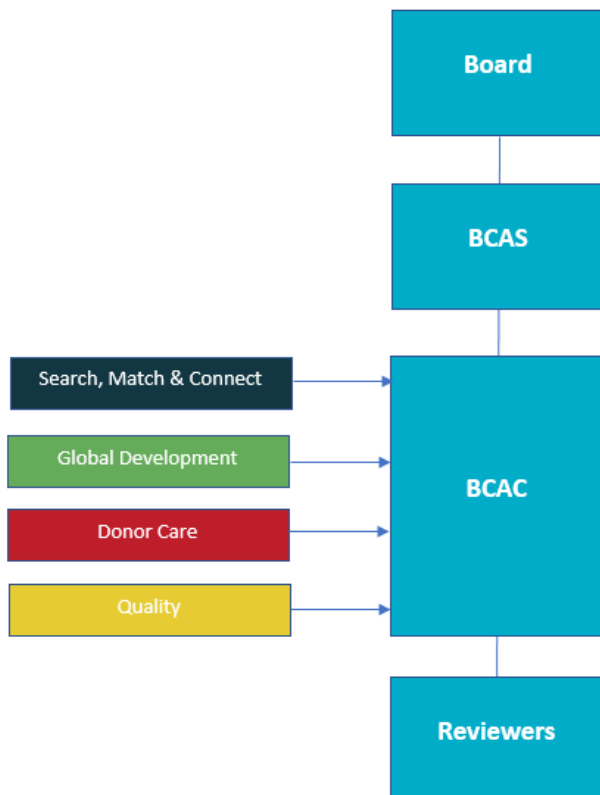
WMDA member organisations demonstrate their commitment to comply with WMDA Standards through this program. The Standards can be found on the [WMDA website](#). The current version of the WMDA Standards is valid from January 1, 2017 till December 31, 2019. Currently, the Standards are under revision to work towards new WMDA Standards in 2020. The timeline is as follows:

Phase	Date
Invitation to submit comments	January 2018
Possibility to submit comments	till 1 June 2018
Consultation WMDA membership at WMDA Fall Meeting and on WMDA website	November 2018
Public consultation WMDA Standards	January 2019-March 2019
Final review WMDA Standards Subcommittee	March 2019
WMDA Board approval on the new version of the WMDA Standards	June 2019
Publication of the WMDA Standards effective on January 1, 2020	July 1, 2019

1.3 WMDA Accreditation Structure

The WMDA Board is responsible for the overall accreditation programme. The WMDA Board has delegated the strategic development and the operation of the accreditation programme to the Board Committee Accreditation (Steering) (BCAS) and the Board Committee Accreditation (BCAC). They oversee the reviewers (Figure 1).

Figure 1. WMDA Accreditation Structure



I. Board Committee Accreditation (Steering)(BCAS)

The BCAS develops, oversees, implements and coordinates the WMDA accreditation programme. The work is divided among five members. Members are identified and appointed by the WMDA Board. The BCAS reports to the WMDA Board.

Operation of the accreditation programme

1. Develop and coordinate the programme during monthly meetings of the BCAS;
2. Communicate and consult with the membership on accreditation issues during WMDA meetings;
3. Announce newly qualified and accredited programs during the WMDA general membership meeting;
4. Advise the WMDA Board on issues related to accreditation

Support applicants, qualified and accredited organisations

1. Ensure reviews are timely, fair, consistent, and unbiased; resolve significant issues arising during reviews;
2. Monitor review of applications;
3. Edit written requests and reports for clarity and consistency;
4. Ensure biennial self-evaluations from qualified/accredited registries are performed and monitored;
5. Provide educational programs / material for applicant organisations;
6. Identify and resolve issues related to potential loss of WMDA qualification or accreditation;

Support reviewers

1. Identify potential reviewers;
2. Provide educational programs / material for reviewers;
3. Assist reviewers in case they need support in their reviews;
4. Monitor reviewer performance to provide feedback

Development of the programme

1. Monitor national / international regulations that might impact WMDA accreditation and implement any necessary changes;
2. Develop, review and revise the program as necessary to maintain consistency with WMDA Standards;
3. Monitor criteria used to evaluate accreditation programmes in general and implement any necessary changes to standardize practice

II. Board Committee Accreditation (BCAC)

The BCAC reviews all written reports prepared by review teams and approves applications for WMDA Qualification or WMDA Accreditation. In addition, the BCAC reviews the biennial self-evaluations submitted by organisations that are WMDA Qualified or WMDA Accredited. The BCAC is composed of WMDA members nominated by Board Committees that represent each of the four WMDA pillars. Each BCAC member brings in expertise in specific areas. The BCAC reports to the BCAS.

1. Meet on regular basis by telephone conference and in-person at WMDA meetings;
2. Oversee reviews and vote on review team recommendations;
3. Review every other year self-evaluations of registries submitted to the WMDA Office;
4. Provide feedback about accreditation policies, operations and procedures

III. Reviewers

WMDA members who are working within or serving as a consultant to a WMDA provisional or regular member registry can apply to become a WMDA reviewer for the accreditation programme. WMDA reviewers participate in reviews (at least 1 review every 2 years) and assist the BCAS with projects. Example of projects include providing guidance to assist registries in understanding how to document compliance with WMDA Standards, developing training modules for reviewers, and workshops for registries.

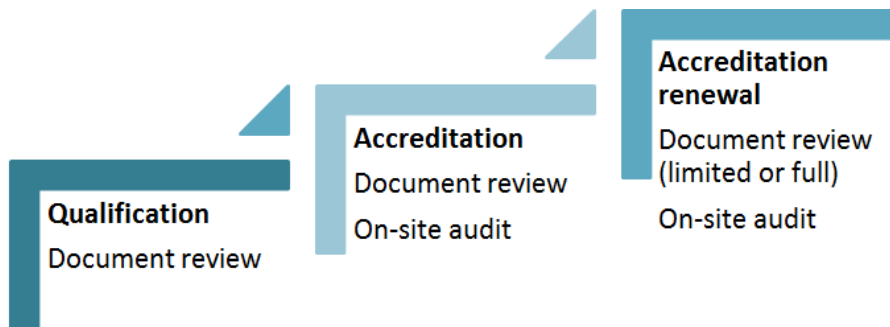
Members of the Board Committee Accreditation (Steering) and Board Committee Accreditation also serve as reviewers.

1.4 WMDA Accreditation Structure

The WMDA Accreditation cycle for registries includes three main phases (Figure 2). It starts with a qualification step. In this phase the registry must submit a stack of documents to show compliance to the WMDA benchmark Standards which will be reviewed by the Accreditation Committee. After qualification, the registry can apply for accreditation. Depending on the degree the registry shows compliance to all WMDA Standards, they can apply for accreditation within two years to maximal 5 years.

For accreditation the registry needs to comply to all WMDA Standards, which the Accreditation Committee will review and subsequently perform an on-site audit. Four years after WMDA accreditation, the registry again must show compliance to several key Standards in a shortened application. Then again, four years later, the registry needs to show compliance to the full package of WMDA Standards. All reaccreditations contain a document review and an on-site audit.

Figure 2. The three phases of the WMDA Accreditation Programme



Registries which have received qualification or accreditation status are required to perform an internal self-evaluation every second year. In fixed format the registry gives information on:

- Significant changes to the registry that have not yet been reported to the WMDA.
- Significant changes to the evaluation table submitted at the last formal review.
- Implementation of new WMDA Standards. How the registry has addressed weaknesses noted in the last external review team report.

The complete accreditation process can be described in 7 steps (Figure 3).

Figure 3. Timeline of the WMDA Accreditation



1. The first step is sending out the Letter of Intent by the registry to show they are ready for submitting their application for qualification or (re)accreditation.
2. The WMDA Coordinator Quality & Accreditation will then start with the preparation. This includes selecting a review team, preparing a restricted page on the WMDA members area website and instruct how and when the registry can start to submit their application for qualification or (re)accreditation.
3. The registry works on the application. This means describe how they comply to the WMDA Standards and uploading the accompanying documents.
4. The registry finishes submitting their application before the deadline set by the WMDA office. For registries that are already qualified and accredited the deadline is half a year before the expiration date of the certificate.
5. The review team will review the documents and if necessary, send a request for more information.
6. If applicable, the Registry replies to the request and sends accompanying documents to be reviewed by the review team.
7. For reaccreditation, the review team will perform an on-site audit.

8. The Qualification / (Re)Accreditation report will be presented to the BCAC who will decide on WMDA certification.
9. The Qualification / (Re)Accreditation report will be finished by WMDA office and the Registry will get the status Qualified or (re)Accredited (Figure 4).

Figure 4. Qualified and Accredited stamps



Table 1 shows the explanation of all the different steps per year for Qualification and (re)Accreditation.

Table 1. Structure of the WMDA Accreditation Procedures

Year -0.5	Application submitted by registry not previously accredited; document review focused on bench mark standards; Accreditation Committee approval within 6 months of application
Year 0	Qualification; certificate awarded for adult volunteers and/or cord blood
Year 2	Qualification; Biennial self-evaluation reviewed Accreditation Committee
Year 4	Qualification; Biennial self-evaluation reviewed Accreditation Committee
Year 4.5	Application for accreditation (comprehensive documentation) submitted; Review and on-site audit
Year 5 Anniversary	Accreditation approved by Accreditation Committee, certificate awarded
Year 7	Accreditation; Biennial self-evaluation reviewed Accreditation Committee
Year 8.5	Application for re-accreditation (shortened documentation) submitted; Review and on-site audit
Year 9 Anniversary	Re-Accreditation
Year 11	Accreditation; Biennial self-evaluation reviewed Accreditation Committee
Year 12.5	Application for re-accreditation (comprehensive documentation) submitted; Review and on-site audit
Year 13 Anniversary	Re-Accreditation

In addition, there are multiple Accreditation programs for Cord Blood and Transplant centres.

The current status of WMDA Member Organisations is shown in Figure 5.

Figure 5. Status of Accreditation, December 2018

Status	Number
% volunteer donors and CBUs in accredited registries	81%
Applications under review for qualification	3
Registries WMDA Qualified	9
* Applications under review for accreditation	1
Registries WMDA Accredited	22
* Applications under review for reaccreditation	0
Letters of intent (registries in progress)	3

2. WMDA Qualification / (Re)Accreditation feedback from Registries

After every Qualification or (Re)Accreditation step, a survey is sent out to ask for feedback on the current Accreditation Process from the relevant applicant organisation (Figure 5). The goals of this is to gain insights from members on the support they require to progress through the Accreditation pathway, to see what works and to find out where there is room for improvement. The recommendations of the registries for the enhancement of the Accreditation Programme will be implemented in 2019, following consultation with the members.

Figure 5. Start of the WMDA Qualification/Accreditation Feedback Survey.



WMDA Qualification/Accreditation Feedback Survey

Feedback from applicant organisation

The purpose of this survey is to provide feedback following the WMDA qualification/(re)accreditation process and to identify potential opportunities for improvement. The comments are confidential and will only be shared with the WMDA office staff and the Accreditation Steering Committee.

WMDA is constantly working to improve the Accreditation Process. The most valuable source of information for that is the feedback we receive from registries who gone through the process themselves. In 2018 nine registries received a WMDA certificate for qualification or (re)accreditation. Eight of them filled in the qualification/(re)accreditation Feedback Survey.

Registry	Status
Swiss Transfusion SRC Ltd. Swiss Blood Stem Cells	Accreditation
Norwegian Bone Marrow Donor Registry	(Re)accreditation
Thai National Stem Cell Donor Registry	Qualification
Cyprus BMDR	(Re)accreditation
Anthony Nolan	(Re)accreditation
Czech National Marrow Donors Registry	(Re)accreditation
France Greffe de Moelle Registry	(Re)accreditation
Australian Bone Marrow Donor Registry	(Re)accreditation

We asked them to rank their satisfaction about all aspects of the program, like the provision of information, coordination by the WMDA office, the work of the reviewers, etc.

In general, the respondents were very satisfied with the program. Some aspects of the program might be considered for improvement:

- The guidance to the WMDA Standards sometimes seems to exceed the Standards.
- It should be made easier to find information on the WMDA website.
- Submitting an application in Share is considered to be a lot of work.
- Coordination of the WMDA office

Most registries feel that the accreditation program did positively affect the operation of the organisation. Working on the submission of an application helped to review the work processes of the registry and contributed to the awareness of daily routines. The unbiased external review provided useful feedback for improvement of processes and documents to be compliant with WMDA Standards.

For those registries considering applying for WMDA qualification, the respondent gave some practical tips:

- Assign one person to supervise/coordinate the process and delegate tasks to a team
- Preparation is key: start preparing early
- Create a time table at the beginning and plan trainings for involved people to inform them of the process
- Make sure the staff has time to work on the application
- Perform a gap analysis on the WMDA standards, as this will give you time to address any shortfalls identified
- Ask for help from other registries that have gone through the process
- Read and understand the guidance. It explains the WMDA Standards and provides detailed information of what should be submitted to comply to the Standards. Do not take the Standards at face value
- Go for it; obtaining your accredited status will improve your performance!

3. WMDA Qualification / (Re)Accreditation feedback from Reviewers

In addition to the registries who receive a survey after the Qualification / Accreditation Process, the reviewers also receive a survey to assess their own review process and the assessment of their fellow WMDA reviewer's performances. This is to investigate how they feel about performing the review. The outcome of this survey will be used to improve the future review training sessions.

Post review assessment of WMDA reviewers performance

The first results are from 16 reviewers (12 experienced and 4 trainees) involved in the review of

Registry	Status
Cyprus Bone Marrow Donor Registry	Accreditation
Norwegian Bone Marrow Donor Registry	Reaccreditation
Marrow Donor Program Registry Belgium	Qualification
Anthony Nolan UK	Reaccreditation
South African Bone Marrow Registry	Accreditation
Czech National Marrow Donors Registry	Reaccreditation
France Greffe de Moelle Registry	Reaccreditation
Australian Bone Marrow Donor Registry	Reaccreditation

All of them indicated they felt that they were adequately trained to perform the review. With one exception they all found they had sufficient time to review the application, even though for some, (much) more time was needed than expected.

The amount of time needed for the review depends on the registry characteristics (like size, professionalism of staff, status of accreditation) but also the experience of the reviewer and the role the reviewer had in the team. The review team consists of a team leader, an experienced reviewer and -if possible- a trainee reviewer.

Team leaders obviously need more time because they are responsible for the coordination of the review and the final report. It is also expected that trainee reviewers need more time than experienced reviewers because they perform a review for the first time. Based on the number of responses (6) and the number of registries involved (3), it is not possible to make any definite comments yet.

The reviewers were asked to assess each other on the following statements: Was the (trainee) reviewer

- Knowledgeable
- Prepared adequately for the review
- Able to identify strengths and weaknesses of the application
- Fair and impartial
- (if on-site audit) professional and positive

All reviewers were positively assessed by their team.

The feedback of the reviewers will be used for the enhancement of the Accreditation Programme in 2019:

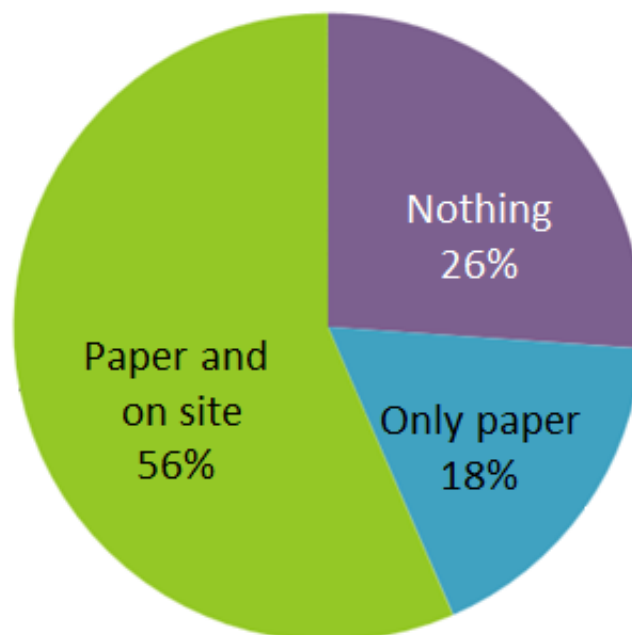
- It was a bit difficult to work with three persons since the work can be done by two reviewers (one talks and the other writes).
- More training on reviews would be helpful before undertaking one review as an experienced reviewer. Need some more familiarization with the standards a process of review.
- Finally, feedback was given on the online application and the on-site checklists.
 - o The IT checklist was missing (in development) and therefore some questions were not asked.
 - o Some files could not be readily reviewed because they were maintained by a donor centre and therefore not available on-site.

In advance to the International Donor Registry Conference in Munich (June 2018) a survey was sent out to all the reviewers to investigate their Education Needs. A total of 23 reviewers filled in this survey.

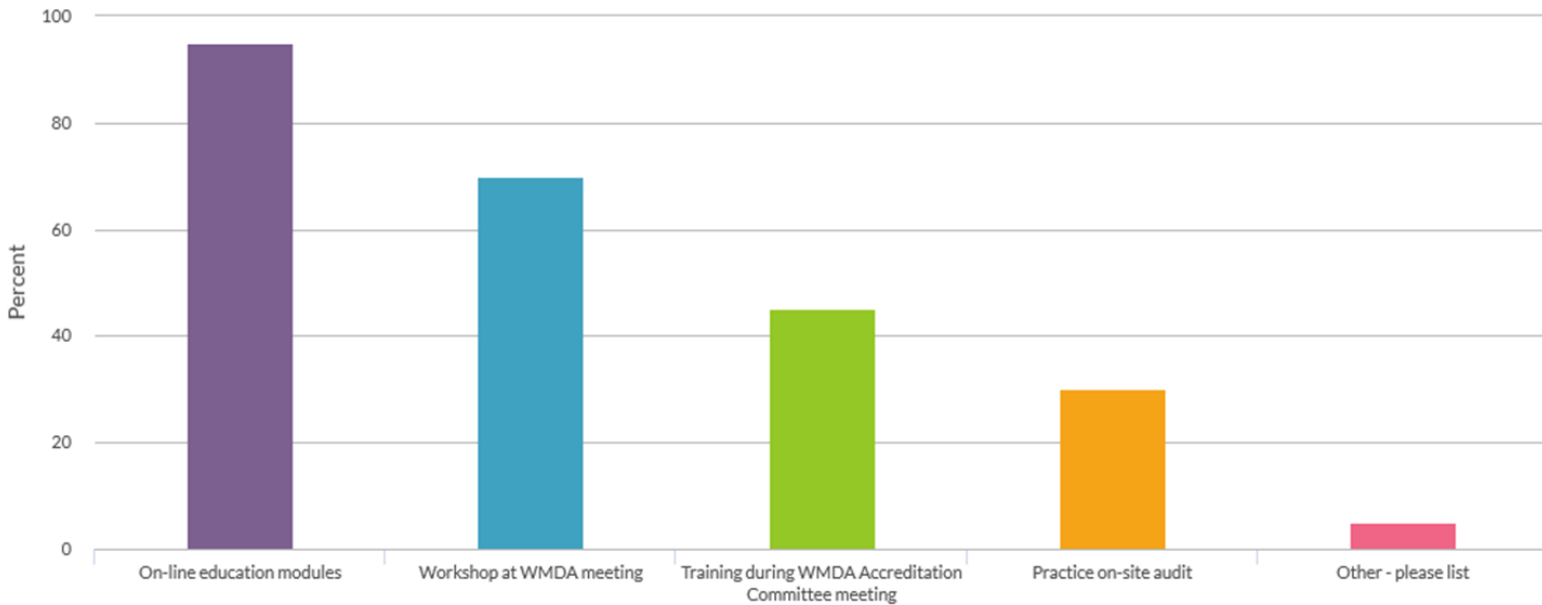
Munich WMDA Meeting June 2018: Reviewer Training Activities Survey

The outcome of this survey was as follows:

Have you participated in the review of a qualification/accreditation application for WMDA?

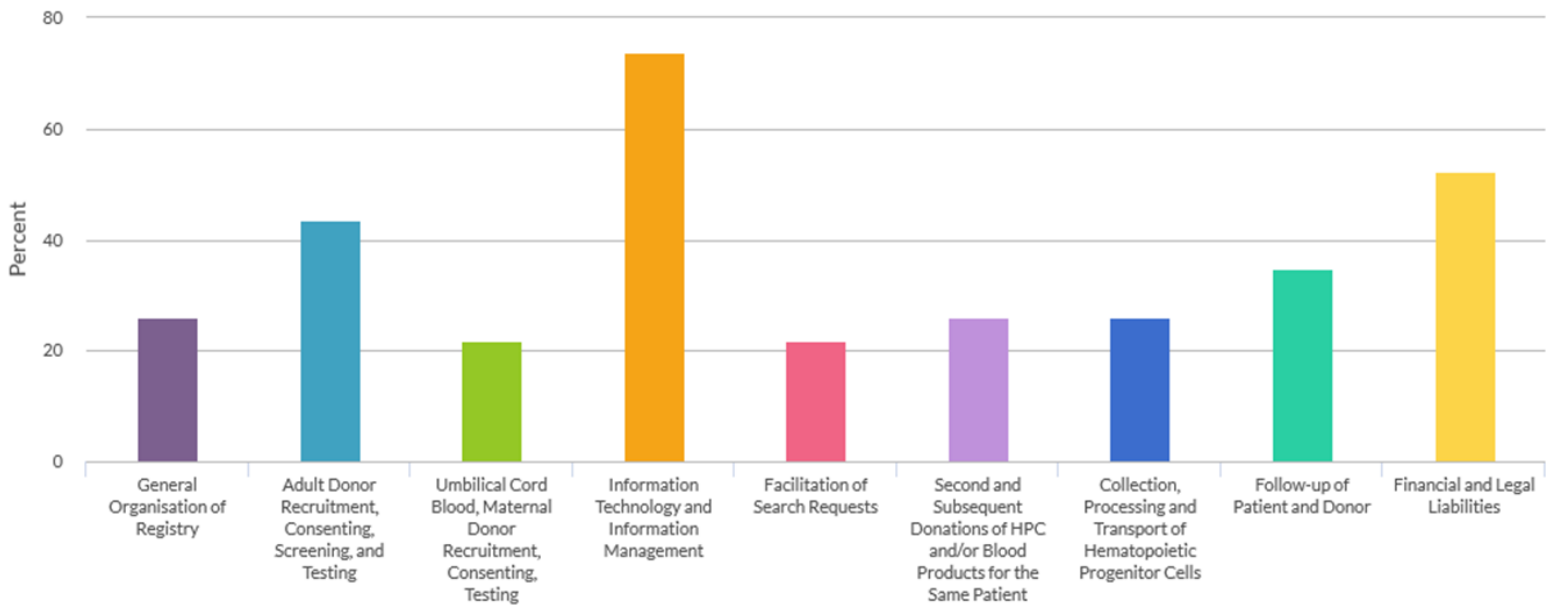


What WMDA reviewer training activities have you participated in? Check all that apply

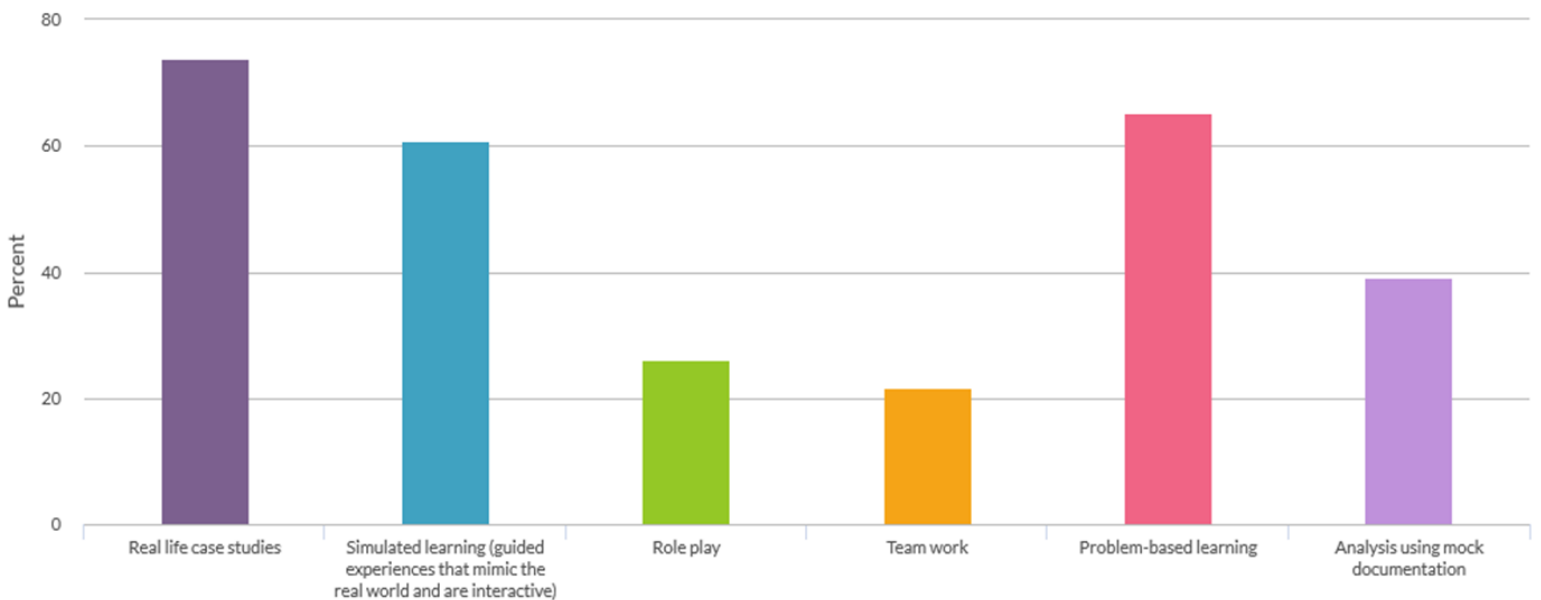


Questions	Answers
<i>Was your on-the-job experience at your registry useful in evaluating an application?</i>	Yes (80% of reviewers who have already participated in a review)
<i>Was your reviewer training through WMDA helpful in evaluating an application?</i>	Yes (60%), but ... “The reviewer training was not so well structured. I do not think the review team leader was aware I was a trainee. This was also before the e-learning program. “Nothing can quite prepare you like being the trainee on a real application”
<i>If you participate in WMDA working groups, has this helped you in evaluating an application?</i>	Yes (75%), but 6 reviewers never participated in a working group and 1 said NO
<i>Has reading WMDA recommendations for best practice helped you in evaluating an application?</i>	Yes (88%), “...the guidance to the standards much more helpful during on site audits”.

What areas of the WMDA Standards do you feel need to be the focus of more training activities?



What kind of learning methodology should be pursued by WMDA to provide enhanced training to reviewers?



Questions	Answer	Response
<i>Do you feel well prepared to participate in an on-site audit?</i>	NO (43%)	<ul style="list-style-type: none"> - No, I have just started the online training. - Not yet finished on-line training (x2). - I have only completed Module 1 and participated in the audit of our own registry. - Doing audits (and mock audits) and seeing how others work helped me the most. - But more from the ~10 years of QM training experience at two registries rather than the training. - Don't work directly for registry. - Not sure. I have participated in on-site audits before new process was implemented.
<i>Do you receive sufficient feedback on your performance during review of an application?</i>	NO (66%)	<ul style="list-style-type: none"> - I would hope if I was doing something wrong or poorly, I would receive some suggestions for improvement.
<i>Do you have any suggestions that will help improve the reviewer training experience?</i>		<ul style="list-style-type: none"> - Make feedback more formalised. - It might be beneficial for review teams to share challenging/unique situations that were encountered during reviews and/or audits, and how they managed these scenarios. This information could serve both as a training supplements for reviewers, and as a reference for future review teams. - I think it is fine that the trainee is the 3rd person on a review.

Additional suggestions for improvement:

1. Give (more) feedback and collect feedback
2. Discuss case reports, problem-based learning, organise workshops on how to check the compliance to a certain standard
3. One of the points of improvement is the lack of reviewers for the WMDA Accreditation Programme. To solve this issue all the Search Coordinators of WMDA were contacted to ask if they were interested in becoming a reviewer. This email was sent out in February this year (Appendix 1). The following events occurred after sending this invitation:

Task	Number of people
Contacted by mail	164
Opened the mail	78
Signed up	21
Met the requirements for becoming a WMDA reviewer	17
Started the review training	13
Obtained the review certificate	1

4. Enhancement of the Accreditation Programme, for 2019

The feedback of the registries and reviewers, described in this report, will be used for the enhancement of the Accreditation Programme in 2019:

4.1 Feedback from registries:

Recommendation	Action	Planning
The guidance to the WMDA Standards sometimes seems to exceed the Standards.	Review of guidance to all WMDA Standards.	December 2018 to February 2019. (see timeline WMDA Standards)
It should be made easier to find information on the WMDA website.	Update WMDA Share to make it more user friendly.	March 2019
Coordination of the WMDA office.	Optimisation of the coordinating and administrative processes of the WMDA office.	January 2019

4.2 Feedback from reviewers

Recommendation / feedback	Action	Planning
It was a bit difficult to work with three persons since the work can be done by two reviewers (one talks and the other writes).	Gather more feedback from Survey "Post review assessment of WMDA reviewer's performance" to evaluate composition of as well as division of tasks within review team.	Last quarter of 2019
More training on reviews would be helpful before undertaking one review as an experienced reviewer. Need some more familiarisation with the standards as process of review.	<ul style="list-style-type: none"> On-line training module for those who didn't attend the accreditation workshop 2018 on scoring on-site situations. Keep track of reviewer performance (on-line training) and attendance to training workshop (during WMDA meetings). 	<ul style="list-style-type: none"> Finished (November 2018) Twice a year (just before a WMDA meeting)
Feedback was given on the online application and the on-site checklists.	<ul style="list-style-type: none"> In the revision of the WMDA Standards - effective from January 2020 – the IT section is extended and completely 	<ul style="list-style-type: none"> June 2019 on-site audit checklist published on WMDA Share. IT checklist to be used in

<ul style="list-style-type: none"> - The IT checklist was missing (in development) and therefore some questions were not asked. - Some files could not be readily reviewed because they were maintained by a donor centre and therefore not available on-site. 	<p>reorganized. The project group working on this section also revised the IT checklist.</p> <ul style="list-style-type: none"> • Yearly evaluation of the on-site checklists: attention for the document “documents available on-site” (to be filled in by registry). 	<p>on-site audits form January 2020</p> <ul style="list-style-type: none"> • Evaluation of on-site checklist by BCAC started October 2018. Finished February 2019.
<p>More focus of training on:</p> <ul style="list-style-type: none"> • Information technology and information management. • Financial and legal liabilities. • Adult Donor recruitment, consenting, screening and testing. • The reviewer training was not so well structured. 	<p>Take feedback into account when the modules of the e-learning are evaluated.</p>	<p>March-May 2019</p>
<p>Learning methodology to provide enhanced training:</p> <ul style="list-style-type: none"> • Real life case studies. • Problem-based learning. • Stimulated learning (guided experiences that mimic the real world and are interactive). • Discuss case reports, problem-based learning, organise workshops on how to check the compliance to a certain standard. 	<ul style="list-style-type: none"> • Develop training exercises covering these 3 elements. • One-day training in Noordwijk, The Netherlands. 	<p>April 2019</p> <p>March 20th, 2019</p>
<p>Suggestions to improve training experience:</p> <ul style="list-style-type: none"> • Make feedback more formalised. • It might be beneficial for review teams to share challenging/unique situations that were encountered during reviews and/or audits, and 	<p>Send out a training update to individual reviewers to inform them about their performances and give them feedback given by review team members (form post feedback survey).</p>	<p>Every two years, starting first quarter of 2019.</p>

how they managed these scenarios. This information could serve both as a training supplements for reviewers, and also as a reference for future review teams.

- I think it is fine that the trainee is the 3rd person on a review.
 - Give (more) feedback.
-

Appendix 1. Invitation to Search Coordinators to become a WMDA Reviewer



Opportunity to become a WMDA reviewer

Dear <<First Name>>,

Your experience as a WMDA-certified search coordinator is valuable. Would you like to share your knowledge, increase your expertise and learn how other organisations have organised their search processes? And would you like to broaden your international experience?



WMDA invites you to become a reviewer for our accreditation programme.

How does it work?

As a WMDA reviewer, you benefit of the chance to look behind the scenes of other organisations. Your participation as a reviewer will enhance your expertise, of which your registry will benefit while preparing an application for WMDA qualification or (re)accreditation itself.

Detailed information available

You will find information about the role of a WMDA reviewer and you can register for the Reviewers Training Programme on the WMDA website:

<https://www.wmda.info/professionals/quality-and-accreditation/learn-about-quality/>.



"The accreditation process is an exciting challenge, new questions arise at every moment. We never get bored!"

Emilie Brondani, experienced WMDA reviewer

France Greffe de Moelle, France

Inspired?

Talk about it with your colleagues or registry manager.

You can contact Jantine Liesting (+31 88 505 7906 or jantine.liesting@wmda.info), if you need more details about being a reviewer.

Interested to apply?

Fill in the [form](#) and check the option that you would like to become a WMDA reviewer. You will start with an online training course and participate as a trainee in a review. This will make you feel comfortable and well trained once you are going on an onsite inspection in an organisation in another part of the world.



If you have further questions, or would like to connect with an experienced or trainee reviewer, please send an e-mail to accreditation@wmda.info .

Kind regards,

Jantine Liesting

Coordinator Quality & Accreditation

On behalf of the WMDA Accreditation Steering Committee



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