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D4.1 Launch an online reporting system to report Serious (Product) Events and Adverse Reactions - S(P)EARs - (unrelated donors)

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1. Background

Annually more than 20,000 volunteer unrelated hematopoietic stem cell donations are performed worldwide for patients with life-threatening diseases such as acute leukaemia. Donor safety issues and donor protection is one of the top priorities for the international cooperation of unrelated stem cell donor registries represented by the World Marrow Donor Association (WMDA). The WMDA promotes global collaboration and the sharing of best practices for the benefit of stem cell donors and transplant patients. In the past 16 years, the WMDA reporting system used to collect Serious (Product) Events and Adverse Reactions - S(P)EAR – has evolved in several steps into the recently developed form.

WMDA aims to become the global leading online platform for stem cell donor organisations to report their S(P)EARs from both unrelated and family donors.

This user-friendly system:

- Allows communication with experts per individual reports
- Enables reporters to keep track of all of their own reports in a dashboard.
- Enables reporters to do their own statistics
- Provides the users the possibility of data-base queries
- Can be used by different organisations working on the same reports
- Can be disseminated to organisations that operate outside the WMDA such as transplant centres caring for related (family) donors.
- Is developed according to the current privacy rules and regulations (EU GDPR)

This Deliverable *D4.1 Launch an online reporting system to report Serious (Product) Events and Adverse Reactions - S(P)EARs - (unrelated donors)* describes the website hosted online that enables the rapid, accurate and complete reporting of S(P)EARs affecting unrelated stem cell donors by member registries. This will provide information and insight that can be used to identify trends and patterns, which can be used to inform improvements to strategies, policy and practice that serve to minimise the occurrence of serious adverse events. The user guide for this online reporting tool is described in D4.2 User guide for new serious adverse events and reactions reporting system (2019). Both Deliverables D4.1 and D4.2 are part of the 2019 work programme of the World Marrow Donor Association (WMDA) for the EU Third Health Programme (2014-2020).

[Online reporting system for S\(P\)EARs](#)

2. Launch of the online reporting system

The timeline for 2019 looked as followed:



WMDA has developed the new online reporting system using a Knack environment based on requirements of experienced reporters and reviewers. At the beginning of 2019, the system was tested by a small group of 3 people from the S(P)EAR Committee. Following these tests, the software developer integrated the suggested changes. The new system was then tested by a larger group, consisting of WMDA members, in March/April. As part of the WMDA meeting in Noordwijk (The Netherlands), a dedicated workshop was organised to provide feedback on the online reporting system and to align the expectation with the actual users of the new S(P)EAR system. In addition, the pre-launch of the system was finalised and eventually the launch of the new online reporting system happened on 1 July 2019, only one month later than scheduled. This was due to last-minute improvements of the system. During this time, S(P)EAR reports from 2018 and early 2019 were added to the system, for both testing and completion.

On 1 July 2019, WMDA launched the robust online reporting system of S(P)EARs in order to provide accurate information about potential risks to donors. The collected data about serious adverse events and reactions occurring in donors is analysed by worldwide experts of the S(P)EAR Committee and used to provide statistics on the type of reports being submitted and put in place best practices on what can be done to mitigate such effects and occurrences. Via annual S(P)EAR reports the results will be disseminated worldwide.

In October 2019, the chair of the S(P)EAR Committee educated the WMDA members during an Education Webinar for S(P)EAR reporters where the purpose of the system was explained and how the system works. Part of the webinar included practical information about what to report and what not to reports followed by a quiz to test the knowledge of the reporters. In-between there was plenty of time for questions. For those, who are not able to attend the webinar a recording is available.

Several personalised mailings were sent to the CEO's and S(P)EAR reporters of the registries to explain the new system and to educate potential users. In addition, social media posts were published to promote the system outside the WMDA community. This includes promotion in WMDA's 3-weekly newsletter Stem Cell Matters. In September the system was promoted during the Cord Blood Connect Day (Miami - USA), workshop in Gdansk and in October at the Congress of European Association of Tissue and Cell Banks (Leiden – Netherlands). In November the system was presented to Belgium transplant centres.

3. Outline of the online reporting system

The confidential information in this overview is blurred due to the EU General Data Protection Regulations.

This chapter describes the outline of the online reporting tool.

3.1 Log-in page



Important note!

The S(P)EAR Committee reviews the reports once a week. If you have a rapid alert that needs to be shared with the community quickly, we urge you to send a separate e-mail to the WMDA office (sear-spear@wmda.info) and call us on: +31 88 505 7900.

WMDA strongly recommends to use anonymised data in the reports you are submitting.

Dear S(P)EAR reporter,

The World Marrow Donor Association (WMDA) has developed an improved reporting system to collect SEAR/SPEAR incidents. This new system makes it possible to prepare informative annual reports, analyse data more extensively and improve communication between WMDA and the reporters.

This robust online reporting system was officially launched on 1 July 2019.

To enter the reporting system, login with your email address and password. If you do not have a password yet, please check with the WMDA office whether you are registered S(P)EAR reporter. If you are registered as a user, you can press the "forgot?" button and you will automatically receive an email with a password.

If you would like to get access to this new system, as a S(P)EAR reporter, please contact the S(P)EAR project coordinator Esther Pustjens by e-mail: sear-spear@wmda.info

The collected data about serious adverse events and reactions occurring in donors is then analysed and used to provide statistics on the type of reports being submitted and put in place best practices on what can be done to mitigate such effects and occurrences. Via the annual S(P)EAR reports the results will be disseminated the the WMDA community worldwide.

The S(P)EAR Committee is available to respond to any questions, you might have.

Kind regards,

WMDA office

Login

Enter your email address and password to login.

Email Address

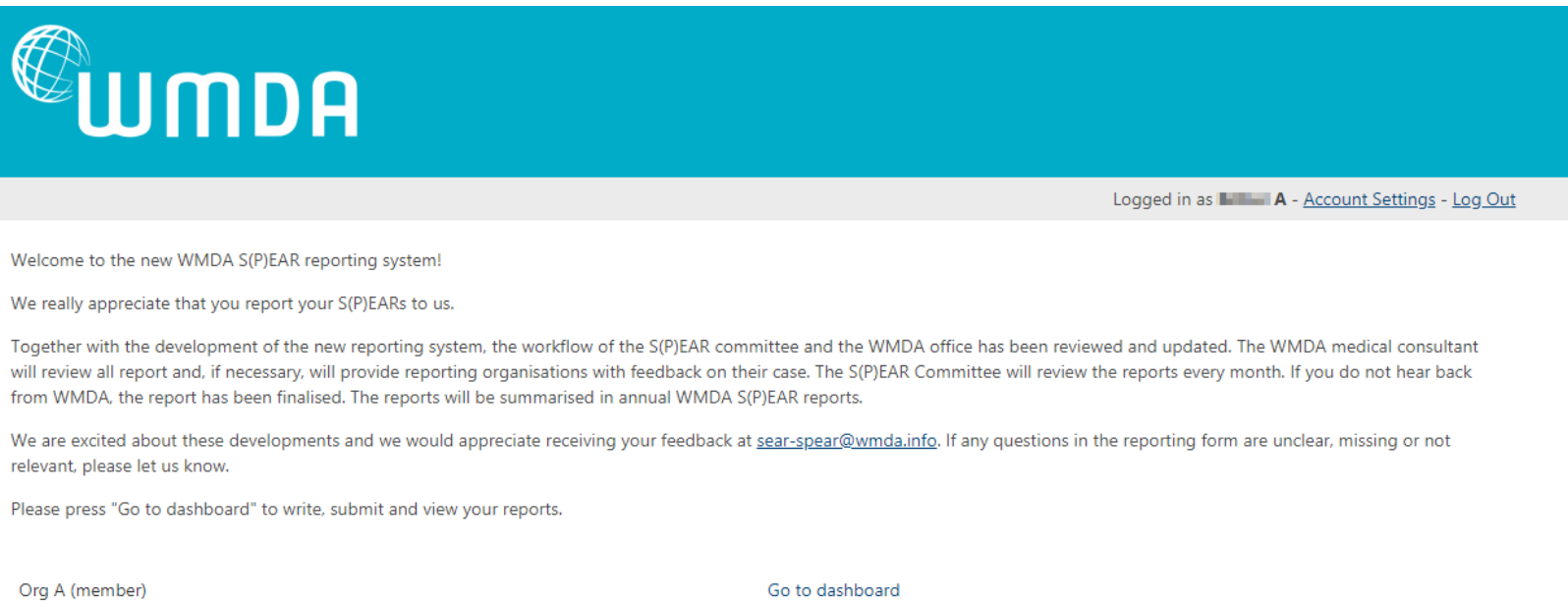
Password (forgot?)

Remember me

By logging in to the S(P)EAR Reporting System you agree to the [Terms of Use](#).

3.2 Welcome page

This shows an example when being logged-in with a test account.



Welcome to the new WMDA S(P)EAR reporting system!

We really appreciate that you report your S(P)EARs to us.

Together with the development of the new reporting system, the workflow of the S(P)EAR committee and the WMDA office has been reviewed and updated. The WMDA medical consultant will review all report and, if necessary, will provide reporting organisations with feedback on their case. The S(P)EAR Committee will review the reports every month. If you do not hear back from WMDA, the report has been finalised. The reports will be summarised in annual WMDA S(P)EAR reports.

We are excited about these developments and we would appreciate receiving your feedback at sear-spear@wmda.info. If any questions in the reporting form are unclear, missing or not relevant, please let us know.

Please press "Go to dashboard" to write, submit and view your reports.

Org A (member) [Go to dashboard](#)

3.3 Dashboard

This shows all reports per organisation in one overview. The reports are subdivided into:

- a. **In Draft**
Shows all reports that are in draft modus. The reports can still be edited or deleted by yourself or a colleague. Reports in Draft modus are not visible for WMDA office or S(P)EAR Committee.
- a. **Submitted to this Organisation**
Shows all reports that are submitted to the reporting member organisation by an affiliated organisation. The reports can be changed by the reporting organisation.
- b. **Additional Information Requested**
Shows all reports that require additional information from WMDA office or the S(P)EAR Committee.
- c. **Unlocked to Edit**
Shows all reports that have been unlocked by WMDA office to make it possible to edit the report. This could be done on request of the organisation.
- d. **Submitted to WMDA**
Shows all reports that have been submitted to WMDA by the reporting member organisation
- e. **Ready for Committee**
Shows all report that have been continued by WMDA office to the S(P)EAR Committee
Note: Only visible for S(P)EAR Committee members and WMDA office
- f. **Reviewed by Committee**
Shows all reports that have been reviewed by the S(P)EAR Committee

Additional Information Requested

[View Stats Reports](#)

Additional Information Requested

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Report ID	Type of Report	Status	ION	Organisation	Created By	Created On	Updated On	View Report
WMDA-2019-00001	Harm to a recipient	Additional Info Requested	WMDA	WMDA (Public Information Officer Request)	Michael Thompson	2019/10/21 12:24PM	2019/10/30 01:33PM	view
WMDA-2019-00002	Harm to a donor	Additional Info Requested	WMDA	WMDA	Michael Thompson	2019/10/28 14:57PM	2019/10/30 01:16PM	view
WMDA-2019-00003	Harm to a donor	Additional Info Requested	WMDA	WMDA (Public Information Officer Request)	Michael Thompson	2019/10/22 11:11AM	2019/10/30 01:05PM	view
WMDA-2019-00004	Harm to a donor	Additional Info Requested	WMDA	WMDA (WMDA)	Michael Thompson	2019/10/09 15:44PM	2019/10/30 01:00PM	view
WMDA-2019-00005	Harm to a donor	Additional Info Requested		WMDA (Public Information Officer Request)	Michael Thompson	2019/07/23 16:46PM	2019/09/24 02:41PM	view
WMDA-2019-00006	Harm to a donor	Additional Info Requested	WMDA	WMDA (Public Information Officer Request)	Michael Thompson	2019/07/24 16:41PM	2019/09/24 02:35PM	view
WMDA-2019-00007	Risk of harm	Additional Info Requested	WMDA	WMDA (Public Information Officer Request)	Michael Thompson	2019/09/17 15:01PM	2019/09/24 02:34PM	view

Unlocked to Edit

Report ID	Type of Report	Status	ION	Organisation	Created By	Created On	Updated On	View Report Details
No Data								

Submitted to WMDA

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Report ID	Type of Report	Status	ION	Organisation	Created By	Created On	Updated On	Edit Report	View Report Details
WMDA-2019-00001	Harm to a donor	Submitted to WMDA	WMDA	WMDA	WMDA	2019/11/20 16:57PM	2019/11/20 05:10PM	edit	view
WMDA-2019-00002	Harm to a recipient	Submitted to WMDA	WMDA	WMDA	WMDA	2019/11/20 16:36PM	2019/11/20 04:56PM	edit	view
WMDA-2019-00003	Risk of harm	Submitted to WMDA	WMDA	WMDA	WMDA	2019/08/08 13:46PM	2019/11/18 03:38PM	edit	view
WMDA-2019-00004	Risk of harm	Submitted to WMDA	WMDA	WMDA	WMDA	2019/07/11 12:08PM	2019/11/18 03:37PM	edit	view
WMDA-2019-00005	Risk of harm	Submitted to WMDA	WMDA	WMDA	WMDA	2019/07/11 11:23AM	2019/11/18 03:34PM	edit	view
WMDA-2019-00006	Risk of harm	Submitted to WMDA	WMDA	WMDA	WMDA	2019/11/07 14:48PM	2019/11/18 09:59AM	edit	view
WMDA-2019-00007	Harm to a donor	Submitted to WMDA	WMDA	WMDA	WMDA	2019/08/29 10:13AM	2019/11/04 02:18PM	edit	view
WMDA-2019-00008	Harm to a donor	Submitted to WMDA	WMDA	WMDA	WMDA	2019/08/29 10:08AM	2019/11/04 02:17PM	edit	view
WMDA-2019-00009	Risk of harm	Submitted to WMDA	WMDA	WMDA	WMDA	2019/08/29 10:02AM	2019/11/04 02:15PM	edit	view
WMDA-2019-00010	Harm to a recipient	Submitted to WMDA	WMDA	WMDA	WMDA	2019/09/11 15:28PM	2019/11/04 01:59PM	edit	view

Ready for Committee

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Report ID	Type of Report	Status	ION	Organisation	Created By	Created On	Updated On	View Report Details
WMDA-2019-00011	Harm to a recipient	Ready for Committee	WMDA	WMDA	WMDA	2019/11/15 12:59PM	2019/11/18 12:01PM	view
WMDA-2019-00012	Harm to a donor	Ready for Committee	WMDA	WMDA	WMDA	2019/10/31 14:38PM	2019/11/08 05:12PM	view
WMDA-2019-00013	Harm to a donor	Ready for Committee	WMDA	WMDA	WMDA	2019/10/31 14:24PM	2019/11/08 05:10PM	view
WMDA-2019-00014	Harm to a donor	Ready for Committee	WMDA	WMDA	WMDA	2019/10/31 14:02PM	2019/11/08 05:09PM	view
WMDA-2019-00015	Harm to a donor	Ready for Committee	WMDA	WMDA	WMDA	2019/10/30 14:57PM	2019/11/08 05:09PM	view
WMDA-2019-00016	Harm to a donor	Ready for Committee	WMDA	WMDA	WMDA	2019/10/30 14:31PM	2019/11/08 05:08PM	view
WMDA-2019-00017	Harm to a donor	Ready for Committee	WMDA	WMDA	WMDA	2019/10/30 14:11PM	2019/11/08 05:07PM	view
WMDA-2019-00018	Harm to a donor	Ready for Committee	WMDA	WMDA	WMDA	2019/07/11 12:00PM	2019/10/30 01:50PM	view
WMDA-2019-00019	Harm to a donor	Ready for Committee	WMDA	WMDA	WMDA	2019/08/08 15:04PM	2019/10/30 01:50PM	view
WMDA-2019-00020	Harm to a donor	Ready for Committee	WMDA	WMDA	WMDA	2019/08/28 10:05AM	2019/10/30 01:49PM	view

Reviewed by Committee

Report ID	Type of Report	Status	ION	Organisation	Created By	Created On	Updated On	Resolution	Reason	View Report Details
[REDACTED]	Risk of harm	Reviewed by Committee	[REDACTED]	[REDACTED]	[REDACTED]	2019/07/24 14:41PM	2019/11/07 10:46AM			view
[REDACTED]	Harm to a donor	Reviewed by Committee	[REDACTED]	[REDACTED]	[REDACTED]	2019/07/23 16:22PM	2019/09/27 12:44PM	Accepted	SEAR Non Critical	view

4. Plan for 2020

This online reporting system for serious adverse events and reactions facilitates efficient documentation, reporting and analysis of adverse events by WMDA member and its affiliated partner organisations. It reflects the findings of a detailed audit of current reporting practices to identify best practice and areas for improvement. The reporting system has been launched on 1 July 2019. In the meantime, some bugs were identified, which were solved in the first months. It is too early to state if the system will lead to better quality reporting.

The focus of WMDA for 2020 will be to educate healthcare professions, who are reporting incidents occurring after unrelated stem cell donation. An important step forward in this era of a growing demand on family donor will be to educate transplant centres to submit their S(P)EARs regarding stem cell donations of family members. For 2020 the main focus will be education of as well WMDA member organisations as transplant centres.

It is important to reassure all potential unrelated and related donors that there is an infrastructure implemented to report serious adverse events and reactions occurring during or after donation, which aims to minimise the risk of adverse outcomes and that there is a continuous learning system which is informed by global reporting.