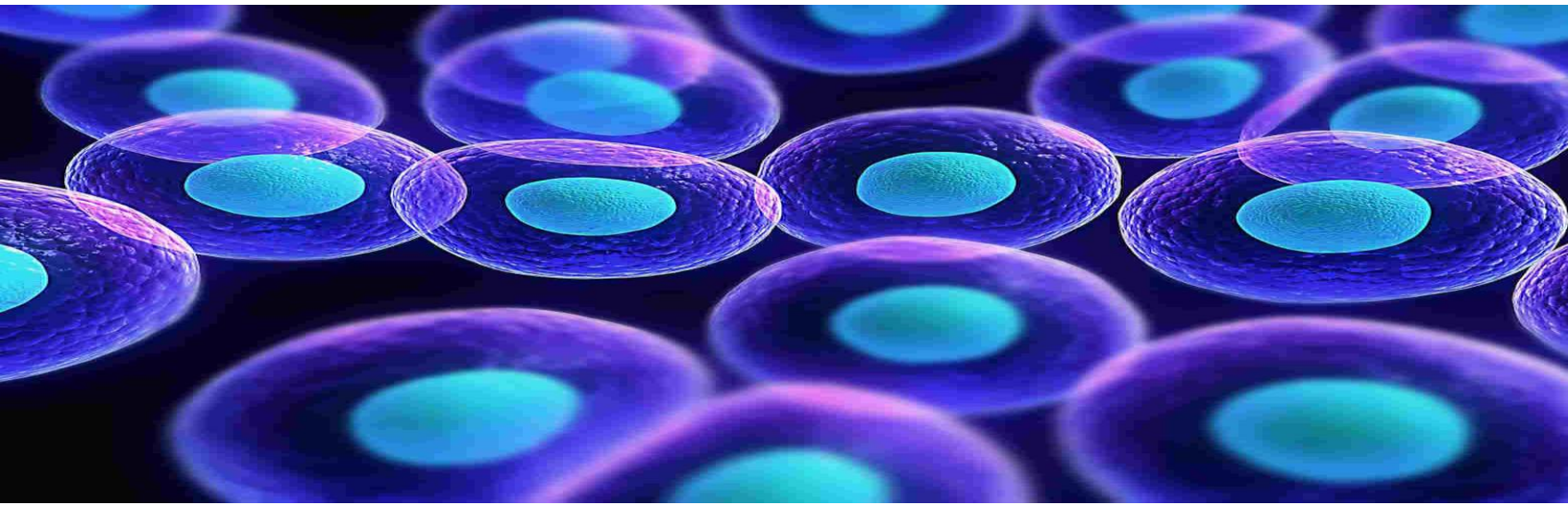
Disclaimer:
"The content of this Deliverable D4.1 represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains."

D4.1 Online reporting system

Grant Agreement number: 811126
Project acronym: SAVDON
Work Package number: WP4

Organisation: **World Marrow Donor Association (WMDA)**
LEAR: Esther Pustjens
Project coordinator: Lydia Foeken
Tel: 0031 88 505 7900
E-mail: lydia.foeken@wmda.info
Organisation website address: www.wmda.info



Co-funded by
the Health Programme
of the European Union

"This Deliverable D4.1 of an activity received funding under an operating grant from the European Union's Health Programme (2014-2020)."

Introduction

This deliverable describes the development of an online reporting system that facilitates efficient documentation, reporting and analysis of adverse events by European WMDA member organisations. This system will reflect:

- The findings of a detailed audit of current reporting practices to identify good/best practice and areas for improvement
- Feedback from and requirements from members and national/international authorities

The system will be accompanied by a series of educational events and a suite of materials to support members to utilise the new functionality. The Deliverable is a link to an educational presentation provided to WMDA members demonstrating the system.

Product:

https://youtu.be/HUnuBnK789w

Thanks to Eventvision BV

The individual slides of the video are also included in this report:

matching donors • serving patients

The road to a new Serious (Product) Events and Adverse Reactions reporting system

Voice-over by Thilo Mengling - MD
Project Manager Scientific-Medical Projects
Medical Department (DKMS)

Content

- Introduction
  - Purpose and scope
  - Serious (Product) Events and Adverse Reactions: S(P)EAR 2019 – aim
  - Why biovigilance?
- New system: key features
  - Personal login
  - Dashboard
  - Flow of report
  - Type of report
  - Late events
- Summary & next steps
  - Project group
  - Contact

Introduction

Purpose and Scope

20170517-SEAR-S(P)EAR Operating Document

PURPOSE & SCOPE

To collect and analyse information on recipient and donor Serious Adverse Events (SAE) and Severe Adverse Reactions (SAR) which affect donors and/or products from all WMDA regular member organisations.

To follow a rapid alert system for disseminating information on SAE/R to all WMDA regular members of the international community in contact with allogeneic donors and patients.

- Introduced 2002/2007
- Originally on paper, since 2010 online submission
- Current system is SurveyGizmo-based
- Current form (intended as an interim solution) since Feb 2018

S(P)EAR 2018 - *Collect, exchange and analyse*

2:08 / 14:36

S(P)EAR 2019 – Aim

The aim is to provide a **streamlined user friendly** system that can be used by organisations across the globe to submit serious event and adverse effects that occur to WMDA as part of their agreed remit to ensure safety of their voluntary donors.

Using the system we can then do further **analysis** on the type of reports being submitted and put in place best practices on **what can be done to mitigate** such effects/occurrences

Why Biovigilance?

1) Collect and analyse adverse events and reactions in (probable) connection to stem cell donation to directly improve donor and recipient safety
   - Disseminate Rapid Alerts
   - Share results with community (WMDA meetings)
   - Publications
   - Adjust standards and procedures

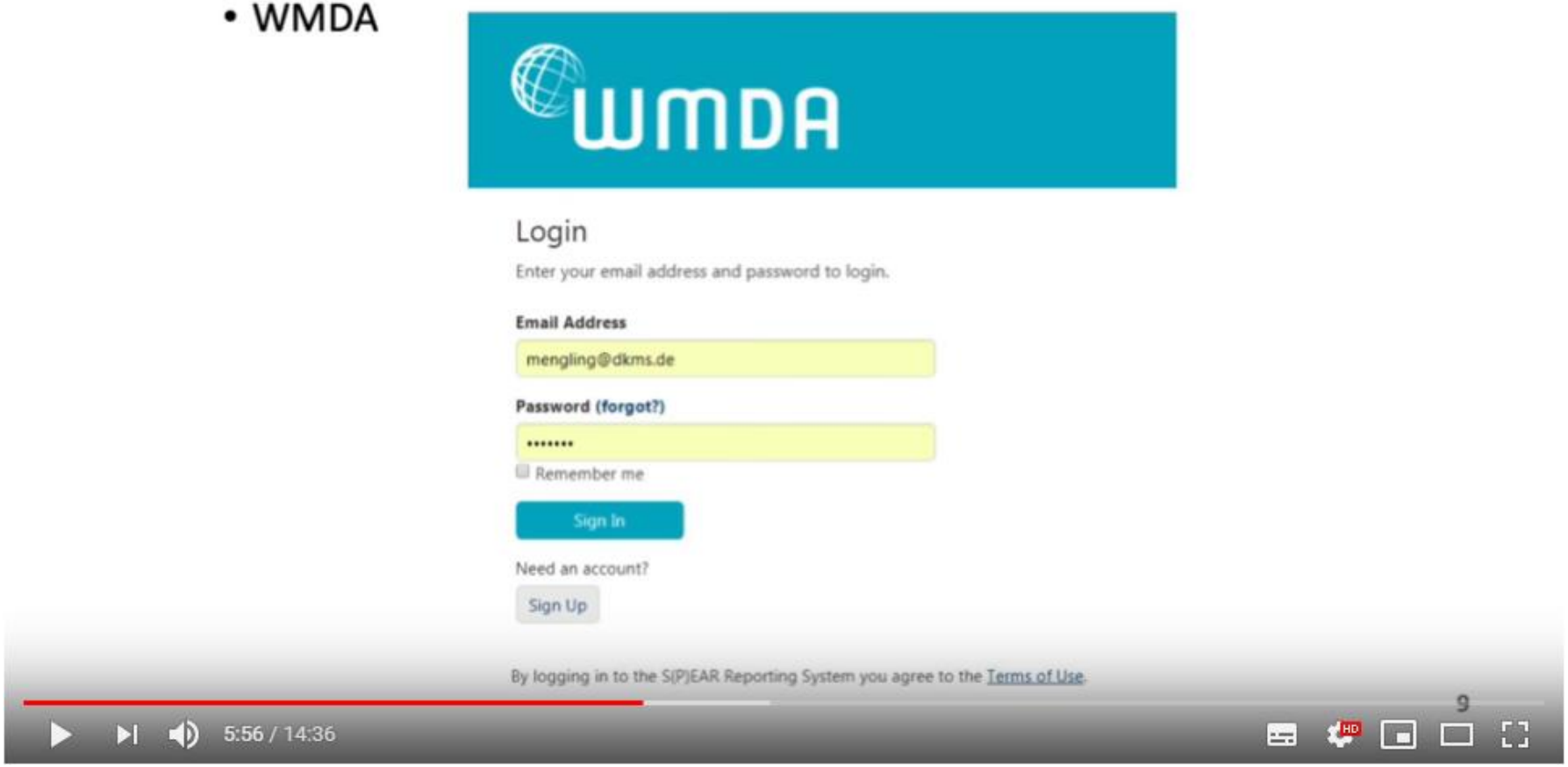
2) Register severe events as long as connection to stem cell donation cannot be ruled out to fulfill regulatory requirements
   - WBMT
   - NOTIFY
   - EU Tissue and Cells Directives
   - Insurances

Upcoming system – key features

Personal Login

Personal profile may contain **different** roles, for example user from

- Donor or collection center (non-member organisation)
- Registry (member organisation)
- WMDA

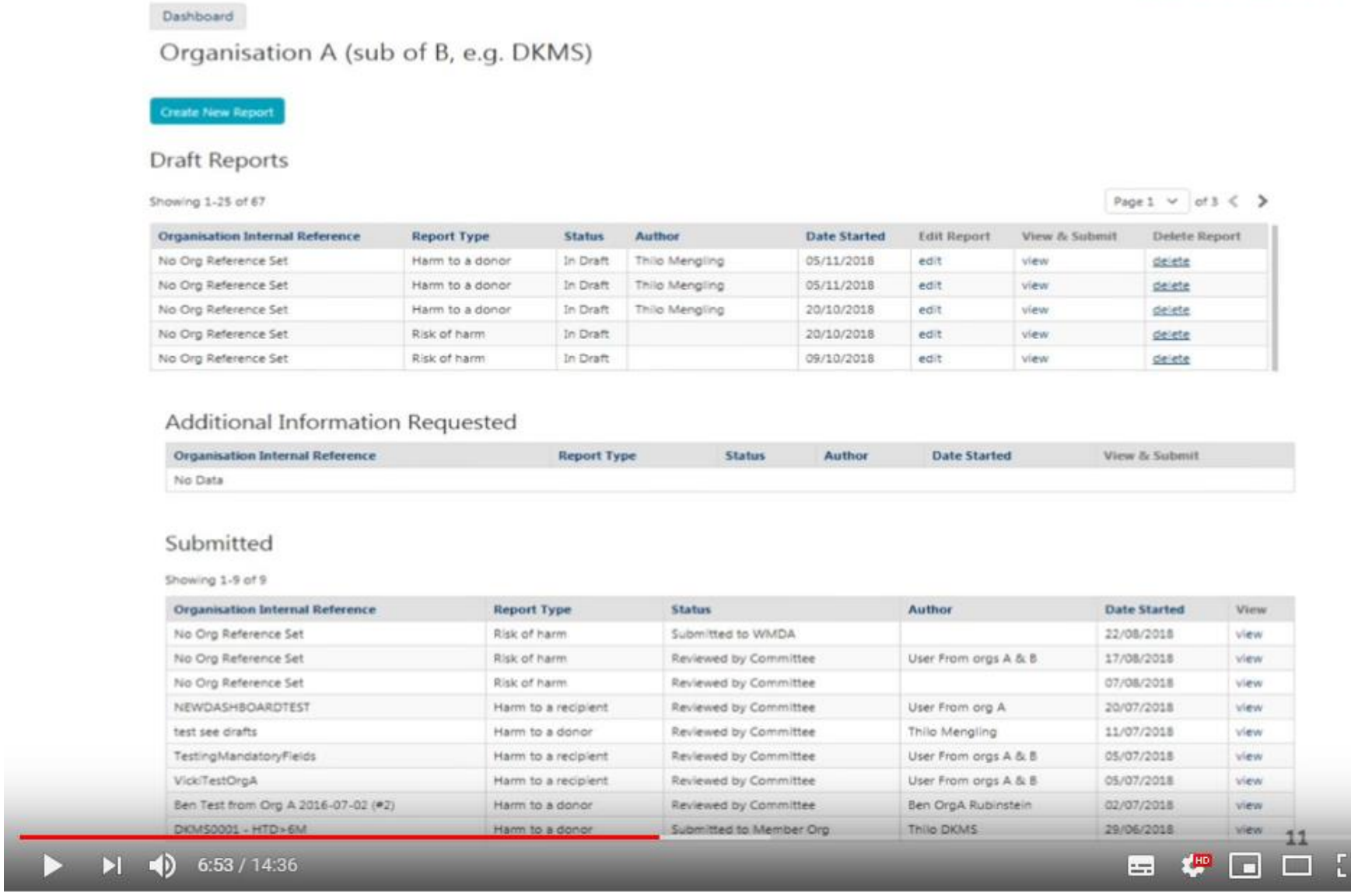


Dashboard

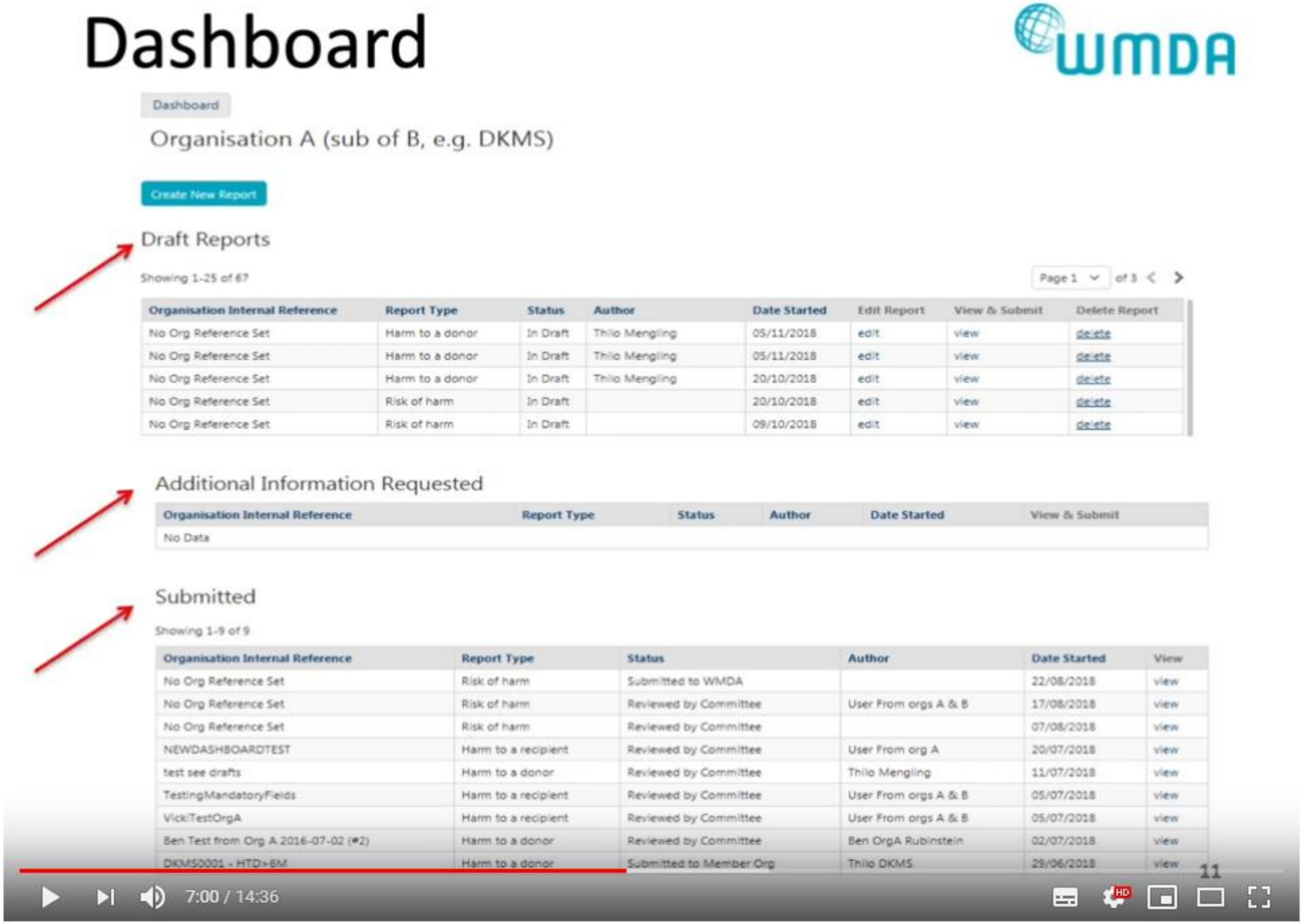
- Central location where users can go and view In progress, previously submitted reports and their associated outcome. Therefore its more:
  - Secure as you only see relevant forms pertaining to the user permissions
  - All communication is internally handled so no risk of emails being hacked or erroneously forwarded and no more need to use email correspondence
  - GDPR compliant
  - Does not require users to have their own backup of reports submitted

- System **auto generated ID** for traceability of reports in draft or submitted

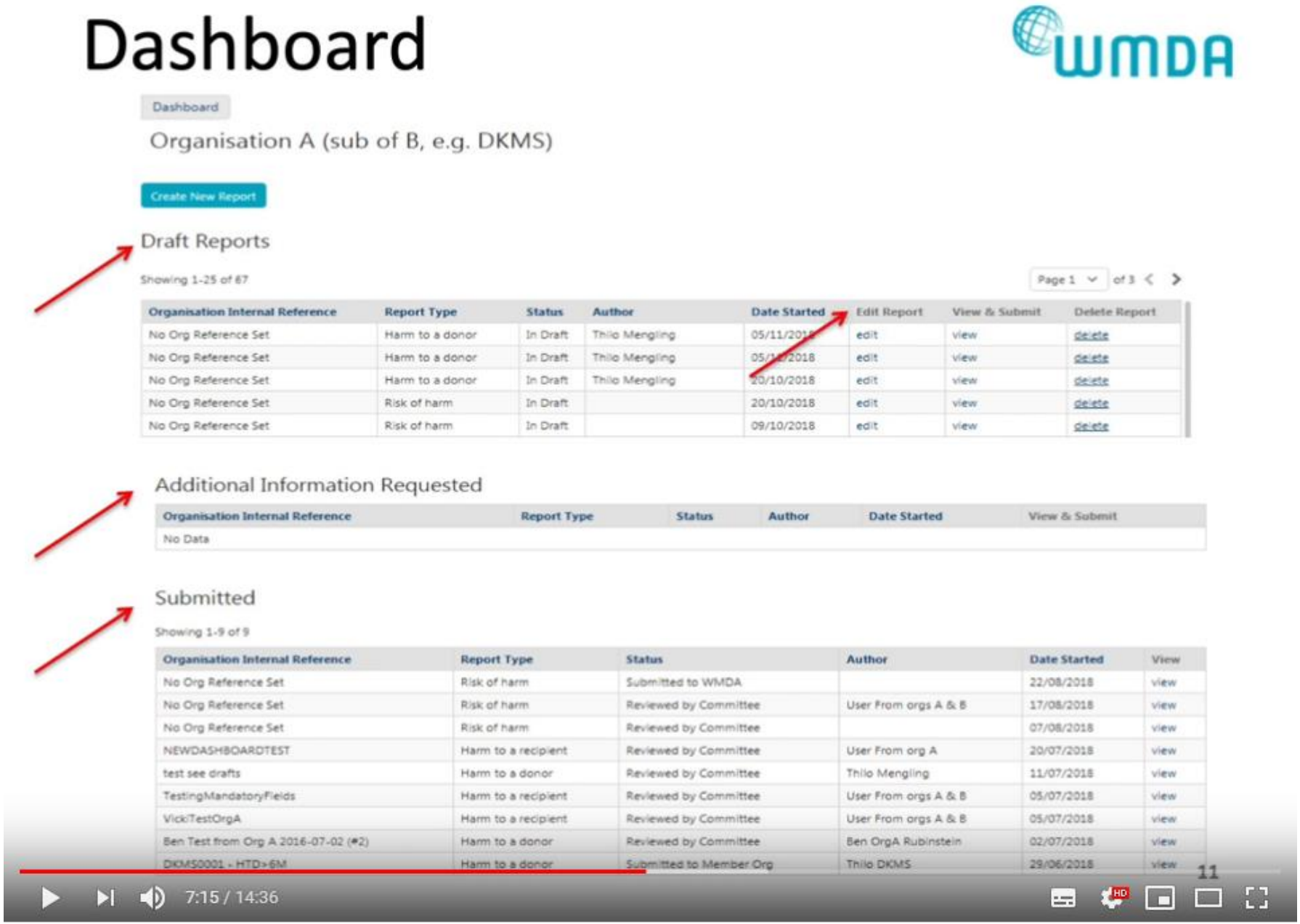
Dashboard


Dashboard
Organisation A (sub of B, e.g. DKMS)
Create New Report
Draft Reports
Showing 1-25 of 67
Page 1 of 3
Organisation Internal Reference | Report Type | Status | Author | Date Started | Edit Report | View & Submit | Delete Report
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 05/11/2018 | edit | view | delete
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 05/11/2018 | edit | view | delete
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 20/10/2018 | edit | view | delete
No Org Reference Set | Risk of harm | In Draft | | 20/10/2018 | edit | view | delete
No Org Reference Set | Risk of harm | In Draft | | 09/10/2018 | edit | view | delete
Additional Information Requested
Organisation Internal Reference | Report Type | Status | Author | Date Started | View & Submit
No Data
Submitted
Showing 1-9 of 9
Organisation Internal Reference | Report Type | Status | Author | Date Started | View
No Org Reference Set | Risk of harm | Submitted to WMDA | | 22/08/2018 | view
No Org Reference Set | Risk of harm | Reviewed by Committee | User From orgs A & B | 17/08/2018 | view
No Org Reference Set | Risk of harm | Reviewed by Committee | | 07/08/2018 | view
NEWDASHBOARDTEST | Harm to a recipient | Reviewed by Committee | User From org A | 20/07/2018 | view
test see drafts | Harm to a donor | Reviewed by Committee | Thilo Mengling | 11/07/2018 | view
TestingMandatoryFields | Harm to a recipient | Reviewed by Committee | User From orgs A & B | 05/07/2018 | view
VickiTestOrgA | Harm to a recipient | Reviewed by Committee | User From orgs A & B | 05/07/2018 | view
Ben Test from Org A 2016-07-02 (#2) | Harm to a donor | Reviewed by Committee | Ben OrgA Rubinstein | 02/07/2018 | view
DKMS0001 - HTD+6M | Harm to a donor | Submitted to Member Org | Thilo DKMS | 29/06/2018 | view
6:53 / 14:36

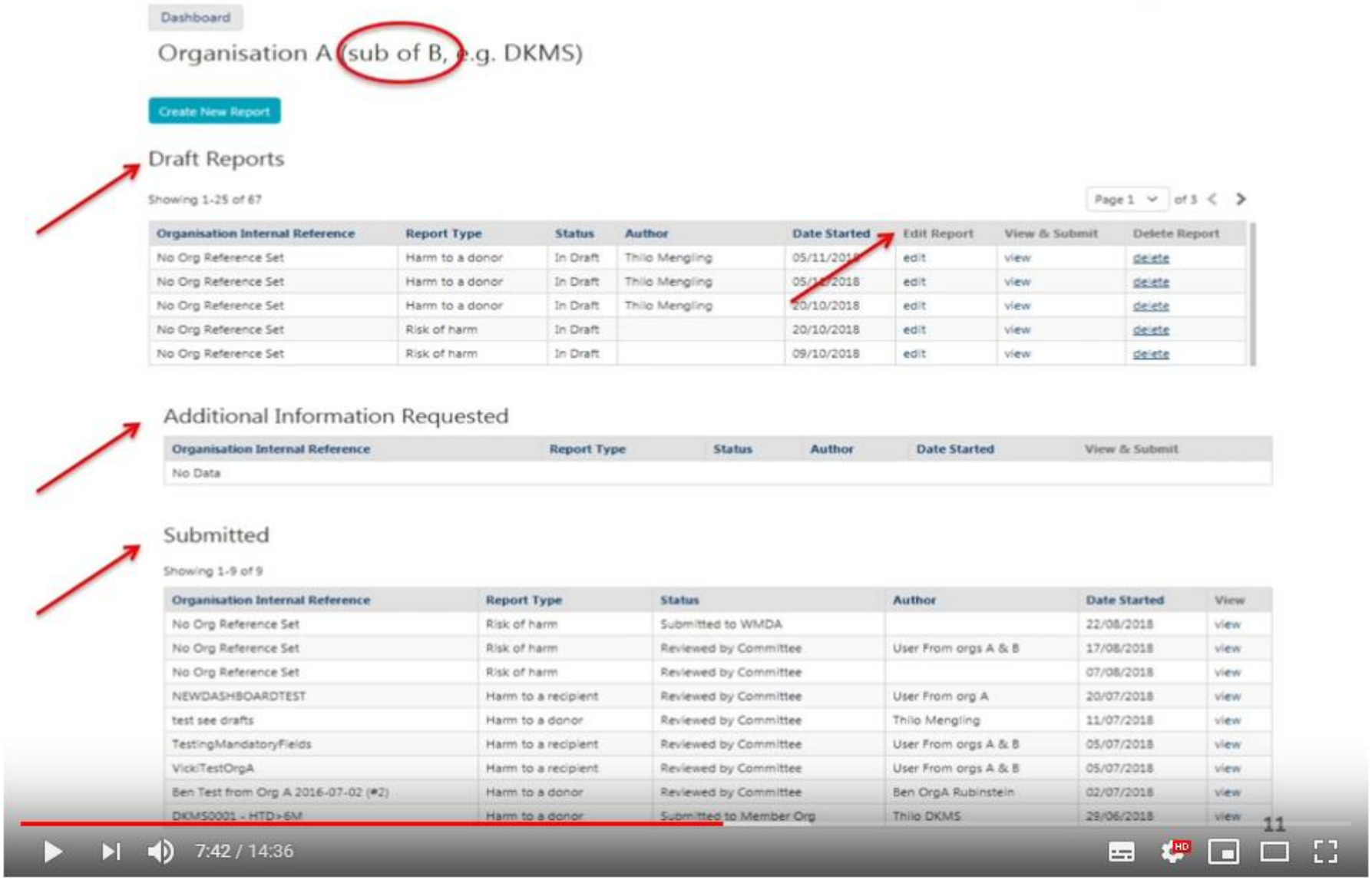
Dashboard


Dashboard
Organisation A (sub of B, e.g. DKMS)
Create New Report
Draft Reports
Showing 1-25 of 67
Page 1 of 3
Organisation Internal Reference | Report Type | Status | Author | Date Started | Edit Report | View & Submit | Delete Report
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 05/11/2018 | edit | view | delete
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 05/11/2018 | edit | view | delete
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 20/10/2018 | edit | view | delete
No Org Reference Set | Risk of harm | In Draft | | 20/10/2018 | edit | view | delete
No Org Reference Set | Risk of harm | In Draft | | 09/10/2018 | edit | view | delete
Additional Information Requested
Organisation Internal Reference | Report Type | Status | Author | Date Started | View & Submit
No Data
Submitted
Showing 1-9 of 9
Organisation Internal Reference | Report Type | Status | Author | Date Started | View
No Org Reference Set | Risk of harm | Submitted to WMDA | | 22/08/2018 | view
No Org Reference Set | Risk of harm | Reviewed by Committee | User From orgs A & B | 17/08/2018 | view
No Org Reference Set | Risk of harm | Reviewed by Committee | | 07/08/2018 | view
NEWDASHBOARDTEST | Harm to a recipient | Reviewed by Committee | User From org A | 20/07/2018 | view
test see drafts | Harm to a donor | Reviewed by Committee | Thilo Mengling | 11/07/2018 | view
TestingMandatoryFields | Harm to a recipient | Reviewed by Committee | User From orgs A & B | 05/07/2018 | view
VickiTestOrgA | Harm to a recipient | Reviewed by Committee | User From orgs A & B | 05/07/2018 | view
Ben Test from Org A 2016-07-02 (#2) | Harm to a donor | Reviewed by Committee | Ben OrgA Rubinstein | 02/07/2018 | view
DKMS0001 - HTD>6M | Harm to a donor | Submitted to Member Org | Thilo DKMS | 29/06/2018 | view
7:00 / 14:36
11

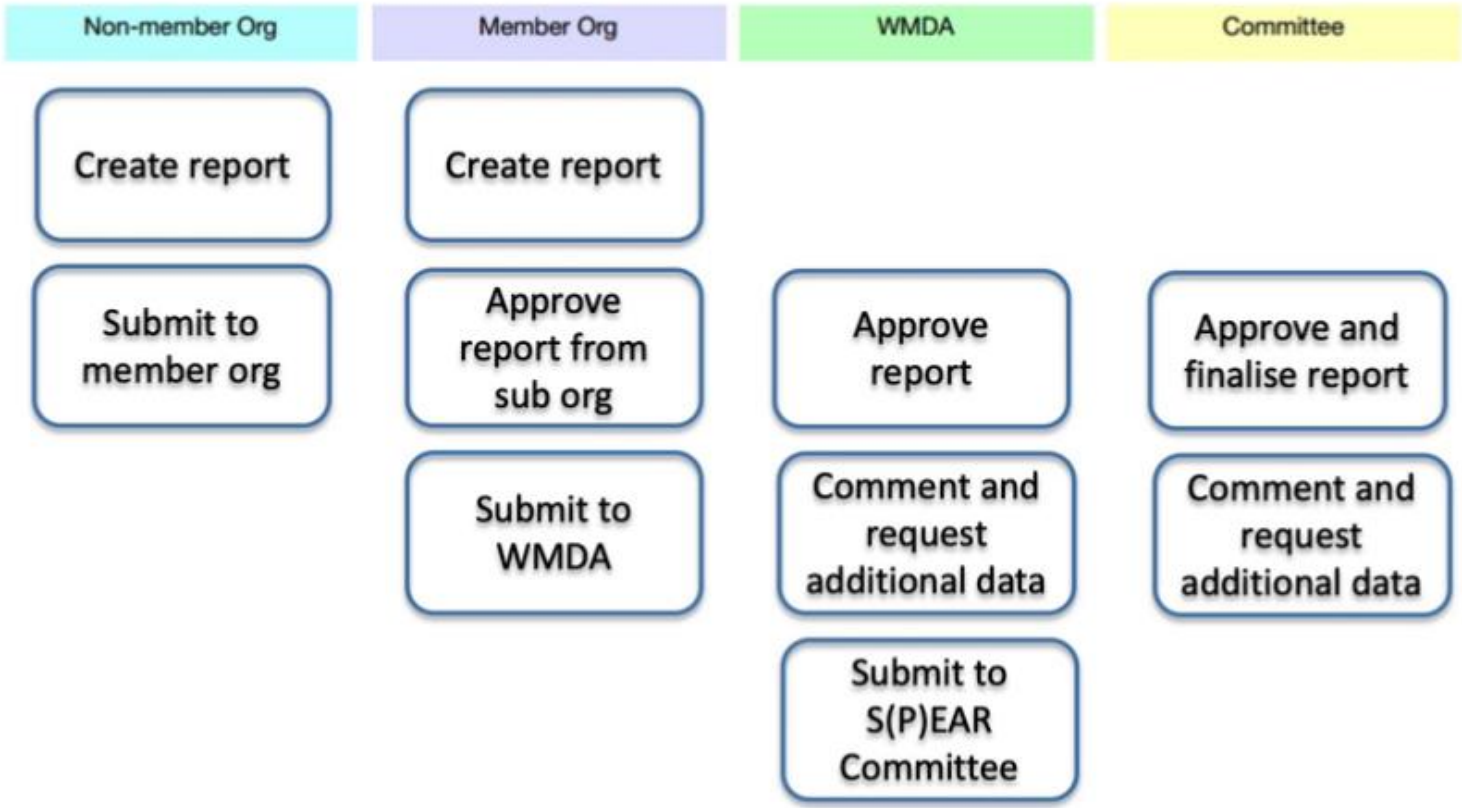
Dashboard


Dashboard
Organisation A (sub of B, e.g. DKMS)
Create New Report
Draft Reports
Showing 1-25 of 67
Page 1 of 3
Organisation Internal Reference | Report Type | Status | Author | Date Started | Edit Report | View & Submit | Delete Report
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 05/11/2018 | edit | view | delete
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 05/10/2018 | edit | view | delete
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 20/10/2018 | edit | view | delete
No Org Reference Set | Risk of harm | In Draft | | 20/10/2018 | edit | view | delete
No Org Reference Set | Risk of harm | In Draft | | 09/10/2018 | edit | view | delete
Additional Information Requested
Organisation Internal Reference | Report Type | Status | Author | Date Started | View & Submit
No Data
Submitted
Showing 1-9 of 9
Organisation Internal Reference | Report Type | Status | Author | Date Started | View
No Org Reference Set | Risk of harm | Submitted to WMDA | | 22/08/2018 | view
No Org Reference Set | Risk of harm | Reviewed by Committee | User From orgs A & B | 17/08/2018 | view
No Org Reference Set | Risk of harm | Reviewed by Committee | | 07/08/2018 | view
NEWDASHBOARDTEST | Harm to a recipient | Reviewed by Committee | User From org A | 20/07/2018 | view
test see drafts | Harm to a donor | Reviewed by Committee | Thilo Mengling | 11/07/2018 | view
TestingMandatoryFields | Harm to a recipient | Reviewed by Committee | User From orgs A & B | 05/07/2018 | view
VickiTestOrgA | Harm to a recipient | Reviewed by Committee | User From orgs A & B | 05/07/2018 | view
Ben Test from Org A 2016-07-02 (#2) | Harm to a donor | Reviewed by Committee | Ben OrgA Rubinstein | 02/07/2018 | view
DKMS0001 - HTD>6M | Harm to a donor | Submitted to Member Org | Thilo DKMS | 29/06/2018 | view
7:15 / 14:36

Dashboard

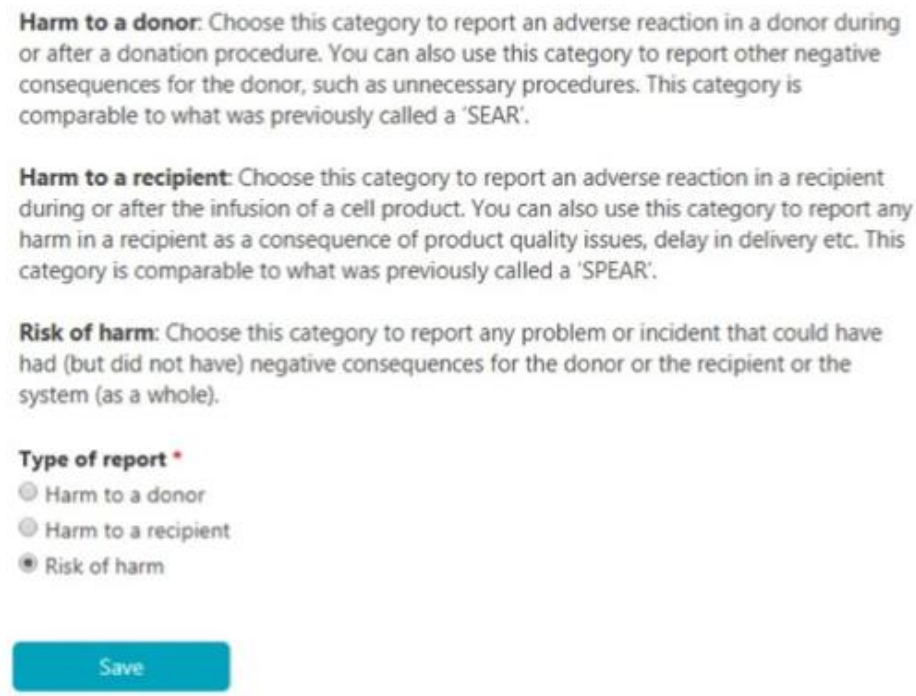

Dashboard
Organisation A (sub of B, e.g. DKMS)
Create New Report
Draft Reports
Showing 1-25 of 67
Page 1 of 3
Organisation Internal Reference | Report Type | Status | Author | Date Started | Edit Report | View & Submit | Delete Report
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 05/11/2018 | edit | view | delete
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 05/10/2018 | edit | view | delete
No Org Reference Set | Harm to a donor | In Draft | Thilo Mengling | 20/10/2018 | edit | view | delete
No Org Reference Set | Risk of harm | In Draft | | 20/10/2018 | edit | view | delete
No Org Reference Set | Risk of harm | In Draft | | 09/10/2018 | edit | view | delete
Additional Information Requested
Organisation Internal Reference | Report Type | Status | Author | Date Started | View & Submit
No Data
Submitted
Showing 1-9 of 9
Organisation Internal Reference | Report Type | Status | Author | Date Started | View
No Org Reference Set | Risk of harm | Submitted to WMDA | | 22/08/2018 | view
No Org Reference Set | Risk of harm | Reviewed by Committee | User From orgs A & B | 17/08/2018 | view
No Org Reference Set | Risk of harm | Reviewed by Committee | | 07/08/2018 | view
NEWDASHBOARDTEST | Harm to a recipient | Reviewed by Committee | User From org A | 20/07/2018 | view
test see drafts | Harm to a donor | Reviewed by Committee | Thilo Mengling | 11/07/2018 | view
TestingMandatoryFields | Harm to a recipient | Reviewed by Committee | User From orgs A & B | 05/07/2018 | view
VickiTestOrgA | Harm to a recipient | Reviewed by Committee | User From orgs A & B | 05/07/2018 | view
Ben Test from Org A 2016-07-02 (#2) | Harm to a donor | Reviewed by Committee | Ben OrgA Rubinstein | 02/07/2018 | view
DKMS0001 - HTD>6M | Harm to a donor | Submitted to Member Org | Thilo DKMS | 29/06/2018 | view
7:42 / 14:36

Flow of reports



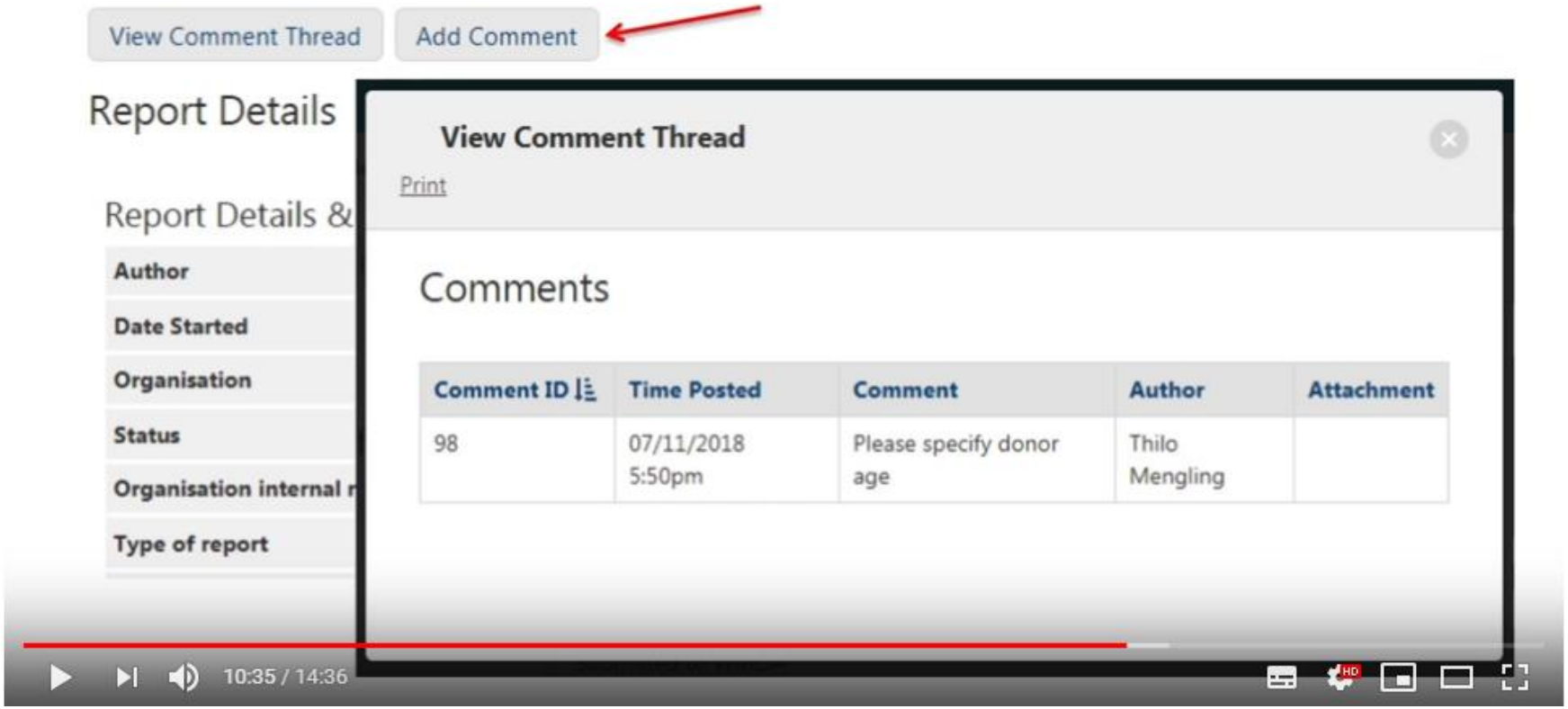
Type of Report

- The new system now clearly defines the type of report being submitted. These are now listed as :
  - Harm to recipient
  - Harm to donor
  - Risk of harm



Comments

Ability to add internal comments allowing for dialogue between WMDA and submitting registry be stored and audited within the system. This makes it easy to request additional information



Late events

- Late events are defined as **Harm to a donor more than 6 months after collection** (= typically everything occurring *later* than the follow-up questionnaire or interview after 6 months)
- Dynamic and user friendly to fill for a late SEAR compared to a critical Risk of Harm (RoH) assessment, where donor or collection **details** mater
- Less than **10** mandatory questions (preliminary)

Question	Data type
What is the type of report?	Radio button
In case of harm to donor: long term or short term?	Drop down
Please describe donor complication/adverse reaction/consequences	Alphanumeric
Type of harm to donor	Multiple options may be selected
ICD-code	Alphanumeric
Type of (intended) cell product	Drop down
(Intended) date of collection	Date finder
Were mobilising agents given to this donor?	Drop down
Which mobilisation agent was used? (conditionally mandatory only)	Multiple choices possible if 29 answer is not No
Which filgrastim? (conditionally mandatory only)	Drop down
Which lenograstim? (conditionally mandatory only)	Drop down
Did a problem or incident occcur which may have resulted in or contributed to harm to donor/recipient?	Drop down
Please describe problem or incident	Alphanumeric
Type of problem or incident - (risk of) harm to donor (conditionally mandatory only)	Drop down

Summary & next steps

Summary

- Focus on events in **close connection** to stem cell collection.
- **Less burdensome** reporting for late events.
- Reports are **submitted** along the reporting line **within** the system.
- Analysis and **statistics** will be available within the system, not only for WMDA but also displayed for users .

S(P)EAR – Next steps

1. Complete development (beginning of 2019)
2. Pilot with a small user group (beginning to mid 2019)
3. Go LIVE (as soon as possible, depending on 2.)