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D2.2 Progress report on the implementation for a secure registry-to-registry communication system

Grant Agreement number: 837354
Project acronym: SAVDON
Work Package number: WP2

Periodic report: 1st 2nd 3rd 4th

Period covered: from 01st January to 31st December 2019

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Co-funded by
the Health Programme
of the European Union

“This Deliverable D2.2 of an activity received funding under an operating grant from the European Union’s Health Programme (2014-2020).”

Executive summary

Please find the glossary list in Appendix 1

This progress report includes information about tools used for registry-to-registry communication and new developments in that specific area. This tool is called WMDA Search, Match & Connect. In 2019, the main focus was to explain the benefits to all EU Member States and to analyse the potential risks and benefits of a new way of working. The study is published in 2019 and is publicly available on WMDA Share (<https://share.wmda.info/x/WxOOF>)

In addition, please find the defined dataset for each step in the search process in Deliverable 1.1 (2019)

WMDA strives to significantly reduce the *time needed for information processing in the search and request processes and to create fully transparent data exchange - including actual process status - across all registries.*

What will be different and better?

- Transplant centres can be advised more quickly about potential matches by consulting one source of data by registry search coordinators.
- Administrative work in the search coordination process will reduce significantly.
- All search coordination tasks and requests can be done without using additional communication mechanisms (e.g. EMDIS, fax, e-mail).
- Reduce growing complexity (rules and regulations) on data exchange and ensuring that data quality, privacy and security are safeguarded, and full transparency is present.

What will WMDA do?

- Provide a global file with - currently - 36 million donors, containing accurate information to select the best possible stem cell source for patients in need of a transplant.
- Provide fast, reliable and complete match lists based on a probabilistic matching algorithm with the possibility to receive updates.
- Provide access to high-performing services (such as the possibility to connect with other organisations to request verification and extended typing and workups) within a less error-prone environment to facilitate the work of search coordinators.
- Together with our members ensure that we develop a secure, reliable and trustworthy system to facilitate data exchange.

What is it important to know?

- WMDA will use the EU operational grant to facilitate the project and will strive to avoid increases in membership fees.
- WMDA will offer a variety of mechanisms to facilitate better communication between registries, e.g. connectivity with EMDIS 3; EMDIS 4; APIs or web interfaces via one single point of connection with Search, Match & Connect.

- WMDA will not mandate changes, as our solutions allow organisations to work with older versions of the application and decide themselves whether and when to move to the new version, for example when resources are available.
- Each registry can decide and follow its own business rules: a registry decides from which registry they would like to receive direct requests.
- WMDA strives to use robust, future proof, high quality, easy adaptable and low maintenance technology.
- WMDA strives to offer low-maintenance solutions for its member organisations.
- Security and data privacy are of key importance.
- This project is driven by and for WMDA members. There is currently direct representation within the project from 20 member organisations. The WMDA project delivery team (representing different types of registries) is merely the facilitator and will communicate and engage with members at every opportunity to ensure solutions meet their needs. Over the last few years, WMDA has developed relationships with many member organisations and both the GRID as XML projects and the EMDIS White Paper have given good insight on the IT capabilities and local systems used within WMDA member organisations. WMDA is exploring with a small number of EMDIS and non-EMDIS registries how we may build prototype solutions that can then be refined for broader use.

How is WMDA going to do it?

Our community is highly dependent on a properly functioning communication system. Our patients must always be able to rely on searches and communication messages being executed promptly and correctly.

This requires active cooperation between the providing registries and requesting registries. The WMDA seeks to ensure an efficient, safe and reliable system to facilitate this.

It is important to drive progress and to maintain momentum, and to ensure the benefits for registries and ultimately patients are realised quickly. Of course, decisions will have to be made and there will be inevitable differences in opinion and interest across our large and diverse global family. We commit to listening to all members and to communicate decisions and the rationale for them. We want a constant conversation with members as the plans are developed and delivered.

The WMDA intends to fully utilise funding from the operational EU grant to realise the vision and deliver our plans and strives to avoid an increase in membership fees. The goal is to develop an infrastructure that can be maintained by the current IT team within the WMDA office.

The WMDA Board and WMDA Search, Match & Connect have listened to members, and this feedback has been reflected in the vision set out in this document, and the planned way forward.

This project is driven by and for WMDA members. The WMDA project delivery team is merely the facilitator. The project delivery group will work in an agile manner, which means that milestones are delivered as soon as they have been developed and tested. Each member of the project delivery group is supported by their senior management to spend time on the project. Pilot groups will be used to validate the reliability and work out the kinks.

Two groups will be accountable for setting the strategic directions and realising the vision:

- WMDA Board (finance)
- WMDA Committee: Search, Match & Connect

Three groups are accountable for ensuring that the subsequent detailed plans and implementation approach are robust and sustainable.

- *Tactical level*: Steering Committee with representation of the WMDA Board
- *Operational level*: Project Delivery Group (Technical Design Authority)
- *Operational level*: Project Delivery Group (User Engagement)

In order to align the technical developments with future EMDIS directions, representatives of EMDIS are member of the Project Delivery Group, Steering Committee and the Search, Match & Connect Board Committee.



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1. Vision of WMDA

WMDA strives to reduce the time needed for information processing in the search and request processes significantly and to create fully transparent data exchange - including actual process status - across all registries.

The vision reflects the feedback received through consultation with the WMDA membership and the experiences from phase 1 and 2 of development of the Search & Match Service, known as BMDW (see *Appendix 2 – Background and Context*).

To achieve this vision, and underpin a safe and sustainable supply of cellular products for its members, WMDA works across three main themes:

- **Search:** Provide WMDA members with accurate donor and cord blood data to select the best possible stem cell source for patients in need of a transplant
- **Match:** Search coordinators can access a reliable and complete match list quickly for their patients based on a probabilistic matching algorithm
- **Connect:** Search coordinators have access to high-performing services within an equitable and predictable working environment to facilitate their work.

Search: Optimise Search – strive for good data available at search

Ensuring that patients are informed quickly about their chances for transplant is a prime task for WMDA member organisations. WMDA will actively contribute to this by ensuring:

- All WMDA member organisations are able to search the best available global donor and cord blood data, which is recognised as ‘the single version of truth’ for all patient searches.
- The proper selection of donors and cord blood products at each moment in time is based on the confidence that donor and cord details presented are up-to-date and checked by WMDA.
- Involving WMDA member organisations where possible. WMDA will further strengthen the relationship with and between WMDA member organisations to ensure that good quality data are available in the global file.
- All patients have equal rights to health treatment. WMDA supports this by striving towards a high-quality data source for all patient searches.

GOAL: provide a global file with accurate information to select the best possible stem cell source for patients in need of a transplant.

Match: Find the best Match

WMDA identifies best practices in donor search and supports the operations of member organisations. To operate the Search & Match Service a probabilistic matching algorithm will be offered that is accessible in different ways. WMDA facilitates this by ensuring:

- Search coordinators and transplant centres can register their patients **manually**, run their search and find the best stem cell source through a variety of filter options in the Search & Match Service
- Search coordinators and transplant centres can register their patients **electronically**, run their search and find the best stem cell source through a variety of filter options in the Search & Match Service
- Search coordinators can automatically run the search from the local software application (such as Prometheus), receive a match list electronically and use their local settings to select the best stem cell source
- Search coordinators receive status updates and updates about new potential matches and donor availability.

GOAL: provide fast, reliable and complete match lists based on a probabilistic matching algorithm with the possibility to receive updates.

Connect: Be connected

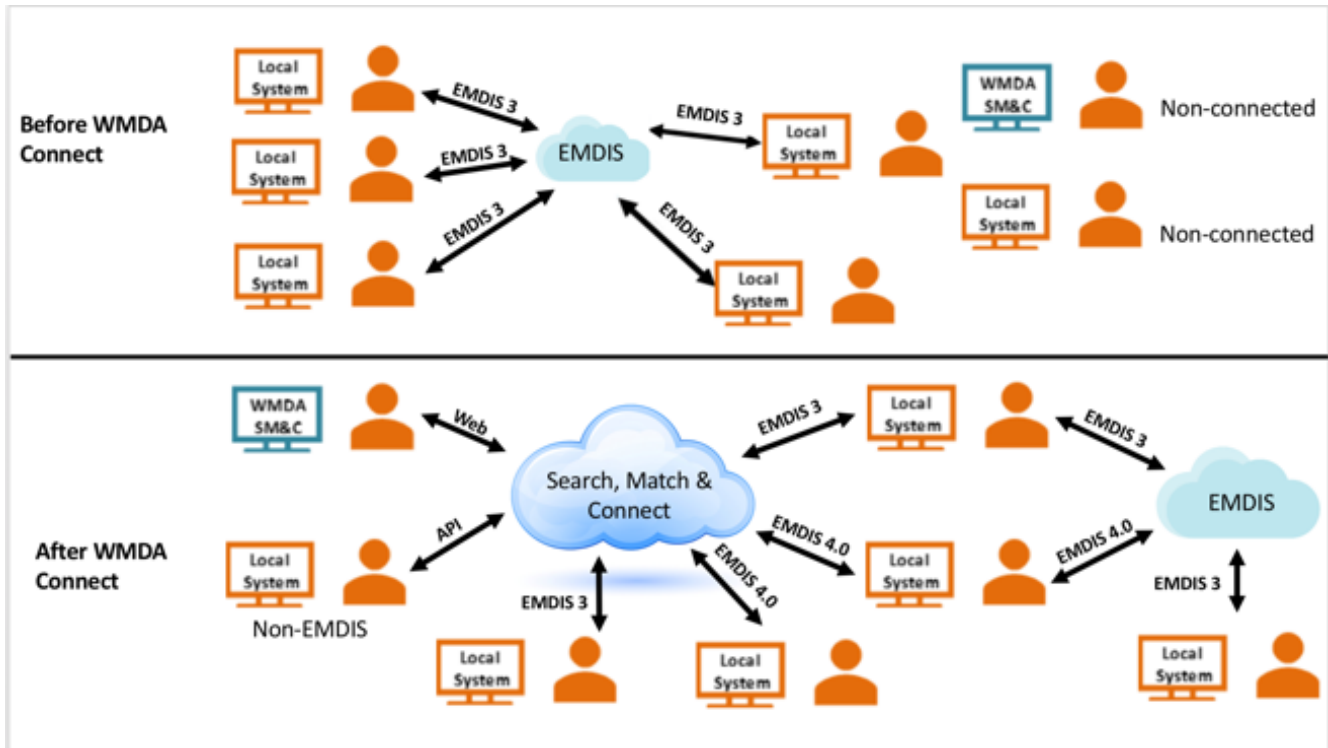
Safeguarding and promoting patient and donor care are the ultimate goals of all WMDA members' operations. WMDA will keep in contact with member organisations to ensure that their needs are understood and considered. WMDA members strive collectively to improve the communication between member organisations to ensure transparency and efficiency and to reduce the time to facilitate requests from transplant centres. WMDA will support this through:

- Accommodating private and secure communication connectors for search coordinators.
- Facilitating easily accessible operational information of member organisations.
- Implementing traceability mechanisms to help search coordinators to keep track of their requests.
- Facilitating low maintenance data exchange for search, testing, typing and work-up requests.
- Allowing registries to make their business decisions and to connect in a well-governed manner.
- Supporting several mechanisms, e.g. EMDIS, web interface and API, to facilitate communication
- Provide adequate tooling for minimising data entry, reducing data errors.

GOAL: provide access to high-performing services to facilitate the work of search coordinators.

The Search, Match and Connect vision will be achieved by realising the following goals:

Figure 1: Summarised vision for Search, Match & Connect



ONE SINGLE SEARCH, MATCH & CONNECT DATA EXCHANGE HUB (described as WMDA Connect in Figure 1)

- Facilitate effective and efficient communication between registries.
- Facilitating registries by offering one single connection point to connect to, for communication to all registries.
- Translation of messages in different data formats including EMDIS.
- Based on EMDIS data semantics; and keep an eye on development in HL7/FHIR.

IMPLEMENTATION OF CONNECTORS TO SEARCH, MATCH & CONNECT FOR REALTIME UPLOADING AND DOWNLOADING DATA (described as API* in Figure 1)

- Search coordinators can obtain the same information in their local system through an API connector as they can obtain when they register a search online through the web application.
- Development of a secure, robust, simple and scalable connector.
- Non-disruptive, backward compatible connector, that allows that registries to continue to use their current operational registry software application.
- Compliance with European Union General Data Protection Regulation (EU GDPR), reducing the need to create a data hub or to have a downloaded copy of the dataset.

EXTENDED FUNCTIONALITY CONNECTORS WITH RESPECT TO EMDIS (described as API in *Figure 1*)

- The connector provides the possibility to exchange more data including documents.
- The connector supports more processes (e.g. verification and extended typing, infectious disease marker testing, work-up requests).
- The connector provides status updates, e.g. request received, request read, etc.
- The connector provides automatically filled-in forms.

MAINTAINING MASTER DATA OF REGISTRIES (described as API in *Figure 1*)

- The connector will allow registries to define their preferences to decide how to collaborate with their international partners.

IMPROVED FUNCTIONALITY (described as API in *Figure 1*)

- Storing/re-use of search criteria (profiles)
- Define user/transplant centre preferences
- Quality monitoring

LIST OF ENVISAGED APIs calls

- Search API: to register a patient in the Search & Match Service (also available for transplant centres)
- Search & Match API: to register a patient and to get a match list in your local system
- Request API verification typing
- Request API extended typing
- Request API infectious disease marker testing
- Workup API
- WMDA forms API

USE OF MODERN TECHNOLOGY

- Low maintenance, non-specialised ICT team available once implemented
- Widely used technologies in-line with standard industry practice, preferably open source
- Implemented via an agile framework, step-by-step delivery to the WMDA member registries
- Cloud native approach allowing for distributed processing, improved resilience and optimised performance
- Open, allowing for inclusion of community developments (added functionality)
- Based on “secure by design” and “privacy by default” with full traceability of performed actions
- Use of automatic quality checks to reduce test effort and improve quality of delivery

IMPROVED AVAILABILITY SEARCH, MATCH & CONNECT

- Improved hosting environment, Connect requires high availability across the world and a scalable environment which is maintained 24x7; business requirements will be developed in collaboration with the Search, Match & Connect Steering Committee.
- Continuous delivery approach for functional enhancements

With the implementation of one single connection possibility communication to any registry is possible regardless if it is an EMDIS registry or not. The connection will translate the message into the right format for the receiver. This way registries do not have to setup and maintain multiple point-to-point connections, thus reducing complexity. It will reduce the workload of search coordinator as only one way of working is needed to retrieve information.

By using API's, the registry systems directly receive the results from the Connect. In case of error situation, the registry system will be the controlling part and receives an error notice. The WMDA only provides a (stateless) translation mechanism which can be used by the registry who will remain responsible. The API's will run in the widely used available cloud infrastructure Microsoft Azure which is high available and has built-in redundancy, reducing the risk of unavailability to almost zero.

**API:*

Application Programming Interface (see: <https://youtu.be/s7wmiS2mSXY>)

An application programming interface is a set of clearly defined methods of communication among various components. It facilitates the communication between computer programs. Those programs do not need to be in the same physical location. An API simplifies programming by abstracting the underlying implementation and only exposing objects or actions the developer needs. In this case the APIs on the side of WMDA enables secure and simple communication between it and the internal software of various registries.

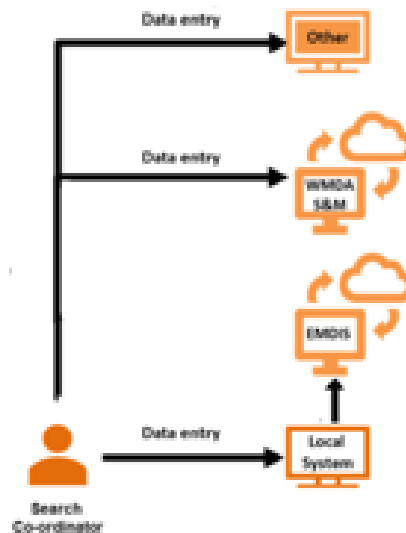
2. Explanation of these changes

2.1 Suboptimal search process

Search coordinators have provided insight into the practicalities of running their daily searches. Things that prevent, delay or frustrate them from performing fast, accurate searches include the following:

- For an accurate match list, different sources need to be consulted (no single source of truth, see *Figure 2*)
- Not all EMDIS registries use a probabilistic matching algorithm to respond to the search requests
- Data protection challenges
- Response times are slow (between a few hours and several days)
- Manually entering HLA typing of patient
- If the EMDIS logic is lacking, a search request is blocked
- Load of transactions on the servers of registries to facilitate the same request on different donor files

Figure 2: Donor search may require manual entry of patient data on to several systems

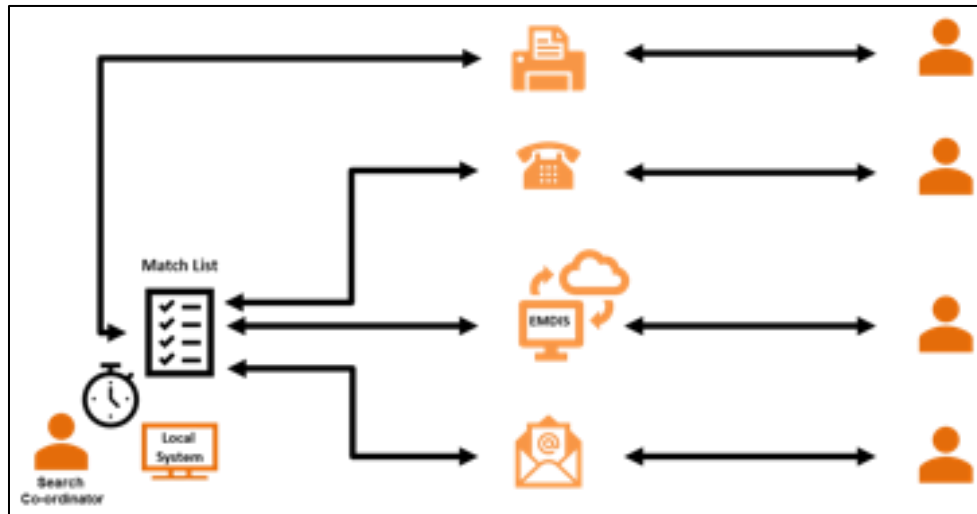


2.2 Suboptimal request processes

Things continue to be sub-optimal once the search coordinator has received results and wishes to move to the extended or verification, infectious disease marker and work-up requests and tracking stages.

- Response time are slow
- Lack of transparency
- Data protection issues
- Use of different communication mechanisms (fax, e-mail, telephone, EMDIS messages) (see *Figure 3*)
- E-mail messages on servers of the registries

Figure 3: Different communication mechanisms to perform requests



2.3 Data quality has been improved in Search & Match Service of WMDA

Search & Match Service of WMDA presents an extended data set to search coordinators in line with EMDIS data definitions. The introduction of an automated data upload facility has resulted in an increasing number of organisations that upload their data daily or weekly. A distributed search (sending search requests to different registries) is becoming less beneficial, because it takes longer time to collect all responses than performing a search in a centralised data set.

2.4 Fragmented systems and communications landscape

WMDA does not aim to be a software provider and is on the other side highly ICT dependant. Registries have a range of options on how they set-up their registry software application. These include the following:

1. Develop registry software themselves or in partnership with an external vendor
2. Join another registry by licensing their software application
3. Buy registry software

The search and extended/verification typing requests between registries take place based on the freely available EMDIS protocol, which is used by 44 of the 99 WMDA member organisations. The protocol comprises an asynchronous peer-to-peer network connecting distributed, heterogenous databases. The implementation and upkeep of the EMDIS protocol takes significant effort and know-how. The manual set-up of connections cause gaps in the EMDIS matrix. Seventy percent of the EMDIS registries have not directly implemented the protocol by themselves and use Prometheus software. For registries with limited resources there is no way to connect except via unstructured email, fax and telephone. The way that EMDIS is set up requires that each organisation uses the same network protocol. A change or update of the protocol is a complex decision-making process and requires IT resources.

2.5 Compliance with data regulation requires good governance of data

EMDIS is based on a peer-to-peer network and does not have centralised administration. Data from donors and patients are stored locally on different servers. If a registry is confronted with a donor or patient that executes the right to be forgotten, the registry faces a challenge to locate and delete donor or patient data.

API web services is a way to communicate between registries. APIs are a robust technology for integrating applications using web technology. There are fears that APIs may open security vulnerabilities, with apps maliciously accessing patient records. In general, when APIs are appropriately managed, they provide better security properties than ad hoc interfaces or proprietary integration technologies. A trend is observed that regulators explore the development of a generic API for the health care sector. APIs are perfectly positioned to address some of the GDPR requirements. API gateways can protect both data and user access at the point at which it enters and leave the system. From the regulatory bodies there is an interest in API as improvement for the healthcare sector. At the last meeting of the European SoHo registries in Brussels, API has been presented as a future step for the healthcare sector. WMDA is striving to have an ISO 27001 compliant environment for Search, Match & Connect to ensure the quality of operation.

2.6 Funding and resource are available

WMDA has secured a 4-year operational grant from the European Union to fund the realisation of our vision. This allows WMDA to move forward with confidence that sufficient budget is available to build our capacity and utilise external expertise where necessary. Volunteers from nineteen different organisations¹ agreed to work on the WMDA Connect project. A motivated group is keen to realise the outlined vision and deliver the roadmap.

2.7 Why API

API interfaces are simple program to program interfaces taking care of secure and controlled data transactions without any business logic build into them. API's require low maintenance and light-weighted governance once implemented. Development is faster at lower costs. A more complex way of communication is using messages via an ESB (enterprise service bus) allowing for embedded business logic and programming but requires strict governance and a skilled maintenance team (supplier dependency) and does not fit in with our vision. API's can easily be used in ESB environments.

¹ List of the 19 organisations: Australian BMDR, Anthony Nolan, Austrian BMDR, Matchis, NMDP, DKMS, ZKRD, France Greffe De Moelle, Canadian Blood Services, Finnish Stem Cell Registry, Datri, Czech Prague (Steiner Software), Singapore BMDP, New Zealand BMDR, Danish Aarhus, Bristol BMDR, South African MR, Italian BMDR

3. Proposed changes

3.1 Optimise Search – obtaining accurate information to select the best stem cell source

WMDA strives to provide accurate information to select the best possible stem cell source for patients in need of a transplant. The aim is to provide one dataset from which all search coordinators can find the best suitable stem cell source. Users can access this data directly from their registry system or via the Search & Match Service web application or through a ‘download’.

Approach to deliver the goal: improve the frequency and consistency of data uploads to Search & Match

WMDA is actively working on data quality. WMDA works towards:

- Timely: an infrastructure that allows real time data upload (‘differential’ file processing);
- Reliable: validation rules to present good quality data that are checked by WMDA; and
- Complete: increase quality checks and provide information about the ‘age’ of the data file.

3.2 Find the best Match – creating a Single Access Point for matching

To reduce time, effort and risk of error in creating a match list for search coordinators. This is achieved by providing tools to automatically upload validated patient HLA data directly from the local software system and automatically receive the matched results back into the local software system.

Search coordinators will be able to:

- Add new patients to the Search & Match Service through a registry’s system
- Update existing patient details in the Search & Match Service through a registry’s system
- Update the patient status in the Search & Match Service through a registry’s system
- Receive automated notifications when new search results are available
- See the results of each international donor and CBU search through a registry’s system
- View a list of all searches performed for a patient through a registry’s system
- Obtain the same information as can be obtained through the web interface
- Store or re-use search criteria (profiles)
- Define user or transplant centre preferences

Approach to deliver the goal: to get reliable and complete match lists quickly

WMDA will develop a set of technical standards – fully aligned to EMDIS semantics – and then build and/or source existing solutions to communicate seamlessly and securely from internal systems to the Search & Match Service. These technical standards will be offered through connectors that allow real-time uploading and downloading of data. The connector will be backward compatible and GDPR compliant.

3.3 Be Connect(ed) – registry Messaging System and Connect API

To improve patient outcomes by reducing the time, complexity and risk involved in finding the best available stem cell source. This will be achieved by creating an integration between systems that allow extended and verification typing requests, infectious disease marker requests, and workup requests in a secure way.

Approach to deliver the goal

WMDA will develop a single Search, Match & Connect data exchange hub ('any-connect'). This data hub will only validate the data exchange between registries. To serve all organisations the data exchange hub will accommodate various data formats, including EMDIS. The data exchange hub will enable organisations to use their internal system as their single 'front end' with all messages and communications between parties being handled securely by the data exchange hub. Storage will be handled in a GDPR compliant way.

A key aspect of our delivery will be sourcing from relevant partners to create the capability to convert traditional EMDIS messages to stand alone message packets, which can be routed to non-EMDIS and EMDIS registries. The EMDIS registries can work through the EMDIS protocol or move to an API. The non-EMDIS organisations can choose to work through an API or through a secure webpage. The API allows that registries can define their preferences of who to connect with.

In the next step, the APIs will be extended to support more processes, status updates and automated filled-in forms. WMDA will implement API connectors based on modern technology. The connectors will be delivered step-by-step ('agile' delivery).

The Connect API will enable registries to connect their internal system to the global community. Search coordinators will be able to:

- Send and receive messages between non-EMDIS and EMDIS users based on EMDIS protocols
- Perform donor availability checks, subject to data quality dependencies
- Conduct verification/extended typing request, Infectious Disease Marker requests and workup requests
- Receive automated acknowledgement, receipt and status notifications.

From an IT management point-of-view the following core principles are safeguarded:

- Low disruption to existing systems and processes and avoidance of 'forced systems migration'
- Ease of implementation to establish connections to all registries
- Low maintenance and overhead for registries
- Security and data protection 'built in' to user authentication and message handling solutions
- Single data model based on EMDIS semantics and used by all registries
- Data quality and governance steered by WMDA and supported by the Data Dictionary Working Group
- Improved transparency and reporting of data flows

- Centralised notification and support for process and business rule related issues (e.g. invoicing problems)

In *Appendix 3* the technical components are presented.

3.4 Core values to deliver our goals

WMDA is guided by five core values:

1. Patient care

Core value statement: Through safe and sustainable supply of cellular products, WMDA member organisations contribute to patient care.

Explanation: Patient care is the ultimate goal of transplant medicine. Safe and adequate supply of cellular products contributes to a well-functioning professional system. All actions that WMDA members take, should therefore serve to improve patients' care.

2. Locally configurable

Core value statement: WMDA member organisations make their own business decisions and determine their own investments.

Explanation: WMDA strives to ensure that all donors and cord blood products are treated equally. WMDA will respect members' investments and intellectual property. WMDA will strive to avoid time-bound pressure to upgrade local systems. WMDA will offer a variety of options that registries can choose from to collaborate and communicate with other registries. WMDA will offer 'backward compatibility' to ensure that all WMDA member organisations can take advantage as long as they are compliant with WMDA's terms of use.

3. Helping each other for optimal use of data: openness in information sharing

Core value statement: On behalf of its 99-member organisations, WMDA offers a complete donor and cord blood data file to facilitate the search for patients in need of a transplant.

Explanation: WMDA member organisations share donor and cord blood data with the goal to facilitate the search for a patient in need of a transplant. WMDA will ensure that privacy and data security are safeguarded, so that there is no need to have a sub-dataset.

Requesting a verification or extended typing and work-up request impacts the finances of WMDA member organisations, when a requesting organisation is not able to pay for the services requested. WMDA respects the members' decision to request pre-payment for services requested. In the technical solution, registry will govern their own business rules.

4. Excellence

Core value statement: WMDA members are striving towards excellence by adopting state-of-the-art processes and practices to reduce administrative steps that delay delivery of donation to the patient.

Explanation: WMDA member organisations constantly monitor how they can improve services to transplant centres. Excellence in stem cell supply chain cannot only be characterised by high productivity

and quality, it means also a well-functioning harmonised data exchange and information processing to ensure transparency to search coordinators and reductions in administrative workload.

5. Safety

Core value statement: Privacy and data security are safeguarded.

Explanation: WMDA is based in the Netherlands which means that the European Data Protection laws (known as GDPR) will be key in further development steps. WMDA will take technical and organisational measures necessary to secure data.

4. Delivering these changes

4.1 Governance

WMDA is building on the experience of phase 1 and phase 2 of development of the Search & Match Service. For phase 3, the decision has been taken to include additional expert groups as the scope of the project is covering the operations of a registry and EMDIS data exchanges. This has resulted in a governance structure where nineteen different organisations are represented and where different registry functions are represented, e.g. search coordinators, ICT specialists, CEOs and operational managers. The groups are a mix of new members and long-standing members. The engagement with the membership so far has reinforced a strong spirit of collaboration and shared endeavour.

Two groups will be responsible for the strategic directions and the vision:

- WMDA Board (finance).
- WMDA Committee: Search, Match & Connect (governance, strategic directions).

Three groups will be responsible for the implementation of phase 3:

- Tactical level: Steering Committee with representation of the WMDA Board.
- Operational level: Project Delivery Group (Technical Design).
- Operational level: Project Delivery Group (User Engagement).

Two groups will be used as sounding boards:

- User group (composed of search coordinators).
- Registry Operations oversight group (composed of operational managers of registries).

4.2 Resources

The WMDA office team has appointed two product owners to work on the project: one product owner Connect and one product owner Data Quality. They are supported by the project manager of phase 1 and phase 2 of developing the Search & Match Service and will bring strong project management experience and expertise.

A collaboration has been established with the Bulgarian software company MentorMate. MentorMate is familiar with the operation of the Search & Match Service, as it developed the current infrastructure. MentorMate is a supplier and is not a member of decision-making groups.

Anthony Nolan – donor registry in the United Kingdom – has gone through transformation of its operations. Experts working on that project have deep insight on EMDIS architecture and are available to advise on the development of the Connect architecture.

This core team is supported by several groups. The team can be adapted as we learn and be guided by members. The project delivery group members subdivided into

- User Engagement
- Technical Team

They are guided by the Search, Match & Connect Steering Committee.

4.3 Communication and reporting

WMDA strives to be transparent to its membership. For this project a communication officer was appointed to ensure effective communication and engagement. The communication officer will collaborate with the User Engagement Group. The aim is to inform the membership through formal presentations and discussions at planned WMDA events; ad hoc group meetings and one-to-one conversations; published materials placed on membership web environment; regular updates in Stem Cell Matters, and; frequent meeting of groups that are active in the project.

The WMDA office team and members of the User Engagement Project Delivery Group are open to schedule a telephone call with you to guide you through the steps and the impact that it may have on your registry operation.

It is important that we monitor whether we are on track to do and achieve what we've set out to, and to understand what may be hindering progress so we can work collectively to find solutions. Work-stream leads will report their progress regularly to the Search, Match & Connect Committee, and the Chair will report overall progress to the WMDA Board. We will share these updates with members to ensure shared understanding of what is being done and achieved. We are required by the EU to track and evaluate whether we have realised the expected benefits from this investment and effort, and we will work with members to assess and evidence this. This information, as well as lessons learned from delivery, will be disseminated to members.

4.4 Phased implementation

This vision and operational document show clear, shared goals and outcomes. The route to achieving them will be based on what we learn. WMDA will adapt, as we learn how the proposed solution is working for its members. Our path will ultimately be charted by members. We want to get this right rather than just do it quickly.

5. Risks for WMDA – Governance, risk & compliance

The Search, Match & Connect Steering Committee is responsible for the governance, risk and compliance of the project. They work closely with the Project Delivery Groups and reports directly to the WMDA Board members representing Search, Match & Connect. The project is a major initiative for WMDA, and it took time to take the decision to initiate. Below is an overview of risk areas that WMDA is aware of and how they have been or will be tackled.

5.1 Security

ACCESS CONTROL

- **LISTING ORGANISATIONS:** WMDA grants access to organisations that have been approved by the WMDA Board. Only registered data uploaders have access to the data upload service. Bi-annually WMDA checks registered users.
- **ACCESS TO SEARCH & MATCH SERVICE:** WMDA grants access to the Search, Match & Service to users appointed by the registry and authorised transplant centres. Bi-annually WMDA checks registered users. To avoid that registries, share passwords between staff members, WMDA does not charge per registered user for provisional and regular WMDA member organisations.
- **ACCESS TO API CONNECTIONS:** WMDA grants access to registries that have proved to comply with WMDA terms of use. These are registries that have signed data use agreements (both data use agreement with WMDA and registry-to-registry data use agreement) and have achieved WMDA qualification status.



DATA BREACH – ROBUST POLICY ON DATA PROTECTION

- **CYBER RISK:** WMDA has an insurance contract for cybercrime.
- **HOSTING:** Hosting provider will be selected in consultation with Data Security Privacy Committee.
- API integrations are secured, e.g. firewall protected, authenticated, authorisation checked, data encrypted). The vulnerability will be checked regularly using PEN-testing
- Data exchange is based on industry standard asymmetric encryption mechanisms, i.e. Message exchange, digital signatures.
- A process will be implemented of security checks and audits by suitably qualified staff or third parties.
- Avoid introduction of additional private donor or patient data.

5.2 Legal

ENSURE A LEGAL FRAMEWORK FOR INTERNATIONAL DATA EXCHANGE

WMDA strives to build a legal framework for international data exchange. At the moment, this is based on three data use agreements:

- Data use agreement between WMDA and the listing entity;
- Data use agreement between listing entities (facilitated by WMDA);
- Data use agreement for organisations that download the data from the global file.



COMPLIANCE WITH EUROPEAN DATA REGULATION (GDPR)

- Access control functions are fully manageable and auditable.
- System access control based on personal accounts and organisational roles.
- All communication between parties is fully encrypted and accessible only for involved parties.
- No new private donor/patient data are introduced.
- Appointment of WMDA data protection officer, who can support registries if they wish.
- License of the privacy management software application OneTrust (<https://www.onetrust.com>).

GOOD GOVERNANCE – WHO IS RESPONSIBLE FOR DECISION MAKING?

WMDA is facing a complex process of decision making. A governance structure has been set up resulting in groups with different responsibilities. A member of the WMDA Board is also serving in the Steering Committee, to make sure that progress in decision making is not delayed.

5.3 IT

HIGH AVAILABILITY – PERFORMANCE & SCALABILITY

The data exchange hub and all newly introduced components are planned in fully redundant setup, with minimum two (2) instances per component, load balanced.



DISASTER RECOVERY – DATA ARE NOT LOST

The solution is designed to be fully redundant and data are automatically backed up. Data Privacy Committee will provide advice on the desired level of recovery point and time. Based on the advice it can allow hosting in the same datacentre or require distribution over multiple locations.

EMDIS DEVELOPMENT – RESOURCES ARE NOT AVAILABLE BECAUSE OF EMDIS IMPLEMENTATION PACKAGES

EMDIS presented a mechanism to replace the e-mail messaging. WMDA invited EMDIS technical representatives to participate in the project delivery group and the chairs of the EMDIS User Group and the EMDIS Technical Group are serving as members of the Search, Match & Connect Board Committee. In addition, WMDA will:

- Develop technical standards based on widely used systems specifications and open source;
- Publish technical documentation for review by all WMDA member organisations;
- Use EMDIS semantics as baseline for data standards; and
- Continue to ensure diverse representation within project delivery team;

WORKING RELATIONSHIP WITH CURRENT SOFTWARE VENDOR TERMINATES

A change of software vendor will require an onboarding investment, to make the new company familiar with the code and the way WMDA is operating. This will require an investment to onboard a software vendor.

MAINTENANCE

WMDA will recruit one additional staff member to maintain the Connect environment and to bring expertise in the core WMDA team. This will reduce the dependency on external software vendors. Based on advice of different experts, one FTE will be sufficient for the maintenance of the Connect environment. Part of the development budget will be used to transfer knowledge from the software vendor to the WMDA core team. Anthony Nolan has developed a similar system, as a back-up their IT team can serve as support.

MATCHING ALGORITHM: The matching algorithm requires a stable hosting solution with high capacity. Changing the hosting solution may require attention and care to keep the matching algorithm operating.

CONFIRMATION OF USER DEMAND AND BASELINE METRICS – AVOID SCOPE CREEP

WMDA needs to do more to communicate the benefits of a more secure and efficient way of facilitating inter-registry communications amongst some established registries. For the transition programme, a project manager will define clear milestones and metrics and visibility to ensure that WMDA reaches the defined goals.

RESOURCE AVAILABILITY

Changes in staff in either WMDA or registries may cause a reduction in capacity and an additional investment to onboard new staff members or volunteers.

5.4 Internal audit

AUDITING WITHIN WMDA:

- NMDP will scan the vulnerability of the Search & Match environment monthly.
- WMDA staff members have signed confidentiality agreements.
- All third-party providers have signed a confidentiality agreement.



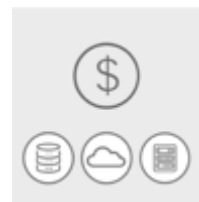
AUDITING OF WMDA MEMBER ORGANISATIONS USING THE API

WMDA Standards 2020 describes data privacy and security standards, according to GDPR. WMDA reviewers will be trained to audit organisations on their data privacy and security.

5.5 Finance

ANNUAL AUDIT OF ACCOUNTS

The activities of WMDA has grown over time. WMDA has replaced the membership audit with an audit by an independent financial accountant.



UNFORESEEN FINANCIAL INVESTMENTS – DEPENDENCY OF MATCHING ALGORITHM:

WMDA is paying an annual licence fee for the matching algorithm, provided by ZKRD. The current license contract does not include retrieval of match lists in the local registry system. WMDA is negotiating with ZKRD and strives to achieve a fee that is feasible for registries. In case the license fee will cause an increase

in membership fees WMDA will explore alternative solutions. This will require an estimated investment of Euro 200.000, - (paid from BMDW reserves).

EU OPERATIONAL FUNDING till 2021

WMDA is receiving an operational EU funding. The grant accommodates annually a fee of Euro 100.000 for software development and the hiring of a software developer. In case the work is more than anticipated and the funding dries up, milestones will be delivered on a slower pathway.

FINANCE REPORTING

WMDA's treasurer receives monthly a forecast. In case investments exceed the budget by more than 10%, the WMDA Board will be informed. The membership is informed annually.

UNFORESEEN INCREASE OF COSTS

Democracy in decision making may have significant impact on the costs (manhours of staff) and on the time of the volunteers as it may elongate the delivery timeline. The idea came out the membership consultation at the 2017 Marseille meeting. This has been worked out in a strategy, presented in Minneapolis 2017. The Search, Match & Connect Board Committee has presented the vision three times at the WMDA meetings (Munich, Minneapolis, Noordwijk). At the 2018 Minneapolis the membership voted positive. This aim of this document is to explain the vision in writing to the membership.

Appendix 1 – Glossary

API

An Application Programming Interface (API) is a set of clearly defined methods of communication among various components. It facilitates the communication between computer programs. Those programs do not need to be in the same physical location. An API simplifies programming by abstracting the underlying implementation and only exposing objects or actions the developer needs.

In this case the APIs on the side of WMDA enable secure and simple communication between it and the internal software of various registries. See: <https://youtu.be/s7wmiS2mSXY>

EMDIS

Initiated in 1992 as a European Union Project in the 3rd Framework Programme "Advanced Informatics in Medicine (AIM)", the European Marrow Donor Information System (EMDIS) has become the standard platform for computer-based registry communication today. The aim of EMDIS is to establish a single virtual international donor registry allowing search coordinators to get the same information and services on international donors as accurately, timely and easily as from their own national donors.

European Union General Data Protection Regulation (EU GDPR)

The General Data Protection Regulation (EU) 2016/679 (GDPR) is a regulation in EU law on data protection and privacy for all individual citizens of the European Union (EU) and the European Economic Area (EEA). It also addresses the transfer of personal data outside the EU and EEA areas.

GRID

The Global Registration Identifier for Donors (GRID) is a standard machine-readable format that can be used by electronic process control systems, as well as a standard format for the human-readable version, has been developed. WMDA collaborates with [ICCBBA](#) (International Council for Commonality in Blood Banking Automation) to use the experience gathered in other areas, like transfusion medicine. Given the global nature of the work done by the organisations providing blood stem cell products, a system to uniquely identify potential donors on a global scale is needed to facilitate communication and prevent errors in identification of donors.

HL7/FHIR

Fast Healthcare Interoperability Resources (FHIR, pronounced "fire") is a draft standard describing data formats and elements (known as "resources") and an application programming interface (API) for exchanging electronic health records. The standard was created by the Health Level Seven International (HL7) health-care standards organisation.

Microsoft Azure

Microsoft Azure (formerly Windows Azure) is a cloud computing service created by Microsoft for building, testing, deploying, and managing applications and services through Microsoft-managed data centers. It

provides software as a service (SaaS), platform as a service (PaaS) and infrastructure as a service (IaaS) and supports many different programming languages, tools and frameworks, including both Microsoft-specific and third-party software and systems.

Prometheus

Prometheus is a free software application used for event monitoring and alerting. It records real-time metrics in a time series database (allowing for high dimensionality) built using a HTTP pull model, with flexible queries and real-time alerting. The project is written in Go and licensed under the Apache 2 License, with source code available on GitHub, and is a graduated project of the Cloud Native Computing Foundation, along with Kubernetes and Envoy.

Search coordinator

A professional involved in unrelated adult donor/cord blood unit search and selection and responsible for in finding the best donor for a patient. To standardise the level of expertise of staff performing searches and providing recommendations on graft selection, the WMDA has developed a global certificate programme

XML

Extensible Markup Language (XML) is a mark-up language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable. The World Wide Web Consortium's XML 1.0 Specification of 1998 and several other related specifications— all of them free open standards—define XML.

Appendix 2 – Background and Context

WMDA took over the operation of the Search & Match Service (known as BMDW) on 1 January 2017. At that time, phase 1 had just been implemented and phase 2 was in progress and would be completed in April 2018. The key features of the phase 1 and phase 2 development projects are summarised below:

2016 (phase 1):

- Introduced predictive matching algorithm
- Modern, user friendly service web site
- Cleaned up who has access to the service
- Secure code, robust hosting

2018 (phase 2):

- Automated data upload (through API or web upload)
- Transition to XML data schema
- Introduced extended dataset
- Improved data quality and good insight on capabilities of registries

The implementation of Connect, or Phase 3, requires input from the whole community. WMDA has actively promoted participation in the project through Stem Cell Matters and during the last three WMDA meetings.

Under the remit of the WMDA's 'Pillar 1 - Optimising 'Search, Match & Connect' strategic theme an outline was presented at the WMDA meetings in November 2017, June 2018 and November 2018. These initial plans were aligned to ambitions articulated by the abandoned *World Match Central* project in 2012 and the 2017 Global Technology Vision agreed by senior registry personnel which stated as follows:

To work towards maximizing the availability, quality, safety and cost effectiveness of hematopoietic stem cells globally by maintaining and developing strong collaborations among organisations that are listing and searching for volunteer donors and umbilical cord blood units

The WMDA community was canvassed via online surveys several times during 2018. Feedback confirmed a demand to 'democratise' the global donor pool and a desire to improve the functionality of the Search & Match Service.

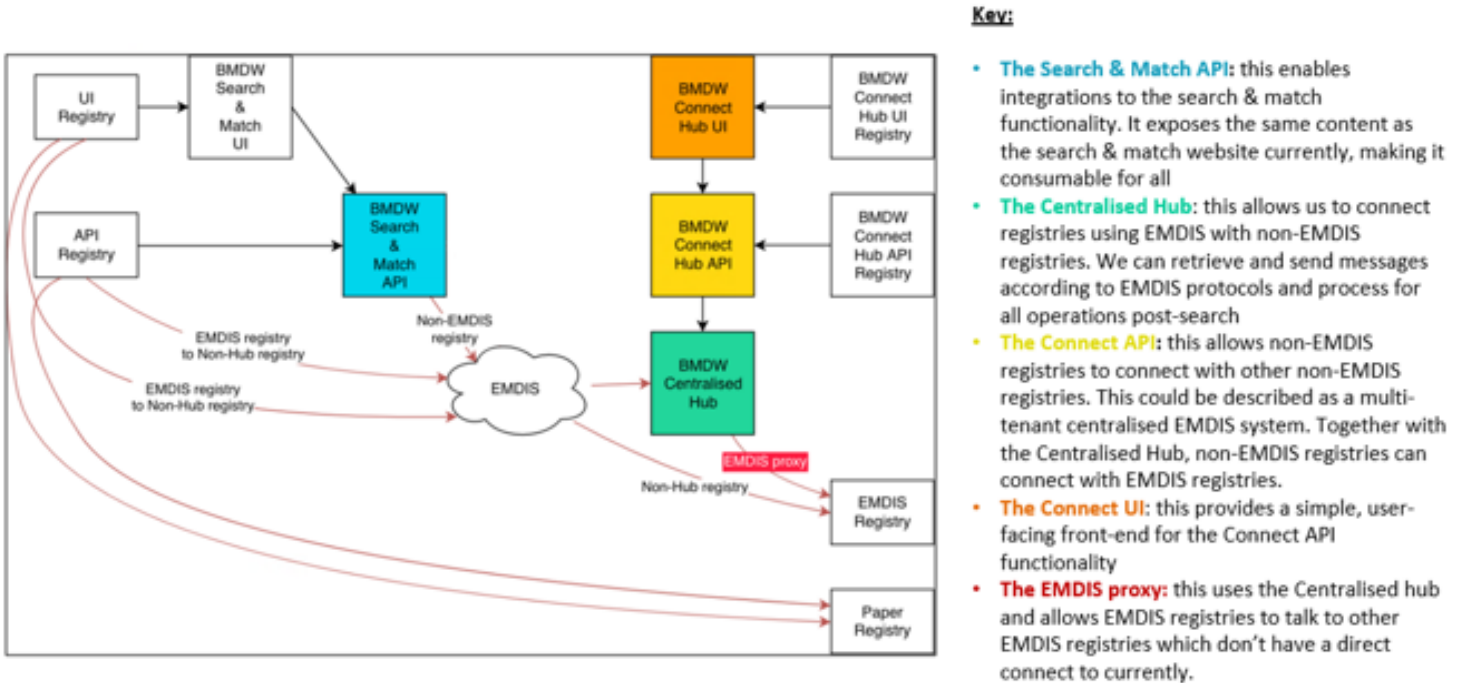
At the WMDA November 2018 meeting delegates were presented with the latest iterations of the proposed Phase 3 plans and they provided strong approval to the integration between EMDIS and Search & Match and the ability to connect to all registries via a single component.

As well as direct member feedback several external ICT experts, who volunteered to help and are active in other industries, have commented that the Phase 3 project is feasible and will not have a significant impact on the financial resources of registries. Nevertheless, several member ICT experts saw barriers and did not feel well informed. These concerns were explored and considered in the design for a customizable solution to help all registries in facilitating their transplants.

Appendix 3 – Technical Design

The design of the WMDA Search, Match & Connect service is described in *Figure 4* below. It is an extension upon the current infrastructure. The coloured boxes are new components.

Figure 4: Design of the WMDA Search, Match & Connect service



SECURITY

Security is integral part of the design of the Search, Match & Connect infrastructure and has been part of the design since its first conception. We have involved software engineers that have experience in developing secure software applications as well as their APIs.

As with web sites, an API is internet-facing and therefore will be subject to random and targeted attacks. Therefore, the security measures that are in place to help protect the WMDA Search & Match website will also protect the API. These include the use of an enterprise grade firewall to protect the infrastructure in general, the use of SSL/TLS for transport of information between client and server and regular security scanning and subsequently solving the security vulnerabilities that are found.

In addition to this we will use:

- OAuth 2.0 authentication. This is an authentication and authorization method that is widely used for APIs and is known for its security
- Input validation
- Constraining of string inputs using regular expressions and lists of allowed values
- Logging and monitoring of input validation failures to improve auditability
- IP access lists to only permit access from approved organisations

These points will ensure that the API will be as secure or possibly even more secure than the current Search & Match website.

At this moment, the infrastructure that is responsible for providing the Search & Match Service is hosted in a datacentre. Because of the way the system is setup it cannot provide the availability guarantees that are to be expected of the finished WMDA Search, Match & Connect Service that is described in this document. Creating the necessary infrastructure will require the setup of an infrastructure that is not financially feasible for the WMDA. We therefore would like to move our services to a cloud provider. Some of the major benefits are:

- High availability because the virtual servers and virtual applications would live on a shared environment with an amount of redundancies that are impossible to achieve by WMDA by ourselves.
- Experienced IT professionals look after security of the platform 24 hours a day. This is not feasible for the WMDA. The security level will therefore only go up.
- When properly designed, application performance can scale up and down when needed. This means that you will not need to pay for resources you do not need but have the ability to use more resources only for a time period where it is desired.
- Based on the business requirements an appropriate calculation can be prepared. WMDA has had initial conversations with several hosting providers and based on these conversations, the WMDA office estimates that the hosting costs will not increase.

As described in Chapter 2, the implementation will be phased. Features will be provided to the WMDA community when they are ready.

COMMUNICATION PATHWAYS

Figure 1 in Chapter 1 and Figure 4 in this Appendix 3 indicate the possible ways in which organisations will be able to communicate with the WMDA Connect environment. Below we will explain each of the possible ways.

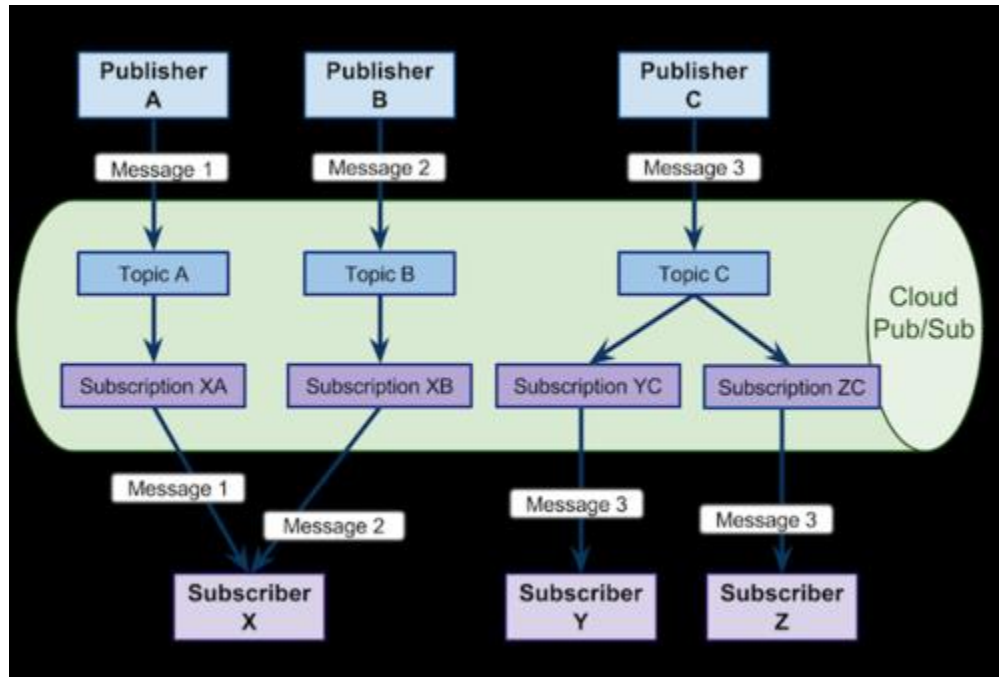
EMDIS 3

Currently many organisations are using EMDIS 3 (the current version) to communicate with other organisations. Most of these might want to keep doing this, at least for now. To enable these organisations to communicate with non-EMDIS organisations, we will provide an “EMDIS proxy”. This proxy will enable organisations to open up communication with all other organisations that are connected to the WMDA connect environment by just adding just one more EMDIS connection to the WMDA Connect EMDIS proxy. Of course, organisations will still have full control which organisations they will be able to communicate with and which organisations are able to contact them.

EMDIS 4

Besides providing EMDIS 3 communication through the EMDIS proxy we will also provide API access. For the connect API backend we will use a messaging service. An example of such a messaging service can be found in *Figure 5* below:

Figure 5: Example of EMDIS 4 messaging service



The messaging services will have the following criteria:

- Simple messaging pipeline
- Messaging API:
 - Synchronously validates messages
 - Auto-scaling PaaS ensures scalability and reduces overheads
- Processing Queue:
 - Holds validated messages for asynchronous processing
- Messaging Processors:
 - Asynchronously process messages and distribute to the appropriate registry queue
 - Serverless technology (Cloud Functions) scales indefinitely with no minimum spend
- Registry Queues:
 - Holds processed messages until the receiving registry is ready to process them

Organisations will be able to directly connect this message service. This will make it easier for existing organisations to migrate from e-mail based EMDIS communication to message service based EMDIS communication. This is a similar way of communication as described in the EMDIS 4.0 white paper.

API

Organisations can also choose to connect to the WMDA Connect environment by using the RESTful API. This will be the best fit for new organisation who are currently not on EMDIS and for organisations that are rebuilding their internal systems. This API will provide a modern, secure way of communicating with other organisations, including EMDIS organisations.

CONNECT HUB USER INTERFACE

For small, starting organisations we will provide a user interface within the Search, Match and Connect website that will provide a basic communication platform to enable communication with other non-EMDIS, but also EMDIS organisations.

SOURCING

Our goal is to make as much use of existing and open-source software as possible. We will also provide services that can be connected to using existing tools and libraries. This will make the implementation of the connection to the WMDA Connect environment as easy as possible.