

# D1.2 Progress report GRID

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GLOBAL  
REGISTRATION  
IDENTIFIER FOR  
DONORS

**GRID**—

UNIQUE DONOR IDENTIFICATION

## Summary

Unrelated hematopoietic stem cell donor registries and issuing organisations (IO) facilitate exchange of stem cell products throughout the world. After a serious adverse event was reported in the 2016, in which a patient was transplanted with stem cells from an incorrect donor in large part due to the inappropriate use of a supposedly unique donor identifier it became even more important to prevent errors in identification of donor. In addition, it was necessary to introduce a system to uniquely and consistently identify potential donors on a global scale and improve the communication across national and international borders. To this end, the World Marrow Donor Association (WMDA) collaborated with the International Council for Commonality in Blood Bank Automation (ICCBBA) to develop and implement a Global Registration Identifier for Donors (GRID). Simply put, the GRID is a new and better way to identify potential donors. It provides a standard format to ensure that every donor is assigned a globally unique identifier. GRID needs to tie in more strongly with donor and patient safety. The main reason why GRID needs to be implemented is to ensure the international community is doing everything in their power to facilitate a safe and successful unrelated donor transplantation for patients in need. Following this, in a Letter of Support the Worldwide Network for Blood and Marrow Transplantation (WBMT) indicated the importance of the work being done by WMDA towards the establishment of GRID.

In this progress report, the envisaged implementation of GRID in relation to existing problems, projected changes, and the challenges of a proactive and collaborative project involving many departments and organisations on a national and international level is described. The most important and most frequently asked questions is ‘Why do we need a globally standardised donor ID although there is already a consistent taxonomy per country?’ First, two different aspects of IDs should be considered: eye-readability and electronically readable presentation. A person’s cognitive process often fades out unnecessary parts like spaces between parts of IDs whereas IT systems simply count every single character. Taking that into consideration, the initial assumption of having a unique donor ID within a country is often not true. In practice, many more problems can result in a time delay for the patient or the risk of choosing the wrong donor. WMDA is working closely with ICCBBA to use their knowledge and experience around transfusion to ensure a smooth implementation of GRID globally.

The GRID project is a multi-phase, multi-year effort to achieve implementation on an international basis and it is ongoing. This progress report defines the project planning, goals, achievements, governance, communication channels, educational events and software development achieved in 2018 and the plan for 2019 to implement the unique donor number.

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## 1. Origin of GRID

In the field of hematopoietic stem cell transplantation (HSCT), with a still growing number of voluntary unrelated donors, it was recognised that a system needed to be developed to uniquely identify potential donors on a global scale to facilitate communication and to prevent errors in the identification of donors. Efforts in this respect resulted in establishment of the Global Registration Identifier for Donors (GRID), with a defined structure and allocated rules. To successfully implement such a project, collaboration among all organisations involved in the process of volunteer donor recruitment, facilitation, and provision of hematopoietic stem cell products is necessary. (1)

The explicit identification of unrelated donors is an inherent part of the HSCT field since its beginnings. During the 1990s, the first big shift evolved from the use of HSC products within geographical determined institutions to regional distributions within clinical networks and groups. (2) No later than in the 2000s, the second big shift evolved towards international distribution, irrespective of border. (3) Both shifts made the need for blood products essential, and request from different countries in a variety of sources where made. This extended the varieties of donor identifiers to be dealt with, hence reinforcing the requirements of interoperability.

The massive and rapid use of donated blood revealed major problems in labelling and barcoding. (4) A report of the US Department of Defense summarised thousands of labelling mistakes and listed key sources of errors; for example: different languages, errors in barcode substitutions and duplication of donation numbers. (1) To overcome these problems, the International Society of Blood Transfusion (ISBT) created a new coding system called 'ISBT 128' using a uniquely defined product identifier and standardised barcode information. The ISBT, the American Association of Blood Bank (AABB), and the American Red Cross established the International Council for Commonality in Blood Bank Automation (ICCBBA) to manage and develop the standard. (5, 6)

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### **What is ICCBBA?**

*ICCBBA (formerly International Council for Commonality in Blood Bank Automation) is an international non-governmental, non-profit organisation in official relations with the World Health Organisation and is responsible for the ISBT 128 Standard. The mission of ICCBBA is to improve patient safety through standardisation of the manner in which critical information is carried on labels of Medical Products of Human Origin (MPHO), including the hematopoietic stem cell products of bone marrow and cord blood.*

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Several incidents of donor mix-ups were reported, from recoverable mistakes in handwritten IDs to a completely HLA-mismatched allogeneic unrelated HSCT due to a series of inadvertences and lack of control. With respect to the reported problems of the whole blood field, to prevent impractical or even inconsistent regulations and improve patient safety, it was an important step for the World Marrow Donor Association (WMDA) to become active. (7)

In 2016, a serious adverse event was reported in the journal Bone Marrow Transplantation in which a patient was transplanted with stem cells from an incorrect donor in large part due to the inappropriate use of a supposedly unique donor identifier. The event was reported to the national authorities as a severe adverse event and to the WMDA Serious (Product) Events and Adverse Reactions

(S(P)EAR) committee. This committee reviewed the serious adverse events (SAE) and due to the possibility, that such event could occur again, a rapid alert was sent from the WMDA to all members and professional societies to raise awareness. This report emphasised, again, the importance of a global unique donor identifier and that this severe adverse event could recur elsewhere. Indeed, since this report was published, the WMDA S(P)EAR committee is aware of a similar case with a mix-up of donors during the workup process. (7) More information about S(P)EAR can be found in the progress report *D4.2 Progress report on the gathering, analysis and provision of data, insight and resources that support members to safeguard the rights and safety of stem cell*.

With increasing numbers of donors, collections, and international shipments the WMDA recognised that a standardised donor identification is necessary to fulfil future requirements in the field of HSCT (figure 1) and to improve patient and donor safety. The Worldwide Network for Blood and Marrow Transplantation (WBMT) indicated the importance of the work being done by WMDA towards the establishment of GRID in a Letter of Support in 2016. (9)

*Figure 1. Data of global stem cell products and donors in 2016*

2016	
<b>HSC products</b>	17,297
<b>Donors</b>	30,973,284
<b>shipped abroad</b>	50%

*World Marrow Donor Association (WMDA): Stem Cell Registries Annual Report 2016. 2016. [www.wmda.info/about-us/publications/30-annual-reports](http://www.wmda.info/about-us/publications/30-annual-reports)*

In 2010, a WMDA project group in cooperation with the ICCBBA developed GRID, which was first approved by the WMDA board in 2014 and revised before implementation could start in 2017. (1) This unique donor identifier is used to ensure confidentiality and anonymity of the donors, so that the identity of the donors and their rights are protected. The number must be unique to ensure traceability between donors and their associated data, and biological material and their participation in the donation process in long term.

The GRID was designed to be compatible with both IT based systems and manual transfers, allowing the transition to safer technological solutions to develop alongside existing manual systems.

The purpose of the GRID is to:

- Facilitate national and international traceability of stem cell products
- Reduce the risk of misidentification of donors or their donation due to the lack of global uniqueness of identifiers
- Facilitate communication by providing a standard machine-readable format (bar codes) that can be used by computer systems

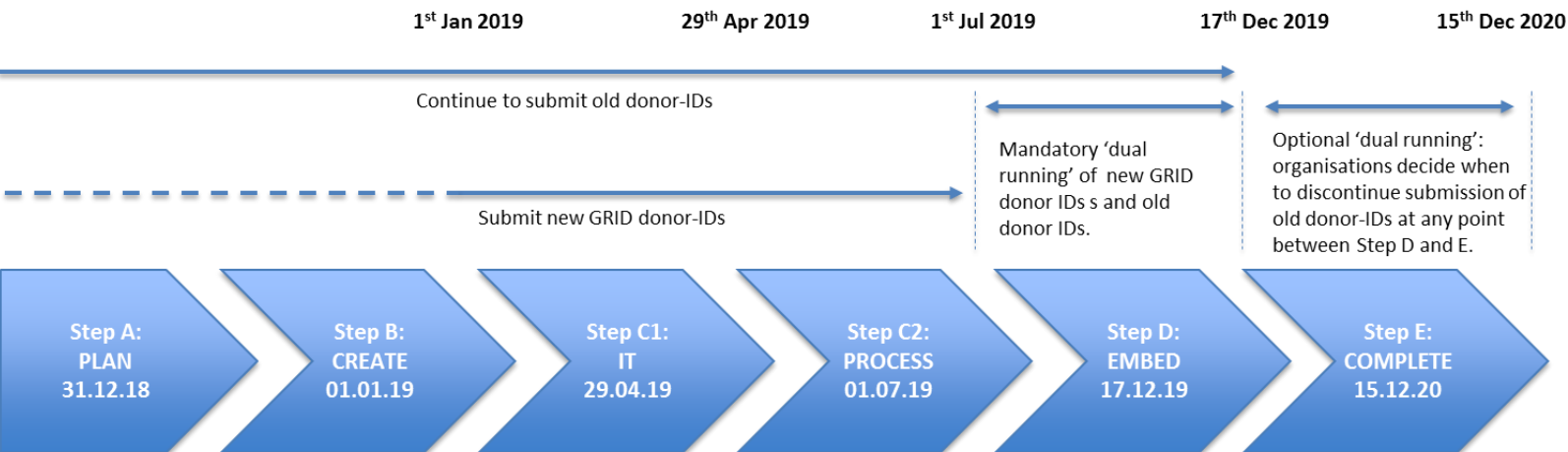
Through discussion with listing organisations and other relevant stakeholders (for example the European Marrow Donor Information System working groups), the WMDA has developed and published a phased approach for the introduction of GRID.

*The European Marrow Donor Information System (EMDIS) is a communication tool used by many registries (45%) to communicate patients, donors, cords and order on a registry to registry basis. Schedules, details and discussion regarding the proposed EMDIS implementation can be found in RFC 60 Introduction to GRID in the new format into EMDIS. EMDIS has their own area on WMDA Share, where details of the GRID Implementation for EMDIS can also be found.*

The plan has been communicated extensively over the course of the last year with clarifications and guidance provided by the GRID Task Force.

In 2018, WMDA received an EU grant to ensure this GRID implementation is successfully embedded globally by 2020. In Figure 2, the timeline for each period, designed by WMDA and approved by the Board and the Task Force is shown.

Figure 2. GRID implementation timetable 2018 – 2020



- All WMDA member organisations can get their ION-registration number from ICCBBA.
- In addition, each organisation defines the plan how to implement GRID in their own organisation.
- Creation of a GRID **field** in the XML data submission to the Search & Match Service (BMDW) is mandatory.
- In case a GRID is assigned to the donors of a listing organisation, it is desirable to submit it in the XML file. The GRID will show in Search & Match (BMDW).
- If the GRID field is blank it will show as blank alongside the old donor IDs.
- All IT systems (for example the registry software; EMDIS; Search & Match Service) **must** have a GRID populated for all donors. GRID is visible in all IT systems.
- If an organisation need more time to roll out operational processes, they have until 1<sup>st</sup> July.
- Ensuring all the operational procedures contain GRIDs (for example labels, paperwork, working instructions) and all the transplant centres, donor centres, collection centres and other stakeholders are fully aware of the GRIDs.
- All member organisations **must** be able to use GRID as the sole donor identifier for their own donors and any incoming donors
- They may continue to use the old donor IDs alongside their GRID as a secondary identifier should they wish to.
- GRID **must** be fully implemented for all listing organisations and will be the only donor identifier to be shown in the Search & Match Service.
- Old donor IDs will no longer be accepted by the Search & Match Service.

## 2. Technical Design of GRID

The design of the GRID consists of fixed length of 19 character, letters and numbers only, no symbols or punctuation. It is composed of three specified elements (figure 3).

The first four-digit number represents the issuing organisation number (ION), which is allocated by ICCBBA in collaboration with the WMDA and provides the necessary part to create uniqueness on a global scale. The middle element provides space for 13 alphanumeric characters for integration of the existing or newly assigned ID prefixed with leading zeros if required. The last two digits of the GRID display the checksum as internal part of the GRID for validation of manual data entry, in order to detect the misidentification of HSC donors due to transmission or typing errors.

*Figure 3. Example of the technical design of GRID*



The design of GRID is structured as follows:

- *Issuing Organisation Number (ION): Every WMDA member organisation has a unique organisation number, assigned by ICCBBA, to track where the donor is registered*
- *Registration Donor Identifier: This number is a donor's personal number, assigned upon registration*
- *Checksum - GRID Checksum Calculator: This checksum is the outcome of running an algorithm. It is used to validate and check the GRID to ensure that the input data is genuine and error free. (8)*

The ISBT 128 Standard – Global Registration Identifier for Donors: ION Database and GRID Rules – from ICCBBA provides information on the structure of the GRID Issuing Organisation Database as well as instructions on how to obtain an ION, how to update the ION information within the database, and how to use a GRID for hematopoietic stem cell donors and potential donors.

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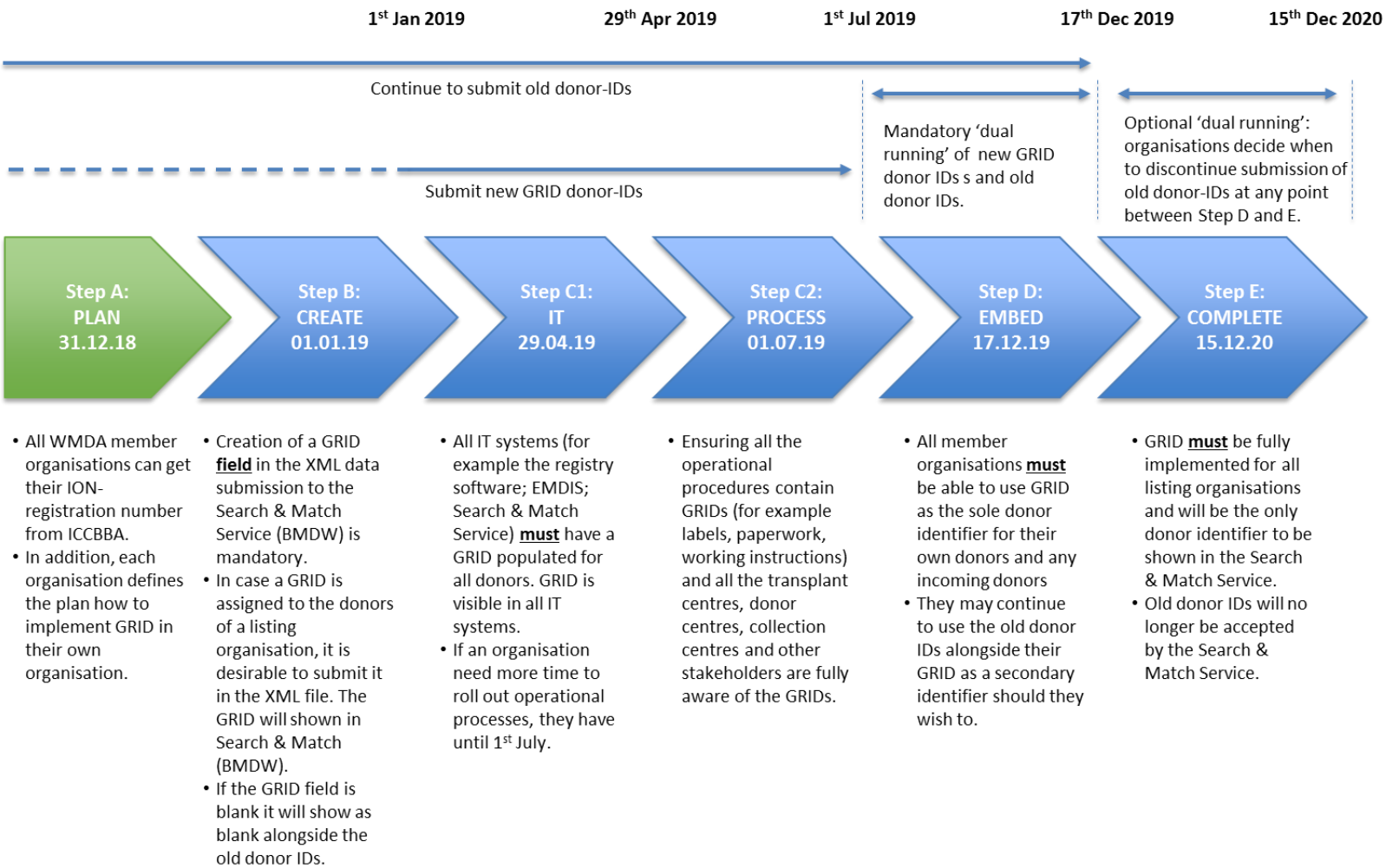
*Version 3.15 of the GRID Issuing Organisation Number Database has been posted on the ICCBBA website in September 2018. This latest version can be viewed via de website: <https://www.iccbba.org/tech-library/databases-reference-tables/grid-issuing-organizations>*

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### 3. Project objectives for the period

GRID is a phased deliverable. The overall goal is to create a system for assigning a globally unique identifier to potential volunteer blood stem cell donors. The current stage is Step A: The start of implementing GRID in every WMDA listing organisation (figure 4).

Figure 4. GRID implementation timetable Step A



As part of Step A, the remit of WMDA is to ensure that the deadline of 31<sup>st</sup> December 2018 is met. This is the first phase of adopting the GRID in each organisation. This means that every organisation has registered an Issuing Organisation Number (ION) at ICCBBA and that they have defined a strategy how to implement GRID in their organisation, in their processes and in their country.

Specifically, for 2018 the goal is to move the GRID project from design mode (at the end of 2017) to the implementation mode (2018). Ideally, 100% of all the listing donor organisations of the global database would have implemented GRID before 01<sup>st</sup> January 2019. This deadline is not met. The status by the end

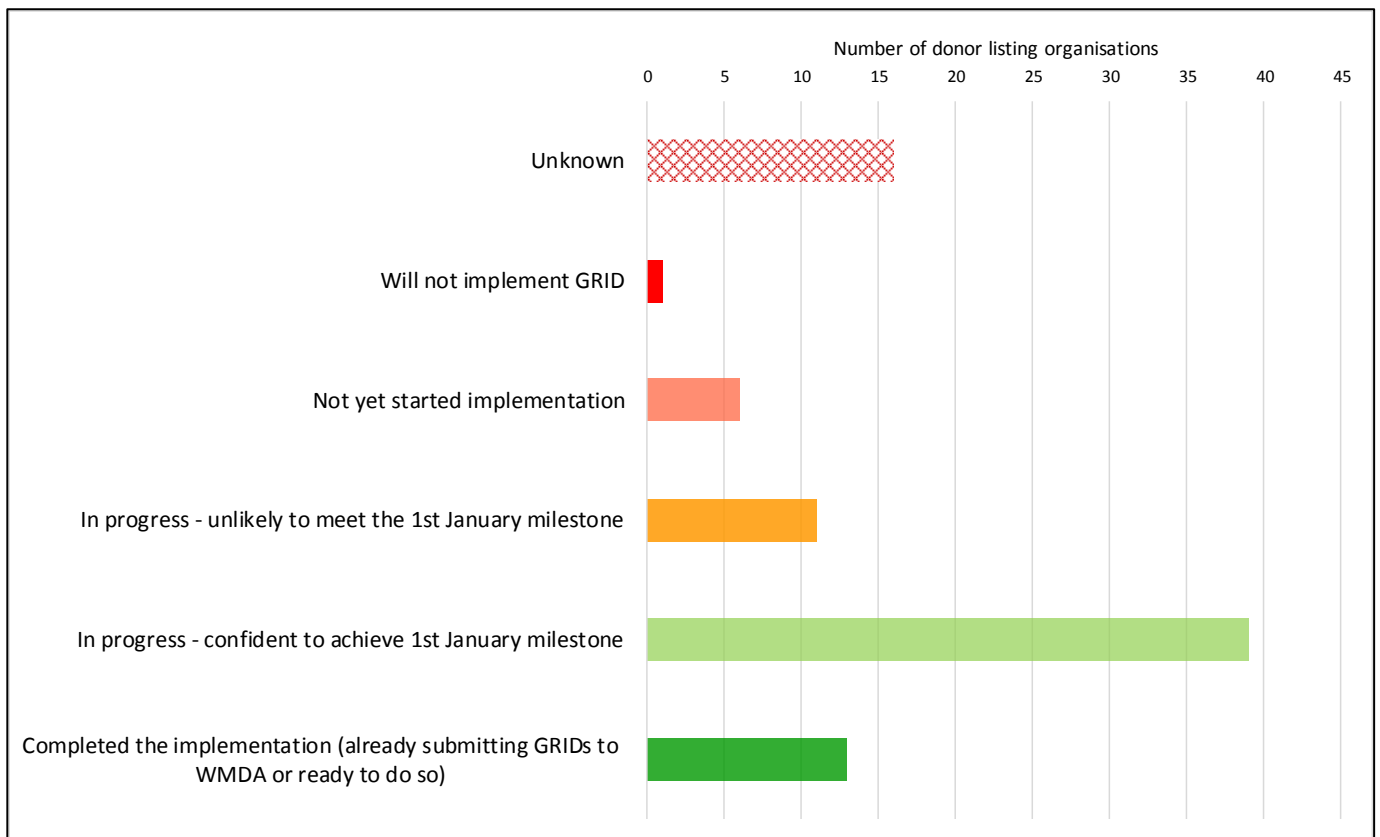


of 2018, is that around 60% of all the organisations have GRID implemented internal and ready for Search & Match, the WMDA donor matching system.

### 3.1 Implementation status by December 2018

The implementation status of the 106 WMDA listing donor organisations at the end of 2018 is shown in Table 1. Unfortunately, not every organisation will be able to have GRID implemented by 1 January 2019. WMDA is doing everything in their power to speed up this process. Furthermore, WMDA is working very hard to contact the organisations that have not yet given a clear reason why they do not want or cannot implement GRID before the 1<sup>st</sup> January milestone. WMDA carried out a survey earlier this year regarding this subject and the findings where that organisations struggle to implement GRID within the agreed timeline, set out by WMDA. However, WMDA is working towards ensuring these organisations are able to transition to GRID by providing support, guidance and where possible IT assistance.

*Table 1. Implementation status of listing donor organisations by December 2018*



- 60% of organisations are on-track to meet the 1<sup>st</sup> January milestone
- 85% of the organisations that are ‘In progress – confident’ rely on Prometheus (a commercial registry software solution, available through Steiner LTD.) to deploy their GRID. 35% of the global registries use Prometheus to store their data. Many of these organisations have not yet fully planned the broader change management aspects of GRID

- The 40% of organisations that currently are unlikely to implement GRID by 1st January account for roughly 8 million donor records (around 25% of the donor list on the global Search & Match service)

Reasons why organisations have not implemented GRID yet include, but are not limited to, political issues, financial issues and capacity issues. In addition, some organisations do not have enough resources or different priorities which results in delay of GRID implementation.

Furthermore, in 2018 the updated GRID webpage was launched, and this progress report was submitted to the European Commission.

## 4. Project management

### 4.1 Governance and capacity building

In 2017, WMDA established a GRID taskforce (made-up of volunteers from across the WMDA community) who will assist with the delivery and the implementation of the GRID in the international stem cell community. They will provide support and guidance to issuing organisations on all operational matters related to the GRID.

The Task Force provide recommendations and guidance to support the implementation of GRID but these recommendations are approved by the WMDA board members before it being communicated to the wider community.

Each task force member is assigned to support the course of events towards implementing GRID by the different WMDA member organisations worldwide. The Task Force need approval from the WMDA board to make changes. The members come from different organisations which brings in a balanced knowledge:

1. The Task Force is being led by the project group chair, a consultant from WMDA, who also keeps in touch with the board.
2. An ICT consultant from WMDA is appointed as a support person for search coordinators and offering operational support. In addition, the consultant is keeping up to date what is the GRID implementation status of each WMDA member organisations and to check who is the contact person within each organisation.
3. An expert from ICCBBA is specialised in barcoding and is specifically available for answering questions. In addition, he is involved in every WMDA congress.
4. People from different registries all over the world; the larger ones as well as and the smaller ones
5. Representative from Prometheus (software supplier).

### 4.2 Consortium management tasks and achievements

The GRID Task Force is committed to provide guidance and practical experience to help and support all listing organisations with their practical implementation plans. It is proactive and have rolled-out a range of materials, templates and FAQs. It has engaged with organisations across the community to identify issues and areas that may require clarification and further support. The Task Force has also become responsible for monitoring the progress of listing organisations against the published milestones for GRID implementation and regularly checking up. The scope of the WMDA GRID project (and the GRID Task Force) does not extend to provide 'hands-on' support and each organisation is responsible for their own GRID implementation activities.

#### 4.2.1 Changes in the consortium

The Task Force used to be smaller and only consist of representatives from the larger registries. Since the smaller registries were not well represented, this year Brazil (April) and South-Africa (July) joined the team. Brazil is a small organisation with a lot of donors (>5 million). Australia was added in July and

represents not only Australia and New Zealand but also Asia Pacific. Recommendation: to Include an expert from the EMDIS technical team to join the Task Force to help align with EMDIS.

#### 4.2.2 Problems and envisaged solutions

A few countries cannot implement GRID due to nation law enforcement. Some other countries do not have the capacity or financial resources to reach the deadline for implementing GRID, therefore implementation is delayed. A solution could be that the Task Force will give support and advice where needed. However, this will not solve all the issues.

Furthermore, the Task Force has identified that they need to be more active. The communication to organisations needs to be more clear, concise and easy to understand by organisations. The official WMDA documentations need to be updated to make it clear that there are two separate parts to GRID implementation (operational and IT).

#### 4.3 Dissemination and outreach

The GRID Task Force have international calls every two weeks, apart from the continuous email trafficking. In addition, the Task Force has project meetings throughout the year. In 2018 the first meeting was in March in London. Following this meeting, the Task Force was expanded to a bigger team because of the high workload. During the Munich Meeting in June, the Task Force had a closed meeting. They made progress on continuing to identify key ways they can support the community in GRID implementation. Furthermore, they discussed opportunities to provide additional clarity to the community around GRID expectations. In this effort they have published a GRID Product Labelling Guide, which was soon followed by a GRID sample Labelling Guide. More guides are expecting to follow in the future, if desired following feedback from the organisations. The last meeting was last September in London. The attendance list of this latest event can be found in appendix 1. In the restricted access working area in WMDA Share Task Force members can upload internal documents and survey outcomes and read the GRID meeting notes.

#### 4.4 Communication between Task Force and the listing member organisations

- The information on the GRID webpages, internal intranet, including FAQs, the checksum and implementation plan on WMDA Share were updated and launched halfway 2018. GRID on wmda.info was updated too. This GRID webpage is very important for guidance purposes.
- GRID was first included in the WMDA member newsletter Stem Cell Matters but in 2018 this was altered into specific GRID newsletters. They are being published 4 times a year and include news updates, additional information and advice on implementing GRID.
- For the European WMDA donor member organisations, a GRID information leaflet was showcased at the European Society for Blood and Marrow Transplantation in March in Lisbon. The same was done for the USA members during the WMDA November meeting in Minneapolis and the Asia-Pacific members during the Congress of the Asia-Pacific Blood and Marrow Transplantation in November in Taipei. This leaflet is shown in Appendix 2.
- In June there was a very productive WMDA Working Group meeting in Munich (Germany). Here the Milestones of 2018 were presented to the organisations. The Australian Bone Marrow Donor Registry (ABMDR), The German National Bone Marrow Donor Registry (ZKRD) and Prometheus

Software gave their insights into how they are moving forward to their GRID Implementation. ABMDR is an example of a smaller registry, ZKRD an example of a bigger registry and Prometheus is a registry operational management software that most of the registries use. During the GRID Open Session, the Task Force found out the latest status about GRID implementation by different registries. In addition, they gave their views on several issues that were thrown up, were open for comments and there was room to ask questions.

- A short survey was sent out to get insights on the organisation's implementation state. These responses enable the Task Force to update the community and to help determine the types of support that they may be able to provide.

A second survey was sent out to get a clear overview of who is the responsible contact person within each WMDA member organisation. This helps to improve the external communication.

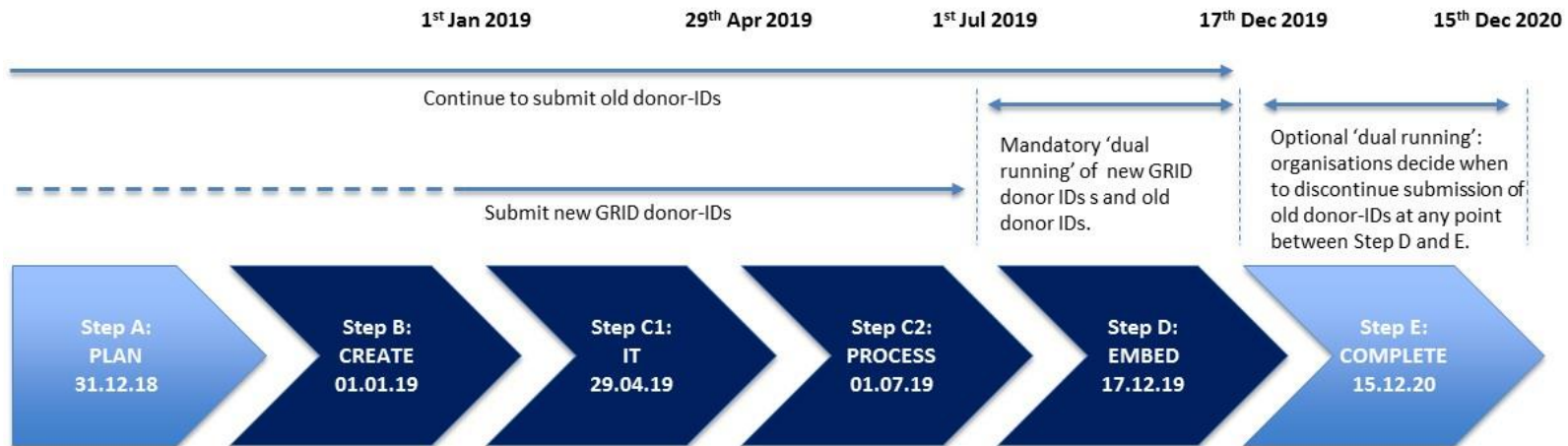
- An overview and examples of external communication regarding GRID is shown in Appendix 2.

The Task Force reviews contributions regularly and reaches out to clarify the organisations answers or follow up. This information has been critical in allowing WMDA insight into the progress of the community towards GRID implementation. In the future they will continue to intermittently issues surveys to get a sense of the progress of the community.

## 5. Project planning and status 2019

The new deadline is that 100% of the organisations implemented GRID in Search & Match on 01-02-2019. The detailed timeline for 2019 is shown in Figure 5.

Figure 5. Timeline for 2019



### Step B:

- Creation of a GRID field in the XML data submission to the Search & Match Service (BMDW) is mandatory.
- In case a GRID is assigned to the donors of a listing organisation, it is desirable to submit it in the XML file. The GRID will show in Search & Match (BMDW).
- If the GRID field is blank it will show as blank alongside the old donor IDs.

### Step C1:

- All IT systems (for example the registry software; EMDIS; Search & Match Service) **must** have a GRID populated for all donors. GRID is visible in all IT systems.
- If an organisation needs more time to roll out operational processes, they have until 1<sup>st</sup> July.

### Step C2:

- Ensuring all the operational procedures contain GRIDs (for example labels, paperwork, working instructions) and all the transplant centres, donor centres, collection centres and other stakeholders are fully aware of the GRIDs.

### Step D:

- All member organisations must be able to use GRID as the sole donor identifier for their own donors and any incoming donors
- They may continue to use the old donor IDs alongside their GRID as a secondary identifier should they wish to.

# Appendix 1. Attendance sheet Task Force Meeting London



ATTENDANCE SHEET

GRID TASK FORCE MEETING  
LONDON

20 SEPTEMBER 2018

Name	Organisation	Signature
Kiriam Kleinmann	DKHS g6ubH	
MARGO URBAN	ANTHONY WOLAN	
Emma Jorstad	NMDP	
Joe Word	SABME	
Anaëlle Rasche	ZK R D	
Darren Hatten	Anthony Nolan	
David Twissley	WMDA	
Esther Pustgens	WMDA	
Morish /ekker	wm PA	

## Appendix 2. Examples of external communication

Type of communication	Title	Example
<b>Leaflets</b>	This leaflet was one of the communications used through the Munich conference, to promote GRID	See Appendix 3
<b>Buttons</b>	GRID Task Force	-
<b>Presentations</b>	How to implement GRID in your organisation?	<p><i>WMDA Spring meeting 2018, Munich DE:</i> Examples by Prometheus, by a big organisation (ZKRD) and by a smaller organisation (Sunflower Foundation)</p> <p><i>WMDA November meeting 2018, Minneapolis US:</i> Open session, by GRID Task Force, where WMDA members could get information about implementing GRID into their organisation</p>
<b>Information guides</b>	Useful Templates, On WMDA Share	<a href="https://share.wmda.info/x/VwCKC">https://share.wmda.info/x/VwCKC</a>



## Appendix 3. GRID Leaflet, WMDA Spring meeting 2018, Munich



Global Registration Identifier for Donors (GRID)

9991 0120 7043 3201 632

Issuing Organization Number (ION) (4 digits)	Registration Donor Identifier (13 digits)	Checksum (2 digits)
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### Why GRID?

- Ensure patient safety
- Prevent errors in identification of donors
- Avoid manual transfers by using bar code scanners
- Moving to quicker facilitation of search requests

GRID info at: <https://www.wmda.info/professionals/optimising-search-match-connect/why-global-identifier/>

### Timeline for implementation

Transition Period dates	Action	Old (Current) donor ID	GRID	Step
Current – 31 Dec 2018	GRID assigned to all existing donors	Mandatory	Optional	A*
1 Jan 2019 – 28 April 2019	GRID submitted to Search & Match (formerly BMDW)	Mandatory	Search & Match required, optional elsewhere	B**
29 April 2019 – 16 Dec 2019	GRID Mandatory in EMDIS	Mandatory	Mandatory	C
17 Dec 2019 – 14 Dec 2020	Registry ID ("Old" ID) optional	Optional	Mandatory	D
15 Dec 2020	Registry ID ("Old" ID) removed	Removed	Mandatory	E

#### \*Step A: till December 2018

Some of the donors already have a unique donor identification number (GRID), when you are performing a search in Search & Match Service of WMDA.

#### \*\*Step B: from January 2019

All donors will have two identification numbers:

- The old donor-ID number
- The new GRID number

Use both numbers in the communication with your national registry.

Ask your GRID questions at: [GRID@wmda.info](mailto:GRID@wmda.info)



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