	WMDA Guidance for Cross-Border Organisations			
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WMDA Guidance for Cross-border Organisations

Authors: WMDA Organisational Implications for Donor Status (OIDS) Task Force: Carolyn Hurley (chair, Georgetown University), Ann O’Leary (Anthony Nolan), Julia Pingel (DKMS Registry), Pinelopi Samara (Orama Elpidas), Ingrid Tistl (ZKRD), Ioanna Varela (Orama Elpidas), Jane Ward (SABMR), Office: Lydia Foeken, Matilde Lartategui; Quality & Regulatory Working Group: Sigal Manor (Ezer Mizion Bone Marrow Donor Registry)

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Organisations that have affiliated donor or patient management entities located in a country different from the country where the parent organisation* resides are confronted with challenges in terms of different national regulations, communication between two distant entities potentially speaking different languages with different cultures, unclear lines of authority, etc. This guidance is intended for all organisations with affiliated cross-border entities and provides recommendations for organisations that are applying for or renewing WMDA certification / qualification / accreditation (C/Q/A).

*Note: An organisation may outsource processes or parts of processes but the responsibility for the service quality and compliance with WMDA Standards remains with the organisation. The parent or central organisation is responsible for and controls the quality management system.

Organisations with cross-border entities will need to provide additional clarification within an application for certification / qualification / accreditation. The parent organisation will be the entity that is/was the source of the letter of intent when applying for WMDA C/Q/A. If the organisation where the central quality oversight function resides has an international partnership, the following information will help demonstrate compliance with WMDA Standards:


Laws and regulations

- Cross-walk of relevant regulations between the two countries
- In case of a transplant centre outside of the country of the primary organisation, requirement for licence or accreditation by national or international entities (e.g., national licence or FACT-JACIE accreditation) might be included in the service level agreement (SLA) or evaluated during the transplant centre evaluation process. Reference: WMDA Recommendation: Criteria for Evaluation of Transplant Centres
- In case of a collection centre outside of the country of the donor centre or primary organisation, requirement for licence or accreditation by national or international entities (e.g., national licence or FACT-JACIE accreditation) should be included in an SLA with the responsible entity.
- For a donor centre, audits by the primary organisation focused on WMDA Standards with the information as to whether staff performing audits travel to the second country.
- For other services (e.g., database and search support) carried out by an entity outside of the country of the parent organisation, requirement for a service level agreement, licence or accreditation by national or international entities (e.g., WMDA if service is provided by an accredited registry) or an audit based on relevant WMDA Standards by the primary organisation.



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Legal status

- Documentation that each entity has some legal standing as required by laws and regulations in the respective country. This could be included in the SLA.

Quality management system

- Organisational chart describing the entire network of the organisation and affiliated entities that provides all the services required from recruitment and search through transport of product to transplant centre.
- Evidence of compliance with WMDA Standards in each organisational entity according to distribution of tasks and responsibilities. If tasks and responsibilities differ among entities with similar responsibilities, clarification of how these differ.
- Organisation may outsource processes or parts of processes but the responsibility for the service quality and compliance with WMDA Standards remains with the organisation seeking or holding WMDA C/Q/A.
- It is not necessary for all of the entities within the organisation to have the same quality management system; however, an applicant organisation should explain how service quality and compliance with WMDA Standards is monitored overall within its “network”. The type and extent of control to be applied to these outsourced processes must be defined within the quality management system of the primary organisation.
- If the international partnerships includes the situation where the organisation’s outsourced activity is hosted by another WMDA C/Q/A organisation, compliance with the relevant WMDA Standards may be shown by a link to WMDA’s website listing C/Q/A organisations or by providing a copy of that organisation’s WMDA certificate.

Medical support

- Availability of medical support in second country or in the region that is readily accessible for donor health issues. Support should include both donation and post-donation support.
- The donor centre / registry must ensure that donors receive the same or superior care as they would in collection centres in their own country, including collection procedure counselling and consenting.
- Documentation of how different Infectious Disease Marker (IDM) risks are handled. This could be included in the SLA.
- Evidence that any cost for the donor is covered and the donor is also properly ensured for all national / international travel requirements.


Communication

- Secure data transmission between all involved (organisation and affiliated entities). This could be included in the SLA.
- Evidence that donor / patient confidentiality is maintained.
- Donor consent and information provided in a language readily understood by the volunteer donor (including umbilical cord blood donor).



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Data protection

- Documentation as to how the organisation and its affiliated entities meet data protection standards in country of the primary organisation and the country of the international entity.
- Data protection agreement covering how the donor’s and/or patient’s personal data will be protected.

Organisational commitment

- SLA defining the international partnership including assignment of responsibilities. If the international entity is formally part of the parent organisation, an SLA might not be needed.
- Description of how two entities communicate; policy for interpretation if two countries speak different languages or defined common working language. This could be included in the SLA.
- A statement of audit rights ensuring that the applicant organisation or organisation already holding WMDA C/Q/A has oversight over compliance with WMDA Standards.