

Registration of International patients and activation of the search in IBMDR

International patient searches for adult donors/ CBU listed in the Italian national database, must be carried out through the IBMDR.

The IBMDR can accept request on behalf of international patients only if coming from a National Registry (HUB), or directly from EBMT-JACIE/FACT accredited TC from countries with no National Registry. The requirements and search procedures for international patients must comply with IBMDR standards and any exceptions must be approved by the relevant IBMDR committees (st.19.15).

If the requesting registry is WMDA certified or in the presence of specific written agreements with IR, exceptions to the eligibility requirements (for patient's age, diagnosis, disease status) and compatibility (both for adult donors and CB units) can be admitted with no specific approval by the IBMDR Committees (st.19.15.1).

To formally activate the search, the patient must be typed for HLA A, B LR and DRB1 HR as a minimum. It is strongly recommended that the patient's HLA-ABC typing is performed at high resolution level using WHO nomenclature (P alleles are permitted). The HR typing must exclude Null alleles (st.19.10).

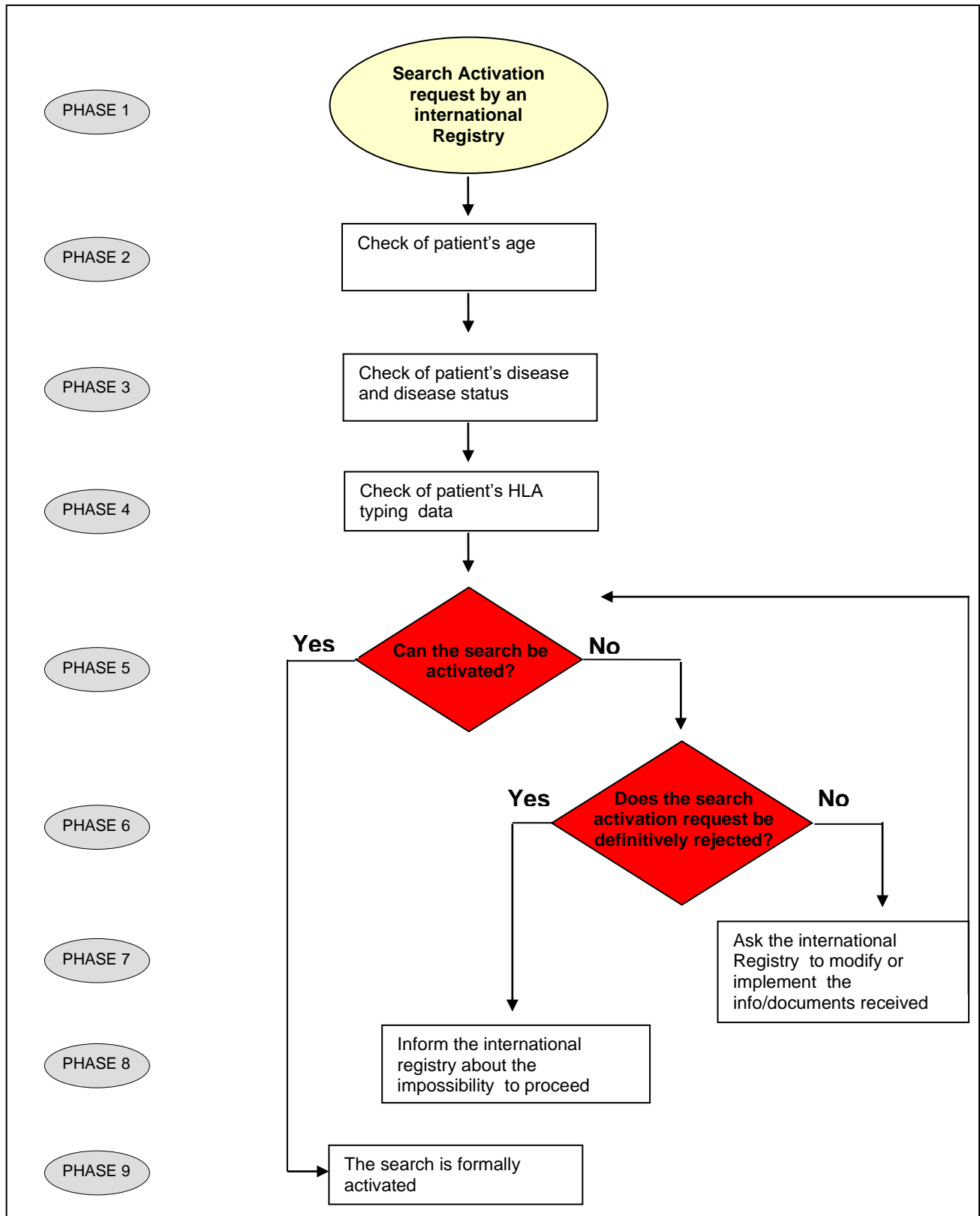
Any preliminary inquire and formal search request has to be sent to the IBMDR through IT SYSTEM (European marrow Donor Information System). In case the Registry is not IT SYSTEM connected, form RC300 must be used or corresponding international form containing the same information.

The search request must be sent by email to search@ibmdr.galliera.it .

IBMDR coordinates the search and will invoice the costs deriving from the services performed by its functional centers to the requesting center, according to the *IBMDR Schedule of fees* (st.19.17)

Additional information and indications can be found in IBMDR Standard Version XXV, 31st Aug. 2024, Chapter 19-20-21-22.

Type of document	Standard of procedure	Version	2
Name of document	4.01.1 SOP-e activation search	Emission date	01 March 2019
Edited by	Search coordinator IBMDR - FV	Approved by	Director IBMDR - NS
Verified by	Search coordinator IBMDR - MV		



Type of document	Standard of procedure	Version	3
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International patient Search Activation

Phase	Who	How	Reference documentation	Notes
1	International Registry	Send by mail or by IT system needed documents	- Form RC301 or corresponding international Form / IT SYSTEM	If the request is not received from an international Registry see the attachment 1 (cases 5 and 6)
2	Search coordinator IBMDR	Verify that patient's age is compliant with IBMDR requirements	- Form RC301 or corresponding international Form / IT SYSTEM	In case of WMDA certified registry or in the presence of written Agreement: see attachment 1 – case 3. If not, see attachment 1 – case 2
3	Search coordinator IBMDR	Verify that patient's diagnosis is compliant with IBMDR Standard	- Form RC301 or corresponding international Form / IT SYSTEM	In case of WMDA certified registry or in the presence of written Agreement: see attachment 1 (case 7) If not, see attachment 1 (case 1 and 7)
4	Search coordinator IBMDR	Verify that the patient's typing is complete and compliant with IBMDR Standards	- Form RC301 or corresponding international Form / IT SYSTEM	See attachment 1 (case 4)
5	Search coordinator IBMDR	Verify that all information and documents needed for the search activation are present and compliant with IBMDR Standards	- Form RC301 or corresponding international Form / IT SYSTEM	If all documentation and information are compliant with IBMDR Standards the search is activated (see phase 9 of this SOP)
6	Search coordinator IBMDR	Evaluate to reject definitively or temporarily the request in case of not compliant/ not complete data	Attachment 1	An IBMDR search coordinator verifies the evaluation
7	Search coordinator IBMDR	If the request has been temporarily rejected, ask the International Registry to modify/implement the documentation previously sent	Attachment 1	The received documentation is temporarily filed in https://donatori.galliera.it/cnc Paz. Esteri-cognome –report preliminare-richi pervenute
8	Search coordinator IBMDR	If the request has been definitively rejected IBMDR notifies the International Registry	Attachment 1	The documentation is archived in "Archiflow – faldoni – ricerche mai attivate" for 6 months. Then it will be definitively eliminated.
9	Search coordinator IBMDR	Search Activation	n.a.	see Standards ver. XXV, 31 st Aug. 2024, chapter 19

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**CAUSES of SEARCH ACTIVATION REJECTION**

	CIRCUMSTANCE	REJECTION REASON	CORRECTIVE ACTION	REJECT	
				TEMPORARILY	DEFINITELY
1	Diagnosis is not included in table III – IBMDR standards	Clinical indication to bone marrow transplant from unrelated donor missing	Ask the international Registry for additional information or clinical report for our Clinical committee GITMO	Wait for information or clinical report	GITMO Clinical Committee expressed a negative opinion or international registry cancels the request
2	The patient's age limit for specific disease is not compliant with IBMDR standards	Clinical indication to bone marrow transplant from unrelated donor missing	Ask the international Registry for clinical report for our Clinical Committee GITMO or an approved IRB protocol	Wait for IRB protocol/clinical report or signed Agreement	See IBMDR standard/Agreement
3	Patient's age >76yy	Clinical indication to bone marrow transplant from unrelated donor missing	None	n.a.	See IBMDR standard/Agreement
4	The patient's typing is not compliant with standard IBMDR	Not compliant with IBMDR standard	Ask the international registry to complete the typing	Wait for complete patient's typing	International registry cancels the request
5	The Search activation request received from an international Transplant center not EBMT/Fact JACIE accredited or accredited by their own Health Authority	Not compliant with IBMDR standard	None	n.a.	See IBMDR standard
6	The Search activation request has been received directly from an international Transplant center, not through the National Registry /hub	Not compliant with IBMDR standard	Ask the transplant center to contact their national registry or another international registry in order to send the request through the Registry	Wait for the search activation request from the registry	The formal request is not provided by the international Registry
7	The Search activation is requested on behalf of a patient affected by solid tumor	Not compliant with IBMDR standard	None	n.a.	See IBMDR standard/Agreement

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