NATIONAL REGULATIONS

Spain

01. Requirement for JACIE

JACIE is a requirement to perform some procedures: It is currently **mandatory for unrelated donor transplants**, highly recommended for CAR-T (in practice it is mandatory) and the intention is to make it mandatory for any allogeneic transplant.
It is not required for autologous.

02. Authorisation and licencing

B1.3.1, CM1.3.1, C1.3.1, D1.2.1

- **Clinical Units**
- **Apheresis Collection Units**
- **Bone Marrow Collection Units**
- **Cell Processing units**

Governmental authority that registers, authorises or certifies: Regional.

Document that demonstrates that the unit complies with the national laws and regulations:

Specific document from each authority, there are 17 different regions in Spain.

03. cGxP training requirements

CM3.3.4 C4.4.2.5 D4.4.2.5

There are no specific requirements.

04. Physicians' licensing / qualifications

B3.1.1, B3.2.1 CM3.1.1 , C3.2.1, D3.2.1

Hematology, Pediatrics , oncology or immunology residency are official training by the Health Autorithy of Spain with specific programs and regulations. There are no formal sub-specialization in transplant.

05. Requirements for the consent from minor donors

B6.2.6

The law has specific requirements concerning who can obtain informed consent: Legal representation and an ethical committee must give approval.

06. Certification of laboratories for donor testing

B6.3.6

Regional transplantation authority authorises the Laboratory for donor testing by means of a license.

07. Additional testing for allogeneic HPC donors

B6.4.9

	Testing required	Risk assessment required	None
Human immunodeficiency virus, type 1	✓		
Human immunodeficiency virus, type 2	✓		
Hepatitis B virus	✓		
Hepatitis C virus	✓		
Treponema pallidum (syphilis)	✓		
Human T cell lymphotropic virus I		✓	
Human T cell lymphotropic virus II		✓	
West Nile Virus		✓	
Trypanosoma cruzi (Chagas' Disease)		✓	

Additional comments

CMV, T. cruzi, toxoplasma, malaria, Dengue, VEB, depending on donor history or cell characteristics

08. Product labelling and coding system

D7.1.2, C7.1.2, CM7.1.2

ISBT128 is used in Collection and Processing facilities, and SEC.

09. Approval of Investigational treatment protocols & patient consent forms

B8.1, B8.2

A document from the regional Health authority accrediting the unit to perform transplants (official document). Also, an ethical committee approval may be required depending on the institution.

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

Spanish legislation doesn't allow for the distribution of products before the donor eligibility process has been completed. This can be done in specific cases, but there are minimum requirements.

11. Biohazard and warning labels

D7.4.4.1/C7.4.4.1/ CM7.4.3.1

Additional comments

In spanish law only biohazard label are required.
No other statements are required.

	Required [by law]	Not allowed [by law]
Biohazard label	✓	
Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"		
Statement "WARNING: Advise Patient of Communicable Disease Risks"		
Statement "WARNING: Reactive TestResults for [name of disease agent or disease]		