NATIONAL REGULATIONS

Italy

01. Requirement for JACIE

JACIE is voluntary for autologous and allogeneic transplantation and mandatory for CAR T treatment

02. Authorisation and licencing

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

Clinical Units

Bone Marrow Collection Units

Governmental authority that registers, authorises or certifies:

Regional competent authority and national competent authority (National Transplant Center – CNT and National Blood Centre -CNS)

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

Institutional authorization and accreditation given by the regional competent authority and certificate of compliance with the applicable law given by the national competent authority (National Transplant Center – CNT- and National Blood Centre -CNS)

Apheresis Collection Units

Governmental authority that registers, authorises or certifies:

See Clinical section

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

Institutional authorization and accreditation given by the regional competent authority and certificate of compliance with the applicable law given by the national competent authority (National Transplant Center – CNT- and National Blood Centre -CNS); the apheresis collection facilities are normally located in the transfusion medicine departments and authorized according to current legislation on transfusion medicine

Cell Processing units

Governmental authority that registers, authorises or certifies:

See Clinical section

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

Institutional authorization and accreditation given by the regional competent authority and certificate of compliance with the applicable law given by the national competent authority (National Transplant Center – CNT- and National Blood Centre -CNS). The processing facilities correspond to the tissue establishment and are listed in the European compendium (TE list)

03. cGxP training requirements

CM3.3.4 C4.4.2.5 D4.4.2.5

There are specific requirements for cGxP in Italy. A training plan and an annual competencies assessment are provided for all transplant program staff

04. Physicians' licensing / qualifications

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

The Medical Doctor must have a degree in Medicine (University), post-graduate qualification for the medical profession (Minister of Health), and post-grade qualification in Hematology or equivalent discipline (University); for paediatric programs, the responsible of Paediatric Clinical Unit must have a specialization in paediatrics. The biologist must have a degree in biological sciences or biotechnology (University) and post-graduate qualification for the medical profession (Minister of Health).

05. Requirements for the consent from minor donors

B6.2.6

Patients are considered paediatric patients up to 18 years of age. However, from the age of 16, donor's and patient's opinion should be taken into account. Informed consent is given by the parents or legal guardian in their absence.

06. Certification of laboratories for donor testing

B6.3.6

Laboratory for donor testing is accredited by the Regional competent authority

07. Additional testing for allogeneic HPC donors

B6.4.9

	Testing required	Risk assessment require	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

Additional test required: NAT for HCV, HBV e HIV; CMV antibody, TOXOPLASMA GONDII antibody, EBV antibody. PCR for DENGUE, Zika, Malaria, Monkey Pox and Chikungunya depending on donor history

08. Product labelling and coding system

D7.1.2, C7.1.2, CM7.1.2

ISBT128 terminology is applied for product description.

Furthermore the TE (Processing Facility) uses the ISBT128 terminology for the composition of the SEC, which applies to each cellular product at the time of release for clinical use

09. Approval of Investigational treatment protocols & patient consent forms

B8.1, B8.2

It depends on the protocol and the experimental study but the opinion of the relevant Ethics Committee is always necessary.

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

The law in Itally does not allow the distribution of products prior to completion of donor eligibility in general situation. In some cases an exception is permitted, provided that at least the minimum requirements are met.

11. Biohazard and warning labels

D7.4.4.1/C7.4.4.1/ CM7.4.3.1

	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]	✓	

Additional comments

if the donor of the cellular product tests positive for a specific infectious disease marker, the label bears the words: "BIOLOGICAL RISK"

12. Others

The donation of cellular products is anonymous, voluntary and free (L219/2015; D.Lsg 191/2007; D.Lsg 16/2010).

Anonymity between donor and recipient is mandatory (GDPR).

The law provides for complete traceability and conservation of documentation (D.Lsg 191/2007; D.Lsg 16/2010).

Direct distribution from the Collection Center to the Clinical Unit is not permitted: all cellular products are distributed by the TE.