NATIONAL REGULATIONS
Belgium

1. Requirement for JACIE

JACIE is a requirement for reimbursement by national authorities (RIZIV/INAMI) of all activities that relate to donor search, collection, processing and clinical use of hematopoietic stem cells (Auto and Allo) as well as donor lymphocytes (not for CAR-T yet)

Additionally, JACIE is a requirement to obtain the accreditation by the National Marrow Donor Program- Belgium (NMDP-B) for search of unrelated donors and unrelated Allo transplantations (three separate accreditations for collection, processing and clinical use).

02. Authorisation and licencing

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

Clinical Units

Governmental authority that registers, authorises or certifies: Ministry of Health

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

General hospital licence (not specified)

Bone Marrow Collection Units

Apheresis Collection Units

Cell Processing units

Governmental authority that registers, authorises or certifies:

Federal Agency for Medicines and Health Products (FAMHP)/in Dutch: Federaal Agentschap voor geneesmiddelen en gezondheidsprodukten (FAGG)/ in French: Agence Féderal des médicaments et des produits de santé (AFMPS)

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

Licence(s) as Tissue establishment (specific for “hematopoietic stem cells” and/or “other human bodily material for cell therapies).

03. cGxP training requirements

CM3.3.4 C4.4.2.5 D4.4.2.5

The National law does not specify requirements for GxP training.

04. Physicians’ licensing / qualifications

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

Physicians hold a Licence for specialist by Ministry of Health (e.g. Clinical Hematologist, Medical Oncologist, Paediatrician (general)).

05. Consent from minor donors

B6.2.6

There are NO specific requirements regarding who can obtain informed consent.

06. Laboratory testing of all donors including autologous

B6.3.6

Sciensano certifies the laboratories for donor testing.

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

Risk assessment is based on medical anamnesis (including travel history).

08. Product labelling and coding system

D7.1.2, C7.1.2, CM7.1.2

ISBT128 is used in Collection and Processing facilities.

09. Approval of Investigational treatment protocols & patient consent forms

B8.1, B8.2

All clinical research protocols/studies (both academic or with pharmaceutical companies) must be approved by an internal ethical committee. For academic studies a special clinical trial licence from FAMHP/FAGG/AFMPS is required (if ATMP manufacturing is involved, a GMP certificate must be obtained as well through the same Agency).

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

The law in Belgium allows products to be distributed prior to completion of donor eligibility.

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

Required [by law]

Not all items are required but all are allowed – see also JACIE Standards

12. Others

B13.4.1 to 4

Cell product files (including information about donor selection, traceability collection, processing, clinical use) must be archived for at least 30 years (after administration of the cell product). Raw data of tests and documents in relation to general QM, device maintenance,... must be archived for at least 10 years.