NATIONAL REGULATIONS
Hungary

01. Requirement for JACIE

JACIE is **voluntary**.
Health institutions authorized to extract and implant tissue for stem cell transplantation are listed in Annex No. 6 to 18/1998. (XII. 27.) EüM decree on health care CLIV of 1997. on the implementation of the provisions of the Act on organ and tissue transplantation and storage and certain histopathological examinations.
60/2003. (X. 20.) ESzCsM decree on the professional minimum conditions necessary for the provision of health services
GMP is required for CAR-T therapy.

02. Authorisation and licencing

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

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

Governmental authority that registers, authorises or certifies:

Annex No. 6 to 18/1998. (XII. 27.) EüM decree + 60/2003. (X. 20.) ESzCsM decree.

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

Annex No. 6 to 18/1998. (XII. 27.) EüM decree + hospital operation licence of the National Center for Public Health and Pharmacy (NCPHP).

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 diploma of hematology specialisation or a diploma of pediatric hematology and oncology specialisation. Renewal of the operating licence is every five years.

05. Requirements for the consent from minor donors

B6.2.6

The consent of the patient's parent or legal representative and the permission of the Hospital Ethics Committee are required.

06. Certification of laboratories for donor testing

B6.3.6

National Accreditation Committee certifies the laboratories for donor testing.

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)			✓

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

The study must be authorized by the Medical Research Council (TUKEB, Tudományos és Kutatásetikai Bizottság) and the local Hospital Ethics Committee.

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

The law in Hungary doesn't allow products to be distributed prior to completion of donor eligibility. The product can be used as an "Out of Specification" product in a non-postponable indication. Detailed written informed consent of the physician and the patient is required for this product.

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]		