NATIONAL REGULATIONS
Germany

01. Requirement for JACIE

JACIE is **voluntary**.

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:

QM and certification of Hospital, e.g. Onkozert, KTQ, ISO etc.,

Bone Marrow Collection units

Governmental authority that registers, authorises or certifies:

Local Authorities (RP, HLPUG, LaGeSo,...)
BM is managed under the tissue, acc. to §20 German Medicines Act (AMG).

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

Manufacturing authorisation (Herstellugserlaubnis), local authorities

Apheresis Collection Units

Processing Units

Governmental authority that registers, authorises or certifies:

Local Authorities (RP, HLPUG, LaGeSo,...) and GMP license.

PBSCs and DLI are managed under the blood products legislation acc. to §13 German Medicines Act (AMG)

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

Manufacturing authorisation (Herstellugserlaubnis), PEI approval

03. cGxP training requirements

CM3.3.4 C4.4.2.5 D4.4.2.5

This is not a legal requirement under German national law, but rather part of JACIE certification and institutional SOPs

04. Physicians' licensing / qualifications

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

Physicians can demonstrate that they have specialist certification or training with the Board Certification and CME certificates

05. Requirements for the consent from minor donors

B6.2.6

The consent process should involve a paediatrician.

06. Certification of laboratories for donor testing

B6.3.6

Paul Ehrlich Institute (PEI)
Part of Manufacturing authorisation (Herstellugserlaubnis) provided by the local authorities

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)			✓

Testing for Hepatitis E is also a legal requirement in Germany.
CMV is not a legal requirement in Germany (Please note this is a JACIE requirement and therefore Centres need to comply. - Tenet 1)

08. Product labelling and coding system

D7.1.2, C7.1.2, CM7.1.2

Eurocode is used in Collection and Processing facilities

09. Approval of Investigational treatment protocols & patient consent forms

B8.1, B8.2

No documents required by law. Institutional Review Board or EMA approval for research or clinical trials, routine consent forms are documents that would demonstrate that a centre has the approval

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

The law in Germany allows the distribution of products 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]	✓	