EGeen CEE / EE / EU Country Chart - Ethics Committee Document Requirements

	Ethics Committee Topic / Document		Country										
1.0	General	Need / Description / Value / Use	Estonia	Latvia	Lithuania	Poland	Czech MEC	Czech LEC	Hungary	Romania	Italy	Germany	Georgia	Ukraine
1.1	EUDRACT No. Confirmation	EudraCT number issued for trial	YES	YES	YES	YES	NO	NO	YES	YES	YES	YES	NO	YES
1.2	Cover Letter	For all submissions; details summary	YES	YES	YES	YES	YES	YES	YES [1]	YES [2]	YES [3]	YES	YES	YES
1.3	Application Form	Required; language per country	YES	YES	YES [4]	YES	YES	YES	YES	YES	YES	YES	YES	YES
1.4	Competent Authorities List	Sent to RA to show cty. Submissions	NO	NO	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES
1.5	Ethics Committee Opinion	Copy sent to RA when available	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	NO
1.6	Scientific Advice	If sponsor has it, compulsory	YES	YES	YES	YES	YES	YES	NO	YES	NO	NO	YES	YES
1.7	Delegation of Authority	From Sponsor to Applicant	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES [12]
1.8	Application in English	Can accept applications in English	YES	YES	YES [5]	NO	NO [6]	NO [6]	YES [7]	NO	NO	YES	NO	NO
2.0	Subject Related	Need / Description / Value / Use	Estonia	Latvia	Lithuania	Poland	Czech MEC	Czech LEC	Hungary	Romania	Italy	Germany	Georgia	Ukraine
2.1	Informed Consent Form (ICF)	Sent with submission; sponsor origin	YES	YES	YES	YES	YES	YES	YES [9]	YES	YES	YES	YES	YES
2.2	Subject Informaton Leaflet	Sent with submission	YES	YES	YES	YES	YES [8]	YES [8]	YES [9]	YES	YES	YES	YES	YES
2.3	Subject Recruitment Info.	Sent with submission	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES	NO	YES
3.0	Protocol Related	Need / Description / Value / Use	Estonia	Latvia	Lithuania	Poland	Czech MEC	Czech LEC	Hungary	Romania	Italy	Germany	Georgia	Ukraine
3.1	Clinical trial protocol	Sent with submission	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
3.2	Protocol in local language	Required; language per country	YES	NO [13]	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
3.3	Peer Review of Trial Value	When available, not compulsory	NO	NO	YES	NO	NO	NO	NO	YES	NO	NO	NO	NO
3.4	PI / CI Ethical Assessment	Special country requirement	YES	NO	YES	NO	NO	NO	NO	YES	NO	NO	NO	NO
4.0	IMP Related	Need / Description / Value / Use	Estonia	Latvia	Lithuania	Poland	Czech MEC	Czech LEC	Hungary	Romania	Italy	Germany	Georgia	Ukraine
4.1	Investigator Brochure	Sent with submission	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
4.2	IMPD	Sent with submission	NO	NO	NO	YES	NO	NO	YES	YES	NO	NO	YES [11]	YES
4.3	Simplified IMPD	For known products	NO	NO	NO	YES	NO	NO	NO	YES	NO	NO	YES [11]	YES
4.4	Product Characteristics	For products with Mktg. Author.	YES	NO	YES	YES	YES	YES	YES	YES	YES	NO	YES [11]	YES
4.5	Active trial outline for IMP	Sent with submission	NO	NO	YES	YES	NO	NO	NO	YES	YES	NO	YES [11]	YES
4.6	IMP Manuf. Auth. If in EU	Copy of Manuf. Auth. Sent	NO	NO	NO	YES	NO	NO	YES	YES	YES	NO	NO	YES
4.7	IMP Manuf. Auth. If Not in EU	QP that IMP is GMP	NO	NO	NO	YES	NO	NO	YES	YES	YES	NO	YES [11]	NO
4.8	GMP Status of Active Biol. Subs.	Copy Sent	NO	NO	NO	YES	NO	NO	YES	YES	NO	NO	YES [11]	YES
4.9	Importer Authorizaton	Copy Sent	NO	NO	NO	YES	NO	NO	YES	YES	YES	NO	YES [11]	YES
4.10	Test Product COA in Exc. Cases	For impurities detected	NO	NO	NO	YES	NO	NO	YES	YES	NO	NO	YES [11]	YES
4.11	Viral Safety Information Data	Sent with submission	NO	NO	NO	YES	NO	NO	YES	YES	NO	NO	YES [11]	YES
4.12	Spec. Char. IMP Authorization	For exceptional IMPs (GMOs, etc.)	NO	NO	NO	YES	NO	NO	YES	YES	YES	NO	NO	YES
4.13	TSE Certificate	Sent when applicable	NO	NO	NO	YES	NO	NO	YES	YES	YES	NO	NO	YES
4.14	Label in National Language	Required, sent with submission	NO	NO	YES [10]	YES	NO	NO	YES	YES	YES	YES	NO	YES

1. In Hungarian language
2. In Romanian language
3. In Italian language
4. If electronic, no cover letter required
5. Both English and Lithuanian
6. Czech language or Czech/English
7. General documents in English
8. Plus Contact person information
9. English plus Hungarian language
10. For authorized products
11. On request
12. Apostilled
13. Only if available

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EGeen CEE / EE / EU Country Chart - Ethics Committee Document Requirements *(cont'd)*

	Ethics Committee Topic / Document		Country										
5.0	**Facilities / Staff Related**	**Need / Description / Value / Use**	**Estonia**	**Latvia**	**Lithuania**	**Poland**	**Czech MEC**	**Czech LEC**	**Hungary**	**Romania**	**Italy**	**Germany**	**Georgia**	**Ukraine**
5.1	Facilities for the Trial	Approvals from facility, sent	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES [13]	YES
5.2	CV of the CI in the MS	Required, sent with submission	YES	YES	YES	YES	YES	YES	YES [12]	YES	YES	YES	YES [14]	YES
5.3	CV of Each PI in Trial	Required, sent with submission	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	NO	YES
5.4	Site Support Staff CV Info.	Required, sent with submission	YES	YES [15]	YES [16]	YES	YES	YES	NO	YES	NO	YES	NO	YES
6.0	**Finance Related**	**Need / Description / Value / Use**	**Estonia**	**Latvia**	**Lithuania**	**Poland**	**Czech MEC**	**Czech LEC**	**Hungary**	**Romania**	**Italy**	**Germany**	**Georgia**	**Ukraine**
6.1	Comp. Indemnity Provision	Sent with submission	YES	YES	YES	YES	YES	YES	YES	YES [17]	YES	YES	NO	NO
6.2	Ins . Indemnity for PI/S Liability	Sent with submission	YES	YES [22]	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
6.3	Investigator Compensation Info	Required, sent with submission	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES	NO	NO
6.4	Subject Compensation Info	Required, sent with submission	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	NO	NO
6.5	Sponsor / Trial Site Agreement	Required, sent with submission	NO	NO [18]	YES [19]	YES	YES [19]	YES [19]	NO	YES	YES	YES	YES [18]	NO
6.6	PI / Trial Site Agreement	Required, sent with submission	YES	NO	YES	YES	NO	NO	NO	YES	NO	YES	YES [18]	NO
6.7	Sponsor / PI COA	Required, sent with submission	YES	NO	YES	YES	NO	NO	NO	YES	NO [20]	NO	NO	NO
7.0	**Country Specific Items**	**Need / Description / Value / Use**	**Estonia**	**Latvia**	**Lithuania**	**Poland**	**Czech MEC**	**Czech LEC**	**Hungary**	**Romania**	**Italy**	**Germany**	**Georgia**	**Ukraine**
7.1	EC Clinical Trial Questionnaire	Which countries require item	NO	NO	NO	NO	YES [21]	YES [21]	NO	NO	NO	NO	NO	NO
7.2	Additional Site Approval	Which countries require item	NO	NO	NO	NO	YES	YES	YES	NO	NO	NO	NO	NO
7.3	CRF	Which countries require item	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	YES	NO

12. If partcipating as PI in trial
13. Authorization to execute clinical trials, agreement to conduct trial
14. Only PI CV
15. Protocol dependent
16. Coordinator CV
17. In Romanian
18. Should be available on request
19. Draft
20. No financial contract allowed
21. In Czech language
22 Only if available