EGeen CEE / EE / EU Country Chart - Regulatory Filing Document Requirements

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

Notes

1. In English and Lithuanian
2. Polish application form
3. Notarized, original sworn translation
4. General documents in English
5. EUDRACT No. to be included in Cover Letter
6. Also in Lithuanian
7. Plus ICF on data protection
8. Plus Contact person information template
9. In Hungarian language
10. Apostilled
11. On request
12. Info in cover letter

EGeen
A Premier, Full Service Eastern European CRO

We Know Eastern Europe

www.egeeninc.com

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

	Regulatory Topic / Document		Country									
5.0	**Facilities / Staff Related**	**Need / Description / Value / Use**	**Estonia**	**Latvia**	**Lithuania**	**Poland**	**Czech Rep.**	**Hungary**	**Italy**	**Germany**	**Romania**	**Ukraine**	**Georgia**
5.1	Facilities for the Trial	Approvals from facility, sent	YES	YES	NO	NO	YES	NO	NO	NO	YES	YES	YES [13]
5.2	CV of the CI in the MS	Required, sent with submission	YES	YES	NO	YES	NO	YES [14]	NO	NO	YES	YES	YES
5.3	CV of Each PI in Trial	Required, sent with submission	YES	YES	YES	YES	NO	YES	NO	NO	YES	YES	NO
5.4	Site Support Staff CV Info.	Required, sent with submission	YES	YES	YES [15]	NO	NO	NO	NO	NO	YES	YES	NO
6.0	**Finance Related**	**Need / Description / Value / Use**	**Estonia**	**Latvia**	**Lithuania**	**Poland**	**Czech Rep.**	**Hungary**	**Italy**	**Germany**	**Romania**	**Ukraine**	**Georgia**
6.1	Comp. Indemnity Provision	Sent with submission	NO	YES	YES	NO	NO	YES	NO	NO	NO	NO	NO
6.2	Ins . Indemnity for PI/S Liability	Sent with submission	YES	YES	YES	YES [16]	NO	YES	NO	NO	YES	YES	YES
6.3	Investigator Compensation Info	Required, sent with submission	NO	NO	NO	YES	NO	YES [17]	NO	NO	NO	NO	NO
6.4	Subject Compensation Info	Required, sent with submission	NO	NO	NO	YES	NO	YES	YES	NO	NO	NO	NO
6.5	Sponsor / Trial Site Agreement	Required, sent with submission	NO	NO	YES	YES	NO	NO	YES	NO	NO	NO	NO
6.6	PI / Trial Site Agreement	Required, sent with submission	YES	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO
6.7	Sponsor / PI COA	Required, sent with submission	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
7.0	**Country Specific Items**	**Need / Description / Value / Use**	**Estonia**	**Latvia**	**Lithuania**	**Poland**	**Czech Rep.**	**Hungary**	**Italy**	**Germany**	**Romania**	**Ukraine**	**Georgia**
7.1	EC Clinical Trial Questionnaire	Which countries require item	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO
7.2	Additional Site Approval	Which countries require item	NO	NO	NO	NO	YES	YES	NO	NO	NO	NO	NO
7.3	CRF	Which countries require item	NO	NO	NO	YES	YES	NO	YES	NO	NO	YES	NO
7.4	Power of Attorney for Signators	Which countries require item	NO	NO	NO	YES	NO	YES	NO	NO	NO	NO	NO
7.5	Delegation of Authority	Which countries require item	NO	YES	YES	YES	NO	NO	YES	YES	NO	NO	NO
7.6	EU Legal Rep. Cert. of Incorp.	Which countries require item	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO
7.7	Payment Statements	Which countries require item	YES	NO	NO	NO	NO	NO	YES	NO	NO	NO	YES
7.8	Licenses of Clinics	Which countries require item	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO	YES
7.9	CRA LP Cert. or CRO License	Which countries require item	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES
7.10	CRO Cert. with Translation	Which countries require item	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES

Notes

13. Authorization to execute clinical trials, agreement to conduct trial
14. If CV is participating in the trial as a PI
15. Coordinator CV
16. Original in Polish
17. Including share of the fee between hospitals and investigators