EGeen

A Premier, Full Service Eastern European CRO

EGeen RNA Program Country Card – **Lithuania**

Lithuania Overview

- Population: 2.98 million
- Five Largest Cities: Vilnius, Kaunas, Klaipeda, Siauliai, Panevezys
- Language: Lithuanian
- EU Member: Yes (2004)
- Govt Type: Unitary Parlimentary Republic
- Govt. Admin.: 10 Counties, 60 municipalities
- Health System: Compulsory insurance fund (NHIF) + fee-for-service

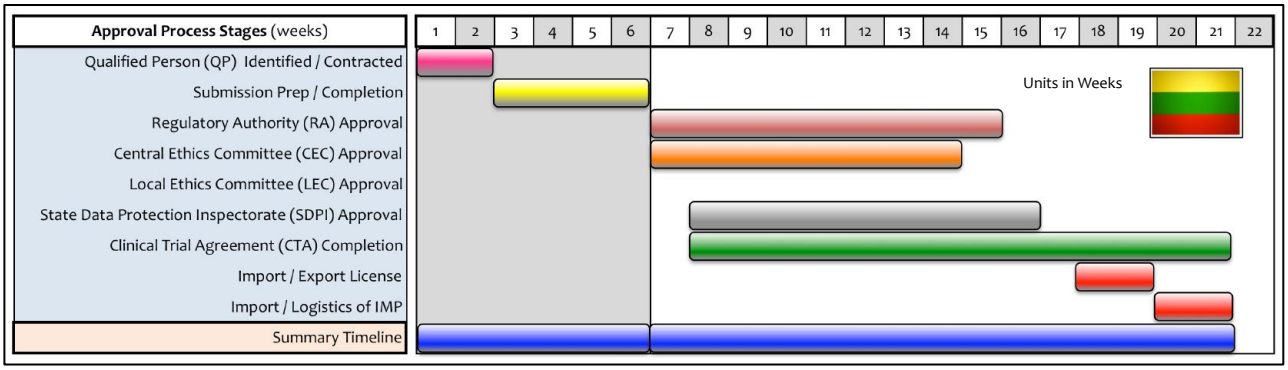
Clinical Trial Network / Comments

- HC Sites: 145 hospitals (66 general) + 62 out-patient clinics; 9.6 beds per 1000
- HC Splits: 98% public / 2% private; 45% inpatient / 55% outpatient
- Investigators: ICH GCP experienced, high quality, motivated, secure data management
- CRAs: Physicians, biologists, nurses; good relations with investigators
- High level of pharmacologically 'naïve' patient population
- 5th highest incidence of ovarian cancer WW; higher-than-average cardiovascular disease

EGeen Clinical Trial Support

- Full range of clinical trial services
- Patient recruitment, clinical monitoring, data management, biostatistics, regulatory
- Pharmacolvigilance, project management, ethics review, quality assurance
- EU Qualified Person (QP) assistance to obtain EU GMP certificate for manufacturing reqs.
- Cost-effective EU / EE / non-EU importation partnerships and local IMP logistics
- Institutional relationships to proactively obtain contract approvals prior to regulatory filings as needed

Lithuania – Clinical Trail Process Overview



Lithuania Approval Process Highlights

- Qualified Person (QP) must be identified and registered prior to approval process beginning
- RA Reviews / Approvals often exceed 60 day EU directive NOTE
- State Data Protection Inspectorate approval mandatory; can begin with promissory letter of RA / CEC pending NOTE
- LECs not involved in reviewing and approving studies
- CTA site contracts can be negotiated during RA, CEC approval process, saving time
- All major submission documents need to be in Lithuanian language NOTE
- IMP import license only required if imported from outside EU
- Summary: Time from QP ID to Importation of IMP estimated at **21 weeks**

Note: Summary time total is an estimated average of trial complexity

About EGeen

EGeen, Inc. is a global, specialized, rapid response CRO. Our business is to advance the drug development of pharmaceutical and biotech companies by offering fast, high quality, cost effective clinical trial mangement services. EGeen is headquartered in Silicon Valley, USA and operates a unique and extensive trial network across Eastern Europe.

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