EGeen

A Premier, Full Service Eastern European CRO

EGeen RNA Program Country Card – **Latvia**

Latvia Overview

- Population: 1.98 million
- Five Largest Cities: Riga, Daugavpils, Liepaja, Jelgava, Jurmala
- Language: Latvian
- EU Member: Yes (2004)
- Govt Type: Parlimentary Republic
- Govt. Admin.: 110 Municipalities + 9 republican cities
- Health System: National Health System (govt.funded) + user charges

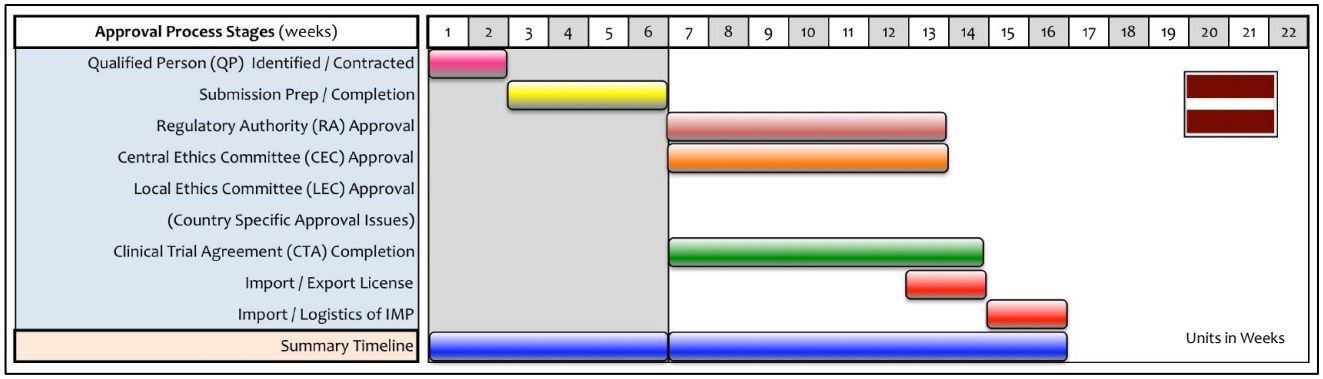
Clinical Trial Network / Comments

- HC Sites: 67 hospitals, >30+ clinics, 3.4 beds per 1000
- HC Splits: 84% public / 16% private; 32% inpatient / 68% outpatient
- Investigators: ICH GCP experienced, high quality, motivated, excellent data
- CRAs: Physicians, biologists, nurses; good relations with investigators
- High level cardivascular disease
- Highest incidence rate of ovarian cancer in the world

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

Latvia – Clinical Trail Process Overview



Latvia Approval Process Highlights

- Qualified Person (QP) must be identified and registered prior to approval process beginning
- CTA site contracts can be negotiated during RA, CEC and LEC approval process, saving time
- RA and CEC approvals can begin concurrently, saving time
- All major submission documents need to be in Latvian language NOTE
- No LEC submission required NOTE
- All major approval processes can run in parallel, saving time NOTE
- Import / Export license required only if IMP is outside EU NOTE
- Summary: Time from QP ID to Importation of IMP estimated at **16 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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