EGeen

A Premier, Full Service Eastern European CRO

EGeen RNA Program Country Card – **Czech Republic**

Czech Republic Overview

- Population: 10.77 million
- Five Largest Cities: Prague, Brno, Pizen, Olomouc, Liberec
- Language: Czech
- EU Member: Yes (2004)
- Govt Type: Parlimentary Constitutional Republic
- Govt. Admin.: 13 Regions + Prague (capital)
- Health System: Compulsory insurance + fee-for-service; GHIF insurance

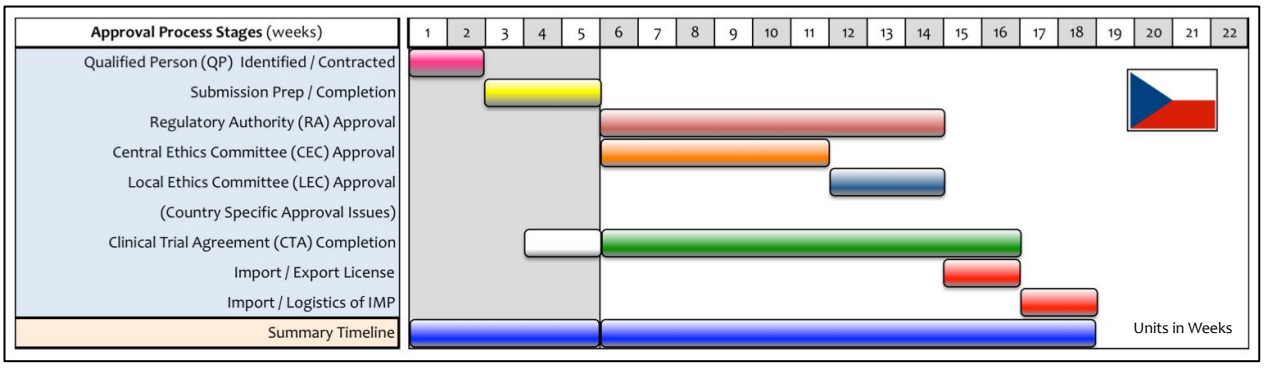
Clinical Trial Network / Comments

- HC Sites: 51 hospitals, >750+ clinics, 77 GHIF sites; 6.84 beds per 1000
- HC Splits: 84% public / 16% private; 32% inpatient / 68% outpatient
- Investigators: ICH GCP experienced, high quality, motivated, excellent data management
- CRAs: Physicians, biologists, nurses; good relations with investigators
- High level of clinical trials amongst CEE countries; excellent infrastructure, execution
- Higher than average renal, pancreatic and colon cancer rates, 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

Czech Republic – Clinical Trail Process Overview



Czech Republic 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 Czech language or Czech / English NOTE
- CEC reviews all study aspects except for site suitability and investigator's qualifications
- LEC reviews only site suitability and investigator's qualifications
- CEC approval docs can include only draft forms of CTAs NOTE
- Summary: Time from QP ID to Importation of IMP estimated at **18 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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