EGeen

A Premier, Full Service Eastern European CRO

EGeen RNA Program Country Card – **Hungary**

Hungary Overview

- Population: 9.88 million
- Five Largest Cities: Budapest, Debrecen, Miskolc, Szeged, Pecs
- Language: Hungarian
- EU Member: Yes (2004)
- Govt Type: Parliamentary Democratic Republic
- Govt. Admin.: 19 Counties + Budapest (capital)
- Health System: Universal healthcare, OEP insurance fund; private fee

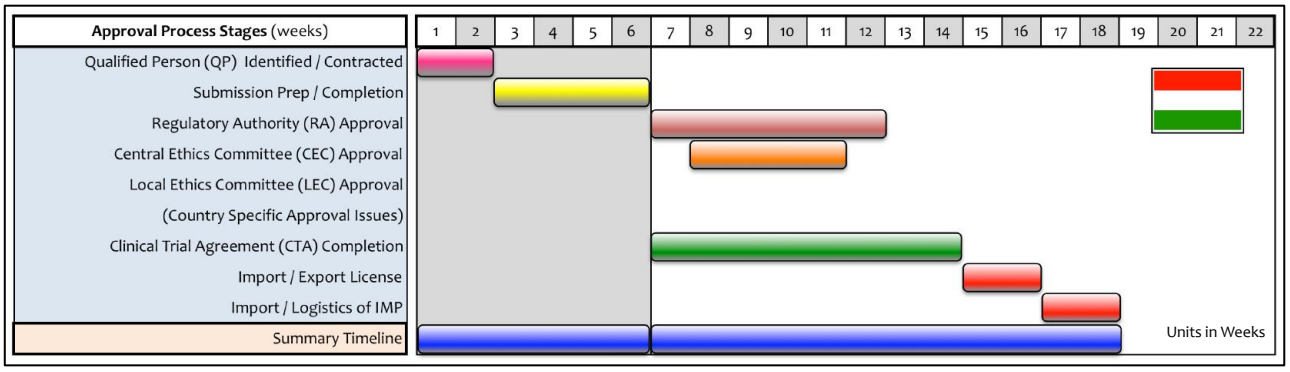
Clinical Trial Network / Comments

- HC Sites: 99 hospitals, two national institutes, >650+ clinics; 7.00 beds per 1000
- HC Splits: 70% public / 30% private; 32% inpatient / 68% outpatient
- Investigators: ICH GCP experienced, high quality, motivated
- CRAs: Physicians, biologists, nurses; good relations with investigators
- High level of clinical trials amongst CEE countries; popular clinical trial country
- Higher than average lung and colon cancer rates; very high cardiovascular rates

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

Hungary – Clinical Trail Process Overview



Hungary 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 approval process, saving time
- RA and CEC approvals can begin concurrently, saving time
- All major submission documents need to be in Hungarian language NOTE
- CEC reviews runs concurrently with RA reviews; may even finish earlier
- LEC reviews and approvals are absent NOTE
- IMP import license only required if imported from outside EU 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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