EGeen

A Premier, Full Service Eastern European CRO

EGeen RNA Program Country Card – **Poland**

Poland Overview

- Population: 38.48 million
- Five Largest Cities: Warsaw, Krakow, Lodz, Wroclaw, Poznan
- Language: Polsih
- EU Member: Yes (2004)
- Govt Type: Representiative Democracy
- Govt. Admin.: 16 Provinces
- Health System: Compulsory insurance + fee-for-service; NFZ govt. fund

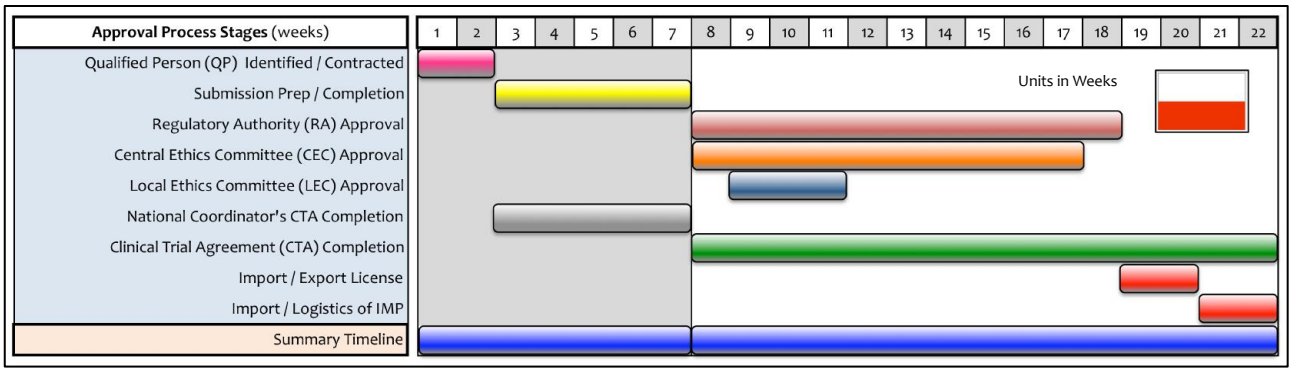
Clinical Trial Network / Comments

- HC Sites: 754 hospitals, >550+ clinics, 16 NFZ branches; 6.7 beds per 1000
- HC Splits: 90% public / 10% private; 42% inpatient / 58% outpatient
- Investigators: ICH GCP experienced, high quality, motivated, excellent healthcare
- CRAs: Physicians, biologists, nurses; good relations with investigators
- Highest level of clinical trials amongst CEE countries; cardiology + oncology as ~50%
- 50+ university hospitals, medical institutes; large population of naïve and pre-treated

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

Poland – Clinical Trail Process Overview



Poland Approval Process Highlights

- Qualified Person (QP) must be identified and registered prior to approval process beginning
- Submission must first be approved by National Coordinator, with executed CTAs upfront
- RA approval timeline only begins after submission is checked for completeness
- All major submission documents need to be in Polish language
- LEC of National Coordinator also serves as CEC, coordinating both approvals NOTE
- Less con-current review timelines lengthen approval process; one of longest in CEE NOTE
- IMP import license only required if imported from outside EU
- Summary: Time from QP ID to Importation of IMP estimated at **=/> 22 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.

Contact Us

EGeen, Inc.
490 North McCarthy Blvd
Milpitas, CA 95035

info@egeeninc.com