EGeen

A Premier, Full Service Eastern European CRO

EGeen RNA Program Country Card – **Romania**

Romania Overview

- Population: 19.51 million
- Five Largest Cities: Bucharest, Cluj-Napoca, Timisoara, Iasi, Constanta
- Language: Romanian
- EU Member: Yes (2007)
- Govt Type: Unitary Semi-Presidential Republic
- Govt. Admin.: 41 Counties + Bucharest (capital)
- Health System: Compulsory insurance + fee-for-service; 42 DHIF funds

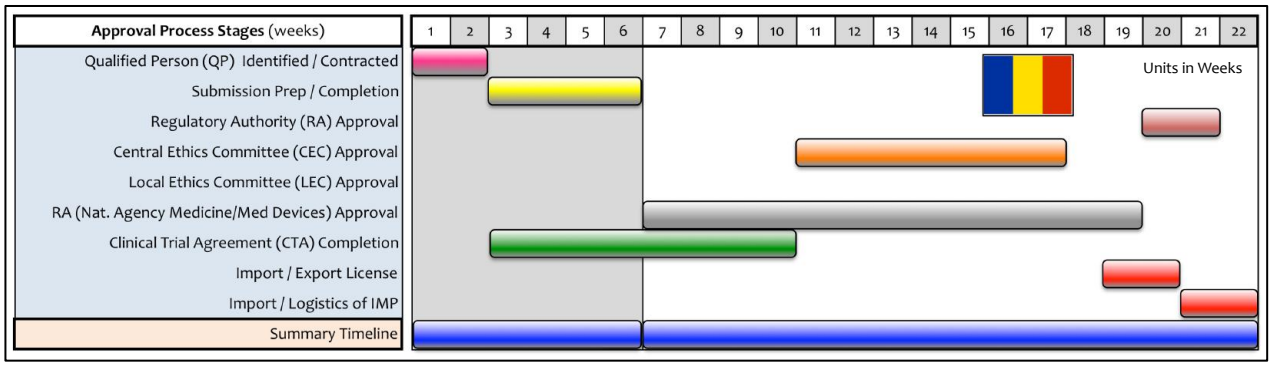
Clinical Trial Network / Comments

- HC Sites: 422 hospitals, >50+ clinics, sites; 6.5 beds per 1000
- HC Splits: 85% public / 15% private; 45% inpatient / 55% outpatient
- Investigators: ICH GCP experienced, motivated, high quality data
- CRAs: Physicians, pharmacists, biologists, nurses; good relations with investigators
- Limited quality of healthcare yields high number of treatment naïve patients
- One of highest levels of cardiovascular disease and hepatitis B in Europe

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

Romania – Clinical Trail Process Overview



Romania Approval Process Highlights

- Qualified Person (QP) must be identified and registered prior to approval process beginning
- All CTA site contracts must be signed before submission to CEC; this can delay approval NOTE
- RA review can be done during CTA negotiations and CEC review, but not approved until CEC NOTE
- All major submission documents need to be in Romanian language
- LEC review and approval is usually not required NOTE
- CTA signatures up-front can 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