EGeen

A Premier, Full Service Eastern European CRO

EGeen RNA Program Country Card – **Ukraine**

Ukraine Overview

- Population: 44.43 million
- Five Largest Cities: Kiev, Kharkiv, Dnipropetrovsk, Odessa, Donetsk
- Language: Ukrainian (official); Russian
- EU Member: No
- Govt Type: Semi-Presidential Constitutional Republic
- Govt. Admin.: 24 Provinces + Kiev (capital), Crimea and Sebastopol
- Health System: Centralized, state-provisions and delivery; no insura

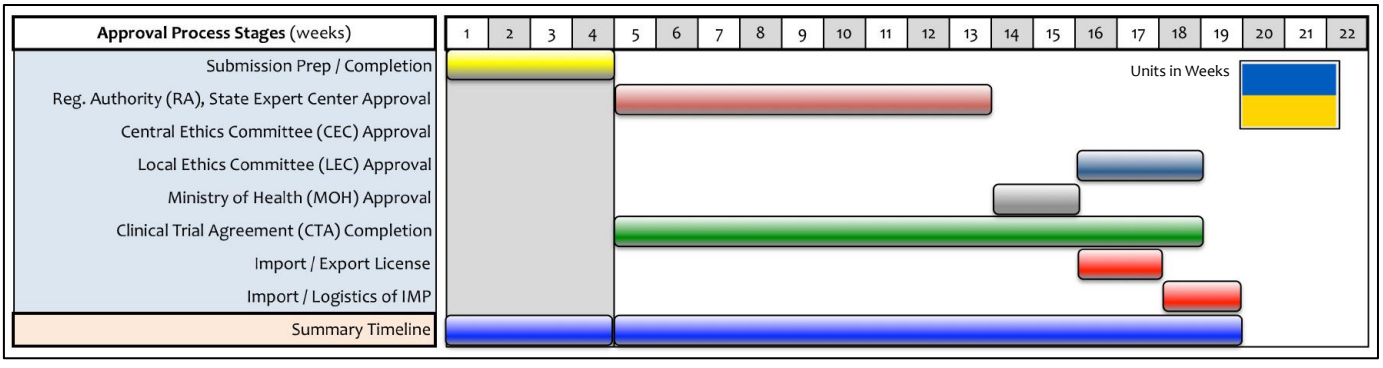
Clinical Trial Network / Comments

- HC Sites: ~ 2700 hospitals, declining; 90% inpatient; 18 university hospitals; 7.2 beds per 1000
- Highly centralized (ex-Soviet) HC delivery; 86% public, 27 admin sites; poor quality, short staffed
- Investigators: ICH GCP experienced, high quality, motivated, excellent data
- CRAs: Physicians, biologists, nurses; good relations with investigators
- Largest patient pool in CEE (exc. Russia); very high rates of cardiovascular disease, HIV
- High percentage of pediatric trials conducted; centralized pediatric healthcare for patient access

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

Ukraine – Clinical Trail Process Overview



Ukraine Approval Process Highlights

- No Qualified Person (QP) required; Ukraine is not an EU member state
- RA approval in two stages; first as State Expert Center with MOH, then approval by MOH itself NOTE
- LEC review and approval only after MOH RA approvals
- All major submission documents need to be into local language
- CTA negotiations, signatures can run concurrent with RA approval process; no CEC approvals
- Importation licenses only after MOH approval NOTE
- Importation permit then required for each study drug shipment
- Summary: Time from QP ID to Importation of IMP estimated at **19 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