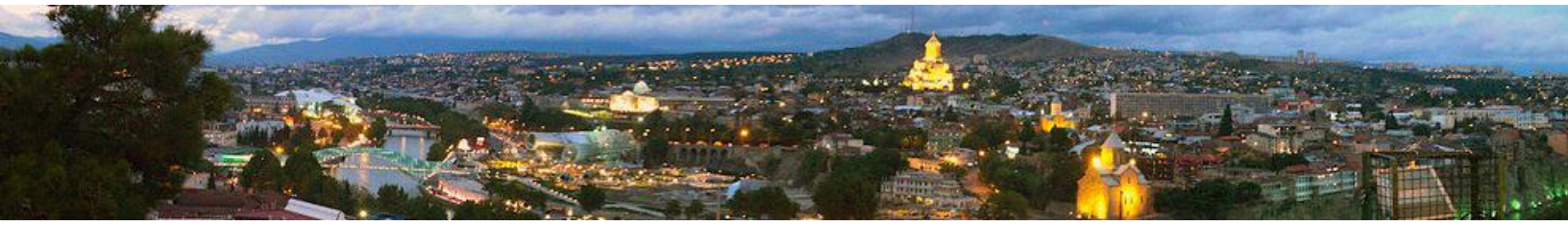
EGeen

A Premier, Full Service Eastern European CRO

EGeen RNA Program Country Card – **Georgia**



Georgia Overview

- Population: 3.73 million
- Five Largest Cities: Tbilisi, Kutaisi, Batumi, Rustavi, Zugdidi
- Language: Georgian
- EU Member: No
- Govt Type: Unitary Semi-Presidential Republic
- Govt. Admin.: 9 Regions + 2 'autonomous' republics
- Health System: State insurance + fee-for-service; SMIC govt. fund

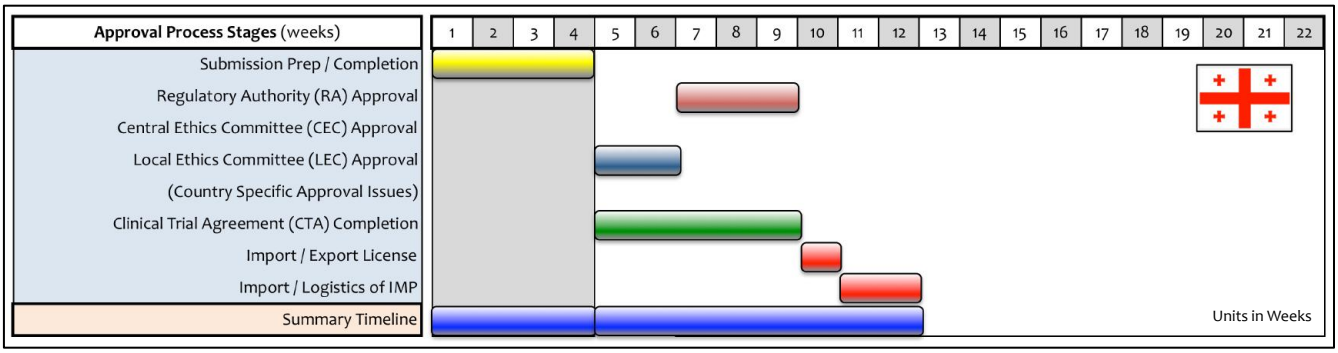
Clinical Trial Network / Comments

- HC Sites: ~ 18 hospitals, ~950 outpatient clinics; most hospitals in Tbilisi; 3.2 beds per 1000
- HC being decentralized, privatized to larger degree; reforms away from ex-Soviet model
- Investigators: ICH GCP experienced, high quality, motivated, excellent data management
- Patient access high due to desire for quality treatment; large population of naïve patients
- High level of clinical trials conducted in Tbilisi and largest cities
- Very high levels of 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

Georgia – Clinical Trail Process Overview



Georgia Approval Process Highlights

- No Qualified Person (QP) required; Georgia is not an EU member state
- No Central Ethic Committee (CEC); no approval needed; saves time NOTE
- LEC Approval prior to submission to RA; highly unusual NOTE
- All major submission documents need to be in Georgian language
- CTA negotiation and signatures can run parallel with LEC approval, saving time
- No need for separate Import License submissions NOTE
- LEC approval serves as defacto import license for IMPs NOTE
- Summary: Time from QP ID to Importation of IMP estimated at **12 weeks**; fastest in CEE

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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