



## EGeen RNA Program Country Card – Estonia



### ● Estonia Overview

- Population: 1.31 million
- Five Largest Cities: Tallinn, Tartu, Narva, Parnu, Kohtla-Jarve
- Language: Estonian
- EU Member: Yes (2004)
- Govt Type: Parliamentary Republic
- Govt. Admin.: 15 counties
- Health System: Compulsory insurance + fee-for-service; EHIF insurance fund



### ● Clinical Trial Network / Comments

- HC Sites: 49 hospitals (four central), >50+ clinics; 5.2 beds per 1000
- HC Splits: 84% public / 16% private; 42% inpatient / 58% outpatient
- Investigators: ICH GCP experienced, high quality, motivated, excellent data mgmt.
- CRAs: Physicians, biologists, nurses; good relations with investigators
- High level of treatment naïve patients
- High rates of ovarian cancer (#6 in the world) and cardiovascular disease

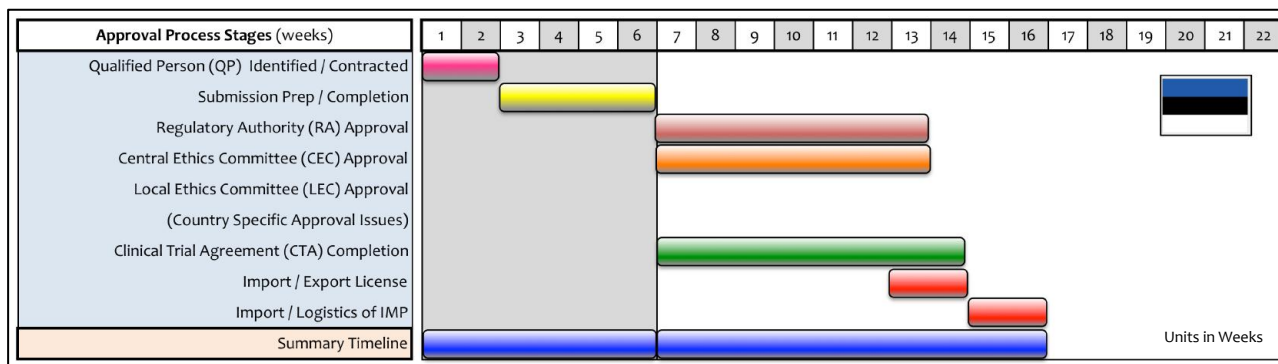


### ● EGeen Clinical Trial Support

- Full range of clinical trial services
- Patient recruitment, clinical monitoring, data management, biostatistics, regulatory
- Pharmacovigilance, 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



### Estonia– Clinical Trail Process Overview



### ● Estonia Approval Process Highlights

- Qualified Person (QP) must be identified, registered prior to approval process
- CTA site contracts can be negotiated during RA, CEC and LEC approvals, saving time
- RA and CEC approvals can begin concurrently, saving time
- All major submission documents need to be in Estonia language **NOTE**
- No LEC submission required **NOTE**
- All major approval processes can run in parallel, saving time **NOTE**
- Import / Export license required, even within EU **NOTE**
- Summary: Time from QP ID to Importation of IMP estimated at **16 weeks**



Note: Summary time total is an estimated average of trial complexity