



## EGeen RNA Program Country Card – Germany



### Germany Overview



- Population: 81.9 million
- Five Largest Cities: Berlin, Hamburg, Munich, Cologne, Frankfurt
- Language: German
- EU Member: Yes (1993)
- Govt Type: Federal Parliamentary Republic
- Govt. Admin.: 16 Federal States
- Health System: Universal Multi-Payer system, 2 types: Statutory, Private

### Clinical Trial Network / Comments



- HC Sites: ~2,100 hospitals, >750+ clinics; 8.25 beds per 1000
- HC Splits: 77% public / 23% private; 32% inpatient / 68% outpatient
- Investigators: ICH GCP experienced, high quality, motivated, excellent data
- CRAs: Physicians, biologists, nurses; good relations with investigators
- High level of clinical trials in Europe, as #2; #3 worldwide; excellent infrastructure
- Higher than average cardiovascular disease and cancer rates

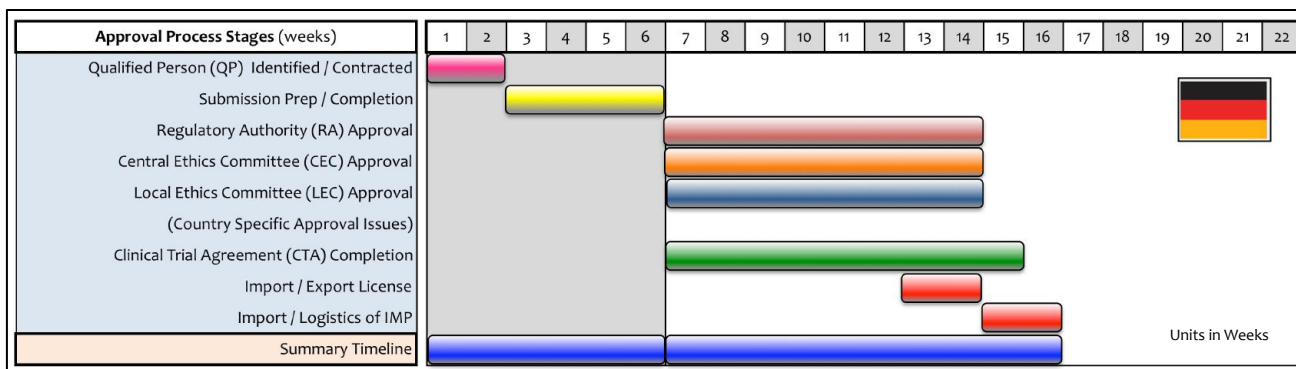
### EGeen Clinical Trial Support



- 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



### Germany – Clinical Trail Process Overview



### Germany Approval Process Highlights



- Qualified Person (QP) must be identified and registered prior to approval process beginning
- CTA site contracts can be negotiated during RA, CEC and LEC approval process, saving time
- RA and CEC approvals can begin concurrently, saving time **NOTE**
- All major submission documents need to be in German language
- RA approvals divided into three oversight institutions: PEI, BfArM, DIMDI **NOTE**
- Approval process follows EU legislation
- Importation license required for IMPs
- Summary: Time from QP ID to Importation of IMP estimated at **17 weeks**

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