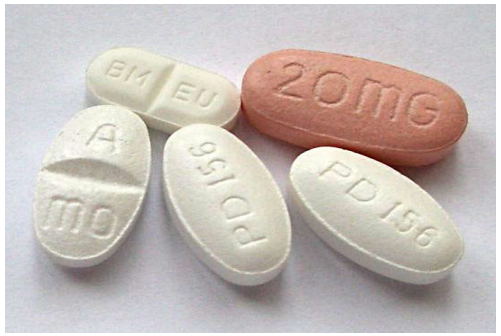
Contract Research Organization (CRO)

Medconsult-Geo



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www.medconsult-geo.com

Medconsult-Geo

- is a contract research organization located in Tbilisi, Georgia

- supports medical and biopharmaceutical companies as well as manufacturers of medical devices in carrying out both preclinical and clinical studies across phases I – IV in various therapeutic areas

Fields of clinical trials

- Haematology and Oncology
- Cardiology
- Gastroenterology
- Neurology
- Endocrinology and Rheumatology
- Allergology - Dermatology
- Neurosurgery and Cardiovascular surgery

- General and Plastic surgery
- Pulmonology
- Microbiology, Virology and Infectiology
- Gynaecology
- Otolaryngology
- Nephrology and Dialysis Therapy
- Urology
- Ophthalmology

Medconsult-Geo

- Offers to clients a truly comprehensive service portfolio
- Converts scientific discoveries worldwide into new therapies
- Carries out its activities mainly in Georgia but plans to network its cooperation with other countries as well

Services

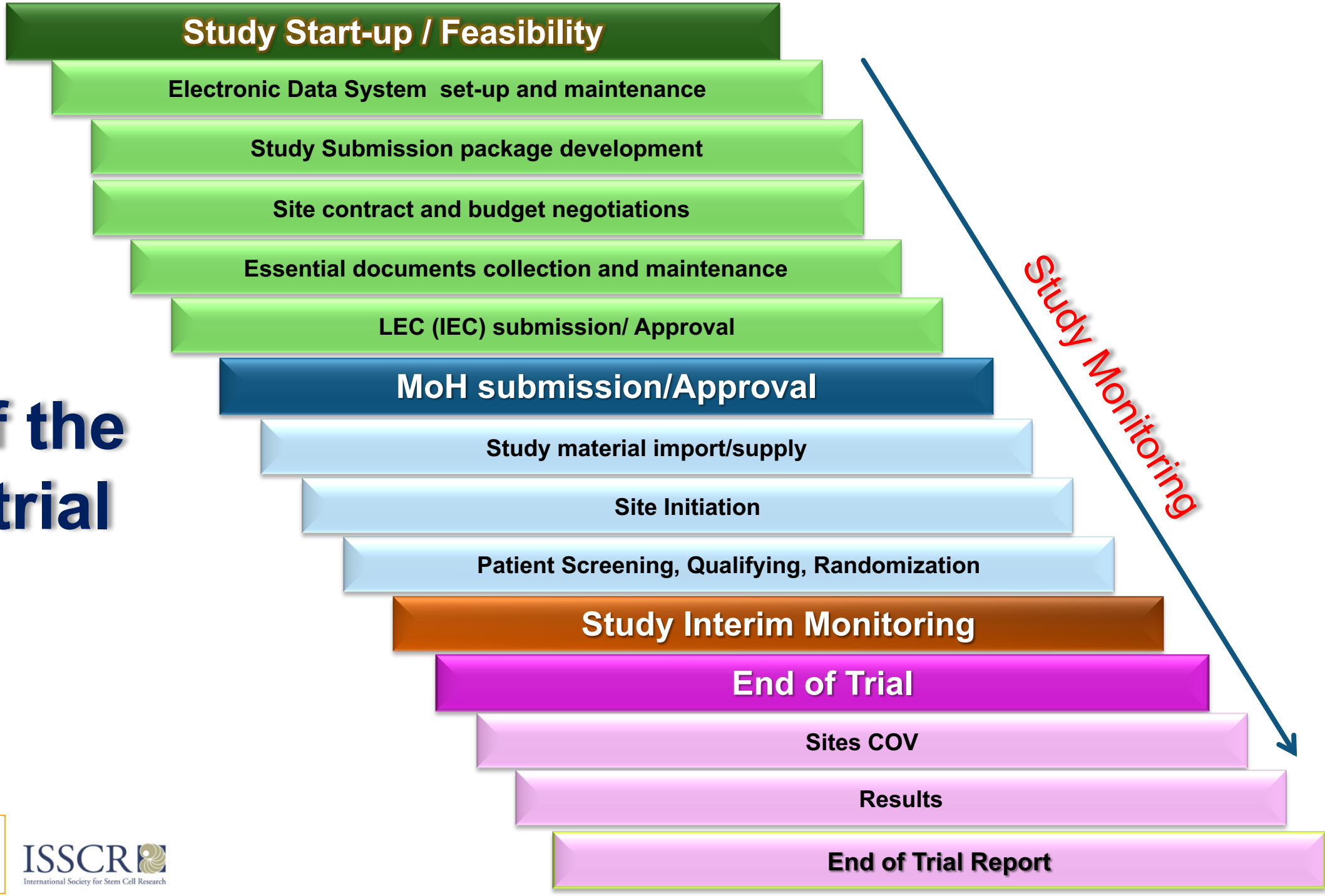
- Preclinical research
- Clinical research
- Clinical trials management

- Site selection
- Regulatory support
- Logistics
- Monitoring and Site management

Why Georgia?

- Shortest timelines for receiving study approval
- High quality service
- Cost effective service for all steps of trial
- No CEC, ethical expertise of all clinical Trials covered only by LEC/IEC
- Import License for IMP is not required
- Export License for biological samples is not required

Steps of the clinical trial



Steps of the clinical trial

Start-up

- Feasibility
- Site selection
- Contract negotiation and LOA development
- Study team assignment & start-up meetings
- Providing with core pack
- LEC/MoH submission / approval
- Logistical activities (Study material import/supply)

Maintenance

- Patient Participation
  - Screening, Qualifying, Randomization, Scheduling Exams
- SDV/SDR
- Site Interim Monitoring
  - Follow up visits and calls
- Expedited safety and annual reporting LEC/MoH
- Electronic Data System maintenance
- Data Entry
  - Review for accuracy

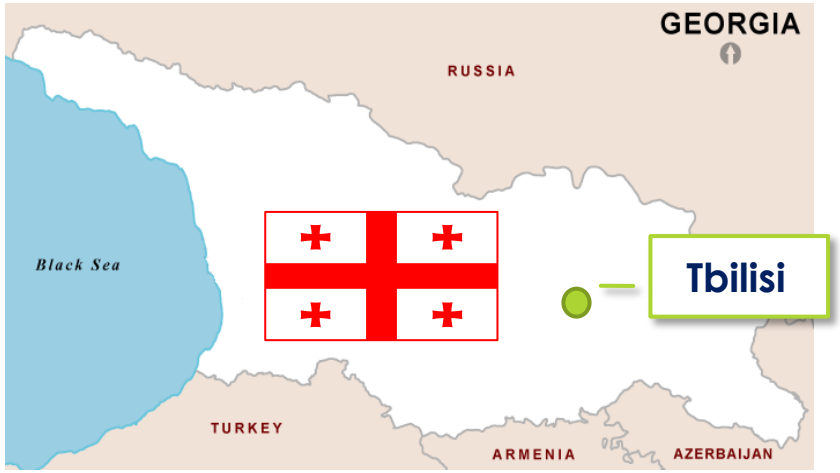
Finalization

- Sites COV
- Data Filing and storing
- Electronic Data System completion
- EOT Report

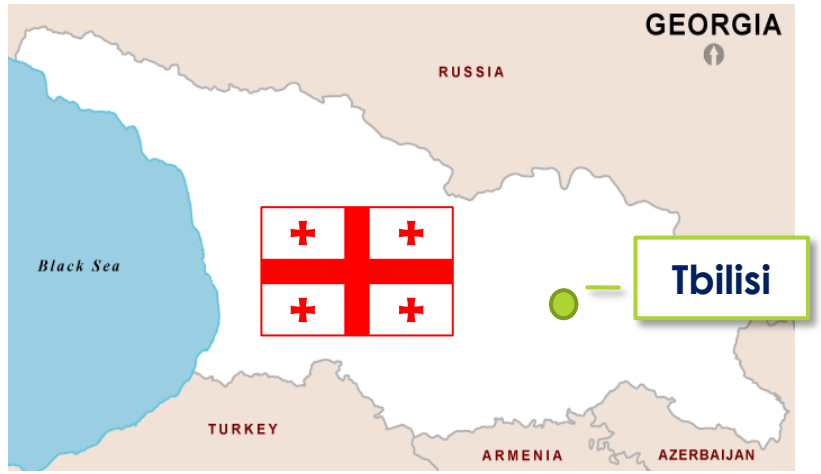
Country information

- Capital: **Tbilisi (1,1 mln people)**
- Official language: **Georgian**
- National currency: **Lari (GEL)**
- Time zone: **GMT+4**
- Population (2019): **3.723 mln**
  - Female population **52%**
  - Male population **48%**
  - Urban population: **58.7%**

- *Wolrdbank Data 2020, Georstats, Statista*



Country information*



GDP per capita

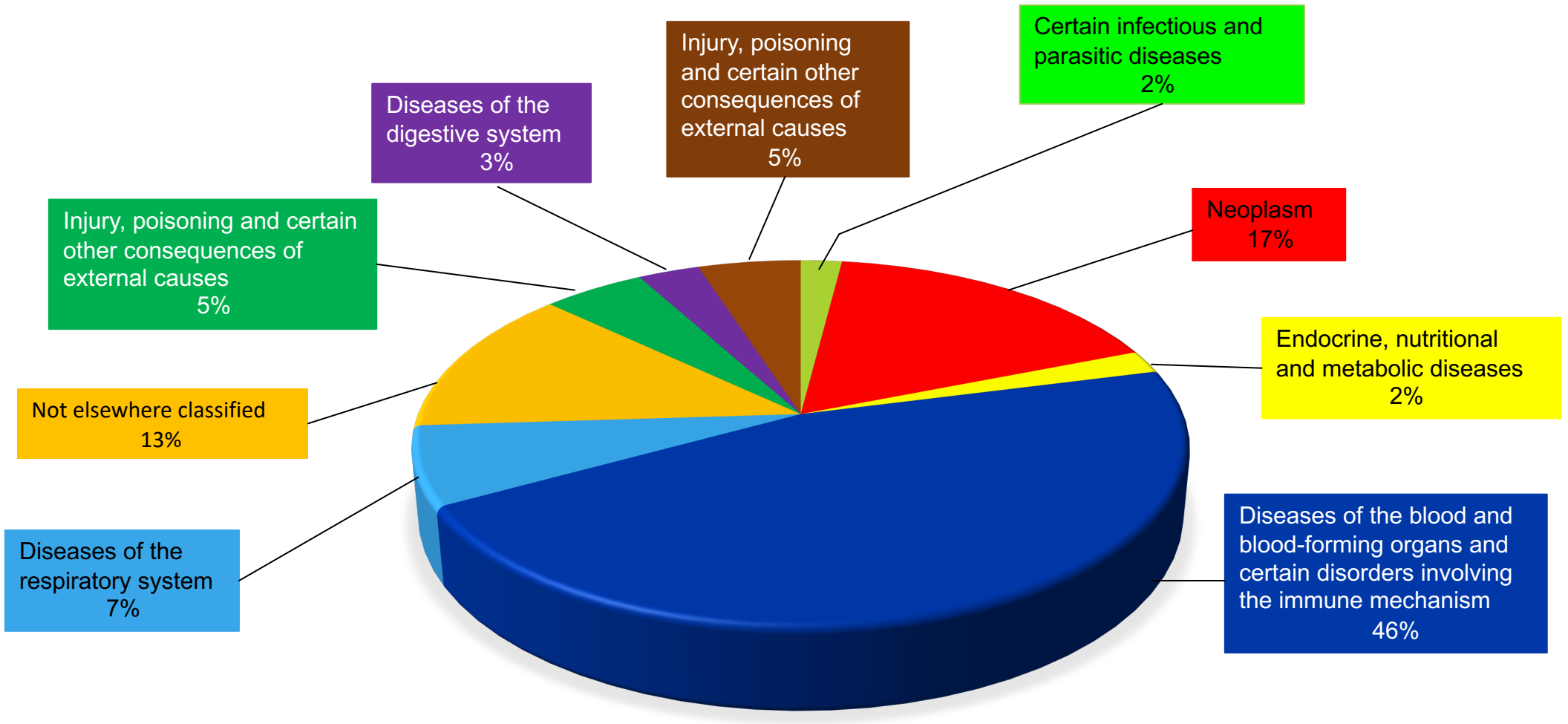
2014	2015	2016	2017	2018	2019
$4,739	$4,014	$4,062	$4,357	$4,722	$4,769

Inflation & Unemployment Stats

	2014	2015	2016	2017	2018	2019
Inflation Rate % (CPI, annual variation)	3	4	2.1	6	2.6	4.9
Unemployment rate %	14.6	14.1	14	13.9	12.7	11.6

*(as of November.2020)

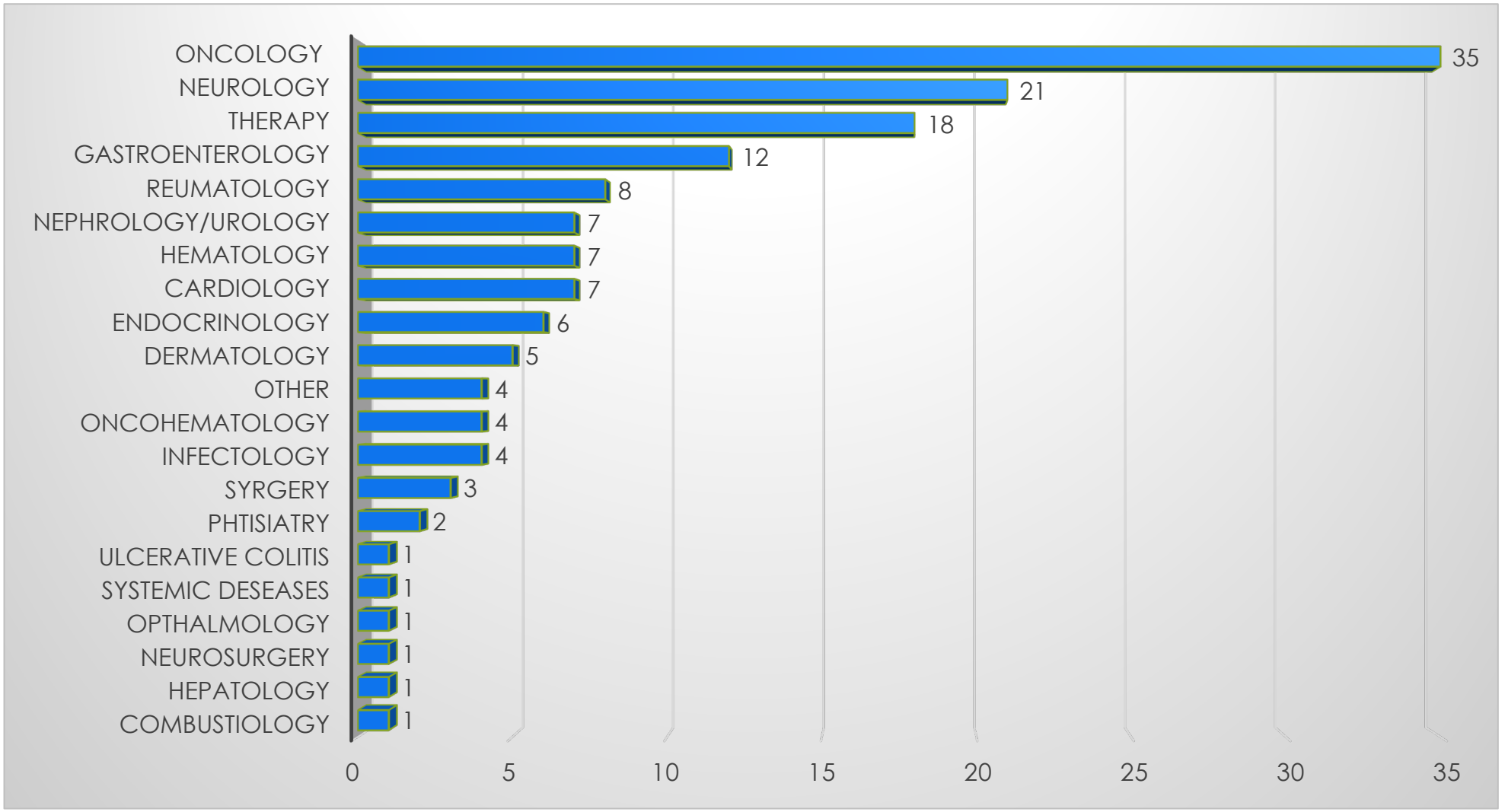
The cause of death at all age in Georgia (2019)



Clinical trial general Information

- Qualified centers largely in Tbilisi (capital), but some of them in Batumi, Kutaisi, Telavi and Gurjaani
- High motivation by investigators to participate in trials
- High motivation of patients to participate in trials

Ongoing Clinical Trials: 149



Important Country Considerations

Regulatory

- Georgia has the fastest MOH approval timelines in the region (~1 month from submission)
- Good for studies where site activation timelines are critical

Import & Export

- Direct to sites shipments are possible but may be more costly compared to bulk shipments
- Import License is only required for drugs not listed in protocol title and study materials
- Export License for biological samples is not required

Important Country Considerations

Contracting

- As a rule, separate Investigator and Institution agreements are used
- Contracts may be in English only (if agreed with the site)
- Sites agree to review and sign CTAs regardless of LEC and/or MOH submissions and approvals

Translation

- Used qualified vendors available to provide high quality translations with notarization (country requirement)

Local Ethics

- Submission to LECs should be done first – precedes MOH submission

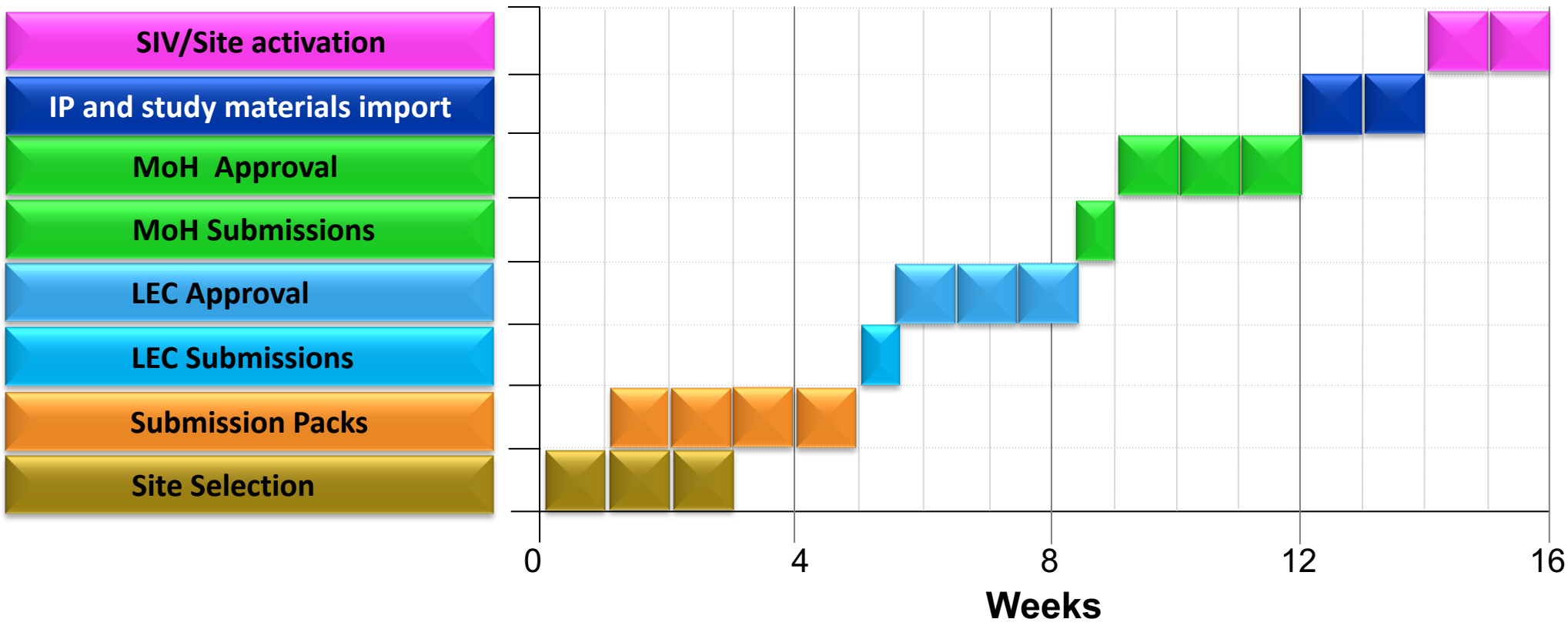
Start-up procedures takes an average of 4 to 5 months

- Translation of all necessary documents, first certification and then insertion of these documents into the appropriate legal format;
- Obtaining all necessary approvals for clinical trials from the Georgian Ministry of Health and ethics committees.
- Establishing cooperation with appropriate clinical study centers and investigators

Regulatory Conciderations Country Submission Timelines

- Georgia became one of the quickest countries in Europe regarding the study Start-up and the attractively fast timelines for the country submissions/approvals
- Generally, it takes approx. 4 months from the receiving Core Packs

Country Submission Timelines



SIV – Site Initiation Visits

IP – Investigational Product

LEC - Local Ethic Committee

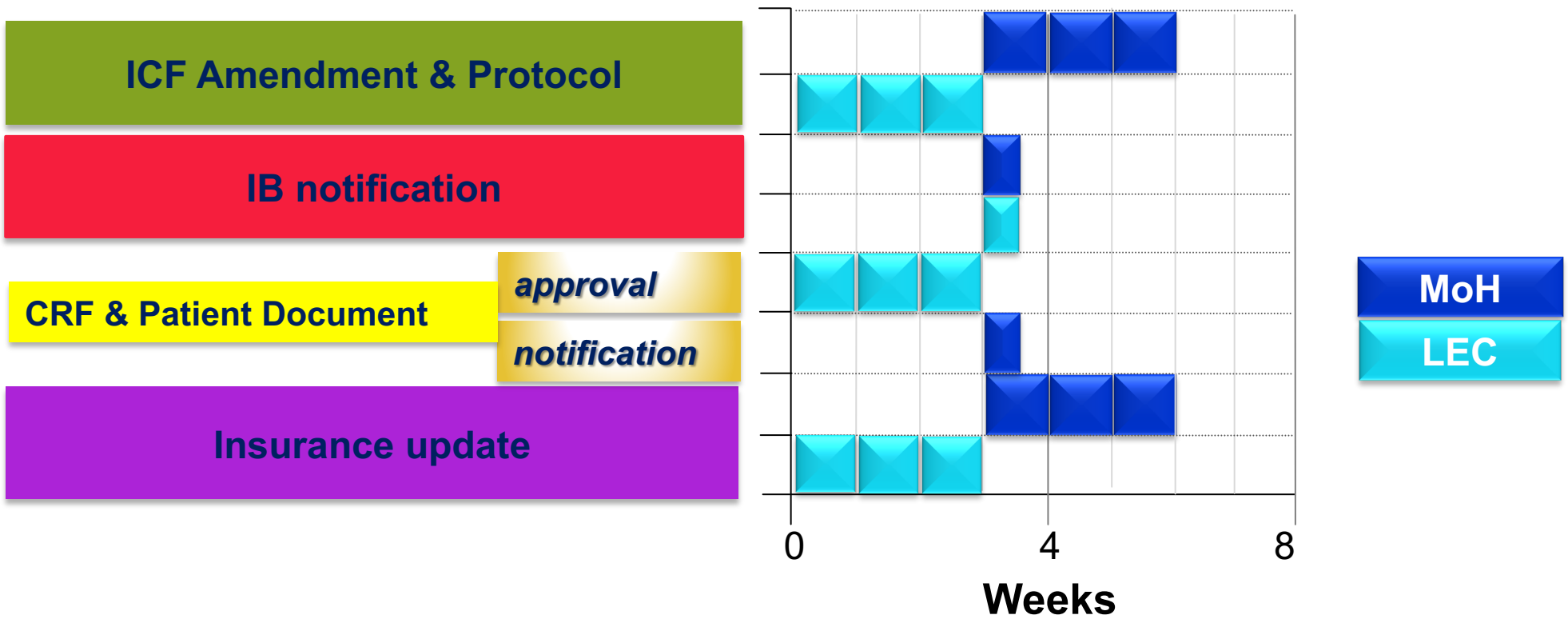
MoH – Ministry of Health

Regulatory considerations country submission timelines

- Find out when at least Protocol, IB, ICF, and especially Insurance Certificate will be available.

- Draw your attention that Clinical Trial Application (CTA) has to be submitted to MoH after LEC(s) approval(s) is received and estimate submission timelines based on these dates (the submission, review, and approval process for LEC requires approximately 14-21 days, for MoH – 21 working days (BEST CASE SCENARIO)

Submission Timelines for Amendments



ICF – Informed Consent Form, IB – Investigational Brochure, CRF – Case Report Form

Insurance

Main requirement for insurance certificates in Georgia:

- Policy number
- The Named insured Address Protocol No Study I title Number of Patients
- Development Phase Period of trial Investigators (site name, address and PI name) - if insurance certificate is in English Language it must be translated and notarized, or bilingual certificate should be provided by sponsor
- The insurance certificate must be signed and dated (original is required)

Cooperation with Laboratories

CRO “Medconsult-Geo” LLC has an excellent opportunity to have a close cooperation with main famous laboratories in Germany and Austria as well as in Georgia:

- **Labor Krone GbR (MVZ Labor Krone GbR, Bad Salzuflen, Germany)**
- **MEDILAB GmbH, Medical-diagnostic laboratory (Salzburg, Austria)**
- **MVZ Labor Dr. Limbach & Kollegen (Heidelberg, Germany)**
- **Institute for Laboratory Medicine, Hospital of the University of Munich (Germany)**
- **Richard Lugar Laboratory Center for Public Health Research (Tbilisi, Georgia)**

Medconsult-Geo Investigators

- High qualified scientists
- Excellent foreign language skills (English, German, French, Italian, Russian)
- Professionally trained/certified in Georgia, Germany, Switzerland and Italy on appropriate specialization
- More then 10 years experience in GCP compliant trials
- High motivation to participate in international trials

Depot and Logistic

- Up to sponsors requirements, study materials
  - ✓ can be stored in depot after customs clearance procedures
  - ✓ as well as they can be delivered directly to sites
- Only the IATA-certified employees are responsible for any logistic procedures
- The study materials can be destroyed locally by certified organization at the request of the sponsor

Medconsult-Geo

- Is only one company in Georgia and Caucasus providing:

Additional Services

- **Pharmacovigilance**
- Clinical trials in **Veterinary**

Pharmacovigilance Services

- Local pharmacovigilance specialist for the product(s) according to the territory
- Assessment of AEs in ICSRs/Exchanging ADRs/AEs between parties in agreed timeframes
- The format of single case data exchange is CIOMS I
- Preparations and submission of ICSRs for submission to the competent authority
- Follow-up of ICSRs in the territory
- Submission of additional information regarding specific ICSRs if requested by competent authorities/Submission of additional information of a more general nature
- Pregnancy ICSRs

Pharmacovigilance Services

- Obtaining additional information (follow-up) for ICSRs reported in the local territory
- Submission of appropriate reports to competent authorities according to the territory
- Submission of PSURs/SUSARS/ACOs to the competent authorities according to the territory (if applicable)
- Local medical/scientific literature search
- Handling of urgent safety issues identified by the local CA
- Local contact point is contacted by CA on any safety-related action, decision or request to notify its partner promptly in writing
- Maintenance/Update of local SOPs to comply with the agreement between parties
- Archiving

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Thank you