

Clinical Trials in South Caucasian Region: A Growing Hub for Research Excellence

Introduction & Objectives



INTRODUCE SOUTH CAUCASUS AS AN
EMERGING CLINICAL TRIAL REGION



HIGHLIGHT GEORGIA'S UNIQUE
STRENGTHS

Global Trends in Clinical Trials



Increasing need for diverse
patient populations



Shift toward cost-effective
emerging markets



Focus on speed, quality,
and regulatory flexibility

Why South Caucasus?

Strategic location: Europe
meets Asia



EU Association Agreements



Growing infrastructure and
skilled professionals

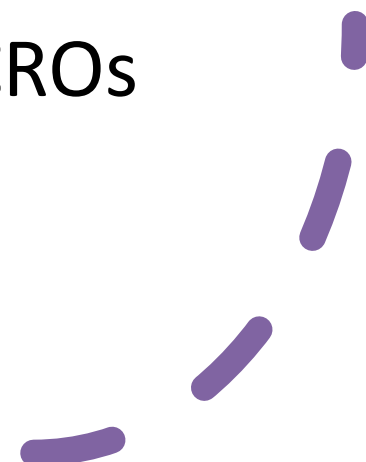


Challenges of Caucasus Region

- Patient Population having willingness to participate in the trial
- Numerous sites who want clinical trials.
- Regulatory Requirement aligned to EMA
- Short time period for Regulatory Approval
- Cost-Effective processes.
- Easy to perform overall study processes.



Weaknesses

- Insufficient Human resources
 - Competitive trials leading to inaccurate recruitment rate.
 - Unexperienced site staff
 - Low trust for local CROs
 - Political conditions
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Spotlight on Georgia

Modern regulatory system

Cost-effective trials

High patient recruitment
and retention

Experienced investigators
and facilities

Regulatory & Ethical Landscape in Georgia

LEPL regulates clinical trials

Fast-track approvals:
30–45 days

Alignment with ICH-
GCP and EMA

Active Ethics
Committees

Infrastructure
& Clinical
Sites

Phase I–IV
capabilities

Central labs, EDC,
imaging

WR-Clinicals' trial-
ready network

Patient
Population
&
Recruitment

Treatment-naïve and
motivated patients

Trusted physician-
patient relationships

Multilingual support
and high retention

WR-
Clinicals –
Your CRO
Partner

Regional experience
and deep local insight

Regulatory, site, and
monitoring services

EDC expertise (e.g.,
Viedoc)

Flexible and responsive
operations

Case Studies / Success Stories

100+ patients enrolled in
<3 months

Regulatory approval
within 30 days

High sponsor satisfaction
and retention

Spotlight on Azerbaijan

Regulatory Enforcement: Weak enforcement of existing laws and regulations can hinder the effective management of clinical trials.

Resource Limitations: Regulatory bodies may lack the necessary resources and manpower to adequately monitor compliance, leading to lapses that can affect public health

Corruption Risks: Instances of bribery and favoritism can undermine the integrity of clinical research, posing risks to patient safety and data reliability.

Regulatory Process in Azerbaijan



FOR DRUGS IT TAKES ABOUT 1-3 MONTHS FROM SUBMISSION TO RA APPROVAL



FOR MEDICAL DEVICES – 3-6 MONTHS FROM SUBMISSION TO RA APPROVAL



CLASS I DEVICES DOESN'T NEED TO BE REGISTERED



Spotlight on Armenia

- **Clinical Trial Authorization:** The process typically takes about 60 days for the verification of the clinical development program, following the preliminary examination.
- **Drug Registration:** The general registration procedure for medicinal products takes no more than 150 calendar days, including laboratory tests. A simplified procedure is available for products registered in the EU, USA, or Japan, reducing the timeline to 31 calendar days.

Opportunities for Collaboration



Site feasibility and start-up support



Full-service clinical trial management



Partnerships with pharma and biotech companies

Thank You / Q&A



Let's explore clinical
research opportunities
together



Contact: contact@wr-clinicals.com



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