Emerging Clinical Research in Armenia: Experience with Bioequivalence Studies and Future Perspectives

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Agenda

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Introduction: Clinical Trials Landscape in Armenia

Armenia is an emerging player in the clinical research landscape

According to EAEU Regulation No. 78, Point 36, part of the clinical trial must be conducted in an EAEU member state, which are mutually recognized.

Clinical trials have grown over the past decade

National regulatory authorities are adopting EAEU regulation and improving oversight mechanisms

Armenia – a combination of a strong medical community, relatively low operational costs, and improving regulatory infrastructure makes it a promising location for sponsors seeking new clinical trial sites

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Current Environment and Progress

Developments

- ✓ Harmonization of clinical trial regulations with EAEU regulations
- ✓ Increasing participation of local centers in Phase I–IV clinical trials
- ✓ Establishment of Independent Ethics Committee (IEC) with more structured review processes
- ✓ Development of specialized unit for BE studies and early-phase research
- ✓ Growing number of trained investigators and GCP-certified professionals

Example:

- In the past two years, Armenia has seen a over 330% increase in active study sites participating in international trials

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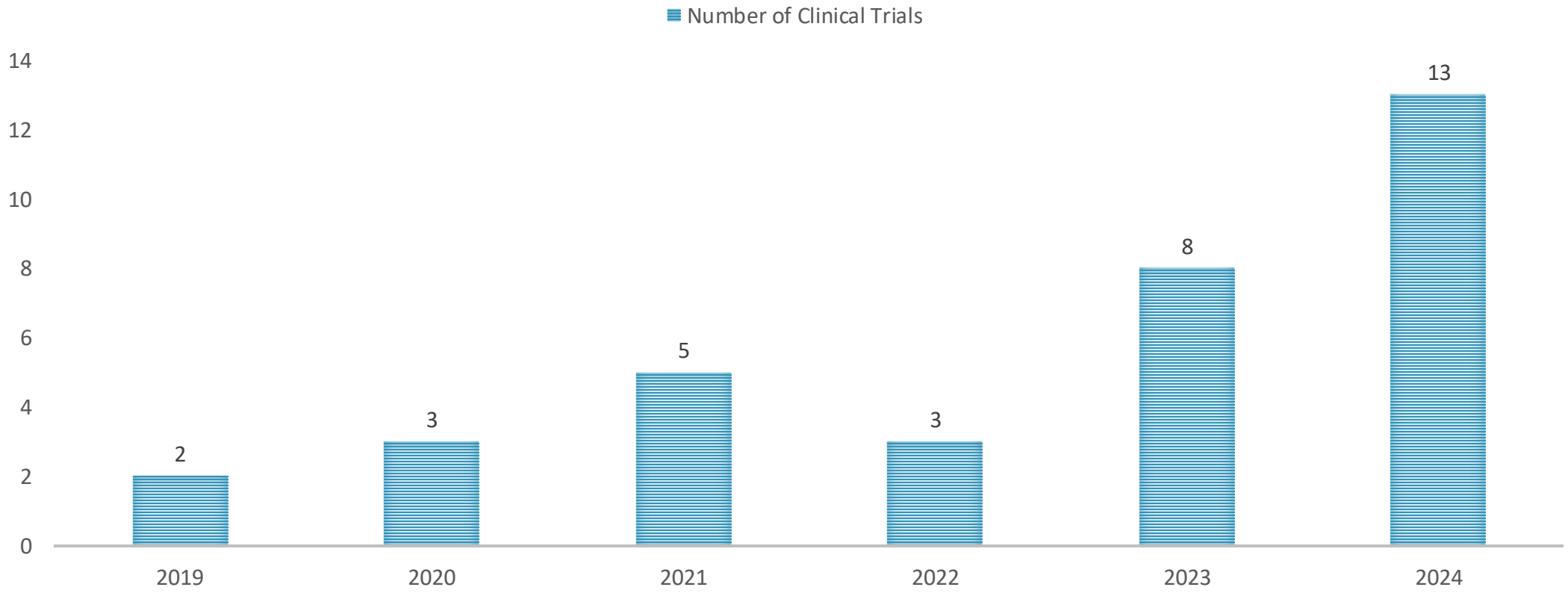
Clinical Trials Authorized in the Republic of Armenia



As of 2024, in Georgia there are approximately 1,905 active clinical trials

Approved Clinical Trials_2024

Key Challenges for Clinical Trials

Lack of a quality system in essential departments

Absence of clinical trial coordinators in hospitals

Lack of GCP (Good Clinical Practice) training

Perceptions and attitudes of patients and healthy volunteers toward clinical trials

Difficulties with the import/export of investigational products, necessary concomitant therapies, and biological samples

Implementation and validation of electronic systems

Contract negotiation processes

These challenges mirror what other emerging markets faced 10–15 years ago — Armenia is currently at a **transformative stage**

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Focus Area: Current Bioequivalence Study

Study Design: Randomized, open-label, multiple-dose, two-period, two-sequence crossover BE study under fasting conditions in healthy male adults

Objective: To demonstrate bioequivalence between the test and reference formulations based on pharmacokinetic parameters (Cmax, AUCt, AUCinf).

Population: 28 healthy adult male volunteers; age range 18–45 years.

Regulatory Status: Approved by Ministry of Health; started in Q1, 2025.
Status-Ongoing

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Challenges Observed During BE Study

Recruitment and Volunteer Barriers:

- Difficulty finding healthy male volunteers who are non-smokers for at least three months.
- Volunteers must have moderate alcohol use and no history of drug use and no concomitant medication use.
- Majority of available volunteers present with higher BMI, affecting eligibility and study enrollment timelines.

Operational Challenges:

- Long clinical stays (up to 9 days) led to logistical demands for volunteer management, comfort, and engagement.
- General population hesitancy and cultural mistrust toward participation in clinical research limited the eligible volunteer pool.

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Operational Challenges and Achievements during BE Study

Pharmacokinetic (PK) Sampling Complexity

- Intensive blood sampling schedules, requiring multiple samples in short intervals, demanded careful logistical planning and precise clinical execution.
- Exact timing of PK draws was essential to avoid deviations impacting primary parameters such as Cmax and AUC.

Dietary Restrictions

- Volunteers were required to strictly adhere to fasting and meal schedules.
- Even minor deviations from dietary protocols could have altered drug absorption and compromised PK data validity.

Washout Period Management

- Full compliance during washout periods was necessary to prevent drug carry-over effects between study periods.
- Continuous medical monitoring was implemented to safeguard volunteer health and maintain study integrity.

✅ **Despite these complexities, through scheduling, rigorous staff training, and strict adherence to protocols, the study was conducted successfully, achieving all critical PK sampling timepoints without major deviations.**

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Achievements and Lessons Learned

Study Success

Recruitment completed according to projected timelines.

No major protocol deviations related to IP administration or sample collection.

Implementation of a **volunteer engagement** strategy significantly improved retention and cooperation.

Strengthened collaboration between site, study nurses, laboratory technicians for timely sample processing.

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Experience With Different Therapeutic Areas

Current

- Urinary Tract System

Upcoming

- Cardiology
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
- Antibiotics
- Direct Oral Anticoagulants (DOACs)

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Opportunities for Conducting Clinical Trials in Armenia

Clinics available for clinical trials (not overloaded with other trials)

New population (less exposed to previous studies)

Short timelines for obtaining trial approval

Competitive pricing compared to Europe and the USA

Qualified medical personnel, pharmacists, and data analysts

Fluency in English and Russian **languages**

Opportunity to position Armenia as a regional hub for bioequivalence, vaccines, oncology, and rare diseases research.

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Future Vision for Clinical Research in Armenia

Building a national volunteer database, increasing public awareness campaigns about clinical research benefits, and establishing long-term partnerships with community healthcare providers.

Developing comprehensive investigator and clinical staff training programs, including GCP refreshers, pharmacovigilance practices, and protocol-specific workshops.

Encouraging collaborations between academic institutions, government, and private clinical research organizations to boost innovation and investment.

Promoting Armenia internationally as a destination for cost-effective, high-quality clinical trials, particularly in the fields of oncology, rare diseases, vaccines, and bioequivalence studies.

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Thank you!

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