

# 10 Reasons to Choose Romania for Clinical Trials

Inspired by the first 'perfect 10' of Nadia Comăneci — a story of precision, rigor and world-class performance. Today, Romania brings that same discipline to clinical research: a central European hub delivering high-quality data, fast approvals and a skilled medical workforce for global sponsors.



PERFECT SCORE

CHOOSE ROMANIA • CHOOSE THE PERFECT 10

## ROMANIA AT A GLANCE • CLINICAL TRIALS

**21.64 M**

POPULATION  
source: INS

**1,795**

TRIALS INITIATED 2020–2025  
WHO Global Observatory on Health R&D

**843**

ON-GOING CLINICAL TRIALS  
EU Clinical Trials Map, May 2026

**438**

ACTIVE SITES  
EU Clinical Trials Map, May 2026

**€45–50 M**

MARKET SIZE  
IQVIA, estimate 2022

**60 days**

GUARANTEED APPROVAL TIMELINE  
ANMDMR • EU CTR 536/2014

## Current clinical research landscape in Romania

Romania is a **key, centrally located European hub for clinical research**, offering access to a large pool of patients, skilled medical professionals, specialized medical services, a supportive regulatory environment and high-quality data. The country is an important player in Central & Eastern Europe for both local and international clinical trial sponsors.

The number of clinical trials and participating patients has increased significantly in the last years, with a goal assumed by Romanian health authorities to **triple the market size in the coming years**. Romania's regulatory process is harmonized with European Union standards, ensuring streamlined approvals for studies from Phase 1 to Phase 4.

The clinical trial market in Romania was estimated at €45–50 million in 2022, contributing over **€12 million annually** to the state budget through VAT, taxes and fees generated by the workforce of the industry.

## KEY ADVANTAGES

# 10 reasons Romania delivers a perfect score

### 01. Supportive regulatory environment

- EU member state applying **EU CTR 536/2014** and CTIS for approval & management of clinical trials.
- National Strategic Plan for Clinical Trials (2024), coordinated by ANMDMR with the Health Innovation Hub.
- 60-day guaranteed approval** timeline from ANMDMR, aligned with EU standards.

### 02. Regulator committed to digitalization

- ANMDMR streamlined process — **tripling the number of trials**, from 293 (2020) to 843 (CTIS, May 2026).
- In 2025, the first National Platform for Clinical Trials was launched, linked to EU CTIS data.
- Real-time data, detailed search and patient educational materials at **studiiclinice.anm.ro**.

### 03. Broad stakeholder coalition

- Clinical trials named a **national healthcare priority** by all relevant stakeholders.
- Health Innovation Hub (2023): Ministry of Health + G6-University Alliance + LAWG, joined by ACCSCR, SNOMR, investigators, patient organizations and **international pharma producers**.
- 2025 Memorandum on a national vision for life-sciences, aligned with EU "Choose Europe for Life Sciences".

### 04. Accessible patient pool

- 6<sup>th</sup> most populous EU member state**, population of 21.64 million inhabitants.
- High incidence in priority therapeutic areas: oncology, cardiovascular, neurology, rare diseases.
- Quick access to patients with diversity of **genetics, pathologies and demography**.

### 05. Excellent healthcare professionals

- Skilled medical workforce, experienced clinicians trained in **Good Clinical Practice (GCP)**.
- 6 leading Medical & Pharmacy Universities forming the **G6-UMF Alliance**, with a common framework for cooperation.
- First **Post-graduate Master's Program in Clinical Trials** launched in Bucharest (2024).

### 06. Committed pharmaceutical industry

- Regional hub for the innovative industry, supported by two industry associations: **LAWG** (PhRMA affiliation) and **ARPIIM** (EFPIA affiliation).
- International sponsors increasingly choose Romania for **cost-efficient, high-quality trial execution**.
- Major pharma companies pledging to boost local clinical-trial infrastructure.

### 07. Advanced national infrastructure

- 120+ hospitals** and medical centers actively involved in trials, including university centers.
- 400+ sites** nationwide, concentrated in 6 university cities.
- Accredited labs, modern diagnostics, Early Phase units and CAR-T centers (Fundeni, Iași).

### 08. Competitive operational costs

- More cost-effective than many Western European peers, without compromising quality.
- High-quality data and results **recognized by the FDA and EMA** and by sponsors.
- Optimal mix: cost efficiency + rigorous execution.

### 09. Digital innovation in research

- Technology-driven optimization of trial design and execution.
- Electronic health records, faster data collection and processing.
- Enhanced **safety monitoring** and data quality controls.

### 10. Patient organizations involvement

- Growing awareness about clinical trials driven by patient organizations.
- Active partners: **COPAC** (chronic conditions) and **APAA** (autoimmune diseases).
- Patient voice integrated in the national strategy and education programs.

## WHY NOW

# Why choose Romania compared to other European states, right now

<p><b>01</b></p> <p>Full alignment with the <b>EU CTR</b> and CTIS, combined with a clearly accelerated national trajectory.</p>	<p><b>02</b></p> <p>Dedicated <b>National Strategic Plan for Clinical Trials</b>.</p>	<p><b>03</b></p> <p>Predictable <b>60-day regulatory timeline</b> at ANMDMR.</p>	<p><b>04</b></p> <p>Newly launched <b>national online clinical trials platform</b> connected to CTIS.</p>	<p><b>05</b></p> <p>Active <b>multi-stakeholder Memorandum</b> supporting a long-term life-sciences vision.</p>
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Together, these developments translate into **faster start-up, reliable oversight, strong patient access and high-quality data** — with the added advantage of competitive operating costs for clinical research in the country.

## How we measure progress

Achieving excellence requires measurable progress. Romania is committed to advance on every pillar — each one contributes to a system where innovation is accelerated and access to future treatments is expanded. Romania sees clinical trials as a critical component of R&D in the life sciences.

Shorter approval timelines	Higher trial participation	Enhanced data quality	Stronger collaboration	Better patient engagement
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*Excellence in clinical research isn't achieved by chance — it is built through shared responsibility. Our collective mission: achieving the 'Perfect 10' for patients, science, and the future of medicine.*

The implementation of a competitive model for clinical trials in Romania — by continuing and consolidating the efforts already made — connects Romania to international medical research, increases patients' access to innovative treatments, attracts foreign investment, contributes to the retention of medical personnel and technology transfer, creates new jobs and increases revenues to the state budget.

## A SHARED MISSION

# Choose Romania for Clinical Trials. Choose the 'Perfect 10'.

Developed with the support of the **Local American Working Group (LAWG)** — the organization of leading American and international research-based pharmaceutical and biotechnology companies present in Romania. *May 2026.*