

CRO Δ TURK



Your Strategic Clinical Partner in Turkey

Bridging Europe to High-Speed Recruitment & Cost Efficiency



Sözleşmeli
Araştırma
Kuruluşları
Derneği

DIA

Turkey is the New Global Powerhouse in Clinical Research

+69%

Growth in Investment Volume

Total investment volume exceeded **17 Billion TL (\$520M+)**. This represents massive momentum in industry-sponsored trials.

Context: This isn't just growth; it's a statement of stability and capability in the global arena.



The Vision: Targeting the Global Top 10 by 2027

Current Status:

- Ranked 10th in Europe for clinical trial volume.
- Ranked 21st Globally.



The Trajectory:

Turkey is rapidly climbing the ladder in industry-sponsored clinical trials, with a strategic goal to **enter the worldwide Top 10 within two years.**

Context: This isn't just growth; it's a statement of stability and capability in the global arena.



645+

**Active Industry-
Sponsored Studies**

Infrastructure

Extensive network of City Hospitals and Centers of Excellence.

Access

A large, diverse, and naive patient population ensuring rapid recruitment rates that consistently outperform Western EU sites.

Speed

Fast approval processes driven by updated TITCK (Ministry of Health) regulations.

Not Just a CRO, Your Local Extension



Strategic Bridge

Acting as a local anchor for global sponsors.



Ankara-Based

Established in the capital for close proximity to the Ministry of Health (TITCK).



European Standards

Proud member of EUCROF, ensuring full alignment with EU directives and ICH-GCP standards.

Operating nationwide with **home-based CRAs** covering **all major Turkish medical hubs**.

A Portfolio Driven by Complexity, Not Just Volume

Delivering excellence from Pre-Clinical to Post-Market in ~100 Projects.

100%



Regulatory Success

Zero rejections from TITCK
and Ethics Committees.

35%



Phase III Studies

Proven capacity for complex
global trials (Oncology, Rare
Diseases).

37



MedTech & IVD Studies

Dominant position in MDR &
IVDR regulatory compliance.

The Zero-Gap Strategy: Eliminating Dead Time



Turkey follows a **Sequential Submission Pathway**. We treat preparation as a unified effort to ensure no time is lost between steps.

Our Speed Guarantee: The 72-Hour Sprint

5 DAYS

Ethics Committee Standard

Upon receipt of signed documents, we guarantee submission to the EC within 5 business days.



72 HOURS

Ministry of Health Sprint

Since the MoH dossier is prepared proactively during the EC review, we guarantee submission to TITCK within 72 hours of receiving EC approval.



The ball never stays in our court. Administrative delays are eliminated entirely.

Parallel Commercial Negotiations

Regulatory submissions are sequential; commercial negotiations are not.

Regulatory Review Process (Sequential)



- We initiate budget and contract negotiations with the hospital's Revolving Fund (Döner Sermaye) simultaneously with the Ethics Committee submission.
- Goal: Contracts ready for signature upon Ministry approval, ensuring the fastest possible First Patient In (FPI).

Specialized Competence: MDR & IVDR Compliance



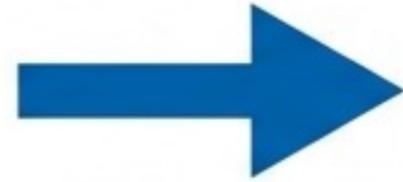
Navigating European Medical Device Regulation (MDR) requires specific expertise distinct from Pharma.

- **Clinical Evidence**: Generating high-quality data for CE marking and Notified Body audits.
- **Post-Market Surveillance**: Managing PMCF (Post-Market Clinical Follow-up) and Clinical Evaluation Reports.
- **Device-Centric Design**: Protocols designed under ISO 14155 standards for interventional, diagnostic, and wearable technologies.

Validating Innovation for Global Markets



Local Startups
(TÜSEB)



CROTURK

Clinical Validation
Bridge



Global Licensing
& Notified Bodies

The Challenge: The biggest bottleneck for local innovations is **Clinical Validation**.

The Solution: We provide the **Clinical Evidence** needed for global licensing.

Strategic Role: We **act as a lever** for Turkish biotech, ensuring data produced locally is **accepted globally**.

The Corporate Imperative: Why Legal Representation Matters



- **The Law:** Sponsors without a registered entity in Turkey must appoint a **Legal Representative**.
- **The Requirement:** The **Legal Representative** assumes liability for the trial's conduct before the Ministry of Health.
- **The CROTURK Solution:** We act as your **Legal Representative**, managing official correspondence, liability, and ensuring your corporate interests are protected under Turkish Law.

Mitigating Compliance Risks

Risk: Freelance/Sole-Trader

Safety: Corporate CRO (CROTURK)

Authority & Validation

Lack legal standing for official authorizations.



Authority & Validation

Authorized corporate stamps and signatures (*imza sirküleri*).



Audit Readiness

Lack verified infrastructure.



Audit Readiness

Established SOPs and QA systems ready for audit.



The Regulatory Umbrella Model

Already have a preferred freelancer? You don't have to give them up.



- **Regulatory Housing:** **CROTURK** acts as the Legal Representative/Liability Holder.
- **Execution:** Your trusted freelancer executes the field work.
- **Oversight:** We provide QA oversight and payroll solutions, converting your consultant into a compliant, insured part of the local team.

Built on Cumulative Leadership Experience



Merter Ortac – General Manager

**20+ Years Cumulative
Leadership Experience**



Corporate Memory: The company DNA is built on the knowledge of hundreds of multi-center global trials.



Rescue Study Expertise: A specific reflex for solving crises. We specialize in taking over stalled or blocked projects and turning them around through proactive risk management.

The Sponsor's Launch Checklist



Appoint a Corporate Legal Representative

Ensure the partner is a legal entity, not just a freelancer.



Verify Entity Type

Confirm Full-Service CRO (capable of liability) vs. SMO (site support only).



Audit Oversight

If using freelancers, ensure they are covered by a corporate QA structure.



Demand Speed

Require a 72-Hour MoH Submission commitment to eliminate sequential gaps.



Don't Let Regulatory Complexity Slow Down Your Innovation.

Partner with CROTURK for a **compliant, transparent,**
and **efficient** study start-up.

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**2026 is set to be the Golden Era for clinical trials in the region.
Are you part of this ecosystem?**