

# Recent Changes in Clinical Trials Regulation in Turkey is Shortening the Start-up Period of Clinical Trials...

The standards of conducting clinical trials in Turkey have dramatically improved in recent years. With the publication of clinical trial-specific law numbered 6225 on 26 April 2011, a **new era** has begun for clinical research in Turkey. Since then, many attempts have been made to enhance the adaptation to international standards. The latest legislation published on 13 April 2013 regarding “**Clinical Trials in Turkey**”, brought international standards to clinical research management and also other areas in relation to clinical research, such as warehouse management.

## Why Choose Turkey for Global Clinical Trials?

Before starting a new clinical research trial, the main concern is the country’s capability of conducting that specific clinical research trial, to a high quality standard and in a timely manner. Countries that have well-established set-up and understanding of global clinical trial management are the ones that the pharmaceutical companies would like to enroll first.

Another important concern is whether the country has enough patient potential to reach the patient target. In particular, niche diseases are the main areas of interest, and there may not be enough patients in well-developed countries in such a clinical research area.

**What Turkey offers to interested parties** is a developing clinical research profile supported by new regulations in clinical research in accordance with international standards. Patient diversity and high population are the second strongest tools that the country has. As a cultural crossroads with a population of 75 million, having 62 university hospitals, 489 private hospitals and 843 government hospitals (TUIK (Turkish Statistics Agency) Hospital Number Report, June 2012), Turkey has high potential, which could lead to it becoming one of the foremost countries in the clinical research area.

## What has Changed Recently, and How does this Affect the Start-up Speed of Clinical Trials?

Before the new regulation was published in April 2013, a clinical trial application (CTA) file would be submitted to the coordinator site’s ethics committee (EC), and after approval was obtained, another clinical trial application file was sent to the regulatory authority with the approval of the coordinator site’s ethics committee.

The recent regulation allows **parallel submission** to the competent authority (CA) and ethics committee.

Approval periods are shortened to **15 days** after the first CTA application for ECs and **30 days** after the

application to the competent authority. Additionally, the necessity for the approval of the coordinator site’s ethics committee is changed into any available ethics committee’s approval. This process is intended to decrease the workload of the major ethics committees in order to allow them to evaluate the submissions **in a timely manner**. The operating standards of the ECs are regulated by the authority, therefore standardisation is also ensured this way.

## Establishing Clinical Research Contracts Consumes Valuable Time at Start-up. How does Turkey Manage the Process?

All approvals are obtained, sites and staff are ready to go, but an obstacle rises up - “contracting!” Contracts with applicable parties block the way to conduct the study most of the time. Sometimes it even causes the recruitment period in clinical research trials to be missed, and all the efforts suddenly go away.

Contracting procedures differ from country to country or even from institution to institution. Different contracting methods are applicable globally.

If we are to investigate how Turkey operates regarding the contracts and go over the key points to shorten the contracting period, we could briefly state the points below:

- In Turkey, the general aim is to sign a **tripartite contract** involving the sponsor, investigator and institution. No other individual contract is needed for other team members to proceed.
- **The latest news is:** A new regulation is being studied regarding the possibility of conducting clinical research trials in private hospitals. This regulation is planned to be in force by the end of 2013.
- For a clinical trial application, a signed contract is not essential, only a draft contract is submitted to the EC and CA. At this point, **the applicant party could start contract negotiations in a reasonable time before study approval, which would prevent the applicant from missing valuable time before study initiation.**
- Clinical research payments, including honoraria, should only be paid to the revolving fund of the institution where the investigator is employed.

## Contract Structure and Language may also Cause Unwanted Problems during the Study...

Most clinical trials last for several years. Therefore, building up a contract that keeps its validity with a strong

structure and adequate language throughout the trial is essential. The key points that should be checked can be summarised as follows:

- Investigator and institution responsibilities and demands should be clearly stated in the contract.
- If the payment is going to be performed in a currency other than local currency, a valid phrase should be inserted into the contract such as “payment will be made using up-to-date exchange rates”.
- In order to prevent further misunderstandings, all the details of the services that are requested from the hospital should be clearly documented. And if the price of the services are listed, a phrase should be added which reflects the fact that the payments will be updated as agreed by both parties.
- Most of the time, the exact number of tests to be performed cannot be defined, as some procedures are only required to be performed under certain circumstances. This case should be discussed between the responsible parties and the contract should be structured accordingly.
- If additional services are to be provided by another vendor, an additional contract needs to be signed with this vendor as well. This additional item should also be clearly identified in the study budget.
- In some cases, local requests may apply, such as compensation to the institution regarding the clinical study staff time, budget development and negotiation fee, site staff training and collection/submission of the regulatory and ethical committee documentation. Study sponsors may not accept these payments since the amount to be paid for the study is defined as a per-patient fee, and all study payments are considered within this budget.

In summary, the regulatory environment in Turkey is becoming well-structured compared to previous years. Besides becoming a major player in the clinical research area, Turkey’s current political approach is also to take a critical role in technology innovation projects. This approach is also emphasised in the Turkish Industry Technology Document for 2011-2014, during which period R&D expenditure increased from 1% to 3%, as approved and published by the Turkish Ministry of Science, Industry and Technology.

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**Sule Mene,**  
MD, CEO, Mene Research  
Email: [sule@meneresearch.com](mailto:sule@meneresearch.com)

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**Tuna Gormez, BE**  
Senior CRA at Mene Research  
E-mail: [tuna@meneresearch.com](mailto:tuna@meneresearch.com)

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**Asli Kaya, M.Sc.**  
Head of Regulatory Affairs at Mene Research  
E-mail: [asli@meneresearch.com](mailto:asli@meneresearch.com)

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**Burcu Cehreli, MBA, M.Sc.**  
Head of Clinical Operations  
E-mail: [burcu@meneresearch.com](mailto:burcu@meneresearch.com)

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