

## Conducting Clinical Studies in Egypt



At the heart of the Middle East, Egypt over the past decade has become a major player when it comes to clinical research, being an Arab, African and Mediterranean country with a population approaching 90 million people. The most populous country in the Middle East has – at the time of writing this article – 360 ongoing clinical trials as per [clinicaltrials.gov](http://clinicaltrials.gov), many of which are global multicentre sponsored clinical trials.

Clinical studies in Egypt are regulated by the Central Directorate for Research and Health Development operating under the Training and Research Sector of the Egyptian Ministry of Health and Population (MOH). The directorate approves clinical studies based on ministerial decrees issued in 2005 regulating clinical studies through a scientific and ethical committee known as the Research Ethics Committee (REC), which operates in accordance with good clinical practice (GCP), Declaration of Helsinki and World Health Organization (WHO) guidelines. The committee is also registered under the Office of Human Research Subjects Protection (OHRP) Federalwide Assurance (FWA).

Approving clinical trials is a lengthy but a straightforward process. This is because the approval process is sequential, meaning that approval of the department comes first, followed by the local ethics committee approval and finally MOH approval, and each approval serves as a prerequisite for proceeding with the next approval. Few restrictions apply to clinical research from the MOH, such as restricting interventional clinical trials to governmental hospitals only. Further security approvals are usually required when there is exportation of biological samples involved.

Egypt is the home of many historically reputable medical institutions, such as Ain Shams University Faculty of Medicine, which is considered one of the largest educational medical schools in Africa and the Middle East; Kasr Alaini Medical School of Cairo University, which is ranked among the highest in Egypt and in Africa; Faculty of Medicine in Mansoura University; and Al-Azhar University and Zagazig University, which are study destinations for many foreign students, particularly from Malaysia and Indonesia.

Despite the World Health Organization's Global Health Workforce Statistics in 2010 indicating that Egypt had a rate of 2.8 physicians per 1000 people – which is a high value compared to 2.4 in the US, 2.7 in the UK and 3.4 in France – yet the healthcare system faces challenges related to lack of resources, and a growing burden of diseases such as HCV, which affects one in five Egyptians, and makes access to and affordability of treatment an issue for most Egyptians.

Clinical research helped in exchanging benefits between pharmaceutical companies and the healthcare system. Ancillary benefits of clinical trials (especially in Phase III studies), such as free access to medication, diagnostic tools, and closer follow-up with their treating physicians, have given patients opportunities that they might not have been entitled to receive otherwise. In addition, it has trained the investigators on aspects of clinical research and has updated them on the latest breakthroughs, allowing them to experiment and take part in the development and advancement of medication. On the other hand, Egypt usually contributes significantly to the global recruitment figures when it comes to disease areas such as diabetology, hepatology, and haematology.

The abundant patient pool and the expertise of the healthcare professionals have attracted pharmaceutical companies into investing more and more in clinical research in Egypt, and have resulted in a boom in the number of CROs and the number of CRO staff in Egypt, thus introducing more patients, physicians, and pharmacists to clinical research. For example, Alexandria University has developed a unique Clinical Research Center (CRC) that serves as a hub for all clinical trials taking place in Alexandria, the second largest Egyptian city. It has been constructed to be dedicated to clinical research with well-trained coordinators, archiving facilities, and even a local lab which has been developed with the assistance of University of Maryland under the twin cities agreement between Alexandria and Baltimore cities. The centre created a good example for all other Egyptian sites, and efforts to create similar centres have already been adopted by other universities. Recently, MOH has also started mandating local and multinational companies to provide clinical data from studies conducted in Egypt, further contributing to this boom.

In conclusion, the role of Egypt in clinical research is becoming more and more significant, and the amount of research activity is booming to overcome the economic and bureaucratic challenges to serve the drug development, the healthcare system and – most importantly – the patients.



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