Hamdi Akan â?? Head of the Executive Board, Clinical Research Association, Turkey

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Dr Hamdi Akan, head of Turkeyâ??s Clinical Research Association, dives into the countryâ??s opportunities and barriers to become a clinical trials hub, including the world-class infrastructure and the need for a revision of the good clinical practice guidelines. Moreover, he explains why TITCK becoming an International Council for Harmonisation (ICH) regulatory member has given the country a seat at the table.

Can you begin by introducing your career and involvement with clinical research?

My first exposure to clinical trials was in the 1990s following drug trials I was conducting on behalf of Pfizer as a professor in the Ankara University Department of Hematology. When I retired from the university, I was the head of the clinical research unit in our department, one of the biggest in Turkey, leading national and international trials in haematology. For many years I have worked in the working parties of the European Bone Marrow Transplant Registry (EBMT), and scientific committees and educational board of the European Hematology Association (EHA) and European Organisation for Research and Treatment of Cancer (EORTC). These experiences led to the realisation that these connections stimulated us to carry out critical trials in our country and, in conjunction with numerous audits, helped us develop our centres.

During my role as head of the Ethical Committee at Ankara Universityâ??s medical school, I noticed there was a lack of communication between the stakeholders and the parties involved in clinical trials. Therefore, the aim of the association we built was to share and educate as many stakeholders and parties as possible about clinical trials.

The website that was launched for our association in 2006 helped communicate news, information and educational activities about clinical trials to local or international news outlets in both Turkish and English. This generated significant interest in clinical trials and increased face to face and virtual contact and communication, leading us to create four national clinical research congresses in Turkey in the last 8 years.

However, there was a general lack of education surrounding clinical trials including the specific terminology and the content of the phases. This pushed us to create a website where online educational courses on clinical trials are found. Recently, we had a course on adaptive clinical trials and on clinical trials in medical devices where the rules have been adapted to correspond to those of the European Union.

What is the status of clinical research in Turkey, what type of trials is the association supporting?

Turkey predominantly conducts phase II and phase III trials because for late-phase clinical trials, accreditation of the centres from the Turkish Medicines and Medical Devices Agency (TITCK) are not required as they are with phase I clinical trials. However, the focus for the future will be establishing a portfolio of new clinical phase I centres, such as phase I oncology centres, due to the ease of development.

National clinical trials are particularly difficult to accomplish due to the prohibitive cost. For example, academic clinical trials for a new drug can cost more than USD 1 billion. Therefore, these must be sponsored predominantly by pharmaceutical companies or international research organisations such as EORTC, NIH, Horizon Europe of EU.

Do you believe there will be more clinical trials in Turkey in the near future?

The prerequisite for more clinical trials is a need for a revision in good clinical practice guidelines. Currently, the wording of some of the guidelines, published initially in 1993 and updated regularly, does not allow for this. The Social Security System wants the company to sponsor everything in a clinical trial and due to this statement in the guidelines, it forces the companies to pay for everything in trials in Turkey. This is a deterrent for pharmaceutical businesses compared to Europe, where companies are not required to pay for routine medical tests and routine treatments.

How significant is it that Turkey became a full member of the International Conference on Harmonisation (ICH)?

The focus of this membership is trying to align ourselves with the European Union. As a result, we have learned a lot through the process of adapting our laws and guidelines for clinical trials to be in harmony with the European regulations. This led our clinical trials to become one of the best-organised processes in Turkey in conformity with the European Union, both in terms of law and

knowledge. Additionally, as a member of an international regulatory system such as ICH, it is not possible to operate outside the terms of constraints. This is a positive move forward that keeps our practices parallel with international regulations. Furthermore, if ICH builds a new guideline, this is accomplished through consultation with its members and not as a snap decision.

From a regulatory standpoint, what are the main barriers preventing a bigger proliferation of clinical trials in Turkey?

Changing regulations or laws in Turkey is difficult and takes time. For example, Turkeyâ??s regulations are not flexible for types of trials such as adaptive clinical trials. These designs are used increasingly for haematology, oncology and other clinical trials as well as vaccines. Therefore, educational committees, ethical committees and researchers need to organise themselves and the information to present to the authorities for further changes in this field.

Beyond the setup, clinical trials increasingly require transparency. We register our clinical trials online for everybody to see, with all stakeholders desiring the data to be published in a transparent manner in a short amount of time. Furthermore, a report we are currently conducting is an analysis of the state of clinical research in the country to then deliver key policy recommendations.

How realistic is it to leverage the huge amount of patient data available in Turkey to create a central patient database?

There are two main problems with creating a central patient database. Firstly, the security issue since databases stored on the cloud needs to be resistant to hackers. The second is a personal identification that is reserved and anonymised. This is the protected deportation of personal identity however it has some limitations in the law. If the security issues can be solved, while developing a database that hides personal identities, this system would be able to use real-world evidence from patients and save a lot of money.

How well prepared is Turkeyâ??s medical infrastructure to continue attracting large scale clinical trials?

The medical infrastructure in Turkey is substantial with many large hospitals. However, for clinical trials, we need more dedicated places to conduct clinical trials, an institutional centralised site coordinator centre, and a formal definition for clinical research nurses and site coordinators. Consequently, the aim is to improve the capacity for clinical trials in these spaces, as well as develop official training programs for everyone involved in clinical trials and record and publicise clinical trials in a database. The Turkish authority, the Turkish Medicines and Medical Devices Agency, successfully developed a specific database open to the public to overcome this task. As a result, although there are some constraints, Turkey has a well-developed intellectual capacity, manpower and infrastructure.

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