Clinical Research in Lebanon: An Introductory Note

Marina El Hajj, MD, MBA
Healthcare Management Consultant

The idea of the special report on clinical research in Lebanon in this issue of "Human and Health" stemmed from the increase in the clinical research activities that we have witnessed over the last years in Lebanon. I recall, not long ago, we had discussed the possibility of having the Institutional Review Board (IRB) at a major academic institution in Beirut, provide services to other hospitals where such a Committee was inexistent. Today, we are beyond this, since most of those centers already have their IRB. Furthermore, the Committee in the former institution is overwhelmed with its own requests and projects. There is a definite increase in the number of research projects in Lebanon, though we are still far from the numbers in the US or in some EU countries.

Parallel to the surge in the research activities, there is an interest from the Ministry of Public Health in Lebanon to regulate this field, and provide oversight at the national level. The World Health Organization is actively involved in the establishment of a Lebanese registry for clinical trials. The clinical research ecosystem, which involves a complex network of academic research institutions, pharmaceutical companies, legal and regulatory framework is witnessing important changes. These will be detailed in the following pages of this issue of "Human and Health".

The times when the volunteers for clinical studies were rare and the patients apprehensive of joining clinical trials seem to be over, to a large extent. Nowadays, the patients and volunteers' rights are established and well defined. Furthermore, when the proper resources are provided, the benefits of clinical research in achieving great progress in the prevention, treatment and cure of diseases are widely recognized. Today's therapies were yesterday's clinical research and by conducting studies today, there is hope in improving the future health indicators.

There are still and there will always be multiple challenges in conducting clinical research in Lebanon, whether in resources, opportunities or regulation. These will also be explored in the articles that follow.

I would like to thank all the authors of the articles about clinical research in Lebanon in the trilingual sections of this magazine. Our aim is to introduce this complex topic to our readers: The review is by no means exhaustive, but it sheds some light on the status of an important field, and the related activities that are behind major advances in health and well-being.

What is Clinical Research?

The National Institutes of Health defines "clinical research" as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Clinical research includes:

- Patient-oriented research – This type of research involves a particular person or group of people, or uses materials from humans. This research can include 1) mechanisms of human disease, 2) therapeutic interventions, 3) clinical trials, and 4) development of new technologies
- Epidemiological and behavioral studies – These types of studies examine the distribution of disease, the factors that affect health, and how people make health-related decisions.
- Outcomes and health services research – These studies seek to identify the most effective and most efficient interventions, treatments, and services.

Clinical Trials

The American University of Beirut defines Clinical Trials as research studies that involve human subjects and which are conducted under conditions controlled by a medical doctor and/or scientist referred to as Principal Investigator (PI). Clinical Trials should be designed, conducted and analyzed according to sound scientific and ethical principles, such as the Helsinki Declaration, to achieve the desired objectives.

Clinical Trials are designed to determine whether new drugs or treatments are safe and effective and/or evaluate a new medical treatment, a drug or a medical device. Their purpose is to find new and improved methods of treating diseases and special conditions. In most cases private companies (referred to as Sponsors), mainly pharmaceutical companies, sponsor such trials.

Clinical Trials are designed either as a "Single Center" or "Multi-Center" trials. In the latter case, the Center becomes one of the sites among other national and/or international sites participating in the conduct of the trial.

Institutional Review Board (IRB):

IRB is an administrative body established to protect the rights, safety and well-being of all human subjects recruited to participate in research activities conducted by members of AUB Faculty, regardless of the funding source. IRB pays special attention to studies that may include vulnerable subjects.

Reference: AUB