

Clinical Research in Lebanon: The Pharmaceutical Industry Perspective



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Earlier this year, there were 206 clinical research studies in Lebanon which were registered at the United States government clinical trials database (www.clinicaltrials.gov). The steady increase in the number of clinical trials in Lebanon during the last decade has been accompanied by a surge in the demand for resources and expertise in the clinical research field. This is good news for patients who are enrolled in clinical studies on new compounds under investigation, and who can access innovative medications that improve their health.

The mission of the biopharmaceutical industry is to discover, develop, manufacture and market innovative medicines that make a difference for patients. Research and Development (R&D) is at the origin of the benefits brought to patients, and more generally to disease prevention and healthcare. Indeed, the pharmaceutical industry has a major role in the longevity of people around the world, as well as in their quality of life. Millions of “death sentences” were lifted with the fatal illnesses that became curable or treated as chronic diseases. Nevertheless and despite the amazing progress over the past 50 years, there remains a

lot to be done: The increase in the incidence of diseases associated with aging – such as cancer, type 2 diabetes, Alzheimer’s disease and osteoporosis to mention a few – demonstrate that the pace of medical progress should be sustained. Today, nearly 3,000 potential drugs are in the development phases in the pharmaceutical industry. We have much more scientific knowledge and data than ever before, and we have the means to translate this science into new therapies.

The escalation in the costs of new drug development is an important challenge faced by the industry. Patent expirations between 2010 and 2014 have resulted in an estimated loss of \$113 billion yearly. Companies are looking for creative approaches in order to accomplish their mission in drug development.

The pharmaceutical industry strives to reduce the lead time until the medications are brought to the patients. In this



regard, the globalization of clinical trials, which has taken place over the last two decades along with the expansion into new geographical areas, has helped significantly. Emerging markets offer a great potential for clinical trials, due to the relatively quick initial phase and the substantial number of patients.

Why is Lebanon a place of choice for clinical trials? The answer lies in the well-defined and bureaucracy-free approval processes, the developed healthcare infrastructure, the expertise of healthcare providers, the relative affordability of healthcare services and the relatively high prevalence of certain chronic diseases. Therefore, Lebanon presents definite advantages compared to the United States, Western Europe and other countries in the region.

The clinical trials in oncology and hematology are the most frequent in Lebanon, followed by infectious diseases, neurology, cardiology and rheumatology. However, in spite of a favorable environment, the global pharmaceutical companies face several challenges in the implementation of clinical trials in accordance with good clinical practices standards and global research guidelines. The choice of the site is critical in order to ensure that all the privacy and ethical requirements for medical research are met. The site (healthcare center) should have a dedicated and trained team for the conduct of clinical trials, including the necessary documentation. Moreover, an effective Ethics

Committee, with clear policies and procedures, should be in place for proper oversight and for the welfare of study participants.

In order to enhance further the development of clinical research in Lebanon, we need a collaborative effort from all the stakeholders involved. Everyone will ultimately benefit from such an undertaking. In the absence of registries for some diseases, the product related information issued from clinical trials, as well as the data from epidemiological studies which is frequently supported by the pharmaceutical companies, can guide healthcare policy decisions.

The reinforcement of Lebanon’s position as a regional hub for clinical research is a shared responsibility.

In order to succeed, we need a coordinated approach that streamlines the efforts of regulators, pharmaceutical companies, clinical research organizations, academicians and professional and advocacy groups. It is essential to avail a stable, transparent, and predictable regulatory framework as well as solid review and control processes; in addition to qualified personnel that operates with the highest clinical practices standards.

By nurturing medical innovation, we will continue the superb progress that transformed human life in the 20th century and add immense value to health, productivity, and life in itself.

Infos

Aluminium: Dangereux pour la Santé ?

L’aluminium a longtemps été considéré comme étant inoffensif pour l’homme en raison de sa très faible absorption intestinale par voie orale. Cependant, en 2000, la cohorte PAQUID révélait un risque de développer une démence ou la maladie d’Alzheimer en cas d’exposition à une eau contenant une certaine concentration d’aluminium. Ce risque serait 2,2 à 2,3 fois supérieur pour les personnes résidant dans des régions où la concentration en aluminium est supérieure à 0,1 mg/L. Or, l’Organisation Mondiale de la Santé (OMS) a fixé la concentration maximale autorisée à 0,2 mg/L d’eau. Cette concentration est

liée à la présence de sulfate d’aluminium, utilisé dans le processus d’assainissement de l’eau afin de la rendre potable. Mais ce n’est pas le seul problème: l’eau n’est pas le seul vecteur d’exposition à l’aluminium. On sait aujourd’hui que l’alimentation en contient, notamment à cause des additifs alimentaires ou des emballages. Les risques d’être exposé à l’aluminium sont donc très importants.