Tunisian Clinical Studies Watch

Tunisia is known for the well-built clinical trials system in its medical, educational and governmental institutions. Many laws and decrees have been enacted to regulate the process of clinical trials, which combine to form a comprehensive environment for fruitful clinical trials.

In Tunisia, there are different structures involved in health research governance; the Ministry of Scientific Research, Technology and Competence Development are in charge of executing government policy in the scientific research sector, as well as technological innovation and development of competence. Besides its direct tutelage on the structures under its control, it also oversees some horizontal assignments which aim to promote research in all sectors.

The Superior Council of Research, chaired by the Prime Minister, consists of representatives of the different ministries involved with research; its role is to give key direction on research in the country. At each ministry, research policy is the responsibility of the Minister, and there is formal governance from the Superior Council.

The Ministry of Public Health has created a directorate (within the General Directorate of Health) which supervises research in the domain of health, whose mission is to promote research in the sector and to assure its follow-up and assessment. The Ministry of Higher Education, through the General Directorate of Scientific Research and Technological Innovation, monitors research conducted in institutions of higher education. The Ministry of Agriculture and Water Resources supervises agricultural research, particularly in the domain of animal health and food security. Tunisia instituted the Comité National d'Ethique Médicale (CNEM) by law on 29 July 1991. Its mandate and the variety of issues for which it is responsible are modeled on the French example, whose wording is sometimes reproduced verbatim.

The Committee comprises a chair and 18 members, each of whom is appointed for a three-year term. The first issue addressed by the Committee was assisted reproduction (Avis No. 1, 1996), followed by aspects of the establishment of local ethics committees and cloning (Avis No. 3, 1997). It is noteworthy to mention that international / multi-centre clinical trials conducted in hospitals and other institutions in Tunisia require the approval of the National Ethics Committee in the Ministry of Public Health, after gaining approval from the local research ethics committee in the specific institution.

Phase II, III and IV clinical studies are performed in Tunisia, with special attention to infectious diseases with epidemic risk, chronic diseases, neonatal mortality and disability oncology, and endocrine. There are nine teaching hospital centers in Tunis; five CHU institutions and one CHU faculty of medicine in Sousse; two CHUs and one faculty of medicine in Monastir – Mahdia; two CHUs and one faculty of medicine in Sfax; two CHUs, one faculty of medicine, thirty-four regional hospitals, one hundred and twenty county hospitals, and sixty-four private hospitals.

Tunisia is known for large-scale collaboration with centers in other countries in clinical trials, including Morocco, Algeria, Jordan, Egypt, Syria, France, Spain, Portugal, Italy, Greece, Turkey, Germany, Norway, the US, Argentina, Japan and India.

The environment in Tunisia is well prepared, in terms of regulations, expertise and resources, for clinical trials. The regulations are clear, easy to follow and well-documented. Clinical research organizations in Tunisia are capable of conducting clinical trials professionally, and the existence of research projects of pharmaceutical companies in North Africa is further evidence that Tunisia is an excellent location for conducting clinical research. ■

Dr. Ranya Shahrouri, MBA/HCM, HDVP, DVM
Regulatory Affairs Manager, ClinArt Fz LLC
Email: Ranya.Shahrouri@ClinArt.net