EDITORIAL
THE DOCUMENT OF THE AMERICAS: GOOD CLINICAL PRACTICES FOR REGULATORY AUTHORITIES

In 1996, when the Guidelines for Good Clinical Practices of the International Conference on Harmonization (ICH) were adopted, they sought to facilitate the actions of regulatory authorities over the different players of clinical research. These guidelines were created and incorporated to the legislation of the three regions of the world (United States, European Union, and Japan) where most of the drugs, vaccines, biologicals, diagnostic tests, and medical devices are produced. The regulatory authorities from those three regions are characterized for their extensive technical capacity to execute their mission of promoting technological advances and protecting communities. However, undertaking this task has been difficult, partially because the ICH Good Clinical Practices defined responsibilities for Ethical Committees, Sponsors, and Investigators; but the regulatory authorities did not precise their own responsibilities or indicate how they would accomplish their duties in that document and, therefore, did not reach the harmonization of their practices in those subjects.

Certainly, this point is one of the major advances offered by the Document of the Americas on Good Clinical Practices: helping the regulatory authorities of the continent to establish a common platform on how to perform their duties regarding clinical research. The possibilities that this common regulatory methodology offers to the authorities from our countries, with greater limitations in budget and in human resources than their ICH counterparts, are promising: it might allow unified staff training, conduction of joint inspections and, even, thinking of a mutual recognition for the actions of the authorities in each country, as occurred in Europe more than three decades ago. However, the promises have not been delivered in the desired extension: despite the March 2005 meeting held in the Dominican Republic, where the Document of the Americas was published, was held in March, 2005, it means almost five years ago, few countries, like Argentina (2007), Brazil (2008), and Colombia (2008) have incorporated this document into their own regulations.

There are interesting experiences such as the Brazilian federal government promotion for the creation of centers to lead clinical research of public health interest in university hospitals, at the same time that the federal regulatory authority implements the new regulation on requirements for clinical research centers. In such experience, the government is not limited to imposing a new standard, but endorses and actively supports universities and the academic community as quality references in research. That allows clinical research to not only become just an additional profitable activity of a few private players, but also builds capacity to solving regional problems. Transferring of such experiences might be easier with the adoption of common platforms within the region.

Having strong regulatory authorities is necessary to move forward from a provider of volunteers, data, and samples for multinational companies to becoming a leader in the solutions for our regional health problems, created from our universities and industries. But the need is even more urgent: the development of innovative products for our health problems created either by multinationals or within the region, requires technically capable interlocutors with close knowledge of the needs of our community.

The Document of the Americas, pioneer initiative of the Pan American Network for Drug Regulatory Harmonization (PANDRH), can be the first step towards a future common regional agency, like the European Medicine Agency (EMEA); a regional agency that would be able to offer technical capacity to the member countries and represent the region in future discussions on research regulation.

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