Dialogue first: Implementation of a phase 1 unit in Argentina under a new regulatory setting

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Background

Implementing an early phase unit in a developing country, poses multiple challenges, particularly within a new regulatory environment.

In Argentina, 90 early phase studies were carried out during the last 10 years. In May 2017 a new legislation was approved regarding phase 1 trials, defining human and physical requirements for sites and an expedite review process at the regulatory level. This led to a reaccreditation process for early phase research centers.

We introduce our university hospital centered strategy as a model that could be replicated in countries facing similar situations.

Methods:

Hospital Italiano de Buenos Aires is a university-affiliated tertiary-care center with 800 beds.

In April 2017 the site personnel along with IRB members attended an early phase workshop coordinated by specialists in Phase I studies and translational medicine. A link was then established in an ongoing basis which enhanced investigator's capabilities and know-how.

In addition the site received an audit performed by the same faculty of the workshop that focused on specific infrastructural requirements for this type of studies.

A number of improvements were underwent in terms of building upgrades, patient monitoring facilities, confidentiality of stored files, standard operating procedures (SOP) implementation and conciliation of institutional SOPs with the national standards, aiming to become ready for the newly required National regulatory Agency's (ANMAT) inspection. In parallel an institutional Healthy Volunteer register was implemented, with IRB approval.

Results:

In August 2017 ANMAT inspected the site, and in November 2017 the site became the first unit approved for phase I studies under this new normative. However, regulatory timelines were longer than expected, reflecting perhaps the hurdles of a learning curve both for researchers and regulators.

Conclusion:

The new regulatory environment provides increasing opportunities for the conduction of early phase studies in our country, while posing new challenges for site establishment and operation. This example of a successful path allowed our site carry on the initial "First in Human" study in Argentina approved under the new regulation. The permanent dialogue between the institutions proved instrumental in obtaining satisfactory results within a learning curve situation.