## MEXICO

Mexico has a population of almost 120 Million people, second largest in LA after Brazil. There are 11 cities with a population of > one Million. Mexico City alone concentrates about 20% of the total population, with almost 22 Million. One third of the Mexican population is below 14 years (30.1%), and only 5.9% is above 65 years.

The Mexican Government has done significant efforts in order to have its population under some option of medical coverage. By 2012, almost half of the population had a form of social security coverage, while the rest uses some type of service provided by the public health care system, or pay for it at a private medical facility.

Currently, Mexico is located as a reference country to conduct clinical trials at worldwide level. According to website www.clinicaltrial.gov (December 2014), Mexico is currently running around 2,240 clinical studies in different therapeutic areas.

The Regulatory Agency, called Mexican Federal Commission for Protection against Sanitary Risks (COFEPRIS), obtained in July 2012 from the Pan American Health Organization (PHO) the recognition as first reference regional regulatory authority in medicines and vaccines matters. This achievement is expected to drive an increase in the investment in R&D for new drugs made in Mexico by the national and international pharmaceutical industry, as well as to improve the process for the registration of new treatments by COFEPRIS, as a consequence of being recognized by the Regulatory Agencies from other Latin American countries.

Regarding the Bioethics review of clinical trials, since 2013 Mexico has official requirements and a clear process to regulate the functioning and integration of the Ethical Review Boards (in Mexico called Committees for Ethics in Research, CEIs). Any CEI must be registered before the Bioethics National Board (CONBIOETICA), as a requirement by COFEPRIS to make sure the CEIs bodies are established according to Mexico´s national legislation and international guidelines to conduct clinical trials. This change in our regulation has improved quality of the CEIs constitution, ensuring a correct ethics and scientific review for patient safety perspective.

In relation with the approval process to approve a clinical trial, COFEPRIS has an official timeline of 90 calendar days to review the dossiers for study authorization. The submission to COFEPRIS requires the previous approval from a CEI.

COFEPRIS announced last March 2014 an initiative involving the National Institutes of Health in Mexico, for them to constitute "Habilitated Units for the Pre-Review of Clinical Trials" (UHAPs)) to pre-approve research protocols, an so reduce the official 90 days response timeline in about 66%. Once the protocols

are pre-approved by the UHAP, COFEPRIS is committed to review and/or approve the protocols in less than 1 month.

In 2010, the CROs in Mexico conformed ACROM (Mexican Contract Research Organizations Alliance), as an strategy to work together as a sector and with other official bodies in Mexican Health System, in order to find solutions to the problems that the Clinical Research in Mexico is facing, and also representing its associates before any kind of organizations, at national and international level.