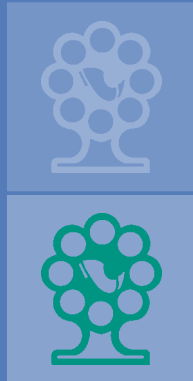


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Opportunities for the Pharmaceutical  
Industry in the Institute of Genomic  
Medicine of Mexico

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Gerardo Jiménez Sánchez  
*Consortium for the Institute of Genomic Medicine,  
Fundacion Mexicana para la Salud & Johns Hopkins University*



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# CUADERNOS FUNSALUD

Número 38

## Opportunities for the Pharmaceutical Industry in the Institute of Genomic Medicine of Mexico

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Gerardo Jiménez Sánchez

*Consortium for the Institute of Genomic Medicine,  
Fundacion Mexicana para la Salud & Johns Hopkins University*



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IN THE INSTITUTE OF GENOMIC MEDICINE OF MEXICO

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## Presentation

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In 1999, doctors Antonio Velázquez and Gerardo Jiménez Sánchez came up with the idea to actively promote genomic medicine in Mexico, given the imminent elucidation of the human genome that would lead to great expectations in the application of knowledge generated by this magnum effort. This initiative led them to seek institutional support at the Mexican Health Foundation (FUNSALUD). Consequently, a group of 16 researchers was formed, with specialists from the National Autonomous University of Mexico and the National Health Institutes. Over the next few months, these researchers participated in several in-depth discussions in order to study the current situation and the feasibility of using the information and knowledge derived from the imminent elucidation of the human genome to benefit the collective health of the Mexican population. The end result of these debates was the elaboration of the following document: *Development of genomic Medicine in Mexico. Center for Genomic Medicine*. This document revealed the situation that prevailed at the threshold of genomic medicine and emphasized the reasons why Mexico should not abstain from participating in the development of genomic medicine.

Since the magnitude of this ambitious project is beyond the scope of any single institution, an alliance between the Health Ministry (SSA), the National Autonomous University of Mexico (UNAM), the Council for Science and Tech-

nology (CONACYT), and FUNSALUD was proposed; this proposal was duly relayed to the heads of each organism at the beginning of the year 2000. On October 3rd, 2000, they all agreed to jointly carry out a feasibility study to create a Center for Genomic Medicine as an vehicle through which to promote research, technological development, formation of specialists, services and, in general, the generation of knowledge regarding the human genome and its benefits.

Consequently, on October 3, 2000 a formal agreement was reached between the National Autonomous University of Mexico (UNAM), the Health Ministry (SSA), the National Council for Science and Technology (CONACYT) and FUNSALUD wherein they resolved to establish a center for genomic medicine and carry out, as a first step, a study of its technical, economic, social and political feasibility.

A technical group with representatives from each of the participating institutions immediately began to work on this feasibility study.<sup>1</sup> The activities were conducted by Guillermo Soberón, who was assigned, by the four institutions, as Executive Coordinator of the project. Renowned scholars, familiar with the topic, were asked to participate and the technical advice of specialized consulting firms was also used to elaborate the study. Throughout its distinct phases, a total of 61 people participated in the project, not only from the Health sector but also from universities and research centers within the country and abroad.

<sup>1</sup> The group included Guillermo Soberón and Gerardo Jiménez Sánchez for FUNSALUD, Juan Pedro Laclette San Román (UNAM), Jaime Martuscelli Quintana (CONACYT) and Roberto Tapia Conyer (SSA), with the participation of Cuauhtémoc Valdés Olmedo as Technical Secretary. When the Federal Administration changed in February of 2001, Alfonso Serrano Pérez Grovas replaced Jaime Martuscelli.

Between October 2000 and August 2001, an informative brochure was published and was abundantly distributed by the institutions themselves and at national and international symposiums on the subject. Moreover, a web page was created ([www.inmegen.org.mx](http://www.inmegen.org.mx)) where general information about the project was made available to the public in general.

On August 27th 2001, the *Feasibility Study for the Establishment and Development of a Center for Genomic Medicine* was delivered to the heads of UNAM, SSA, CONACYT and FUNSALUD. They approved its contents and agreed to continue onto the next stage: the creation of a genomic medicine institute. The feasibility study contains information that supports and confirms the viability of a Mexican Genomic Medicine Institute, using infrastructure currently available in Mexico, such as human resources, institutions, academic programs, connections in the business sector, collaborations with Mexican academic and health institutions, as well as the participation of foreign organisms that support the creation of the Mexican Genomic Medicine Institute (INMEGEN).

On November 22nd 2001, the heads of the four participating institutions signed a new agreement to establish a Promoting Consortium for the Genomic Medicine Institute. Its objective was to promote and carry out executive and detailed studies to establish and develop the Genomic Medicine Institute as well as to promote horizontal connections with any national and international institutions willing to cooperate in the elaboration of research programs, the formation of human resources and the dissemination of information regarding genomic medicine, through the articulation of projects. On that occasion, it was also decided that the future organization should be part of the health sector and should fit the profile of a National Health Institute.

During that same period, Antonio López de Silanes, President of FUNSALUD's Board of Trustees, recommended

the establishment of a FUNSALUD Support Group for INMEGEN, whose activities would be entrusted to Associates with ties to the health care field, such as those in the pharmaceutical industry, insurance companies and any other interested parties, in order to explore ways for the private sector to participate in the development of the Genomic Medicine Institute. At a later date, in order to inform society in general and acquaint academic forums on the subject, an intense dissemination campaign was carried out, including a luncheon-conference, which took place on April 19th 2001, to present the project to the entrepreneurial sector. It was organized by the Industrials Club and FUNSALUD, and both Guillermo Soberón and Gerardo Jiménez Sánchez participated in the event. The next day, a symposium was also held, organized by El Colegio Nacional, the National Academy of Medicine and FUNSALUD, with the participation of Francisco Bolívar, Barton Childs, Gerardo Jiménez Sánchez, Julio Frenk, Guillermo Soberón and David Valle. Moreover, during the elaboration of the study, several other works were produced and published in scientific and other informative magazines.

At the beginning of this year, the Support Group for INMEGEN was acquainted with ways the pharmaceutical industry could participate in the development of the Genomic Medicine Institute. This document now appears in English, in *Cuadernos FUNSALUD*. The Spanish version was published in *Gaceta Médica de México*,<sup>2</sup> the official organ of the National Academy of Medicine.

The publication we are presently submitting is aimed at the non-scientific community and communities abroad, and

<sup>2</sup> Gerardo Jiménez Sánchez, "Opportunities for the pharmaceutical industry in the Genomic Medicine Institute". *Gaceta Médica de México* (138):3, 291-294, May-June, 2002.

contains information about the new opportunities that will be made available now that Mexico is about to acquire a National Institution whose main objective will be the generation of more accessible health interventions for its inhabitants, and the ability to harness the power derived from the new source of knowledge in order to create a more positive impact on health care.

# The Human Genome and Genomic Medicine

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The Human Genome Project has been able to determine the exact sequence of more than 90% of the nearly 3,200 million nucleotides in the human genome, and to developed a map locating the 30,000-40,000 genes contained in it (1, 2).

Analysis of this project has made possible the integral examination of approximately 1,000 genes responsible for monogenic diseases (3), and has identified thousands of the single-nucleotide polymorphisms (SNPs, pronounced “snips”) which confer individuality (4). Genetic individuality includes susceptibility or resistance to develop common diseases, such as diabetes mellitus, asthma, cancer or hypertension, among many other world health problems. These multifactorial traits also include the ability of an individual to respond to drugs, or develop of adverse reactions, which represents a significant burden to the pharmaceutical industry.

The knowledge of human genomic variability and its relationship to disease, led to the concept of genomic medicine, defined as the routine use of genotypic analyses to improve health care (5). This new paradigm in medical practice is based on the ability to identify those SNPs that confer susceptibility or resistance to common diseases before it shows clinical manifestations. From this, it is clear that genomic medicine will result in a more individualized, predictive, and preventive medical practice, allowing physicians

to identify pre-symptomatic individuals, making preventive interventions more effective, delaying or preventing clinical manifestations, complications, and sequels from diseases (6, 7). Moreover, it will make it possible to identify those subjects in which many of the routinely used medications act effectively, and those in which they do not, or even those in whom such medication may lead to a health- or life-threatening situation.

In average SNP occur every 1,000 nucleotides, with a frequency of at least 1% in the general population (8). Combinations resulting from SNPs throughout the human genome give rise to genetic individuality, which bestows both susceptibility and resistance to common diseases, as well as response to drugs. In 1999, APBiotech, AstraZeneca, Aventis, Bayer, Bristol-Myers Squibb, F. Hoffman, La Roche, Glaxo Wellcome, IMB, Motorola, Novartis, Pfizer, Searle, SmithKline Beecham, and The Wellcome Trust established "The SNP Consortium" with the goal of accelerating SNP finding and ensuring public access to those databases. Up to June 2002 this Consortium has identified and made public 1,389,655 SNPs (<http://snp.cshl.org/>) which will speed up the development of genomic medicine.

# Pharmacogenomics

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Pharmacogenomics examines the implications of genomic variability in the individual response to drugs (9) and use this information to customize more individualized drugs as well as to develop new pharmaceutical products. Identification of genomic variability in every individual will lead to development of genomic profiles and anticipate patient response to medications. This novel practice will provide valuable data both on efficacy and safety of a medication in every patient, leading to significant changes in medical practice and positive implications in health economy (10). The development of this discipline will be hastened by the knowledge of the human genome, resulting in new strategies to develop more individualized and effective drugs, with less adverse effects. It is also predicted that the routine use of DNA chips will be integrated to medical practice examining gene variations involved in the metabolism of a number of commonly used pharmaceutical drugs. With this, it will be possible to select the most effective and least toxic medication for every patient. These new strategies foresee significant financial benefits for the pharmaceutical industry as they will build on captive markets, and will identify other populations to target specific efforts. In addition, this new era in medicine will decrease time and costs in phases II and III of clinical trials by the knowledge of genomic features from patients involved (11).

## **Importance of population studies in pharmacogenomics**

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Association studies between variations in human genome and multifactorial traits are the central principle of genomic medicine. Since genome variations are inherited, they concentrate in the different populations. There are geographic patterns of genetic variation in almost all genes analyzed. These include genes encoding enzymes involved in drug metabolism and genes encoding drug targets. Such evidence make it reasonable to predict geographic variation of inter-individual response to medications (12). Recent studies show how association patterns vary significantly between populations. For this, current strategies for association studies are directed to specific populations, more so in “case and control” study designs in which participants share environmental factors, in addition to their geographical area (13).

## **Emerging opportunities to develop pharmacogenomics in Mexico**

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Mexico has a population of unique genomic makeup as a result of its history. As of February 14, 2000, Mexico had a total of 97,483,412 inhabitants, occupying the 11th place among the most populated nations on earth, with an annual population growth rate of nearly 1.58%(14). The vast majority of the Mexican population emerged from a mixture between Meso-American native groups and Spaniards. Among Mexico's population, there are nearly 60 different ethnic groups (15), distributed in almost every state of the Mexican Republic (14).

Thus far, there are no formal studies of genetic polymorphism associated to drug responses in the Mexican population. This and other areas of genomic medicine are considered among the priorities of Health Sector in Mexico, as shown in the National Health Program 2001-2006(16). This commitment of the Mexican government is consistent with the position adopted by the National Commission for the Human Genome in the sense that the human genome from the Mexican population must be studied in Mexico. Political willingness to develop different areas of genomic medicine in Mexico is supported both by a long scientific and medical tradition of excellence in the country, and the interest shown by Mexican and international industries in developing genomic medicine in Mexico. These elements anticipate a solid platform for the successful development of pharmacogenomics in Mexico.

# The Institute of Genomic Medicine of Mexico

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On November 22, 2001, after careful evaluation of the feasibility study elaborated by over 60 investigators, an inter-institutional agreement was signed, with the objective of establishing an Institute of Genomic Medicine (INMEGEN) in Mexico. By means of this document signed by the Health Secretary, the Rector of the National Autonomous University of Mexico (UNAM), the Director General of the National Council for Science and Technology (CONACYT), and the Executive President of the Mexican Health Foundation (FUNSALUD), formal work is initiated for the creation of the INMEGEN ([www.inmegen.org.mx](http://www.inmegen.org.mx)) which will become a National Institute of Health based of the Health Sector. In addition to its own facilities and personnel, the INMEGEN will actively encourage its horizontal association both with national and international institutions capable of carrying out research projects in this area, training new human resources, and contribute to public education in areas related to genomic medicine (17).

The feasibility study for the INMEGEN identified three main strategic areas of development, namely basic, clinical and public health research, along with strong development of extramural projects. INMEGEN is expected to be located on a 20,000 m<sup>2</sup> area, starting off with 10 research laboratories, and high technology core units including DNA synthesis and sequencing facilities, SNPs genotyping, expression

analysis through chips and microarrays, production of knockout and transgenic animals, animal housing room, and a clinical unit. The latter will provide clinical facilities for data collection and development of clinical projects, as well as for short-term stay studies such as pharmacokinetic curves, metabolic assessments, etc. This layout makes evident why the INMEGEN will develop multidisciplinary research projects in genomic medicine. For this, the INMEGEN will recruit specialized personnel in basic and applied medical sciences, social sciences, as well as medical personnel from different clinical specialties.

# Initial areas of opportunity for the pharmaceutical industry at the INMEGEN

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The development plan of the INMEGEN include development of productive relationships with the industrial sector, particularly with the pharmaceutical industry. Several areas of opportunity are foreseen during the development of the INMEGEN. Following are some of them:

*a. Association Studies.* These studies will be aimed to identify haplotypes in Mexican patients, and their association to multifactorial traits such as variation in drug response. The outcomes of these studies will contribute both to the understanding of the Mexican population genome, and to implementing diagnostic systems that can result in a rapid and effective way to identify patients in whom drugs act safety and effectively. This strategy can contribute to identifying captive markets within the Mexican population.

*b. Collaborative projects with pharmaceutical industry headquarters.* Resources available at INMEGEN will provide the appropriate infrastructure to develop collaborative projects with pharmaceutical companies, both at the local and headquarters level. Examples of these projects can include population studies of drug response-related SNPs identified by pharmaceutical companies. Furthermore, INMEGEN will be able to carry out projects related to the molecular response of Mexican patients to specific drugs in different conditions

such as cancer, infections, among others, through the use of DNA microarrays.

*c. Improvement of product safety profile.* Adverse reactions caused by drugs are severe enough to produce clinical complications or permanent changes in quality-of-life and lead to significant financial burdens. INMEGEN will be able to perform projects related to the identification of polymorphisms associated to patients in whom adverse reactions are detected. Such strategies are directed to implementing systems to identify such polymorphisms and thus avoid administration of the drug in question, to at-risk patients.

*d. Validation of new products in the Mexican population.* The INMEGEN clinical research unit will be able to carry out clinical trials for the study of new drugs, in genetically targeted populations, supported by genomic and public health information. Over the next few years pharmaceutical laboratories will be forced to manufacture more customized drugs. The introduction of new drugs to the Mexican market will require validation in a clinical unit capable of genotyping patients in whom these new products would be validated.

*e. Identification of new markets.* It is anticipated that INMEGEN will have a solid horizontal structure leading to permanent collaborations both at the national and international level. Of particular interest will be those programs with Latin American countries where INMEGEN will lay-out genotyping systems allowing identification of haplotype frequencies in those populations.

These projects will result in development of operational academic networks with potential interactions that could lead to new market opportunities for pharmaceutical companies. In addition, interactions between the INMEGEN and research laboratories in Latin America will provide a Spanish-based platform to facilitate collaborative projects with populations from that region of America.

*f. Training programs in Genomic Medicine.* One of the main goals of the INMEGEN is the production of human resources in the different areas of genomic medicine such as comparative, functional and medical genomics, pharmacogenomics, bioinformatics and genomic epidemiology. This will be of benefit to different research organizations in Mexico and abroad. In particular, the Pharmaceutical Industry can benefit from these programs that would provide high quality human resources in this area.

*g. Support to comply with law and regulation.* Development of genomic medicine already estimates that within the next 3 years, legislation will be generated requiring genomic studies prior to administration of specific drugs in order to define its efficacy and toxicity, and prevent adverse reactions in patients taking them. The INMEGEN will be a unique resource to carry out these kind collaborative projects.

*h. A national platform to integrate research on genomic medicine, and its ethical, social and legal areas.* Association with INMEGEN itself will be of great interest for the Pharmaceutical Industry since it will be the national reference center for the development of research in the different areas of genomic medicine for the general population, which will accelerate the implementation of genotypic studies associated with drug metabolism, safety and efficacy. Moreover, the INMEGEN will constitute an ideal platform for research on the ethical, social and legal issues associated to genomic medicine.

*i. Fiscal incentives.* Participation of the Pharmaceutical Industry in the INMEGEN can be stimulated by the new fiscal incentives authorized on November 2001 the Mexican Government for industries investing in scientific research in Mexico.

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