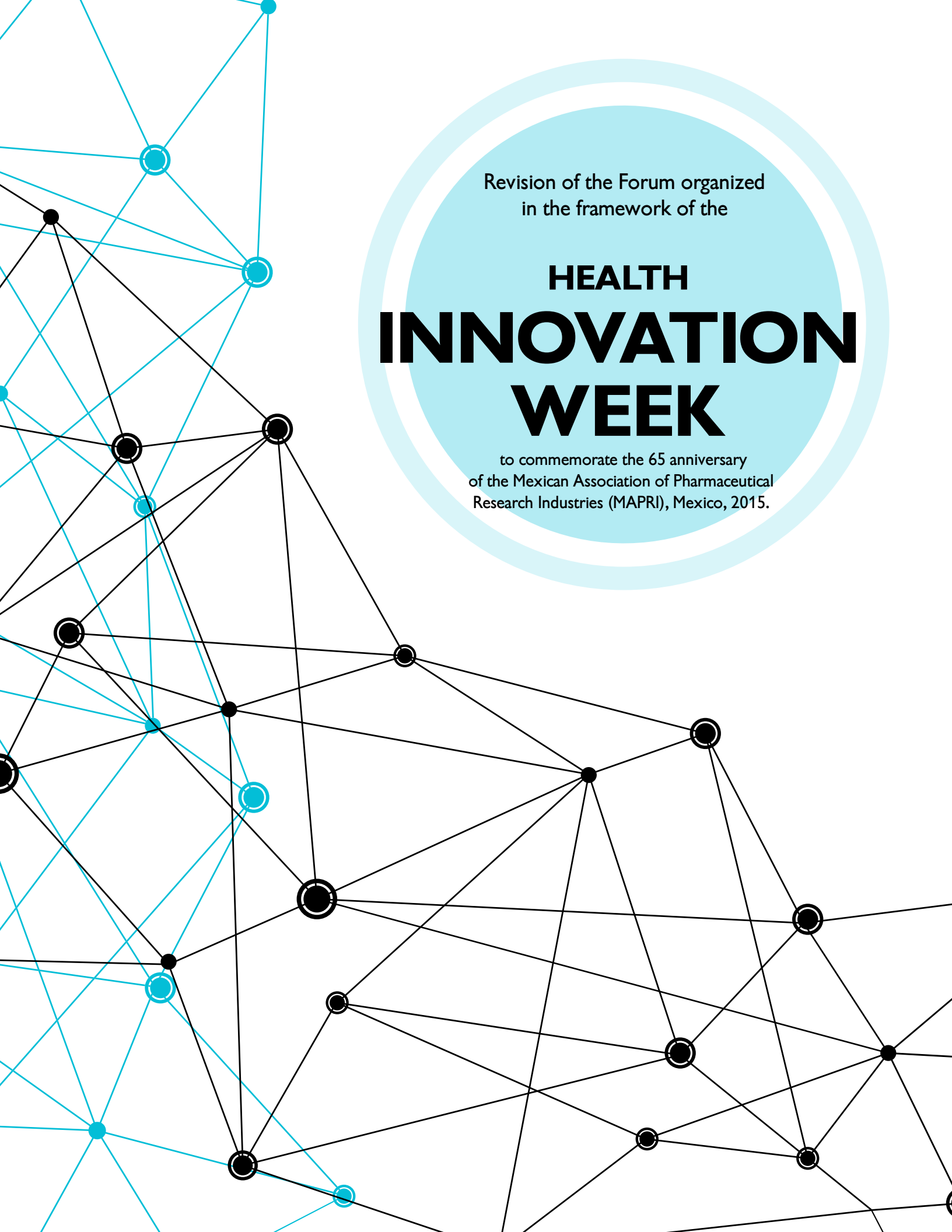
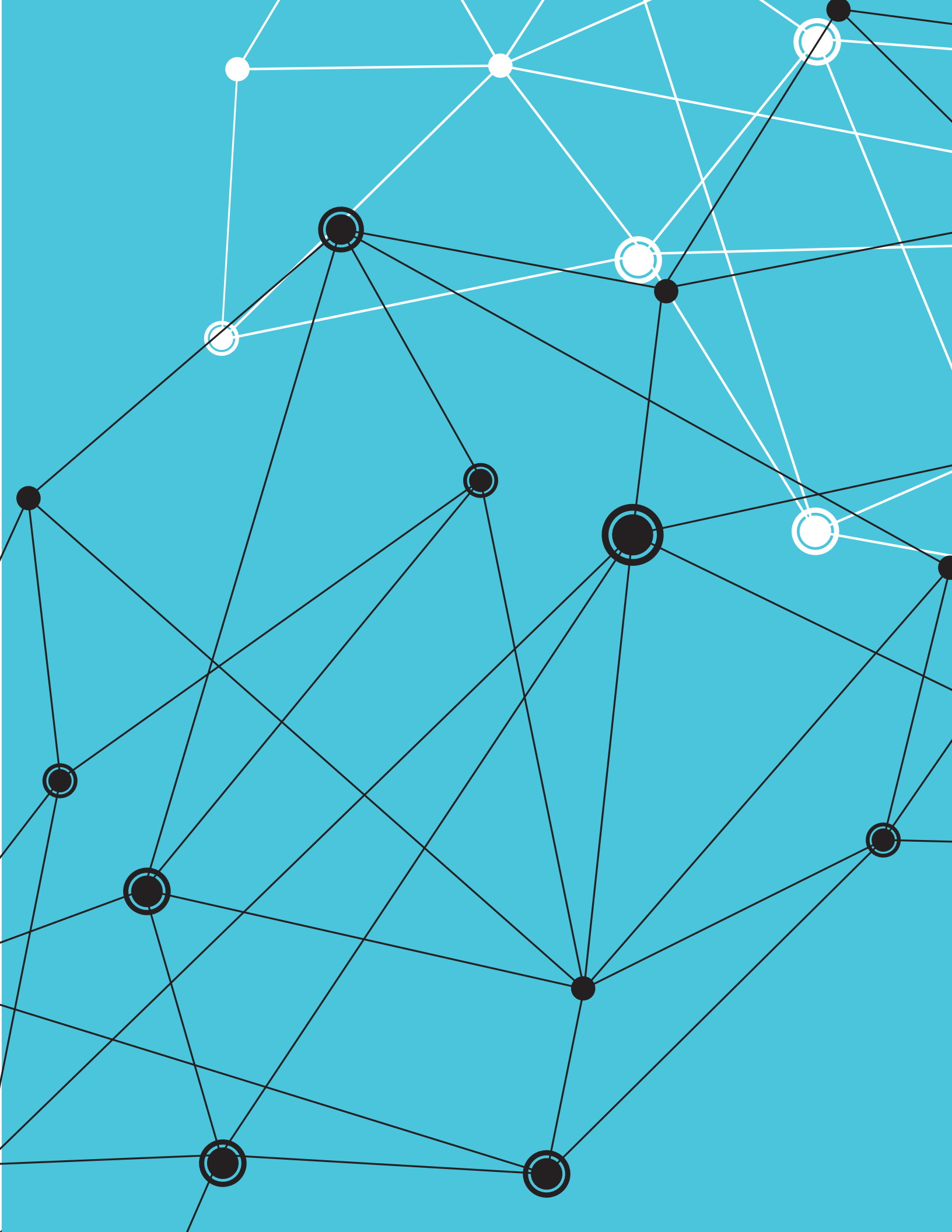
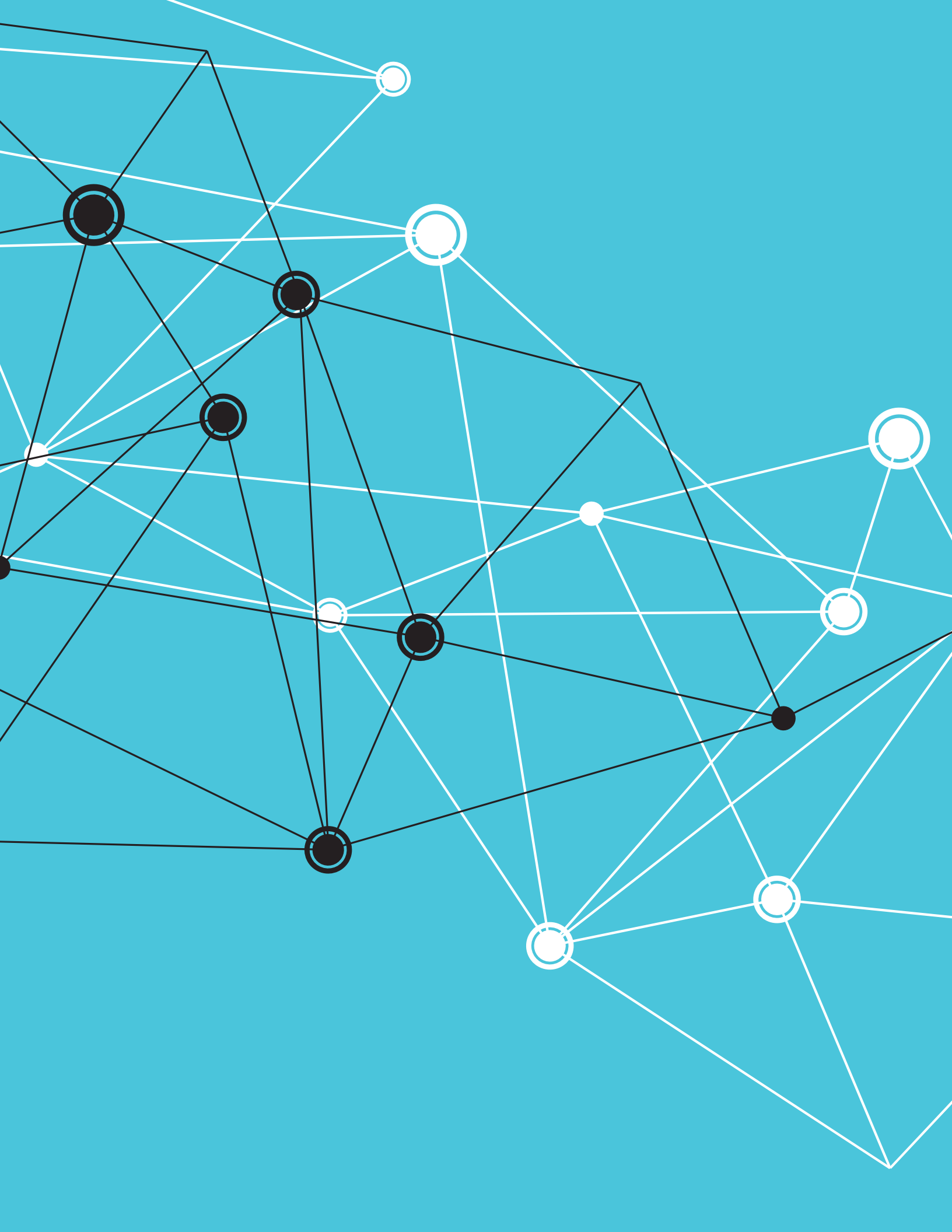
Revision of the Forum organized
in the framework of the

HEALTH INNOVATION WEEK

to commemorate the 65 anniversary
of the Mexican Association of Pharmaceutical
Research Industries (MAPRI), Mexico, 2015.







HEALTH, INNOVATION AND CLINICAL RESEARCH

> “From a holistic point of view we understand that there is a government vision to have a productive and competitive Mexico in the long run.

Cristóbal Thompson,
Executive Director of the Mexican Association of Pharmaceutical Research Industries AC

Currently, Mexico attracts investments of an estimated **160 million dollars** per year for clinical research, and has the potential to increase them to **500 million dollars**. An increase in the investment would place the country among one of the top **15** in this field on a global level”.

THE OBJECTIVE

Examining the state that Health and its general institutions in general hold in Mexico, particularly the pharmaceutical industry, with hopes of discussing and outlining measures aimed at strengthening it during the following years was the objective of the Health, Innovation and Clinical Research Forum, held on Thursday March 26, 2015.

INAUGURAL PODIUM

The following participated in the act that commenced the labors of the meeting: Mr. **Julio César Sánchez y Tepoz**, Health Promotion Commissioner of the Federal Commission for Protection against Health Risks (COFEPRIS); doctor **Javier Dávila**, Director of Medical Benefits of the Mexican Social Security Institute (IMSS); Doctor **Manuel Ruiz de Chávez**, Chairman of the Board of the National Bioethics Commission (CONBIOÉTICA); Mr. **José Campillo**, President of the Mexican Health Foundation AC (FUNSALUD); Mrs. **María Cristina Díaz Salazar**; Mr. **José Alberto Peña**, Vice-president of the Mexican Association of Pharmaceutical Research Industries AC, (AMIIF) and Mr. **Cristóbal Thompson**, Executive Director of the same organization, these last two as hosts of the event.


9.1%
of the GDP
is the proportion the OCED recommends as an increase in health investment.

> Investing in health is equivalent to doing so in all areas of development.

CONSIDERATIONS REGARDING THE REFERENTIAL FRAMEWORK

As a manner of establishing and narrowing the Forum's field of discussion, José Alberto Peña and Julio César Sánchez y Tepoz made some prior comments related to the same subject.

The first emphasized the need to increase the volumes of financing of the pharmaceutical industry, reminding that on a global level it reaches around $50 billion dollars (B) whereas Mexico, in the same period, is of the order of $160 mm. Given that investing in health is equivalent to doing so in all areas of development, the perspectives of countries are encouraging to the extent that it is feasible to increase the current investment to an estimated $500 mm during the upcoming years.

For its part, the Organization for Cooperation and Economic Development (OCED) recommends for Mexico to make an effective increase of the health investment which takes the current rate of 6.1% of the Gross Domestic Product (GDP) to a proportion of 9.1%.

In turn, Julio César Sánchez y Tepoz referred to the progress made on the matter of authorizations of innovative medications and the convenience of continuing to improve the mechanics used for that process.

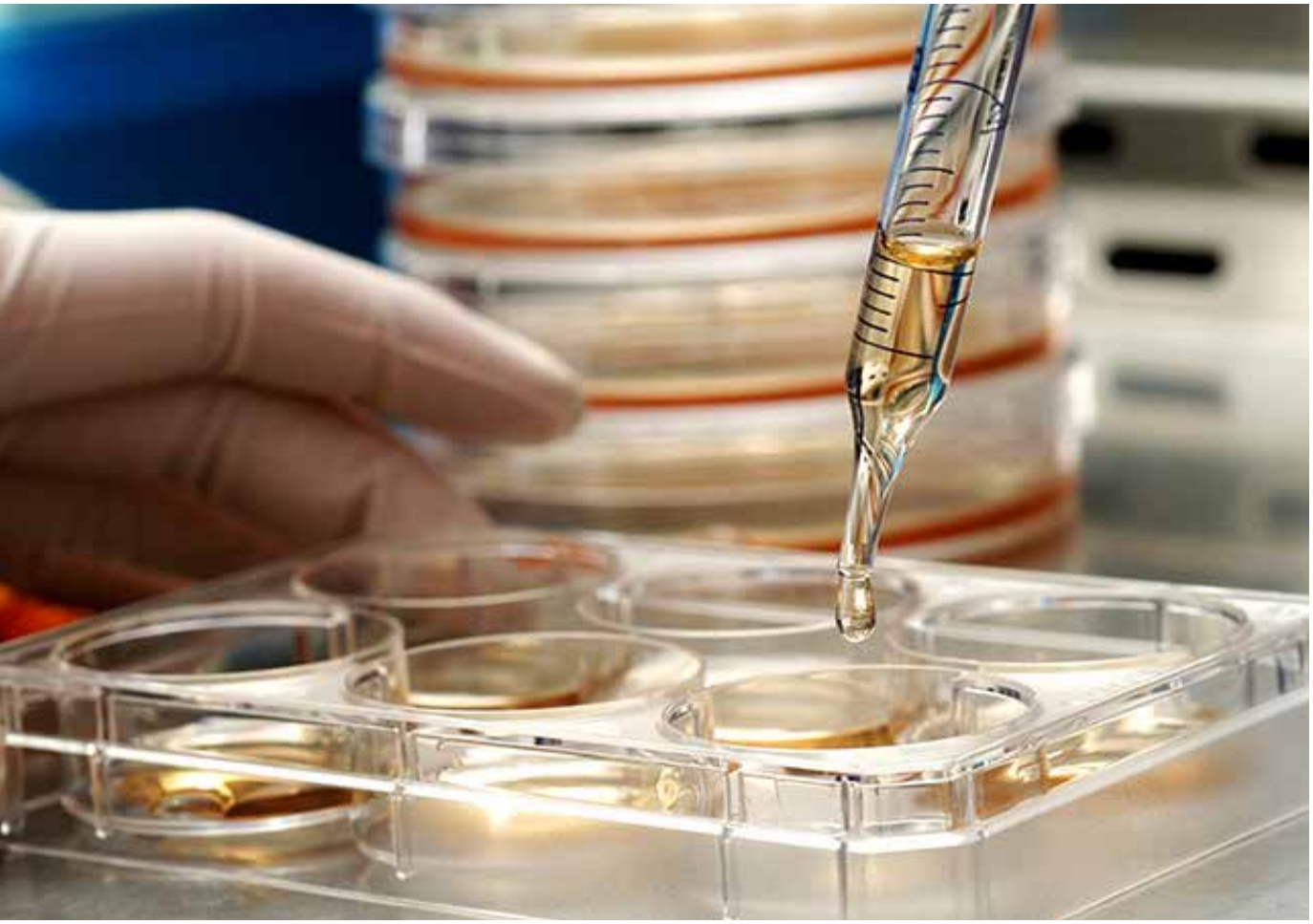
Some years ago, the time required to register an innovative molecule in Mexico was approximately three years. In the period of 2009-2010, that lapse was reduced to some 360 business days, and it currently does not surpass 60 days. In the same manner, it was previously imperative for molecules with these characteristics to have been tested in other countries before proceeding to register them, while now, if they have been the subject of studies in Mexican territory they may, in the new valid regulatory framework on the particular, come into country with no inconveniences. In parallel, the progressive decrease of the regulatory load on the health authorization processes of innovative medications has contributed to speeding up and energizing the sector, making possible the objective of more easily placing new and improved pharmaceutical products at the disposal of all levels of the company.

THE INVESTMENT

Multiplying the investment in this field is a way to replace the current notion of health as a cost for that of health as a social investment that, in this sense, plays a leading role in the productive development of the country.

ACHIEVEMENTS

The development of genomics, metabolics, proteomics and the perfecting of nano-technology applied to research have contributed to expanding desires of knowledge regarding health, allowing services better adapted to individual requirements to be offered, and doing so at a lower cost.



HEALTH IS NOT AN EXPENSE, **IT IS AN INVESTMENT**

HEALTH CARE TECHNOLOGY

Presentation of Roberto Tapia Conyer

A brief historic review indicates that the investment in the health field leads, among other things, to a better development of cognitive capacities and a greater strengthening of the stages that are crucial for human growth. A hard fact that shows this is the existing correlation between the percentage of the GDP assigned to health and the population's life expectancy, where the larger the former, the longer the latter.

An increase in the investment in the different levels of the health system almost inevitably implies the introduction of technological innovations in that field, and shows the need to gradually substitute the traditionally used reactive focus - that is, curative focus - for a prevention vision of health. A substantial decrease of the costs that each service system demands is added to the strictly sanitary benefits that this offers, in the extent that it is proven to be cheaper to provide the population with preventive care than attend to it to alleviate, moderate or remedy consumed damaged.

We currently assist a growing personalization of health service. Indications of this are, for example, the fact that it is possible to find more than 100 thousand applications -apps- related to health in the Google Play and Apple Stores platforms, which apps can be easily accessed by users, and the constant growth curve that the number of patients in the different areas of health experiences, on an international level, but also in the Mexican Republic.

From a strictly scientific point of view, the development of genomics, metabolics and proteomics, among other disciplines, united to perfect the nano-technology applied to research, have contributed -and continue to do so- to expanding desires of knowledge regarding health while at the same time constituting an opportunity to offer services better adapted to individual and collective requirements to be offered, and doing so at a lower cost.

The foregoing manifests the need the Mexican health system has of incorporating these innovations to its structure in the framework of the public policies adopted for the sector. This incorporation must be accompanied by a technical update of the first-rate health service personnel, which in general is out of date with regards to such innovations, to achieve a complete, flexible, personalized system present throughout national territory.

One model with these characteristics is constituted by the so-called Health System 2.0, in whose database the integral transformation of the first level of service is found, which stands out due to its proactive, precise, participative and public nature. To date, the system is being applied in 102 health units located in different geographical points of the country, and the authorities of the sector foresee that during the upcoming three years it will apply to all of them entirely.

It is imperative to note that one of the properties of the system must be its transparent nature, in the sense of offering the users certainty with respect to its suitability, functioning and management of the resources that it has.

> "The investment in the health field leads to a better development of cognitive capacities and a greater strengthening of the stages that are crucial for human growth.

Roberto Tapia Conyer

HEALTH RESEARCH IN THE FRAMEWORK OF THE NATIONAL DEVELOPMENT PLAN

Presentation of Julio César Sánchez y Tepoz.

The existence of a strong health agency, this concept including an efficient and defined regulatory framework, is closely linked to a generally elevated level of economic development. The consolidation and good use of the regulation can transform the market, favorably impacting the growth of the national economy as a whole.

The National Development Plan provides and contains specific guidelines to allow for the Mexican population to be in conditions to more easily access health services and receive them in the best way possible. The establishment of national regulatory agencies -NRA- has the purpose of driving the adoption of good practices that contribute to creating an environment of full confidence both in the same agency and in its operation mechanics, in this case in the environment of the pharmaceutical and health industries in more ample terms. The history of the health authorization processes in Mexico indicates that before the new policies are applied on the particular, said processes demanded more time and required a greater number of processes, which reduced the number of authorizations per year and restricts the availability of medications in the market.

Currently, COFEPRIS operates in the practice as a regulatory mega-authority, given the amount of activities that it regulates, which activities account for 9.8% of the national DGP. At the same time, the evolution experienced by the pharmaceutical regulation in Mexico has in recent years determined to strengthen the tendency to conform a market composed of two types of medications: innovative ones and generic ones, by which on one side the availability of new drugs is extended, and on the other side savings are increased for the health system. It is important to mention that the percentage of penetration of the generic ones in the Mexican market in recent years rose from 54 to 84%, which places the country among the most notable in the world in that field.

5k%
increase
in the issuance of innovative medication records; encouraging data created by the new policies.

At the same time, the reduction of the times to carry out the imperative processes to release health records, which fact places a greater number of medications at the population's disposal. And one of the most encouraging pieces of data generated by the new policies in the health field is an increase of 5,000% in the issuance of records of innovative medications.

Notwithstanding the recorded advances, the convenience of adopting a holistic point of view on the matter of public policies remains, which relates the regulatory measures, the need to increase the efficiency of the pharmaceutical market and the dynamics of the economic development. It is important to mention that the health expense made in Mexico, as a proportion of the GDP, dropped from 28.3% in 2010 to 27.1% in the most recent measurement carried out by the OCED.

Lastly, the progressive growth of the pharmaceutical market in the country is underlined, which between 2011 and 2014 grew to 13.2%, a significant percentage if it is taken into account that it only reached 1.8% in the 2008-2010 period.

> "The consolidation and good use of the regulation can transform the market, favorably impacting the growth of the national economy as a whole.

Julio César Sánchez y Tepoz

THE PANORAMA FROM THE LEGISLATIVE FIELD.

Presentation of María Cristina Díaz Salazar

During recent legislative periods, congress enriched the regulations referring to health in general, and the field of the pharmaceutical industry in particular.

Among the provisions enacted in this last field are the granting of legal attributions to the COFEPRIS to pursue conducts focused on the sale of so-called miracle products and the marketing of medical samples, as well as the demand to have medications and equipment holding a health record for establishments that practice plastic and aesthetic surgeries.

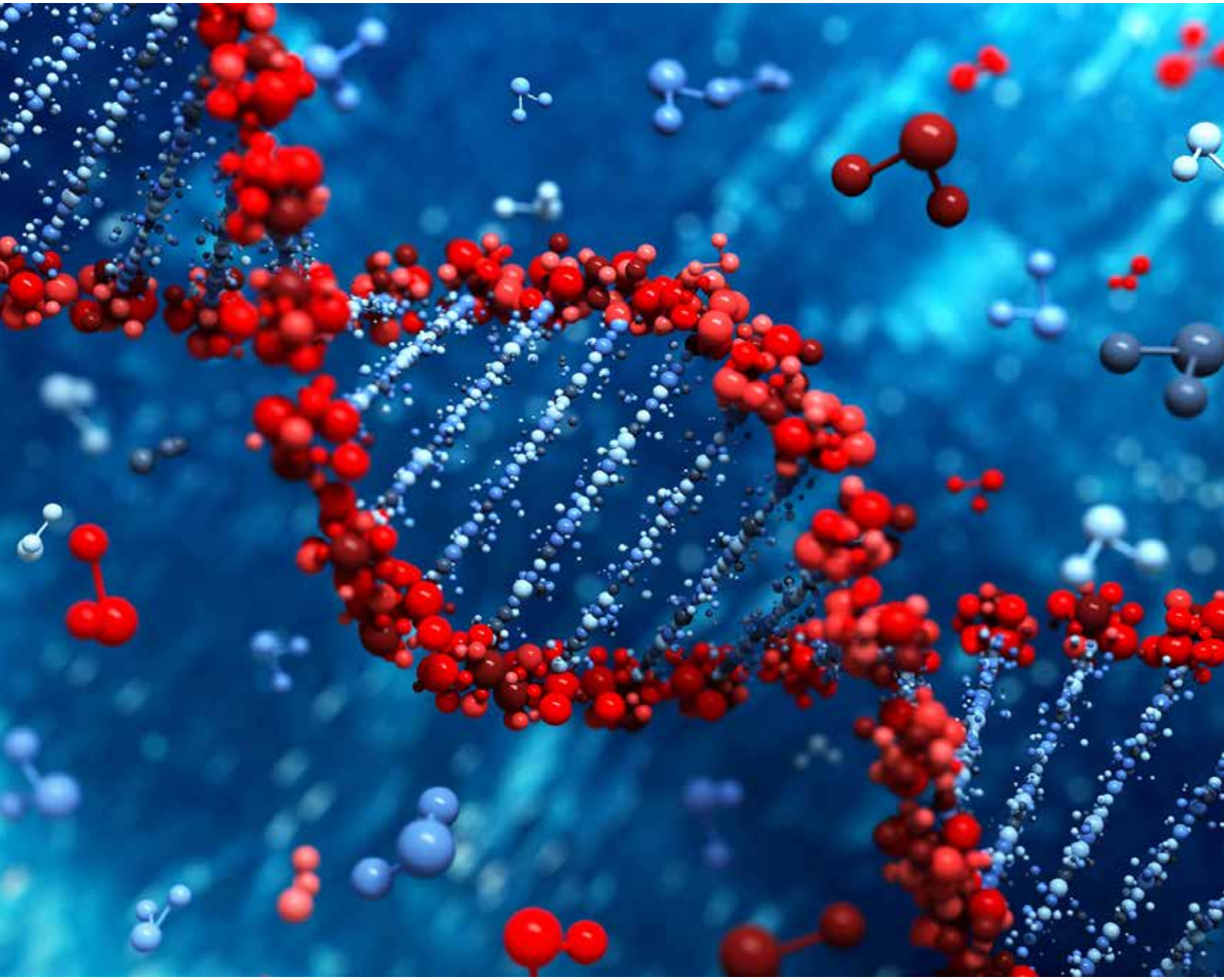
Specific initiatives added to the General Health Law likewise managed to accelerate the processesfor releasing new medications, allow the participation of authorized third parties for the approval of research protocols, simplify import processes and include the term and the notion of "informed consent" on the matter of human research.

However, in order to continue promoting clinical and pharmaceutical research, it is imperative to continue improving the regulations intended to establish the quality criteria to be fulfilled by the institutions authorized for it; better define the criteria for the activity of the research ethics committees responsible for approving the development of the clinical studies in said institutions; and creating registration and follow-up mechanics in the country of all health activities through electronic means, especially those involving human beings.

María Cristina Díaz Salazar

THE ADVANCES

Specific initiatives added to the General Health Law managed to accelerate the processes for releasing new medications, allow the participation of authorized third parties for the approval or research protocols, simplify import processes and include the term and the notion of "informed consent" on the matter of human research.



PANEL
"THE INSTITUTIONAL VISION OF CLINICAL RESEARCH"

The following participated in this phase of the forum: Doctor Germán Fajardo Dolci, head of the Health Policies and Research Unit of the Mexican Social Security Institute; Doctor Guillermo Ruíz Palacios, Commissioner of the Coordination of National Institutes and High Reference Hospitals; Mrs. Teresa de León Zamora, Director of CONACYT technology marketing; and Doctor Gloria Soberón of the Department of Molecular Biology and Biotechnology of the UNAM, at a table moderated by Alexis Serlin, Chairman of the Board of Directors of Novartis México.

> The task of the institutes is to generate scientific knowledge and form human resources that facilitate balanced access of the population to highly specialized and efficient health services with proven quality.

Guillermo Ruíz Palacios

THE IMPORTANCE OF HEALTH SCIENCES IN MEXICO

Presentation of Guillermo Ruíz Palacios

The Inter-institutional Health System, dependent of the Coordinating Commission of National Institutes and High Reference Hospitals, has in recent stages registered a progressive growth with regards to the number of researchers that integrate it. In a parallel manner, a growing productivity can be seen in each one of the institutes while the research labors are not reduced only to the health field, but rather tend to be increasingly connected to other areas of sciences, both "hard" and social. This is due to a dynamic projected and put into practice, but also to the fact that medicine, by its own characteristics, has the feature of impacting distinct modes in many other scientific spaces.

Taking the foregoing into account, a restructuring of the making of scientific medications is taking place in the alluded system through a model whose methodology is distinct from the traditional models used for this purpose. The axis of this model does not propose for each group to be independently developed in its field of work, but rather for it to be done interactively, creating synergies with the others in order to have a more extensive panorama of health related problems.

The task of the institutes is to generate scientific knowledge and form human resources that facilitate balanced access of the population to highly specialized and efficient health services with proven quality. In such sense, it can be affirmed that the model contributes to strengthening social justice. The so-called "transfer medicine" is integrated as the laboratory researchers carry out their labor collectively with their clinical counterpart and the epidemiological area, which has among its goals that of adopting measures that decrease the existing gap between the laboratory and the patient's bed.

This offers a promising outlook in the health field given that there are, even on a world scale, few integral structures with a large number of researchers in health sciences concentrated in spaces such as research and medical service centers that make up the mentioned Inter-institutional System.

The body provides half a million consultations, **4,500 surgeries** and **1,200 deliveries.** It has **50 thousand beds, 2,300 units** for the provision of health services, **1,500 first-rate units, 1,500 family medicine units, 250 second-rate hospitals** and **25 high-specialty medical units.**

Germán Fajardo

THE IMMS AND HEALTH RESEARCH

Presentation of Germán Fajardo

Just a few numbers are enough to realize the physical and operative magnitude that the infrastructure of the Medical Social Security Institute has. Every day the body provides half a million consultations, 50 thousand of which are emergencies. It performs 4,500 different types of surgeries and attends to 1,200 child births. It likewise has 50 thousand beds, 2,300 units for the provision of health services, 1,500 first-rate units, 1,500 family medicine units, 250 second-rate hospitals and 25 high-specialty medical units (HSMU).

The institution is made up of 72,000 doctors, 12,000 interns and more than 100 thousand nurses, and the same offers 421 libraries, 13 educational research centers and 30 research units with a staff of 510 researchers, to which infrastructure seven nursing schools are added.

In its current stage, the IMSS is trying to strengthen research with hopes of favoring clinical research in first-rate service. In this sense, it is noted that a high number of research protocols that the research center uses [around 600] are being financed by this, given that 327 receive financing from the National Board of Science and Technology (CONACYT), and a slightly higher number from the pharmaceutical industry. Based on the agreements signed in 2014 with the COFAPRIS, and this year (2015) with the AMIIF, it is estimated that the number of protocols will tend to increase naturally. In order to fluidly manage this increase, the institution has made a strong investment aimed at renewing the equipment that it has for the research.

With regards to the characteristics of the mentioned protocols, 60% of them correspond to clinical studies, 20% to basic research, 7% to epidemiological research, the same percentage to clinical studies on health systems, and 5% to diverse educational subjects.

THE FUNCTIONS OF THE CID

- Guide the college community regarding the processes of connection between the industry andhigher education institutions.
- Identify the innovative ideas arising in the different fields of research.
- Provide the service company and incubation of new companies based on university developments.

> "The UNAM produces around 30% of the total articles on scientific research that are published in Mexico.
>
> **Gloria Soberón Chávez**

INNOVATION IN THE HEALTH FIELD

THE CASE OF THE UNAM

Presentation of Gloria Soberón Chávez

The UNAM produces around 30% of the total articles on scientific research that are published in Mexico, and among them naturally are those related to the different areas of health and medicine. The university is, on the other hand, the institution that has the largest number of members of the National Research System (NRS).

In general, there are three functions of the Innovation and Development Coordination (IDC):

The first consists of guiding the college community regarding the processes of connection between the industry and higher education institutions (the same UNAM in this case), supporting researchers in the process that goes from the protection of intellectual property of their works to the marketing of the same. These works are generated in a wide number of university spaces, which include, in addition to the Faculty of Medicine, diverse institutes among those that have Biotechnology, Ecology, Cellular Physiology, Biomedical Research, Neurobiology and Chemistry, as well as the Center of Genomic Sciences and the Humanities area of the Institute of Legal investigations and several faculties and schools of said area.

A second function for which the CID is responsible is to identify the innovative ideas arising in the distinct fields of scientific research. A third is to provide the service company and incubation of new companies based on university developments of a various nature.

The research lines on which these developments linked to health and medicine are driven include the monoparticular branches, treatment of human infections, development of antineoplastic compounds, biomarkers for diagnostic, antifungal medications, repairs and regeneration, or in other words, use of peptides, reversal of the inflammatory processes, principles for the elaboration and of vaccines, development of coatings, anti-hypertensives, medical devices, natural extracts, development of veterinarian products and other specialties not mentioned in this list.

The presentation described in detail the processes operated with regards to cases of developments carried out in an equal number of fields of study as a way of illustrating the work that is executed in such sense.

THE SUPPORT THE CONACYT has created a Technology Research Fund that supports undertakings in the fields of science and technology, helping the products of private research to reach the market.

> On the matter of innovation, Mexico is among the last places, affecting its Global Competitive Index.

Teresa de León Zamora

CONACYT PROGRAMS OFFER

Presentation of Teresa de León Zamora

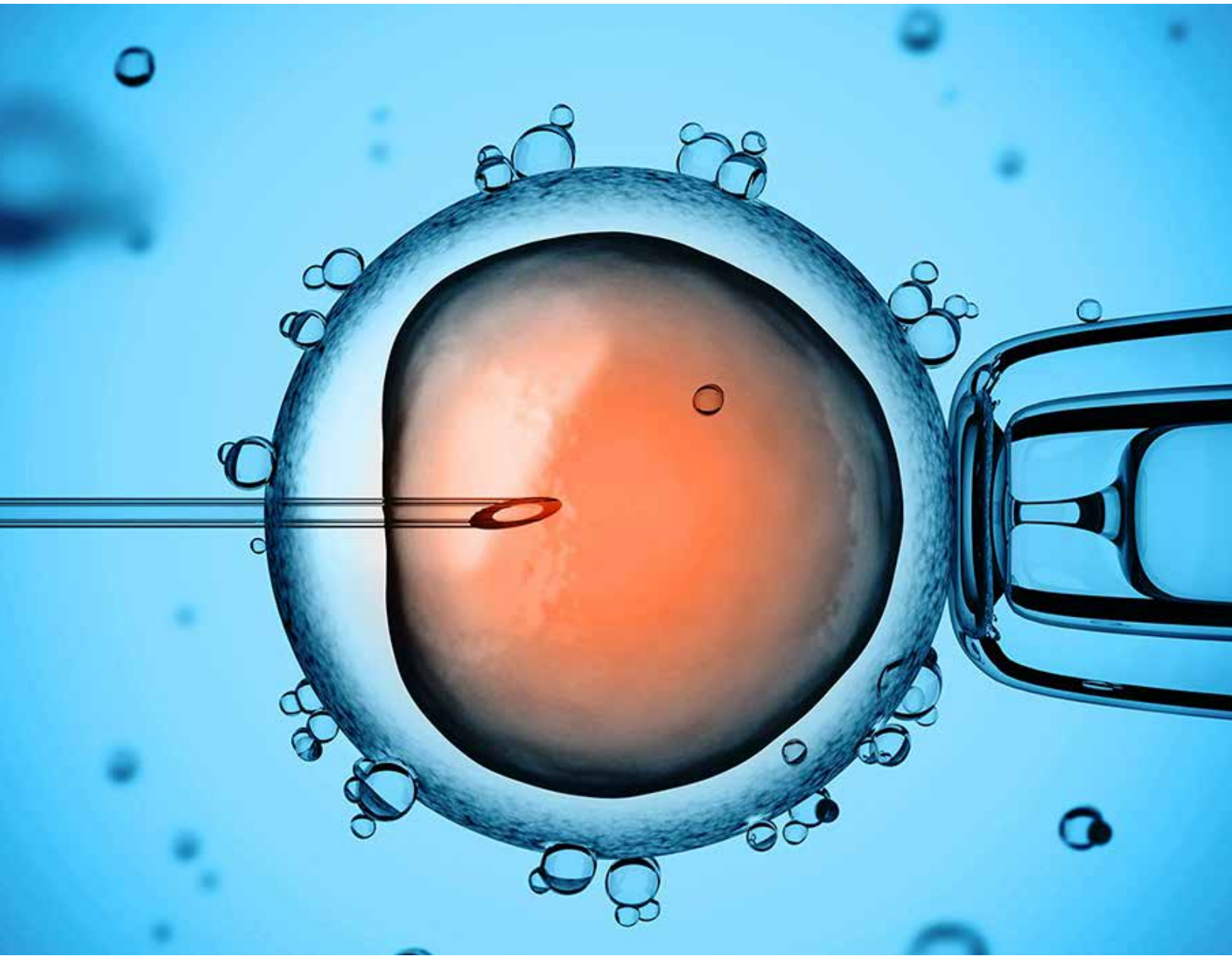
The National Board of Science and Technology bets on the technology innovation and the substitution of imports, and among the notable routes it uses for it are the promotion of the strengthening of installed capacity in the scientific and technology fields, and the necessary support in order for the investigations carried out in those fields to have possibilities of reaching the market. For such purpose, the Board is committed to detecting the failures that make the process difficult or obstruct it.

It is important to indicate that on the matter of innovation, Mexico is among the last places, considering the factors that are taken into account for the elaboration of the Global Competitiveness index.

In addition to the same concept of innovation, said factors include the quality of the scientific research institutes; the levels of institutional development expenses, the connection between university, research centers and business environment; the magnitude of the purchase of technological products by the government; the availability of scientists and researchers, and the index of the patent systems, all of them defined in the World Economic Forum framework.

The mentioned factors are taken by the CONACYT when establishing the articular axes of its policy in the fields of science and technology. One of this policy's objectives is to know the state and investment tendencies in science and technology, contribute to forming and strengthening the human capital present in those fields, promote and consolidate regional development, encourage the connection between the researchers and the productive sector, and reinforce the existing scientific and technological infrastructure in the country.

In order to reach its objectives, the CONACYT has put in practice a series of programs related to basic research, applied research and technological development, new product development support, marketing of technology, medicine and health sciences. It has likewise created a Technology Research Fund whose finality is to support undertakings in the fields of science and technology to contribute to both newly created companies



and individual persons with entrepreneurial activity to be in conditions to take the products of their research to the market.

Given that the CONACYT also handles detecting researches conducted on health and technology of the same, in this context the institution launched a convocation addressed to the knowledge Transfer Offices (TO) to identify new investigations in those fields that are feasible in the financial and market aspects. 50 investigations on health were presented in the first phase of the process, from which 20 were selected, which number was reduced to nine after the corresponding feasibility studies were conducted, which constitutes an indicator regarding the difficulties that placing innovative products in the market implies. This experience ratified the need to strengthen both the TO's as well as the internal training of health institutions on subjects such as regulatory framework, intellectual property, protocols and internal processes, while at the same time promoting higher specializations for professionals on the matter of technology transfer.

CONSIDERATIONS
REGARDING THE PANEL

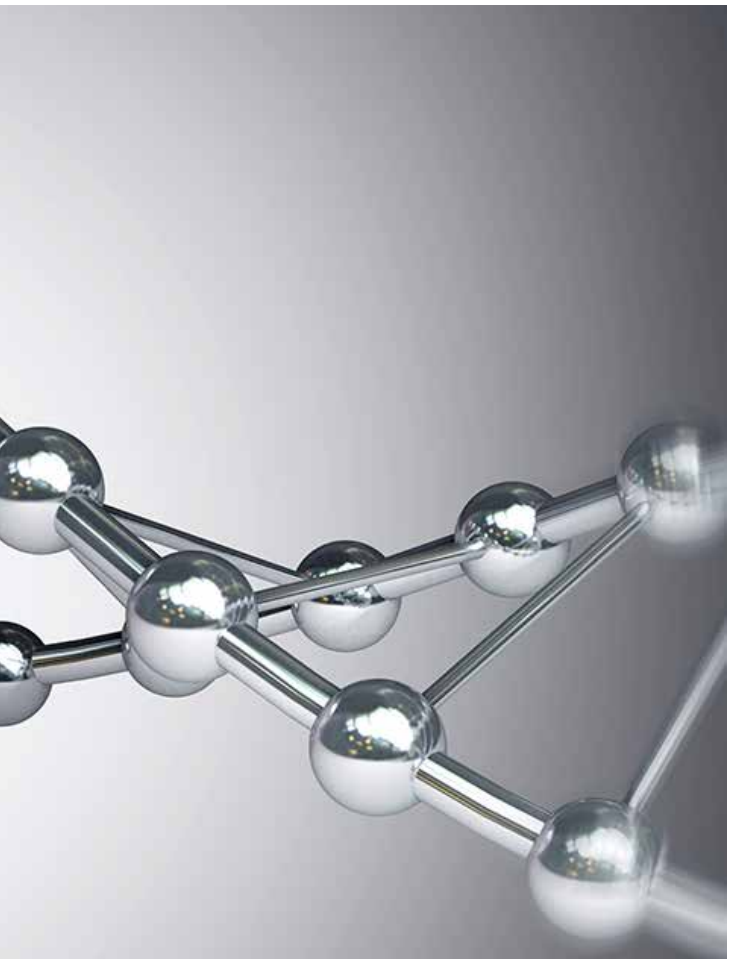
NOTABLE POINTS

- It is urgent to recover academic leadership in the three levels of service in the health system.
- One considerable obstacle lays in the legal structures, which have not evolved at the same rate as the research labors.
- One of the challenges to overcome for the UNAM is that the institutes where knowledge is generated find great difficulties accessing the sphere of the companies in order for them to develop their products.

Synthetically, what are the main challenges that the country faces regarding the problem addressed in the session described above?

Guillermo Ruiz Palacios. The main challenge consists of transferring the knowledge of the innovation in the practical field to the establishment. In Mexico there is a critical mass of researchers, possibly the largest among Latin America countries, which produce much knowledge on the subject of transformation medicine, and it is imperative that all those involved actively participate to make that transition effective.

Germán Fajardo. From the view of the IMSS, it is urgent to recover academic leadership in the health system's three levels of service.



Among the objectives to reach are the following: the need to promote the incorporation of more researchers into the SIN, fully develop programs such as that which the same CONACYT, and provide incentives for researchers to participate in the pharmaceutical industry.

In essence, the elements that present different challenges are the large volume of the institution (with regards to physical size); the need to obtain greater economic-financial resources to maintain the fluid operation of the structure, and the convenience of numerically increasing the Institute's human resources.

It is imperative to recover the mysticism that converts research into an element present in the every-day clinical lives of doctors.

Teresa de León. Among the objectives to reach are the following: a) the need to promote the incorporation of more researchers into the SIN b) in the academic field, fully develop programs such as that which the same CONACYT intends to make effective, at least until the close of the present administration, and c) provide incentives for researchers to participate in the pharmaceutical industry through specific periods of stay in the companies that compose it, in order to deeply understand their problems and bring the knowledge and expertise acquired back with them to their companies.

Gloria Soberón. In the case of the UNAM, one of the challenges for it to overcome is that the institutes where knowledge is generated find great difficulties accessing the sphere of the companies in order for them to develop their products. Consequently, there is a large amount of molecules that do not reach the clinical phase, with the prejudice that this bears for the health field.

What areas of the pharmaceutical industry could better help the development of the research and innovation in the country?

Guillermo Ruiz Palacios. One considerable obstacle lays in the legislation that the public institutions have regarding their relations with the private sector, which phenomenon is due to legal structures not evolving at the same rate as research labors. To modify this state of things, the National Health Institutes Act is currently under process of modification in order to facilitate private participation in the fields of research.

Germán Fajardo. It is imperative for research institutions and the private sector to come together,but not only on the matter of the investigations, but also in that of the respective spheres in a process that must be open, fluid, transparent and ethical to benefit both parties.

PANEL

"THE CLINICAL RESEARCH OFFER FROM THE PRIVATE INITIATIVE POINT OF VIEW"

Moderated by Mrs. Patricia Guerra, President of the IMSS Foundation, this panel was participated in by Biologist Valentina Kurovic-Perisic, Director of Global Clinical Operations of Novartis; Doctor José Luis Viramontes Madrid, President of the CRO Alliance of Mexico (ACROM); Todd Georgieff, Director of Clinical Testing of Roche, and Doctor Francesca Carvajal, Executive Director of Clinical Research Operations for the Americas of MSD.

Only Novartis makes an investment of

$15 mm.

total financing as the receive 25 developments that take place in Mexico.

Valentina Curovic-Perisic

THE STRATEGIC ASSIGNMENT OF TESTS

Presentation of Valentina Curovic-Perisic

Novartis, a pharmaceutical company that is among the 25 largest in the world on the subject of market capitalization and is present in 140 countries. It has conducted sales operations for a total of $50.6 B. Of that amount, about 9 billion was designated to diverse actions of research and development, with which the company has placed itself among those that apply the most amount of resources in that field as well.

Novartis has 11 institutes for research and development of new medicines. On the issue of studies, the North America region, particularly the United States and Canada, receive special attention by the company, to the point that 23% it corresponds to the clinical study field. There are 25 developments in Mexico that receive a total financing of 15 mm derived from a fund of 200 mm that the company has assigned for this purpose.

The complexity of the research protocols constantly increases as a result of new clinical challenges that appear. To guarantee the success of the protocols that it supports, the company chooses nations where the quality processes are efficient, the medical experience and that of the researchers shows an adequate level, and the local infrastructure is appropriate. Among other factors, it likewise takes into account the dominion of the language (the dominion of English is imperative on the matter of medical and pharmaceutical research), the rolled-out logistics for the respective developments and the eventual negative perceptions that there may be before each one of the investigations in question.

José Luis Viramontes

THE CLINICAL RESEARCH INDUSTRY FROM THE PERSPECTIVE OF THE CRO' S (COMPANIES OF RESEARCH BY CONTRACT)

Presentación de José Luis Viramontes

The main objective of the CRO's is to try to bring this type of research (mainly pharmaceutical, although also regarding devices) to the countries in which they operate. The clinical research market presents a large number of risks, especially due to the elevated cost of many clinical studies, which requires a very large investment.

45% of the active clinical studies are in the United States, 27% in Europe, and the rest in geographical areas outside those countries. Around 5% of the total studies were conducted in Latin America, of which number Mexico possesses between 21 and 22%, even when the country has the potential capacity for that percentage to be substantially amplified. Clinical research in the world grows year by year, but in Mexico this tendency is reversed, for which it is imperative to detect why the country is not being attractive for studies of that type.

In recent years, in order to bring down costs, large pharmaceutical companies have began outsourcing services, particularly their research labors, which propitiates the functioning and growth of the CRO's through which greater operational efficiency is sought. In Mexico, through the ACROM, the association of CRO's in Mexico, there are 15 companies that are responsible for developing the majority of the investigations in the sector (it is estimated that there is a certain number of smaller companies that are dedicated to that activity, but they are not in the records of the association).

5 %
of the total
clinical studies on a global level were conducted in Latin America.

The challenges of Mexico in this area are linked to the perception of insecurity in the country, which negatively impacts the collection of foreign investment. The poor professionalism on the clinical research level; the institutional bureaucracy on almost all levels, and the administrative inconsistencies that translate to the demand of requirements more or less unforeseen for the execution of the studies.

In all, Mexico has a wide panorama of opportunities to attract investments in this field, and the development of new centers of excellence, the creation of more professionals and the promotion of good practices are some of the ways to achieve it.

Todd Georgieff

THE CLINICAL RESEARCH OFFER FROM THE PRIVATE INITIATIVE PERSPECTIVE

Presentation of Todd Georgieff

One of the determining characteristics for large pharmaceutical companies to decide to invest in a country is for it not to present unpredictable difficulties that delay the recruitment process of the research participants. In the terms calculated by Roche, that first stage must not demand more than six months. Otherwise, the company considers that said country does not show favorable conditions for the execution of the project. On an international level, the recruitment methods are experiencing favorable changes, especially since they include the growing use of digital technologies and social networks to achieve their task.

Mexico constitutes an area that facilitates the development of clinical institutions, to the point that 5% of the total global patients that make up the final phases of the studies developed by Roche belong to this country.

THE IMPLICATIONS OF INVESTING IN CLINICAL RESEARCH

Presentation of Francesca Carvajal

In the last five years, MSD has invested approximately $58 mm, beginning studies in 107 research centers. The investment numbers, however, have suffered constant variations, which indicates the need to work to increase the participation of the country in the company's portfolio of studies.

The constant increase of clinical research costs has determined that the pharmaceutical industry seeks for the scheduled time cycles for the studies to be timely fulfilled, for said costs to be balanced and for the quality standards to guarantee that the project must not be discarded in its final stage. The key factors for deciding the assignment of studies also include the epidemiological data, the available infrastructure, the experience of personnel on the matter of clinical research, the existence of successful previous experiences, the protection of the patients and the quality and speed of data processing.

Particularly in Latin America and Mexico, the times for approval of the clinical research projects by health authorities, ethics committees and research centers must be sufficiently short in order for the studies to be competitive as they are in the United States and Canada, where projects of that nature are approved in lapses between 60 and 80 days.

RESEARCH

In the last five years, MSD has invested approximately $58 mm, beginning studies in 107 research centers.

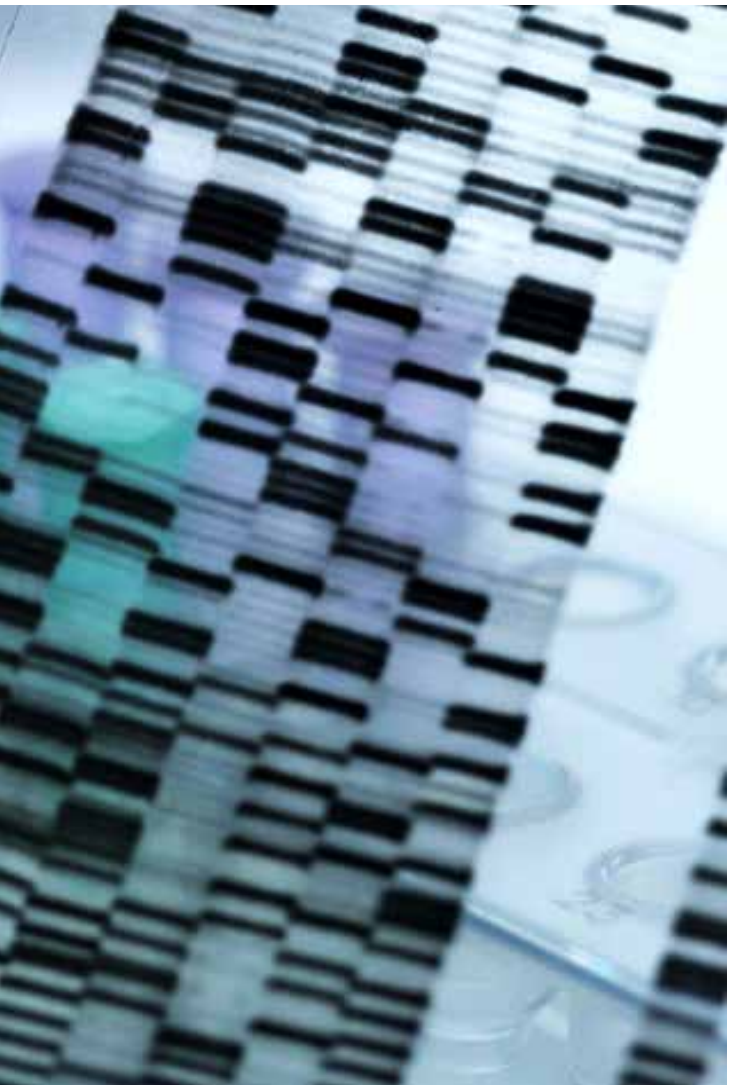
Francesca Carvajal

CONSIDERATIONS REGARDING THE PANEL

NOTABLE POINTS

- The mechanics for working together and harmonizing the labor of the researchers and the different research centers must be refined with hopes of reaching a single objective.
- In Mexico, the approval times of the projects must be accelerated, and the predictability in the different bodies involved in the research works increased.

It is imperative to center attention on that which is not being done anymore in the Latin America area and determines the success on the matter of competitiveness, obtained in other regions of the world. Based on that presented, it is inferred that the times that are used to conduct good clinical research assume special relevance, and it is necessary to stimulate early training on the matter of innovative medications.



We should pay close attention to the process step where ethics committees are involved, because it is essential to shorten deadlines.

What are the challenges that must be overcome to amplify clinical investment in Mexico?

José Luis Viramontes. In essence, competitiveness should be understood as the comprehension that in a global environment it is imperative to manage reasonable operation times in all stages of the investigation process, and not only in some. But additionally, the mechanics for working together and harmonizing the labor of researchers and the different research centers must be refined with hopes of reaching a single objective.

Todd Georgieff. In Mexico, the approval times of the projects must be accelerated, considering this point as well in regulatory matters, and the predictability of the different instances involved in the research works increased.

Francesca Carvajal. With regards to the mentioned need to speed up times, it is convenient to focus on the stage of the process where the ethics committees intervene and the handling of research on the level of the centers that develop it, because there too it is imperative to reduce times. The term "costs" not only refers to the financial investment, but also to that made in questions of time. It is convenient to focus on the stage of the process where the ethics committees intervene, because there too it is imperative to reduce times.

In order to address the subject Innovative Experiences linked to technologies of the pharmaceutical industry, the Forum met with Mrs. Rosa María Ceballos Blanco, representative of the Mexican Association of Medical Device Industries (AMID); Doctor Enrique Rivas, Director of Clinical Development for Latin America from Sanofi Pasteur; Doctor Eduardo Ortega-Barría, Vice-president and Director of Research, Clinical Development and Medical Affairs for Latin America and the Caribbean from Glaxo SmithKline; Doctor Víctor Manuel Rincón Ponce, Associate Medical Director for the Metabolic Field of MSD Mexico; Doctor María Eugenia Sánchez Nozari, Director of Regional Clinical Operations in Latin America from Eli Lilly; Mr. Joaquín Miranda Sansores, Director of Consultoría de IMS Health, and Doctor Lina Sofía Palacio, Assistant Academic and Research Director of the Information Center for Public Health Decisions (CENIDSP).

> “Mexico is the fifth largest global exporter of medical devices, in part because the manufacturing costs in the country are 23% lower than in the United States.

Rosa María Ceballos

TECHNOLOGY INNOVATION IN MEDICAL DEVICES

Presentation of Rosa María Ceballos

Medical devices, as opposed to medications, are present in the entire process of medical service, that is, prevention, diagnosis, treatment and rehabilitation of the patient. This makes not only the development a challenge, but especially the evaluation of said devices. Mexico is the fifth largest global exporter of medical devices, in part because the manufacturing costs in the country are 23% lower than in the United States.

In terms of innovation, in first place is that of the device itself, which tends to be miniaturized, have “intelligent” functioning, whose control is increasingly more in the patient’s hands. In second place falls the innovation of the applications, an example of which is the evolution of the pacemaker, which was originally designed only to send pulses to the heart and currently performs a much larger amount of tasks. On the other hand, the innovative trend also reaches the communications systems between different devices, allowing them to give reciprocal feedback to optimize their functioning, as well as form local systems that facilitate the general organization of the health systems.

The challenges in this field consist of timely evaluating the quality, efficiency and cost of the new devices (due to the quickness of the changes), overseeing the functioning that they show in time (to prevent eventual failures), and equally distributing these supplies whose production is increasingly more expensive.

VACCINES Since 2004, Sanofi Pasteur has mounted different clinical sites, committed to facilitating the realization of a large study of efficiency for the anti-dengue vaccine.

QUADRIVALENT DENGUE VACCINE

Enrique Rivas

A MODEL OF INNOVATION IN CLINICAL RESEARCH AND PUBLIC HEALTH

Presentation of Enrique Rivas

To create an anti-dengue vaccine, develop it and, through testing, conduct the corresponding efficiency studies, one needs to go where the sickness is. There are generally no researchers or infrastructure there, for which it is imperative to design and apply an epidemiological surveillance system and have at least a clinical work space. It is possible to thus create a model that must privilege the establishment of connections between the pharmaceutical industry, the authorities of the three orders of government, the academic area and the community, as proceeded in Tizimin and in Valladolid, Yucatan, where two rural health centers that have served as spaces for the mentioned development operate.

From 2004 to date, Sanofi Pasteur has mounted different clinicalsites, all of them committed to facilitating the realization of a large study of efficiency for the anti-dengue vaccine. More than 50 million pesos have been invested in that period, which become health service works, while at the same time indispensable human capital has been formed to continue developing different clinical research projects. All of this implies, in a complementary manner, the creation of new direct employments in the respective areas.

The community impact of the project stands out, which in addition to linking the health and educational sectors, also required the participation of parents and leaders of the communities in order to earn the trust necessary to carry out the studies on the vaccine.

The outlined model adjusts to the notion of innovation, and could be reproducible in other environments and regions.

Eduardo Ortega-Barría

CONTRIBUTION OF MEXICO TO THE DEVELOPMENT OF THE ATTENUATED HUMAN ROTAVIRUS VACCINE

Presentation of Eduardo Ortega-Barría

Currently, 27 diseases can be prevented through vaccines, with which 3 million deaths and 750 thousand handicaps are also prevented annually. According to investigations conducted in the University of Harvard, 6.30 dollars are saved in medical costs for every dollar invested in vaccination, and around 18.40 dollars in social costs. Immunized children receive significantly more elevated school performance percentages in language and mathematics and possess a higher intellectual coefficient. Hence the potential of the vaccines is inferred for the improvement of public health and productivity of the nations.

Before the development of the anti-rotavirus vaccine, 500 thousand children died per year as a consequence of it. In Mexico three children a day died for that reason.

Mexico participated in diverse studies on the disease and the vaccine in all their stages and aspects, and was determinant for the latter to be licensed in nations with a greater presence of rotavirus. For this it was determinant to have the virtuous triangle formed through collaboration of researchers, regulatory authorities and sponsors.

6.30

are saved in medical costs for every dollar invested in vaccination, and around 18.40 dollars in social costs.

The vaccine was licensed in the country in 2004, launched in 2005, introduced into the states withgreater presence of the disease in 2006, universalized in 2007, and approved by the Food and Drug Administration (FDA) in 2008 when Mexico proved that it reduced death from diarrhea by up to 45%.

In summary, thanks to the collaboration between researchers, pharmaceutical industry and Mexican academic institutions, with the support of regulatory authorities and adequate clinical operations equipment, Glaxo SmithKline led on a national level the launch of a vaccine that was, for the first time, simultaneously available for all segments of society. This historic act accelerated the universal vaccine for ten years.

THE INFORMATION

Between the year 80 and 2010, diabetes mellitus rose from the ninth to the second leading cause of death in Mexico.

CONTRIBUTING TO THE FIGHT AGAINST VT2 SITAGLIPTINA, A CASE OF SUCCESS

Víctor Manuel Rincón Ponce

Presentation of Víctor Manuel Rincón Ponce

Between the year 80 and 2010, diabetes mellitus rose from the ninth to the second leading cause of tdeath in Mexico. The first are cardiovascular diseases, 50% of which have diabetes as a component.

The exhaustive works that culminated in the synthesis of sitagliptin were practically applied for the first time in Mexico, the first country holding this compound for any patient (two months before the United States).

THE TRASCELERATE PROJECT

María Eugenia Sánchez

Presentation of María Eugenia Sánchez

This name identifies the initiative by which, since 2012, a group of pharmaceutical companies work collectively for the research and development of new molecules that substantially help patients and can be low cost. The ecosystem of the project is composed of industries, regulatory agencies, research centers and CRO's, and operates with resources contributed by the participating companies. Originally integrated by eleven companies, to date their number ascends to 21.

The organization has an innovative character as far as the fact that it has managed to bring together companies that are competitors in search of a common purpose, both in areas of research and in the market space.

Lina Sofía Palacio

DIABETES OBSERVATORY

PILOT STUDY USING THE CLINICAL FILE OF COLIMA

Presentation of Lina Sofía Palacio (invited to present in the intervention of Joaquín Miranda Sansores)

The collaboration between the Health Department of Colima, the National Institute of Health Public and the company IMS Health makes it possible, through the Diabetes Observatory project, to make a retrospective analysis with clinical and resource consumption information to follow up on customer service.

This type of analysis, extended to other diseases, can help to create valuable indicators regarding diverse aspects of the same (risk factors, prevalence, incidence, quality of the service to the affected persons, treatment, prescription of medications, monitoring of cases, eventual associated complications, etcetera). It would therefore serve for doctors to have graphs on which to base their decisions aimed at improving service to patients, and for the Health Department to verify the state of the affected population, level of adherence to the respective protocol, and what measures are being efficient or inefficient in the treatment of the ailment.

The pilot experience of Colima opens the possibility of applying the model on a national level, harmonizing the structure of the state databases in order to add records and thus create observatories for different diseases.

Francisco González Díaz

PROMEXICO, VISION, IMPULSE AND PERSPECTIVES

Presentation of Francisco González Díaz, General Director of ProMéxico

Mexico, the second most important pharmaceutical market of Latin America and notable producer of medications, has become fertile terrain for new productive investments in that field. The following step consists of pharmaceutical products not only being manufactured in the country, but also for the development of the research regarding the particular to be promoted.

The pharmaceutical industry of Mexico has 700 specialized companies that market products with a high added value based on the research, with more than 93 thousand patents obtained (eleventh place on a global scale in the 2003-2012 period, above the United Kingdom, Italy, India and Singapore). The main research and development processes are phase 3; that is, that in which information is compiled and collected regarding safety and effectiveness of a product studying the types of populations that they impact, doses and combinations of medications. In all, the objective of ProMéxico is, in collaboration with AMIIF and the different companies of the branch, to promote a strategy to attract more investments capable of strengthening the different phases of medical and pharmaceutical research.

HOW TO PLACE MEXICO WITHIN THE TOP 10 COUNTRIES WITH BETTER HEALTH RESEARCH

CONCLUSIONS TABLE

The last table of the Forum, moderated by Doctor Julio Sotelo Morales, representative of the National Academy of Medicine, had the participation of Doctor Juan Carlos Gallaga, Health Authorization Commissioner of the COFEPRIS; Doctor Gabriela Dávila Loaiza, Vice-president of the Clinical Research Commission in Canifarma; Doctor Samuel Ponce de León, Director of Research of the Faculty of Medicine of the National Autonomous University of Mexico, and Doctor Francisco Díaz Vázquez, Director Clinical Research and Institutional Evaluation of the Coordinated Commission of National Health Institutes and High-Specialty Hospitals (CCINSHAE).

The dynamics of the table were established based on the following questions, formed by members of the AMIIF to the participants:

- **How is the productivity of an institution or scientific group evaluated in terms of innovation and practical health contributions?**
- **How should the diverse actors of scientific research interact to improve the terminal products and for them to be effectively useful for patients?**
- **How can Mexico be led to hold one of the top places in the world on the matter of clinical research?**
- **What can the different areas represented in the Forum do to improve the international position of Mexico as a first-rate scientific information producer?**

> Significant achievements have been reached: processes that were previously carried out in terms greater than 300 days are currently performed in less than 100.

Gabriela Dávila

Gabriela Dávila. Dávila. If the progress of the country is intended to be strengthened on the matter, it is indispensable for those who perform activities in one area or another of the same to meet and exchange ideas with the end purpose of working concertedly. The operative conjunction of authorities, academy, pharmaceutical industry and other actors linked to research and development must continue to be focused on improving the times in the different stages of the process that culminate when the products reach the market and the patient.

However, it is at all times imperative to ensure the quality of the adherence to the protocol, the responsibilities of the researcher and the sponsor, the data, the research sites, the development centers and in general all components of said process. It is likewise imperative to continue fulfilling the marked provisions both for local regulations and for national and international ones. With strict adherence to this simple line of work, in a few years it will be possible to notice a substantial increase in clinical research in Mexico.

On another front, it is required to take care of the aspects linked to human resources and learning from that research. There are spaces, institutions and patients, but frequently the mistake is made to confuse extensive knowledge of a subject with the capacity to adequately research (in the sense of knowing well and making the best use of the clinical procedures and good practices). Significant achievements have been reached: processes that were previously carried out in terms greater than 300 days are currently performed in less than 100. But it is likewise convenient not to lose sight of the need to simplify processes in order to continue progressing.

Samuel Ponce de León

Samuel Ponce de León. The pharmaceutical industry is doing a very good job, but it is in the institutional part where some failures are noted, in which a certain tone of complacency is perceived. It is essential to recognize the in insufficient amount of research has been produced in the country, and that it does not have the imperative work force to increase the existing amount.

In other words, it does not manage to form a critical mass that detonates the process and allows a growing accelerated rhythm to be maintained in it. Reaching this point requires money, for the government to designate many resources for the area, for the authorities to commit to obtaining a greater flow of investment, in such a way that the research can adapt to the dynamics that the pharmaceutical industry follows.

Francisco Díaz Vázquez

THE RESULT

The CCINSHAE reaffirms its commitment with regards to financial management intended to increase research. There are currently around **1,100** institutional researchers and **1,400** in the National System of Researchers.

Francisco Díaz Vázquez. The CCINSHAE reaffirms its commitment with regards to financial management intended to increase research. Year by year, the Health Department carries out processes to increase the percentage of assignment of resources for its sector, and thus be able to be in conditions of applying part of them to research labor.

Additionally, it is the Department's commitment to promote the processes of forming new human resources and strengthening the already existing ones. There are currently around 1,100 institutional researchers and 1,400 in the National System of Researchers, which number is insufficient, but the situation is worsened by the fact that many of them go to other countries, for which notable intellectual capital is lost. It is necessary, then, to make efforts to retain them, offering them not only salary increases, but also infrastructure, equipment and appropriate commodities for them to develop quality work that makes the country competitive in international terrain.

Juan Carlos Gallaga

Juan Carlos Gallaga. From the authority's point of view, the first thing that it is imperative to examine is regarding the certainty, which must proceed from the legal standpoint. The need to reduce times has been addressed, but above all when a protocol is being authorized it is convenient to know if that authorization is going to be given or not. On the other hand, it is key to better professionalize research by the authority, the regulatory bodies, the investigators themselves and the spaces where they work. In this respect, what is urgent is to design a national policy that promotes professionalism and is responsible not only for Health authorities, but also for those of Finance and Economy.

Is there any expression of a desire for Mexico to be able to intensify its development on the matter of clinical research?

Samuel Ponce de León.
1) Have a research budget that rises to at least 1.5% of the national GDP.
2) Have a quick enough regulation to allow from human resources to research protocols to be developed.
3) For the health budget to be increased, which holds a very limited installed infrastructure and is the second to last among the 34 countries that form a part of the OCED.

Gabriela Dávila.
1) Simplify the operational processes for the COFEPRIS, enabled units, customs offices and clinical research. For the latter to receive a substantial boost thanks to which all actors of the same can perform their processes without the complications that they now run into.
2) Create a national program to train and professionalize all participants in clinical research, not only in the Federal District, but throughout the Republic.
3) Acquire predictability. For the periods and terms originally established for the different processes to be fulfilled as they were provided, which, in addition to accelerating the respective processes, would allow the external image of the country to improve, which currently has difficulties participating in international protocols.

Juan Carlos Gallaga.
1) Specify the necessary interrelation to create legal certainty, avoid delays in the elaboration of regulations and stimulate the participation of all parties involved in the same.
2) Work for the authority to carry out its task not from a distrustful standpoint regarding research processes and the suitability of the participants, as currently occurs, but trusting in a certification of the same that is created by third parties.

Francisco Díaz Vázquez. For the CCINSHAE, continue strengthening alliances between the different institutions. With the COFEPRIS, make the regulations more efficient to quicken the processes related to the authorizations of clinical protocols, and for the times they require to be reduced; with the UNAM, continue strengthening the academic programs and receive support for the elaboration of clinical protocols in order to conduct research; with the pharmaceutical industry, for it to contribute to attracting more budget for that field.

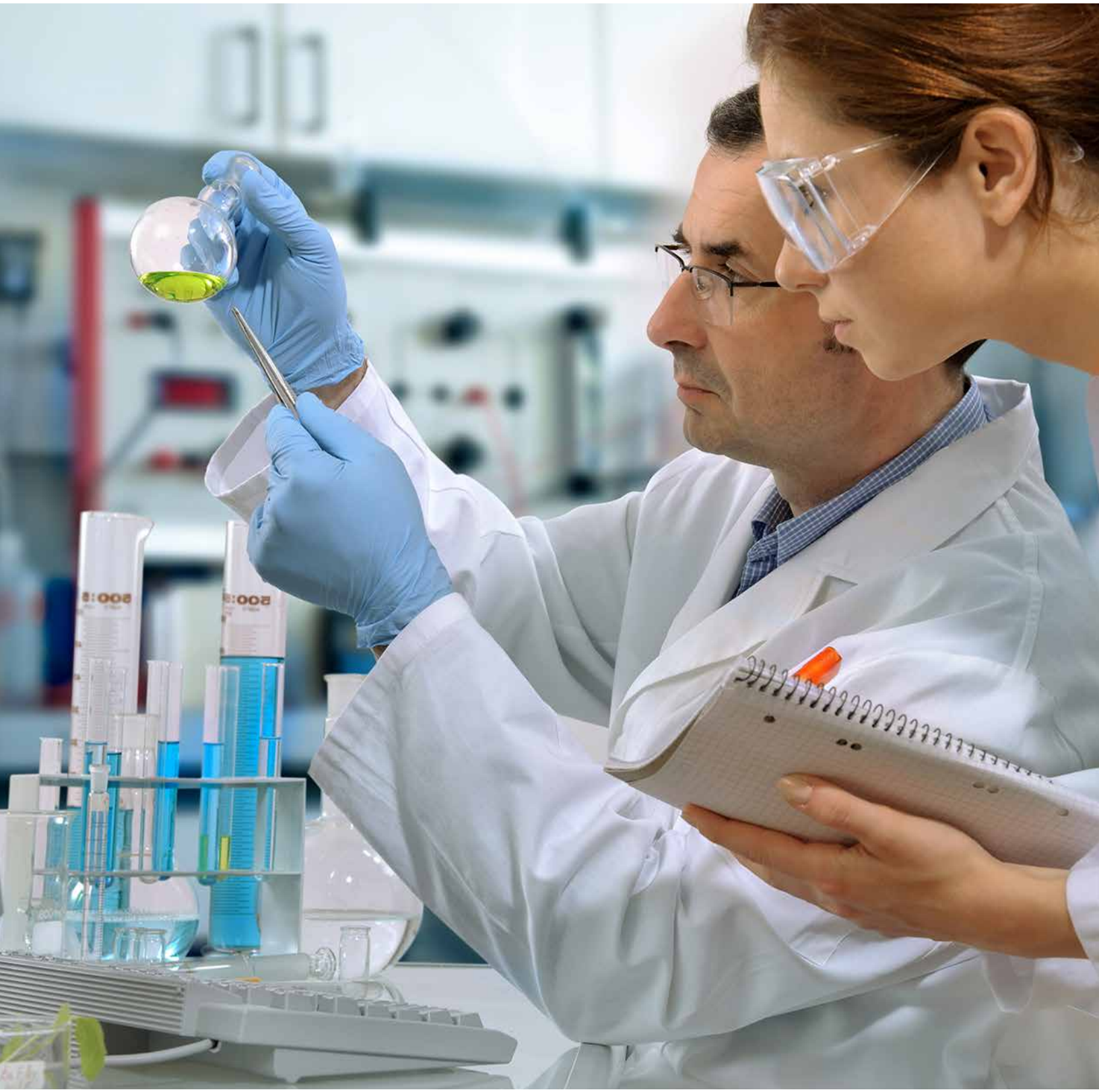
Thus, research that is at first made in national institutes and subsequently overtakes the domestic units of the republic would increase the quality of scientific articles, research projects and the researchers themselves.

Julio Sotelo

A CONSIDERATION OF THE MODERATOR JULIO SOTELO

Mexico records a large, far-reaching trajectory of clinical research. The advance that gathered the most brilliant minds in the field of medicine in the history of the XX century was the synthesis and population of steroid hormones, including the contraceptive pill, and fundamental Mexican scientists and European scientists received in Mexico participated in it.

It would be good for the Mexican Association of Medicine Faculties and Schools (ANFEM) to organize meetings that gather researchers, college students and auditors to promote the research and incorporation of the scientific advances generated in the national laboratories to the industry of medical and pharmacological progress instruments.



> The merit of the Forum as far as gathering the public and private sectors for the first time in an extensive space of discussion and exchanging of ideas in order to analyze different ways to progress clinical research and manage for the investment in that field to increase significantly.

CLOSING CEREMONY

In the act with which the Forum closed, the Executive Director of AMIIF, Cristóbal Thompson, gave public recognition to the Institution's team in charge of organizing and developing the event, and reaffirmed the vision of AMIIF, consisting of contributing to the increase of productivity and competitiveness of the pharmaceutical industry of Mexico. For this he manifested that it is imperative to continue working and contributing ideas aimed at improving the health system as a whole. He likewise stressed the importance of introducing innovative medications into the country and facilitating for the same to effectively reach the entire population.

He continued by noting the merit of the Forum as far as gathering the public and private sectors for the first time in an extensive space of discussion and exchanging of ideas in order to analyze different ways to progress clinical research and manage for the investment in that field to increase significantly. In such sense, he indicated the commitment of creating a work front between the Association and the different actors participating in the Forum in order for Mexico to be able to leave behind the 221st position that it holds in this type of research and rise to among the top ten places worldwide.

Finally, he mentioned the invitation to consolidate a multi-sectorial team to, from different artists and levels of intervention, offer a collective impulse to Mexico, as well as consolidate the commitment of the Pharmaceutical Industry to increase the investment in that sector and sign collaboration agreements with the corresponding governmental bodies, which allows work results obtained in collaboration to be presented the following year.

THE PARTICIPANTS (speakers)

Francesca Carvajal

Doctor from the university El Bosque and specialist in nuclear medicine from the University Javeriana of Bogotá, Colombia. She is the Executive Director of Clinical Research for the Americas in Merck/MSD. She began as a monitor of research studies in Schering Plough, being subsequently promoted to Director of Clinical Research for Colombia, and then over Ecuador, Venezuela and Puerto Rico. She isthe leader of the Center for Management of Regional Clinical Research projects for the Americas of MSD/Merck.

Rosa María Ceballos

Biomedical engineering through the Ibero-American University and masters in Evolution of Technologies through the University of Montreal. She has collaborated with the World Health Organization and the Technical Board of Biomedical Engineering of the UI. She is a member of the International Society of Evolution of Health Technologies, the International Society of Drug economics and Investigation of Results and the Mexican Society of Biomedical Engineering. She formed a part of the founding group of the National Center of Technological Excellence in Health and the Board of General Health, being the Director of Health Technology Evaluation of the Basic Table and Catalog of Supplies of the Health Sector. She is the manager of Economic Evolution and Access of Medtronic México.

Valentina Curovic-Perisic

Licensed professional of biological sciences, masters in health management, with 20 years in the pharmaceutical industry, specializing in clinical trial management. She has handled bone metabolism, deep vein thrombosis, amyotrophic lateral sclerosis, multiple sclerosis, chronic obstructive pulmonary disease and asthma. She has been a member of Novartis for the last 10 years, initially working in the organization of operations in the United States before passing to global management.

Gabriela Dávila Loaiza

Graduate of the Faculty of Medicine of the University La Salle. She completed a specialty in clinical neurology in the University of Paris VI Pierre et Marie Curie in the Hospital of Pitie-Salpétriére. She obtained the electrophysiology diploma in the same university, and is certified by the Mexican Board of Neurology. Founder of the Medical College Lasallista, she is an active associate of Canifarma and Vice-president of the Clinical Research Commission in that organization. She additionally acts as the President of the Research and Development Commission. In March, 2012, she was promoted to lead Mexico, Central America, the Caribbean and Puerto Rico under a new work scheme with strategic partners from the company Pfizer.

María Cristina Díaz Salazar

A member of the Health Commission, she is a licensed professional in law and social sciences thruogh the Autonomous University of Nuevo León. Mayor of the County of Guadalupe, Nuevo León from 2006 to 2009 and the Mexican Health Network Counties from 2007 to 2008. She has been the Interim president, General Secretary and again Internal interim president of the National Executive Committee of the PRI. She was a federal congressw man on several occasions and is currently the General Secretary of the National Confederation of Popular Organizations of that party.

Germán Fajardo Dolci

Graduate of the Mexican School of Medicine of the University La Salle, otolaryngologist through the General Hospital of Mexico and masters in Upper Management. She was a medical sciences researcher through the Coordinating Commission of National Health Institutions and professor of the UNAM Faculty of Medicine. She has performed in the Health Sector as a medical specialist, Assistant director of Education of the General Hospital of Mexico, Director of Education and General Director of the General Hospital "Dr. Manuel Gea González". She held the positions of National Commissioner of Medical Arbitration and Undersecretary of Integration and Development of the Health Sector. She is the head of the Unit of Education, Investigation and Health Policies of the Mexican Social Security Institute.

Juan Carlos Gallaga

Medical surgeon through the University of Guanajuato (UDG) with a specialty in clinical pathology through the Popular Autonomous University of the State of Puebla, certified by the Specialty Board, and teacher in the Faculty of Medicine of the UDG. Active member of the Clinical Pathologist Society of the Republic, he was also the Director of the State Laboratory of Public Health of Guanajuato and Commissioner of Analytical Control and Coverage Extension. Since 2013 he acts as Commissioner of Health Authorization.

Eduardo Ortega-Barría

He finished his medical studies in the Autonomous University of Guadalajara and completed his residency in pediatrics in the National Institute of Pediatrics of the City of Mexico, and a sub-specialty in infectious pediatrics diseases in the Children's Hospital of Mexico. He received training in research in cellular biology in the Tufts University School of Medicine/New England Medical Center, Division of Geographic Medicine and Infectious Diseases and served as an medical instructor in the Department of Medicine of the New England Medical Center of Boston, Massachusetts. He completed post-doctoral training in infectious pediatrics diseases in Lucile Salter Packard Children's Hospital, Division of Pediatric Infectious Diseases, Stanford University, and post-doctorate studies in cellular and molecular biology from Toxoplasma Gondii, in the Department of Microbiology and Immunology of the Stanford University School of Medicine. He was a member of the Gorgas Commemorative Institute for Health Studies, Panama, Florida State University-Panama, and the Institute of Advanced Scientific Researches and High Technology Services of the National Department of Science, Technology and Innovation, Panama. He is the Vice-president and Director of Clinical Research and Development and Medical Affairs for Latin America and the Caribbean of GlaxoSmithKline Vaccines.

Samuel Ponce de León

Graduate of the UNAM, he has the specialties of internal medicine and infectology in the National Institute of Nutrition, Salvador Zubirán. He completed a masters in sciences in hospital epidemiology in the university of Virginia, Charlottesville Va., United States. He implemented the Infections Control Program in the INCMNSZ and was the Assistant Director of Hospital Epidemiology, Diretor of the National Program of Prevention and Control of AIDS in Mexico (CONASIDA), and General Director of Biologicals and Reagents of Mexico (BIRMEX). He is the Head of Research of the UNAM Faculty of Medicine and belongs to the SNI Level III. He is also a member of the National Academy of Medicine, the Mexican Academy of Sciences and the Mexican Academy of Surgery, as well as the editorial boards of Public

Health of Mexico, Archives of Medical Research and National Geographic in Spanish.

Víctor Manuel Rincón Ponce

Associate Medical Director for the metabolic area in MSD Mexico, he is a graduated internist from the National Medical Center Century XXI, masters in medicine, and attending physician assigned to the Internal Medicine Service of the General Hospital of Zone 47 of the IMSS. Collaborator in the Pharmaceutical Industry as an Associate of Clinical Research, he is the leader of the Clinical Research project (respiratory, gastrointestinal, antibiotics and cardiovascular areas) and Medical Manager of the pharmaceutical company AstraZeneca.

Enrique Rivas

Graduate from the School of Medicine of the University La Salle, he specialized in pediatrics in the National Institute of that discipline and participated in a collective program of the Epidemiology Intelligence Services of the Centers for Control and Prevention of Diseases (CPD, United States) and the Mexican Ministry of Health. Masters in child psychotherapy through the University of Veracruz, he obtained an additional master's degree in quality management from that house of studies, and received his PhD in the Autonomous University of Madrid, Spain. He joined Sanofi Pasteur in 2008 and held the position of Sr. Regional Director of Clinical Development for Latin America.

Guillermo Ruíz Palacios

Graduate of the UNAM Faculty of Medicine with honorable mention, specialty in internal medicine in the National Institute of Medical Sciences and Nutrition Salvador Zubirán (INCMNSZ), sub-specialty in infectology, post-doctorate in the University of Texas and stay in clinical microbiology in the Department of Infectology of the Clinic Mayo in Rochester. He created the Department of Infectology in the INCMNSZ, currently the center for training of specialists, masters and PhD's in the most important area of infectious diseases and microbiology in Latin America. Together with his collaborators, he has created microbiology and virology laboratories, as well as diagnostic reference centers.

María Eugenia Sánchez Nozari

Chemist-pharmacist-biologist through the University La Salle, he also has a diploma in finances. Since 1997 he performs in the field of clinical research, commencing as an Associate of Clinical Research of Oncology, and then as the Clinical Operations Manager. In 2010 he was named Director of Clinical Operations for Latin America. In this position he is responsible for the implementation of clinical trials from phase I to phase IV in said region. He participates in the main initiatives of transition within Lilly, as well as in initiatives of innovation to improve the application of clinical trials on a global level.

Julio César Sánchez y Tepoz

Licensed professional in Law through the Free School of Law of Puebla and masters in economic development through the Complutense University of Madrid. He has specialized studies in foreign commerce, regulatory economics, competition policy, investigation of monopolistic practices, growth and competitiveness, foreign investment, legal arguments, publicity and intelligence. He labored in the Attorney General's Office, the Federal Commission of Competition and the Federal Consumer Prosecution (PROFECO). He also collaborated with the Federal Police, assigned to the coordination of International Analysis of the Intelligence Unit. In March of 2011 he joined the COFEPRIS as Coordinator of Advisors of the Federal Commission,and since July 2012 he has acted as Health Promotion Commissioner in said institution.

Gloria Soberón Chávez

She studied (bachelor's, masters and PhD) in the UNAM in the Basic Biomedical Research Program. She was a member of the Nitrogen Fixation Center (today Center of Genomic Sciences), the Center of Genetic Engineering and Biotechnology (today Institute of Biotechnology) and the Institute of Biomedical Investigations, where she worked in molecular genetics of the bacteria Pseudomonas aeruginosa. She has level 3 in the National System of Researchers. She is a member of the Mexican Academy of Sciences and the National Academy of Medicine. Since February 2014 she acts as the General Director of Connection in the Coordination of Innovation and Development of the UNAM.

Julio Sotelo

Medical surgeon through the UNAM, specialist in clinical neurology, he has a postgraduate degree in research in neuroimmunology in the University of London, England, with John Holborow, Professor Emeritus on Immunology, and in neurovirology in the National Health Institutes of the United States with professor Carleton Gajdusek, Nobel Prize of Medicine in 1976. He is the Supervisor of the Neuroimmunology Unit of the National Institute of Neurology and Neurosurgery, and has been the Department of Health Consultant Coordinator, head of the Coordinating Commission of National Health Institutes and High-Specialty Hospitals, and General Director of the National Institute of Neurology and Neurosurgery of Mexico.

Roberto Tapia Conyer

Medical specialist in health policies, Masters in Public Health and Sciences through the University of Sciences of Harvard and PhD in Health Sciences through the UNAM. He is the General Director of the Carlos Slim Foundation, Chairman of the Board of Trustees of the Juvenile Integration Centers and member of the Continuous Consulting Board of the Mexican Public Health Society, National Academies of Medicine and Surgery and the Mexican Academy of Sciences. He is a Level III researcher of the SNI and member of the Health Consulting Committee of the Initiative of the University of California with Mexico, the Scientific and Medical Consulting board of the ISSSTE, the Steering Committee Partnership for Dengue Control, the America's Dengue Prevention Board of Dengue Vaccine Initiative and the International Task Force for Disease Eradication of The Carter Center.

José Luis Viramontes Madrid

Doctor through the UNAM, with specialty in pneumology, masters in sciences through the same university, with the MSc degree in clinical epidemiology and health economy through the University of McMaster in Hamilton, Canada. He is the head professor of the Controlled Clinical Trials and Bioethics Module in the masters of clinical epidemiology of the National Public Health Institute. He has been the founding President of ACROM and worked 15 years in Merck Sharp & Dohme in the medical area, in clinical research, in marketing and in special projects. He is currently the Regional Director in PPD of the Remote Site Monitoring and Management center.

Todd Georgieff

Leader of the Therapeutic Area and areas of Immunology, Infectious Diseases, Ophthalmology and Neurosciences of Roche. He was in charge of the operative supervision of this company for the Development of the CRO's, as well as in Genentech. He previously formed a part of the executive leadership team of a global CRO based in Canada and conducted Clinical Operations of Abbvie in that country.


UNDEFINED
DATA

BRIEF PHOTOGRAPHIC REVISION

OUR ASSOCIATES AND COLLABORATORS

Collaborating with obesity control.

ACKNOWLEDGEMENTS

The presence of expert personnel from the Federal District Government was enjoyed during the referenced event. There was also an exercise machine as a part of the Health Station, and a pedometer was given to the people that did ten squats.


65 aniversario
AMIIF
Innovación para la vida
ACROM
Alianza de CROs de México
30 aniversario
FUNSALUD