IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

The only international organisation for everyone involved in Pharmaceutical Medicine

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Chieko Kurihara, Member of the IFAPP Ethics Working Group

Please allow me to introduce myself. I am Chieko Kurihara, specially appointed Professor at Kanagawa Dental University, and Senior Researcher/Vice-Chair of the Certified Review Board, at the National Institutes for Quantum Science and Technology, Japan. My expertise is bioethics, especially research ethics. I joined the IFAPP Ethics Working Group in 2017 and, since 2021, have been the IFAPP Delegate of the National Member Association in Japan, JAPhMed.

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I am very engaged in bioethics study, in particular research ethics. My special interest is to seek for core fundamental principles of research ethics. Simultaneously, I have a strong interest in areas where ethical principles have not been well established. For this purpose, I have been studying internationally agreed principles and research regulations, and I am enjoying collaboration with bioethicists in the whole world. My ordinary job is mainly ethics committee management as well as quality assurance of and consulting for non-GCP research involving humans.

After graduation in 1983 from the Department of Economics, School of Political Science and Economics, Waseda University, Tokyo, I have been engaged in book/journal publications, editorial and theatre works and then in the study of bioethics. Also, I have been working for a long time as an editorial staff member and then editor of the Japanese journal “Clinical Evaluation”, which was established in 1972 with the policy to promote publication of “negative results” of clinical trials, now dealing with science and ethics of research involving humans.

I have also been engaged in other international activities, as a member of the Task Group 109, Ethics in radiological protection for diagnosis and treatment, the International Commission of Radiological Protection (ICRP) (since 2018), following the previous Task Group aimed for ICRP Publication 138 to identify the ethical foundation of radiological protection system of the ICRP.

My notable commitment to the Ethics Working Group of IFAPP is to discuss data-driven research and privacy protection, with the objective to make a proposal for future revision of the World Medical Association’s Declaration of Helsinki on research involving humans, linking it to the Declaration of Taipei on health databases and biobanks as demonstrated in this article of which I am the lead author:
Kurihara C, Baroutsou V, Becker S, Brun J, Franke-Bray B, Carlesi R, Chan A, Collia LF, Kleist P, Laranjeira LF, Matsuyama K, Naseem S, Schenk J, Silva H and Kerpel-Fronius S. Linking the Declarations of Helsinki and of Taipei: Critical Challenges of Future-Oriented Research Ethics. Front. Pharmacol. 2020. 11: 579714. doi: 10.3389/fphar.2020.579714

Chieko Kurihara, BSocSc.
IFAPP Delegate of JAPhMed, Japan, Member of the IFAPP Ethics Working Group

AMEIFAC - Over 50 Years Old and Still Strong in Mexico

In 1967, the Association of Medical Directors of the Pharmaceutical Industry (ADIMED – Asociación de Directores Médicos) was founded - at first comprised by Medical Directors from the pharmaceutical world in Mexico. In 1992, this group of medical directors decided to legally formalise the association and changed its name to the Association of Medical Specialists in the Pharmaceutical Industry, A.C. (AMEIFAC – Asociación de Médicos Especialistas en la Industria Farmacéutica, A.C.).

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The association was created by a group of medical directors from different pharmaceutical companies, who were characterised by having an important professional awareness and a specific keen interest in pharmaceutical medicine, a medical specialty unknown to most at the time but that involves the discovery, development, evaluation, registration and surveillance of medicine, their quality, as well as aspects of its commercialisation, marketing and sales distribution.

Today as always, AMEIFAC's mission is to be the most committed and referenced association in guidance and educating its members and society on pharmaceutical medicine, as well as on issues related to the pharmaceutical arena, whether from the medical-scientific point of view, to clinical research, patient safety and the practice of medicine that benefit patients, doctors and institutions related to health, and through the development, research and commercialisation of medicines by the Pharmaceutical Industry. Its vision is to promote in our country, as well as worldwide, the study, analysis, creation and dissemination of pharmaceutical, scientific, regulatory knowledge and provide support for pharmacovigilance through the close collaboration with national or international institutions, whether public or private, from academia, researchers together with the Pharmaceutical Industry.

The association is also dedicated to developing and maintaining high standards in the practice of pharmaceutical medicine for the benefit of patients, stimulate the level of medicine both in the scientific and public spheres, promote all public benefit that brings advancement of knowledge and education in pharmacy medicine, as well as acting as an authorised body for consultations about pharmaceutical medicine.

The association has been active for over 55 years and plans to continue to grow nationally and internationally. It is currently planning on teaching two courses on pharmaceutical medicine and MSL activities, in addition to sharing stages with other associations.

Becoming a member of AMEIFAC provides exclusive access to certain content on its website, a diploma as proof of being a member, a membership card and lapel pin, discounts on courses held by CINVESTAV, the Dalinde Medical Center, and the Anahuac University. Membership also provides preferential costs for attendance to national and international meetings, free monthly access to academic sessions related to medical and regulatory matters, etc. All academic sessions are available for members, important networking, invitations to workshops and discussion panels, free publication of articles in the Latin American Journal of Clinical Sciences and Medical Technology, direct interaction with national and international societies and associations, and direct access to the association´s digital library.

The 2021-2023 Directive Board is comprised of Dr. Manuel Lavariega Saráchaga – President; QA. Dinath González Riverón – Vice President; Dr. Alejandro Rangel Delgado – Secretary; Dr. Katia Pineda Menez, Dr. Marlen Sánchez Peña, and Dr. Gilberto Castañeda Hernández – Academic Commission; Dr. Dara Fuentes Armenta and Dr. Brenda Aloisi Vega – Finances; Dr. Gerardo Sánchez - Mejorada Fernández and Mr. Juan Luis Serrano Leets – Normativity, Government and Authority Relations; Mr. Ángel Bosch Torrano, Dr. Edith Zárate Rodríguez, and Ms. Paulina Rea Jiménez – Communications Commission; Dr. Marlene Llópiz Avilés, Dr. Yolanda Cervantes Apolinar – International Relations Commission; Dr. María de Jesús Vázquez and Dr. Erika Barrón Ortiz

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– Medical Colleges/Certifications and Recertifications Commission; Dr. Rodolfo Guajardo Moguel, Dr. Iván González Gómez and Dr. Javier de la Vega Duarte – MSL Commission; Mr. Héctor Guzmán Hernández and Dr. Ana G. Romero Gómez – Digital and Social Media Commission.

AMEIFAC will continue its efforts in continuous growth and relations with international organisations such as IFAPP in cooperating and collaborating with global partners in pharmaceutical medicine.

Dr. Marlene Llópiz Avilés, International Relations Commission AMEIFAC

conect4children – a New Public-Private Partnership Project

The implementation of Regulation (EU) No. 1901/2006, the so-called Paediatric Regulation, was a big step forward for a better and paediatric-centric treatment of children with medicinal products.

New, innovative medicines for children are needed but also a better understanding of medicinal products currently used 'off-label' in many circumstances, in babies, children and young people.

Besides this regulatory framework and to foster the implementation and execution of the mandated development plans, additional actions seemed to be necessary to overcome several barriers like inconsistent processes and historically driven, non-harmonised stakeholder approaches.

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Since the first implementation of the Paediatric Regulation, both the number of clinical studies for new medicinal products approval or to produce additional information for medicinal product labels in children, and the number of children to be involved in such studies, has increased steadily in the EU resulting in a growing number of new treatment options being approved for use in children.

At the same time, the paediatric research infrastructure needed to conduct such studies was not developing at the same pace to meet these growing needs, combined with a generally low number of patients available for study in many paediatric indications. We see that about 40% of Paediatric Investigation Plans (PIPs) are not completed as planned (1) and that there is also an increased competition between studies about shared resources (investigators, sites, patients).

Conducting clinical trials involving children is a multi-faceted challenge:

- Finding the right indication and population
- Lack of sufficient trial infrastructure
- Diverse standard of care across Europe
- Use/acceptance of innovative study designs
- Impact on daily lives of patients and families
- Divergent ethical standards
- Lack of appreciation of need for clinical research in children in society
- Contradictory local regulations
- Small patient populations – competing developments
- High number of participants compared to the number of paediatric patients with the condition under study, leading to slow recruitment and delayed completion.

Given the number and type of challenges, a broad multidisciplinary public-private collaboration is required to meet them, and it must be transformative and to collectively address children's needs for better medicines.

The conect4children, in short c4c, pan-European network (https://conect4children.org/) has formed such a collaboration aiming to provide:

- High quality input in study design and preparation through rigorous strategic and **operational feasibility assessment**
- **Efficient implementation** by adopting consistent approaches, aligned quality standards and coordination of sites at national and international level
- A **single point of contact** for all sponsors, sites, and investigators
- **Collaboration** with EU paediatric specialty networks.

c4c will also increase the mutual understanding of standards for trial conduct, metrics for trial performance, and the quality framework.

c4c facilitates the design and implementation of clinical trials relevant to early and late phase. It will overcome the difficulties in that each trial has to develop its own network of sites which will result in inefficiencies and poor quality of trials. This will lead to improved PIPs and study designs, more efficient implementation and conduct of paediatric clinical trials and improved data quality, better trial feasibility and faster enrolment.

Where c4c makes a difference - areas of highest impact:

Design and planning of studies

- Providing advice to sponsors about innovative study designs, methodological aspects
- Outcomes directly impacting studies designed and conduct
- Reports supporting discussion with Regulatory Authorities

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Trial feasibility and opening of sites

- Aligned unique processes across the entire network to increase efficiency and quality
- Increase in number of high-quality sites available for site selection and feasibility

Data standards

- 1st Paediatric Data Dictionary established to allow standardisation of data collection across paediatric studies

Education

- Providing standardised training to all study sites and site personnel
- Advanced Course in Paediatric Clinical Trials and Drug Development

Patient and Public Involvement (PPI)

- Working with National Hubs, sites, and sponsors to improve PPI engagement plans of ensuring systematic involvement across all stages of development
- Directly impacting design and planning of studies

Nineteen National Hubs are serving 21 countries across Europe. This net of National Hubs is providing a national corporate memory that meets specific needs of Sponsors, Contract Research Organisations, and Academic Investigators during trial setup and conduct.

Sustainability in this harmonisation process is key for the long-term improvement of availability of medicinal products for children to circumvent the unmet medical need.

c4c is currently developing a business model. The new legal structure will be implemented before the end of the funding period of the current consortium in spring 2024.

c4c will provide services in relation to trial development and conduct, expert advice, involvement of patients and families, interaction of National Hubs and networks of sites and also education and training to support the use of the network and broader needs in paediatric medicinal product research.

A defined strategy is given in the outline (2) of c4c which covers interactions in relation to the clinical trial protocols, national networks, and cross-referencing with specialty networks, a Single Point of Contact for sponsors and investigators and a coordinating Network Infrastructure Office.

Conclusion:

The c4c project will make a culture change that fosters international and global approaches with cooperation and collaboration across paediatric clinical trial development and conduct. It will deliver high-quality high-stringency data sets thereby promoting quality-by-study design and interoperability. There will be documentation of communication across various initiatives, thereby avoiding working in silos and duplicating efforts.

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conect4children is combining preparatory and implementation work as a public-private partnership under Europe's Innovative Medicines Initiative 2 Joint Undertaking (IMI 2 JU) (https://www.imi.europa.eu/projects-results/project-factsheets/c4c). The IMI 2 JU c4c project was launched in May 2018 and the IMI2 grant will end in April 2024.

Parties involved

Under the name c4c, the research consortium unites pharmaceutical companies, paediatric national networks as well as EU multinational sub-specialty networks, large patient advocacy groups, children's hospitals, and other public research organisations from across Europe.

For details on the project and the partners please visit https://conect4children.org/.

(1) 10-year report to the European Commission on Regulation (EU) No.1901/2006

(2) https://conect4children.org/feasibilityadviceservice

Heidrun Hildebrand, Bayer AG, Pharmaceuticals, Pediatric Development & c4c Project Co-leader
Birka Lehmann MD PhD GFMD, Senior Expert Drug Regulatory Affairs, EAB c4c Project

1st Course RECLIP-AMIFE: Clinical Research in Paediatrics

Coordination: Dr Lucas Moreno and Dr Julián Sevilla

A great increase in the number of clinical trials in paediatrics have been observed after the implementation of the European Regulations on Paediatric Research (No 1901/2006 of the European Parliament and Council). To incorporate clinical trials in daily medical practise is a new challenge and there exists an important need for an appropriate and complete training of paediatric health professionals in this field. This need for training in specific aspects of paediatric clinical trials may affect physicians, nurses, or coordinators of clinical trials. RECLIP, Spanish Network of Paediatric Clinical Trials, together with AMIFE, the Spanish Association of Pharmaceutical Medicine, invited postgraduate residents in paediatrics, paediatricians, research nurses and study coordinators (pharmacists, nurses) to learn about the fundamentals of clinical research in paediatrics and get acquainted with the day-to-day running of a clinical trial in children.

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The Faculty of this Course on Clinical Research in Paediatrics included the following professionals: Elena Andretta, Study Coordinator, Vall d Hebron Institut de Recerca, Barcelona; Francisco Bautista. Clinical Scientist, Trial and Data Centrum, Princess Maxima Centrum, Utrecht, The Netherlands; Cristina Calvo, Head of Paediatric Department and Infectious Diseases, University Hospital Universitario La Paz, Madrid; Joana Claverol, Director of Clinical Research Unit, Hospital Sant Joan de Deu, Barcelona; Marta Cubells, Nurse, Hospital Sant Joan de Deu, Barcelona; Isabel Echave, Senior Clinical Operations Manager, Bristol Myers Squibb, Madrid; Lourdes Herreros, Manager Study Start Up Delivery, ICON plc, Madrid; Silvia Martín Prado, Pharmacist, Specialist in Hospital Pharmacy, University Children Hospital Niño Jesús, Madrid; Federico Martinon, Head of Paediatric Department, Clinical University Hospital, Santiago de Compostela; Lucas Moreno, Head of Paediatric Haematology and Oncology, Hospital Vall d'Hebron, Barcelona; Begonya Nafria, Coordinator of Patient Engagement, Institut de Recerca Sant Joan de Déu, Barcelona; Nicolás Palomo Moreno, Senior Clinical Operations Lead, Roche Farma, Madrid; Carmen Rodríguez Tenreiro, Doctor in Pharmacy, Research Coordinator, GENVIP, Hospital Clínico Universitario de Santiago de Compostela, Spain; Julián Sevilla, Head of Haematology and Haemotherapy, University Children Hospital Niño Jesús, Madrid; Pilar Suñé Martín, Doctor in Pharmacy, Coordinator of Clinical Trials Unit, Pharmacy Department, Hospital Vall d'Hebron, Barcelona; Ana Zamora, Director Clinical Operations, Pharmaceutical Product Development (PPD), Madrid.

We are very pleased with the feedback received after completing the first edition of our RECLIP-AMIFE Course on Clinical Research in Paediatrics. The faculty included a wide representation of all stakeholders included in the clinical research process such as clinicians, academic researchers as well as representatives from pharma, regulators, and patients. With everyone's view included, the course offers a great overview of key aspects of clinical research involving children and adolescents. Students have greatly appreciated the practical sessions on day-to-day aspects of clinical trials. We are looking forward to future editions of the course and hope to consolidate it in Spain and internationally.

Dr Lucas Moreno, Head of Paediatric Haematology and Oncology, Hospital Vall d'Hebron, Barcelona

Continuing the Conversation on Digital Transformation with the EPF CONGRESS 2022

The European Patients' Forum is pleased to announce the EPF Congress 2022 – Continuing the conversation on digital transformation - will be held on 23 and 24 June 2022 in a live-streamed format. This unique event will take place at the DoubleTree by Hilton, set in a prime location in the heart of Brussels, Belgium, with the option of online participation for those who wish to join us remotely.

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2022 EPF Congress

Continuing the *conversation*
on digital transformation

DOUBLETREE BY HILTON BRUSSELS

23 - 24 JUNE 2022

The EPF Congress 2022 will include a wide audience of patient representatives, policymakers, health systems experts, healthcare profession representatives, academics, and industry representatives, from Europe and beyond.
Join us and hundreds expected to exchange on the path forward for integrated digitalised healthcare on 23 and 24 June for two days of learning, exploring, testing ideas, and co-creating solutions.

More details, registration and preliminary programme are now available on our dedicated website www.epfcongress.eu.

The European Patients' Forum (EPF) is an umbrella organisation that works with patients' groups in public health and health advocacy across Europe. We currently encompass 78 patient organisations representing 21 countries and an estimated 150 million patients across Europe, making national coalitions of patients and specific chronic disease groups visible at the EU level. More information on our work can be found on our website: www.eu-patient.eu.

Chiara Boni, EPF's Communications Officer

Conference to Pave the Way for the Next Decade of Rare Diseases

"Only Europe can make the invisible visible, and finally serve all of its citizens' needs."

– Amanda, Belgium (#30millionreasons campaign)

EURORDIS RARE DISEASES EUROPE

While great progress has been made thanks to scientific advances and efforts at the EU and national levels, the last rare disease strategy and the only one so far was over a decade ago. Since then, technology, science and indeed legislation have progressed, but many people living with a rare disease are still facing unmet needs and inequities in accessing a diagnosis, treatments, and care, leaving them marginalised in society. A coordinated strategy is the only way to ensure that actions are considered and coordinated in a comprehensive manner to reach meaningful goals for patients, families and for society at large.

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This will be the focus of the largest patient-led European Conference on Rare Diseases and Orphan Products (ECRD) 2022, an official event of the 2022 French Presidency of the Council of the EU. This 11th edition follows a pivotal two-year Rare 2030 Foresight Study, supported by the European Parliament and European Commission, that guided a large-scale and multi-stakeholder reflection on rare disease policy in Europe through 2030.

"The EU has the science, the healthcare and the industry to help patients suffering from rare diseases. Political will and incentives can turn science into treatments."

– Boris, France (#30millionreasons campaign)

The ECRD 2022 programme mirrors current political opportunities and policy milestones – such as the United Nations Resolution on Addressing the Challenges of Persons Living with a Rare Disease adopted last year – and also presents an opportunity to hear from the European and international institutions, key opinion leaders working in the field, and persons living with a rare disease to shape the best possible future framework of policies. This framework would provide an opportunity to set three ambitious goals and a number of sub-targets to tackle Europe's challenges, including:

- Ensuring healthy lives and promoting well-being for all people living with a rare disease at all ages;
- Reducing inequality within and among countries by focusing on equity for people living with a rare disease;
- Building resilient infrastructure, promoting inclusive and sustainable industry and fostering innovation for people living with a rare disease.

Aligned with several of the UN Sustainable Development Goals (SDGs), these goals would help accelerate Europe's contribution to achieving the UN Agenda 2030.

Taking place online from 27 June to 1 July, the ECRD is recognised globally as the largest, patient-led rare disease policy event in which collaborative dialogue, learning and conversation take place, forming the groundwork to shape goal-driven rare disease policies and allow for important and innovative discussions on a national and an international level to take place.

Leading, inspiring and engaging all stakeholders to take action, the Conference is an unrivalled opportunity to network and exchange invaluable knowledge with over 1,500 stakeholders in the rare disease community – patient advocates, policy makers, researchers, clinicians, healthcare professionals, healthcare industry representatives, academics, payers, regulators, and Member State representatives.

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"A rare disease makes life difficult for the whole family. Even the slightest help can make a huge difference in the lives of every family member."

– Patricia, Germany (#30millionreasons campaign)

Don't miss out on this unique opportunity to drive change for a better future for the 30 million Europeans living with a rare disease. Register now at: https://www.rare-diseases.eu/register/

Stanislav Ostapenko, Communications Manager,
Email: stanislav.ostapenko@eurordis.org

Two Years Later: A Look Back, Part 1

In this three-part series, Marlene Llópiz looks at how the pharmaceutical world was affected by the COVID-19 pandemic.

On March 11, 2020, the World Health Organization (WHO) announced the start of a pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The virus and disease were first identified in December 2019 in Wuhan, China, rapidly spreading worldwide.

The number of cases and the number of deaths continued to rise rapidly in the following months, requiring countries to escalate their response and take action as soon as possible. Such actions were to help delay the pandemic, giving healthcare systems time to prepare and assimilate the impact. However, the virus was much faster.

Irrespective of the disease's trajectory in each country, there were several actions that needed to be taken. There was no one-size-fits-all approach across the world. The past two years have been full of incongruities from health organizations, governments and people, as well as paradoxes and absurdities. Was/is COVID-19 a common enemy? Are we still at its mercy?

In some ways it is or has been. And yes, we are somewhat at its mercy still.

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However, each country has approached the pandemic differently, following:

- their own timelines
- facing difficulties with previously established budgets
- never contemplating or having experienced this emergency and
- tackling the problem as swiftly as possible

Was/is there worldwide solidarity? Were the pharmaceutical companies part of that solidarity?

It is often said that confusion is often but a first step toward clarity. The world is/was/has been confused. Are we still confused? Have all our questions been answered? Far from it.

The word “pandemic” is not a word to be used lightly or carelessly. It is a word that, if misused, can cause unreasonable fear, or unjustified acceptance that the fight is over, leading to unnecessary suffering and death. Describing the situation as a pandemic did not change the WHO’s assessment of the threat posed by this virus. It didn’t change what the WHO was doing, and didn’t change what countries had to do at the time and further on. We have never before seen a pandemic sparked by a coronavirus. This was the first pandemic caused by this virus.

Describing the situation as a pandemic required countries to accelerate their efforts, striking the right balance between protecting health, preventing economic and social disruption, and respecting human rights. This was no different for pharmaceutical companies. They had to intervene in all the steps along the way.

While every country was responsible for determining the nature and timing of measures introduced to prevent or slow down viral transmission, the WHO considered that social distancing and quarantine measures needed to be implemented in a timely and thorough manner. This was also true at pharmaceutical firms, offices and manufacturing plants.

Some of the measures that countries considered adopting were: closures of schools and universities, implementation of remote working policies, minimizing the use of public transport in peak hours and deferment of nonessential travel.

We soon learned that COVID-19 impacted the elderly and those with pre-existing health conditions most severely. In a spirit of solidarity, we all had to be ready to contribute our part to protect those at the highest risk. As individuals, practicing good hygiene and prevention measures, as well as applying measures of social distancing, including avoiding crowded places, still today, continue to be very important.

It was recommended that those who do not feel well should stay home and contact their healthcare providers. Solidarity meant that we had to strictly abide by the regulations and procedures being put in place by health authorities in our countries, register symptoms, get tested (once it was available), and finally vaccinated as vaccines rolled out.

Many government health authorities have taken an active role, working side by side with countries and regional partners in their efforts to prevent or mitigate the impact of COVID-19 on our citizens.

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The WHO and government authorities from each country have humbly acknowledged that COVID-19 has been a fast-evolving situation. We may not always have the best evidence at hand on which to base our decisions, but we did not have the luxury of time to wait until better evidence became available.

In the face of such an alarming situation with a heavy toll on our healthcare services and vulnerable individuals, there could be no doubt that the time-honored precautionary principle needed to guide our decisions when concerning the pharmaceutical world.

Two aspects need to be considered as part of the same puzzle: 1. the pharmaceutical industry as a company and provider, and, 2. its massive number of employees.

No doubt the pharmaceutical industry had to change its way of doing business.

So, what did the pharmaceutical industry do?

- Sent everyone home
- Canceled all face-to-face meetings: advisory boards, focus groups, medical visitations
- Postponed internal gatherings for all personnel
- Changed training sessions
- Canceled hiring new staff in the usual way
- Put on hold clinical research trials on other topics
- Focused on COVID for vaccines and treatment

Home-offices became a new world for all. It was a difficult switch to become used to. Staff staying at home would never be the same as having them in the next cubicle, office or on another floor. Communication was different, impersonal, long distance – even if within the same city. The "personal touch" was gone. There was no interaction, sharing of work or even life and family events. Longer hours were consumed on work – burnout, resilience and mindfulness came to be common and highlighted in our everyday jobs.

The pharmaceutical world suffered.

No doubt the pharmaceutical industry had to change its way of doing business. Patient centricity was at a stalemate. Medical representatives, medical and scientific liaisons were kept from visiting physicians and key opinion leaders. Clinical research trials were paused or came to a standstill for a while.

Part 2 of this series will touch upon how the pharmaceutical companies optimized and guided their employees in such a critical situation.

Marlene Teresa Llópiz Avilés
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This article has been reprinted from Mexico Business News (https://mexicobusiness.news/health/news/two-years-later-look-back-part-1) with kind permission of the publisher.

Belle Arts Palace in Mexico City
(Daniel Mejía, Mexico City)

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Postgraduate Education in Pharmaceutical Medicine

Trinity College Dublin, the University of Dublin is pleased to announce their MSc and Postgraduate Diploma in Pharmaceutical Medicine courses are open for September 2022 enrolment.

Course Description and Recognition

These established courses provide suitably qualified healthcare professionals and health science/research professionals with specialist knowledge and skills in all aspects of pharmaceutical medicine to enable them to elevate their professional role within the pharmaceutical industry and healthcare system.

Students on the courses will deepen their understanding of each stage of the lifecycle of medicines and medical devices. Topics such as clinical development, licensing procedures, biotechnology, and pharmacovigilance will be covered from a regulatory, ethical, legal, and scientific perspective.

Pharmaceutical Medicine is a global discipline establishing a skills base to meet the demands of an evolving Pharmaceutical Healthcare industry. We are an accredited Centre of Excellence for Pharmaceutical Medicine training by the PharmaTrain Federation who provide the highest recognition available in Medicine Development Training.

The courses are recognised as part of the Higher Specialist Training in Pharmaceutical Medicine by the Royal College of Physicians of Ireland. Additionally, Ireland's Minister for Health gave formal recognition to Pharmaceutical Medicine as a medical specialty in 2005.

Information on the Course

The courses are run part-time to offer busy professionals flexibility in learning. To facilitate this we utilise blended learning, interactive workshops, in-person teaching and e-learning.

Educational support is provided by the Faculty of Health Sciences in Trinity and experts from the National Centre for Pharmacoeconomics and National Medicines Information Centre in Ireland; national and international regulatory authorities; patient organisations; and the pharmaceutical industry.

Location: Trinity College Dublin, Ireland (2-3 days per module) and Online

Language: English

Duration: 24 months (MSc)/ 18 Months (Postgraduate Diploma)

Closing Date: 31st July 2022

For more information please click here.

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THE FLAG

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