IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

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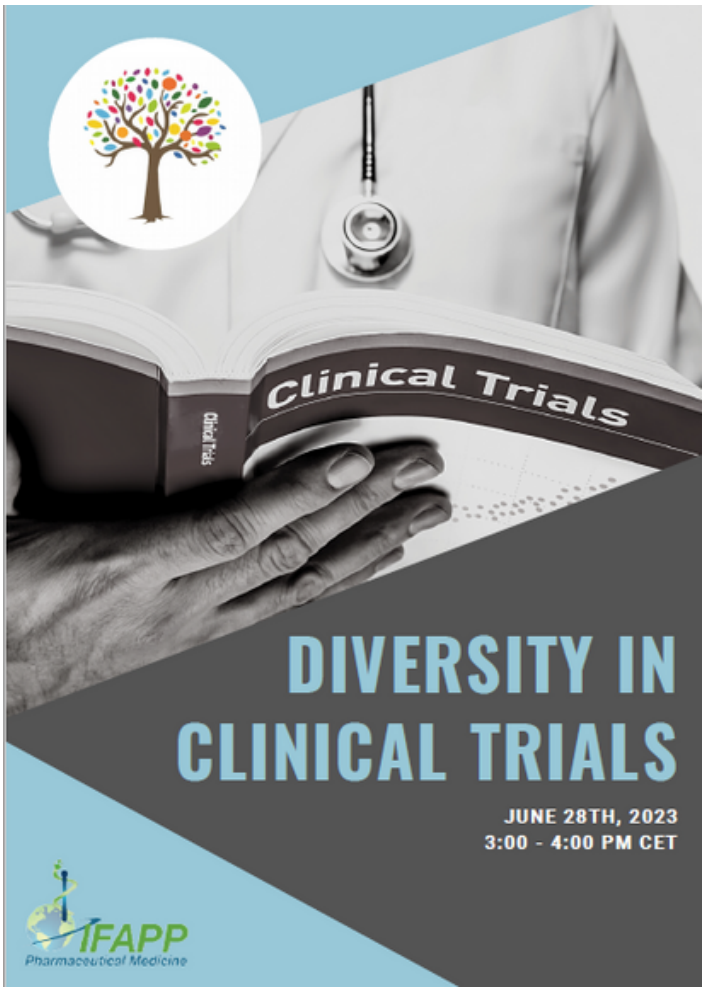

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Diversity - A Key Focus of Clinical Trials

It is important that subjects participating in clinical trials truly represent the complete target population. However, there is the methodological need for standardisation of in- and exclusion criteria as well as the study conditions to reduce data variability and ultimately the required number of enrolled patients to be able to show the true difference between two treatments.

The new EU Regulation on Clinical Trials aims at facilitating diversity by defining the ethical and legal conditions for enrolling vulnerable patient groups like minors and pregnant or breastfeeding women. But the request for more diversity goes beyond this.

It is of outmost relevance to design a clinical trial protocol and to conduct clinical trials with increased diversity to avoid

- neglecting patient groups in need for access to a new treatment option only offered in a clinical trial
- restrictions on the future labelling of a medicine
- concerns of healthcare practitioners that the information for use determined by the competent authorities does not reflect the population they want to treat; therefore, they are uncertain about how to use the medication.

It's essential that clinical trials include people with diverse characteristics in ethnicity, genome, age, sex, and sexual orientation, so that all communities can benefit from scientific advances as soon as possible.

REGISTRATION

- This webinar is free to everybody
- Click here for registration

After registering, you will receive a confirmation e-mail containing information about joining the webinar.

Speaker:
Kerstin Breithaupt-Grögler (MD, PhD)
Board Certified Specialist in Clinical Pharmacology
AGAH Regent (Association of Applied Human Pharmacology, AGAH e.V.)
AGAH Delegate to EUFEMED

Moderator:
Ingrid Klingmann (MD, PhD)
President, PharmaTrain
Chairman, EFGCP
Member of the Board, EUFEMED

Time Schedule
09:00 - 10:00 AM EST
01:00 - 02:00 PM GMT
03:00 - 04:00 PM CET
10:00 - 11:00 PM JST

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PharmaTrain Syllabus Revision Project 2023

The importance of education and training in pharmaceutical healthcare is readily understood. The genesis for PharmaTrain was based upon this principle, striving to elevate knowledge in the lifecycle of medicines initially within Europe and now expanding globally as the not-for-profit organisation "PharmaTrain Federation" (www.pharmatrain.eu).

As with many elements of the pharmaceutical industry, harmonisation brings rewards in terms of a more timely, cohesive approach. The coordinated work of the PharmaTrain Federation ensures quality in the Pharmaceutical Medicine education provided. They achieve this by applying common standards and guidelines for universities and denote centres that have gained PharmaTrain recognition as well as centres of excellence.

A key element of this harmonisation is the PharmaTrain syllabus of Pharmaceutical Medicine that defines learning outcomes for course providers from which curriculum and assessments are derived. The earliest version of the syllabus was devised as part of the IMI (Innovative Medicines Initiative) European PharmaTrain project and subsequently revised for Version 2.0 in 2018 encompassing 160 topics across 13 sections. This procedure was coordinated by a collective of experts from IFAPP, the PharmaTrain Federation, and the Faculty of Pharmaceutical Medicine.

The field of Pharmaceutical Medicine is continually evolving with areas such as Real-World Evidence, electronic health, decentralised trials, Artificial Intelligence, and the ripple effect of COVID-19 to highlight a few. To maintain up-to-date knowledge and professional development, the PharmaTrain syllabus must also be kept current. Revision of the PharmaTrain syllabus commenced towards the end of Q1 of this year, managed again under the auspices of the three bodies with Prof Peter Stonier as Project Convenor.

Introductory meetings were held in April to discuss the aim of the Syllabus Revision Project and operations for completion. Given the scope involved, each section has a designated lead as well as members with experience consenting to be assigned to it. The process will allow time for the members to review topics, address research developments in the field and consult with colleagues on where amendments should be rationally made. The project coordination group will then carefully consider the revisions proposed against the backdrop of Pharmaceutical Medicine as a discipline, and the implementation of the syllabus by course providers. The process is envisaged to take several months to complete but is an important renewal step to take ensuring current knowledge and expertise is maintained in Pharmaceutical Medicine.

Author: Dr Joanne M Ramsey, Assistant Professor of Pharmaceutical Medicine,
Trinity College Dublin; PharmaTrain Syllabus Revision Project Coordinator for IFAPP.

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Conect4children: From IMI Project to a Sustainable Pan-European Paediatric Clinical Trial Network

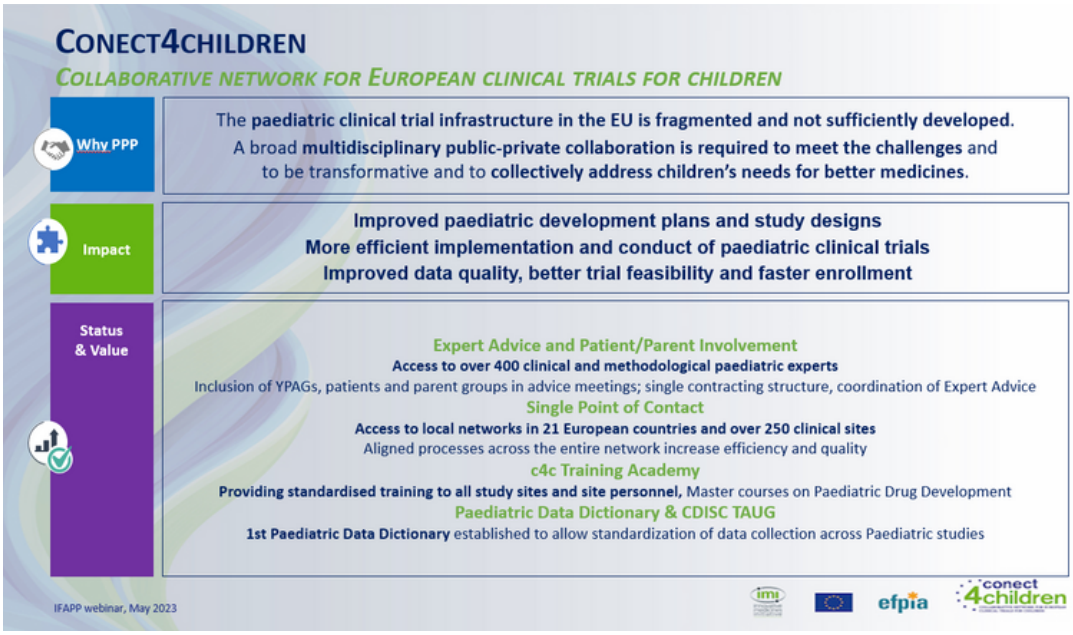
Report from the IFAPP Webinar on 4 May 2023

Professor Dr. Mark Turner BSc; MBChB; CCST in Paediatrics/Neonatal Medicines Institute of Life Course and Medical Sciences, University of Liverpool, c4c co-ordinator, and Heidrun Hildebrand, Research and Development, Pharmaceuticals, Bayer AG, Germany, c4c co-project lead, presented the topic.

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 paediatric investigation plans (PIPs), additional actions are necessary to overcome fragmentation of the European paediatric research landscape leading to several barriers like inconsistent processes and historically driven, non-harmonised stakeholder approaches.



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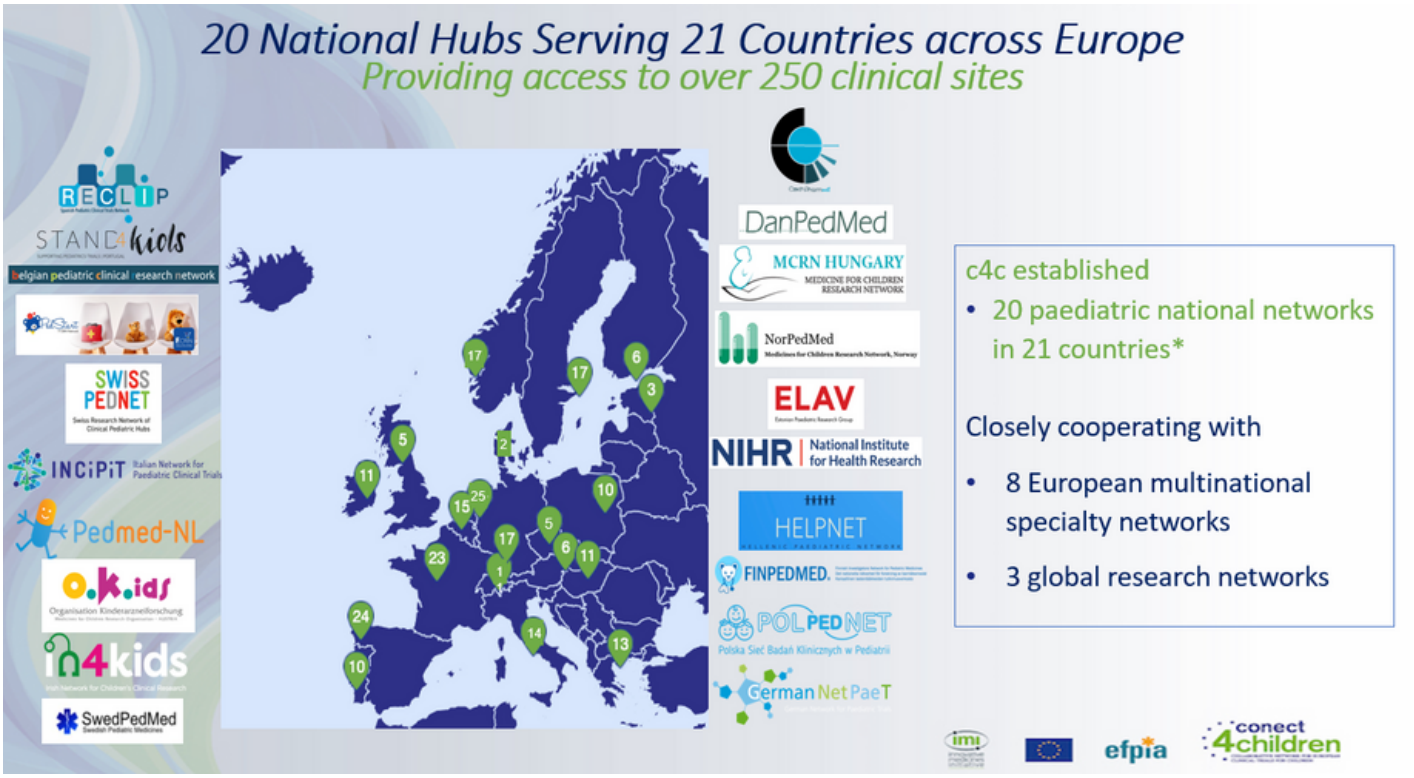
c4c (conect4children) is a large collaborative European network that facilitates the development of new drugs and other therapies for the entire paediatric population. It constitutes a pioneering opportunity to implement high-quality multinational paediatric clinical trials while ensuring the needs of babies, children, young people, and their families are met.

Recognising the challenges within the European paediatric research landscape and the needs of its main stakeholders, c4c has developed a forward-looking strategy with a cutting-edge service portfolio that addresses these prevailing challenges. Services consist of Expert Advice, so-called "Strategic Feasibility Advice" during design and planning of clinical studies, trial feasibility, support during site identification and set-up; as well as during study conduct ensuring high quality and aligned way of working across all network sites, education, and training – all these services are opened for all types of sponsors and accessible through a single point of contact. In addition, c4c has developed standards for data collection in paediatric studies.



Initiated in 2018 with funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) the consortium includes 35 academic, 10 industry and around 500 affiliated partners. Since start of the project c4c has built a functioning network and is in the process to implement a sustainable successor organisation, a Dutch not-for-profit, the "conect4children Stichting (c4c)".

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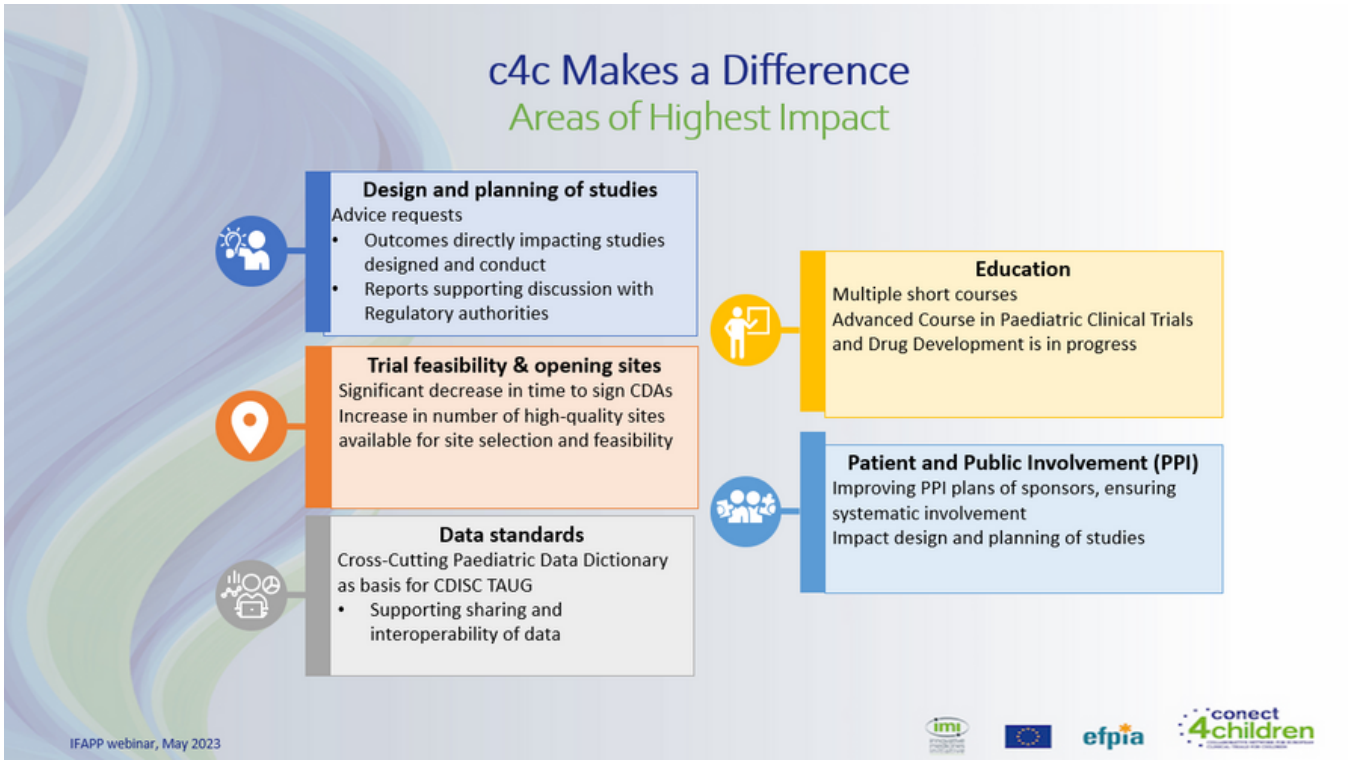

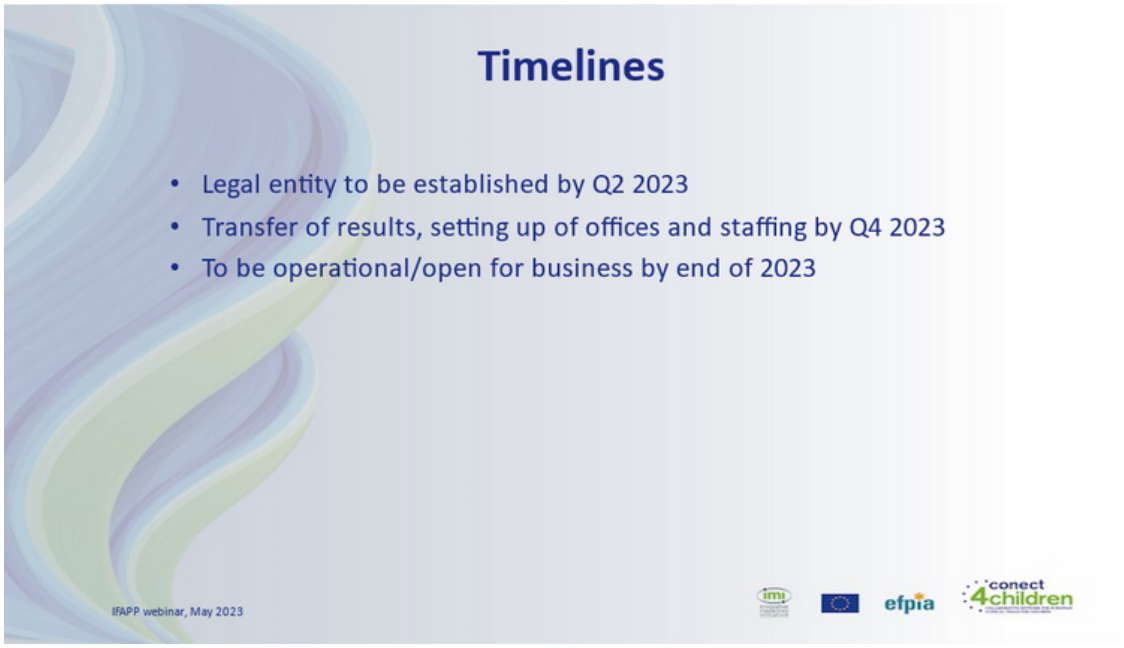

Authors:

Heidrun Hildebrand, Research and Development, Pharmaceuticals, Bayer AG, Germany, c4c co-project lead

Birka Lehmann, MD PhD, GFMD, IFAPP Education and Certification Working Group Chair, Senior Expert Drug Regulatory Affairs

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Regulatory Science: Approaching the Future of Medicine

Summary Report of EL.E.F.I. Scientific Webinar on Regulatory Science, 23 Feb 2023

Pharmaceuticals are products that have a profound impact on the health and well-being of individuals. The regulation of pharmaceuticals is essential to ensure that these products are safe and effective, for these reasons regulatory agencies across the globe imply strict guidelines for the approval and follow-up of treatments.

Regulatory affairs refer to the set of activities that pharmaceutical companies undertake to ensure that their products are safe, effective, and compliant with regulatory requirements and guidelines in order to facilitate the approval and marketing of pharmaceutical products. These activities include preclinical and clinical research, drug development, and post-marketing surveillance, among others.

While the basic principles of regulatory affairs have remained the same over the years, in recent years, pharmaceutical companies have faced new challenges that require a re-evaluation of existing practices and the adoption of new strategies. In this article, we will explore some of the new challenges facing pharmaceutical regulatory affairs and how companies can adapt to them.

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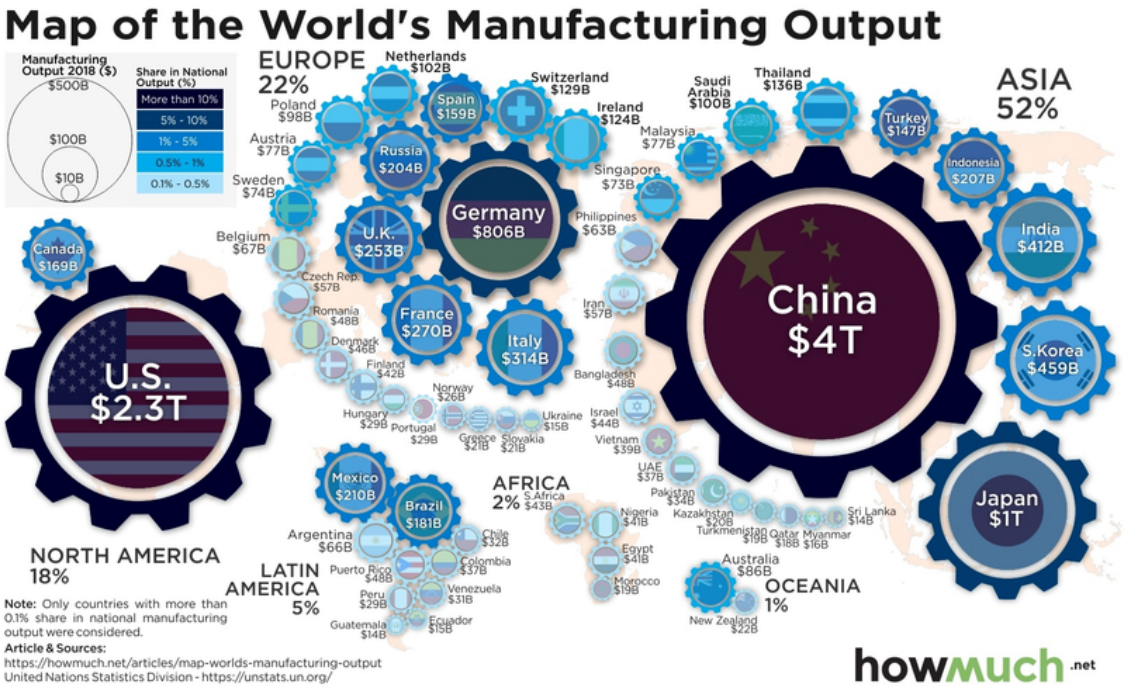
Increasing Regulatory Complexity and Globalisation:
Regulatory agencies across the globe have become more sophisticated in their requirements for drug approval, with more stringent standards for safety, efficacy, and manufacturing. On top of this, many modern pharmaceuticals are biologics, which are derived from living cells or complex artificial bio-nanostructures that are able to encapsulate biomolecules for therapeutic purposes. Biologics and nanostructures are more complex than traditional chemical-based drugs and require a different regulatory approach. Another issue is the approval of off-patent generic, biosimilar and nano-similar products. While generic drugs have not a very big complexity in regulatory processes, biosimilar and nano-similar products create also a huge challenge for regulatory affairs and authorities.

Additionally, the use of combination products, such as drug-device combinations, presents a new complexity for regulatory affairs. These products require the coordination of multiple regulatory agencies to ensure their safety and efficacy.

Another challenge is the globalisation of pharmaceutical development and manufacturing. The outsourcing of pharmaceutical manufacturing to countries with lower labour costs has led to an increase in the number of products coming from emerging markets. China for instance became the biggest pharmaceuticals manufacture globally. This development has created new uncertainties for regulatory affairs. Additionally, the regulation of clinical trials conducted in emerging markets requires higher vigilance for regulatory affairs.

The increasing complexity of regulations has resulted in longer approval times, higher costs, and a more significant risk for companies. In addition, as pharmaceutical companies increasingly operate in global markets, they must navigate a complex patchwork of regulatory requirements across different countries and regions as regulatory requirements may differ between countries, adding an additional layer of complexity and increased costs for companies that operate globally.



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Emergence of New Technologies & Digital Health:
The rapid pace of technological innovation in the pharmaceutical industry has brought new opportunities for drug development and delivery, but it has also introduced new regulatory incertitude. While the use of advanced analytics, artificial intelligence (AI) and machine learning in drug development and clinical trials hold enormous promise for the future of medicine, it has raised questions about how to validate and regulate these tools. FDA is taking steps to promote innovation and support the use of AI-based medical devices or approves 3D printed drugs, but this is not evident for all health authorities across the globe. The use of AI in healthcare, for example, requires a new regulatory framework to ensure its safety and efficacy.

Innovative digital technologies in healthcare, including telemedicine, electronic health records, wearables and mobile health applications are increasingly being used to collect data on patients in real-time. These technologies have the potential to transform healthcare delivery.

While these technologies offer great promise for improving patient outcomes, they also raise questions about data privacy and security, as well as how to regulate these new forms of data.

Precision or Personalised Medicine:
An additional challenge for pharmaceutical regulatory affairs is the growing trend of precision or personalised medicine. Personalised medicine is the tailoring of medical treatment to the individual characteristics of each patient. It concerns medical treatment that target specific genetic mutations, biomarkers, or other unique characteristics. Advances in genetics and molecular biology have made personalised medicine a reality and created the opportunity to cover the unmet medical need for the treatment of rare diseases.

While personalised medicine may offer better treatment options for patients, it also triggers scepticism in terms of long-term safety but also in terms of affordability of increasing costs by healthcare systems. Although precision medicine such as gene therapies have the potential to improve patient outcomes and reduce overall healthcare costs including societal cost, currently the existing new treatments have higher prices than traditional treatment options. Despite that the investment in personalised medicine to treat a previously untreatable rare disease has an overall positive long-term societal outcome, the initial investments needed by healthcare systems are hardly affordable for most national healthcare providers.

The current regulatory framework was designed for drugs that treat broad patient populations, making it difficult to evaluate drugs that are only effective for a small subset of patients. Moreover, traditional clinical trial designs may not be suitable for personalised medicine, as the treatment must be tailored to each patient's specific needs. Additionally, the use of biomarkers, companion diagnostics and other diagnostic tools which are medical devices subject to their own regulatory requirements, increase the complexity of the regulatory framework.

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RWD & Big Data:
The use of real-world data (RWD) to support regulatory decision-making has also gained traction, creating new requirements for data collection, analysis, and evidence generation.

Real-world evidence (RWE) is the evidence derived from RWD collected outside of traditional clinical trials. This can include data from electronic health records, claims data, and patient-generated data. RWE has the potential to provide valuable insights into the safety and effectiveness of drugs in the real world.

However, using RWE requires new regulatory assessment approaches. Regulators must ensure that the data is reliable and accurate, and that it meets relevant quality standards.

Pharmaceutical companies must also invest in the development of new data management and analysis tools that can handle the large volumes of data assessed to generate RWE. They must also work closely with regulators to ensure that their use of RWD meets all regulatory requirements.

The Impact of COVID-19:
The COVID-19 pandemic has highlighted the importance of pharmaceuticals, and their regulatory environment, like never before. Governments around the world have been quick to respond to the pandemic by enacting emergency measures to ensure that vaccines and treatments can be developed and distributed quickly. However, these measures have raised challenges that need to be addressed. One of the most significant challenges was the need to balance speed with safety. The rapid development and deployment of COVID-19 vaccines and treatments have been unprecedented. This has raised concerns about the safety and efficacy and the well-being of trial subjects. On the one hand, the implementation of innovative remote monitoring measures for clinical trials in order to increase speed, and on the other hand the advanced analytics supported by RWE and big data created a new environment in development trials.

Regulatory affairs have had to work quickly in close collaboration with regulatory authorities to assess the safety and efficacy of patients while ensuring that new standards meet necessary requirements.

Patient-Centred Drug Development & Increasing Demands for Transparency:
In the last decades it became evident that the pharmaceutical industry should include patient experience in all steps of drug development. Patients and advocacy groups are increasingly demanding more transparency and involvement in the drug development process, while payers and policymakers are looking for ways to control rising drug costs. Regulatory affairs must also grapple with evolving societal expectations around drug safety and access.

Patient-centred drug development involves engaging patients throughout the drug development process to ensure that their needs and preferences are considered. The rise of patient-centred drug development is a high priority area for regulatory affairs. This approach requires a new regulatory framework with greater emphasis on patient-centred drug development by ensuring that patient input is adequately incorporated into the drug development process and regulatory decision-making.

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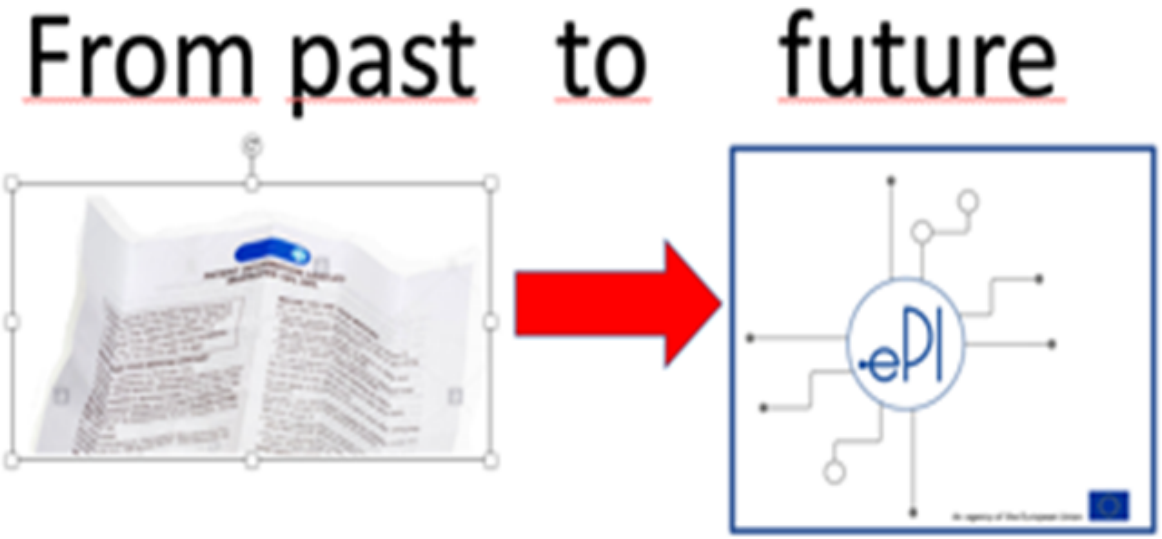
Conclusion:
Pharmaceutical regulatory affairs are facing new challenges with increasing complexity of modern pharmaceutical products. To address all these novelties, pharmaceutical regulatory affairs will need to adopt new strategies and embrace innovation. One key approach is to leverage new technologies, such as artificial intelligence and machine learning, to improve the efficiency and accuracy of drug development and regulatory decision-making. Manufactures currently implementing advanced data acquisition and analytics tools supported by AI and digital technology in order to improve quality, mitigate risks and reduce time of process verification and quality controls.

The need to balance speed with safety, the rise of personalised medicine, the increasing complexity of pharmaceutical products, the globalisation of pharmaceutical development and manufacturing, the use of digital technologies in healthcare, the rise of patient-centred drug development and evolving societal expectations are all presenting important priorities for regulatory affairs. Addressing these changes will require a combination of new strategies, innovative approaches, and a coordinated effort across regulatory agencies, pharmaceutical companies, healthcare providers, and patients. By rising to these challenges, pharmaceutical regulatory affairs can help ensure that patients have access to safe, effective, and affordable medicines that meet their needs.

Author: Grigorios Rombopoulos MD, Consultant in Endocrinology & Diabetes, Vice President Hellenic Society of Pharmaceutical Medicine (EL.E.F.I.)

ePI – Electronic Product Information

Report from the IFAPP Webinar on 20 April 2023



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Professor Tatyana Benisheva MD, Dsci, MRDA, Bulgarian Association for Drug Information – BADI, presented this topic.

Directive 2001/83/EC paves the way that the electronic package leaflet should be provided as a supplement to the paper package leaflet in the outer package of the medicinal product.

Acc. to Article 58:
The inclusion in the packaging of all medicinal products of a package leaflet (PL) shall be obligatory unless all the information required by Articles 59 and 62 is directly conveyed on the outer packaging or on the immediate packaging.
And Article 62 permits symbols or pictograms for the purpose of providing information in the outer (and immediate) packaging and the PL and, therefore, a reference to the use of mobile technologies.

The European medicines regulatory network (European Medicines Agency (EMA), Heads of Medicines Agencies (HMA) and European Commission (EC)) adopted an EU common standard for electronic product information (ePI) with the following goals:

- It will pave the way for wider dissemination of the unbiased, up-to-date information on all medicines available to patients in the EU through electronic channels.
- The ePI can be updated immediately, as soon as new information becomes available.
- The structured nature of the ePI will also offer new opportunities to personalise the product information to individual needs and to make it more easily accessible to users.
- Future developments of ePI could include functionalities such as automatic update notifications, access to supportive videos or audio content and online adverse reaction reporting tools.

What are the advantages of Product Information 4.0 (GI 4.0)?
The requirements for instructions for use are manifold: First and foremost, they must be correct, up-to-date, and understandable.

Furthermore, they should also be accessible anytime and anywhere as well as be clear and usable.
The Product Information 4.0 offers a convincing approach to combine all these points.

The up-to-date and rapid availability are ensured by the electronic version of the package leaflet. The up-to-date, correct instructions for use are provided by the pharmaceutical companies. In addition, the user-friendly presentation meets the desire of many patients for easy availability and easy findability of the information.
In accordance with legal requirements, the paper version, the so-called "package insert", will continue to be included in the drug package.

Challenges are remaining:
For regulatory reasons, this information must still be provided in paper form.
Having additional structured electronic version of package leaflets or Healthcare Professionals' summaries, via a convenient and easily accessible digital platform, offers significant personalised benefits to all parties.

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It will make it easier to search for information on medicines of interest, to receive automatic update notifications, to access authorised or supportive video or audio content, or other interactive materials.
Innovations such as online reporting tools to capture information about adverse reactions is significant in a digital context.

Healthcare Professionals (HCP) could compare the old version of the PI with the new one in order to identify the differences. The option of identifying the changes, e.g., by using the track-change mode, can be quickly applied by the patients and Healthcare Professionals.

Authors:
Tatyana Benisheva, Professor, MD, Dsci, MRDA, BADI
Birka Lehmann, MD PhD, GFMD, IFAPP Education and Certification Working Group Chair, Senior Expert Drug Regulatory Affairs

Invitation 28th Annual Swiss Symposium in Pharmaceutical Medicine 2023

Optimising Patient Engagement and Ensuring Access to Treatment

29 November 2023 at Musikschule, Florhofgasse 6, Zurich

Dear Colleagues

This year's Annual Symposium in Pharmaceutical Medicine will again take place at Florhof in Zurich. This year's meeting is dedicated to Patient Engagement. The Meeting will be opened by a Key Note Speech on Patient Involvement in Medicines Development showing how the patient is nowadays engaged as a central partner in Drug Development.

This presentation will be followed by an Ethics Committee View on Informed Consent as one of the most important features of clinical trials. Patients have to be properly informed to enable them to agree to the investigations and medical tests foreseen in a clinical trial.

Patients need to be trained, in order to understand how and why clinical trials are performed to test new medicines. Such a training was developed some ten years ago by the European Patients' Academy on Therapeutic Innovation and there will be speakers who present its availability for Swiss patients. A representative of SAKK, the Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung, will talk about their Patient Advisory Board and how it operates. For the patient to understand research results a 'Good Lay Summary Practice' was developed for the general public and will be addressed in this symposium. It provides recommendations on how to prepare, write, translate, and disseminate summaries of clinical trial results in lay language.

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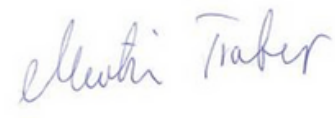
The symposium will continue with a talk on Decentralised Clinical Trials followed by an overview on the CIOMS Report on Patient Involvement in the Development, Regulation and Safe Use of Medicines published in 2022. The very important topic of world-wide and local Drug Shortages and what this means for the patient will also be presented and the last talk will deal with the very special topic of Business Continuity of Drug Development under Crisis Conditions by using the Ukraine Conflict as an example.

We look forward to an interesting day with lively discussions.
Yours sincerely,



Dr. med. Martin Traber
President SGPM
Swiss Society of Pharmaceutical Medicine

Optimising Patient Engagement and Ensuring Access to Treatment
29 November 2023 at Musikschule, Florhofgasse 6, Zurich

PROGRAMME
08:30 Opening of Registration Desk
09:00 Welcome by SGPM, President Martin Traber
Welcome by IFAPP

INTRODUCTION

SESSION I: Patient Involvement in Drug Development
09:15-10:00 Patient Involvement in Medicines Development – Progress and Gaps
Ingrid Klingmann; EFGCP and PharmaTrain, Brussels, Belgium

SESSION II: Informed Consent
10:00-10:30 Informed Consent – View of the Ethics Committee
Annette Magnin, KEK, Zurich, Switzerland

10:30-11:00 Coffee Break

SESSION III: Patient and Public Involvement
11:00-11:30 Enable the Involved Patient
Ivo Schauwecker, President EUPATI Switzerland, Board Member Positive Council Switzerland, and Barbara Peters, Head Training & Education, Clinical Research Department, University of Basel, Switzerland

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11:30-12:00 The SAKK Patient Advisory Board – Lessons Learned
Christine Aeschlimann, SAKK, Berne, Switzerland

12:00 – 12:30 Good Lay Summary Practice – How to Clearly Communicate Research Results
Kerstin Breithaupt-Groegler, -kbr- clinical pharmacology services, Frankfurt/Main, Germany

12:30-12:50 Music Performance

13:00-14:00 Lunch Break

SESSION IV: Patient Inclusion in Clinical Trials
14:00-14:30 Decentralised Clinical Trials – Adapting to Patients Needs
Lada Leyens, F. Hoffmann-La Roche, Basel, Switzerland
14:30-15:00 Patient Involvement in the Development, Regulation and Safe Use of Medicines
(CIOMS WG XI Report) Lembit Rägo, Council for International Organizations of Medical Sciences (CIOMS), Geneva, Switzerland

15:00-15:30 Coffee Break

SESSION V: Coping with Crisis for the Patient's Safety
15:30-16:00 Coping with Drug Shortages
Stefan Muehlebach, University of Basel, Basel, Switzerland
16:00-16:40 Developing Situationally Adaptive Approaches for Clinical Research in Addressing Crisis Situations. e.g., COVID-19, the Ukraine Conflict)
Francis P Crawley, Good Clinical Practice Alliance - Europe (GCPA), Leuven, Belgium

16:45-17:00 Résumé

Apéro

Early-bird Registration

Please register at http://annual-meeting.ch/registration/index.php

Participation fee

SGPM/SwAPP/IFAPP Members:	CHF 250.- until 1 October, 2023 early-bird fee
	CHF 350.- from 2 October, 2023
Non-Members:	CHF 450.- until 1 October, 2023 early-bird fee
	CHF 550.- from 2 October, 2023
Students:	CHF 100.-

This applies for students who graduated no more than 2 years before the symposium.

Groups or patient representatives, please contact us: info@annual-meeting.ch.

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Payment
Payment is required prior to the symposium.

Credit Points 1
SwAPP/SGPM: 6 credit points will be given.
SGKPT: 6 credit points will be given.
GSASA: 50 FPH-Punkte in Spitalpharmazie will be given.

Venue
Musikschule, Florhofgasse 6, CH-8024 Zurich (next to Kunsthaus Zurich, Tram No. 3)

Cancellation Policy
The registration is binding and entails a cost consequence. You may cancel 10 business days before the symposium and receive a full refund minus the cancellation fee of CHF 50.-. Cancellations less than 10 business days before the symposium date will not be refunded.

Update of programme:
The latest version of the programme can be found under: www.annual-meeting.ch
CVs will continuously be hyperlinked to the updated programme.

THE FLAG

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IFAPP is the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine.

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