IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE:

IFAPP's Key Achievements in the 1st Half of 2024

Dear IFAPP Colleagues and Members, Stakeholders and Community,

Allow me to share with you some of the key achievements of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine, IFAPP, in the first half of 2024.

1. Monthly editions of the IFAPP TODAY Journal

Your trusted Pharmaceutical Medicine companion in drug and medical device development, data-driven research and biomedical research ethics from the IFAPP Communication Working Group.

The IFAPP Communication Working Group has published six (40th - 45th) issues of "IFAPP TODAY" in the first half of 2024, a monthly journal that informs the global Pharmaceutical Medicine community about the latest news.

The IFAPP Journal welcomes contributions from all National Member Associations, individual affiliates, stakeholders and supporters.

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2. 2024 IFAPP Fellows

IFAPP honoured 26 biomedical scientists for their achievements in Pharmaceutical Medicine.
We are delighted to congratulate the 2024 IFAPP Fellows! These individuals have made significant contributions to the field of Pharmaceutical Medicine, and we are delighted to recognise and award them in the following categories:

- o Rising Star Fellow Award in Pharmaceutical Medicine: 1
- o Fellow Award for Scientific Excellence in Pharmaceutical Medicine: 13
- o Fellow Award for Scientific Leadership in Pharmaceutical Medicine: 12

3. IFAPP Publications

The IFAPP Ethics Working Group, which focuses on ethical considerations in Pharmaceutical Medicine, published a major peer-reviewed publication on the "Declaration of Helsinki (DoH): ethical norm in pursuit of common global goals" in Frontiers in Medicine on 02 April 2024, proposing revisions to the DoH on emerging new clinical trial designs and for optimal conditions for vulnerable people, contributing to the ongoing efforts of the WMA.

Check for updates

OPEN ACCESS

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Declaration of Helsinki: ethical norm in pursuit of common global goals

Chieko Kurihara[1,2*], Sandor Kerpel-Fronius[2,3], Sander Becker[2,4], Anthony Chan[2,5], Yasmin Nagaty[2,6], Shehla Naseem[2,7], Johanna Schenk[2,8], Kotone Matsuyama[2,9] and Varvara Baroutsou[2]

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4. IFAPP new Pharmacovigilance Working Sub-Group of Education and Certification WG

IFAPP welcomes, supports and celebrates the kick-off meeting of the IFAPP new Pharmacovigilance Working Sub-Group on 17 June 2024 and wishes the team a successful course and results.

5. IFAPP's active contribution to public consultations

IFAPP President Varvara Baroutsou, on behalf of the IFAPP Board, in collaboration with the Ethics Working Group and the External Affairs Working Group, submitted IFAPP's comments on the use of RWD-RWE in regulatory decision-making in response to the European Medicines Agency's public consultation in April 2024.

6. IFAPP registered in the European Union Transparency Register

IFAPP's application was approved and activated on 18 June 2024 and is now registered in the EU Transparency Register thanks to the External Affairs Working Group. Reg: 970411692295-33.

Transparency Register

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7. IFAPP's application to become an EMA stakeholder
IFAPP's application was successfully submitted to the EMA on 19 June 2024 by IFAPP's Executive Board and External Affairs Working Group.

8. IFAPP's Networking and Advocacy
Active participation of the IFAPP in the WMA revision of the DoH during the first half of the 2024 workshops through the involvement of volunteer members of the Ethics Working Group involvement.
IFAPP contribution to the VolREthics (Volunteers in Research and Ethics) initiative - Global Ethics Charter for the Protection of Healthy Volunteers in Phase I Clinical Trials: contribution to the public consultation in collaboration with volunteer members of the Ethics Working Group.
Election of the IFAPP President as a member of the CIOMS Executive Committee on 25 June 2024.

9. IFAPP Webinars
Five webinars successfully conducted by the Education & Certification Working Group:
"The Future of Clinical Trials: The Promise of AI and Key Trends" on 30 January 2024.
"The New Era of Cell Therapy: Innovative Approaches from Discovery, Production to Commercialisation" on 12 February 2024.
"The PharmaTrain Syllabus Revision 3", to be published by the PharmaTrain Federation, on 24 April 2024.
"CAR T-Cell Therapies, Ethical Aspects and Patient Involvement", on 29 May 2024.
"EU CTR Update Workshop" on 27 June 2024.

10. IFAPP International Conference on Pharmaceutical Medicine - ICPM 2025
Our flagship event is announced for 9-11 April 2025 in Amsterdam at the De Koepelkerk Renaissance Amsterdam Hotel. The conference promises to be an exceptional global platform for exchanging knowledge, fostering collaborations, and exploring the future of Pharmaceutical Medicine.

The scientific programme is meticulously designed to cover a broad spectrum of topics that are critical to the development and use of medicines. We are proud to highlight the following key categories that will be the focus of keynote lectures, oral presentations, panel discussions, and pro-con debates covering preclinical & clinical research, clinical operations, RWD-RWE, data-driven research, patient centricity, health economics & HTA, regulatory affairs, pharmacovigilance, medical devices, digital therapeutics, medical affairs, new technologies & AI and more.

More detailed information can be found in the monthly IFAPP TODAY Journal, IFAPP LinkedIn, the IFAPP website, IFAPP publications and IFAPP educational resources.

In closing this report, I would like to acknowledge the great work and dedication of the IFAPP Board Officers, IFAPP Working Group Leaders & Members, National Member Associations (NMAs) and Individual Affiliates (IAs) support.

I thank you for your continued support and commitment to the IFAPP community and wish you all the very best for the second half of the year and the upcoming holiday season.

Dr Varvara Baroutsou
IFAPP President

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Announcement: ICPM 2025 Conference

The International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) and the Dutch Association for Pharmaceutical Medicine (NVFG) are excited to announce that the International Conference on Pharmaceutical Medicine (ICPM) 2025 will be held from April 9 to 11, 2025, in the beautiful city of Amsterdam.

The theme of ICPM 2025 is **"Purpose for Future - in Pharmaceutical Medicine."** This theme underscores our commitment to advancing the field and shaping a future where innovative and effective medicines are developed and delivered with purpose and precision.

ICPM 2025 promises to be an exceptional platform for exchanging knowledge, fostering collaboration, and exploring the future of Pharmaceutical Medicine. The conference will feature a meticulously designed scientific programme covering a broad spectrum of critical topics, including:

- **Non-clinical Research:** Explore the fundamental scientific discoveries that drive pharmaceutical innovation, with a focus on drug discovery, molecular biology, biochemistry, gene and cell therapies, and the optimisation of translational animal models. Discover how artificial intelligence can enhance preclinical development for the future.
- **Clinical Research:** Explore the design, conduct and analysis of clinical trials. Gain insights into patient recruitment, ethical considerations and data management, as well as the impact of pharmacogenetics and reimbursement discussions on clinical trial design. As AI, new technologies and decentralisation become the norm, what will the future bring?
- **Clinical Operations:** Address operational challenges and solutions in clinical trials, including project management, site selection and logistics. Learn about innovative strategies to improve trial efficiency and quality, including the impact of the updated ICH-GCP R3 guidelines.
- **Health Economics:** Understand the economics of healthcare, focusing on cost-effectiveness, health outcomes and the economic impact of new therapies. Discuss global challenges in ensuring patient access to new medicines, health technology assessments, pricing strategies and the impact of real-world evidence on health economic evaluations.
- **Medical Affairs:** Explore the role of medical affairs professionals in bridging the gap between clinical development and patient care. Discuss scientific communication, medical education, stakeholder engagement and future best practices in medical strategies.
- **Pharmacovigilance:** Learn about the latest advances in drug safety monitoring, risk management and regulatory compliance. Gain insights into the detection and evaluation of adverse drug reactions and the implementation of robust pharmacovigilance systems.
- **Regulatory Affairs:** Navigate the complex regulatory landscape with a focus on obtaining and maintaining product approvals. Discuss the latest trends and changes in regulatory guidelines, submission processes and compliance, particularly relevant given the conference's location in Amsterdam, home of the European Medicines Agency.

We invite researchers, practitioners and professionals in Pharmaceutical Medicine to respond to the Call for Abstracts. This is a unique opportunity to share your latest research, findings and innovations with a global audience.

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Details of how to submit an abstract can be found on our official conference website, and we invite you to submit abstracts before 1 December 2024. The key abstracts' themes will include RWE/RWD, secondary data use, EHD, Big Data,Digital therapeutics,practical implementation of AI, Medical Device research.

Join us in Amsterdam for ICPM 2025 to engage with renowned scientists, industry leaders and regulatory experts and be part of the discussions that will shape the future of Pharmaceutical Medicine.

For more information, to register and submit your abstract, please visit our official conference website at icpm2025.com.

We look forward to welcoming you at ICPM 2025!

IFAPP Intensifies Engagement in Pharmacovigilance - New Working Group in Place

On 17 June 2024, the newly established Pharmacovigilance Working Group (PVWG) met for its kick-off meeting. With implementing this new group IFAPP emphasizes the importance of Patient Safety & Pharmacovigilance within Pharmaceutical Medicine.

The founding members (from Greece, Spain, Germany and the USA), all of them with a long history in Pharmacovigilance, will actively work on PV matters in a global setting beyond their national engagement (in National Member Associations or as Individual Affiliates).

Regular interactions amongst the WG members with their diverse backgrounds, e.g., by exchanging knowledge and sharing **best practices**, are expected to support their own professional development.

Engaging in **PV education & training** - i.e., helping others to grow in this area - is another intention of the WG members as solid skills/qualifications are considered key for performing a high-quality job.

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Since the patients and their well-being are in the centre of any PV activity, **patient engagement** (incl. patients, physicians, pharmacists, students, caregivers and others) will play a major role for activities by this group as well.

Sharing know-how about special PV approaches/requirements for **new therapies** (e.g., cell & gene therapies), incl. their desirable harmonisation across regions/countries, will also be subject to discussions and actions in this WG.
Further important aspects where the group will focus on are options for the automation of PV processes and the practical use of new technologies (e.g., **artificial intelligence**).

The further **PV legislation** evolution might be supported by the WG as well by leveraging the international umbrella organisation; close collaborations with other IFAPP WGs and initiatives may facilitate respective efforts.

Hence, an exciting mission is lying ahead, and the WG members look forward to diving into their first projects.

Stay tuned - more information and actions to come!

Author:
Monika Boos, M.D., Ph.D., LL.M.
Individual IFAPP Affiliate

P.S.: If you have any request on which services/projects the WG could get to work on in order to support or amend national PV efforts, feel free to get in touch (Contact@BoosConsulting.de).

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Report from IFAPP EU-CTR Update Workshop, 27 June 2024

Only 6 months left for transition!

Speaker and moderator: **Dr. Ingrid Klingmann**,
PharmaTrain

Speaker: **Oskia Bueno Zaragueta**,
European Medicines Agency (EMA),
Scientific Specialist, Data Analytics and Methods Task Force

Speaker: **Nicole Woik**,
Biogen, EU Legal Representative, Global Clinical Operations

The 'Clinical Trials Regulation' (CTR), Regulation EU 536/2014, has been valid since 31 January 2022 and mandatory since 31 January 2023. The "Transition Period" will end on 30 January 2025. The CTR Update Workshop informed about the latest developments from EMA and sponsor perspectives.
Ingrid Klingmann gave an excellent overview of the development in the implementation of the EU Clinical Trials Regulation since the IFAPP workshop conducted in March 2023:

New Developments since CTR Workshop in March 2023

- Constant improvements in CTIS functionalities
- Monthly EMA updates on new developments in CTIS newsflash
- Quick Guide to CTR vs 5 from the EU Commission
- More training options
- New transparency rules and new version of the "Public Portal"
- New guidances presented in EudraLex Volume 10:
  https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en
- Expanded Q&A vs 6.8


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 June 2024
EMA/264069/2024
European Medicines Agency

CTIS newsflash – 14 June 2024

Introduction

This regular CTIS newsflash provides key updates on CTIS and links to useful reference materials.

The next issue will be circulated on 28 June 2024.

Previous issues of the CTIS Newsflash are available on the EMA website.

Spotlight: Launch of revised CTIS transparency rules on 18 June 2024

The revised CTIS transparency rules become applicable on 18 June 2024, with the launch of an updated version of the CTIS public portal. Sponsors can refer to the quick guide for users for an overview of the changes.

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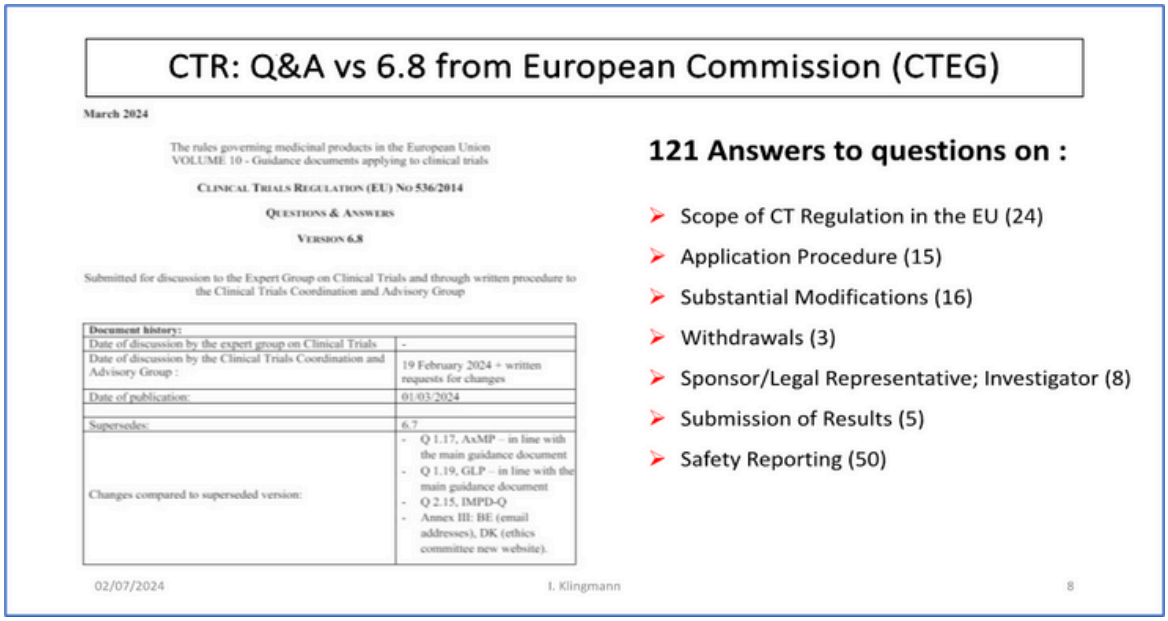
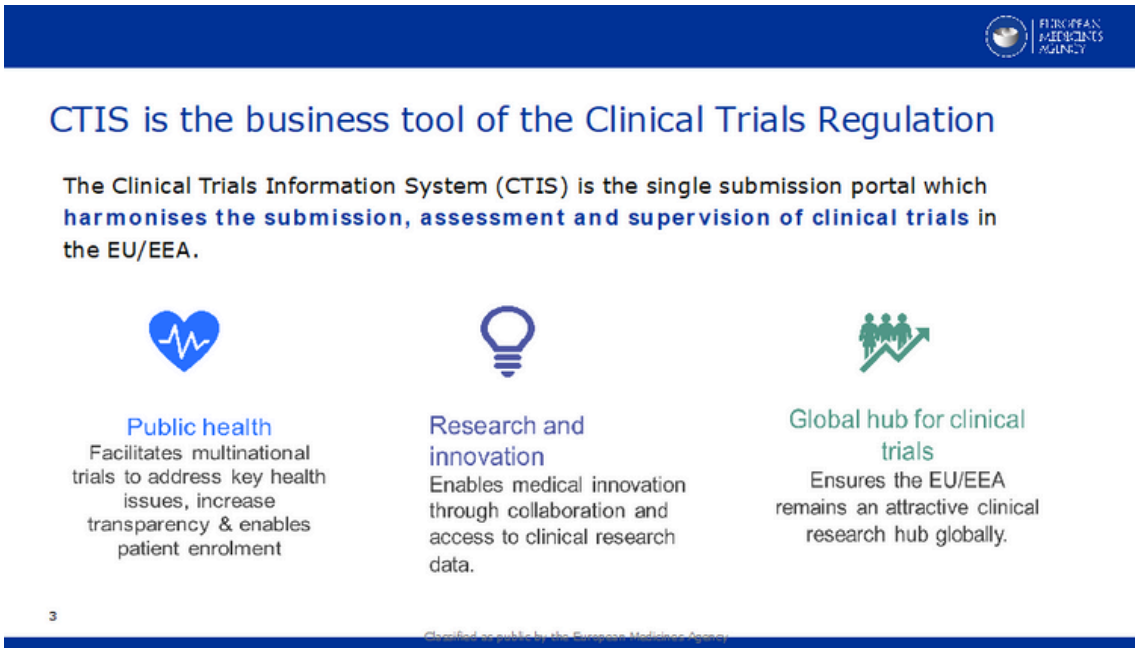
She also recommended to take the new version of the Q&A document by the European Commission into account:



She also gave references to the new CTIS transparency rules and the new approach for getting scientific advice simultaneously from different NCA in the EU as a new tool in the framework of ACT-EU.

Oskia Bueno Zaragueta (EMA) highlighted the importance of the Clinical Trials Information System (CTIS) as a core element in the implementation of the EU-CTR.



She presented the updates and improvements in CTIS.

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CTIS improvements in 2023-2024 (1/2)

- Improve user experience:
  - User management area
  - Request for Information (RFI)
  - Transition trials
  - Download
  - Notifications
- New features:
  - Individual Participant Data (IPD) sharing statement
  - Change of sponsor details via Non-Substantial Modification
  - Change of sponsor organisation via Substantial Modification (ongoing)

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CTIS improvements in 2023-2024 (2/2)

- CTIS became WHO data provider (May 2023)
- CTIS secure website and the new Public Portal in line with the revised transparency rules (June 2024)
- Implementation of the top 5 End users' improvements:
  - Increase flexibility for changes done via NSM
  - Allow the download of the list of user roles
  - Allow the download of the documents/list with metadata
  - Warning message for the creation of draft applications while others are under evaluation
  - Assess RFI task in subsequent RFIs

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She drew the attention of the participants to the new transparency rules which are linked to the CTR requirements.

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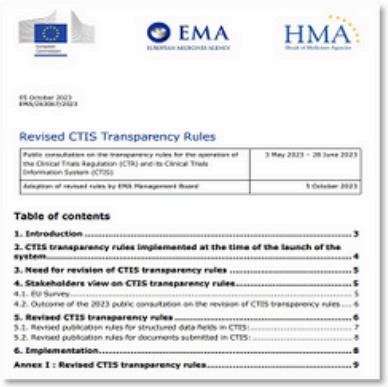
Revised CTIS transparency rules: key changes

Main differences with previous rules:

- Publication focused on key documents of interest
- Documents are published earlier in time, due to the removal of deferral functionality
- Use of redaction as the method to protect Commercially Confidential Information (CCI)


EMA HMA

Revised CTIS Transparency Rules

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As of 18 June 2024 (see quick user guide):

- All trials' applications submitted on or after 18 June follow the revised rules
- All trials submitted before 18 June ('historical' trials) have their structured data published

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Revised CTIS transparency rules: useful material

The Guidance and Q&As section of the CTIS website and the ACT EU website on Implementation of the CTR include all resources and support materials on transparency in CTIS.

Details are provided on data and documents that will be published and on all those trials submitted before the launch ('historical trials').

- Quick guide for users on revised transparency rules
- Guidance document on how to approach the protection of PD and CCI
- ACT EU Q&A on the protection of Commercially Confidential Information and Personal Data while using CTIS
- CTIS Bitesize talk on the transparency rules (Video recording available soon)

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Nicole Woik complemented this webinar with practical aspects for the handling of Part I and Part II and the mandatory transition of on-going clinical trials in CTIS.

Practical Aspects to consider for the Initial Application

Options to submit an Initial Clinical Trial Application

- Submission of Part I + Part II together
- Submission of Part I only (Part II after Part I is accepted)
- Submission of Part I of the Dossier for all MSCs and Part II for a subset of MSCs

Considerations for the Initial Clinical Trial Application in CTIS

- The final decision of a EU Member State Concerned is the result of the assessment Report on Part I and the assessment Report on Part II
- CTIS only allows for a Modification (incl. Additional MSC) after a full set of Part I and IIs are accepted.
- Request For Information on Part I and Part II(s) might be received in parallel.
- A Part I Request For Information might impact Part II documentation
- The applicant is not aware which country or body raised a consideration in the Part I RFI
- Communication is with the Reporting Member State only
- CTIS calculates and controls the timelines under CTR

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Aspects to consider regarding the submission content

- The country and translation requirements to Part I are easier to find than the requirements to Part II
- Patient Facing Material is split upon Part I and Part II (Regulation (EU) No 536/2014 Q&A, Version 6.8)
- Local requirements might result in the additional upload of documentation
- The visibility of information in CTIS if several stakeholders have access to CTIS
- CTIS is an intuitive tool that pulls information from other systems/databases. The applicant has to make sure the information in EMA systems e.g. OMS or xEVMPD is accurate
- The size of documents uploaded to CTIS is limited
- Documents that get published require a redacted Version to protect Personal Protected Data (PPD) and Commercially Confidential Information (CCI). The redacted Version needs to be uploaded first which means the document can only be uploaded once the redacted Version is available.

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Practical Aspects to consider during the Preparation

- The CTIS sections allow for the upload of information AND documents. A multi-national submission might include many documents. CTIS placeholder allow the system to perform an initial check for completeness but there is no possibility to check for double-upload of documentation and the system will not identify missing information for fields that require the upload of multiple documents e.g. translations
- Structured Data and Documents can be downloaded using the 'Download' button. There is very limited options to pull reports/ customize reports from CTIS
- The Clinical Trial Application is created with the creation of the trial in CTIS. Never „cancel" an Initial Application as it will delete your trial in CTIS
- The audit trail is not directly visible to the sponsor. It is very tricky to identify the reason for changes to the system, e.g. deletions, malfunctioning, errors
- Documents uploaded to CTIS need to be named correctly according to the CTIS naming convention

She also recommended to be aware of the end of the transition period in relation to the assessment time required by the National Competent Authorities.

Transition Requirements and Steps

Guidance for sponsors - Application for transition of clinical trials from the CTD to the CTR, Version 4 May 2024 :

From 31 January 2025 onwards only the Clinical Trials Regulation (EU) 536/2014 (CTR) and its Delegated Acts will apply, as laid down in Article 98 thereof.

Ongoing clinical trials currently governed by the Clinical Trials Directive (CTD) and expected to continue after 30 January 2025 will need to transition to the CTR regulatory framework.

If such clinical trials have not transitioned to the CTR by that date, they will be considered non-compliant and in breach of the CTR.

- Identification of Clinical Trials
- Strategic Planning
- Closure of Countries and Sites after LPO
  Complete the Recruitment
- Harmonization or Consolidation of the Trial Documentation
- Administrative Shift into the EU-Portal / CTIS
- Transition authorization until 30 January 2025

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The minimum transition application in CTIS

Guidance for sponsors - Application for transition of clinical trials from CTD to CTR, Version 4 May 2024 :

The maximum timeline for the expedited transition procedure of minimum dossiers for multinational trials restricted to documents already approved under the CTD is estimated to be maximum **22 days provided that no Requests For Information.** Each Member State decides on the assessment of Part II documents. This could **delay the notification of whether the transition application is accepted or not by a few days.**

- Minimum Dossier: protocol, investigator's brochure and IMPD (harmonized or consolidated amongst the EU Member States), GMP relevant documents, documents related to non-investigational medicinal products (i.e. auxiliary medicinal products under the CTR, if applicable), subjects' information sheet(s) and the informed consent form(s)
- For a minimum transition it is acceptable that the sponsor:
  - uploads a document in the corresponding document slots in CTIS clarifying that this aspect was assessed by the NCA and/or ethics committee who has given a positive opinion on the clinical trial under the CTD (and therefore is covered by the conclusion of the assessment under the CTD)
  - **provides the document as part of the first substantial modification** at its best convenience after the authorization of the transitioning application.

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Summary on considerations when working in CTIS

- The submission of a clinical trial in Europe in the future will require strategic thinking and a mindful preparation of the clinical trial dossier to limit the impact of regulatory timelines on the conduct of the trial and to prevent the publication of Commercial Confidential Information and Personal Protected Data
- The Go-Live of CTIS for the Revised Transparency Rules resulted in less documents requiring redaction of CCI and personal data and a removal of the deferral mechanism which results in reduced workload and simplified transparency rules BUT also in the early publication of important trial information (e.g. the Clinical Trial Protocol).
- Clinical trials that end after 30 of January 2025 and not transitioned into the new legislation will be considered non-compliant and in breach of the CTR. The EU offers the possibility to accelerate the transition by using a minimum dossier and to provide the rest of the documents as part of the first substantial modification.

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

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Quality is a Must – Excellence is a Gift

PHARMATRAIN's Shared Standards of Quality for Training and Education in Pharmaceutical Medicine and Medicines Development

PharmaTrain Federation is an accrediting and certifying not-for-profit organisation (www.pharmatrain.eu). It has established top-quality Global Shared Standards for Education and Training in Medicines Development (1).

PharmaTrain implemented its quality management system by a team of industry and academia partners that first established and now oversees and manages its shared quality standards. These are applied to all programmes in PharmaTrain at all levels: participating students, faculty members, courses, training sites, university sites and overall conduct of training programmes.

The basis consists of the revised PharmaTrain Syllabus, jointly developed by PharmaTrain and IFAPP (https://www.pharmatrain.eu/resources/syllabus/PharmaTrain%20Syllabus%20-%20Rev.%203.0%20-%202024.pdf) and nine cross-project quality standards together with its general principles on which they are based (1).

All PharmaTrain centres agreed of being subject to continuous quality checks, called PharmaTrain assessments and re-assessments applying a formal review process every second year (https://www.pharmatrain.eu/pharmatrain-recognition). PharmaTrain is using a dedicated team of assessors and publishes the results accordingly.

During this assessment process the following areas are critically reviewed: the accreditation and the quality assurance and quality management process of the centre, the adherence to the PharmaTrain syllabus, the facilities and infrastructure, the assessment of student achievements along defined learning outcomes, collection of student feedback, the use of reference material, etc. https://www.pharmatrain.eu/assessment-procedures.

By help of this quality management system a growing number of affiliated PharmaTrain centres is improving their quality standards and have successfully achieved the level/award of a Centre of Excellence.

My thanks go to the PharmaTrain centres and their dedication to continuously improve their quality and thanks to the PharmaTrain assessors and referees.

Ref: Klech, H. et al. European initiative towards quality standards in education and training for discovery, development and use of medicines. Eur. J. Pharm. Sci. 45, 515–520 (2012).

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Head Quality Assessment and Treasurer, PharmaTrain Federation, Brussels

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EUPATI Sweden Empowers Patients and Gives them the Opportunity to Make a Difference

The need for patient involvement in medicines and medical device R&D is increasing. EUPATI Sweden is part of this growing trend. Here are some statements and questions and answers from EUPATI managers:

- “Patients need to be involved in the whole development process. We believe it is important to develop better treatments and better solutions," says Ola Cornelius, Education Manager EUPATI Sweden.

In November, last year, a digital training course for patients and patient advocates was launched, developed by EUPATI Sweden. It consists of pre-recorded videos combined with short questions. The training is free of charge and open to all, i.e., patients, medical device users, relatives and representatives. The entire training has been developed together with representatives from the patient movement, industry, academia and public authorities.

What do we hope the training will achieve?

- "The aim is to train patients to become equal partners with academia and industry in both drug development and research studies at EU level," says Cristin Lind, Project Manager of EUPATI Sweden.

Participants will increase their knowledge of drug research and development, medical technology, precision medicine and the pathway from idea to patient. The training also focuses on the authorisation process: What is required for a drug to be approved and possibly subsidised?

What challenges can training help solve?

- "We want to increase participation in the drug development process by the training of patients and patient representatives and highlight the value of trained patients by contributing their expertise as equal actors in the creation of good health," says Cristin Lind.

By increasing the competence and participation of patients and patient representatives, patient power and the ability to influence will also increase.

Once the patients and/or patient advocates/representatives have completed the training, which takes about 12-15 hours, they will receive a diploma that allows them to call themselves EUPATI Sweden expert patients and they will then be part of EUPATI Sweden's collaboration network. Today there are already approximately 200 EUPATI Sweden expert patients.

EUPATI Sweden has been funded by the Swedish Inheritance Fund from September 2021 to September 2024.

What happens after September 2024?

- EUPATI Sweden has formed a non-profit organisation, a collaborative initiative where patients, industry, academia and the public sector co-create new solutions within life science.

“Our aim is to become a long-term investment so we can develop more training, other services and things that are needed," says Ola Cornelius, Training Manager EUPATI Sweden.

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What is the main goal for the non-profit organisation EUPATI Sweden?

- EUPATI Sweden works for increased patient involvement within life science by being a neutral arena for collaboration between patients, industry, academia and the public sector. We will offer training for patients and patient representatives thus providing a source of inspiration and information for professionals and matchmaking between patients and professionals. “EUPATI Sweden as a national and neutral collaboration platform is eagerly awaited”, says Eva Helmersson, communication officer at EUPATI Sweden.

Funding members are welcome

This autumn, 2024, there is a possibility to become a funding member at EUPATI Sweden. For more information turn to our webpage: www.eupati.se.

Author: Eva Helmersson, EUPATI Sweden Communication Offer

Philippine Pharmaceutical Medicine Education: Answering Regulatory Developments and the Drive Towards Medical Specialty Recognition

The Need

The Philippine College of Pharmaceutical Medicine (PCPM) was established in 1971 as an organisation that seeks to advance the practice of Pharmaceutical Medicine in the Philippines. As such, one of its overarching goals is to make Pharmaceutical Medicine a duly recognised medical specialty organisation. Its membership continues to grow, making the objective of becoming a professional specialty organisation more compelling.

Also, Philippine regulatory developments drastically evolved in 2014. The Food and Drug Administration, in its desire to standardise competencies of pharmaceutical medical affairs practitioners, compelled the pharma industry to professionalise even further. It required medical directors to either earn a Diploma in Pharmaceutical Medicine or pass the specialty board of Pharmaceutical Medicine within three (3) years of being employed by a pharmaceutical company in the Philippines. This development gave the PCPM an urgent reason to fast-track its initiatives

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to establish a formal training programme, professionalise, and work for its bid to become a recognised medical specialty society in the country.

The Response and the Specialty Course

At quick pace, alongside other continuing medical education activities, a formal specialty course on Pharmaceutical Medicine was established. The course was officially designated as Diploma in Pharmaceutical Medicine and Management (DPMM). It became a joint undertaking between the Philippine College of Pharmaceutical Medicine (PCPM) and the Ateneo De Manila University - one of the most prestigious universities in the Philippines. PCPM designed the programme and provided the technical faculty for the pharmaceutical sciences, while Ateneo University took care of the management and leadership faculty as well as of the academic platform on which the programme was established. Together, the PCPM and the Ateneo certified the diploma to anyone who successfully completed the course.

As it connotes, the course was designed for participants aiming to develop competencies in pharmaceutical sciences and management skills crucial to the pharmaceutical industry. The initial step in planning the curriculum was a thorough analysis of the Core Competencies of Pharmaceutical Physicians and Drug Development Scientists set by the International Federation of Associations of Pharmaceutical Physicians (IFAPP), which paved the way for the curriculum design. Adhering to the seven (7) core competency domains, the curriculum was developed into seven (7) modules, aligned to each of the IFAPP Core Competency Domains. The lecture topics that were developed and included were derived to fit the PharmaTrain Syllabus, with the addition of Philippine pharma contexts to fit the local needs.

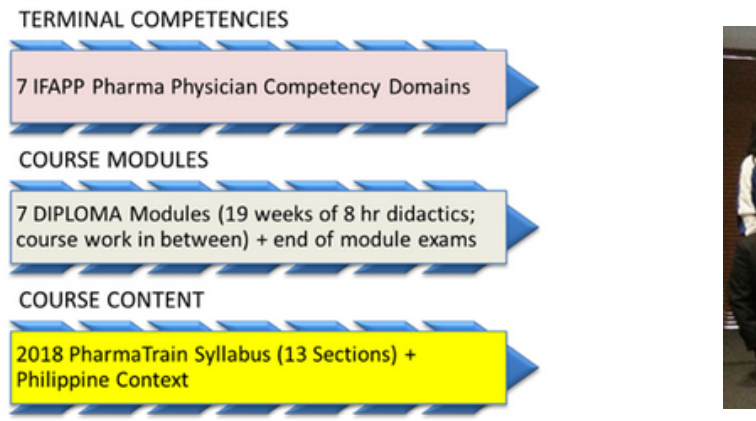

Figure 1: The rationale and composition of the curriculum

Diploma in Pharmaceutical Medicine and Management

In the end, the finalised programme was a 19-week diploma course. Each of the weeks had 8-hour didactic lectures on specific topics. In-between the lectures, the participants were also expected to work together in smaller groups to discuss cases and other academic coursework which were then presented in plenary sessions, attended by all participants and the facilitators. To cap each module, all participants had to take and pass end-of-module examinations. In total, to complete the course, the participants will be required to attend 35 lecture modules which represent 152 hours. In-between the lectures, participants would need to work in smaller groups on 6 cases and 28 exercises and other assigned coursework, take and pass seven (7) end-of-module examinations in a span of 19 weeks, all within minimum grading requirements.

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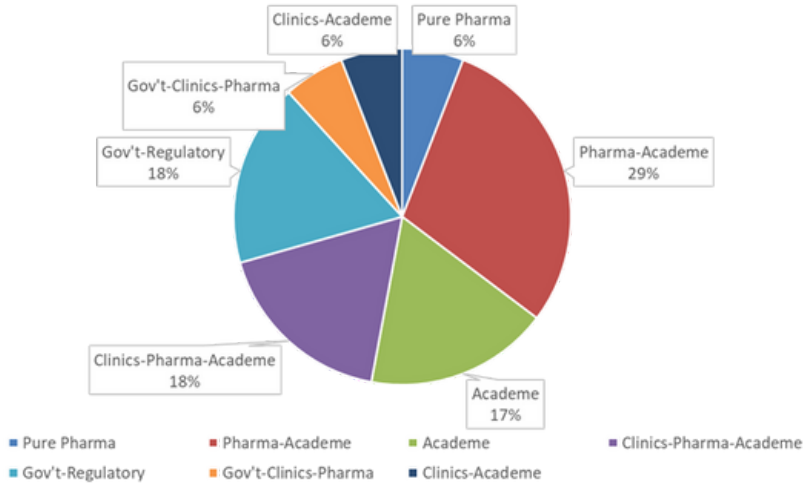
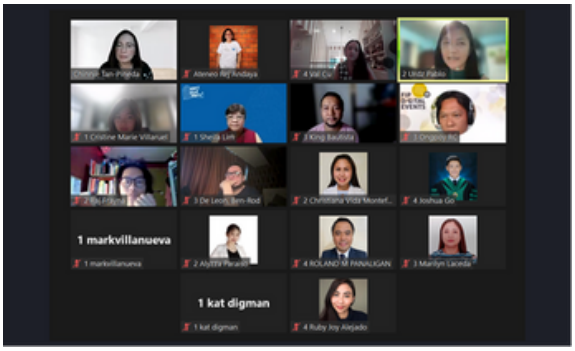
The faculty was carefully chosen depending on the needs of the diploma course. Members of the faculty came from or in combinations of medical affairs practitioners, academe, government regulatory personnel, and clinicians who were also in pharma industry positions. The majority of the faculty members either previously had or are currently occupying medical affairs positions in both local and multinational pharmaceutical companies. It was well noted that the best faculty composition came as a result of those who were performing multiple roles within the industry, clinics, and academe altogether. The best faculty on drug regulation came from the government regulatory agencies – department director level.





Full Online Class

Figure 2: The faculty composition and profile as of 2022

The Experience

The programme was initiated with the first batch starting in April 2016. With growing interest in the course, it became an annual offering with the average number of participants at the ideal 20 per batch. The majority of the participants held senior medical affairs positions: Medical Directors (32 %) and Medical Affairs Managers (30 %), with the other participants coming from other medical affairs positions. Rarely, there were participants from non-pharma companies who were using the training programme to be able to enter different medical affairs functions within the Philippine pharma industry.

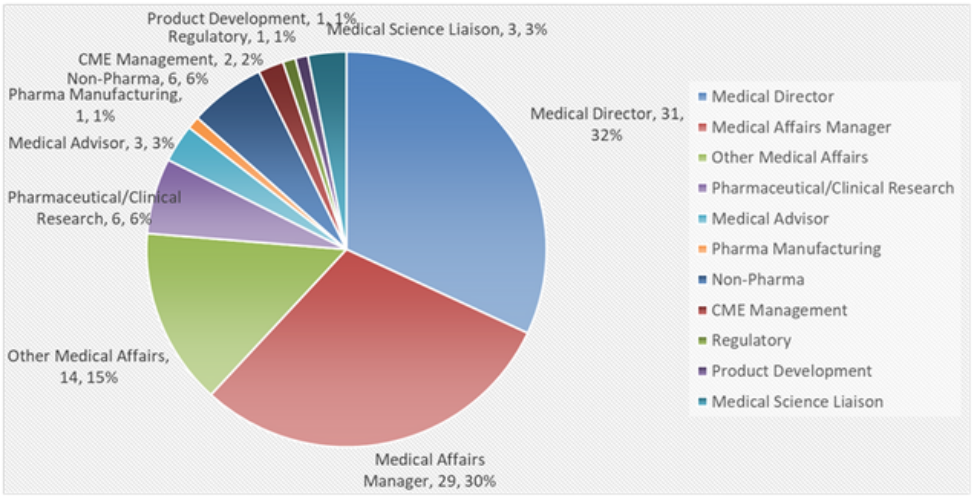


Figure 3: Participants profile as of 2022

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The programme continued with producing three more batches but had to stop in 2020 because of the COVID-19 pandemic. During this period, in order to be able to serve the requirements of those who needed formal medical affairs training, the programme was forced to evolve into an online offering, thus enabling it to continue. The year 2021 was special in the programme's history when the course became a purely online offering, and with a participant coming from South Korea. This showed the suitability and readiness of the programme as an online offering, capable of being accessed by participants from other countries. In 2022, the second recalibration of the curriculum was done to fit and stay as close as possible to the 2018 PharmaTrain Syllabus. To date, the programme has already produced six (6) batches representing 116 participants with an approximate 85 % completion rate.

Future Directions

Definitely, the programme (https://cce.ateneo.edu/index.php/program-calendar/7th-pcpm-ateneo-cce-diploma-pharmaceutical-medicine-management) will continue with fulfilling the requirements of Philippine pharma regulations and serving the needs of the members of the organisation and industry. Recently, the programme was discovered by IFAPP, and was presented in a roundtable at ICPM 2022. It is currently being looked upon as a possible option to serve the formal training needs of the Asian region. As such, it is planned to undergo recalibration once again to follow the latest PharmaTrain Syllabus V 3.0 in preparation for a formal submission for course recognition.

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Graduation

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The Future of the Job: Key Soft Skills for 2027

Professional maturity is characterised not only by technical skills, but also and above all by transversal skills, the so-called soft skills. In an increasingly VUCA (Volatile, Uncertain, Complex and Ambiguous) [1] world, one of the fundamental keys to professional growth is to constantly update oneself with the skills required by the labour market, which today, more than ever, is changing rapidly and continuously.

The World Economic Forum's Future of Jobs 2023 published a report [2] which identifies ten basic skills, defined as "life skills", that the job market will demand over the next five years to 2027:

1. Analytical thinking: the ability to provide and produce data for business decisions.
2. Creative thinking: the ability to use tools and techniques to innovate and solve problems creatively.
3. Resilience, flexibility, and agility: the ability to achieve goals in the face of constant challenges.
4. Motivation and self-awareness: the ability to control your own motivation and understand your personal and professional goals.
5. Curiosity and lifelong learning: the ability to keep learning in a world where knowledge has a limited lifespan.
6. Technological literacy: the ability to know and functionally use new technologies to achieve goals.
7. Reliability and attention to detail: self-awareness and the ability to pay attention to detail.
8. Empathy and active listening: the ability to communicate effectively and resolve conflict.
9. Leadership and social influence: the management of relationships as a leader or as a co-worker to influence the achievement of goals.
10. Quality control: ability to manage and assess the quality of a product or service.

According to "Future of Jobs 2023", by 2025, 50 % of employees will need to upgrade their skills, and at the same time, 40 % of employees will need "life skills".

According to 'Future of Jobs 2023', 50 % of employees will need to develop their skills by 2025, and at the same time, 40 % of employees' 'life skills' will change in the next five years. This highlights the growing need to develop resilience (better known as an individual's ability to adapt, face and overcome an event, difficult period and/or change) in relation to work and professional life, as well as the need to keep up with new technologies. The document also highlights the most innovative skills:

- Artificial Intelligence (AI) and Big Data: the knowledge and functional use of AI to achieve specific goals.
- Talent management: the ability to get the best out of employees.
- Customer service: active listening, task prioritisation, communication, and time management skills.

The life sciences industry is highly impacted by new technologies and market changes. Professional roles are evolving and changing rapidly due to

- Blockchain
- Artificial Intelligence
- Industry 4.0 and 5.0.

Based on these findings:

- How will the face of life sciences change with 5.0 and AI?
- What are the implications for the clinical research sector if it fails to adapt to the evolving world?
- How important is it for companies to bring their skills up to date with those that the World Economic Forum has predicted will be fundamental to the labour market?

To stand still is to risk becoming "obsolete"; the key to success is to constantly improve and update yourself, not only as an individual but also in collaboration with your work groups and professional network.

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In short, life skills and networking: the ingredients for real growth through a comprehensive, cross-cutting commitment!

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[2] - https://www.weforum.org/publications/the-future-of-jobs-report-2023/

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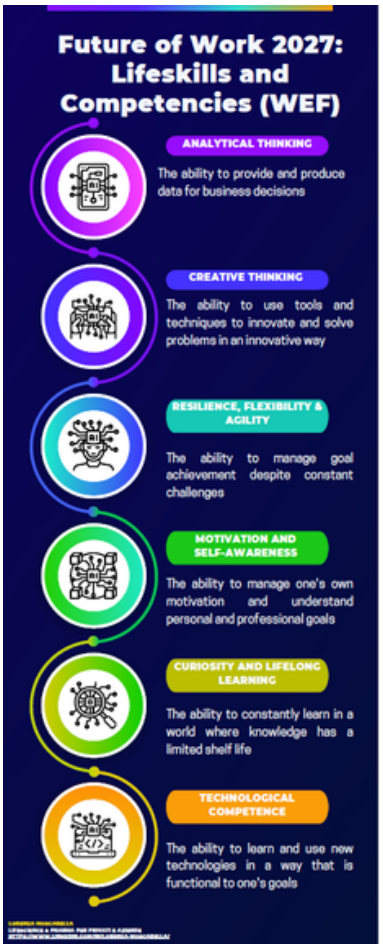

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IFAPP is the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine.

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