IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE:

IFAPP President at the MEAPP Inaugural Conference

I was truly delighted to join the Middle East Association of Pharmaceutical Professionals - MEAPP Inaugural Conference in Cairo at the end of February, extend a warm welcome to MEAPP delegates and talk about IFAPP activities that can create capacity for our National Member Associations (NMAs).

In parallel I had the opportunity to meet and greet the MEAPP emerging Pharmaceutical Medicine community, feel their eagerness to explore synergies and alliances for serving their mission to establish Pharmaceutical Medicine as a contemporary specialty that could cherish regional clinical research and clinical trial aspirations.

It was my privilege to be part of the panel discussion with King's College London (KCL) and Faculty of Pharmaceutical Medicine (FPM) colleagues, Prof. Peter Stonier and Dr. Flic Gabbay respectively, and exchange views on Pharmaceutical Medicine history, evolution of activities and convergence of our discipline with public health and public involvement in research.

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Moreover, as IFAPP President I emphasised on our current leadership strategy in developing next generation leaders by:
Elevating *young and middle* career colleagues in Pharmaceutical Medicine across the globe from Academia, CROs, Pharma/Biopharma/MedTech, SMEs, Regulatory Agencies, Health Organisations, Research Institutes, Healthcare Professionals Community to contribute to an innovative, inclusive, and diverse multidisciplinary Pharmaceutical Medicine future.

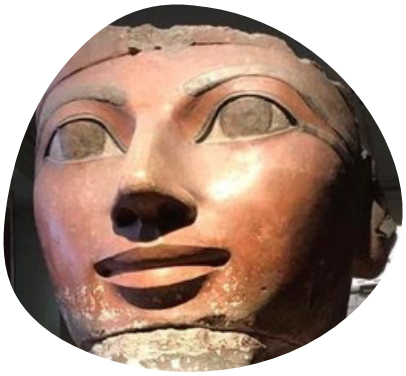
The conference dialogue pointed out the unique impact of IFAPP, as the only international organisation, since 1975, for everyone involved in Pharmaceutical Medicine, with a global outreach to 32 countries in 5 continents.

During the works of the conference, I highly appreciated the openness of MEAPP to engage with IFAPP's vision, mission, and goals.

The President of MEAPP, Dr. Assem el Baghdady, shared passionately his enthusiasm and commitment to cultivate the Pharmaceutical Medicine education in MEAPP by starting off in Egypt, a two-week training on "clinical trial protocol development" and consequently aiming at providing educational lectures, webinars and workshops in collaboration with stakeholders, e.g., IFAPP, KCL, FPM and regional Research Centres among others.

As a concluding note, I would like to reiterate that it is of utmost importance to develop talented colleagues who are eager to augment their capacity through agile learning, breakthrough changes, challenges and growth in Pharmaceutical Medicine and become the future leaders of a generative, inclusive IFAPP organisation without generation gaps.
Wishing lots of success to MEAPP in fulfilling their mission and looking forward to supporting MEAPP and other interested NMAs in the pursue of excellence in Pharmaceutical Medicine.

Dr. Varvara (Barbara) Baroutsou
MD, PhD, GFMD, EMAUD
Consultant in Internal Medicine
Pharmaceutical Medicine Consultant
Research &Experimental Development in Medical Sciences Expert
ELEFI President
IFAPP President



Pharao Queen Hatshepsut 1478-1458 BC

Egyptian Museum Cairo

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IFAPP Mission & Vision

Mission
Advance the Discipline of Pharmaceutical Medicine in the 21st Century

Vision
IFAPP recognised as a Leading Authority for Scientific and Educational Programmes which Advance Pharmaceutical Medicine

IFAPP Working Groups

- **Communication** — Monthly Newsletter on Current Developments, Challenges and Perspectives
- **Education & Certification** — Continuing Education to Support Needs of NMAs, IAs* and the IFAPP Community
- **Ethics** — Impact of Evolving Science, Research and New Technologies on Ethical Aspects
- **External Affairs** — Engagement with Stakeholders on Common Interest Projects
- **Young Professionals** — Support Professional Development in Pharmaceutical Medicine

• NMAs = National Member Associations
IAs = Individual Affiliates

IFAPP Strategic Drivers and Trends

IFAPP Strategy Drivers

Advocacy - Stakeholders

IFAPP Impact

Research | Publications | Education | ICPM Adaptive Models

Membership
NMAs - IAs - Regional

Strategic Trends

- Shifts in Pharmaceutical Medicine Profession
- Science &Technology Evolution
- Continuously Evolving Regulatory Environment
- Changing Life Sciences, Industry

IFAPP Key Areas of Focus in Pharmaceutical Medicine (PM)

IFAPP Engagement

International Collaborations & Partners

- PharmaTrain
- Trinity College Dublin
- The European Center for Pharmaceutical Medicine - ECPM
- The Faculty of Pharmaceutical Medicine – FPM
- CIOMS
- World Medical Association - WMA

Global Footprint

- Number of NMAs: 26 countries
- plus Individual Affiliates: 14 countries
- 5,000+ Members
- Engagement
- ≈2,000 IFAPP Followers on LinkedIn

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Report from the Training Workshop 'Introduction to the New EU Clinical Trials Regulation'

A new offering of IFAPP's Continuous Professional Development Programme on 1 and 2 March 2023 was moderated by **Dr Birka Lehmann** and **Dr Ingrid Klingmann**.

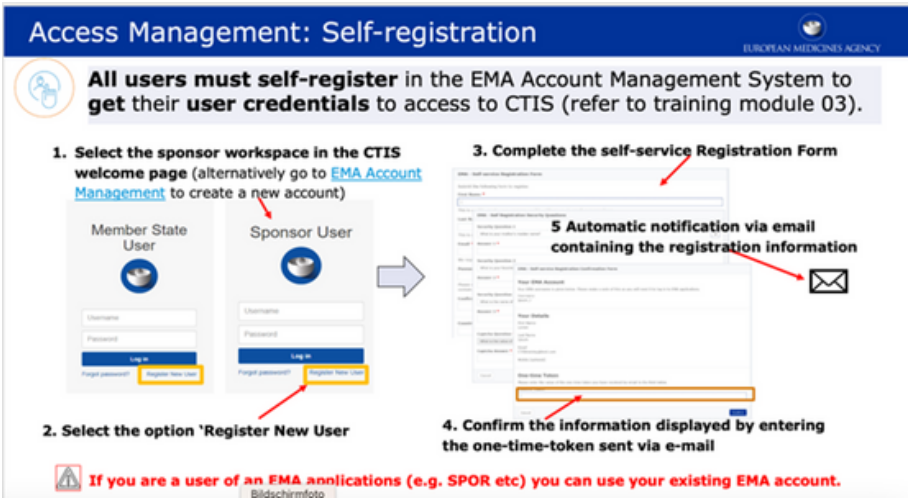
As of 31 January 2023, all clinical trials with new medicines must be authorised, handled and reported according to the rules lined out in the Regulation EU No 536/2014 (Clinical Trials Regulation). The transition from CTD (Directive 2001/83/EC) to the CTR (Regulation (EU) No 536/201) will end on 31 January 2025. By this timepoint also all on-going clinical trials' documentation will have to be transposed into the new Clinical Trials Information System (CTIS).

Transition period for clinical trial sponsors

- until 30 January 2023, clinical trial sponsors may use CTIS to apply to run a clinical trial under the Clinical Trials Regulation (Regulation EU No 536/2014) or may choose to apply to run a trial under the Clinical Trials Directive Directive 2001/20/EC.
- from 31 January 2023, clinical trial sponsors will need to use CTIS to apply to start a **new clinical trial** in the EU/EEA;
- from 31 January 2025, **any trials approved** under the Clinical Trials Directive that continue running will **need to comply with the Clinical Trials Regulation** and their sponsors must have recorded information on them **in CTIS**.

Birka Lehmann (Adaptation of EMA press release)

All requirements of the new Regulation have by now to be implemented in the workflow of industry and academia sponsor applicants and National Competent Authorities (NCA) enabling communication with CTIS which is hosted by the European Medicines Agency (EMA).



Ana Rodriguez

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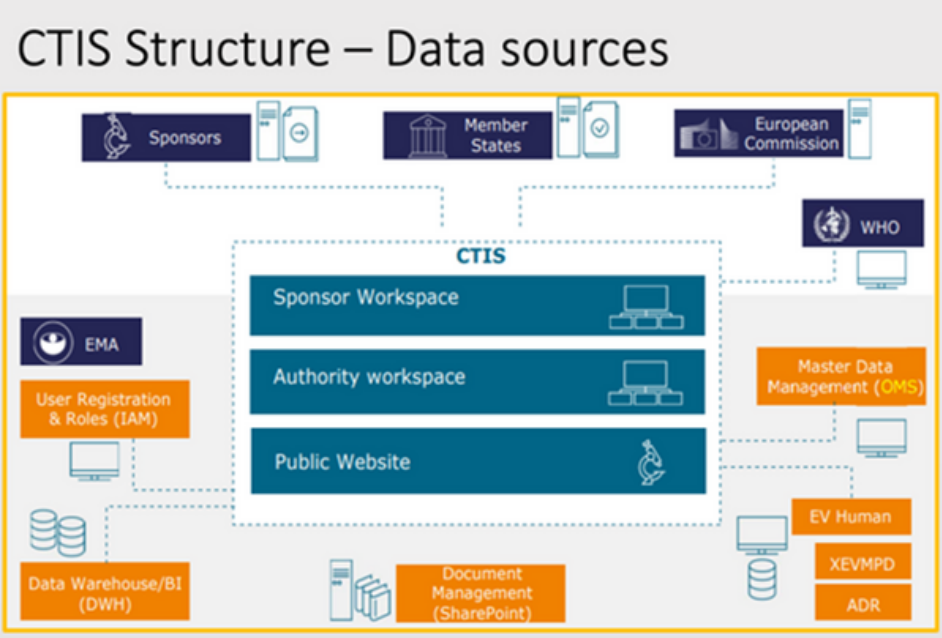
The intention of the training workshop was to provide an introduction to the new concepts, requirements, processes, procedures and obligations of the parties involved and thus to facilitate the preparation and conduct of clinical trials in the EU under the new legislative framework.

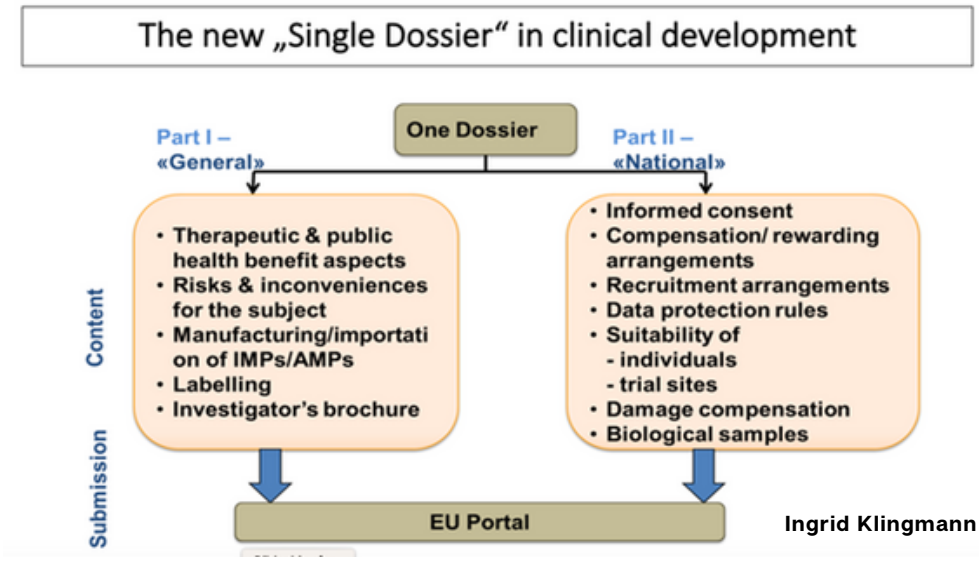


Speakers from EMA, Academia and Industry shared their knowledge and experiences with the new systems as well as the challenges expected and already gained within the new clinical trials environment.

The Regulation introduces an authorisation procedure based on a single submission via a single EU portal and data base, a coordinated assessment procedure handled by the European Member States' competent authorities, leading to a single decision.

Nicole Woik

This was presented and discussion with the focus on the handling of the new digital approach and the adaptation to the short timelines provided to the sponsor to answer questions raised during the procedure by the National Competent Authorities and Ethics Committee.



Ingrid Klingmann

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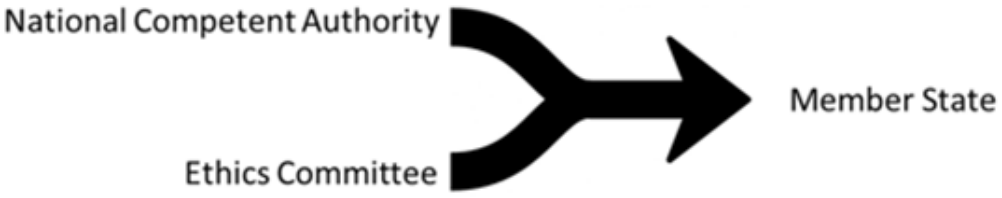

Sean Klibride

The interaction of the requirements in Pharmacovigilance and the new CTR in respect to safety reporting including serious breaches were discussed and additional information was given on how the different data bases are connected.

Reporting obligations

The Geographer
Jan Vermeer (1632-1675)
Städel Museum, Frankfurt/M

- **Trial conduct:**
  - Reporting in context of study management
  - Pharmacovigilance reporting
- **Trial results:**
  - Clinical study report / technical summary
  - Lay summary of trial results
  - Deferral of commercially confidential information?

Kerstin Breithaupt

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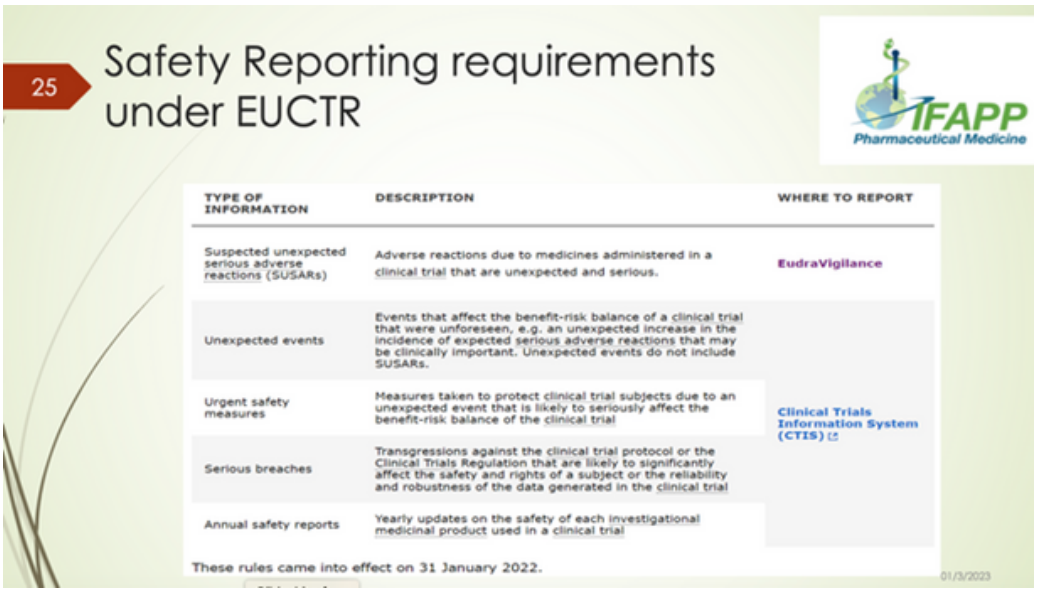

Varvara (Barbara) Baroutsou

The need to re-define the interaction of sponsor, CRO, investigator, and all other relevant partners involved in a clinical trial were presented and discussed in practical terms.
Example:

New Clinical Trial Organisation

2.2 SPONSOR VIEWER ROLES*

*Viewer roles do not get notices and alerts related to the mentioned business tasks, unlike other user roles.

Permissions	Part I Viewer (excl. Q-IMPD)	Q-IMPD Viewer	Part II Viewer	Notifications Viewer	CT results Viewer
Form: cover letter, proof of payment, Compliance Reg. 2016/679 and deferral					
MSC					
Part I dossier: Q-IMPD/ scientific advice restricted document					
Part I dossier: excl. Q-IMPD					
Part II dossier					
RMS selection (from the evaluation tab)					
RMS selected (from the summary tab)					
Validation information: RFI/RFI response - Q-IMPD					
Validation information: RFI/RFI response – excl. Q-IMPD					
Validation information: validation conclusion					
Assessment Part I information: assessment Part I information – quality-related information					
Assessment Part I information: assessment Part I information - excluding quality-related information					
Assessment Part I information: part I conclusion					
Assessment Part I information: part I disagreement					

Ingrid Klingmann

The rules on the protection of participants, particular conditions for informed consent in vulnerable populations, and reporting requirements were presented in the light of the obligation to increase the transparency of on-going and finalised clinical trials and to make this information available to the public.

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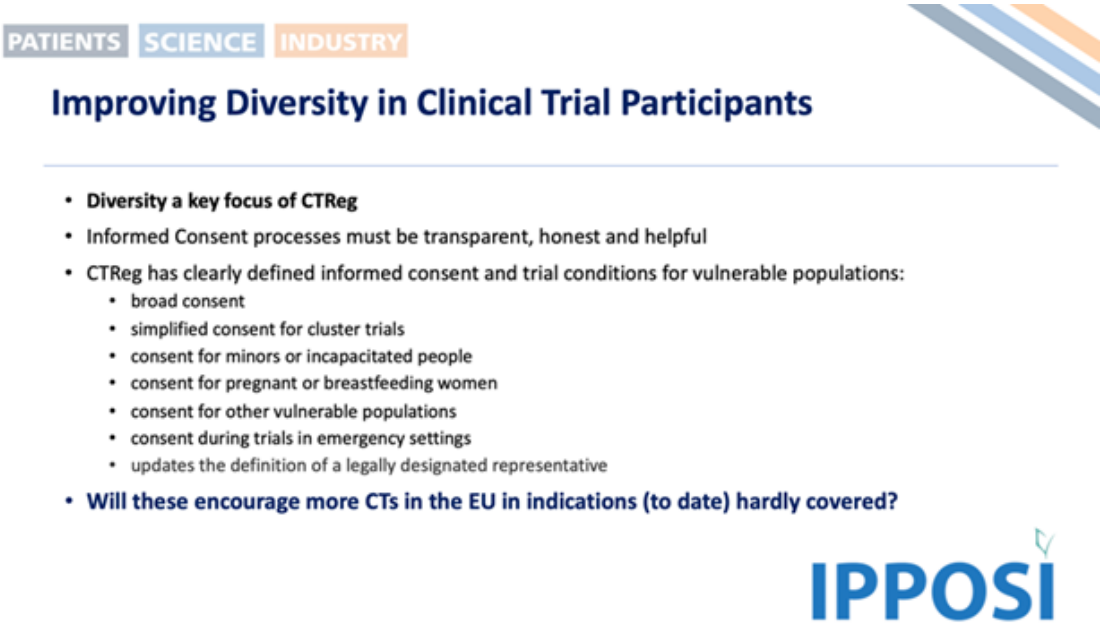
To increase diversity in clinical trials is one of the topics which are not only taken up by the CTR but is also a demand coming from the society to have medicinal products in place to treat e.g., pregnant women safely based on results from clinical trials.



Derick Mitchell

Last but not least the changes in IMP management and labelling obligations under the new CTR were presented in comparison tables GMP Annex 13 and CTR.

General case rules that should appear on the primary packaging and on the secondary packaging

Requirements primary and secondary package label	Annex 13 - § 26		CTR - 536/2014 – Annex VI - A.1.	
Language	☺	*§ 28 - Particulars should appear in the official language(s) of the country in which the investigational medicinal product is to be used. (...omissis...) Other languages may be included.*	☺	*§ 69 - The language of the information on the label shall be determined by the Member State concerned. The medicinal product may be labelled in several languages.*
(a) name, address, telephone of sponsor, CRO or investigator (*the main contact for information on the product, clinical trial and emergency unblinding*);	☺	*need not appear on the label where the subject has been given a leaflet or card which provides these details and has been instructed to keep this in their possession at all times.*	☺	*need not appear on the label where the subject has been given a leaflet or card which provides these details and has been instructed to keep this in their possession at all times.*
(b) pharmaceutical dosage form, route of administration, quantity of dosage units and in open trials, the name/identifier and strength/potency;	☺		☺	*in the case of blind clinical trials the name of the substance is to appear with the name of the comparator or placebo on the packaging of both the unauthorised investigational medicinal product and the comparator or placebo*
(c) the batch and/or code number to identify the contents and packaging operation;	☺		☺	
(d) a trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;	☺		☺	
(e) the trial subject identification number/treatment number and where relevant, the visit number;	☺		☺	
(f) the name of the investigator (if not included in (a) or (d));	☺		☺	
(g) directions for use (reference may be made to a leaflet or other explanatory document intended for the trial subject or person administering the product);	☺		☺	
(h) "For clinical trial use only" or similar wording;	☺		☺	
(i) the storage conditions;	☺		☺	
(j) period of use (use-by date, expiry date or re-test date as applicable), in month/year format and in a manner that avoids any ambiguity.	☺		☺	
(k) "keep out of reach of children" except when the product is for use in trials where the product is not taken home by subjects.	☺		☺	
Recommendation	😐	*§ 31 Symbols or pictograms may be included to clarify certain information mentioned above. Additional information, warnings and/or handling instructions may be displayed.*	😐	*Annx.VI 2 Symbols or pictograms may be included to clarify certain information mentioned above. Additional information, warnings or handling instructions may be displayed.*

Antonio Severino

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In summary, the new Regulation will lead to harmonised conditions for all aspects of clinical trials with medicinal products throughout the EU and closer communication and collaboration between sponsors, competent authorities and ethics committees in the interest of more efficient and safer development of new treatments for patients.

We once again thank all the speakers for their presentation and input and the more than 110 participants for not only joining but also raising important questions leading to fruitful discussions and increasing knowledge for everybody.

All presentations will be uploaded on YouTube in the near future. The pertinent link will be announced in the April issue of IFAPP TODAY as well as on the IFAPP Company Page on LinkedIn.

Ingrid Klingmann, MD PhD, President of PharmaTrain Federation
Birka Lehmann, MD PhD GFMD, IFAPP ECWG chair, Senior Expert Drug Regulatory Affairs

Tips for Clinical Trial Sponsors: Regulation (EU) No 536/2014

A quick guide on the rules and procedures of the updated Clinical Trials Regulation (CTR) EU No 536/2014 was released on 30 January 2023. This guidance, drawn up by the Clinical Trials Coordination and Advisory Group (CTAG), is meant as a practical approach for clinical trial (CT) sponsors and investigators to help implement the new rules.

Even though we are still in a transition period until 31 January 2025 for full CTR application, by then all sponsors who wish to conduct clinical trials of a medicinal product (national and multinational) in the European Union (EU) / European Economic Area (EEA) will have to comply with the updated CTR.

First, sponsors should carefully assess the relevance and feasibility of the planned CT. The protocol and dossier should be prepared in advance, insurance/compensation should be in place, and the safety surveillance and capability for Suspected Unexpected Serious Adverse Reactions (SUSAR) reporting to EudraVigilance should be organised before the submission takes place.

To access the Clinical Trials Information System (CTIS) sponsor workspace, a user will need to self-register for a European Medicines Agency (EMA) account (i.e., user name & password), and the ones already using another EMA application (i.e., Eudralink, SPOR, IRIS, EudraVigilance, OMS) can use the same login information. If one works externally for a sponsor, then permissions must be given by the administrator(s) of this organisation before starting to work in the CTIS workspace.

Sponsors should ensure that the details of the medicinal products used in the CT have already been registered in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) – a dictionary that includes all medicinal products authorised in the EU/EEA, as well as products under development. Of course, a placebo can be added manually without pre-registration in the system.

The documents required for a CT application will vary depending on the type of application or notification submitted; but there are three essential sections defined in the CTIS:

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(1) Basic forms and the Member State Concerned (MSC);
(2) Part I, consisting of CT details (e.g., Protocol, Investigator's Brochure, etc.);
(3) Part II, consisting of CT site and investigator details, and practicalities related to recruitment and informed consent.

In the case of a multinational CT, the sponsor proposes one member state to be the Reporting Member State (RMS). The RMS will be responsible to validate whether the clinical trial application is complete and within the scope of the CTR. If the clinical trial application is valid, the first assessment phase starts, led by the RMS. This is followed by the second part of the assessment, which is made by each individual member state where the CT will take place. All-in-all, it should not take more than 45 days for this assessment process to take place; and a maximum of 91 days from initial CTIS portal validation to the final notification.

In case a medical device is involved in the CT, three possibilities arise:

(1) The object of the study is one integral product which is a 'combination' of a medical device and a medicinal product - particular account shall be taken to the principal mode of action, CTR applies;

(2) The object of the study is a medicinal product, however during the clinical trial medical devices are used without these being the subject of the study – CTR applies, and the medical devices used must comply with the medical device regulation (MDR) EU rules;

(3) The object of the study is two separate products, one "arm" is a medicinal product and the another "arm" is a medical device – in this case, CTR applies to the medicinal product "arm", and medical device conformity assessment EU rules apply to the other "arm".

To promote trust in the society and to support innovative and meaningful trials in the EU, while at the same time acknowledging the legitimate economic interests of sponsors, the new regulation recognises that personal data and commercially confidential information (CCI) should be exempted from publication rules. To enable such data protection, the CTIS offers users the possibility to upload redacted document versions "for publication" and unredacted document versions "not for publication".

Even if 2025 seems a faraway date, sponsors are advised to start as soon as possible applying the new CTR, so that by then there are no lingering CTs in need of rescue.

For more information please visit:

- EudraLex Volume 10, Clinical trials guidelines
- EudraLex, Volume 10, Question and Answers

Catarina Carrão, Science Writer at Gouya Insights GmbH & Co. KG

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CTIS: A Single-Entry Point for EU Clinical Trials

The Clinical Trials Information System (CTIS) has become mandatory as the single-entry point for the submission and assessment of clinical trial data for sponsors and regulators in the European Union (EU).

The new Clinical Trials Regulation (CTR) (EU) No 536/2014 entered into application a year ago repelling the Clinical Trials Directive (EC) No. 2001/20/EC, with the CTIS launched at this time over a one-year transition period. Prior to the new Regulation, clinical trial sponsors had to submit applications separately to national competent authorities and ethics committees in each country to gain regulatory approval to run a clinical trial. The Regulation now enables sponsors to submit one single online application via the CTIS platform in order to run a clinical trial in several European countries. The CTIS makes it more efficient to carry out multinational trials, since EU Member States can evaluate and authorise such applications together, via one single platform.

The aim of the new legislation and the CTIS is to ensure the EU offers an attractive and favourable environment for carrying out clinical research on a large scale, with high standards of public transparency and safety for clinical trial participants. As such, the CTIS also includes a public searchable database of all ongoing clinical trials in the EU and the wider European Economic Area (EEA) not only for healthcare professionals, but also for patients and the general public.

During the transition period, some users have experienced problems with the system. For example, the portal did not flag or send information to sponsors when new information was received – meaning sponsors had to frequently check for updates. As such, the European Medicines Agency (EMA) has invested additional resources to improve the CTIS user experience for core CTIS processes, hopefully resolving such technical glitches by the effective date of 31 January 2023.

Training materials are also available to help sponsors submit information on their clinical trial data, which are updated regularly to reflect information needs. EMA is also running regular training webinars with sponsors to explain the system and listen to their complaints, so that it can quickly address concerns. For example, multiple reports have come to light that certain Member States are requiring documents that are not specified in the CTR – which, hinders the purpose of the new regulation. EMA advises sponsors to use the CTIS support service and not be deterred.

Clinical Trial evaluation timelines (updated 26/01/23)
CTIS training programme page
Clinical Trial Sponsor Handbook

Catarina Carrão, Science Writer at Gouya Insights GmbH & Co KG

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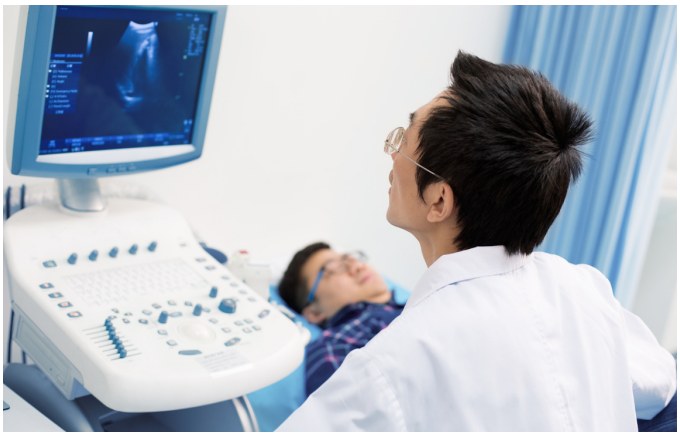
An Update on the Implementation of the Medical Device Regulation 747/2017 in Europe

A revised set of rules for medical devices, known as the Medical Device Regulation 745/2017 (MDR) was published in 2017, and came into initial effect in May 2021. The MDR is a fundamental revision of the regulatory rules, and it is likely to bring about significant change to the medical devices sector in the European Union, as medical device companies move from compliance with the prior Directive based system, to the MDR.

The regulation of medical devices in Europe, is very different to the rules concerning medicinal products. The initial Directives for medical devices helped to establish a single market by removing differing national standards, however they had limited rules concerning the need for clinical trials (called 'clinical investigations' in the regulations). This is not a problem for the vast majority of medical device products, which are of relatively low risk – for example wound dressings or thermometers. For higher risk products however, such as heart valves, the Directive rules allowed many products to access the market without any trial.

A series of scandals in recent years involving hip implants (1) and industrial silicone in breast implants (2) provided a political impetus to improve the system. More recently, the implant files (3) investigation of the international consortium of investigative journalists, and ongoing problems with mesh products (4) have demonstrated the ongoing safety challenges that medical device technologies can present.

The MDR retains the basic structure of the old system, however it introduces over 100 new articles, with a much greater number of plans, reports and procedures required. These rules apply to both new products and ones marketed under the previous rules. There was no scientific analysis of



the impact of the MDR to determine the effect of increased clinical evidence requirements, or a public impact assessment conducted to determine the effect these rules would have on the market or public health.

Transitional provisions in the MDR allowed for previously approved products to continue marketing until 2024 at the latest, when full compliance with the MDR would be required. Due to challenges in implementing the MDR, these timelines will now be revised. The legislative proposal of the European Commission to amend the timelines has been passed by the Council and Parliament and is awaiting publication in the Official Journal of the European Union (OJEU) at which point it becomes legally applicable. This is expected to happen later this month. Depending on the risk classification of the device, it may be possible to continue marketing under the Directive based approval until the end of 2027 or 2028. This is subject to a number of conditions such as the need to have a contract with a notified body to assess the product, and compliance with some aspects of the MDR, for example with respect to quality systems or post-marketing safety reporting.

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At a European Council (EPSCO) meeting of health ministers in December 2022, Commissioner for Health, Stella Kyriakides noted - 'We are facing a risk of shortages of life-saving medical devices for patients. This this is a risk we cannot take'.

Current challenges in implementation

The primary challenge for the regulatory system is the notified body bottleneck. At the time of writing, there are 37 notified bodies designated to the new rules for the MDR. This is a much smaller number when compared with approximately 10 years ago when there were up to 96 notified bodies operating in Europe. As a result of a reduction in notified body capacity, in addition to an increased amount of work needed to assess devices to the new rules, both the time and cost of an assessment for CE marking have increased. Some small companies have reported that it was not possible to access a notified body assessment, and some were told to come back at a later time. When we consider that the medical device sector is made up of over 30,000 companies with a majority of small and medium enterprises, these bottlenecks raised real challenges for the introduction of new products. For the first time, signals are emerging (5) that MedTech companies now prefer to introduce new products in the United States rather than the European Union market – a paradigm shift for the sector.

From a public health perspective, the change in market access dynamics have presented a risk of essential product withdrawals. The Biomedical Alliance in Europe have conducted a number of surveys to clinicians to help to identify devices at risk of withdrawal. In a paper in Pediatric Cardiology (6), these challenges and possible solutions, are discussed in more detail. There is no provision in the MDR for orphan or paediatric devices to support their development and marketing. This is different to the regulation of medicines in Europe, and the regulation of both medicines and medical devices in the United States. A Medical Device Coordination Group (MDCG) taskforce for these products is working on a definition of an orphan device and is considering possible policy solutions.

Conclusion

The initial discussions to recast the regulatory system in Europe began in 2008, and when the transition period ends, the EU will have been working on a system redesign for 20 years. The challenges of implementing the regulation, and some of the public health challenges that have arisen have generated increased attention on the need to improve the functioning of the system, in addition to updating the legal rules.

The Heads of Medicines Agencies (HMA) core group for medical devices noted in December that a comprehensive critical appraisal and review must be conducted at European level, to examine both the root causes of the current certification issues and the issues faced by the regulatory system in its effective application in practice. The additional time for the system to certify products will certainly help with the certification 'bottleneck', however it is likely that greater system improvements will be needed to ensure that the regulatory system truly achieves the stated aim in preamble 1 of the MDR which is to establish a robust, transparent, predictable, and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

Trinity College Campanile

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References

(1) Cohen, D., 2012. How safe are metal-on-metal hip implants? BMJ, 344, e1410.

(2) Increased scrutiny following breast implant scare. Politico. March 4, 2023.

(3) An ICIJ Investigation Implant Files.

(4) First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review. July 2020.

(5) Interstates and Autobahns. Global Medtech Innovation and Regulation in the Digital Age. March 2022.

(6) Melvin T, Kenny D, Gewellig M, Fraser AG, 2023. Orphan Medical Devices and Pediatric Cardiology–What Interventionists in Europe Need to Know, and What Needs to be Done. Pediatric Cardiology, 2023 Feb;44(2):271-279.

Tom Melvin, Course Director of a new MSc in Medical Device Regulatory Affairs, Trinity College Dublin, Ireland

Artificial Intelligence for Breast Cancer Screening – Today´s Future

On 14 February 2023 IFAPP had the honour and privilege of hosting a webinar on "Artificial Intelligence and Breast Cancer Screening" given by Jonas Muff, the founder of Vara – a spin-off from Merantix Venture Studio.

Vara´s main purpose is to create safe, reassuring opportunities for reliable breast cancer screening, while in addition, making them more accessible for all patients. Combining proven, state-of-the-art technology with the experience and expertise of leading physicians, Vara delivers a measurable impact, backed by clinical evidence.

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Vara´s main purpose is to create safe, reassuring opportunities for reliable breast cancer screening, while in addition, making them more accessible for all patients. Combining proven, state-of-the-art technology with the experience and expertise of leading physicians, Vara delivers a measurable impact, backed by clinical evidence.

In January 2019, the first screening centres in Germany joined Vara´s journey as development partners. In September of that same year, Vara was certified as a CE (Class IIb) medical device. In May of 2020, Vara was awarded a €6.5M Series A led by OMERS Ventures, Toronto. In February 2022, Vara teams up with Mamotest to launch the company's first international breast screening unit in Mexico, followed in March by the certification given by European Medical Device Regulation (MDR). Later on in March, Vara brings AI-driven breast screening to Greece with its new partner MITERA, while conducting with the University of Lübeck the first-ever prospective AI study for breast cancer screening in Germany. In April of 2022, the largest study of its kind was published in the European Journal of Radiology showing promising results in preventing missed breast cancer with AI. The Lancet Digital Health writes on the novel, complementary approach to applying AI to breast cancer screening while improving accuracy.

Source: Vara website

From the start, it has been Vara´s mission to provide millions of women across the world around the globe access to high-quality breast screening. Its innovative and AI-based platform the company has recently launched in Egypt and is about to enter the Indian market. Vara´s international team of healthcare professionals, engineers and entrepreneurs are combining world-class engineering and scientific excellence to redefine breast cancer screening.

In the world's most developed countries, approximately 1 in 8 women will be diagnosed with invasive breast cancer. And when detected early, their chances of survival improve drastically.

In sum, Vara, AI and human expertise will continue to work together to improve the future of women worldwide. For the time being, no woman should go without having their annual mammogram interpreted by a radiologist or a cancer specialist. AI is a currently a complement and aid in decreasing false negatives and false positives during breast cancer screening. We can only hope mammograms, AI and qualified radiologists and cancer specialists become available worldwide to decrease and eventually nullify cases of breast cancer in all.

As those at Vara believe, because behind every case of breast cancer is a person, someone's mother, daughter, sister, partner, friend – in the end one of us – we should all contribute to combat a disease that changes every family´s life.

Dr. Marlene Llópiz Avilés
IFAPP President-elect
Global Oversight Director PPD-Thermo Fisher

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THE FLAG

IFAPP secretariat - Leidsestraatweg 41d - 3443 BP Woerden - The Netherlands
Chamber of Commerce 30224375 – VAT number NL817747321B02
Phone: (+31) 6 2291 1039 – e-mail: secretariat@ifapp.org – website: www.ifapp.org

IFAPP Communication Working Group
Ghazaleh Gouya-Lechner (Chair), Varvara Baroutsou, Anna Jurczynska, Ana Rita Lima, Rita Lobatto, Kotone Matsuyama, Helio Osmo, Joanne Ramsey and Johanna Schenk (IFAPP TODAY Editor-in-chief).

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