PEC PHARMA EDUCATION CENTER

EUROPEAN REGULATORY AFFAIRS FORUM 2025

21 - 22 MAY | ONLINE

Pharma Education Center is excited to invite regulatory affairs professionals to the upcoming **"EUROPEAN REGULATORY AFFAIRS FORUM 2025."**

As the annual meeting of European Regulatory Affairs experts, the Forum aims to foster an environment of knowledge-sharing. We are proud to provide a platform for industry professionals to exchange experiences, discuss industry challenges, highlight current issues and changes, gain insights into effective regulatory strategies, and explore the latest trends in European regulations.

In addition to fostering networking opportunities, the Forum will feature experts who will share their invaluable "hands-on" experiences. This will provide delegates with a unique opportunity to gain practical insights and enhance their professional skill sets and expertise.

We look forward to your participation and joining us in a productive and engaging discussion.

WHY ATTEND

- Connect with leading Regulatory Affairs experts, opinion leaders, and regulatory body representatives
- Stay updated on the latest EU regulations and policy changes
- Gain valuable, practical insights from industry specialists
- Expand your professional network

WHO SHOULD ATTEND

Regulatory Affairs & Market Access VP, Directors, Manager, Head and Professionals of Pharma, Biotech and Medical Device Industries.

In collaboration with

PLG ProductLifeGroup

PHARMA D&S PHARMACEUTICAL DEVELOPMENT & SERVICES A ProductLifeGroup Company

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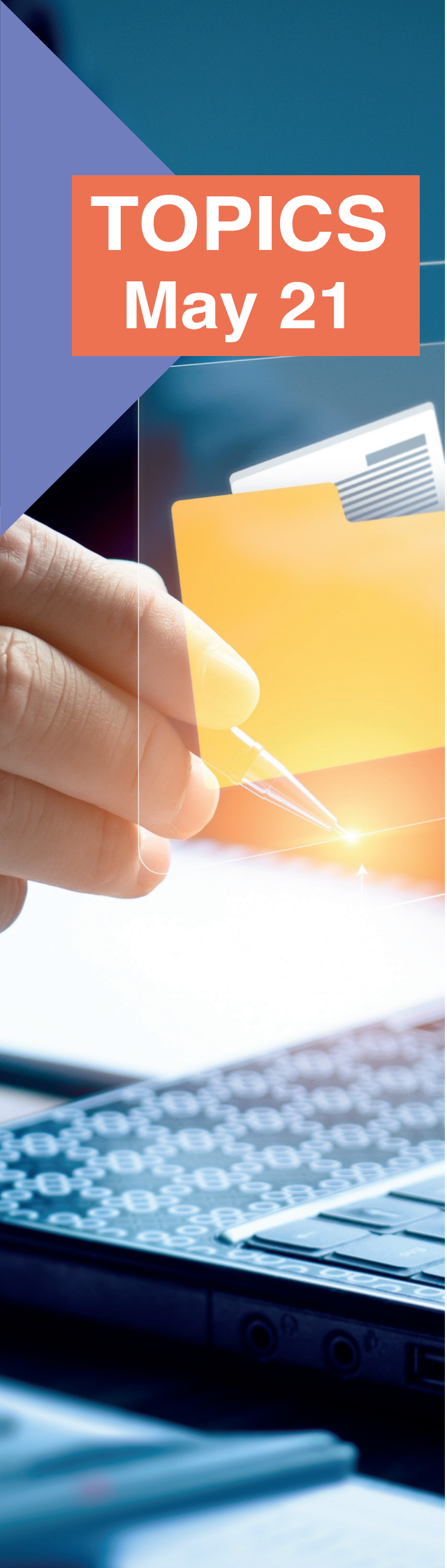
TOPICS May 21



SESSION I - NEW EU VARIATIONS FRAMEWORK

The European Commission has revised the rules governing the procedures for post-authorisation changes to the terms of a marketing authorisation for medicinal products for human use.

The amendment of the EC Variations Regulation 1234/2008 and the Variations Classification Guideline aims to make the lifecycle management of medicinal products for human use more efficient and aligned with evolving technology and regulatory needs.

Representatives from regulatory bodies and pharmaceutical companies will share insights into the new challenges and initial experiences related to the implementation of this regulation across the product lifecycle.

Key discussion points:

- Updates on post-authorization changes and procedures for medicinal products for human use
- New challenges and first experiences of the application of this new regulation from regulatory bodies and pharma companies
- Implications for product lifecycle management

SESSION II - SHORTAGES AND CRITICAL MEDICINES ACT: WHAT DOES THE FUTURE HOLD?

The shortage of essential medicines is currently a priority issue for the EU and is part of the agenda of the first 100 days of the new European Commission.

The Critical Medicines Act aims to address serious shortages of essential medicines such as antibiotics, insulin and painkillers in the EU and make the supply of active ingredients more predictable, reducing dependence on foreign countries.

The representatives from Regulatory bodies and pharma companies will share first experiences of the new platform and the future challenges and the measures for reducing the shortage problem.

Key discussion points:

- Future challenges and measures for reducing the medicine shortages and supply chain vulnerabilities
- Regulatory measures to mitigate risks
- Future strategies for ensuring a stable supply of critical medicines

TOPICS May 22

SESSION III - NAVIGATING AND DISCUSSING THE NEW HTA REGULATION AND JOINT CLINICAL ASSESSMENTS

The introduction of the HTA Regulation (HTAR) in 2022 marks a significant milestone in the field of Health Technology Assessment (HTA).

Join us as we explore how this new legislation heralds a new era in evaluating the joint clinical assessment of pharmaceuticals and medical devices.

What do the joint clinical assessments (JCA) in Europe mean for pharma or MedTech companies?

Key discussion points:

- Implications of Joint Clinical Assessments (JCA) for pharma and MedTech companies
- Keynote presentations by experts in the field
- Interactive panel discussion with speakers and delegates

SESSION IV - CTR: AFTER 3 YEARS SINCE THE IMPLEMENTATION – EXPERIENCES AND UNMET EXPECTATIONS

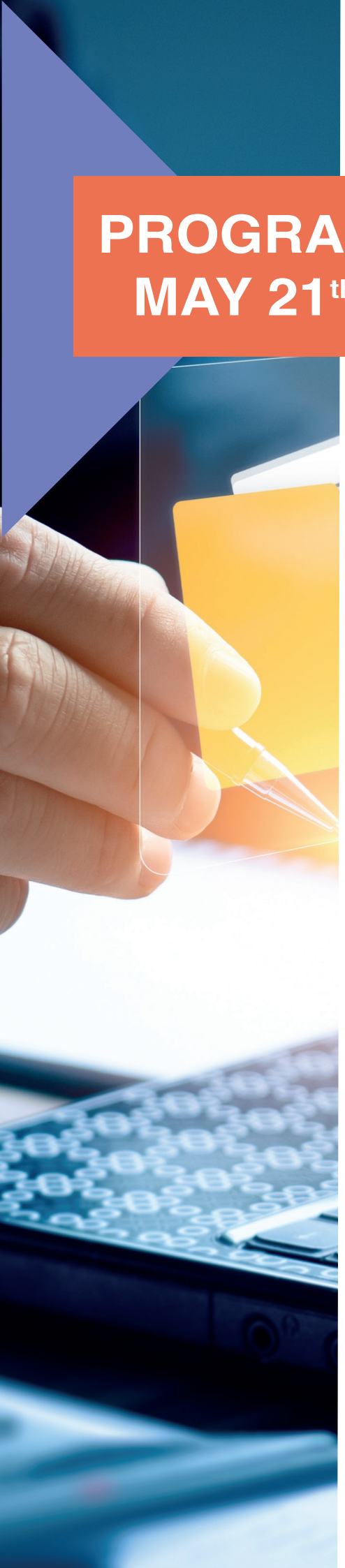
With the implementation of the CTR, the European Union aimed to increase the efficiency of clinical trials, by stimulating innovation and research, reducing duplication of assessments, creating a favourable environment for conducting clinical trials in the EU, harmonising assessment rules and processes with higher safety standards and increasing **transparency**, via the Clinical Trials Information System (CTIS).

After 3 years of CTR implementation and the go live of CTIS, what are the results? Are there some expectations not yet fulfilled?

The session will feature keynote presentations offered by representatives from Regulatory Bodies and from pharma industry for a final panel discussion with the involvement of speakers and delegates.

Key discussion points:

- Achievements and challenges after three years of implementation
- Unmet expectations and areas for improvement



PROGRAM MAY 21th

SESSION I
NEW EU VARIATIONS FRAMEWORK

2.00 pm — **Welcome**
Chairperson, *Pharma Education Center*

2.10 — **Introduction to the agenda**
Raffaella Pandini, *Italy Regulatory Affairs & Operations BU Director | Pharma D&S, a PLG Company*

2.20 — **New EU Variations Regulation**
Laura Braghiroli, *Post Authorization Procedures Office | AIFA*

2.50 — **Sharing of experiences**
Raffaella Pandini, *Italy Regulatory Affairs & Operations BU Director | Pharma D&S, a PLG Company*

3.20 — **Panel Discussion**
L. Braghiroli, R. Pandini,
G. Barretta, *Head of RA Italy | Alfasigma S.p.A.*

4.00 — **Coffee Break**

SESSION II
SHORTAGES AND CRITICAL MEDICINES ACT: WHAT DOES THE FUTURE HOLD?

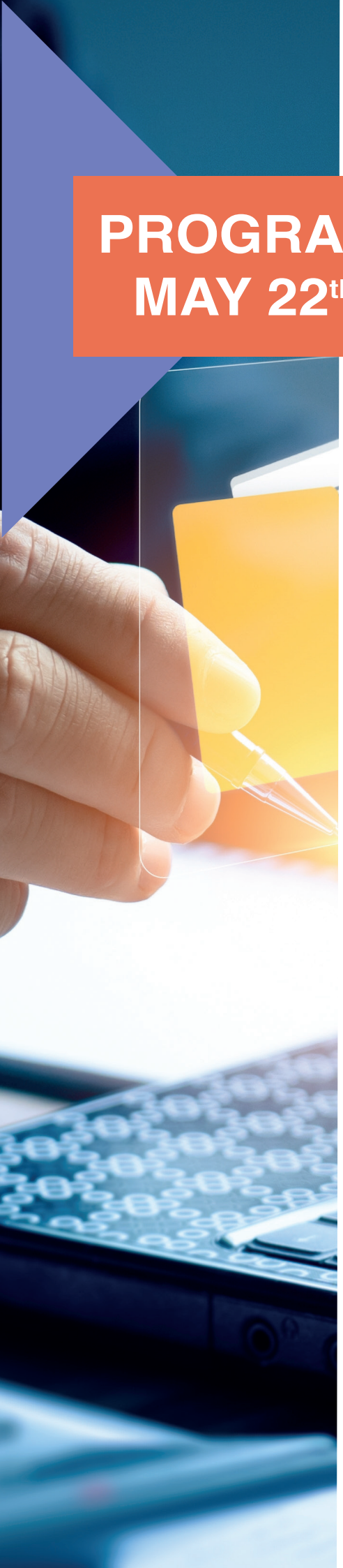
4.15 — **A future-proof EU Regulatory Ecosystem: what to expect?**
Patrizia Ciavatta, *Global Regulatory & Pharmacovigilance Chief | Angelini Pharma*

4.35 — **Shortages related activities in Europe**
Domenico Di Giorgio, *Head of Inspection & Certification Department and of the Pharmaceutical Crime | AIFA*

5.05 — **CMA and CMAct the journey of the legislation and outlook for more impact**
David Jauch, *Vice President Governmental Affairs & Public Policy | Fresenius SE & Co. KGaA*

5.30 — **Panel Discussion**
P. Ciavatta, D. Di Giorgio, David Jauch,
R. Pandini

6.00 — **Closure of the day**
Raffaella Pandini, *Italy Regulatory Affairs & Operations BU Director | Pharma D&S, a PLG Company*



PROGRAM MAY 22th

SESSION III
NAVIGATING AND DISCUSSING THE NEW HTA REGULATION AND JOINT CLINICAL ASSESSMENTS

2.00 Introduction to second day agenda
Raffaella Pandini, *Italy Regulatory Affairs & Operations BU Director | Pharma D&S, a PLG Company*

2.05 (JCA) model: implications, emerging needs, strategic development of new tools and processes.
Mariangela Prada, *Market & Patient Access BU Head | Intexo, a PLG Company*

2.15 The implementation of the new HTA Regulation: experiences from Europe
Entela Xoxi, *Senior Scientific Advisor & Lecturer with Collaboration Agreement for Research Projects | Università Cattolica del Sacro Cuore - Italy*
Asis Ariznavarreta, *Global Strategy Director | Outcomes'10 – Spain*
Dominique Amory, *Partner Nextep, Market Access for drugs and medical devices - France*
Paul Craddy, *Managing Director: Pricing and Market Access | Remap Consulting – UK*
Sandra Kiehlmeier, *Director Market Access DE / EU | Value & Dossier - Germany*

3.05 Coffee Break

SESSION IV
CTR: AFTER 3 YEARS SINCE THE IMPLEMENTATION – EXPERIENCES AND UNMET EXPECTATIONS

3.20 Introduction to SESSION IV
Raffaella Pandini, *Italy Regulatory Affairs & Operations BU Director | Pharma D&S, a PLG Company*

3.30 Navigating Clinical Trial Regulation with Special Focus on Safety in Clinical Trials: Strength, Challenges, and Future Perspectives - The Belgian Experience
Elena Prokofyeva, *Coordinator of Drug Safety Unit, DG Post, FAMHP*

3.50 CTR & CTIS: main features and experiences after 3 years of effect
Alessia Cipriani, *Regulatory Affairs Specialist | Zwiers Regulatory Consultancy BV, a PLG Company*

4:20 From Obstacles to Advantages: A Sponsor's Perspective on EU Clinical Trial Regulation 536/2014
Christel Gremion Viatte, *Director, Global regulatory CTA | CSL Behring*

4.50 Panel discussion
R.Pandini, A. Cipriani, E. Prokofyeva, C. Gremion Viatte

5.30 Closure of the day
Raffaella Pandini, *Italy Regulatory Affairs & Operations BU Director | Pharma D&S, a PLG Company*

SCIENTIFIC BOARD

Patrizia Ciavatta
Global Regulatory & PV Chief | Angelini Pharma

Paolo Dametto
Director, Regulatory Affairs | Deciphera

Ilaria Brocchi
Regulatory Affairs Senior Project Manager | Pharma D&S a PLG company

Raffaella Pandini
Italy Regulatory Affairs & Operations BU Director | Pharma D&S, a PLG Company

SPEAKERS

Patrizia Ciavatta
Global Regulatory & PV Chief | Angelini Pharma

Laura Braghiroli
Post Authorization Procedures Office | AIFA

Domenico Di Giorgio
Head of Inspection & Certification Department and of the Pharmaceutical Crime | AIFA

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ENTRY FEE
350 € Early bird single day
400 € Single day

600 € Early bird 2 days
700 € 2 days

Early bird fees expire on April 21th

VAT not included

Discounts are not cumulative

For multiple registrations contact:
info@pharmaeducationcenter.it

REGISTER HERE

For further information and/or further assistance please contact +39 (0) 055 0465336 or email: amministrazione@pharmaeducationcenter.it

EVENT CANCELLATION
If the minimum number of participants is not reached, Pharma Education Center reserves the right to cancel or schedule the event for another date. Formal communication will be given within 5 days before the event date. In this case Pharma Education Center will refund the registration fee in full and without additional charges. Alternatively, the participant can request a spendable coupon for participating in another PEC event scheduled in the current year.

CANCELLATION TERMS
In order to cancel enrolment to a event, please email info@pharmaeducationcenter.it within 2 weeks before the starting date of the event. Once this term will be expired, the entire fee will be charged.

ATTENDEE REPLACEMENT
It is possible to replace a participant with another without additional costs, simply by contacting info@pharmaeducationcenter.it. It is asked to notify the participant replacement request within 5 days before the starting date of the event, specifying the full name and surname of the enrolled participant as well as the full name and surname of the substitute.

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