SYMPOSIUM 2026 UTRECHT

Human Medicines Programme

Monday 19 October 2026 – Wednesday 21 October 2026

Beatrix Building, Royal Jaarbeurs, Utrecht, The Netherlands

Please note, the programme may be subject to change.

	Human Medicines Stream		Human Medicines tickets also provide access to the Combination Products and SME streams.	
MONDAY 19TH OCTOBER 2026				
11:00 – 12:00	Registration			
12:00 – 13:30	Welcome Speech & HM1 – Regulatory Transformation: Preparing for the Legislative Wave			
13:30 – 14:40	Lunch Break – Meet the Benelux IN Group			
14:40 – 16:00	HM2 – Regulatory Sandboxes – From Concept to Implementation across Pharma, AI and Medical Devices		CP1 – Combo Group: Aligning Regulatory Practice for Combination Products	
16:00 – 16:40	Networking Break			
16:40 – 18:00	HM3 – Navigating the New Normal: Medicines Regulation in a Shifting Landscape		CP2 – Global Approaches to Combination Products	
TUESDAY 20TH OCTOBER 2026				
09:00 – 10:20	HM4 – Driving Innovation in EU: Can the Recent Initiatives Optimise the Fragmentation of the EU Regulatory CT Framework	PS4 – Optimising Post-Approval CMC Changes: Leveraging new EU Variations Guidelines, ICH Quality Updates and Regulatory Q&As for Future Lifecycle Management	CP3 – Potential gaps in post-market compliance for combination products	
10:20 – 11:00	Networking Break			
11:00 – 12:20	HM5 – Strengthening CMC Strategy to Accelerate Global and US/EU Market Access	PS5 – Evolving Benefit-Risk Frameworks: Calibrating Evidence generation and assessment for Novel Clinical Trial Designs	CP4 – Effectively Managing Changes to Drug-Device Combination Products	
12:20 – 14:00	Lunch Break			
14:00 – 15:20	HM6/MD7/IVD7 – The Future of Combined IMP/IVD Trials in Europe: COMBINE, CTIS Integration, and the Emerging Regulatory Model	PS6 – From Regulation to Readiness: Leveraging the European Health Data Space Transition Period for Europe's Competitiveness		SME1 – How can SMEs navigate the regulatory legislative wave: small but compliant
15:20 – 16:00	Networking Break			
16:00 – 17:20	HM7 – Unlocking Regulatory Capacity: How AI Tools Are Transforming Regulatory Practice in European Pharmaceuticals	PS7 – From approval to access—aligning RWE, Regulatory Approval, HTA, and reimbursement to deliver patient benefit	CP5 – Combination Products of the Future	SME2 – Rare disease regulatory pathways. Plausible mechanisms, prior knowledge and novel licensing pathways
WEDNESDAY 21ST OCTOBER 2026				
09:00 – 10:20	HM8 – The evolution of (e)-Product Information	PS8 – Evolving Accelerated Paths in Europe		SME3 – The Criticality of Regulatory and Product Strategy for Innovative Drug Companies
10:20 – 11:00	Networking Break			
11:00 – 12:20	HM9 – Making patient engagement actionable across drug development and evidence generation	PS9 – Securing the Medicines Supply Chain: Critical Medicines & Shortage Prevention		SME4 – From Innovation to Investment: Using Regulatory Strategy to Win Grants and Funding
12:20 – 14:00	Lunch Break			
14:00 – 15:20	HM10 – Accelerating Regulatory Science in medicines R&D: Europe's Role in Advancing Novel Evidence & Methodologies for Patients	PS10 – From Inclusion to Evidence: Advancing Regulatory Frameworks for Special Populations		SME5 – Lessons Learned from SMEs Taking Their First Asset to Clinic

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Monday 19 October 2026 – DAY 1

Time	Session
11:00–12:00	Registration
12:00–12:10	Welcome Speech

Speakers

- Dr. Samantha Atkinson, Chief Executive Officer, TOPRA, United Kingdom
- Carlos Langezaal, Independent Regulatory Consultant/Chair of the TOPRA Human Medicines Symposium Working Party (HMSWP), Langezaal Regulatory Consultancy, United States of America

12:10–13:30	HM1/PS1 – Regulatory Transformation: Preparing for the Legislative Wave

The European regulatory landscape for medicines and biotechnology is entering a new era. The reform of the EU pharmaceutical legislation (GPL) and the forthcoming Biotech Act are part of a broader policy shift aimed at strengthening Europe's competitiveness in life sciences, accelerating innovation, and ensuring timely patient access to medicines. In this opening keynote, senior leaders from the European Commission and the European Medicines Agency will set the stage for the symposium by placing these legislative developments in the context of the EU's wider Research & Innovation strategy and the EMA's regulatory science and network strategy. Together, these initiatives signal a coordinated effort to modernise Europe's regulatory ecosystem and support the next generation of innovations in Life Sciences. Designed to frame the discussions that follow over the next three days, this session will provide a high-level perspective on how policy, research, and regulation are aligning and what this means for the future of medicines development in Europe.

Learning Objectives

- Understand the strategic direction of the evolving EU regulatory framework, including general pharmaceutical legislation reform and the proposed EU Biotech Act.
- Recognize how EU policy initiatives and regulatory strategies are aligned to support innovation, competitiveness, and patient access.
- Identify key themes and implications for the future of medicines regulation in Europe that will be explored throughout the symposium.

Session Leaders

- Maren von Fritschen, Professor & Translational Medicine Advisor, University of Applied Sciences, Germany
- Sabine Haubenreisser, Principal Scientific Administrator - Stakeholders and Communication, EMA, The Netherlands

Speakers will include...

- Rainer Becker, Director DG SANTE, European Commission, Belgium
- Joep Muijers, General Partner, Glide Healthcare, The Netherlands
- Valentina Strammiello, Executive Director, European Patients' Forum, Belgium
- Emer Cooke, Executive Director, EMA, The Netherlands

13:30–14:40	Lunch Break
14:40–16:00	HM2/PS2 – Regulatory Sandboxes – From Concept to Implementation across Pharma, AI and Medical Devices

Regulatory sandboxes are emerging as one of the most innovative policy tools to support transformative and high-impact technologies while maintaining robust patient safeguards. The proposed EU Pharmaceutical Legislation introduces a dedicated Regulatory Sandbox framework (Articles 113–115), while similar approaches are now embedded in the EU AI Act and proposed amendments to the Medical Device and IVD Regulations.

Building on the strategic context established in the opening keynote session, this panel will take a practical deep dive into how Regulatory Sandboxes could operate across medicines, AI-enabled healthcare solutions, advanced therapies, platform technologies and medical devices along the value chain from academic research to patients' benefit. The

session will explore how regulators, innovators, academia and healthcare systems in the EU can collaborate in controlled regulatory environments to accelerate innovation while generating regulatory learning and maintaining public trust.

Speakers from the European Commission, EMA, academia, industry and the medical device sector will discuss the evolving legal framework, operational implementation and real-world use cases. Particular focus will be placed on the EMA Innovation Task Force (ITF), the EFPIA/IHI BRIDGE initiative, cross-sectoral coordination under the AI Act, and the convergence of medicines and device regulation for integrated technologies and combined studies.

The session will also examine broader European experiences with Regulatory Sandboxes across sectors and Member States, highlighting lessons learned for governance, eligibility, stakeholder engagement and regulatory experimentation.

Learning Objectives

- Understand the evolving European regulatory framework for Regulatory Sandboxes across pharmaceuticals, AI and medical devices, including key provisions in the revised EU Pharmaceutical Legislation, EU AI Act and MDR/IVDR amendments.
- Explore how Regulatory Sandboxes can support the development, evaluation and implementation of innovative health technologies while ensuring patient safety, regulatory oversight and public trust.
- Discuss practical implementation challenges and opportunities for collaboration between regulators, academia, industry and healthcare stakeholders to enable regulatory learning and innovation across the European life sciences ecosystem.

Session Leaders

- Maren von Fritschen, Professor & Translational Medicine Advisor, University of Applied Sciences, Germany
- Emmanuel Cormier, Head of Regulatory Science and Innovation, EMA, The Netherlands

Speakers

- Florian Schmidt, Deputy Head of Unit, European Commission, Belgium
- Nick Sykes, Policy Advisor – Regulatory Strategy, EFPIA, Belgium
- Stephen Gilbart, Professor of Medical Device Regulatory Science, TUD Dresden University of Technology, Germany
- Valentina Cordò, Scientific Specialist, EMA, The Netherlands

16:00–16:40	**Networking Break**
16:40–18:00	**HM3/PS3 – Fireside Chat: Navigating the New Normal: Medicines Regulation in a Shifting Landscape**

The European Medicines Agencies' network strategy to 2028 sets out an ambitious agenda centred on three interrelated imperatives: building agility to anticipate transformative change; creating conditions where predictability encourages the long-term investments required for medicines development; and securing the sustainability of the network's scientific and regulatory capacity. These are not isolated goals — they are mutually reinforcing. A network that cannot sustain its scientific expertise cannot be agile. A system that lacks agility cannot be predictable. And without predictability, the investment that sustains innovative medicines development in Europe is at risk.

In addition, the new pharmaceutical legislation demands a fundamental shift in committee functioning, more agile regulatory processes, and greater transparency — all while the network must evolve in step, building expertise in emerging therapeutic areas and maintaining the institutional continuity that sponsors depend on when making decade-long development commitments.

Predictability, however, is not simply a procedural metric. It is the foundation upon which sponsors allocate capital and plan regulatory strategy. The current global context is sharply instructive: surprise shifts in FDA decision-making have created an air of unpredictability that threatens biotech investment confidence. EMA and the Network have a genuine and time-sensitive opportunity to position the European framework as the global standard for trustworthy, stable, and developer-friendly scientific dialogue.

This fireside chat brings together leading voices from EMA, the Regulatory Network and Industry to probe where the system is genuinely evolving, where structural barriers persist, and whether EMA can convert the current geopolitical moment into lasting confidence that advice given in Europe will be advice that holds.

Session Leaders

- Francesca Buttigieg, Regulatory Affairs Executive Director, RhyGaze, Switzerland
- Sabine Haubenreisser, Principal Scientific Administrator - Stakeholders and Communication, EMA, The Netherlands

Speakers

- Aimad Torqui, Deputy Director, CBG-MEB, The Netherlands
- Francesca Day, Head of Therapeutic Areas Department, EMA, The Netherlands
- Bruno Sepodes, Chair of the Committee of Human Medicinal Products (CHMP), EMA, Portugal
- Sabine Atzor, Head of EU Regulatory Policies, F.Hoffmann-La Roche, Switzerland

18:00–18:05	Closing Speech – Day 1

End of Day 1

Tuesday 20 October 2026 – DAY 2

Time	Session
08:55–09:00	Welcome to Day 2
09:00–10:20	HM4 – Driving Innovation in EU: Can the Recent Initiatives Optimise the Fragmentation of the EU Regulatory CT Framework

A more simplified and streamlined clinical trials regulatory ecosystem is essential to Europe's transition toward a more effective, and competitive approach to clinical research. The European Commission has proposed in December 2025 an ambitious package of measures to improve the health of EU citizens, while ensuring the long-term resilience and competitiveness of the health sector. The package includes a Biotech Act significantly amending Clinical trial regulation (EU) 536/2014, and revised rules for medical devices which aim to accelerate the development of innovative new therapies (both medicines and medical devices) for patients. Similarly, several National Competent Authorities (NCAs) and Ethics Committees opened in January 2026 coordinated fast-track pilot for evaluating multinational clinical trials. This initiative, known as FAST-EU (Facilitating and Accelerating Strategic Trials), aligns with the European Commission's other legislative initiatives. By offering practical insights into the feasibility and challenges of the accelerated assessment model it supports the future implementation of the EU Biotech Act. The FAST-EU approach outlines clear and ambitious timelines along with coordination mechanisms designed to provide trial sponsors with greater predictability regarding evaluation and authorization timelines for multinational clinical trials in the EU. This initiative aims to bolster sponsors' confidence in the European regulatory system, facilitate research investment, and maintain high scientific, safety, and ethical standards. The session will feature a panel discussion with representatives from the European Commission, Member States, trade associations, and industry leaders to explore the future opportunities to the clinical trials environment in Europe presented by these pivotal evolutions.

Learning Objectives

- Identify the current challenges in EU clinical trials, and the COVID-19 pandemic lessons learnt.
- FAST-EU: Objectives, mechanism and key process elements.
- Future changes in the context of the Biotech Act: key characteristics, stakeholders, significance, relationships to existing regulatory frameworks, timelines, implementation and strategic implications for sponsors.

Session Leaders

- Christopher Price, Strategist, Global Regulatory Affairs Oncology, Merck Healthcare KGaA, Germany
- Martin Dreyling, Professor of Medicine, LMU University Hospital, Germany

Speakers

- Monique Al, Special Advisor, CCMO, The Netherlands

- Edit Szepessy, Policy Officer, European Commission, Belgium
- Martin O'Kane, Regional Head RA EU Policy & Liaison, Novartis, United Kingdom
- Ana Zanoletty, Head of Clinical Trials Transformation, EMA, The Netherlands
- Jan Mol, Patient Advocate, Lymphoma Coalition Europe, The Netherlands

09:00–10:20	PS4 – Optimising Post-Approval CMC Changes: Leveraging new EU Variations Guidelines, ICH Quality Updates and Regulatory Q&As for Future Lifecycle Management

Post-approval changes are largely driven by Chemistry, Manufacturing and Control (CMC) updates, requiring efficient and well-defined regulatory approaches to support ongoing product improvement. While the new EU Variations Guidelines are already in effect, lessons learned from their implementation, combined with evolving quality guidance from the ICH and the increasing use of regulatory Q&As and Reliance procedures, are reshaping how lifecycle management is approached in Europe. In parallel, ongoing work with the EMA is focused on improving and optimising how simple post-approval changes are managed across the EU network, including through digitalisation initiatives. This session will explore how these developments have improved regulatory clarity and efficiency, what challenges remain, and how digital tools can support more streamlined post-approval processes. Speakers from regulators and industry will share practical perspectives, followed by a question-and-answer session to discuss how these lessons can guide future CMC strategies while maintaining product quality, safety, and compliance.

Session Leaders

- Cristina Dragan, Associate Director and Regulatory Policy and Intelligence, Novartis, United Kingdom
- Francisco Baptista, Senior Regulatory Affairs Manager - Team Lead, Arriello, Ireland

Speakers

- Kora Doorduijn-van der Stoep, Former chairperson of CMDh and EU representative at the Medicines Evaluation Board, The Netherlands
- Bryn Raven, Regulatory Operations Senior Associate, Reckitt, United Kingdom
- Brian Dooley, Pharmaceutical Quality Senior Specialist, EMA, The Netherlands

10:20–11:00	Networking Break

11:00–12:20	HM5 – Strengthening CMC Strategy to Accelerate Global and US/EU Market Access

Chemistry, Manufacturing and Controls (CMC) issues remain a leading cause of regulatory delays worldwide. Deficiencies observed in regulatory submissions are often both recurring and predictable, yet they continue to affect dossier quality and approval timelines. This session will explore key trends from European/United States and international regulatory experiences, highlighting common CMC challenges and practical strategies to address them proactively during development, as described in the article "Learning from the EMA experience". Participants will learn how focusing on potentially preventable deficiencies early in the process can streamline reviews and accelerate global market access. Speakers from regulators and industry will share their insights, followed by a question-and-answer session where participants can discuss how to apply these learnings to future submissions and improve efficiency in getting products to market.

Session Leaders

- Sandra Luísa de Sousa Lourenço, Director of Regulatory Affairs, Arriello, Ireland
- Lisa Hinchcliffe, Director, LangAllan CMC Regulatory Solutions Ltd, United Kingdom

Speakers will include...

- Christian Zeine, Senior Manager, Scientific Affairs EMEA, United States Pharmacopeia (USP), Switzerland
- Lisa Eisenbeiss, Senior Quality Assessor, SwissMedic, Switzerland

11:00–12:20	PS5 – Evolving Benefit-Risk Frameworks: Calibrating Evidence generation and assessment for Novel Clinical Trial Designs

The release of ICH E6(R3) Annex 2 marks a pivotal shift toward "proportionate and risk-based" approaches to clinical trial conduct, particularly for trials utilizing complex, novel data sources. Simultaneously, the CIOMS XII Working Group has provided the roadmap for a Structured Benefit-Risk Framework (SBRF). However, a gap remains: how must traditional benefit risk frameworks adapt when the "benefit" and "risk" are derived from non-traditional streams like wearables, EHRs, and decentralized platforms?

Objectives

This panel discussion is designed to explore the evolution of benefit risk assessment frameworks as viewed by regulators.

The presentation will focus on two recent adaptations required for modern B-R frameworks:

1) Risk-Proportionate Quality Management & Novel data sources incorporation (ICH E6(R3) Alignment): Traditional B-R assessments focus on the drug; but how should we assess the data source risk? We will examine how Annex 2 addresses these, including the addition of RWD, Pragmatic and decentralised elements within trials

2) Uncertainty Quantification (CIOMs report): A central principle of the CIOMS report is the explicit quantification of uncertainty. Within the structured benefit risk framework, Real-World Evidence (RWE) plays a key role in narrowing "knowledge gaps" about long-term safety, particularly as traditional trials are often insufficiently powered to identify these risks. We will discuss this further, and how these two advancements work together.

Conclusion

To achieve "fit-for-purpose" evidence generation, B-R frameworks can no longer be fixed documents. Together with regulators, we will discuss how B-R frameworks are evolving, and how sponsors can respond to this evolution, to enable better regulatory decision making.

Learning Objectives

- Together with regulators, we will discuss how B-R frameworks are evolving, and how sponsors can respond to this evolution, to enable better regulatory decision making.
- Audience will learn about recent guidance documents such as E6R3 Annex 2 and CIOMs report on Structured Benefit-Risk Framework (SBRF) and how these will affect regulatory assessments

Session Leaders

- Gracy Crane, Global Regulatory Topic Lead, RWD & Pragmatic Trials, Roche, United Kingdom

Speakers will include...

- Flora Musuamba Tshinanu, Assessor, FAHMP, Belgium
- Stefanie Prilla, Head of Methodology (TDA-MET), EMA, The Netherlands

12:40–14:00	**Lunch Break**
14:00–15:20	**HM6/MD7/IVD7 - The Future of Combined IMP/IVD Trials in Europe: COMBINE, CTIS Integration, and the Emerging Regulatory Model**

The regulatory landscape for combined clinical trials involving investigational medicinal products (IMPs) and in vitro diagnostic medical devices (IVDs) is undergoing significant transformation. Building on the analysis published in the 2026 February edition of the Regulatory Rapporteur, this session will provide an updated perspective on the latest developments in the European Commission's EC COMBINE initiative, including progress on harmonisation pilots, early CTIS integration concepts, and potential future models for unified IMP/IVD submission pathways.

With the introduction of the new EU Biotech Act, additional changes are expected that may reshape requirements for supporting evidence packages, oversight processes, and the interaction between the Clinical Trials Regulation (CTR) and the In Vitro Diagnostic Regulation (IVDR). Particular attention will be given to how Request for Information (RFI) pathways could evolve under this new legislative framework, and what these changes may mean in practical terms for clinical trial sponsors, especially those conducting biomarker driven or co-development trials.

The session intends to offer a cross-industry view of emerging regulatory and operational expectations, incorporating lessons learned from ongoing engagement across sponsors, competent authorities, and notified bodies. Operational and authority perspectives will be shared by co presenters enabling a multi stakeholder discussion on practical challenges, anticipated system behaviour, and opportunities for greater procedural alignment. Attendees will gain an up to date understanding of current developments, near term industry implications, and forward-looking considerations for planning and executing combined IMP/IVD trials in the EU.

Learning Objectives

- Understand emerging EU requirements for combined IMP/IVD trials under CTR, IVDR, and the COMBINE initiative.
- Analyse how COMBINE outputs and the proposed EU Biotech Act may reframe RFI roles, sequencing, and authority interactions.

- Consider the implications for future regulatory governance and procedural alignment under CTR and IVDR.

Session Leaders

- Amber McNair, Associate Director, Clinical Trials Regulatory, IQVIA, United Kingdom
- Margareth Jorvid, Chief Executive Officer, Methra Uppsala, Sweden

Speakers

- Deepa Subramaniyan, Senior Clinical Trial Regulatory Lead, Roche, Switzerland
- Maurice Steenhuis, Medical Technology Assessor, CCMO, The Netherlands
- Olga Tkachenko, Policy Officer, European Commission, Belgium
- Stiina Aarum, Scientific Officer, EMA, The Netherlands

14:00–15:20	PS6 – From Regulation to Readiness: Leveraging the European Health Data Space Transition Period for Europe's Competitiveness

The European Health Data Space (EHDS) has the potential to be a cornerstone of Europe Union's regulatory and research competitiveness. However, its impact will depend on how effectively stakeholders align and operationalise health data access beyond compliance. While initiatives such as DARWIN-EU have demonstrated the value of real-world data in regulatory decision-making, there remains a gap in understanding how regulators, HTA bodies, industry and patients can collaborate to design sustainable data-sharing models under the EHDS framework.

This panel will explore how sector stakeholder can support EHDS implementation during its transition period, while implementing acts are being finalised towards 2027. This interim phase represents a critical opportunity to shape practical approaches to secondary use of health data in clinical research and regulatory evidence generation. The discussion will focus on EHDS provisions relevant to clinical trials, the role of Health Data Access Bodies, and cross-border data discovery via the emerging HealthData@EU infrastructure.

The panel will examine opportunities for multi-country collaboration during this transition phase, highlighting how early piloting and cross-stakeholder engagement can enable efficient data discovery and access across Member States.

The session will conclude with a forward-looking discussion on how early collaboration under the EHDS can strengthen Europe's competitiveness in clinical research, evidence generation and regulatory decision-making. Delegates will gain actionable insights into steps that can be taken in 2026, including participation in pilots, engagement with Health Data Access Bodies, and development of shared governance and trust principles to support successful EHDS implementation.

Learning Objectives

- Explain how the EHDS implementation transition period can be used to strengthen Europe's competitiveness in clinical research and evidence generation.
- Identify opportunities and barriers for multi-country data discovery and access under the EHDS.
- Apply practical approaches for cross-stakeholder collaboration to support EHDS readiness and competitiveness.

Session Leaders

- Estelle Michael, Public Policy Lead, UCB, Belgium

Speakers

- Sofia Peltola, Specialist, International Health Data Projects, The Finnish Innovation Fund Sitra, Finland
- Christine Leopold, Assistant Professor of Drug Regulatory Science, Utrecht University, The Netherlands
- Katarina Nedog, Director Regulatory Policy, EFPIA, Belgium
- Daniel Morales, Senior Epidemiologist, EMA, The Netherlands

15:20–16:00	Networking Break

16:00–17:20	HM7 – Unlocking Regulatory Capacity: How AI Tools Are Transforming Regulatory Practice in European Pharmaceuticals

Artificial Intelligence (AI) and machine learning (ML) tools are increasingly embedded across all areas of the medicinal product lifecycle, from target identification to post-marketing surveillance. In Europe, the pace of digitalisation is accelerating — and the regulatory community is at the centre of this transformation.

As AI/ML technologies become woven into the regulatory landscape, a critical question emerges: are we fully exploiting the potential of these tools to unlock capacity and create meaningful efficiencies in regulatory business? Tools such as large language models and generative AI are already being applied to support drafting, compilation, translation, and review of global medicinal product dossiers. National Competent Authorities and the European Medicines Agency are actively developing and deploying AI-enabled solutions to modernise regulatory workflows. In addition, industry is exploring how AI can streamline other regulatory activities such as regulatory intelligence, submission tracking, and translations.

Beyond delivering the status quo more efficiently, these innovations hold the potential to drive the next generation of regulatory science and practice. Will AI tools free up regulatory professionals to focus on higher-value scientific and strategic work? Or will their responsible use demand greater — and more sophisticated — oversight? This session brings together perspectives from the EMA, a National Competent Authority, and industry to explore what is being used today, what is on the horizon, and how the EU regulatory community can lead the way.

Session Leaders

- Rebecca Lumsden, Head of Regulatory Science & Policy EU/AMEE, Sanofi, United Kingdom
- Aneta Tyszkiewicz, Director, Science & Regulatory, EFPIA, Belgium

Speakers

- Seamus Doyle, Data Scientist and AI Assessor, MPA, Sweden
- Inger Ødum Nielsen, Associate Director, Novo Nordisk, Denmark
- Aneta Tyszkiewicz, Director, Science & Regulatory, EFPIA, Belgium
- Joaquim Berenguer, AI implementation Lead, EMA, The Netherlands

16:00–17:20	PS7 – From approval to access—aligning RWE, Regulatory Approval, HTA, and reimbursement to deliver patient benefit

Despite scientific innovation and accelerated regulatory pathways, patient access to new medicines remains slow and fragmented across Europe and globally. A key driver of this gap is the inconsistent integration of Real-World Data (RWD) and Real-World Evidence (RWE) across regulatory, HTA, and reimbursement decision-making. This session addresses how can regulators, HTA bodies, industry, and patients work together earlier to close evidence gaps and accelerate access.

The IHI IDERHA project, (Integration of Heterogeneous Data and Evidence towards Regulatory and HTA Acceptance) has conducted a comprehensive review of global RWD/RWE policies across key agencies including FDA, EMA, NICE, and HAS. While meaningful progress has been made over the past five years, notable gaps persist in data quality assessment, fitness-for-use evaluation, and RWE interpretation, including digital health, AI-driven solutions, and personalized medicine. Critically, the lack of a shared framework for what constitutes "Good RWE Practices" continues to undermine the relevance and acceptability of RWE submissions across both regulatory and HTA processes. Building on this landscape analysis, IDERHA is developing actionable policy recommendations aimed at defining what Good RWE Practices should look like in practice to ensure RWE is not only generated but trusted and used consistently by regulators and HTA bodies. The upcoming European Health Data Space (EHDS) will also be discussed as a potential enabler for more consistent and transparent evidence generation in Europe.

This session will examine the policy and process gaps between regulatory approval and real-world patient access, explore opportunities for parallel rather than sequential evidence generation for regulatory and HTA engagement, and discuss how aligning on RWE standards can bridge the approval-to-access divide. Our goal is to redefine success as innovation that is not only approved but prescribed, reimbursed, and accessible to patients in a timely way.

Session Leaders coming soon...

- Amaia Clemente, Regulatory Science & Policy Associate Director Europe, Sanofi, Spain
- Kwee Lan Tan, Head of Team Regional Regulatory Lead Oncology and Inflammation, Boehringer Ingelheim, Germany

Speakers will include...

- Bianca Pop, Project Officer, European Patients' Forum, Belgium
- Amaia Clemente, Regulatory Science & Policy Associate Director Europe, Sanofi, Spain

17:20–17:25	Closing Speech

End of Day 2

Wednesday 21 October 2026 – DAY 3

Time	Session
08:55–09:00	Welcome to Day 3
09:00–10:20	HM8 – The evolution of (e)-Product Information

This session will highlight how some of the elements of (e)-product information fit together across the lifecycle of product information. A more connected user-centric Patient Information ecosystem is the direction many regulators and pharmaceutical companies are moving toward.
In this session, we cover how digital transformation is shaping regulatory practice by building interoperable regulatory systems to enhance regulatory workflows and data exchange. An industry representative will present a global analysis of e-labelling adoption with digitalisation of patient information (ePIL). The third item to be discussed will be the usability and navigation in product information which will include pictograms.

Session Leaders

- Carlos Langezaal, Independent Regulatory Consultant, Langezaal Regulatory Consultancy, United States of America
- Jasper-Hugo Brouwers, Head of Corporate and Stakeholder Affairs, Medicines Evaluation Board, The Netherlands

Speakers

- Sabine Faber, Senior Regulatory Affairs Manager Labelling GSA, Sanofi, Germany
- Katja Pečjak Reven, Owner & Managing Partner — Strategic Regulatory Advisory, Billev Pharma East Ltd., Slovenia
- Yara Mangindaan, Pharmacist Patient Information, Medicines Evaluation Board, The Netherlands
- Elizabeth Scanlan, ePI Product Owner, EMA, The Netherlands

09:00–10:20	PS8 – Evolving Accelerated Paths in Europe

The European regulatory landscape for accelerated pathways is undergoing significant transformation. With the implementation of the new Pharmaceutical Legislation (NPL) and evolving expectations from industry, regulators, and patients, how are accelerated pathways adapting to meet 21st-century healthcare needs? This session brings together perspectives from industry, National Competent Authorities, EMA, SMEs, and patients to explore current experiences, emerging challenges, and the future of expedited regulatory routes in Europe.

Learning Objectives

- Understand current challenges and successes with European accelerated pathways from multiple stakeholder perspectives.
- Identify key changes and opportunities arising from NPL implementation.
- Recognize best practices for successful accelerated pathway submissions.
- Appreciate the balance between speed and scientific rigor in regulatory decision-making.
- Anticipate future evolution of accelerated pathways in the European regulatory landscape

Session Leaders

- Stephane Callewaert, Director, Regulatory Policy EMEA, Global Regulatory Policy & Intelligence, Johnson & Johnson, Belgium
- Rebecca Lumsden, Head of Regulatory Science & Policy EU/AMEE, Sanofi, United Kingdom

Speakers

- Stephane Callewaert, Director, Regulatory Policy EMEA, Global Regulatory Policy & Intelligence, Johnson & Johnson, Belgium
- Catherine Paugam-Burtz, Director General, ANSM, France
- Kristina Larsson, Head of Orphan Medicines, EMA, The Netherlands
- Shekhar Natarajan, Vice-President of Regulatory Affairs, Dyne Therapeutics Europe, United Kingdom

10:20–11:00	**Networking Break**
11:00–12:20	**HM9 – Making patient engagement actionable across drug development and evidence generation**

Meaningful patient involvement is no longer optional—it is becoming a practical requirement for developing medicines to address real-world needs and generate evidence that is credible, usable and decision relevant. This symposium explores how to make patient engagement operational—turning patient voice and Patient Experience Data (PED) into concrete choices in protocol design, endpoint selection and post marketing real world evidence (RWE) generation, while aligning with evolving regulatory and HTA expectations.

The discussion will cover structured approaches to co create evidence with patients, caregivers and patient organisations, including co creation workshops, burden of participation assessments, and community validated patient reported outcome (PRO) tools—particularly relevant in rare and complex diseases where traditional evidence may be limited. Speakers will share examples of how early engagement can improve feasibility, reduce unnecessary burden, strengthen recruitment and retention, and ensure endpoints better reflect daily functioning and quality of life.

The session will then move on to examine current and emerging guidance on patient involvement and PED (including European developments), looking at what developers may be expected to provide in submissions, how patient insights are evaluated in decision making, and how patient relevant information can be communicated transparently in public-facing documents. Clarity for example on SmPC or patient information leaflet to help inform the joint patient-physician decision in the selection of the most suitable therapeutic option is still lacking.

This session will bring together voices from developers, patients and care-givers, EMA and HTA bodies to share insights on current and future frameworks for patient focused drug development to identify actionable changes so the patient voice is systematically included during drug development.

Panellists from patient advocacy, industry, regulators and HTA will address practical implementation challenges (data quality, representativeness, bias mitigation, governance and sustainability) and propose actionable approaches to embed patient voice across the medicinal product lifecycle.

Session Leaders

- Sandra Paci, Director, Patient Advocacy & Policy (Developed Markets), Argenx, Belgium
- Amaia Clemente, Regulatory Science and Policy Associate Director, Sanofi, Spain

Speakers will include...

- Mencia de Lemus, CEO, FundAME, Spain
- Amaia Clemente, Regulatory Science and Policy Associate Director, Sanofi, Spain
- Kaisa Immonen, Patient Liaison Expert, EMA, The Netherlands

11:00–12:20	**PS9 – Securing the Medicines Supply Chain in Europe: Critical Medicines, Shortage Prevention and Emerging Regulatory Expectation**

Ensuring a stable, secure, and resilient medicines supply chain has become a central priority for regulators worldwide. This session will explore the regulatory implications of the Critical Medicines Act, and emerging requirements for Supply Prevention Plans in the context of the General Pharmaceutical Legislation.
Speakers will examine how these initiatives collectively reshape obligations for marketing authorisation holders, manufacturers, and distributors. Attendees will gain insight into risk assessment, shortage mitigation planning, quality

system enhancements, and enforcement trends — with a focus on translating policy into practical compliance strategies.

Session Leaders

- Francesca Buttigieg, Executive Director Global Regulatory Affairs, RhyGaze, Switzerland
- Cristina Dragan, Associate Director Regulatory Policy and Intelligence, Novartis, United Kingdom

Speakers will include...

- Laure Geslin, Team Leader, European Commission, Belgium
- Britt Vermeij, Senior Director Regulatory Policy & Intelligence, Teva Pharmaceuticals, Netherlands
- Ana Coelho, Head of Supply and Availability of Medicines and Medical Devices, EMA, The Netherlands

12:20–14:00	**Lunch Break**
14:00–15:20	**HM10 – Novel Methodologies: Accelerating Regulatory Science in medicines R&D: Europe's Role in Advancing Novel Evidence & Methodologies for Patients**

Regulatory science innovation in Europe is transforming how we generate evidence for medicines development, with patient benefit as the central focus. Traditional R&D approaches often fall short in complex diseases, necessitating evolution toward novel methodologies that can accelerate understanding and treatment access.
Innovative approaches are generating robust evidence where traditional methods prove insufficient. Novel evidence sources are replacing or complementing conventional medicines R&D, including External Control Arms using Real-World Evidence (RWE), Modelling & Simulation Data, Digital Twins, Model-Informed Drug Development (MIDD), novel clinical trial designs, and mechanistic models. These innovations accelerate disease and treatment understanding while shaping regulatory environments to accept and encourage novel evidence generation, potentially shortening development timelines and accelerating approvals.
This collaborative approach between industry, regulators, and academia aims to accelerate access to innovative medicines for patients through continued dialogue and acceptance of regulatory science innovations

Learning Objectives

- Understand how European regulators are driving regulatory science innovations to accelerate drug development.
- Learn about novel evidence sources including RWE, digital twins, and MIDD that complement traditional R&D.
- Explore practical applications of innovative methodologies in complex diseases for patient benefit.

Session Leaders

- Michelle Blake, Associate Director and Principal Consultant, DLRC Ltd., United Kingdom

Speakers

- Marjon Pasmooij, Head of Science Department/Associate Professor, Medicines Evaluation Board/Utrecht University, The Netherlands
- Gloria Garcia-Palacios, Head EU Regulatory Expert, Global Regulatory Affairs, Sanofi, France
- Nick Sykes, Policy Advisor – Regulatory Strategy, EFPIA, Belgium
- Pierpaolo Moscariello, Scientific Specialist, EMA, The Netherlands

14:00–15:20	**PS10 – Specialised Populations: From Inclusion to Evidence: Advancing Regulatory Frameworks for Special Populations**

Regulatory authorities are increasingly prioritising robust data generation for populations historically underrepresented in clinical development. This session provides a forward-looking analysis of regulatory and scientific developments affecting geriatric patients, lactating women and paediatric extrapolation approaches.
Through case examples and policy insights, speakers will discuss evolving legislative drivers, methodological challenges, and practical implementation strategies. The session will highlight how early integration of specialised population considerations can reduce development risk and strengthen regulatory outcomes.

Session Leaders

- Andrea Laslop, Regulatory Expert, Malta Medicines Authority, Austria
- Sandra Luísa de Sousa Lourenço, Director of Regulatory Affairs, Arriello, Ireland

Speakers

- Karl-Heinz Huemer, Owner & Director, khhconsult, Austria
- Ewa Balkowiec-Iskra, Associate Professor, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products/University of Warsaw, Poland
- Christine Taeter, Head of Developed Brands Benefit Risk and Medical Safety Unit, UCB, Belgium

15:20–15:30	**Closing Speech**

End of the Human Medicines Symposium