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.

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 Consultant/Chair of the TOPRA Human Medicines Symposium Working Party (HMSWP), United States of America
12:10–13:40	**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, Lecturer, HTW Berlin, Germany • Sabine Haubenreisser, Principal Scientific Administrator - Stakeholders and Communication, EMA, The Netherlands
	Speakers will include... • Rainer Becker, Director for Medical Products and Innovation, European Commission, Belgium
13:40–14:40	**Lunch Break**
14:40–16:00	**HM2/PS2 – The Art of Implementation: Strategizing Regulatory Sandboxes Amidst the GPL and the IHI Project Lifecycle... And Beyond**
	The inclusion of regulatory sandboxes in the General Pharmaceutical Legislation (GPL) signals a paradigm shift toward anticipatory regulation. However, a significant strategic challenge has emerged: sandbox provisions are reported to take effect without the 24-month transition period allotted to the rest of the package. This creates a temporal tension between the immediate legal mandate and the ongoing work of the IHI project, which is tasked with "architecting" the tool's actual operation. This session will explore the art of implementation in the face of this discrepancy. Rather than seeking technical solutions for eligibility or prioritization, the panel will reflect on the high-level strategies required to ensure policy ambition translates into an effective regulatory reality.

	Key areas of strategic reflection include: • Managing the Implementation Gap: Strategies to bridge the timeline between 2026 legal effectiveness and the 2028 conclusion of the IHI project. • The Risk of Fragmentation: Assessing the risks and opportunities of parallel sandbox initiatives within the Biotech Act and the targeted revisions of IVDR and MDR. • Implementing Acts as Enablers: How to draft secondary legislation (delegated/implementing acts) that preserves the "experimental" nature of the sandbox without succumbing ex-ante prescriptive modalities? Policy leaders from the EC, EMA, IHI consortium, and industry will deliberate on how to navigate these implementation risks. The goal is to move from a conceptual "experimentation tool" to a sustainable, effective regulatory tool that contributes to secure a competitive EU life science ecosystem. The session will utilize live polling to capture the community's perspective on where implementation efforts should be prioritized to avoid a "compliance-first" trap that could stifle the tool's intended agility.
	Learning Objectives • Analyse strategic risks and opportunities in implementing the GPL sandbox provisions without the standard 24-month transition period. • Evaluate implementation strategies that leverage the foundational work of the IHI project. • Design a roadmap for delegated and implementing acts that balances legal certainty with the agility required for regulatory experimentation.
	Session Leaders • Maren von Fritschen, Lecturer, HTW Berlin, Germany
	Speakers will include… • Florian Schmidt, Deputy Head of Unit, European Commission, Belgium
16:00–16:40	**Networking Break**
16:40–18:00	**HM3/PS3 – Fireside Chat**
	Information coming soon…
	Session Leaders • Francesca Buttigieg, Executive Director Global Regulatory Affairs, RhyGaze, Switzerland • Sabine Haubenreisser, Principal Scientific Administrator - Stakeholders and Communication, EMA, The Netherlands
	Speakers coming soon…
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, Associate Director, Regulatory Strategy Oncology, Merck, Germany
	Speakers will include… • Monique Al, Special Advisor, CCMO, The Netherlands • Edit Szepessy, Policy Officer, European Commission, Belgium
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 will include…

	• Bryn Raven, Regulatory Operations Senior Associate, Reckitt, United Kingdom
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 Lourenço, Director of Regulatory Affairs, Arriello, Ireland • Lisa Hinchcliffe, Director, LangAllan CMC Regulatory Solutions Ltd, United Kingdom
	Speakers coming soon...
09:00–10:20	**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, Regulatory Policy Leader, Roche, United Kingdom
	Speakers coming soon...
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 Regultory, IQVIA, United Kingdom • Margareth Jorvid, Chief Executive Officer, Methra Uppsala, Sweden
	Speakers will include... • Deepa Subramaniyan, Senior Clinical Trial Regulatory Lead, Roche, Switzerland • Maurice Steenhuis, Scientific Staff Member in Medical Technology, CCMO, 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, Policy and Public Affairs, UCB, Belgium
	Speakers will include... • Sofia Peltola, Specialist, The Finnish Innovation Fund Sitra, Finland
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
	Speakers coming soon...

16:00–17:20	**PS7 – From approval to access—aligning RWE, Regulatory Approval, HTA, and reimbursement to deliver patient benefit**
	Information coming soon…
	Session Leaders coming soon… • Amaia Clemente, Regulatory Science and Policy Associate Director, Sanofi, Spain • Kwan Lan Tan, Head of Team Regional Regulatory Lead Oncology and Inflammation, Boehringer Ingelheim, Germany
	Speakers coming soon…
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 Consultant/Chair of the TOPRA Human Medicines Symposium Working Party (HMSWP), United States of America • Jasper-Hugo Brouwers, Head of Corporate and Stakeholder Affairs, Medicines Evaluation Board, The Netherlands
	Speakers will include… • Sabine Faber, Senior Regulatory Affairs Manager, Sanofi, Germany • Katja Peçjak Reven, Director BD, Sales and Marketing, QPPV, Billev Pharma East Ltd., Slovenia • Yara Mangindaan, Pharmacist Patient Information, Medicines Evaluation Board, The Netherlands
09:00–10:20	**PS8 – Expedited Pathways – How to Implement the Expedited Regulatory Pathways in the New GPL in a Way to Make EU Attractive for Innovation**
	How can the EU fully realise the potential of its new pharmaceutical legislation to strengthen regulatory excellence, predictability and global competitiveness? Pharmaceutical research and development is global by nature, with regulatory environments increasingly influencing where and how innovation progresses. Leading authorities worldwide are refining Expedited Regulatory Pathways (ERPs) to provide earlier patient access to therapies addressing unmet medical needs, while maintaining high standards of quality, safety and efficacy

	through adaptive regulatory science and digital tools. When fully leveraged, such pathways can enhance patient outcomes, system efficiency and innovation. The EU has established a strong regulatory toolbox, including PRIME, Conditional Marketing Authorisation, Accelerated Assessment and Exceptional Circumstances pathways, to support timely access to innovative medicines. Experience suggests that, if applied more consistently and pragmatically, these mechanisms could deliver a greater impact. Opportunities remain to further simplify processes, clarify eligibility expectations—particularly around Unmet Medical Need—and optimise the use of regulatory expertise across the European Medicines Regulatory Network. The introduction of Phased Review provides a timely opportunity to advance towards a more dynamic, knowledge-driven assessment model, enabling earlier engagement, improved resource planning and greater predictability for both regulators and developers. This panel will challenge experienced regulatory professionals from industry and authorities to explore how EU regulatory mechanisms can evolve from well-designed tools into consistently effective enablers of innovation. The discussion will focus on practical, collaborative approaches to improve implementation, support earlier patient access and ensure the EU remains a competitive and attractive environment for global pharmaceutical R&D.
	Learning Objectives • The objective of the session is to identify practical aspects to consider for efficient implementation of the Expedited Regulated Pathways proposed in the new GPL, making the EU Regulatory System more appealing for innovative medicine development.
	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 coming soon... • Stephane Callewaert, Director, Regulatory Policy EMEA, Global Regulatory Policy & Intelligence, Johnson & Johnson, Belgium
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 • Elizabeth Young, Director Early Development Lead, Argenx, Belgium • Amaia Clemente, Regulatory Science and Policy Associate Director, Sanofi, Spain
	Speakers coming soon...
11:00–12:20	**PS9 – Securing the Medicines Supply Chain: Critical Medicines & Shortage Prevention**
	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 coming soon...
12:20–14:00	**Lunch Break**
14:00–15:00	**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.
	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, Senior Regulatory Consultant and Team Leader, DLRC Ltd., United Kingdom
	Speakers will include... • Marjon Pasmooij, Head of Science Department, Medicines Evaluation Board, The Netherlands • Gloria Garcia-Palacios, Head EU Regulatory Expert, Global Regulatory Affairs, Sanofi, France • Nick Sykes, Policy Advisor – Regulatory Strategy, EFPIA, Belgium
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, Lecturer, University of Innsbruck, Austria • Sandra Lourenço, Director of Regulatory Affairs, Arriello, Ireland
	Speakers • Karl-Heinz Huemer, Scientific & Regulatory Consultant, khhconsult, Austria • Ewa Balkowiec Iskra, CHMP Topic Lead of EMA Geriatric Expert Group, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, 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