DIA EUROPE 2025

COLLABORATING FOR HEALTHCARE INNOVATION

18-20 MARCH | BASEL

CALL FOR ABSTRACTS

Abstract Submission Deadline: 14 May

Details

General Submission Requirements

Please read the following instructions carefully; incorrect or incomplete abstracts will not be considered.

- ✓ All abstracts must be submitted online. The deadline for abstract submissions is Tuesday, 14 May 2024, 23:59 CEST.

- ✓ Submitted abstracts must not overtly endorse or recommend a specific product or service.

- ✓ Proposed abstract title must reflect the abstract content accurately and concisely.

- ✓ Chairs and speakers of the accepted session will receive a one-day complimentary registration for the day of their scheduled presentation.

A special upgrade registration fee will be made available for those interested in attending the entire DIA Europe 2025.

Sessions at DIA Europe

- ✓ A session abstract can be delivered as a
  - o Full Session
  - o Forum
  - o Panel Discussion
  - o Presentation
  - o Interactive Workshop
  - o Masterclass
- ✓ **Session length: 70 Minutes**
- ✓ Required number of speakers: 2-5
  Selected speakers should represent diverse organisations and stakeholder groups
  (E.g. regulators, industry, patients, HTA bodies, academia, etc.)
  The session chair should practively propose a diverse group (i.e. gender,race, age etc.)
- ✓ The abstract author acts as session chair to coordinate efforts in recruiting speakers and manage the session according to the timelines provided by DIA.

Abstract Structure

1) Abstract Title (125 character limit, including spaces)

2) Submission Topic (select one from the list)

3) Keywords (100 character limit, including spaces)

4) Level of Difficulty (Select one):

   - Basic: Appropriate for individuals new to the topic/subject area.

   - Intermediate: Appropriate for individuals who already have a basic understanding of the topic/subject area.

   - Advanced: Appropriate for individuals with an in-depth knowledge of the topic/subject area

5) Objectives (400 character limit, including spaces)

6) Overview (250 character limit, including spaces)

7) Abstract Details (2000 character limit, including spaces)

1. Clinical Trials Innovation

Lada Leyens, Takeda
Monique AI, CCMO

Teaser

A modern Clinical Trial (CT) ecosystem for Europe, at the forefront of the ecosystem globally should consist of two key components:

1) clinical trials that use fit-for-purpose innovation, are patient, care giver and site centric and support efficient decision-making (i.e. regulatory, ethics, HTA, clinical decisions, depending on their objective);

2) an efficient and risk based regulatory ecosystem that enables patients and HCPs to identify the right trials for them and purposeful transparency provisions.

This track will cover both these components, provide a status update and have critical discussions on where we want to go to continue to build a modern CTs ecosystem in Europe. The sessions should be based on concrete case studies, identify gaps and opportunities, and through thought-provoking multistakeholder discussions, identify with the audience the best path towards an attractive European CT ecosyst em that incentivises faster, smarter and more patient centric Clinical Trials.

Who is this Track Designed for?

Professionals involved and/or interested in Clinical Trials Design & Operations:

- Regulatory Authorities, Ethics Committees, HTA bodies and payers.
- Commercial and non-commercial sponsors.
- Industry: Regulatory Policy, Regulatory Affairs professionals, Clinical sciences, clinical operations and biostatistics.
- ROs, service providers.
- Patients, carers and HCP representatives.
- Any other stakeholders involved in clinical research.

Proposed Topics for Call for Abstracts

1. **Moving forward with Clinical Trial Innovation**
   a. Implementing novel CT Technologies
   b. Implementing Innovative Designs
   c. Using novel data sources (e.g. external controls)
   d. Adopting new ICH frameworks and methodology guidance related to CTs
   e. Data linkage and tokenisation

2. **How to foster Clinical Trials in Europe?**
   a. Cross-border trials
   b. Fit-for-purpose transparency
   c. Optimisation of treatments
   d. Early development CTs
   e. Unmet medical need (e.g. N = 1 trials)

3. **How to facilitate and support patient involvement and caregivers in the complete trial process, from the idea up to the publication of the results?**
   a. Patient relevant and fit for purpose endpoints,
   b. Strategies for better recruitment and increased awareness of CTs
   c. Improving the informed consent process,
   d. How to maintain the trial participants in the CT
   e. Publication/sharing of (intermediate) results

4. **Towards an EU ecosystem that enables early access to Clinical Trials and innovative medicines for everybody**
    a. Clinical trial in special populations, such as paediatrics and elderly patients
    b. Clinical trials with pregnant and lactating women
    c. Enabling trials that recruit populations representative of potential groups who may benefit from the intervention
    d. Early Access schemes that enable access and data collection (between clinical trial and full marketing authorisation)

5. **European CT ecosystem**
    a. Scientific Advice Pilots to enable a connected end to end drug development
    b. The role of Ethics within the ecosystem
    c. Impact of regulatory initiatives (ACT-EU, CTCG, MHRA, others)
    d. Clinical trials after the three years transition period
    e. Strategies on Public Health Emergency (PHE) Preparedness Interplay between CTR/MDR/IVDR and how to align the regulatory framework for combined studies

6. **Other topic – in case the abstract topic does not fall under any of the mentioned categories** *(examples include, but not limited to)*
    a. Updating the declaration of Helsinki (revision 8): Proportionality and critical to quality factors: are we ready for a new way of running clinical trials?
    b. A global drug development ecosystem: initiatives on global collaboration

2. CMC & Product Quality

Mark Pellet, AstraZeneca
Co-Lead TBC

Teaser

Innovation in CMC (Chemistry, Manufacturing and Controls) is at the heart of the pharmaceutical industry. Advances in regulatory practice and novel approaches to supply are key to this topic. This track will provide insights into how manufacturers and regulators can collaborate to deliver this revolution without risks to the supply of medicines.

Who is this Track Designed for?

This track is recommended for regulatory affairs, manufacturing, supply chain, quality assurance, and other professionals who want to keep up to date with the most recent developments in regulatory science and technology impacting CMC/GMP related activities.

Proposed Topics for Call for Abstracts

1. **Advances in Regulatory Reliance**
   a. Marketing Authorisation applications
   b. Post-Approval Changes
   c. Cloud-based platforms
   d. Industry-NCAs readiness

2. **Ensuring safety of Medicines globally**
   a. Nitrosamines
   b. PFAs
   c. Sustainability – Environmental impact

3. **Ensuring continuous supply of medicines globally**
   a. Use of Advanced Manufacturing
   b. Biosimilars
   c. Generics

4. **ICH knowledge sharing**
   a. Cell & Gene Therapy
   b. General Guidelines updates

5. **Acceleration through agile Regulatory CMC strategies**
   a. PACMPs
   b. Acceptance of Prior-Platform Knowledge
   c. Innovative Stability approaches

6. **Other topic – in case the abstract topic does not fall under any of the mentioned categories** *(examples include, but not limited to)*
   a. EU General Pharmaceutical Legislation

3. Data Science, RWE & Artificial Intelligence

Estelle Michael, UCB
Gracy Crane, Roche

Teaser

Data Science, RWE and AI have shown us that faster, better drug development is within our reach - and yet it always seems to be slightly out of our grasp, or is it?

This track will specifically focus on the progress made in the application of RWE and AI for product development (e.g., medical devices, medicines), in addition to the related area of data science, and where there are still challenges/hurdles to be overcome.

- We will take a look at RWE/AI use cases in product development.
- We want to hear from health authorities as to their progress in advancing thinking around RWE and AI, and look at intersection/interplay between these two areas.
- We invite use cases on the use of AI for improving RWD data sources/datasets.
- We are interested in the use of AI and/or RWD for evidence generation, such as in clinical trial design, including for refining inclusion/exclusion criteria, for validation of outcomes, and for long-term follow up etc.
- We also invite use cases from pragmatic trials.
- Current EU policies and regulation on RWE and AI in medicines compared with AI regulations for medical devices.

We will also aim to discuss the important area of ethical considerations for AI and the patient perspective and look for successful examples of how organisations may have addressed the challenge of bridging between the explorative data science vs. the traditional development space for clinical operations, statistics and epidemiological sciences.

Who is this Track Designed for?

This track is designed for anyone in, passionate about, curious on or working with Data Science, RWD/E and Artificial Intelligence in healthcare and medicines development.

Proposed Topics for Call for Abstracts

1. **RWE / AI throughout the product (medical devices, medicines, e.g.) lifecycle**
    a. Optimisation of evidence generation
    b. Analytics and development of products
    c. How is RWE and AI used to maintain product life cycle
    d. Case studies / Real life examples

2. **Global Medicines Regulatory Developments in AI and RWE**
    a. European space
        i. Learnings / Challenges around the use of EMA AI Position Paper
        ii. Update on the roll-out of EC AI Regulation and the EHDS
        iii. European network thinking around the use of RWD for decision-making
        iv. Use cases from European initiatives such as DARWIN, EU-PEARL, More-EUROPA, e.g.
    b. Global developments in this space
        i. How to better harmonize guidances between regulatory agencies

3. **RWE / AI Health Authorities frameworks**
    a. How are we dealing with this in the European landscape? Case studies / real-life examples
    b. Application of data quality framework RWD Annex

  c. How to navigate the eco-system of tools and guidance surrounding RWE and AI
  d. Fit for purpose assessment

4. **Patient experience and ethics considerations**
  a. Update on international regulatory policy of use of patient experience data
  b. Ethical considerations of sharing patient level data

5. **Bridging the gap between Data Science and Clinical Operations, medicines development, epidemiology, statistics, etc.**
  a. Examples of challenges and successful collaborations between the explorative data science areas and the traditional clinical operations

6. **Other topic – in case the abstract topic does not fall under any of the mentioned categories** *(examples include, but not limited to)*
  a. How benefit risk assessment is affected by new data types
  b. New joint clinical assessments related to RWD
  c. Any other topic that you think is relevant and interesting!

4. Global Insights & Collaboration

Sara Torgal, DIA

Teaser

In the mist of global challenges and the implementation of flexibilities to accelerate patients' access to medicines, collaboration is the key to advance. In this track, different regulatory bodies and organisations from around the world will share updates related to their regional success stories and lessons learnt from the interactions with the various healthcare stakeholders, while discussing the practical aspects of collaboration.

Who is this Track Designed for?

Regional health authorities' representatives, key industry leaders in these regions and any professionals curious about global collaboration and regional developments.

Proposed Topics for Call for Abstracts

1. **Regulatory Reliance, Harmonisation and Work-sharing initiatives**
   a. Case studies
   b. Results from global pilots
   c. Lessons-leant, challenges and opportunities

2. **Updates, developments and lessons-learnt for the various regions**

3. **Other topic – in case the abstract topic does not fall under any of the mentioned categories**

5. Innovative Therapies, Precision Medicine & Diagnostics

Claudia Dollins, BMS
Co-lead TBC

Teaser

Innovative therapies (such as cell and gene therapies) and precision medicine approaches are both based on the use of complex technologies, and potentially even employ the use of different regulated product types (e.g. biologics & devices or in vitro diagnostics). These areas are experiencing rapid evolution: growing scientific insight and clinical evidence, led to the development of highly effective therapies not only in rare disease but also in development for more prevalent and chronic conditions.

As their development requires integration of complex technologies (either in manufacturing processes or molecular evaluation of disease biology), regulators, policy makers and payers are adapting their approaches to evolve. We have seen many changes globally in their approach - how does Europe compare?

Who is this Track Designed for?

Developers of innovative therapies (such as gene and cell therapies), precision medicines and diagnostics: global biologics and IVD regulators, policy makers, industry leaders, academics, patients, HTA bodies representatives and payers.

Proposed Topics for Call for Abstracts

1. **What is the future of Precision Medicine?**
   a. As our understanding of the molecular mechanism of disease biology is growing, Precision Medicine approaches are becoming more prevalent.
   b. What are the current challenges and opportunities for the integration of Precision Medicine approaches in medicinal product development?
   c. How are regional regulatory changes impact the ability to conduct global precision medicine development efforts?
   d. What are currently hurdles to reimbursement for both medicinal product and reimbursement?

2. **Clinical Trial Development in Innovative Therapies, Precision Medicines and Diagnostics – Contextualizing Europe with other Countries**
   a. Only a small proportion of cell and gene therapy product development efforts include studies within Europe. Evaluation of challenges and opportunities.
   b. What is the impact of new Pharmaceutical Legislation to Innovative Therapies, Precision Medicine and Diagnostics?
   c. Complex Clinical Trials: Exploring the interface among relevant legislative frameworks (MDR, CTR, IVDR, SOHO) in Europe. What are the unique hurdles and opportunities?
   d. How can Europe stay competitive when only a small proportion of cell and gene therapy development is conducted here? What are efforts to address this?

3. **Creating certainty in the effectiveness and durability of innovative therapies and precision medicine**
   a. Best practices in the delivery of innovative therapies and precision medicine.
   b. Value-based contracts linked to RWE data collection/ eHealthcare data (potentially cross-border, so data are not jeopardised during collection and can be informative for the reimbursement criteria)

    c. At the end of 2022, 7 of the 24 approved ATMPs were withdrawn from the market. What role do innovative payment & reimbursement models play in driving commercial success?

    d. The complexity of the drug delivery to the hospitals for administration (centralise at EU level the clinical site selections – ideally linked to the ERNs)

    e. Leverage patients' advice/PROMs to inform the real medical need of the innovative drug (technology wise it could be very interesting, but then perceived as too risky by the patients as compared to the standard of care for their disease?)

    f. When and Who engaging during early drug development to seek advice by HTA Bodies/Payers

    g. Help access to treatment for rare diseases: how can we leverage COVID-19 learnings to foster a new centralized procurement and access model?

4. Clinical trial innovation through Precision Medicine

    a. The use of healthcare technology is evolving clinical trial design.

    b. Decentralized Precision Medicine Clinical Trials: Can we move patient inclusion criteria outside of the central laboratory? Where are the opportunities and challenges?

    c. Pan-tumour approaches for rare diseases- are we truly ready to redefine disease in terms of their molecular target. What are the unique challenges to basket/platform or umbrella trial designs?

    d. Novel biomarkers: How can we derive and analyse data derived from continuous biomarkers in the context of targeted therapies? What are unique considerations for the incorporation of AI enabled/complex diagnostics?

5. Sustainability & the Environment

    a. How can we apply concepts of sustainability in the innovative therapies and precision medicine space?

    b. Sustainability in manufacturing

    c. Can cell and gene therapies be a truly sustainable model?

    d. What role should wastage and disposal play in the development and reimbursement of innovative therapies, precision medicine and diagnostics?

    e. GMO Legislation

    f. Re-usability and re-purpose of medical devices and instruments. A dream or reality? Exploring examples of successful examples and lessons learned along the way.

6. Other topic – in case the abstract topic does not fall under any of the mentioned categories

6. Medical Devices & Combination Products

Sabina Hoekstra-van den Bosch, TÜV SÜD
Thomas Wejs Møller, Novo Nordisk

Teaser

Healthcare systems worldwide face a range of challenges - from rising rates of chronic diseases and aging populations to a lack of healthcare professionals. These challenges can be addressed in part through innovative therapies and concepts that improve patient empowerment and autonomy. To achieve this, the worlds of medical devices and pharmaceuticals must move closer, creating a regulatory environment supportive of rapid digital innovation and the merging of technologies – starting with better devices for medicines' application and extending to new smart applications to assist patients, caregivers, and healthcare professionals. Digital innovation has the potential to revolutionize the healthcare industry, from AI-powered medical devices that can diagnose diseases more accurately to telemedicine platforms that enable remote consultations and monitoring. By embracing digital innovation, we can improve patient outcomes, increase efficiency, and reduce costs in the healthcare system.

Who is this Track Designed for?

We welcome interest and involvement from a broad spectrum of individuals and organisations – including but not limited to - authorities, Notified Bodies, patient organisations, and manufacturers of devices and combination products.

Proposed Topics for Call for Abstracts

1. **Medical Devices and Pharmaceuticals interaction**
   a. Where are we now, and where are we heading? The direction of regulation in 2025
   b. Combination products regulated as Medical Device (MDR Rule 14)
   c. Combination products regulated as Medicinal Product (Art. 117)
   d. Co-packaged devices

2. **AI/ML and Medical Devices**
   a. EU AI Regulation interaction with MDR/IVDR: Implementing the AIR in MedTech
   b. Development of standards for AI/ML in medical devices
   c. How to regulate dynamic AI/ML – Global perspective
   d. The future of AI/ML powered medical devices

3. **Update on General Pharma Revision's impact on MD/IVD and Combination Products**

4. **Update on the implementation of MDR/IVDR**

5. **Combined studies between CDx, MD and/or MP**

6. **Other topic – in case the abstract topic does not fall under any of the mentioned categories** *(examples include, but not limited to)*
   a. Early experiences with EMA's scientific advice pilot on high-risk medical devices
   b. Environmental sustainability
   c. Reusables: where are we and where next?
   d. Strategies for replacing PFAS in medical devices
   e. Patient Engagement
   f. Women's health
   g. Incentivizing Innovation

7. Pharmacovigilance and Safety

James Whitehead, AstraZeneca
Willemijn van der Spuij, Bristol Myers Squibb

Teaser

This track provides an overview of, and insight into, the global patient safety environment for medicinal products and medical devices. The focus is on pragmatic vision for ensuring patient safety and ensuring that the patient voice is properly heard in the complex and evolving safety ecosystem. The forward-thinking sessions will address the complexities of operating in a global environment and look at how we apply new technologies and methods for streamlining safety systems and processes. This will help enhance patient safety as products become progressively more complex, new data sources drive new analytical techniques and regulatory requirements.

Who is this Track Designed for?

Anyone curious/interested, established safety professionals who are seeking to increase their network of like-minded colleagues; share their thoughts and practices with others; learn the most current safety regulatory views and gain practical knowledge in key areas in pharmacovigilance.

Proposed Topics for Call for Abstracts

1. **Innovation & Future Directions of Safety Organisations – Strategy and Disruptions**
   a. Sustainability – How can Pharmacovigilance contribute to sustainability?
      i. Evolution of the safety organisation
      ii. Insourcing VS Outsourcing
   b. How to innovate in a highly regulated environment?
   c. Talent Development and Learning: what does the next Patient Safety professional look like?

2. **Patients and HCP Involvement in Patient Safety**
   a. How will risk management and communication evolve alongside an evolving digital healthcare system
   b. Patient empowerment in safety
   c. Interplay between Agencies, MAHs, HCPs and Patients
   d. How will patient safety evolve along digital health evolution? Wearables, 3d printing tablets, e.g.

3. **Technological Developments in PV**
   a. How will technological developments in PV impact patient safety process?
   b. How will it impact PV departments: recruiting, training, people development
   c. Use of AI in: patient generated data; signaling; other areas – Practical Use Cases
   d. Emerging technology trends and novel approaches to perform pharmacovigilance
   e. Agencies expectations in the era of Digital Health

4. **Use of RWD/ RWE - Are we making the most of it to deliver patient safety?**
   a. PASS studies: How to obtain timely and valuable safety information post authorisation
   b. Registry design: Product vs disease registries
   c. Large data projects: How can Industry, regulators and academics work together

5. **International Activities and Collaboration – Regulations and Good Practices**
   a. Globalization of Pharmacovigilance Activities - Managing Global Regulations
   b. ICH and CIOMS Updates
   c. Safety submissions to Regulators - Is the mark being hit? Are we lost in data?
   d. How to deal with the growing regulations that do not fall under the GVP?

       i.   Bringing together medicines, devices and digital – can they co-exist?

6. Other topic – in case the abstract topic does not fall under any of the mentioned categories

8. Professional Development
Cláudia Ferreira, DIA

Teaser

This track is focused on topics for improving and supporting continuous personal development for career and team success. This broad category addresses interpersonal skills, soft skills, leadership, career growth, entrepreneurship, among others. The dynamic and interactive sessions should aim to unlock the participants' potential and elevate their career, while delving into essential soft skills and cultivating their professional acumen.

Who is this Track Designed for?

This track welcomes all stakeholders within the pharmaceutical ecosystem, including industry professionals, regulatory authorities, academia, patients, and aspiring students and young professionals - whether their just starting on their careers or seeking to enhance their continuous development.

Proposed Topics for Call for Abstracts

1. **Effective Communication Strategies**
   a. Enhancing interdisciplinary communication within teams.
   b. Strategies for engaging with stakeholders and patients effectively.

2. **Leadership Development in Pharma**
   a. Cultivating transformative leadership skills for driving innovation.
   b. Managing change and fostering a culture of excellence in pharmaceutical organizations.

3. **Flexibility and Adaptability**
   a. Cultivate flexibility in navigating changing environments.
   b. Adapt to new challenges and opportunities in the pharmaceutical landscape.

4. **Career Advancement and Mentorship**
   a. Unveiling pathways for career progression in the pharmaceutical industry.
   b. Establishing robust mentorship programs to foster professional growth.

5. **Diversity, Equity, and Inclusion**
   a. Promoting diversity and inclusion initiatives within pharmaceutical organizations.
   b. Addressing equity gaps and fostering inclusive practices across the industry.

6. **Other topic – in case the abstract topic does not fall under any of the mentioned categories**

9. Regulatory Operations

Kate Porch, JnJ
Tim Powell, Biogen

Teaser

Regulatory Operations optimisation and transformation continues to be at the forefront of change across both the private and public sectors. We are now seeing real progress in the implementation of the EU-wide telematics strategy. There are many ongoing topics linked to digital transformation such as IDMP and ePI, as well as emerging technologies for structured data and cloud to facilitate collaborative reviews between regulators and new thinking around 'Personalised Health Care - Putting the patient first' that are important for us to discuss and share updates on.

Who is this Track Designed for?

This track is ideal for life sciences professionals leading and working in regulatory operations and regulatory labelling, including those supporting and being supported by these functional groups. It is also intended to be of interest for Health Authority professionals assessing and approving dossiers, and organisations and vendors supporting this effort, including patient advocacy organisations that support initiatives that aim to ensure that the needs of patients are met.

Proposed Topics for Call for Abstracts

1. **Digital Transformation**
   a. Artificial Intelligence, Machine Learning, Large Language Models, Automation
   b. Cloud technology as an enabler
   c. Digitalisation around the world
   d. eCTD changes

2. **Global Harmonisation & Data Standards**
   a. FHIR standard and use cases
   b. Global move to interoperability standards
   c. Identification of Medicinal Products (IDMP)
   d. Electronic Application Form (EMA PLM Web Form)
   e. Latest updates and timelines

3. **Structured Content**
   a. M4Q(R2) & Impact to e-Submissions
   b. FDA PQ/CMC
   c. Labeling

4. **Case studies illustrating innovative solutions and optimisation of systems**
   a. Process improvements
   b. Organisational transformation
   c. Technology implementations

5. **ePI**
   a. EMA Pilot feedback
   b. Impact of legislation & roadmap to implementation
   c. How ePI will enable patient centricity
   d. Sustainability benefits of moving to ePI

6. **Other topic – in case the abstract topic does not fall under any of the mentioned categories**

10. Regulatory Strategy & EU Pharmaceutical Policy

Rebecca Lumsden, Sanofi
Co-lead TBC

Teaser

The Regulatory Strategy & EU Pharmaceutical Policy track is composed of sessions addressing regulations and policies governing biopharmaceutical product development, approval, and maintenance. Themes will revolve around evolution of the European regulatory ecosystem and impacts for global development strategies. In the context of revision of the EU General Pharmaceutical Legislation as well as the Orphan Drug and Paediatric Regulations, sessions will focus on how the framework can be optimised to support regulatory science and the sustainability of innovation. Representatives from the European Commission, EMA, National European Health Authorities and other regulatory stakeholders will provide updates, insights, and discussion on current issues through interactive forums.

Who is this Track Designed for?

Regulatory strategy and policy professionals interested in exploring both the strategic implications of the evolving regulatory ecosystem as well as focused sessions on key aspects of regulation impacting the development of medicines.

Proposed Topics for Call for Abstracts

1. **EU Regulatory Framework and Governance**
   a. EMA mandate; how might this evolve?
   b. Defining Unmet Medicinal Need and implications for regulatory strategy.
   c. Understanding the Sandbox concept in exploration of new approaches.
   d. Regulator evidence expectations.
   e. The role of Network stakeholders.
   f. Sustainability of the EU Regulatory Network – Training and Resources.

2. **Paediatrics**
   a. The role of step-wise PIPs.
   b. How should product mechanism of action be used in determining paediatric populations to study?
   c. Dialogue and advice for paediatric development.

3. **Orphan Drugs**
   a. Orphan designation in regulatory strategy.
   b. What have we learnt from significant benefit determinations and how should the concept evolve?

4. **Regulatory Assessment Procedures**
   a. Predictability of regulatory procedures.
   b. Evolution of expedited pathways.
   c. From Phased Review to iterative assessment?
   d. Framework for Multi-national assessment teams.
   e. Emergency use authorisation.

5. **Scientific Dialogue and Advice**
   a. Learning from experience with Parallel and Joint advice with other stakeholders
   b. Evolution of the qualification procedure

6. **Other – in case the abstract topic is not under any of the mentioned categories**

11. Value & Access
Inka Heikkinen, MSD
Kostas Papadakis, Bayer

Teaser

2025 is an exciting year for Europe from the access perspective: the EU HTA Regulation enters into force with first JCA submissions; NICE and HTA bodies from other parts of the world are evolving their collaboration; and the General Pharma Legislation aims to improve access across Europe. This track seeks to discuss these aspects, and some others further in the horizon, such as Net Zero impact of new technologies to the environment.

Who is this Track Designed for?

Value demonstration and patient access is relevant across different stakeholders. This track is designed for clinical, regulatory, patient, and value and market access experts who are interested in the link between technology innovators, regulatory, HTA and local decision-making, and how collaboration and engagement can improve patient access.

We invite abstracts containing multifunctional/multistakeholder perspectives (at a minimum Regulatory and Access perspectives) and gender balance is encouraged.

Proposed Topics for Call for Abstracts

1. **Implementation of EU HTAR**
    a. Implementation of EU HTAR
    b. Patient and/or clinical expert involvement
    c. Learnings from the first submissions/first preparations for submissions
    d. PICO – results from simulation exercises – implications for policy
    e. Methodologies 2.0? /Adopted methodology guidelines
    f. Capacity building and resourcing on the national level with impact on the broader ecosystem

2. **International voluntary collaborations**
    a. NICE-led consortium with other UK, US, Canada, Singaporean and Australian HTA bodies
    b. Voluntary collaborations under the HTA Regulation
    c. Other international collaborations

3. **3 As of EU General Pharmaceuticals Legislation (access, availability, affordability) + 3 Cs (competitiveness, climate, combatting AMR) possibly**
    a. Equitable access: what is the real issue based on evidence?
    b. What is required to boost innovation and competitiveness in Europe?
    c. Evidentiary standards – finding the right balance without compromising scinetific integrity of regulatory approvals   nm

4. **Gazing to the future: Net Zero impact on the environment: how to account for environmental impact during the assessment of new health technologies?**
    a. Future methodologies, related to Academia
    b. Trade-offs/Balance between benefits, economics and environment
    c. NICE green assessment

5. **Access to diagnostics**
    a. Gene sequencing

6. **Other topic – in case the abstract topic does not fall under any of the mentioned categories**