Integrated Scientific Advice Workshop: ISPOR Glasgow

Early Integrated Scientific Advice in Product Development: Get Real and Adapt to Accelerate Patient Access

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Overview

At today's patient-centered research workshop, experts from ICON, Mapi, and across the industry will share their knowledge, insights, and experience on a topic that is vital to a project's success. As leading voices in patient-centered research, ICON and Mapi are happy to present this important workshop to all attendees.

Mapi, now a member of ICON, offers Integrated Scientific Advice (ISA) training workshops and consulting services to support manufacturers in optimizing their product development programs to generate evidence that is relevant to regulators, HTA bodies, and payers for timely patient access.

A shift in the regulatory/HTA paradigm is occurring, driven by affordability concerns, efficacy-effectiveness gaps, patient centricity, and early access to important medicines. The value of early integrated scientific advice is to support navigating this paradigm shift, manage uncertainty and de-risk, manage evidence complexity in HTA submissions, and promote company collaboration to eliminate the "silo effect". The most important reason for seeking integrated scientific advice is to provide support for timely access to innovative medicines.

Transformational medicines may be made available to patients up to 4 years earlier through the Early Access to Medicines Scheme (EAMS) in the UK, Compassionate Access programs or expanded access studies. Obtaining this designation will require integrated early dialogue between the regulatory authorities, payers, and HTA agencies to support these new changes to align the regulatory and HTA bodies earlier.

Today, we'll discuss the considerations from the regulatory, payer, and HTA perspectives with respect to the overlap and synergies in the consideration of the definition of population, study design and comparators, outcomes, and subgroups. The importance of the value proposition is emphasized in the development of a robust briefing book to provide a framework to develop "value added" questions for the agencies. Additionally, the importance of patient involvement in these early engagements will be discussed to support early alignment of all stakeholders to optimize the clinical development plan and identify potential gaps.

Presenters Include:

Dr. Matthew Bending
Director, Head of HTA, Strategy & Communication
Real World Strategy & Analytics, Mapi Group

Rory Graham
Senior Director,
EU Regulatory Services, Mapi Group

Dr. Amina Udechuku
Senior Research Consultant,
Real World Strategy & Analytics, Mapi Group

Guy Sherwin
Lead Consultant,
EU Pricing and Market Access, ICON Commercialisation & Outcomes

Dr. Jacoline Bouvy
Scientific Adviser,
NICE

Dr. Sabine Latour
Global Market Access Director,
Debiopharm

Register Now:

Early Integrated Scientific Advice in Product Development: Get Real and Adapt to Accelerate Patient Access

November 6th
13:00–17:00

Please visit: mapi.bz/ISAglasgow to register today

Join experts from Mapi, Debiopharm, and others across the industry

NICE National Institute for Health and Care Excellence

The UK's National Institute for Health and Care Excellence is responsible for developing national guidance, standards and information on providing high-quality health and social care, and preventing and treating ill health. NICE helps health, public health and social care professionals deliver the best possible care.

Agenda Topics

SESSION I

Welcome and Value of Multi-Stakeholder Scientific Advice

SESSION II

Current and Future Trends for Multi-Stakeholder Scientific Advice

SESSION III

Key Considerations for Integrated Scientific Advice

SESSION IV

Roundtable Discussion Panel

ISA Workshop | November 6th | 13:00–17:00

Hilton Garden Inn, Glasgow City Centre – Finnieston Suite

Since opening in early 2012, the Hilton Garden Inn Glasgow City Centre hotel (formerly a MINT property) has continued to evolve and has been awarded Scotland's most prestigious business hotel honor. The property is ideally located on the waterfront next to the SECC.

Located on the first floor of the hotel is a contemporary lobby and 24-hour Pavilion Pantry with a range of sundries, snacks, beverages and ready-made meals. Enjoy the very best in casual dining at City Café Bar and Grill. Our AA Rosette restaurant serves modern, locally sourced dishes in an enviable riverside location.

Register today at: http://mapi.bz/ISAglasgow

Overview

SESSION I: Welcome and Value of Multi-Stakeholder Scientific Advice

13:00–13:20
Welcome and Value of Multi-Stakeholder Scientific Advice

Presenters: Dr. Matthew Bending, Mapi Group
Rory Graham, Mapi Group

- Welcome from the ICON/Mapi team
- A brief introduction to the value of multi-stakeholder scientific advice
- An overview of the workshop agenda and objectives

SESSION II: Current and Future Trends for Multi-Stakeholder Scientific Advice

13:20–13:50
The Evolution of Regulatory Scientific Advice Landscape

Presenter: Rory Graham, Mapi Group

- Overview of European regulatory scientific advice procedures
- The role of enhanced scientific advice within the EMA PRIME initiative
- A review of the EMA Adaptive Pathways process from a regulatory perspective and the role of wider stakeholder advice opportunities in the new drug development paradigm

13:50–14:10
Overview of Integrated HTA and Regulatory Processes and Key Considerations

Presenter: Dr. Matthew Bending, Mapi Group
Dr. Amina Udechuku, Mapi Group

- What is integrated scientific advice?
- What are the key HTA scientific advice processes?
- What are the key HTA considerations in scientific advice?
- Current and future trends in integrated scientific advice

14:10–14:25

Coffee Break

SESSION III: Key Considerations for Integrated Scientific Advice

14:25–15:05
Adaptive Pathways: Key Considerations from a NICE Perspective

Presenters: Dr. Jacoline Bouvy, NICE

- NICE have been a participant in the EMA adaptive pathways pilot and a partner/work package lead in the Innovative Medicines Initiative (IMI) funded ADAPT-SMART project (launched in 2015) which is a multi-stakeholder platform for coordinating adaptive pathways activities in Europe. This session will discuss:
    - Early dialogue with HTA bodies and use of real-world evidence to supplement RCT data are key components of adaptive pathways but how might the concept work in practice?
    - Post-launch evidence generation is foreseen to reduce uncertainty, but how ready are Europe's healthcare systems to utilise additional evidence generation for outcomes-based managed entry agreements?

15:05–15:25
Outcomes-Based Agreements and Innovative Contracting for Biopharmaceuticals

Presenters: Guy Sherwin

- Evolution in pharma contracting approaches to address the increasing challenges in reimbursement of new products
- Current trends and anticipated innovations, including the use of outcomes-based agreements
- Key considerations to be incorporated in a structured approach for designing innovative contracting agreements

15:25–16:05
Industry Learnings from Seeking Integrated Scientific Advice to Reimbursement and Timely Patient Access

Presenters: Dr. Sabine Latour, Debiopharm

- The importance of early engagement with HTA bodies and payers from an industry perspective
- How to overcome internal hurdles within the company: achieving marketing authorisation is not a license to sell
- PRIME, adaptive pathways, and orphan drug status: what are the implications for reimbursement?
- Key differences between US and Europe and how to address these differences

16:05–16:20
Coffee Break

SESSION IV: Roundtable Discussion

16:20–16:50
Roundtable Discussion Panel on Multi-Stakeholder Integrated Scientific Advice

Presenters: All

- What factors influence the company decision to undertake an adaptive pathways approach with enhanced early multi-stakeholder dialogue? What are the implications for pricing, reimbursement and patient access?

16:50–17:00
Closing Questions and Answers

Presenters: All

17:00–18:00
End of Workshop Followed by Networking Drinks

Presenters

Dr. Matthew Bending

Director, Head of HTA, Strategy & Communication, Real World Strategy & Analytics, Mapi Group

Dr. Matthew Bending, a Director of Real World Strategy & Analytics, is a health economist with 10+ years of consulting experience. He heads projects for HTA submissions, scientific advice, market access, literature reviews, economic modeling, payer advisory boards, and global value dossiers. Before joining Mapi, Dr. Bending was a Senior Consultant for York Health Economics Consortium. He earned a PhD in Health Sciences from the University of York; his thesis explored the use of HTA in international reimbursement decision-making. He has an MSc and BSc (Hon.) in Economics from the University of Warwick.

Rory Graham

Senior Director, EU Regulatory Services, Mapi Group

Mr. Graham has facilitated numerous aspects of drug and medical device development during his 25 year career in the pharmaceutical, biotechnology and device industries. Mr. Graham has held senior positions in the area of regulatory affairs in companies in Europe and Asia-Pacific. He has arranged and directly participated in meetings with many global agencies including FDA, EMA, PMDA, TGA and European National Agencies. He has experience in various therapeutic areas including CNS, Oncology, Hematology, Immunology, Diabetes, Analgesia and Wound-Care. He has achieved orphan designations for pharmaceutical products in the EU, US and Australia. Mr. Graham leads a talented team of regulatory professionals that produce client-specific regulatory and development strategies, as well as solutions for global and local market needs.

Dr. Amina Udechuku

Senior Research Consultant, Real World Strategy & Analytics, Mapi Group

Dr. Udechuku is an evidence-based pricing and market access consultant with over 9 years of expertise in HTA engagements in both healthcare academia and strategic consulting. Amina has experience with a wide variety of health economics and outcome research (HEOR) projects for pharmaceutical, vaccine, and medical device companies. Amina specialises in Health Technology Assessment (HTA) submissions, integrated scientific advice engagements with HTA and regulatory agencies, and value communication strategy and methods. Amina provides leadership on projects in antimicrobials, oncology, neurological disorders, mental health disorders, cardiology and various orphan diseases.

Presenters

Guy Sherwin
Lead Consultant, EU Pricing and Market Access, ICON Commercialisation & Outcomes

Guy Sherwin is Lead Consultant on EU Pricing and Market Access for ICON Commercialisation & Outcomes. He has spent over six years advising on global pricing, market access and commercialisation strategy, specializing in early access programs and managed entry agreements to support market access. Mr. Sherwin consults with clients across a wide variety of therapeutic areas including cardiovascular disease, oncology, metabolic disorders, ophthalmology and orphan diseases.

Dr. Jacoline Bouvy
Scientific Adviser, NICE

Dr. Jacoline Bouvy is a Health Economist specialising in the interface between marketing authorisation and health technology assessment (HTA) of medicines. She works at the National Institute for Health and Care Excellence (NICE) in London within the Science, Policy & Research team for several research projects on topics such as adaptive pathways and big data for better outcomes in Alzheimer's disease.

Before joining NICE, Jacoline worked at the European Medicines Agency where she was involved in the EMA registries initiative. Before that, she held postdoctoral positions at Erasmus University Rotterdam and Utrecht University in the Netherlands where she worked on various drug regulatory science and health economics topics.

Dr. Sabine Latour
Global Market Access Director, Debiopharm

Dr. Sabine Latour is a physician with diverse pharmaceutical experience through her work for major pharma, medical device companies, and start-ups. Specializing in value identification, as well as clinical and economic evidence generation, Dr. Latour earned her medical degree and completed courses in Pharmaceutical Medicine and Health Economics. She leads international, strategic discussions with regulatory and reimbursement authorities, and payer bodies, both individually, with country HTA entities (GBA, NICE, TLV, AIFA, HAS), and also through joint scientific council with EMA and HTA entities.

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About ICON

ICON plc is a global provider of outsourced development solutions and services to the pharmaceutical, biotechnology and medical device industries. The company specialises in the strategic development, management and analysis of programmes that support clinical development. With headquarters in Dublin, Ireland, ICON currently operates from 97 locations in 38 countries and has approximately 13,100 employees. Further information is available at ICONplc.com.