RWE4Decisions

Public Webinar

How Can Horizon Scanning Support Early Dialogues and RWE Generation?

Co-moderators: Matias Olsen (EUCOPE) and Karen Facey (RWE4Decisions)

15 July 2026

15:00-16:30

Via Zoom

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Matias Olsen
Associate Director, Public Affairs & Policy, EUCOPE

Karen Facey
Senior Advisor HTA, RWE4Decisions

RWE4Decisions REAL WORLD EVIDENCE

Mission

HTA/Payer-led, multi-stakeholder Learning Network

RWE4Decisions brings together experts from all stakeholder groups to engage in dialogues that consider how fit-for-purpose RWE can be generated over the life cycle of **highly innovative medicines** through:

- **horizon scanning systems that identify medicines which are most likely to need RWE**
- identifying what RWE is needed to inform HTA/Payer decisions
- clarifying how RWE should be generated by stakeholders and evaluated by HTA/Payers
- aligning planning and execution of effective Post Launch Evidence Generation (PLEG) studies.

RWE4Decisions REAL WORLD EVIDENCE 2026 Steering Group

HTA BODIES / PAYERS / INSURERS

Niklas Hedberg
TLV

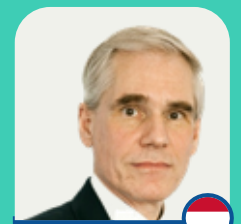
Piia Rannanheimo
Fimea

Cláudia Furtado
INFARMED

Christian Dehlendorff
Danish Medicines Council

Shaun Rowark
NICE

Elena Lungu
CDA-AMC



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INTERNATIONAL ORGANISATION

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SENIOR HTA ADVISORS

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François Meyer, MD

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Rotterdam University

Victoria Hodgkinson
Calgary University, Registry developer

INDUSTRY

EUCOPE

astellas AstraZeneca

Chiesi

MSD Roche Takeda

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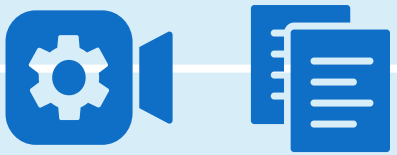
Agenda (CEST)

15:00 – 15:10	**Welcoming remarks** • **Karen Facey**, Senior HTA Advisor, RWE4Decisions • **Matias Olsen**, Associate Director, Public Affairs & Policy, EUCOPE
15:10 – 15:25	**Keynote presentation** **Anticipating what's next: Horizon scanning and early dialogues in a changing global landscape** • **Marcus Guardian,** General Manager, International Horizon Scanning Initiative (IHSI)
15:25 – 15:50	**Panel Reflections** • **Kim Helleberg Madsen,** Chair Sub-Group for Identification of Emerging Health Technologies (EHT), Director of the Pharmacoeconomics and Availability Department, Danish Medicines Agency • **Björn Wettermark,** Professor, Department of Pharmacy, Drug Epidemiology, Uppsala University; More-EUROPA project • **Lara Wolfson,** Associate Vice President & Head of HTA Statistics, MSD
15:50 - 16:28	**Multi-stakeholder discussion: Q&A from audience**
16:28 – 16:30	**Closing remarks and next steps**



PRINCIPLES OF ENGAGEMENT

Adherence to anti-corruption and anti-bribery rules
Participants must not make any direct or indirect promise or payment that could lead to a governmental act or decision helping parties obtain/retain business or enjoy any kind of preferential treatment.

Compliance with National and European Competition Laws
Participants must not engage in any discussion about or sharing of commercially sensitive information, e.g. net **prices** (including discounts and rebates), future list prices, customers, costs, strategic plans and output.

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Setting the Scene

Matias Olsen
Associate Director, Public Affairs & Policy, EUCOPE

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Panellist Introductions

Kim Helleberg Madsen
Chair Identification of Emerging Health Technologies (EHT) Subgroup, Director of the Pharmacoeconomics and Availability Department, Danish Medicines Agency

Björn Wettermark
Professor, Department of Pharmacy, Drug Epidemiology, Uppsala University; More-EUROPA project

Lara Wolfson
Associate Vice President & Head of HTA Statistics, MSD

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Keynote Presentation:

Marcus Guardian
General Manager,
International Horizon
Scanning Initiative (IHSI)

HORIZON SCANNING · EARLY DIALOGUES · REAL-WORLD EVIDENCE

Anticipating What's Next

Horizon scanning and early dialogues in a changing global landscape

Marcus Guardian · General Manager, International Horizon Scanning Initiative (IHSI) | RWE4Decisions Webinar · 15 July 2026

WHO WE ARE

One database, tracking every product from trial to market access

IHSI is a not-for-profit organisation that tracks pharmaceutical products from Phase I through market access in a single, structured, continuously refreshed evidence base. Three of its capabilities are, to our knowledge, world-firsts.

CAPABILITY	DISTINCTIVE ADVANTAGE
Lifecycle product-tracking database. Phase I to market access, 152 structured fields per indication record	One consistent structure across the whole pipeline
28-day refresh cycle (LLM, NLP, ML)	Signals surface while there is still time to act on them
Estimated Indication. Predicts the likely indication at EMA market-access application, from trial data	Shows where a product is heading, years ahead of label
Custom Drug Class taxonomy. No global standard exists	Enables class-level cost, time-to-market and comparability analysis
Emerging Drug Class signal. Data-driven detection of disruptive developments	A defined, evidenced signal for genuinely novel developments

CURRENT USE CASES

What member states and payers use horizon scanning for today

Budget impact and forecasting

Anticipating the fiscal impact of the incoming pipeline, so payers and ministries can plan ahead.

Capacity and service planning

Preparing clinical pathways, workforce and infrastructure for products before they arrive.

Class-level foresight

Seeing every product moving through a disease area at once, using the Drug Class taxonomy.

Assessment and negotiation readiness

Giving HTA bodies and payers a common early evidence base before formal assessment begins.

FROM SIGNAL TO EVIDENCE NEED

Horizon scanning can identify which products legitimately need real-world evidence

1

Detect

The Emerging Drug Class signal identifies products entering with genuinely novel mechanisms or endpoints.

2

Diagnose the gap

Standard trial evidence often cannot answer the HTA and payer question: novel endpoints, no comparator, small or heterogeneous populations.

3

Flag the RWE candidate

These are the products where real-world evidence is a genuine, anticipatable requirement, identifiable at trial-design stage.

Identified early, the requirement for real-world evidence becomes a planned, product-specific design question, addressed before the trial locks.

A FRAMEWORK FOR EARLY DIALOGUE

From a flag to an early dialogue

Who convenes	IHSI acts as the neutral convener and first point of contact, identifying the flagged product and the member states with a stake, and making the first introduction.
Incentive, company side	Earlier line of sight into what HTA bodies and payers will require, lowering the risk of generating evidence that turns out to be the wrong evidence.
Incentive, payer and HTA side	Time to align on endpoints and shape data collection before the trial design locks.
One-off or ongoing	An ongoing exchange. The signal refreshes every 28 days, so the dialogue can stay current.
Product-specific or above-product	Both. A specific molecule can trigger a dialogue, and the more valuable conversation is often at drug-class or therapeutic-area level.
Stakeholders	Patients and clinicians are in the loop from the start, because they define which real-world outcomes and endpoints matter.

WHERE THE NEGOTIATION HAPPENS

Early dialogue based on IHSI intelligence

IHSI

Identification and early dialogue.
Neutral, and before negotiation.

National

Individual member-state processes where sovereignty or scale requires it.

Regional

BeNeLux, Nordic and Valletta-type collaborations for shared leverage.

Critical Medicines Act

Where security of supply and strategic-dependency considerations apply.

WHO Europe initiative

Where a broader multilateral platform is the right fit.

Readiness. The same signal shows HTA bodies, payers and clinical systems where expertise will be needed, so the right people are ready when the dialogue takes place.

IN SUMMARY

Anticipate early, engage in good time

- Horizon scanning can identify which products legitimately need real-world evidence, early enough to act.

- IHSI can serve as the neutral convener: flag the product, bring the interested member states together, open the dialogue.

- The negotiation stays with member states, whether national, regional or multilateral. The anticipation is a shared task.

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Panel Discussion

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Chair Identification of Emerging Health Technologies (EHT) Subgroup, Director of the Pharmacoeconomics and Availability Department, Danish Medicines Agency

Björn Wettermark
Professor, Department of Pharmacy, Drug Epidemiology, Uppsala University; More-EUROPA project

Lara Wolfson
Associate Vice President & Head of HTA Statistics, MSD

Thank you!

A report will be published on our website: www.rwe4decisions.com

In the meantime, follow us on LinkedIn: @RWE4Decisions.

Save the date for our next RWE4Decisions event:

Invitation-only In-Person Symposium: *"Optimising RWE to Deliver Value in Healthcare"*, 23 September, 9:00-14:00 CEST.

Get in touch at secretariat@rwe4decisions.com if you would like to receive an invitation.