VIRTUAL EVENT

DIA

Regulatory Science Strategy Info Day

Advancing Patient-Centred Access

10 June 2020 | 08:30 - 16:10 CEST

PROGRAMME COMMITTEE

Virginia Acha
Global Lead, Global Regulatory Policy, MSD

Niklas Hedberg
Chair of the Executive Board, EUnetHTA

Anthony Humphreys
Head of the Regulatory Science and Innovation Task Force, European Medicines Agency (EMA)

Susan Longman
Head Regulatory Affairs Region Europe, Novartis Pharma AG

Elena Popa
Scientific Programmes Manager, Drug Information Association (DIA)

Overview

The Regulatory Science Strategy Info day provides the participants with the overview of the priorities of European regulators for the next 5 years. It will also bring in the view from other stakeholders and how they partner to advance the important topics promoted by the regulatory science strategy. There will be ample time for questions and discussion on how the strategy will be implemented and what will be the impact to the healthcare ecosystem as a whole.

Objectives

What will you get from this event?

- An overview of the priorities of European Regulators, following the "EMA Regulatory Science to 2025" publication and public consultation;
- Insights into the perspective from other stakeholders and how they will partner with regulators to advance the topics promoted by the regulatory science strategy;
- Participate on the discussion on how the "EMA Regulatory Science to 2025" strategy will be implemented;
- Meet Health Authorities, HTA bodies and Industry representatives leading the implementation of the strategy and related collaborations.

Key Topics

1. Contribution to HTA's preparedness and downstream decision making for innovative medicines;
2. Bridging from evaluation to access through collaboration with payers;
3. Patient relevance in evidence generation;
4. High-quality Real World Data (RWD) in decision making;
5. Network competence and specialist collaborations to engage with big data.

Who Will Attend?

Professionals who:

- Prepare value dossiers
- Evaluate and prepare clinical narrative for HTA bodies or payers
- HTA policy leads
- Are involved in regulatory strategies
- Collect and disseminate regulatory intelligence
- Work with regulatory science in academia, industry or governmental institution
- Lead scientific advice or early access programmes
- Design real-world evidence studies
- Lead patient engagement
- Work with HCP communication and labelling

AGENDA | WEDNESDAY, 10 JUNE 2020

08:15 LOG-IN AND CONNECT

08:30 WELCOME AND INTRODUCTION TO THE INFO DAY

Elena Popa, Scientific Programmes Manager, Drug Information Association (DIA)

08:45 SESSION 1

SETTING UP THE SCENE: DECISION MAKING FOR INNOVATIVE MEDICINES

Session Chair:
Anthony Humphreys, Head of the Regulatory Science and Innovation Task Force, European Medicines Agency (EMA)

Evolution of EMA-EUnetHTA Work Plan and other Platforms
Michael Berntgen, Head of Product Development Scientific Support Department, European Medicines Agency (EMA)

Bridging the two Decision Makers – is the time right?
Niklas Hedberg, Chair of the Executive Board, EUnetHTA

Q&A

09:45 BREAK

10:00 SESSION 2

BRIDGE FROM EVALUATION TO ACCESS THROUGH COLLABORATION WITH PAYERS

Session Chair:
Virginia Acha, Global Lead, Global Regulatory Policy, MSD

Aspirations and Challenges for Early Payer Interaction
Ansgar Hebborn, Head – European Access Policy Affairs, F. Hoffmann-La Roche AG, Switzerland

Work towards addressing the Evidence Gap
Michael Berntgen, Head of Product Development Scientific Support Department, European Medicines Agency (EMA)

Payer's Perspective
Evert Jan van Lente, Director EU-Affairs, AOK Bundesverband (Federal. Insurer)

Q&A

11:15 BREAK

11:30 SESSION 3

PATIENT RELEVANCE IN EVIDENCE GENERATION

Session Chair:
Niklas Hedberg, Chair of the Executive Board, EUnetHTA

The Patient's voice in HTA Assessment
Anne Willemsen, Project Manager, Joint Production Co-Lead Partner – Pharmaceuticals, ZIN - National Health Care Institute

Patient Important Outcomes in Regulatory Decisions
Juan Garcia-Burgos, Head of Public Engagement Department, European Medicines Agency (EMA)

Q&A

12:30 LUNCH

13:00 SESSION 4

HIGH-QUALITY REAL WORLD DATA (RWD) IN DECISION MAKING

Session Chair:
Susan Longman, Head Regulatory Affairs Region Europe, Novartis Pharma AG

Registry Initiatives Across Europe
Xavier Kurz, Head of Surveillance and Epidemiology Service, European Medicines Agency (EMA)

Examples of Successful RWE use and what can be fed to Future Strategy
Karin Van Baelen, Head, Global Regulatory Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson

Trusting the Data: Quality, Ethics, Privacy
Jesper Kjær, Director of Division - Data Analytics Center (DAC), Danish Medicines Agency (DKMA)

Q&A

14:15 BREAK

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14:30 SESSION 5

NETWORK COMPETENCE AND SPECIALIST COLLABORATIONS TO ENGAGE WITH BIG DATA

Session Chair:
Virginia Acha, Global Lead, Global Regulatory Policy, MSD

Upskilling Regulatory Reviewers
Shahid Hanif, Life Science Consultant, Avenzoar Consulting

How can Academia support?
Hubert Leufkens, Professor of Pharmaceutical Policy and Regulatory Science, Utrecht University

Q&A

15:30 WRAP-UP AND CLOSING REMARKS

Anthony Humphreys, Head of the Regulatory Science and Innovation Task Force, European Medicines Agency (EMA)

15:45 VIRTUAL HAPPY HOUR

16:45 END OF THE INFO DAY

Disclosure Policy

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About DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation that has its Global Center in Washington, DC, USA and the Europe, Middle East and Africa office in Basel, Switzerland. DIA has additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.DIAglobal.org or call DIA EMEA: +41 61 225 51 51.