



**GETREAL**  
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PUTTING REAL WORLD EVIDENCE  
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**1<sup>st</sup> GetReal Institute Annual Conference**  
**“A European Outlook on Real World Evidence in a Global Context”**

**16<sup>th</sup> March 2023**

**Jaarbeurs, Utrecht, The Netherlands**

**Register Now**

The GetReal Institute is pleased to announce its inaugural Annual Conference taking place on the **16<sup>th</sup> of March 2023 in Utrecht, the Netherlands.**

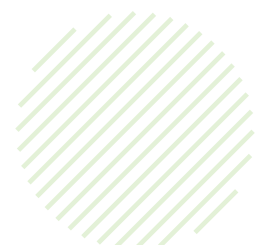
The conference will discuss RWE developments in a global context, reflecting upon progress in Europe, North America, Latin America, and Asia Pacific.

The aim of the conference, and the GetReal Institute, is to inform the RWE community of recent developments and the future direction of RWE, highlighting emerging initiatives and ongoing challenges, but more importantly the opportunities to collaborate and collectively address these challenges.

Join us at our first conference where we will discuss the following topics:

- RWE and the Global Research landscape. What is the Future?
- RWE and the Changing EU Landscape. The Pan European perspective.
- Can RWE Bring (Drug) Development Back to Europe? Pragmatic trials & historical controls, why don't we use RWE?
- Increasing Use of RWE in Asia
- Generation and Use of RWE for regulatory purposes in the USA
- Experiences and challenges of using RWE for decision-making in Latin America

<https://www.getreal-institute.org/annual-conference-2023/>





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**Conference Programme:**

<i>Registration &amp; Coffee</i>	08:30 – 09:00
<b>Opening address</b> Shahid Hanif, Managing Director GetReal Institute & Irene Nunes, Chair of the Executive Board, Get Real Institute	09:00 – 09:20
<b>Session 1: Setting the Scene: RWE and the Global Research landscape. What is the Future?</b>  Andrew Roddam, Our Future Health UK Bettina Ryll, MPNE Wija Oortwijn, HTIa Peter Mol, CBG-MEB  Moderator: Ginny Acha, MSD Format: Presentation and Discussion	09:20 – 10:10
<b>Keynote Session: RWE and the Changing EU Landscape. The Pan European perspective.</b>  Catherine Cohet, EMA  Moderator: Shahid Hanif, GetReal Institute Format: Presentation and Q&A	10:10 – 10:50
<i>Coffee break</i>	10:50 – 11:10
<b>Session 2: Can RWE Bring (Drug) Development Back to Europe? Pragmatic trials &amp; historical controls, why not use RWE?</b>  Rick Grobbee, UMC Utrecht Francois Houyez, Eurordis Iris Goetz, Lilly Anja Schiel, NOMA (tbc)  Moderator: Andrew Roddam, Our Future Health UK Format: Panel Session	11:10 – 12:00



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**Session 3: Increasing Use of RWE in Asia**

12:00 - 12:50

Dr Uyama, PMDA, Japan (tbc)

Azri Nasruddin, National Pharmaceutical Regulatory Agency (Malaysia) (tbc)

Prof Gau, National University Taiwan

Moderator: Gracy Crane, Roche

Format: Presentations and Q&A

*Lunch break*

12:50 – 14:00

**Session 4: How do US Stakeholders use RWE for a better understanding of value?**

14:00 – 14:50

Susan Winckler, Reagan-Udall Foundation (tbc)

Donna Rivera, FDA

Irene Nunes, Flatiron

Darren Toh, Sentinel

Moderator: Mark McLelland, Duke Margolis

Format: short presentations and discussion

**Session 5: RWE in Latin America, Leapfrogging for Growth in Clinical Trials.**

14:50 – 15:40

Sebastián García Martí, IECS (Argentina)

Fabrizio Carnaro Di Oliveira, ANVISA (Brasil) (tbc)

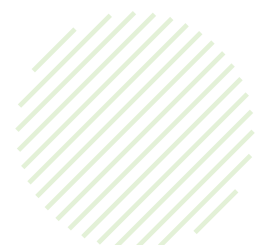
Otavio Berwanger, Hospital Albert Einstein (Brazil) (tbc)

Moderator: Nahila Justo – Evidera

Format: Presentation & Discussion

*Coffee break*

15:40 – 16:00





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### **Abstracts presentation sessions**

16:00 – 17:00

#### Creating and curating evidence

1. EHDEN, Nigel Hughes, JnJ
2. Trials@Home, Mira Zuidgeest, UMCU
3. DARWIN EU, Peter Rijnbeek, Erasmus

#### Emerging methodologies

1. GetReal Project: Pivotal Evidence: Marieke Jansen, LUMC
2. GetReal Project: Shared Learning Forum: Inka Heikkinen, MSD
3. GetReal Project: External Comparators: Wim Goettsch, UU

#### Patient-centered approaches to RWE

1. 'The patient value of RWE', Bettina Ryll, MPNE
2. Patient Focussed Medicine Development, Hailey Chapmann, The Synergist
3. World Duchenne Organisation, Dimitrios Athanasiou, WDO (tbc)

### **Closing Keynote address**

17:00 – 17:25

Mark McLelland, Duke Margolis

### **Closing Remarks**

17:25 – 17:30

Shahid Hanif, GetReal Institute

### *Reception*

17:30 – 19:00

### **Confirmed speakers:**

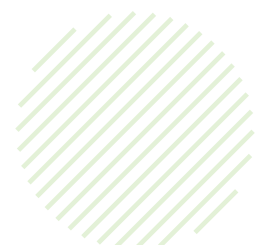
- Irene Nunes, VP, Head of Regulatory Affairs, Flatiron Health, Chair of the Executive Board GetReal Institute
- Catherine Cohet, Pharmacoepidemiology Senior Specialist, Data Analytics and Methods Task Force, European Medicines Agency (EMA)
- Mark McClellan, MD, PhD, Robert J. Margolis Professor of Business, Medicine, and Policy, and founding Director of the Duke-Margolis Center for Health Policy at Duke University
- Inka Heikkinen, Director, Global Regulatory Policy, EMEA, MSD
- Wim G. Goettsch, Professor HTA of Pharmaceuticals, WHO Collaborating Centre for Pharmaceutical Policy and Regulation; Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht University
- Donna Rivera, Associate Director of Pharmacoepidemiology, RWD & RWE at FDA Oncology Center of Excellence



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- Churn-Shiouh Gau, Adjunct Professor, School of Pharmacy, National Taiwan University
- Sebastián García Martí, Coordinator of Health Technology Assessment (HTA) and Economic Evaluation, IECS (Argentina)
- Wija Oortwijn, PhD, Senior researcher, Radboud university medical center/HTAi President
- Rick Grobbee, Professor of Clinical Epidemiology, University Medical Center Utrecht (UMCU)
- Churn-Shiouh Gau, Adjunct Professor, School of Pharmacy, National Taiwan University
- Bettina Ryll, Founder, Melanoma Patient Network Europe (MPNE)
- Darren Toh, Principal Investigator, Sentinel Operations Center, Harvard Medical School & Harvard Pilgrim Health Care Institute
- Virginia Acha, Associate Vice President - Global Regulatory Policy, MSD
- Andrew Roddam, Chief Executive Officer, Our Future Health UK
- Gracy Crane, International Regulatory Policy Lead for RWD, Roche Products Limited
- Peter Mol, Principal Clinical Assessor CBG-MEB (Dutch Medicines Evaluation Board); Professor of drug regulatory science, University Medical Center Groningen; Member SAWP
- Marieke Janssen, Leiden University Medical Centre
- Nahila Justo, Executive Director Integrated Solutions, Evidera
- Nigel Hughes, Scientific Director, Observational Health Data Analytics/Epidemiology, Johnson & Johnson & EHDEN Project Lead
- Mira Zuidgeest, Epidemiologist and Associate Professor, University Medical Center Utrecht (UMCU)
- Hayley Chapman, Senior Program Director, The Synergist
- Shahid Hanif, Managing Director, GetReal Institute





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**Venue:**



[Jaarbeurs Utrecht](#)

Jaarbeursplein  
3521 AL Utrecht

**Register Now**

**Target audience:**

The GetReal Institute is an independent, neutral and transparent multi-stakeholder collaboration between public and private partners. The GetReal Institute Annual conference aims to gather all these stakeholders so they can share experiences and insights in the field of RWE.

**Suggested hotels:**

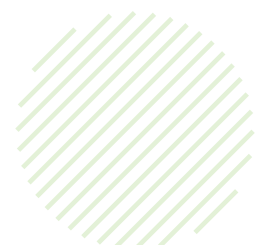
[NH Utrecht](#)

[ParkPlaza Utrecht](#)

[Inntel Hotels Utrecht Centre](#)

[Crowne Plaza Utrecht](#)

[Hampton by Hilton Utrecht](#)





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**Ticket Prices:**

(excl. 21% VAT)

**EARLY BIRD Rates (until 31 Jan 2023)**

- PhD/student/patient - €99
- Academia/Government/Non-Profit - €199
- Regular ticket - €399
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**From 1 Feb 2023 until 10 March 2023**

- PhD/student/patient - €149
- Academia/Government/Non-Profit - €249
- Regular ticket - €499

**Media Partner:**



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