



14th MAY | GetReal Conference 2024

GROWING CONVERGENCE: RWE FOR REGULATORY & HTA DECISION-MAKING

08:00 – 09:00	Registration & Welcome Coffee
09:00 – 09:15	#1a. Opening Remarks <ul style="list-style-type: none">• Shahid Hanif – GetReal Institute
09:15 – 10:30	#1b. Fireside Chat: “Throw back” to last year, how is regulatory and HTA converging? <ul style="list-style-type: none">• Per-Olof Thuresson – Roche• Irene Nunes – Genmab• Marcus Guardian – Dierks+ Company, former EUnetHTA• Shahid Hanif – GetReal Institute (moderator)
10:30 – 11:00	Coffee Break
11:00 – 12:30	#2 What does good look like? Progress in Regulatory Decision Making with RWE <p>RWE in regulatory decision making on guidance and use cases. How do we get there collectively, as a community? What progress are we making? What does good look like in RWE? What are the steps in-between?</p> <ul style="list-style-type: none">• Patrice Verpillat – EMA• Donna Rivera – FDA• Alison Cave – MHRA• Katrien Oude Rengerink – CBG-MEB• Álmath M. Spooner – AbbVie (moderator)
12:30 – 14:00	Lunch & Networking
14:00 – 15:30	#3 The Big Debate: This house believes we are making good progress towards adopting RWE as part of the HTA Regulation <p>What progress are European HTAs making in adopting RWE and how is this benefitting patients?</p> <ul style="list-style-type: none">• Iñaki Gutierrez Ibarluzea – BIOEF• Inka Heikkinen – MSD• Juan Carlos Rejón Parrilla – AETS)• Anke van Engen – IQVIA• Shahid Hanif – GetReal Institute (moderator)
15:30 – 16:00	Coffee Break
16:00 – 17:30	#4 Deploying methods in HTA: the experiences of HTA bodies using RWE methods <p>Which RWE methods are HTA bodies using and why? Are some easier to use than others? What do stakeholders say? Do some give more robust answers? What is their experience? What are the barriers? Examples and HTA methodology approaches straight from the horse’s mouth</p> <ul style="list-style-type: none">• Stephen Duffield – NICE• Farah Husein – Canada’s Drug Agency• Anja Schiel – NOMA• Blythe Adamson – Flatiron (moderator)



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08:30 – 09:00	Welcome Coffee
09:00 – 09:05	Opening Remarks
09:05 – 10:20	#5a Methods Deep-Dive: A Scientific Discussion on RWE Methods Being Applied <ul style="list-style-type: none">• Bettina Ryll – MPNE: The Scientific Value of RWE for Patients• Delphine Saragoussi – Evidera / ISPE RWE Collaborative SIG: RWE Methodologies Applied Across Medicinal Products Development & Lifecycle Management• Miriam Surkenboom – VAC4EU: Syntactic & Semantic Harmonization in Transforming RWD to RWE, Examples from VAC4EU and ConcePTION• Shahid Hanif – GetReal Institute (moderator)
10:20 – 10:50	Coffee Break
10:50 – 12:05	#5b Methods Deep-Dive: A Scientific Discussion on RWE Methods Being Applied <ul style="list-style-type: none">• Manuel Gomez – UCL: Using Target Trial Emulation for Estimation of Treatment Effects Using Real-World Data• Guillermo Pérez Garcia & Silvia Moler Zapata – HTA Unit, Institute for Health Sciences of Aragon (IACS), Spain: Defining the role of Real-World Data in Health Technology Assessment in Spain: Some Lessons Learnt and a Glimpse at the Future• Shahid Hanif – GetReal Institute (moderator)
12:05 – 13:20	Lunch
13:20 – 14:20	#6 KEYNOTE: A Vision For The Future: What If We Accelerate The Convergence of Regulatory & HTA? <ul style="list-style-type: none">• Patrice Verpillat – EMA• Niklas Hedberg – TLV• Shahid Hanif – GetReal Institute (moderator)
14:20 – 14:50	Coffee Break
14:50 – 16:20	#7 CLOSING DISCUSSION: Regulatory & HTA Town Hall <p>An opportunity for all voices to be heard. What are the needs, and are these complementary or competitive?</p> <ul style="list-style-type: none">• Iñaki Gutierrez Ibarluzea – BIOEF• Elena Petelos – University of Crete/HTAi• Wim Goettsch – Sustain-HTA• Patrice Verpillat – EMA• Donna Rivera – FDA• Bettina Ryll – MPNE• Elizabeth Vroom – World Duchenne Organization• Niklas Hedberg – TLV (moderator)
16:20 – 16:30	Final Remarks