GETREAL INSTITUTE | PUTTING REAL WORLD EVIDENCE INTO PRACTICE

GetReal® 2025 Conference, 1-2 October

# REAL WORLD EVIDENCE WITH REAL WORLD CONFIDENCE: SHAPING THE FUTURE OF HEALTHCARE

## CROWNE PLAZA, UTRECHT, THE NETHERLANDS

**DAY 1:** STANDARDS FOR RWE GENERATION AND FOSTERING COLLABORATION ACROSS PRODUCT DEVELOPMENT

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| **08:30 – 09:00** | **Registration & Welcome Coffee** |
| **09:00 – 09:10** | **Opening Remarks** |
| **09:10 – 09:30** | **Keynote presentation** |
| **09:30 – 10:15** | **1. Revolutionizing RWD Standards Across the Product Lifecycle** |

**Panel Discussion**

- The value RWE brings across the lifecycle.
- What drives the uptake of RWE at various stages of the product lifecycle?
- Moving beyond traditional frameworks to develop technology-driven RWD collection and integration throughout drug development

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| **10:15 – 11:00** | **2. Rethinking Evidence Generation in Interventional Studies: From Trials to Treatment Decisions** |

**Panel Discussion**

- Applying key lessons to continuously improve data integrity, usability, and methodological robustness.
- Addressing key challenges in data collection, quality, access, privacy, interoperability, and ethical considerations in integrating diverse data sources.
- Pragmatic trials and disease registries.

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| **11:00 – 11:30** | **Coffee Break & Networking** |
| **11:30 – 12:00** | **3. Designing Stronger RWE Studies to Meet Evidence Thresholds for Various Stakeholders** |

**Presentations and Q&A**

- **Presentation 1: External Control Arms and Best Practice Framework**
- **Presentation 2: Exploring the role of Target Trial Emulation (TTE)**

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| **12:00 – 12:35** | **Poster Presentation Spotlight** |

Three research abstracts selected for presentation

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| **12:35 – 14:00** | **Networking Lunch** |
| **14:00 – 15:00** | **4. Submitting RWE to Regulators, HTAs, and Payers** |

**Interactive** session simulating a real challenge: what happens when a pharmaceutical company submits an RWE based evidence package to regulators, HTA bodies, and payers - all of whom have different evidence expectations.

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| **15:00 - 15.45** | **5. The Future of RWE-Based HTA, Pricing & Reimbursement Models** |

**Presentations and panel discussion**

- **Presentation 1: WHO Global Framework on MEAs & RWE Use (2023-2024)**
- **Presentation 2: RWE Tools & Frameworks**
- The changing landscape of evidence generation, drivers of adoption of RWE
- Strategies to minimise redundancy and improve efficiency in evidence generation.
- Developing and implementing consistent methodological guidelines across healthcare systems.

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| **15:45 – 16:15** | **Coffee Break & Networking** |

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| **16:15 – 17:00** | **6. Next-Generation RWE Strategies for Regulatory Decision-Making** |

### Presentations and panel discussion

- Transforming regulatory evidence – European initiatives and implementation realities
- Ambitious RWE initiatives

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| **17:00 – 17:20** | **Closing Remarks for Day 1** |

- **Summary and key takeaways.**

## **DAY 2:** ADVANCING RWE METHODOLOGY & INNOVATION ACROSS THE LIFECYCLE

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| **08:30 – 09:00** | **Registration & Coffee** |
| **09:00 – 09:45** | **7. AI & RWE: Innovation Meets Evidence Across the Product Lifecyle** |

### Panel Discussion

- Leveraging innovative technologies to refine RWE methodologies
- Pilot applications illustrating the potential of AI
- Developing best practices for improving causal reasoning, data quality, and study validity.
- Use of Gen AI to mine unstructured data

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| **09:45 – 10:30** | **8. Enhancing Patient-Centric RWE & Digital Health Integration** |

### Panel Discussion

- Addressing issues of data transportability, bias, and standardisation.
- Providing practical guidance for primary and secondary care providers on effective RWE data collection and the role of wearables, PROS, and digital biomarkers.
- Approaches that centre on **patient-centric RWD** to improve the relevance and impact of real-world evidence RWE in clinical and regulatory decision-making.

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| **10:30 – 11.00** | **Coffee Break & Networking** |
| **11.00 – 11:45** | **9. From RWD to Decision-Grade RWE** |

### Panel Discussion

- Practical guidance on data curation, bias mitigation, and statistical methods to turn RWD into accepted RWE
- The value of **RWE Frameworks** to help assess compliance with HTA and regulatory expectations. Helpful tools or distraction?

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| **11:45 – 12:30** | **Moderated poster presentations and Networking** |
| **12:30 – 13:30** | **Networking Lunch** |
| **13:30 – 14:15** | **10. Multi-Stakeholder "Hot Seat" Debate: Strengthening RWE Acceptability** |

### Panel Discussion

- Communicating the “Good, the Bad, and the Ugly” for multi-stakeholder groups: Best Efforts vs. Expectations.
- Navigating the intersection of data quality, accessibility, and transparency to build trust in RWD.
- Evolving evidence landscape and how do we meet the evidence threshold for submissions, how does RWE factor into the Joint Clinical Assessment (JCA)
- Balancing transparency in reporting exploratory data with insights into what worked well.

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| **14:15 – 14.30** | **Closing Session & Key Takeaways** |