THE GETREAL 2026 CONFERENCE

DRAFT PROGRAMME

Translating Real-World Data into Decision-Ready Evidence: Bringing Data, Methods, and Decision Context Together

29–30 June 2026 | Crowne Plaza, Utrecht, The Netherlands

DAY 1: MONDAY, 29 JUNE 2026

14:30 **Registration & Welcome**

Delegates arrive and collect badges

15:00 **OPENING ADDRESS**

Welcome from the Chair, The GetReal Institute

15:10 **KEYNOTE**

The Year Everything Changed: Towards a New Era of Evidence-Driven Decision Making for Therapeutic Interventions

15:40 **SESSION 1**

Understanding the Decision Context: What do Regulators, HTAs & Payers Actually Need?

- One core evidence package but multiple decisions
- A mock case study will be used to illustrate the challenge

16:40 **SESSION 2**

Data Foundations: Assessing Fitness for Purpose Across the Evidence Lifecycle

- Building and using decision-grade data assets: EHR linkage, federated networks, DARWIN EU, and the European Health Data Space in 2026, how does this impact data quality and governance

17.40 **Close of day 1**

18:30 **Networking Dinner**

DAY 2: TUESDAY, 30 JUNE 2026

08:30 **Registration & Morning Coffee**

09:00 **Parallel Workshop SESSION 3A**

Target Trial Emulation: From Framework to Submission

Parallel Workshop SESSION 3B

Patient Engagement: Embedding the Patient Voice in RWE

10:30 **Coffee & Networking**

11:00 **SESSION 4**

AI & Machine Learning: Accelerating the Translation of RWD into Decision-Ready Evidence

- AI is rapidly transforming real-world evidence, but are decision-makers ready to trust it? This session examines where we are today, what regulators and HTA bodies actually expect from AI-generated evidence, and why acceptance remains limited. From governance, ethics, and transparency to bias and accountability, we explore the foundations of trust, while looking ahead to emerging approaches such as agentic AI and what they could mean for the future of evidence generation and decision-making.

12.00 **POSTER PRESENTATIONS**

Showcasing latest research and real-world evidence studies

3 x 10 min poster presentations

12:30 **Networking Lunch & Poster gallery**
Delegates invited to visit and engage with poster authors

13:30 **SESSION 5**

Real-World Evidence in Action: Key Results & Policy Lessons from the MetReal Project Cluster

- Six EU-funded MetReal cluster projects at final phase: headline results on RWD fitness-for-purpose, study design validation, and evidence acceptability across regulatory and HTA settings
- From findings to policy: what the collective evidence base tells us about where RWD use is accelerating, where barriers remain, and what needs to change in guidance, infrastructure, and practice
- Open discussion: what would it take to move from promising results to systematic adoption (review and critique of recommendations) and what commitments can regulators, HTA bodies, and industry make?

14.15 **SESSION 6**

EU Joint Clinical Assessment: One Year In, What Have We Learned?

- The first JCA reports are in: what evidence was accepted, what was flagged insufficient, and what that tells us about the true bar for RWE in oncology and ATMP submissions
- The PICO problem: 90-day dossier timelines and unpredictable scope requests forcing evidence teams to design RWE studies years earlier
- Perspectives from an HTA assessor, manufacturer, and methodologist: where JCA works, where it creates gaps, and what must change before orphan drugs join scope in 2028

15.00 **Coffee & Networking**

15.20 **SESSION 7**

Meeting Long-Term Follow-Up Obligations: challenges and opportunities for Post-Approval Evidence Generation

- RWE for long-term follow-up of gene therapies - FDA and EMA LTFU requirements, fit-for-purpose registry design for ATMPs, and the 15+ year follow-up challenge in practice
- Introduce important uncertainties identified (EMA and HTA bodies)
- Challenges from an industry perspective (Orchard Tx)

16.05 **SESSION 8**

Closing Panel: Translating Learnings into Commitments

- What does truly decision-ready RWE look like in 2026? Reflections from regulators, HTA bodies, payers, industry, and patient advocates on what has changed - and what still needs to be done
- The credibility gap: where evidence generation is still falling short of decision-maker expectations and what the field must do differently
- Practical commitments from each stakeholder group - announcing GetReal® collaborative workstreams and initiatives for 2026/27

16.50 **CLOSING REMARKS**

Close from the Managing Director, The GetReal Institute

17.00 **Conference Close**

End of the 2026 GetReal Conference

** Timings are indicative and subject to change. Final programme to be confirmed.*

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