

A Message from the Managing Director

Dear Colleagues,

It's been a busy few months at The GetReal Institute, and there's plenty to share.

In June, the GetReal community came together in Utrecht for the GetReal Conference 2026. This year's theme, *Translating Real-World Data into Decision-Ready Evidence*, brought regulators, HTA bodies, industry, academia and patients together around a question that sits right at the heart of our work. We've moved past asking whether real-world evidence has value. The question now is how to use it well when real decisions are being made.

The Conference Report, the 2026 Abstract & Poster Book and a Conference Highlights page are now all available, so you can revisit the sessions or share them with colleagues.

Our five Topic Groups have also moved from planning into delivery, and you'll find an update on each of them inside.

We've been strengthening the Institute itself, too. We've welcomed University College London and Takeda as members, set up our new Advisory Board, launched a refreshed website and Resource Centre, and started preparing to relaunch the GetReal Academy this winter.

The strength of the GetReal Institute lies in bringing together different perspectives from patients, regulators, HTA bodies, industry, academia and research partners. I'd like to thank our members and partners for contributing their time, expertise and ideas, and we always welcome new members who can bring fresh perspectives to our community. As we look ahead to 2027, we'll be consulting with members and external stakeholders to help shape our programme and identify where the Institute can add the most value.

Mariam Bibi

Managing Director, The GetReal® Institute

GetReal Conference 2026 | Conference Recap

On 29–30 June, the GetReal community came together in Utrecht for our 2026 Annual Conference:

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

Over the two days, we looked at what it really takes to turn real-world data into evidence that is relevant, robust and timely enough to support decisions. Sessions covered decision context, whether data are fit for purpose, Target Trial Emulation, patient engagement, AI and machine learning, lessons from the MetReal project cluster, the first year of EU Joint Clinical Assessment, and long-term evidence generation after authorisation.

Across the discussions, one practical challenge kept returning: evidence must answer the question facing a particular decision-maker. The conference explored what this means for choosing data, applying methods and planning evidence generation across the lifecycle. Our published report captures the different stakeholder perspectives and the questions still to be resolved.



Missed Anything from Utrecht?

Whether you were there or not, there are three ways to revisit the conference:

Title	Format	What you'll find
GetReal Conference 2026 Report	Report	The full account: every session, the discussions, and the policy and methods lessons.
2026 Abstract & Poster Book	Report	The research our contributors presented, including the selected oral abstracts and posters.
2026 Conference Highlights	Web page	A quick snapshot of the programme and the key moments from Utrecht.

A big thank you to everyone who spoke, moderated, sat on a panel, presented an abstract or poster, or simply joined the conversation. It wouldn't have been the same without you.

2026 Topic Groups | From Planning to Delivery

Our topic-based way of working is now well established, with each of the five groups tackling a focused question with practical outputs in mind. Here's where each one has got to.

Topic Groups at a Glance

Topic Group	Where things stand
Topic 1 AI in Regulatory and Healthcare Decision-Making	The first sub-topic is a systematic literature review and landscape study of how far regulators, and HTA bodies accept AI-generated evidence. It will review the scientific literature alongside agency, policy and methods sources (including FDA, EMA, NICE, IQWiG, HAS and CDA-AMC) to map where AI-generated evidence is accepted, under what conditions, and where the red lines and gaps lie.
Topic 2 Target Trial Emulation (TTE)	The Target Trial Emulation Topic Group conducted expert interviews and, separately, held a workshop at our 2026 Annual Conference. Together, these explored why the framework is gaining momentum, what is needed to improve its application and where it should go next. The findings and recommendations will be published in a white paper in Q4 2026.
Topic 3 Patient Engagement and the Patient Voice	The Patient Engagement Topic Group held a workshop at our 2026 Annual Conference, using an oncology case study to explore where patient voices are missing in RWE and how they can be better integrated into regulatory and HTA decision-making. The findings and practical recommendations will be published in a white paper in Q4 2026.
Topic 4 Surrogate Endpoint Validation	The Surrogate Endpoints Topic Group has developed a protocol and undertaken preliminary searches for a pragmatic literature review exploring how real-world evidence can be used to validate surrogate endpoints. The review aims to identify current approaches, barriers and evidence gaps.
Topic 5 External Comparator Framework	The next phase builds on our External Comparator Framework publication to produce practical recommendations for stakeholders, covering topics the existing guidance doesn't yet address. The work will run in four stages: a gap analysis of the guidance reviewed in the framework; a consensus workshop to agree priority topics; focus groups drawing on stakeholder interviews and targeted literature reviews; and consolidated recommendations on the conduct and methodological standards of external control arms.

Interested in Our Work?

To find out more about our work or about membership, please contact the GetReal team: info@getreal-institute.org

Welcome to New Members

We're delighted to welcome University College London (UCL) and Takeda to the GetReal Institute.



**University College
London**
United Kingdom



Takeda
Global

Growing our membership is a real priority for us, and UCL and Takeda bring valuable methodological, health economics, pharmaceutical research and development expertise to our community. We're looking forward to working together across our scientific programme, Topic Groups and education activities.

Membership is open to organisations across the RWE community. If your organisation would like to learn more, please get in touch at info@getreal-institute.org.

Introducing Our Advisory Board

We've set up a new Advisory Board to give us independent, strategic advice and to strengthen our links across the wider RWE community. It sits alongside the Executive Board, bringing different perspectives as we shape our scientific programme, education activities and longer-term strategy. Please join us in welcoming:

Carole Longson | HTA Expert seat | Independent Senior Adviser

Leo Russo | Industry seat | Scientific Adviser

Massoud Toussi | CRO seat | Vice President, Real World Evidence

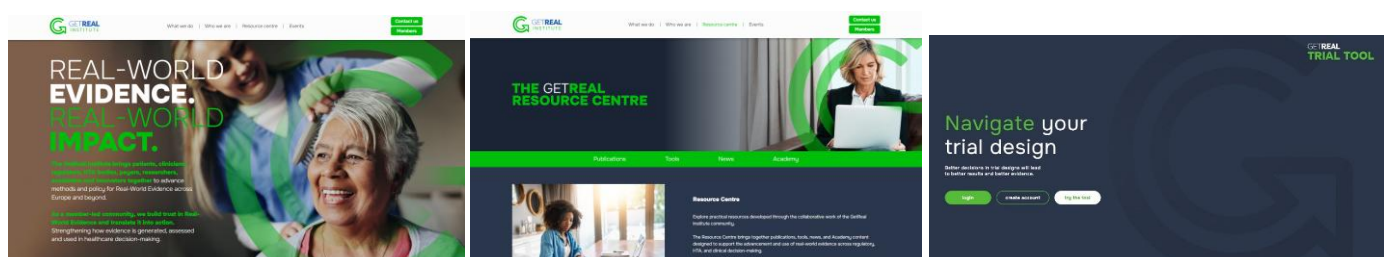
A Refreshed Website and Resource Centre

Our new website is live. It gives a clearer picture of who we are, how members can get involved, and how our work supports the use of RWE in healthcare decisions. It also shows how our topic-led research works, from horizon scanning and choosing topics through to workplans, outputs and sharing what we've learned.

The new **Resource Centre** brings our publications, news, methodological frameworks, webinar and workshop reports and conference resources together in one place. When the GetReal Academy relaunches this winter, the Resource Centre will move into the Academy, giving all our learning and resources a single home.

We're also updating our established tools, originally developed as part of the IMI programme. Once they're ready, you'll find them in the Academy:

GetReal Trial Tool **Real-World Evidence Navigator** **GetReal Glossary of Key Terms** **Real-World Evidence Study Design Landscape Tool**



GetReal Academy | Relaunching This Winter

We're relaunching the GetReal Academy this winter. It brings our training and educational resources together, as part of our wider mission to build RWE capability across the community. The first two courses will be:

Structured Benefit–Risk Assessment of Medicinal Products

Developed by UMCG · Self-paced

Real-World Evidence in Medicine Development

Developed by UMCU · Self-paced

The Academy will also become the new home of our Resource Centre and, once they're updated, our established tools. We'll share more on access and course content as we get closer to launch.

Looking Ahead | GetReal Conference 2027

SAVE THE DATE

18–19 May 2027

Crowne Plaza Utrecht
The Netherlands

Planning for next year is already under way, and we're heading back to the Crowne Plaza Utrecht. We're building the 2027 programme around what we heard this year, and around the scientific, methodological and policy questions that are shaping how RWE is generated, assessed and used. Tickets should go on sale in Q4, with more programme news to follow.

Coming Up Before the End of 2026

Q4	More from our Topic Groups Two white papers are planned for Q4, drawing on our TTE interviews and workshop and our patient engagement workshop. Work will also continue on AI evidence acceptance, surrogate endpoint validation and the External Comparator Framework.
Q4	Shared Learning Forum Our next Forum will bring members and invited experts together for a focused discussion on an important area of RWE generation and use. We'll confirm the topic, speakers and date soon.
Q4	Shaping our 2027 programme We'll ask members and external stakeholders where we can add the most value next year. What we hear will shape the 2027 scientific programme.
Q4	Thought Leadership on Rare Diseases We'll publish our article, Making Real-World Evidence Work for Rare Diseases in Europe, exploring how RWE can be integrated into evidence generation throughout the medicine lifecycle.
Q4	Conference 2027 preparations We'll develop the programme, start inviting speakers and get ready for ticket release.
Winter	GetReal Academy relaunch The GetReal Academy will be relaunched, and the Resource Centre will move into the Academy.
December	December member newsletter A round-up of our 2026 outputs and a first look at 2027.

Thank you for your interest in the GetReal® Institute. We look forward to sharing more with you in the December newsletter, and to welcoming you to Utrecht next May.

getreal-institute.org