

PRESS RELEASE

Launch of the GetReal Institute, a multi-stakeholder organisation that builds on the success of the IMI GetReal Initiative

Utrecht, The Netherlands, 14 April 2021

The **GetReal Institute** -- a not-for-profit multi-stakeholder organisation with a mission to facilitate the adoption and implementation of real world evidence (RWE) in health care decision-making in Europe -- will launch 28 April 2021.

The Netherlands-based Institute will serve as:

- A **convening platform for key stakeholder groups in Europe** – including regulatory agencies, health technology assessment (HTA) bodies, health care systems, patient organisations, academia, industry, and data partners – to reach common understanding and prioritisation of critical opportunities and challenges in the generation, evaluation, and use of RWE
- An **incubator and design lab** for demonstration projects to clarify scientific and operational uncertainties in RWE approaches and methods and for development of practical tools to facilitate adoption of RWE
- A **hub for sharing learnings** among initiatives, consortia, and organisations working to strengthen the use of RWE in health-care decision-making in Europe, and
- A source of **trusted, high quality RWE education and training** resources through the established and highly regarded GetReal Academy.

The Institute will initially prioritise efforts in **three Focus Areas**:

1. **Reducing barriers to the secondary use of data sources for health care decision-making**, including challenges with real world data discoverability, quality, and accessibility
2. **Bridging the gap between RWE and conventional randomised controlled trial (RCT) approaches** through, for example, incorporation of “real world” elements in RCT design and implementation, use of real world data-based external comparator arms in clinical trials, and use of non-interventional study designs
3. **Addressing the evidence needs of “downstream” decision-makers** -- HTA bodies, payers, clinical guideline developers, clinicians, and patients -- whose perspectives and decision contexts are as important as those of regulatory agencies.

Like its IMI predecessor, the Institute's work will initially centre on the use of RWE to enhance understanding of the benefits, risks, and value of medicines and vaccines.

The GetReal Institute will be formed as a not-for-profit member association in the Netherlands, meaning its members are the organisation's ultimate governance authority. An elected Executive Board will determine the Institute's strategic and programmatic direction on behalf of the members, aided by a Scientific Advisory Board and with implementation led by the Institute's Managing Director. The Institute will be funded through a combination of membership fees, revenue from the GetReal Academy and other programmes, and grants.

Who is part of the GetReal Institute?

Any organisation involved in the generation, evaluation, or use of RWE may join the GetReal Institute.



The following organisations have expressed their intention to join (pending finalisation and execution of membership agreements):

- Clinical Practice Research Datalink (CPRD) (UK)
- Eli Lilly and Company
- F. Hoffmann-La Roche
- GlaxoSmithKline
- International Alliance of Patients' Organizations (IAPO)
- Janssen, Pharmaceutical Companies of Johnson & Johnson
- National Institute for Health and Care Excellence (NICE) (UK)
- Norwegian Medicines Agency (NoMA)
- University Medical Center Utrecht (UMCU)

Additional participating organisations will be announced in due course.

Virtual public information event, 28 April 2021

Coinciding with its launch, the organisations forming the GetReal Institute will host a virtual information event about the Institute and its objectives on **28 April 2021, 13:30-14:45 CET**. This Zoom webinar is free and open to the public. Time will be allotted for audience questions.

To register for the information event and to learn more about the GetReal Institute, including membership opportunities, please visit getreal-institute.org

About the IMI GetReal projects

The GetReal Institute will build and expand on the work and outputs of [IMI GetReal](#) (2013 - 2017) and the [IMI GetReal Initiative](#) (2018 - 30 April 2021). Both projects were part of the [Innovative Medicines Initiative \(IMI\)](#), a public-private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA), and included regulators, HTA bodies, industry, academia, and other partners. The IMI GetReal projects aimed to demonstrate how robust new methods of real world data collection and synthesis can be integrated earlier in pharmaceutical research and development and healthcare decision-making processes. In addition to 30+ research publications, development of tools such as the [RWE Navigator](#), [GetReal Trial Tool](#), and the [Aggregate Data Drug Information System \(ADDIS\)](#), and highly regarded skills development training, the IMI GetReal projects demonstrated that trust gained through multi-stakeholder collaboration is essential to advancing the use of RWE in health care decision-making.

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