

GetReal

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Research Areas



Tool Development

Data Sharing



Biomarker Research



Basic Research



Data-Sharing Enabler

At a Glance

- Status: **Active Consortium**
- Year Launched: **2013**
- Initiating Organization: **Innovative Medicines Initiative**
- Initiator Type: **Government**
- Location: **Europe**

Abstract

Incorporating data from real-life clinical settings into drug development and associated decision-making represents a serious challenge for pharmaceutical companies, regulators, and health authorities alike. By bringing together all key stakeholder groups (i.e., industry, academia, regulatory agencies, reimbursement agencies, healthcare budget holders, and patient groups) to share their insights and know-how, GetReal will develop new approaches for incorporating real-life data into drug development and will pave the way for a greater consensus on this issue. The expected duration of the project is 39 months.

Mission

The challenge is to incorporate relative effectiveness research into the earlier stages of drug research and development. Among other things, GetReal will analyze existing processes and methodologies for HTA. It will also generate a decision-making framework to help pharmaceutical companies design drug

development strategies.

GetReal also aims to develop tools that will allow different stakeholders in drug development and approval to test different mathematical models in their decision-making and assess their impact.

A significant part of the project is devoted to organizing training activities for researchers, healthcare decision-makers, and other stakeholders on relative effectiveness concepts and how they can be applied.

Finally, GetReal will create a network of regulators, HTA organizations, companies, academics, healthcare professionals, patients, and other societal stakeholders. This is important because the challenges faced by the pharmaceutical industry, regulators, and other healthcare decision-makers are linked.

GetReal will help to generate a consensus on best practice in the timing, performance, and use of real-life clinical studies in regulatory and reimbursement decision-making. It will also help to create a strong platform for the communication of results and for future discussions in this important area.

Consortium History

Jan. 10, 2013: Project started

Jan.9, 2014: Website launched

Jan. 29-30, 2014: Kick-off meeting held in Zeist, Netherlands

Financing

This project is funded by the Innovative Medicines Initiative (IMI), a public-private partnership between the European Union (EU) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), the resources of which are composed of financial contribution from the EU Seventh Framework Programme and EFPIA members' in kind contributions. Large pharmaceutical companies participating in IMI projects do not receive IMI funding.

IMI has contributed €8.0 million, EFPIA members have contributed €6.0 million in kind, and other sources have contributed €2.3 million, for a total cost of €16.3 million.

Intellectual Property

The IMI intellectual property (IP) policy governs the IP regime of all projects funded by the IMI Joint Undertaking. To assist with specific IP queries, IMI has set up a dedicated IP Helpdesk, which can be contacted by emailing IMI-IP-Helpdesk@imi.europa.eu. The IMI IP policy can be accessed at the http://www.imi.europa.eu/sites/default/files/uploads/documents/imi-ipr-policy01august2007_en.pdf

Patent Engagement

Patient organizations are involved in IMI, through which GetReal works. The International Alliance of Patient Organizations is one of the participant/sponsor groups involved in the project.

Data Sharing

According to IMI's IP policy, the participants undertake to disseminate the data as soon as reasonably practicable but not later than one year after the termination or expiry of the project. The project Agreement shall include a description of the material, which must be disseminated in accordance with the IP policy and referenced in the grant agreement. If the participants do not disseminate within such time periods without good reason, then the Executive Office has the right to disseminate such results in a manner consistent with the grant agreement.

Impact/Accomplishment

The expected impact of the GetReal project is that it will contribute to the knowledge base, particularly to inform clinical decision-making and improve the efficiency of the research and development process.

Links/Social Media Feed

Homepage

<http://www.imi-getreal.eu/>

Other website

<http://www.imi.europa.eu/content/getreal>

Points of Contact

Diederick E. Grobbee

The Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht

phone: +31 88 75 5958

email: getreal@umcutrecht.nl

email: d.e.grobbee@umcutrecht.nl

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