Time to Get Real about Real-World Data in HEOR and Epidemiological Research:
Three Necessary Conditions for Better Data

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The Real-World Data (RWD) or Big Data revolution is upon us. From retail to engineering, from advertising to predicting travel patterns, we are subject to daily analysis of electronic pieces of information. In healthcare, much of the advance is happening in clinical research; linking genomics data to outcomes allowed us to go beyond a mere correlation analysis towards causality discussions in discovering why some are more prone than others to face certain health conditions.

Yet, the field of epidemiology and health economics and outcomes research (HEOR) is still struggling to fully grasp the possibilities. RWD are fragmented – they include only a sector of healthcare or are geographically constrained. RWD are incomplete – key outcomes are missing or are not routinely collected, and time stamps for major health

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events are not present or are subject to reporting bias. Access to RWD is restricted – many data owners do not allow external access to their data. Generating real-world evidence to support new product launches for present-day indications has become a challenge.

Many of these constraints are inherent to how the real-world evidence support system has developed; barriers were created and insufficient facilitators established. Reliance on existing data collection methods (claims data or electronic health records), confidentiality protection or data ownership laws, and the rules of research funding all contributed to the current situation yet are completely understandable given the history of the field and investment needed to generate patient-level information in a longitudinal way.

Are we therefore stuck with the imperfect system? Not necessarily, as there is a growing recognition that improvement is needed. Innovative Medicines Initiative's (IMI) GetReal is one of the initiatives recognizing the need to do better.[1] It aims to show how robust new methods of RWD collection and synthesis could be developed and considered for adoption earlier in pharmaceutical research and development and the healthcare decision

making process. (For more in-depth description of IMI GetReal goals, please read the interview with Rob Thwaites in this issue of *the Evidence Forum*). It is the **collaboration** of multiple stakeholders involved in real-world evidence generation that is the first of the necessary conditions for improved RWD. Development of standards, making more complex and robust approaches part of research standards, and ensuring comparability of findings through the use of tools such a common data model should be the desired outcomes of this increased collaboration.

The second necessary condition is an extension of the first one – real-world evidence needs to produce **stakeholder-relevant**, and in particular **clinically-relevant, outputs**. The drug development process has become increasing multidisciplinary, and issues related to market access and HEOR supporting market access are now discussed early as part of multifunctional brand teams. This increased visibility, which involves real-world evidence generation, requires going beyond technical delivery. For instance, RWE translational research should help clinicians understand what to expect from RWD studies, what constitutes good research practices, and how clinicians can get engaged in the design and interpretation of these studies; all these activities would only improve the value of investment in generated evidence. This would also help overcome the stigma of observational research as being lower in the hierarchy of scientific evidence than randomized clinical trials.

Finally, we need **faster research outputs.** In many cases, it takes more than a year to get access to data from the most recent calendar year. Examples are plentiful of the negative impact this has on research quality and impact.

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Analyses of real-world treatment patterns or outcomes are outdated by the time they are made public. Post-authorization safety studies, focused on confirming that the drug is safe in actual clinical practice, are prone not only to challenges associated with a new drug gaining the necessary market share but also with data availability delays, causing them to run for several additional years. This extends beyond studies involving existing data sources; data collection studies do not produce results for several years, with frequent interim analyses often being cost prohibitive for the study sponsor. Many of these challenges cannot be easily overcome and will require non-research solutions, but there are some steps that researchers can take, in particular an increase in the use of technology and automation to speed up data management and analysis.

Real-world evidence has the potential power to change the way drug development works – adaptive licensing is one area where the need to use RWD early is essential. By focusing on collaboration among stakeholders and the importance of clinically-relevant and faster outputs, the healthcare industry can revolutionize the way we view real-world evidence and open up new, life changing, and even life-saving, treatments for improved health outcomes on a global scale. Barriers are meant to be broken.

REFERENCE

[1] Innovative Medicines Initiative. GetReal. Available at: www.imi-getreal.eu/About-GetReal/Overall-objectives. Accessed March 28, 2016.