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ACCEPTED MANUSCRIPT

The positive impacts of Real-World Data on the challenges facing the evolution of biopharma

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Highlights

- Some current challenges facing the biopharmaceutical industry are outlined.
- The importance of Real World Data and Real World Evidence is identified.
- Pre-competitive, collaboration (PCC) is recommended to address the issues.
- Existing PCCs could be used to specify common functionality and best practices.
- Service providers could implement cloud-based systems to be shared by the industry.

Teaser: The biopharmaceutical industry must access, manage, and analyze Real-World Data (RWD) to generate Real-World Evidence (RWE), but does each company need to build their own in-house capability? Precompetitive collaboration should lead to better, more-cost-effective solutions.

Demand for healthcare services is unprecedented. Society is struggling to afford the cost. Pricing of biopharmaceutical products is under scrutiny, especially by payers and Health Technology Assessment agencies. As we discuss here, rapidly advancing technologies, such Real-World Data (RWD), are being utilized to increase understanding of disease. RWD, when captured and analyzed, produces the Real-World Evidence (RWE) that underpins the economic case for innovative medicines. Furthermore, RWD can inform the understanding of disease, help identify new therapeutic intervention points, and improve the efficiency of research and development (R&D), especially clinical trials. Pursuing precompetitive collaborations to define shared requirements for the use of RWD would equip service-providers with the specifications needed to implement cloud-based solutions for RWD acquisition, management and analysis. Only this approach would deliver cost-effective solutions to an industry-wide problem.

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