IN CONVERSATION WITH **NIGEL HUGHES**

Scientific Director, Janssen Pharma R&D

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A former UK NHS healthcare & voluntary sector professional working in the pharmaceutical and diagnostics industry with a 360° experience in the blood borne virus market based on a professional heritage in the viral hepatitis, liver disease & HIV fields spanning thirty years, inclusive of ten years in the voluntary sector and being a Dept. of Health advisor. Formerly working for Roche, Gilead, Novartis, and now Janssen, he has focused latterly on strategic marketing for new diagnostic solutions for personalized medicine via bio-informatic tools, health information technologies and biomarkers in infectious or chronic diseases, with a particular emphasis on real world data. He now works on the IMI European Medical Information Framework (EMIF) as the Industry Platform Co-Coordinator, developing digital cohorts, and integration of real world evidence into Quantitative Sciences programs. Married with two adult siblings, he lives in Belgium, in the countryside with his wife and ten cats.

How important is stakeholder collaboration in RWE/ RWD, and what are the key opportunities?

Working with real world data to generate real world evidence is impossible without collaboration. When interacting with RWD created in and by the clinic, patient, physician, or a myriad of others, context is critical, as is a dialogue with such stakeholders to agree to such a collaboration. It is important to understand the RWD available, what question it can answer (and not), and what are the rules of engagement to interact with RWD (assuming this is not contract data, such as CPRD or OPTIMUM for instance). Also critical is the engagement of stakeholders who would be evaluating the RWE generated, such as regulators, payers and HTA bodies, patient groups/NGOs, and national/international professional bodies, who would receive this 'new currency' in the hierarchy of evidence. As such stimulating a dialogue between RWD generators, RWD users and RWE recipients is pivotal to establishing a common approach, especially with such heterogeneity of data and evidence, its interpretation and application. Working with RWD requires a continuing dialogue between all involved to ensure the optimum evidence generation.

What are the key obstacles within RWE/RWD and how can these be overcome?

There are a multiple number of obstacles, but let's focus on a few key ones. First, RWD is not necessarily created by those who want to generate RWE, such as the Industry, and it is an imperative that a quid pro quo, a mutually convergent rationale for enabling access or interaction to RWD is part of the collaboration engagement. Many data sources will not provide direct access or sharing with their RWD, and approaches such as federation, or distributed querying, where the query is circulated, not the data itself, are becoming more commonplace as a consequence. Of course, especially with the enforcement of the GDPR, privacy and security are in focus, though this was all the same issue prior. There is nothing in the interpretation of GDPR that should inhibit the utilisation of RWD, if it is adhered to appropriately, despite all the current hysteria. Lastly, the challenge of interoperability of systems, such as EHRs, and the convergence of different, heterogenous data has led to the development of approaches such as common data models, for instance OMOP, or SENTINEL, which will facilitate real world research on a global basis.