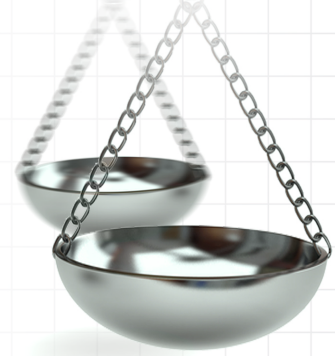
Conference Report



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How can real-world evidence be used in practice to demonstrate drug value and improve patient care?

Evidence Europe 2017, Victoria Park Plaza, London, UK, 22–23 February 2017

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The Evidence Europe 2017 meeting took place in February 2017 in London (UK). This year's event focused on the use of real-world evidence in practice, both before and after a product has been approved. Speakers and attendees represented a broad spread of stakeholders, including national bodies, industry and academia. The event involved expert presentations, lively panel discussions and networking opportunities, allowing everyone involved to improve their knowledge of how real-world evidence is being used and potential opportunities for the future.

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Evidence Europe is a 2-day event, which this year took place in London (UK) [1]. This year's focus was on real-world evidence (RWE), and particularly how it can be used in practice to understand and demonstrate drug value and improve patient care.

RWE (or rather, real-world data), has been defined by the International Society for Pharmacoeconomics and Outcomes Research Task Force on Real-World Data as "data used for decision-making that are not collected in conventional randomized controlled trials (RCTs)" [2]. In the 10 years since the publication of that report, RWE has garnered increasing interest as an important source of patient-relevant information. However, RWE is not always considered to be as high quality as the data gathered in RCTs, as discussed in White's recent Editorial [3].

In a series of presentations and panel discussions, the speakers at Evidence Europe discussed aspects of using RWE to help understand the value of a drug at various stages of its development and use. M Russell (Truven Health Analytics) spoke about his experience of using multicriteria decision analytic modeling when examining the value of a biosimilar compared with the licensed drug. In addition, SW Andersson (Independent Consultant) spoke about how RWE could be used throughout the drug development to add value and also reduce the time taken for a drug to become available (improving timely access to patients and also reducing costs). In particular, adaptive licensing was discussed, whereby the approval of a medicine occurs in a staggered way – initial approval in a restricted patient population, followed by further evidence gathering, and potentially extending the license to a broader population. Of course, an important part of this process is, therefore, to gather RWE following the initial approval. The aim of this process is ultimately to allow patients access to medicines more quickly.

On a related theme, an area discussed in several presentations at Evidence Europe was that of rare diseases. Of course, processes, such as, adaptive licensing pathways are particularly relevant to treatments for rare dis-

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eases, where RCTs can be hard to conduct due to small patient numbers. Also discussed, by Dr R Jandhyala (RWE Genesys), was a study on rare disease registries conducted by RWE Genesys. Registries are a way of gathering information on how interventions are performing in real patients. Registries can be privately or publicly funded – global, national or regional – and be disease- or product-specific. Many hundreds of registries exist across a broad range of disease areas, as documented in a recent Orphanet report [4]. In this particular study, Dr Jandhyala discussed how their study had assessed the perceived 'success' of various registries, based on publication count. It was found that the most publications resulted from privately funded, product-specific registries [5].

A further interesting area of discussion was how technology can support efforts to gather RWE. B Byrom (ICON) discussed the use of digital technologies in outcomes research, including the use of apps in clinical trials, either on a device provided by the study investigators or on a patient's own device (so called 'bring your own device' studies). Of course, there are many health-related apps and wearables already in existence, so an interesting development will be whether data gathered in this way can reach a high enough quality to be put to use [6]. Byrom also highlighted the idea of 'shareables' – health stations available for use by the general public (i.e., in a doctors surgery or pharmacy) for gathering information, such as, blood pressure and weight. Technology such as this allows good quality, objective data to be obtained without the need to distribute hardware or for patients to own a suitable device.

In a subsequent presentation, M Kane (NorthWest EHealth Ltd) discussed the use of electronic health records and other RWE to support the clinical trial process. In particular, she discussed her organization's work on the Salford Lung Studies [7], looking at a new treatment for chronic obstructive pulmonary disease. This study involved a novel approach to clinical trial design that utilized electronic health record data from patients in an everyday clinical practice setting, via 80 general practices and 130 pharmacies in Salford and the surrounding Greater Manchester area. This approach allowed the inclusion of patients who might normally be excluded from RCTs, such as, those being treated for other conditions alongside chronic obstructive pulmonary disease – thereby potentially more accurately reflecting how a treatment might perform in the real world.

Overall, this conference has highlighted the important and growing role of RWE throughout the life cycle of a drug. Going forward, it will be important to ensure the quality of the evidence, so all stakeholders can be confident in the value of the information being generated, and that best practice is followed to ensure security of patient data.

Financial & competing interests disclosure

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