Real-world Evidence: An upcoming trend

The focus of our healthcare industry has shifted from being solely dependent on medical interventions to encompassing additional factors that could continually help deliver quality patient care. These factors include genomics, behavioural and environmental influences, claims and billing data, patient data from registries and medical apps, etc., that comprises the real-world data (RWD). Analyses of these massive pools of RWD provides real-world evidence (RWE) of hundreds of millions of patients provides us with interesting insights, helps by preparing us for study shortcomings and lets us gain better perspective of various therapeutic areas.

Physicians, regulatory bodies, pharmaceutical and medical device manufacturers rely on RWD to guide their decision-making. FDA's efforts in cross-linking RWD and creating a unified structure to monitor safety of medical products, or attempts by the National Institutes of Health (NIH) Common Fund to incorporate RWD into robust, easily accessible databases; are just ways to increase easy data accessibility allowing researchers to identify treatment limitations, target special patient populations and aid their decision-making[1].

RWE can better capture treatments in real-life settings, effectively characterize patients and help us better understand new treatment methodology where randomization may seem impossible or when randomized controlled trials (RCTs) cannot provide the required data.

Countries like Germany, France and the Nordics have successfully generated nation-wide databases, but they lag behind owing to the uneven quality and narrow spectrum of RWD sources. Lack of complete access to RWD and a dearth of standardized methods to analyse RWE undercuts its broader usability. RWD also needs to confirm elimination of biases, higher data quality and wide-range distribution[2]. A bigger challenge remains in convincing that the benefits of RWD can outweigh the risks of sharing such sensitive patient information. However, these barriers can be overcome by concerted efforts of stakeholders across the entire healthcare value chain[3].

As RWE becomes increasingly accepted, we can expect it to become integral across a product's lifecycle. Additionally, with improved methodology and greater clarity, RWE analysis could help support therapeutic efficacy, generate tailor-made treatment solutions for special patient cohorts, and fulfil post-marketing requirements.

We at CBCC, aim to shape an integrated, adaptive ecosystem by strengthening academic collaborations that would give us access to novel data sources. Since its inception in 1984, we have been continually expanding to become the largest freestanding, privately held cancer research centre in the nation, and have been the first centre in the globe for Electronic Medical Records (EMR) by Varian Medical System. They also joined forces with Dignity Health, and since 1996, became associated with the UCLA community research network to provide cancer care to the community. CBCC envisioned the digitalization of healthcare systems and collaborated with Mendel AI in 2017 to convert their vast EMR data into research-ready analysable data. We have on-board, various subject matter experts who are adept at developing RWE strategies, successfully lead the execution of a RWE study, and effectively communicate result outputs. CBCC has built platforms to analyze robust data in a rapid, low-cost fashion leading to decreased turnaround time, increased feasibility, and credible study outcomes.

References

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3. Scott E.,"Real-world evidence-what is it and what can it tell us?" NEJM, 2016