EXPLORING RWE RWD-BACKED REGULATORY DECISIONS IN IMMUNO-ONCOLOGY

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Background Real-world data (RWD) and real-world evidence (RWE) has long been used in drug development programs: to help generate hypotheses and assess the feasibility of clinical trials, or for post-marketing surveillance purposes. There is a wealth of RWD sources; data can be gathered from medical records, registries and wearables, among others. This data is then analysed to obtain RWE. Today, RWD/RWE is also increasingly being used to support regulatory decisions, especially during market authorisation approval for new drugs or new indications. A number of immuno-oncology drug products have owed their approval to the use of RWD/RWE.

Methods The objective of this experiment is to identify and trace the regulatory history of selected immuno-oncology products to understand how RWD/RWE has been applied in their drug development programs to market, and the perspective of the regulators at the time of review. Using Cedience, we identify the RWD/RWE-generating trials used in an immuno-oncology drug’s submission. Cedience is a next-generation regulatory intelligence platform that allows a user to answer regulatory precedent questions, monitor topics of interest, and analyse past development strategies by using a database of documents compiled from various regulatory agencies. We have previously used Cedience to identify drug products associated with RWD/RWE and reconstruct a timeline of said drug products by collecting correspondence letters from the FDA.

Results Using Cedence, case studies were built that show the timeline of a drug’s regulatory history; a picture of the drug’s journey through development. This timeline focuses on RWD/RWE-generating trials used to examine the immuno-oncology drug, as well as the evidence available prior to said trials. In the context of these regulatory submissions, RWD/RWE functions to support randomised clinical trials by providing a second source of data that is more generalisable to the wider population.

Conclusions From this data, an analysis of how RWD/RWE was used in the real world could be seen: what percentage of FDA approvals are RWD/RWE-backed, the clinical evidence that can be generated from RWD/RWE, and what type of study designs are appropriate for the generation of RWD/RWE. The regulator’s perspective could be seen as well: how they evaluate RWD/RWE, and whether any issues or concerns are raised.