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PAID FOR CONTENT: Toward A Real World Intelligence™ View Of The Market

by

Technology is advancing such that, soon, the systems used for care delivery and clinical research will converge around a common infrastructure that relies heavily on Electronic Health Records. In this sponsored content, Jim Carroll, vice-president of Real World Evidence at ICON, shares his view.

Clinical research and clinical practice will come together, providing a more complete patient treatment experience while creating a "Learning Health System." This system will be capable of supporting both Real World Evidence (RWE)-based patient care and value strategy development to the benefit of patients, providers and payers.

With Electronic Health Records (EHRs) forming such a strong foundation for generating RWE, we foresee acceleration towards a patient-centric, data-driven, and value-based approach to meet the needs of various stakeholders. Manufacturers will have the ability to proactively collect and analyze Real World Data (RWD) to provide evidence to regulators, providers, payers and patients. They will be able to answer questions such as:

- How will patients respond to a product when it enters the real world?
- How does its value proposition hold up within the competitive set and current standards of care?
- Which subset of patients is likely to see the greatest benefit?

It is no wonder that the demand for RWD and the evidence that it can produce is at the forefront of healthcare discussions.

The RWD Landscape – EHRs And Post-Marketing Research

RWD is on the radar of many regulatory and policy shaping bodies. The US Food and Drug

Administration (FDA) has indicated that use of RWD for agency decision-making is a "top programmatic priority." In the EU, where as early as 2008 the European Commission set a goal of cross-border interoperability of EHRs, their use is expanding rapidly. The EUROREC Institute, a not-for-profit organization, is developing certification, testing, and assessment processes to promote the use of EHRs. The EHR4CR project, funded by the Innovative Medicines Initiative (IMI) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), was specifically undertaken to provide solutions for using EHR data in clinical research.

Today, 98% of all *hospitals* and 83% of all office-based *physicians* in the US have adopted EHRs, creating a vast stream of RWD that is improving awareness of patient outcomes for providers and providing a trove of information for clinical research purposes. RWD is being used effectively in observational studies and pragmatic clinical trials (PCT).

The demand for post-marketing studies to report on safety, efficacy, and cost-effectiveness continues to grow, and these undertakings can be costly when conducted traditionally. Observational studies, which often incur high costs in site contracting and honoraria, patient enrollment and tracking, may be conducted more cost effectively through the use of EHR systems and datasets. EHR data can support retrospective and prospective studies, case-control studies, and cross-sectional studies by providing large datasets that are easy and inexpensive to maintain for large populations over a long period of time.

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Pragmatic clinical trials (PCTs) can also benefit from the RWD collected in EHR systems. Traditionally, identifying patients to be part of a PCT is labor intensive and left to the physician's initiative, and enrollment is dependent upon patients presenting themselves for a visit. This hit-or-miss methodology has always presented a sizeable challenge to enrollment. Instead, an EHR system can be used to identify patients, monitor them, and gather information on outcomes. Trial criteria may be built into the EHR system, which is then programmed to alert physicians to suitable patients within their practices. These prospective participants, if they are interested, can then enroll and consent into the trial. As the trial progresses, treatment details and outcomes are captured in the EHR for study and analysis.

A recent analysis of clinicaltrials.gov showed that more than 220 currently open trials are tagged as pragmatic. As the popularity of PCTs grows, there is great opportunity to use EHRs as their

information backbone. Nevertheless, use of EHRs as RWD sources is not without challenges. Currently, data from multiple systems cannot be readily combined to create a larger dataset, although standards are being developed for EHR systems that will alleviate this hurdle. To ensure that the best data source is chosen for the outcome measure sought, researchers must be attuned to the specificity of data and the potential for missing data.

Putting RWE To Work – Driving The Value Story

Ultimately, manufacturers will be able to combine data sources to create a full Real World Intelligence™ view of the market and product landscape. This evidence can then be applied to improving their decision making, supporting regulatory submissions, informing a product's value story, and expanding patient access.

The FDA has recently released specific draft guidance to address the use of RWE to support regulatory decision making for medical devices. The agency stresses that RWD should be collected and analyzed in such a way that limits bias and suggests a number of requirements that are paramount to ensuring that data are presented in a standardized, significant way. Manufacturers will need to follow this and any future guidance to leverage their findings for optimal review, as well as to increase value perceptions of payers and patients alike.

Along with this RWE, product value stories are developed to communicate effectively to payers on what sets a product apart from the competition in the marketplace, as well as what costs the product can offset based on outcomes. By communicating positive findings of RWE-supported, post-marketing research to payers, manufacturers can boost perceptions of the product's value and seek improved access and reimbursement. On the flip side, if unanticipated outcomes are discovered, manufacturers can proactively mitigate risk and refine research investment decisions. By taking the time to identify, at the outset, what RWE will best support the desired patient and economic outcomes, manufacturers can provide a broader baseline for a product's value story.

By using cost-effective RWD sources, manufacturers have the opportunity to monitor RWD on an ongoing basis and present evidence quickly when regulatory mandates require post-marketing research support after a product has been approved. Manufacturers can identify how to quantify the value of the product's differentiation and support it with evidence that demonstrates the product's clinical and economic benefits to payers and patients. Continual dissemination of RWE that shows a product is providing these benefits to patients and payers may be, in the future, the difference between a successful product and a stagnant one. In treatment categories that are saturated with many products, a given product can be set apart from the competition based on the long-term study of outcomes powered by cost-effective, EHR data collection and analysis.

Conclusion

The vast knowledge that can be obtained by studying and analyzing RWD from EHRs and other

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available systems will begin to shape the future of healthcare, improving patient outcomes and economic value. By staying ahead of the curve in providing RWE to support a product's value story, manufacturers have an opportunity to increase the value perception of a product. Progressive companies are already discovering that tapping EHR data for observational studies and pragmatic clinical trials is efficient, cost-effective, and statistically sound. Evidence generated by RWD sources is set to provide a competitive edge in proving and maintaining a product's value to regulators, providers, payers, and patients.

Positive RWE-supported, post-marketing research can boost perceptions of the product's value.

The world is changing, and payers are becoming more assertive in defining requirements for reimbursement based on RWE, just as regulators are becoming more proactive in seeking RWE to support a product's safety and efficacy. Manufacturers who move in lock step with this shift by determining the evidence that will best support greater access and reimbursement will lead the way forward.

Jim Carroll has over 25 years of industry experience including leadership roles in the application of Real World Evidence (RWE) across the biopharmaceutical product lifecycle. At ICON plc, he is leading the development of an integrated RWE Center of Excellence, to deliver scientifically valid evidence and insights that drive global and local value demonstration and support more informed decision-making. He can be reached at james.carroll@iconplc.com.