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"A GAME CHANGER FOR PHARMA"

Expanding the RWD Horizon

10-MIN SUMMARY

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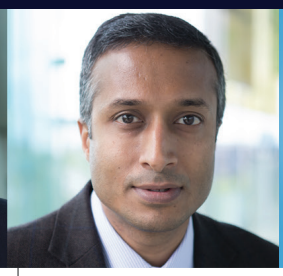

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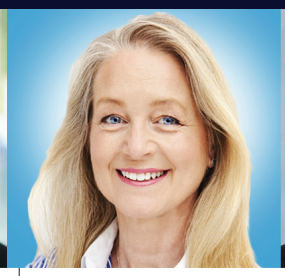

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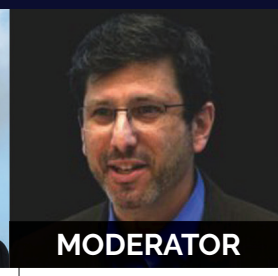

CRAIG LIPSET
MODERATOR
Advisor and Founder, Clinical Innovation Partners; Former Head of Clinical Innovation, Pfizer

Real-world data (RWD) is defined as the information captured at the bedside or in clinical practice. Real-world evidence (RWE) is generated by applying technology and statistical methods to RWD, which provides meaningful insights for different stakeholders.

The combination of RWD and conventional or advanced analytics offers great promise for informing the production of safe and effective treatments and for accelerating the delivery of clinical trials. RWD can also support access to personalization of treatments, by identifying subgroups of patients that are responding well and with limited side effects. Combining patient-level data, generated through an application or device, with RWD, provides a robust way to build models that predict outcomes that are important for healthcare professionals (HCPs) and patients.

However, to do this successfully, new competencies in-house are required to generate new evidence. Moreover, there are challenges in rolling out large platforms using advanced analytics in an environment that is traditionally siloed.

> *"Keep the data and platform centrally but have hubs in different parts of the business that can interrogate the data to answer their specific questions."*
>
> - Bernard Hamelin

Currently, it is acknowledged that there is unrealized potential with the use of RWD. The leap from RWD to RWE requires centralization of data and analytics platforms within the organization, bridging R&D through commercial, and even corporate, functions, to look across the whole drug lifecycle. Data experts must have a seat at the strategic table. The organizational structure should enable dedicated teams to focus

on the conversion of RWD into RWE. Hubs in different parts of the business should be able to interrogate the centralized data to answer their specific questions. This democratizes access to information, while fully leveraging limited talent and resources.

> *"We have to apply technological advancements and statistical methods to play with RWD and convert them to meaningful insights that could be useful to different stakeholders."*
>
> **- Ravinder Dhawan**

To achieve success with this model, there must be a culture shift within the organization, too. Pharma should invest in people with more flexible and creative mindsets who can create feedback loops. Companies need to be willing to undertake a "team sport" metamorphosis and break down institutional boundaries. If teams are brought along in the process to witness the healthcare benefits that can be achieved, any initial inertia can be overcome. They also have to accept that they need to take some risks. Company employees are both producers and consumers of data, irrespective of their job titles. They need to find ways to connect the data and use them.

Existing data and tools can be used to answer new questions in the product life cycle. While RWD has been used primarily for reimbursement and dossier submissions; more recently, it has been applied to patient journeys to understand feedback loops and inform trial designs and dossiers for optimized commercialization.

Evidence has to be generated throughout the life cycle of the product to address various needs at the different phases of the drug development process. From the outset, evidence is generated so that the team can begin assessing the cost and burden of disease. This allows predictive modeling, from an economic standpoint, to see where the product will stand in terms of patient access and reimbursement once it reaches the market. When it is on the market, RWE is utilized to strengthen its value proposition and demonstrate to stakeholders how the drug performs in the real world. HTAs, payers, HCPs, and patients, as well as the organization's clinical development and commercial teams, all want up-to-date information.

> *"Companies need to participate in a team sport metamorphosis. There are institutional boundaries but, if you get it right, you can overcome the initial inertia."*
>
> **- Terri Bresenham**

RWD can add a lot more meaning to the target profile of the product. Sometimes, the data needed to get approval may not be sufficient to get access, because either the standard of care has changed, or further evidence is required. Therefore, pharma needs to find ways to incorporate RWD in parallel to the discovery and development of new medicines. The use of synthetic control arms, for example, can reduce the sample population and speed trial time. Better methodologies are needed to assess comparative effectiveness with treatments that are already on the market, and lots of tools are

available to help achieve this vision by leveraging the right data.

With the right amount of data, which represents all the nuances that happen in the delivery process, all the information about a therapeutic treatment can be coupled with the rest of the clinical picture to drive better decisions and eventually lead to better patient outcomes.

Use of this data is still limited by guidance from the FDA and EMA, but the number of cases where they can be applied will accelerate rapidly once new guidance is issued later this year. The regulators are receptive to innovation.

It is vital to build trust and confidence among stakeholders in the RWD that are being used to generate evidence. Alongside the organizational changes, data must be made accessible and usable, and this takes a lot of effort, and trial and error, to perfect. Challenges in terms of the quality and completeness of the data still remain. There can be disparity and bias across data collectors and aggregators, unstructured data, and a lack of standardization, in terms of the algorithms applied. In addition, research quality data can be complicated to find. While pharma is building its own data repositories, it must also look to work with external sources and federated data, wherein the data remain in the hospital and the tools are taken there to run the analytics. Technological and analytics advances, besides the use of machine learning and natural language processing with unstructured data, are improving the situation, but there is still a long way to go.

> *"We have re-purposed existing data and tools to answer new questions in the product life-cycle."*
>
> - Tifani McCann

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