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Julie Cahill, MD
VP, Consulting and Medical Director Services

Fostering Data Generation to Build the Value Story

An opportunity for Medical Affairs to move the needle

Introduction

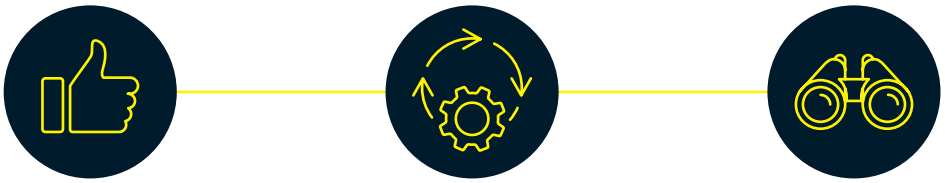
New drugs must undergo rigorous assessments, including extensive company-sponsored clinical trials, when seeking approval. However, even with comprehensive datasets supporting regulatory application, gaps in information still exist and may adversely impact clinical and reimbursement decisions. Common gaps include:

- Patients excluded from clinical trials
- Subgroups with limited representation in clinical trials
- Details about the natural history of the disease
- Endpoints not included in clinical trials
- Differences in practice in the real-world setting
- Comparison to competitors not included in the control arm(s)

Authored by Zipher Medical Affairs Co., LLC now part of Lumanity.

The role of Medical Affairs

Medical Affairs fosters data generation to help fill these gaps, thereby increasing the scientific body of understanding and expanding the available efficacy and safety data. In addition to supporting the launch of a new drug, data generation is also a vital component in the lifecycle of a drug. Data generation beyond registrational trials can:



Complement clinical development

Adapt to changes in the treatment landscape

Seek new signals and explore potential opportunities

Altogether, these pieces help build the value story of the drug. The stronger the value story, the more potential there is to impact:

- Clinical guideline updates
- Label changes
- Reimbursement criteria
- Physician / patient treatment decisions

Data sources

Data can be gathered from multiple sources depending on the gap being addressed and the required information.

When choosing a source, giving consideration to potential limitations of the data and biases is necessary. Opportunities for data generation led by Medical Affairs include:

- Post hoc analyses
- Phase IV trials
- Investigator-sponsored studies (ISS)
- Collaborative programs
- Health economics & outcomes research (HEOR)
- Real-world evidence (RWE)

Interest in real-world evidence has been increasing, given its more accurate representation of clinical practice and its quicker availability compared to traditional clinical trials.

In addition, certain questions, such as the comparison of two novel competitors, can be addressed in a real-world setting, while pharmaceutical companies may not be willing to risk an evaluation in a clinical trial. Real-world data can be gathered from a variety of sources:

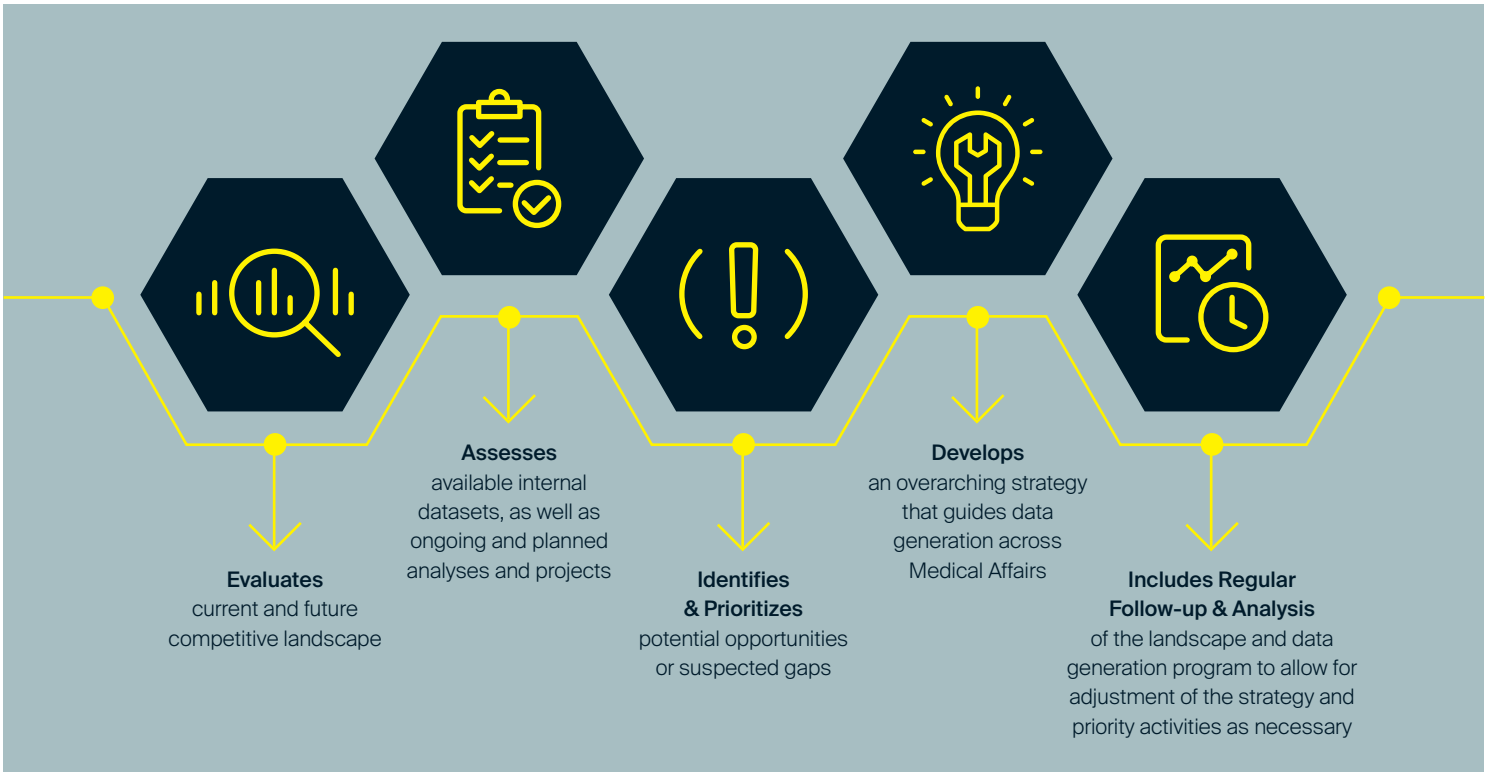
- Prospective registries
- Claims data
- Chart reviews
- Case studies
- Observational studies
- Patient surveys

Similar to the considerations given to other data sources, these datasets have limitations and biases as a result of the data points collected, the manner in which the data were gathered, the method for how the data were recorded, and the timeframe in which the data were collected. Choosing the right data source can be a complex decision-making process, given the necessity of balancing accurate information and the need for quick responses to questions that may affect use. As a result, a strategic plan that directs these choices is imperative.

Developing a data generation program

To make an impact and move the needle, Medical Affairs teams need an organized and unified data generation program that coordinates the efforts of the multiple functions involved in data generation activities. The program must also align with the other pillars of a pharmaceutical organization, Research & Development and Commercial.

Figure 1
A solid data generation program



Source: Lumanity analysis

The key to a data generation program is starting with a thorough situational analysis on which to build the strategy. This involves gaining insights from advisory boards, engagements, and medical inquiries, gathering competitive intelligence to evaluate the landscape, and conducting workshops to assess internal datasets and brainstorm data gaps. When developing the strategy, additional considerations include the benefits and risks of filling the identified gaps, the feasibility and timelines for completing any analysis or study, any additional datasets or resources needed, including budget, and any country-/region-specific requirements.

Preparation and assessment need to start at least a year prior to launch as even analyses of available datasets can take at least six months to complete and publish.

With a well-planned, comprehensive data generation program, Medical Affairs can fill key clinical gaps, demonstrate the value of a drug, and assist in optimizing medical and reimbursement decisions.

Medical Affairs can translate data into action, make an impact, and move the needle.

Lumanity applies incisive thinking and decisive action to cut through complex situations and deliver transformative outcomes to accelerate and optimize access to medical advances. With deep experience in medical, commercial, and regulatory affairs, Lumanity transforms data and information into real-world insights and evidence that powers successful commercialization and empowers patients, providers, payers, and regulators to take timely and decisive action.

Contact us to learn more about how Lumanity can support your unique challenge.

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