ELEVATE

Using Medical Insights to Improve Medication Access

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ABSTRACT:

Medical Affairs (MA) can help optimize access strategy across a portfolio of products through generation and analysis of crucial medical insights on therapeutic area dynamics, competitor data, and value proposition to payers. With intensified public pressure to reduce drug spending, the trend of using MA to communicate value-based messages related to medical insights generated from stakeholders will continue. This article is an opportunity to discuss how MA leaders are equipped with capabilities to improve medication access through medical insights utilization. Some examples of medical insights to improve medication access are: identifying areas to generate Real-World Evidence for differentiating clinical outcomes; adapting clinical-trial design for medication access-relevant endpoints; patient preferences and services that boost medication adherence and compliance; targeted therapeutics to reduce payer budget impact by identifying populations that receive the maximum benefit; and, value-based contracting to mitigate the clinical uncertainty of a high-cost treatment. These are just a few of the many opportunities that exist to utilize insights.

INTRODUCTION:

"Medical Affairs (MA) has the opportunity to leave behind its former status of principally being a support function to forge a new role as a primary strategic pillar of the organization alongside Research and Development, Commercial, and Market Access". [1]

MA, in its dual externally/internally facing role, may help optimize medication access strategy across a portfolio of products through generation and analysis of crucial Medical Insights on therapeutic area dynamics and value proposition to payers.

Therapeutic area dynamics can encompass a spectrum of externally focused activities from foundational disease state education to management goals, therapeutic choices, and outcomes. Medical Insights can help quantify and visualize progression through the health care professional's (HCP's) scientific journey, that maps to a patient's/caregiver's decision journey, from awareness to familiarity, consideration, and finally adoption (Figure 1).[2] Thus, Medical Insights generated about therapeutic area dynamics can help improve medication access.

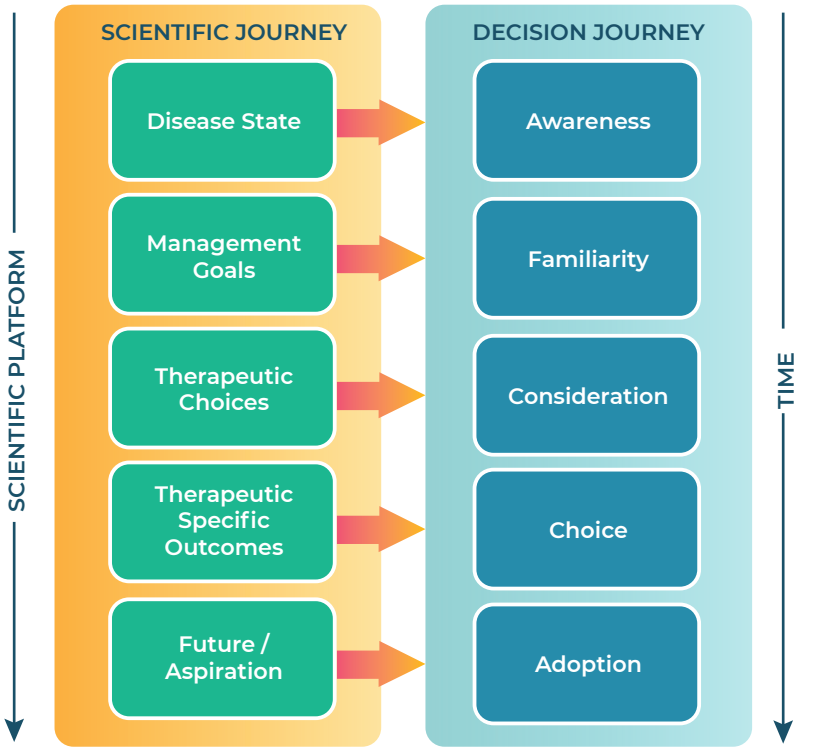

Figure 1. Insights Scientific Position.[2]

In this article we clarify the role Insights play to enhance medication access and provide multiple examples to illustrate the topic. Through Medical Insights activities, MA brings the voice of the HCP back to their respective organizations and integrate that voice into MA strategic planning and decision making.

With intensified public pressure to reduce drug spending, the trend of using MA to communicate value-based messages based on the Medical Insights generated from external experts will increase. We discuss how MA leads the enhanced understanding of treatment landscape through Medical Insights[3] and creates actions in a variety of scenarios resulting in improved access to medications.

Insights that impact medication access can be generated from various MA functions (e.g., Medical Information, Field Medical, Therapeutic Area Disease Experts). We have identified several typical scenarios. Below are illustrative examples:

1. Medical Insights for generating Real-World Evidence for differentiating clinical outcomes: Insights from Real-World Evidence are becoming increasingly more important in getting the right treatment to the right patient at the right time. The recent advances in digital and advanced analytics have enhanced the role of Real-World Evidence (RWE)[4] to measure outcomes and demonstrate the value of interventions.

Example

Background:

In condition X, the efficacy of available treatment options is similar, but adverse event (AE) profile and duration of AEs differs between the drugs, consequently resulting in a different Quality of Life (QoL) for a patient.

Insight:

There was a need to see QoL data across all drugs used in condition X, to identify a drug with the highest value based on combining efficacy, AE profile, cost, and QoL data.

Actions:

To generate QoL data, Medical Affairs initiated a study in which a validated QoL questionnaire was used over a prespecified period of time in patients treated with any of drugs used to treat condition x to generate RWE demonstrating the value of the medication.

Impact:

The results of this RWE study will help inform payors, HCPs, and patients and provide additional evidence in selecting the most appropriate treatment choice.

2 Medical Insights for adapting clinical trial design for "market access" relevant endpoints: Insights generated for many disease states demonstrate how traditional approaches to clinical trial design fall short. Several innovative trial designs have emerged to facilitate accelerated access including real-world data and digital tools usage to improve patients' lives. Innovative trial designs can be broadly categorized in three ways: biomarker-led design, adaptive design, and cohort-led design.[5] However, other approaches to data generation can also be utilized.

Example

Background:

Data on prevalence, symptom burden, patient perceptions, treatment history, and economic implications of condition y are incomplete, and sparse in some geographies. To overcome this limitation, global Health Economics and Outcomes Research (HEOR) team completed a global survey online of 3,500 persons with condition Y. Objectives were to better understand prevalence, symptom burden, patient perceptions, treatment history, and economic implications, and results were discussed at a global Advisory Board with clinical experts.

Insight:

Advisors believe prevalence data yielded in the survey is consistent with current understanding of the disease due to survey's the global remit and large sample size. The impact and burden of condition y based on survey data supports communicating epidemiology, humanistic and economic burden to HCPs, Health Technology Assessment (HTA) bodies, and payors.

Actions:

Based on feedback from the advisors, the most clinically and payor relevant components of the survey are selected for publication(s).

Impact:

Generating evidence regarding the economic and humanistic burden of the disease and communicating the results will provide a foundation for future Phase 3/Phase 4 study endpoints necessary for payor and HTA approvals.

3 Medical insights help identify relevant focus for post hoc analyses aimed at addressing HTA needs: During communication with HTA bodies there is a frequent ask for specific outcome variables that are not included in clinical trials. Insight can also be gained by analyses of previous HTA rulings for drugs within the same therapeutic area.

Example

Background:

Market access is typically determined in drug assessment process by national HTA bodies. The lack of upfront input into early study design for local HTA purposes may result in a limited "value" of studies' results to demonstrate an additional benefit in a given country. To overcome that challenge, MA sought early advice with the national HTA body to discuss the development and design of the Phase 3b study. A national HTA was approached to get confirmation on the appropriate comparator, patient relevant endpoints and the definition of specific sub-populations.

Insight:

The national HTA body provided comprehensive comments and important insight regarding protocol design and execution of the Phase 3b study.

Actions:

The Phase 3b study design and endpoints will be updated to incorporate the feedback of the HTA body.

Impact:

Having the proper sub-populations and endpoints included in the study design will ensure timely and efficient regulatory approval and help avoid the need for additional studies.

4 Patient related Insights may lead to enhancements in patient convenience or patient services that boost adherence and compliance of medication: As pharmaceutical companies strive to be more patient centric, patient-related Insights become crucial. Patient outcomes can be improved through patient Insights, for example, by tailoring of medicines. In addition, the unmet needs of the patients should be recognized and addressed, such as by developing support tools for better medication access and education of patients. These tools include smart phone apps which provide medication reminders to help patients adhere to the medication regimes.[6]

Example

Background:

Hormonal deficiencies in children need prolonged treatment with frequent injections over a long period of time.

Insight:

Poor compliance observed in this patient population can result in permanent developmental problems resulting in both individual and social treatment failures, such as less favorable clinical outcomes, lower quality of life and higher healthcare costs.

Actions:

Advancement in the pen devices have led to development of self-injection pens (also with tracking systems) and needle-free devices.

Impact:

Pen devices with a good tracking system not only increase compliance to treatment but allow effective and objective monitoring of treatment adherence by the physicians. This results in reliability, ease of use, reduction of pain during injection, safety in use and storage, and minimum number of steps before injection preparation. This patient-centric service has served as a boon to patients.

Several other examples highlight the role of the medical insights, such as targeted therapeutics to reduce payer budget impact by identifying target populations that receive the maximum benefit and value-based contracting to mitigate the clinical uncertainty of a high-cost treatment.

Medical Insights collection and analysis will continue to lend value to enhancing patient access and ensuring optimum medical therapy by conveying its importance to clinicians and healthcare payors throughout the clinical development lifecycle of drugs and devices. This will ensure that when reviewing commercial decisions, patient health and well-being is the main focus, thus embracing patient-centric healthcare.[4,5,6] Medical Insights generated by engaging and liaising with a wide range of external stakeholders, including HCPs, patients/caregivers and payors, will help fully address the growing need of increasing medication access across the globe, especially in difficult times such as the pandemic.

CONCLUSION

In this article we showed that Insights generated by MA have wide outreach within a pharmaceutical company, with use of Insights expanding from shaping of strategy and tactics towards new areas of interest such as facilitating medication access. By continued contribution to the acceleration of treatment access through generation of MA Medical Insights from a variety of external sources, MA enhances its "third pillar" role within the pharmaceutical company and demonstrates value as a key driver in activities directly affecting patient outcomes.

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