Optimizing Drug Value and Access Using Implementation Science

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Implementation science (IS) provides solutions to barriers that impede uptake and access to drugs. IS helps to ensure that considerations important to patients and other key stakeholders are prioritized in the drug development process.

By identifying and considering potential barriers to uptake early in the drug development process, research funding can be applied strategically throughout the process to maximize return on investment.

Real-World Example

Identifying Barriers

A company is developing a new oral medication to treat glioblastoma, which works by hindering the growth of tumor-related blood vessels (anti-angiogenesis). During phase 1, a contextual analysis conducted using focus groups with healthcare professionals (HCPs) revealed a barrier: clinicians would be hesitant to prescribe the medication for patients with cognitive impairment because of concerns with adherence.

Developing Solutions

During phase 2, a network of key stakeholders (e.g., patient advocates, HCPs, care partners, payers) was created to identify a solution. They proposed an interactive adherence support tool to improve communication between care partners and HCPs regarding adherence challenges. This tool was refined (e.g., to autogenerate reminders or to include instructional videos) based on insights from HCPs and patients.

Evaluating Outcomes

As part of phase 3 and following product launch, an independent study was performed to evaluate the effectiveness of the adherence tool in a real-world setting. After drug launch (phase 4), the company offered the tool to a sample of early-adopter HCPs. Use of the tool improved HCPs' willingness to prescribe the drug to patients with cognitive impairment and patient adherence.

Scaling Solutions

As a result, the company offered the adherence tool to all HCPs to increase HCP confidence in prescribing the oral medication to patients with cognitive impairment.

PHASES *of* DRUG DEVELOPMENT

PHASE 4

- **Need:** Evaluate the effectiveness of the tool or strategy in a real-world setting. Consider scalability and refinement, integrating into a healthcare system, and adapting to different settings and healthcare systems.
- **How:** Collect and analyze data using pre-post or randomized study designs that assess the effectiveness of the tool or strategy.
- **Benefit:** Can quantify the impact of the tool or strategy on improving key metrics such as willingness to prescribe, willingness to pay, patient satisfaction and access to high-quality and effective therapies for patients and their families.

PHASE 3

- **Need:** Through collaboration with the network built in phase 2, evaluate the tool or strategy to address major barriers.
- **How:** Integrate potential solutions into the phase 3 protocols by embedding implementation outcomes into clinical trials using a hybrid design.
- **Benefit:** By evaluating IS outcomes in phase 3 and following product launch, companies can maximize their ability to gather meaningful and informative data within the planned clinical trials. Companies can then incorporate feedback into further refining their solutions.

PHASE 2

- **Need:** Consideration of different strategies to address the barriers identified in phase 1.
- **How:** Develop a network of key stakeholders (e.g., patients, care partners, patient advocates, HCPs, payers) to support developing and championing the solutions.
- **Benefit:** The feasibility of solutions and the benefit to patients and their families can be determined early in the clinical development process. There is efficiency in developing these strategies now so that they can be integrated into the ongoing clinical trial program. Solutions should be ready going into phase 3.

PHASE 1

- **Need:** Identify potential barriers that may impede uptake and access to the drug.
- **How:** Perform a simplified contextual analysis as part of developing the early value dossier to identify barriers involving patients, clinicians, and payers. Data from secondary or primary sources such as literature reviews, surveys, focus groups, and interviews can be used.
- **Benefit:** Enables early identification of major obstacles and determination about whether these barriers are addressable using a minimal investment of research dollars.

How to use IS now:

- Raise awareness among your teams.
- Educate your workforce.
- Incorporate IS concepts into study protocols from phase 1 to postlaunch and publish findings.

The Consolidated Framework for Implementation Research (CFIR) can help guide or organize the identification of barriers.

FRAME-IS can help teams document or organize any modifications that are made to a strategy or tool.

3 short standardized measures can be used to assess the feasibility, acceptability, and appropriateness of a new drug or solution (e.g., the adherence tool) to increase the impact of a drug.

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