Insight Guide

Implementation Science

The value of starting early

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Executive Summary

In the Insight Guide *Implementation Science: The Art of Intended Consequences,* we explored the important role Implementation Science plays in the development evidence-based practices (EBPs), their uptake into routine healthcare, and how it can provide value to a host of varied stakeholders. In this Insight Guide, we will explore how benefits of use of Implementation Science are maximized by using them early in development.

The inherent link between Implementation Science and the implementation of products and practices into routine healthcare may lead many to believe it is a tool to use only when the full body of evidence is available, such as post-launch when a medicinal product has entered the market. Exploring the benefits of applying Implementation Science principles earlier in the development process, including in both research and clinical studies, shows this assumption is false. Simply put, the assumption is that the development of new products or practices comes first and the use of Implementation Science to understand their implementation comes second. These benefits can be iteratively built throughout the development process prior to real-world deployment to optimize its launch and post-deployment to support its sustained use.

Advantages of beginning early

Optimal application of Implementation Science occurs when a practice or product is in development or pre-deployment. This enables the insights to be built upon as research continues, and to inform the strategy for deployment and its sustainability post-deployment.

A key advantage of deploying aspects of Implementation Science in parallel or as part of development activities is the proactive reduction of risks prior to deployment and increased chances of maximizing successful deployment during implementation and beyond.

The value of the early application of Implementation Science is not realized just for the product or practice owner, but for all stakeholders as it ensures proper deployment preparation which will maximize benefit to patients and those that care for them.

Aspects of Implementation Science

The application of Implementation Science during development can take different forms. For example, it can help with identifying needs and insights as well as developing processes and selecting frameworks to support different activities that may be needed.

Here, we will focus on three aspects: contextual analysis, impact planning, and preparatory action. These aspects are not restricted to just the pre-launch period; similar activities can be conducted post-launch, but moving early gives key stakeholders the opportunity to be optimally ready for deployment by both maximising its benefits (e.g., greater or more successful reach, accurate use, etc.) and minimising unnecessary burdens caused by unpreparedness (e.g., inefficient use of resources to fill a gap). Likewise, these activities may be applied in whole or in part and may not necessarily happen sequentially. For example, a contextual analysis may be used to understand a product or practice that has already been actively implemented and is struggling. A brief description of each aspect, how it can be conducted, and the value it offers, is below.

1. Contextual analysis

Contextual analysis can be used in multiple different ways. First, it can connect what is known or expected from a controlled trial environment to what is important to know or expect in the real-world environment where an intervention is intended to be implemented (e.g., routine healthcare).

For example, this could include understanding context-specific variations in local characteristics that might influence implementation. This could include differences in care provision in different countries or regions, variations in different patient populations, (e.g., those newly diagnosed versus those diagnosed for some time), and variations among providers or differences in practices of general practitioners versus specialists.

In another example, a contextual analysis may also be used in a more targeted way, such as to understand why a care gap exists (e.g., a patient-related factor, a provider/clinician-related factor, a system-level factor or a combination of factors). This information is used to inform the selection of strategies to enhance implementation success and close gaps in the delivery of care.

For example, an intervention may target improvements in a known gap in the delay of diagnoses among patients who require evaluation by a specialist. This could be done by providing a decision support tool to facilitate greater understanding of when a patient should be referred from primary care to a specialist. The contextual analysis would be used to understand the reasons for the gap (e.g., limited patient / clinician awareness, insufficient access to key diagnostic testing, etc.) and to identify implementation strategies to support uptake of the intervention targeted to close the gap.

2. Impact planning

Often run alongside or as part of a clinical trial investigating efficacy and/or safety, an impact planning study reviews how different delivery options may work in the real world. These studies involve identifying stakeholders, pathways (e.g., activities and processes), measurement and analysis approaches (e.g., indicators to measure impact and methods for collecting and analyzing metrics), strategies for identifying and manging risk, and plans for communication (e.g., stakeholders and broader community). This enables sponsors to gather the insights needed to launch with a plan that can improve efficiency and maximize delivery and impact.

3. Preparatory action

If sponsors identify potential barriers and facilitators early, they can package the intervention with evidence-based implementation strategies to minimize or mitigate barriers and facilitate deployment. By preparing the healthcare setting to increase awareness, likelihood of initial and sustained success increases. Proactive measures should be taken before deployment to make these changes so the preparatory actions can have the biggest impact. These insights can also enhance strategy once deployment has begun; for example, by using data or insights from initial deployment wto prepare for subsequent deployments in other settings.

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Things to consider

As outined above, engaging in Implementation Science activities early in the clinical development or deployment process can bring significant benefits to the deployment of new practices. However, there are important things to consider to ensure expectations are aligned with the level of collaboration and rigor needed, as well the required time and resources. By taking the time to align, teams ensure the necessary adaptations are made to maximize the productivity of activities to be as impactful as possible.

Collaboration in this environment ideally involves all future stakeholders, including, patients, physicians, payers, healthcare organizations, etc. Early stakeholder engagement ensures all voices are heard so any choices for changes are not a surprise, are well-received, and beneficial for all.

Activities in this environment also greatly benefit from close communication and collaboration between teams working in clinical development. At a time when the focus is on gaining regulatory approval, the choices that may benefit its real-world implementation may be overlooked or forgotten. But when teams invest effort into the types of pre-launch or pre-deployment activities described above, it is vital that their work and findings are shared and acted upon alongside the ongoing clinical development work. This ensures any beneficial choices can be made in a timely and effective manner, including the potential to gather evidence for those choices if the work is being done as part of or in-parallel to an ongoing trial.

Rigor in Implementation Science comes down to ensuring the use of appropriate frameworks, processes, study designs, and methodological approaches to enable high-quality data to drive insights. Contextual analysis can be hampered by preconceptions of what the barriers and facilitators might be rather than utilizing rigorously collected, high-quality data to identify what they are and use that data to drive insights. Similarly, the strategies deployed as part of preparatory actions ideally should not be driven by "what came before," but by what fits the current information, either from contextual analysis or impact planning activities.

Implementation Science studies should be designed to provide in-stream and ongoing insights that teams can use to meet expectations and make informed decisions over a sustained period. This ensures challenges of time and resources, and the need for immediate actioning are met in the short and long-term.

Making the most of timing

Using time to your advantage, and iteratively building on and refining insights, gives more time to understand and potentially adapt to the environment. Starting Implementation Science activities early in research pipelines enables the best chance at maximising success, value achievement, and optimized outcomes. Stakeholders who do not consider Implementation Science as a pre-deployment tool miss the opportunity to provide insights into the contextual aspects of its use, identify potential barriers, and facilitate future use in subsequent trials and clinical practice.

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Case study

Client Question:

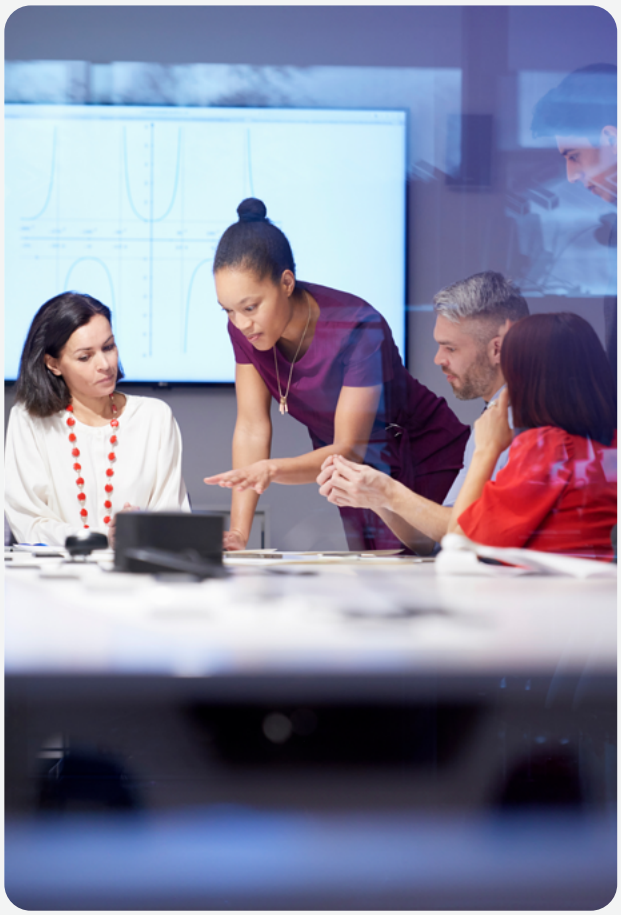
How can I learn about the treatment experience of patients and healthcare providers for our new treatment during our clinical development program?

Challenge

During clinical development, the focus is typically on clinically-focused outcomes that support the demonstration of efficacy and safety, and clinical teams understandably want to minimize the burden to site-staff and patients. The inclusion of implementation-focused questions may be seen as unnecessary distraction, but when done correctly and when working closely with the clinical team, this concern is minimized or mitigated entirely. The clinical team becomes a member of the stakeholder team, understanding the significant value offered by answering the questions that may have an impact on the design of later phases of clinical development and to the preparation for providing treatment to patients in the real world.

IQVIA solution

A mixed qualitative and quantitative approach to gather insights from patients and site-staff during a Phase II trial will provide insights to improve the Phase III design, including considerations for site staff to better support their required activities and the selection of PROs. IQVIA's combined Implementation Science, data solutions, clinical trial, and scientific expertise ensures the design can answer the implementation-focused questions alongside the primary trial activities whilst not interrupting the flow of the clinical trial and without overburdening study site and patient participants.



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