IMPACT REPORT: EXCITE International's Risk-Reduction for Technology Adoption in the U.S.

Insights on the value of the EXCITE International's (EXCITE) Early Technology Review (ETR) from seven randomly selected innovative companies who had undertaken an ETR

We report on seven companies who provided insight into the value and impact of the ETR process. A not-for-profit initiative that represents a global collaboration of key stakeholders, EXCITE helps non-drug medical technology innovators along the post regulation pathway to adoption with greater certainty, at lower cost. The only organization that connects med tech companies directly with multiple large payers in the U.S. and renowned clinical experts early in the development cycle, EXCITE's approach helps to reduce the disturbingly high 55% rejection rate by payers (CMS) of FDA approved non-drug technologies and the long average time of 5.7 years to a decision for technologies fortunate to be approved for coverage. Early insight into stakeholder expectations is expected to improve this reality and make sure that clinical trials to satisfy FDA expectations, costing millions of dollars, include the additional expectations.

Since 2016 EXCITE has deployed its Early Technology Review (ETR) process – which involves virtual meetings with the largest payers in the U.S. and internationally renowned expert clinicians guided by an a-priori Framework of Expectations and developed by expert panels representing the interests of the company, payers, world class clinicians and methodologists – to help companies from around the globe enter the U.S. market. An early evidence review provides the systematic evidentiary basis to inform panel proceedings.

While numerous examples of generic outcomes from completed ETRs have recently been published, we present the results of randomly selected interviews with seven senior executives from companies that have completed an ETR. Access the peer reviewed article here.

A dynamic approach to market adoption

A look at these seven real-world examples provides solid evidence of the value of EXCITE's Early Technology Review— which includes innovators/industry, regulators, payers, health systems, scientists, and end-users.

Three examples of the value-add of this approach in which the Panel contextualizes evidence, which then aligns technology development with real-world expectations and needs are provided below. It is not only evident for premarket evaluation at the proof-of-concept stage, but up to and including trial development. Two companies in particular – both in diagnostics – have

achieved successful U.S. market adoption after completing an ETR and including the insights gathered during their application process.

In the first example, EXCITE's expert panel provided a European diagnostics company with insight into the evidentiary approach and presentation of clinical evidence information to payers and potential business partners. By gaining a better understanding of the payer landscape, as well as the clinical fit in the marketplace, commercial partner and investor targeting was de-risked. As a consequence, the company is confident that the ETR report, and the knowledge gained, were instrumental in securing business partners who are also key clinical implementers and adoption decision-makers.

In the second example, a company with a precision medicine technology gained insight into the evidentiary requirements of clinicians and payers. Crucially, these newly found requirements were beyond those being developed in the company's ongoing pivotal trial. Result? The ETR helped the company position and communicate its evidence package in a meaningful way with providers and was instrumental in securing a successful commercial engagement with a large U.S. health system.

In a third example, EXCITE assisted a Canadian company with a commercialized product for emergency medicine. The high quality of the information from the ETR shed light on R&D cost requirements, and the commercial viability of the product, thus informing critical business decisions.

Early-stage targets

As the above examples show, the EXCITE process is not only for early, seed stage companies, but can also assist across the range of R&D progression.

Of critical benefit here is target market adjustment, which significantly reduces risk while expediting adoption.

Three EXCITE clients have important testimonials in this regard.

In the first example – in which a US company, funded by private placement equity, was conducting pre-clinical research – the ETR identified a change in the clinical endpoint. This resulted in a product strategy that was of greater relevance to both healthcare professionals and payers.

In a second the case, in which a Series A funded Canadian company had achieved FDA breakthrough status, the ETR resulted in a corrected target deployment to an earlier clinical setting. This finding came directly from the advice of clinicians and was supported by the payers on the expert panel. The company has identified this as high value output from the ETR, as it will allow them to focus on the correct evidentiary requirements for optimizing market adoption and commercial success, while also providing information on obtaining a Current Procedural Terminology (CPT) code.

In the third case, a company, also with FDA breakthrough status, was able to discover a clinical endpoint comparator that was more relevant to the expectations of healthcare professionals, and payers. This surgical implant company may now realize considerable time savings for R&D completion, with the right evidence in place for optimal market adoption. Of note, the company has retained an advisor from the expert panel for ongoing clinical application development.

The above-mentioned examples are of heightened relevance given the slow adoption – or outright rejection – of innovative health technologies as detailed in the introduction.

This can be daunting when at the proof-of-concept stage.

In addition to the six cited examples provided above, in the seventh and final example of an EXCITE client engagement, an early-stage company with an innovation to address a chronic disease was able to determine the optimal evidentiary requirements for both clinical and payer stakeholders. The company believes this can support a strong communication plan, which will add considerable value in optimizing market adoption.

A range of benefits

What is evident from these seven examples is that EXCITE has provided value and impact to diverse companies independent of where they fall on the development and funding spectrum: from grant money to angel investors, to series A and B, and to those that have private placement equity, or are FDA approved and commercialized.

This diversity is also reflected in the benefits. Given the breadth and depth of knowledge and experience on the expert panel, client companies have received complex effectiveness analysis – inclusive of intended use, protocol development, and clinical comparators – that's relevant to health professional and payer requirements.

Among the seven company examples cited here, EXCITE's ETR process also aligned company teams, and enhanced confidence in their direction. It enabled innovators to fix or enhance go-to-market development plans, to obtain insight and to align messages with what key opinion leaders (KOLs) and payers value, thus enhancing credibility with potential partners and investors.

With a better understanding of opportunities, barriers, and evolving requirements in target clinical settings, the companies are also able to develop more effective communication plans for successful go-to-market engagement with KOLs and payers.

Ultimately, EXCITE International's ability to provide meaningful engagement with stakeholders has been shown to positively affect medical technology adoption, with the streamlined and risk-mitigating approach having a positive impact for SMEs, many of whom continue to engage with EXCITE following completion of an ETR.

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