EXCITE INTERNATIONAL

An international collaborative focused on fixing unacceptable market adoption problems for Innovative Non-drug Medical Technologies

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The problem to-be-fixed

Due to current assessment pathways, many amazing new innovative non-drug medical technologies face a high risk of rejection, or slow paths to market adoption. In fact, it is estimated that payers/health systems outright reject greater than 50% of regulatory approved medical technologies. This has a negative impact on patients' and health care systems' ability to access these safe and efficacious technologies, and is unacceptable.

An NFP Collaborative formed to determine and implement a "fix" to the problem

In response, a group of influential payers, scientists, health systems, industry and clinical end-users got together and formed the NFP collaborative, EXCITE International to fully investigate this problem and determine how to fix it.

First, identify the cause of the problem and then determine the best approach to a fix

The group set out to develop an approach that would maximize the probability of adoption of innovative non-drug medical technology into world markets. Their review of the situation revealed that the major issue negatively impacting market adoption is related to evidence, specifically the fact that most innovators design their pre-market clinical evidence development program focused on regulatory approval requirements, rather than also meaningfully including the expectations of payers, health systems experts, scientists and clinical end-users in these evidence development plans. It was determined that an approach was needed to help innovators of non-drug medical technologies generate the right evidence to suit the needs of payers and other adoption decision makers.

EXCITE International's approach: influential stakeholder involvement in clinical evidence development

The collaborative worked to set up an approach that facilitates bringing together some of the largest and most influential payers, health system and clinical end-user experts to work with an innovator in structured multi-meeting engagements. These engagements provide insight and perspective on how to best achieve strategic advantage and adoption approval for the innovation in question.

Applying the Approach to Maximize Adoption

"Leveraging an Expert Panel of Influential Stakeholders"

EXCITE International solutions are built upon the foundation of a unique, structured engagement with the company and innovation in question. Within this engagement, an expert panel of payers, clinical end-users, and scientists align clinical Evidence Development plans to the needs and perspectives of these adoption decision makers.

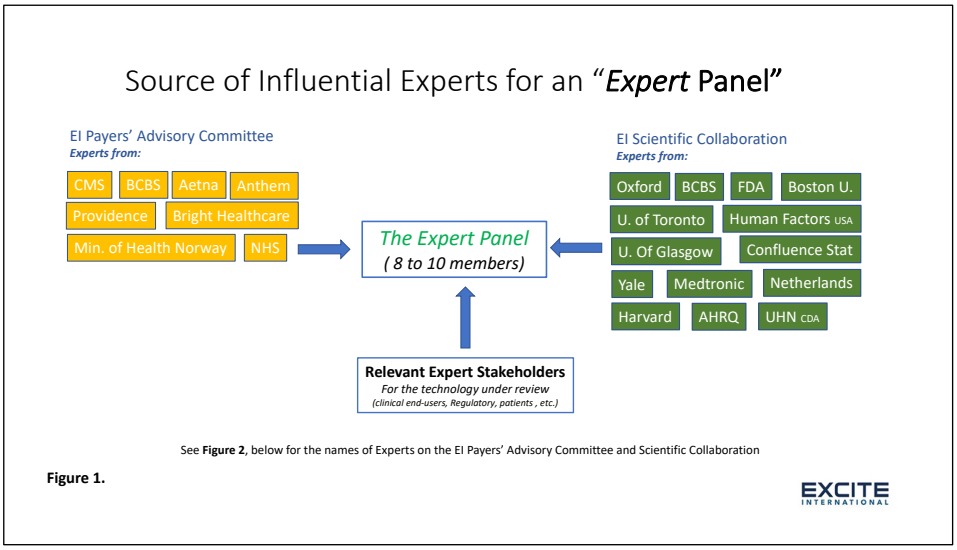

Figure 1.

1) ***Early Technology Review Process (ETR)*** The ETR involves engaging the Innovator of a non-drug medical technology directly with an *expert panel* of adoption decision makers. This is done under EXCITE international's umbrella. Advice is given regarding clinical development plans and strategies focused on optimizing reimbursement and overall adoption for the Innovator's technology. Expert panels for each review are chosen from the EXCITE Payers Advisory Committee (PAC) and Scientific Collaboration (SC), as well as the addition of relevant stakeholders and experts for the technology undergoing the ETR. *Click here for more information on the ETR*.

2) ***Clinical Trial Development and Execution Solution*** This solution involves the design of customized clinical trial protocols with input from international payers, health systems, the scientific community, as well as expert end-users and other relevant key stakeholders. EXCITE International then develops and executes the protocol, which is intended to meet the evidence needs of the key pre- and post- market decision-makers in collaboration with EXCITE's world-class methodological centres and clinical trial network. *Click here for more information on the Clinical Trial and Execution Solution*.

Payers' Advisory Committee & Scientific Collaboration

EI Payers Advisory Committee

USA:

- Robert McDonough Chair (Aetna)
- Naomi Aronson Immediate past chair (BCBS Association)
- Rob Garnett (Anthem)
- Alan Rosenberg (Consultant and recently Anthem)
- Laurel Soot (Providence Health Plan)
- Amin Hakim (Bright Healthcare)
- Ed Pezalla (Consultant and recently Aetna)
- Larry Simon (BCBSLA)
- Tamara Tyrek Jensen (CMS)

Other:

- Nina Pinwill NHS UK
- Stig A. Slørdahl (Ministry of Health Norway)

EI Scientific Collaboration

- Mike Gibson – Chair SC; Prof Medicine Harvard; CEO Baim Institute USA
- Peter McCulloch - Prof. Surgery; Fellow Trinity College Oxford University and John Radcliffe Hospital, Oxford. Head of IDEAL, UK
- Naomi Aronson - Executive Director of Clinical Evaluation, Innovation, and Policy, Blue Cross Blue Shield Assoc. USA
- Rod Taylor –Prof. Population Health Research, University of Glasgow, UK
- Amit Oza – Med Director Cancer Clin Research Unit and Head Medical Oncology/ Hematology PMH, CEO Ozmosis, Prof Medicine, U of T CDA
- Joseph Ross - Center for Outcomes Research and Evaluation, Assoc Prof Medicine, Yale School of Medicine US
- Mike Argentieri, ECRI - Usability/Human Factors USA
- Danica Marinac-Dabic - Director Division of Epidemiology (FDA) USA
- Elise Berliner - Director, Technology Assessment Program (AHRQ) USA
- Maroeska Rovers, Evidence Synthesis RadBoud/MedValue, Netherlands
- Joe Cafazzo, UHN - Director Global e-Health (Usability) Canada
- Fiona Miller - Qualitative/ Patient preference Univ Toronto Canada
- Gheorghe Doros - Professor Biostatistics, Boston University USA
- Jason Connor - President, Confluence Stat USA
- Jeffrey Popma – VP and CMO for Coronary, Renal Denervation & Structural Heart at Medtronic

Figure 2.

If you are interested in gathering more information on an Early Technology Review or a Clinical Trial Development & Execution Solution, contact

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