

For any company looking to penetrate the U.S. market, there are three important hurdles to cross.

1. Regulatory approval - without which it is not possible to sell a technology
2. Convince health professionals to use the technology
3. Get payers to approve funding for the technology

Most companies appropriately initially focus on regulatory approval, which requires a lot of resources, especially if a clinical trial is needed. However, the evidence needed to satisfy regulators will often not meet the expectations of payers or health professionals so that while there is permission to sell the technology, there is no one willing to use or pay for it.

Alternatively, a less-risky and more efficient process would be to align “evidence development plans” so that the expectations of payers and clinical experts are included at the same time as evidence required for regulatory approval.

EXCITE INTERNATIONAL - ALIGNING EXPECTATIONS

EXCITE International's process achieves this efficiency and risk reduction through **early direct engagement** with some of the largest payers and most accomplished clinical experts that allows evidence development to proceed while meeting the expectations of these important stakeholders. This direct high-quality evidence-based engagement is unparalleled in its scope and depth which is why EXCITE is an international leader in this development.

The EXCITE process is based on a collaborative helpful approach that includes the company at every stage. The first hallmark product is an Early Technology Review (ETR) which includes an early evidence review, a framework of expectations agreed to by the company, and the appointment of an expert panel that includes payers and leading clinical experts. The panel reviews the technology and lays out expectations for the company to be aware of. This includes selection of appropriate comparator technologies, target populations, outcome measurements and advice on evaluation including clinical trial design. Advice is provided regarding opportunities and barriers to uptake and ways to benefit or avoid these respectively.

The ETR takes four months to complete and forms the platform for a clinical trial, the protocol for which once again benefits from payers and clinical expert engagement. This approach maximizes the opportunity to meet expectations of regulators, payers and clinical experts. This approach saves time and money and accelerates and de-risks the pathway to market.

EXCITE has developed a high-level international collaboration consisting of experts, methodologists and payers which is at the disposal of companies that engage with it.

PAYERS' ADVISORY COMMITTEE & SCIENTIFIC COLLABORATION

El Payers' Advisory Committee

USA:

- **Robert McDonough** Chair, (Aetna/CVS)
- **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)
- **John Spoors** (NHS, UK)

El Scientific Collaboration

- **Mike Gibson** - Chair; 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** - Global Senior Principal of Real-World Evidence Strategy, CernerEnviza Potomac
- **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

EXCITE's work is transformational and is designed to de-mistify and de-risk the pathway from innovation to patients. We are committed to helping companies succeed in moving impactful technologies to patients and health systems because, in the process, patient outcomes and health system efficiencies will be improved.

To learn more contact

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