Blazing a Trail for Access To Disruptive Technologies

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Two Stories – One Solution
Focused Ultrasound

Benefits for Treating Fibroids
• Alternative to surgery
• Non-invasively destroy fibroid tissue
• MRI used for guidance
• High safety profile
• No hospitalization
• Next day return to normal activity

Benefits for Bone Mets Pain
• No ionizing radiation
• Relief soon after treatment
• Retreatment possible
• High safety profile
• No hospitalization
Focused Ultrasound in the Future

Movement Disorders
Brain Tumors
Neuropathic Pain
Psychiatric Disorders
Epilepsy
Stroke

Breast Cancer
Pancreatic Cancer
Soft Tissue Tumors
Prostate Cancer
Time-to-"Market Acceptance" is Increasing

New technologies increasingly must demonstrate enhanced outcomes and cost effectiveness.

- Efficacy
- Safety
- Outcomes
- Efficacy
- Safety
- Outcomes
- Cost Effectiveness

1980's  1990's  2000's
Understanding stakeholder needs

Proving innovation value requires understanding evidence needs across a multitude of stakeholder groups.

- **Institutions**: Evidence to enable clinical adoption (highest quality and "best" practice of medicine).
- **Health Technology Assessors**: Evidence to support positive appraisal and policy recommendation.
- **Patients**: Evidence to support consumer choice and personal preference.
- **Regulators (FDA/EU/CFDA)**: Evidence for clearance and approval regarding the introduction of new products and services.
- **Distributors**: Evidence to manage risk and product inventory.
- **Specialty Societies**: Evidence to recognize technology as clinically appropriate.
- **Payers**: Evidence for routine and optimal payment.
- **Evidence for pre-market approval and post-market surveillance of clinical safety and efficacy.**
Health Reform is Changing Care Delivery Models, Patient Demographics, and the Value Environment, Increasing Provider Financial Risk

With Providers taking on more risk, medical technology and services innovators need to communicate the value of products in terms of broader evidence-based economic impact, practice level impact, and clinical outcomes.
Goal

Establish **path for success** so patients will have **access** to a breakthrough non-invasive therapy.
Reimbursement Working Group
Strategic Framework

1. Establish Value Proposition
2. Generate Insight
3. Generate Evidence
4. Seed Interest
5. Develop Strategy for Market Access
The Path Ahead
Budget/Financing

• Foundation provides staffing support
• Most costs shared between companies
• Foundation contributing a portion of direct costs for registry
Building Access to Disruptive Technologies in an Evolving Health System

Understand the Ecosystem

Generate Evidence

Demonstrate Value

Bridge Interests

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