WELCOME *To the*

2026 SYMPOSIUM

From Bedside to Back Table:

Navigating the Gauntlet from Concept to Commercialization in Dialysis Access

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Disclosure

While the Echelon Development Group consults for early seed through commercial stage device companies, I have no financial conflicts relative to this generic presentation.

Reality Check

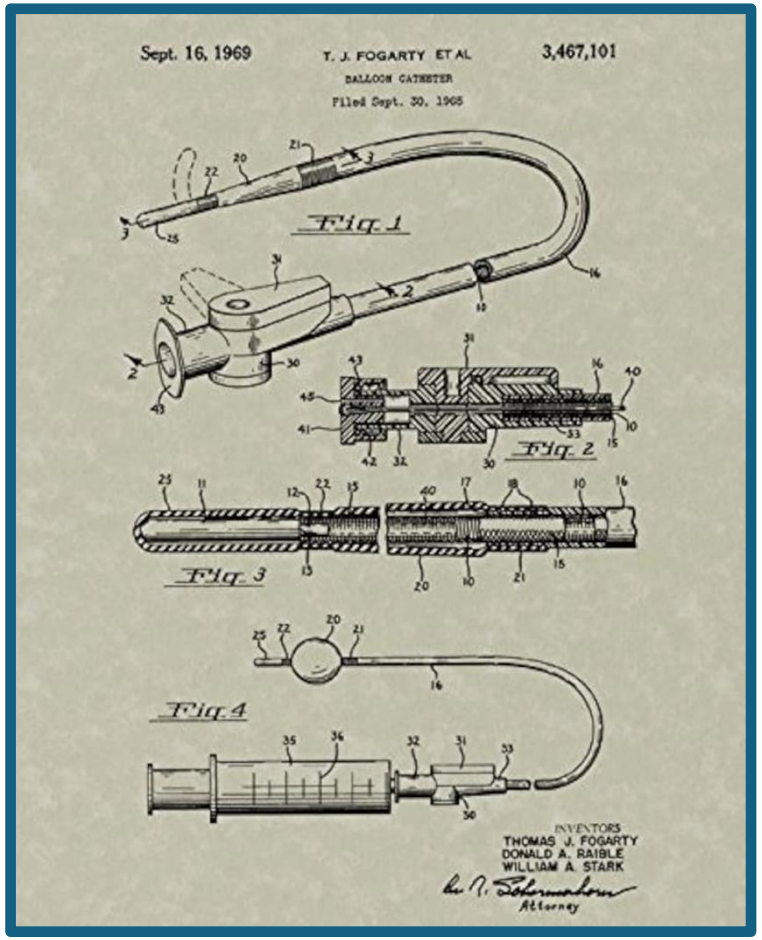
- High unmet need persists in dialysis access
- Most good ideas never become products
- Less than 10% of the over 1000 devices granted Breakthrough Designation by FDA have made it to market successfully!
- The cause of failure is not usually in the idea, but in a poorly crafted development pathway.

Start with the Right Problem

- Begin by precisely defining an unmet clinical need:
  - catheter dependence
  - maturation failure
  - access failure
  - infection
  - reintervention burden
- Avoid technology-first thinking
- Target real-world clinical pain points

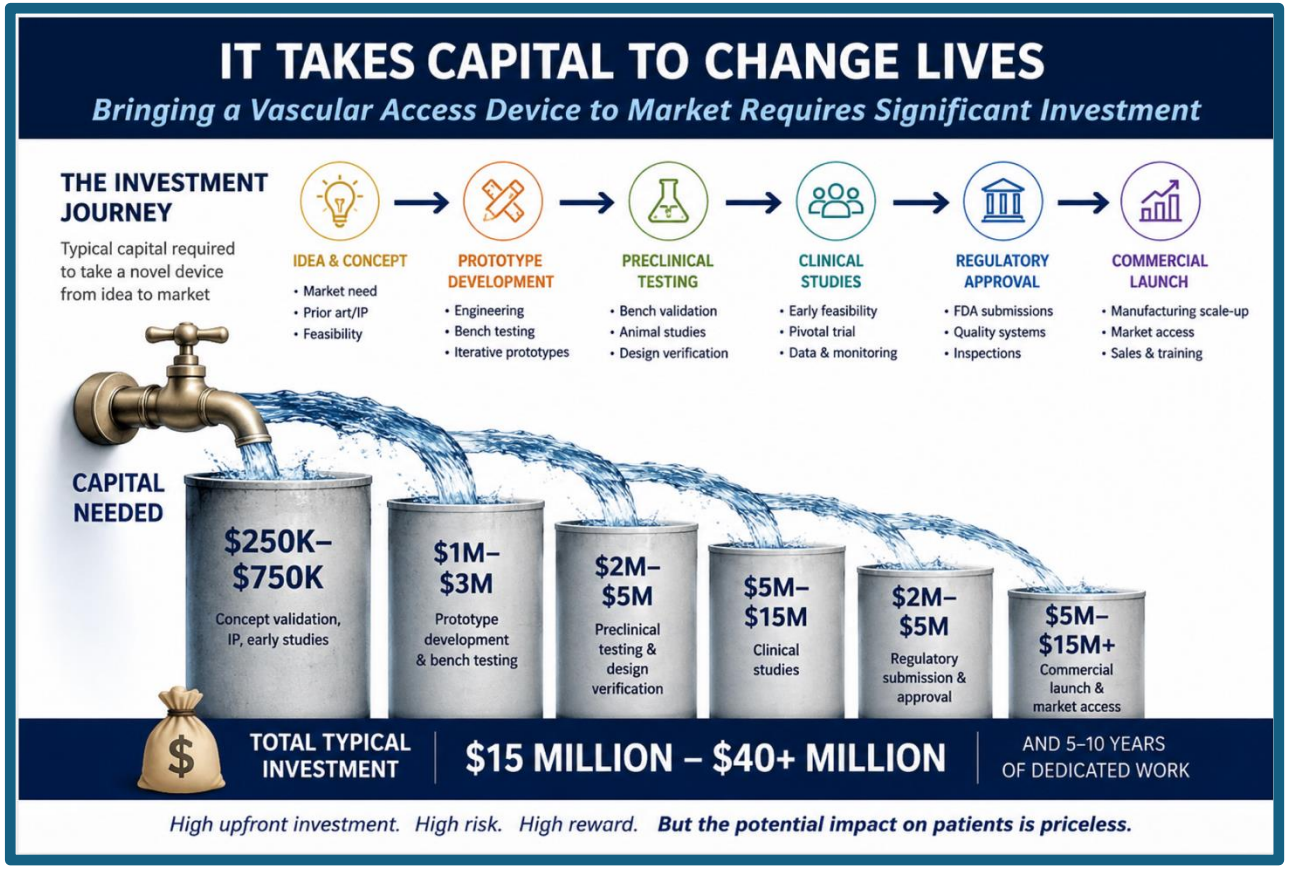
Go From Concept to Prototype

- Sketch → bench model → prototype
- Engineering collaboration is critical
- Expect multiple redesign iterations
- Considerable testing burden for FDA!
  - Bench Testing
  - Preclinical animal testing



Funding the Journey

- Investors demand:
  - Regulatory clarity
  - from FDA
  - Reimbursement potential from CMS
- Adequate capital reduces the failure risk



Defining the Regulatory Pathway is Critical

- Engage FDA early!
- The presubmission process is free
- Defining the regulatory pathway is critical:
  - Class II device = 510(k): “substantial equivalence”
  - Class III = Pre-Market Approval: pivotal study to provide a “reasonable assurance of safety and effectiveness”
  - De Novo: may need a clinical study to help categorize the product as a class II or class III device

Defining the Regulatory Pathway is Critical

- For novel devices an Early Feasibility Study (EFS) in a limited number of subjects can accelerate learnings as to device risks and better inform your pivotal study
- You don’t want to jump into a pivotal phase study until you are sure your device design is near final

FDA is not the obstacle: a sponsor’s misalignment with FDA’s expectations is.

FDA APPROVAL ≠ CMS COVERAGE!

- For device approval or clearance, FDA wants to see:

  "A reasonable assurance of safety & effectiveness"

- For coverage, CMS wants to know if the product is:

  "Reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member"

FDA approves or clears devices. Payors drive adoption!

Design Clinical Trials That Matter

- Design your study for not just for FDA approval & CMS reimbursement, but also to establish clinical relevance
- Does your product make sense with workflows in the HD unit or OP access center?
- Prospectively defining economic and utilization metrics is as critical as choosing the proper regulatory endpoints

The most expensive clinical trial is one you run twice!

Commercialization Is the Final Battlefield

Idea → Prototype → Funding → FDA approval → Clinical Trials → CMS reimbursement → **Commercialization**

Engage an Experienced Consulting Team

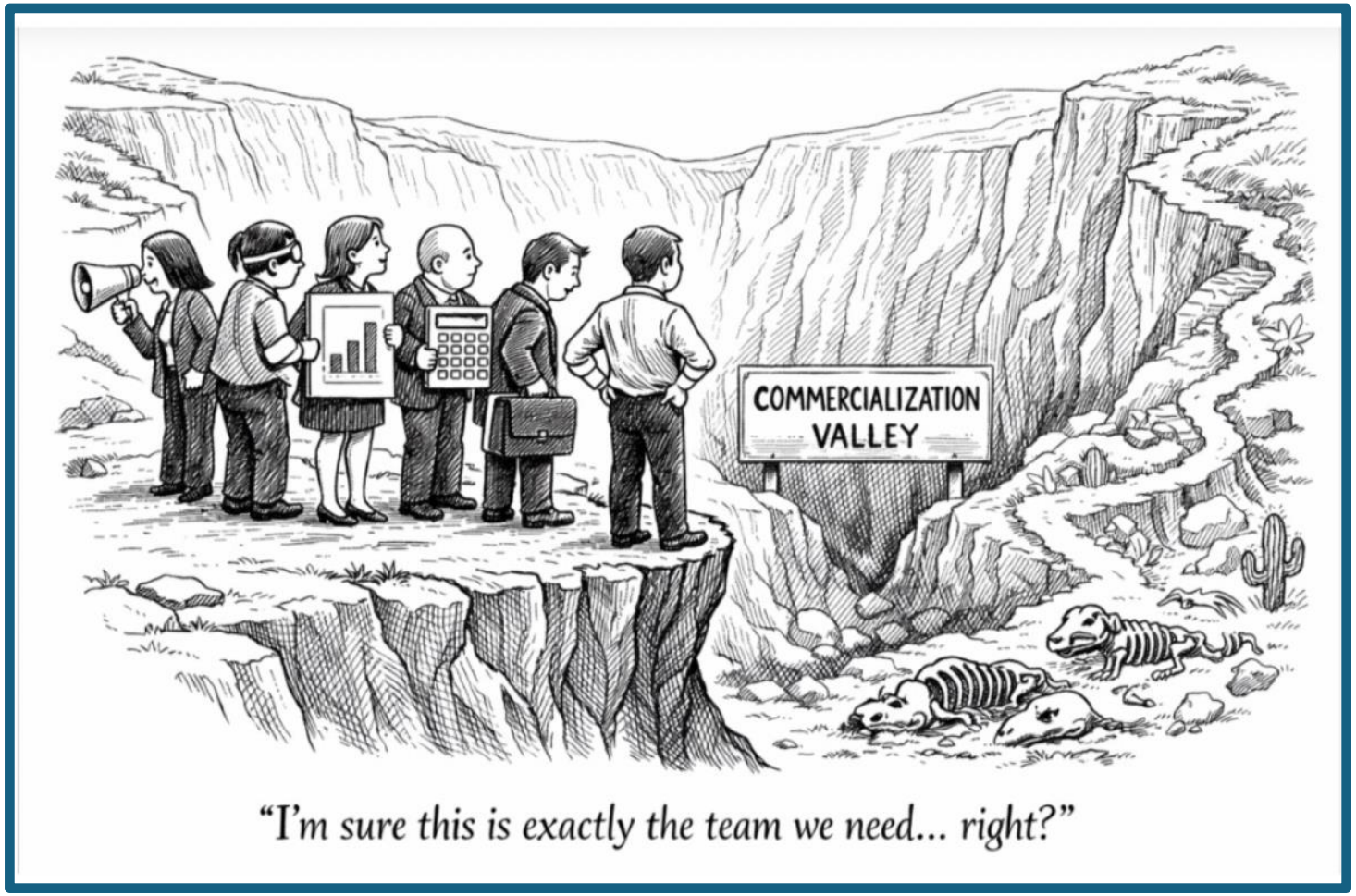
- Bridging innovator's clinical knowledge with the regulatory and reimbursement insights required to assure success in navigating the gauntlet from bench to bedside
- How to gain FDA approval and CMS reimbursement are two of the key hurdles that need to be considered early on in your device development plan

Running the Gauntlet from Bench to Bedside

- Innovators can transform dialysis access when they understand the pathway from concept to commercialization is fraught with many hurdles.
- Those who succeed in running the gauntlet do so via a properly planned and well executed device development pathway, crafted with an expert team.

Pathways to the Valley of Device Death

- Poor trial design
- No reimbursement strategy
- Capital exhaustion



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Questions after the meeting ?

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