MEDICAL INNOVATION CENTER
UNIVERSITY OF MICHIGAN

Multi-Disciplinary Innovation at the Front End

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Commercialization Director
Medical Innovation Center (MIC)
University of Michigan

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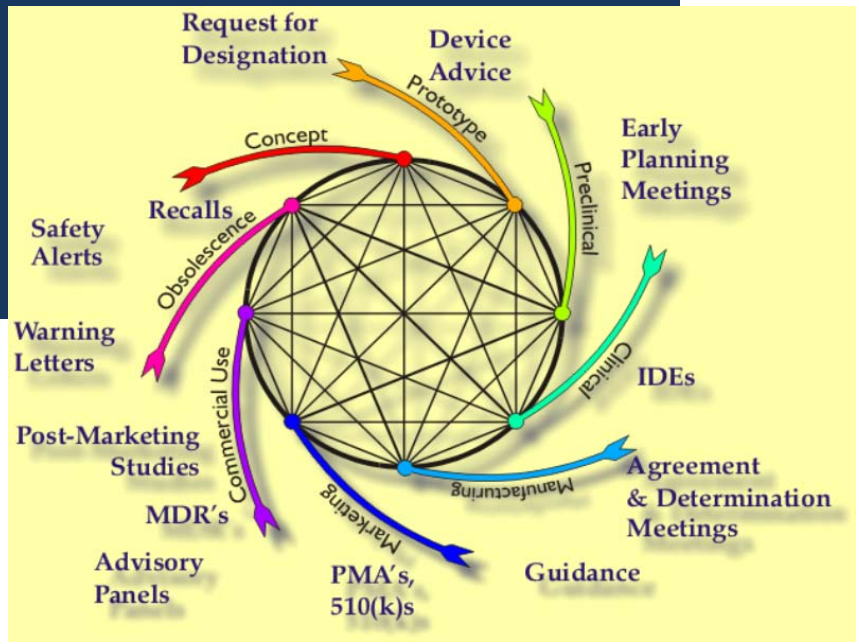
University of Michigan MIC: Overview

Our mission, at all stages of the TPLC:

- Assist Inventors
- Educate Innovators
- Create Prototypes



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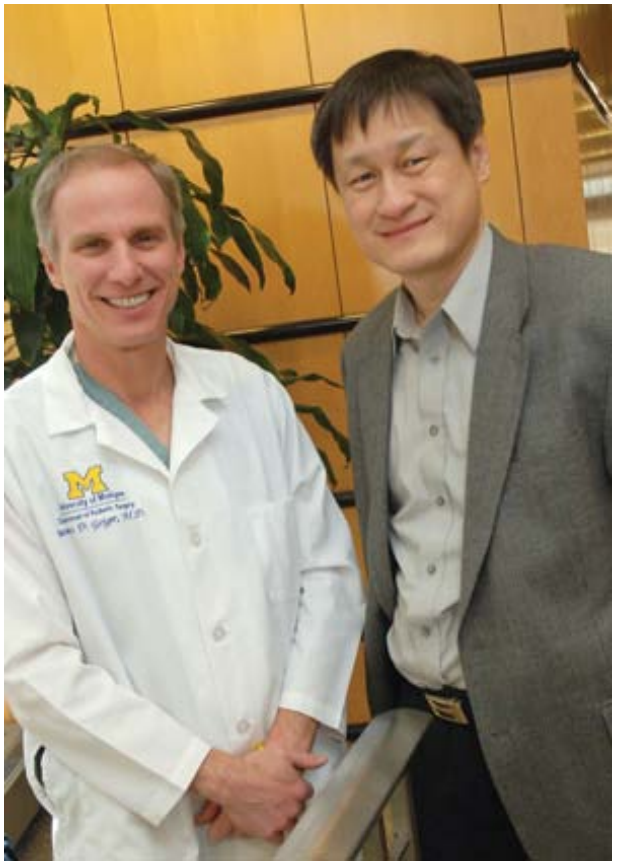
Commercialization – Focus and Approach



The U-M Medical Innovation Center (MIC) Concept to Commercialization Program is focused on the inventor and offers:

1. A multipart, commercially-oriented assessment
2. Risk mitigation
3. Project management
4. Product development guidance related to:
   - identifying engineering and clinical collaborators
   - developing designs, prototypes (in-house with MIC's Prototype Lab and in-coordination with external partners)
   - determining regulatory, reimbursement pathways
   - IP coordination with the Office of Technology Transfer
   - developing partnership and funding strategies

Commercial Challenges:

- Intellectual Property
- Market Size, Dynamics
- Engineering/Design
- Regulatory
- Reimbursement
- Financial

Concept to Commercialization Program: **Process**

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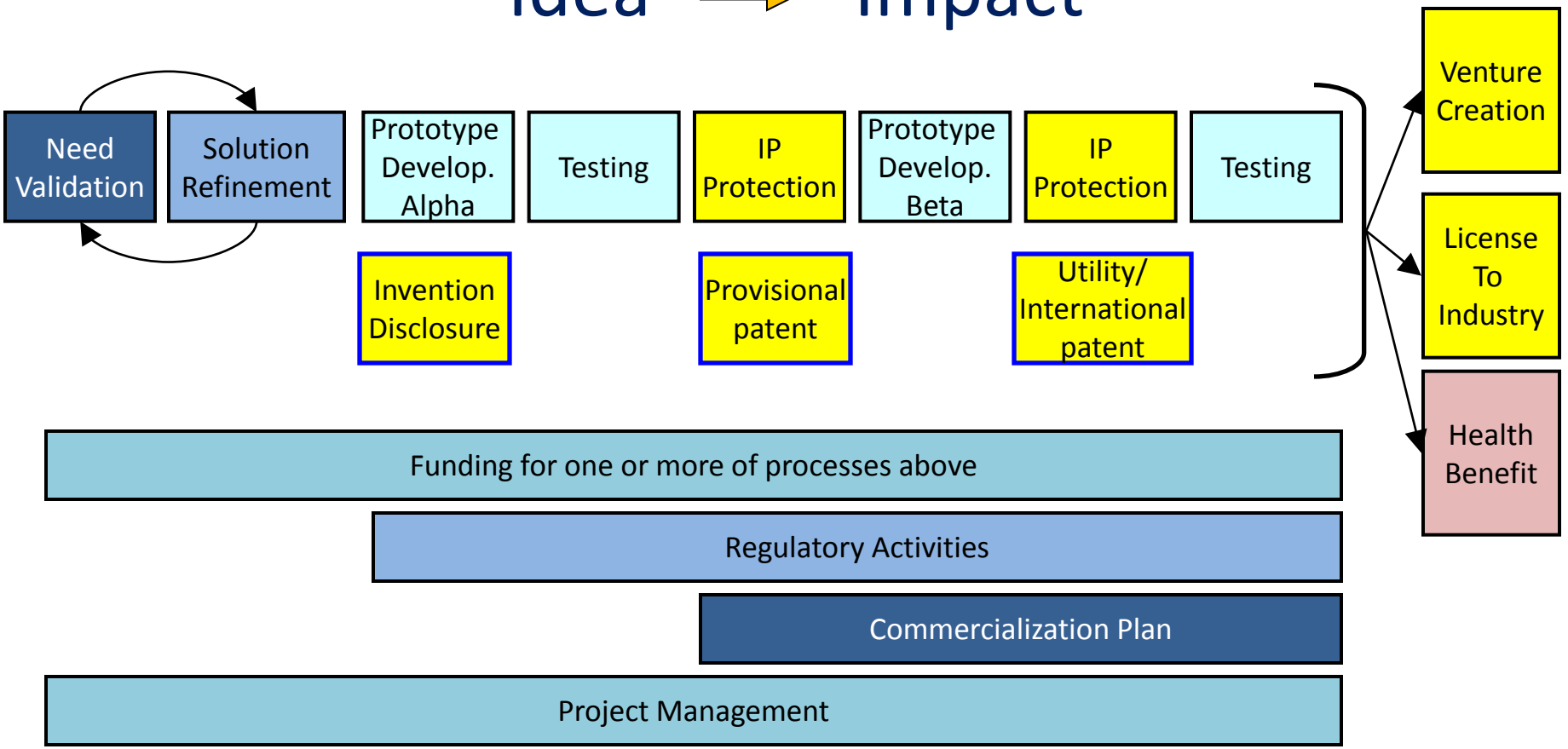
Idea → Impact



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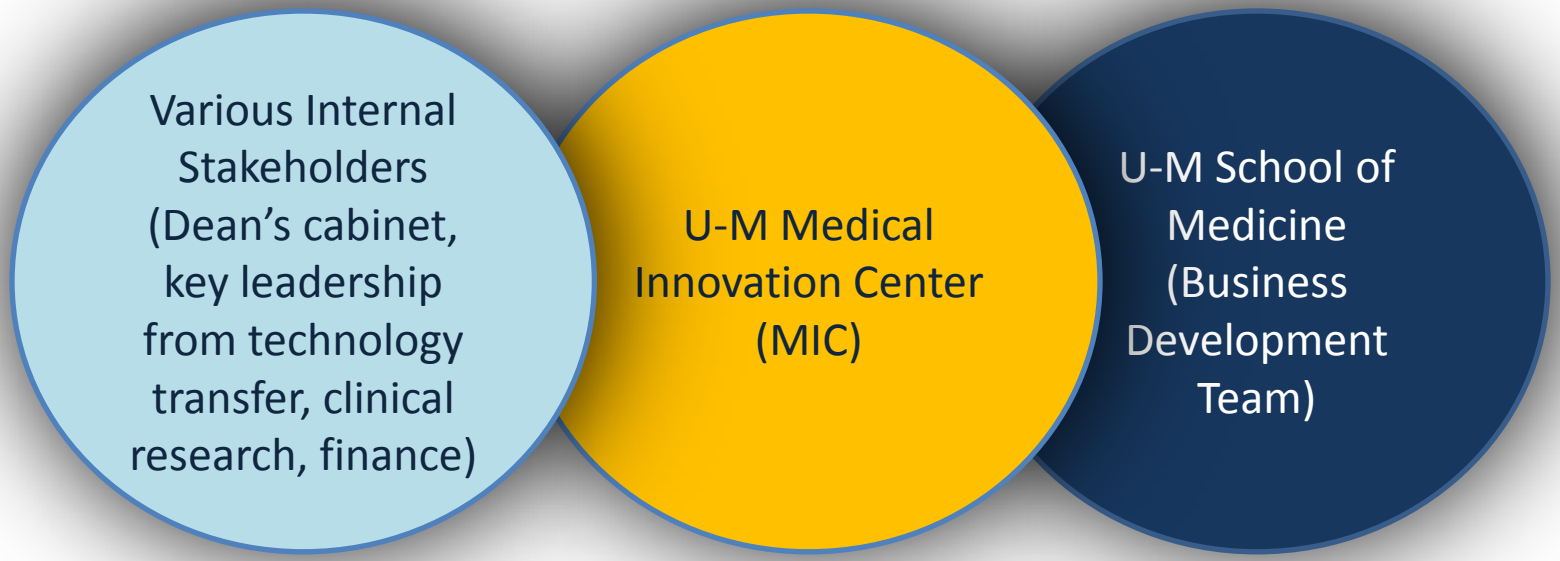
Concept to Commercialization Program:
Multidisciplinary Approaches to Early-stage Funding



Investment Portfolio Subject Matter Experts

External Stakeholders (Industry, VCs, Angels)

External Stakeholders (Industry, VCs, Angels)

Driving the technology pipeline!

Establishing funding pool!

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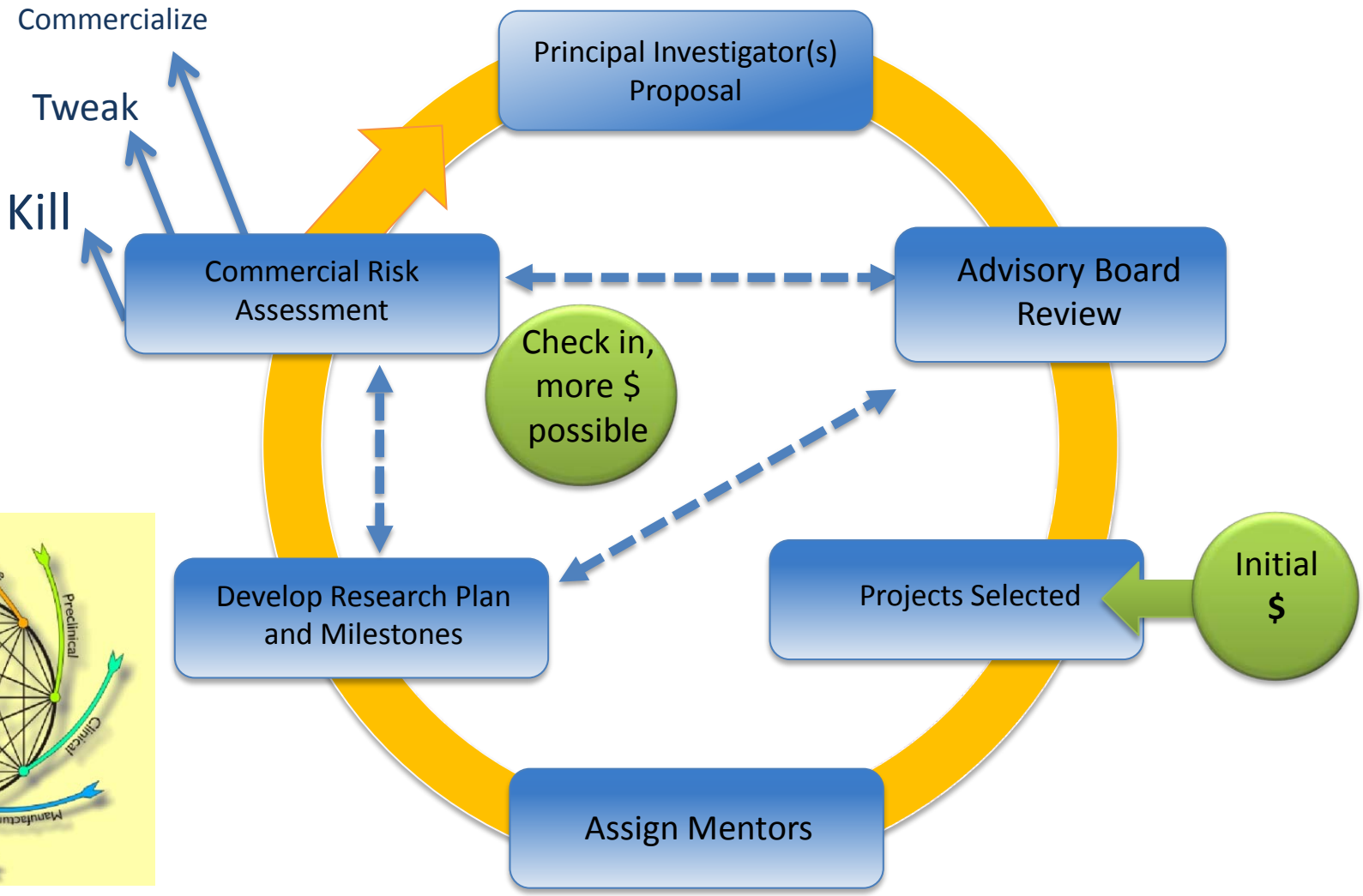
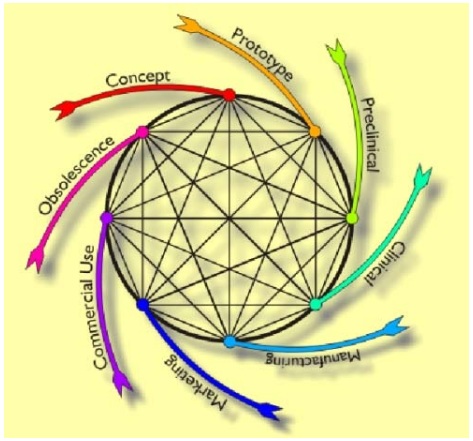
Enabling Funding Mechanisms at the Front End





Concept to Commercialization Program Portfolio: Current State

Portfolio Growth Highlights:

- Increase in pediatric- specific inventions and focus paralleling FDA medical device consortium engagement
- 5-20 new ideas/month
- Significant increase in diagnostics (screening platforms, biomarkers, imaging, etc.)
- Both surgical and non-surgical interventions
- Strong interest in cost-effective, high-impact solutions

Sample Development Stages

0 = Inactive
1 = Concept Stage
2 = Preclinical prototype and testing stage
3 = Clinical Testing stage
4= Design for manufacturing stage
5= FDA approval/clearance stage
6 = Commercialized

Summary Table	January 2010	April 2010	July 2010	October 2010	Change for this quarter
P50 Funded - UM	2	2	2	2	
P50 Funded - PMDI	0	0	0	0	
UM-MPED	11	21	28	36	Increased by 8
PMDI	16	16	16	17	Increased by 1
Total	**29**	**39**	**46**	**55**	**Increased by 9**

*Over 160 ideas, in various stages of development, have benefitted from the MIC Concept to Commercialization Program since its inception.

MIC Fellowship Team 2009-2010

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Jeff Groom, MSE

- Biomedical Engineer, Biomaterials
- Experience in Medical Device Design
- Experience in Basic Science Research
- Dare to Dream, 2008 design grant recipient

Sanjay Shah, MBA

- Experienced in Healthcare Operations
- Expertise in Marketing and Finance
- Experienced Sales and Business Management

Yuri Haverman, MBA

- Experienced Entrepreneur
- Expertise in Business Development and Finance
- Consultant to Venture backed companies
- Dare to Dream, 2008 integration grant recipient

Aaron Swick, MSE

- Biomedical Engineer, Biotechnology
- Experience in Medical Device Design and Testing
- Experience in Basic Science Research

One Year Fellowship

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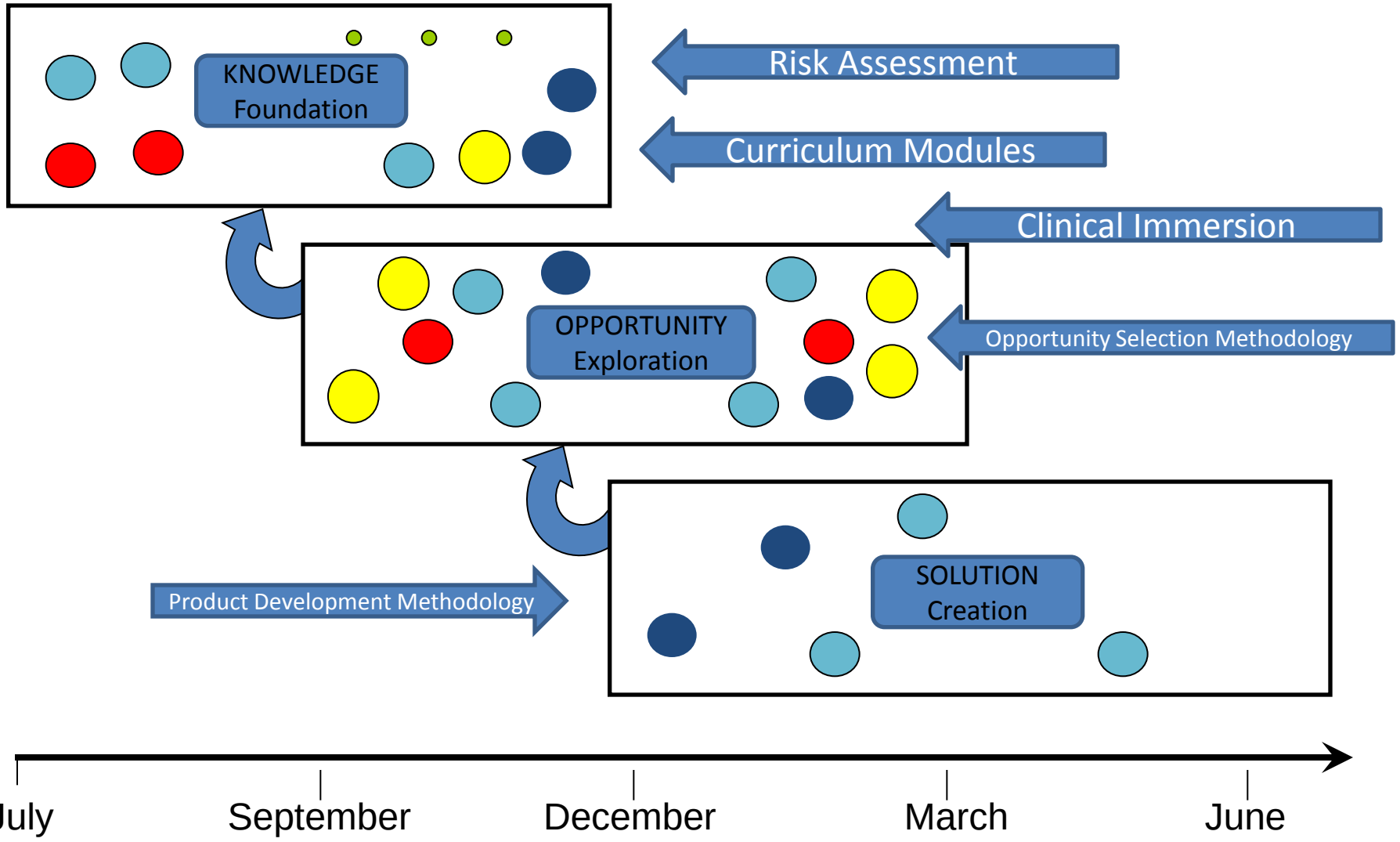

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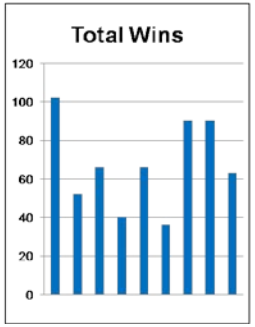
MIC Fellowship Process: **Front-End Innovation**

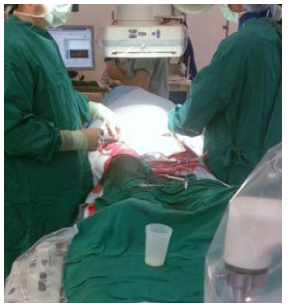


Definition
- Sub-domains selection
- Community mapping
- Technology/Process mapping
- Market analysis

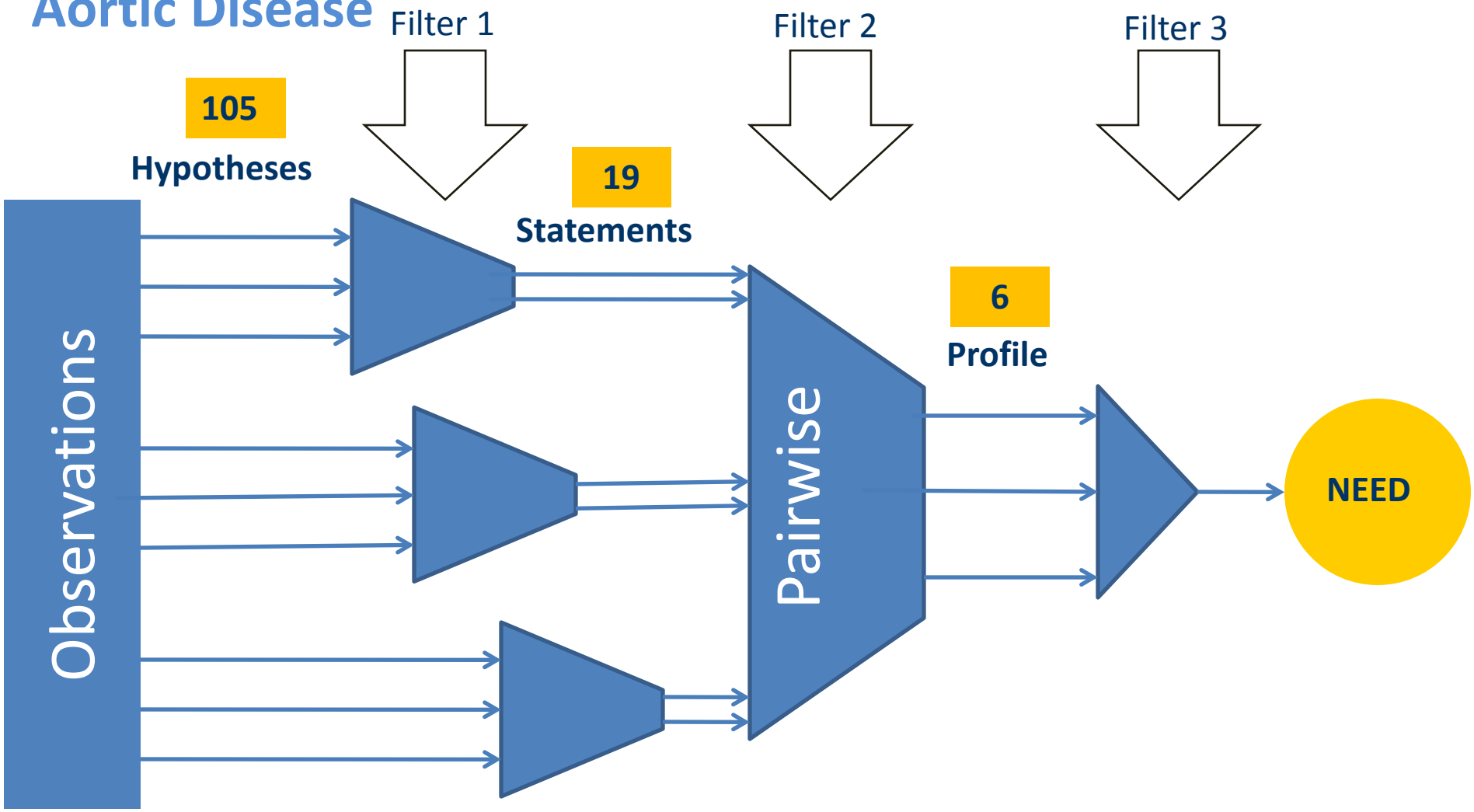
Exploration
- Clinical immersion
- Secondary research
- Education
- Community engagements

Validation
- Hypotheses research
- Community voting
- Expert/user engagements
- Preliminary feasibility study

Creation
- Ideation
- Predictive testing
- Prototyping
- Commercialization



Opportunity Discovery:
Aortic Disease



Filter 1: Clustering, secondary research, engagements

Filter 2: Pairwise comparison, initial feasibility, markets, engagements

Filter 3: Technical Advisory Group Evaluation, feasibility, markets, Gut feeling

Pressing Clinical Needs

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Observation

- Any vascular procedure that involves vessel puncture ultimately requires closure of the access site
- Interventional cardiologists , radiologists and vascular surgeons often struggle to achieve hemostasis (“closing the hole”)
- Complication rate is significant

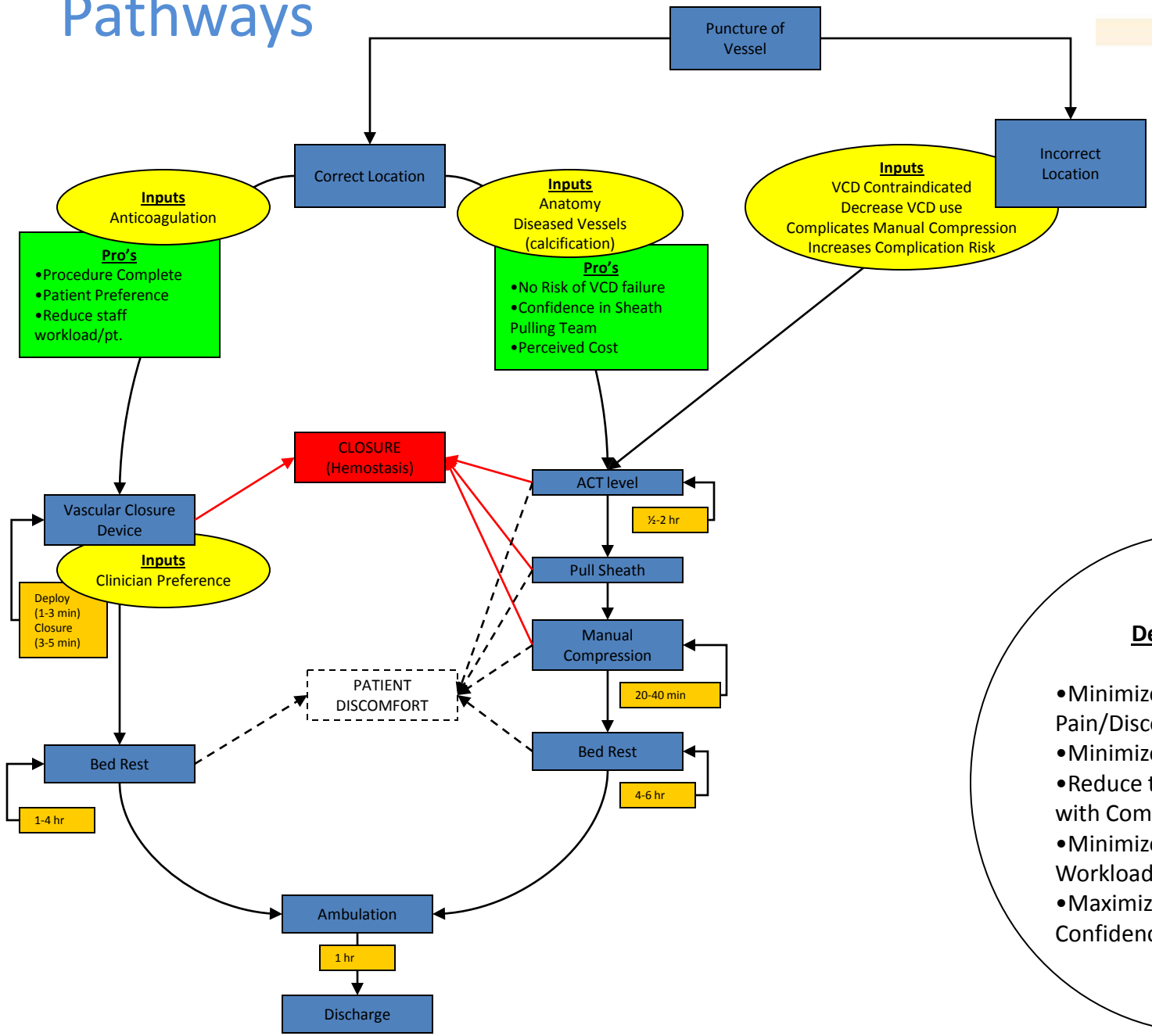
Current Options

- Manual Compression
  - Labor and time intensive
  - Patient discomfort
- Vascular Closure Devices:
  - Difficult to use (multiple steps)
  - Clinically equal and sometimes inferior to manual compression

Needs and Desires

- Reduce complication rate
- Facilitate time to ambulation
- Easy to learn and operate, one-size –fits-all device

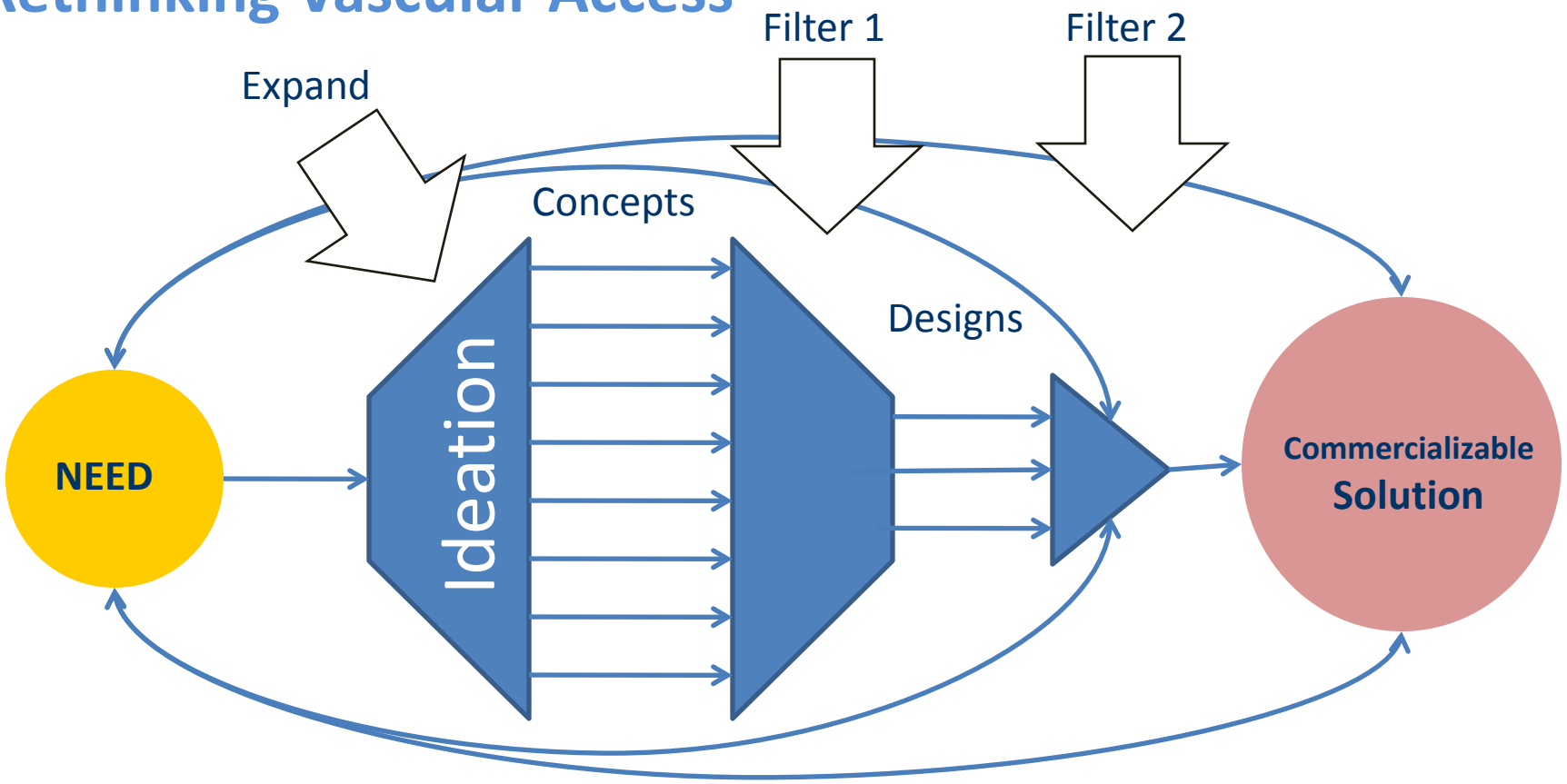
Pathways



Desired Effects

- Minimize Patient Pain/Discomfort
- Minimize Complications
- Reduce the Costs Associated with Complications
- Minimize Staff Workload/Patient
- Maximize Operator Confidence in Closure

Solution Creation:
Rethinking Vascular Access



Ideation: Multi-disciplinary groups from around campus focused on idea generation

Filter 1: Leverage technology from around campus, focused observations, engagements, FDA, IP

Filter 2: Rapid prototyping, validation testing, market exploration, costumer research

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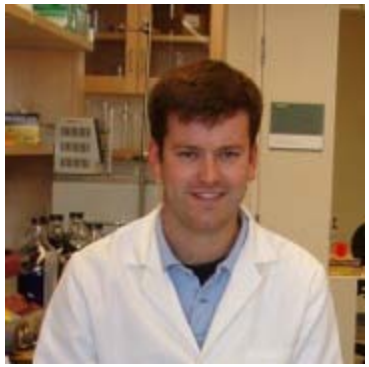
2010-2011 Pediatric Focus:
MIC Fellow Perspective

Doug Mullen, PhD



- Mechanical Engineering and Materials Science, BSE, MSE
- Macromolecular Science and Engineering, PhD

- Rewards to multi/anti-disciplinary, team-based approach
- Challenges faced to-date
- Lessons learned to-date