

Medical Device Development from a Small Business Perspective

Early-stage fundraising for pediatric
products requires innovative approaches



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MC3: small scale, full service medical device development

Corporate collaborators

Inventors

Universities



Corporate collaborators

Startup formation

Out-license

Technology development

Pilot manufacturing

Regulatory/clinical introduction

Business accelerator

Small R&D Company Perspective on Developing Pediatric Devices

- ▶ Access to ideas
- ▶ Access to clinicians
- ▶ Nimble R&D
- ▶ Difficult to survive lengthy development cycle
- ▶ Availability of \$\$\$

Advantages



Disadvantages



A large gap exists between an idea and clinical application for pediatric devices, because of large development costs



Early development and de-risking is needed to attract investment

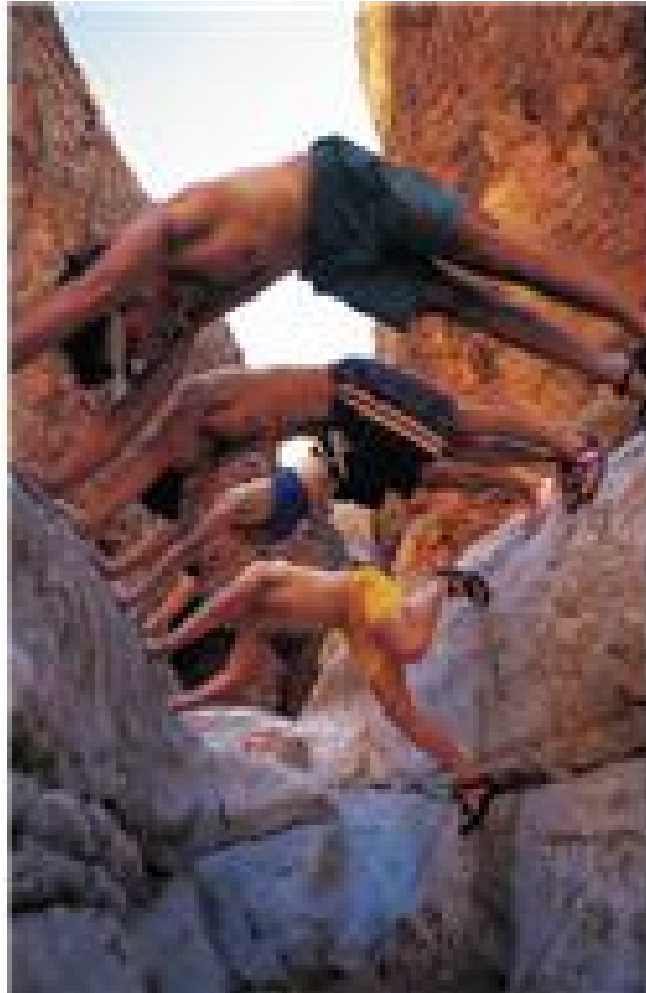
Private investment



Strategic partnerships



Creative solutions are needed to bridge the development gap.



Private investment



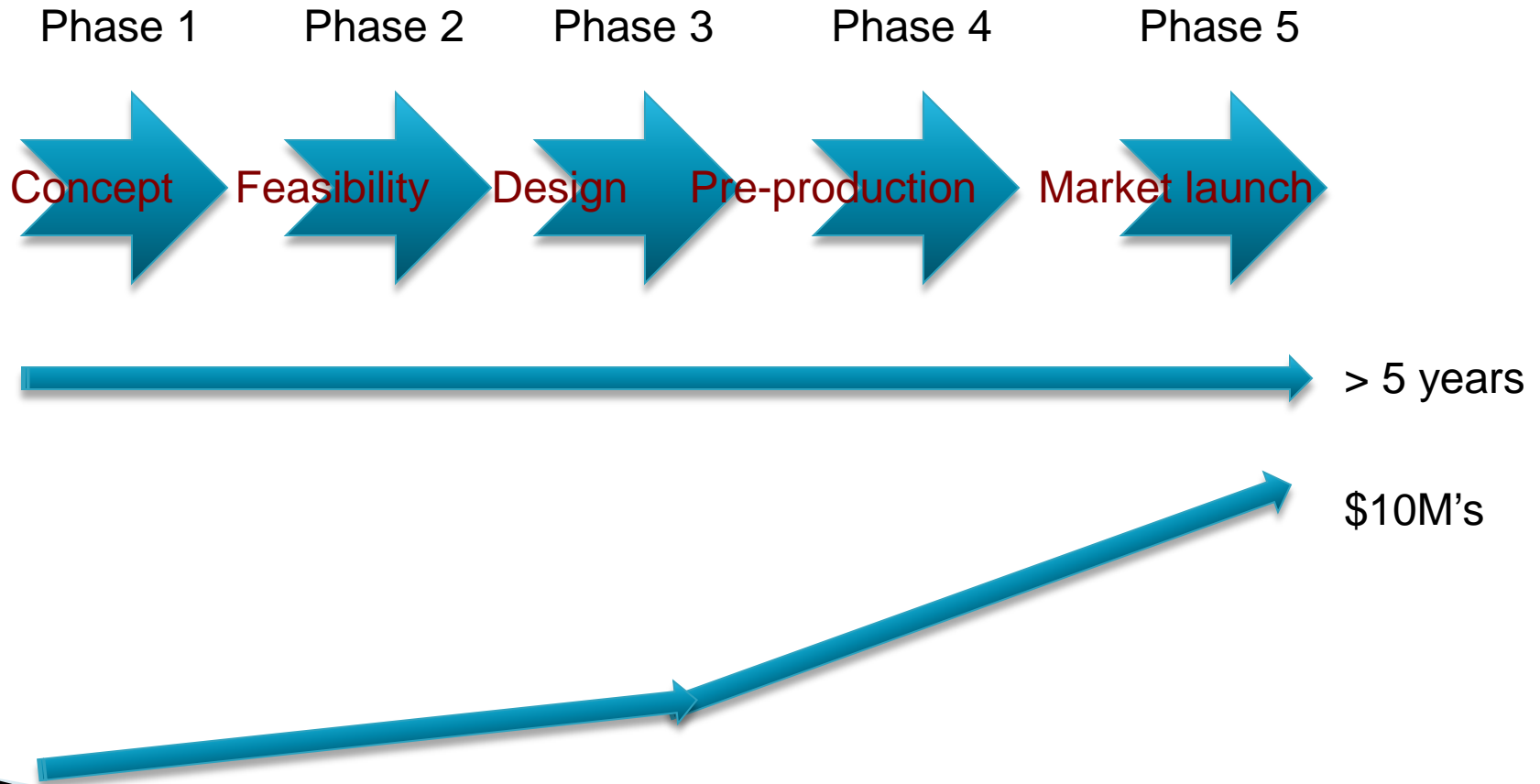
Strategic partnerships



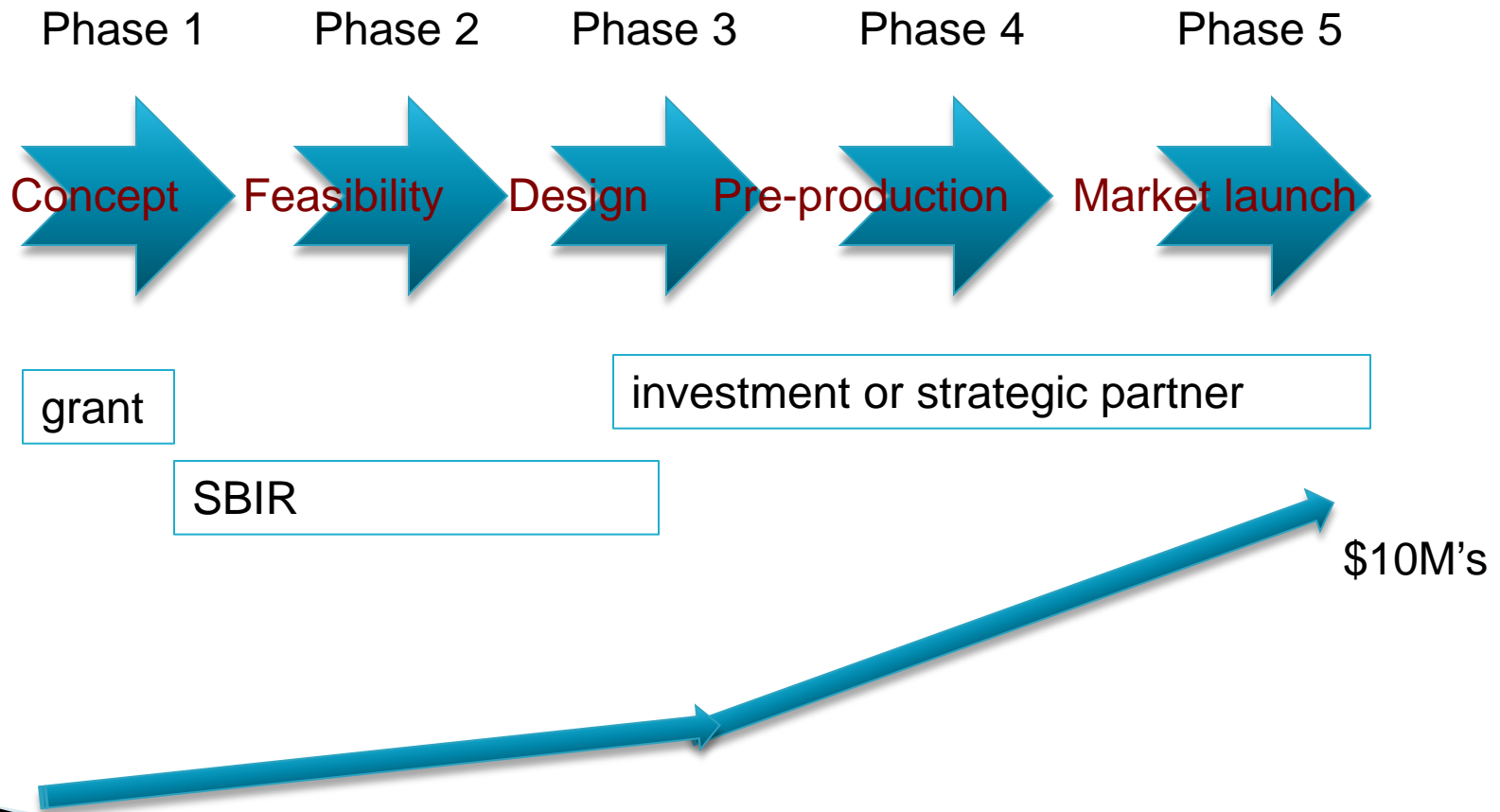
Funding sources available in early stages

- ▶ Private investment (Angel)
- ▶ Non-dilutive funding
 - FDA
 - NIH
 - SBIR
- ▶ Collaborative funding
 - Academic grants
 - Non-profit: Program Related Investments

Device development: cost and timeline



Funding for Development



Example 1: Blood pump

- ▶ Approximately 400,000 adult surgeries in U.S. each year use cardiopulmonary bypass pumps.
- ▶ Pediatric market 10% of adult market size: not an HUD but below investor interest threshold
- ▶ MC3 has developed a pediatric pump that is safer and less expensive than existing pumps: \$5M and 3 years needed to get to market.



Pricing: not proportional to market size



Medtronic BP50 Pediatric

1/10th market size

\$200



Medtronic BP80 Adult

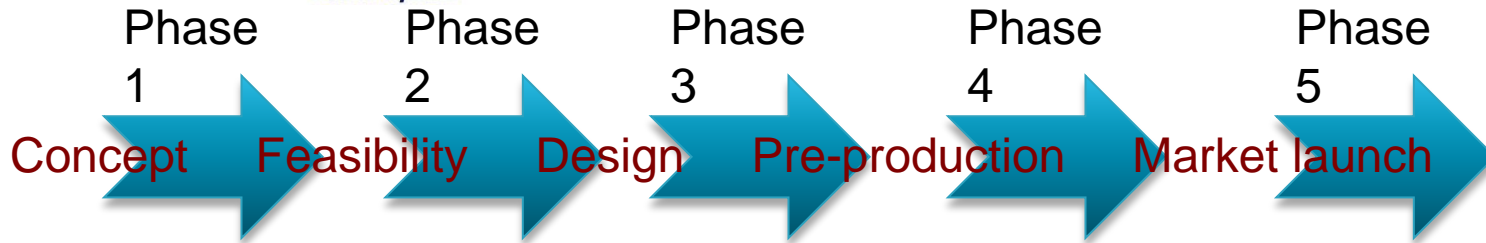
Total market 400,000/year

\$200

Collaborative development



University of Michigan
Health System



\$5M



Department of the Treasury
Internal Revenue Service



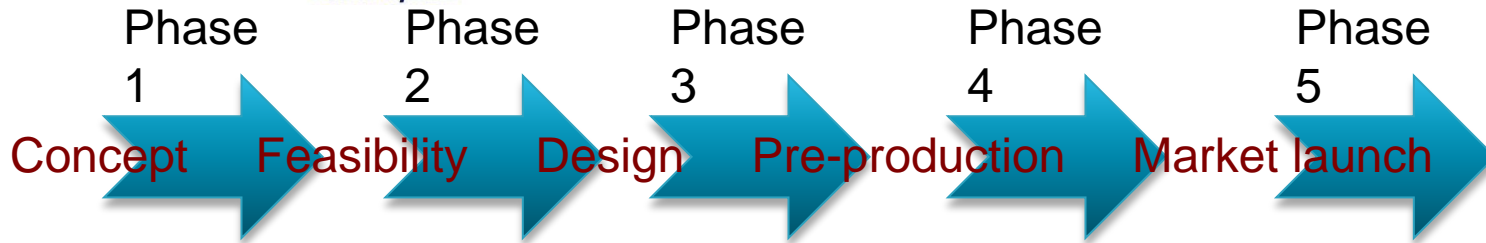
National Heart
Lung and Blood Institute



Collaborative development



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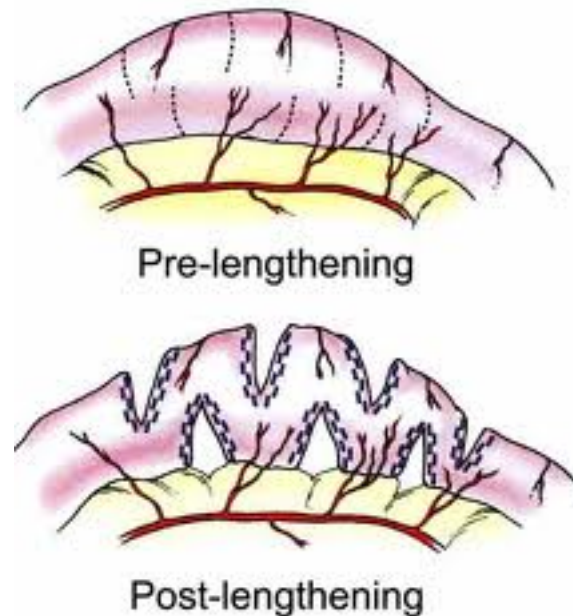
National Heart
Lung and Blood Institute



Industry
Partner

Example 2: Short bowel syndrome

- ▶ Market size in the hundreds per year
- ▶ Life expectancy < 10 years, with medical costs in \$M's
- ▶ Limited surgical options



Example 2: Short bowel syndrome

Device development challenge:

500 devices per year

Development: 5 years and \$10M +



Example 2: Short bowel syndrome

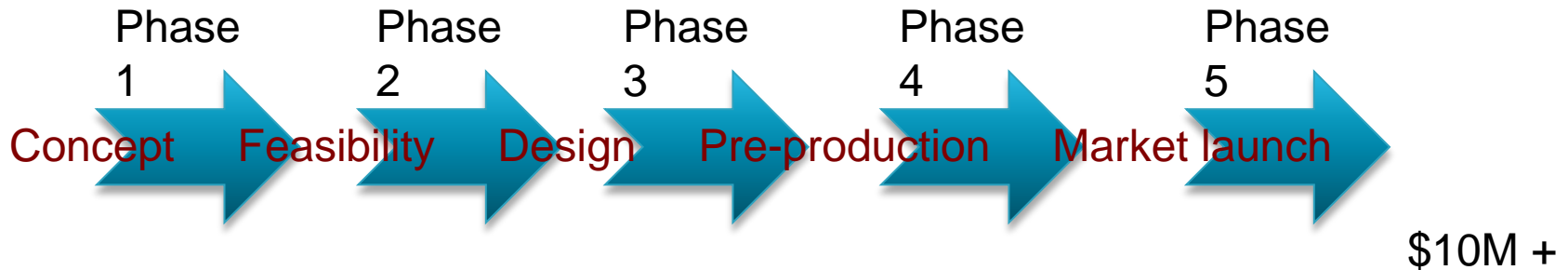
Device development challenge:

500 devices per year

 Too small for outside investment

Development: 5 years and \$10M +

Collaborative development



Industry Partner

Collaborative development



Summary

- ▶ Raising capital for pediatric device development is challenged by small market size
- ▶ Seed funds can be used for early-stage development and de-risking that can increase the chances for fundraising.
- ▶ Innovative fundraising can lead to devices that otherwise might not be possible
- ▶ Small business has access to ideas and funding sources, and can play a role in realizing new pediatric devices.