Needs Finding

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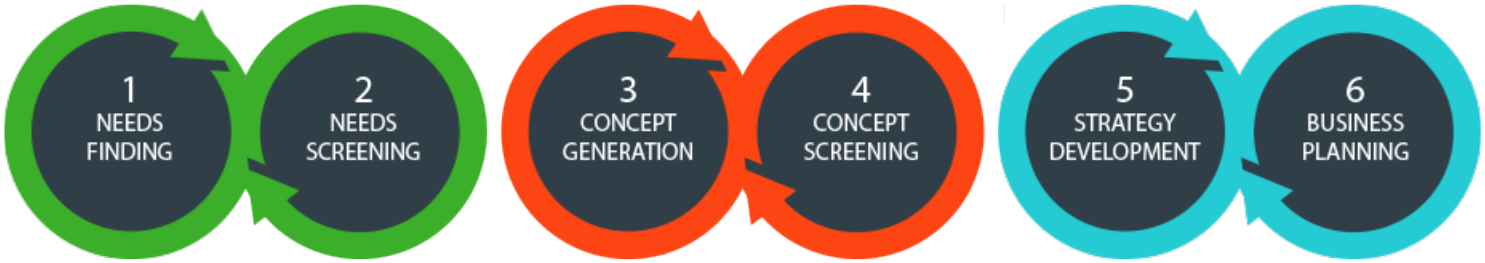
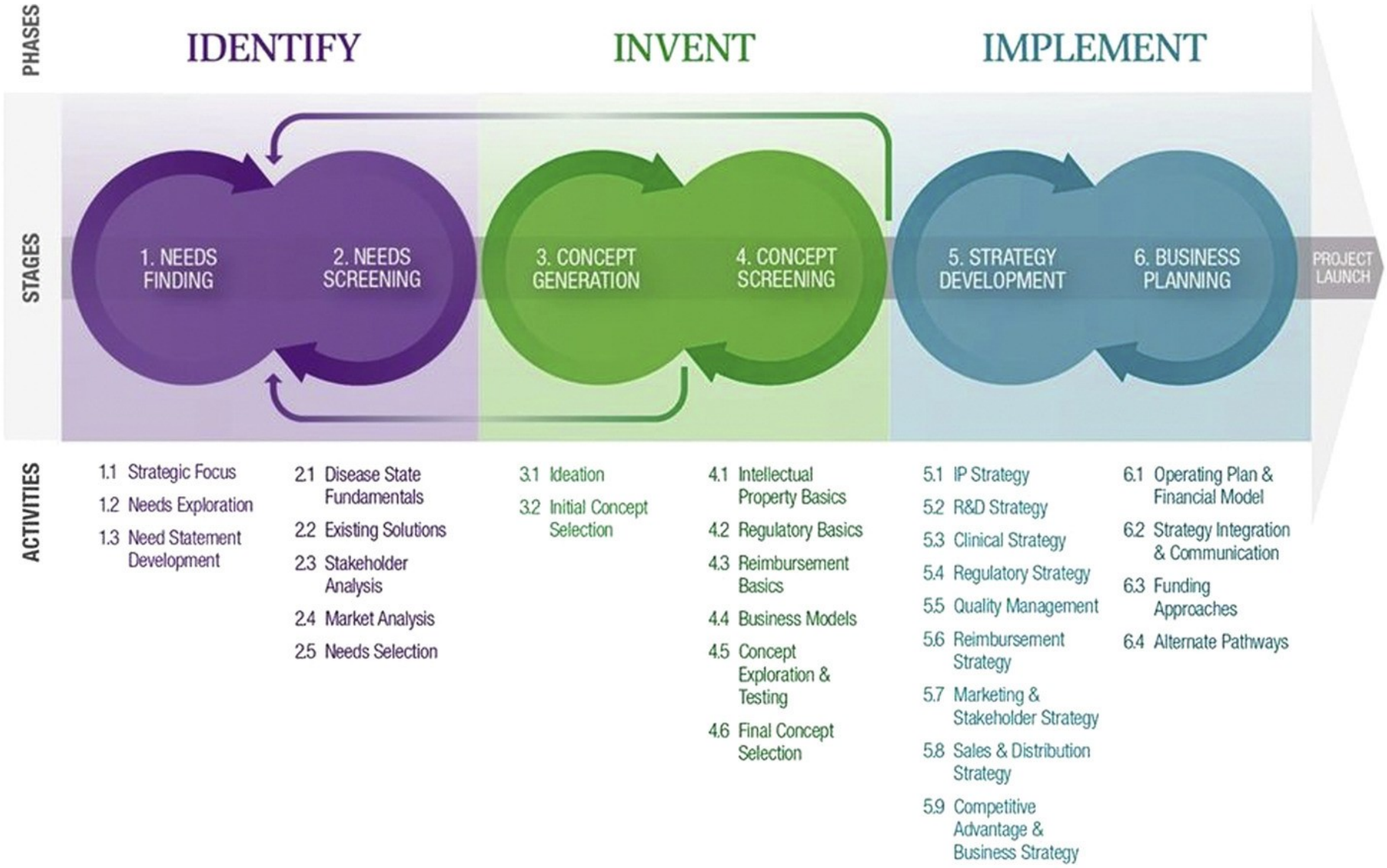
IDENTIFY

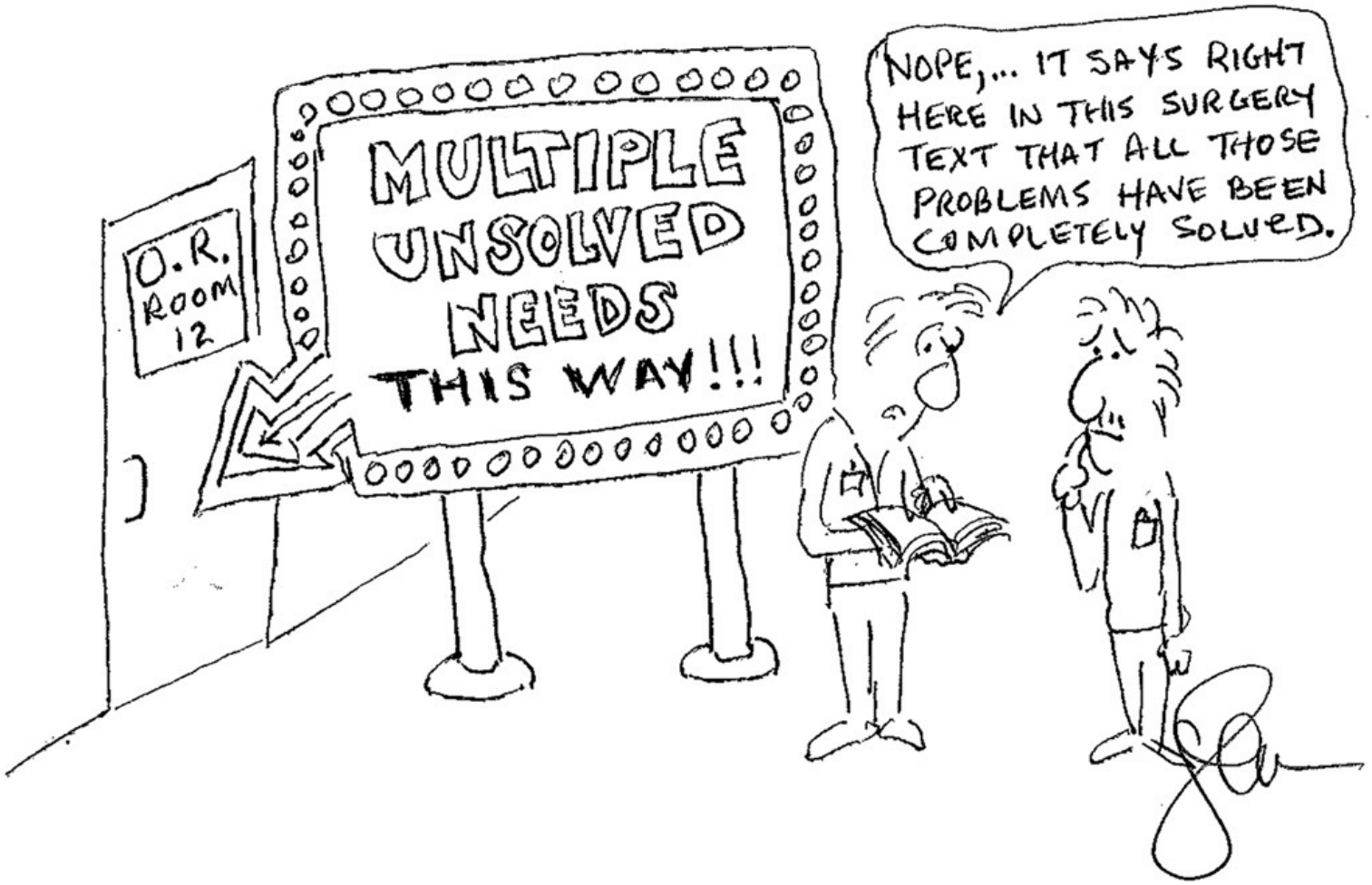
INVENT

IMPLEMENT




PHASES
IDENTIFY
INVENT
IMPLEMENT
STAGES
1. NEEDS FINDING
2. NEEDS SCREENING
3. CONCEPT GENERATION
4. CONCEPT SCREENING
5. STRATEGY DEVELOPMENT
6. BUSINESS PLANNING
PROJECT LAUNCH
ACTIVITIES
1.1 Strategic Focus
1.2 Needs Exploration
1.3 Need Statement Development
2.1 Disease State Fundamentals
2.2 Existing Solutions
2.3 Stakeholder Analysis
2.4 Market Analysis
2.5 Needs Selection
3.1 Ideation
3.2 Initial Concept Selection
4.1 Intellectual Property Basics
4.2 Regulatory Basics
4.3 Reimbursement Basics
4.4 Business Models
4.5 Concept Exploration & Testing
4.6 Final Concept Selection
5.1 IP Strategy
5.2 R&D Strategy
5.3 Clinical Strategy
5.4 Regulatory Strategy
5.5 Quality Management
5.6 Reimbursement Strategy
5.7 Marketing & Stakeholder Strategy
5.8 Sales & Distribution Strategy
5.9 Competitive Advantage & Business Strategy
6.1 Operating Plan & Financial Model
6.2 Strategy Integration & Communication
6.3 Funding Approaches
6.4 Alternate Pathways

The Importance of Direct Observations



Cartoon by Josh Makower.

If I had an hour to solve a problem and my life depended on the solution, I would spend the first 55 minutes determining the proper question to ask, for once I know the proper question, I could solve the problem in less than five minutes.

Albert Einstein (1879 - 1955)

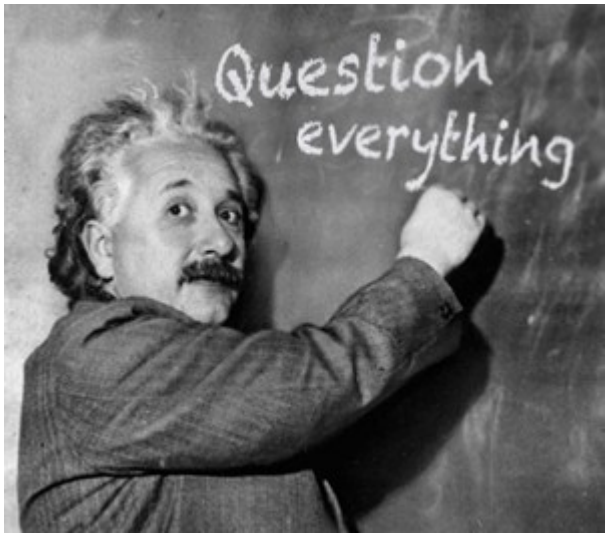
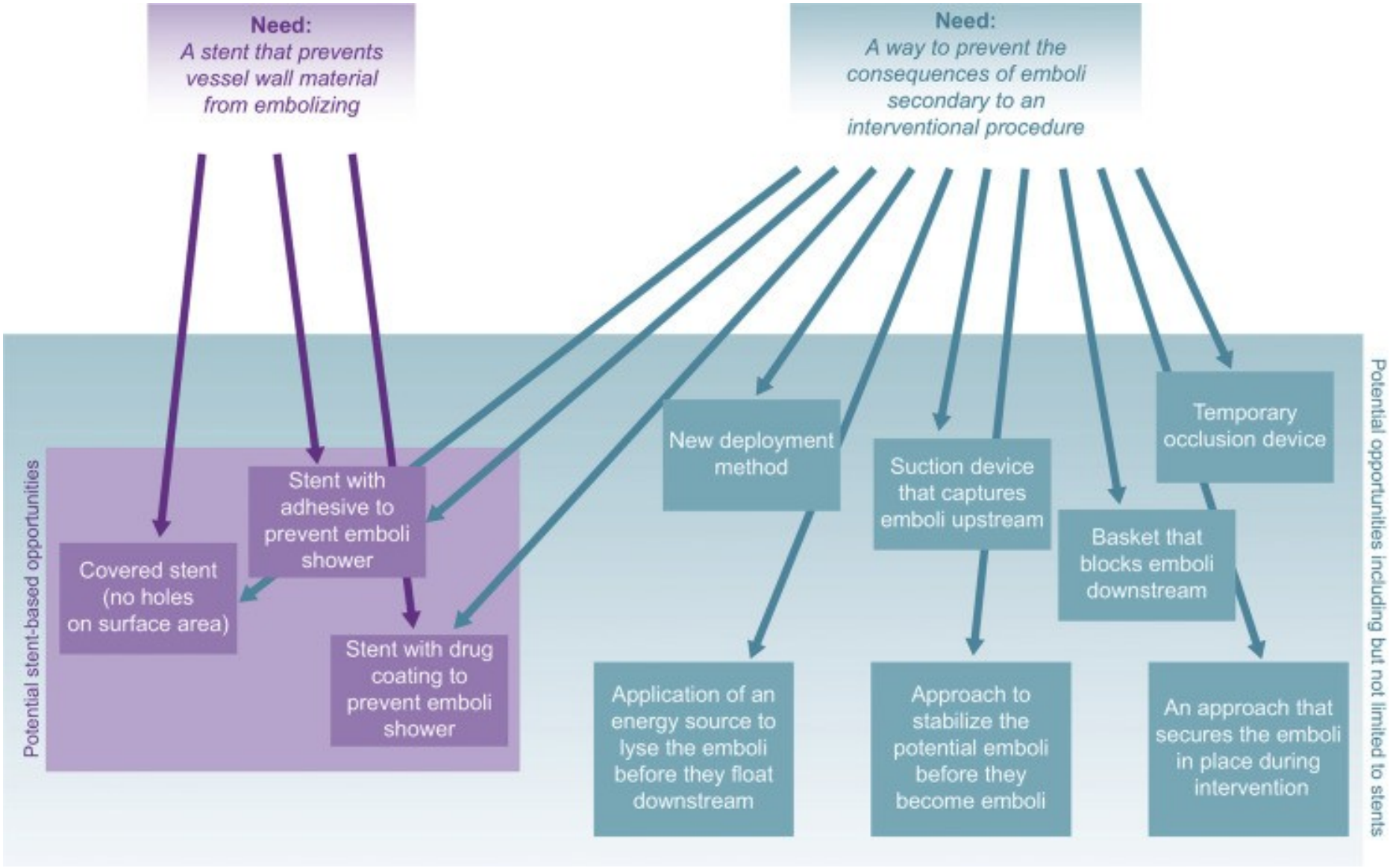


FIGURE 1.1.1
Using a structured approach that takes internal and external factors into account can help lead innovators to a strategic focus that provides a good fit.

How to “needs find”

- Observe first hand
  - Need Primary Source
- Directed interview questions
- Speaking with stakeholders
  - Doctors, nurses, patients
- Generate a needs statement (problem, population and outcome)
- **Try to see the world without corrections**


Need:
A stent that prevents vessel wall material from embolizing
Need:
A way to prevent the consequences of emboli secondary to an interventional procedure
Potential stent-based opportunities
Covered stent (no holes on surface area)
Stent with adhesive to prevent emboli shower
Stent with drug coating to prevent emboli shower
New deployment method
Suction device that captures emboli upstream
Temporary occlusion device
Basket that blocks emboli downstream
Application of an energy source to lyse the emboli before they float downstream
Approach to stabilize the potential emboli before they become emboli
An approach that secures the emboli in place during intervention
Potential opportunities including but not limited to stents

Stakeholders

The Patient

- What did the patient have to undergo in terms of pre-operative tests, appointments, etc.?
- What time did the patient have to get up to prepare for the procedure?
- Was s/he allowed to eat the night before?
- What sort of preparation was required?
- Did the preparation have any negative or unintended side effects?
- What did the patient experience when s/he arrived at the hospital?
- How long did s/he have to wait?
- Was the patient taken to the operating room in a wheel chair or on a gurney?
- How long did the procedure take?
- What were the steps of the procedure and how long did each one take?
- Did the procedure require a general anesthetic?
- How much pain (or discomfort) did the patient experience during the procedure? Post-operatively? After discharge?
- What was involved in the post-operative process?
- What sort of bandage did the patient receive?
- How often was the bandage changed/wound drained?
- Was a urinary catheter required?
- Was intravenous (IV) access required?
- Were there any complications that resulted from these procedures?
- How long was it before the patient could discontinue the drain, catheter, or IV?
- Are there any variations in the ways patients are prepared for, treated during, or cared for after a procedure, depending on the environment?
- Did the patient need to stay in the hospital overnight? For how many nights?
- Did the patient need any assistance after hospital discharge?
- What was the plan for post-operative medications to address infection and pain control?
- What was the time required before the patient could resume normal activities?

The Provider

- What training and certification is required to perform the procedure?
- Who prepares the patient for the procedure?
- How many people are present in the operating room?
- What are their various roles?
- Does the same person perform the procedure from start to finish?
- Are practitioner staffing levels and roles the same across different environments?
- Why is work allocated across practitioners in this way?
- How long has this been the standard of care?
- How was the procedure performed before the current approach became standard?
- What are the accepted primary limitations or difficulties associated with the current procedure?
- Do the devices (or other tools used in the procedure) perform as the providers want/need them to?
- How does the provider use the device?
- Does the provider appear confident using the device?
- Did the provider have difficulties using the device? Operating it? Implanting it?
- How many hands were required to operate/implant/use the device properly (i.e., did the provider need assistance operating the device)?
- Did the provider make any errors while using the device?
- Was there any evidence of operator fatigue or distraction during the case?
- How much follow-up is required of the surgical provider(s) after the procedure?
- What are the most common complications associated with the procedure?
- Who treats the complications?
- How (and where) are they treated?

Others in the Healthcare System

Facility, Payer, etc.

- How much is billed for the procedure?
- At what rate is the procedure reimbursed?
- Does reimbursement for the procedure differ depending on the payer?
- Is the procedure profitable?
- What factors are most likely to drive up (or down) costs?
- How long does the procedure take to perform?
- What aspect(s) of the procedure take the longest to complete?
- How many resources are tied up as the procedure is being performed?
- What facilities (e.g., rooms) are tied up as a result of the procedure?
- What devices, equipment, or supplies are required to support the procedure?
- How much do the devices, equipment, and supplies cost?
- To what extent do they affect the profitability of the procedure?
- Is the procedure performed in only one setting (e.g., operating room) or can it be performed in other venues (e.g., outpatient procedure or radiology lab)?
- If there are complications to the procedure, who bears this cost?

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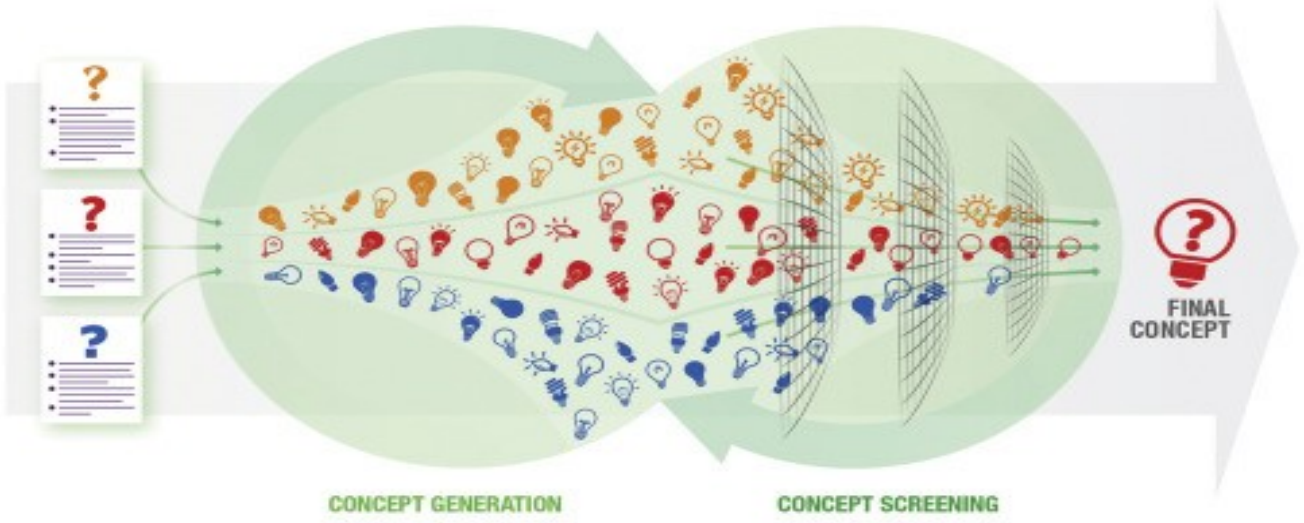
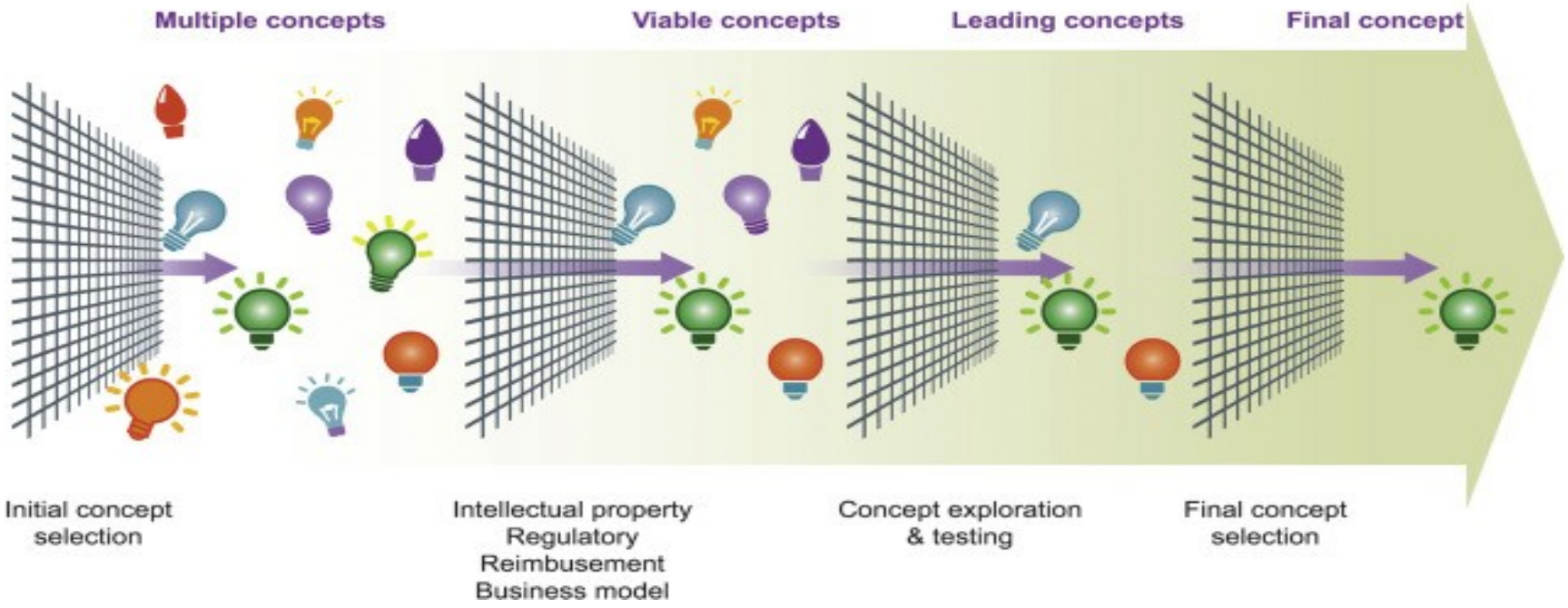

FINAL CONCEPT
CONCEPT GENERATION
CONCEPT SCREENING


Multiple concepts
Viable concepts
Leading concepts
Final concept
Initial concept selection
Intellectual property
Regulatory
Reimbusement
Business model
Concept exploration & testing
Final concept selection

Clinical observation

- **Do your homework**
- Take notes
- Ask questions
- Be thankful, respectful and polite
- Follow up

People First Language

- **Never define someone by their disability**
  - Use people with disabilities vs. disabled people
  - Interact with user (person with disability)
- Recognize cues
- Be thankful, respectful and polite
- Ask client their perspective