INNOVATION SPARKED BY INDUSTRY

VINCENT C. THOMAS, MD, MHA

MEDICAL SAFETY OFFICER

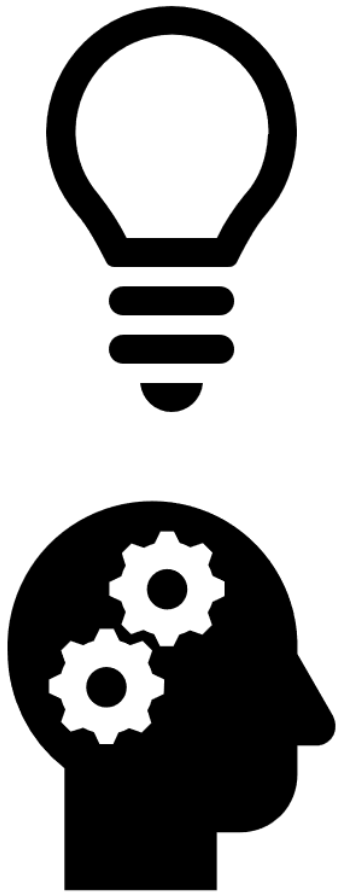
BIOSENSE WEBSTER- A JOHNSON & JOHNSON COMPANY

DISCLOSURES

- Employee of Johnson & Johnson
- Salary
- Stock

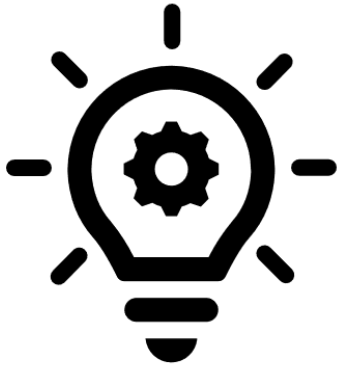
OBJECTIVES

- Discuss the development of ideas in industry
- Review pathways within industry to achieve product
- Explain how to connect clinical work with industry and innovation



SPARK

- Innovation always starts with an unmet need
- Key words:
  - UNMET
  - NEED



TWO BROAD PATHWAYS

- Incremental Change
- Disruptive Change

COMPARISON

INCREMENTAL	DISRUPTIVE
✓Existing data and experience	✓New design and limited experience
✓Less costs	✓New added costs
✓Reduced regulatory concerns (510K process)	✓Full regulatory review

DECISIONS

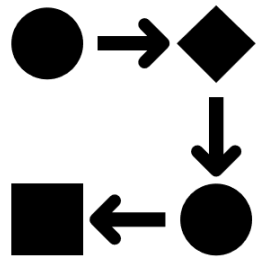
- Define the opportunity
  - What problem are we trying to solve?
  - What value do we bring to our stakeholders?
  - What must the product do to bring that value?
  - What is the regulatory pathway?
- Business overview
  - What is the source of volume?
  - What product may be cannibalized?
  - What are the estimated COGS (cost of goods sold)?
    - Bring me a “product”, not a concept

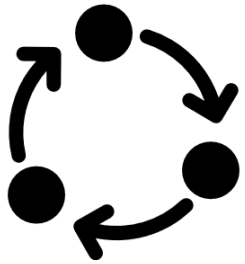
VOICE OF CUSTOMERS

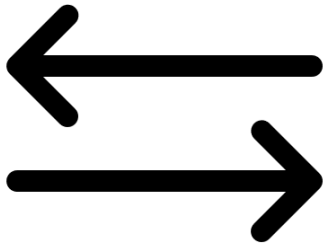
- Take concept and get opinions
  - Key Opinion Leaders (KOLs)
- Consolidate opinions into critical components
- Rank critical components by priority
- Market Assessment

NOW WE'RE READY TO START

- Lengthy process but well-defined
- Constant evaluation and re-evaluation
- Steps forward often involve steps back
- All deliverables must be obtained before moving forward in the process

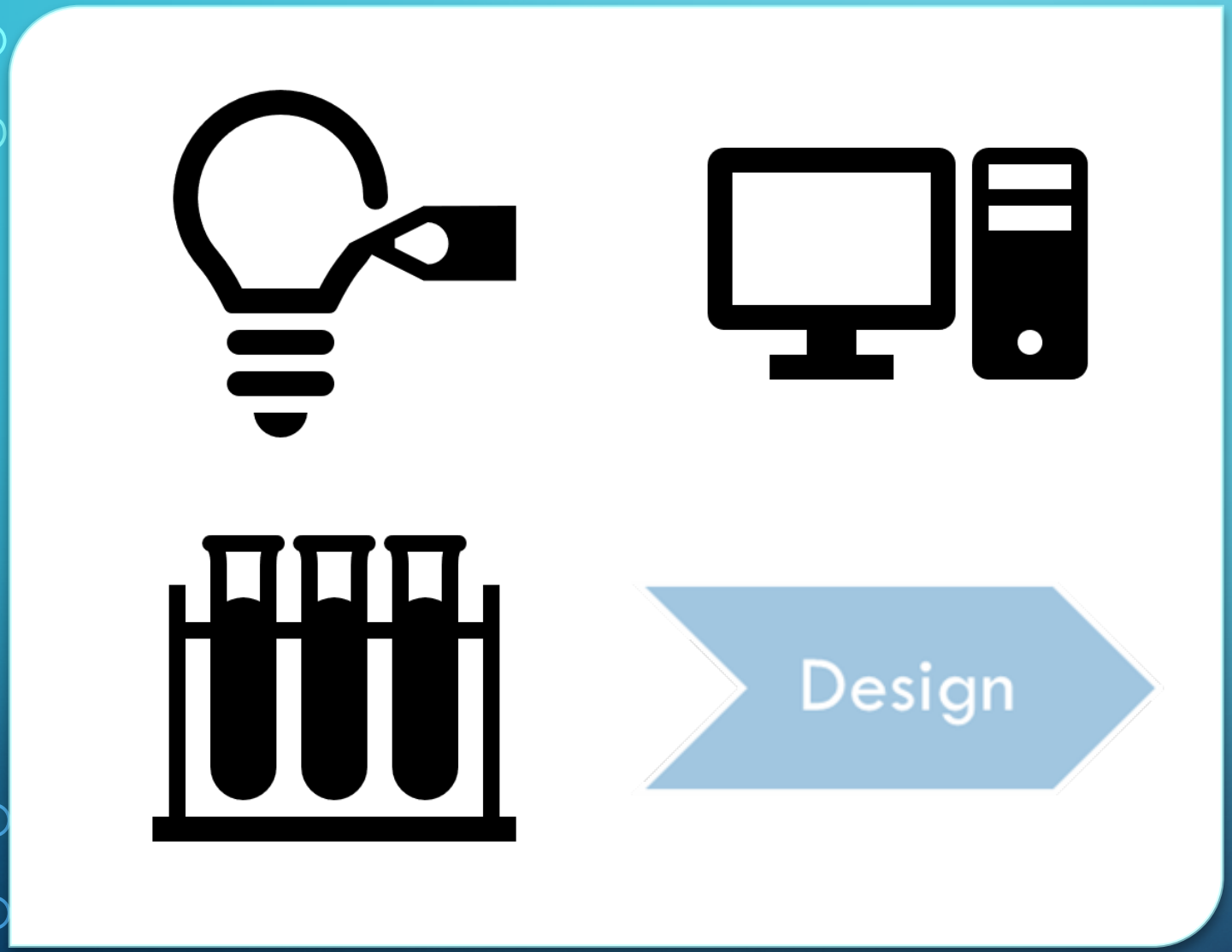






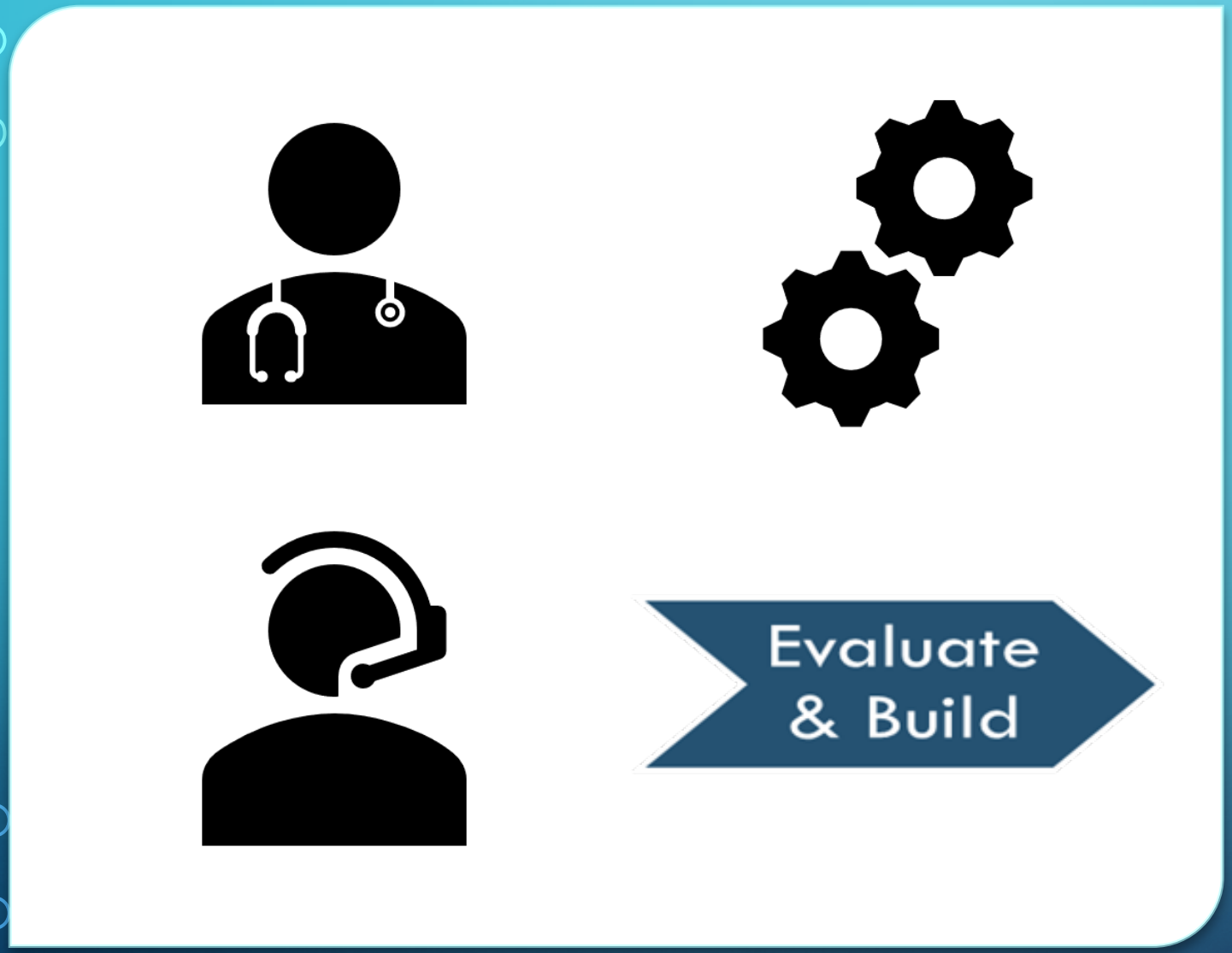
GENERAL OVERVIEW

- Design & Development Plan
- Quality Plan
- Risk Management Plan
- Worldwide Marketing Plan
- Regulatory Strategy
- Usability Analysis

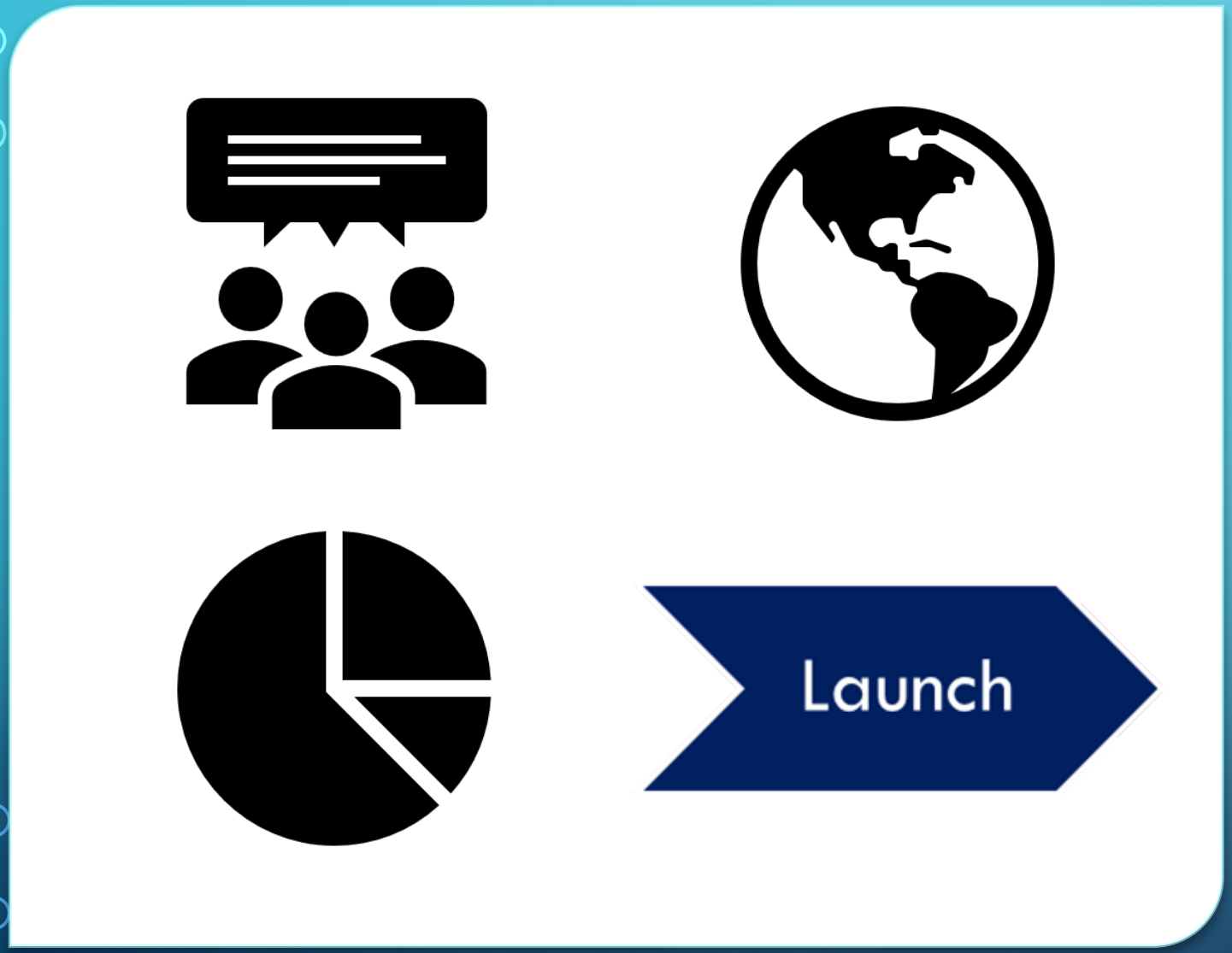


- Design History File
- Design Output Review*
- External evaluation plan
- Evidence/clinical study plan
- Appropriate mitigations in design

- Design verification- Confirms that the design output meets the desired design input requirements using objective evidence
- Design validation*- Ensuring that product meets the defined user needs
- Process validation



- Market Readiness Review
- Customer External Evaluation
- First-in-human*
- Design transfer* to production
- Scale
- Post-market & Technical Services



- Design Closure Review
- Post-Launch Report
- Regional Launch Approval

EU MDR

- CE Mark
- Breast implant and Hip Implant
- Increased scrutiny
- Time
- Resources (small vs big)

ROLE OF THE CLINICIAN

INNOVATION IN INDUSTRY

UNMET NEED

- What are we missing for our patients?
- Market driven = patient driven

CONFLICTED

- “Get Conflicted”
- Share experiences
- Define the problem, not the solution
- Intellectual Property

KEY OPINION LEADER

- Innovative
- Influence
- Podium Presence
- Publish

CONCLUSION

- Innovation in industry is driven by the market (i.e. patients & you)
- Development of new product is a long & challenging process
- Partnership between clinicians and industry are necessary to generate better product solutions for clinical problems