



# Safety and Usability Testing



# Agenda

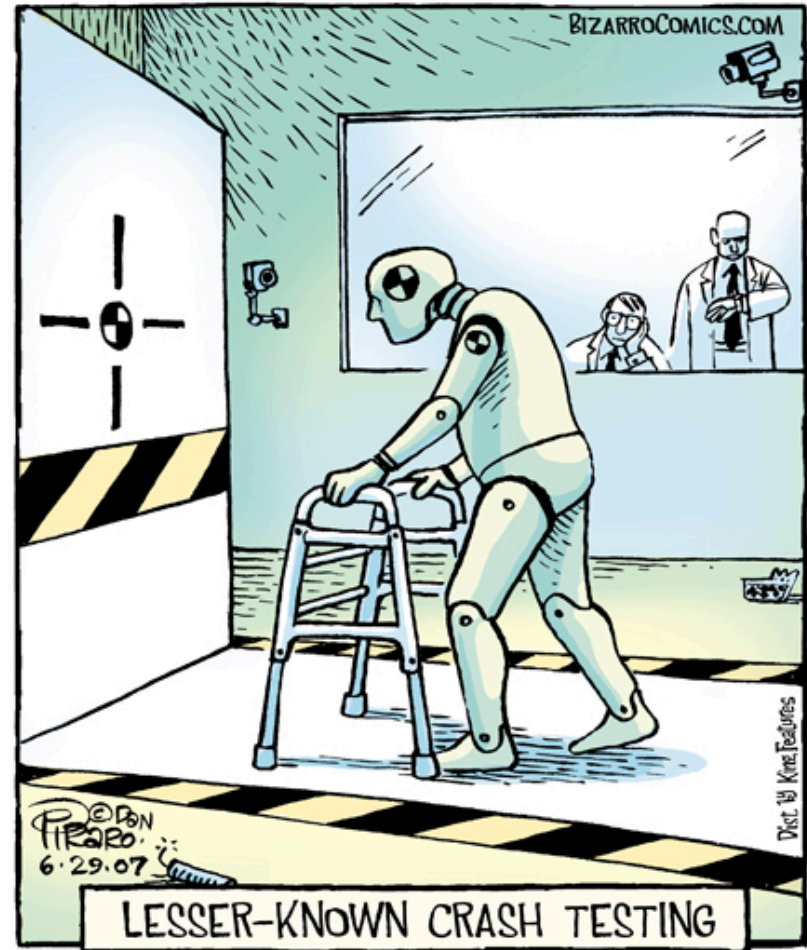
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- Learning Objectives
- What is Safety & Usability Testing?
- How to Identify Key Research Questions
- Resources
- Next Steps
- Wrap Up



# Learning Objectives

- Understand the role of safety & usability testing
- Identify steps to developing evidence of safe and usable design



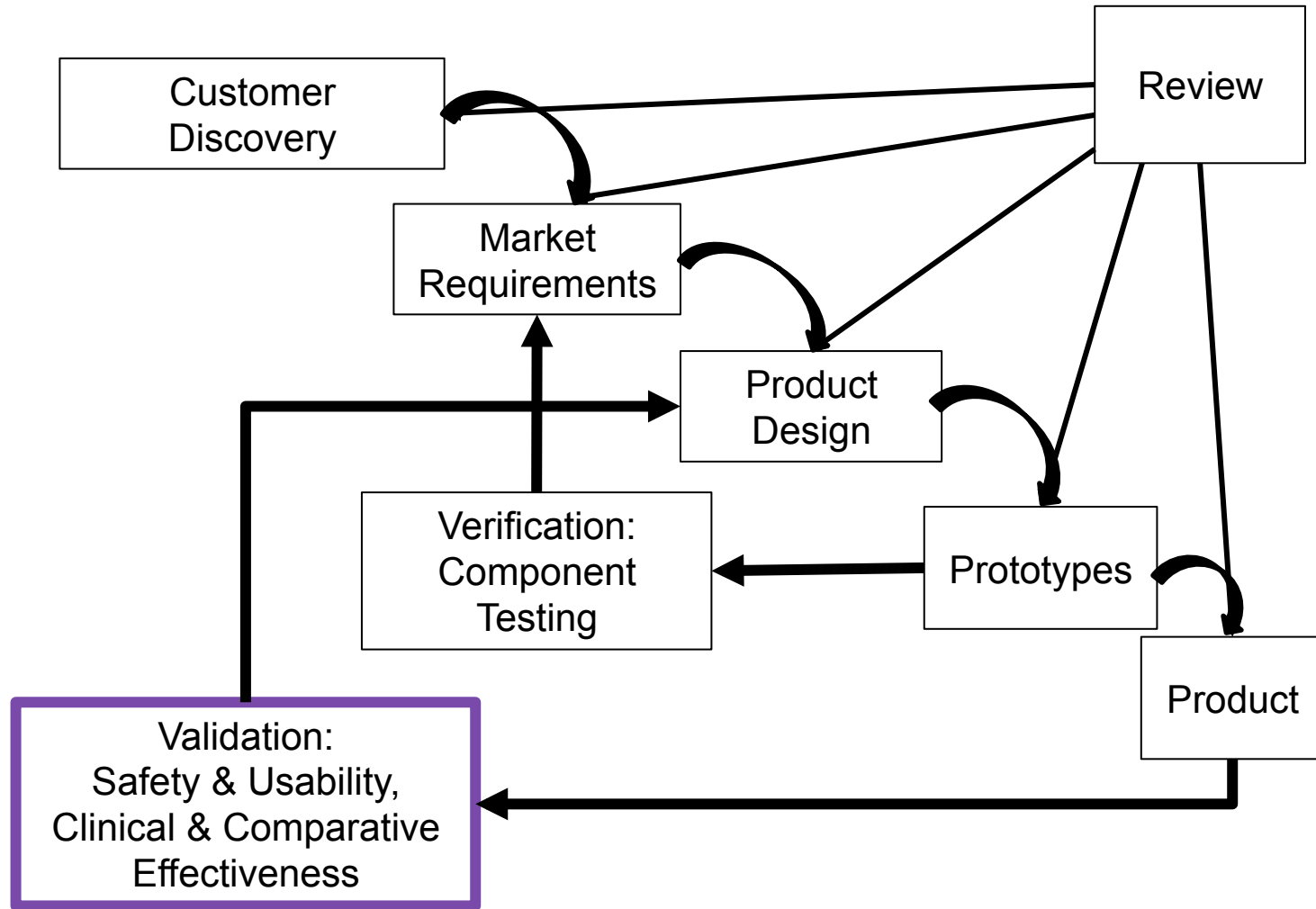


# Safety & Usability Testing

- **Safety & Usability Testing** involves systematic, controlled observation of users to test whether they can use the product as intended, safely and with ease.
- In contrast, to validate that the product meets needs of users, customers and buyers, we recommended focus groups, interviews, and surveys.



# Design Process



Adapted from Application of Design Controls to Waterfall Design Process. Source: Medical Devices Bureau, Health Canada



# Goal

Test that the technology is...

**Safe**

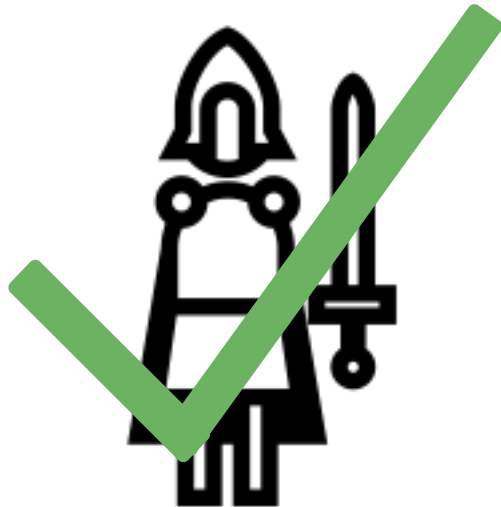




# Goal

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**Safe**

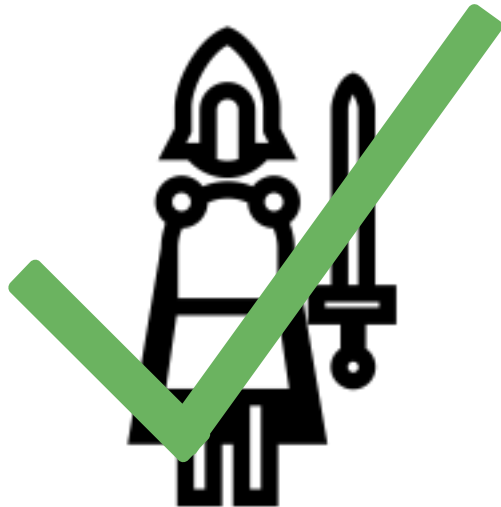




# Goal

Test that the technology is...

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**&**

**Usable**



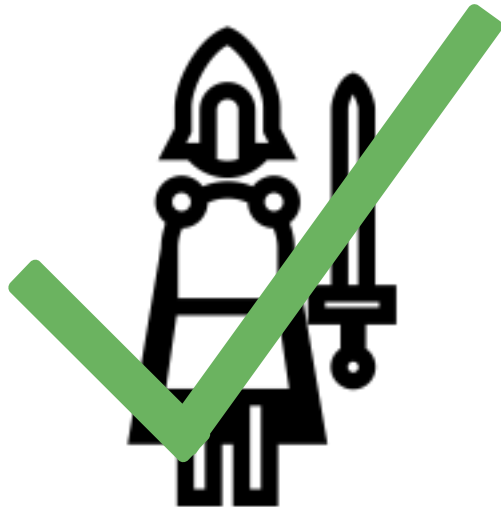




# Goal

Test that the technology is...

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**&**

**Usable**

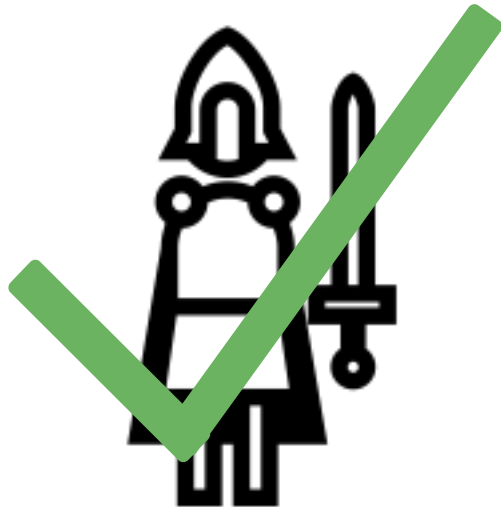




# Goal

Test that the technology is...

**Safe**



**&**

**Usable**



for it's **Intended Use**, by the **Intended User**.



# Connecting Development Pathways

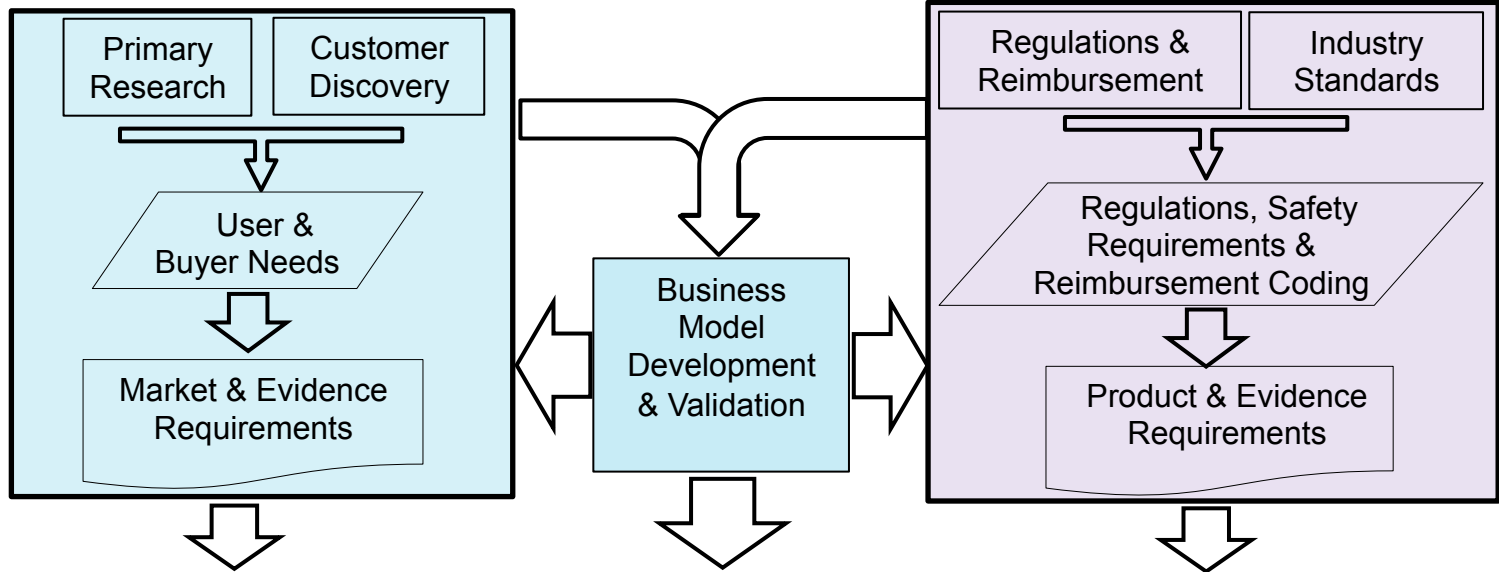
**Main Business Development Pathway**

**Main Product Development Pathway**

**Main Evaluation Pathway**



# Connecting Development Pathways

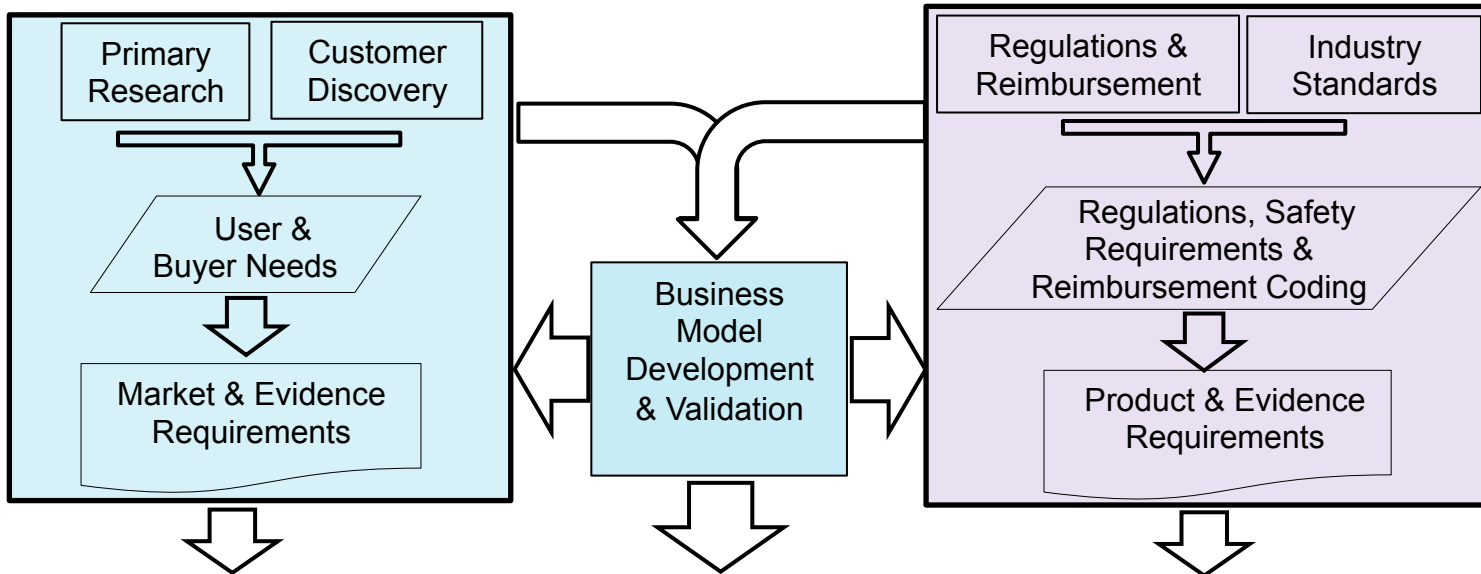


**Main Product Development Pathway**

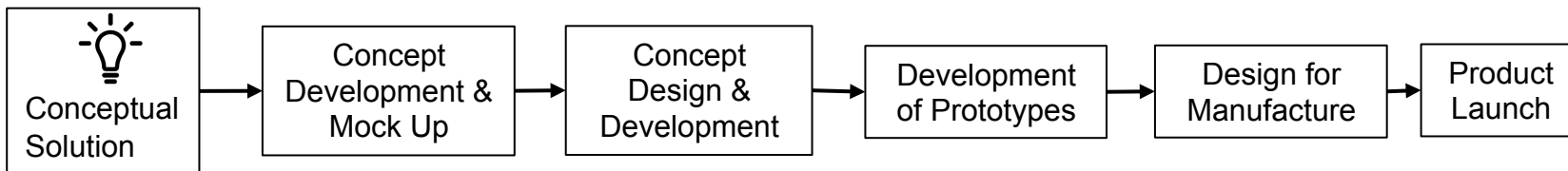
**Main Evaluation Pathway**



# Connecting Development Pathways



## Main Technology Development Pathway



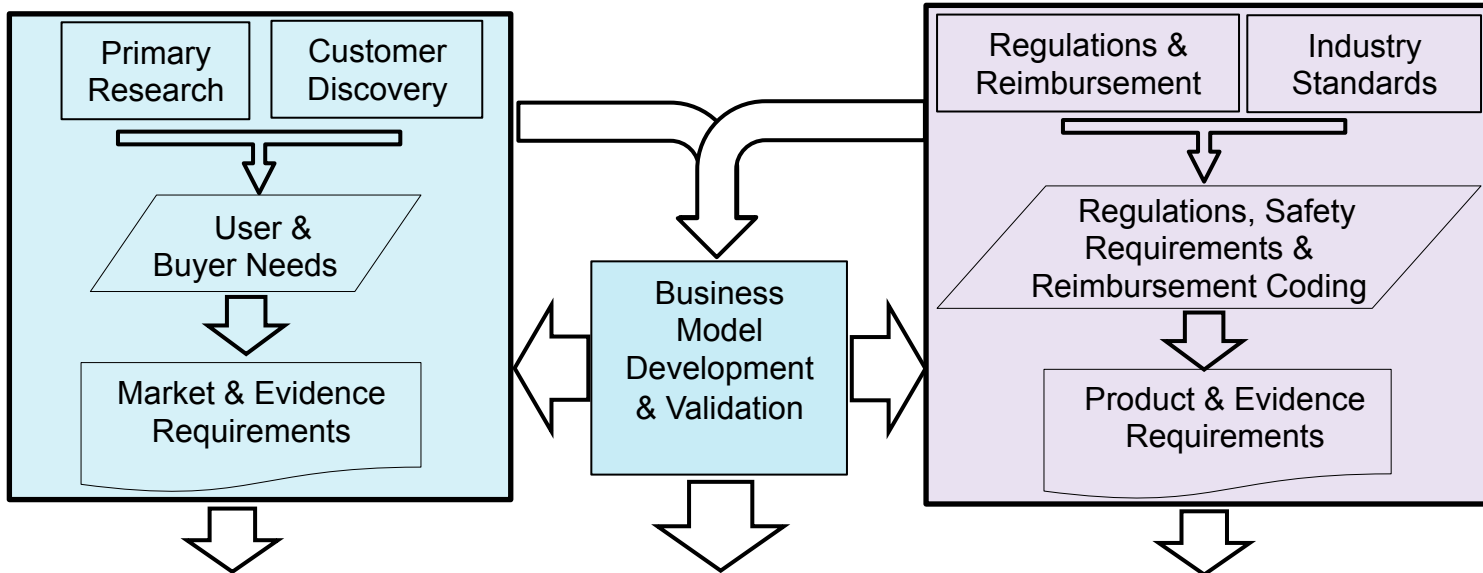
## Main Evaluation Pathway



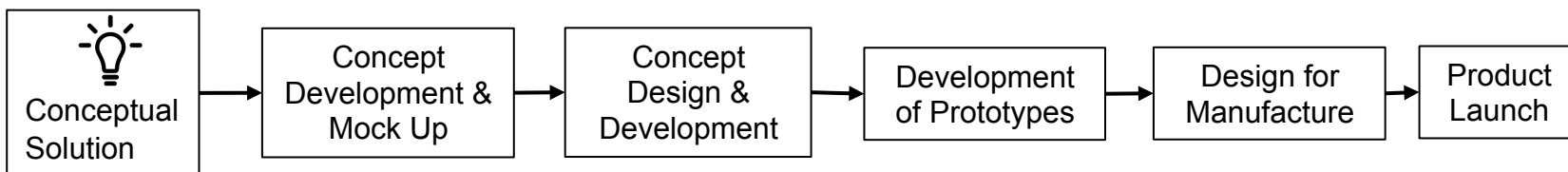
# Connecting Development Pathways



Research & Stakeholder Input



Main Technology Development Pathway

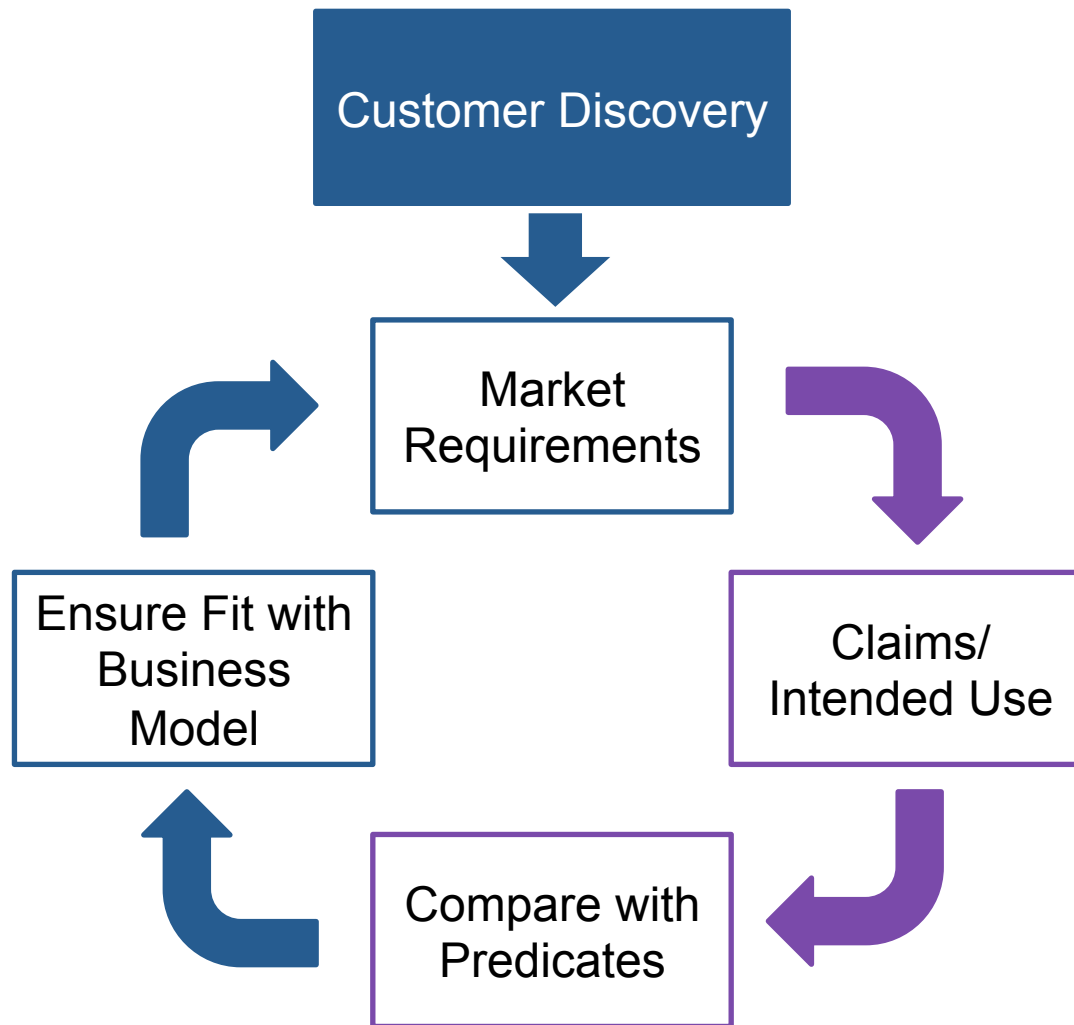


Evaluation Activities



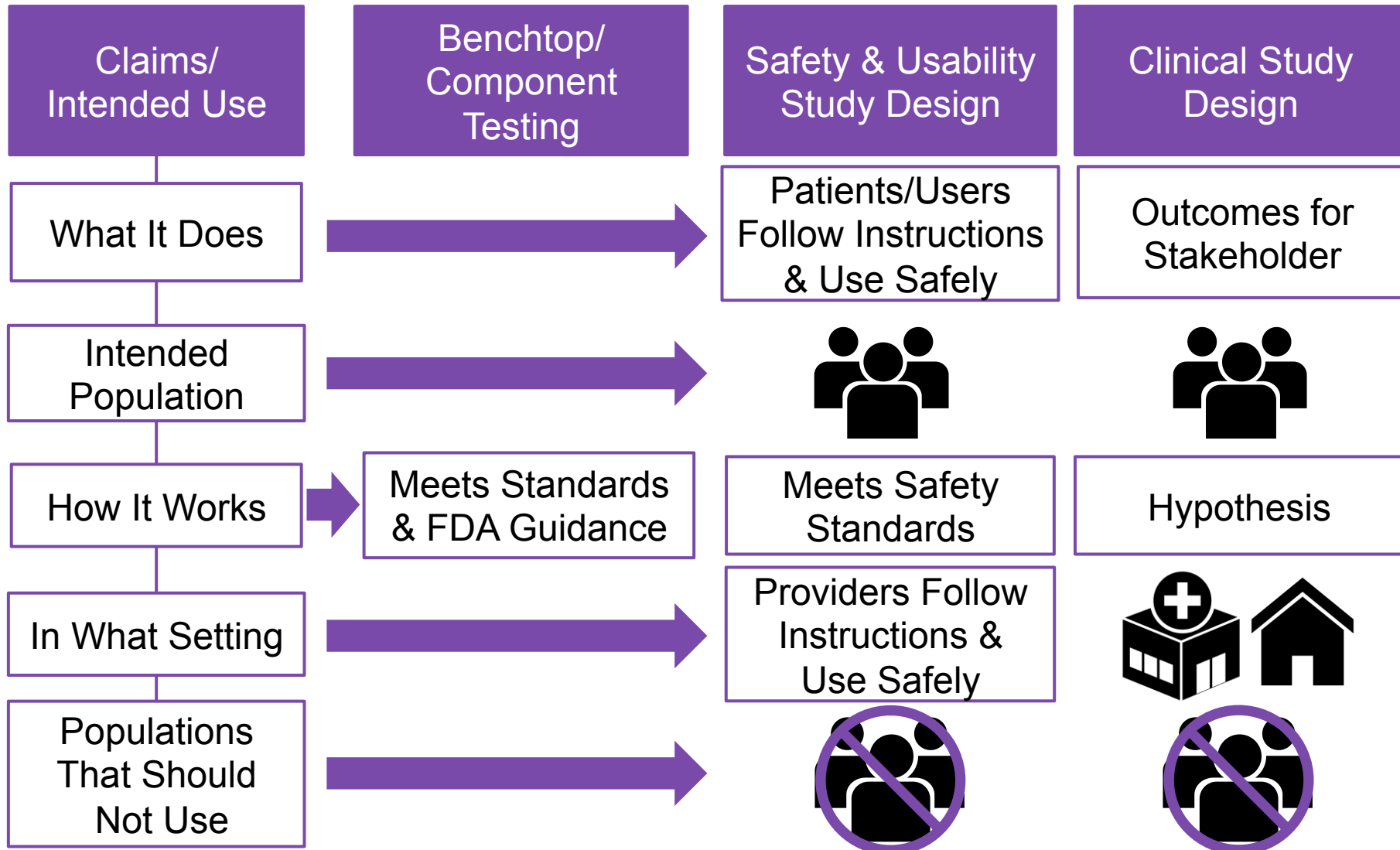


# The Iterative Decision Making Process





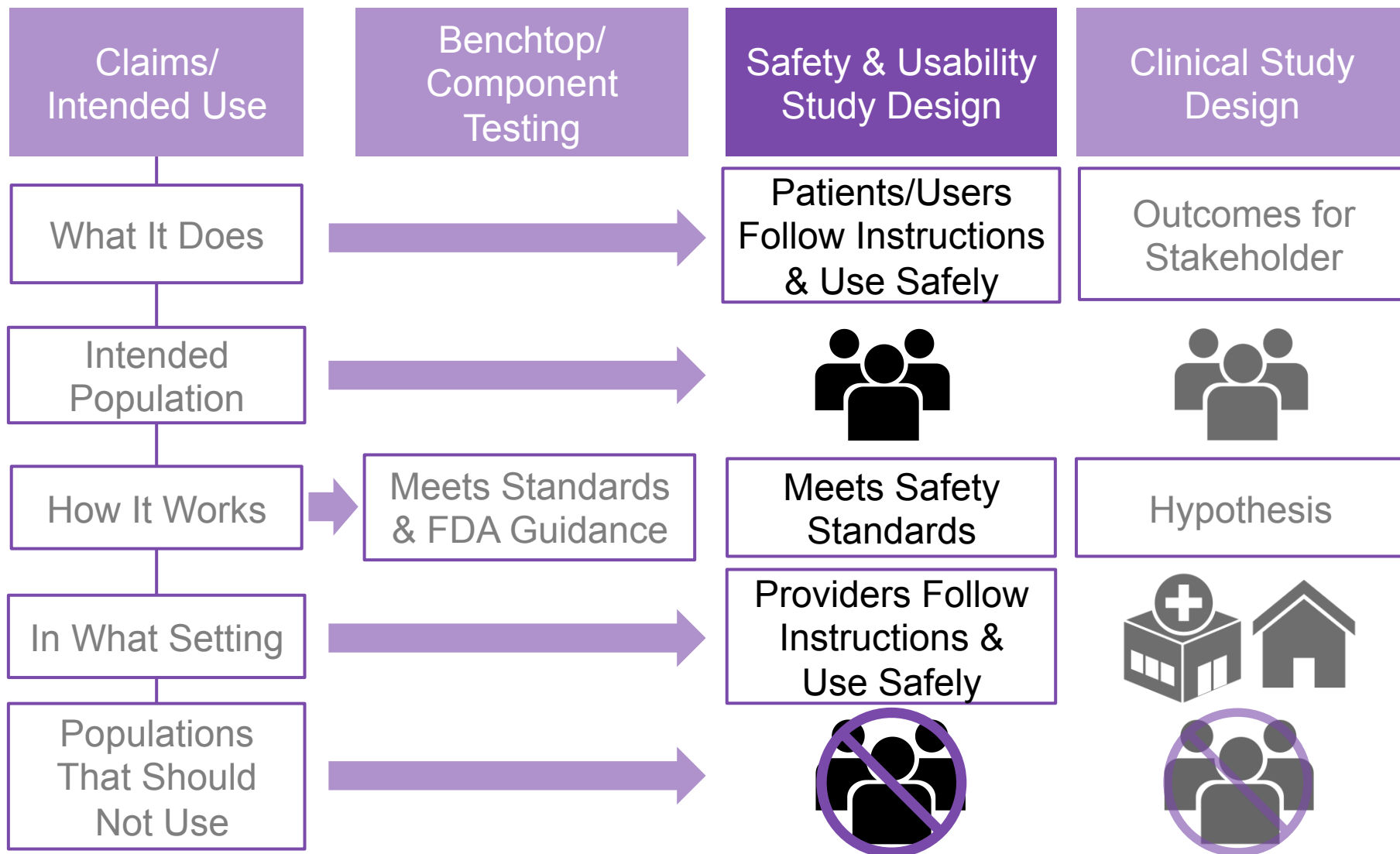
# The Decision Making Process: Evaluation







# The Decision Making Process: Evaluation





# Sample Questions

- Can the user
  - read the labeling?
  - open/apply the product?
  - perform the necessary steps to adjust/fit the product?
  - perform the necessary steps to complete the desired action with the product?
- How would you measure success/failure?
  - Timed completion
  - Performance measures
  - Document evidence of difficulty



# Resources

- **[Device Advice](#)**: Device Regulation and Guidance  
This website provides comprehensive technical and regulatory information about FDA requirements for medical devices.
- **[Division of Industry Education \(DICE\)](#)**  
DICE answers questions from the medical device industry and develops educational resources to help the medical device industry understand FDA regulations and policies.
- **[MEDICAL DEVICE REGULATIONS: Global overview and guiding principles](#)**
- **[Frequently Asked Questions \(FAQs\) at FDA](#)**  
Addresses medical device basics, the device review process, information about devices, and device safety.



# Next Steps

- Consider if **Safety & Usability Testing** is necessary for your technology
  - Identify **Relevant Questions** to answer
    - Develop potential **study designs** to answer questions
  - Determine when in development testing must be completed



# Wrap Up

- Estimated Completion Date:

- Return Deliverable: **Draft Research Questions for Safety & Usability**

- Next Meeting Date: