Clinical Research Education Series 2019

# Steps to Market Medical Devices or Diagnostic Tests

Presentation will begin at 11:45AM

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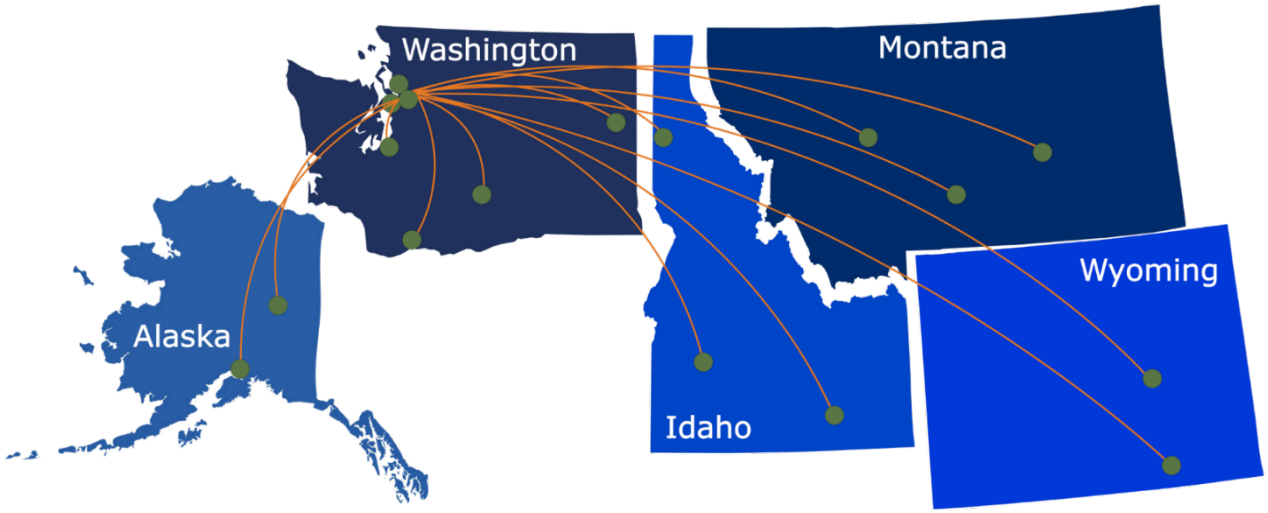


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# Contact our **Research Navigator**

- **Project Consultation**
- **Strategic Direction**
- **Resources and Networking**

**Melissa D. Vaught, Ph.D.**
**ithsnav@uw.edu**
**206.616.3875**

# Feedback

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.

# Steps to Market Medical Devices or Diagnostic Tests

Presented by Dr. Terri Butler, PhD
ITHS Drug & Device Advisory Committee

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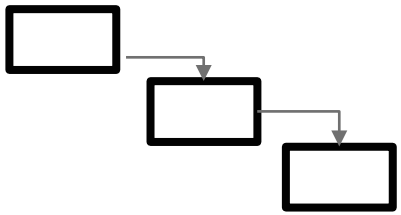
# Learning Objectives

1. Identify steps to bring a product to market
2. Identify expertise needed to bring a product to market
3. Identify challenges to bring a product to market

# BRINGING PRODUCTS TO MARKET: MEDICAL DEVICES AND DIAGNOSTICS

## Steps To Market

- Commercializing a biomedical product



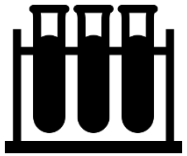
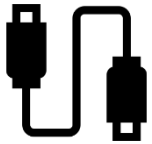
## FDA Regulatory Requirements

- Legal and regulatory framework
- How to research FDA requirements and databases
- Examples of recent regulatory submissions

## Prototyping to Production

- Prototyping process
- Design controls
- Production
- L:aunch

# FDA Overview of categories of regulated products

| Drugs | Biologics | Medical Devices | Diagnostics | Digital Health Tools | Clinical Decision Support Tools |
|---|---|---|---|---|---|
|  |  |  |  |  |  |
| *Therapeutics: small molecule, repurposed* | *Antibodies, vaccines* | *Implanted devices, external devices* | *Laboratory, point-of-care, or home-based kits* | *Monitoring, therapeutic, control systems* | *In clinic standard of care information systems* |

## Primary Concerns: Safety and Efficacy

# Steps to Market

1. **Is there a true need?**
2. **Business model?**
3. **FDA requirements?**
4. **Prototype to production**

# Steps to Market

Discovery or Unmet Need

!

Possible New Product or Service

"Customer Discovery" Validate the need

# Steps to Market: Is there a True Need?

"Customer Discovery"
Validate the need

**Talk to 100+ people!**
**Continually update!**

Who will benefit?

*Patient*
*Physician*
*Hospital Administration*
*Insurer/employer*

Current alternatives?

*Current practices*
*"Do nothing"*
*Side effects*
*Cost issues*

Up and coming alternatives?

*Alternatives in the works*
*Comparison to your approach*
*Timing to market*

# Steps to Market

√ 1. **Is there a true need?**
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# Steps to Market

Discovery or Unmet Need

!

Possible New Product or Service

"Customer Discovery" Validate the need

Business Model

# Steps to Market: Business Model?


Patentable?

*Novel*
*Non-Obvious*
*Useful*
*Prior art*

Regulatory requirements?

*Category of product*
*Risk*
*Prior use in humans*
*Clinical trial requirements*

Who will pay for it?

*Insurer*
*Hospital or clinic*
*Included in procedure*
*Added cost*

# Steps to Market: Business Model?

Business Model

Team members?

*Clinical expertise*
*Regulatory expertise*
*Product development expertise*
*Business experience*
*Legal advice*
*…more*

Distribution channels?

*Large companies?*
*Targeted distributors?*
*Direct to patient?*

Development partners?

*Device design shops*
*Manufacturing partners*
*Large device companies*

# Steps to Market: Business Model?

**Now you know…**

- **WHAT your product will do.**
- **WHO wants your product.**
- **Who will PAY for your product.**

# Steps to Market

√ 1. **Is there a true need?**

√ 2. **Business model?**

3. **FDA requirements?**

4. **Prototype to production**

# Steps to Market: FDA Requirements

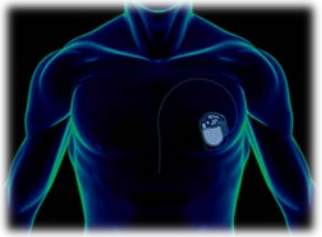
## Medical Devices

Bandage

Tongue depressor

Artificial limb

Pacemaker

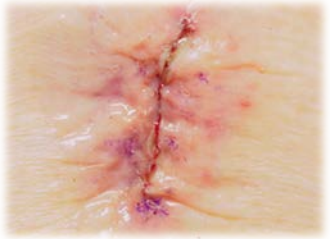


Blood Pressure Cuff

Surgical robots

Dental materials

Surgical glues



# Steps to Market: FDA Requirements

## FDA History

1820 First pharmacopeia

1902 Pure Food and Drug Act

- Prohibits interstate transport of adulterated and misbranded food and drugs

1912 Sherley Amendment

- Prohibits false therapeutic claims

1938 Federal Food, Drug, and Cosmetic Act

- New drugs must be shown to be safe, authorized factory inspections

**1976 Medical Device Amendment**

- Must register device with the FDA and follow quality control procedures

1980 Safe Medical Devices Act

- Hospitals and other facilities must report medical device related incidents causing death or serious injury

2016 21st Century Cures Act

- Accelerate medical product development, patient perspectives

# Steps to Market: FDA Requirements

## FDA CDRH

## Center for Devices and Radiological Health

**Learn:** https://www.fda.gov/training-and-continuing-education/cdrh-learn

### Radiation-emitting devices, medical and non-medical

- Medical analyzers, cauterizing lasers, medical scanning devices
- Ultrasonic cleaners, microwaves, TVs, black lights, welding equipment…

### Medical Devices

- Classes I-III, low to high risk
- Surgical devices, dental devices, implants, 3D printed devices…

### In-Vitro Diagnostics

- Companion diagnostics, Direct-to-consumer, Drugs of Abuse, Home Use, Precision Medicine…

# Steps to Market: FDA Requirements

## Medical Device

https://www.fda.gov/medical-devices/classify-your-medical-device/product-medical-device

**"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:**

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals…"

# Steps to Market: FDA Requirements

## Medical Device

**Medical Device Manufacturers must:**

- Establishment registration – manufacturing and distribution sites
- Medical Device Listing – products made
- Premarket Notification (unless exempt) or Premarket Approval
- Investigational Device Exemption (IDE) for clinical studies – allows device to be used in clinical studies to support an FDA submission
- Quality System
- Labeling Requirements
- Medical Device Reporting

# Steps to Market: FDA Requirements

## Medical Device Classes

https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels

**Class I:** low risk

- Most are exempt from filing 510(k) premarket notification (some exceptions). Examples: bandages, patient scale, ice bag, gas pressure gauge

**Class II:** medium risk

- Most need to file 510(k) premarket notification (some are exempt). Examples: mercury thermometer, electrically powered spinal fluid pressure monitor, acupuncture needle

**Class III:** high risk

- Premarket Approval (PMA) more rigorous application. Clinical study data likely required.

# Steps to Market: FDA Requirements

## Medical Device Premarket Notification 510(k)

https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels

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# Steps to Market: FDA Requirements

## Medical Device Premarket Notification Exempt

### FDA List of Exempt Class I & II Devices:

No premarket notification needed but do need to register establishment that is manufacturing or distributing device.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm

Examples:

| Exempt | Non-exempt |
|---|---|
| Cell culture supplies | Microbial growth monitor |
| Centrifuge | Bilirubin test system |
| Enzyme preparations | Liquid bandage |
| Elastic bandage | Hot or cold disposable pack |
| Microbiological incubator | Mechanical wheelchair |

# Steps to Market: FDA Requirements

## Medical Device Premarket Notification

## 510(k) Process

Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. **This order "clears" the device for commercial distribution.**

Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalence claims.

# Steps to Market: FDA Requirements

## Medical Device Premarket Notification

## 510(k) Process

**Substantially Equivalent**

Same intended use AND same technological characteristics

OR

Same intended use AND different technological characteristics and does not raise different questions of safety and efficacy AND information submitted to FDA demonstrates device is at least as safe and effective as legally marketed device.

**Does not need to be identical.**

# Steps to Market: FDA Requirements

## Medical Device Premarket Notification
## 510(k) Process

### Flowchart and overview of 510(k) process

- https://www.fda.gov/media/82395/download

### Find a predicate device

- https://www.fda.gov/medical-devices/premarket-notification-510k/how-find-and-effectively-use-predicate-devices
- Search similar devices – names, manufacturers, uses
  - Classification into medical specialty “panels”
    - https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels
  - 3-letter product code

# Steps to Market: FDA Requirements

## Medical Device

### Searching FDA Medical Device Databases:

- https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

### 510(k) Clearances

- https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

# Steps to Market: FDA Requirements

## Medical Device Premarket Notification
## 510(k) Process

**Example**

Sept 2019 Clearances

https://www.fda.gov/medical-devices/510k-clearances/september-2019-510k-clearances

INTAI Technology Corporation Surgery Navigation System

https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180523.pdf

# Steps to Market: FDA Requirements

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**Class III:** high risk

- Premarket Approval (PMA) more rigorous application. Clinical study data likely required.

# Steps to Market: FDA Requirements

## Medical Device Premarket Approval - PMA

- Class III medical devices
- Support or sustain life – high level of risk
- Most stringent application type
- May be new type of device not yet in PMA database
- Need a lot of information submitted in modules under a "PMA shell:"
  - Module 1: Device description, nonclinical studies
  - Module 2: Nonclinical studies, device validation/verification
  - Module 3: Manufacturing information
  - Final Module: All previous modules plus clinical data, financial disclosure, proposed labeling

# Steps to Market: FDA Requirements

## Medical Device Premarket Approval - PMA

### Example

Medtronic MiniMed Insulin Pump

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150001

Summary of Safety and Effectiveness

https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150001B.pdf

Labeling

https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150001C.pdf

Approval Order

https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150001A.pdf

# Steps to Market: FDA Requirements

## Medical Device PMA

### Examples of New Technology Medical Devices 2019

https://www.fda.gov/medical-devices/recently-approved-devices/2019-device-approvals

### Cochlear Implant

https://www.fda.gov/medical-devices/recently-approved-devices/med-el-cochlear-implant-system-p000025s104

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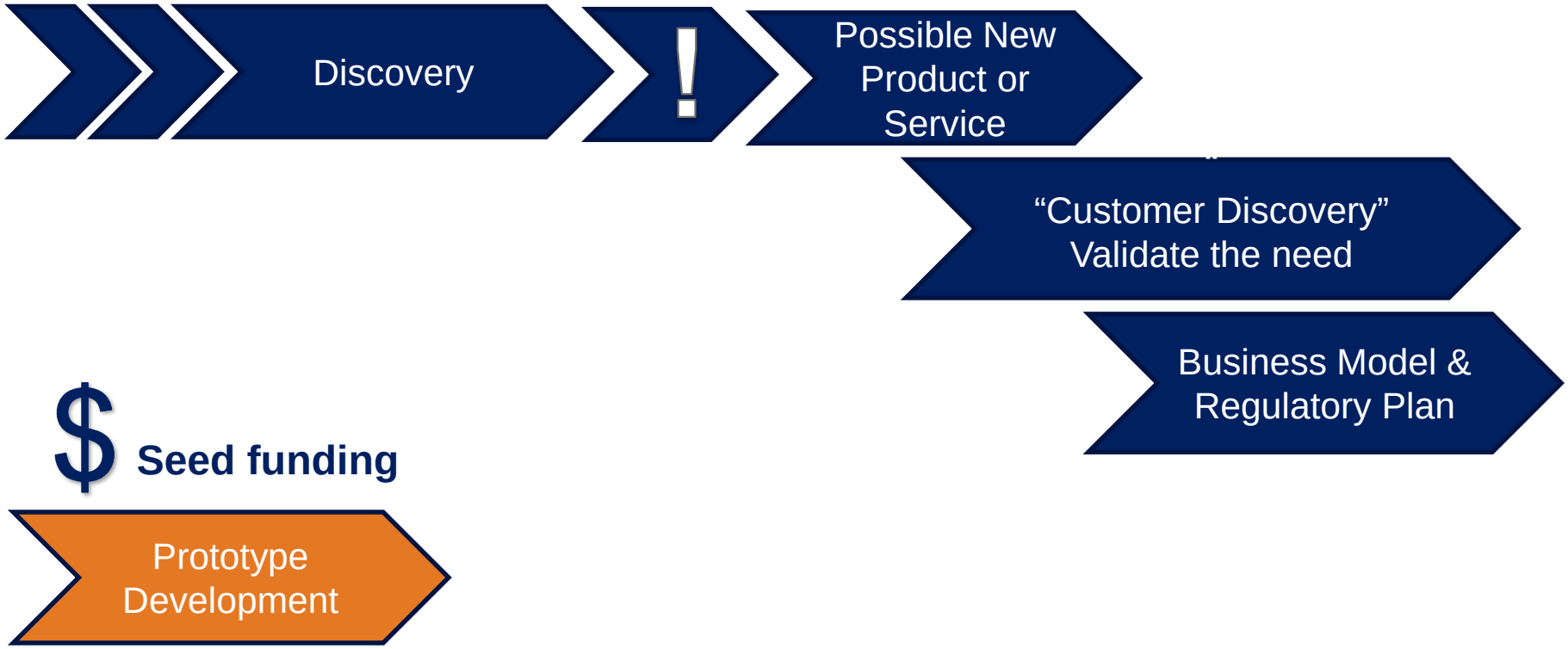
# Steps to Market



# Steps to Market: Prototype to Manufacturing

Prototype Development

- **Images/mockups (1 unit)**
- **Quick prototype build to demonstrate feasibility, components, cost estimates (1 unit)**

# Steps to Market: Prototype to Manufacturing


- Images/mockups (1 unit)
- Quick prototype build to demonstrate feasibility, components, cost estimates (1 unit)
- **“Real” product prototype for testing, user input (1-5 units)**
- **Refined product prototype for user testing and clinical trials (1-5 units)**

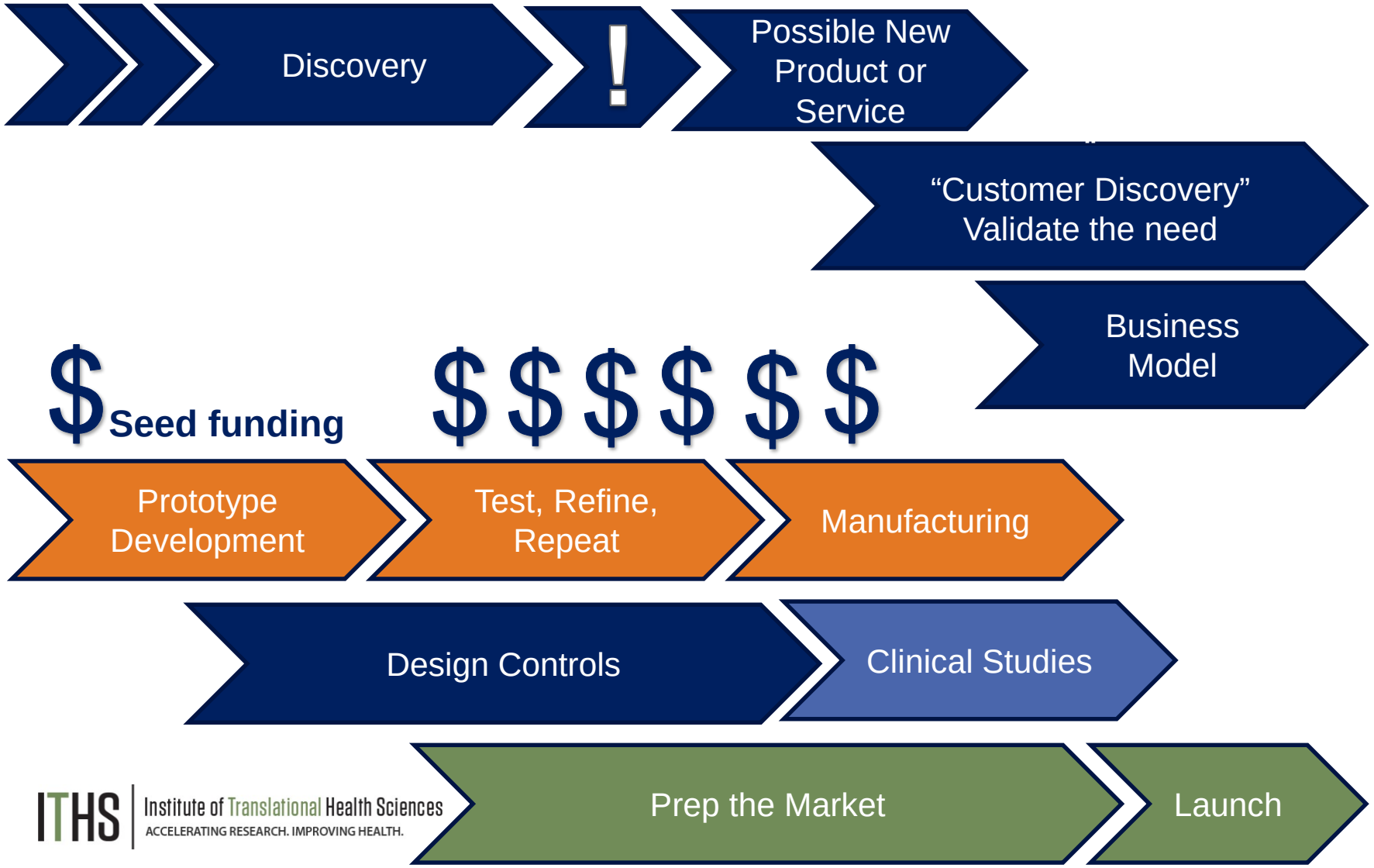
# Steps to Market: Prototype to Manufacturing


- Images/mockups (1 unit)
- Quick prototype build to demonstrate feasibility, components, cost estimates (1 unit)
- “Real” product prototype for testing, user input (1-5 units)
- Refined product prototype for user testing and clinical trials (1-5 units)
- **Pilot production soft launch working to scale (30-100 units)**
- **Full production of final product (10,000 – 1M units)**

# Steps to Market: Design Controls Documentation


- Project Proposal, User Requirements Specs
- Project Development Plan, User Requirement Specs, Hazardous Situation List, Software Development Plan, Block Diagrams
- Component and Software Requirements Specs, Hazard Situation Assessment, Design History File, early Device Master Record, FDA pre-submission meeting
- Device Master Record, Component Verification Specs and Requirements, Software Verification Specs and Requirements, Risk Management Report, Verification and Validation Protocols, Manufacturing Procedures, Test Plans
- File 510(k), update Device Master Record, Risk Management Reports, Verification and Validation Reports
- Post market Surveillance and Reporting

# Steps to Market



# Steps To Market

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# Drug and Device Advisory Committee

## REGULATORY REQUIREMENTS ADVISORY PROGRAM


**Supporting investigators who are taking their research from bench to bedside.**

- Contact Terri Butler, PhD, TLButler@uw.edu
- Committee formed in 2008
- 11-15 members
- Industry experience
- Assisted 130+ teams in past 10 years
- Experience in:
  - National and international regulations
  - Preclinical requirements
  - Clinical study design
  - Manufacturing scale up
  - Marketing requirements
  - Partnerships

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# Questions?


## Terri Butler, PhD

TLButler@uw.edu


https://www.iths.org/investigators/services/prd/ddac/

# Thank You

Open for Questions

# Feedback Survey

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.

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