

# NUCATS & INVO Translational Research Office Hours

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*Northwestern University Clinical and Translational Sciences Institute (NUCATS), and the  
Innovation + New Ventures Office (INVO)*

**March 26, 2025**

**PRESENTER:**

Katie Hammond- Center for Clinical Research

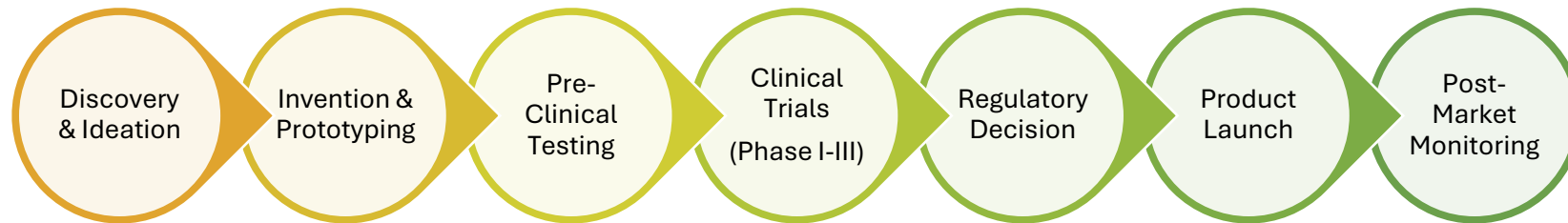
**Please register here:**



# NUCATS & INVO Translational Research Office Hours

## (NITRO)

**NUCATS** and **INVO** are pleased to host monthly collaborative office hours, designed to support academic innovators across the Northwestern University campus.



Office hours are hosted the **last Wednesday of every month, between noon and 1 p.m.** Office hours are held in a hybrid format, with both an in-person location and a virtual Zoom room.

- The first 20 minutes will consist of educational content surrounding translational research and commercialization.
- Following the education session, standing topics will include current commercialization resources and programs at the university, as well as funding opportunities.
- The remaining time will be devoted to questions and discussion, include time for individual conversation.

# NUCATS & INVO Translational Research Office Hours

## 2025 Schedule

Date & Time	Location & Link	Presentation Topic (first 20 minutes)
February 26, 2025 12 – 1 pm	McGaw 2-321 <a href="#">Zoom and Registration Here</a>	<b>Protecting your intellectual property</b> Lindsay Stolzenburg, Senior Invention Associate, INVO
March 26, 2025 12 – 1 pm	SQBRC 2-200 <a href="#">Zoom and Registration Here</a>	<b>Pre-consulting workshop and the Center for Clinical Research</b> Katie Hammond, Managing Director, CCR, NUCATS
April 30, 2025 12 – 1 pm	SQBRC 2-200 <a href="#">Zoom and Registration Here</a>	<b>Licensing and Startup 101</b> Katie Butcher, Director License Strategy & Business Development, INVO
May 28, 2025 12 – 1 pm	SQBRC 2-200 <a href="#">Zoom and Registration Here</a>	<b>Biostatistics Collaboration Center</b> Leah Welty, Director, BCC
June 25, 2025 12 – 1 pm	SQBRC 2-200 <a href="#">Zoom and Registration Here</a>	<b>Patient Engagement/Advocacy and the Consortium for Technology &amp; Innovation Pediatrics</b> Juan Espinoza, Director, CTIP
July 30, 2025 12 – 1 pm	SQBRC 2-200 <a href="#">Zoom and Registration Here</a>	<b>Chicago Biomedical Consortium</b> Michelle Hoffmann, Executive Director, CBC Eric Schiffhauer, Senior Director of Translation, CBC

# Pre-FDA Consulting Workshop

## Center for Clinical Research



# Agenda

- Center for Clinical Research
- Devices, Drugs, Software & Apps
  - Definitions
  - Regulatory Milestones
  - Devices
    - Risk Determination
    - Regulatory Controls
    - Class & Submission Types, Estimated Timelines
    - 510(k) pathway
- Consultancy Support
- Funding Opportunities

# Center for Clinical Research

- **Centralized Support for Clinical Research:**  
The Center for Clinical Research (CCR) provides essential, centralized services to streamline the clinical research process, reduce investigator burden, and ensure the highest quality and efficiency of all programs.
- **Key Service Units:**
  - Clinical Research Unit
  - Regulatory & Finance
- **Additional Resources:**
  - Trial Innovation Network
  - Recruitment
  - ClinicalTrials.gov



**Anju Peters, MD**  
Director



**Katie Hammond, MBA, CCRP**  
Managing Director

# Devices, Drugs, Software, & Apps

FDA definitions in an evolving landscape...

## Drug



- Intended for use in the **diagnosis, cure, mitigation, treatment, or prevention** of disease.
- Intended to **affect the structure or any function of the body**.
- Recognized by an official **formulary**.
- Intended for **use as a component of a medicine** but not a device, or a component, part or accessory of a device.
- **Biological products** are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

## Device



- An **instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article**, including...
1. 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
  2. Intended to **affect the structure or any function of the body** of man or other animals
  3. **A component part or accessory** which is recognized in an official **formulary**, or the United States Pharmacopoeia or any supplement to them

## Software



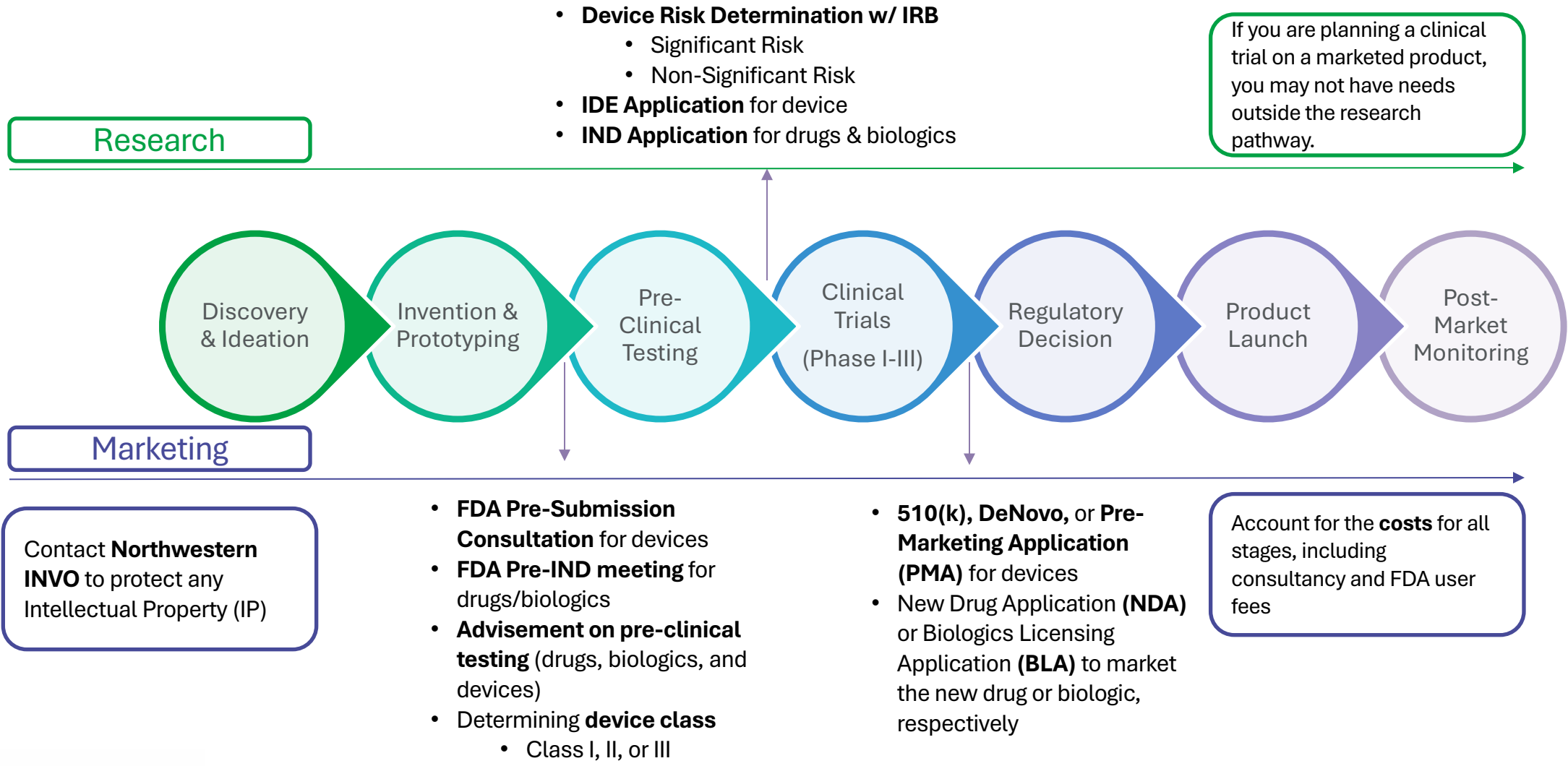
1. Software **as** a medical device (**SaMD**)
  - Regulated like traditional medical devices.
  - Examples include ECG analysis software, AI-driven radiology applications, and remote patient monitoring apps.
2. Software **in (or integral to)** a medical device. (**SiMD**)
  - Example include software that controls an MRI machine, heart rate monitoring apps, and software that analyzes medical images to aid in diagnosis.
3. Software used in the **manufacture or maintenance** of a medical device.

## Apps



- Mobile **medical apps** are those intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease (device)
1. **Diagnostic** apps that analyze medical data or images.
  2. Patient **monitoring** apps that track health parameters and provide feedback.
  3. Apps that use a mobile platform's built-in features (like light, vibration, camera) **to perform medical device functions**.
  4. Apps that control or analyze data **from regulated medical devices**.
- FDA has Enforcement Discretion\* for even minimal risk apps

# Regulatory Milestones





# Device Risk Determination

## Research Regulation

- For use in supporting or sustaining human life.
- For use of a sustaining importance in diagnosing, curing, mitigating, or treating disease.
- Is intended as an implant and presents a potential for serious risk to the health, safety, and welfare of a subject.
- Otherwise, presents a potential for serious risk to a subject.

*\*Proposed use*

Significant Risk  
(SR) Device



- Does not meet the category of significant risk.
- [Use IRB Checklist 418- Non-Significant Risk Devices](#)
- With IRB approval, is considered to have an approved IDE; referred to as an **Abbreviated IDE**.

Non-Significant  
Risk (NSR) Device



- Using FDA approved device to test a physiologic principle where no data is collected about the device.
- Using an FDA approved device to address a research question, and no data is collected about the device.
- Using an FDA approved device for clinical purposes.
  - Non-diagnostic device without confirmation of an approved diagnostic.

Exempt from IDE  
Requirements

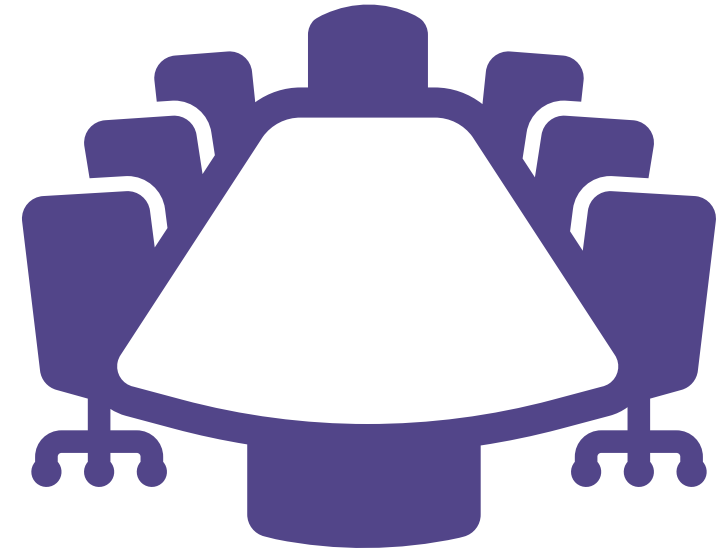


# Device Risk Determination

## Research Regulation

### Local Process

1. Sponsor or Sponsor-Investigator makes initial risk determination.
2. Risk Assessment is presented to IRB panel & reviewed at a convened meeting.
3. If IRB should disagree with a NSR determination, the PI may be asked to contact the FDA to obtain an IDE.



# Device Class Determination

## Marketing Regulation

Think about **Intended Use** from the beginning and if you are making a specific claim about your device (Class I vs. II)

Class	Risk	Potential Harm	Regulatory Controls	Submission Type	Approx % of Devices in Class
I	Lowest	Present minimal potential for harm <b>Examples:</b> Scalpels, Dental Floss, Exam Gloves. <b>Timeline (Submission to approval):</b> <1 month (2017 est.).	General Controls	<ul style="list-style-type: none"> <li>• <b>510(k) exempt</b></li> <li>*97% are exempt</li> <li>• DeNovo (no predicate)</li> <li>• 510(k)</li> </ul>	47%
II	Moderate	Higher risk than Class I devices FDA clearance based on “substantial equivalence” to a legally marketed device (predicate) <b>Examples:</b> Infusion pumps, absorbable sutures, powered wheelchairs <b>Timeline (Submission to approval):</b> 6-9 months	General & Some Special Controls	<ul style="list-style-type: none"> <li>• <b>510(k)</b></li> <li>• DeNovo (no predicate)</li> <li>• 510(k) exempt</li> </ul> <p>*Only 8% exempt 10% of submissions require clinical trial data or real-world evidence</p>	43%
III	Highest	Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Most complex, novel intended uses <b>Examples:</b> implantable pacemakers and breast implants <b>Timeline (Submission to approval):</b> 18-30 months	General and Special Controls	<ul style="list-style-type: none"> <li>• <b>PMA</b></li> </ul> <p>*Most require Clinical Trial(s) data</p>	9%

# Predicate Devices & the 510(k) Pathway

## Marketing Regulation

### Definition

- A Premarket Notification [510(k)] is a premarketing submission made to FDA to demonstrate that the device to be marketed is safe and effective by proving substantial equivalence (SE) to **a legally marketed device (predicate device)** that is **not** subject to Premarket Approval (PMA).
  - Usually utilize recently cleared devices under 510(k)
  - However, any legally US marketed device can serve as a predicate
  - This includes devices that were Class III and later down-classified

# Predicate Devices & the 510(k) Pathway

## Marketing Regulation

### Substantial Equivalence (SE)

- The legally marketed predicate
  - Same intended use **AND**
  - The **same technological characteristics or different**.
    - A claim of substantial equivalence **does not** mean the device(s) must be identical (provided you do not raise different questions of safety and efficacy).
- Substantial equivalence is established with respect to...
  - intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, biocompatibility, standards, and other applicable characteristics.

# Finding a Predicate

## Marketing Regulation



### Classification Methods

- 1) Search for an appropriate product classification
- 2) Search for a similar device by clearance or approval
- 3) Search for a similar device by device listing
- 4) [Section 513\(g\) Request](#) Appropriate when a formal product classification is requested. FDA response does not constitute approval or clearance

- [FDA Medical Devices: Product Classification Database](#)
- [FDA Medical Devices- 510\(k\) Premarket Notification Database](#)
- [FDA Medical Devices- Premarket Approval \(PMA\) Database](#)
- [FDA Medical Devices- De Novo Classification](#)
- [Establishment Registration & Device Listing](#)

# Regulatory Controls

## General & Special Requirements

### General Controls

- Applicable to all medical devices (any class)
  - Manufacturer Registration & Listing
  - Good Manufacturing Practices (GMP)
    - **21 CFR Pt. 820- Quality Management System (QMS)**
      - Includes Design Controls: Validation, Verification, & Review Process. How do you meet your own requirements, some of which are FDA general controls?
  - Reporting of Adverse Events & Recalls
  - Device Labeling Provisions
    - Prohibits misbranding, adulteration, false or misleading claims, sales of banned devices
  - Record Maintenance, Reports to the FDA

### Special Controls

- When General Controls are insufficient. May include...
  - Performance Standards
  - Special Labeling Requirements
  - Mandatory Performance Standards
  - Premarket Data Requirements
  - Post-market Surveillance

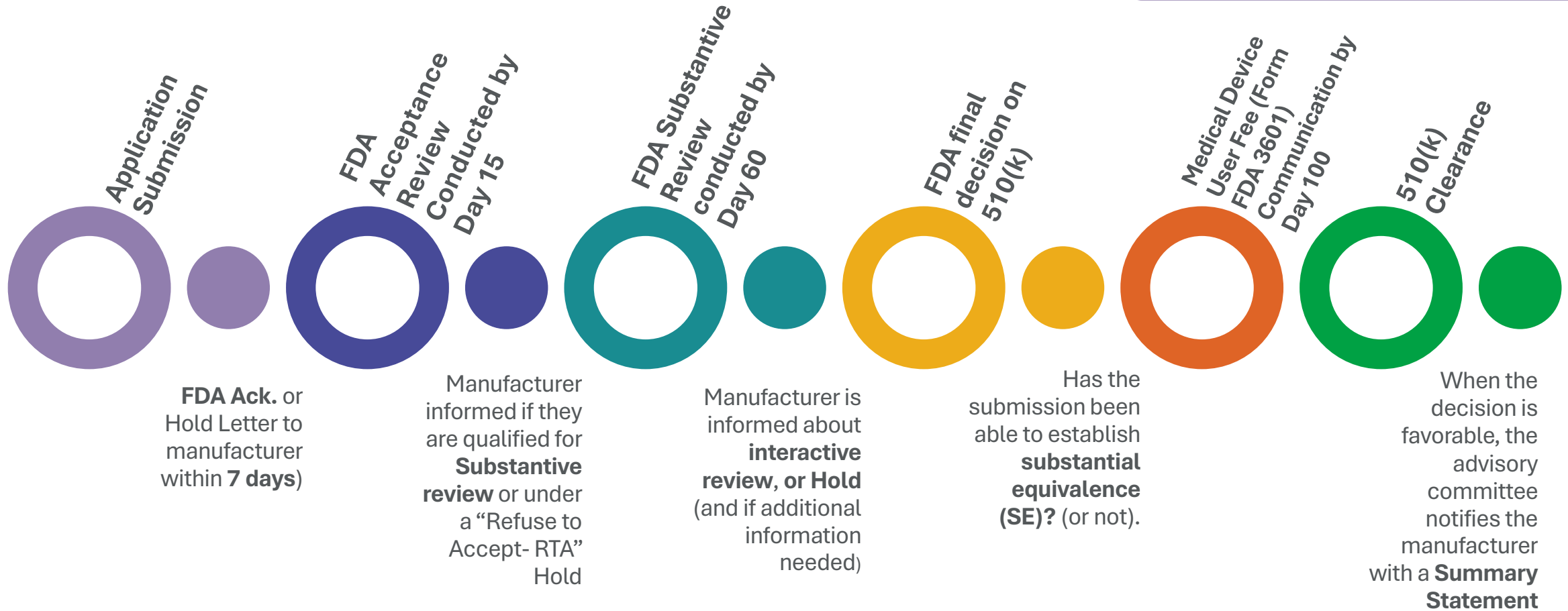
[FDA.gov: Special Controls](https://www.fda.gov/special-controls)



# Traditional 510(k) Process

## Premarket Notification

**Special 510(k):** modifications to an existing, legally marketing device  
**Abbreviated 510(k):** relies on FDA guidance documents, compliance data, or voluntary consensus for SE





# Consultancy Support

## Benefits



Timing



Regulatory  
Approach



Science



Submission  
Content



Expectations



Exit Strategy

# Consultancy Support



## How to find a consultant?

- 1) Look for in-house FDA experience
    - Experience in your specific area
  - 2) Regulatory Affairs Professional Society (RAPS)
    - Certified/Credentialed
  - 3) Industry/Corporation experience
    - Regulatory Affairs
- 3) NUCATS CCR- External FDA Consulting

# Consultancy Support



## Timing

- 1) Incorporate your regulatory strategy into your business planning from the very beginning.
- 2) You may be advised to utilize the simplest version of your device/innovation, even if it's not the version you intend to sell.



## Regulatory Approach

- 1) Small changes in device design or the target population can have major implications.
- 2) Closely monitor the FDA website and publications for new 510(k) & PMA approvals.
- 3) Hire a regulatory affairs consultant if you do not have the expertise on your team.

# Consultancy Support



## Science

- 1) Utilize product specific standards and guidance whenever possible. Document deviations.
  - Provide results (testing)
- 2) Large animal testing (if needed)
- 3) Key guidance and standards for software, bioavailability, sterilization, electrical safety
  - Example: GMP/GLP



## Submission Content

- 1) FDA e-Copy format is strict
- 2) 510-(k) “refuse to accept” criteria is strict. Include a table of contents
- 3) Be strategic with your data and have it tell a story vs. just providing the FDA with it.
- 4) The user-fee payment system is complex. Allow for extra time online.

# Consultancy Support



## Expectations

- 1) Have focused conversations with the FDA vs. general advice
- 2) Systematically address issues the FDA identifies.
- 3) Ensure a well-thought out, comprehensive submission
- 4) Every branch, office and reviewer has different communication standards

# Biologics Consulting®

## Advisement & Submission

- Teams can establish specific Statement of Work (SOWs), for their specific needs
- Work order pricing can be outlined to project milestones and timelines.
  - Please note that the costs of the consultancy fall to the responsibility of the investigator.
  - Investigators must secure adequate funding prior to signing an SOW.
  - Additionally, the consulting team is available for ad-hoc regulatory advisement.

## Subject Matter Expertise...

- CMC (Chemistry, Manufacturing, & Controls)
- Non-Clinical/Toxicology Data
- Clinical & Medical Writing Services
- Medical Devices
- Combination Products
- Regulatory Operations: E-Publishing & Submission
- [NUCATS External FDA Consulting- Link](#)



# Funding Opportunities



# Funding Opportunities

## Translational Research

- Cures Within Reach
- InQbation Lab
- N.XT Fund
- **NUCATS**
- Translational Science Pilot Awards
- Additional Pilot Funding
- Ryan Family Acceleration Fund
- Chicago Biomedical Consortium
- Accelerator Award
- CBC-HITES –



- FFMI fastPACE Fall 2024. University of Michigan: Week 3: Regulatory Considerations. “Medical Device Regulations Updated” & “Regulatory & Clinical Trials for Therapeutics”.
- FFMI fastPACE February 26, 2025. University of Michigan: Commercialization Education. “FDA Regulation of Medical Devices” (Parts 1-3). <https://www.youtube.com/watch?v=yZAG51ogVhE>, <https://www.youtube.com/watch?v=am7lluTS8nY>, <https://www.youtube.com/watch?v=gbpMTeWuryk>
- U.S. Food and Drug Administration. How is My Medical Device Classified. CDR Kimberly Piermatteo, MHA. Consumer Safety Officer. Division of Industry & Consumer Education. CDRH, FDA. December 15, 2020. <https://www.youtube.com/watch?v=YOFbLtjJppY>

## Citations