NUCATS & INVO Translational Research Office Hours

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The Center for Translational Innovation (CTI)

--- PART OF ---

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:

Northwestern University NUCATS Clinical and Translational Sciences Institute

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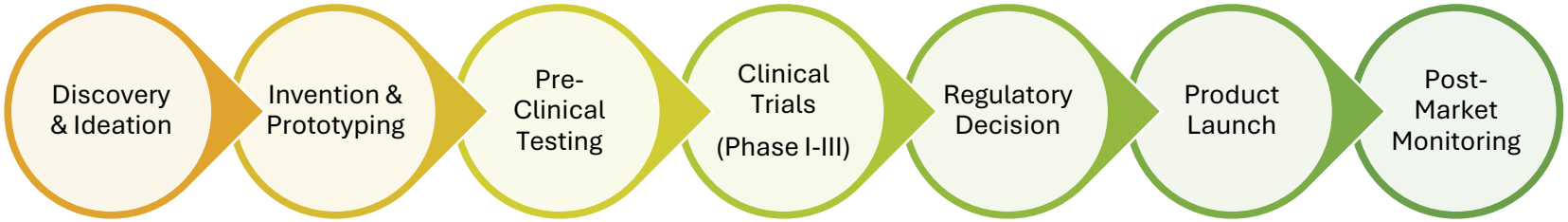
NUCATS & INVO Translational Research Office Hours

(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.

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2025 Schedule

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

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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

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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**.

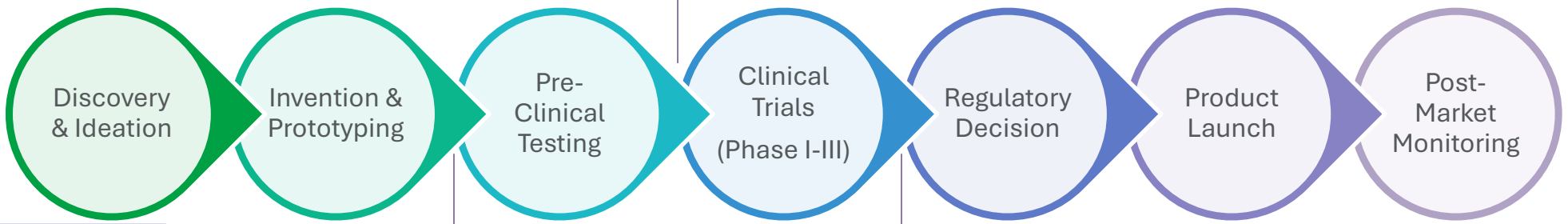
- FDA has Enforcement Discretion* for even minimal risk apps

Regulatory Milestones

- **Device Risk Determination w/ IRB**
  - Significant Risk
  - Non-Significant Risk
- **IDE Application** for device
- **IND Application** for drugs & biologics

If you are planning a clinical trial on a marketed product, you may not have needs outside the research pathway.

Research



Marketing

Contact **Northwestern INVO** to protect any Intellectual Property (IP)

- **FDA Pre-Submission Consultation** for devices
- **FDA Pre-IND meeting** for drugs/biologics
- **Advisement on pre-clinical testing** (drugs, biologics, and devices)
- Determining **device class**
  - Class I, II, or III

- **510(k), DeNovo,** or **Pre-Marketing Application (PMA)** for devices
- New Drug Application **(NDA)** or Biologics Licensing Application **(BLA)** to market the new drug or biologic, respectively

Account for the **costs** for all stages, including consultancy and FDA user fees

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.

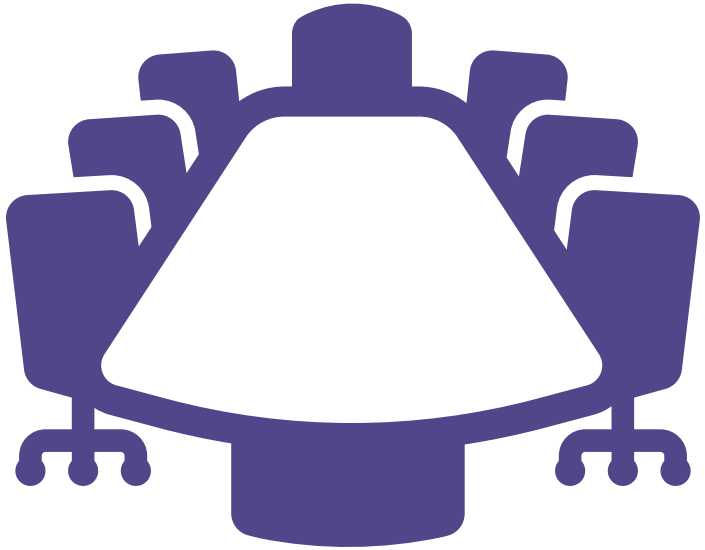
Exempt from IDE Requirements

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 **Examples**: Scalpels, Dental Floss, Exam Gloves. **Timeline (Submission to approval):** <1 month (2017 est.).	General Controls	• **510(k) exempt** **97% are exempt* • DeNovo (no predicate) • 510(k)	47%
II	Moderate	Higher risk than Class I devices FDA clearance based on "substantial equivalence" to a legally marketed device (predicate) **Examples:** Infusion pumps, absorbable sutures, powered wheelchairs **Timeline (Submission to approval):** 6-9 months	General & Some Special Controls	• **510(k)** • DeNovo (no predicate) • 510(k) exempt **Only 8% exempt* 10% of submissions require clinical trial data or real-world evidence	43%
III	Highest	Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Most complex, novel intended uses **Examples:** implantable pacemakers and breast implants **Timeline (Submission to approval):** 18-30 months	General and Special Controls	• **PMA** **Most require Clinical Trial(s) data*	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

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

FDA Ack. or Hold Letter to manufacturer within **7 days**)

Manufacturer informed if they are qualified for **Substantive review** or under a "Refuse to Accept- RTA" Hold

Manufacturer is informed about **interactive review, or Hold** (and if additional information needed)

Has the submission been able to establish **substantial equivalence (SE)?** (or not).

When the decision is favorable, the advisory committee notifies the manufacturer with a **Summary Statement**

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Consultancy Support

Benefits

- Timing
- Regulatory Approach
- Science
- Submission Content
- Expectations
- Exit Strategy

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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

Biologics CONSULTING

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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 –

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- 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=am7IluTS8nY, 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