BIOMEDE 350

Introduction to Biomedical Design

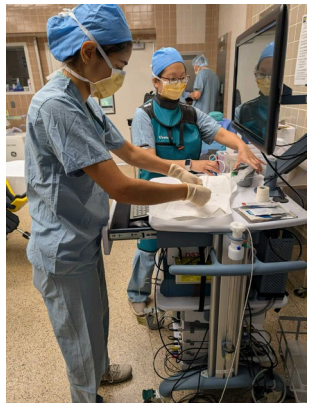
WELCOME!

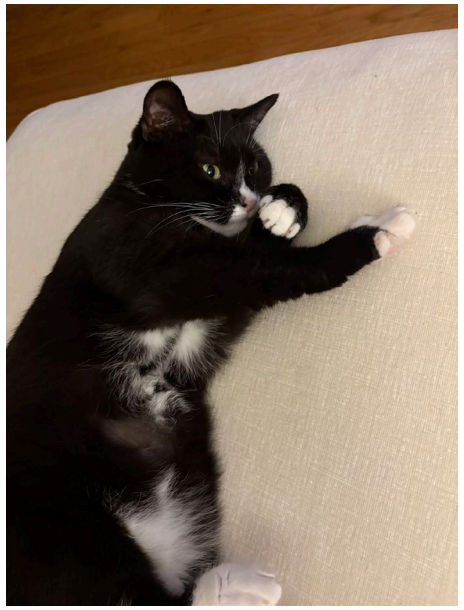
Overview for today

- Introduction to the Teaching Team
- Syllabus and Class expectations
- Introduction to Design
- BME Design, FDA, and Ethics
- *BREAK*
- Project Overviews
- Teamwork Preview

Dr. Elizabeth Mays

- Lecturer IV in Biomedical Engineering Department
  - BSE and MSE – Biomedical Engineering, UofM!!
  - PhD – Biomedical Engineering, Wayne State University
- Office Hours: By Appointment
  - 2220 LBME
  - Calendly.com/elimays
  - Email: **elimays@umich.edu**
    - NOTE there's a devimays@umich.edu who is NOT me, but we get mixed up sometimes
- Hobbies & Interests
  - Camping, Travel, PokemonGO
  - Cosplay, Anime, & Fantasy novels
  - Video Games
    - Currently Playing: Blue Prince
  - Musicals & Showtunes





Sonia Bhaskaran - GSI

- 2nd Year Biomedical Engineering PhD Student (pNEURO Lab)
  - Originally from Southern California, near LA
  - BS in Biomedical Engineering at the University of California, Davis in Northern California
  - PhD research in electrical nerve stimulation for pelvic organ disorders
- Office Hours: By Appointment
  - Email: sabhaska@umich.edu
- Hobbies & Interests
  - Baking
  - Reading (mostly fantasy and sci-fi)
  - Playing violin (fun fact: I play in a Scandinavian folk music band and in a cover band I started with some other BME PhD students)
  - Running, tennis, hiking, dance

Sarah Horst

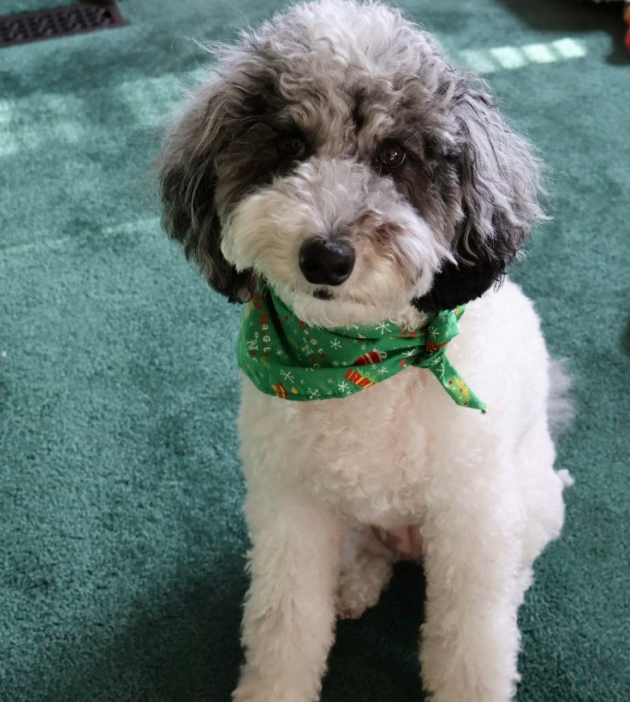
- GSI for BIOMEDE 350.001
  - BSE – Biomedical Engineering from UMich, currently pursuing M. Eng (AMPED)
  - IA for 350 in WN25
  - Former GSI of Michigan Marching Band
- Office Hours: Fridays at 1PM (?), as needed
  - Zoom
    - Meeting ID: 948 5831 6452
    - Passcode: BME350
  - Email: sbhorst@umich.edu
- Hobbies and Interests
  - Crocheting, reading (fantasy and fiction), playing piano, watching sports, playing board and video games (Stardew Valley)

Jansen Sullivan

- IA for BIOMEDE 350.001
  - Currently pursuing BSE in Biomedical Engineering - Senior
    - Also on the pre-med track!
- Office Hours: TBD
  - Email: jansens@umich.edu
- Hobbies and Interests
  - Member of the Michigan Marching Band and Michigan Winter Ensemble
  - Reading!
    - Currently reading: Will of the Many
  - Also the gym, cooking, and all kinds of music
  - Fun fact: Recently, I adopted a cat named JJ

Shahzad Sohail

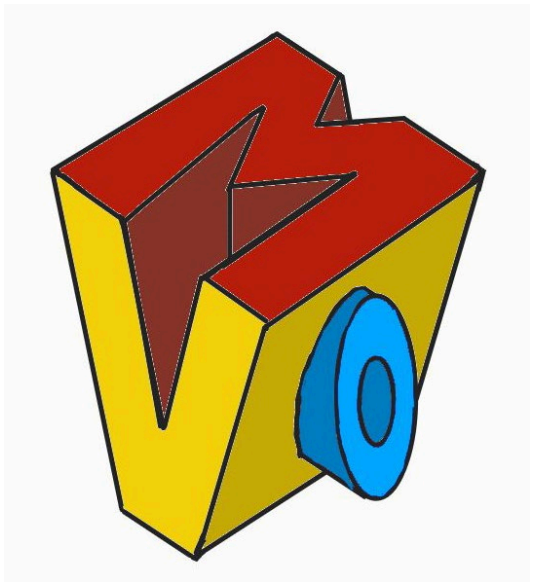
- From Fairfax, Virginia
- Junior studying BME w/ Math Minor
- Pre-Med
- Hobbies/Interests
  - Dance
  - Reading
  - Travel



Jadyn Taylor

- Jadynt@umich.edu
- Junior in BME and your grader this semester!
- Interests:
  - Medical Device Development
  - 3D Printing
  - Tennis
  - Biking

• I'm close to trying every boba place in Ann Arbor!



Welcome to the “Company” Valid Models Only, LLC.

Our mission at VMO is to support our parent companies: Design-A-Gem (Prof. Schmedlen), Pure Chemistry (Prof. Wrobel), and AMaize Inc. (Prof. Mays) by developing accurate models of biomedical products and training our future R&D engineers!

During your time here at VMO, you will be supporting the R&D department by providing **initial reports** and **models** related to the Design Controls required for FDA approval of medical devices

Course Website Overview

- Modules
- Syllabus
- Schedules
- Files
- Piazza!
  - Clarifying questions? Everyone will likely have the same question!
  - Faster response time
  - Personal questions? Email is fine:
    - VMO.management@umich.edu for the whole teaching team - faster
    - Top Secret? elimays@umich.edu

Overview for today

- Introduction to the Teaching Team
- Syllabus and Class expectations
- Introduction to Design
- BME Design, FDA, and Ethics
- *BREAK*
- Project Overviews
- Teamwork Preview

What is Design?

- “Design: to create, fashion, execute, or construct according to plan.”[1]

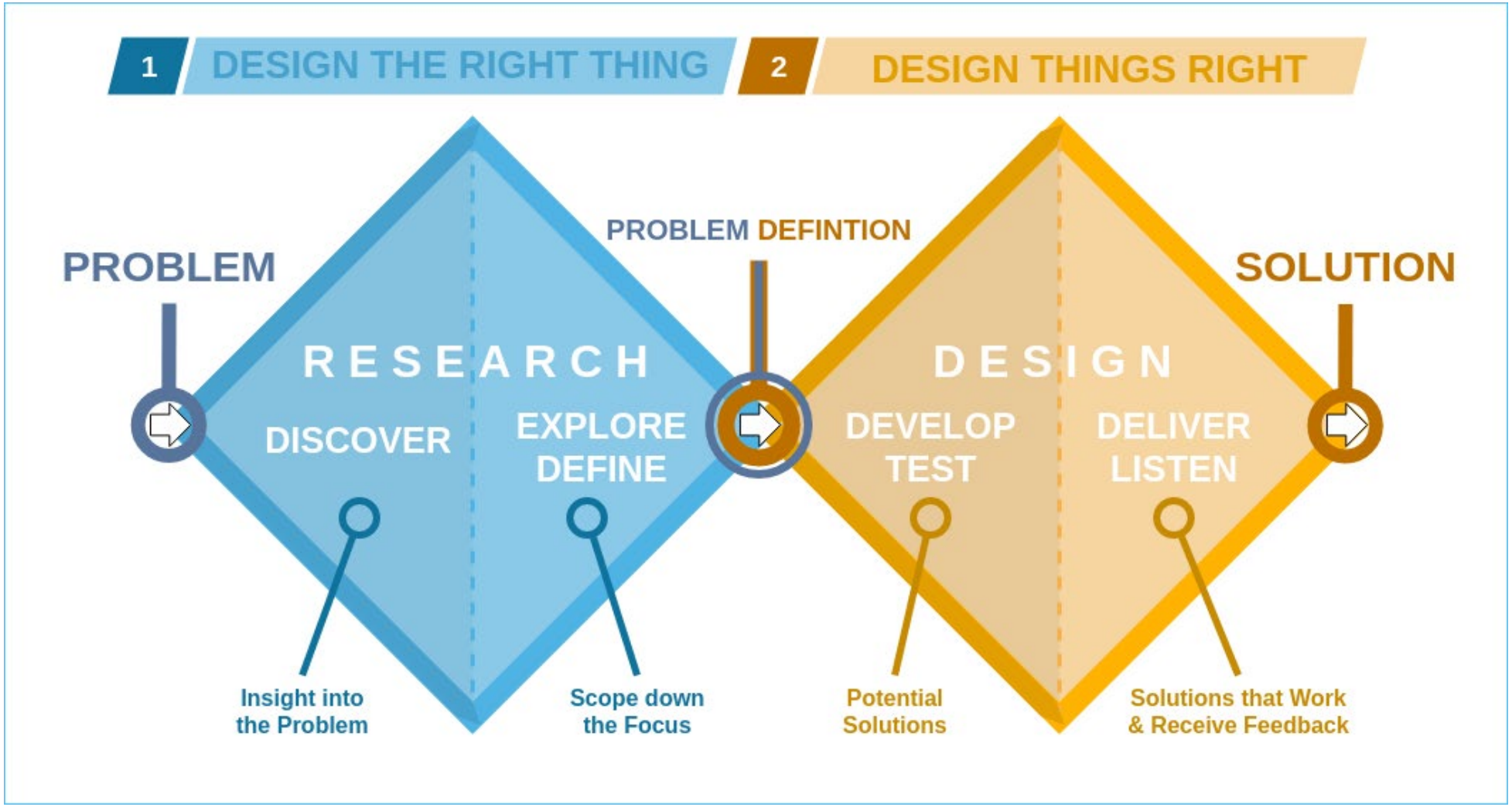
- “What does it mean to Design?”[2]
  - Evidence-based decision making
  - Organized translation
  - Personal synthesis
  - Intentional progression
  - Directed creative exploration
  - Freedom

Many MANY different ways to approach design

Many MANY different Design Processes

1) “Design” *Merriam-Webster.com.* 2021. https://www.merriam-webster.com/dictionary/design (May 12, 2021)
2) S. R. Daly, R. S. Adams and G. M. Bodner, "What Does it Mean to Design? A Qualitative Investigation of Design Professionals' Experiences," *J Eng Educ,* vol. 101, *(2),* pp. 187-219, 2012.

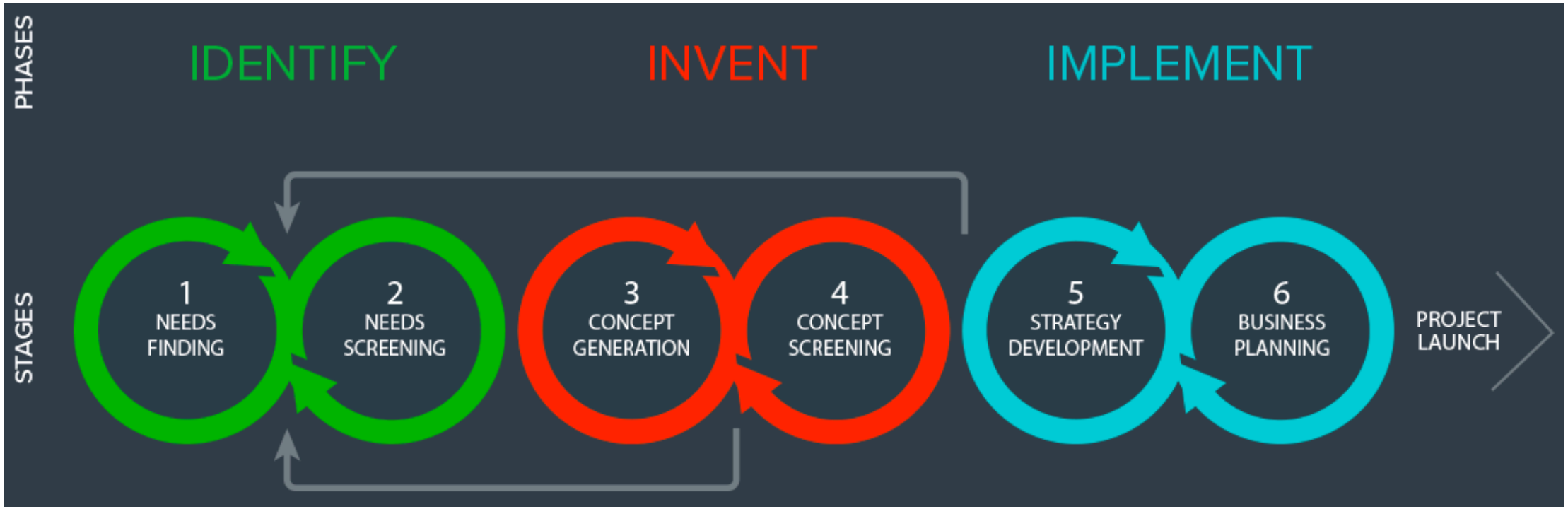
Double Diamond design process model



Ayre, J., “Innovation by Design – Evolving the Double Diamond”, Equal Experts (website), August 16th, 2022, accessed 8/27/2023

https://www.equalexperts.com/blog/our-thinking/innovation-by-design-evolving-double-diamond/

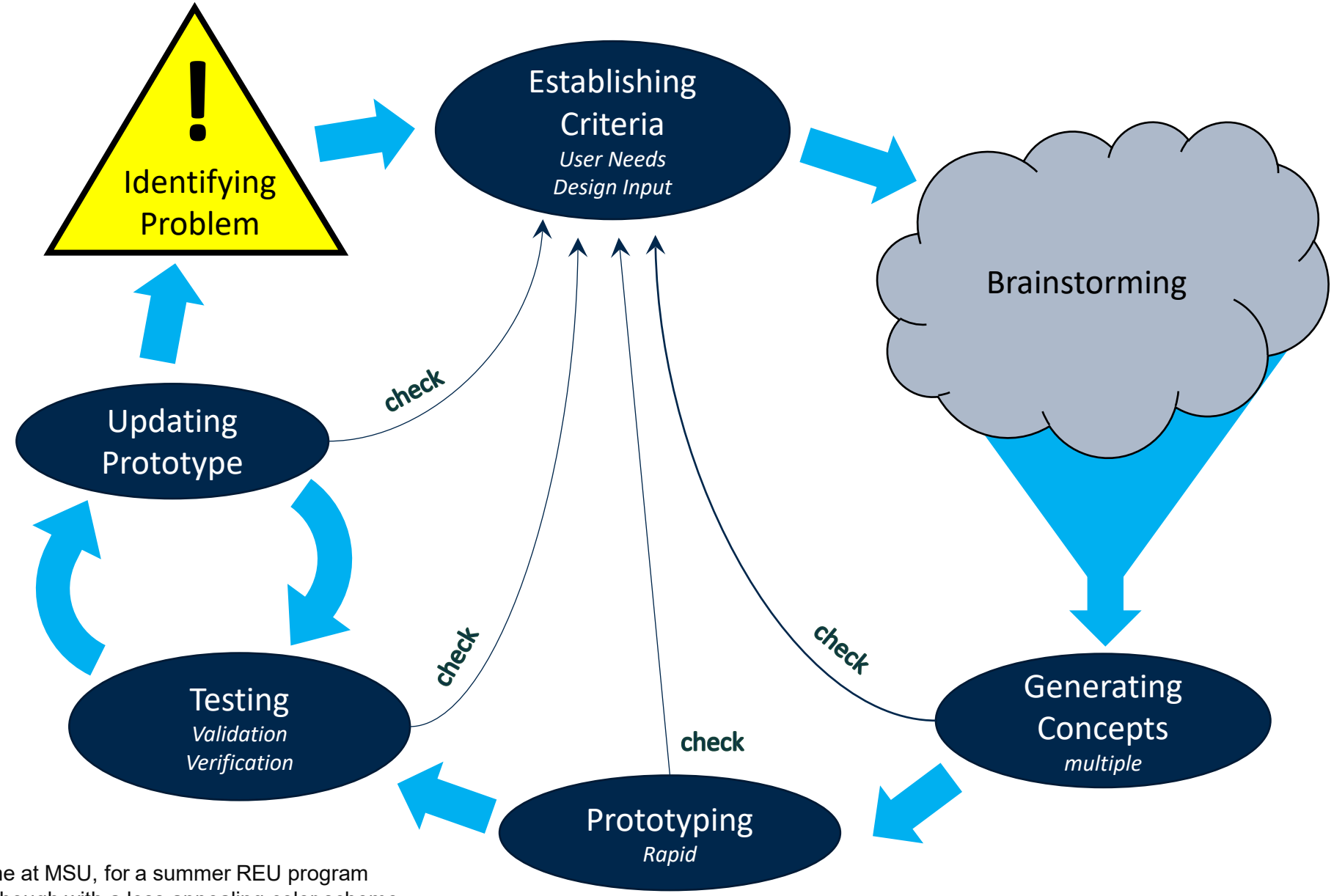
From Biodesign textbook! Available for free through UofM library



https://biodesign.stanford.edu/about-us/process.html → explains just this figure

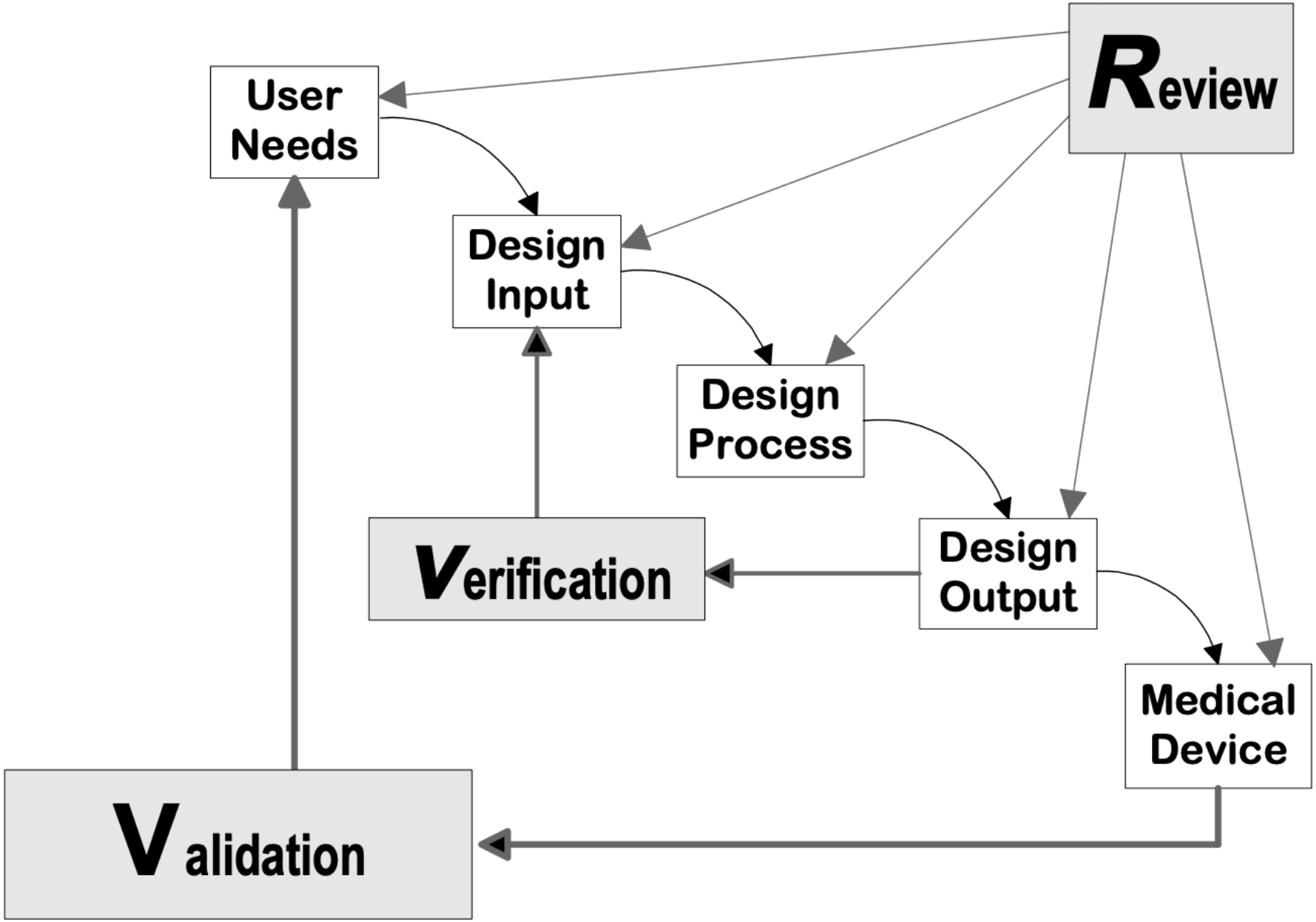
UM Library link for whole book: https://search.lib.umich.edu/catalog/record/99187447397606381

Empathetic Design Process[1]



(1) I created this during my time at MSU, for a summer REU program teaching Empathetic Design, though with a less appealing color scheme

And another! (spoilers – this is the important one for BME 350!)



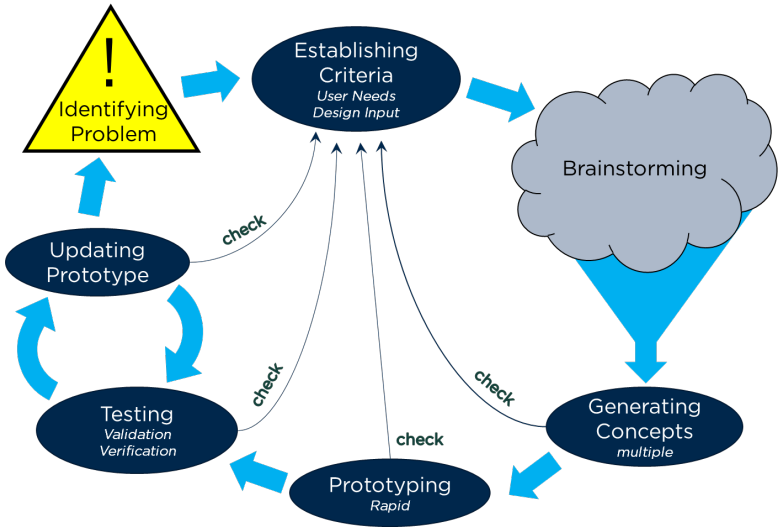
Oversimplified Example
A New Shower Caddy

- Bar soaps
  - Switched to reduce plastic waste
- Degrade too fast
- Keep getting stuck

NEED: something to hold these at about face level, while allowing to dry and not get stuck

Identifying Criteria

- User Needs:
  - Keep the bar soaps in place
  - Stay on the tile wall, even while wet
  - Must be removable
- Requirements and Specifications
  - Shampoo and Conditioner bars = 2 inches wide at the widest point
  - Body wash bar = 2”x3”
  - Fixtures to wall
    - Must withstand weight
    - At least several weeks
  - If possible: would like it to look nice



Brainstorming

Easier to buy suction cups than to reinvent one

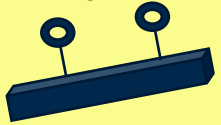
Online search for best suction cup (mini- design process)

Criteria:
Must be strong on wet tile,
Also not too pricey

Individual spot for each bar soap

Decoration!

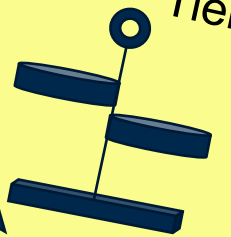
All level on caddy?



Frog face?

Tree?

Tiered hanging system?

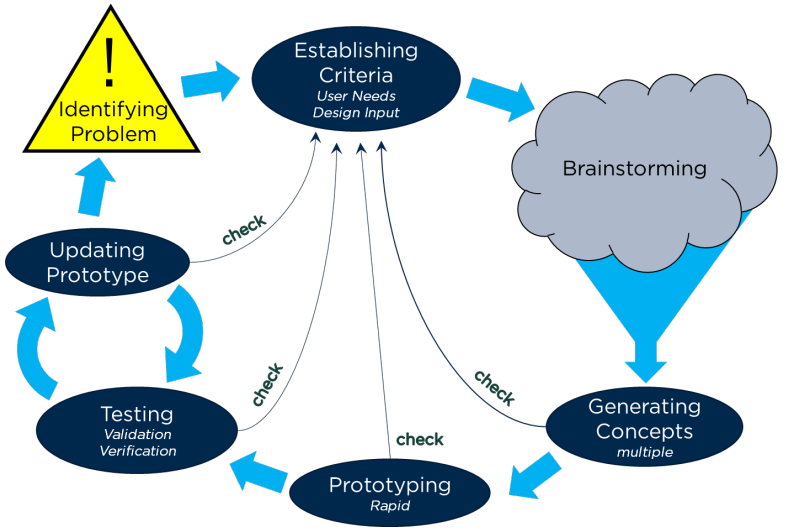


Decorative trim/edge?

Based on need to not dissolve quickly

New Design Requirement:
Add holes for drainage!

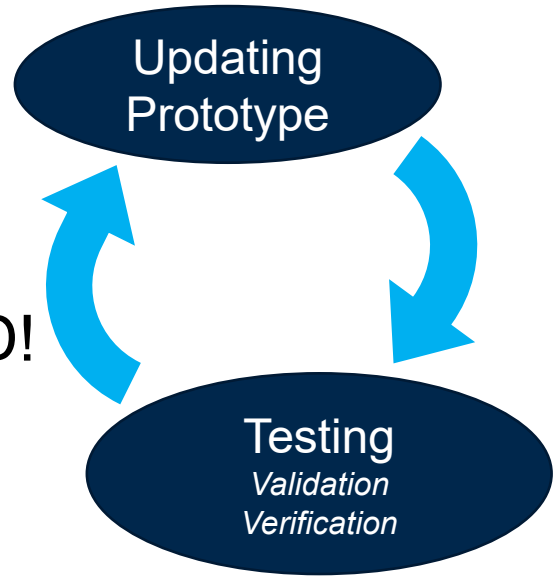
Generating Concepts

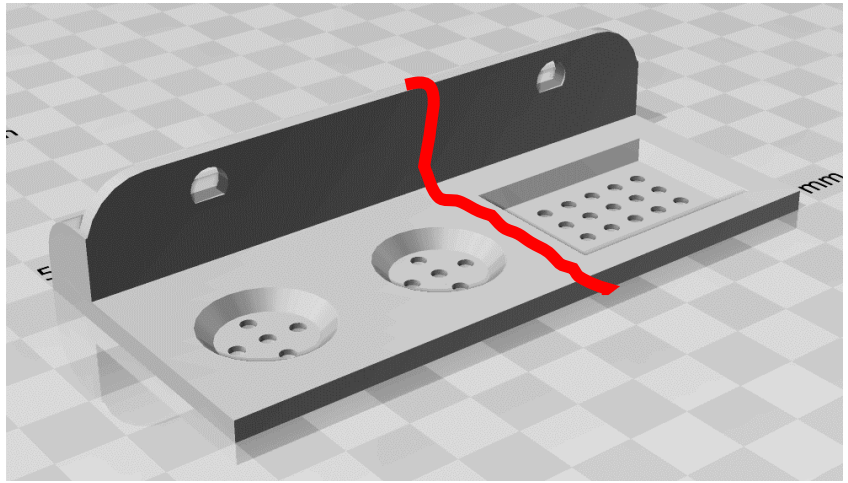


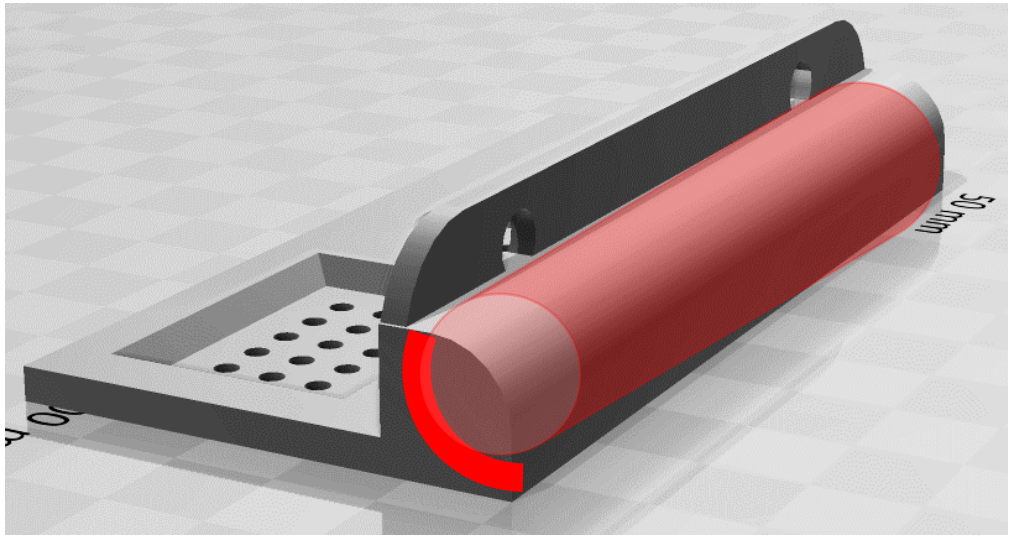
- Ideas present in most brainstorming:
  - Insets for each bar
  - Holes in insets for drying purposes
  - A way to connect to store bought suction cups
    - Support backing to keep base level
- Ideas that varied
  - Backing that was artistic to match décor
  - Backing that was adjustable
  - Decorative trim around base

Prototyping, Testing, Updating

- 3D Modeling and Printing
  - Concept Art
  - Rapid Prototyping
- NEW USER NEEDS & REQUIREMENTS IDENTIFIED!
  - Simple Art – bc I was lacking modeling ability
  - Size constraints – to fit print bed
  - Minimize material – time to print too long

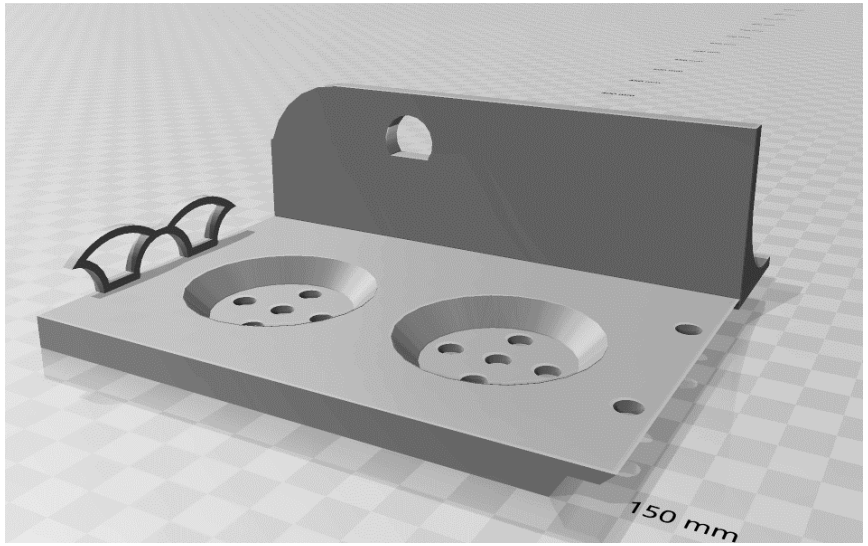


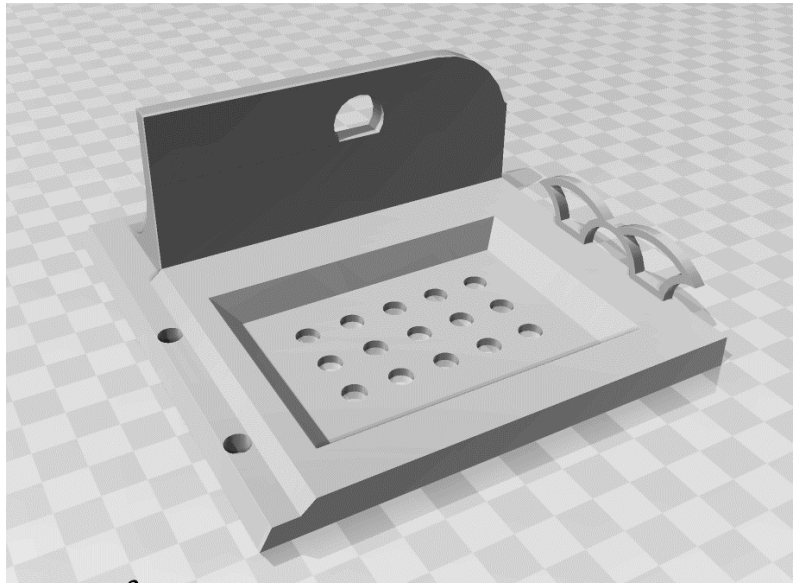


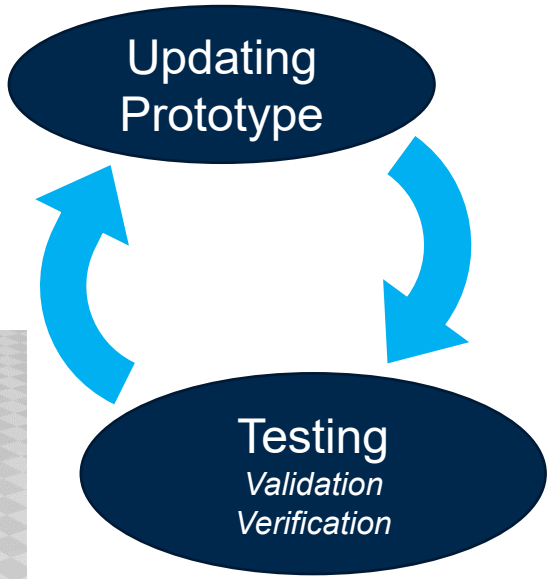


Prototyping, Testing, Updating

- Added
  - Junction between parts
  - Side rails
- Curved out back







NEW USER NEEDS:
- NO JUNCTION -
Glue is sufficient for this use

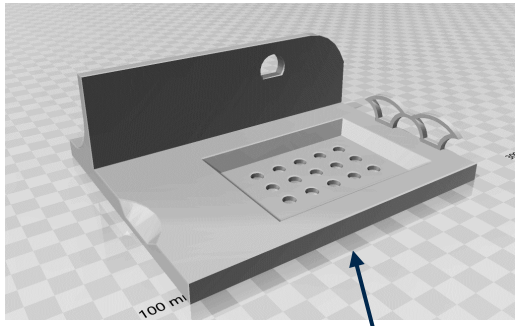
Final Product

Validate User Needs and Verify Design Inputs

- Hold soaps
  - 2” diamete
  - 2”x3”
  - Allow
- Removal
  - Held by
  - Backing holds plat upright
- Aesthetically pleasing
  - While still 3D modeled

Insets for each bar, with drying holes

How about Medical Devices?

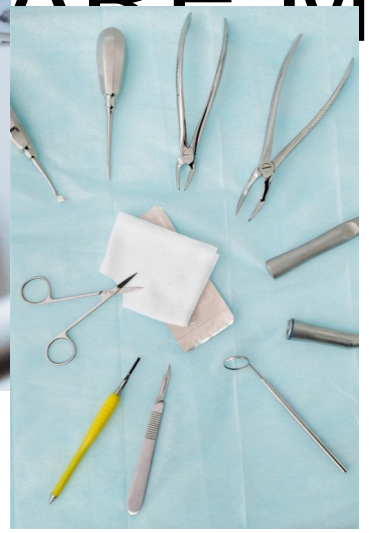


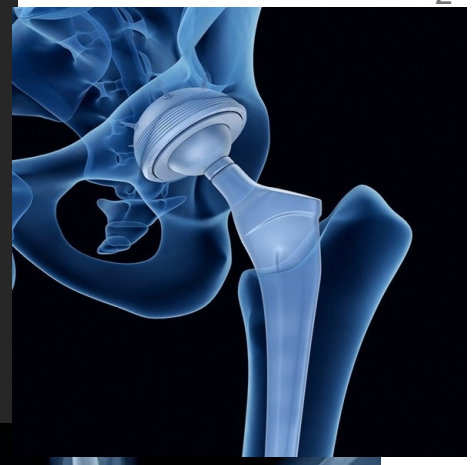
3D model of ne, half ece lo junction

Backing is hollowed out, but still holds the caddy flat

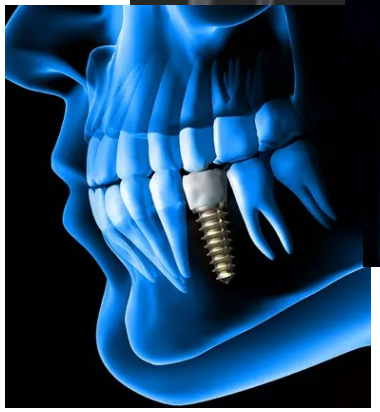
Final form – hanging on the shower tile with store-bought suction hooks

ARE Medical Devices?





2



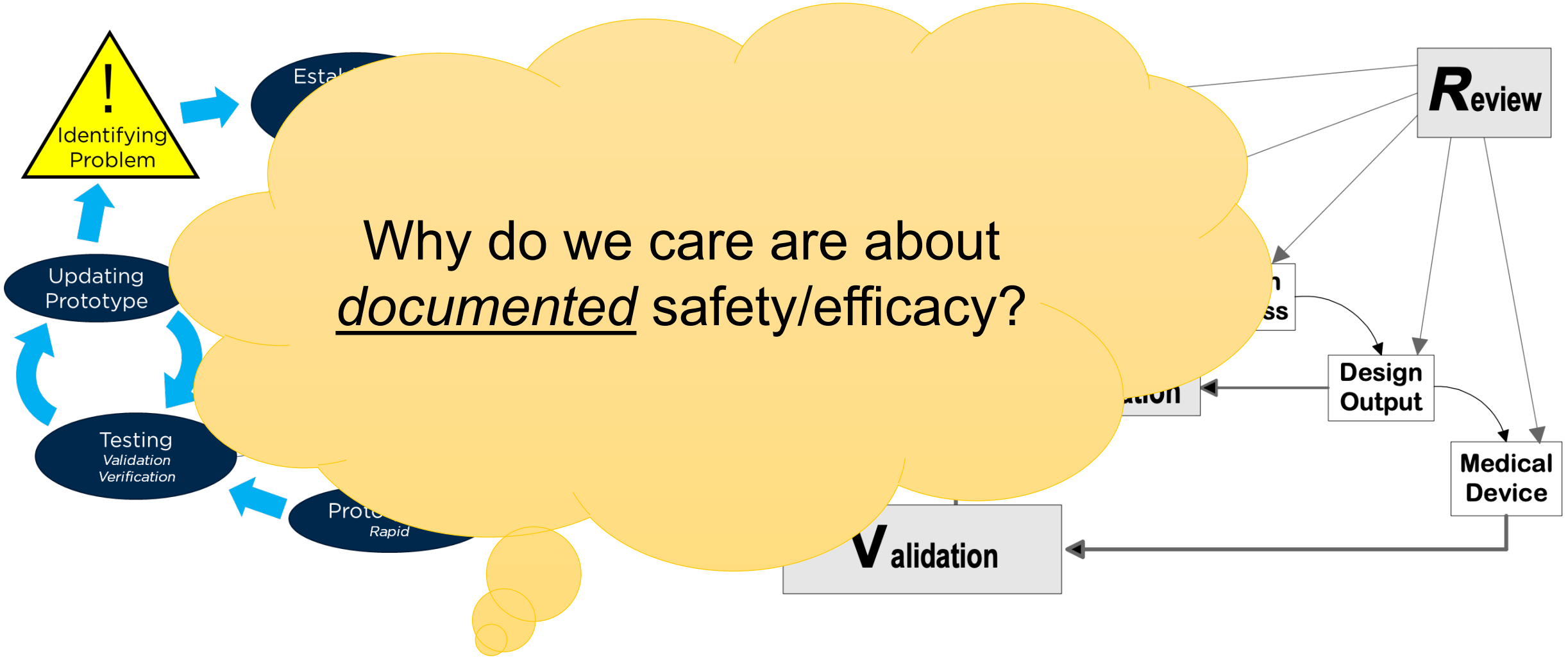
1

3

1. https://www.fuchs.com/dk/en/products/download-center/articles/innovative-cutting-fluids-and-their-key-role-in-making-medical-implants/
2. Shutterstock.com/AlexMit
3. https://indusscrolls.com/3d-printed-patient-specific-medical-implants-technology-transferred-to-the-industry/

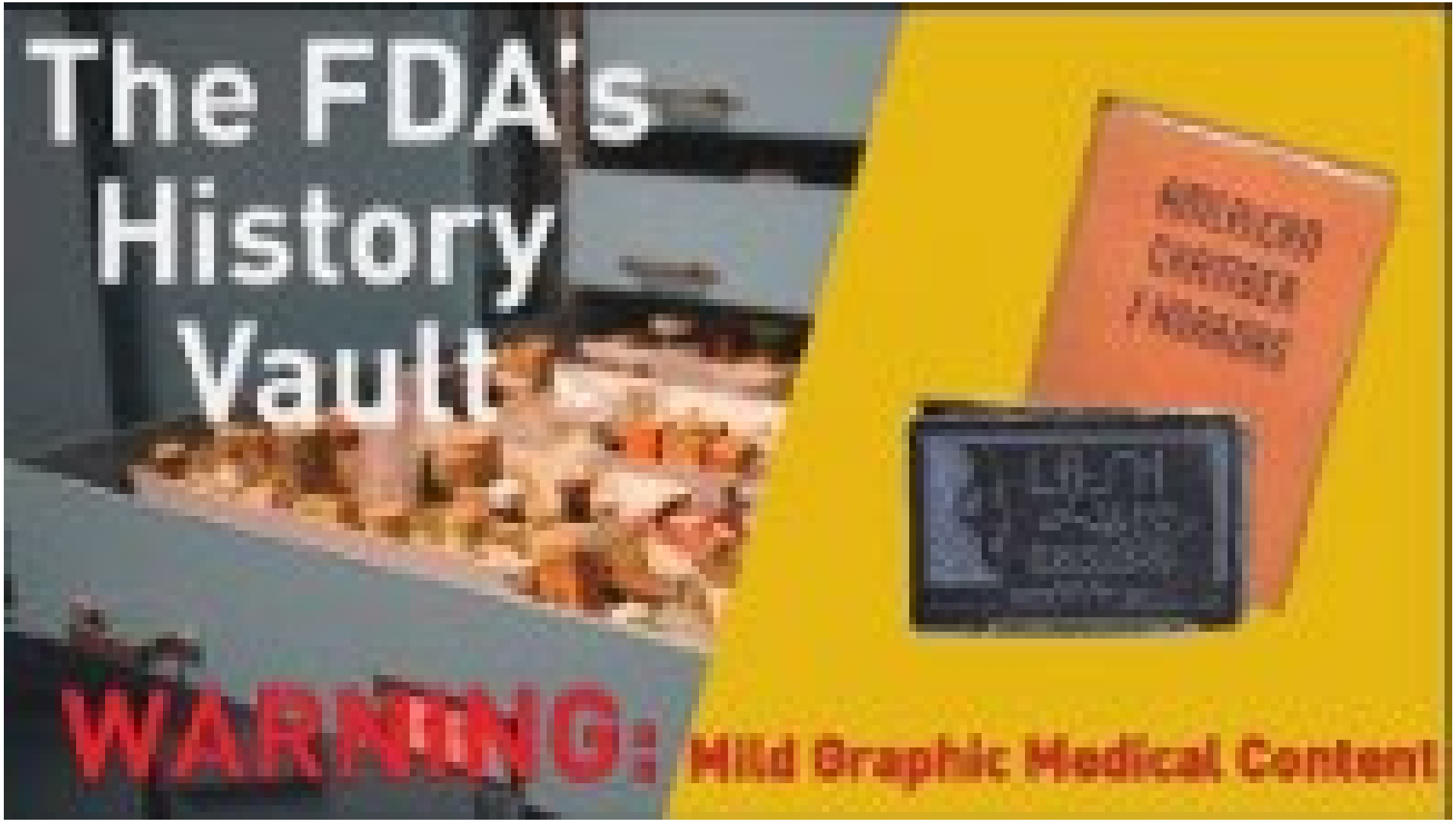
All others from free domain

We care that our designs are safe and effective, and well-documented to address the **User Need**



"Design Control Guidance for Medical Device Manufacturers", FDA, March 11, 1997

80 years of FDA and Cosmetic Act (CW: gore)



https://www.fda.gov/about-fda/fda-history-exhibits/80-years-federal-food-drug-and-cosmetic-act (4min video)

Even today,

Anyone can say anything about a product to sell it.

Biomedical Engineers have a unique intersection with regards to **ethics**

Engineering Code of Ethics

Hold paramount **the safety, health, and welfare of the public**.

Perform services **only in areas of their competence.**

Issue public statements only in an **objective and truthful manner**.

Act for each employer or client **as faithful agents or trustees.**

Avoid deceptive acts.

Conduct themselves honorably, responsibly, ethically, and lawfully so as **to enhance the honor, reputation, and usefulness of the profession.**

https://www.nspe.org/resources/ethics/code-ethics

Hippocratic Oath

I will **respect the hard-won scientific gains** of those physicians in whose steps I walk, and **gladly share such knowledge** as is mine with those who are to follow.

I will apply, for the benefit of the sick, all measures [that] are required, **avoiding those twin traps of overtreatment and therapeutic nihilism.**

I will remember that there is **art** to medicine as well as science, and that **warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug.**

I will not be ashamed to say "I know not," nor will I fail to call in my colleagues when the skills of another are needed for a patient's recovery.

I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know. Most especially must I tread with care in matters of life and death. If it is given me to save a life, all thanks. But it may also be within my power to take a life; this awesome responsibility must be faced with great humbleness and awareness of my own frailty. **Above all, I must not play at God.**

I will remember that **I do not treat a fever chart, a cancerous growth, but a sick human being**, whose illness may affect the **person's family and economic stability**. My responsibility includes these related problems, if I am to care adequately for the sick.

I will prevent disease whenever I can, **for prevention is preferable to cure.**

I will remember that **I remain a member of society**, with special obligations to all my fellow human beings, those sound of mind and body as well as the infirm.

—Written in 1964 by Louis Lasagna, Academic Dean of the School of Medicine at Tufts University, and used in many medical schools today.

https://www.pbs.org/wgbh/nova/article/hippocratic-oath-today/

Balancing Risk and Benefit
US Food & Drug Administration

FDA Mission Statement (link)

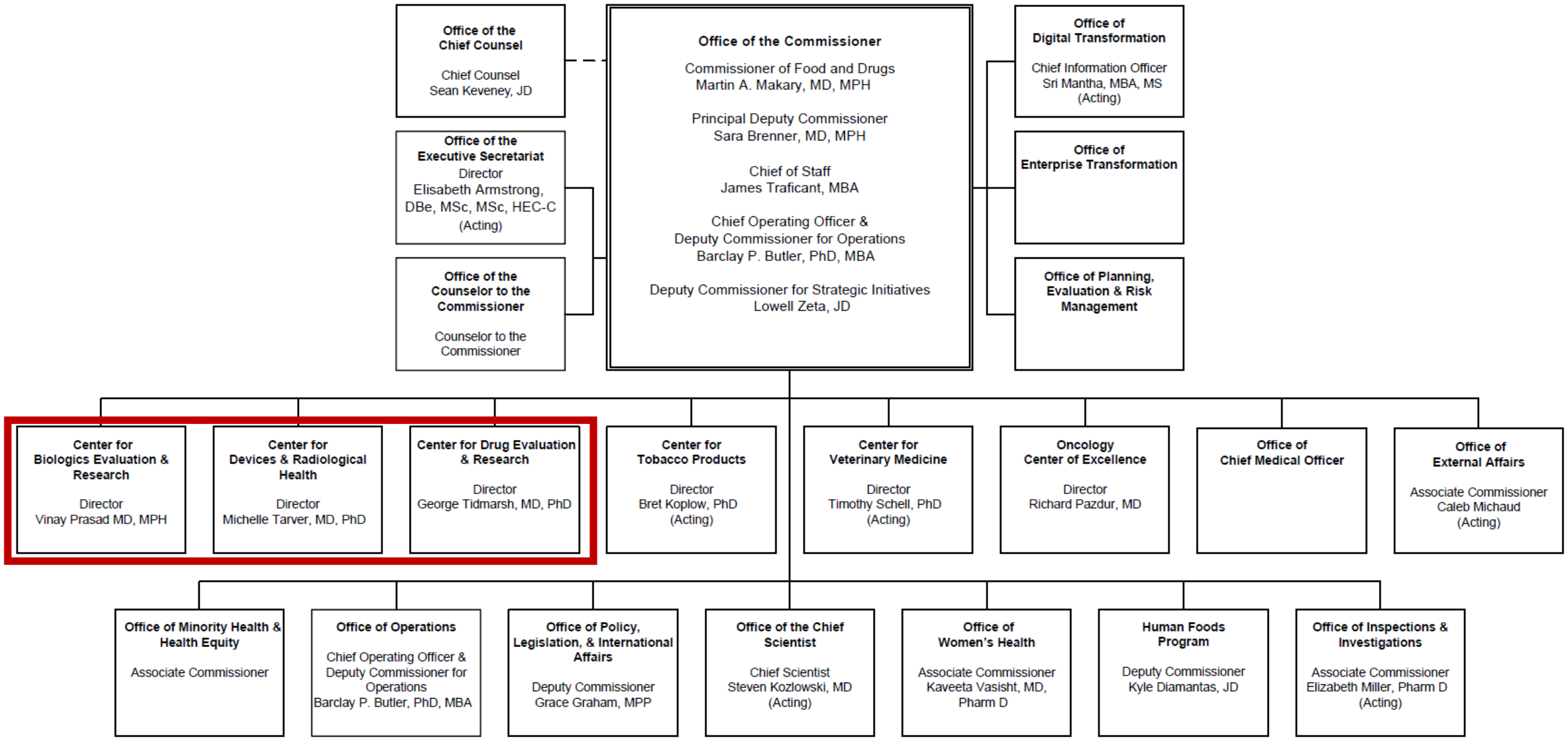
"The Food and Drug Administration is responsible for **protecting the public health** by ensuring the **safety, efficacy, and security** of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

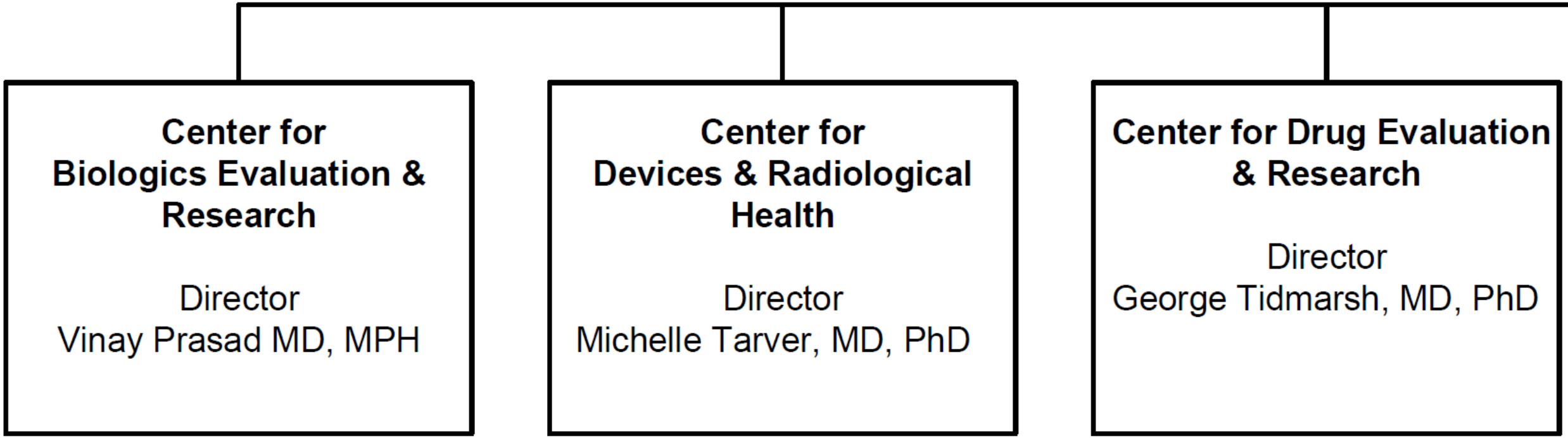
…

FDA is responsible for advancing the public health by helping to **speed innovations** that make medical products more **effective, safer, and more affordable** and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health."

Department of Health and Human Services
Food and Drug Administration

August 21, 2025





Biologics (CBER)
Complex mixture of components
Complex biological entities

Drugs (CDER)
Well characterized chemical entity made by chemical actions

Medical Devices (CDRH)
"Instrument, apparatus, machine"
-primary purpose not achieved through chemical action
-not dependent on being metabolized

Note: products can be *combinations*!

Device Regulation Depends on classification

Class I	Present **minimal potential for harm** to the user and are often simple in design (47% of devices) *e.g. bandages*	General Controls
Class II	Present **some risk** to health of patient (43% of devices) *e.g. powered wheelchairs*	General + Special Controls
Class III	Devices which are life-supporting, life-sustaining, implanted, and/or for which **malfunction poses serious risks** (10% of devices) *e.g. implantable pacemakers*	General + Pre-Market Approval

Design *Controls* based on classification

General controls
Facility registration with FDA
Medical device listing
General FDA labeling requirements
Compliance with quality system regulation (QSR)

Special controls
Special labeling requirements
Mandatory performance standards
Post-market surveillance

Pre-Market Approval
Clinical trials

Device Classification Pathways

Pre-market notification: 510(k)
Claims that a device is substantially equivalent to an **existing Class I or II device** (or in rare cases, Class III), called a **predicate device**

Class I & II Exemptions
A list maintained by the FDA of Class I and II devices which are required neither to undergo PMA nor 510(k) (find device in device classification database, check submission type for exemptions)

De Novo
Claims that despite a lack of predicate device, the product can be safely managed by General (class I) or General + Special (class II) controls

Without any of these...
Clinical trials & Pre-Market Approval

When in doubt, consult FDA's device classification database

Product Classification

FDA Home › Medical Devices › Databases

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA Premarket Review organizations, and other regulatory information.

learn more...

Search Database

Help Download Files

Device

Product Code

Review Panel

Submission Type

Implanted Device

Life-Sustain/Support Device

Summary Malfunction Reporting

Go to Quick Search

1 to 10 of 34 results

hip prosthesis

1 2 3 4 >

Results per page 10

New Search

Export to Excel Help

Product Code	Device		Regulation Number	Device Class
JDH	Prosthesis, Hip, Hemi-, Trunnion-Bearing, Femoral, ...	Hip Joint Femoral (Hemi-Hip) Trunnion-Be...	888.3380	3
JDL	Prosthesis, Hip, Semi-Constrained (Metal Cemented ...	Hip Joint Metal/Metal Semi-Constrained, ...	888.3320	3
KWA	Prosthesis, Hip, Semi-Constrained (Metal Uncemente ...	Hip Joint Metal/Metal Semi-Constrained, ...	888.3330	3
KWB	Prosthesis, Hip, Hemi-, Acetabular, Cemented, Meta ...	Hip Joint (Hemi-Hip) Acetabular Metal Ce...	888.3370	3
KXB	Prosthesis, Hip, Pelvifemoral Resurfacing, Metal/ ...	Hip Joint Metal/Polymer Or Ceramic/Polym...	888.3410	3
KXD	Prosthesis, Hip, Constrained, Metal	Hip Joint Metal Constrained Cemented Or ...	888.3300	3
LTO	Spacer, Cement	Hip Joint Metal/Metal Semi-Constrained, ...	888.3320	3
OCG	Prosthesis, Hip, Pelvifemoral Resurfacing, Metal/P ...	Hip Joint Metal/Polymer Or Ceramic/Polym...	888.3410	3
LPF	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Ceramic, Cemented			3
MRA	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Ceramic/Metal, Cemented Or Uncemented			3

Device Classific

Pre-market notification: 510(k)
Claims that a device is substantially equ
Class III), called a **predicate device**

Class I & II Exemptions
A list maintained by the FDA of Class I a
510(k) (find device in device classificati

De Novo
Claims that despite a lack of predicate d
or General + Special (class II) controls

Without any of these...
Clinical trials & Pre-Market A

When in doubt, consult FDA's device classification database

Device	Bandage, Elastic
Regulation Description	Elastic bandage.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	FQM
Premarket Review	Drug Delivery and General Hospital Devices, and Human Factors (DHT3C) Drug Delivery and General Hospital Devices, and Human Factors (DHT3C)
Submission Type	510(K) Exempt
Regulation Number	880.5075
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	Yes

Note: This device is also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), *as long as the device is not labeled or otherwise represented as sterile.*

Summary Malfunction Reporting	Eligible

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

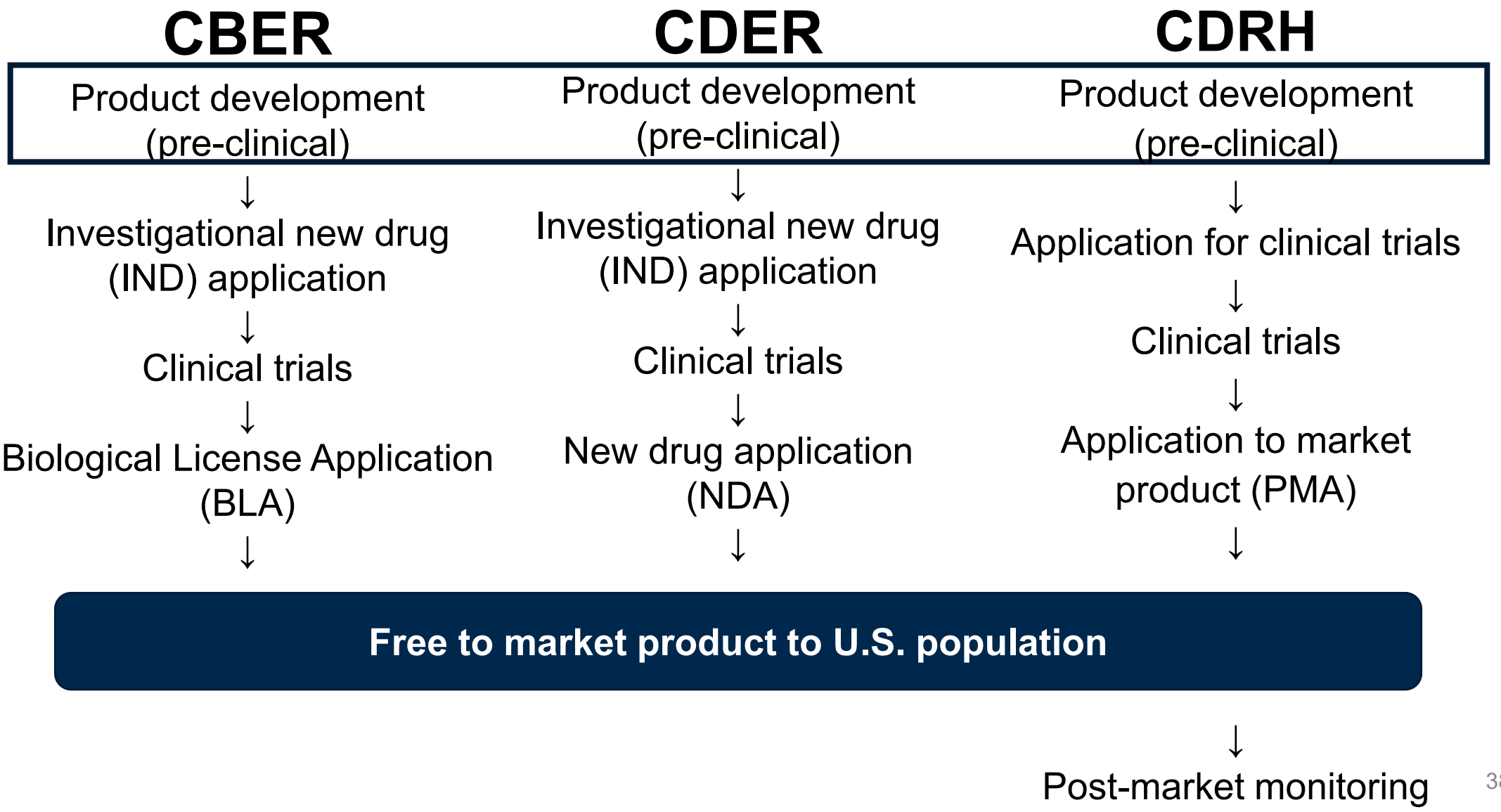
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Clinical Trials take time and money to verify safety and efficacy

Therapeutic Area	Phase 1	Phase 2	Phase 3	*Phase 1, 2, & 3 Subtotal [d]*	FDA NDA/BLA Review Phase [c]	Phase 4	Total [d]
Anti-Infective	$4.2 (5)	$14.2 (6)	$22.8 (5)	*$41.2 (3)*	$2.0	$11.0 (12)	**$54.2 (10)**
Cardiovascular	$2.2 (9)	$7.0 (13)	$25.2 (3)	*$34.4 (10)*	$2.0	$27.8 (4)	**$64.1 (6)**
Central Nervous System	$3.9 (6)	$13.9 (7)	$19.2 (7)	*$37.0 (6)*	$2.0	$14.1 (11)	**$53.1 (11)**
Dermatology	$1.8 (10)	$8.9 (12)	$11.5 (13)	*$22.2 (13)*	$2.0	$25.2 (7)	**$49.3 (12)**
Endocrine	$1.4 (12)	$12.1 (10)	$17.0 (9)	*$30.5 (12)*	$2.0	$26.7 (6)	**$59.1 (7)**
Gastrointestinal	$2.4 (8)	$15.8 (4)	$14.5 (11)	*$32.7 (11)*	$2.0	$21.8 (8)	**$56.4 (8)**
Genitourinary System	$3.1 (7)	$14.6 (5)	$17.5 (8)	*$35.2 (8)*	$2.0	$6.8 (13)	**$44.0 (13)**
Hematology	$1.7 (11)	$19.6 (1)	$15.0 (10)	*$36.3 (7)*	$2.0	$27.0 (5)	**$65.2 (5)**

Cost of studies in US $ **Millions** - Sofpromed, https://www.sofpromed.com/how-much-does-a-clinical-trial-cost

PMA Pathways for centers of interest to BME 350



GUIDANCE DOCUMENT

Design Control Guidance For Medical Device Manufacturers

Guidance for Industry

MARCH 1997

Download the Final Guidance Document

Final

Share | Tweet | Linkedin | Email | Print

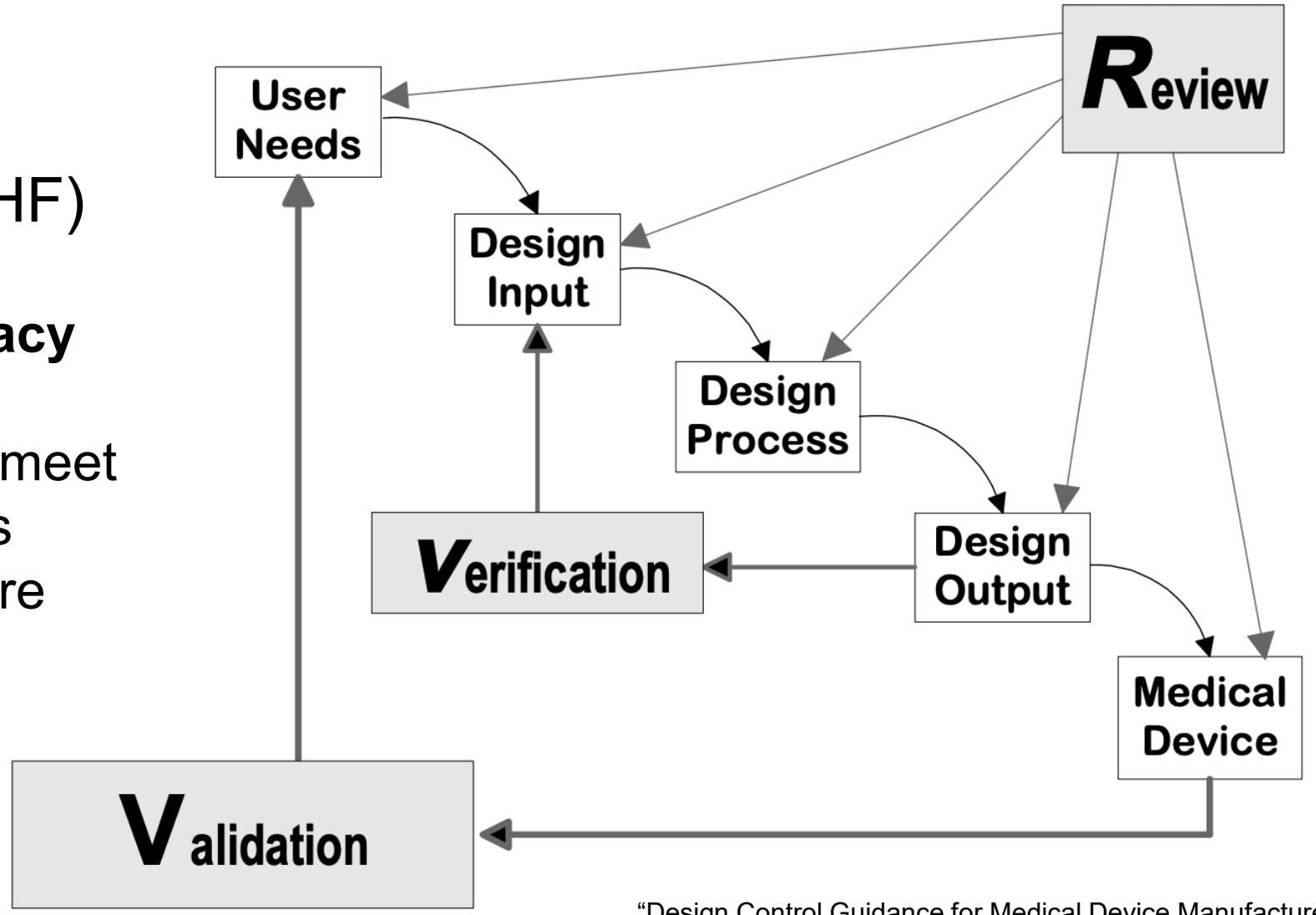
Docket Number: FDA-2020-D-0957

Issued by: Center for Devices and Radiological Health

This document is intended to provide guidance to those involved in designing clinical studies intended to support pre-market submissions for medical devices and FDA staff who review those submissions. Although the Agency has articulated policies related to design of studies intended to support specific device types, and a general policy of tailoring the evidentiary burden to the regulatory requirement, the Agency has not attempted to describe the different clinical study designs that may be appropriate to support a device pre-market submission, or to define how a sponsor should decide which pivotal clinical study design should be used to support a submission for a particular device. This guidance document describes different study design principles relevant to the development of medical device clinical studies that can be used to fulfill pre-market clinical data requirements. This guidance is not intended to provide a comprehensive tutorial on the best clinical and statistical practices for investigational medical device studies.

We care that our designs are safe and effective, and well-documented to address the **User Need**

- Design History File (DHF)
  - Document the process
  - Show **safety** and **efficacy** of device
  - **Verify** Design Outputs meet the safety requirements
  - **Validate** User Needs are met by the device

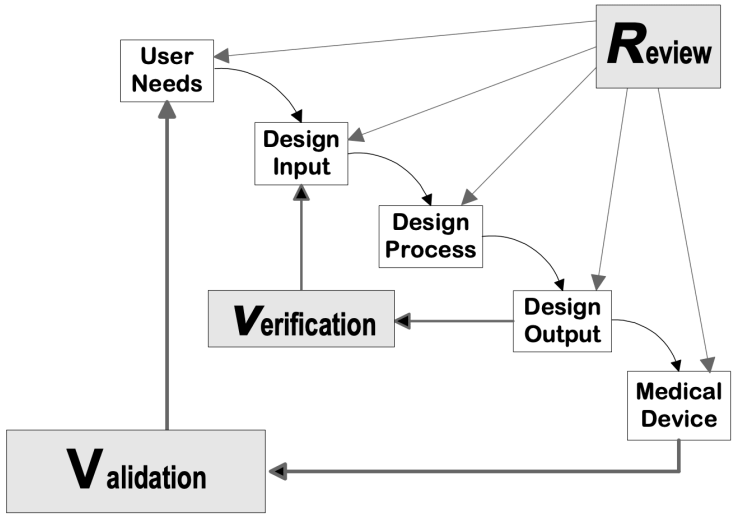


"Design Control Guidance for Medical Device Manufacturers", FDA, March 11, 1997

BME 350 – The Design History File

Documentation required by the FDA when applying for approval of a Class II or Class III Medical Device. Consists of:

- User Needs and Problem Definition
- Design Inputs
- Design Outputs
- Design Review
- Design Verification
- *Process Validation – not covered in 350/450/1/2*
- Design Validation
- *Design Transfer – not covered in 350/450/1/2*
- Design Changes (throughout the above)



Take a 5-minute Break!

Versailles, France – August 2025

Overview for today

- Introduction to the Teaching Team
- Syllabus and Class expectations
- Introduction to Design
- BME Design, FDA, and Ethics
- *BREAK*
- Project Overviews
- Teamwork Preview

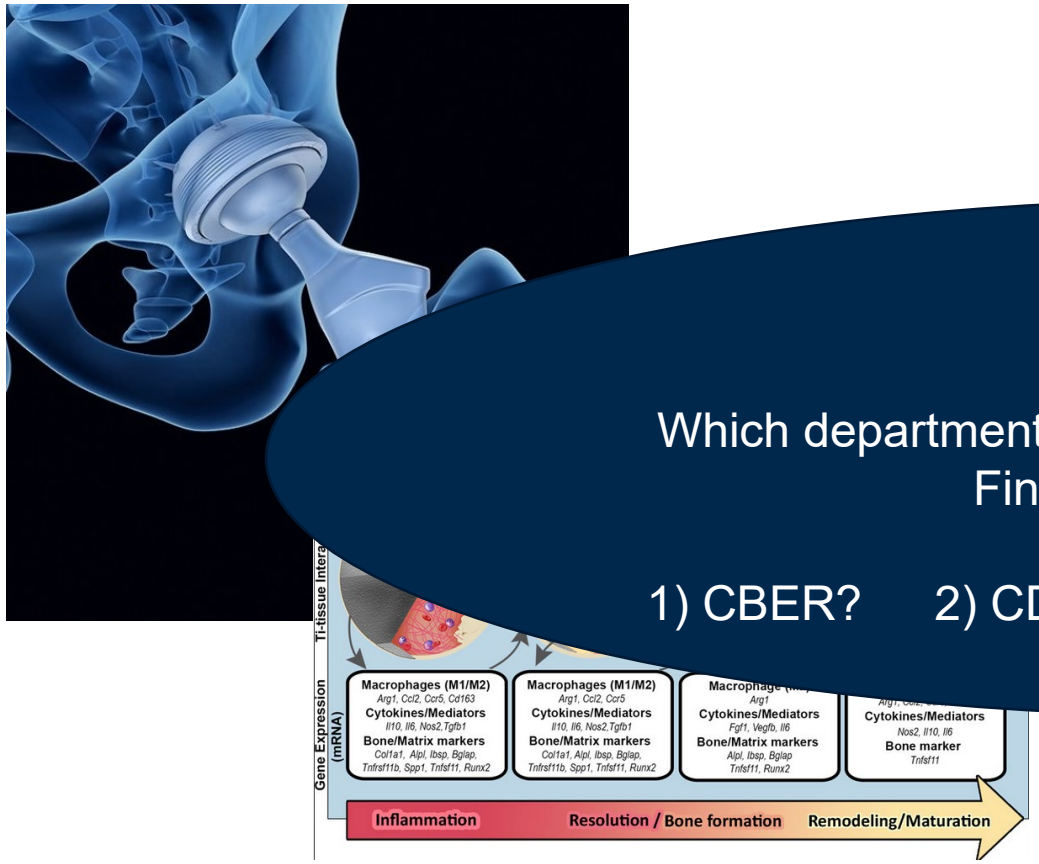
Design Projects

- A keen-eyed viewer may have noticed…

In-Class activities = 2%	
Teamwork Reflection & CATME	0.5% (0.25% each)
Team Contract	0.5%
Reference Hunt	0.5%
Sketches	0.5%
Design Assignments = 12%	
User Needs & Problem Definition	4%
Design Inputs: Requirements & Specifications	4%
Validation & Verification Plan	4%
Computational Assignments = 36%	
MATLAB	3%
Solidworks 1	5%
Solidworks 2	5%
Solidworks 3	5%
COMSOL 1	6%
COMSOL 2	6%
COMSOL 3	6%
Design Deliverables = 40%	
Preliminary Design Review (PDR)	10%
Final Design Review (FDR)	15%
Final Design History File (Report)	15%
Peer Evaluation = 10%	
PDR Peer Eval	5%
FDR Peer Eval	5%

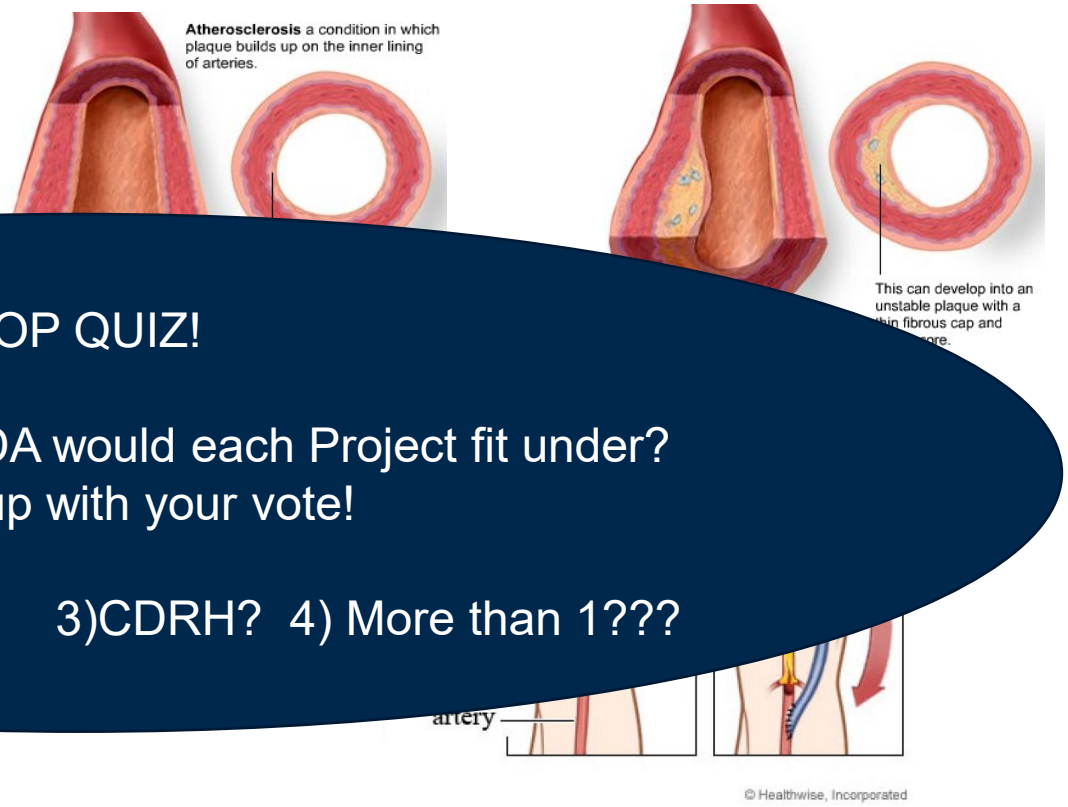
Two Projects available to you

Hip Implant with Growth Factors



ACS Biomater. Sci. Eng. 2021, 7, 6, 2392–2407
Publication Date:February 24, 2021
https://doi.org/10.1021/acsbiomaterials.0c01420

Drug Eluting Bypass Graft



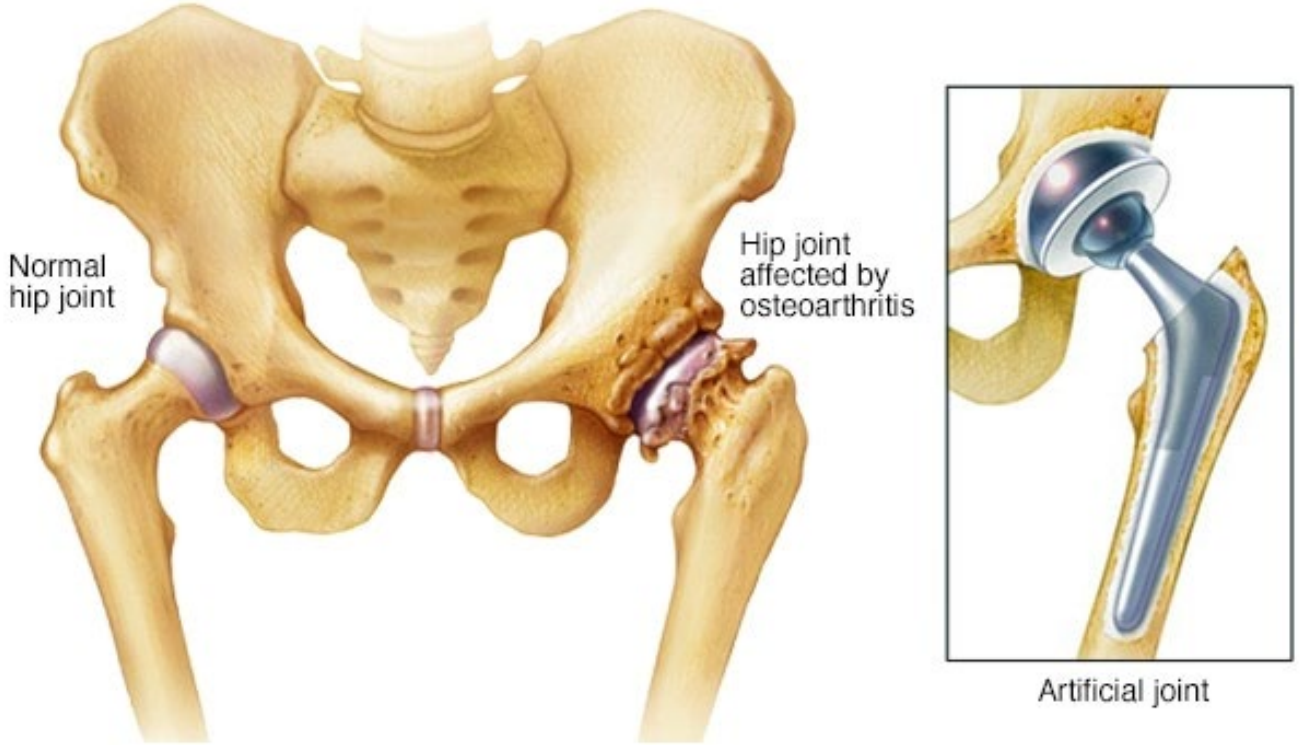
Mayo Clinic Staff - https://www.mayoclinic.org/tests-procedures/coronary-bypass-surgery/about/pac-20384589

POP QUIZ!

Which department of FDA would each Project fit under?
Fingers up with your vote!

1) CBER? 2) CDER? 3)CDRH? 4) More than 1???

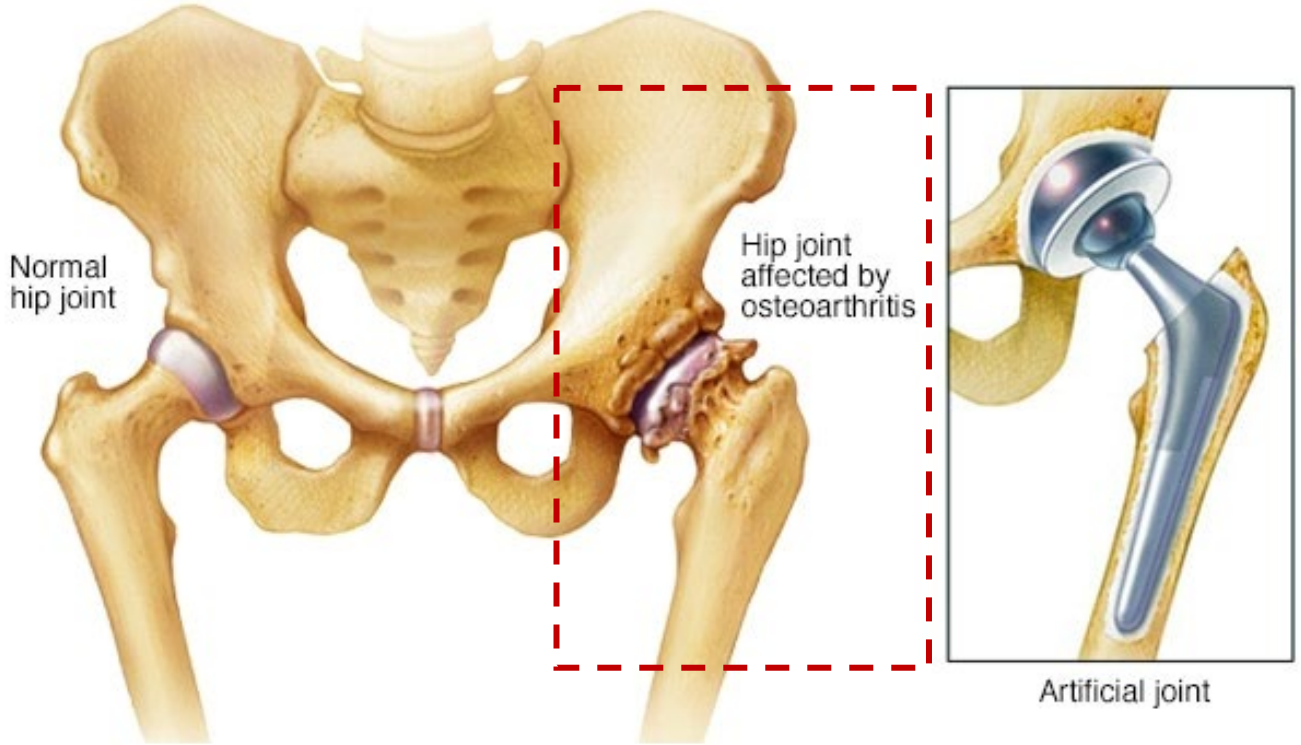
Project Overview: Hip Implant



Mayo Clinic

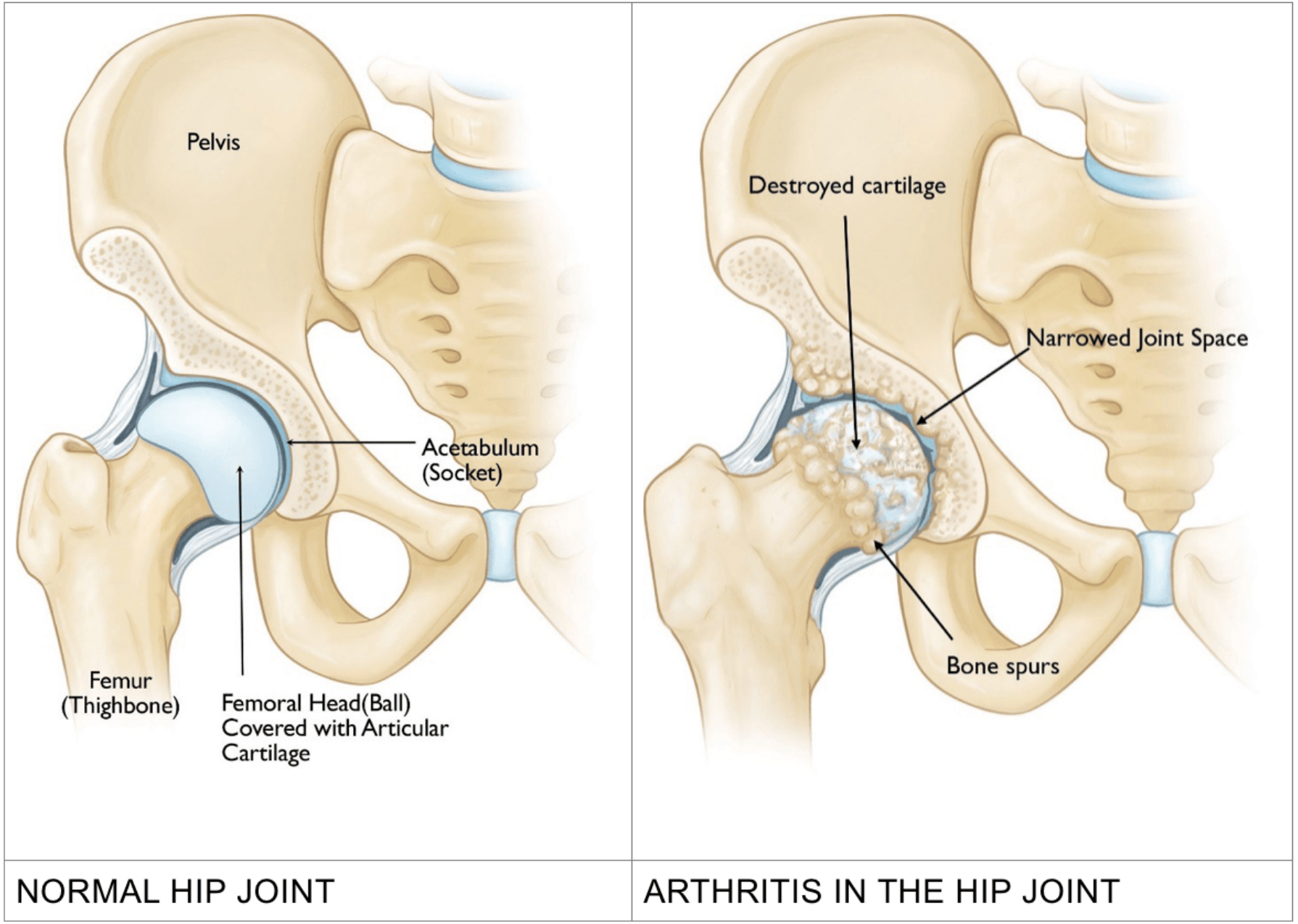
Osteoarthritis
Prevalence and Risk Factors

- 240M cases globally
- >30M cases in U.S.
- Females at higher risk
- Combination of genetics, injury, lifestyle factors



Note! These numbers are from Mayo Clinic (several semesters ago!), you should find your **own sources** for this information in your User Needs! There may be ***better, newer*** sources out there!

Mayo Clinic

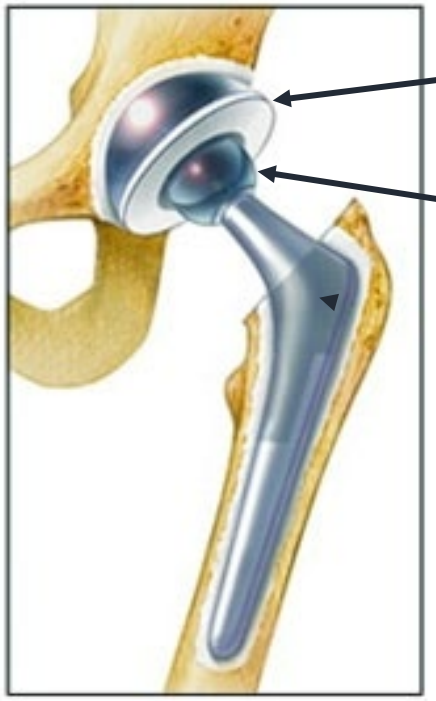


NORMAL HIP JOINT

ARTHRITIS IN THE HIP JOINT

American Academy of Orthopedic Surgeons

Total hip arthroplasty (THA)

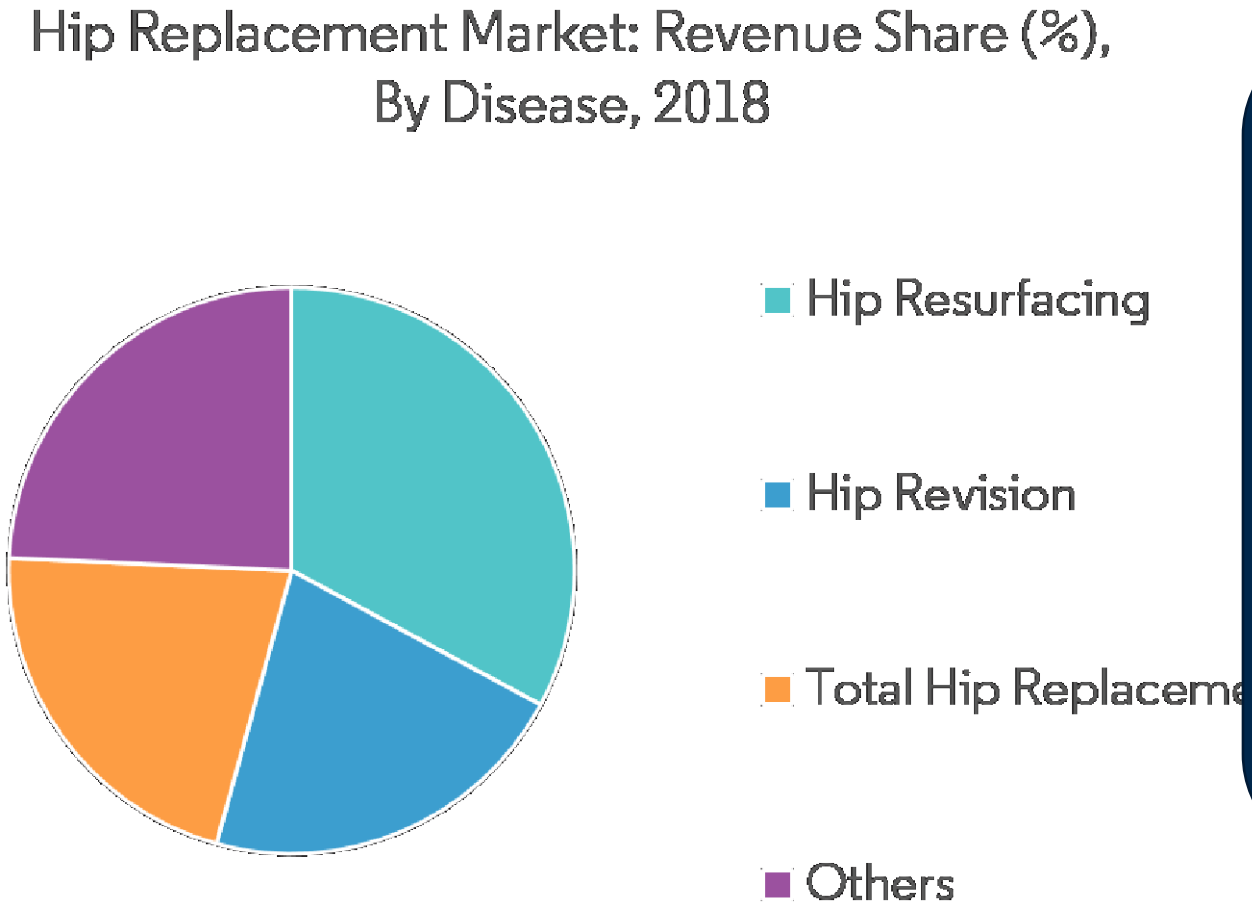


Artificial joint

- Acetabular cup
- Femoral head (ball)
- Femoral stem

American Academy of Orthopedic Surgeons

Reasons for THA, via market share



Note! These numbers are from 2018!

You should find your **own sources** for this information in your User Needs! There may be ***newer*** sources out there!

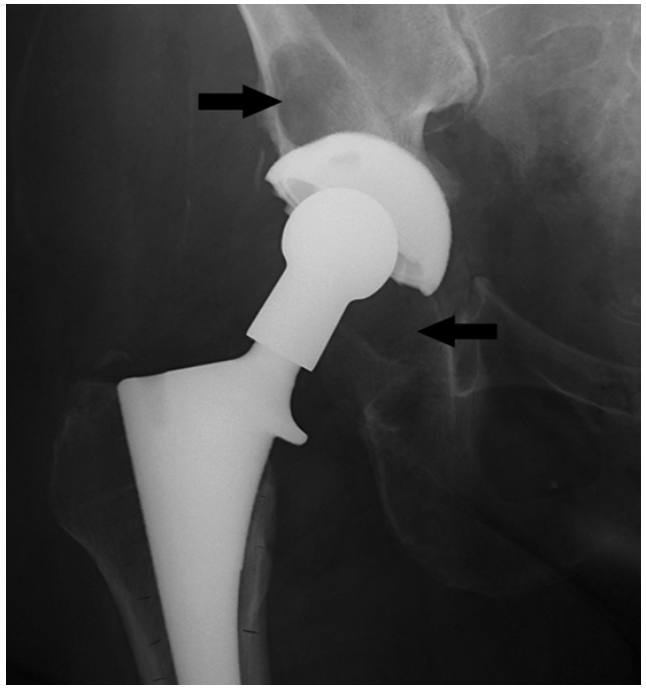
(Also what does this pie chart even mean? See why Tech Comm hates pie charts with this link: https://bernardmarr.com/why-you-shouldnt-use-pie-charts-in-your-dashboards-and-performance-reports/)

Source Mordor Intelligence

Total hip arthroplasty (THA)
causes for revision surgery

Inflammatory imbalance leading to bone loss around implant

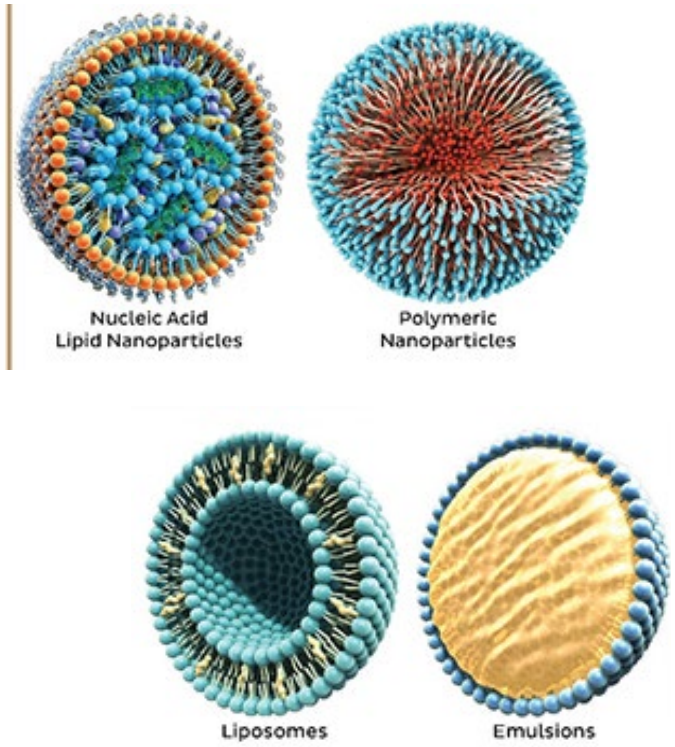
Failure Mode	Total Number of Failures	Percent of Total Failures	Percent of Revisions
Aseptic Loosening	305	23.19%	3.06%
Dislocation	295	22.43%	2.96%
Infection	291	22.13%	2.92%
Instability	85	6.46%	0.85%
Mechanical Complications	82	6.24%	0.82%
Bone Fracture	50	3.80%	0.50%
Component Fracture	25	1.90%	0.25%
Pain	22	1.67%	0.22%
Wear	11	0.84%	0.11%
Other	149	11.33%	1.50%

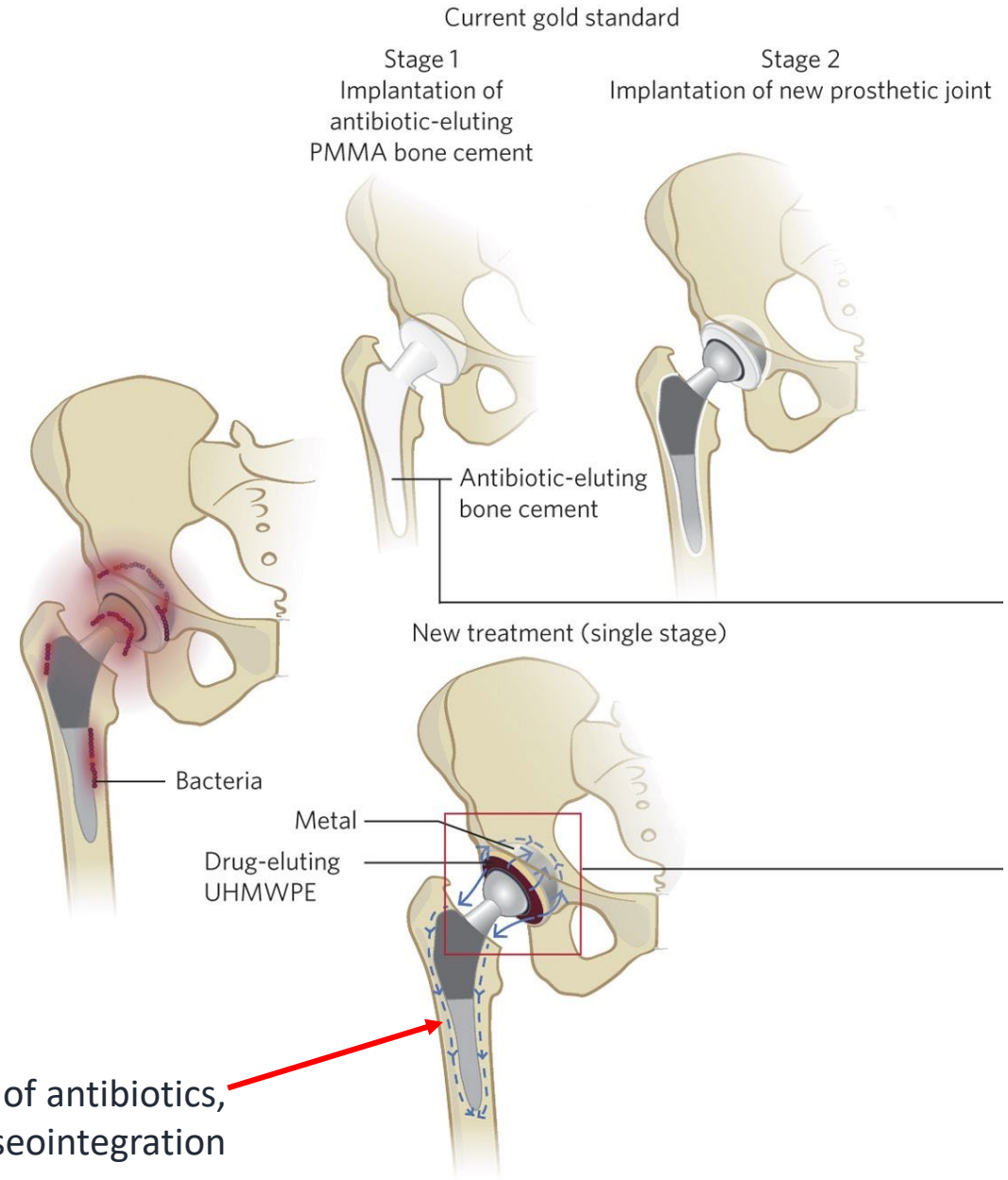


C Kenney, J Orthopaedics, 2019, Abu-Amer, Arthritis Res Ther 2007

Morlock, Bishop, Huber; Biomechanics of Hip Arthroplasty, 2011

“Controlled Release”





instead of antibiotics,
biologic to promote osseointegration

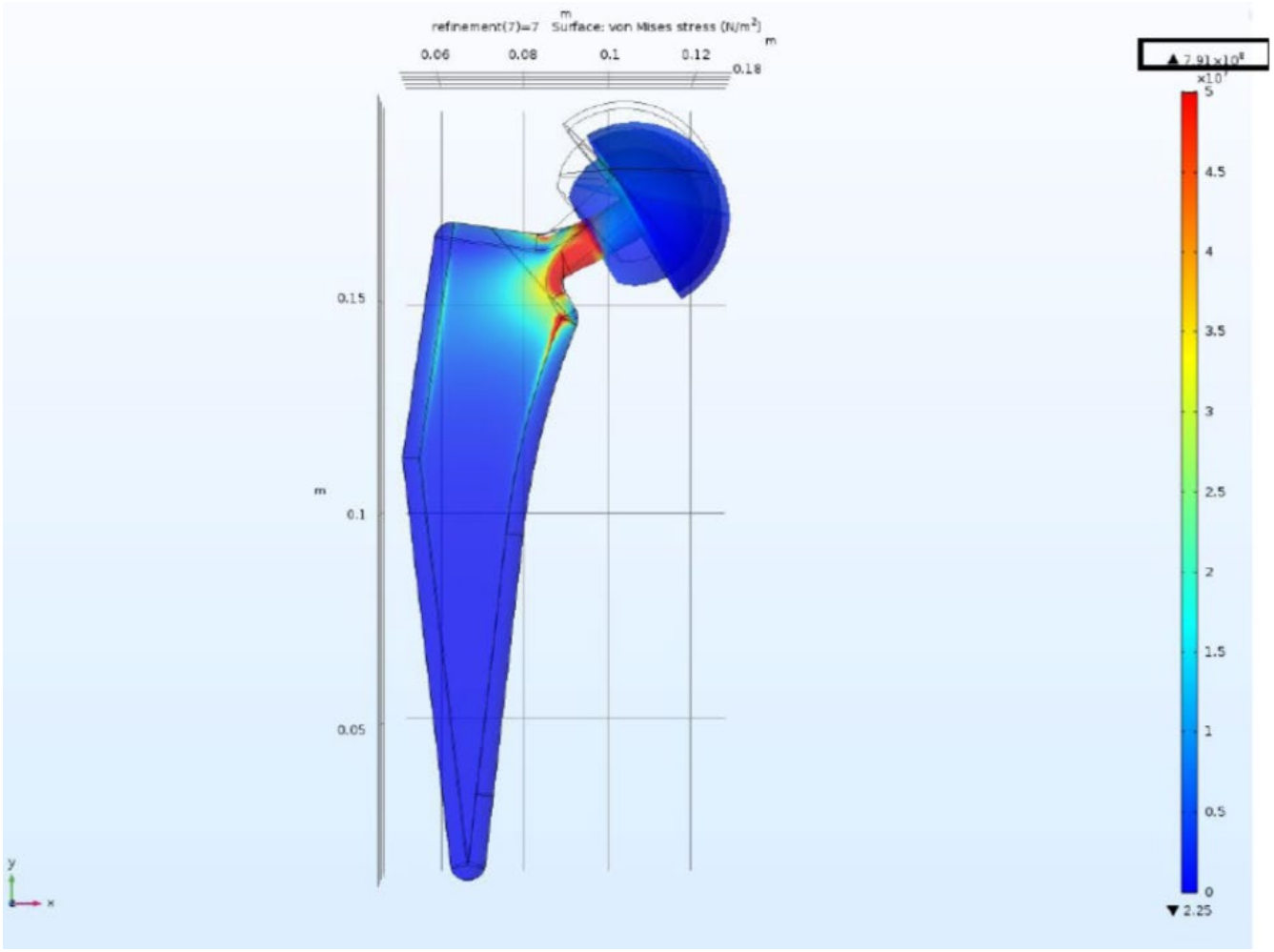
Precision Nanosystems

V Suhardi, Nat Biomed Eng, 2017

The *initial* Needs Statement

"…design a **hip replacement implant** that can **effectively release growth factors** to promote new bone growth over time, to ultimately favor good bone-implant integration and **prevent a need for a revision surgery**"

Future Mechanics Modeling



How does the implant bear the physiological load?

Governed by stress-strain-displacement relationships

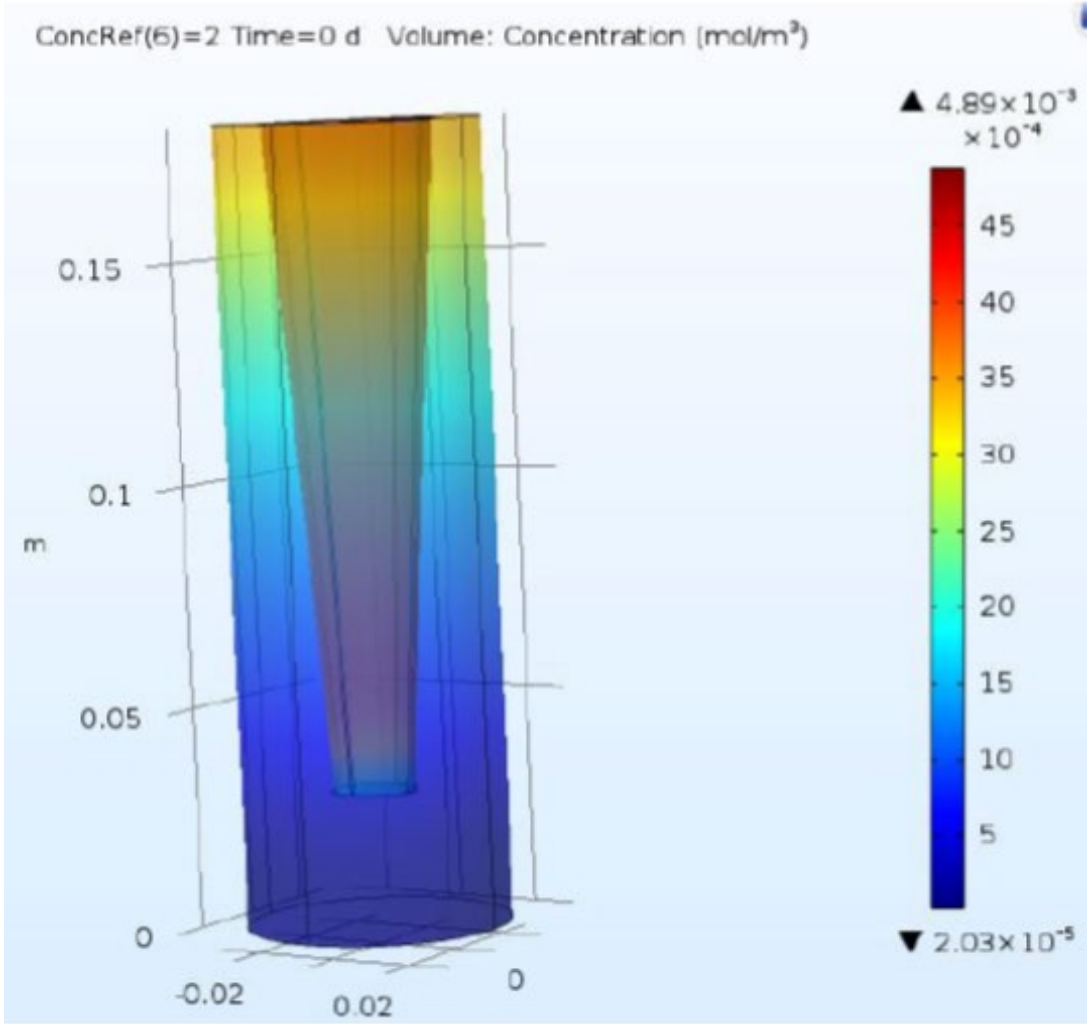
of linear elastic materials

$$\nabla \cdot \underset{\sim}{\sigma} + \vec{F} = 0$$

$$\underset{\sim}{\sigma} = \underset{\sim}{\sigma}_0 + E\underset{\sim}{\epsilon}$$

$$\underset{\sim}{\epsilon} = \frac{1}{2}(\nabla\vec{u} + (\nabla\vec{u})^T)$$

Future Drug Transport Modeling (Bone)



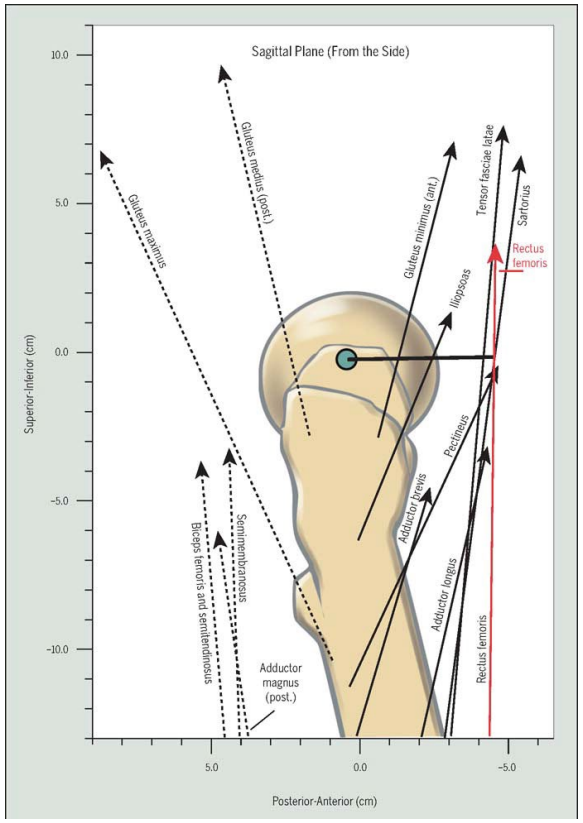
How is the drug delivered throughout the bone over time?

Governed by transport (advection-diffusion) in porous media:

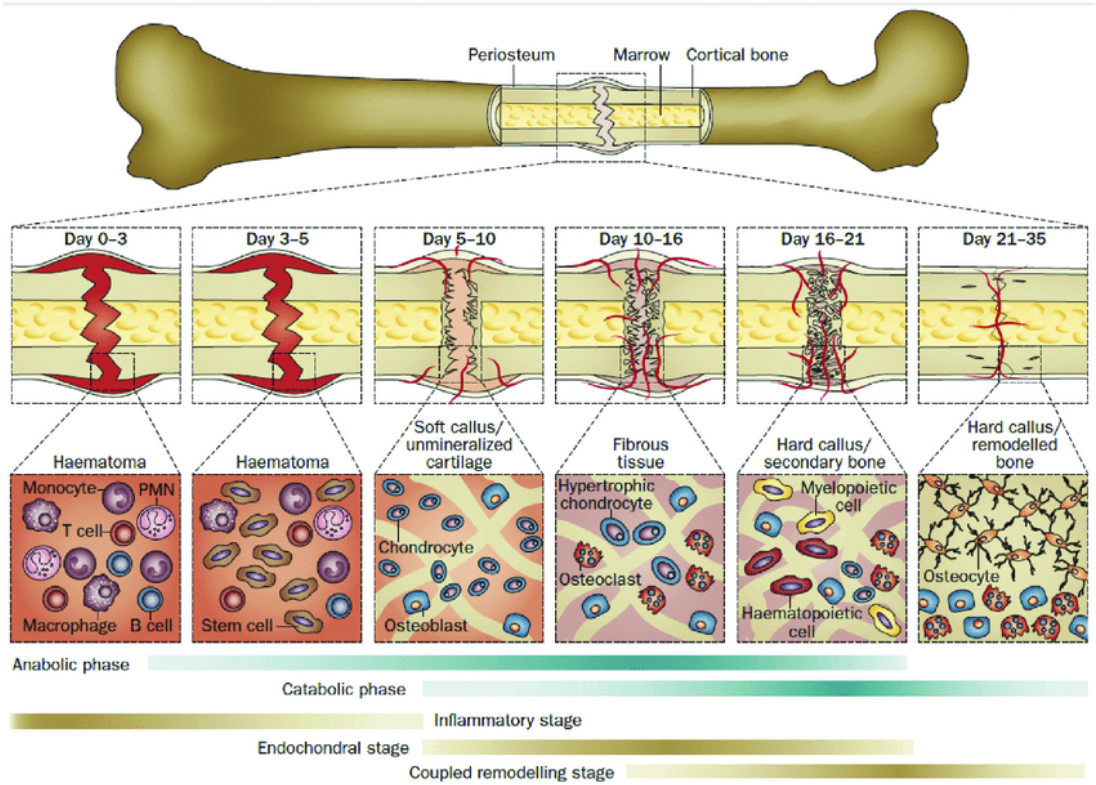
$$\frac{\partial \varepsilon C}{\partial t} + \vec{u} \cdot \nabla C - \nabla \cdot (\varepsilon D \nabla C) = R + S$$

Simplifying to balance accuracy and speed

We must simplify, but we have a responsibility to be aware of the complexity.



D Neumann, J Ortho Sports Phys Ther, 2010



W Wang, Bioact Mater, 2017

Project Overview: Bypass Graft

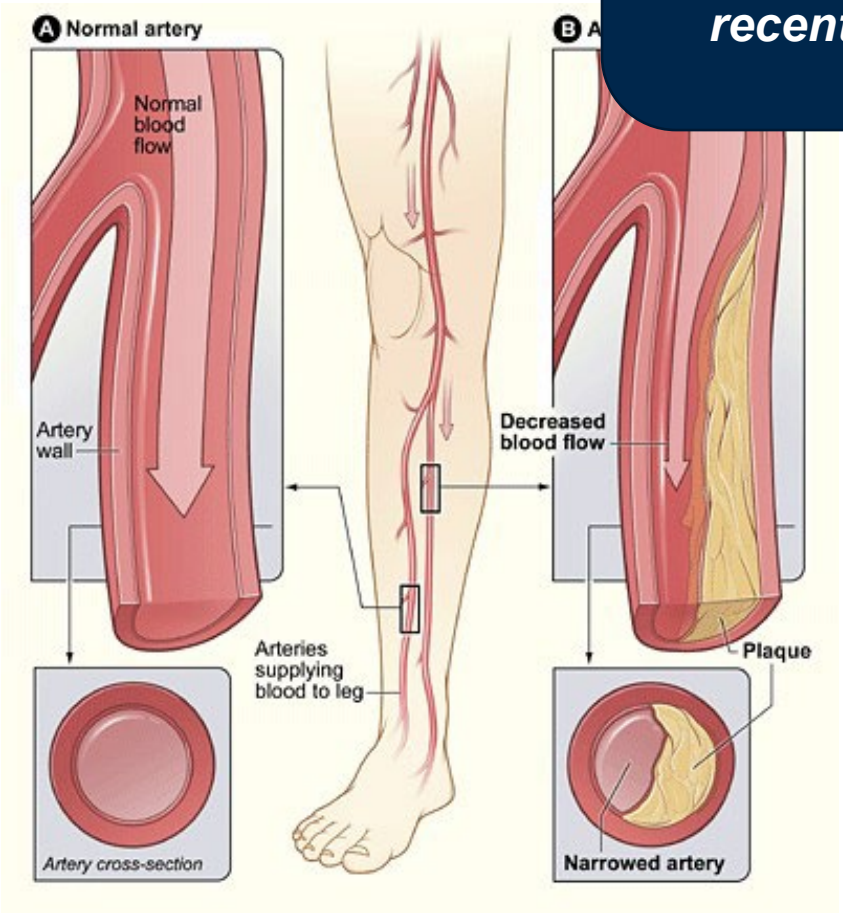
Remember! You should find your **own sources** for this information in your User Needs! There are be ***better, more recent*** sources out there!

Peripheral Artery Disease (PAD)

- Obstructive atherosclerosis in **peripheral** arteries
- Most commonly lower extremities
- Leads to pain and tissue damage
- Extreme cases: limb loss, death
- Coronary heart disease risk equivalent
- Affects >8M in U.S. alone

Atherosclerosis

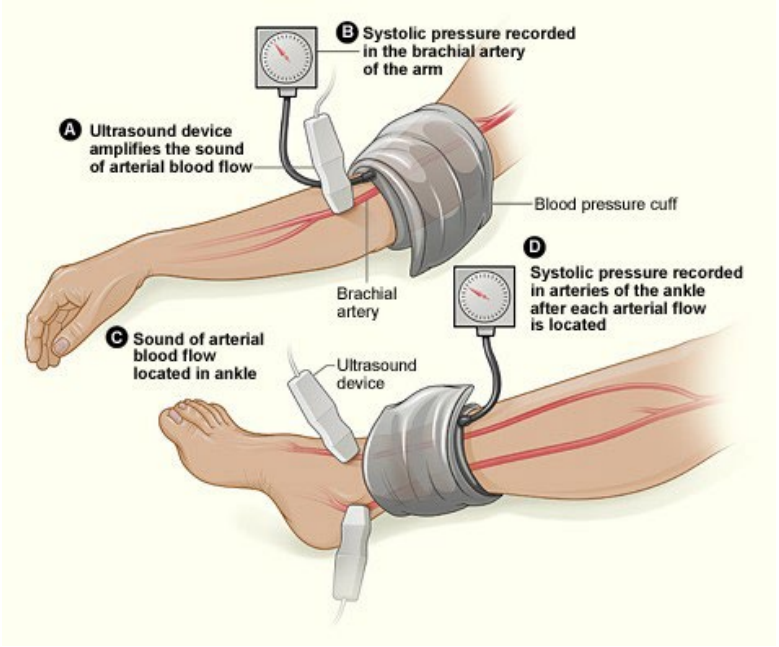
- Subintimal buildup of plaque in arteries
- Decreases patency (openness) of vessels



NIH

Peripheral Artery Disease (PAD) *diagnosis and severity*

- **Ankle-Brachial Index (ABI)**
- Blood pressure at ankle / blood pressure at arm
- Diagnostic for *lower extremity* PAD (most common)

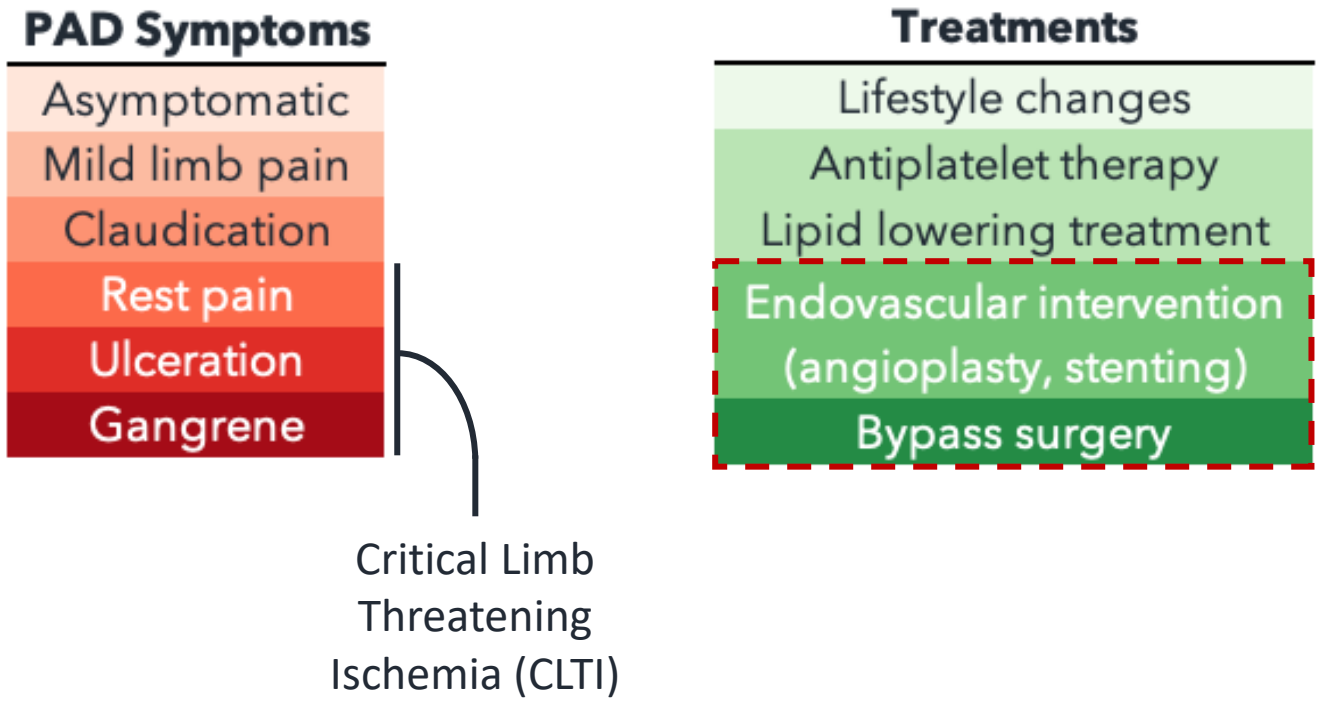


ABI	PAD Severity
≥ 1.0	Healthy
0.9 - 1.0	Borderline
0.7 - 0.9	Mild
0.4 - 0.7	Moderate
≤ 0.4	Severe

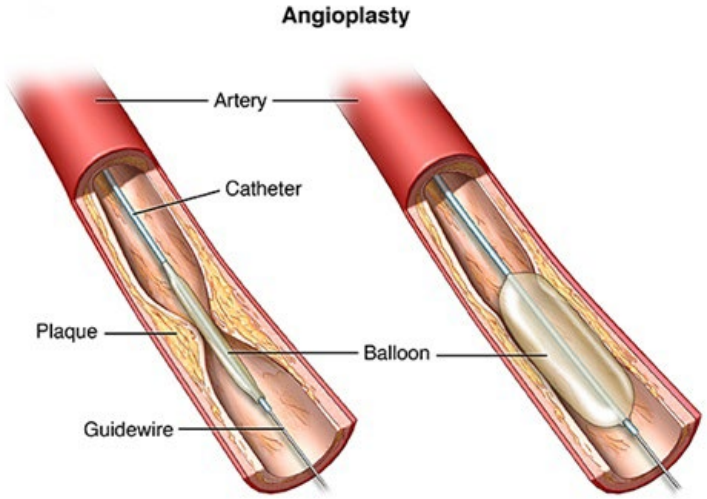
NIH

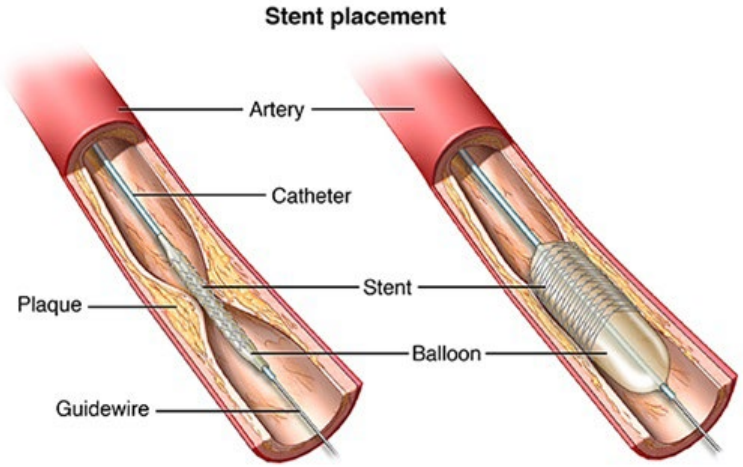
Peripheral Artery Disease (PAD)
Treatment

Treatment varies with severity, usually judged by symptoms



Endovascular interventions





- Lesion is “crossed”
- Balloon inflated, often multiple times
- Obstruction is compacted

Mesh stent inflated w/ balloon

(or self-inflated)

Bare metal, coated, and/or drug-loaded

Benefits of both:

Minimally-invasive

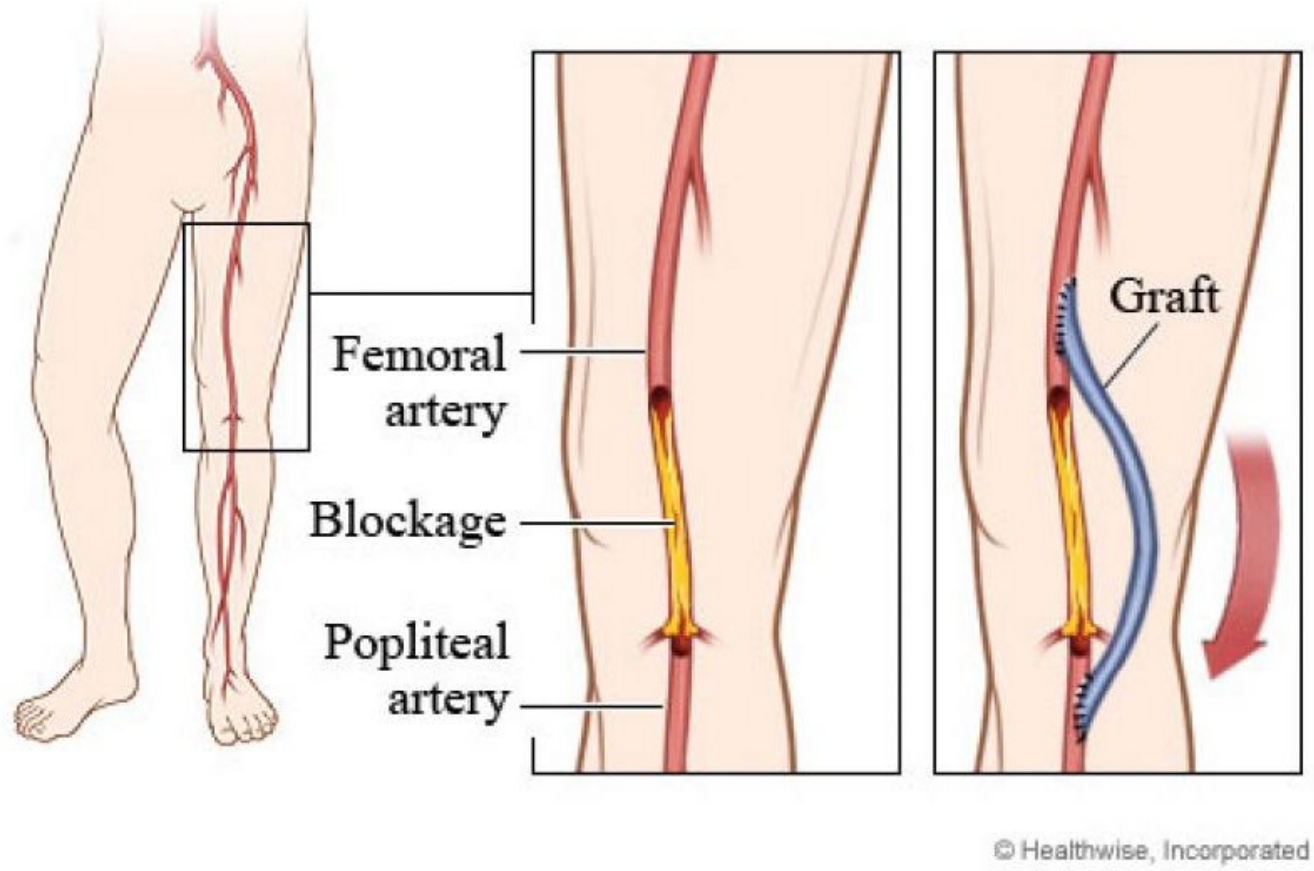
Good for smaller, less severe lesions

Johns Hopkins

Bypass grafts are necessary when endovascular isn't viable

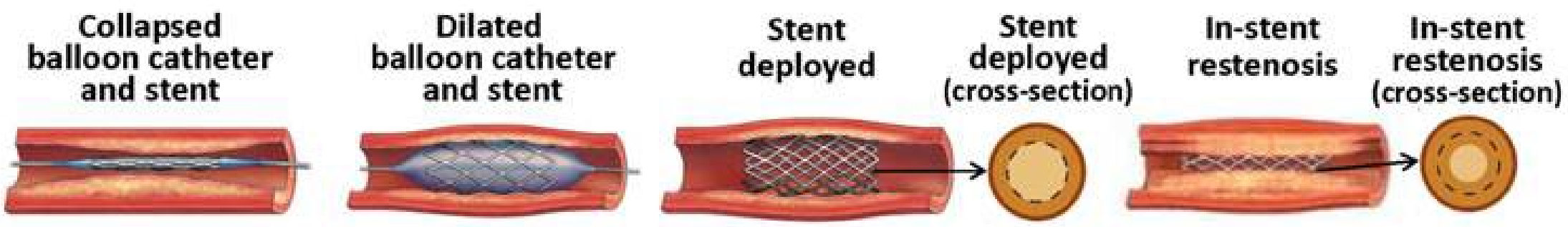
Potential reasons include:

- Long (>15 cm) stenosis
- Complete blockage
- Disease severity
- Recurrence



Procedure
Graft (autogenous vein or synthetic) bypasses blockage

Neointimal hyperplasia
a complication for both endovascular & bypass



- **Neointimal hyperplasia causes *restenosis***
- A response to injury, foreign material, redirected flow, etc.
- Smooth muscle cells in walls proliferate, re-occluding the vessel
- Can lead to re-intervention, limb loss, death

Yin, et al. 2014, Theranostics

The *initial* Needs Statement

"…to create a **drug-eluting bypass graft** that can achieve the following two engineering goals:

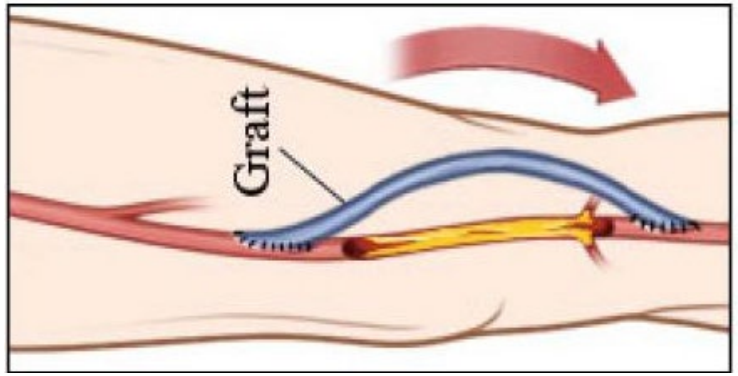
1) to provide adequate blood supply to the distal vascular beds

and

2) to maintain its patency over time, eliminating the risk of restenosis"

Future Fluid Flow Modeling

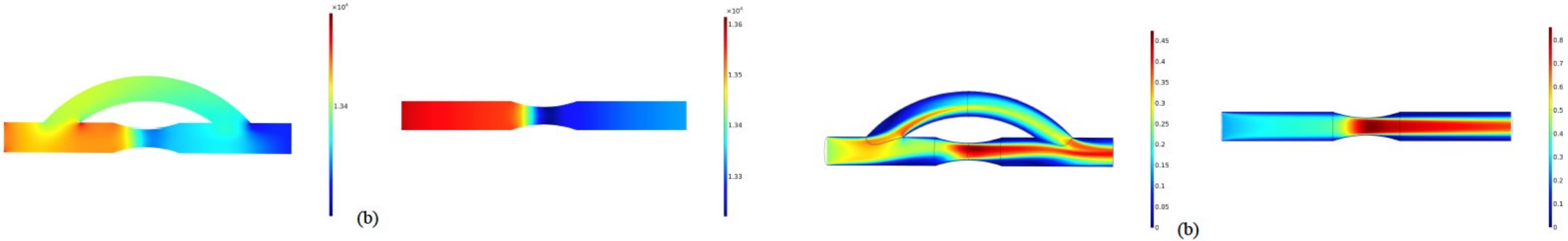
How does bypass graft affect local hemodynamics?



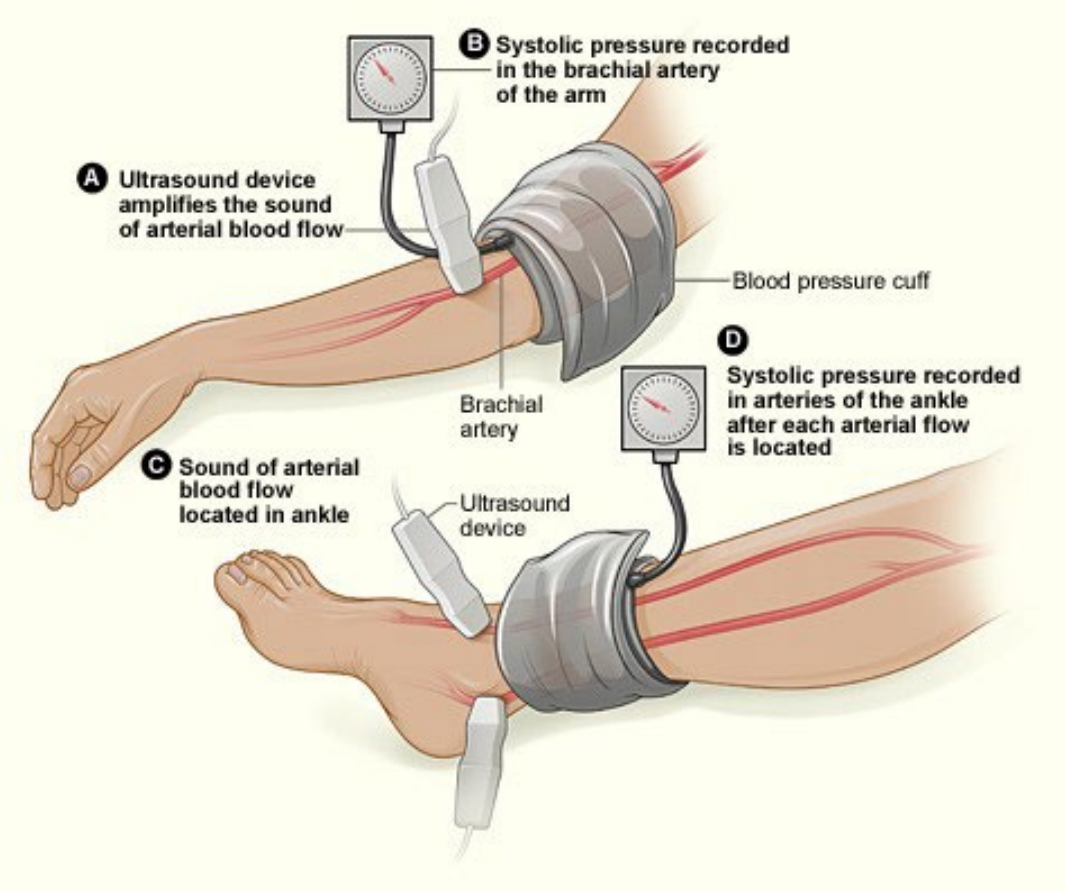
Governed by Navier-Stokes equations:

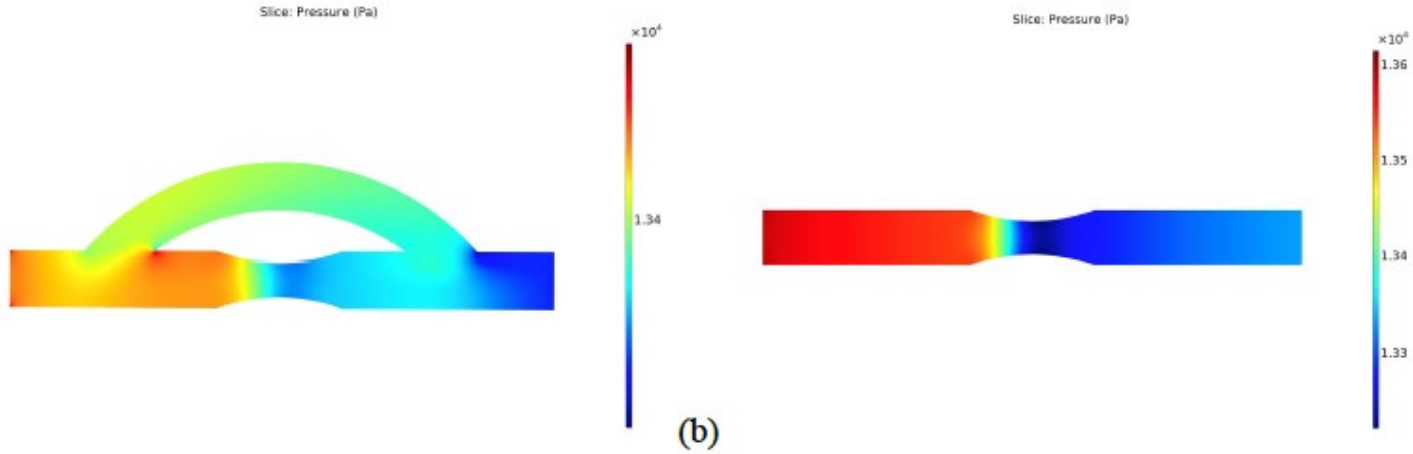
$$\frac{\partial \vec{u}}{\partial t} + \vec{u} \cdot \nabla(\vec{u}) = -\frac{1}{\rho}\nabla p + \vec{F} + \frac{1}{\rho}\nabla^2 \vec{u}$$

$$\nabla \cdot (\vec{u}) = 0$$



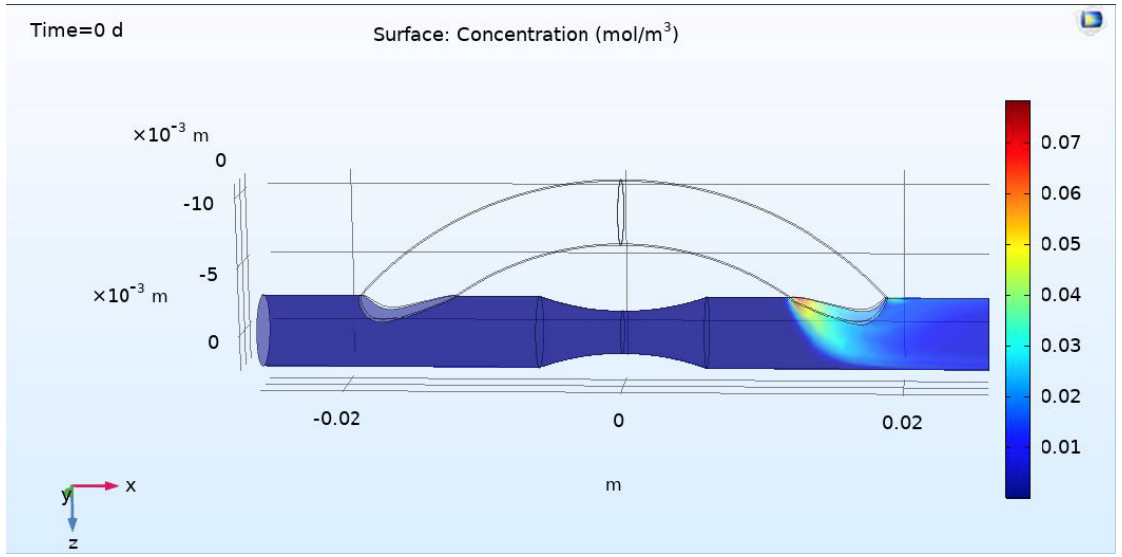
Future Fluid Flow Modeling ≠ ABI





Note to Future You:
ABI does not describe what your model will look like.
ABI specifications can NOT be used to justify Design requirements related to pressure

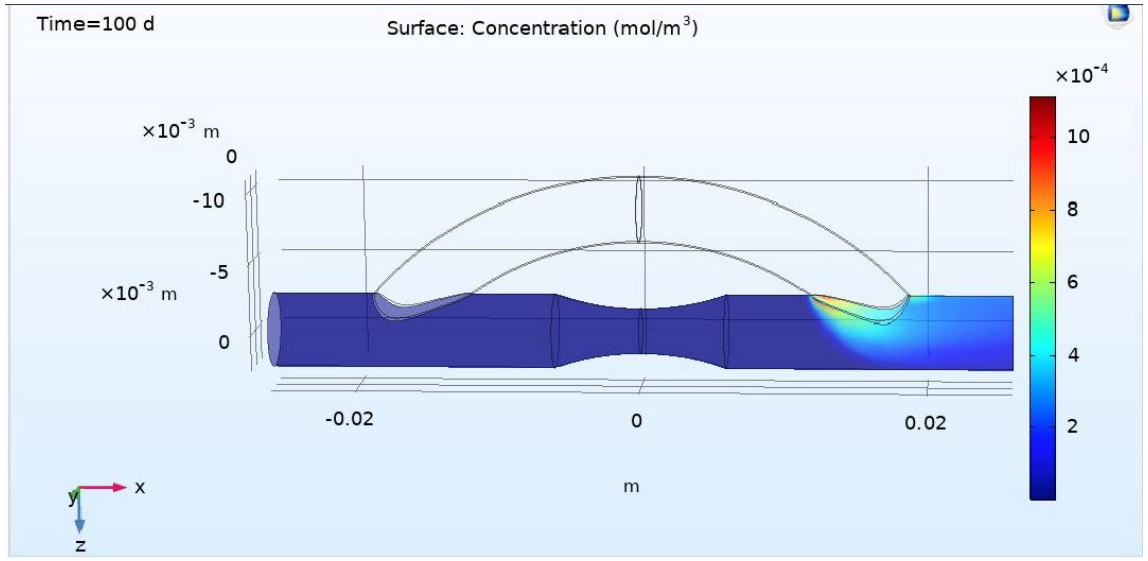
Future Drug Transport Modeling (Bypass)

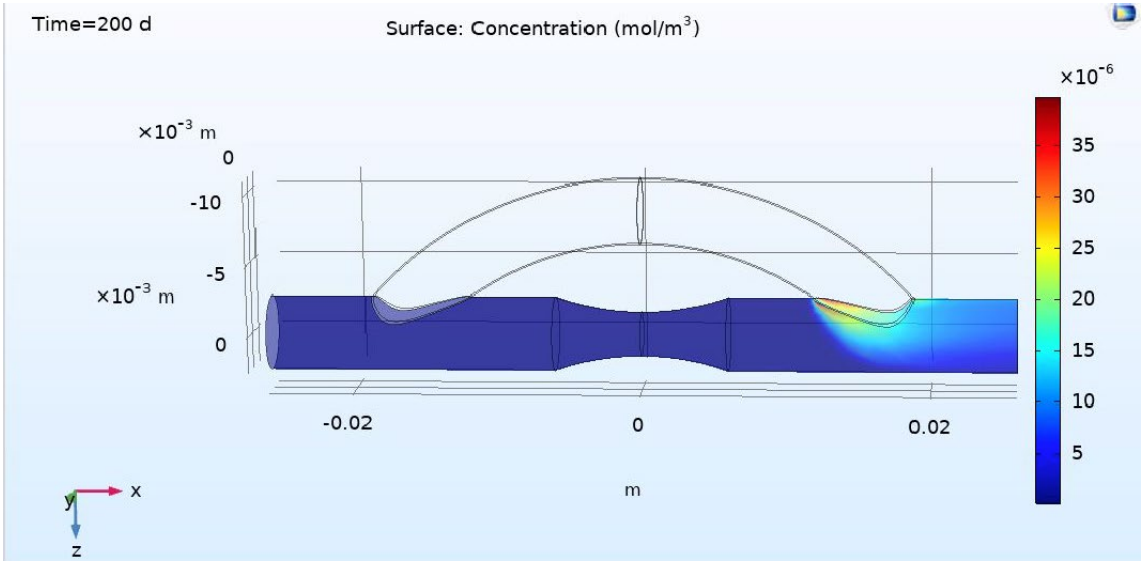


How is the drug delivered through the vessel lumen over time?

Governed by transport (advection-diffusion) equation:

$$\frac{\partial C}{\partial t} = \nabla \cdot (K \nabla C) - \vec{u} \cdot \nabla C + R + S$$





Simplifying the Bypass model

Again, we must simplify but have a responsibility to be aware of the complexity.

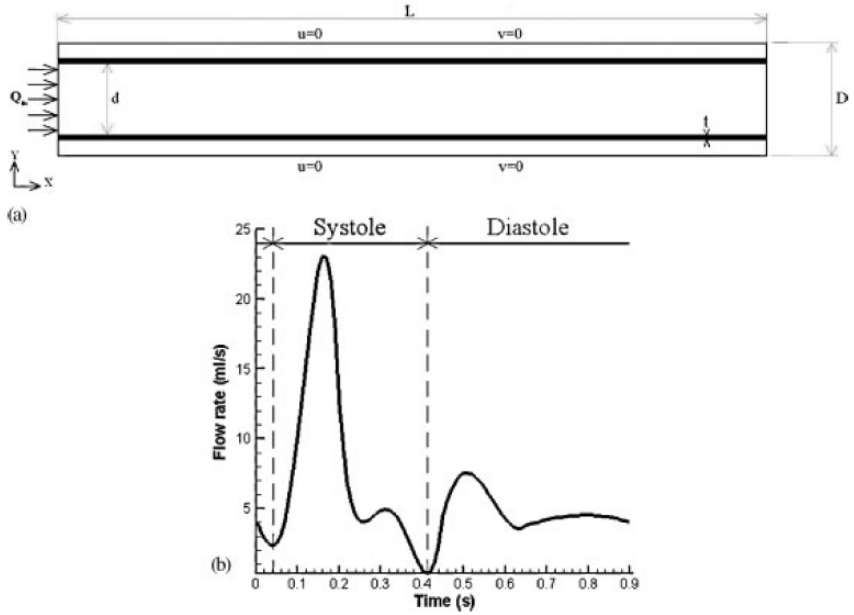


Figure 1. Pulsatile flow in a healthy carotid artery: (a) schematic of pulsatile flow in a healthy carotid artery and (b) flow rate from Holdsworth *et al.* [56].

Int. J. Numer. Meth. Fluids (2008)
DOI: 10.1002/fld

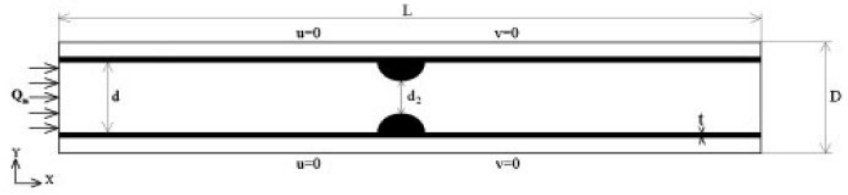


Figure 3. Pulsatile flow in a constricted carotid artery.

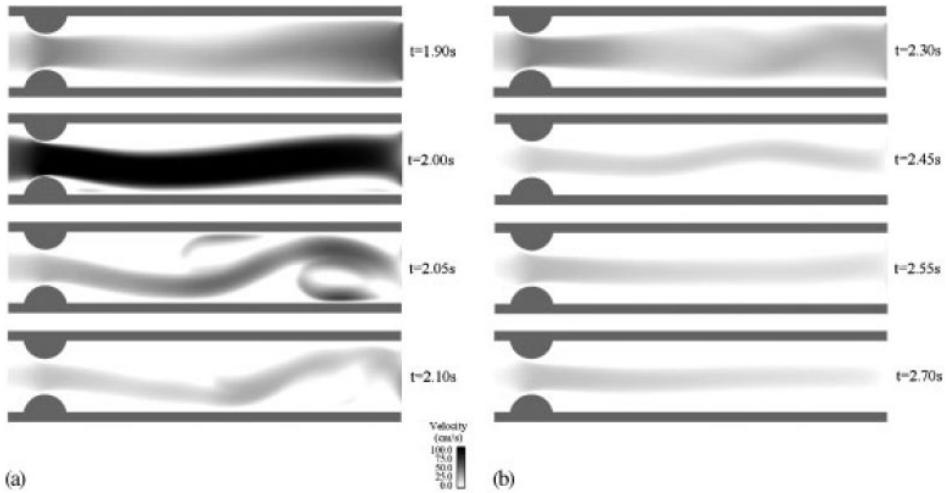


Figure 4. Velocity contours in a moderate (50%) stenosed artery during a cardiac cycle: (a) systole and (b) diastole.

Gay, Mickael & Zhang, Lucy. (2009). Numerical studies of blood flow in healthy, stenosed, and stented carotid arteries. International Journal for Numerical Methods in Fluids. 61. 453 - 472. 10.1002/fld.1966.

Considerations and Recommendations

On modeling

Start simple! Make many assumptions first, then add

Consider 2D models vs. 3D

On research

Find *original* scientific literature

On design

Well-defined goals go a very long way

Creativity is good – novelty is not necessary

On reporting

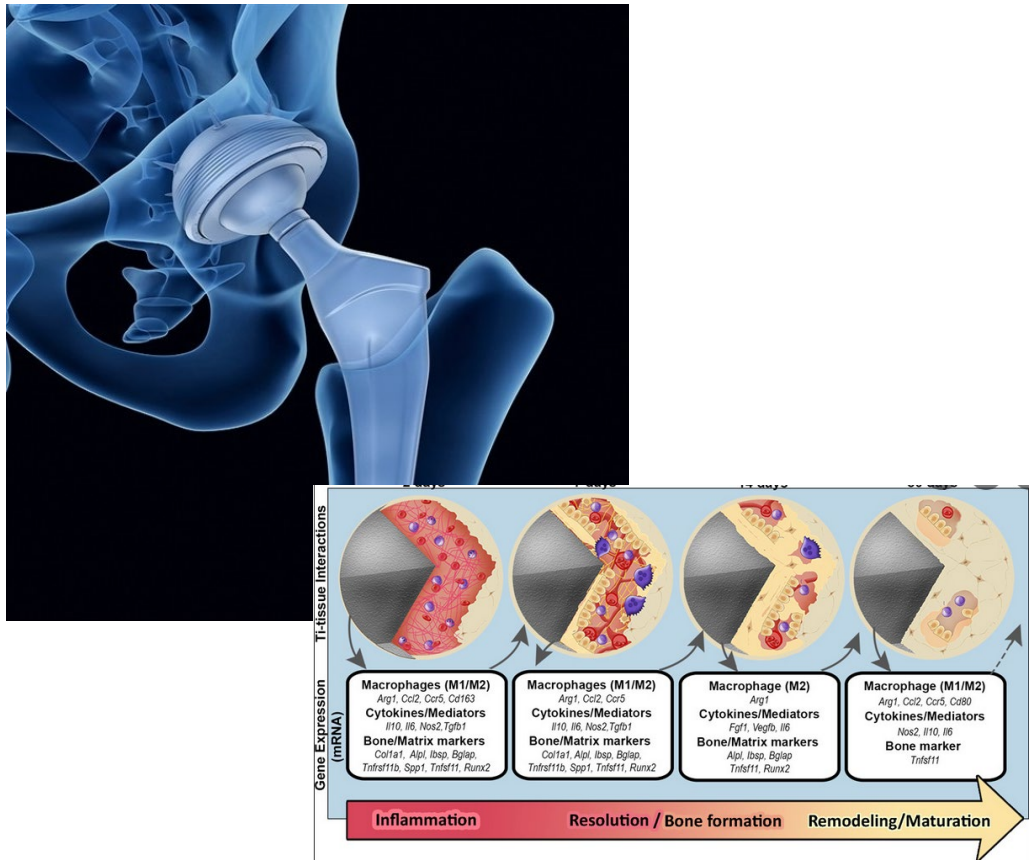
Document, justify all assumptions

Even if things don’t work – what improvements can be made?

Two Projects available to you

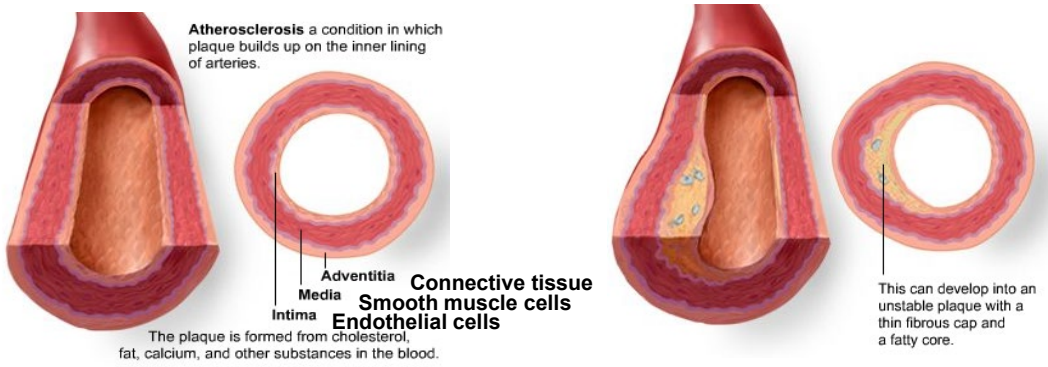
Which one do you prefer?
CATME Teammaker will ask you to pick your preference

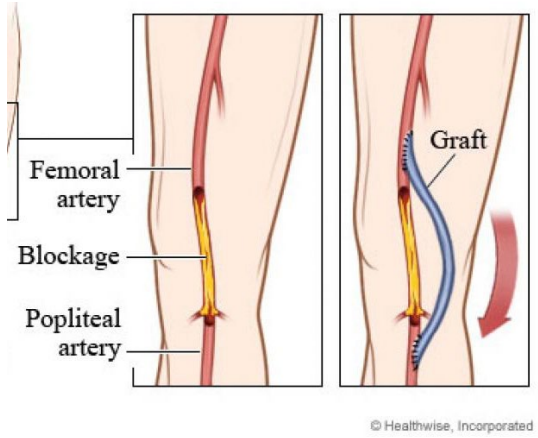
Hip Implant with Growth Factors



ACS Biomater. Sci. Eng. 2021, 7, 6, 2392–2407
Publication Date:February 24, 2021
https://doi.org/10.1021/acsbiomaterials.0c01420

Drug Eluting Bypass Graft





Mayo Clinic Staff - https://www.mayoclinic.org/tests-procedures/coronary-bypass-surgery/about/pac-20384589

Project Teams

- 5-6 students per team
- CATME Teammaker quiz
  - Schedules
  - On campus vs. Off campus
  - Leadership scores
  - Project Preference! Hip or Bypass!
  - At end, option for message direct to teaching team

But first! Some team guidelines and tips!

Engineering Effective Teamwork – Self Awareness

Assignments: Team Formation & Reflection

- CATME Questions – **Due 1/9 at midnight**
  - Schedules
    - Read and answer carefully!
    - Consider yourself BUSY during class
  - You don’t need to screenshot CATME, we will know if you did it or not.
- Reflection Assignment submission – **Due 1/13 at midnight**
  - Short reflection on your previous teams and what you hope for and/or want to improve on for the future.
  - Preparation for in-class teamwork charter / expectations document

Next time…

- User Needs & Problem Definition
  - In general
  - specific to projects
- Library Tools
  - How to find these!
- In-Class assignment
  - Reference Hunt

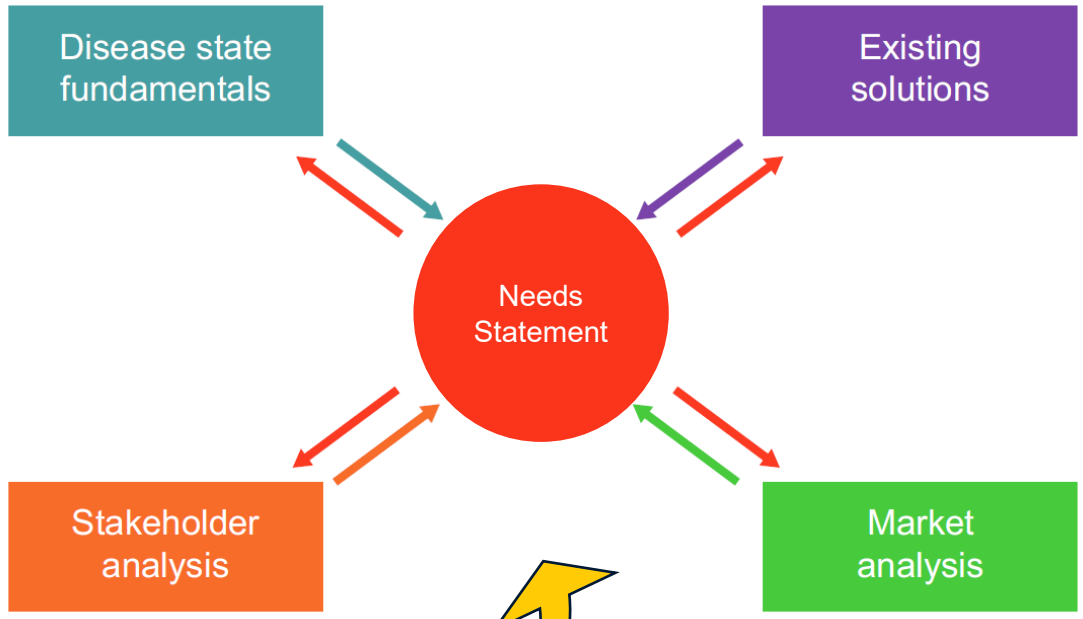


FIGURE 1.2.2
Maximizing the value of needs exploration requires a fundamental understanding of disease, existing solutions, stakeholder, and market factors.