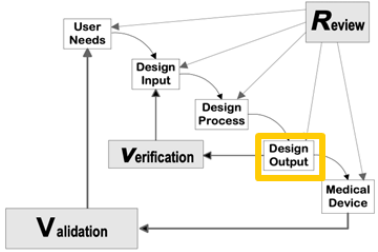
Today's Plan: Brainstorming & Process Check-in

- Engineering Analysis Intro
- Therapeutic Delivery Options
- Geometry notes
- *Break*
- Project Work Time
  - Solidworks 2
  - Brainstorming/Developing Outputs
    - Geometries
    - Therapeutic delivery method (coating, soaking, etc)



Updating Prototype

Testing
Validation
Verification

User Needs

Review

Design Input

Design Process

Verification

Design Output

Medical Device

Validation

Fuzzy lines between Design Outputs and Validation & Verification

All to show we meet the "goal posts"

Engineering Analysis can help!

Engineering Analysis
at any stage

- Paper calculations
- Mathematical Modeling and Simulations
- Mock-up experiments
- Prior work in literature
  - (less analysis, but can be used)

Criteria	Current Design	Elastic Ring Holder	Multiple Loops	Bent Finger Holder	Weight
Safety	0	-1	0	-1	x3
Retractability	0	+1	+1	+1	x3
Component failure	0	-1	0	0	x3
Feasibility	0	+2	+2	0	x3
Holding capsule	0	0	0	0	x2
Release capsule	0	0	-2	0	x2
Bulkiness	0	+1	+1	+1	x2
Capsule stability	0	0	-2	0	x2
Cost	0	0	0	0	x1
Ease of Use	0	0	-1	0	x1
Visibility	0	+1	+1	+1	x1
Totals:	**0**	**+6**	**+3**	**+3**	

Engineering Analysis
Mathematical models
Estimations
Simulations (COMSOL!)

Force body Diagrams
Fluid dynamics
Material properties (Young's Modulus, E)

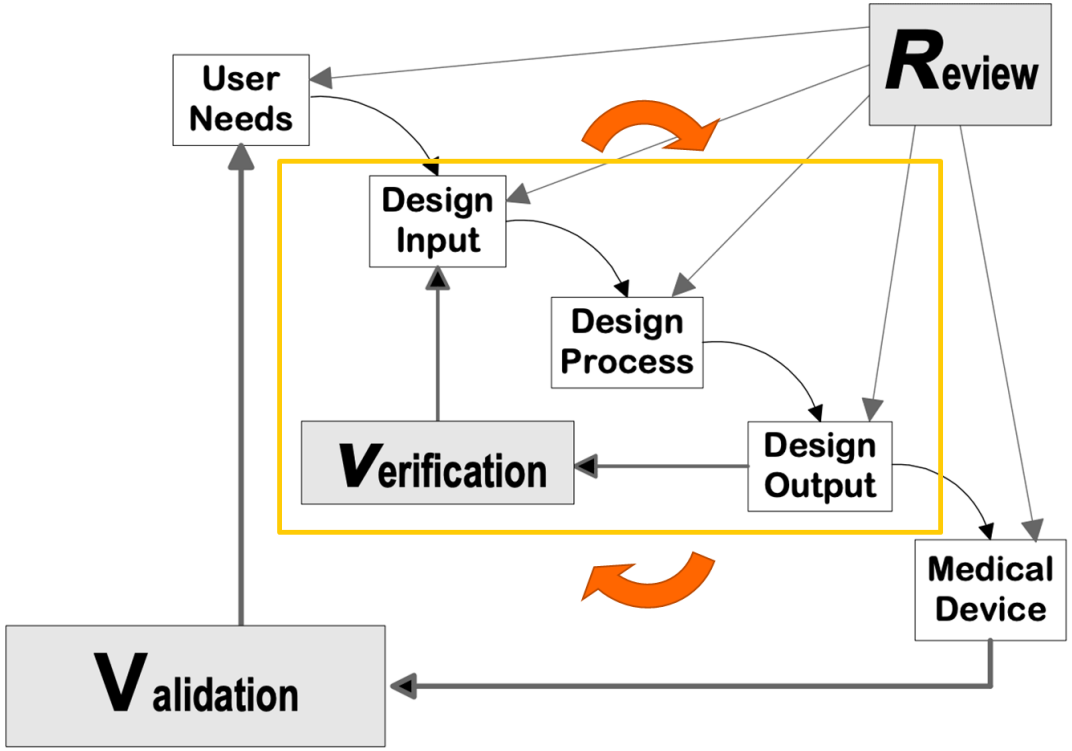
What do you expect to happen?

Will it be enough?

EA During *Inputs* and *Brainstorming*

Sketches & Lit Review

- How do you choose product specs?
  - Literature review
  - “napkin math”
  - Iterate as needed!
- Justify Pugh Matrix decisions
- Sketches
  - Geometries of implants
  - What parts of the body will you need to keep track of as well?
  - Therapeutic agent positioning
  - Layout drawings



Iterate with less detail and more assumptions FIRST

Once more confident in design, THEN add in your details and spend time

Ideation and Concept Generation

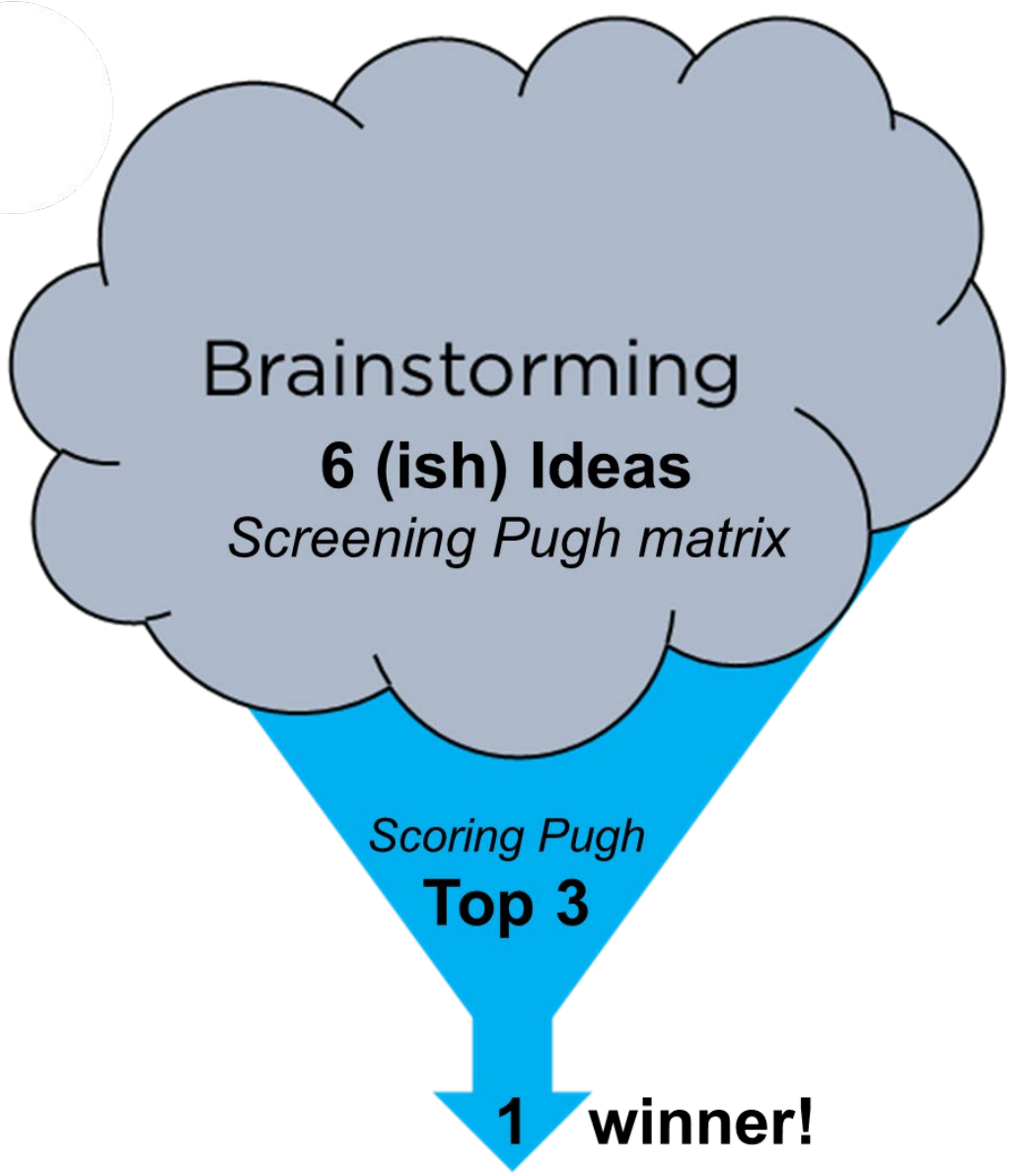
Ideation will be related to decisions on:

1) Materials
2) Therapeutic
3) Geometries

4)Coating methods

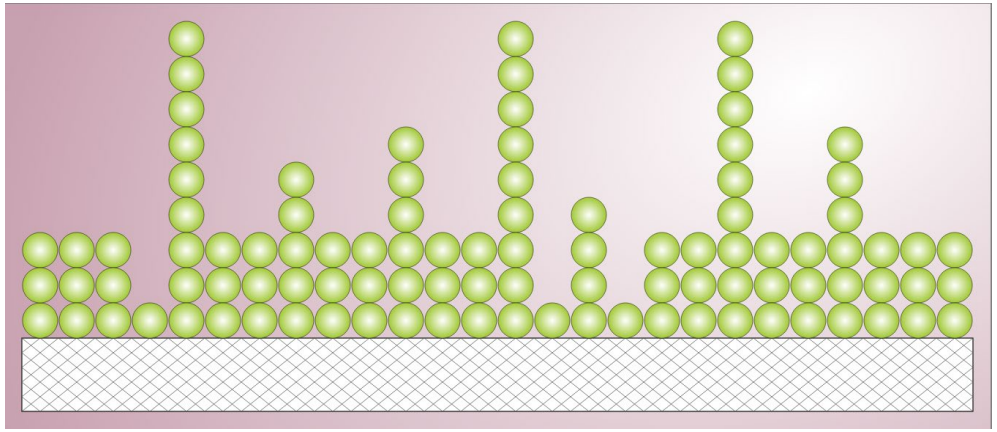
Where will drug be released?
(hint: not ALL surfaces)

How will drug be released?
Adsorption? Diffusion?
(hint: avoid chemical immobilization)

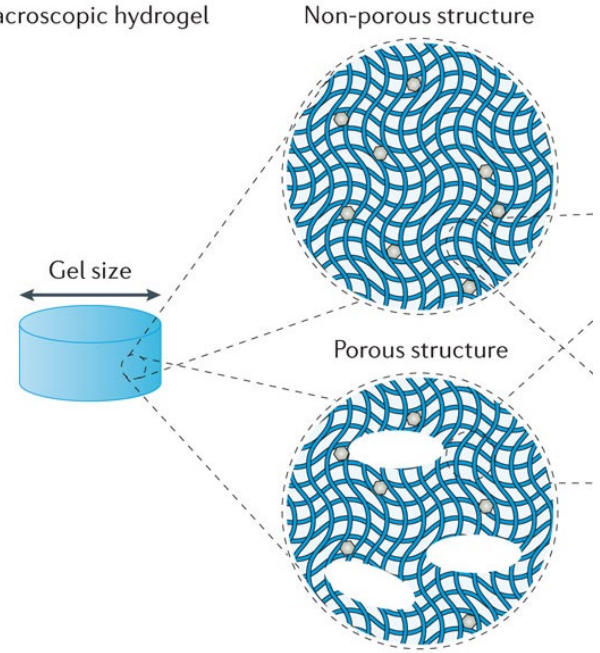


Quick note on drug delivery

- Most likely candidates for you
  - Coating with no additional layer
    - Keywords:
      - Adsorption
      - surface deposition
      - Surface free energy
    - Some methods (Ghandi, Murthy, 2012)
      - Dip coating
      - Brush coating
      - Air brush / spray
  - Coating with an additional layer
    - Key words
      - Diffusion
      - Electrostatic and cleavable linkages
    - Hydrogels
    - Nanoparticles (NP)*
      - May also be used as a *coating* of NPs
    - Meshes



Brunauer, Emmett and Teller's model of multilayer adsorption is a random distribution of molecules on the material surface.
*Brunauer, Stephen; Emmett, P. H.; Teller, Edward (1938). "Adsorption of Gases in Multimolecular Layers". Journal of the American Chemical Society. **60** (2): 309–319. Bibcode:1938JAChS..60..309B. doi:10.1021/ja01269a023. ISSN 0002-7863.*



Part of Figure 1: Multiscale properties of hydrogels, cropped to illustrate hydrogels
Li, J., Mooney, D. Designing hydrogels for controlled drug delivery. *Nat Rev Mater* **1**, 16071 (2016). https://doi.org/10.1038/natrevmats.2016.71

Gandhi, Pankaj J ; Murthy, Zagabathuni Venkata Panchakshari. “Investigation of Different Drug Deposition Techniques on Drug Releasing Properties of Cardiovascular Drug Coated Balloons.” *Industrial & Engineering Chemistry Research*, vol. 51, no. 33, Washington, DC: American Chemical Society, pp. 10800–23, doi:10.1021/ie3006676.

Deposition example methods

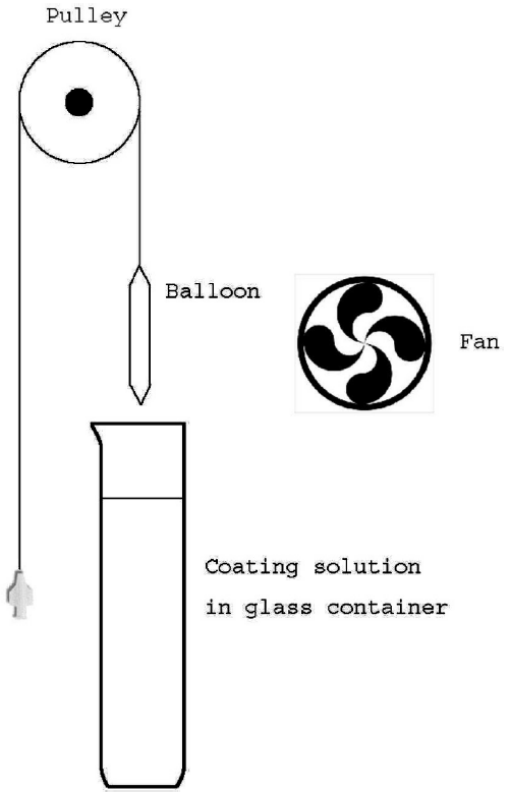


Figure 1. Schematic of dip coating arrangement for balloon catheter.

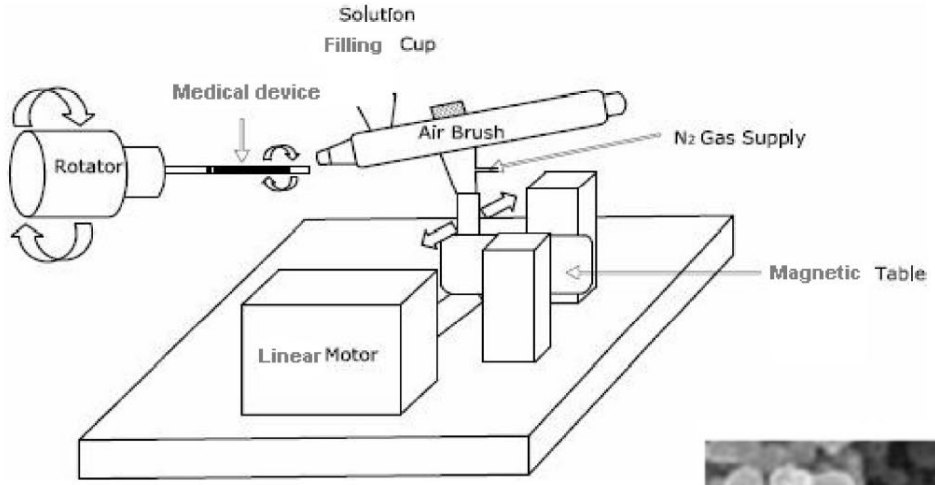
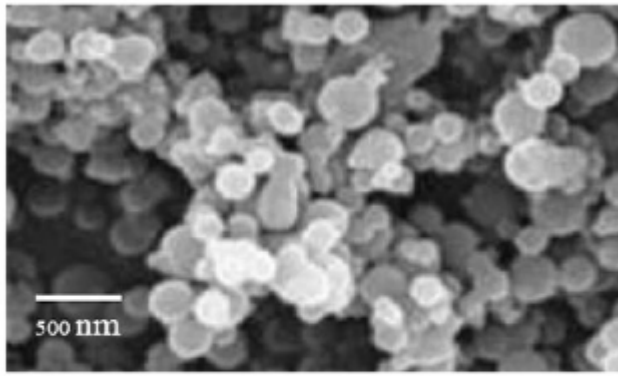


Figure 2. Schematic arrangement of air brush coating of balloon catheter.

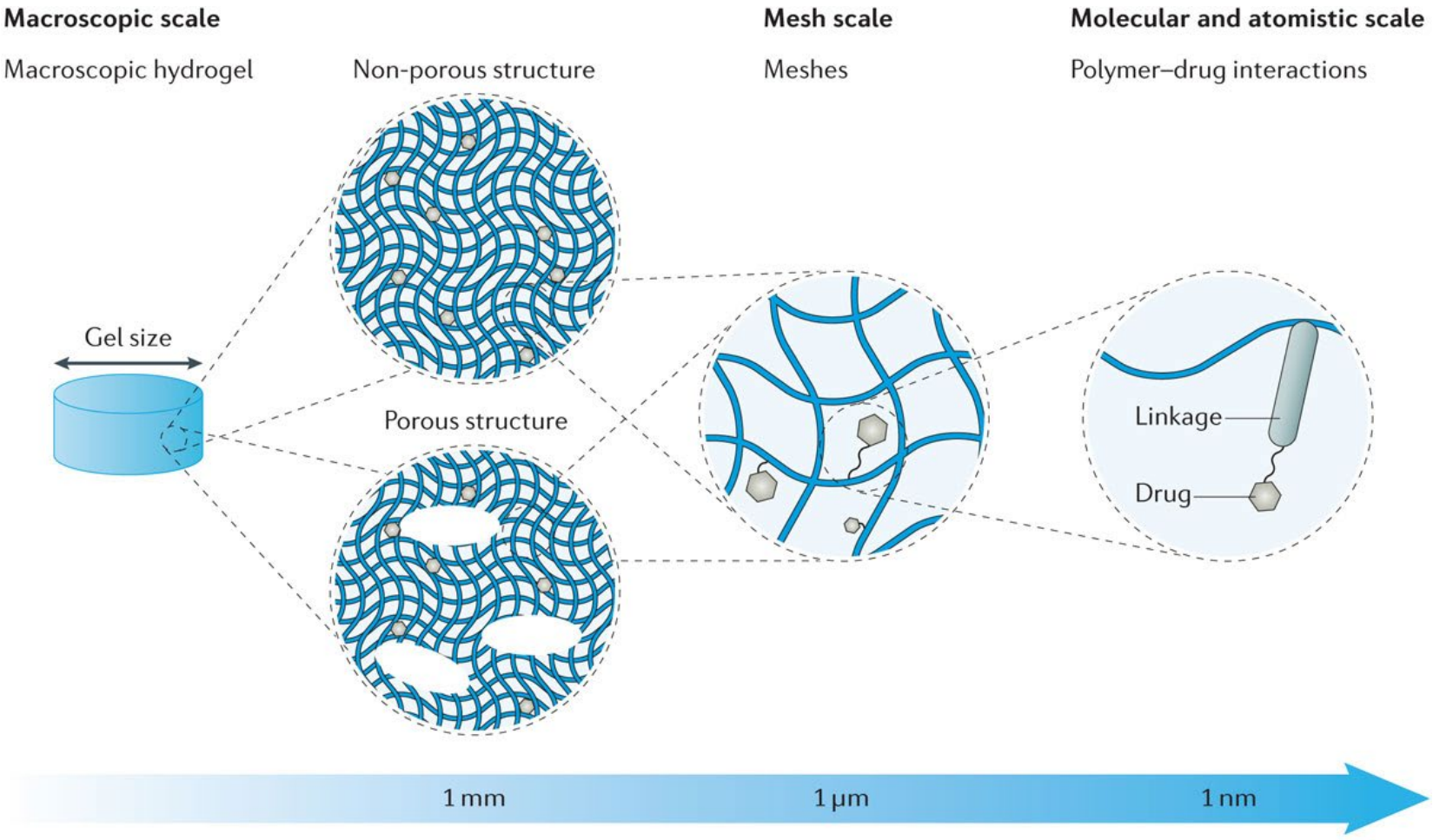


(d) SEM of NPs from balloon surface.

Gandhi, Pankaj J ; Murthy, Zagabathuni Venkata Panchakshari. “Investigation of Different Drug Deposition Techniques on Drug Releasing Properties of Cardiovascular Drug Coated Balloons.” *Industrial & Engineering Chemistry Research*, vol. 51, no. 33, Washington, DC: American Chemical Society, pp. 10800–23, doi:10.1021/ie3006676.

Additional layers, such as hydrogels *also* deposited, but the drug is delivered through diffusion, rather than from surface interactions

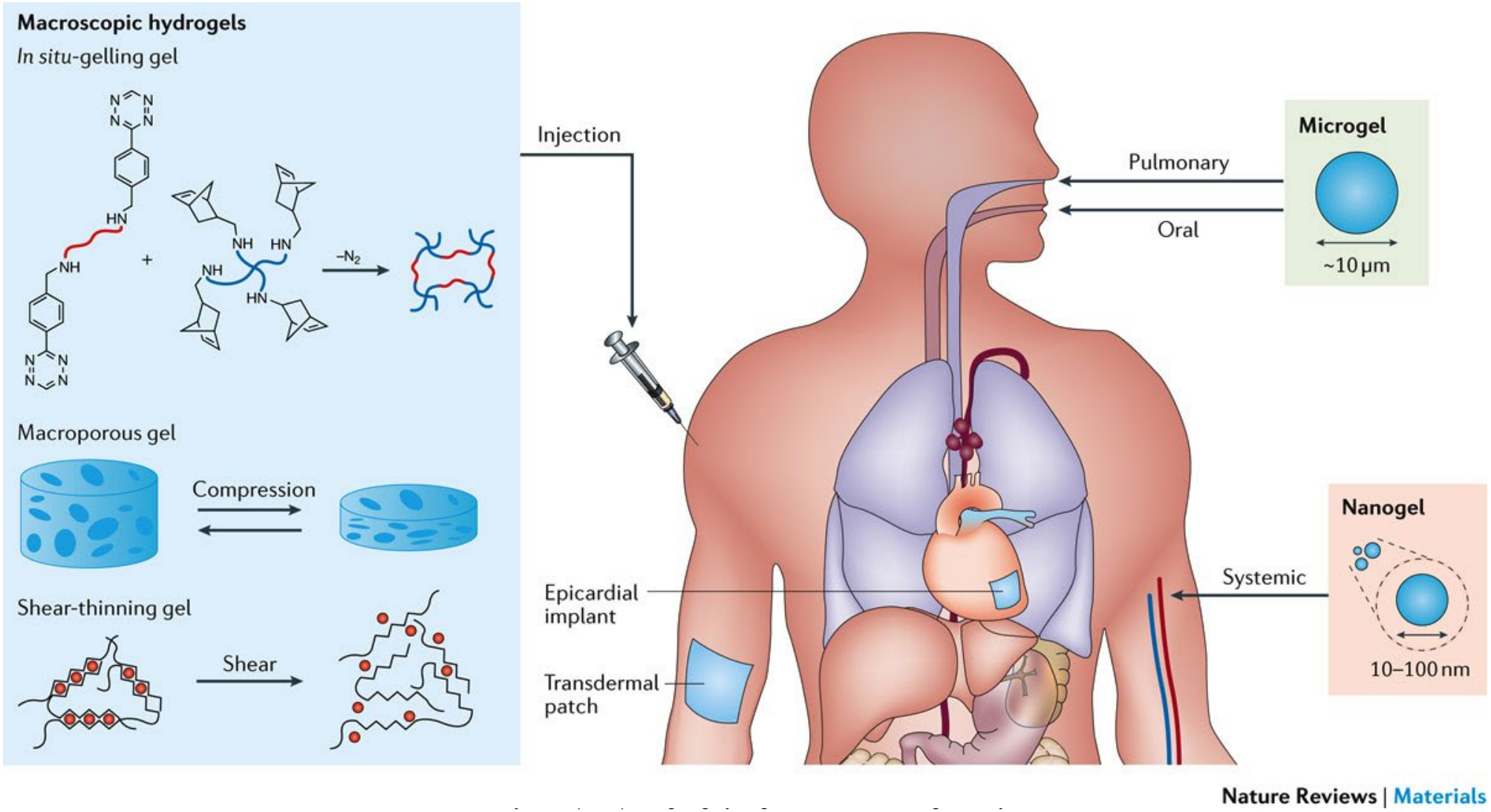
Figure 1 Multiscale properties of hydrogels



Li, J. & Mooney, D. J. (2016) Designing hydrogels for controlled drug delivery
Nat. Rev. Mater. doi:10.1038/natrevmats.2016.71

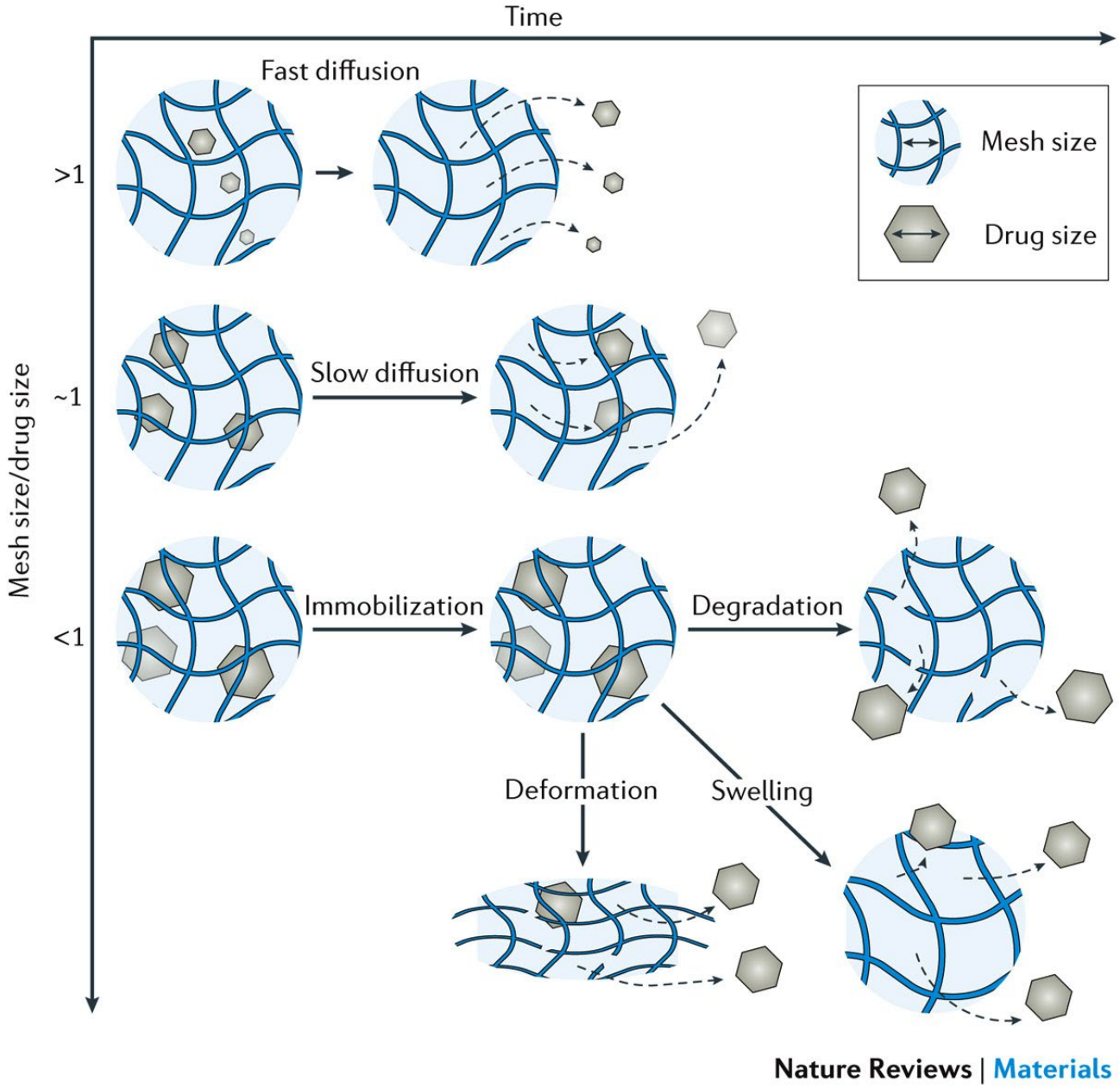
Nature Reviews | Materials

Figure 2 Macroscopic design determines the delivery route



Nat. Rev. Mater. doi:10.1038/natrevmats.2016.71

Figure 3 Mesh size mediates drug diffusion



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Diffusion rate is based on Material AND solute

Usually in volume or mass **per unit time**

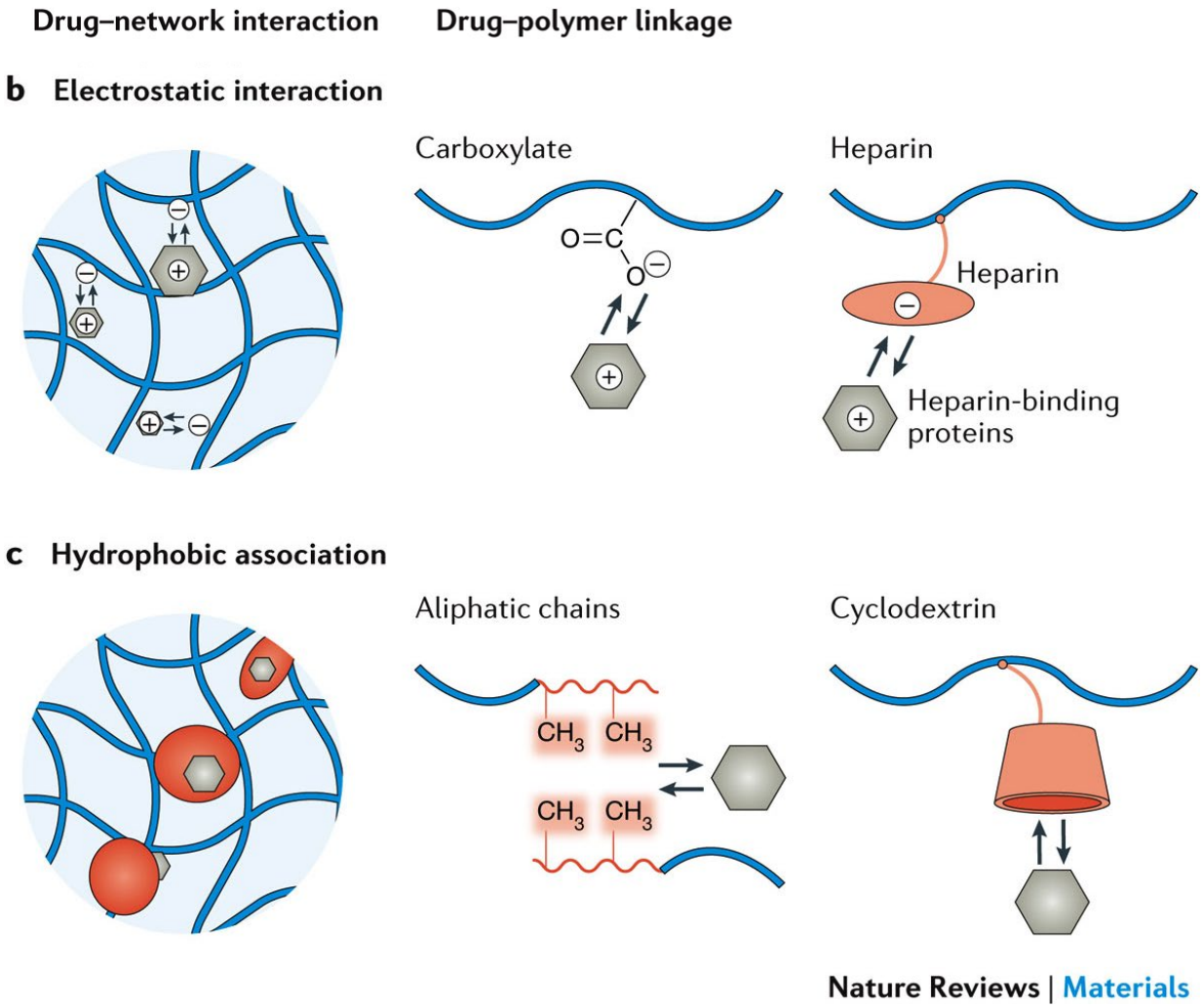
Describes how quickly the solute can leave the medium

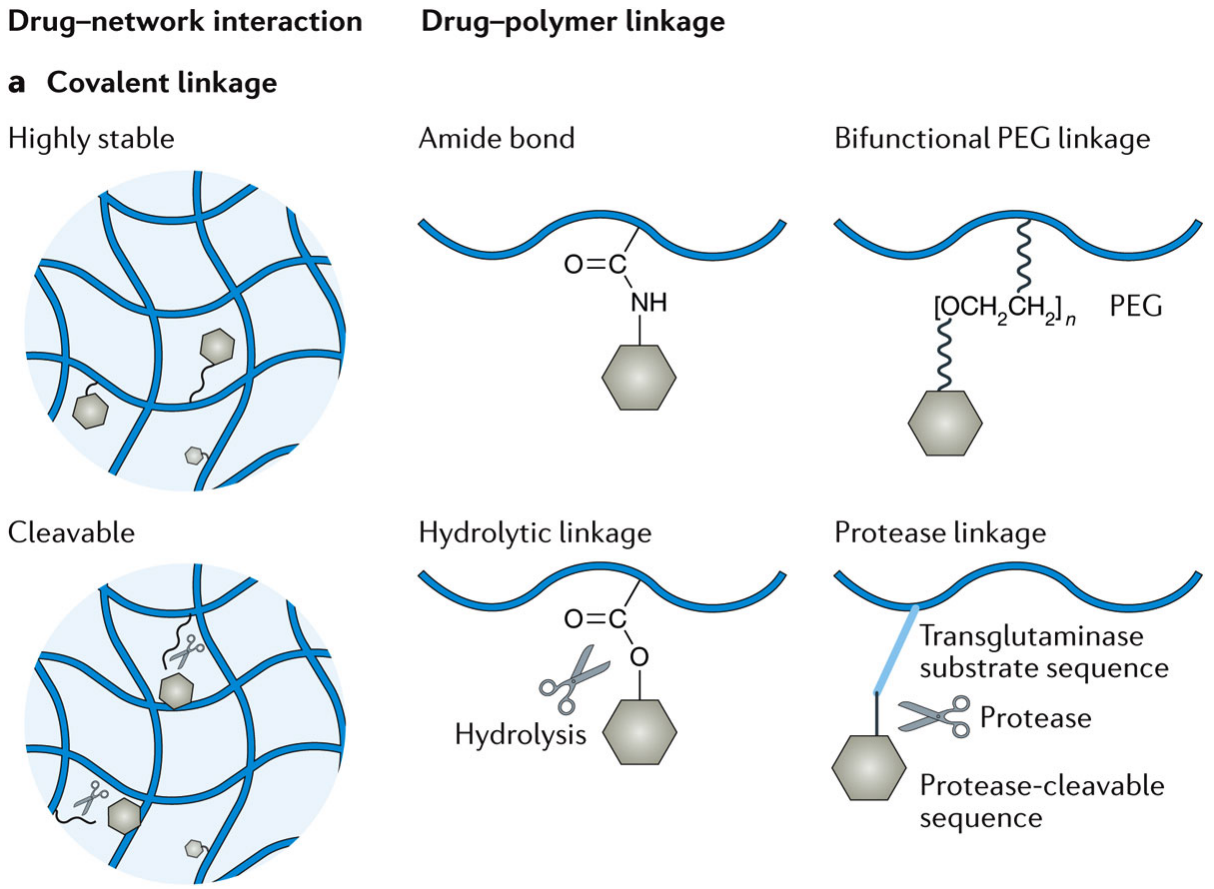
Diffusion rates are usually determined experimentally

How much solute escapes a volume over a certain amount of time?

Usually, an **exponential function**

Figure 4 Chemical interactions mediate drug release





^^Covalent linkages require additional reactions for drug to be released! Unless you can guarantee these reactions are instantaneous, consider immobilization methods TOO complex for VMO

Adapted from Li, J. & Mooney, D. J. (2016) Designing hydrogels for controlled drug delivery *Nat. Rev. Mater.* doi:10.1038/natrevmats.2016.71

Drug delivery expectations

- We don’t expect you to know exactly what methods you’re using
  - Ie. 3% w/v Hyaluronic Acid Hydrogel, 10% collagen hydrogel in a 4:1 mixture, UV cured with methacrylate and Irgagure 2959
- But we **do** want to know:
  - What *style of delivery* are you using?
    - Does it include a thin layer of material?
      - How thin? 1-2mm? 100um? 10nm?
    - How are you adding it? And how does it leave?
      - Diffusion or surface energy?
    - What concentration of therapeutic will you be applying?
    - ***How quickly will it diffuse away?***
      - ***What will it be diffusing through (coating, bypass, bone, other)?***

A few things to watch out for

- Bisphosphonates
  - Tends to “collect” in places and never truly leave
  - Not the only drug to do this, but worth considering for safety & efficacy
- Diffusion constants are upcoming
  - Diffusion constants are based on the solute AND the material
    - Diffusion constant of a drug will be different in bone vs. water vs. hydrogel
  - This will take time to find
  - May need to approximate using
    - Similar drugs/growth factors/molecules OR
    - Similar materials
  - If using a coating method with another material layer
    - Will need diffusion constant through that material AND your local tissue (bone or vasculature)

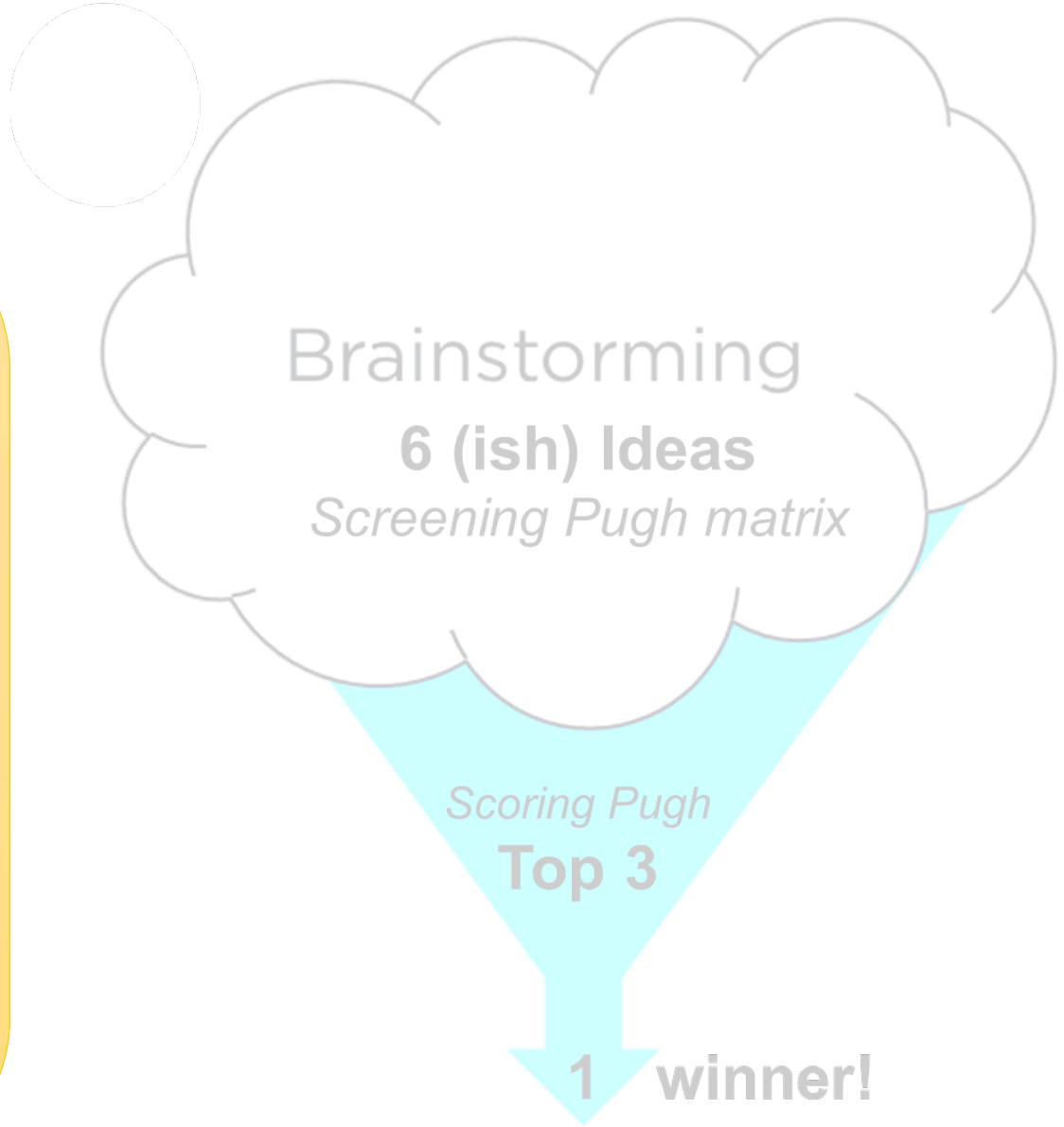
Ideation and Concept Generation

Ideation will be related to decisions on:

1) Materials
2) Therapeutic
3) **Geometries**
4) Coating methods

What angles will you use? What diameters? Shapes?
(Where did you get these numbers?)

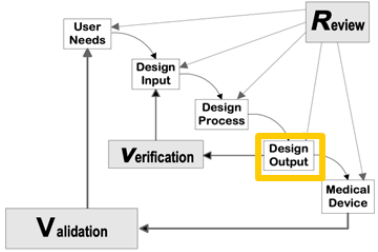
How will you split the Solidworks modeling portion?



Quick note on dimensions

- Your design requirements will likely have a range of acceptable ranges
- You can only model ONE distinct size
- Choose which size you're planning to make and *justify your choice*
  - Average? For what population?
    - Is there an age, sex, etc that is more likely to need your device?
  - Min or Max? Why?
    - Underserved population?
    - Worst case scenario for drug safety?

Consider how to split the modeling work



Hip

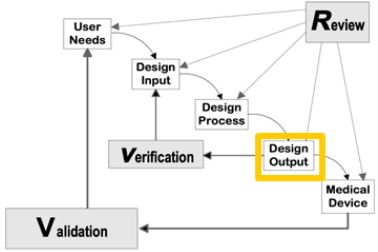
- Splitting the hip implant into pieces
  - Acetabular cup, lining, femoral head, femoral stem?
- Modeling a Femur
  - Will need for COMSOL

Bypass

- Making a peripheral artery with a bypass
- Peripheral artery **without** a bypass

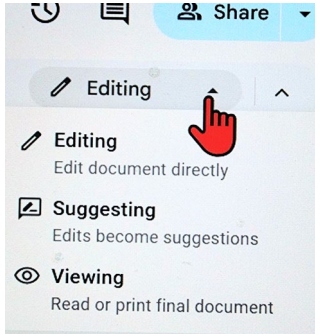
BOTH: sketch out plans BEFORE trying to model them
Where will drug/growth factor *go* on the model?
What are the dimensions you need? What basic shapes should you start with?

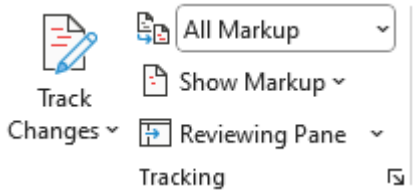
Assigning Tasks & Version Control
Communication & Labeling are Key!



Documents

- Name-date.docx
- Name-v1.docx
- Name-subpart-v1.2.docx
- Google version history
  - Suggestion Mode
  - Comments
- Microsoft Word Track Changes (Review)





Software Files

- Consider: Main and branches
  - Main is most stable version
  - Branches – “checked out” versions being edited.
- Solidworks has “rollback” options within a file

Consider how you want to communicate and organize so that one person is not stuck with the whole part/piece of a project

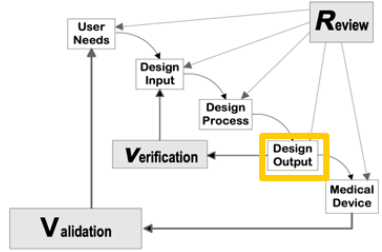
Trunk/Main can branch then merge

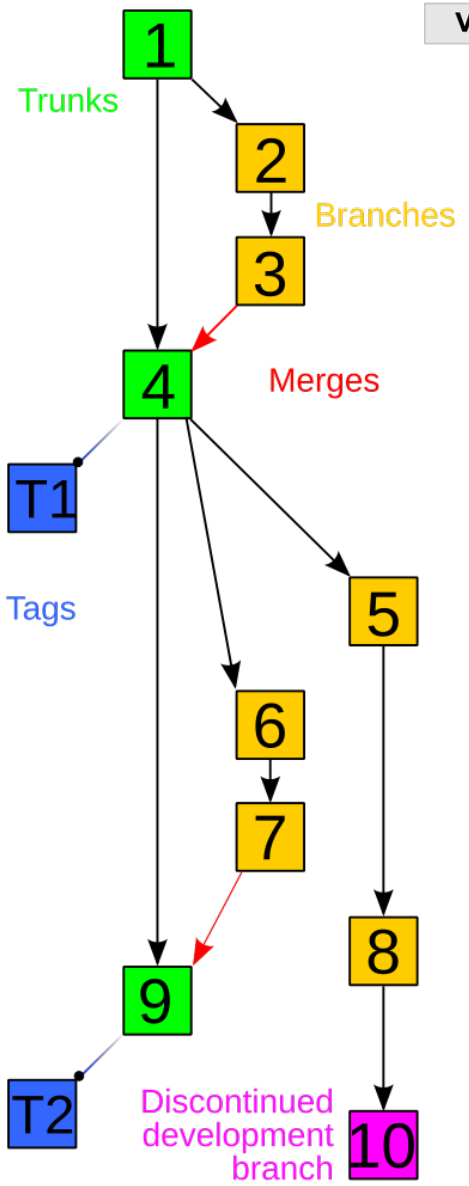
Once a branch becomes ~final, you can put it back into the main folder, and put the old “main” into a “prior versions” folder

- Part 1
  - Part1_v3.sldprt
  - Branches(folder)
    - Par1_V3.1
  - Older versions (folder)
    - Part1_v2.sldprt
    - Part1_v1.sldprt

If you choose this route, consider “Checkout” and “Check-in” folders, texts, notes, or some kind of Communication with team.
(more examples: https://serengetitech.com/tech/introduction-to-git-and-types-of-version-control-systems/)

Avoid being stuck for days! Check something back in and let someone else work on it!





Up Next

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- Therapeutic Delivery Options
- Geometry notes
- *Break*
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Take a 5-minute Break!

Versailles, France – August 2025