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Design Foundation, Part 1

BME 590L

Engineering Design

"*Engineering design is the process of devising a system, component, or process to meet desired needs.*"

ABET

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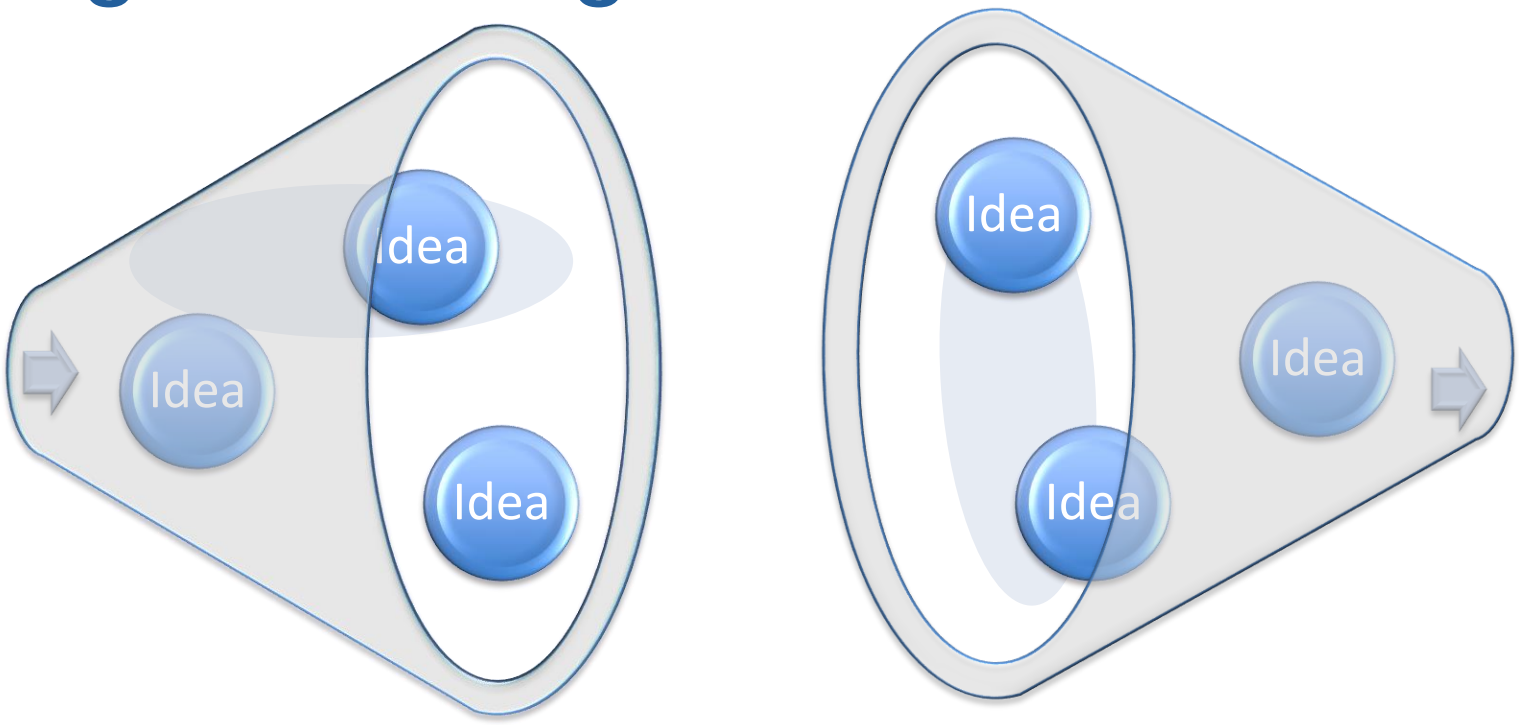
Design Thinking



Divergent Thinking:

Asks: What is possible?
Looks for Possibilities
The more ideas the better!

Convergent Thinking:

Asks: What is?
Looks for Fact
Most Common in Education

"Engineering Design Thinking, Teaching, Learning" Dym et. al, Journal of Engineering Education, January 2005

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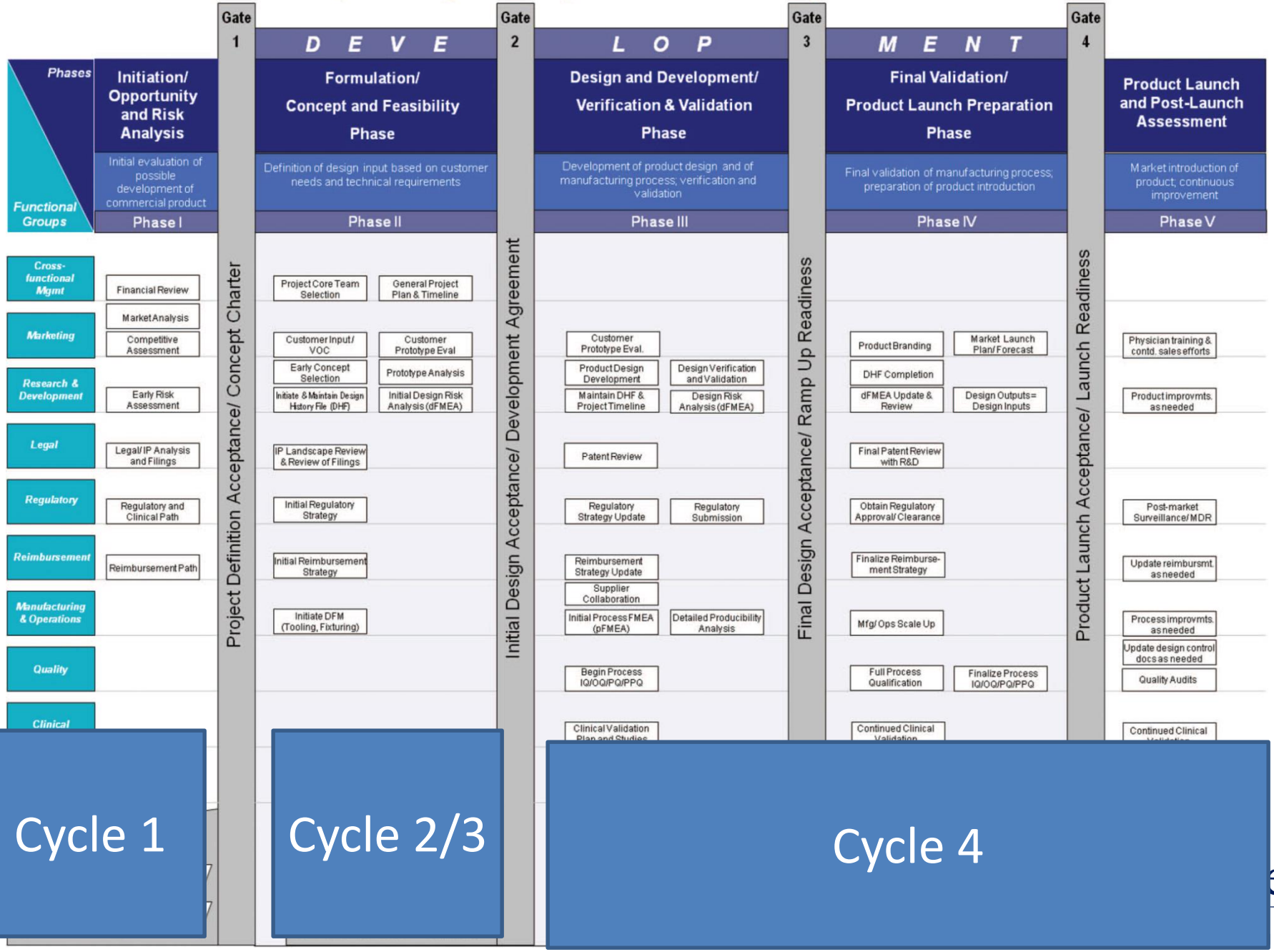
Medical Device Development: High-level Representation of Development Phases and of Functional Activities



	Start of Course	Cycle 1 - PREP/ID	Fall Break	Cycle 2- DESIGN	Winter Break	Cycle 3 - PROTOTYPE	Spring Break	Cycle 4 - TESTING	End of Course
Lecture Topics		Disease State Analysis, Patient Flow Competitive Options, including IP landscape Market Analysis Customer Needs Specifications, Constraints (including Standards/reg)		Functional Decomposition and System-level Design Concept Generation Concept Selection Testing strategies Two "concept feedback" lectures		DFM, LBM Quality: DOE, Statistics, FMEA Clin/Reg Strategy and IRB IP Disclosure and Strategy		Design Poster Presentations Oral Presentation Tips & Tricks Final Presentation Dry-runs	
Written Delieverables		Design Foundation Document, which includes DSA, Patient Flow, IP, Market Analysis (Basically the intro section to the final report) HOQ (Customer needs mapped to preliminary specifications and constraints)		Functional Decomposition (Appendix 1 of Final Report) Sketches/CAD of top designs (Appendix 2 of Final Report) Pugh Matrices (Appendix 3 of Final Report) Updated HOQ/specs Testing Strategy (rough proposal) Rev 2 of DFD		Final design desciption (both form and function, including CAD/photos of prototype) Testing proposal (essentially the methods section of final report) Implementation Strategies (LBM, FMEA, Clin/reg strategy and IRB proposal (if needed)) Updated, Final HOQ/specs Rev 2 of Appendices Competition Submission Plan		Final Report, which includes: 1) DFD 2) HOQ 3) Final Design Document 4) Test Methods and Results 5) Implementation Strategies 6) Appendices Competition Submission IP Disclosure (if applicable) IRB documentation (if applicable)	
Presentation Deliverables		Project Intro slides (content of DFD, up to specs), 10 slides		Intro slides, plus five slides showing top 3 concepts/prototypes/subfunctions (Video/photos/CAD encouraged)		Intro slides, final design slides (3-4 slides showing final prototype), and implementation slides (3-4 slides showing LBM, FMEA, Clin/reg strategy)		Final Presentation (Intro slides, final design slides, tesing results, implementation slides, conclusion slides - polished) Poster Presentation (leveraging their existing slide deck and final report)	
Presentation Format		10 minutes in-class presentation		30 minute time slot, with mentors and part of class (four other teams?)		15-20 minute in-class presentation		30 minute time slot, with mentors and part of class (four other teams?)	
Prototyping		Prototyping skills introduced		Initial prototyping; low to medium fidelity prototype and/or working subfunctions completed by winter break		Prototype refinement; functional, integrated prototype ready by spring break		Prototype tested against all specs in a statistically-driven approach	

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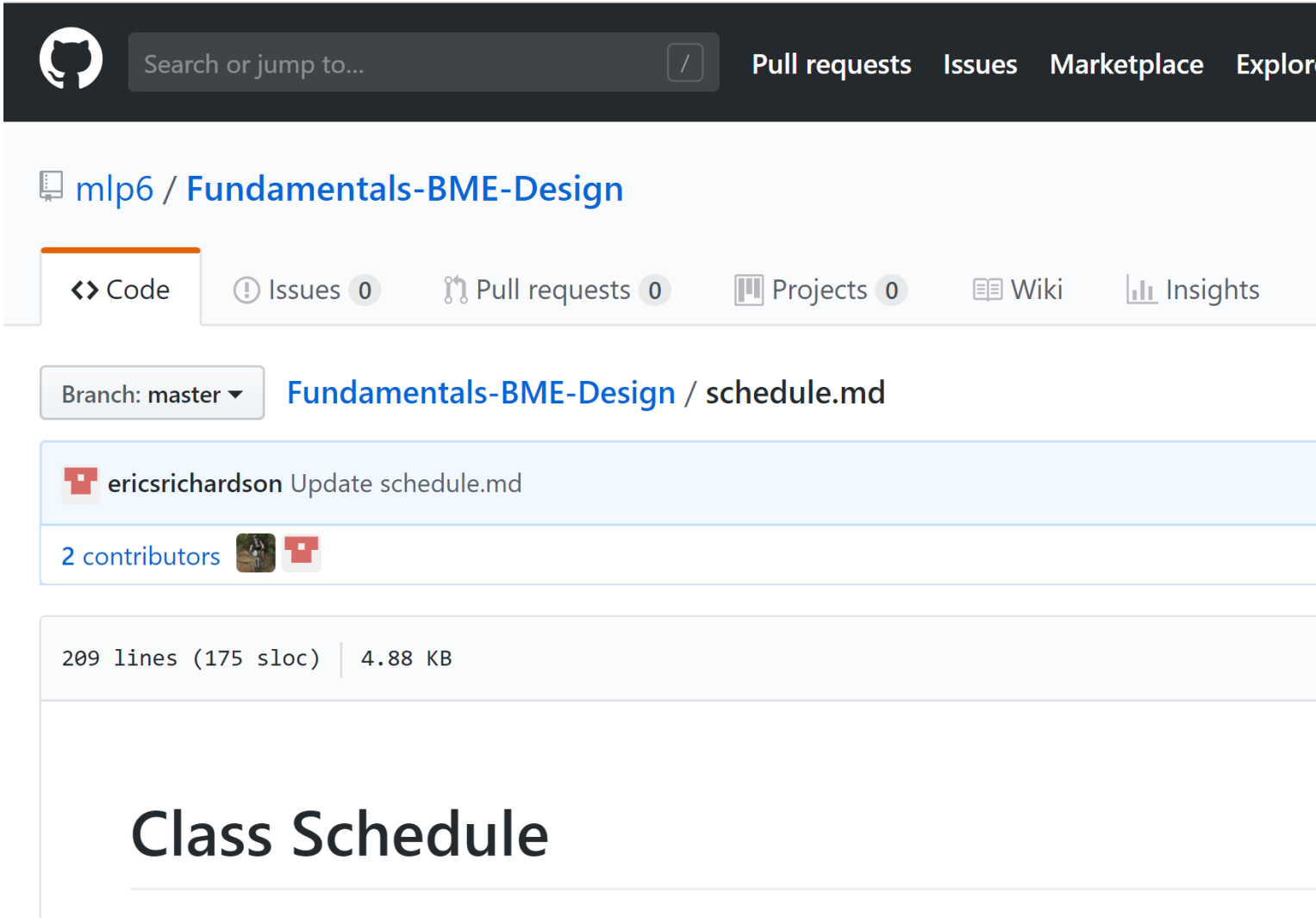
Github Repo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Pull requests 0
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Fundamentals-BME-Design / schedule.md
ericsrichardson Update schedule.md
2 contributors
209 lines (175 sloc)
4.88 KB
Class Schedule

Course Philosophy

- Provide practical process skills and integrate existing engineering skills
- Two parts to every design:
  - Design/Prototyping
  - Process/documentation
- When done well, they complement each other, when done poorly:
  - Design/Prototyping = endless chaos
  - Process/documentation = endless boredom

Course Philosophy, continued

- Process lectures and skills lectures throughout the year
- For process lectures:
  - Introduction of material, then team time, the sharing with class (Think, Pair, Share)
  - The purpose of process lectures is to get your started on process with profs nearby
  - It will feel fast and incomplete, but take advantage of the time you have as a team

Course Philosophy, continued

- Course deliverables are relatively large and separated
- Interim assignments are not graded, but give an opportunity for you to get feedback
- Successful teams: steady climb
- Unsuccessful teams: peaks and valleys

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Today

- Announce teams
- Team dynamics
- Team contract, communication with sponsors
- Design Foundations, Part 1

Teams

Neonatology	**Sarah Blau**	**Palmeri**
	Elise Fernandez	
	Melissa Horowitz	
	Helen Tan	
Bladder	Enoch Chang	Palmeri
	Michael Good	
	Apoorva Ramamurthy	
	Naomi Morales-Medina	
Hand Measure	Jen-Wei(Rich) Wang	Richardson
	Miranda McMickens	
	Tanvi Kamat Tarcar	
	William Ding	
GI Endo	Xiaoyu Qi	Richardson
	Lucy Liang	
	Pratik M Bokadia	
	Urvi Telang	
BP	Erick Lorenzana	Palmeri
	Howard Li	
	William Ding	
	Rebecca Cohen	

Teams

	Pratik M Bokadia	
	Urvi Telang	
BP	Erick Lorenzana	Palmeri
	Howard Li	
	William Ding	
	Rebecca Cohen	
Intubation	Jason Cooper	Palmeri
	Kyle Janson	
	Zhiwei Kang	
	Ashish Vankara	
Needle	Stephen Xu	Palmeri
	Edward Yao	
	Kayla Wright-Freeman	
	Chance Fleeting	
Derm Scan	Gina Lee	Richardson
	Ethan Ho	
	Raj Borra	
	Edward Hsieh	
Medical Waste	David Faulkenberry	Richardson
	Alexander Culbert	
	Jason Fischell	
	Gregory Goldman	

Seating arrangements

Front of Class		
Neonatology	Bladder	Hand Measure
BP	Intubation	Needle
GI Endo	Derma Scan	Medical Waste
Caves' Teams	Caves' Teams	Caves' Teams
Back of Class		

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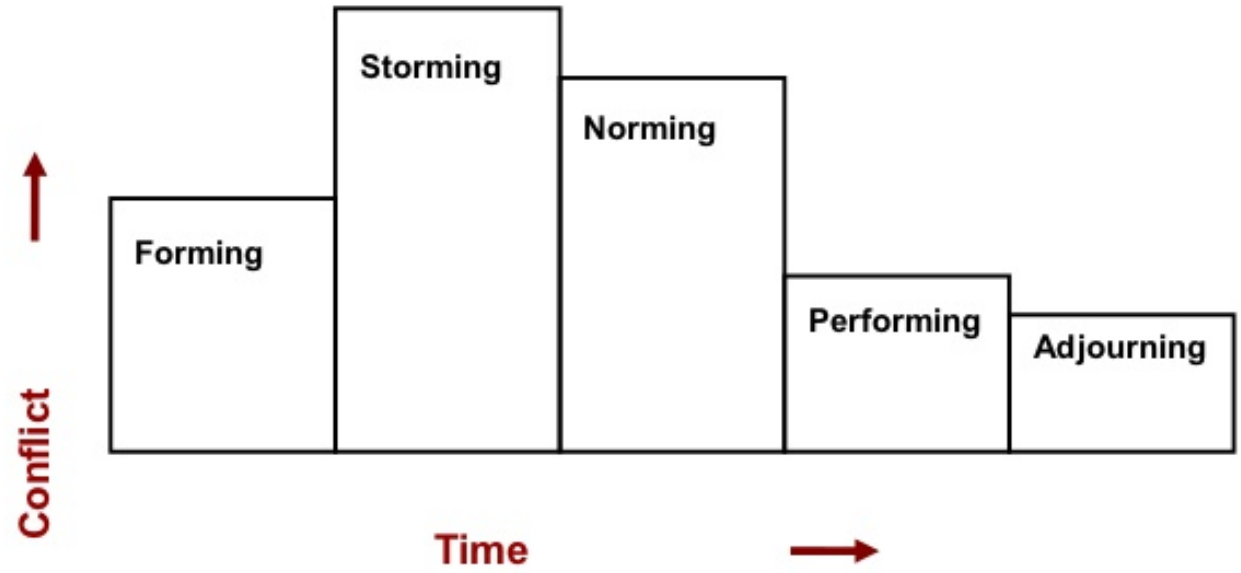
Stages of Team Building



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Launching project teams

The formation phase is the single most important determinant of future team performance

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Conflict: Good or Bad?

What types of conflict can your team encounter, and are these types good or bad?

Conflict

- Interpersonal conflict – Bad
- Process conflict – Bad
- Task Conflict – It depends…

“Task conflict and team performance were positively associated under conditions of high psychological safety”

https://www.researchgate.net/publication/51466530_Reaping_the_Benefits_of_Task_Conflict_in_Teams_The_Critical_Role_of_Team_Psychological_Safety_Climate

Mitigating interpersonal conflict: Know thyself

MBTI - 16personalities.com

Mitigating Process Conflict: The Shared Mental Model, or the blind pass

Mitigating negative task conflict: Psychological Safety

What Google Learned From Its Quest to Build the Perfect Team

New research reveals surprising truths about why some work groups thrive and others falter.

BY CHARLES DUHIGG FEB. 25, 2016

William

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Psychological Safety:
Best Indicator of team performance

“A shared belief that the team is safe for interpersonal risk taking”

Team Contract (Draft Due Friday)

- Living document, less than one page, containing:
  - **Vision**
  - **Process** for communication, meeting, and/or roles (SMM to mitigate process conflict)
    - How will you communicate to each other? Where/when will you meeting?
  - **Process** for conflict management
- Value is in the conversation

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Team Name and Photo

- Come up with a team name
  - Short
  - Relevant
  - Appropriate
- Take a picture of your team, label your team members (preferred individual names under each member) and label your team
- Email to Palmeri, Richardson and Caves (if applicable) by Friday midnight

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Example

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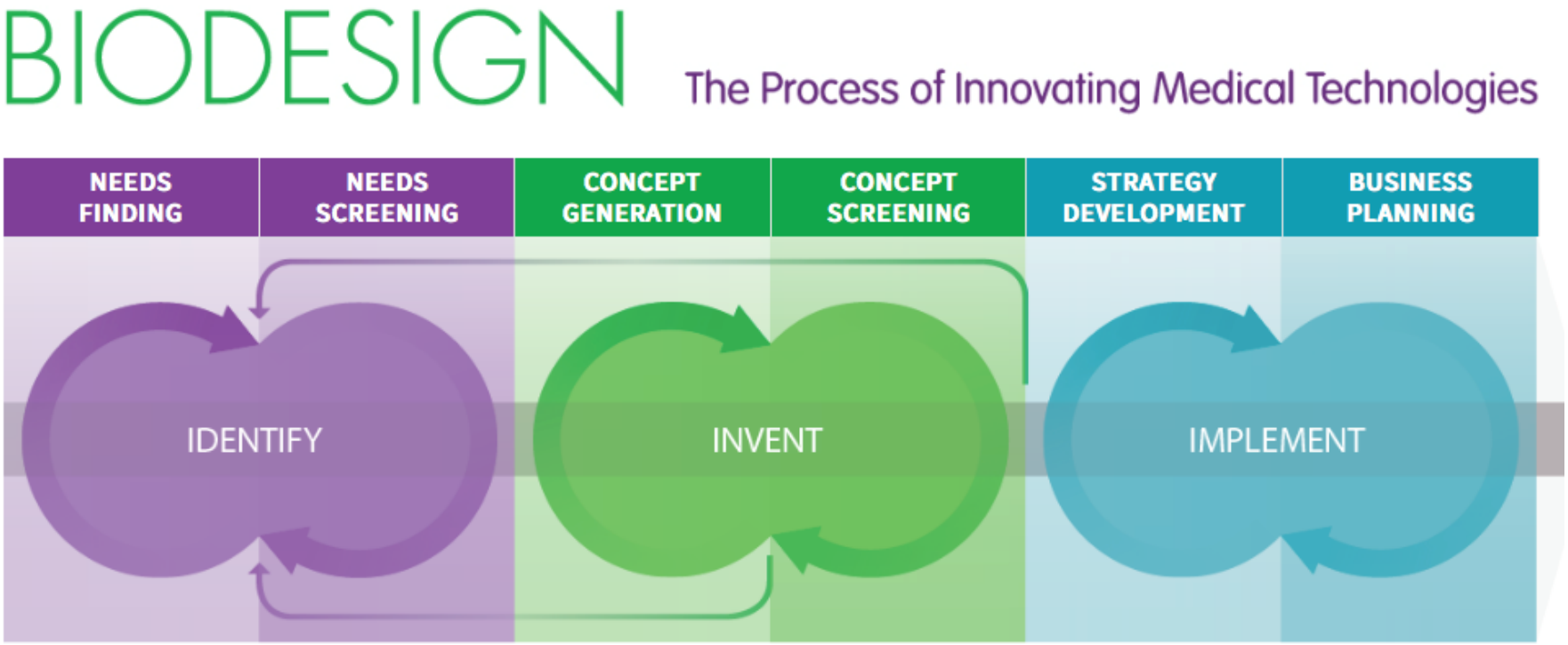
Team time (15 minutes)

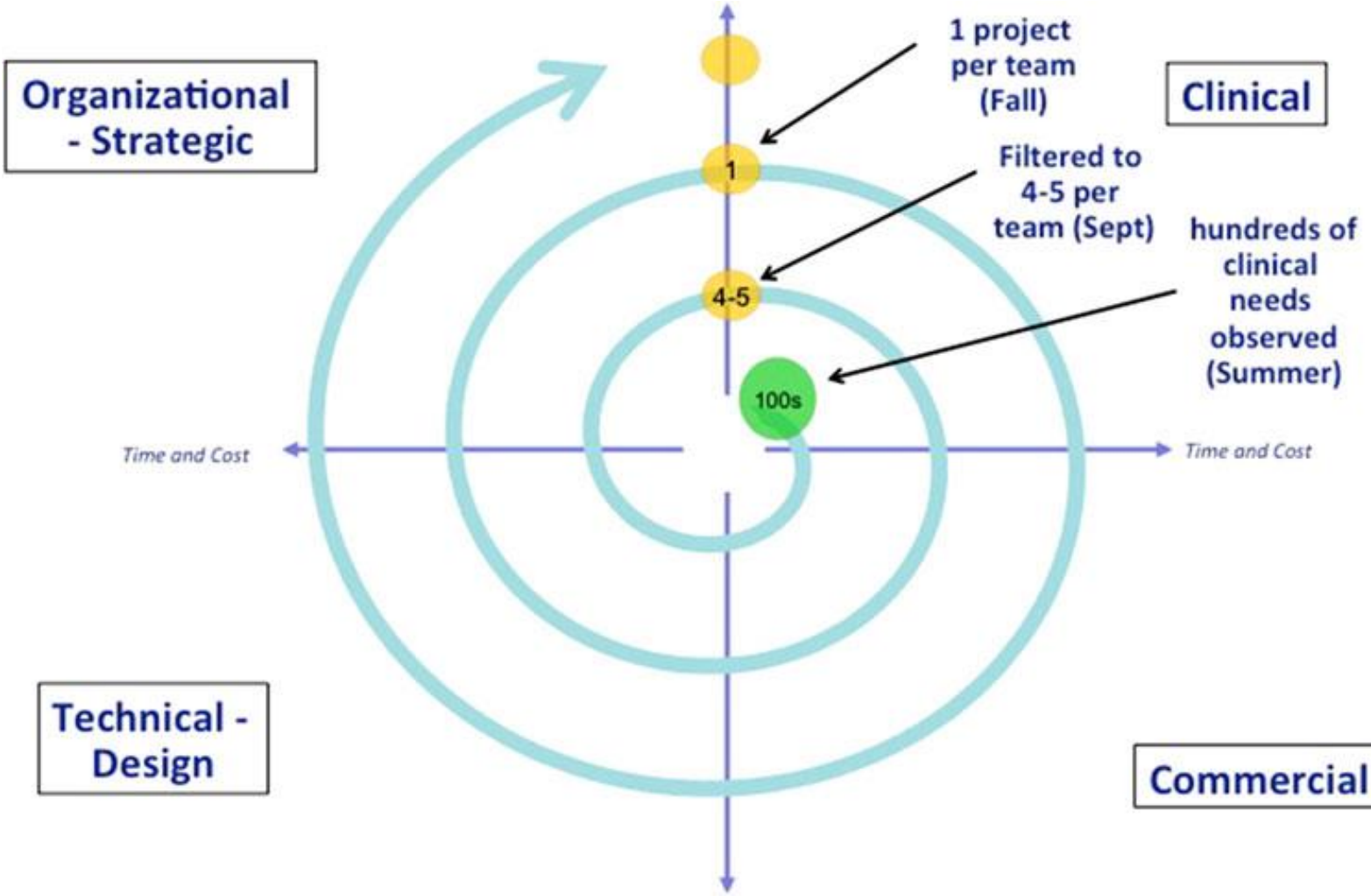
- Recommendations
  - Take a photo
  - Ideas name
  - Start discussions about team contract

Needs finding and validation: The most important phase of the Product Development Process!

Stanford Biodesign Model



Hopkin's CBID Spiral Innovation Model



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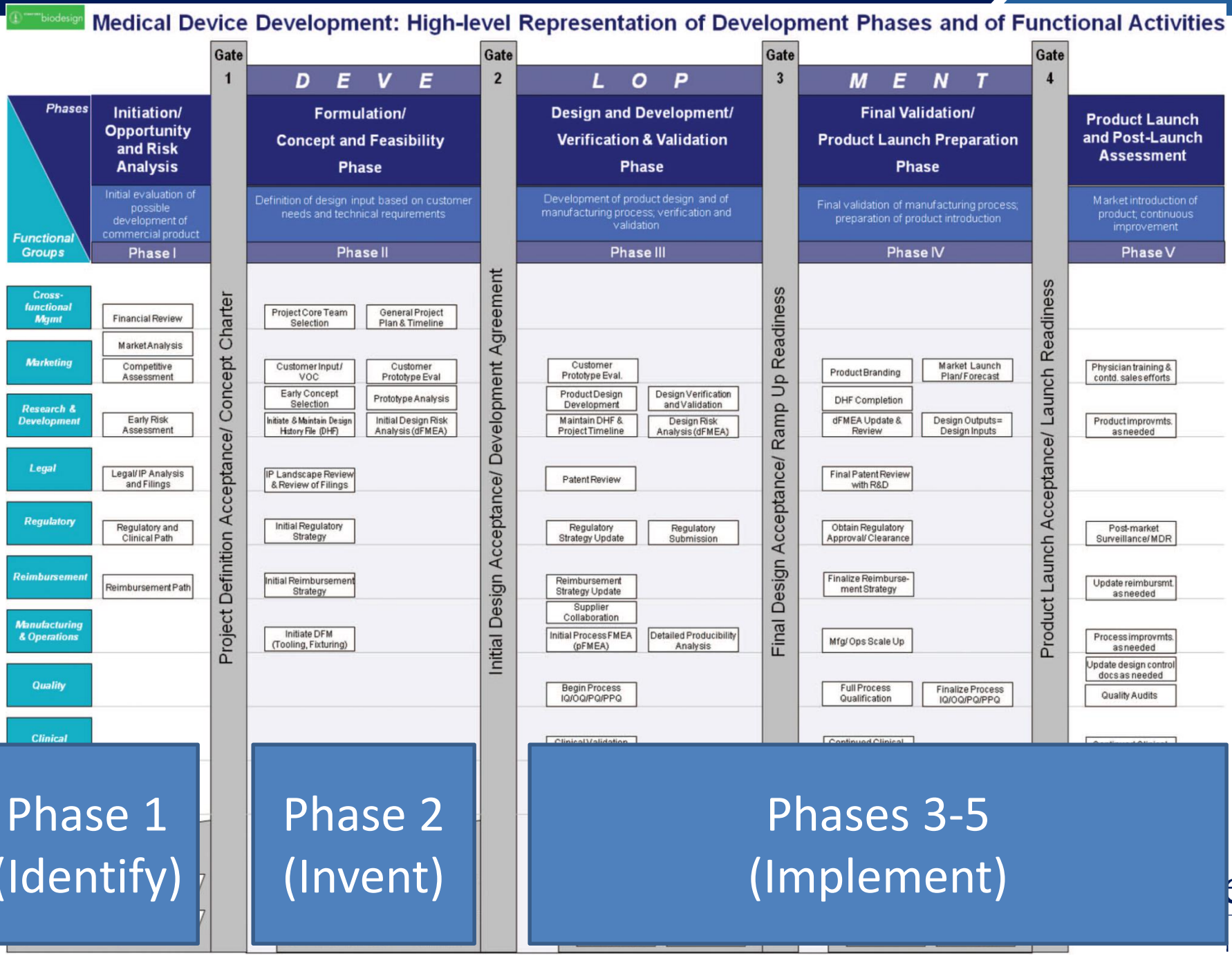
biodesign
Medical Device Development: High-level Representation of Development Phases and of Functional Activities
Gate 1
Gate 2
Gate 3
Gate 4
D E V E L O P M E N T
Phases
Functional Groups
Initiation/ Opportunity and Risk Analysis
Initial evaluation of possible development of commercial product
Phase I
Formulation/ Concept and Feasibility Phase
Definition of design input based on customer needs and technical requirements
Phase II
Design and Development/ Verification & Validation Phase
Development of product design and of manufacturing process; verification and validation
Phase III
Final Validation/ Product Launch Preparation Phase
Final validation of manufacturing process; preparation of product introduction
Phase IV
Product Launch and Post-Launch Assessment
Market introduction of product; continuous improvement
Phase V
Project Definition Acceptance/ Concept Charter
Initial Design Acceptance/ Development Agreement
Final Design Acceptance/ Ramp Up Readiness
Product Launch Acceptance/ Launch Readiness
Cross-functional Mgmt
Marketing
Research & Development
Legal
Regulatory
Reimbursement
Manufacturing & Operations
Quality
Clinical
Financial Review
Market Analysis
Competitive Assessment
Early Risk Assessment
Legal/IP Analysis and Filings
Regulatory and Clinical Path
Reimbursement Path
Project Core Team Selection
General Project Plan & Timeline
Customer Input/ VOC
Customer Prototype Eval
Early Concept Selection
Prototype Analysis
Initiate & Maintain Design History File (DHF)
Initial Design Risk Analysis (dFMEA)
IP Landscape Review & Review of Filings
Initial Regulatory Strategy
Initial Reimbursement Strategy
Initiate DFM (Tooling, Fixturing)
Customer Prototype Eval.
Product Design Development
Design Verification and Validation
Maintain DHF & Project Timeline
Design Risk Analysis (dFMEA)
Patent Review
Regulatory Strategy Update
Regulatory Submission
Reimbursement Strategy Update
Supplier Collaboration
Initial Process FMEA (pFMEA)
Detailed Producibility Analysis
Begin Process IQ/OQ/PQ/PPQ
Product Branding
Market Launch Plan/ Forecast
DHF Completion
dFMEA Update & Review
Design Outputs= Design Inputs
Final Patent Review with R&D
Obtain Regulatory Approval/ Clearance
Finalize Reimburse-ment Strategy
Mfg/ Ops Scale Up
Full Process Qualification
Finalize Process IQ/OQ/PQ/PPQ
Physician training & contd. sales efforts
Product improvmts. as needed
Post-market Surveillance/ MDR
Update reimbursmt. as needed
Process improvmts. as needed
Update design control docs as needed
Quality Audits
Phase 1 (Identify)
Phase 2 (Invent)
Phases 3-5 (Implement)

Where can needs come from?

- Direct observation
- Physician and nurse interviews
- Friends and Family who have had this disease
- Textbooks
- Market research that has been done in the area
- Company activity in the area (Financial/strategic reports)
- Venture capital/startups
- Other online resources:
  - Associations for certain disease (AHA, NCI, etc.)
  - Chat rooms and patient advocacy groups

Clues for Unmet Needs (1.2.4)

- Patient
  - Pain
  - Complications
  - Stress
  - Time and Convenience
- Provider
  - Risk
  - Malfunction
  - Uncertainty
  - Dogma
- Payer/System
  - Inefficiency
  - Information Gaps
  - Cost

Need Statements

- Need Statements:
  - Problem: What is the pain point?
  - Population: Who is affected?
  - Outcome: What is the desired change?
- Example: “A way to address (Problem) in (Population) that (Outcome)”

Observations

- Rules:
  - Be respectful of patient privacy
  - Ask questions when appropriate
  - Caution with electronic devices
  - Take notes of what is happening, not your interpretation!

Interviews

“If I had asked my customers what they wanted, they would have said a faster horse”

Interviews

- What effective interview techniques have you used (or seen used) in the past?
  - Ask why (5 times!)
  - Never say usually
  - Encourage stories
  - Look for inconsistencies (Do what I say, not what I do)
  - Pay attention to body language
  - Don’t be afraid of silence
  - Do not suggest answers to questions
  - Avoid binary questions
  - Document! (Appropriately)

Interview Exercise

- Interview your partner about his/her breakfast experience: What needs does he/she have?

Common Pitfalls of Need Statements

- Too general
- Too specific
- Stuck in current practice
- Embedded Solution
- Built on a negative

What is your need statement?

"A way to address (Problem) in (Population) that (Outcome)"

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Communication with Sponsor

- Please send a short email to your sponsor introducing yourselves
- Send her/him your draft need statement
- You will be providing them with weekly updates over email (more later)
- Tips:
  - Don’t expect quick turn around on emails/meeting requests (up to 2-3 days for email responses, 1-2 weeks for meeting availability)
  - If meeting with sponsors, dress/act appropriate for the environment, and be on time

Summary

- Course Philosophy
- Team formation
- Design Foundation
- Due before Friday Midnight:
  - Team photo/name to profs via email
  - Team contract on Sakai (?)
  - Email sponsor with intros and need statement, copy profs