

Design Thinking Workshop

PhUSE Single Day Event
July 26, 2018

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ROCK

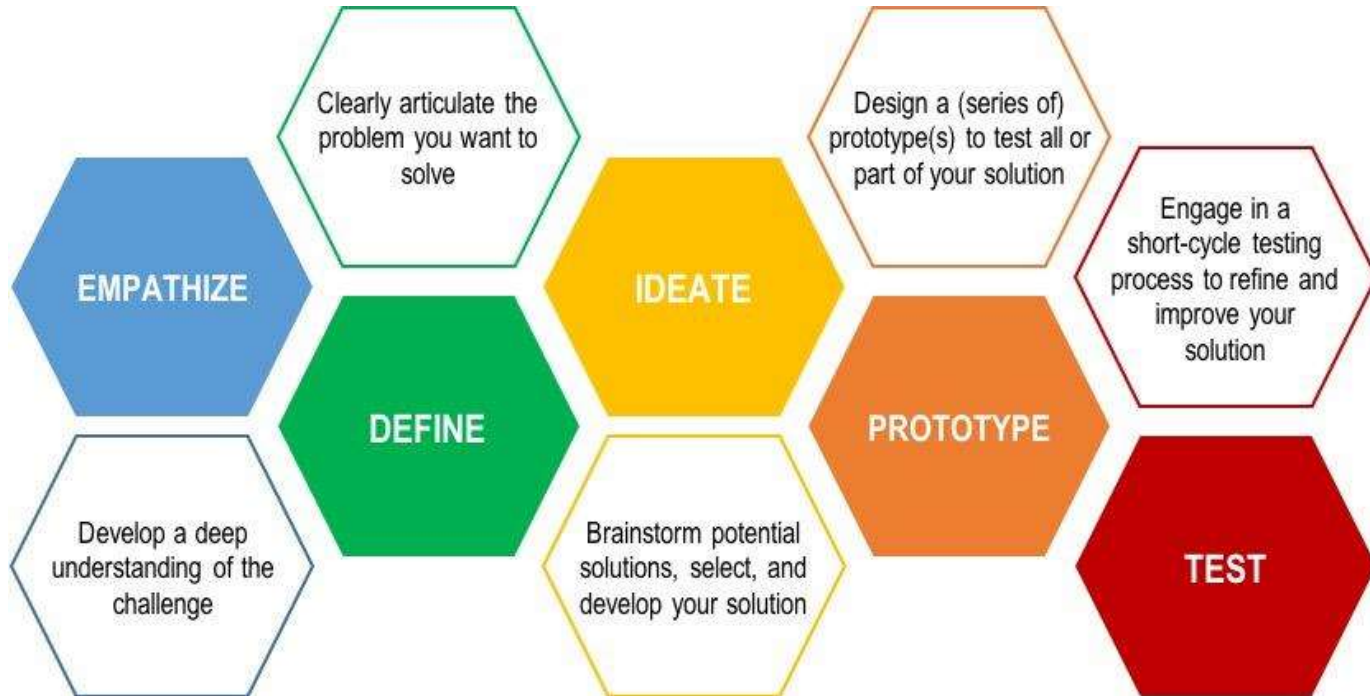


SCISSORS



PAPER

Design Thinking



Role of the Decision Maker

- Birthday closest to July 26th
- Before you begin, it's important to know who the Decision Maker is
- The role of the Decision Maker is to keep the solution progressing, and the prevent churn
- The decision maker can follow the consensus of the table, or choose something else
- Once a decision is made, everyone supports the decision

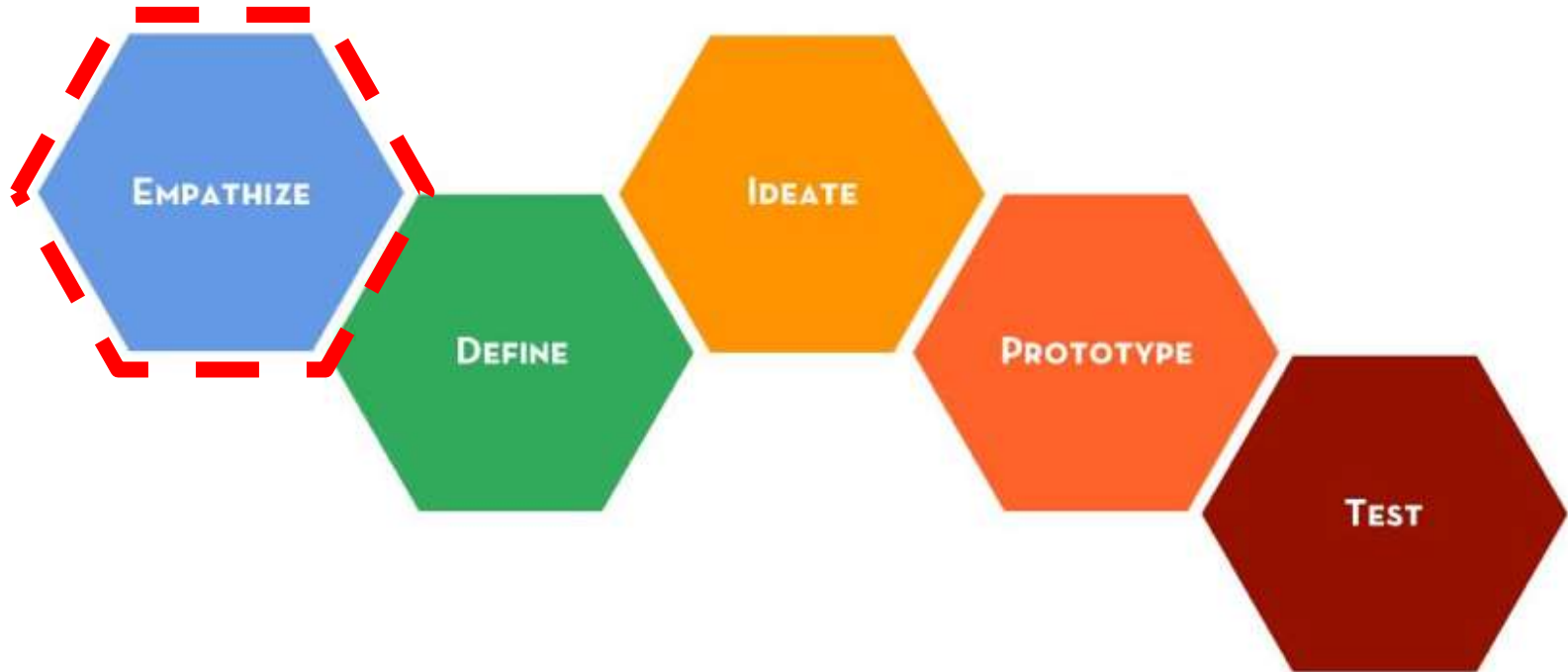
Problem Statement

- As part of an NDA submission to the FDA, data artifacts must pass a series of validation checks before being deemed acceptable for review. How can the industry innovate on the creation, maintenance, and submission of these artifacts while still remaining compliant?

Problem Statement (cont.)

- Activity:
 - At your table, take 3 minutes to talk through problem statement to come to an understanding of what is being presented, and what we'll be working on for the remainder of this session

Empathy



Alarm Clock



Empathy Map

- An effective solution requires understanding the true problem and the person who is experiencing it
- A simple, easy-to-digest visual that captures knowledge about a user's behaviors and attitudes
- Helps teams better understand their users
- Performed after user research but before concepting and ideation

What does he/she

Think and feel?

what really counts?
major preoccupations?
worries & aspirations?

What does he/she

Hear?

what friends say?
what boss say?
what influencers say?

What does he/she

See?

environment?
friends?
what the market offers?

What does he/she

Say and do?

attitude in public?
appearance?
behavior toward others?

Pain

fear, frustration, obstacles,...

Gain

wants/needs, measures of success, obstacles,...

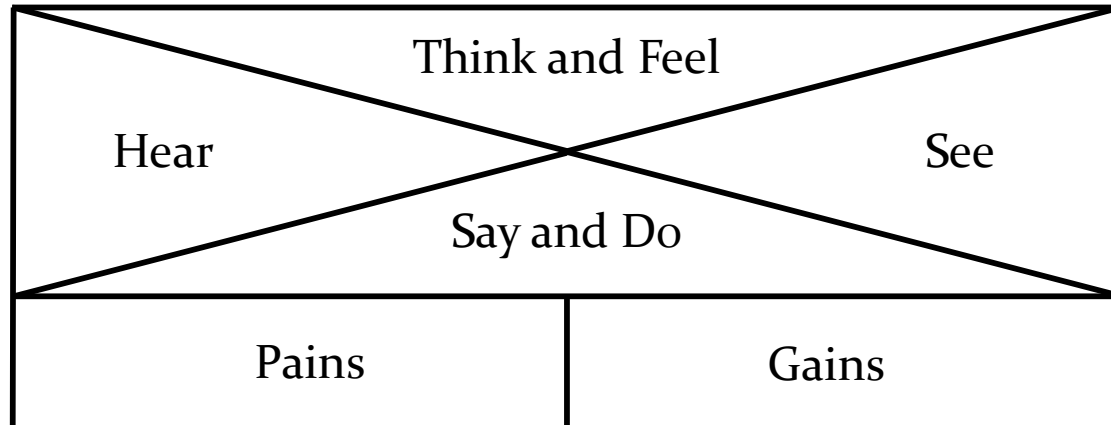


Personas

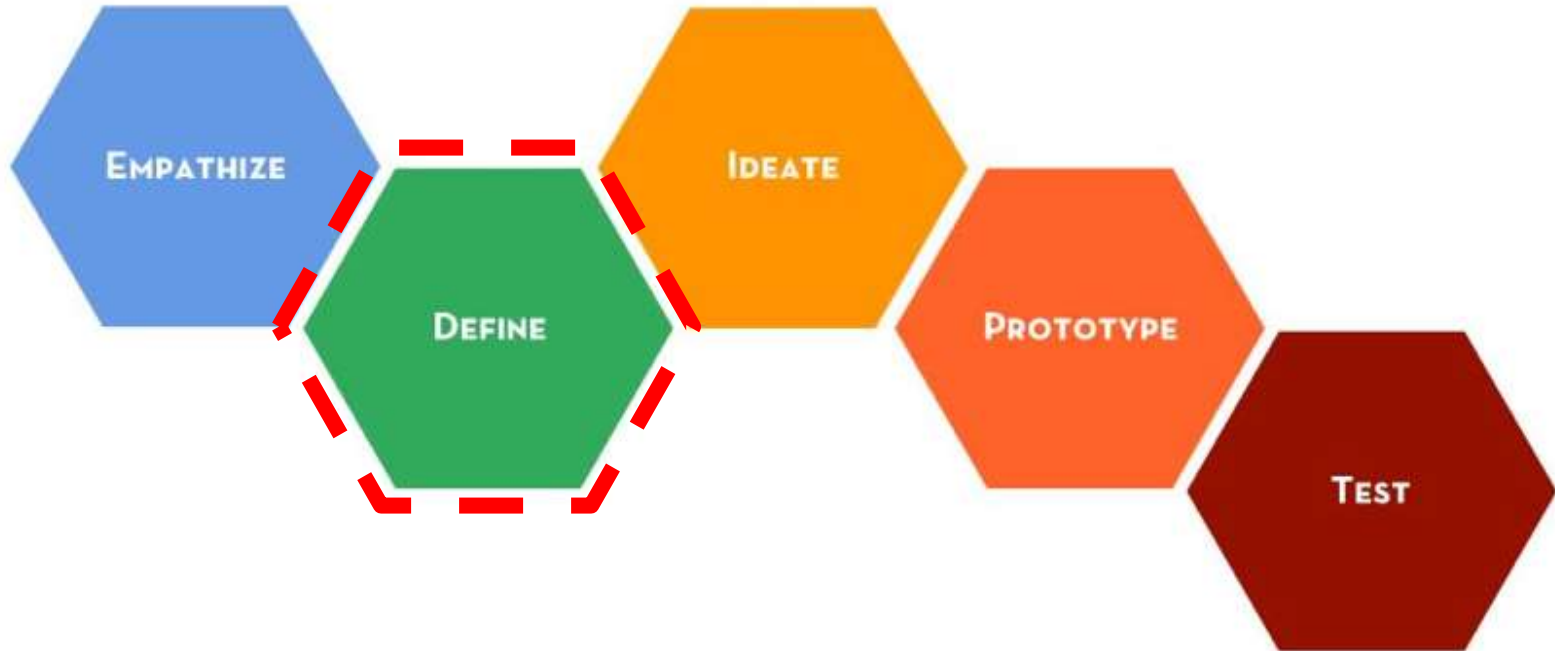
- Data preparer
- FDA reviewer
- Focus on the reasons why each of these types of people would need validation rules

Empathy Map

- Activity:
 - Pick a persona to focus on
 - Create a empathy map for that persona using post it notes



Define



Validation Rules

FDA Business Rule ID	FDA Business Rule	FDA Validator Rule	Domains	SDTM 3.1.2	SDTM 3.1.3	SDTM 3.2	SEND 3.0
FDABoo4	AE, CE, CM, DS, EG, EX, LB, MH, PC, PP, SE, SV, and VS should be submitted if collected.	Disposition (DS) dataset should be included in every submission.	DS	X	X	X	
		Adverse Events (AE) dataset should be included in every submission.	AE	X	X	X	
		Lab Test Results (LB) dataset should be included in every submission.	LB	X	X	X	
		Vital Signs (VS) dataset should be included in every submission.	VS	X	X	X	
		Subject Elements (SE) dataset should be included in every submission.	SE	X	X	X	
FDABoo6	All death information must be populated for subjects that died during the study including any post treatment follow-up.	Date/Time of Death (DTHDTC) should be provided, when subject died (DTHFL=Y).	DM		X	X	
FDABoo8	All exposure records should occur between First and Last Study Treatment dates.	Start Date/Time of Treatment (EXSTDTC) variable value must be greater than or equal to Date/Time of First Study Treatment (RFXSTDTC).	EX, EC		X	X	
		Start Date/Time of Treatment (EXSTDTC) variable value must be greater than or equal to Date/Time of Experimental Start Date (EXPSTDTC).	EX				X

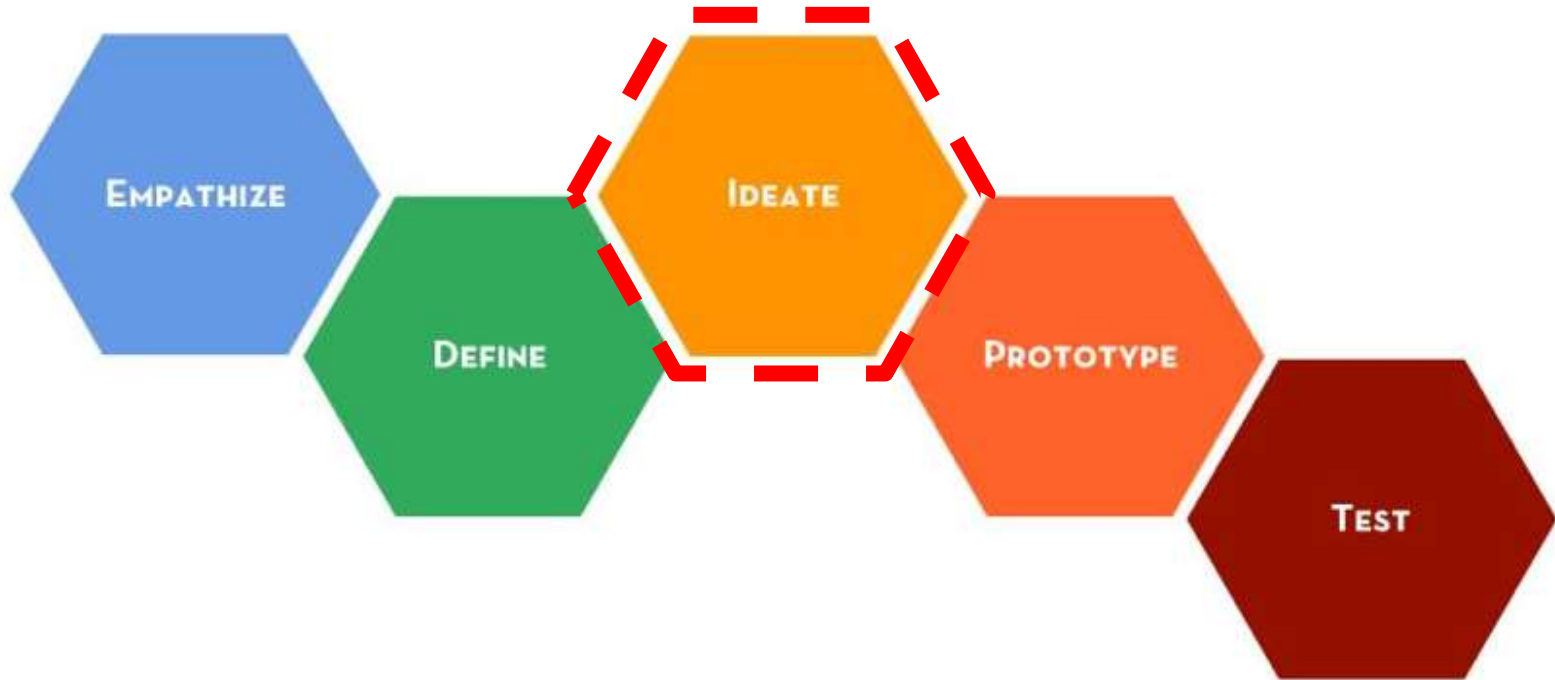
Voting – Choose a Validation Rule

- Make a decision and move forward
- Rather than debate an issue where one or two voices are heard, put it up for a vote, where all opinions are displayed
- In silence - using the handout, each person will vote for one validation rule by placing a small dot on the page
- After everyone has voted, The Decider for your table uses a large dot to confirm validation rule and persona that you will use for the rest of this session
- 3 minutes to complete this step

Assumptions

- What are some possible assumptions you are bringing into solving this problem?
- "First Principles" – What are the immovable objects?
- Do you have a good understanding of the validity of these assumptions?
- What if you didn't have these assumptions?
 - How would your solutions be different?

Ideate



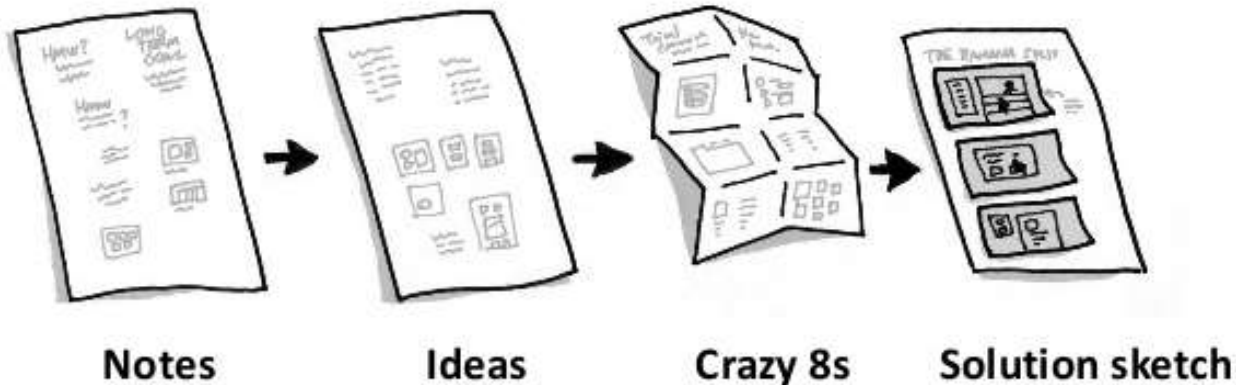
Ideation – Divergent Thinking

- Work Individually
- Be Creative
- Think wide, not deep
- Go beyond the obvious
- Defer Judgement

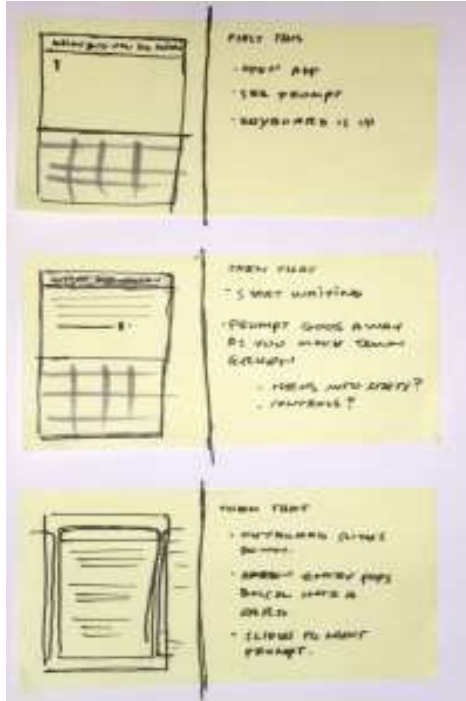


Ideation Exercises

- Notes and ideas – 5 minutes
- Crazy 8s – 4 minutes
- Solution sketching – 20 minutes

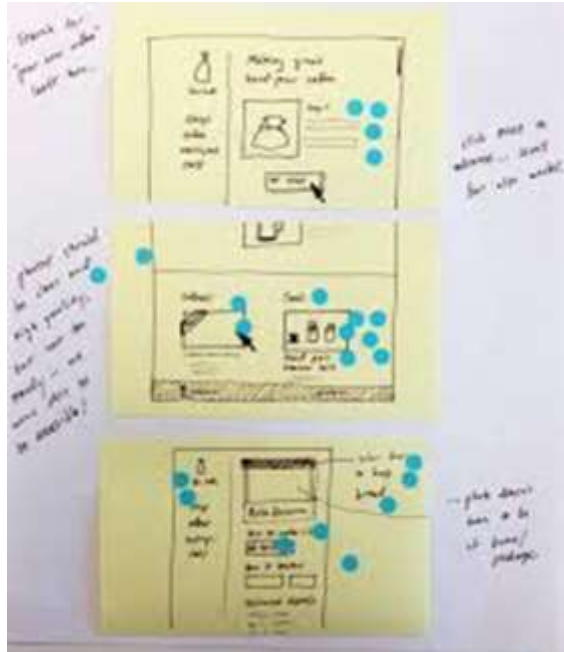


Divergent Thinking – 3 Panel Solution



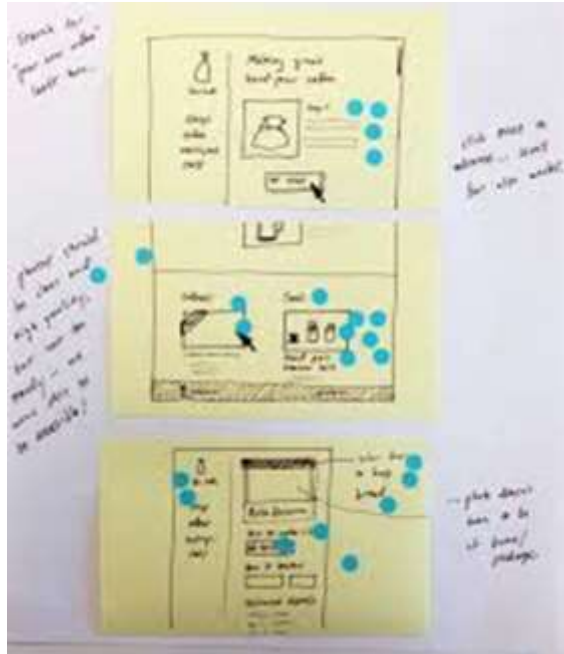
FDA Business Rule ID	FDA Business Rule
FDAB004	AE, CE, CM, DS, EG, EX, LB, MH, PC, PP, SE, SV, and VS should be submitted if collected.
FDAB006	All death information must be populated for subjects that died during the study including any post treatment follow-up.
FDAB008	All exposure records should occur between First and Last Study Treatment dates.

Convergent Thinking



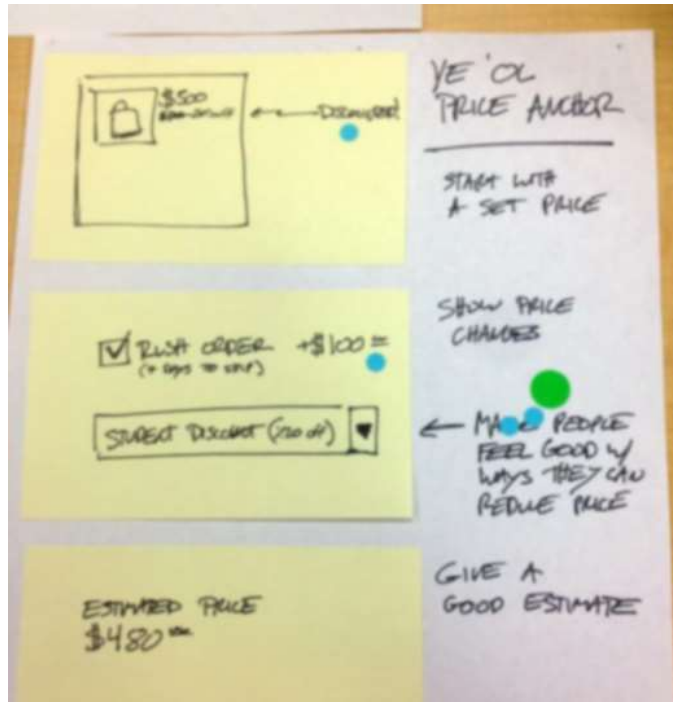
1. Museum Walk
2. Vote – small dots

Speed Critique



- Choose a Facilitator

Convergent Thinking – Straw Poll



- 1 Large Dot Vote

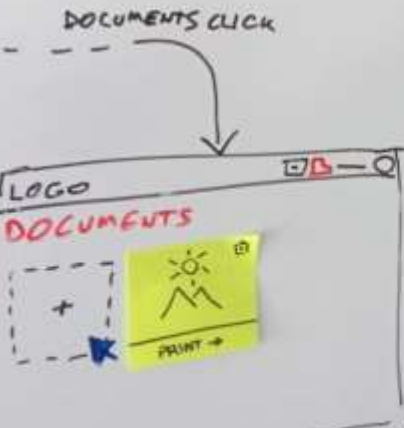
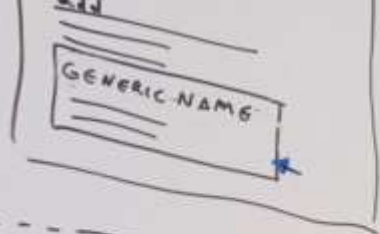
Convergent Thinking – Decider Votes



- Decider Vote – 3 Large dots

Prototyping – Making a Storyboard

- Next you would create a storyboard of what your prototype will look like
- A storyboard
 - Lays out the steps user(s) will go through using your solution
 - Incorporate the winning sketch ideas
 - Be a complete set of instructions to create a physical (or digital) prototype
- The Decider decides
- When in doubt, take risks
- Keep it short and digestible



Prototyping – Making it Real

- The idea:
 - Make your solution into something that you can test with users
- Optimize between speed, cost, fidelity
- Design tools – Invision, UXPin, Figma
- Needs to be “good enough”
 - To get feedback on your idea

User Testing and Feedback



Discussion

- Decider – Did they go with the table?