



Otsuka Pharmaceutical

Director of Product Design, User Research & Human Factors



Pharmaceuticals

100-year History

Global, Tokyo-Based

Revenue of \$8.9B (2021)

10 Drugs, 4 Categories

NEUROSCIENCE

ABILIFY (aripiprazole)

MAINTENA (aripiprazole)
Injectable

NUEDEXTA (dextromethorphan)

REXULTI (brexpiprazole)

NEPHROLOGY

JYNARQUE (tolvaptan)

SAMSCA (tolvaptan)

DIGITAL INNOVATION

ABILIFY MYCITE
Tablets with sensor

ONCOLOGY

DACOGEN (decitabine)
Injectable

IV BUSULFEX (busulfan)

SPRYCEL (dasatinib)



Director of User Experience

Hands-on Leadership –concept to launch

.Strategy .Product Concept .Validation

.Design (Industrial, Interaction, Visual) .Documentation

.Human Factors .Ethnography .Usability

VP-Level Collaboration on Strategic Initiatives:

.Venture Funding and Acquisitions

.Innovation Strategy and Process

.Global HF and Usability Research Standards



Director of User Experience

14-person Design and Research Team

.6 User Experience .5 Industrial Design .3 Human Factors

Collaboration Across 12+ Functional Areas:

.Engineering (Mechanical, Electrical, Production, Software)

.Regulatory .Quality .Clinical .Manufacturing & Supply Chain

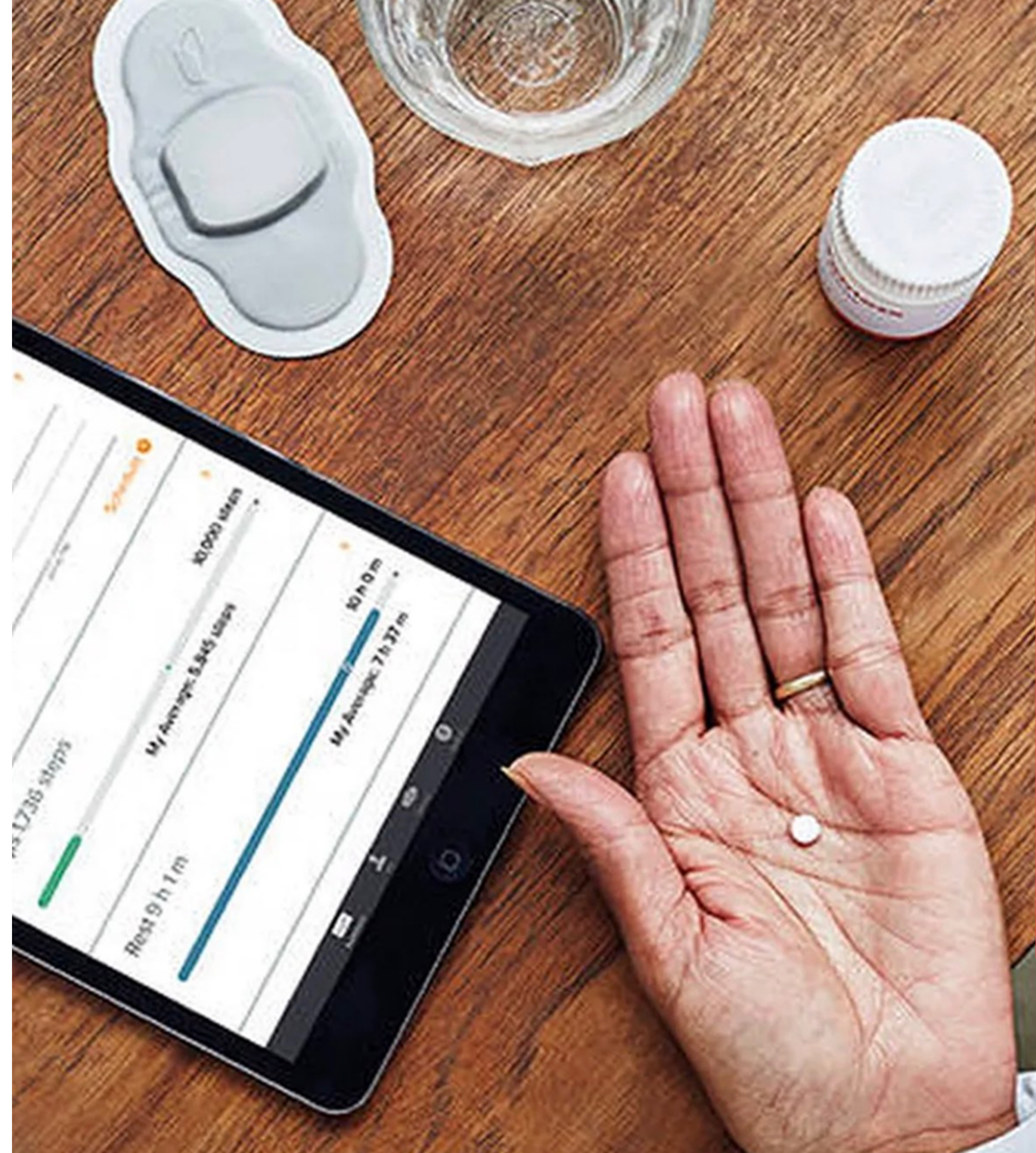
.Product Marketing .Product Management .CX



Abilify MyCite is an Otsuka combination medical device.

Addresses Medication Adherence for adults with serious mental illness: schizophrenia, bipolar disorder, or depression.

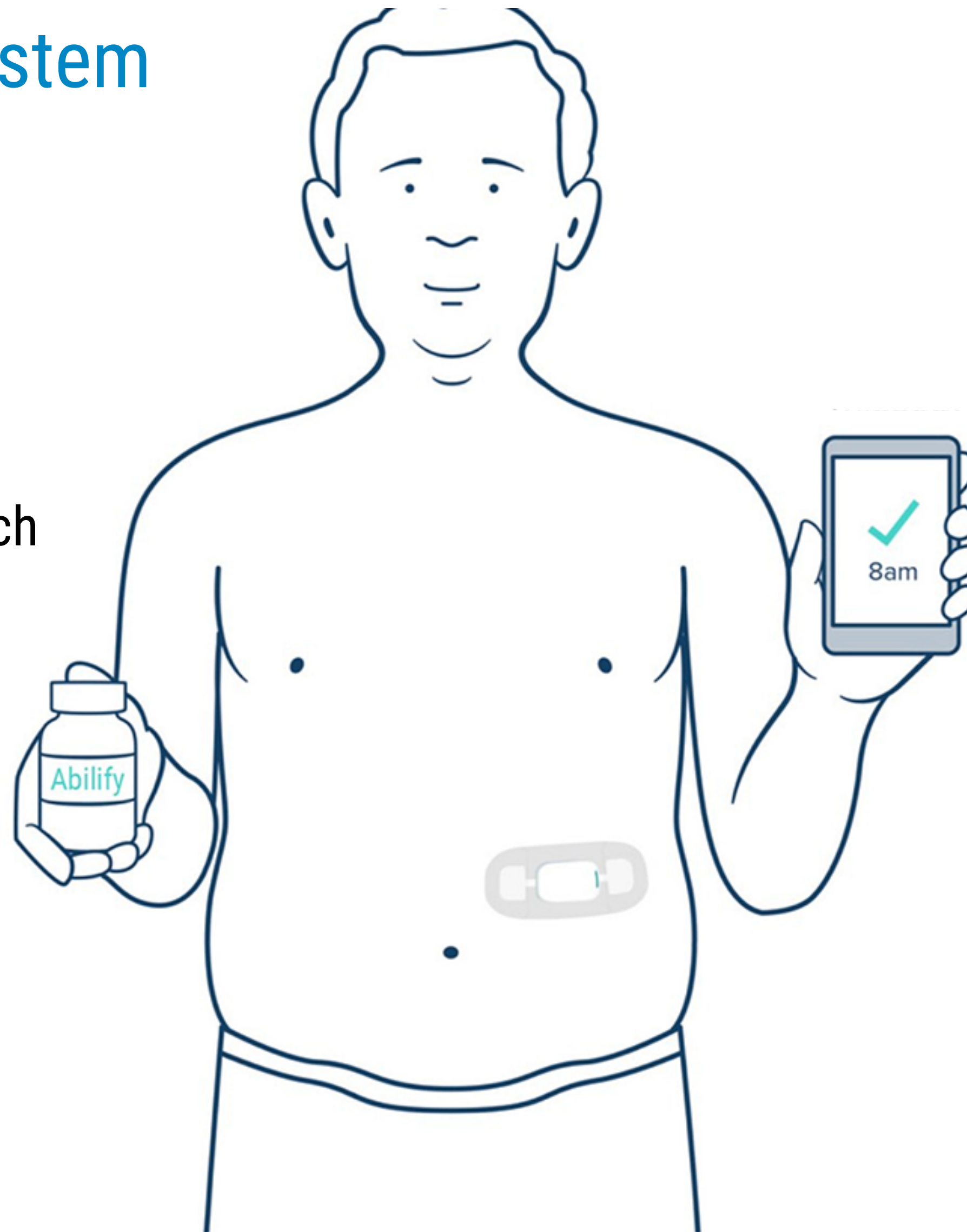
>> Patients with schizophrenia often stop taking their medicine, triggering psychotic episodes that can have severe consequences.



3-Component Ecosystem

Pill

- Aripiprazole Tablet
- Integrated sensor
- Upon digestion, signals Patch



App

- Receives ingestion and activity data
- Patients use app to review and report missed dose, rest quality and mood.
- HCPs use app to review Patient activity and intervene if needed.

Patch

- Patch is a non-medicated sensor
- Recognizes signals from the Pill
- Captures activity and rest data
- Sends data via Bluetooth to device.

3-Component Ecosystem



- Aripiprazole Tablet
- Integrated sensor
- Detectable upon digestion



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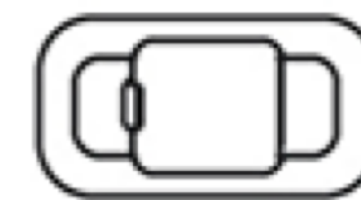
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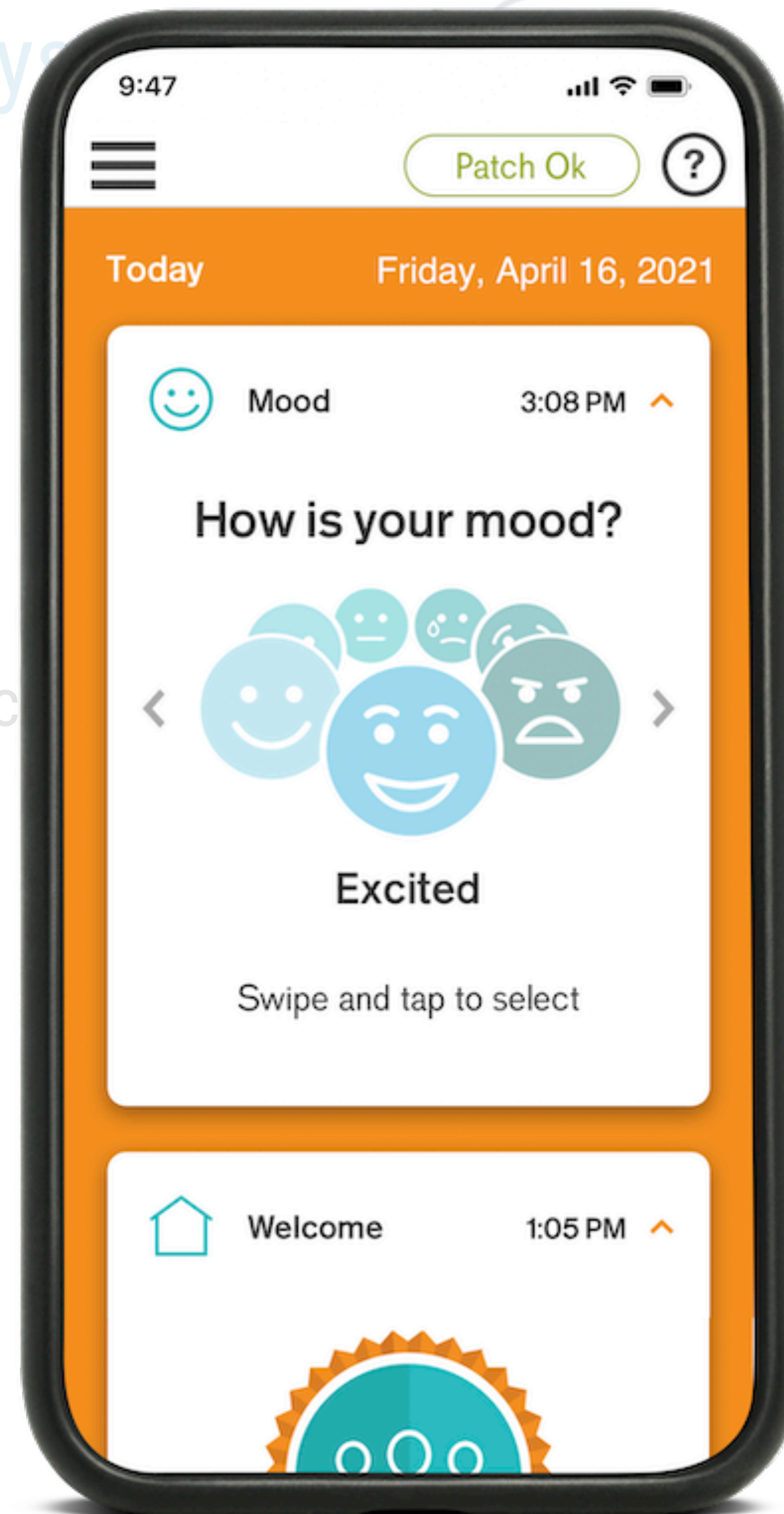
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Present State

On Market Since 2017

Lukewarm Response

Expensive (\$1650/mo)

Patch Wearability

Bluetooth Reliability



Challenges & Solutions

MyCite Concept

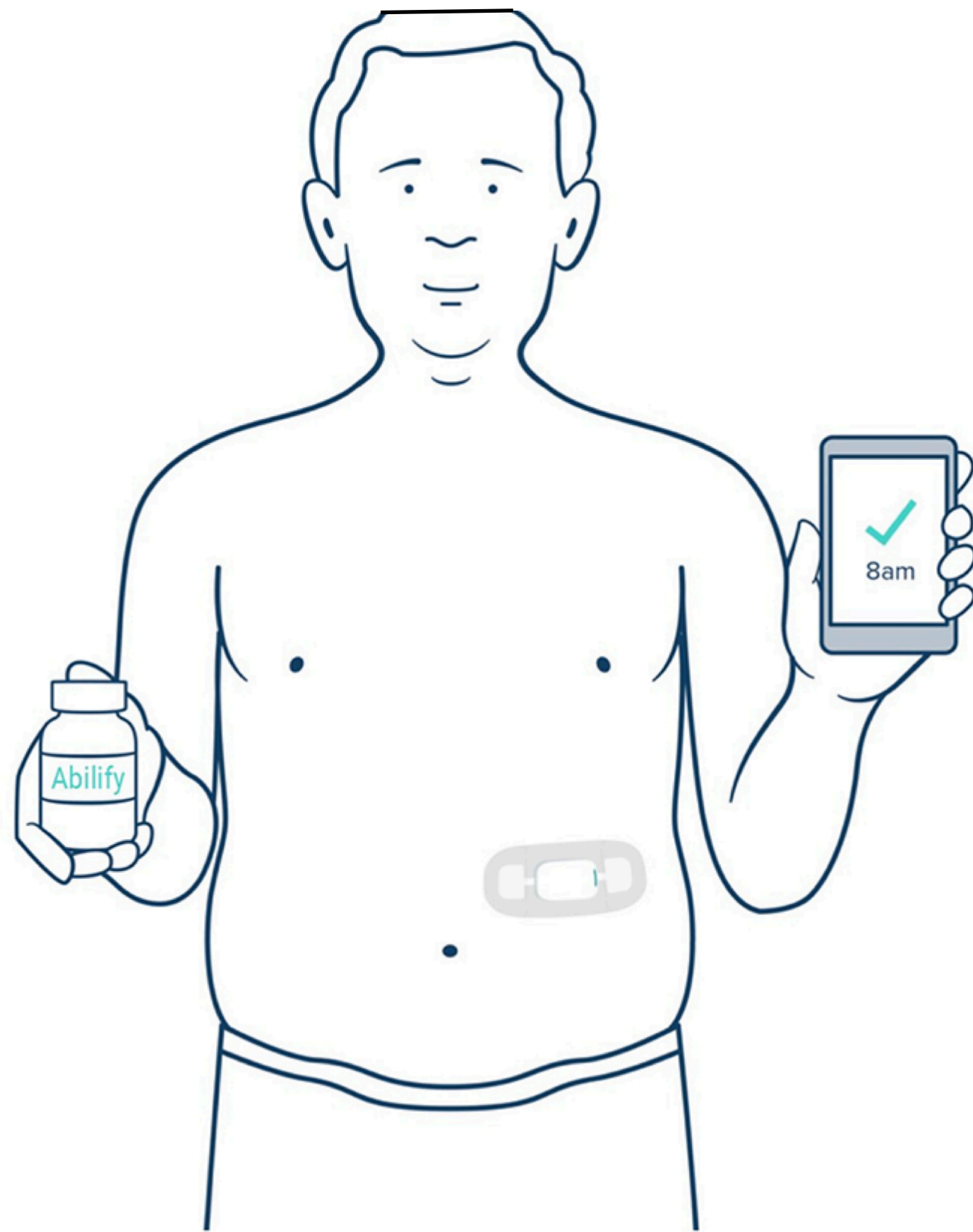
Software User Experience

Human Factors

Stakeholder Synchronicity

Challenge

MyCite Concept



MyCite concept completely foreign.

- Prompts disbelief, concern, misunderstanding

A pill with a computer chip?

Is it tracking me?

What if it gets stuck?

Where is the battery?

What's a patch?

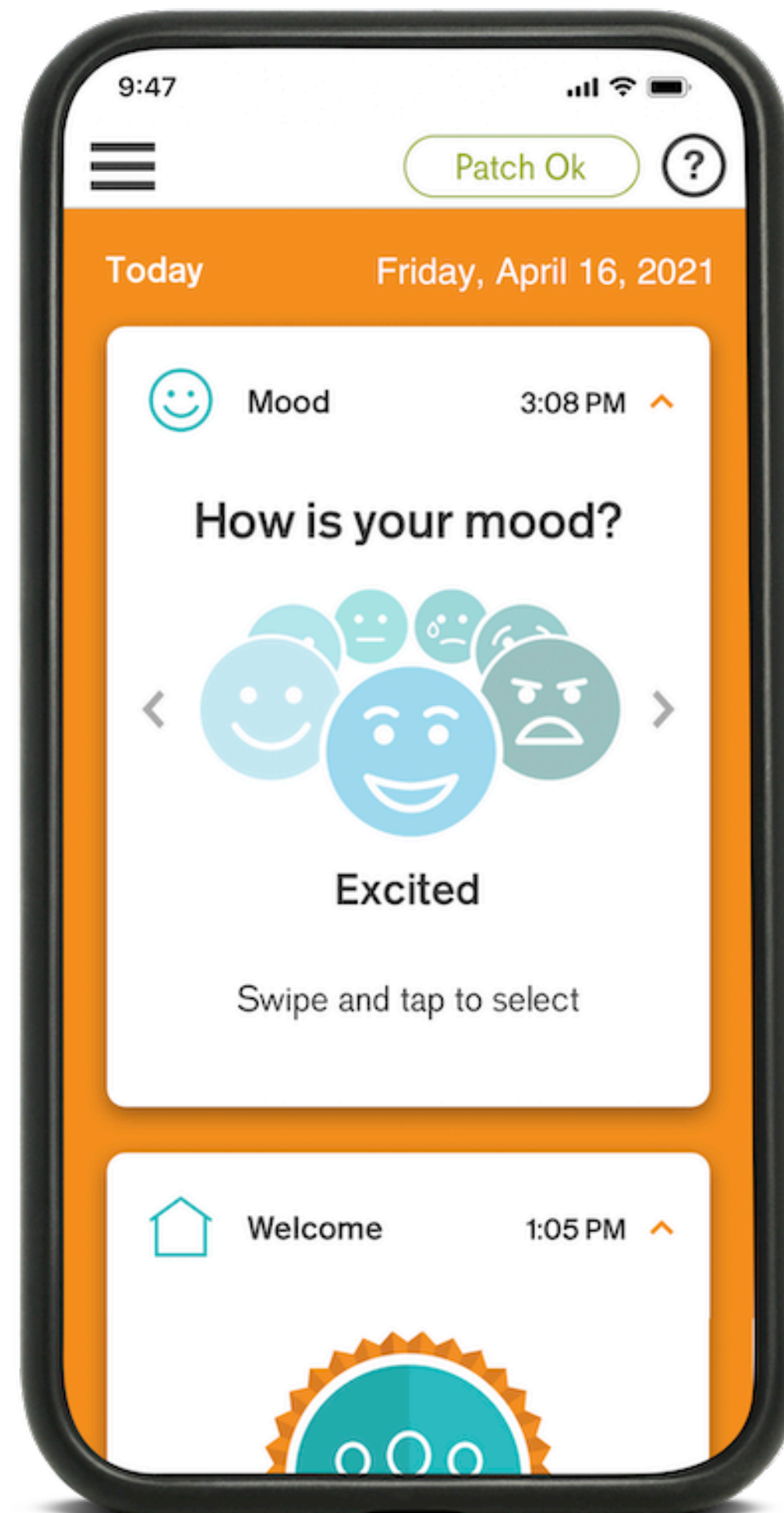
Why is there a patch?

Like nicotine patch –medicated?

Pill can't connect to my phone?

Challenge

Software User Experience



Software difficult to use; mixes modalities; often does follow not fundamental Usability concepts.

- Lower cognitive ability patients struggled with smart phones tasks.
- Registration excessively long. Lacked functionality and payoff.
- Too many modality-shifts (Patch, App, Pill, Device), disrupting focus.
- Lacking clear visual representation, procedure details.
- Navigation inconsistent and ambiguous. Non-standard UI patterns.
- Lacked notification settings and unambiguous language, infographics

Challenge

Human Factors



Human Factors studies unproductive, consistently delivered failures.

- Difficult to assess Patch durability and comfort:
- Single-day session vs Seven-day patch period use.
- Patches tested not on skin, but on proxy material.
- Include more variety (1) gender, skin types, with/without hair and (2) lifestyle and environment.
- Onboarding required multiple devices and significant Moderator intervention.
- Software prototype were incomplete, buggy.

Challenge

Human Factors



The screenshot shows the FDA website page for Combination Products. The header includes the FDA logo and the text "U.S. FOOD & DRUG ADMINISTRATION". The main heading is "Combination Products" with a subtitle "Therapeutic and diagnostic products that combine drugs, d". Below this is a large image of a person's arm receiving an injection from a syringe. To the right of the image is a blue sidebar with the text "About Combination Products" and a "Learn" button. At the bottom, there are three columns of links: "Guidance & Regulatory Information", "Classification and Jurisdictional Information", and "Feedback Product".

Guidance & Regulatory Information
Combination products rules, regulations, and guidance documents.

Classification and Jurisdictional Information
Jurisdictional information for human medical products.

Feedback Product
Details on with the (Products.

Product requirements more appropriate to traditional drugs.
Usability as a combination medical device overlooked.

- Business and FDA Label target wide audience of cognitive ability;
- Lowest common denominator (unusable) experience;
- Does not address subtleties real everyday use.

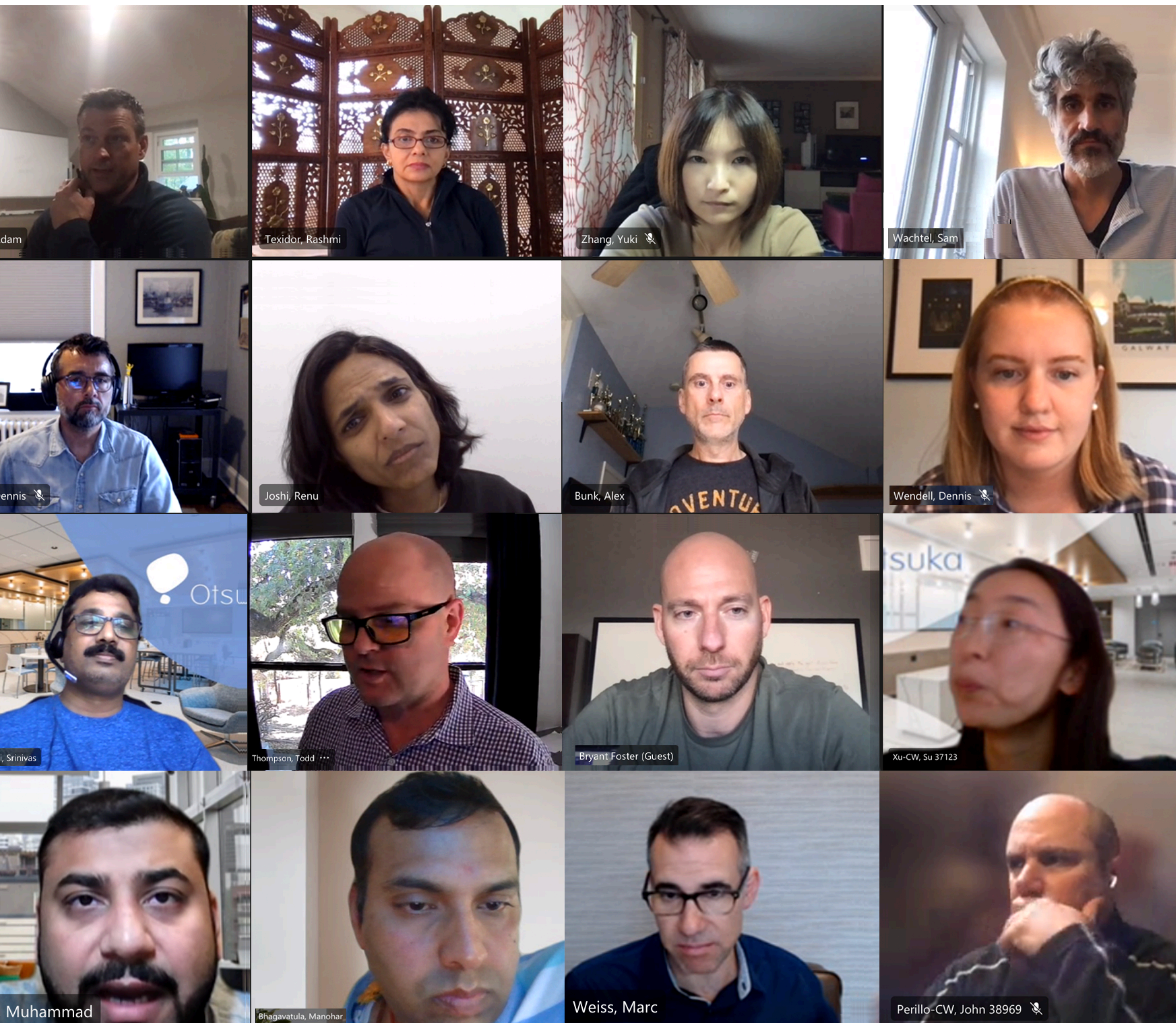
Where do I put Patch? • Patch keeps falling off. • What if Patch gets wet?

Bluetooth not working. Can I use WiFi instead? • Do I always need phone nearby?

What is an account code? • Who can I call for help —Doctor? Pharmacy? Otsuka?

Challenge

Stakeholder Synchronicity



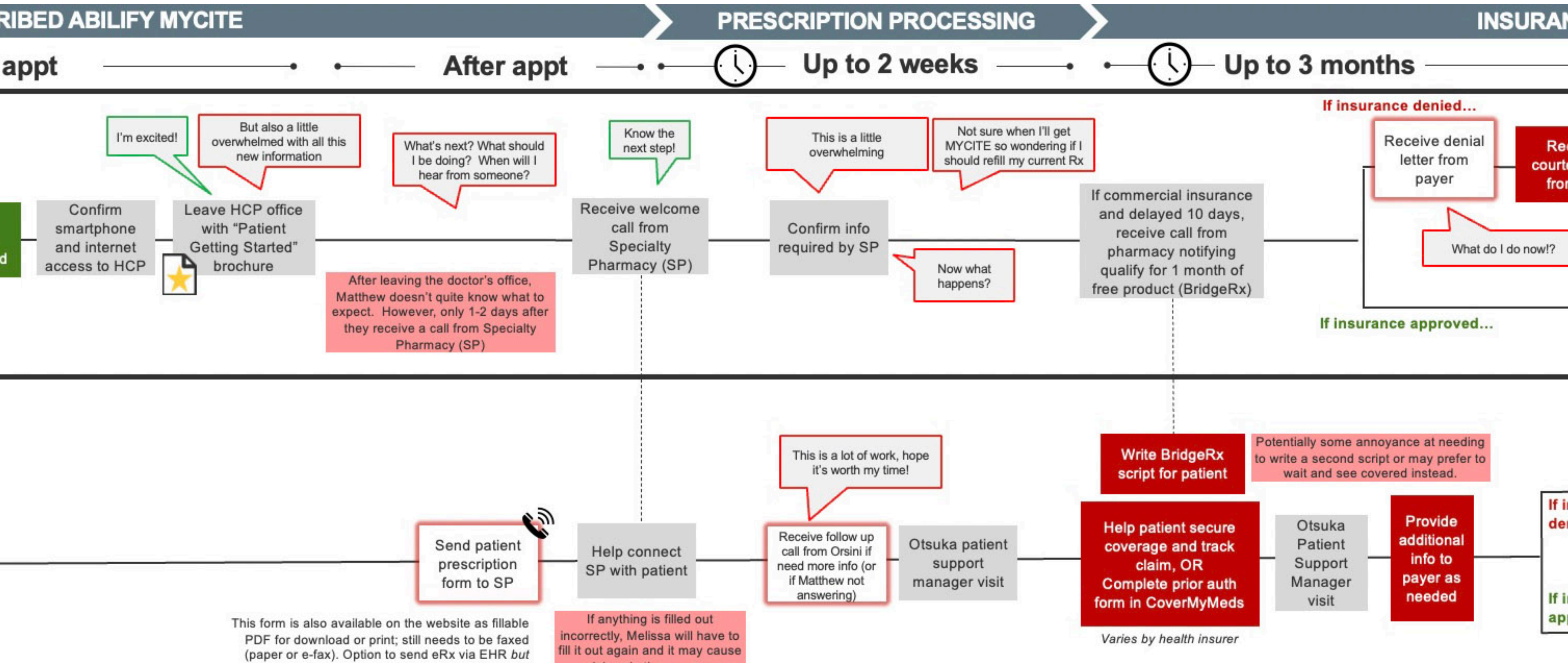
Digital Therapeutics rely on decentralized domain experts from across the company.

- Engineering Teams work independently of each other Product Management, Design, Marketing.
 - Lack of MyCite-specific reporting structure and mutually agreed-upon metrics.
- Digital Therapeutics not yet integrated into Otsuka standard procedures.
 - Quality Teams rely on requirements most appropriate for traditional carbon-based drug development.
- Little coordination with overall business strategy.

Solutions

First Steps

Identified Business Cases with Real-world Workflows

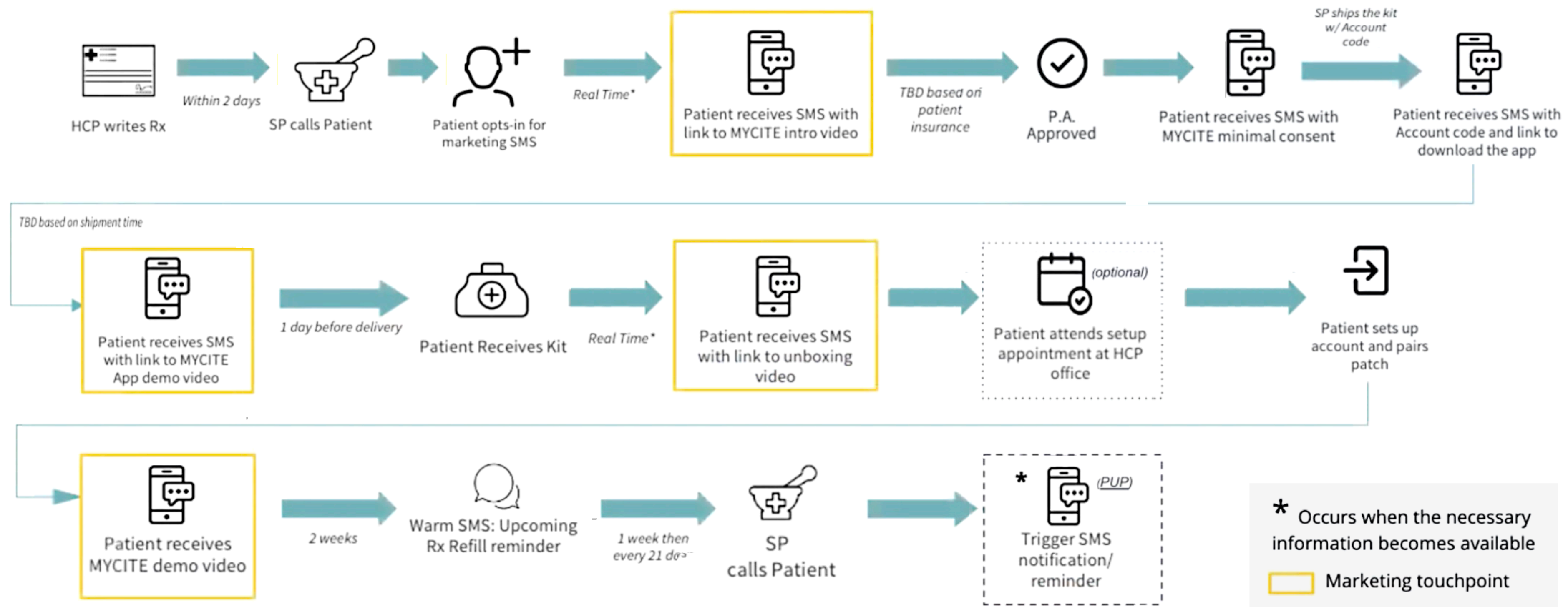


Solutions

First Steps

Identified Stakeholders and Defined Needs

Patient Experience - Split Consents



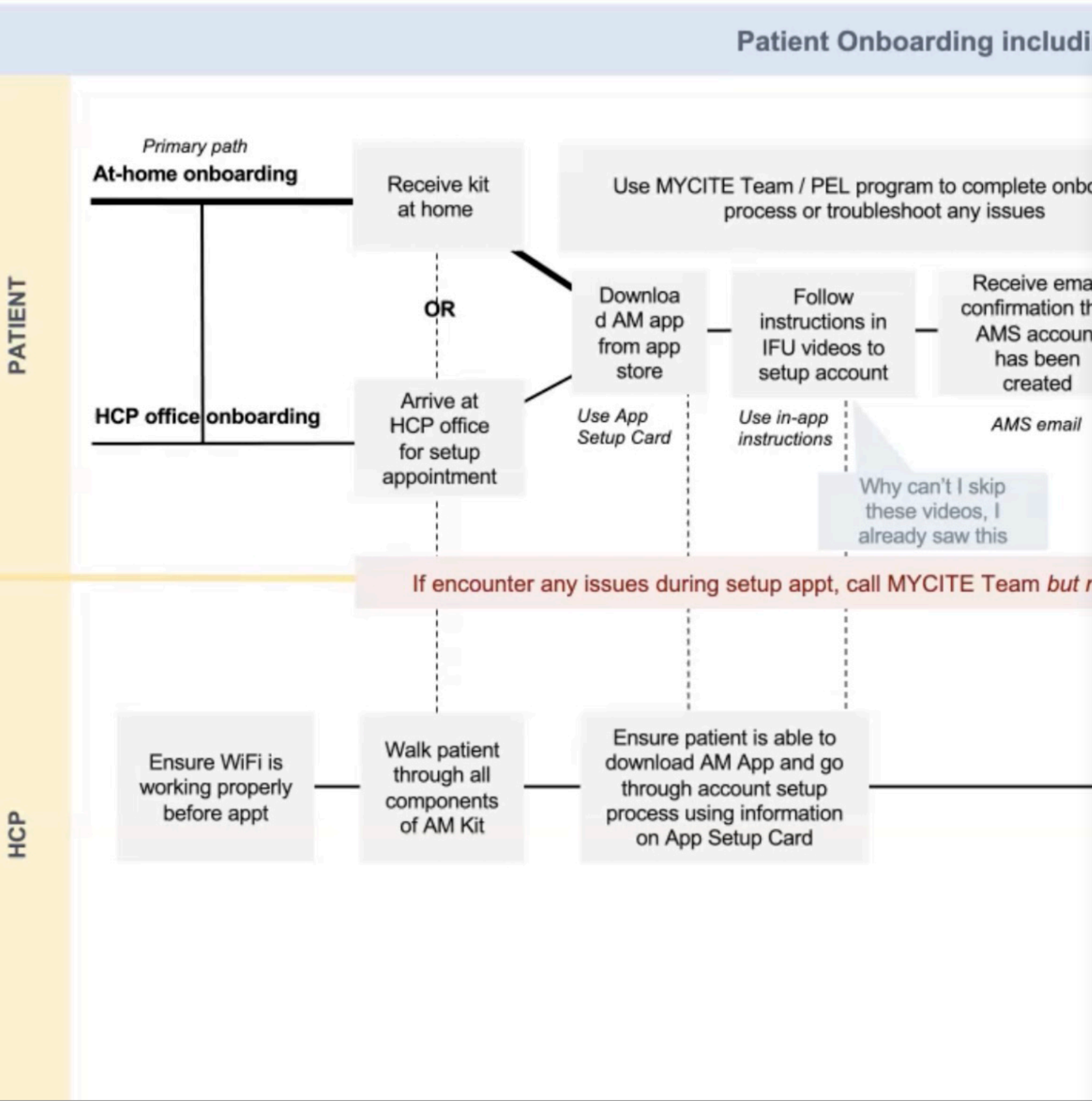
Solutions

First Steps

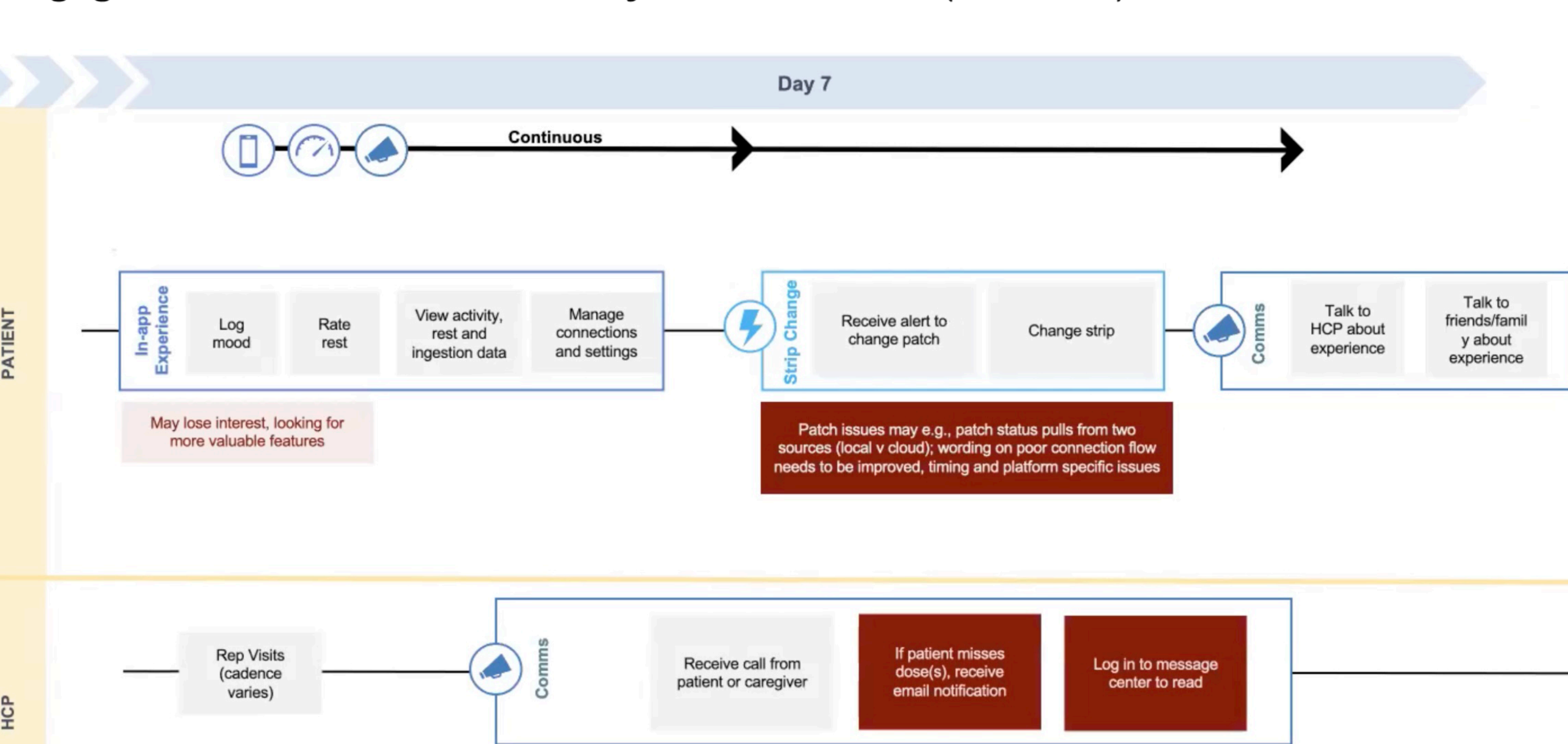
Create User Experience Workflows

Current State Journey: Patient Onboarding (continued)

Starts with AMS kit arriving



Engagement - Current State Journey: First Month Use (continued)



Notifications are to frequent and do not provide any information as to which patient and what the message is about.

Solutions

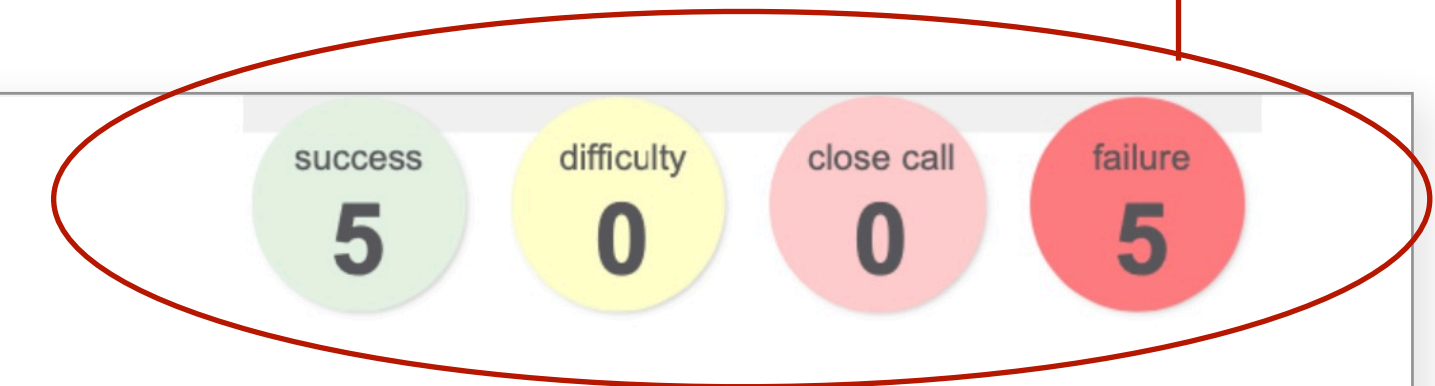
Next Steps

Human Factors & Usability Testing

Devise Scoring:
Clearly define issues

Study Findings

Succinct illustration
of issues....

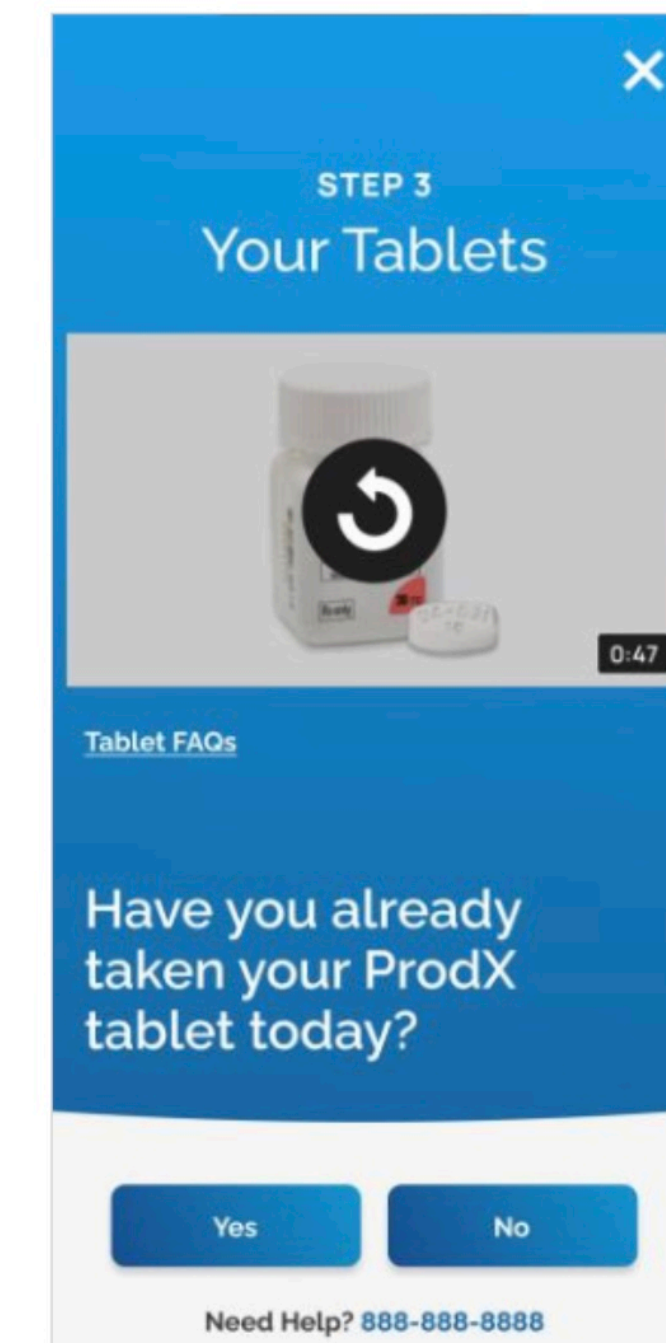


Issue 3: ... failing to take their first tablet

- Some participants did not recognize that the screen is asking about “their” tablet
- Design emphasizes section intro and video. Question is secondary... Wrong focus.
- Primary activity is watching a video. If video watching is rejected, the secondary action (question about tablet) is easily dismissed with it (by hitting “X”).
- This video is generic. It is not about them and their tablet.

GOALS

- Revert the priority of elements. Isolate the question.
- Focus it on the user. Not a general process as in video,



Solutions

Next Steps

Observations and Recommendations

Best practices: Minimize interaction mode switches

Simplified illustration of issues.

Fixes that are achievable given existing schedule...

- Vetted with SW Engineering

- Minimize interaction mode switches (physical/virtual, video/image/text/object)
- Mode switches are cognitively taxing and possible sources of errors
- Users tend to be most focused when they stay in one mode to achieve a task.

* Doing an analysis over time (in a user journey) of when and how we switch would be beneficial.

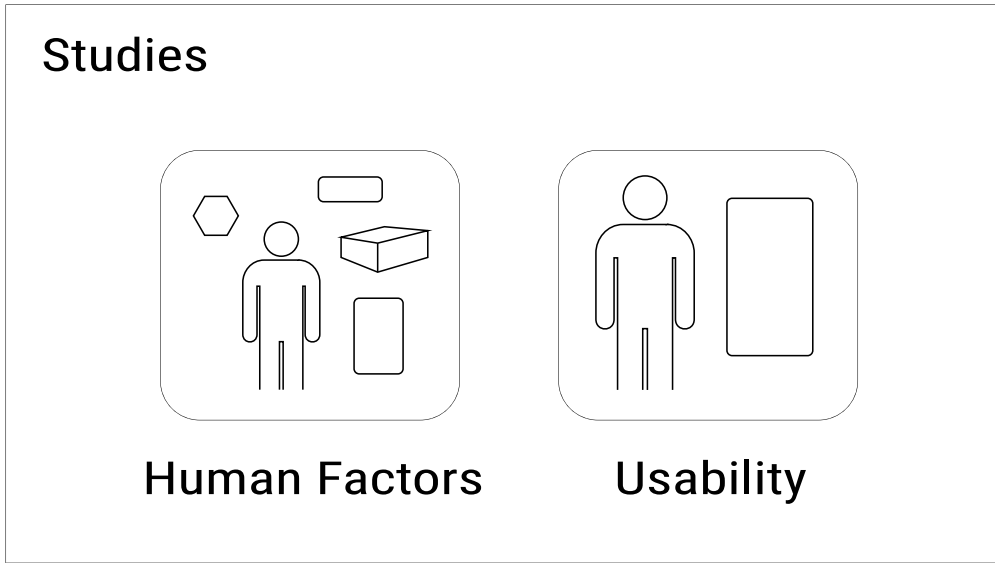
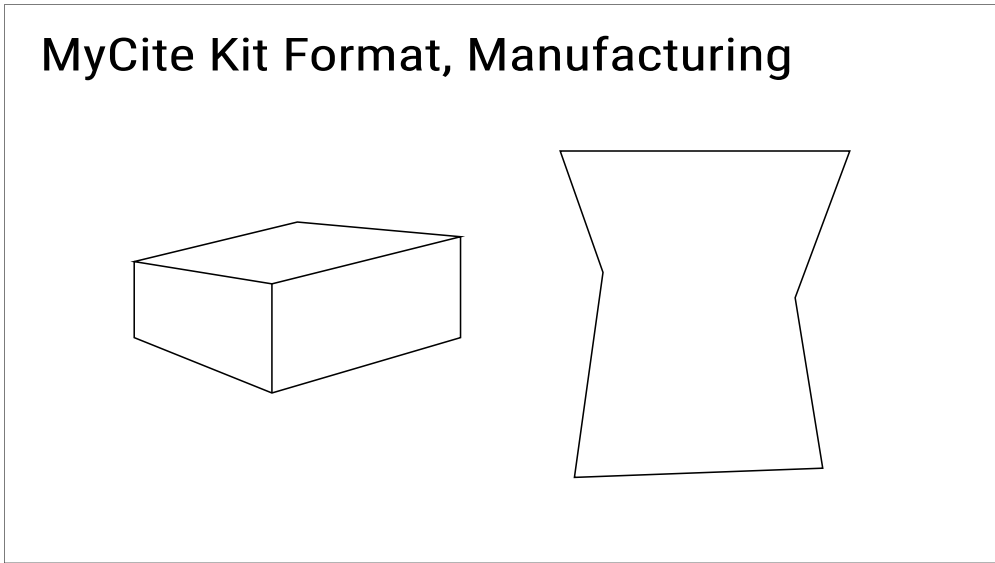
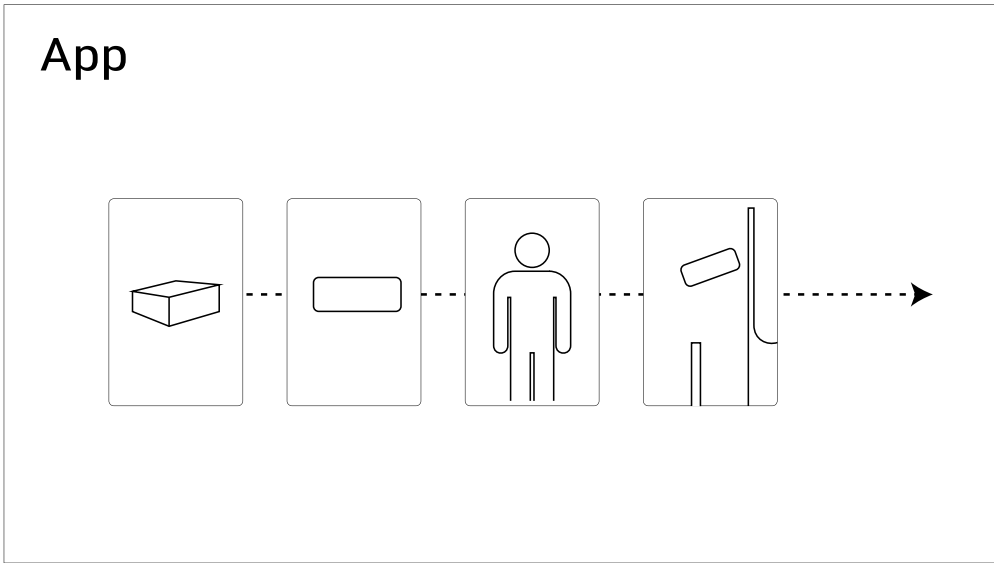
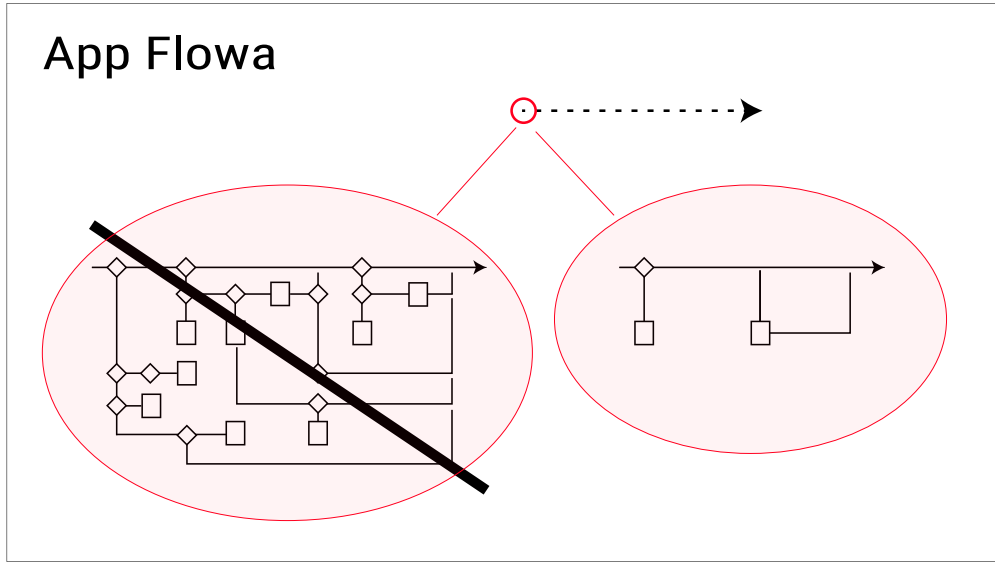
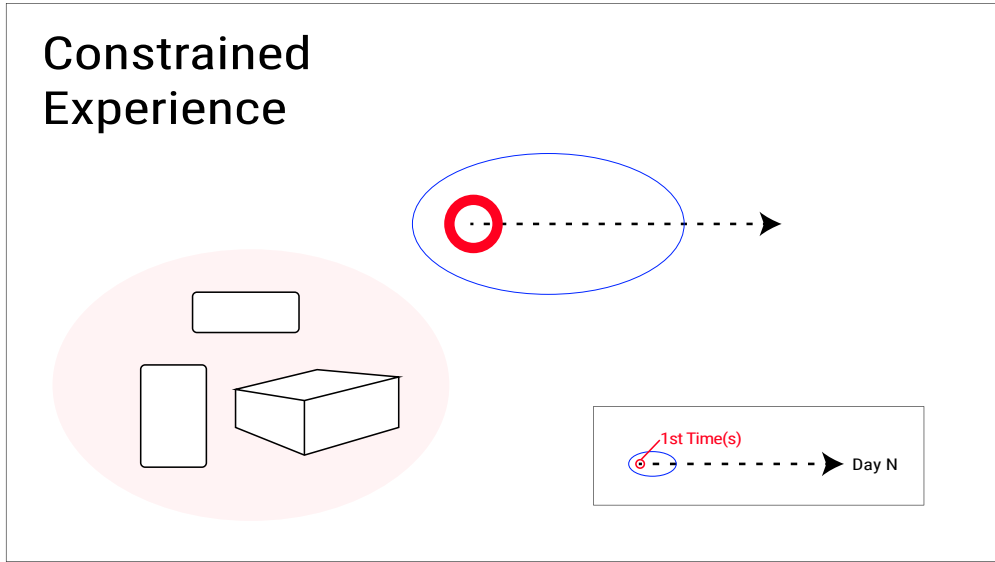
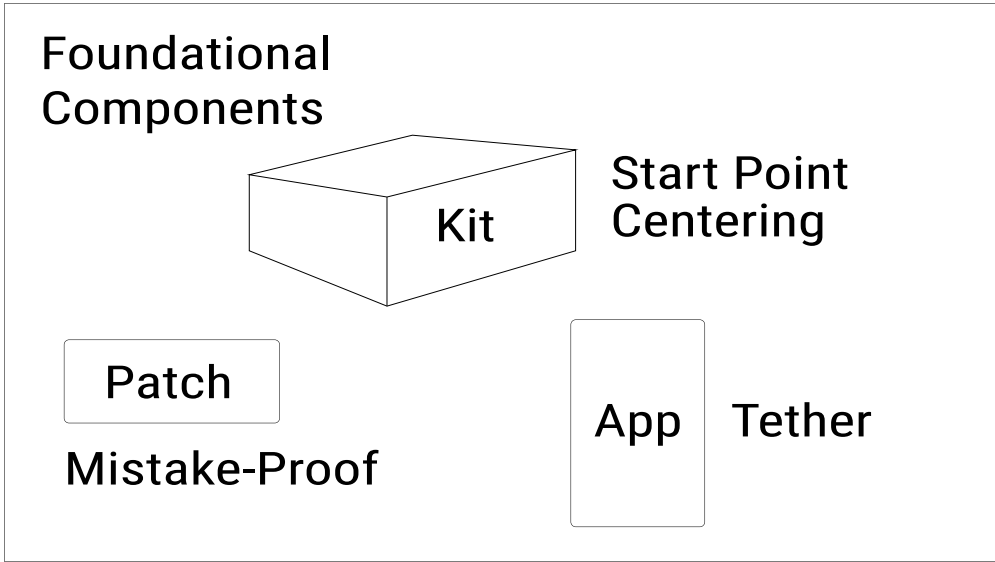
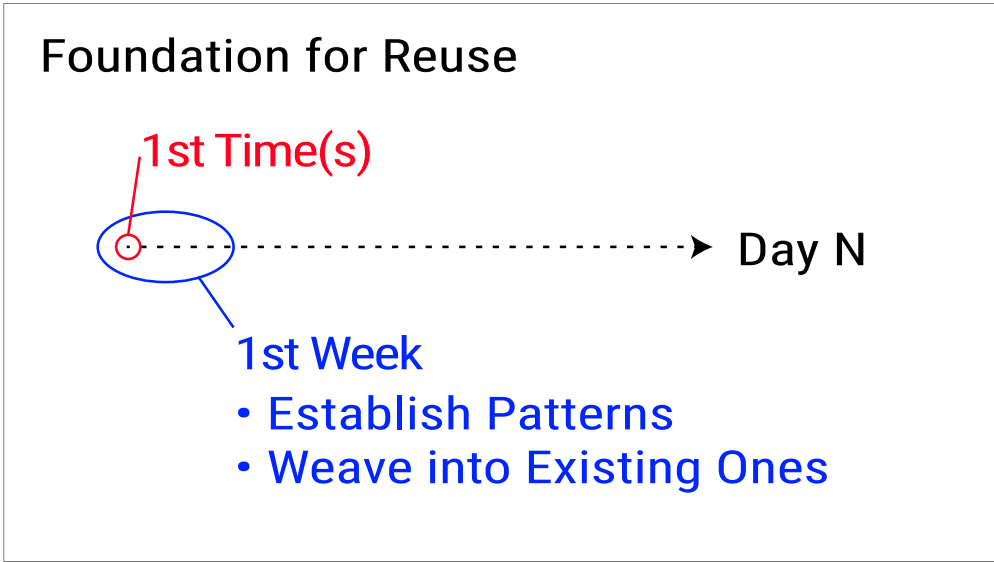
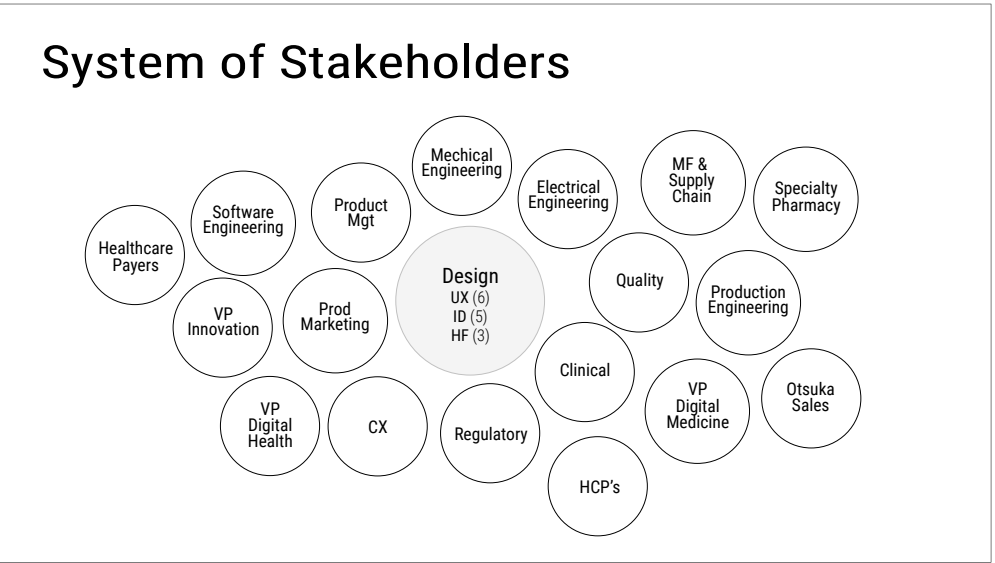
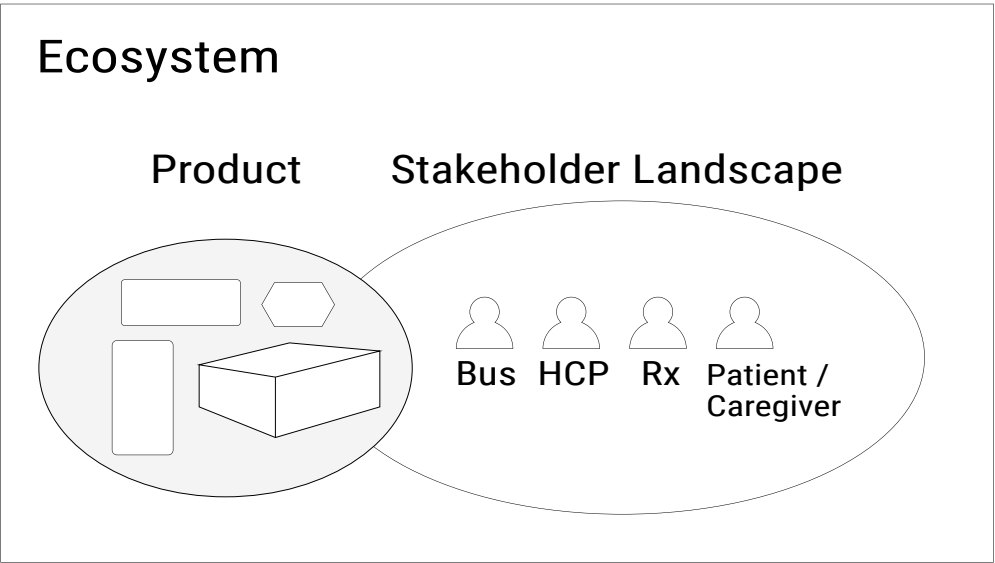
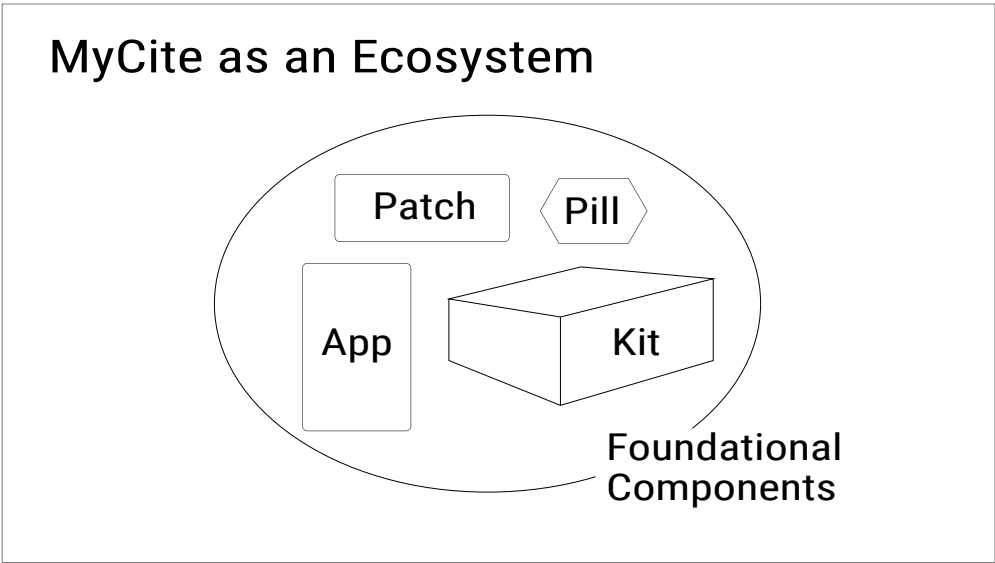
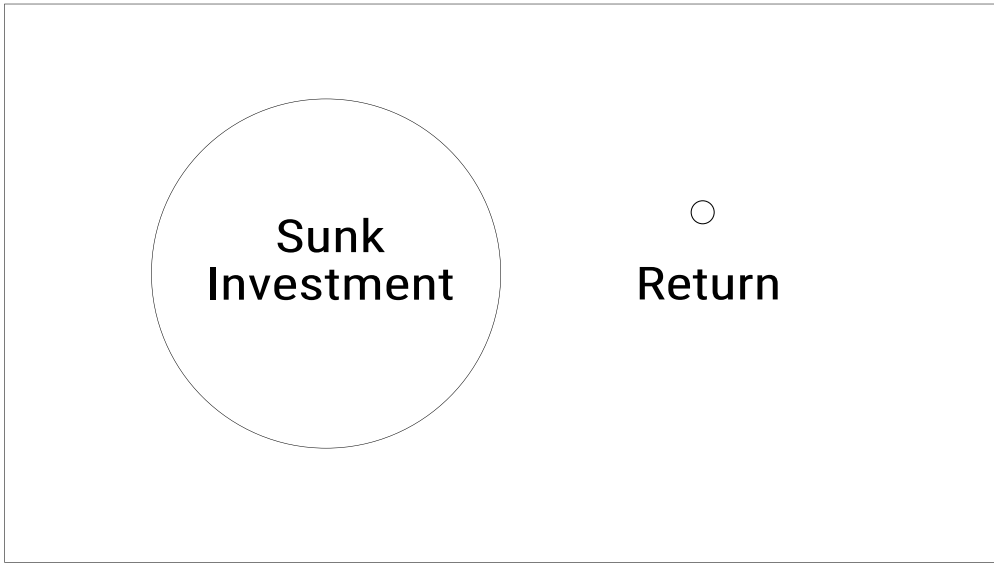
We have many interaction modes in this process

- Interact with people (?) (Pharmacist?)
- Interact with objects (box, patches, tablets)
- Read text on objects (Intro card, packaging labels)
- View image on screen
- Read text on screen
- Make selection/action on screen
- Enter text on screen
- Watch video on screen

Solutions

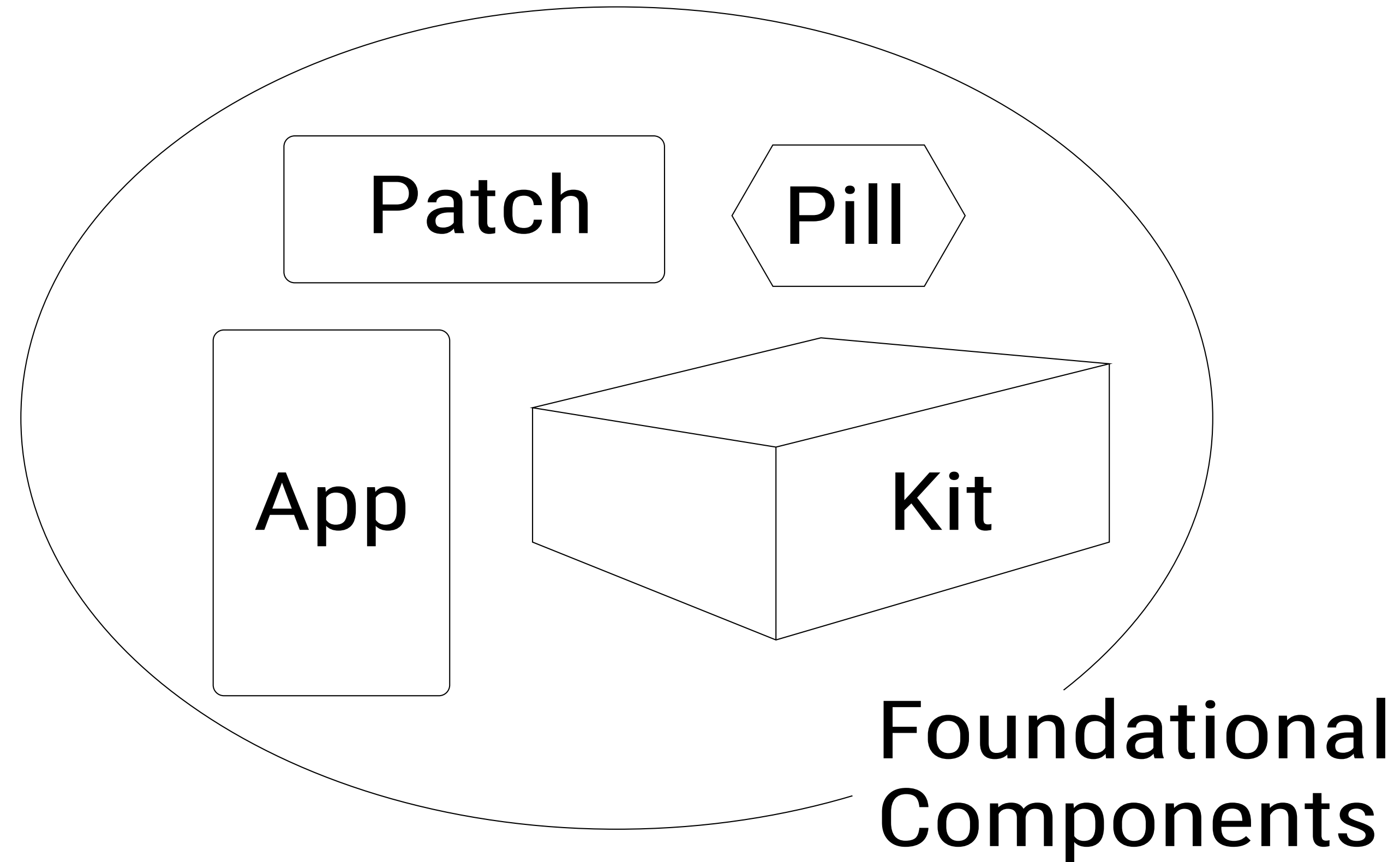
Next Steps

Conceptual Modeling of the Experience



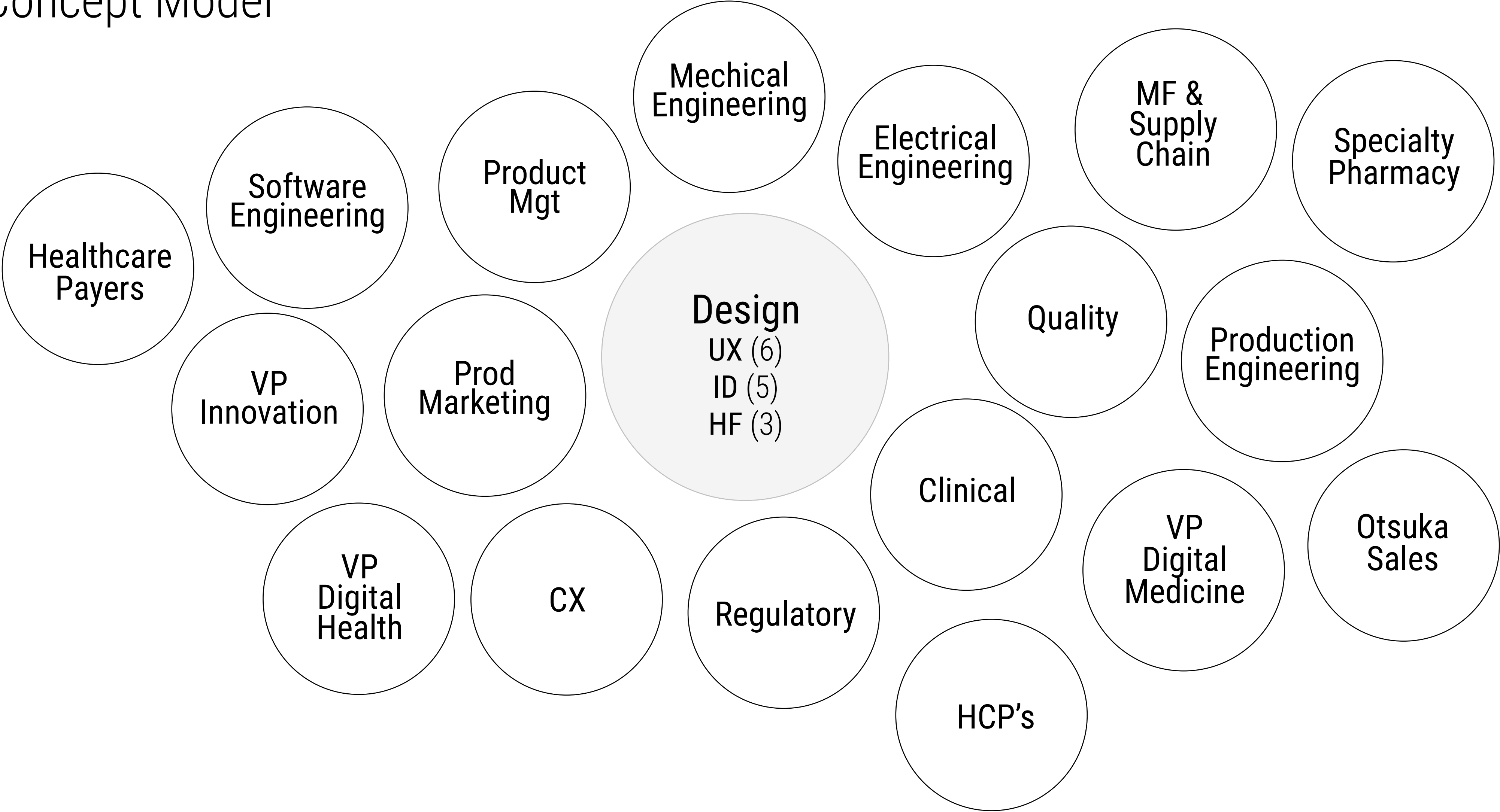
MyCite as an Ecosystem

Concept Model



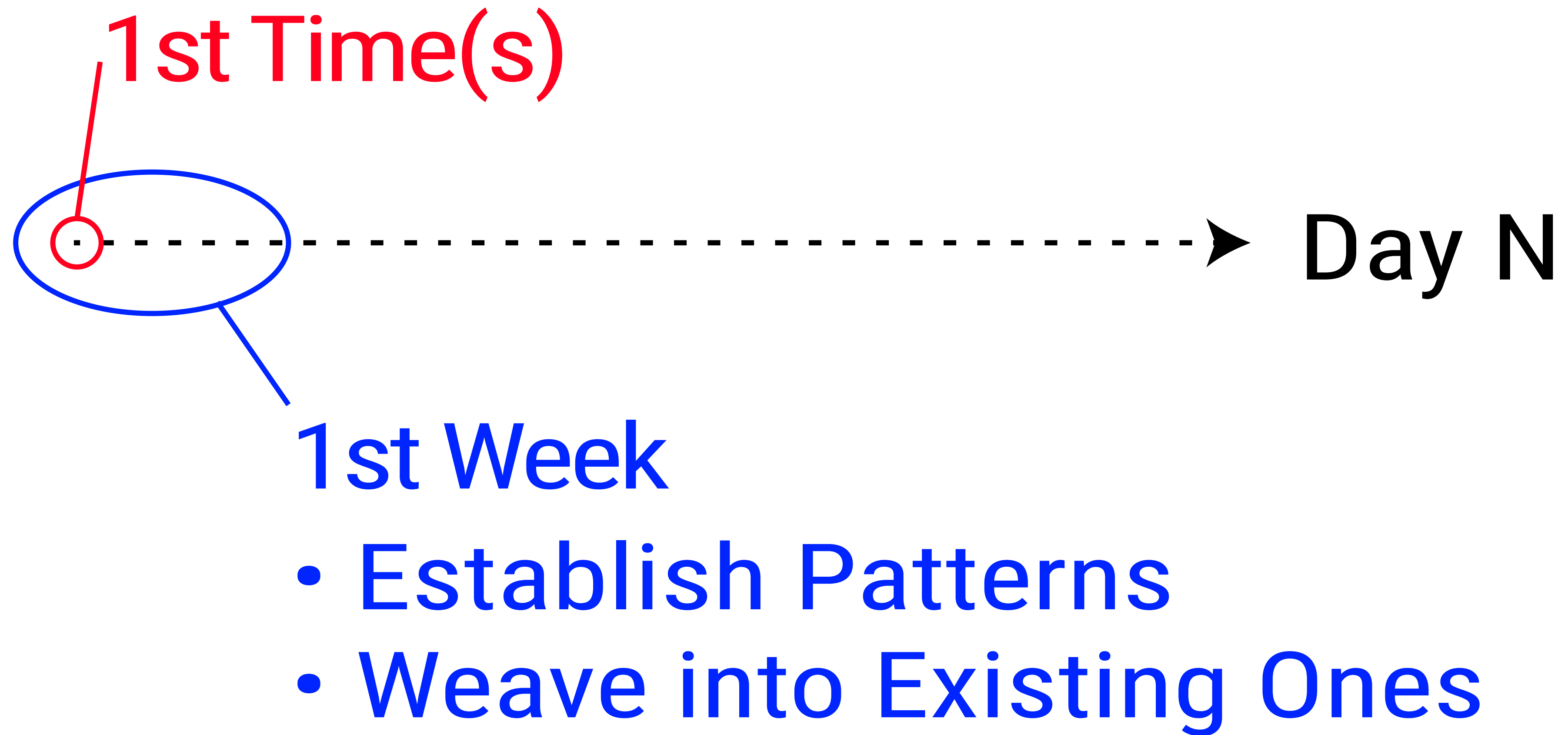
System of Stakeholders

Concept Model



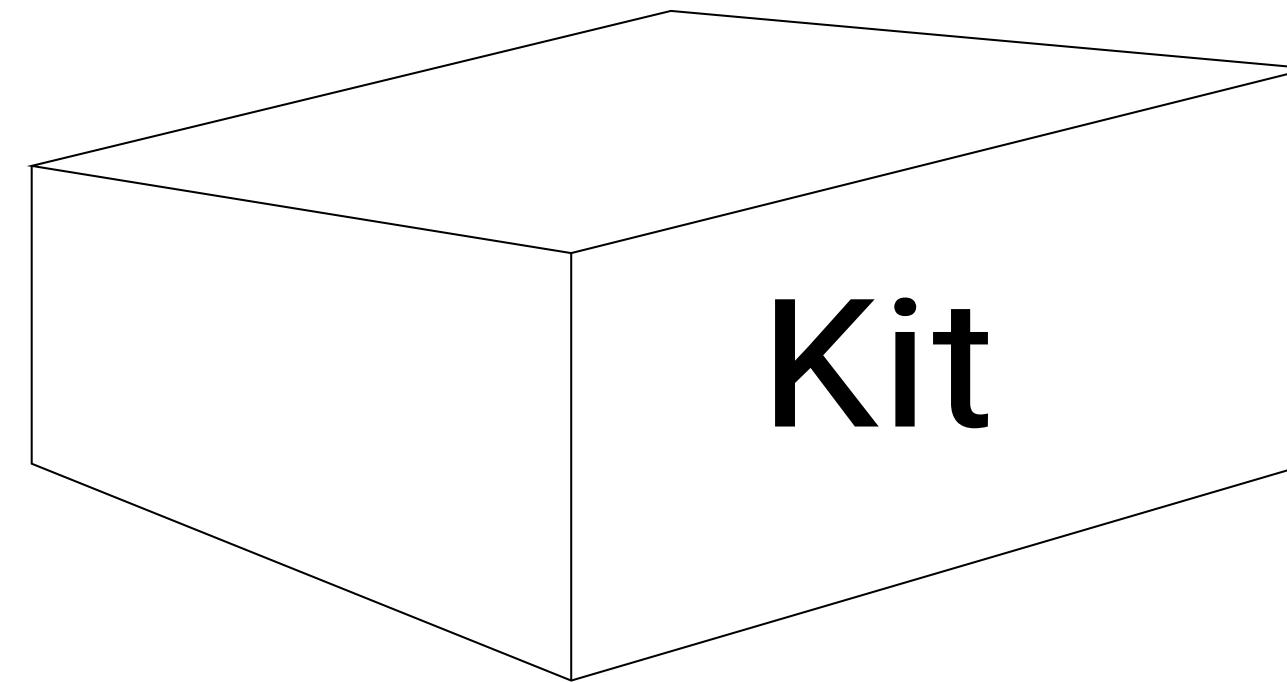
Foundational for Reuse

Concept Model



Foundational Components

Concept Model



- Starting Point
- Centering Device

Patch

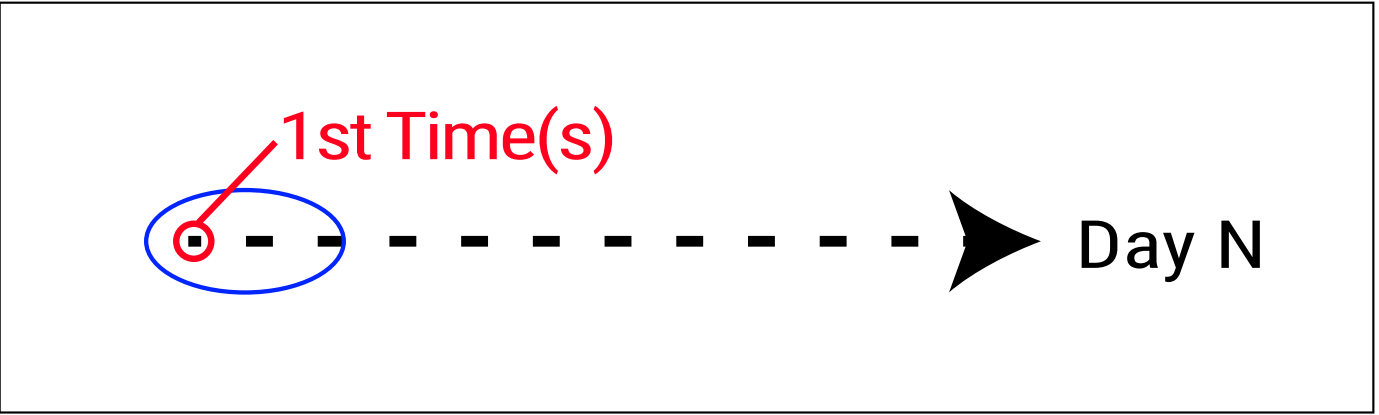
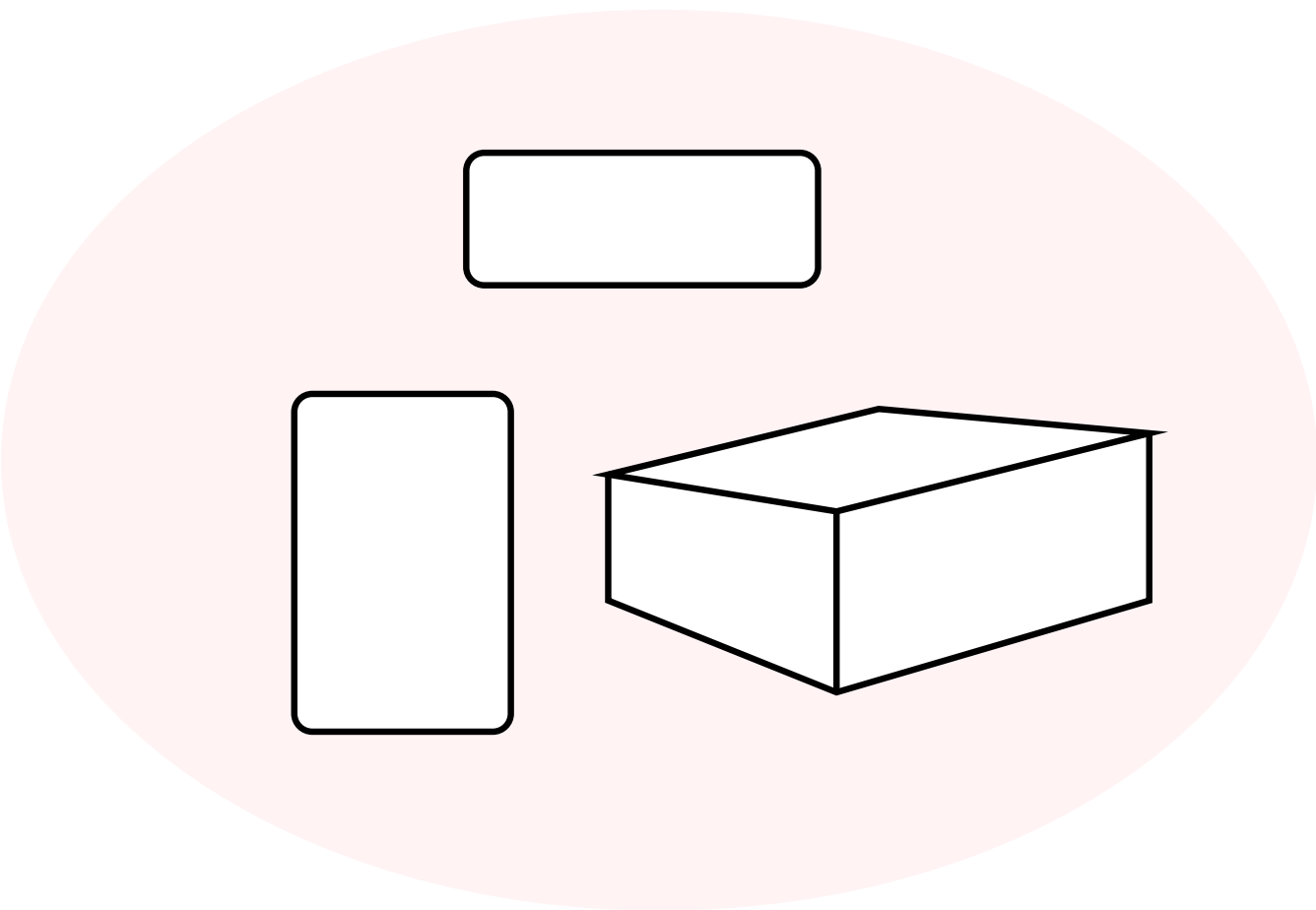
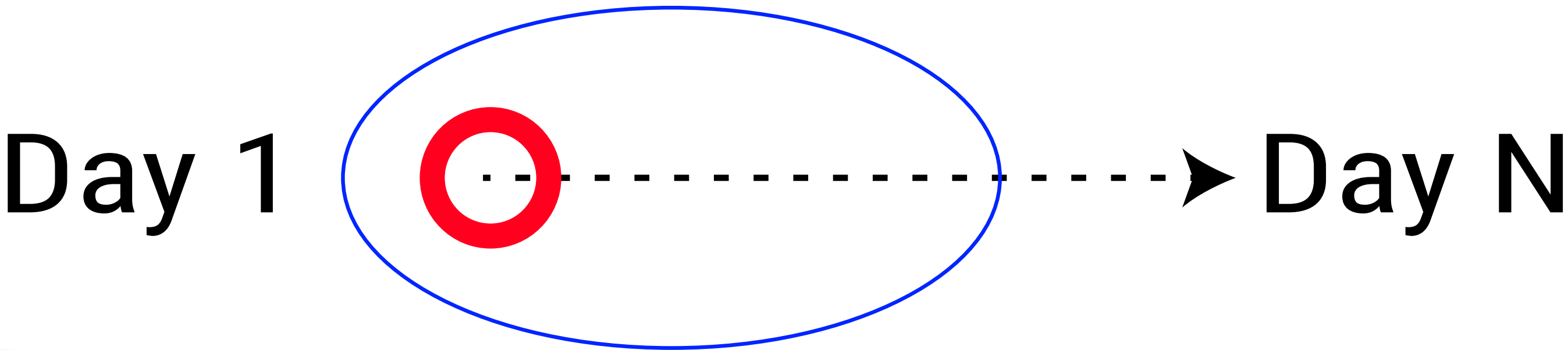
Mistake Proof Wearable

App

Tether

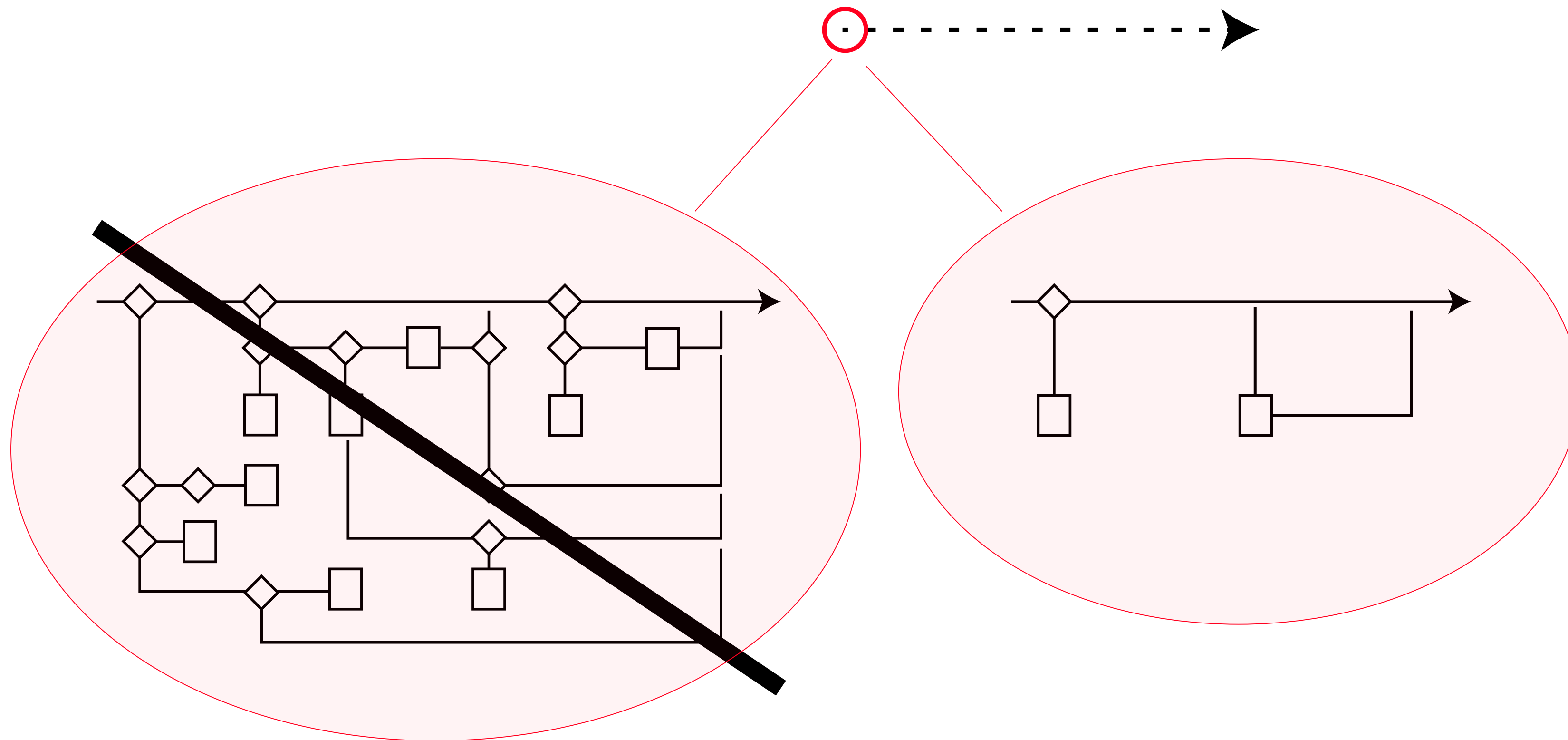
Constrained Experience

Concept Model



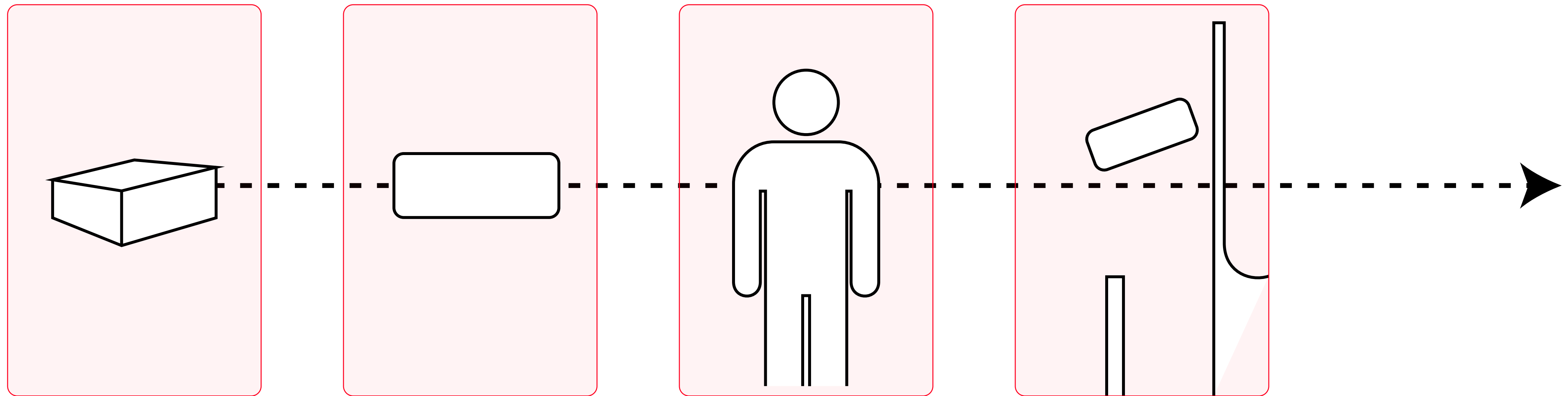
Constrained App Flow

Concept Model



Detailed Step-by-Step Procedure Demo

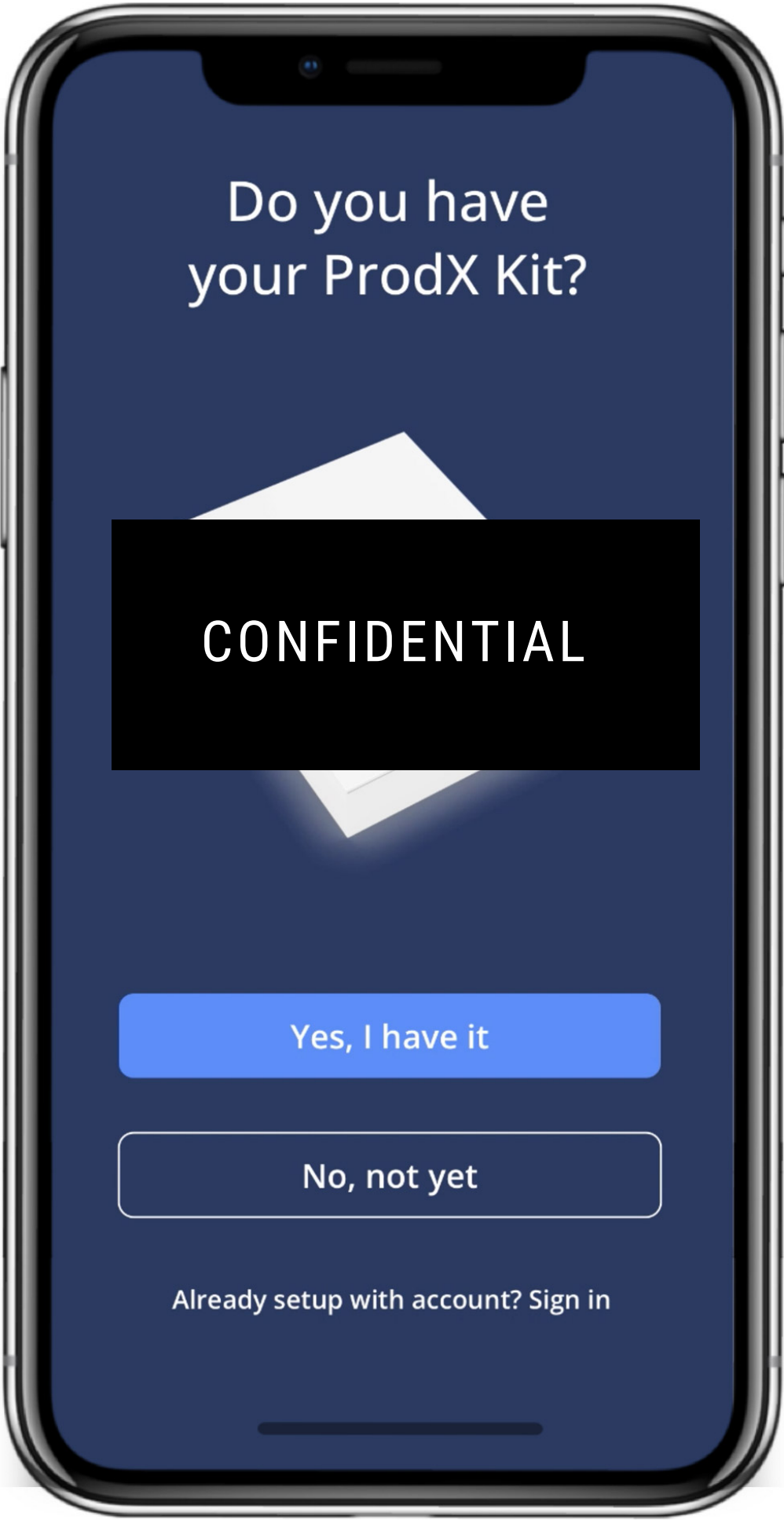
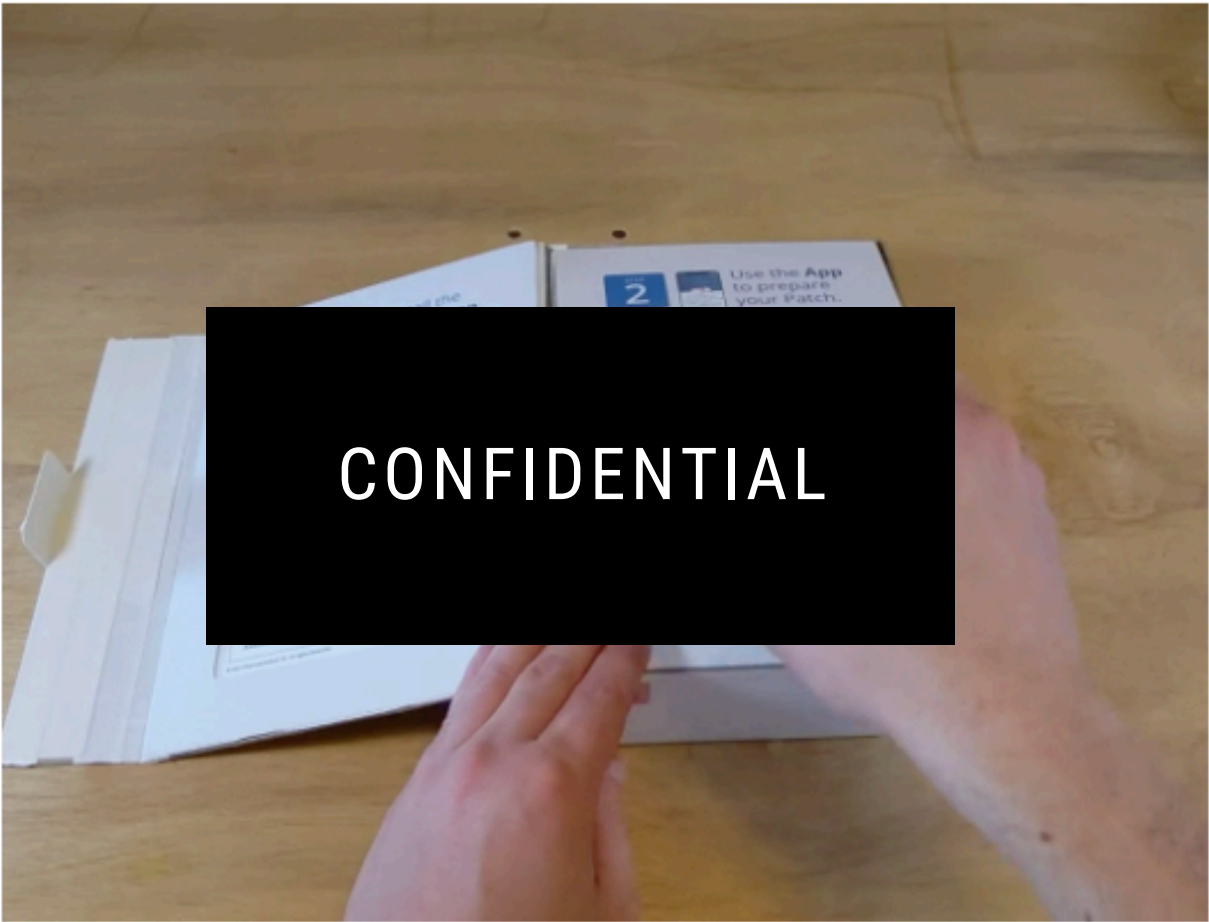
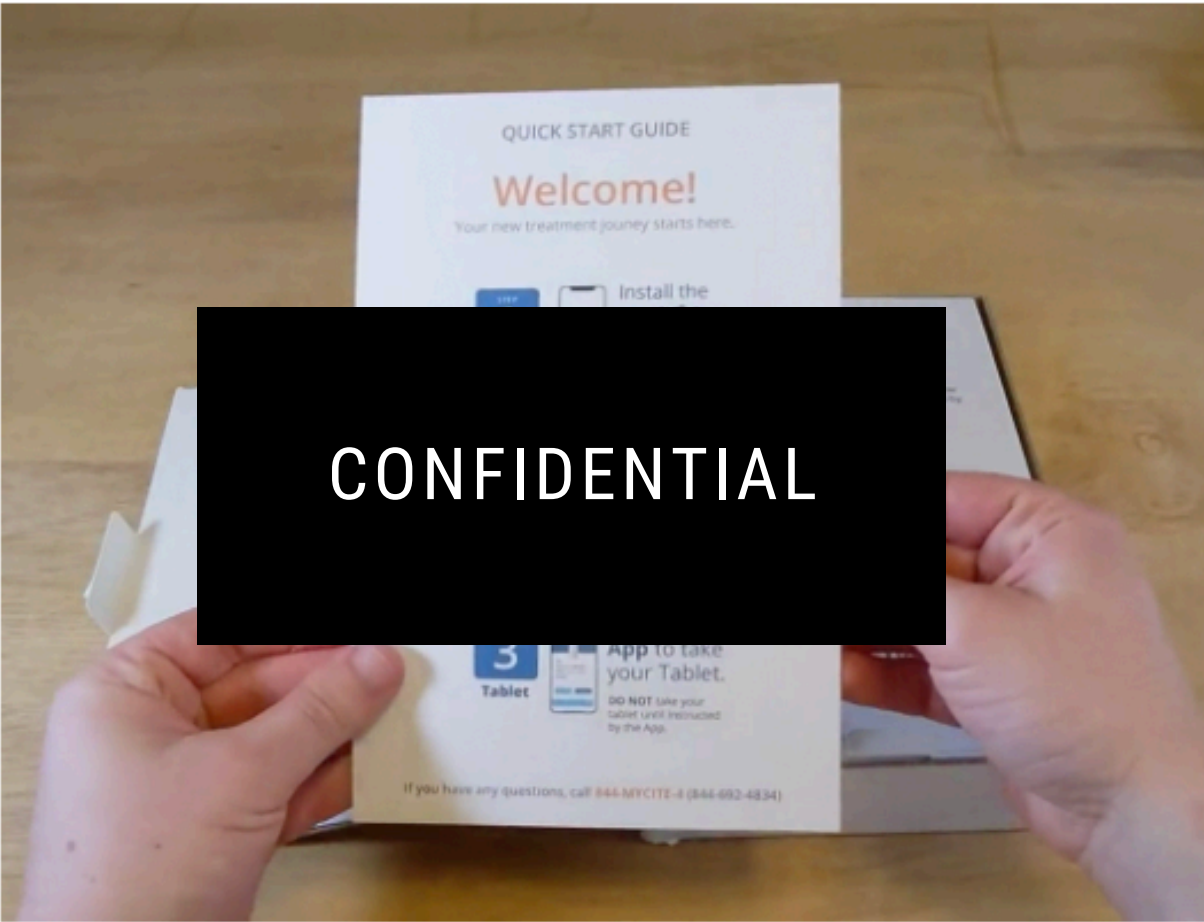
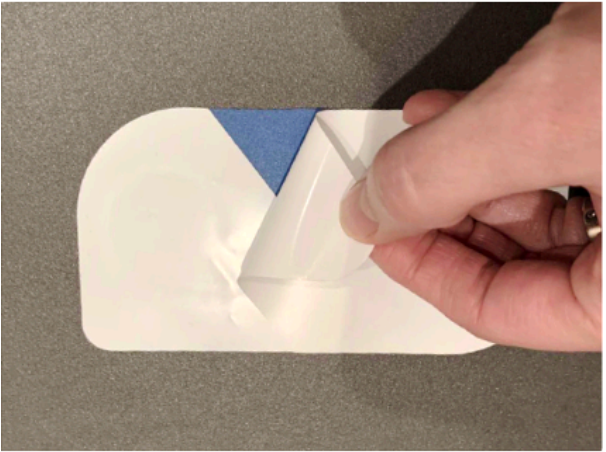
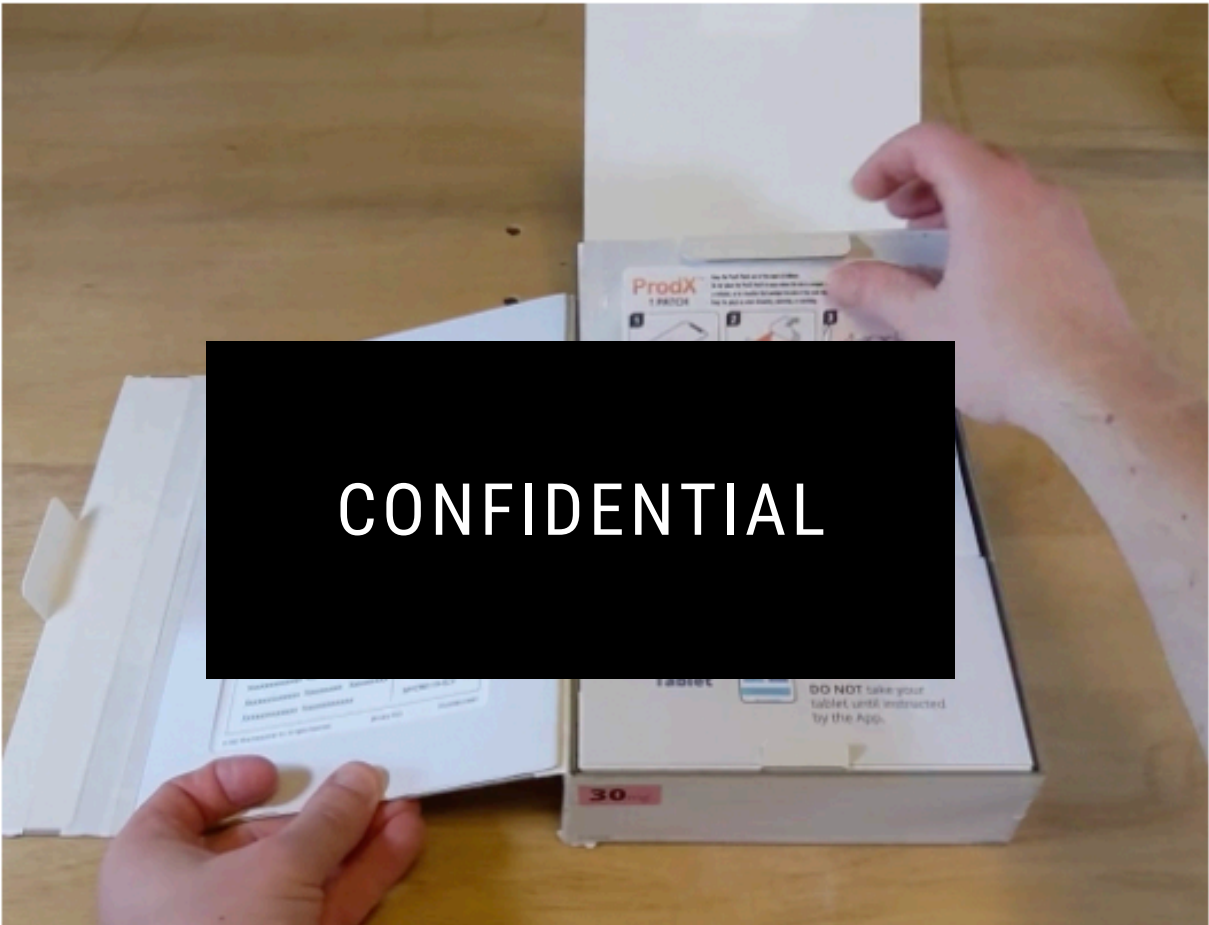
Concept Model



Solutions

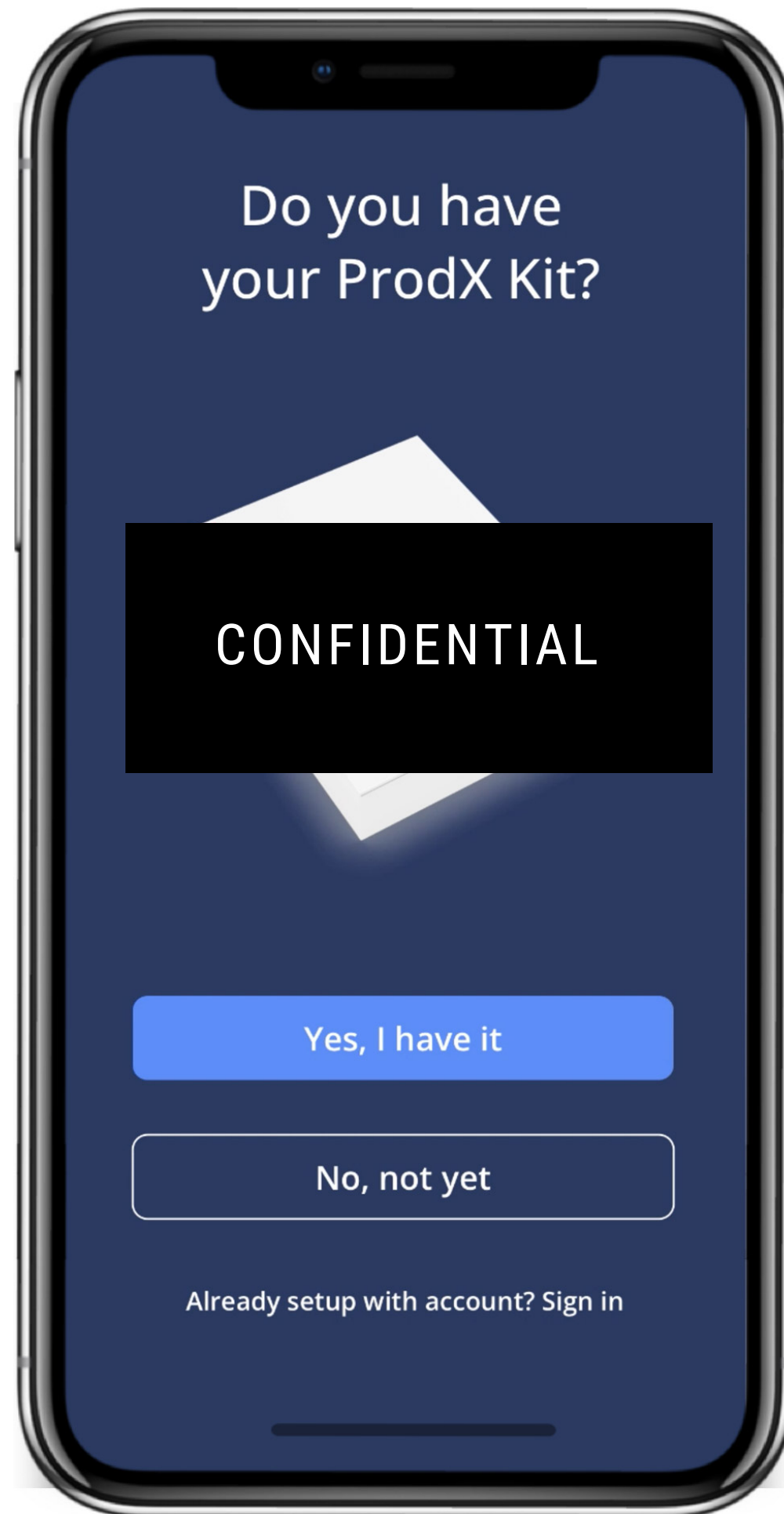
MyCite Concept

Ecosystem Experience: Kit, Patch, App



Solutions

Software UX



Ecosystem Experience: Kit, Patch, App

App Experience

- Live-video explainers Describe Each Process Step.
- Added optional fine detail drill-downs, power features
- In-context FAQs to address common to edge cases questions.
- Unambiguous, brief and focused work flows.
- Clear, consistent navigation; common interaction patterns for reliability and familiarity.

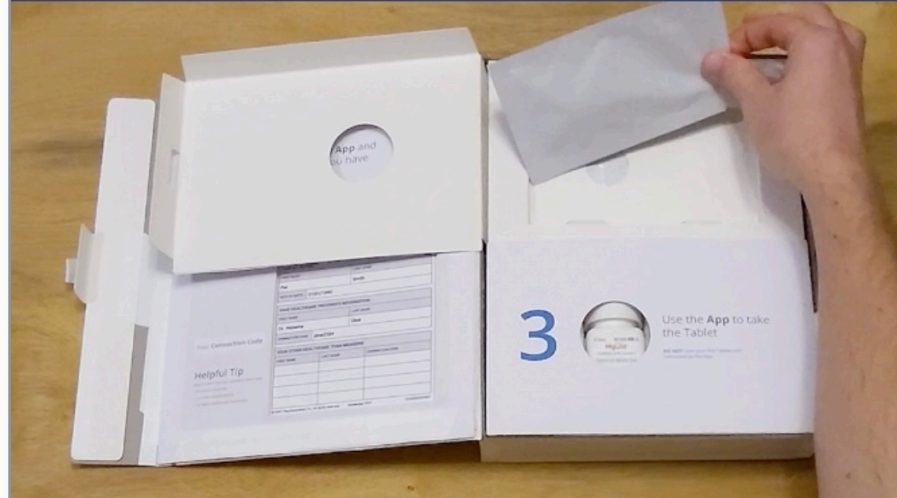
Solutions

Software UX

Ecosystem Experience: Kit, Patch, App

2 Your Patch

Back●●●●●●●●Next



Get a single patch out of your kit.

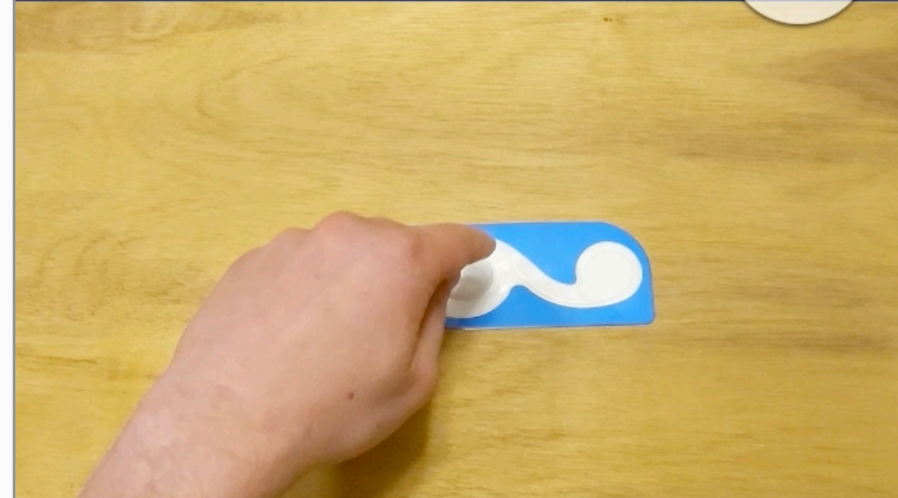
Take it out of its packaging & place it in front of you.

Next, you will pair it.

Need Help? XXX-XXX-XXXX

2 Your Patch

Back●●●●●●●●Next



On your patch, hold down the power button for 5 seconds, until you see a blinking light.

I don't see a blinking light.

Need Help? XXX-XXX-XXXX

2 Your Patch

Back●●●●●●●●Next



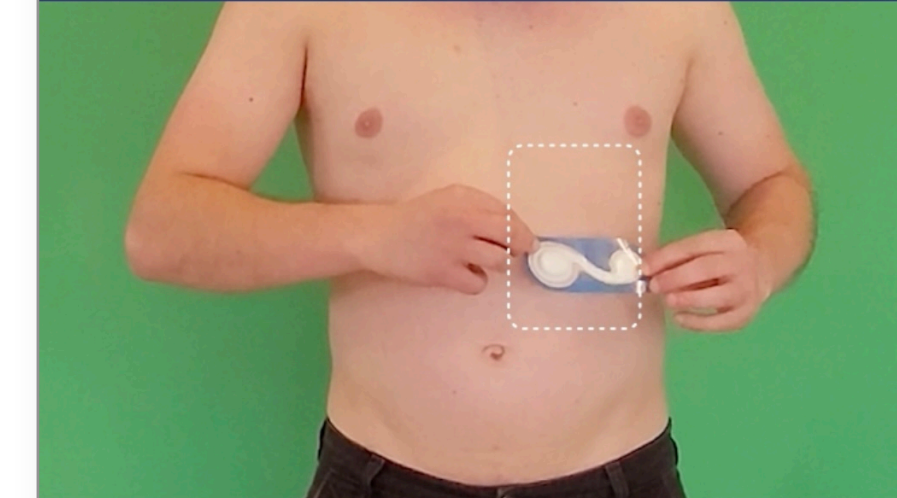
Carefully remove just the white liners from the patch.

Avoid touching the sticky area.

Need Help? XXX-XXX-XXXX

2 Your Patch

Back●●●●●●●●Next



Sit up straight, place the patch, with the blue backing, on the clean area.

Gently smooth it in place.

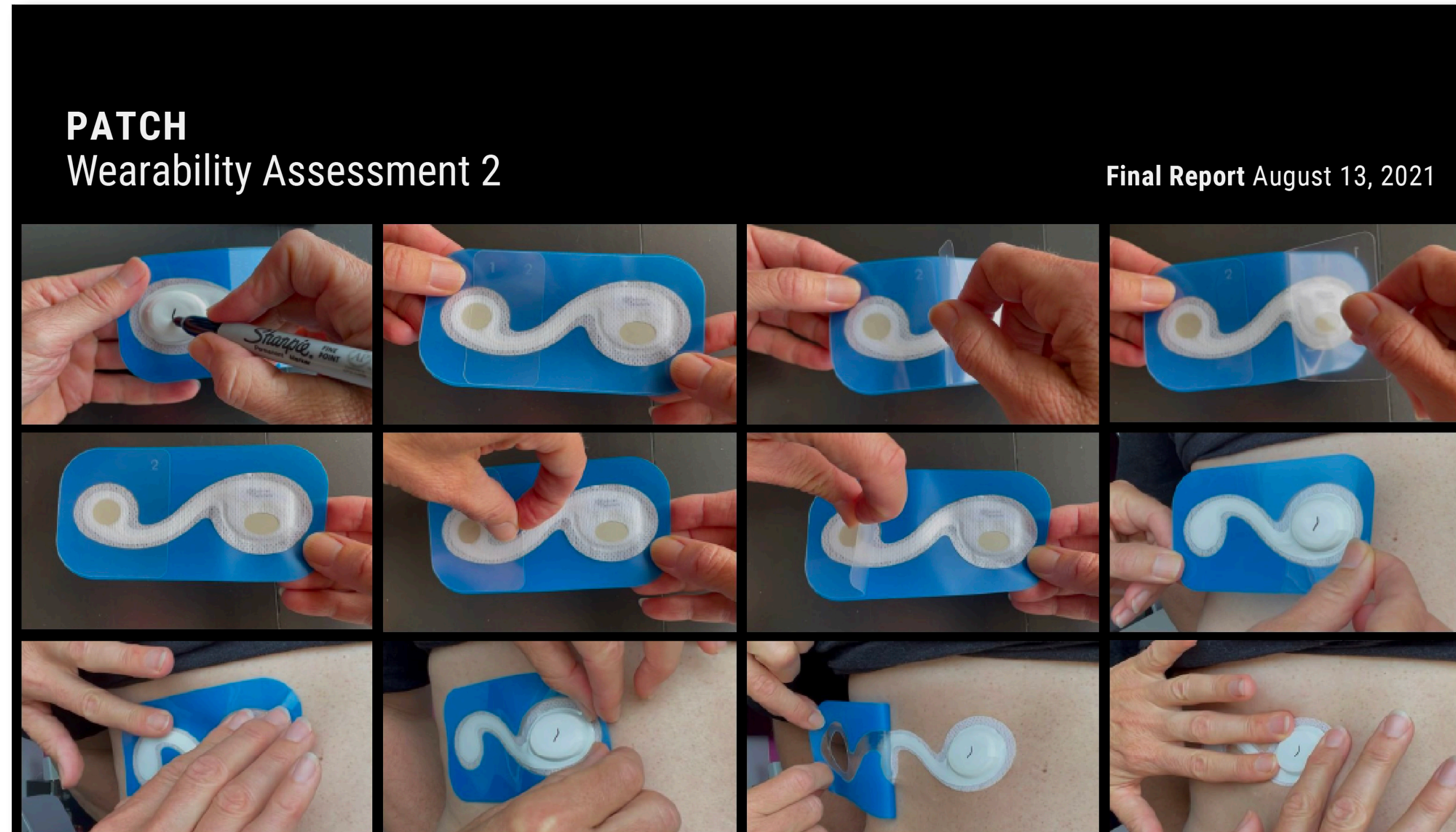
Need Help? XXX-XXX-XXXX

Solutions

Human Factors

Conducted Real World Testing

App Experience



- Devised new 10-day “on-skin” Patch study.
- Qualitative and quantitative feedback:
 - . Qual: Observations, photos, diary
 - . Quan: Comfort, Look, Design, Adhesion
- Compare lifestyle and enviro factors.
- New, real-world reactive prototype: single device addressing modality-switching
- In studio and at-home prototype testing.

Solutions

Human Factors

Durability of Patch Adhesion a Major Success Factor.

Balanced with qualitative feedback.

Quantitative analysis of Patch adhesion.

Wearability: Adhesion

Some patches that shifted stayed adhered, left residue

For 5 participants (P01, P09, P14, P20, P24) patches shifted during wear evidenced by adhesive residue on the skin in the original location.

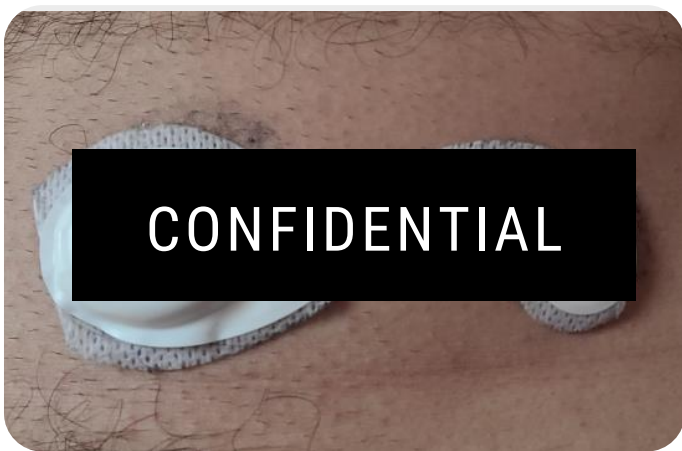
- When shifting occurred without reports of rubbing (load carrying, concert-going), patches **stayed on until Day 10** (P09, P20).
- Patches on **3** (of the 5) participants (P01, P09, P20) **stayed on past day 7**.
- The 2 participants (P24, P14) that reported losing patches before Day 7 reported **carrying loads against their body** (P24) and **patch rubbing at a concert** (P14) immediately preceding patch loss.
- 4 participants (P01, P09, P14, P24) reported **comfort issues** with their **shirts getting stuck** on the adhesive residue, in daily life and/or when undressing.



P01, Day 8



P09, Day 7



P14, Day 5



P20, Day 7



P24, Day 6

“

There is sticky adhesive that I can see and feel on my skin. It's taken on a grey tint wherever the skin is exposed, and it feels kind of gross.

P09, Patch 1, Day 5

“

This morning both of the patches got caught on my shirt and started to come off more as I was moving around and carrying/moving boxes at work. They ended up both falling off afterward.

P24, Day 8, Patch 1 & 2

Solutions

Human Factors

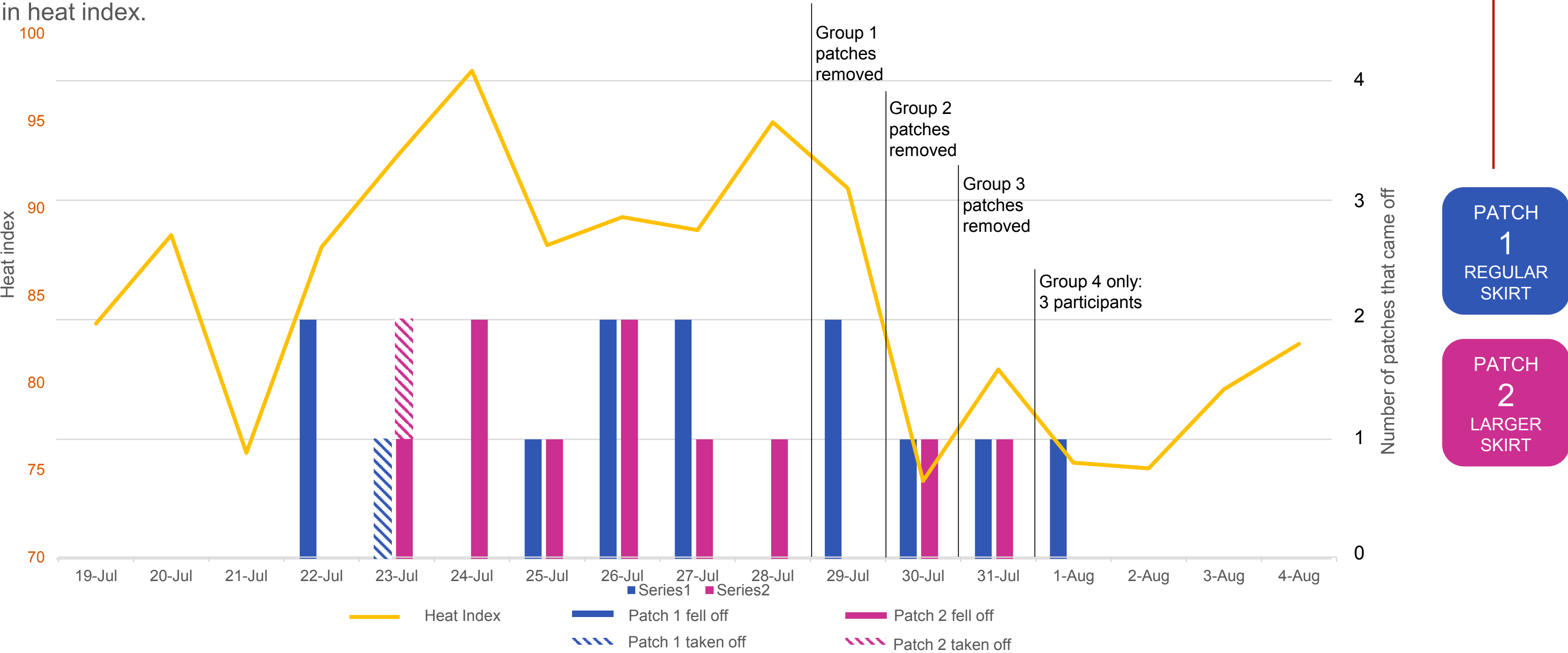
Quantitative analysis
of Patch adhesion.

Feedback-driven
Patch variation.

Wearability: Adhesion

Heat index did not correlate with patches falling off

While patch adhesion may have been impacted overall by high heat indexes, there was no correlation between patches coming off and changes in heat index.



Solutions

Human Factors

Suggest fixes that are achievable given existing schedule and goals.

Achievable structural changes pre-vetted with MEng + EEng

Considerations & Recommendations

Considerations for ongoing patch design: Use cases



Consider challenges of certain use cases in the design

All design considerations involve trade-offs that only the design team can determine. Below are some brainstorming starters that leave the trade-off decisions to the design team.

- Sweating and showering
 - 🔍 Skin adhesive material that is water-resistant/**does not saturate** may improve adhesion (perhaps at the expense of comfort).
- Carrying loads against the body
 - 🔍 **Sloping edges more** on raised patch nodes may make them less likely to be dragged along with loads (perhaps at the expense of size/node footprint).
- Wearing underwire bras
 - 🔍 Provide **patch location instructions** that instruct patients to **apply patches at lowest position** if they wear underwire bras. Any forward flexion along the spine can cause a bra that was clear of a patch when applied while standing with an extended spine to contact a patch in daily life.
- Hair growth at patch site
 - 🔍 Consider whether a **shorter patch replacement interval** is in order for this group.

Sloped node edges

option: maintaining node base diameter

option: maintaining node top diameter



Lower patch position for bra clearance

This participant experienced node separating and bra interference on Patch 2, which was higher but still very clear of her lower bra line.



Considers realistic variety of lifestyle conditions

EPILOGUE

MyCite Expected to Re-Launch in 2023

- Formative FDA submission delivered, approved
- Redesigned mobile application
- Patch updated for Usability, Comfort, Durability
- MyCite Kit to be introduced
- Revision to Otsuka Human Factors Requirements with consideration for Usability.

THANK YOU

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