

Unified Intake Tool (UIT)

Project Timeline



U.S. FOOD & DRUG
ADMINISTRATION

Office of Operations | November 13, 2025



Agenda



- Historical designs
- Research timeline recap
- Who did we interview
- Research quotes
- High level recommendations
- Current design prototypes
- Questions
- Next steps

Historical designs

USDS Designs – February 2025



Report a Problem to the FDA (Draft) - Feb 2025

Drug > Someone was harmed

Report a problem to the FDA

Your report is critical for ensuring the safety of products for the American public.

We will ask you to describe the product, what happened, and optionally, who was harmed.

While we review every submission, we are unable to answer questions about your individual report. If you choose to provide contact information, we may follow up for more details.

Get Started

The problem

What was the product?*

☐ Cosmetic

☒ Drug

☐ Dietary Supplement

☐ Food

☐ Medical Device

☐ Tobacco

☐ Vaccine

☐ Veterinary (animal food, drug, or device)

☐ Other / Don't know

What happened?*

Select all that apply

☒ Someone was harmed (injury, illness, death, loss or death)

☐ Something was wrong with a product (quality, safety, or labeling issue)

☐ Someone used a product incorrectly (description TBC)

☐ Illegal activity, fraud or misconduct (Whistleblower, confidential source or trade related complaints)

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The product

Upload product photos (optional)

Include photos of the entire product and package and any text, including the barcode, lot number, and expiration dates.

Upload

Product name*

Include as much detail as possible, including the brand.

UPC number (optional)

This 12-digit number is on the barcode of the product or packaging.

NDC number (optional)

This code starts with NDC followed by 11 numbers, such as "NDC 12345-6789-01."

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What happened

Describe what happened, step by step, and the timing*

When first using the product, how long did it take before problems started, and did issues go away after stopping the product?

4000 characters remaining

When did this happen?*

For example: Oct 1, 2024

If you don't know, give an approximate date

Month Day Year*

- Select - 1 2024

Did any of the following happen? (optional)

Select all that apply

☒ Hospitalization

☐ Death

What was the diagnosis and how was it treated? (optional)

4000 characters remaining

Upload additional files (optional)

This may include medical records.

Upload

Did you already report this problem to the company that makes this product? (optional)

☒ Yes

☐ No

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Who was harmed (optional)

[Skip this step](#)

This information is helpful for tracking product problems and conducting investigations.

Age (optional)

0 Years

Sex (optional)

☒ Female

☐ Male

☐ Prefer not to say

Provide their medical details (optional)

List any products taken at the same time, including over-the-counter medications, supplements, and any allergies.

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How to reach you (optional)

[Skip this step](#)

Can we contact you with any follow up questions? (optional)

We will only contact you to ask questions about this product complaint.

☒ Yes

☐ No

Can we share your contact information with the manufacturer so they may reach out? (optional)

☒ Yes

☐ No

First or given name (optional)

For example: Jose, Darren, or Mai

Last or family name (optional)

For example: Martinez Gonzalez, Gu, or Smith

Email*

Name@domain.com

☒ I don't have an email address

Phone number*

555-555-5555

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Review your submission

Review your information below to make sure it is correct. After you submit, you will not be able to update this report.

To make changes, tap on any section to edit.

Product [Edit](#)

Product type

None

What happened [Edit](#)

What was wrong narrative

Who was harmed [Edit](#)

Age

Sex

Medications

Your Contact Information [Edit](#)

First name Last Name Email

Submit

Report successfully submitted

Thank you for submitting report 123456.

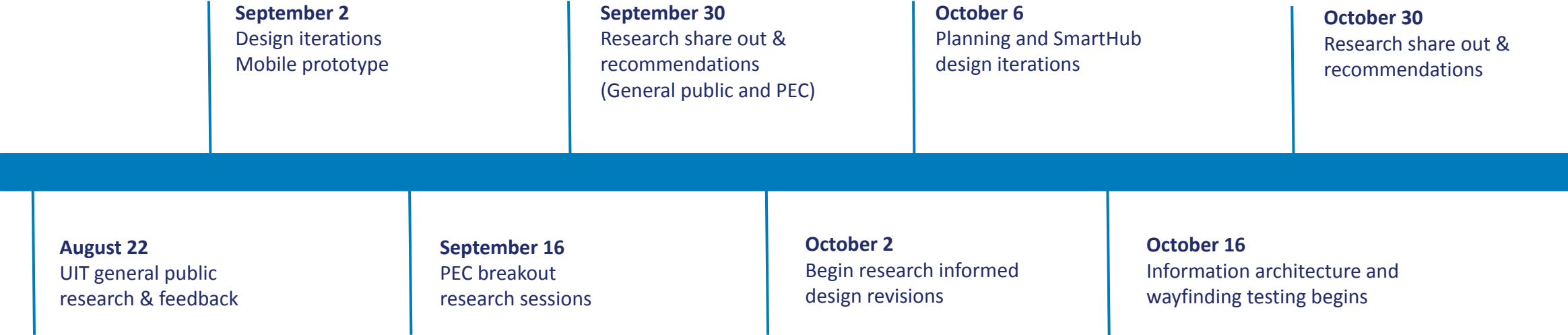
We usually look at submissions within 2 weeks, to track the safety of FDA-regulated products and to take action on safety problems.

If we need additional information, we will reach out to you directly.

Because of the volume of reports we receive, we cannot answer questions about your submission.

If you want to add more information, submit a new report. Include case number **[123456]** so we can connect your reports.

Project timeline



Research overview

Who did we interview?



General public research (Food and Drug)

11 total participants

Age Ranges 19 - 64

50% high school education

Backgrounds ranging from retail, retired, carpentry, writing and food licensing

Patient Engagement Collaborative (PEC)

16 total participants

12 in person, 4 virtual

Ages ranging from college student to mid 50's

Majority of PEC members have high levels of education

All have a background as a patient or medical advocate

General public research (Information Architecture)

7 total participants

Age Ranges 19 - 60

2 high school education, 5 higher education

6 English, 1 Bilingual (Spanish)

Backgrounds ranging from flight attendant, social worker, engineer, designer and data tech

User quotes

“ *If this is a longer questionnaire, it would entice me to underreport.*

Patient Engagement Collaborative Member and Professional Healthcare Advocate

”

“ *I would be willing to spend 10 minutes to fill this out.*

Age 35, Digital Accessibility Tester

”

“ Why don't all these product categories have examples listed beside them to help me decide which one to choose?”

Carpenter, age 64

High level recommendations

High level recommendations

Content focused revisions

- Reduce the number of questions from MedWatch by 70%, goal to have users complete the form in under 5-10 minutes
- Improve product category language and include examples
- Make headings and questions more empathetic and user-centered

Question revisions

- Add more severity options
- Add option to specify whether report is for user or someone else

Design revisions

- Improve help text and tool tips for UPC/NDC
- Ensure progress bar steps completed is visible on all pages
- Button placement and wayfinding improvements



Step 1 Getting started

Report a problem to the FDA

Your report helps improve the safety of the products sold in the U.S. We review every report and take necessary action, such as issuing safety product alerts or product recalls.

If this is a medical emergency, call 911.

i Types of reports the FDA collects

- Problems caused by a product, e.g. injury, sickness, or other harm
- Problems with a product, e.g. damage, defect, or labeling issue
- Misconduct, e.g. illegal activity, whistleblowing, or trade-related complaints

Reporting is easy. Tell us about the problem and the product. You should have the product with you, if possible. The form should take 5-10 minutes, depending on how much detail you share.

Get started

URL & Wayfinding

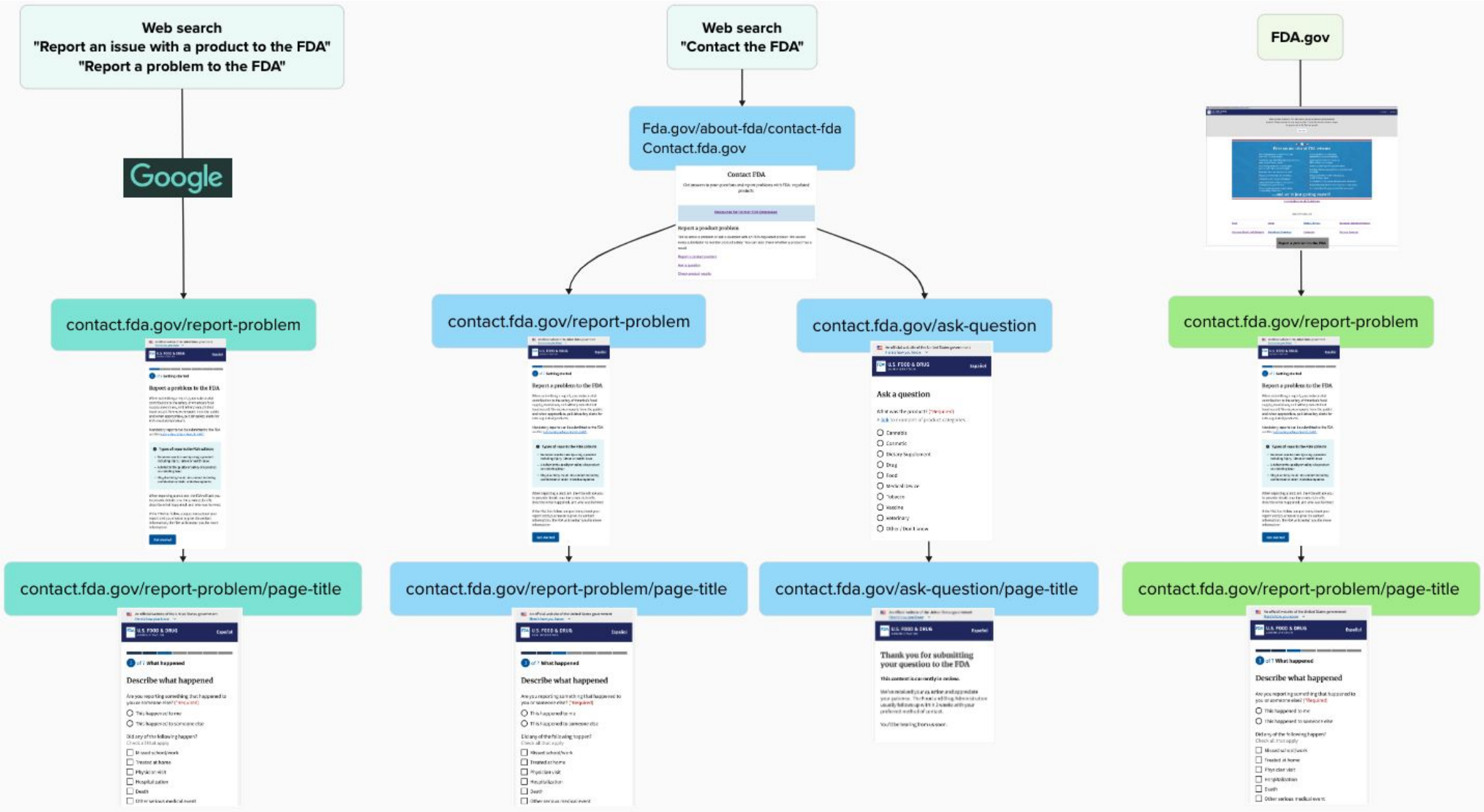


Navigation revisions

- UIT will own contact.fda.gov subdomain
 - contact.fda.gov/report-problem - URL for report a problem
 - contact.fda.gov/ask-question - URL for inquiries
- [FDA.gov](https://fda.gov) homepage
 - Instead of linking to SmartHub page hosted on [FDA.gov](https://fda.gov), we will link directly to UIT to streamline user flow and reduce number of clicks
 - CTA URL: contact.fda.gov/report-problem
 - Future consideration: Include CTAs and supporting text for “Report a problem” and “Ask a question” on the [FDA.gov](https://fda.gov) homepage

Content/Design revisions

- Make content and design recommendations to the team that owns fda.gov/about-us/contact-us for helping users navigate to contact.fda.gov/report-problem and contact.fda.gov/ask-question



Navigation revision diagram

Current designs

