FDA's Strategic Plan for Regulatory Science

• Mission Statement
  – Responsible for protecting the public health [1]

• Regulatory Science

• Designing the Solution
  – Know the audience
  – Reach the audience
  – Ensure audience understanding
  – Evaluate the effectiveness of communication about FDA regulated products

[2] (FDA, 2016)
[3] (Environics Research, 2018)
Current Access to Information through the FDA

MedWatch

VAERS

Safety Reporting Portal

MAUDE

openFDA API

"We recognize it can be challenging to figure out where to report concerns or problems to the FDA"

-Anna Fine, Pharm.D., M.S., director of the FDA's Health Professional Liaison Program [1]

Consumers need a centralized, customizable portal to report, and learn about, problems, complications, or recalls regarding FDA regulated products in real time.

[1] (FDA, 2016)
FDA ALERT is a smartphone-based mobile app
Approved Listings & Explanations of Regulated Technology

- Scan a QR code on product label
  - Access all FDA verified/approved information
- Feature that gauges user understanding
- Alert feature for "subscribed" products and medications when changes, recalls, etc. occur
- Feature for reporting adverse events/side effects

[1] (FDA, 2018)
[2] (FDA, 2018)
Impact/Benefits of ALERT

• Provides users with up to date information/warnings on FDA regulated products
• Easily accessible to consumers when making medical decisions & purchases
• Ensures the consumer has been presented with pertinent information
• Allows for comparison of similar products/medications to help consumer make a more informed decision
• Consolidate adverse event/side effect reporting