



# PrescripChain

*A modern-day app solution to post-marketing surveillance*



# OUR TEAM



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# OUTLINE

01

**FDAPriorities**

How our app is relevant

02

**Post-Marketing Surveillance**

Overview of current infrastructure

03

**The Problem**

Cons of current infrastructure and areas for innovation

04

**The Solution**

PrescripChain and its advantages

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PrescripChain vs. current smartphone apps

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**Summary**

PrescripChain highlights and take-home



01.

# FDA Priorities

# FDA PRIORITIES

## FDA Center/Office Regulatory Science Research Priority Areas for CERSI Program

“Develop methods and tools to improve and streamline clinical and postmarket evaluation of FDA-regulated products, including...

...Approaches to leveraging large, complex data to inform regulatory decision-making, including use of “real world” data sources and mobile technologies”





02.

# Post-Marketing Surveillance

# CURRENT INFRASTRUCTURE

- **MedWatch**
  - Reporting done by consumers, caregivers and health care professionals
- **FDA Adverse Event Reporting System (FAERS)**
  - Public dashboard to store and analyze safety reports

U.S. Department of Health and Human Services  
 Food and Drug Administration  
**MEDWATCH**  
 FORM FDA 3500 (2/19)  
 The FDA Safety Information and  
 Adverse Event Reporting Program

For VOLUNTARY reporting of  
 adverse events, product problems  
 and product use/medication errors

Form Approved: OMB No. 0910-0291, Expires: 11-30-2021  
 See PRA statement on reverse.

Page 1 of 2

FDA USE ONLY  
 Trace unit  
 Institution #  
 FDA Rec. Date

Notes: For date prompts of MM-mm-yyyy, please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2018.

**A. PATIENT INFORMATION**

1. Patient Identifier #1 #2

2. Age (check one)  
 Year(s)  Month(s)  
 Week(s)  Day(s)  
 or Date of Birth (e.g., 08 Feb 1925)

3. Gender (check one)  
 Male  Female  
 Transgender  
 Prefer not to disclose

4. Weight (check one)  
 lb  kg

5. Ethnicity (check one)  
 Hispanic/Latino  
 Not Hispanic/Latino

6. Race (check all that apply)  
 Asian  American Indian or Alaskan Native  
 Black or African American  White  
 Not Hispanic/Latino  Native Hawaiian or Other Pacific Islander

**B. ADVERSE EVENT, PRODUCT PROBLEM**

1. Type of Report (check all that apply)  
 Adverse Event  Product Problem (e.g., defect/malfunction)  
 Product Use Error  Problem with Different Manufacturer of Same Medicine  
 Medication Error

2. Outcome Attributed to Adverse Event (check all that apply)  
 Death Date of death (MM-mm-yyyy)  
 Life-threatening  Disability or Permanent Damage  
 Hospitalization (initial or prolonged)  Congenital Anomaly/Birth Defects  
 Other Serious or Important Medical Events  
 Required Intervention to Prevent Permanent Impairment/Damage

3. Date of Event (MM-mm-yyyy) 4. Date of this Report (MM-mm-yyyy)

5. Describe Event, Problem or Product Use/Medication Error  
 (Continue on page 2)

6. Relevant Tests/Laboratory Data Date (MM-mm-yyyy)  
 (Continue on page 2)

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)  
 (Continue on page 2)

**C. PRODUCT AVAILABILITY**

1. Product Available for Evaluation? (Do not send product to FDA)  
 Yes  No  Returned to Manufacturer on (MM-mm-yyyy)

2. Do you have a picture of the product? (check yes if you are including a picture)  Yes  No

**D. SUSPECT PRODUCTS**

1. Name, Strength, Manufacturer/Compounder (from product label) #1 #2 Yes  
 Does this report involve cosmetic, dietary supplement or food/drug/medical feed? #2 #3 Yes

#1 - Name and Strength #1 - Lot # #1 - NDC # or Unique ID

#2 - Manufacturer/Compounder #2 - Lot # #2 - NDC # or Unique ID

#3 - Name and Strength #3 - Lot # #3 - NDC # or Unique ID

#4 - Manufacturer/Compounder #4 - Lot # #4 - NDC # or Unique ID

**E. SUSPECT MEDICAL DEVICE**

1. Brand Name

2a. Common Device Name 2b. Pcode

3. Manufacturer Name, City and State

4. Model # Lot # 5. Operator of Device  
 Health Professional  
 Patient/Consumer  
 Other

Catalog # Expiration Date (MM-mm-yyyy)

Serial # Unique Identifier (UDI) #

6a. If Implanted, Give Date (MM-mm-yyyy) 6b. If Explanted, Give Date (MM-mm-yyyy)

7a. Is this a single-use device that was reprocessed and reused on a patient?  Yes  No  
 7b. If Yes to Item 7a, Enter Name and Address of Reprocessor

8. Was this device serviced by a third party service?  Yes  No  Unknown

**F. OTHER (CONCOMITANT) MEDICAL PRODUCTS**

1. Product names and therapy dates (Exclude treatment of event)  
 (Continue on page 2)

**G. REPORTER (See confidentiality section on back)**

1. Name and Address  
 Last Name: First Name  
 Address: State/Province/Region  
 City: State/Province/Region  
 ZIP/Postal Code: Country  
 Phone #: Email:

2. Health Professional?  Yes  No 3. Occupation

4. Also Reported to:  
 Manufacturer/Compounder  
 User Facility  
 Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box

FORM FDA 3500 (2/19) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.  
 \* Please see instructions.

# OTHER POST-MARKETING SURVEILLANCE PROGRAMS

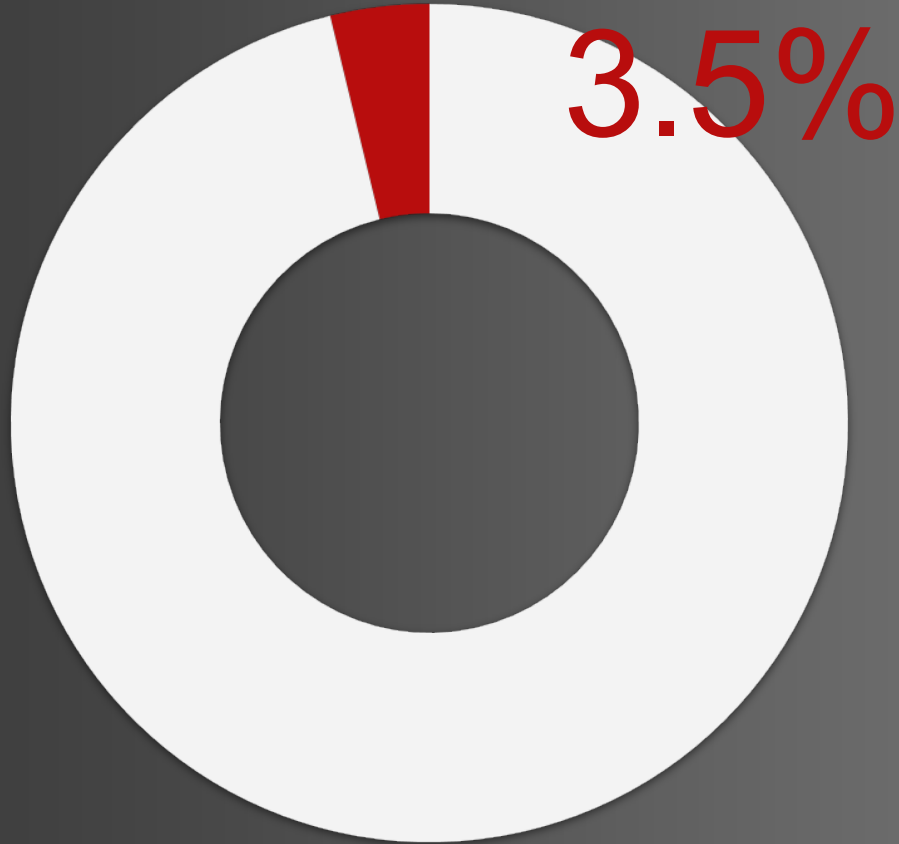
- **FDA Safety Reporting Portal (SRP)**
  - Tobacco
  - Vapes
  - Hookah
  - Chewing tobacco
- **Vaccine Adverse Event Reporting System (VAERS)**
  - Vaccines only





2,222,711

number of adverse events reported in  
2020\*



Portion of adverse  
events reported  
voluntarily through  
**MedWatch**  
2020\*



03.

# The Problem



Heartbeat: Only 1 out of 1000 (HealthCentral data) consumers said they would even use MedWatch (too complicated and time intensive) #FDASM



Replying to @domkchan and @accpinfdprn

And, MedWatch data entry form is still unnecessarily cumbersome. People wonder why ADE reporting is so low.

11:48 AM · Jun 19, 2020 · Twitter Web App



Zuckerman: Medwatch form "dehumanizing" and hard to understand. Should be explanation on why to fill it out. #FDAsm



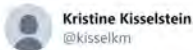
Replying to @edrneelesh

@edrneelesh @pharmaguy @mjseres MedWatch Plus takes 40m to complete, too long. At PLM we prefill the data we have to cut time by half.

4:50 AM · Oct 12, 2013 · Twitter for iPhone



In US, MedWatch not well publicized, very difficult and burdensome for consumers 2 understand and complete reports. Needs overhaul. #hcsmeu



I just can't bring myself to care about medwatch at this hour on a Sunday..... 🙄👉👈

10:49 PM · Aug 11, 2013 · Twitter for iPhone

1 Like



Medmarx and medwatch is confusing

5:45 PM · Mar 11, 2013 · Twitter for iPhone



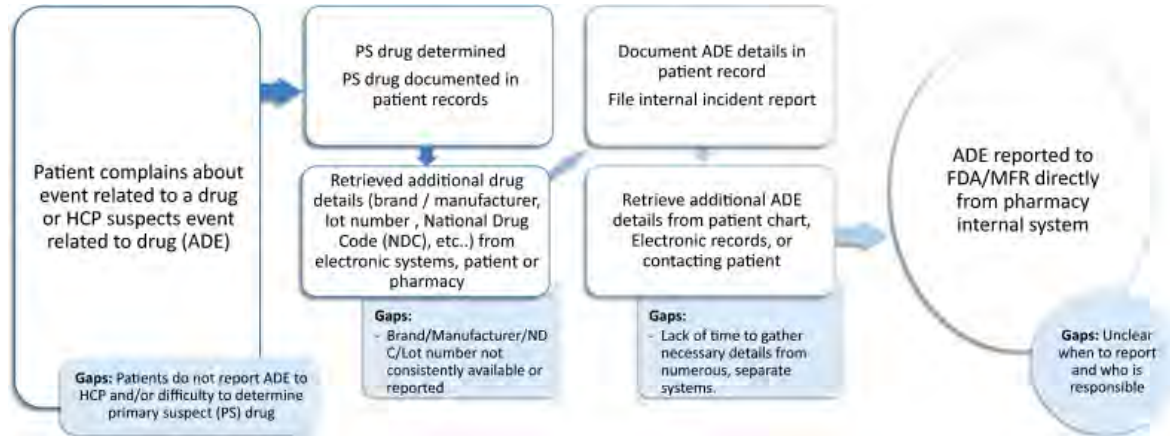
Heartbeat: 3. Make it radically easier for consumers to file AE (MedWatch too complex...see earlier tweet on this) #FDASM



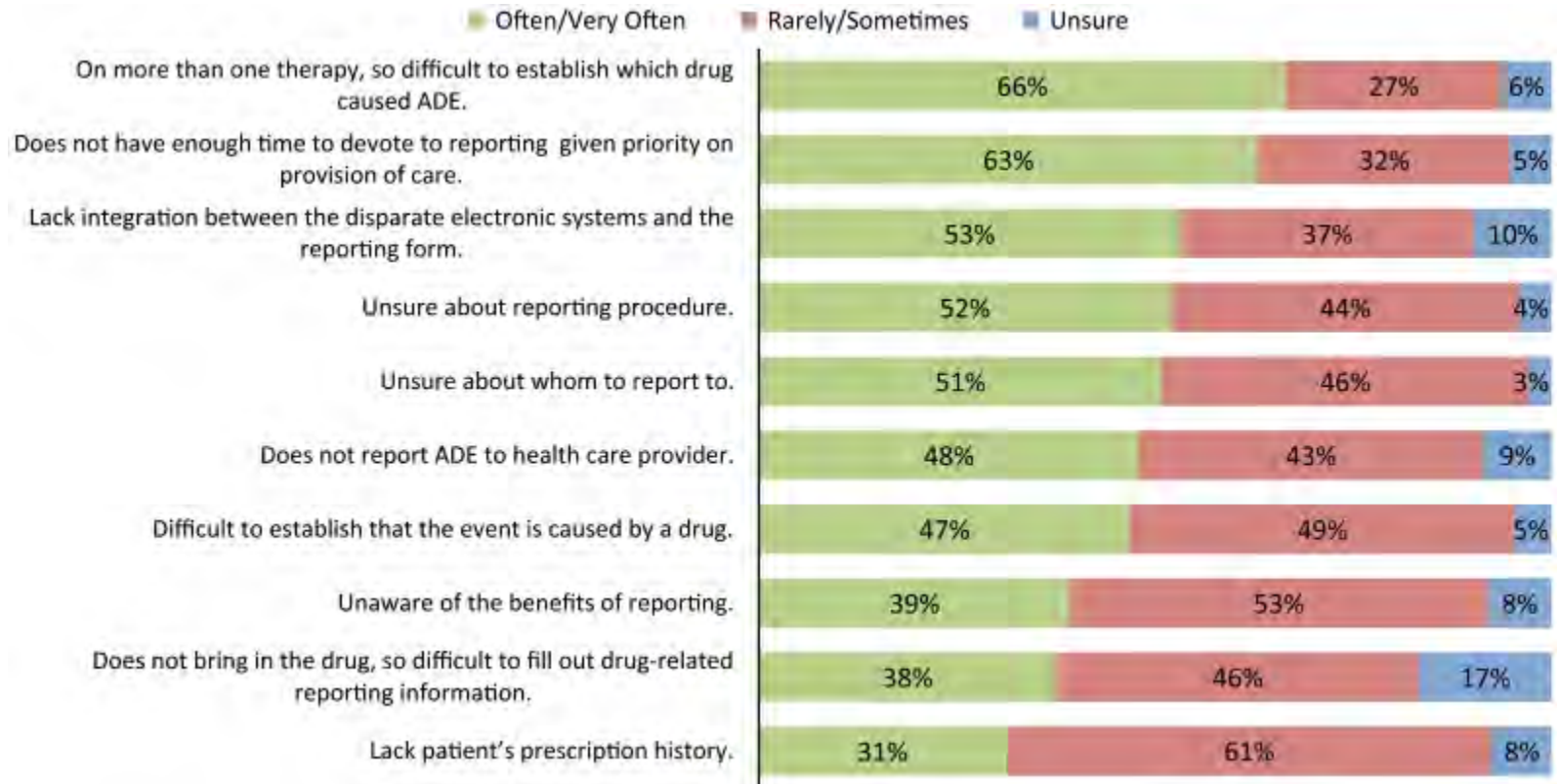
#fdasm #ConsumersUnion says MedWatch home page good; form to fill out tough for many consumers

8:33 AM · Nov 13, 2009 · Twitter Web Client

# UNDERREPORTING



# UNDERREPORTING



# CONS OF FAERS

- **Awareness**
- **Dashboard functionality**
- **Interpretation of information**
- **Patient safety**
- **Delay in accessible information**

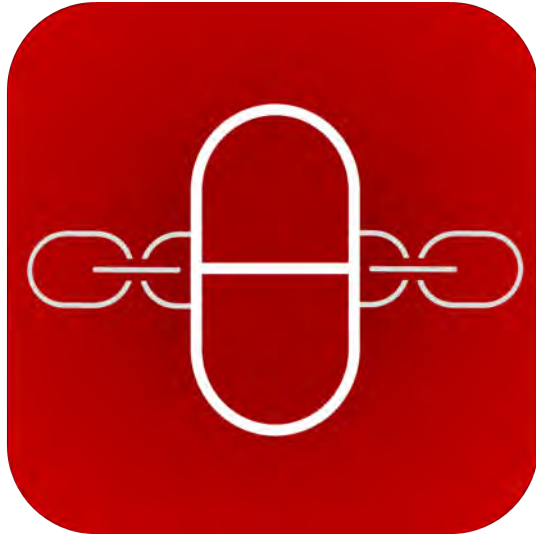




04.

The Solution





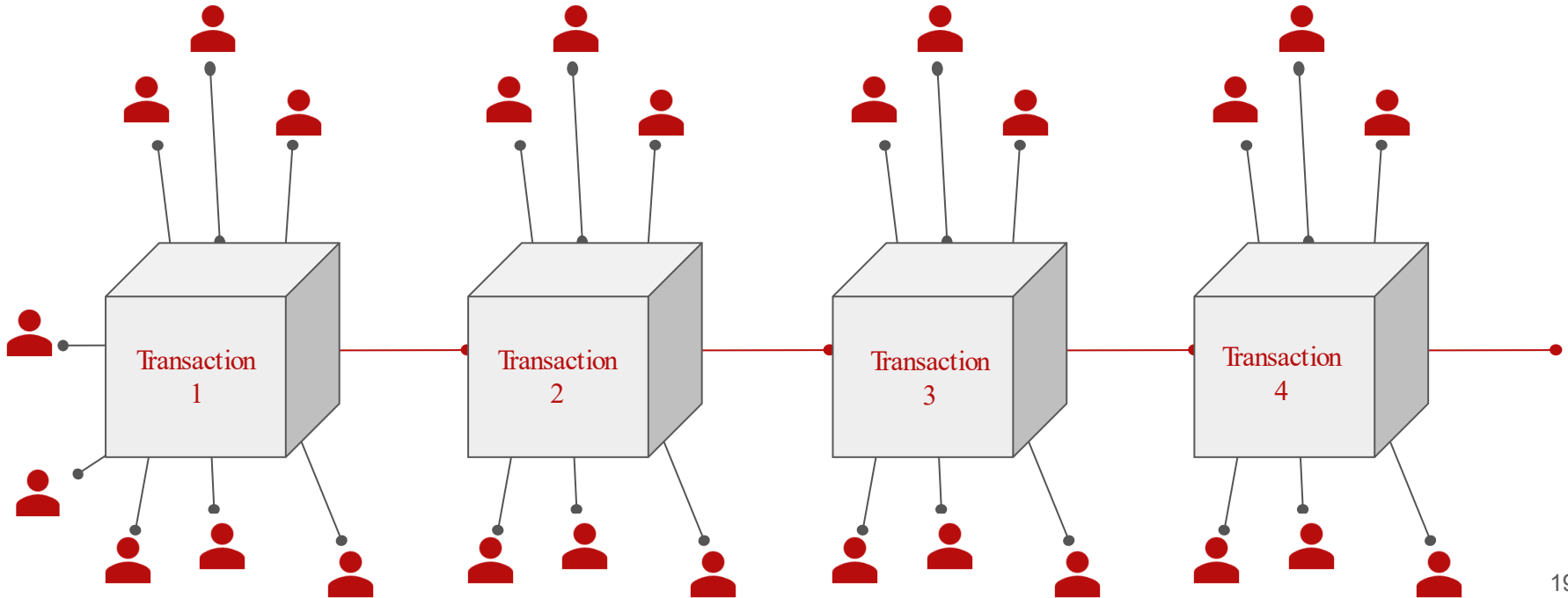
**PrescripChain**

A user-friendly app  
for **adverse event  
reporting** that  
utilizes **blockchain**  
technology to  
provide automatic,  
**bench-to-bedside**  
tracing of the  
**entirety of a  
pharmaceutical's  
lifespan**



# WHAT IS BLOCKCHAIN?

1. Information organized into successive “blocks”
2. Each “block” is added to a chain
3. Creates a decentralized public ledger of transactions



# BLOCKCHAIN USAGE



**CRYPTOCURRENCY**

Bitcoin



**BANKING**

VISA B2B



**ENERGY**

Shell



Unilever



**SUPPLY CHAIN**

De Beers Diamonds

Unilever

WALMART

Ford



**SMART CONTRACTING**

Spotify



**EHR**

CDC



**SHIPPING**

DHL

# WHY BLOCKCHAIN?

## Advantages for Post Marketing Surveillance

**SECURE**

Decentralized technology and complex hashing incredibly difficult to hack

**IMMUTABLE**

Universal ledger resistant to alterations

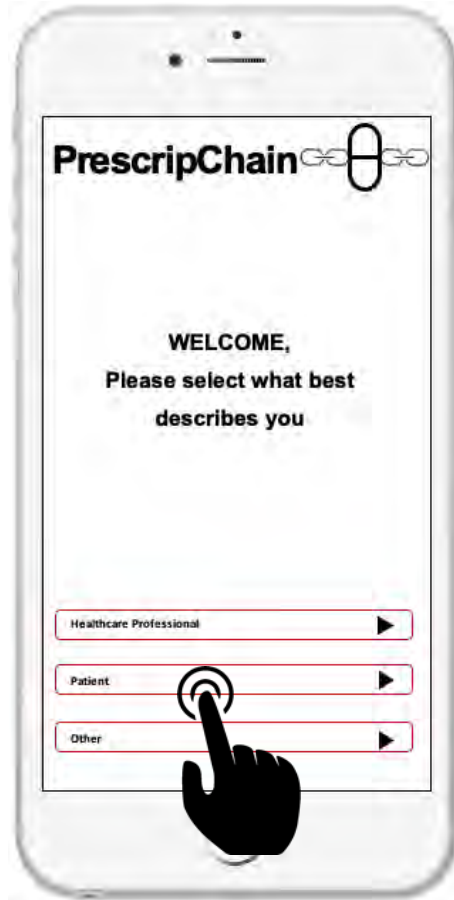
**TRANSPARENT**

Every transaction visible to users

**REAL-TIME**

Negligible delay in report updates

Initial account  
registration for  
**patients, healthcare  
providers, and  
industry  
professionals**



# USE CASES



A **healthcare provider** uses **PrescripChain** to report excessive bleeding after administration of Remdisivir to a COVID-19 patient.



A **seizure patient** uses **PrescripChain** to report anaphylaxis reaction to gabapentin.



# USE CASES



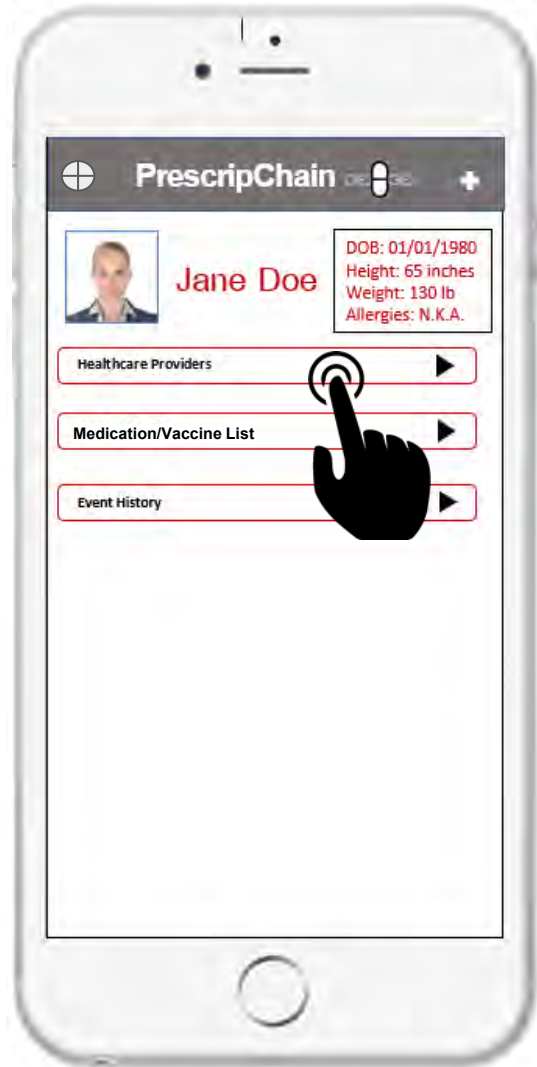
An **essential worker** uses **PrescripChain** to report an allergic reaction to the Pfizer BioNTech vaccine.



A **FDA official** uses **PrescripChain** to analyze a number of allergic reactions to a biosimilar drug and trace it to specific lot number and API.









Jane Doe

DOB: 01/01/1980  
Height: 65 inches  
Weight: 130 lb  
Allergies: N.K.A.

Healthcare Providers



Name: Mr. Primary  
Role: Primary Care Physician  
Location: Kaiser Permanente 1234 KP Road  
Contact: 123-456-7890 email@KP.com



Name: Ms. Skin  
Role: Dermatologist  
Location: Eczema Center 1234 EC Court  
Contact: 123-456-7890 email@EC.com



Name: Mr. Medicine  
Role: Pharmacist  
Location: CVS pharmacy 1234 Pharmacy Lane  
Contact: 123-456-7890 email@CVS.com

Medication/Vaccine List

Event History



Jane Doe

DOB: 01/01/1980  
Height: 65 inches  
Weight: 130 lb  
Allergies: N.K.A.

Healthcare Providers

Medication/Vaccine List



Drug: Atorvastatin Calcium, 40mg  
Start Date: 01/01/2021  
Prescriber: Mr. Primary  
Manufacturer: Teva (Lot# AC1234567)  
Tap for information of past dispensed Atorvastatin Calcium



Drug: Lisinopril, 20mg  
Start Date: 02/01/2021  
Prescriber: Mr. Primary  
Manufacturer: Lupin (Lot# LIS1234567)  
Tap for information of past dispensed Lisinopril



Drug: Pimecrolimus Cream, 1%  
Start Date: 02/01/2015  
Prescriber: Ms. Skin  
Manufacturer: Teva (Lot# PC1234567)  
Tap for information of past dispensed Pimecrolimus

Event History



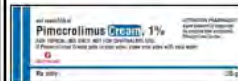
Jane Doe

DOB: 01/01/1980  
Height: 65 inches  
Weight: 130 lb  
Allergies: N.K.A.

Healthcare Providers

Medication/Vaccine List

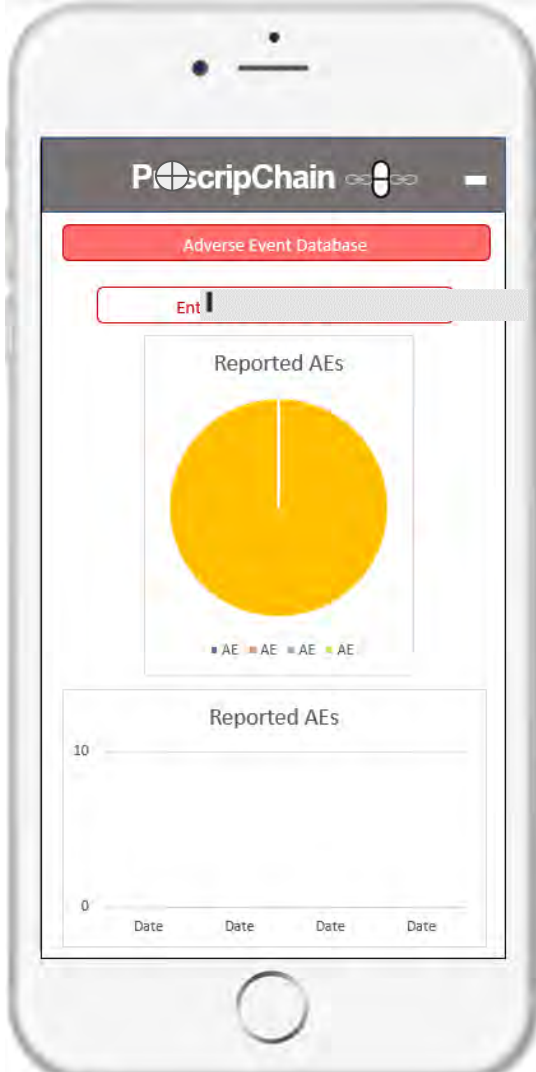
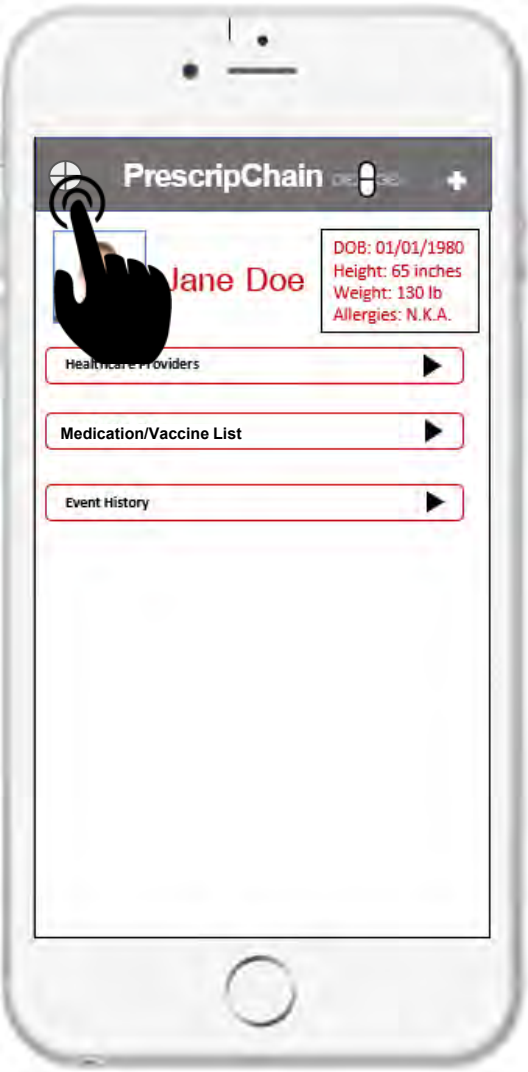
Event History

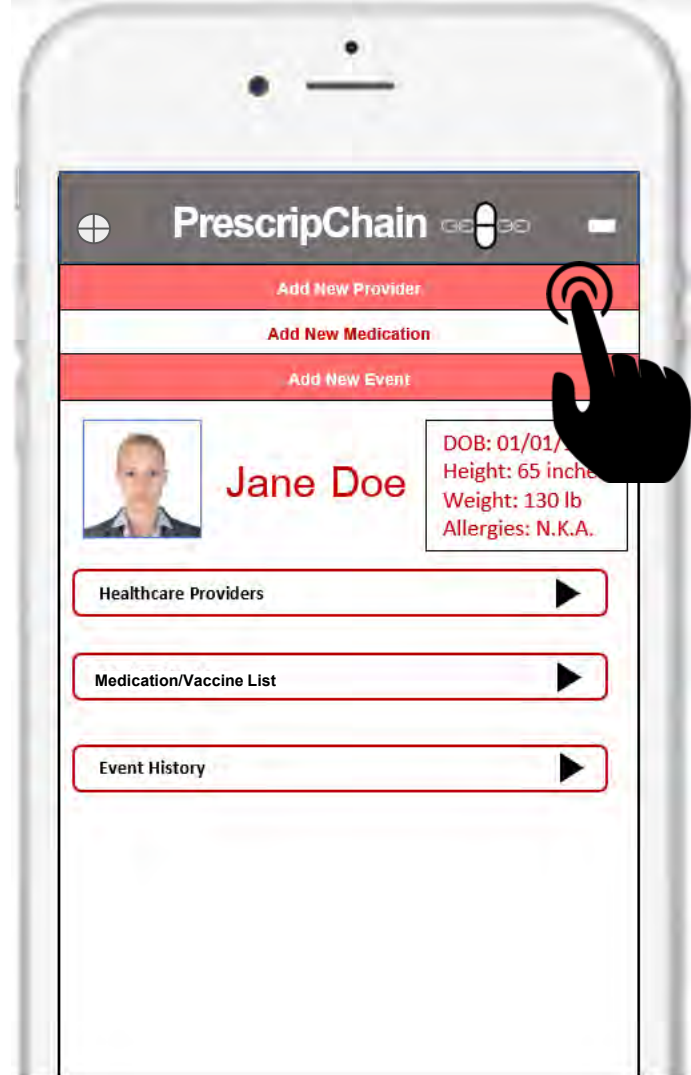
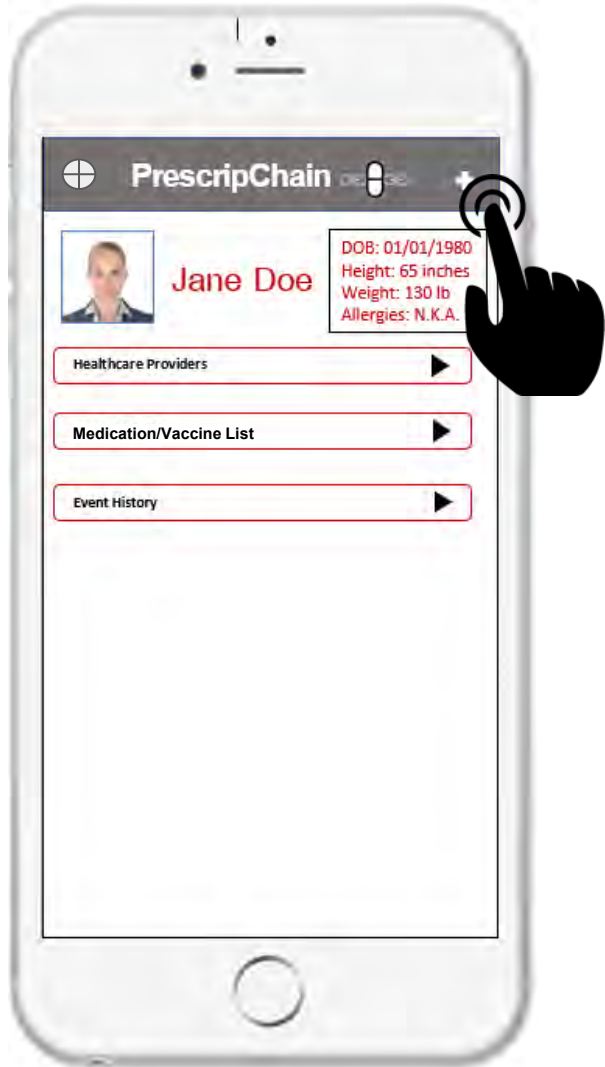


Drug: Pimecrolimus Cream, 1%  
Start Date: 01/01/2015  
Prescriber: Ms. Skin  
Manufacturer: Glenmark (Lot#PC1234567)  
Event: AE reported (Intense Burning)

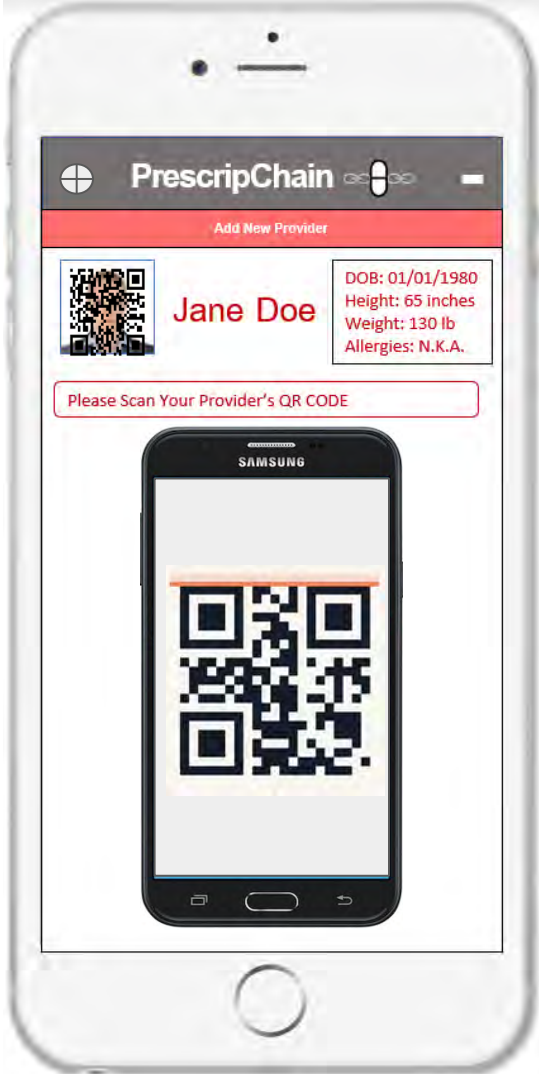


Drug: Lisinopril, 20mg  
Start Date: 01/01/2015  
Prescriber: Ms. Primary  
Manufacturer: Watson (Lot# PC1234567)  
Event: Drug Recall











05.

# Competing Apps

# INTERNATIONAL APPS



**V-Safe**

**Med Safety**

**HALMED**

**Yellow Card-MHRA**

**UAE-RADR**

# COMPARISON



	V-safe	Med Safety	HALMED	Yellow Card	PrescripChain
Blockchain technology	✗	✗	✗	✗	✓
Tracing from manufacturer to consumer	✗	✗	✗	✗	✓
Quick and easy adverse event reporting	✓	✓	✓	✓	✓
View number of reports received	✗	✓	✓	✓	✓



06.



Summary

# SUMMARY

USER-FRIENDLY

REAL-TIME  
SURVEILLANCE

TRANSPARENT

BLOCKCHAIN



# Acknowledgements

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- **Wendy Klein-Schwartz**, PharmD
- **James Polli**, PhD
- **Gillian Woollett**, DPhil

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