Collection of Patient-Provided Information through a Mobile Device Application for Use in Medical Product Safety Surveillance

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Background

The Food and Drug Administration (FDA) Sentinel project is a multi-institutional distributed network that conducts medical product safety surveillance studies using a distributed database of 193 million individuals with 351 million person-years of data.[1] It is made up of claims and some EHR data formatted into the Sentinel Common Data Model (SCDM).[2]

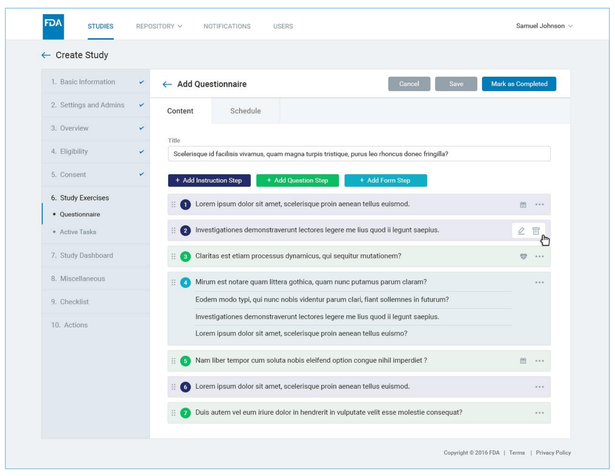
Problem

Some healthcare outcomes, exposures, and confounder information necessary for comparative safety and effectiveness research is not readily available in health care claims or EHR data. This limitation contributes to potential biases and limits the ability of the FDA to conduct some assessments.

Solution

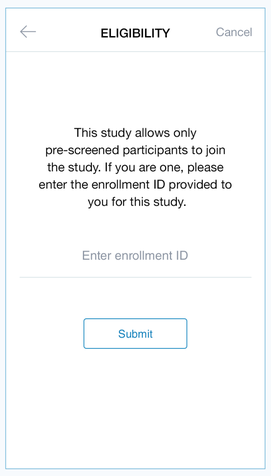
Create a customizable mobile device application based on existing mobile research frameworks to collect patient data in real time and augment the Sentinel Common Data Model for individual assessments as needed. Develop and utilize a web-based tool for creation and distribution of questionnaires via the mobile application.[3]

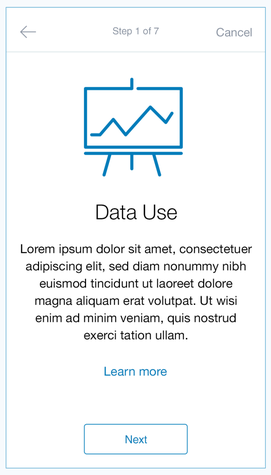
Create



- Configure questions, active tasks, frequency and recurrence, informed consent, and eligibility criteria
- Create patient enrollment tokens and map them to patient IDs in local data sources (the SCDM)

Enroll

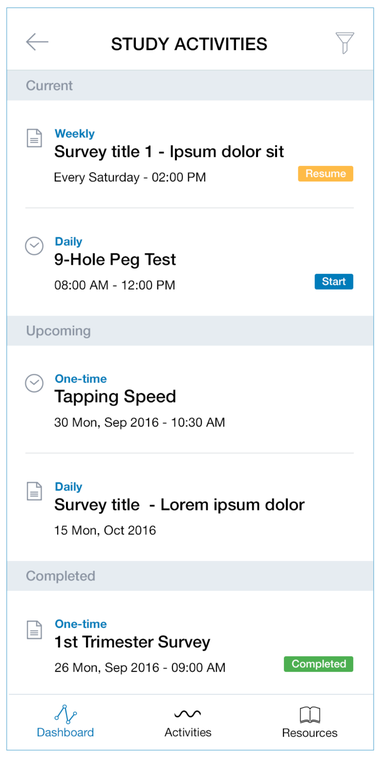




- Pre-select a cohort and distribute patient enrollment tokens
- Participants download the app in iOS or Android app stores
- Participants complete eligibility and informed consent processes

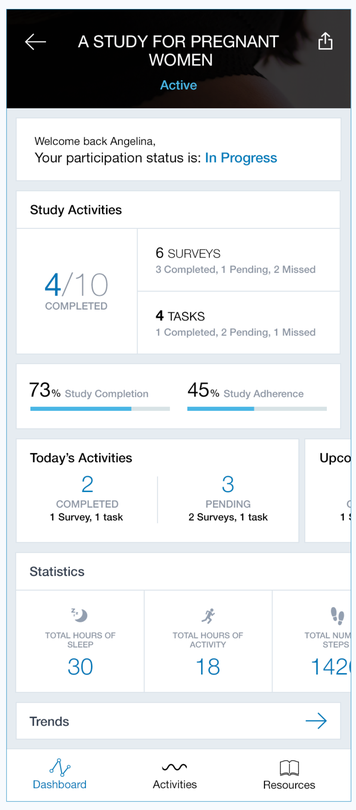
Collect

- Distribute surveys and active tasks to the app
- Participants respond to questions and active tasks on a pre-defined schedule
- Remind participants to engage via configurable in-app reminders



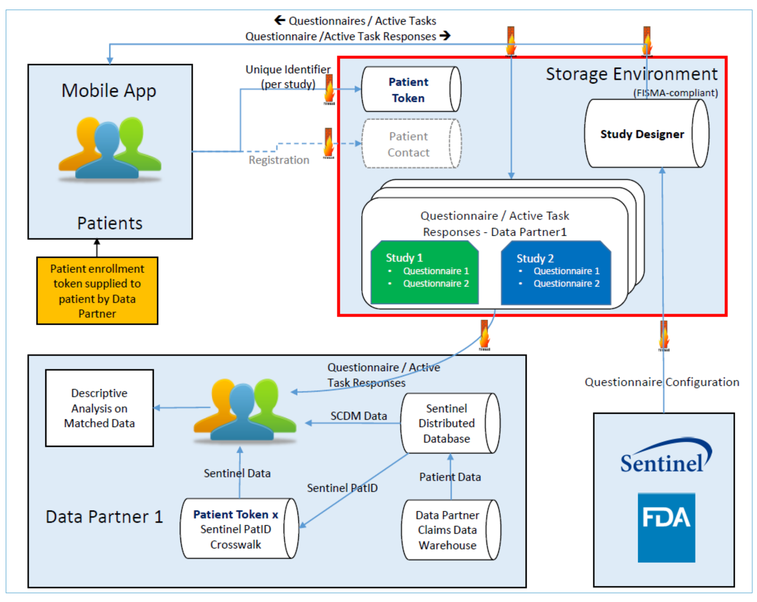
Engage

- Publish study specific resources
- Send notifications for new resources and study tasks
- Participants visualize their own data on the study dashboard



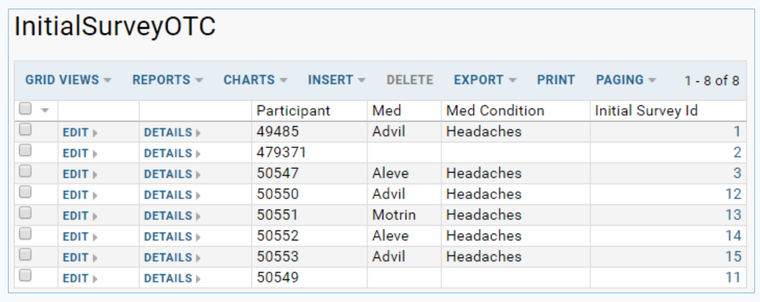
Store

- Securely store participant response data in a FISMA compliant data center
- Partition responses by administrator-defined organizations



Analyze

- Download responses in Excel, SAS and other common formats
- Match study participants' response data to data in the SCDM for descriptive analysis using the patient enrollment token mapping
- Visualize responses in a variety of chart types



InitialSurveyOTC

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		Participant	Med	Med Condition	Initial Survey Id
EDIT	DETAILS	49485	Advil	Headaches	1
EDIT	DETAILS	479371			2
EDIT	DETAILS	50547	Aleve	Headaches	3
EDIT	DETAILS	50550	Advil	Headaches	12
EDIT	DETAILS	50551	Motrin	Headaches	13
EDIT	DETAILS	50552	Aleve	Headaches	14
EDIT	DETAILS	50553	Advil	Headaches	15
EDIT	DETAILS	50549			11

Results

- The initial use case is an analysis of health outcomes related to medication use, drug use, and other behavioral/social factors among pregnant women
- Data collection will begin in July 2017 on a cohort of approximately 50 pregnant and recently pregnant women

Future Use Cases

- Complement assessments conducted by PCORnet or Sentinel with patient provided data
- Facilitate data collection for disease or treatment registries and pragmatic clinical trials

Scan to download the app prototype

Sources

1. Behrman RE, Benner JS, **Brown JS**, McClellan M, Woodcock J, Platt R. Developing the Sentinel System - A national resource for evidence development. N Engl J Med 2011; 364:498-499.
2. Curtis LH, Weiner MG, Boudreau DM, Cooper WO, Daniel GW, Nair VP, Raebel MA, Beaulieu NU, Rosofsky R, Woodworth TS and **Brown JS.** Design considerations, architecture, and use of the Mini-Sentinel distributed data system. Pharmacoepidemiol Drug Saf. 2012;21(S1): 23–31.
3. ResearchStack to Extend ResearchKit(™) Studies to Android [Internet]. Cornell Tech. 2016 [cited 1 May 2016]. Available from: http://tech.cornell.edu/news/researchstack-to-extend-researchkit-studies-to-android