

ELSI ISSUES IN mHEALTH

STORIES FROM THE FRONT LINES

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What was LifeMap Solutions?

Founded in

2014

Office Locations



SILICON
VALLEY

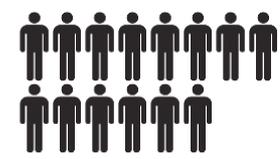


NEW
YORK
CITY

Subsidiary of



15

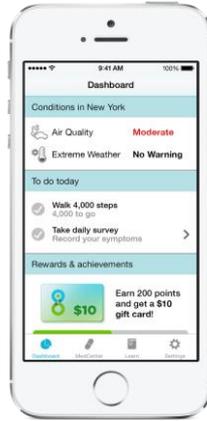


Employees

LifeMap Products

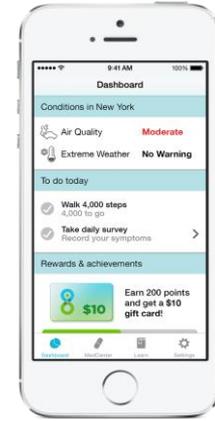
COPD Navigator

- Clinical care
- Disease Journal
- Patient app
- Doctor dashboards



Mount Sinai NY

- Hospital access



DTC Carrier Screening

- Acquired by Sema4
- Released on Helix



ResearchKit Apps

- Studies on iPhone
- Focus today



Asthma Health by Mount Sinai

MyHeart Counts

ResearchKit is a Framework for Research Studies

ResearchKit is an **iOS software development kit (SDK)** that includes

- Informed Consent (required)
- Tasks
- Charts
- Passcode/TouchID app security
- ...and more

ResearchKit is only part of the story

- Need study protocol approved by IRB
- Need to build most of app (AppCore or Sample)
- Need backend to store data (ie. Sage Bridge)
- Need to share data with other researchers (ie. Sage Synapse)

Apps that use ResearchKit are special

- Able to use ResearchKit logo
- Promoted in ResearchKit section of Medical Apps



ResearchKit launched with 5 studies



- Ambitious skunk works project
- Collaboration between Apple, outside developer team and scientific partners
- Released March 9th, ready or not, to coincide with Apple Watch



Asthma Health by Mount Sinai



GlucoSuccess



Parkinson mPower study app



MyHeart Counts



Share the Journey

Big launch, but continued engagement is an issue

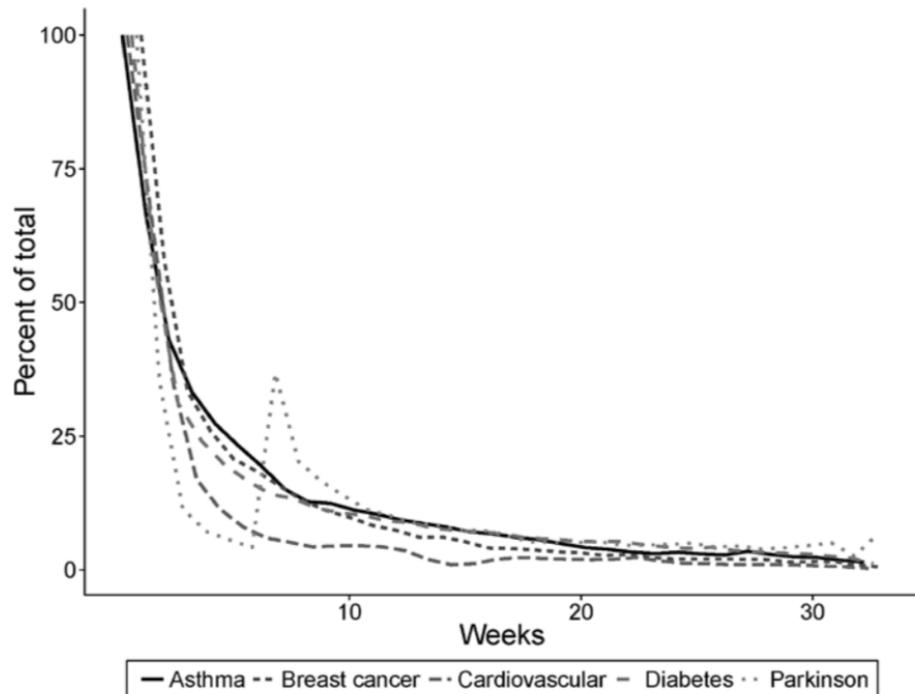
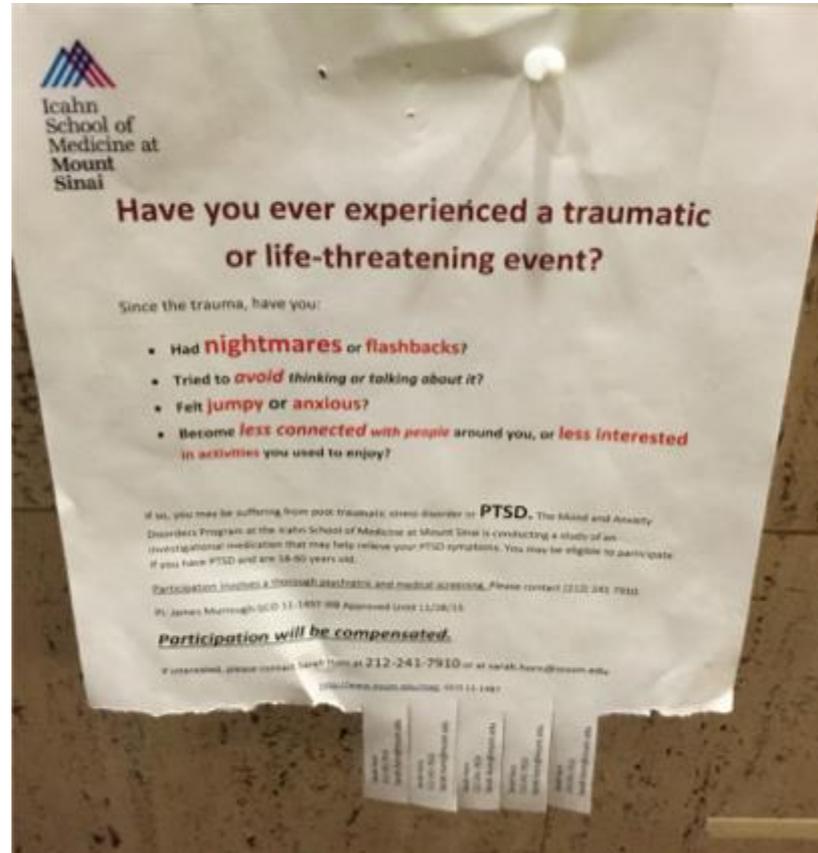


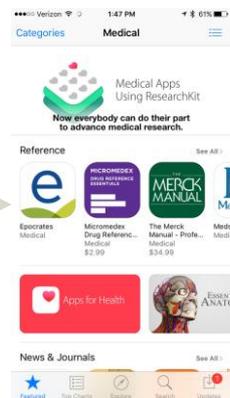
Figure 1 Proportion of daily users in the first five smartphone research apps developed using ResearchKit, March 9 to October 5, 2015.

Goodbye fliers

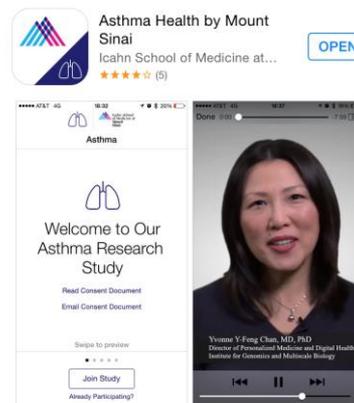
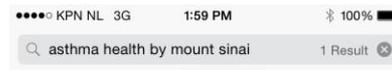


Onboarding: find RK studies through the App Store

ResearchKit
Section of
Medical
Apps



Search



Onboarding: Eligibility Criteria

●●○○ KPN NL 3G 1:43 PM 100%

< Eligibility Next

Are you 18 or older?

Yes | No

Do you have asthma as confirmed by a doctor?

Yes | No

Are you currently taking any medicines (including inhalers, aerosols or tablets) for asthma?

Yes | No

●●○○ KPN NL 3G 1:43 PM 100%

< Eligibility Next

(including inhalers, aerosols or tablets) for asthma?

Yes | No

Do you live in the United States of America?

Yes | No

Are you pregnant?

Yes | No | N/A

●●○○ KPN NL 3G 1:43 PM 100%

< Eligibility



You are eligible to join the study.

Tap the button below to begin the consent process

Start Consent

Consent: How do you fit 13 pages into an app?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others. People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care at Mount Sinai.

We have provided the contact information for the study's principal investigator above. If you have questions, please ask them. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

Basic information about this study will appear on the website <http://www.ClinicalTrials.gov>. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls "applicable clinical trials" a description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The purpose of this study is to understand whether using an asthma mobile health application Version 2.0 (AMHA2.0 or "asthma app") that you download onto your iPhone will help you to monitor your asthma. Although "apps" have been made to help people monitor certain health problems, medical researchers still do not know if they really work well or if they really can help improve your health. This research study will be different in that unlike typical research studies, you will not need to come to a hospital clinic or a study center. Part of this research is to see if we can study the use of the "asthma app" completely by phone without visits to a study center or clinic and to study how well the "asthma app" features work. Since you will be using the app for up to 6 months, we cannot be certain that the app will help you with your asthma. We will use information about how you use the app to make the app better and see if the "asthma app" helps you with your asthma. If you join this study you will still be able to join future studies if you choose.

Funds for conducting this research are provided by the Icahn School of Medicine at Mount Sinai, with technology support from Apple, Sage Bionetworks, and LifeMap Solutions.

Your participation in this research study is expected to last for six months.

The number of people expected to take part in this research study is difficult to predict but may be hundreds to tens of thousands of people

This consent form tells you about the study to help you make your choice on whether or not to take part. Please take the time to read this carefully before making your choice. If you have any questions or anything is unclear please contact the study team. If you choose to participate in this study you will be asked to give permission by using your phone to sign the consent form electronically. You should not give consent or start any part of the study until your questions are answered and you are ready and able to begin. If you participate in this research study, you should also tell any health care providers who treat you that you are in the study.

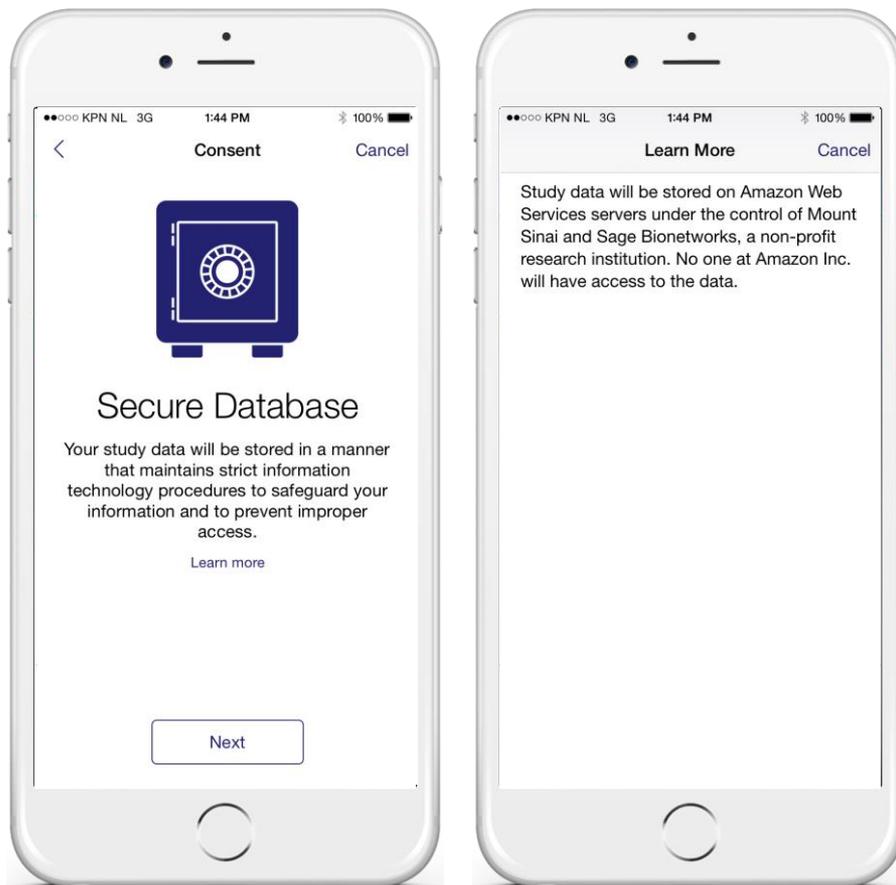
Asthma is a very common condition, and patients with asthma do best if they monitor or take care of their asthma. Some things patients can do to take care of their asthma are to use regular medication as prescribed by their doctor, keep track of their own symptoms, and stay away from certain situations that may make their asthma symptoms worse (we sometimes call these asthma triggers). The "asthma app" is designed to help you do all of these things right on your mobile phone. The "asthma app" will help you learn more about your asthma, take your asthma medicine as prescribed, and learn what triggers your asthma. The "asthma app" does not replace your usual medical care. Our goal is that you will be able to use the "asthma app" to learn more about asthma. This consent will give you more details below about what types of things you will be asked to do in this study. The information about your asthma that you give us through this "asthma app" will be joined together with information from other study participants so researchers can learn more about asthma and how an app can help monitor asthma. This information will be separated from your name and other ways to identify you or know it is you.

You may qualify to take part in this research study because you are 18 years of age or older, have asthma, own an iPhone, and are not currently pregnant.

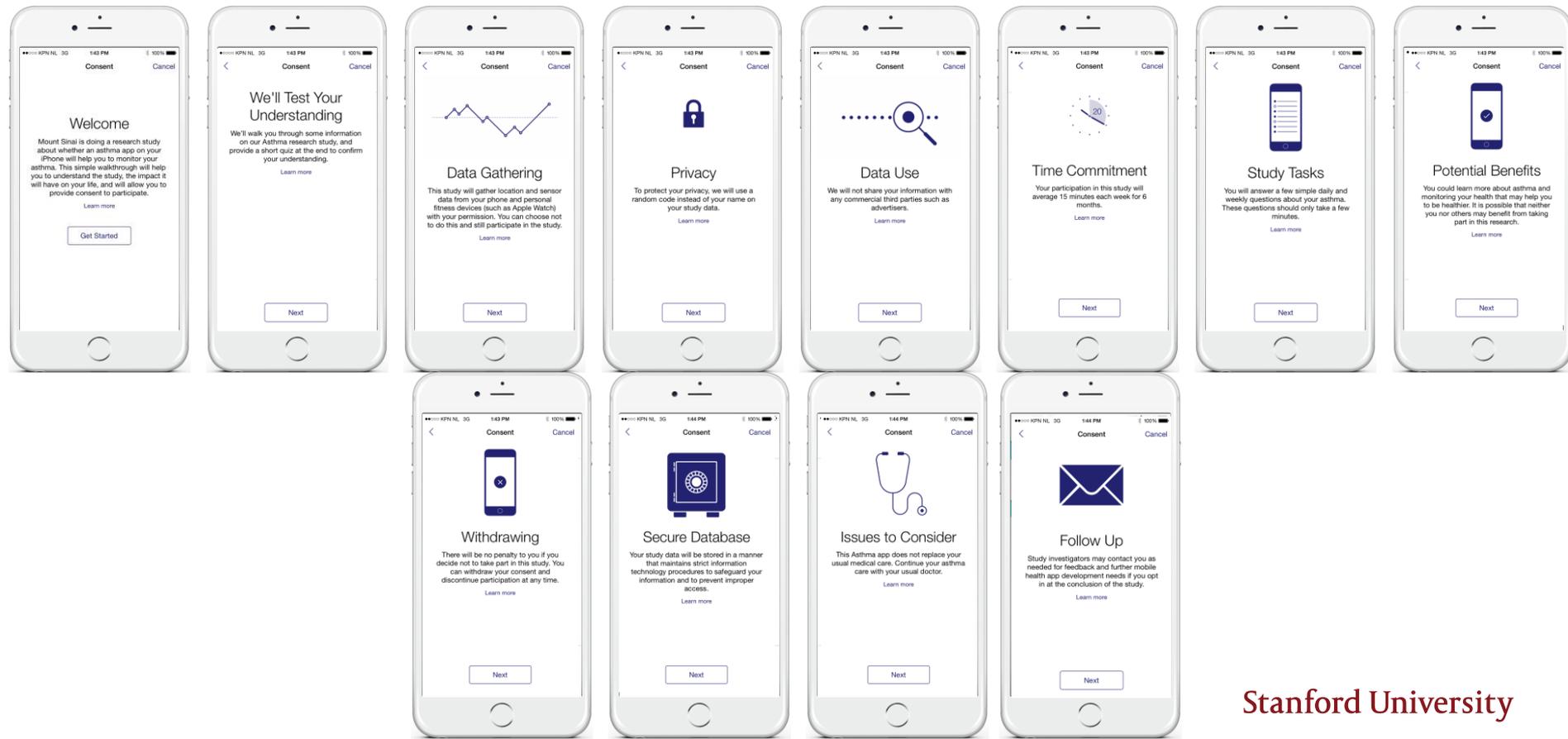
If you agree to participate in this research study, this is what you will be asked to do:

- Download a mobile app (free). You need to have the AMHA2.0 app on your iPhone in order to participate in this study
- View a brief optional video that describes the purpose of the study and introduces the study team
- Complete a screening questionnaire on the iPhone.
- **Register an account:** Once you give your consent, you and everyone else who enrolls will complete an electronic registration process through the AMHA2.0 app. Registration will include entering your email address and other general information about yourself.
- **Health Surveys:** We will ask you to answer questions about yourself, your asthma, what types of things trigger your asthma symptoms (that is, make them worse), what asthma medicines you take, other medical problems you may have, and your current health. You may choose to leave most questions you do not wish to answer blank. Of course, the more information you can give us, the more we may learn about how the app works. For certain features of the app to work, you will need to enter what asthma medicine you are taking so that the app can send you reminders about your medicine and keep track of any changes in your medicine. Those functions will not work unless you put in that information. When you fill out a daily, weekly, or monthly survey, you will have to fill out most of the questions in order to complete the survey. Other than that, you may choose to not answer any question that makes you uncomfortable.

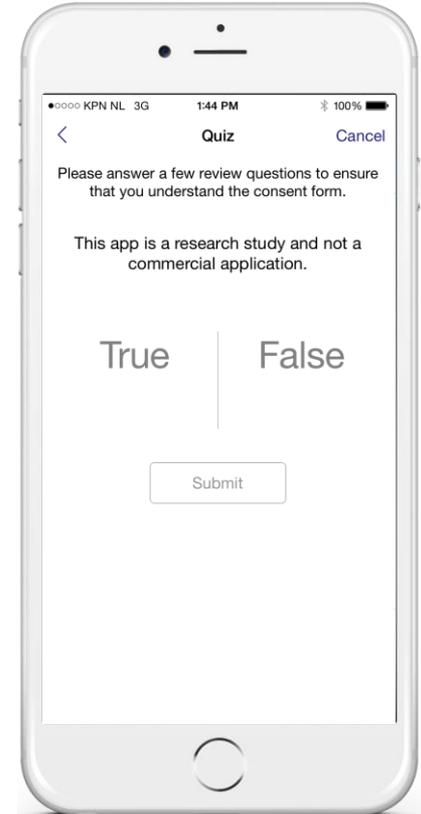
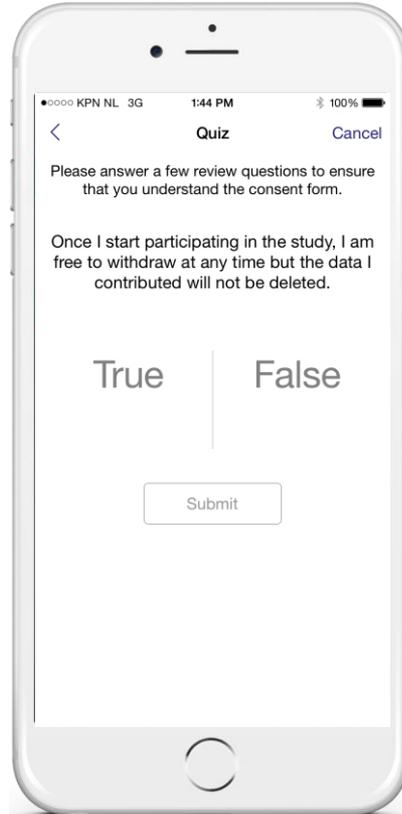
Onboarding: Consent Vignettes with “learn more” link



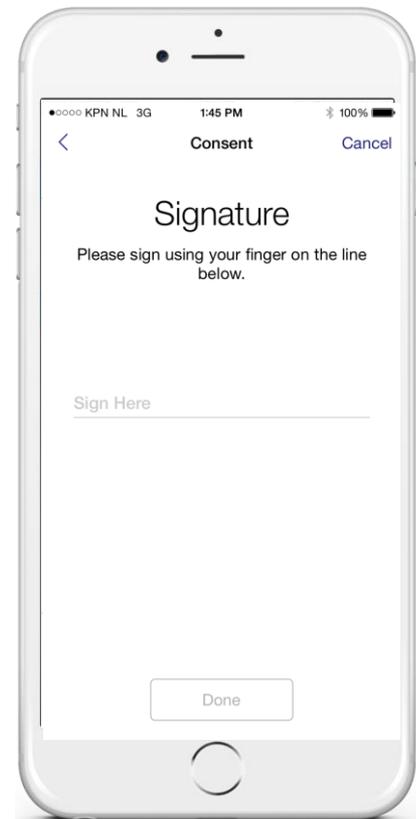
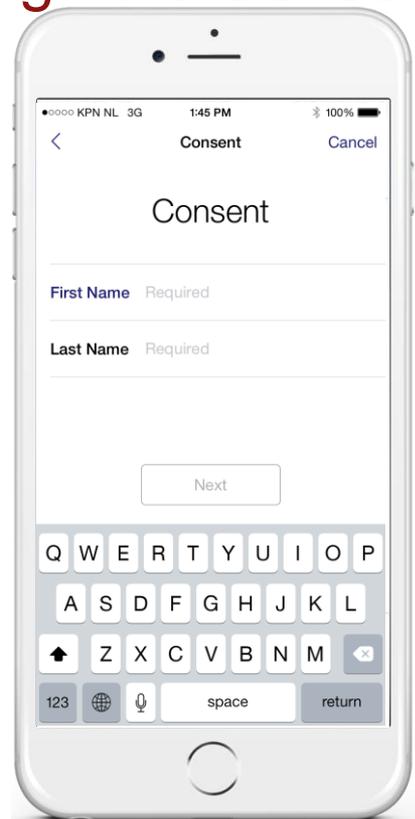
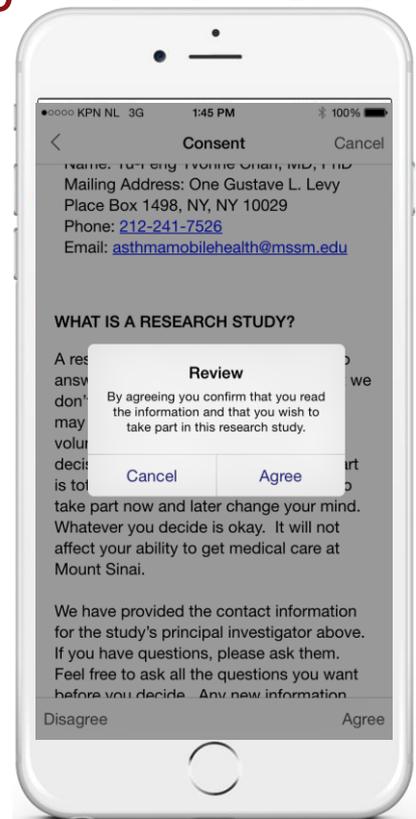
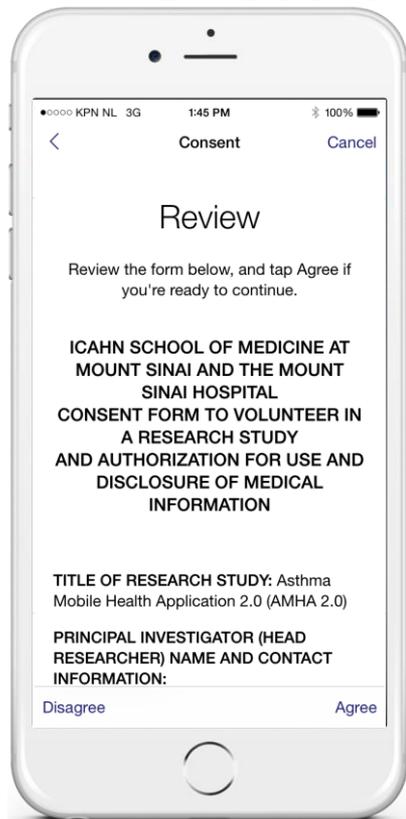
Onboarding: Consent Vignettes



Onboarding: Comprehension Quiz



Onboarding: Review and Sign the Consent



Consents differ between apps

Asthma Health

- Strict eligibility criteria
- Comprehension quiz
- Signature captured for consent

MyHeart Counts

- Looser eligibility criteria
- No comprehension quiz
- No signature captured for consent

Mount Sinai Asthma Study

What is your birthday?

Are you over 18 years old? Yes No

Are you eligible to join the study? Yes No

Has this been confirmed by a doctor? Yes No

Welcome

This research study will help you understand the study, the impact it will have on your life, and what you need to provide consent to participate.

Data Gathering

This study will gather personal data from your phone and personal fitness trackers to understand the study.

Privacy

To protect your privacy, we will use a random number instead of your name on your study data.

Data Use

We will only gather your information with any consented third parties such as a researcher.

Time Commitment

This participation in this study will average 10 minutes each week for a 4 weeks.

Personal Information

We will collect your personal contacts, other applications, phone use history, text messages, calendar phone or website related.

Study Tasks

We will provide a simple data questions about your asthma and a few survey questions about your asthma. These questions should only take a few minutes.

Withdrawing

You are free to withdraw your consent and discontinue participation at any time.

Secure Database

Study data will be stored on Amazon Data Drive located under the control of Mount Sinai. No one at our institution will have access to the data.

Secure Database

Study data will be stored in a manner that maintains data integrity and confidentiality through technology procedures to safeguard your information and to prevent improper access.

Follow Up

Study investigators may contact you in order to feedback and further resolve health and developmental needs if you opt in at the conclusion of the study.

Consent

First Name:

Last Name:

GoodBuses

Are you 18 years of age or older? Yes No

Have you been diagnosed with asthma or COPD? Yes No

Do you wish to participate in this study? Yes No

Welcome

This research study will help you understand the study, the impact it will have on your life, and what you need to provide consent to participate.

Data Gathering

This study will help you keep track of how your asthma changes over time through GoodBuses. You will be able to share your data with researchers.

Privacy

Participants will choose a username or screen name to be used for the study. We will not collect your name or any other personally identifiable information.

Data Use

We will use your phone both to communicate with you and to collect your data.

Time Commitment

This study may require a few minutes each week for a 4 weeks.

Study Survey

By analyzing an identified data across all app users, researchers will be able to better understand how relationships.

Study Tasks

Complete tasks, text, activity, notifications, and other app information will be collected through the app.

Withdrawing

If you choose to start the research study, but later wish to stop, simply contact the research team through the app.

Combining Data

You will be able to visualize your data and potentially learn more about trends in your health.

Utilizing Data

You will be able to visualize your data and potentially learn more about trends in your health.

Potential Benefits

Some questions may make you uncomfortable. Simply do not respond to your health.

Risk to Privacy

Some of the data that you provide may be sensitive. We will identify your data and use secure technology to protect your information.

Issues to Consider

Some questions may make you uncomfortable. Simply do not respond to your health.

Risk and Benefits

Participating in this study may change how you feel. You may feel more tired, but, energized, or happy.

Consent

First Name:

Last Name:

My Heart Counts

Are you 18 or older? Yes No

Do you have the latest version of Android? Yes No

Welcome

This research study will help you understand the study, the impact it will have on your life, and what you need to provide consent to participate.

Data Gathering

This study will gather sensor and health data from your phone.

Privacy

Participants will choose a username or screen name to be used for the study. We will not collect your name or any other personally identifiable information.

Sensor and Health Data

This study will gather sensor and health data from your phone.

Issues to Consider

This study will take about 10-15 minutes to complete.

Study Survey

By analyzing an identified data across all app users, researchers will be able to better understand the relationships.

Study Tasks

Complete tasks, text, activity, notifications, and other app information will be collected through the app.

Withdrawing

If you choose to start the research study, but later wish to stop, simply contact the research team through the app.

Potential Benefits

Some questions may make you uncomfortable. Simply do not respond to your health.

Risk to Privacy

Some of the data that you provide may be sensitive. We will identify your data and use secure technology to protect your information.

Issues to Consider

Some questions may make you uncomfortable. Simply do not respond to your health.

Risk and Benefits

Participating in this study may change how you feel. You may feel more tired, but, energized, or happy.

Consent

First Name:

Last Name:

Share the Journey

Are you 18 or older? Yes No

Do you have the latest version of Android? Yes No

Welcome

This research study will help you understand the study, the impact it will have on your life, and what you need to provide consent to participate.

What's involved: Activities

This study will help you keep track of how your asthma changes over time through Share the Journey. You will be able to share your data with researchers.

What's involved: Sensor Data

This study will gather sensor and health data from your phone.

De-identification

Participants will choose a username or screen name to be used for the study. We will not collect your name or any other personally identifiable information.

Combining Data

We will use your phone both to communicate with you and to collect your data.

Utilizing Data

You will be able to visualize your data and potentially learn more about trends in your health.

Potential Benefits

Some questions may make you uncomfortable. Simply do not respond to your health.

Risk to Privacy

Some of the data that you provide may be sensitive. We will identify your data and use secure technology to protect your information.

Issues to Consider

Some questions may make you uncomfortable. Simply do not respond to your health.

Issues to Consider

Some questions may make you uncomfortable. Simply do not respond to your health.

Issues to Consider

Some questions may make you uncomfortable. Simply do not respond to your health.

Withdraw

If you choose to start the research study, but later wish to stop, simply contact the research team through the app.

Consent

You consent to participate in this study by entering your name, age, and "Starting Today".

Full Name First and Last Name Age Consent

LifeSpan

Are you 18 or older? Yes No

Do you have the latest version of Android? Yes No

Welcome

This research study will help you understand the study, the impact it will have on your life, and what you need to provide consent to participate.

What's involved: Activities

This study will help you keep track of how your asthma changes over time through LifeSpan. You will be able to share your data with researchers.

Sensor Data

This study will gather sensor and health data from your phone.

De-identification

Participants will choose a username or screen name to be used for the study. We will not collect your name or any other personally identifiable information.

Combining Data

We will use your phone both to communicate with you and to collect your data.

Using the Data

You will be able to visualize your data and potentially learn more about trends in your health.

Potential Benefits

Some questions may make you uncomfortable. Simply do not respond to your health.

Risk to Privacy

Some of the data that you provide may be sensitive. We will identify your data and use secure technology to protect your information.

Issues to Consider

Some questions may make you uncomfortable. Simply do not respond to your health.

Issues to Consider

Some questions may make you uncomfortable. Simply do not respond to your health.

Issues to Consider

Some questions may make you uncomfortable. Simply do not respond to your health.

Exiting the Study

If you choose to start the research study, but later wish to stop, simply contact the research team through the app.

Consents differ between apps

Asthma Health

- Strict eligibility criteria
- Comprehension quiz
- Signature captured for consent

MyHeart Counts

- Looser eligibility criteria
- No comprehension quiz
- No signature captured for consent

Consent concerns

- Should there be standards around consent to prevent these differences?
- Are people comprehending anything?
- What is the best way to present consent? Short text, video, etc.

App Lifecycle – plan for these events!

- Consent renewal
 - Asthma Health's original consent had a duration of 6-months.
 - IRB let us to ask users to renew for 1 year but this required mad-dash development
- App maintenance
 - iOS updates
 - Consent document expiration
- App shutdown
 - How will the app behave after the study ends?
 - Can all servers be turned off?

Data



Overview of Security Features



TouchID or Passcode protection on phone

All information transferred to servers are encrypted

All stored data is de-identified

PHI is stored separate from study data (if possible)

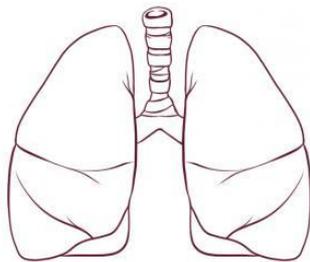
Asthma Health: Data Collected

Study
Data



HealthKit Data

Steps, Peak flow, Inhaler usage, height, Weight, age



Asthma Data

Medications, symptoms, triggers, healthcare utilization



Other Data

Air quality, **location**, medical history, demographics, **genotypes**

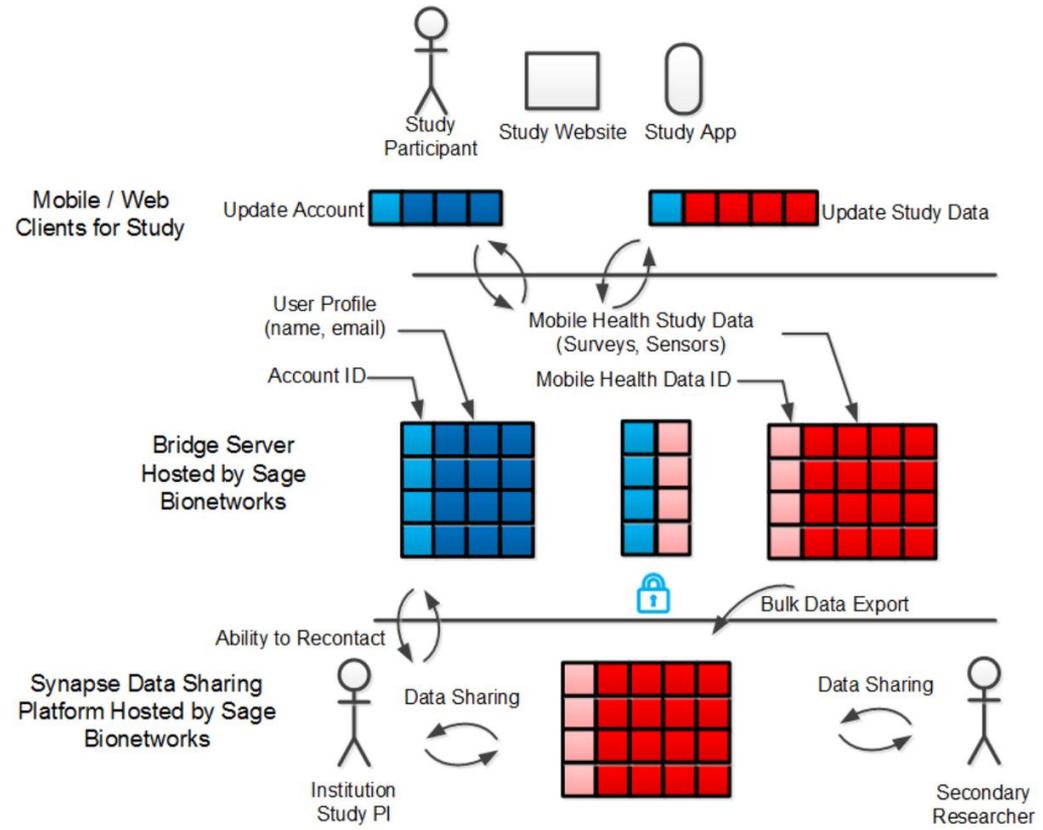
Other Data

Other Data

Name, email

Bold = PII

Sage Backend Stack: De-identification via Bridge; Distribution with Synapse



- All data sent to Bridge is encrypted with Sage's public key
- All PII data sent to Bridge is additionally first encrypted with Mount Sinai's private key



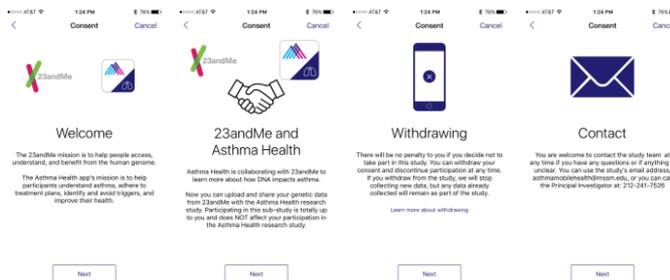
23andMe

- 23andMe is a DTC genetic testing service that genotypes ~1M SNPs
- They released base code to link to their API for existing customers who want to of genetic data
- In March 2016, we launched updates to AH & MHC with 23andMe integration

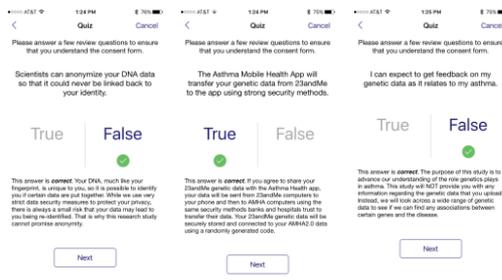


23andMe in Asthma Health

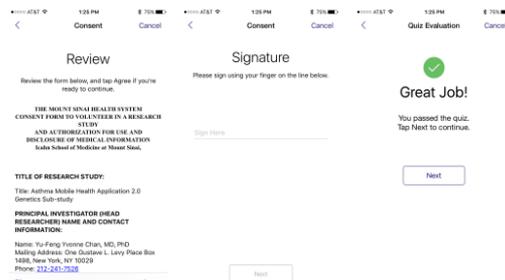
Consent



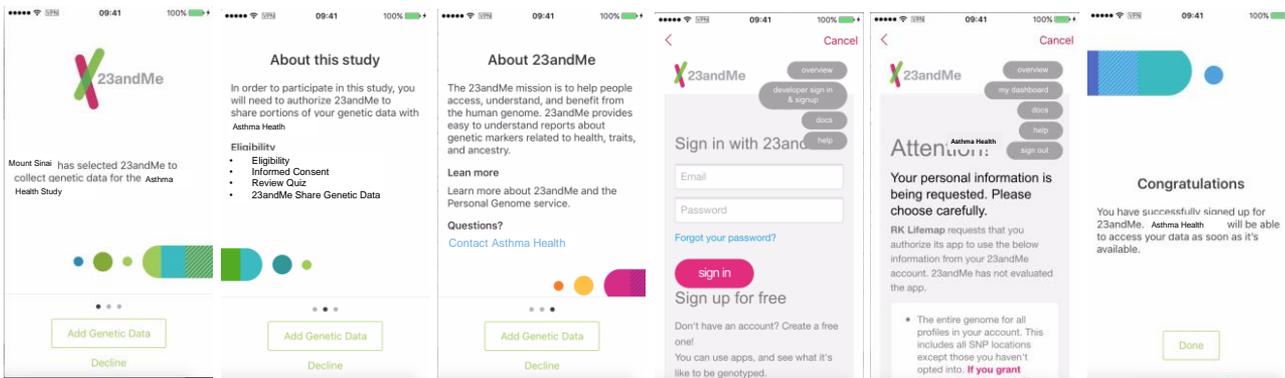
Comprehension Quiz



Signed consent



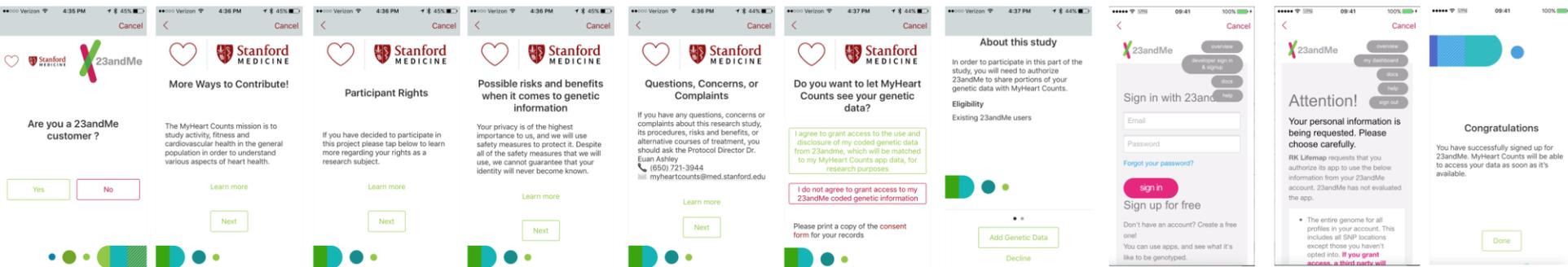
Link to 23andMe is only available after signing consent



API keys are used by the app to download data which is encrypted*2 and stored in Bridge

Stanford University

23andMe in MyHeart Counts



API keys are sent to auxiliary server run by Stanford

Data concerns

- Accuracy of data presented to user
 - Caution resulted in limited user feedback in Asthma Health
 - Not just data but also reminders – what if a medication reminder fails?
 - Could a never ending 6MWT kill you?

Subject: myheart counts

Date: September 28, 2017 at 2:31:58 PM PDT

To:

I've been trying to use this app and the 6 minute walk always times out and fails to capture my walk..

- Data loss
 - App issues
 - Server issues
 - Connectivity issues
 - Breaking randomization
- Can we use the data?

Smart inhaler: killed by legal risks



What's Next

- Platforms to make apps without developers (ie Medable Axon, Quantextual)
 - More apps → more opportunities for harm
 - Will this mean less control of data servers? Possible a good thing
- Apps that do more
 - Feedback
 - MHC would like to offer a genetic heart risk
 - A/B testing for usability
- Studies on mHealth apps
 - A/B testing for usability studies
 - Consent comprehension studies
- Apps on Android

Conclusions

- Compared with my previous life doing genetic sequencing, I consider the ELSI issues in mHealth to be less dicey
 - No Adverse events to date
- Risk remain
 - Need understanding on comprehension, value to participants
 - I consider Asthma Health's PII perpetually at risk
- Don't forget to plan your study app's lifecycle!

Thank you for your time and to my collaborators & supporters

