Study Protocol

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Managing Asthma Patients with AMAZE™: A Novel Disease Management Platform, A Clinical Pilot Study

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation or special term	Explanation
ACT™	Asthma Control Test
AE	Adverse event
AZ	AstraZeneca
CFR	Code of Federal Regulations
COPD	Chronic obstructive pulmonary disease
CRF	Case report form
CRO	Clinical research organization
DES	Data entry site
EMR	Electronic medical record
ePRO	Electronic patient-reported outcome
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HCP	Healthcare practitioner
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council for Harmonization
ICS	Inhaled corticosteroid
ID	Identifier
IEC	Independent Ethics Committee
IRB	Institutional review board
LABA	Long-acting beta agonist
MC	Marketing company
MEOR	Medical Evidence and Observational Research
MGH	Massachusetts General Hospital
OCR	Optical character recognition
SD	Standard deviation
SOP	Standard operating procedure
SUA	Severe uncontrolled asthma

RESPONSIBLE PARTIES

Name	Professional Title	Role in Study	Affiliation	Email Address
PPD	PPD US Respiratory Medical	Team Lead	AstraZeneca	PPD
PPD	PPD	Medical Lead	AstraZeneca	PPD
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PROTOCOL SYNOPSIS

AMAZE™ Asthma Implementation Clinical Pilot Study: MGH

Background/Rationale: AstraZeneca (AZ) has developed the AMAZE™ disease management platform to be used across multiple disease indications to provide a unified experience for the management of patients throughout their patient care journey. AMAZE™ integrates multiple systems, including a patient Application where patients can enter daily symptoms and impact to communicate this information to their healthcare provider (HCP), as well as access disease educational materials. Both the patient Application and a clinician dashboard are integrated with the patient's electronic medical records (EMR) to provide a clear view of the patient's health status both in and out of the clinic. Implementation of AMAZE™ within clinical practice has not yet been evaluated. The results from this study will be used to inform any changes or modifications that need to be made to the technology platform, its implementation process, and explore impact on clinical outcomes.

Objectives and Hypotheses:

The primary study objective is to generate evidence as to the feasibility, usability, perceived value, and potential benefits of implementing the AMAZE™ platform into clinical practice. This objective will be accomplished through the generation of evidence in two key outcome types:

1. **Technology Outcomes**: Key questions to be asked regarding the technology outcomes are:
    - How much is the platform utilized, and what is the perceived value by both clinical staff and patient users?
    - How user friendly is the platform?
    - Are staff comfortable with the display and type of data shown?
    - Which features are/are not useful to patients and clinicians?
    - Which features need removed or improved upon?
    - What, if any, bugs are encountered?
    - How accessible is the app/portal?
    - What is the optimal frequency of completing the patient log that is achievable and meaningful for asthma management?

2. **Process outcomes**: How does the implementation of AMAZE^{TM} affect clinical process? For example, is patient communication improved, or is there an increase or decrease in time spent with patients?

The exploratory objectives are:

1. **Clinical outcomes**: How does the implementation of AMAZE^{TM} affect clinical outcomes? For example, is there an increase or decrease in utilization of patient services, emergency department visits, or clinician contacts?
2. To identify which segments of patients are most likely to benefit from using AMAZE^{TM}.

Since this study is exploratory regarding the feasibility, usability, and perceived benefit of using an electronic platform for disease management, there is no hypothesis testing.

Methods:

Study design: This is a longitudinal study in which the process of integrating the AMAZE^{TM} disease management platform (DMP) into clinical practice will be assessed by implementing this program at MGH for six months.

For the clinical pilot study, patients with asthma of varying severity will be recruited. A target of up to 50 total patients will be recruited and consented for the purposes of the clinical pilot study, consisting of approximately 33 young adult (18-35 years old) and up to 17 adult patients (36 years of age and older). Approximate recruitment targets for the study include a subset of patients who are new to the practice (less than 3-month history with the practice) and with uncontrolled asthma (n = approx. 10) as well as patients experiencing at least 1 exacerbation in previous 12 months (n=approx. 40). Exacerbations are defined as a change in asthma symptoms requiring a course of oral steroids or steroid injection and/or a hospitalization or emergency department visit for asthma. MGH staff responsible for recruiting patients will participate in a training prior to recruitment starting, including the workflow for steps for the clinical pilot.

After collecting electronic informed consent via Research Electronic Data Capture (REDCap), participants will be instructed to download the AMAZE^{TM} application software (app) to record their daily asthma symptoms and access educational materials and other features of the app. Participants will be allowed to retroactively complete their daily asthma symptoms log for up to 7 days prior to the current date. All entries will be date and time stamped to track entries. After downloading the app, participants will be emailed a sociodemographic form to complete. If the participant enables reminder notifications within the app, they will be sent one notification a day at their preferred time if they do not

access the app daily. On a monthly basis, the app will prompt them to complete the Asthma Control Test (ACT™). Importantly, participant responses to the app will be monitored twice daily by a clinical and research team and alerts may be sent to their physician based on responses (e.g. participant reports of ED visits, multiple "bad" day reports, etc.) via the AMAZE™ interface to facilitate communication and to guide treatment.

A random selection of up to 12 participants will be asked to participate in longitudinal follow-up interviews at study months one, three, and six with the Evidera study team to monitor the implementation of the AMAZE™ platform. MGH personnel will be consented prior to completing any interviews. At study months 2, 4, and 5, a one-time random selection of up to 5 participants may be selected to complete a follow-up interview by the AZ DMP product team. During the follow-up longitudinal and cross-sectional interviews, participants will be asked questions regarding their use of the app/platform and what features may need improvements or are particularly of value.

Additionally, all participants will be asked to complete a patient user experience survey at study months 1, 3, and 6, as well as the System Usability Scale (SUS) at study months 1and 6. All electronic surveys sent outside the app will be sent through REDCap. Clinical staff research participants will be asked to complete the SUS at study months one and six. Lastly, any time a participant attends a clinic visit (in-person or telehealth), they will be emailed a link to complete a patient visit experience satisfaction survey. At the end of the study, HCPs will be asked to complete a post-study survey via emailed link, while patients will be asked to complete the Patient Satisfaction Questionnaire (PSQ-18).

Study Sites: MGH outpatient adult and pediatric pulmonary clinics will be implementing the clinical pilot study.

Data Source(s): MGH was selected to implement AMAZE™ into their clinical practice based on the principal investigators' experience and qualifications, the number of asthma patients treated in the clinic, the diversity of the asthma patients treated by the clinic, the ability of the site to complete the study tasks in the allotted timeframe, and the anticipated unique component of clinical pilot initiatives anticipated by the study site.

Study Population: Clinic staff will invite eligible patients age ≥18 years with a diagnosis of asthma to enroll in the study. Up to 50 patients will be enrolled, including approximately 33 young adults (18-35 years old) and up to 17 adults (36 years of age and older).

Exposure(s):

Participants will complete the following measures at differing timepoints:

- AMAZE™ Patient App, including a daily symptom log, daily medications, healthcare resource utilization (HCRU), ACT™ completed every month, and educational resources
- Demographic characteristics questionnaire
- Patient User Experience Survey
- Patient Visit Experience Survey
- SUS
- Qualitative Semi-structured Interviews
- PSQ-18

MGH personnel will complete the following measures:

- Screening script for patient recruitment (CRC)
- Clinical Case Report Form (CRF) (CRC)
- Chart Review CRF (CRC)
- SUS (Clinical staff)
- Post-Study Survey (Clinical staff)

Outcome(s):

- Onboarding process evaluation
- Product attributes
- Patient visit and user experience
- Clinical staff experience
- Clinical process assessment
- SUS scores
- PSQ-18 scores
- Post-study survey responses
- Qualitative interview responses

Sample Size Estimations: As the aim of this study is to assess the process and feasibility of implementing AMAZE™, inferential statistics will not be performed, and a formal sample size estimation is not applicable. MGH will target up to 50 patients. Implementing AMAZE™ among up to 50 patients will provide MGH with enough experience to provide feedback on the outcomes, barriers, benefits, challenges, ease of implementation, and areas for improvement for future integration as a platform.

Statistical Analysis: Descriptive statistics (n, frequency, mean, and standard deviation [SD]) will be used to characterize the sample in terms of sociodemographic and clinical characteristics. The sociodemographic and clinical characteristics will be summarized for the sample overall as well as for each site. Descriptive statistics (n, frequency, mean, and SD) will also be used to summarize the results from the patients' frequency of use of the daily log and educational resources, ACT™ scores, responses to the Patient Visit Experience Survey, the SUS, and the results of the patient PSQ-18 and HCP Post-study survey.

Qualitative interviews will be summarized based on interviewers' notes using a detailed interviewer matrix. The interviews will be audio recorded, and transcribed by a third-party vendor (TransPerfect), should the audio need to be reviewed to summarize findings. The interview results will be summarized in tabular format, with key recommendations, advantages, and disadvantages grouped. Specifically, barriers, benefits, challenges, ease of implementation, and areas for improvement will be summarized.

Safety Handling Plan: A Safety Handling Plan has not been developed for this study.

AMENDMENT HISTORY

Date	Section of study protocol	Amendment or update	Reason
		N/A	

MILESTONES

Milestone	Planned date
Final Protocol	Q4 2020
Internal Review Board Approval	Q2 2021
Site Trainings	Q2 2021
First Participant In	Q2 2021
Last Participant in	Q2 2021
Database Lock	Q4 2021
High Level Results in Tabular Format	Q4 2021
Final Report	Q1 2022

1. BACKGROUND AND RATIONALE

1.1 Background

Uncontrolled and severe uncontrolled asthma (SUA) are common disorders that are often difficult to identify and manage. The clinical and economic burden of SUA is disproportionately high, accounting for nearly 40% of asthma-related costs[1,2] and uncontrolled asthma affects over 50% of children and adults with asthma. With advances in asthma therapies, an urgent need exists to optimize uncontrolled and SUA recognition and clinical management.

1.2 Rationale

Poor asthma control is often unrecognized as asthma patients learn to adapt to their disease and adjust to a suboptimal level of control. This can result in frequent exposure to systemic steroids along with frequent urgent care/ER visits and hospitalizations. The AMAZE™ platform aims to address this clinical need through better communication between patients and their clinical teams regarding the patients' level of asthma control with the ultimate goal of improvement asthma management and improved health outcomes. This study aims to test the feasibility of implementing AMAZE™ in a specialist clinical practice to manage asthma.

2. OBJECTIVES AND HYPOTHESES

2.1 Primary Objective(s) and Hypothesis(es)

The primary study objective is to generate evidence on the feasibility, usability, perceived value, and potential benefits of the AMAZE™ disease management platform implemented in clinical practice. Since this is an exploratory study involving a mobile app and DMP, there is no hypothesis testing. The primary objective will be assessed through the following key outcomes:

1. **Technology Outcomes:** Key questions to be asked regarding the technology outcomes are:

    - How much is the platform utilized, and what is the perceived value by both clinical staff and patient users?
    - How user friendly is the platform?
    - Are staff comfortable with the display and type of data shown?
    - Which features are / are not useful to patients and clinicians?
    - Which features need removed or improved upon?
    - What if, any bugs, are encountered?

- How accessible is the app/portal?
- What is the optimal frequency of completing the patient log that is achievable and meaningful for asthma management?

2. **Process outcomes:** How does the implementation of AMAZE™ affect clinical process? For example, is patient communication improved, or is there an increase or decrease in time spent with patients?

2.2 Secondary Objective(s) and Hypothesis(es) (Optional)

There are no secondary objectives for this study.

2.3 Exploratory Objective(s) and Hypothesis(es) (Optional)

There are two exploratory objectives for this study.

1. **Clinical outcomes:** How does the implementation of AMAZE™ affect clinical outcomes? For example, is there an increase or decrease in utilization of patient services, emergency department visits, or clinician contacts?

2. To identify segments of patients that are most likely to benefit from using AMAZE™.

3. METHODOLOGY

3.1 Study Design – General Aspects

This is an implementation study to assess the feasibility, usability, perceived value, and potential benefits of integrating the AMAZE™ DMP at MGH. The AMAZE™ platform (developed by AstraZeneca/BrightInsight) consists of a clinician dashboard to guide treatment and asthma management, and a patient application to enter daily symptoms and medications that can trigger alerts to the clinician dashboard. For this implementation study, the sites will be trained on the use of the AMAZE™ platform and will launch the program in the target patient population.

For clinical pilot study launch, MGH will recruit up to 50 patients with asthma, including approximately 33 young adults (18–35 years old) and up to 17 adults. Approximately 10 new patients to the practice (less than 3-month history with the practice) but with uncontrolled asthma will be recruited, along with approximately 40 patients who have had at least one exacerbation per year. Eligible participants will be invited to participate in the study either in person or via telephone or Zoom call using a standardized recruitment script (Appendix A). Alternatively, a recruitment email will be first sent from a physician with a flyer attached to introduce the app and the study to participants (Appendix C). A follow-up Zoom video conversation can also be scheduled with the participants. If interested in participating in the study, they will provide their

email address to the site staff so that a consent form can be sent to them via email (Appendix B) to sign via REDCap. The MGH staff will confirm the email address provided by the participant is consistent with the email address within the DMP dashboard system. If the email address differs, the staff will modify the dashboard to the correct email. The email address collected during the screening visit will be used for emailing the surveys throughout the study. The MGH staff will review the consent with the patient either in person or via telephone or Zoom call and answer any questions they may have.

After consenting to participate, patients will be sent an introductory email (Appendix D) with link to download the app (Appendix E), and register as a patient with a unique identifier (ID). Once the app has been downloaded, the patient will be asked to create their unique ID. Within the app, participants will be provided with access to all educational materials and asked to complete the daily symptom log. The MGH research staff will complete a clinical case report form (CRF; Appendix F) to record baseline clinical information about the patient, while participants will be asked to complete a sociodemographic form (Appendix G) via an emailed link. If the participant enables reminder notifications within the app, they will be sent one notification a day at their preferred time if they do not complete the app daily. BreezoMeter, a third-party air quality vendor, will be assisting in the tracking and alerting of the air quality in the participant's location if the location setting is turned on.

After study launch, Evidera will conduct qualitative, longitudinal, follow-up interviews regarding process implementation with a random selection of patient participants (approximately 1 out of 5) at study months one, three, and six to gain a deeper understanding of the feasibility of implementing the asthma AMAZE™ platform. Prior to launching the interviews, approximately 12 patient participants will be randomly selected to participate in the qualitative interviews at study months one, three, and six to understand the feasibility and usability of the patient app over time, the perceived benefit (e.g., if there is an increase in the patient's ability to interact with their physician, if it enhances speed and/or quality of response, etc.), and how it can be improved. In addition to the longitudinal interviews, a one-time, cross-sectional interview may be conducted by the AZ DMP Product Team at months 2, 4, and 5 with a random selection of up to 5 patient participants at each timepoint (excluding the up to 12 participants who will be participating in the longitudinal interviews). The cross-sectional interviews are meant to help capture any new features or feedback from participants during the off-months in the longitudinal interviews and will be conducted on an as-needed basis.

In addition to the qualitative interviews, patient participants will be emailed a link to complete an electronic patient visit experience survey (Appendix H) after attending an in-person or telehealth visit with their doctor to evaluate their overall satisfaction with AMAZE™ and its impact on the visit. Evidera will receive a data report from BrightInsight with participant BrightInsight ID, date of visit, and status of visit completion. Evidera will then share the IDs with MGH to generate a

visit survey email. All participants will be asked to complete electronic Patient User Experience surveys, sent via email, as well as the SUS at study months one and six. These surveys are meant to allow participants the opportunity to provide feedback on the app as they continue to interact with the app longitudinally throughout the study. At the end of the study (approximately 3 months after completion of enrollment) prescribing providers and study coordinators at MGH will complete a Post-study Survey (Appendix I) and patient participants will complete the PSQ-18 (Appendix J). The focus of these questionnaires will be to obtain additional feedback on the implementation of AMAZE™ and participant satisfaction with the medical care they receive, respectively. All electronic surveys sent outside the app will be sent through REDCap. At study month Six, MGH staff will also be asked to complete a chart review CRF (Appendix K) for each patient. The patient app and/or clinician dashboard may be revised throughout the clinical pilot study based on feedback from patients and clinical staff.

3.1.1 Data Source(s)

Participants will be recruited from MGH. MGH will recruit approximately 33 young adults (18–35 years old) and up to 17 adults for a total sample of up to 50 patients. In addition, MGH will aim to recruit patients who are new to the practice (less than 3-month history with the practice) but with uncontrolled asthma (n= approx. 10) and patients experiencing at least 1 exacerbation in previous 12 months (n=approx. 40).

3.2 Study Population

Clinic staff will invite patients age ≥18 years with an asthma diagnosis who are presenting for a clinic visit or via telephone to download the AMAZE™ App. Up to 50 patients will be recruited.

3.3 Inclusion Criteria

Patients must meet all the following criteria to be considered for enrollment:

1. ≥18 years of age at the time of enrollment
2. Clinically confirmed diagnosis of asthma (with or without COPD)
3. Access to a smartphone with internet access with the following requirements: iOS (Operating System iOS 13 or newer and Devices iPhone 8 or newer) or Android (Operating System 8.0 or newer)
4. Able to understand and speak English sufficiently to be able to use the AMAZE™ patient app
5. Willingness to participate in a telephone interview and be audio-recorded
6. Consenting to participate in the study

3.4 Exclusion Criteria

Patients meeting any of the following criteria will not be included in the study:

1. No current diagnosis of asthma
2. Has a cognitive impairment, hearing difficulty, acute psychopathology, medical condition, or insufficient knowledge of the English language that, in the opinion of the investigator, would interfere with his or her ability to agree to participate and/or complete the ACT™.

4. VARIABLES AND EPIDEMIOLOGICAL MEASUREMENTS

4.1 Exposures

Prior to enrollment in the study, MGH staff will approach patients during an in-person or telehealth clinic visit or via telephone to assess interest and confirm eligibility. For the clinical study launch, a standardized screening script (Appendix A) will be used that provides an overview as to the purpose and nature of the implementation study, as well as a description of the potential to participate in the longitudinal or one-time follow-up interviews (if randomly selected to participate).

The timing of each key procedure/exposure, and the responsible party for each procedure is depicted below in Table 1. Following the baseline visit, Evidera will randomly select up to 12 patient participants for longitudinal interviews, as well as up to 5 participants per timepoint to take part in cross-sectional interviews. A detailed workflow of the implementation of the DMP in MGH clinical practice is included in Appendix L.

Table 1. Schedule of Study Assessments

Procedures	Baseline	Month One	Month Two	Month Three	Month Four	Month Five	Month Six
Screen and Recruit[1]	M						
Consent via RedCap for Participants	M/P						
Download App	P						
Completion of App	P	P	P	P	P	P	P
Monitor Clinician Dashboard	M	M	M	M	M	M	M
Clinical CRF	M						
Sociodemographic Form	P						
Patient User Experience Survey		P		P			P
System Usability Scale		P/M					P/M

Procedures	Baseline	Month One	Month Two	Month Three	Month Four	Month Five	Month Six
Patient Visit Experience Survey[2]		P	P	P	P	P	P
Participant Longitudinal Follow-up Interviews (n=approx. 12)		P/E		P/E			P/E
Participant Cross-sectional Follow-up Interviews (n= approx. 5)			P/AZ		P/AZ	P/AZ	
Consent for MGH staff participating in surveys		M					
Patient Satisfaction Questionnaire-18							P
MGH Staff Post-Study Survey							M
Chart Review CRF							M

[1]MGH will recruit approximately 50 patients for the clinical pilot study. Any additional patients invited to use the app beyond the maximum sample size will not be included in any analyses.
[2]The Patient Visit Experience Survey will be sent after a confirmed visit with their HCP at the site following baseline visit.
Abbreviation: AZ=AstraZeneca DMP Product Team; CRF = case report form; E=Evidera; M=MGH; P=Participant

Patient participants will be compensated $10 after completion of applicable surveys from baseline through month 6. In addition, if a participant is randomly selected for an interview, they will also be compensated $75 per interview completed. Patient participants will be randomized into one of three groups, and will only complete one of these groups:

1. Longitudinal (three total) interviews and receive up to $265
2. Cross-sectional (one-time) interview and receive up to $115
3. Not randomized to be interviewed and receive up to $40

Below is a table outlining the remuneration payment schedule for patient participants.

Table 2. Remuneration Payment Schedule for Patient Participants

Procedures	Baseline	Month One	Month Three	Month Six
Completion of Electronic Surveys	$10	$10	$10	$10
Completion of Interview (*if randomly selected*)		$75	$75	$75
Total Possible Remuneration	**$10**	**$85**	**$85**	**$85**

4.1.1 Patient-Completed

4.1.1.1 AMAZE™ Patient App

At the initial baseline visit, participants will be asked to download the AMAZE™ app (Appendix D). The patient app includes a daily log of asthma symptoms, as well as additional questions on their asthma experience. As a part of the app, patients will have access to educational resources about their asthma and asthma medication. The resources are meant to be informative in nature based on how the participant responds to questions in their daily log. The app allows participants to communicate with the MGH staff as well as see daily and weekly trends in their asthma. My plan, a component within the app, contains medications, air quality and information regarding upcoming appointments.

Every four weeks, the ACT™ will also be administered and completed by the participant.[3] The ACT™ consists of five items with the total score used to identify participants with poor asthma control. The ACT™ classifies well controlled as ≥20, not well controlled as 16–19, and very poorly controlled as ≤15. The ACT™ questions with a four-week recall period address medication use, asthma symptoms and asthma-related impairment. The English version will be used in this study only.

4.1.1.2 Patient Demographic Questionnaire

Participants will complete a brief self-administered Patient Demographic Questionnaire (Appendix G) following download of the patient application and providing their informed consent to participate; this questionnaire will be sent to all participating patients via an email link. This form collects the participant's age, ethnicity, living situation, employment, and education, and will be used to describe the sample and assist with interpreting the results.

4.1.1.3 Patient User Experience Survey

All participants who consent to participate in the full clinical study will be emailed at months 1, 3, and 6 the patient user experience survey (Appendix M). The survey is meant to allow participants the opportunity to provide feedback on a monthly basis as they continue to interact with the app. The survey results will be reviewed to identify if any changes to the app are needed.

4.1.1.4 Patient Visit Experience Survey

The patient visit experience survey (Appendix H) will be sent electronically any time a participant attends an in-person or telehealth clinic visit. Bright Insights will generate weekly reports to provide Evidera with IDs for those who completed clinic visits. Evidera will subsequently notify the electronic survey vendor to send the survey via email. This survey will evaluate patient satisfaction with their visit and any benefits the App provided for the visit.

4.1.1.5 System Usability Scale

The System Usability Scale (SUS) (Appendix N.1) will be sent electronically at months one and six for participants to provide feedback on the AMAZE patient app. The SUS has been validated in previous usability studies to quantitatively evaluate the usability of a system, including mobile apps.[4]

4.1.1.6 PSQ-18

At the end of the clinical pilot study (approximately 6 months), all participants who consented and participated in the clinical pilot study will be emailed a link to the Patient Satisfaction Questionnaire-18 (PSQ-18; Appendix J).[5] The PSQ-18 is a generic measure used to assess patient's overall satisfaction with their medical care and interactions with their HCPs. A higher score indicates greater satisfaction.

4.1.1.7 Follow-up Process Interviews with Patients

Longitudinal Interviews

A semi-structured interview guide (Appendix O) will be used to obtain information from a randomly selected subset of patients at months one, three, and six during longitudinal, follow-up interviews to gain a deeper understanding of the feasibility of implementing the AMAZE™ platform. The semi-structured interview guides will include an introduction and follow with specific questions and probes designed to facilitate discussion and optimize consistency across interviews. The interview guide will elicit recommendations for improving the AMAZE platform experience for patients. Additional unscripted probes may also be used to gain further information or clarification. The interview guides may be modified as necessary during the study.

Cross-Sectional Interviews

Semi-structured interview guides for months 2, 4, and 5 (Appendix O) may be used to obtain information from a randomly selected subset of patients at months 2, 4, and 5 during one-time, follow-up interviews with the AZ DMP Product team to gain a deeper understanding of the usability of the AMAZE™ platform. The interviews will be conducted as needed. The interviews are meant to be briefly provide feedback on any new roll outs or issues with the app that cannot be captured during the longitudinal interviews. The semi-structured interview guides will include an introduction and follow with specific questions and probes designed to facilitate discussion and optimize consistency across interviews. The interview guide will elicit recommendations for improving the AMAZE platform experience for patients. Additional unscripted probes may also be used to gain further information or clarification. The interview guides may be modified as necessary during the study.

4.1.2 MGH Completed

4.1.2.1 Clinical Case Report Form

For each participant, MGH will complete a paper clinical case report form (CRF; Appendix F) during the initial site visit after informed consent is obtained. The clinical CRF serves to characterize patients based on their history of asthma, current medications, and the HCP's rating of the patient's asthma severity and control.

4.1.2.2 Chart Review Case Report Form

For each participant, MGH will complete a chart review clinical CRF (Appendix K) at month six. The follow-up clinical CRF will evaluate exacerbation history during the last 6 months, healthcare resource utilization, change in therapy, and COVID-19 diagnosis.

4.1.2.3 System Usability Scale

The SUS (Appendix N.2) will be asked verbally to clinical staff during the telephone interviews at months one and six to provide feedback on the clinical dashboard.

4.1.2.4 Post-study Survey

All clinical staff who participate will be asked to complete the Post-study Survey (Appendix I) after patient enrollment has completed (approximately four months after study launch). The purpose of this survey is to obtain feedback on the implementation of the AMAZE™ platform within each site's medical practice.

4.2 Outcomes

4.2.1 Primary Outcome

To address the primary objective to generate evidence on the feasibility, usability, perceived value, and potential benefits of the AMAZE™ implemented in clinical practice, the following outcomes will be assessed:

- **Technology Outcomes:** Technology outcomes will be assessed in a variety of ways throughout the clinical pilot study. Usage metrics will be collected by BrightInsight to assess the frequency of use by patients completing the daily log, and utilizing the educational resources provided. The usage of the clinical dashboard will also be tracked to evaluate the utility of the dashboard to MGH. Usage metrics will be analyzed by Evidera once provided by BrightInsight.
    - The qualitative interviews from the longitudinal months one, three, and six interviews as well as the cross-sectional months two, four, and five interviews will provide data regarding the usefulness of the technology from a patient perspective.

- The patient user experience surveys may be evaluated as well to determine how the platform is being utilized and the user friendliness of the App.

- **Process Outcomes:** Similar to the technology outcomes described above, process outcomes will be evaluated using the patient follow-up interviews, patient visit experience survey, PSQ-18 scores, SUS scores, and post-study survey results. Analyses for the process outcomes will focus on variables evaluating the impact of AMAZE^{TM} on clinical practice, including duration of patient visits and services, as well as responses to survey items on changes to timing of scheduling visits, communication during the visit, and satisfaction with medical care received.

4.2.2 Secondary Outcome

There are no secondary objectives for this study.

4.2.3 Exploratory Outcome One

To address the first exploratory objective to assess how the implementation of AMAZE^{TM} affects clinical outcomes, the following outcomes will be assessed:

- **Clinical Outcomes:** As part of AMAZE^{TM}, all patients will be asked to utilize the App by completing the daily log and monthly ACT. Additionally, sites will be asked to complete a baseline clinical CRF and a six-month chart review CRF for each participant. The baseline clinical CRF will capture information on the patient's asthma and smoking history as well as current asthma medications. The chart review CRF will include questions on recent exacerbations, healthcare resource utilization, change in asthma therapy, and exposure to COVID-19. The variables collected from these CRFs will be used to evaluate how AMAZE^{TM} impacts key clinical outcomes of interest. Descriptive statistics (n, frequency, mean, and SD) will be utilized.

4.2.4 Exploratory Outcome Two

To address the second exploratory objective on identifying which segments of patients are most likely to benefit from using AMAZE^{TM}, information collected from the patient sociodemographic form and clinical CRF will be used and analyses will be stratified by patient subgroups/segments. The following patient segments may be considered: age cohorts (TBD); sex; asthma severity cohorts (TBD); educational cohorts (TBD); and minority cohorts (TBD). Other patients' segments may be considered after reviewing sample distribution.

4.3 Other Variables and Covariates

Demographic and/or clinical patient data will be used to summarize the sample overall and by site.

5. STATISTICAL ANALYSIS PLAN

5.1 Statistical Methods: General Aspects

Descriptive statistics (n, frequency, mean, and SD) will be used to characterize the sample in terms of sociodemographic and clinical characteristics. The sociodemographic and clinical characteristics will be summarized for the sample overall as well as for each site.

5.1.1 Primary Objective: To generate evidence on the feasibility, usability, perceived value, and potential benefits of the AMAZE™ implemented in clinical practice

The technology outcomes described in section 4.2.1 above will be analyzed both qualitatively and quantitatively. The interview (longitudinal and cross-sectional follow-up) results will be summarized in tabular format, with key recommendations, advantages, and disadvantages grouped. Specifically, barriers, benefits, challenges, ease of implementation, and areas for improvement will be summarized. Results from the patient visit experience survey, monthly patient user experience surveys, PSQ-18, post-study survey, and usage metrics provided by BrightInsight will be analyzed using descriptive statistics (n, frequency, mean and SD).

The process outcomes described in section 4.2.1 above will be analyzed similar to the technology outcomes. The interview results will be summarized in tabular format; survey results will be analyzed using descriptive statistics.

5.1.2 Secondary Objective(s)

There are no secondary objectives for this study.

5.1.3 Exploratory Objective One: To assess how the implementation of AMAZE™ affects clinical outcomes

The variables collected from the baseline Clinical CRF and six-month chart review form will be used to evaluate how the AMAZE™ patient App impacts key clinical outcomes of interest (e.g. clinician visits, healthcare resource utilization, change in therapy). Descriptive statistics (n, frequency, mean, and SD) will be utilized.

5.1.4 Exploratory Objective Two: To identify patients who are most likely to benefit from using AMAZE™

The variables collected form the patient sociodemographic form and Clinical CRF will be used to stratify patients into segments/subgroups. Proposed variables of interest are age, sex, asthma severity, educational subgroups, and minority status. Additional variables may also be used in the

exploratory analyses. Descriptive statistics (n, frequency, mean, and SD) will be used to characterize patients most likely to benefit from the App across these variables.

5.2 Bias

5.2.1 Methods to Minimize Bias

Bias may occur with patient selection into the study based on availability of the appropriate phone and operating system. For this initial implementation study, the age and sex of patients who are interested in participating but do not have access to the appropriate devices will be tracked.

5.2.2 Adjustment for Multiple Comparisons

Not Applicable.

5.2.3 Strengths and Limitations

The strengths of this study are that it aims to include a diverse sample of patients across MGH. The limitations of this study include that MGH may not be generalizable to all clinical sites treating asthma patients across the US and that the sample of patients may not be generalizable to all asthma patients ≥18 years of age.

5.3 Sample Size and Power Calculations

As the aim of this study is to assess the process and feasibility study of implementing the AMAZE™ in clinical practice, inferential statistics will not be conducted, and a formal sample size estimation is not applicable. MGH will target 50 patients. Implementing the AMAZE™ with up to 50 patients will provide MGH with enough experience to provide feedback on the outcomes, barriers, benefits, challenges, ease of implementation, and areas for improvement for future integration as a platform.

6. STUDY CONDUCT AND REGULATORY DETAILS

6.1 Study Conduct

6.1.1 Procedures

6.1.1.1 Recruitment

Participants will be recruited from MGH. MGH will identify potential participants through chart/database/electronic medical record (EMR) reviews. Potentially eligible patients will also be identified using the Research Patient Data Registry (RDPR) Scheduled Query feature. We will search for patients diagnosed with asthma with or without COPD. Upon receipt of each updated patient list, study staff will perform a chart review of listed patients to confirm eligibility. Once patient eligibility is confirmed, study staff will provide the confirmed list to appropriate clinical

staff who, at their discretion, will approach their patients regarding participation in the research study.

MGH staff will approach patients during a regularly scheduled clinic visit or call potentially eligible participants and introduce the study using an introductory script (Appendix A). The script provides an overview as to the purpose and nature of each study. Alternatively, a recruitment email will be first sent from a physician with a flyer attached to introduce the app and the study to participants (Appendix C). A follow-up Zoom video conversation can also be scheduled with the participants. For the clinical pilot study, best efforts will be made to recruit approximately 10 patients who are new to the practice (less than 3-month history) but with uncontrolled asthma and approximately 40 patients experiencing at least 1 exacerbation in the previous 12 months. In addition, over half the sample will be young adults (18–35 years old). The research staff will document patient interest and the recruitment quota using the Recruitment Tracking Log (Appendix P), including documentation of the number of patients who choose not to participate.

6.1.1.2 Baseline Visit

During the baseline visit, interested participants that have verbally consented to participate will be sent an email (Appendix B) by the clinic staff via REDCap to provide electronic consent to participate in the clinical pilot study. The email address will be confirmed during screening and staff will add the email address in the dashboard system if it differs from the email address in the dashboard. MGH staff will review the consent either in person or via telephone and answer any questions they may have. Once the participant and MGH staff have signed, a fully executed version will be available for download. The consent will acknowledge the random selection of patients who will be asked to complete either a longitudinal or cross-sectional follow-up interview. After consent, patients will be provided with a link to download the App (Appendix E) and register as a patient with a unique identifier (ID). After completion of the baseline visit, patients will be emailed a brief sociodemographic questionnaire (Appendix G). MGH will also be asked to complete a clinical CRF (Appendix F) to capture initial clinical characteristics. Patients will be remunerated $10 for completing the sociodemographic questionnaire at the baseline visit. Evidera will provide the email addresses collected at the screening visit to the web survey vendor in order to email the follow-up survey links.

6.1.1.3 Longitudinal Follow-up Interviews and Assessments

Throughout the study duration, participants will be able to access the daily log of symptoms, questions on their asthma experience, and educational resources each day they interact with the AMAZE™ app. Every month, the app will prompt the completion of the ACT™. Based on the responses on the patient App, a notification or alert may be triggered in the clinician dashboard for the sites to contact the patient and assess the severity of their symptoms and propose next steps (e.g., complete a clinic visit). In addition to the daily App completion, patients will be emailed a

monthly patient user survey to complete, as well as the SUS at months one and six. Patients will be remunerated $10 with payment at months 1, 3, and 6 on their ClinCard for completion of applicable surveys. In addition, patients who are randomly selected will be compensated $75 for each successfully completed interview.

Up to 12 randomly selected patients from MGH will be asked to participate in qualitative, longitudinal, follow-up interviews at months one, three, and six to evaluate the implementation and convenience of AMAZE™. Interviews will be conducted over the phone with Evidera staff. The interviews will be audio recorded and transcribed by a third-party vendor (TransPerfect). Interviews are expected to last approximately 30 to 45 minutes for patients. Patients will be remunerated $75 for their time via ClinCard at each interview time point.

6.1.1.4 Cross-Sectional Follow-up Interviews and Assessments

Participants will be asked to complete the patient visit experience survey after attending an in-person or telehealth visit with their doctor. The survey will be emailed to participants after confirmation of completion of the visit.

A random selection of up to 5 patients at MGH will be asked to participate in a cross-sectional, one-time, follow-up interview either at month two, four, or five. The cross-sectional interviews will be conducted by AZ DMP Product team. Evidera will contact the participants to schedule the cross-sectional interview. To maintain data privacy, a teleconference line will be provided to the participants and AZ team. The goal of the one-time interview will be to evaluate any usability and feasibility issues with patients and provide an opportunity for participants to provide feedback on areas for growth or change in the patient App that cannot be captured during longitudinal interviews. Patient participants will be remunerated $75 at the completion of the interview and paid at months 2, 4, and 5.

Approximately 6 months after first patient in, MGH staff will be asked to complete a post-study survey and patients will complete the PSQ-18, both provided via email to provide final feedback on the implementation of feasibility of the AMAZE™ patient App and clinician dashboard, and satisfaction with medical care received, respectively. MGH staff will also complete a 6-month clinical CRF.

6.1.1.5 Claims Data Export

After the participants consent to participate, Evidera, and AZ will work to export deidentified claims data at months 6. The linking of deidentified data with the clinical pilot de-identified data will be outlined in detail in a subsequent study amendment prior to month 3. Alternatively, claims data may be linked to clinical pilot participants. The processes related to claims linking will be revised during an amendment. Any procedures related to this will not be implemented until IRB approved.

6.1.2 Quality Control

6.1.2.1 Monitoring

Before the first subject is recruited into the study, the Medical Evidence and Observational Research (MEOR) Delivery Director, MEOR Operations Lead or CRO Representative (i.e., Evidera) will:

- Establish the adequacy of the facilities and the investigator's capability to appropriately select the sample; and
- Discuss with the investigator(s) (and other personnel involved with the study) their responsibilities with regards to protocol compliance, and the responsibilities of AZ or its representatives. This will be documented in an Interventional Study Primary Agreement or equivalent between AZ/delegate and the investigator.

During the study the local marketing company (MC) representative or delegate can implement different activities to assure compliance with AZ standards of quality. These activities could include but are not limited to:

6.1.2.2 Contacts with the sites to:

- Provide information and support to the investigator(s)
- Confirm that the research team is complying with the protocol and that data are being accurately recorded in the CRFs
- Ensure that the CRFs are completed properly and with adequate quality

6.1.2.3 Remote Monitoring activities for:

- Checking informed consent forms (ICF)
- Review enrollment forms and subsequent CRFs
- Export of claims data

The extent and nature of monitoring will be decided during the study planning based on design, complexity, number of subjects, number of sites, etc. Interventional Research Center (multi country)/MC will give some recommendations that could be locally adapted.

Different signals (e.g., high rejection rate in a site) should be used as potential identification of low protocol compliance by investigators.

If these or any other signal occurs or if the CRO is suspicious of a potential non-optimal level of protocol compliance by the site investigator, specific measures should be adopted to evaluate the situation, identify the issue and implement specific action plans to correct the situation.

6.1.2.4 Training of Study Site Personnel

Evidera will ensure training of MGH personnel for the implementation of AMAZE™ clinical pilot study procedures outlined in the study protocol. MGH principal investigators will ensure that appropriate training relevant to the study is provided to MGH staff, and that any new information relevant to the performance of this study is forwarded to the staff involved.

6.1.2.5 ePRO Programming and Hosting

REDCap will be used for the electronic patient and clinical site staff surveys and clinical case report forms (CRFs). The survey hosted will include the sociodemographic form, monthly patient user experience survey, patient visit experience survey, SUS, post-study survey, and PSQ-18. A separate HIPAA-compliant vendor, BrightInsight, will host the data management system to collect and monitor data captured by AMAZE™.

For both vendors, the quality assurance process will include extensive end-to-end testing. During all data collection, the survey responses will be tracked by unique participant identifiers—not participant names. All electronic surveys will be emailed to patient participants and clinical staff research participant through REDCap.

MGH will export and transfer the CRF and survey data in SAS format to Evidera via MGB Secure File Transfer. The CRF and survey data will then be entered into the database and reviewed by project scientific staff. Data discrepancies will be identified and resolved.

The web survey developed for the patient and MGH staff surveys will be tested prior to study launch.

6.2 Protection of Human Subjects

This Interventional Study will be performed in accordance with ethical principles that are consistent with the Declaration of Helsinki, ICH GCPs, GPP and the applicable legislation on Non-Interventional Studies and/or Interventional Studies.

The Investigator will perform the clinical pilot Study in accordance with the regulations and guidelines governing medical practice and ethics in the country of the clinical pilot Study and in accordance with currently acceptable techniques and know-how.

The final protocol of the clinical pilot Study, including the final version of the Patient Informed Consent Form, must be approved or given a favourable opinion in writing by the Ethics Committee/Institutional Review Board (IRB)/Independent Ethics Committee (IEC).

The Ethics Committee/IRB/IEC must also approve any amendment to the protocol and all advertising used to recruit subjects for the study, according to local regulations.

6.2.1 Informed Consent

MGH staff will be responsible for ensuring that each participant (patients and MGH staff) fully understands the study's nature, purpose, procedures, risks, and benefits. For those patients and MGH staff taking part in the clinical pilot launch, electronic consent will be presented to them via REDCap. At the screening, the MGH staff will confirm the email address to send the REDCap document to and update the dashboard as needed with any patient email addresses that are not in the system. Evidera will provide the email addresses collected at the baseline visit to the web-based survey vendor via secure portal. MGH staff will review the consent (either in person or via telephone) and answer any questions. MGH staff will confirm the email address with the participant during the initial screening process.

Participants (patients and MGH staff) will also be informed of their rights as a participant, including that they may refuse to take part or withdraw at any time without penalty or giving up any benefits to which they are otherwise entitled. The participants also will be informed that, should they choose not to participate in all or any part of the study, their current or future treatment at the site will not be affected.

This study involves participant-completed measures for information purposes only; the study does not involve the use of an investigational drug or device. There are no known risks or benefits to participants. During or following the research study, patients may become more aware of how they feel about their condition—and how their condition may affect certain aspects of their life. Patients will be encouraged to talk with their asthma provider about their questions or concerns. The elements of federal regulations pertaining to consent procedures, disclosure of potential risks and benefits, and patient confidentiality will be strictly observed.

6.2.2 Confidentiality of Study/Patient Data

All data collected will be strictly confidential, in accordance with local, state, and federal law. Personnel from the following organizations may examine the research study records: Evidera, AZ, and regulatory agencies (such as the FDA and the IRB). Only MGH staff involved in participant recruitment, clinical data extraction, and questionnaire administration will know the identities of the patients. Staff will be instructed to maintain complete confidentiality of all collected data. Participant data files collected by MGH and shared with either Evidera or AZ will be kept in a locked file cabinet separate from their identifying information and will be destroyed per Evidera's SOPs after a period of seven years. The summary report generated from the completed questionnaires will not contain any participant-identifying information. Medical data collected will not be associated with personal health identification data. All study data will be de-identified.

Evidera retains records for a minimum of two years on site, and an additional five years off site. Upon enrollment, participants will be assigned unique identification numbers. These unique

identifiers will be used to track the participants throughout the study. Only the unique participant identification numbers and participant initials will be entered into the database and recorded on the participant questionnaires—not participant names.

This interventional study will be performed in accordance with ethical principles that are consistent with the Declaration of Helsinki, International Council for Harmonization (ICH), Good Clinical Practice (GCP), and the applicable legislation on Interventional Studies.

The investigators will perform the clinical pilot study in accordance with the regulations and guidelines governing medical practice and ethics in the country of the interventional study, and in accordance with currently acceptable techniques and know-how.

The final clinical pilot study protocol, including the final version of the Patient and MGH Informed Consent Form, must be approved or given a favorable opinion in writing by the Ethics Committee/IRB/Independent Ethics Committee (IEC).

The Ethics Committee/IRB/IEC must also approve any protocol amendment and all advertising used to recruit subjects for the study, according to local regulations.

6.3 Collection and Reporting of Adverse Events/Adverse Drug Reactions

6.3.1 Collection of Adverse Events

This is an interventional study with no requirements to actively collect adverse events during the study since enrollment in the study is based on disease diagnosis and does not require the administration of an AZ drug. However, if an investigator (or patient) would like to report an AE that is not required to be collected, this can be reported as a spontaneous report according to local regulations. The open-ended question in the feedback section of the App will be monitored for AE reporting by the AZ Production team.

6.3.2 Reporting of Adverse Events

It is not necessary to report potential AEs based on answers to the ACT™.

The rationale is, the signs and symptoms collected by these instruments are prevalent among asthmatic patients. It is not feasible to evaluate associations between a specific drug and events reported by patients based on these instruments due to lack of baseline disease information and temporal relationship of drug and event. According to the literature, more than 50% of asthma patients who are under medication will have such signs and symptoms.

Patients will be informed that their healthcare providers (including MGH staff and their clinician) will not be reviewing their responses to the study questionnaires in real time. They will be

instructed to report any health concerns or issues that they may experience directly to their healthcare providers.

6.3.3 Aggregate Safety Review from PRO Instruments

An aggregate data report (in the form of a summary) of the PROs' scores from patients on AZ product(s) will be provided to the Global Safety Physician (GSP) and Safety Surveillance and Management Team (SSaMT) Lead for their review at the end of the study, so that the data can be considered in the context of the overall benefit: risk assessment of the product(s).

7. REFERENCES

1. Moore WC, Bleecker ER, Curran-Everett D, et al. Characterization of the severe asthma phenotype by the National Heart, Lung, and Blood Institute's Severe Asthma Research Program. *J Allergy Clin Immunol.* 2007;119(2):405-413.

2. Nunes C, Pereira AM, Morais-Almeida M. Asthma costs and social impact. *Asthma Research and Practice.* 2017;3(1):1.

3. Nathan RA, Sorkness CA, Kosinski M, et al. Development of the asthma control test: a survey for assessing asthma control. *J Allergy Clin Immunol.* 2004;113(1):59-65.

4. Bangor A, Kortum PT, Miller JT. An Empirical Evaluation of the System Usability Scale. *International Journal of Human–Computer Interaction.* 2008;24(6):574-594.

5. Marshall GN HR. The Patient Satisfaction Questionnaire Short-Form (PSQ-18). In. Santa Monica, CA: Rand Corp.; 1994.

8. APPENDIX A. PATIENT SCREENING SCRIPT

Prior to initiating screening contact, please confirm the following from the patient's chart:

The patient has a clinical diagnosis of asthma	Confirmed ☐
The patient is at least 18 years of age (*Recruitment quota: approximately 33 young adult patients (18–35 years of age)*	Confirmed ☐
Recruitment Quota only: New patients to the practice (less than 3-month history) and with uncontrolled asthma	Confirmed ☐
Recruitment Quota only: At least one exacerbation per year	Confirmed ☐

Introductory Script for Clinical Pilot Study Participants

Hello [patient name], my name is [interviewer name] and I am working with MGH and AstraZeneca on a research study to evaluate a new smart phone app called AMAZE™ to monitor asthma symptoms and to provide resources that may be helpful for asthma patients like you. I will provide some basic information about this study and ask you some questions to find out if you might qualify for the study. This conversation will take about 20 minutes, is this a good time to talk? _____Yes _____ No

If no, thank you for your time today!

If yes, thank you for your interest.

We are participating in a research study with Evidera and AstraZeneca, a health outcomes research organization and Pharmaceutical company, to evaluate a new patient App that will help you monitor your asthma daily and provide resources that may be helpful for asthma patients like you. The goal of this study is to see if the patient App helps improve your care. Information from your medical records, such as your age, medications, existing medical conditions, will be collected for this study.

You will be asked to use the App over the next six months by completing the daily questions and will have access to educational materials provided in the App. A brief sociodemographic form will be sent via email for your completion, as well as periodic surveys to gain additional

information about your experiences using the App. If you agree to participate, you will be emailed a link to download the App with a unique ID. You will be compensated $10 for each visit completed and paid at baseline, months 1, 3 and 6 for a potential total of $40.

As a part of this study, some participants will be randomly selected to complete a series of telephone interviews (around 1, 3, and 6 months after enrolling in the study) or just one interview (around 2, 4, or 5 months after enrolling in the study) to be conducted by Evidera or AstraZeneca. If selected for the interviews, the interview will be audio recorded and transcribed by a third-party vendor (TransPerfect), and should last approximately 30 to 45 minutes.

Subjects will get $10 for each visit completed and $75 for each interview. The maximum each subject may receive for completion of visits is $40. Subjects will be randomized into one of three groups. Participants will only complete one of these groups:

4. Longitudinal (three total) interviews and receive up to $265

5. Cross-sectional (one-time) interviews and receive up to $115

6. Not randomized to be interviewed and receive up to $40

As a participant in this research study, there will be no direct benefits for you; however, information from this study may help health care providers improve the way they ask patients questions about their asthma.

The risks of the study are expected to be minimal. There is the risk that allowing us to record your name with your answers and accessing your health information is a possible loss of confidentiality. We will take reasonable steps to protect the confidentiality of your information.

Taking part in this study is voluntary. You may choose not to take part in this study, or if you decide to take part, you can change your mind later and withdraw from the study. Your decision will not change any present or future relationships with MGH or its affiliates.

Are you interested in participating this study? _____Yes _____ No

If no, thank you for your time today!

If yes, thank you for your interest.

Before moving forward, would you be willing to answer some questions to find out if you might qualify for the study? I will record your answers in writing, but only collect detailed contact information if you qualify for the study. May I begin? _____Yes _____ No

Can you confirm if you have a smartphone with internet access? _____Yes _____ No

If yes, what type of smartphone and operating system do you have?
_____iPhone (OS and Type) _____ Android (OS) _____Other

If the participant does not have an iPhone 8 or newer with an Operating System of 13 or newer or an Android with an Operating System of 8.0 or newer, the participant is not eligible to participate and thank them for their time!

As a part of the study you will be sent an emailed link with your unique ID to log-in to the application as well as instructions for how to download the app.

I need to collect some information from you to share with Evidera in order to make your profile for the reloadable gift card, ClinCard, and share your email address for sending you the study consent form and for future survey completion.

Do you grant permission for the study team to send you the full study consent form via email for you to review and sign? _____Yes _____ No

Do you grant permission for the study team to leave a brief voice mail message if you are not available when the study team schedules calls? _____Yes _____ No

Contact Information (AMAZE™ App)

Dear Research Participant,

Thank you for taking part of the AMAZE™ Asthma Research Study at Massachusetts General Hospital (MGH).

As part of the study procedure, please complete the form below to confirm your contact information. This will be used to set up your profile for payment.

If you have any questions, please contact the Study Team at CCI .

Thank you!

First Name (Please enter your First Name in full, do not use an initial)

_____

Last Name (Please enter your Last Name in full, do not use an initial)

_____

Date of birth: _____

Street or PO Address: _____

City:_____ State:_____ Zip code:_____

Phone Number: (Home) _____ (Work) _____ (Cell) _____

Email: _____

Do you grant permission for the study team to leave a brief voice mail message if you are not available when the study team schedules calls?

☐ Yes
☐ No

Preferred location to call:

☐ Home
☐ Work
☐ Cell

Best time to call (Monday-Friday 9am-5pm):_____

9. APPENDIX B. ELECTRONIC CONSENT EMAIL

Signature Line Subject:
AMAZE™ Health Management MGH Asthma Mobile App Study – Electronic Consent Form

Body of Consent E-mail:

Dear [Participant]:

Thank you for your interest in our research study about a newly developed mobile app for asthma patients.

Prior to participating in the study, you will need to provide consent electronically. **When instructed to do so by the MGH staff, please go to the following URL: *<insert consent URL>***

Thank you,

<insert MGH contact person signature line>

10. APPENDIX C. RECRUITMENT EMAIL AND FLYER

Recruitment email to be sent to the patient participants:

Subject: MGH AMAZE Asthma Study Participation
Attach: MGH Flyer PDF (**check latest version of this**)

Dear Salutation Last Name,

We invite you to participate in a research study alongside AstraZeneca (**a pharmaceutical company**) and Evidera (**a health outcomes research organization**) to evaluate a smartphone application (**app**) called, **AMAZE™** that may assist you in monitoring your asthma on a daily basis. The overall goal of this study is to evaluate if the patient App helps improves your care!

If interested, and you decide to participate in this voluntary study, you will be asked to use the App for six months by completing a daily assessment logs (**~1 minute per day**). You will also be asked to complete periodic user feedback surveys to gain insight about your experiences using the App. There will be total of approximately 7 surveys throughout the study and would take no more than a few minutes to complete each, and you would receive $40 total for completion of all surveys. For this study, if you choose to participate, some participants will also be asked to be randomly selected to complete a set of three telephone interviews (**or a one-time interview**) which will be conducted by Evidera, our health outcomes collaborator. For these additional interviews, you will be paid $75 for each completed interview (**if randomly selected**).

The risks of the study are expected to be minimal. There is the risk that allowing us to record your name with your answers and accessing your health information is a possible loss of confidentiality. We will take reasonable steps to protect the confidentiality of all your information.

If you are interested, please respond to this email and we can set up a brief discussion to address project details and the informed consent documentation. Following the informed consent process, we can then download the app and set up your account.

Attached is the study flyer providing a brief introduction to the app.

We look forward to your response either way!

Thanks in advance,

Signature block of provider and either PPD **or** PPD

MGH AMAZE™ Asthma Study Team
Massachusetts General Hospital
55 Fruit St. Boston, MA 02114
CCI

Recruitment email to be sent to the clinical staff research participant:

Dear _____,

Thank you for your interest in our research study about a newly developed mobile app for asthma patients. In this research study we want to evaluate the AMAZE™ App to help monitor MGH asthma patients. The goal of this study is to learn about the impact of this digital disease management platform on the quality of life, outcomes, and treatment of asthma patients.

If you decide to join this research study, it will take you about 6 months to complete the study. You will be asked to provide your personal opinion (by completing the post-study survey and system usability scale surveys), as a MGH clinical staff involved in the study, to gain a deeper understanding of the feasibility of implementing the asthma AMAZE™ platform. There will be a total of 3 surveys throughout the research study and would take no more than a few minutes to complete each survey, and you will not be paid for completing these surveys.

Prior to participating in the study, you will need to provide consent electronically. **When invited to do so by the study staff, please go to the following URL: *<insert consent URL>***

For questions, please send an email to the study team: CCI

Thanks,

MGH AMAZE™ Asthma Study Team

MASSACHUSETTS GENERAL HOSPITAL

A research study to monitor your asthma through an app:

Introducing Key Features

Daily Log
Share information like symptoms, triggers, and more directly with your care team.

Trends
Spot patterns in your asthma through weekly charts and graphs.

Medications
View your list of medications and set reminders so you never forget to take them.

Air Quality
See the latest air quality conditions and set air alerts so you know when it is safe out.

Messaging
Message your care team any non-urgent medical questions.

Safe and Secure
Your personally identified health data will be safe and secure on the platform and only shared directly with your care team.

Amaze App
Stay connected for better asthma control

GET IT ON Google Play

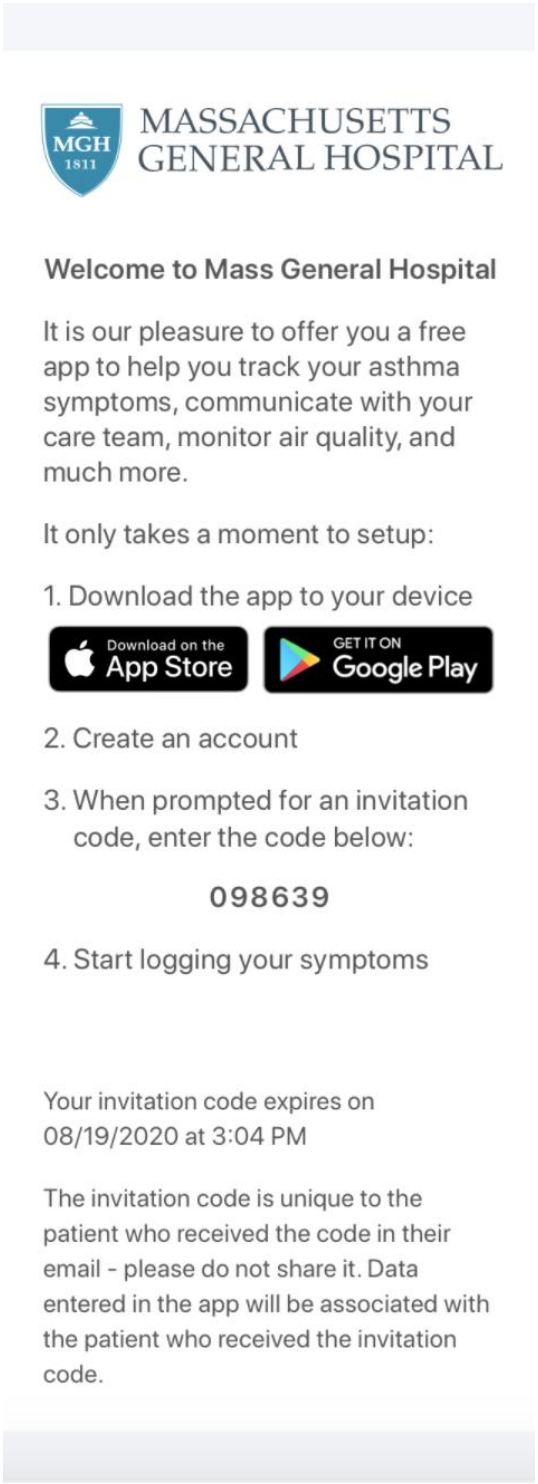
Download on the App Store

If you have any questions, please contact the research study team at:

CCI [redacted]

11. APPENDIX D. INTRODUCTORY EMAIL

The code and invitation code expiration date and time will be modified for each individual participant.



12. APPENDIX E. AMAZE™ PATIENT MOBILE APPLICATION SCREENSHOTS

12.1 Flyer for App

MASSACHUSETTS GENERAL HOSPITAL

Amaze App
Stay connected for better asthma control

Scan the code with your phone's camera and download the app.

GET IT ON Google Play

Download on the App Store

Introducing Key Features

Daily Log
Share information like symptoms, triggers, and more directly with your care team.

Trends
Spot patterns in your asthma through weekly charts and graphs.

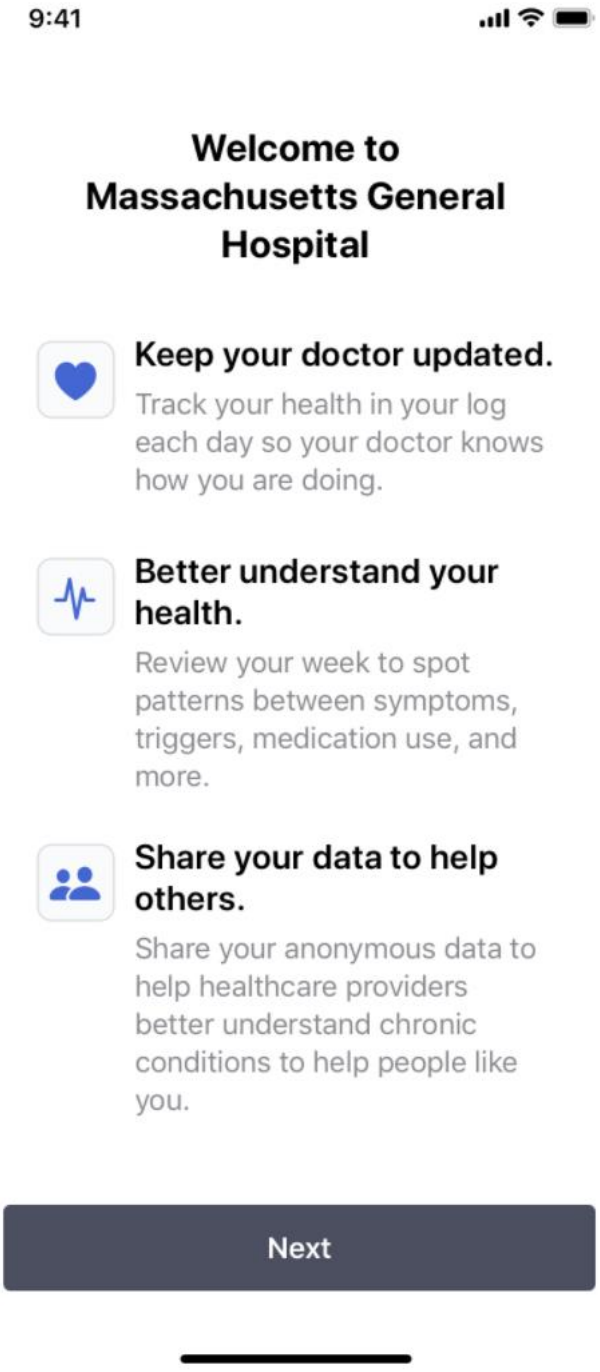
Medications
View your list of medications and set reminders so you never forget to take them.

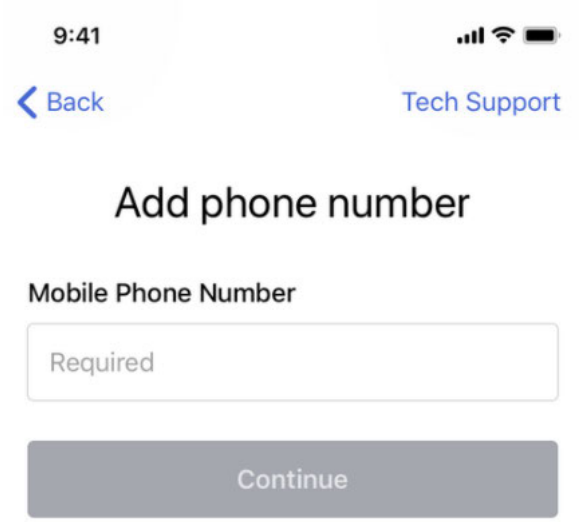
Air Quality
See the latest air quality conditions and set air alerts so you know when it is safe out.

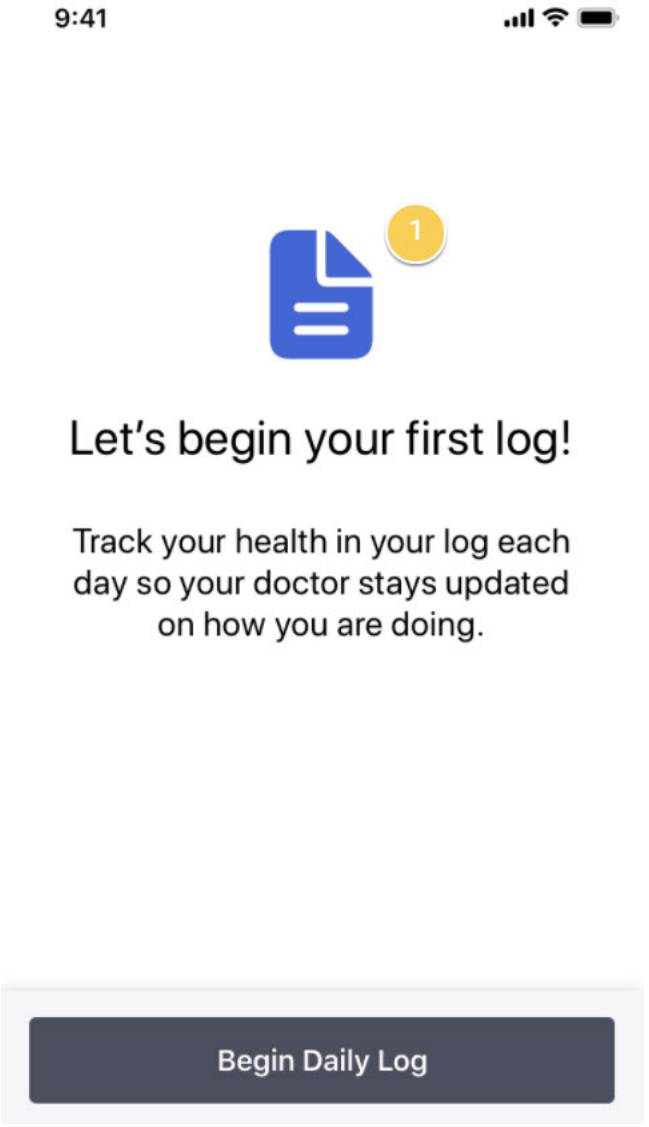
Messaging
Message your care team any non-urgent medical questions.

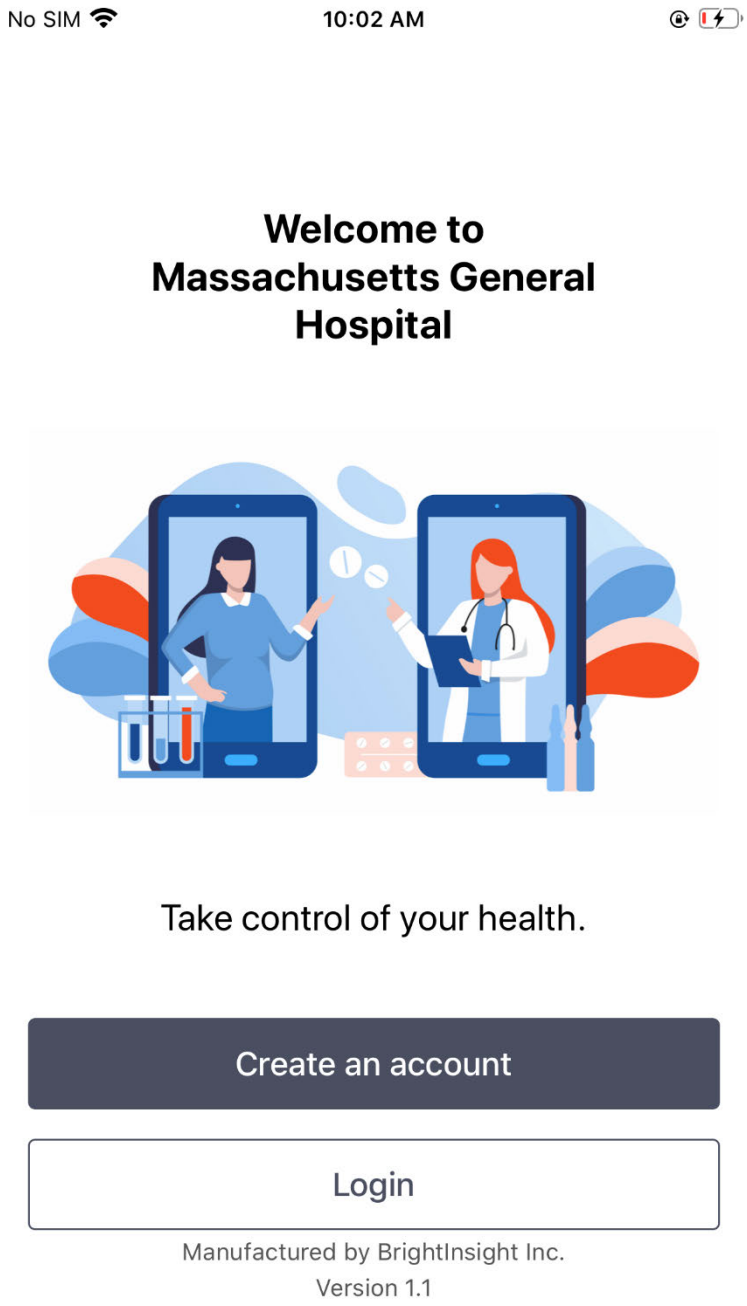
Safe and Secure
Your personally identified health data will be safe and secure on the platform and only shared directly with your care team.

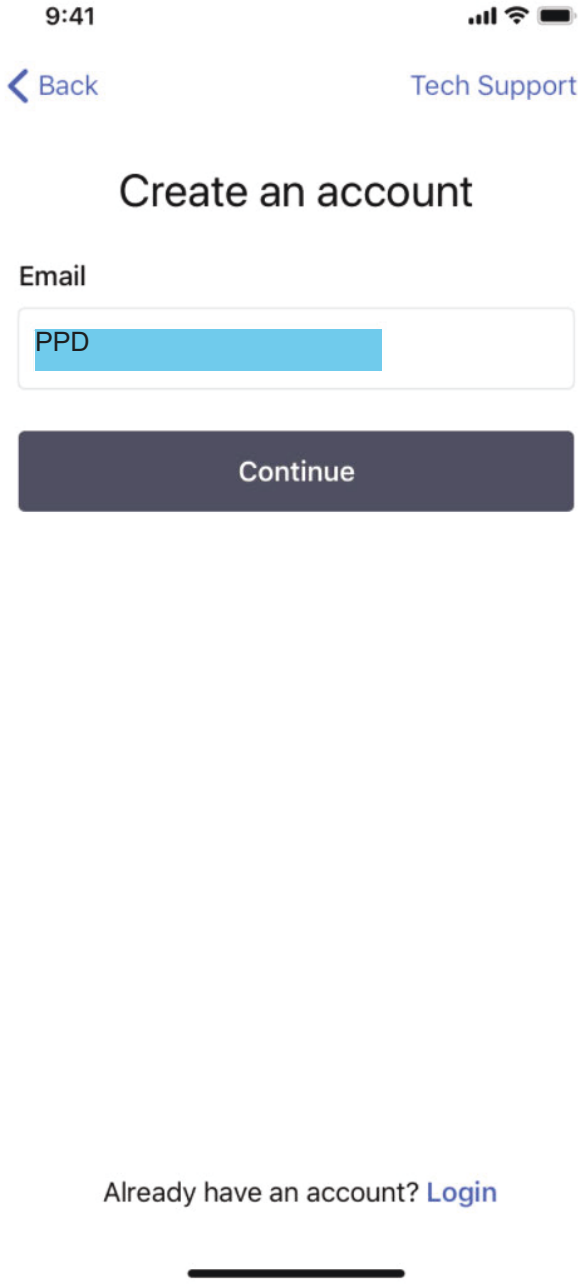
12.2 Account Creation and Login

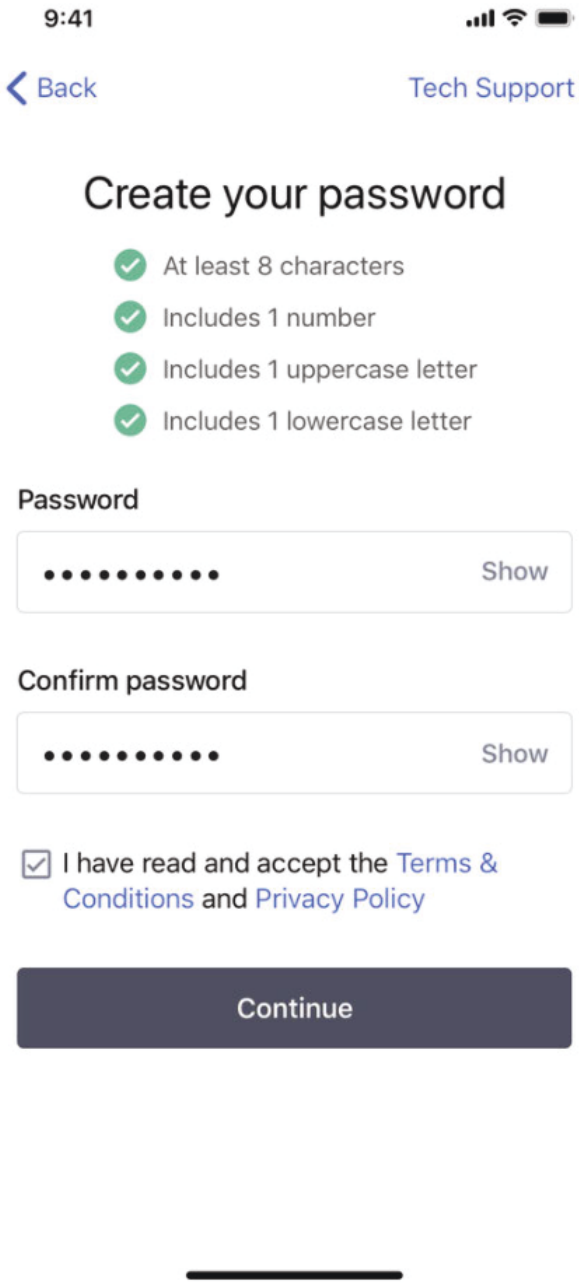


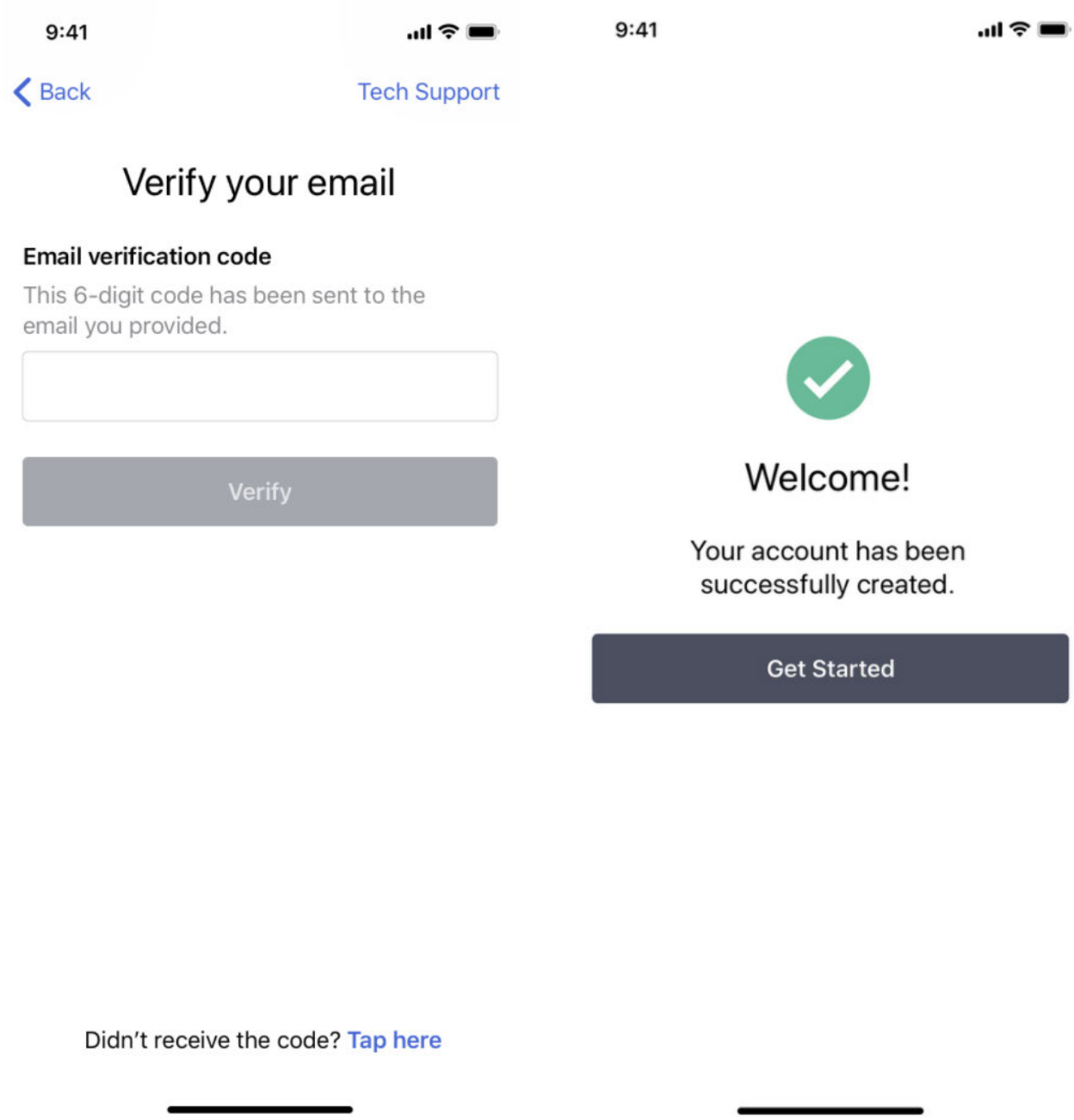

9:41
Back
Tech Support
Add phone number
Mobile Phone Number
Required
Continue


9:41
1
Let's begin your first log!
Track your health in your log each day so your doctor stays updated on how you are doing.
Begin Daily Log


No SIM
10:02 AM
Welcome to Massachusetts General Hospital
Take control of your health.
Create an account
Login
Manufactured by BrightInsight Inc.
Version 1.1


9:41
Back
Tech Support
Create an account
Email
PPD
Continue
Already have an account? Login


9:41
Back
Tech Support
Create your password
At least 8 characters
Includes 1 number
Includes 1 uppercase letter
Includes 1 lowercase letter
Password
Show
Confirm password
Show
I have read and accept the Terms & Conditions and Privacy Policy
Continue



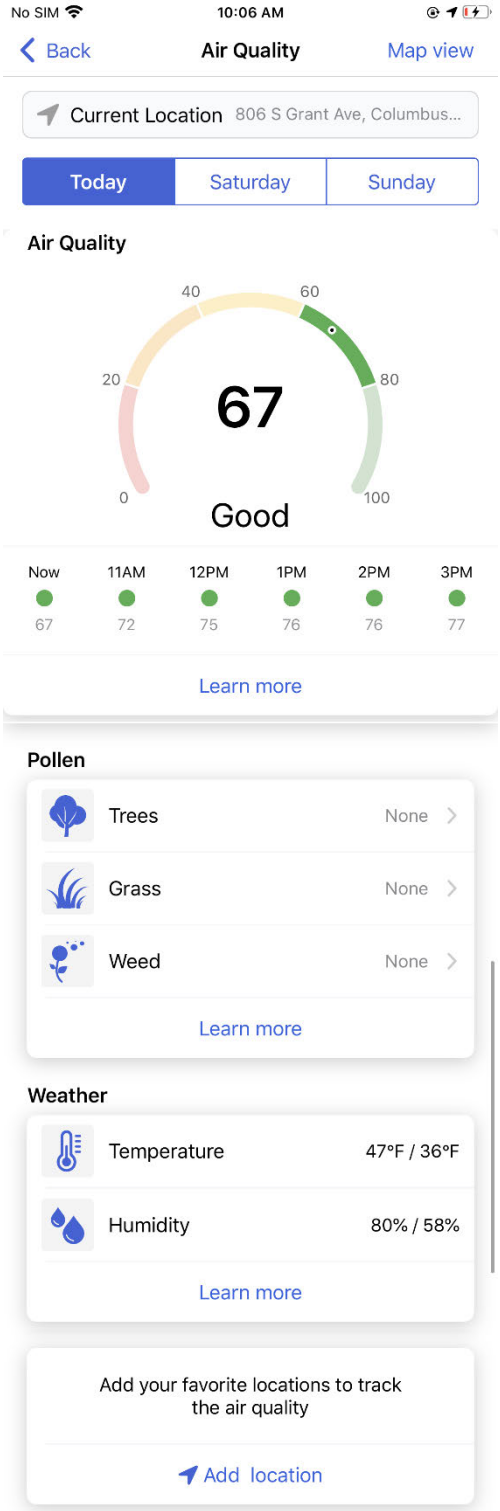
12.3 Terms of Use

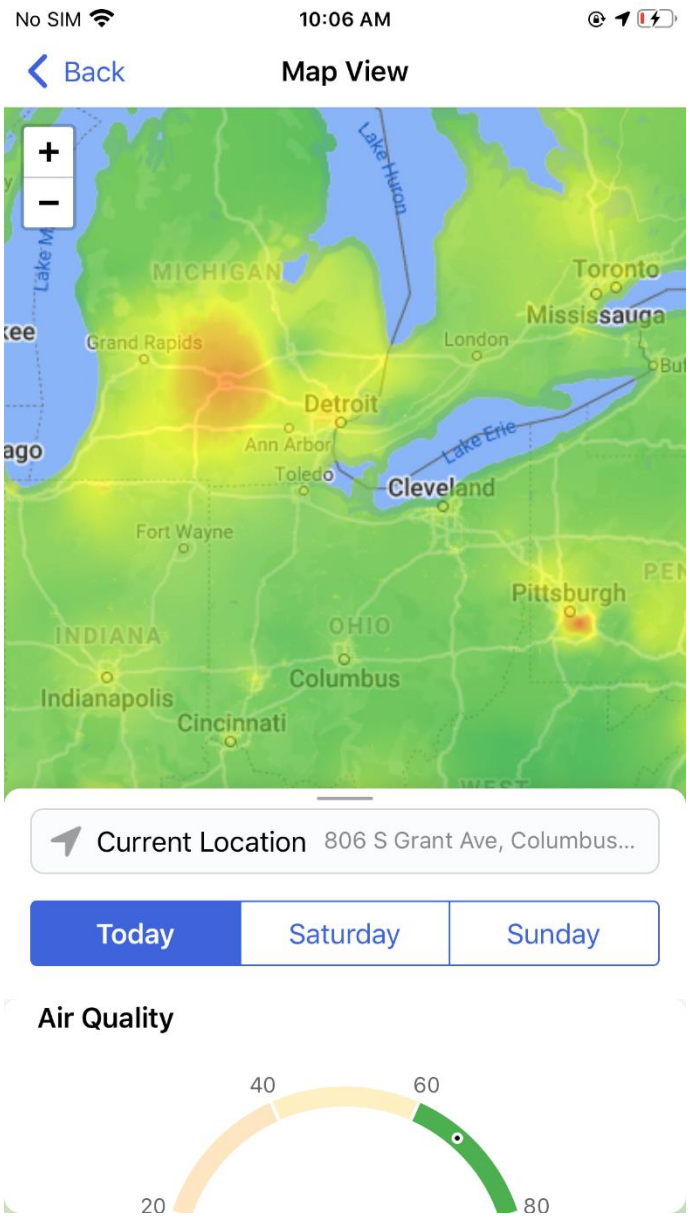
AZ - MGH - AMAZE
DMP - Clinician Port

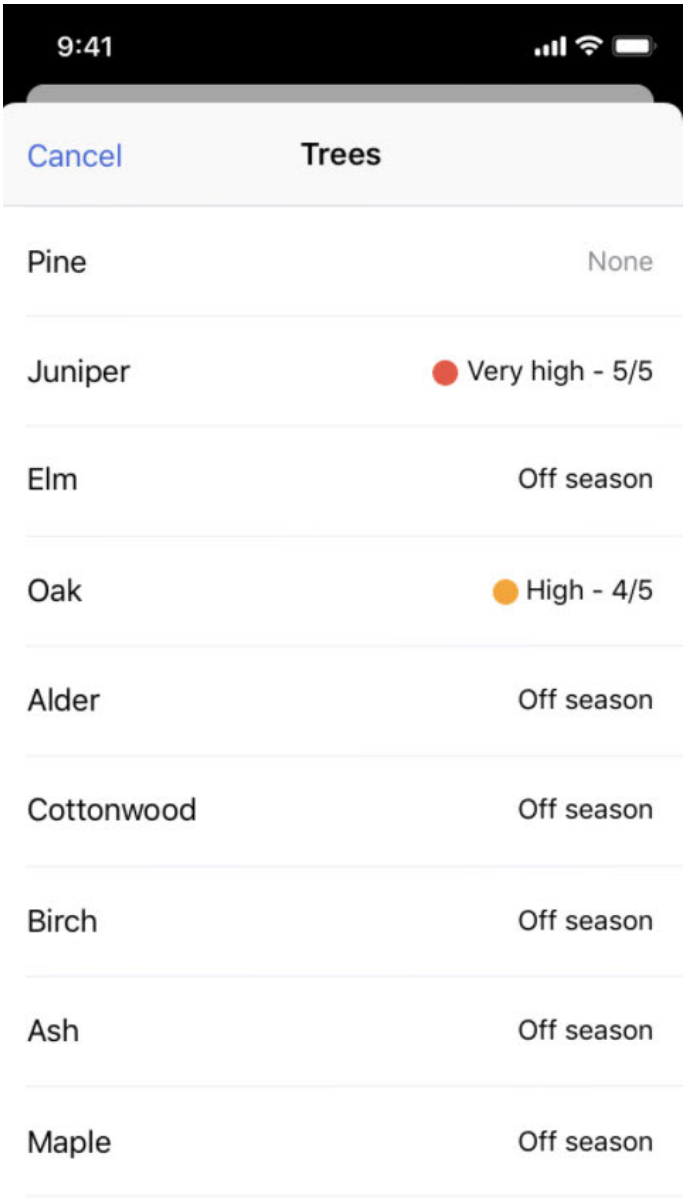
AZ - MGH - AMAZE DMP - Privacy Policy

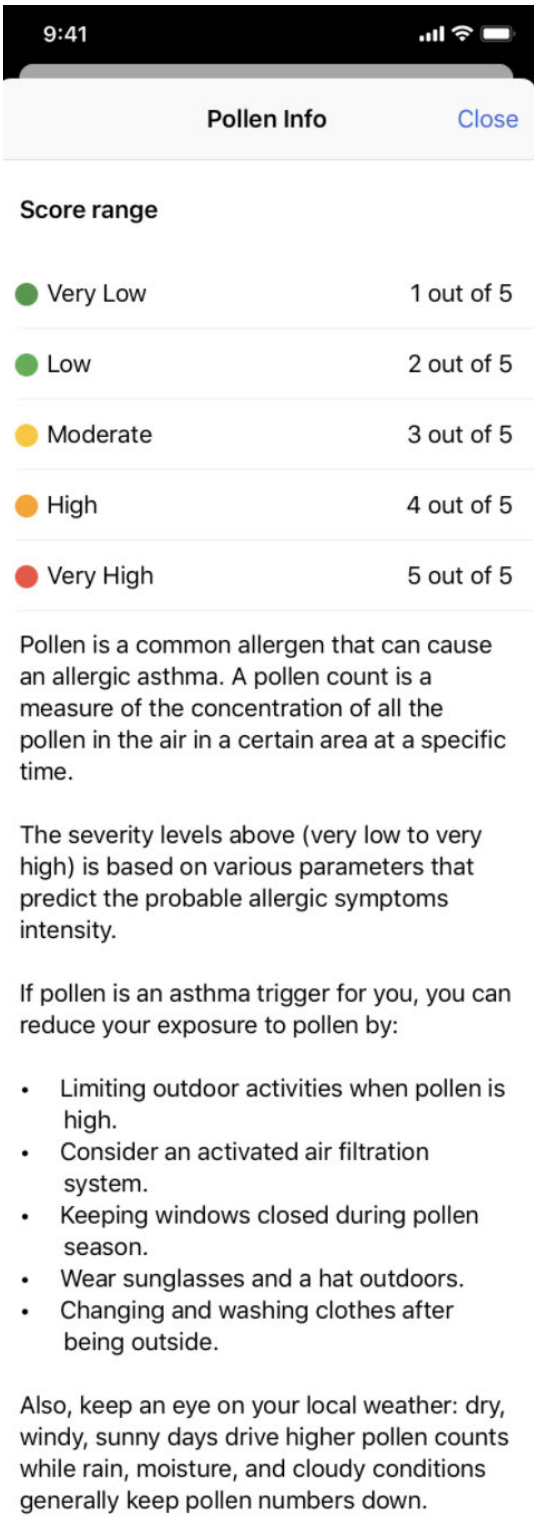
AZ - MGH - AMAZE DMP - Patient Terms

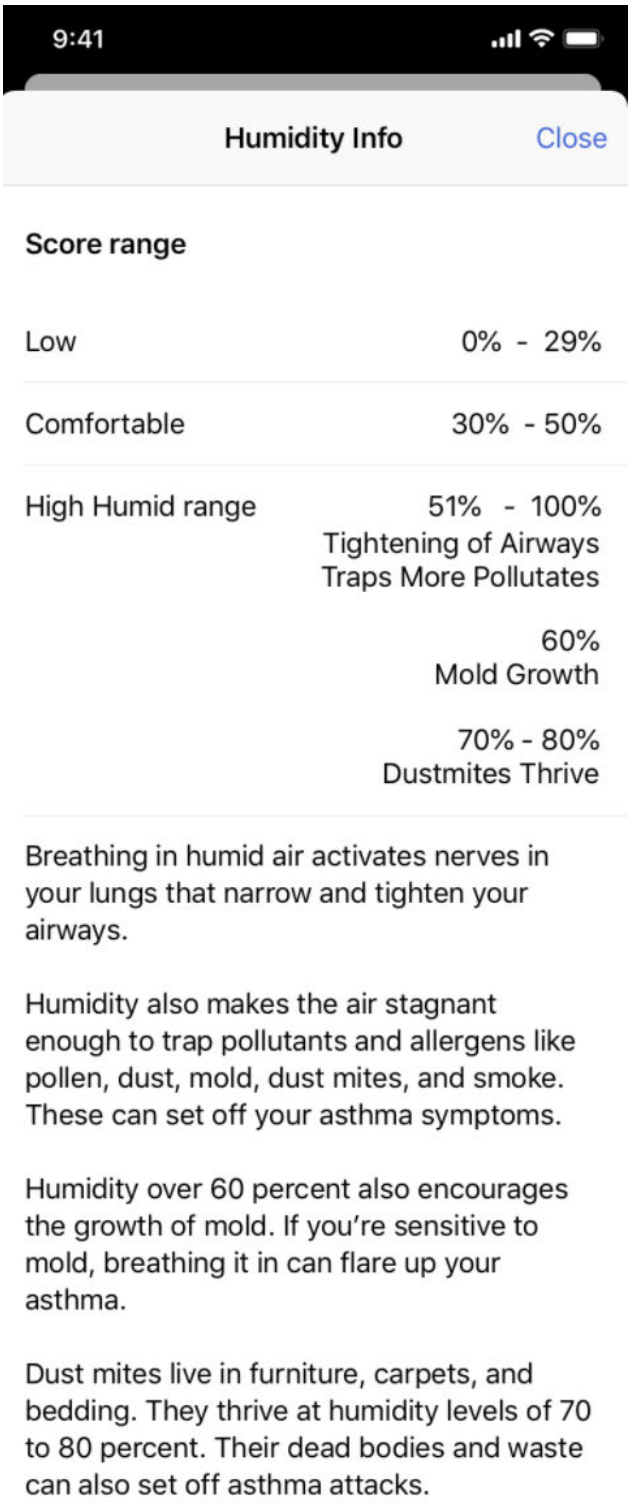
12.4 Air Quality





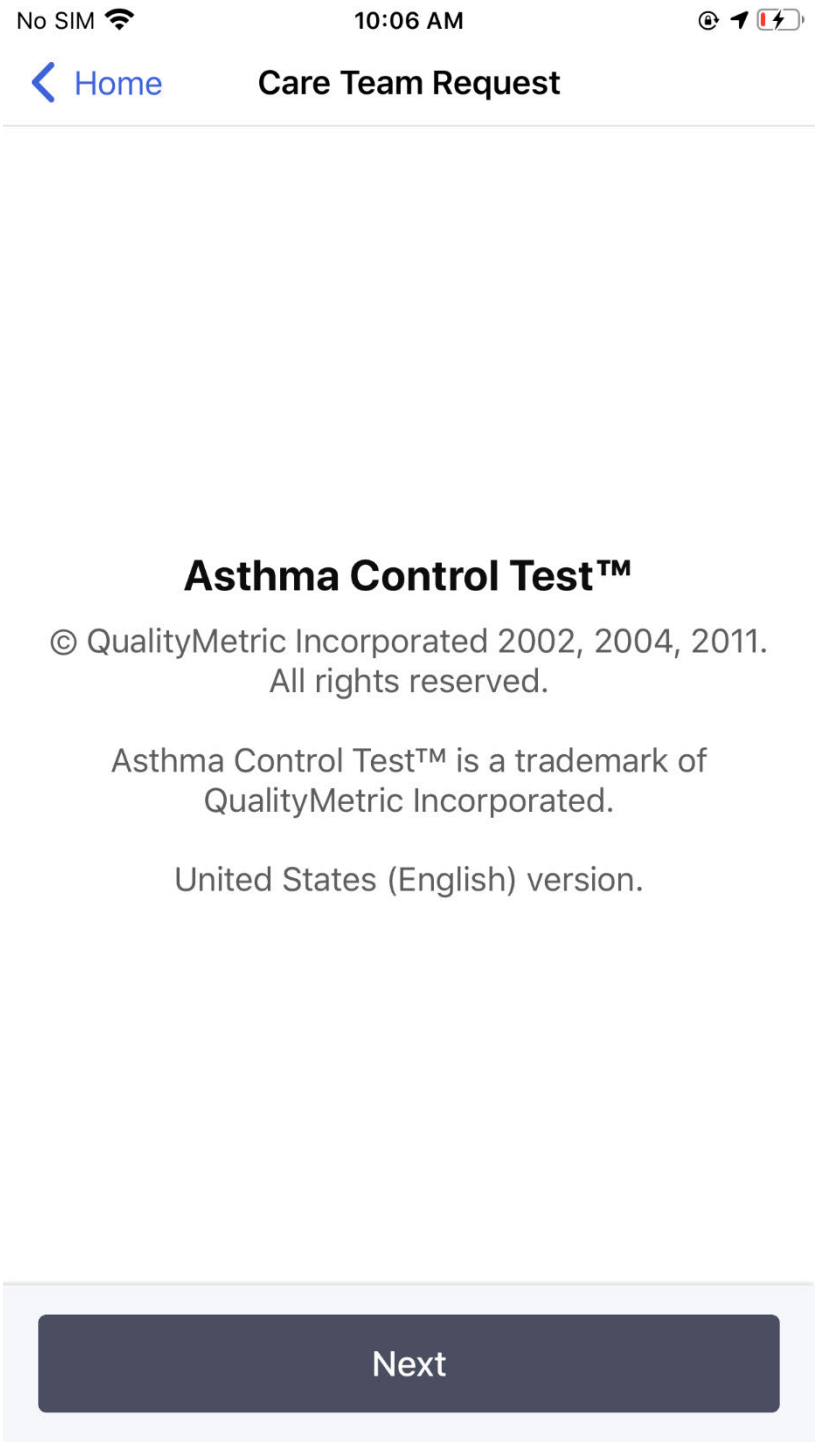

9:41
Cancel
Trees
Pine
None
Juniper
Very high - 5/5
Elm
Off season
Oak
High - 4/5
Alder
Off season
Cottonwood
Off season
Birch
Off season
Ash
Off season
Maple
Off season


9:41
Pollen Info
Close
Score range
Very Low
1 out of 5
Low
2 out of 5
Moderate
3 out of 5
High
4 out of 5
Very High
5 out of 5
Pollen is a common allergen that can cause an allergic asthma. A pollen count is a measure of the concentration of all the pollen in the air in a certain area at a specific time.
The severity levels above (very low to very high) is based on various parameters that predict the probable allergic symptoms intensity.
If pollen is an asthma trigger for you, you can reduce your exposure to pollen by:
• Limiting outdoor activities when pollen is high.
• Consider an activated air filtration system.
• Keeping windows closed during pollen season.
• Wear sunglasses and a hat outdoors.
• Changing and washing clothes after being outside.
Also, keep an eye on your local weather: dry, windy, sunny days drive higher pollen counts while rain, moisture, and cloudy conditions generally keep pollen numbers down.

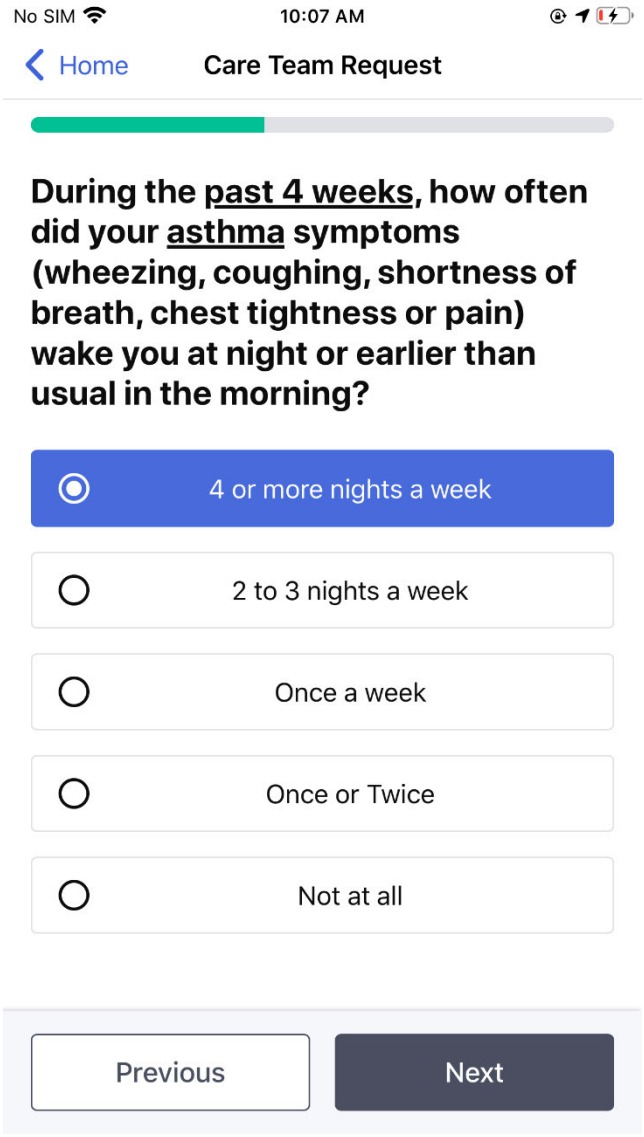


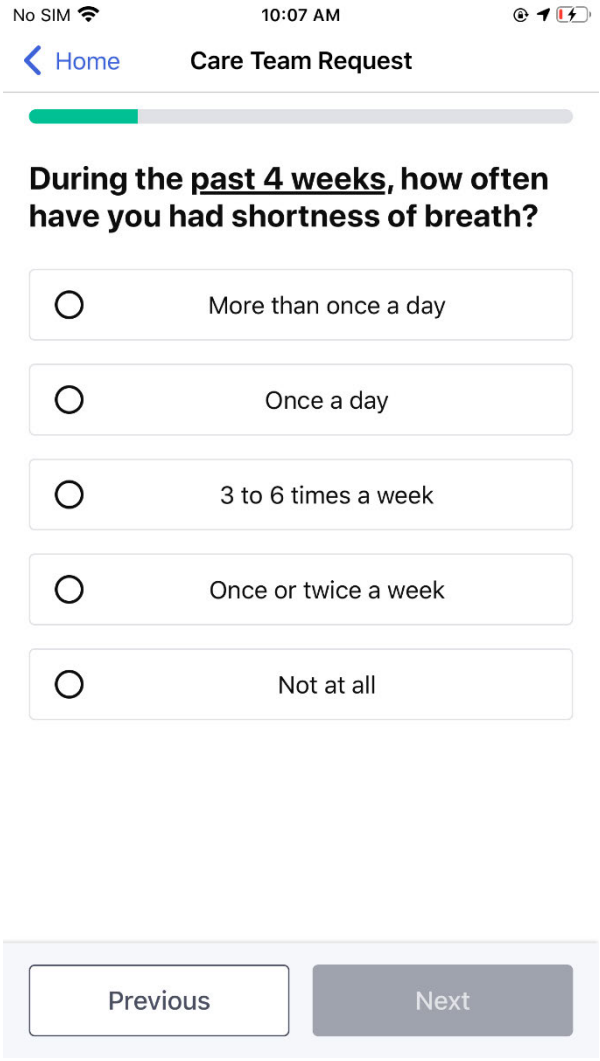
12.5 Appointments

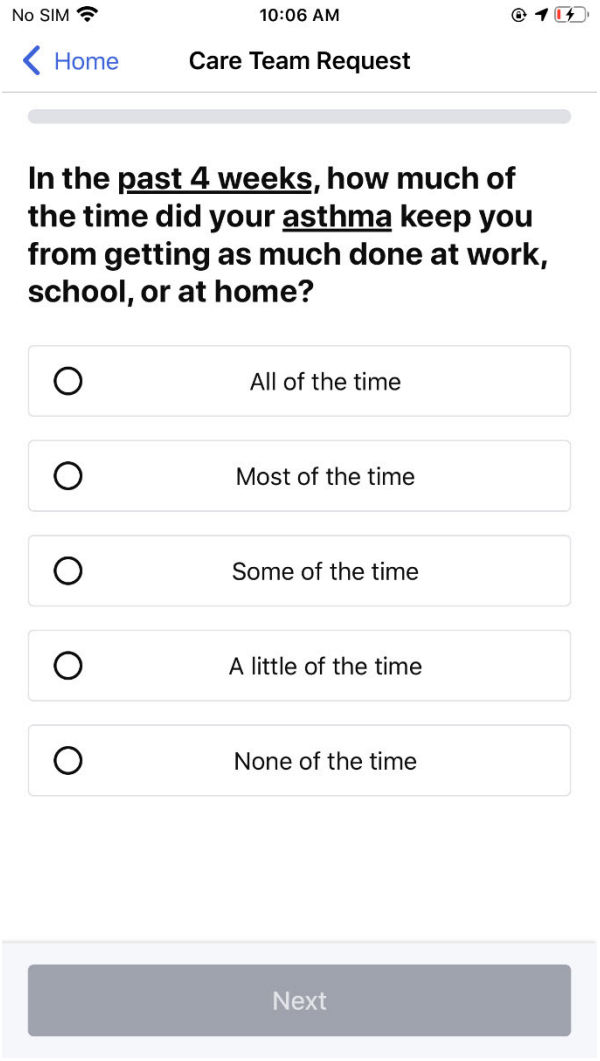
12.6 Asthma Control Test

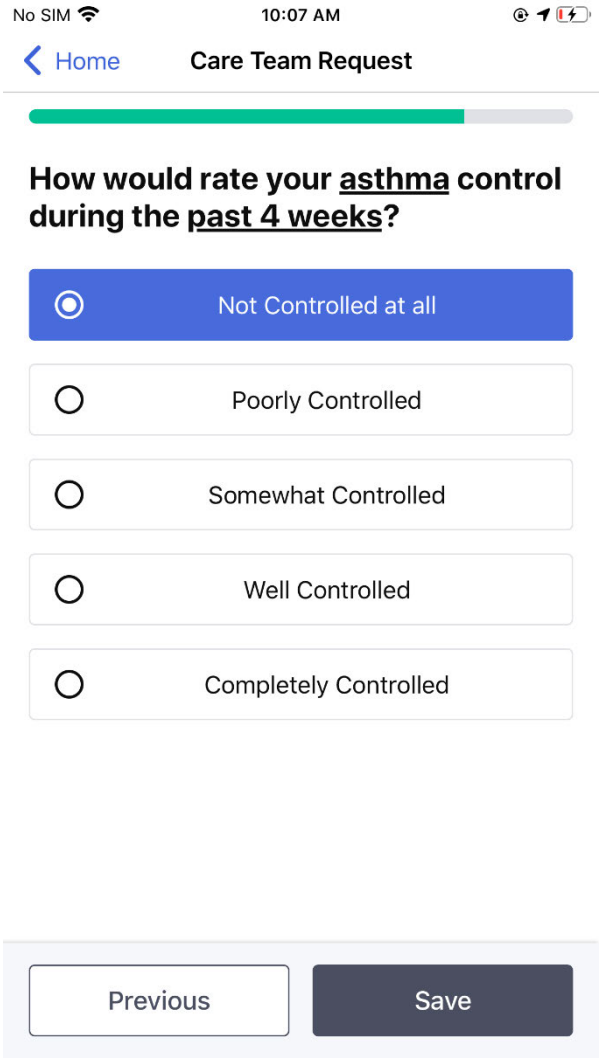


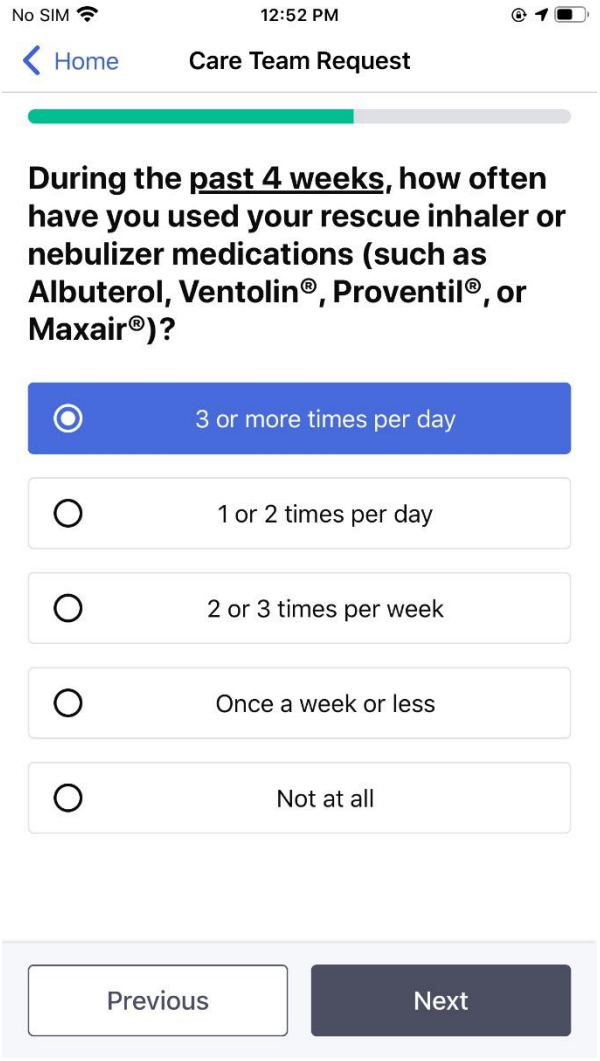

No SIM
10:06 AM
Home
Care Team Request
Asthma Control Test™
This survey was designed to help you describe your asthma and how your asthma affects how you feel and what you are able to do. For each of the following questions, please select the one response that best describes your answer.
Next


No SIM
10:07 AM
Home
Care Team Request
During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you at night or earlier than usual in the morning?
4 or more nights a week
2 to 3 nights a week
Once a week
Once or Twice
Not at all
Previous
Next

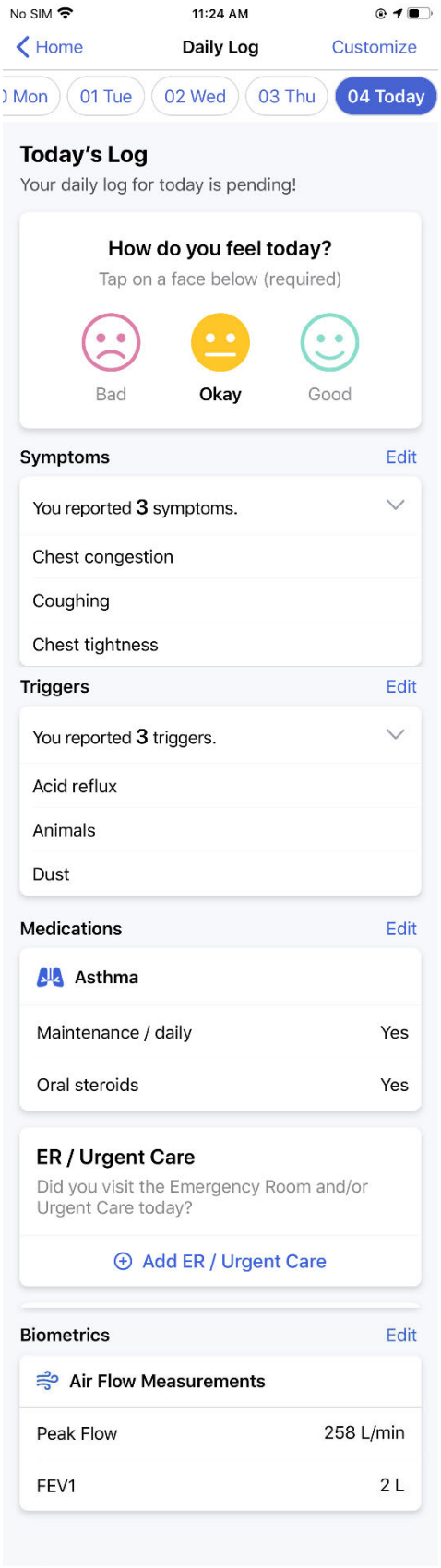

No SIM
10:07 AM
Home
Care Team Request
During the past 4 weeks, how often have you had shortness of breath?
More than once a day
Once a day
3 to 6 times a week
Once or twice a week
Not at all
Previous
Next

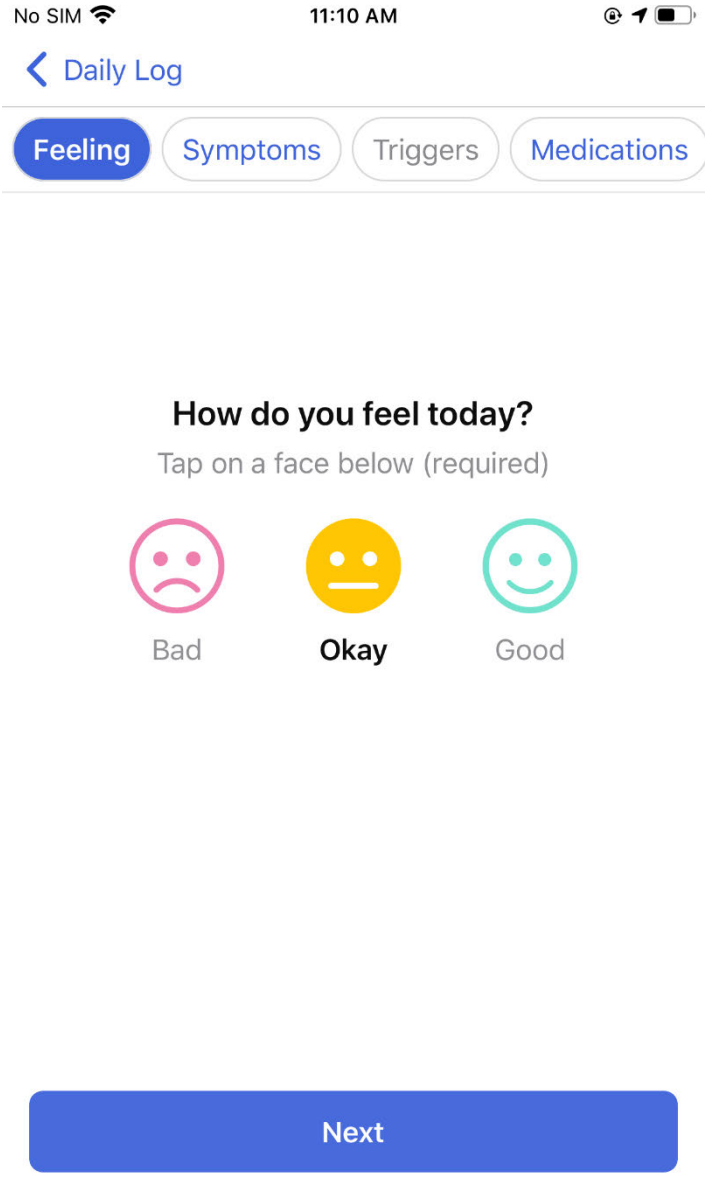

No SIM
10:06 AM
Home
Care Team Request
In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school, or at home?
All of the time
Most of the time
Some of the time
A little of the time
None of the time
Next

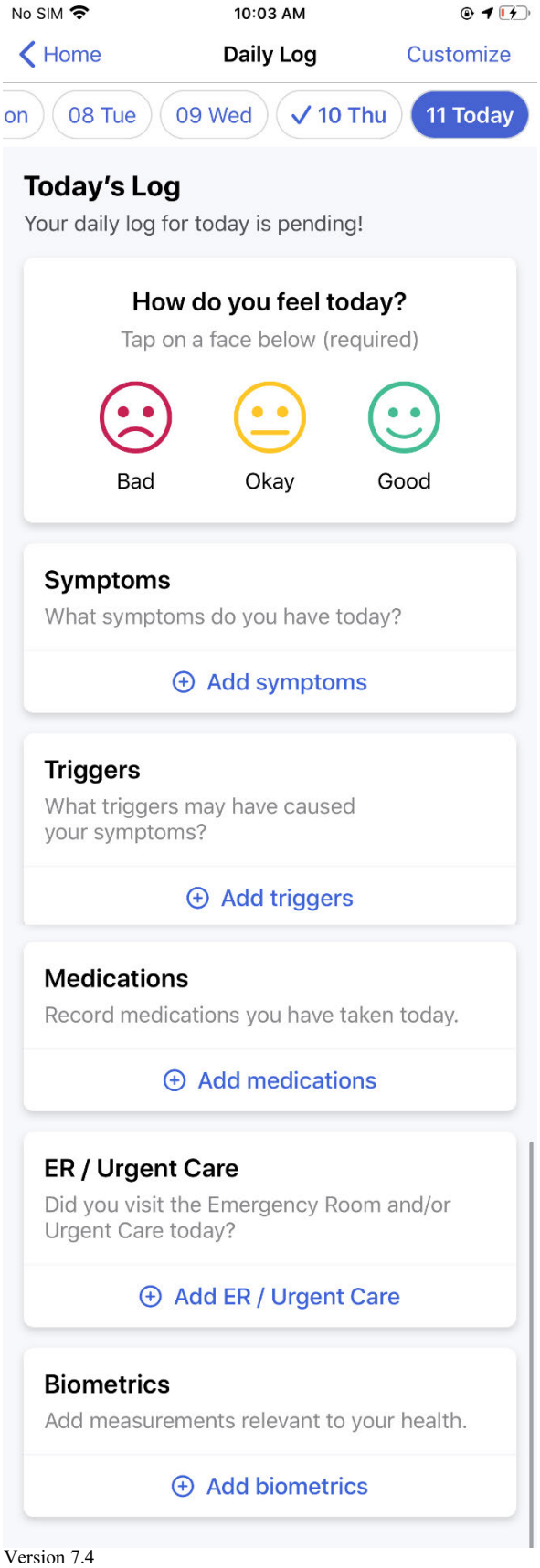

No SIM
10:07 AM
Home
Care Team Request
How would rate your asthma control during the past 4 weeks?
Not Controlled at all
Poorly Controlled
Somewhat Controlled
Well Controlled
Completely Controlled
Previous
Save

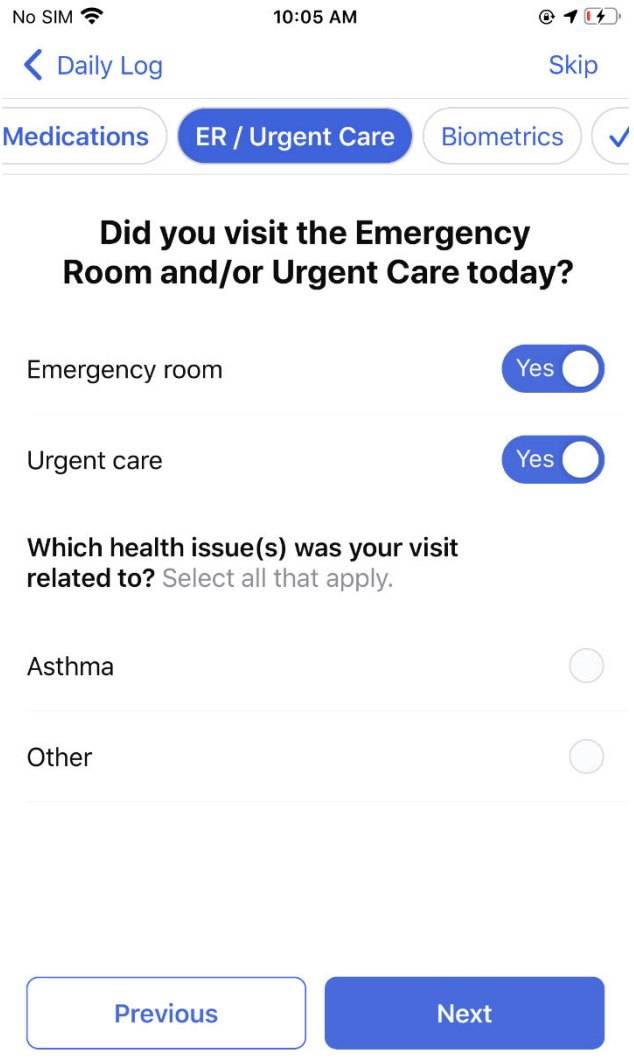

No SIM
12:52 PM
Home
Care Team Request
During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medications (such as Albuterol, Ventolin®, Proventil®, or Maxair®)?
3 or more times per day
1 or 2 times per day
2 or 3 times per week
Once a week or less
Not at all
Previous
Next

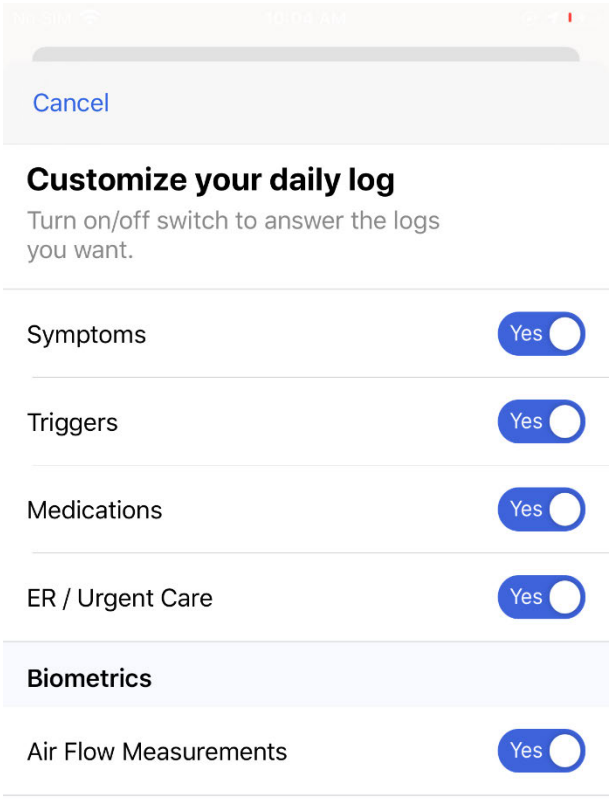
12.7 Daily Asthma Log

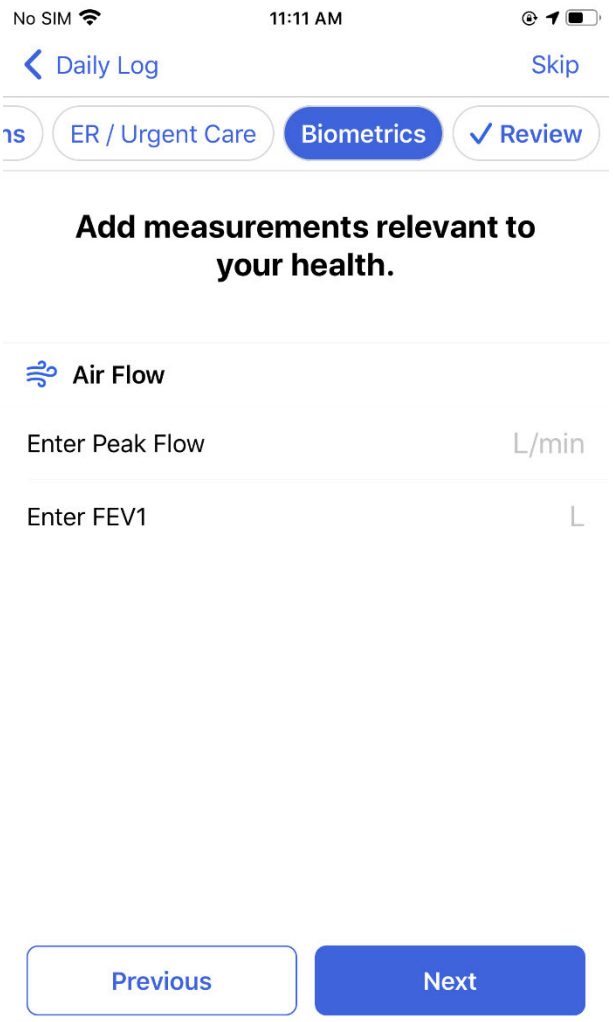

No SIM
11:24 AM
Home
Daily Log
Customize
Mon
01 Tue
02 Wed
03 Thu
04 Today
Today's Log
Your daily log for today is pending!
How do you feel today?
Tap on a face below (required)
Bad
Okay
Good
Symptoms
Edit
You reported 3 symptoms.
Chest congestion
Coughing
Chest tightness
Triggers
Edit
You reported 3 triggers.
Acid reflux
Animals
Dust
Medications
Edit
Asthma
Maintenance / daily
Yes
Oral steroids
Yes
ER / Urgent Care
Did you visit the Emergency Room and/or Urgent Care today?
Add ER / Urgent Care
Biometrics
Edit
Air Flow Measurements
Peak Flow
258 L/min
FEV1
2 L

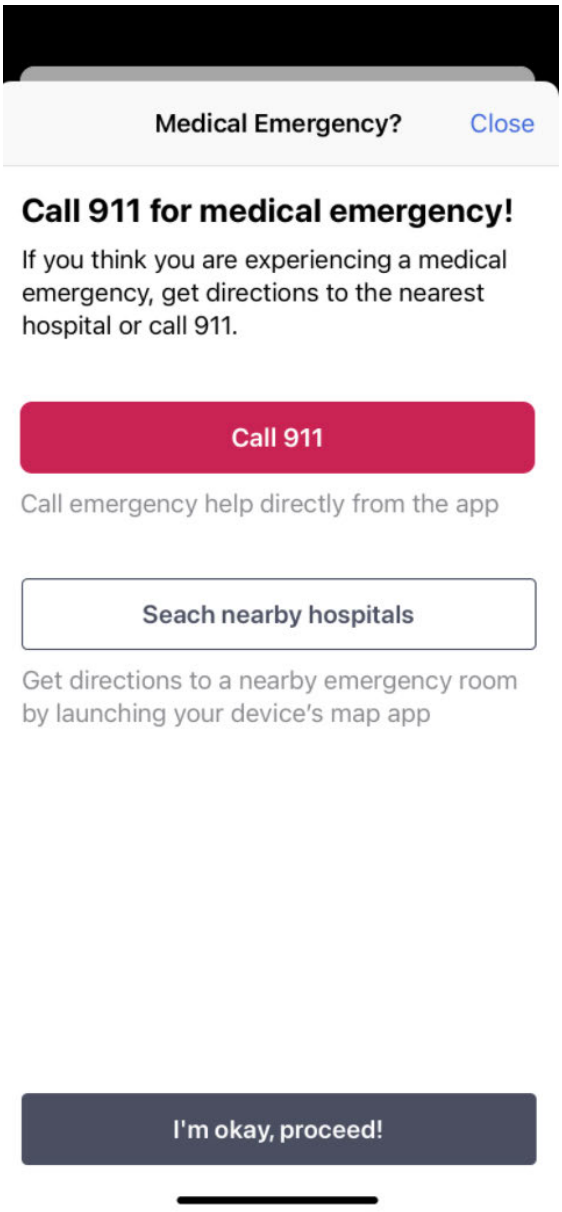

No SIM
11:10 AM
Daily Log
Feeling
Symptoms
Triggers
Medications
How do you feel today?
Tap on a face below (required)
Bad
Okay
Good
Next

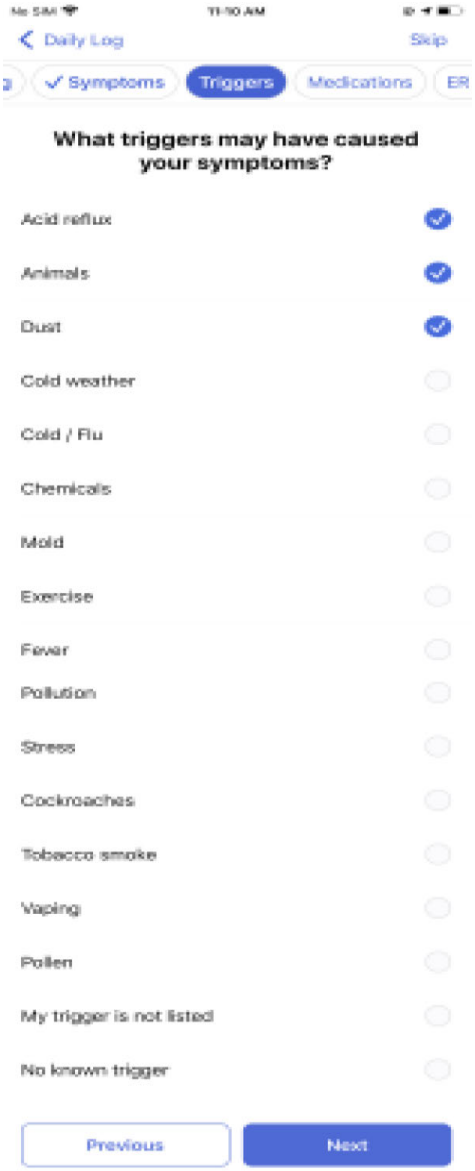

No SIM
10:03 AM
Home
Daily Log
Customize
on
08 Tue
09 Wed
10 Thu
11 Today
Today's Log
Your daily log for today is pending!
How do you feel today?
Tap on a face below (required)
Bad
Okay
Good
Symptoms
What symptoms do you have today?
Add symptoms
Triggers
What triggers may have caused your symptoms?
Add triggers
Medications
Record medications you have taken today.
Add medications
ER / Urgent Care
Did you visit the Emergency Room and/or Urgent Care today?
Add ER / Urgent Care
Biometrics
Add measurements relevant to your health.
Add biometrics

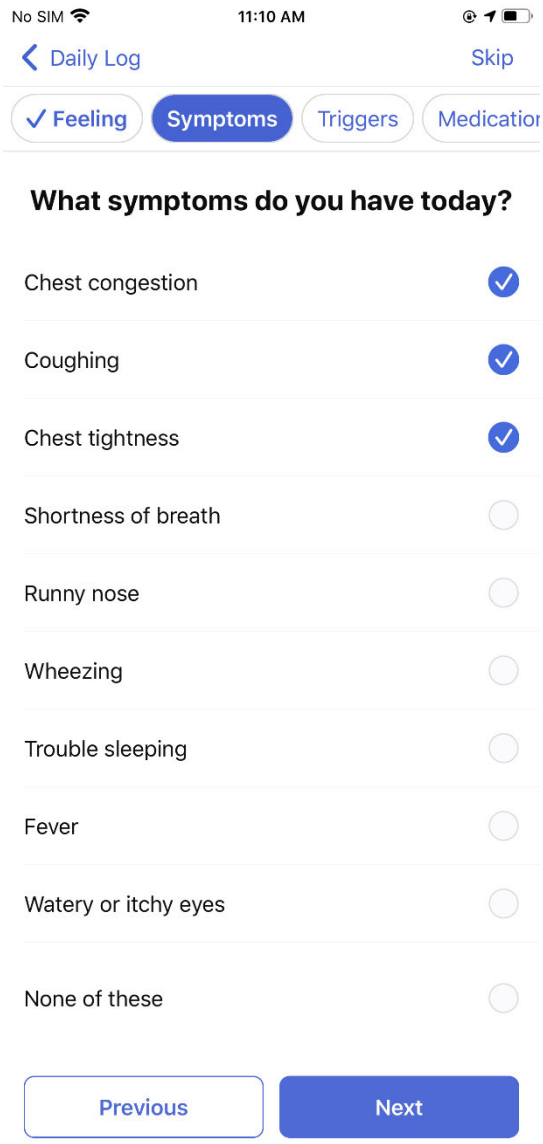

No SIM
10:05 AM
Daily Log
Skip
Medications
ER / Urgent Care
Biometrics
Did you visit the Emergency Room and/or Urgent Care today?
Emergency room
Yes
Urgent care
Yes
Which health issue(s) was your visit related to? Select all that apply.
Asthma
Other
Previous
Next

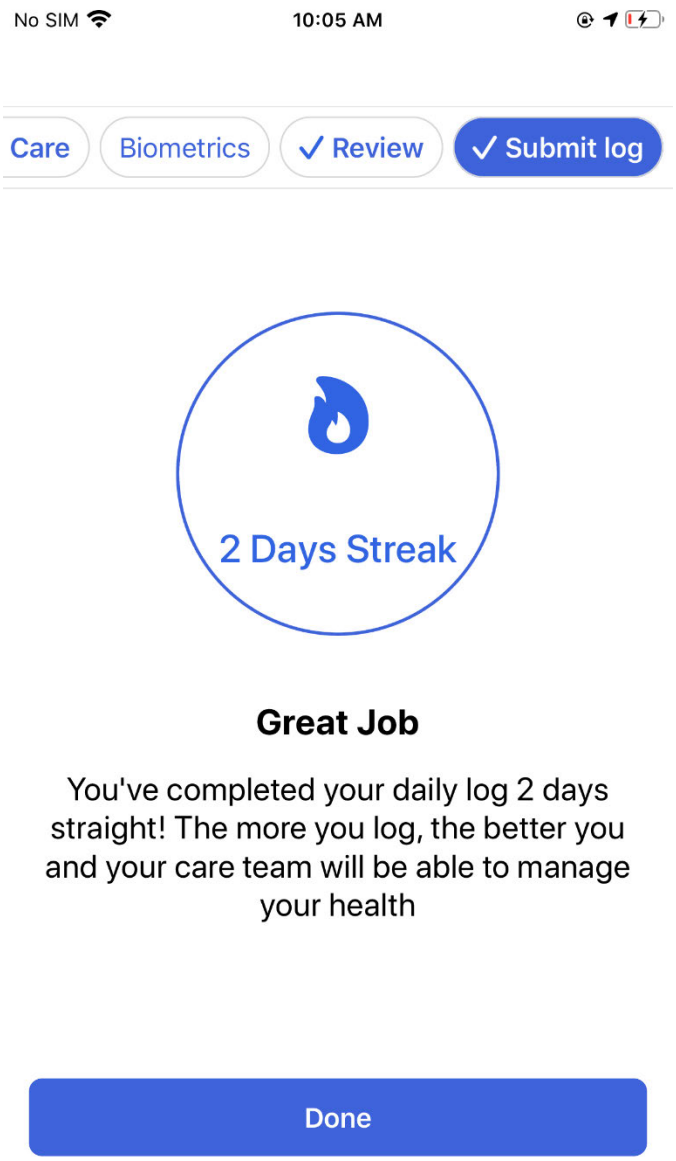

Cancel
Customize your daily log
Turn on/off switch to answer the logs you want.
Symptoms
Yes
Triggers
Yes
Medications
Yes
ER / Urgent Care
Yes
Biometrics
Air Flow Measurements
Yes

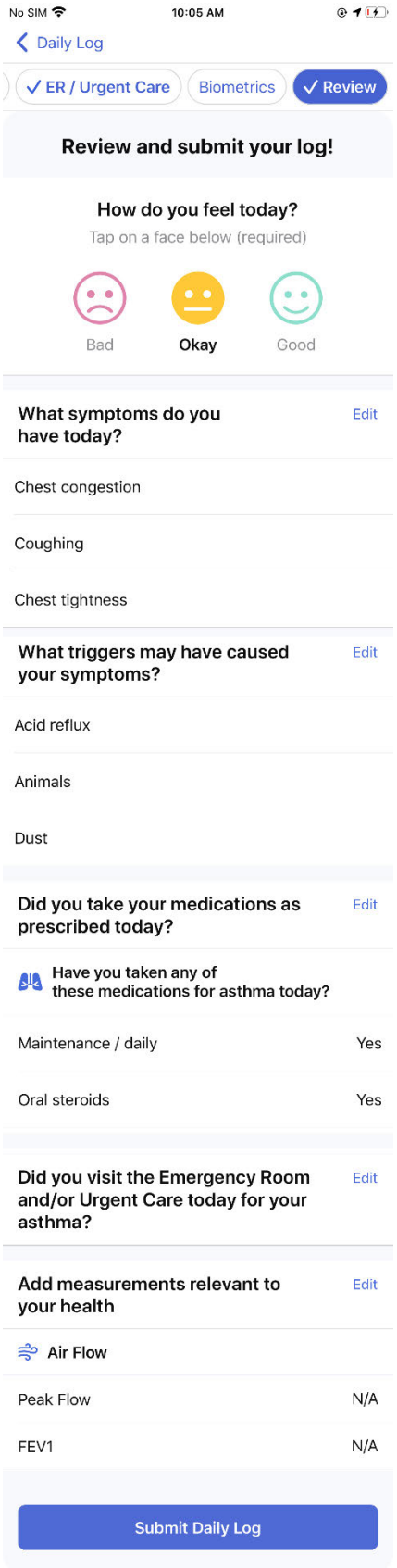

No SIM
11:11 AM
Daily Log
Skip
ER / Urgent Care
Biometrics
Review
Add measurements relevant to your health.
Air Flow
Enter Peak Flow
L/min
Enter FEV1
L
Previous
Next


Medical Emergency?
Close
Call 911 for medical emergency!
If you think you are experiencing a medical emergency, get directions to the nearest hospital or call 911.
Call 911
Call emergency help directly from the app
Seach nearby hospitals
Get directions to a nearby emergency room by launching your device's map app
I'm okay, proceed!

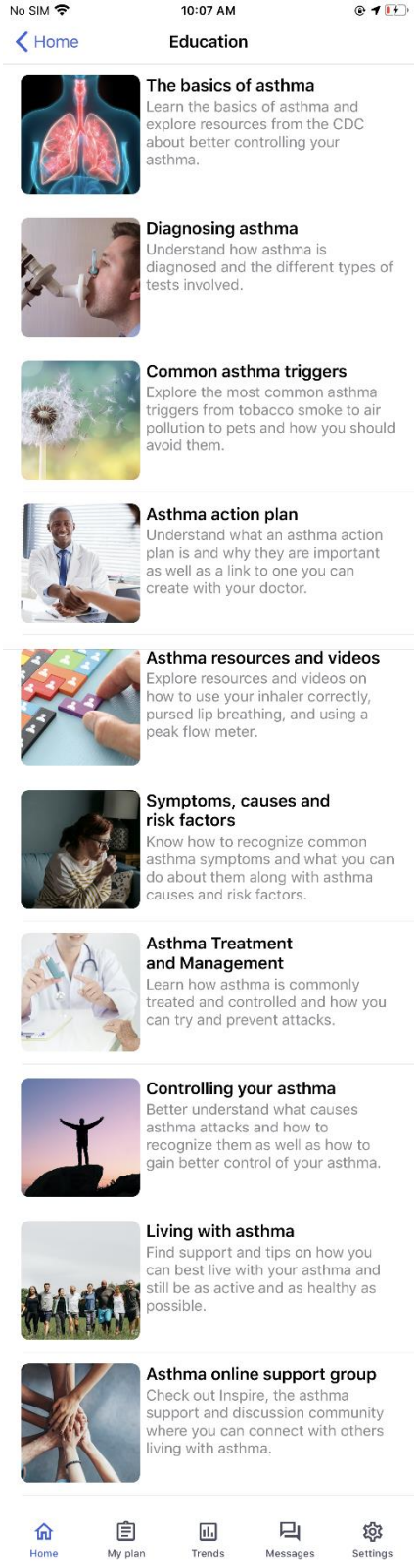

Daily Log
Skip
Symptoms
Triggers
Medications
ER
What triggers may have caused your symptoms?
Acid reflux
Animals
Dust
Cold weather
Cold / Flu
Chemicals
Mold
Exercise
Fever
Pollution
Stress
Cockroaches
Tobacco smoke
Vaping
Pollen
My trigger is not listed
No known trigger
Previous
Next


No SIM
11:10 AM
Daily Log
Skip
Feeling
Symptoms
Triggers
Medicatior
What symptoms do you have today?
Chest congestion
Coughing
Chest tightness
Shortness of breath
Runny nose
Wheezing
Trouble sleeping
Fever
Watery or itchy eyes
None of these
Previous
Next


No SIM
10:05 AM
Care
Biometrics
Review
Submit log
2 Days Streak
Great Job
You've completed your daily log 2 days straight! The more you log, the better you and your care team will be able to manage your health
Done

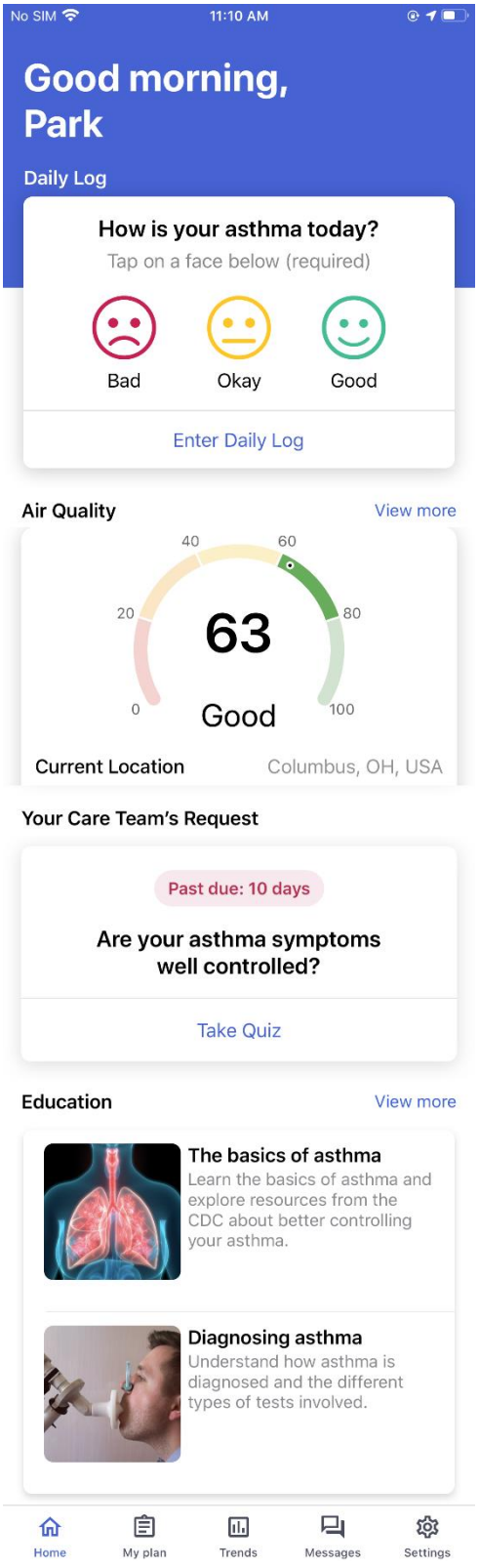

No SIM
10:05 AM
Daily Log
ER / Urgent Care
Biometrics
Review
Review and submit your log!
How do you feel today?
Tap on a face below (required)
Bad
Okay
Good
What symptoms do you have today?
Edit
Chest congestion
Coughing
Chest tightness
What triggers may have caused your symptoms?
Edit
Acid reflux
Animals
Dust
Did you take your medications as prescribed today?
Edit
Have you taken any of these medications for asthma today?
Maintenance / daily
Yes
Oral steroids
Yes
Did you visit the Emergency Room and/or Urgent Care today for your asthma?
Edit
Add measurements relevant to your health
Edit
Air Flow
Peak Flow
N/A
FEV1
N/A
Submit Daily Log

12.8 Education

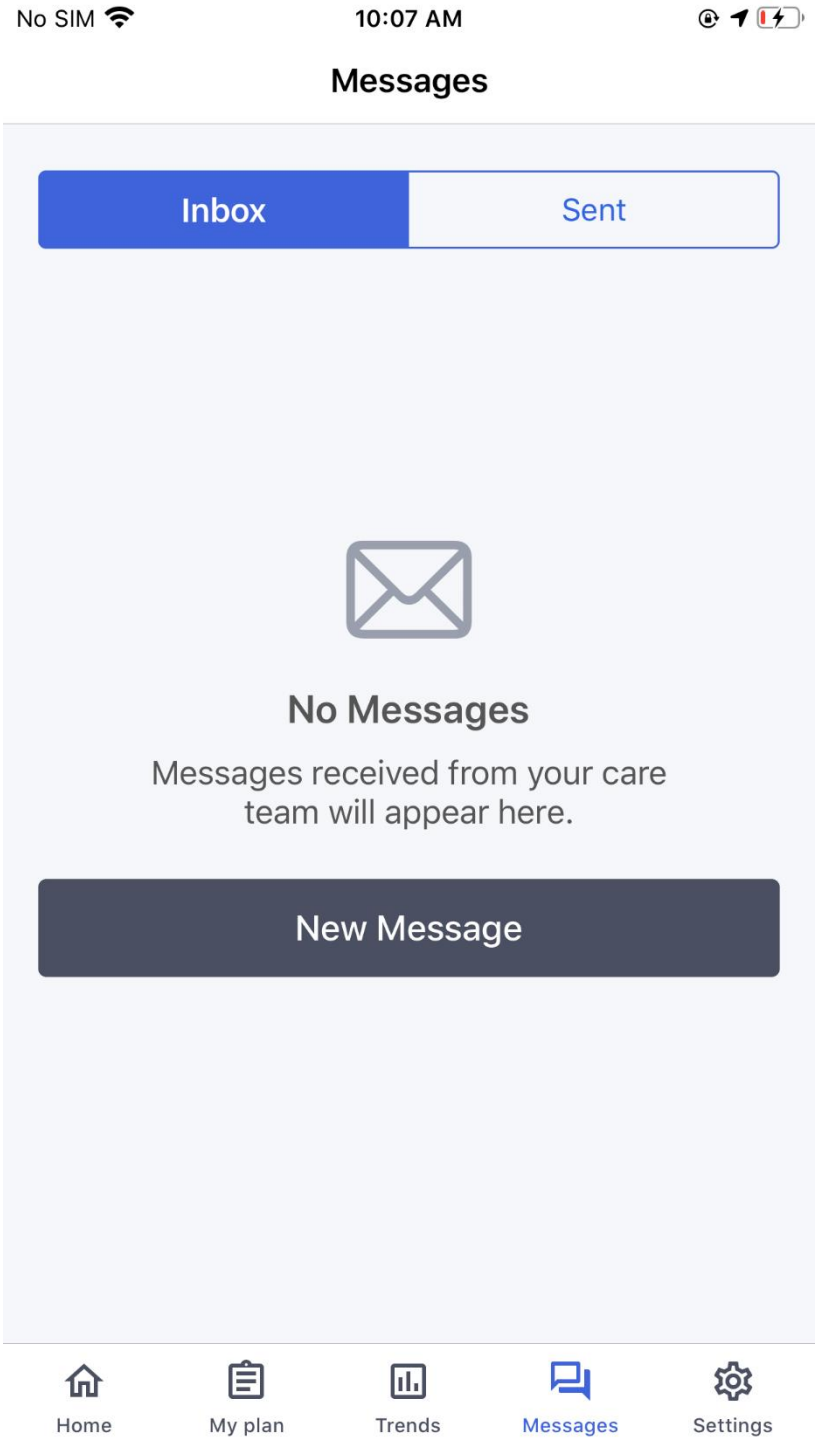


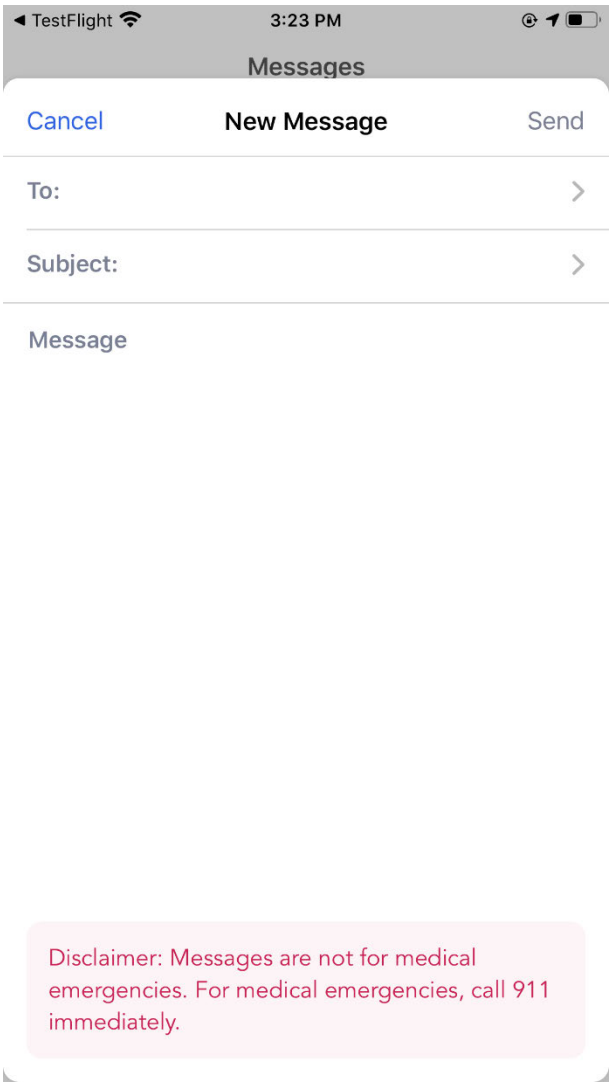
12.9 Email Password Reset

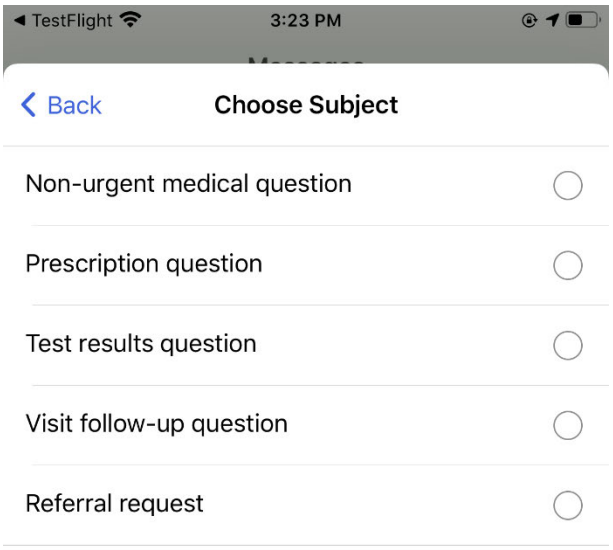
12.10 Home

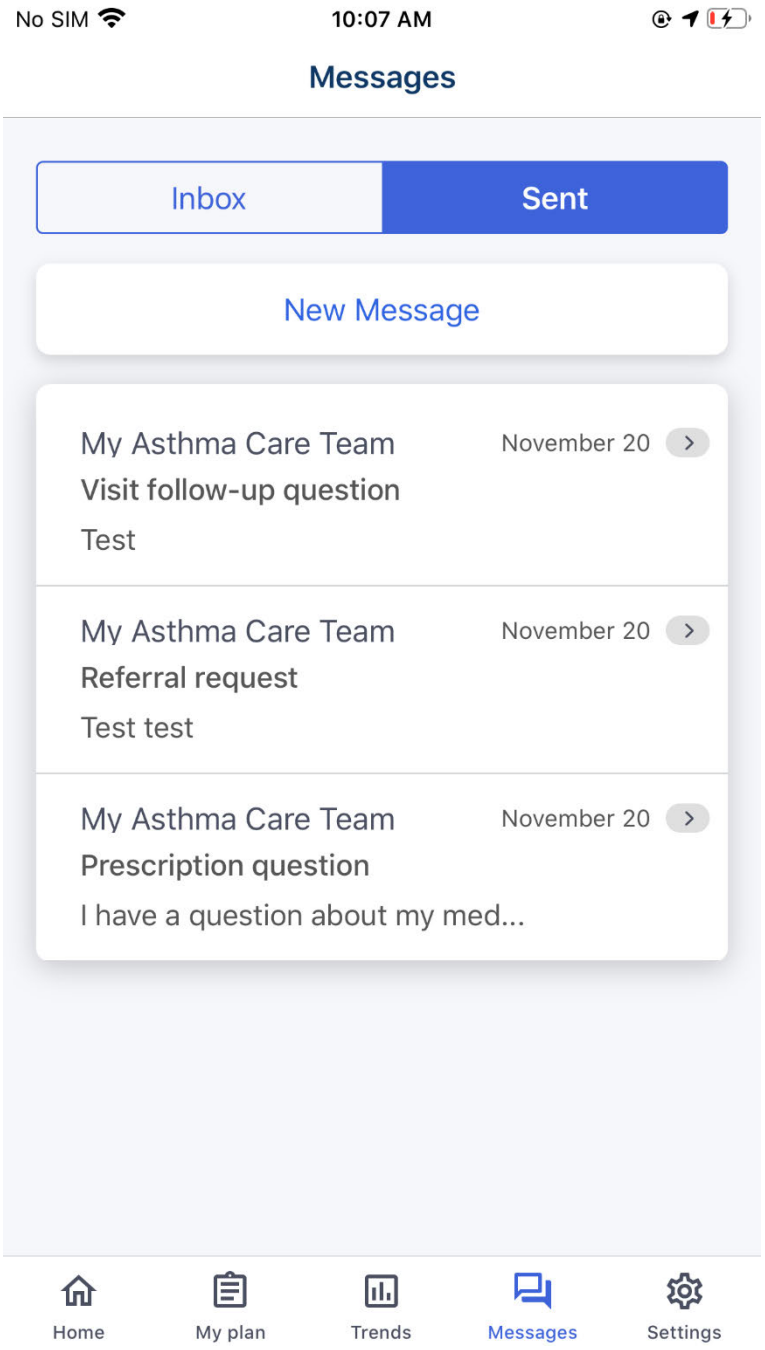

No SIM
11:10 AM
Good morning, Park
Daily Log
How is your asthma today?
Tap on a face below (required)
Bad
Okay
Good
Enter Daily Log
Air Quality
View more
40
60
20
80
63
0
100
Good
Current Location
Columbus, OH, USA
Your Care Team's Request
Past due: 10 days
Are your asthma symptoms well controlled?
Take Quiz
Education
View more
The basics of asthma
Learn the basics of asthma and explore resources from the CDC about better controlling your asthma.
Diagnosing asthma
Understand how asthma is diagnosed and the different types of tests involved.
Home
My plan
Trends
Messages
Settings

12.11 Messages

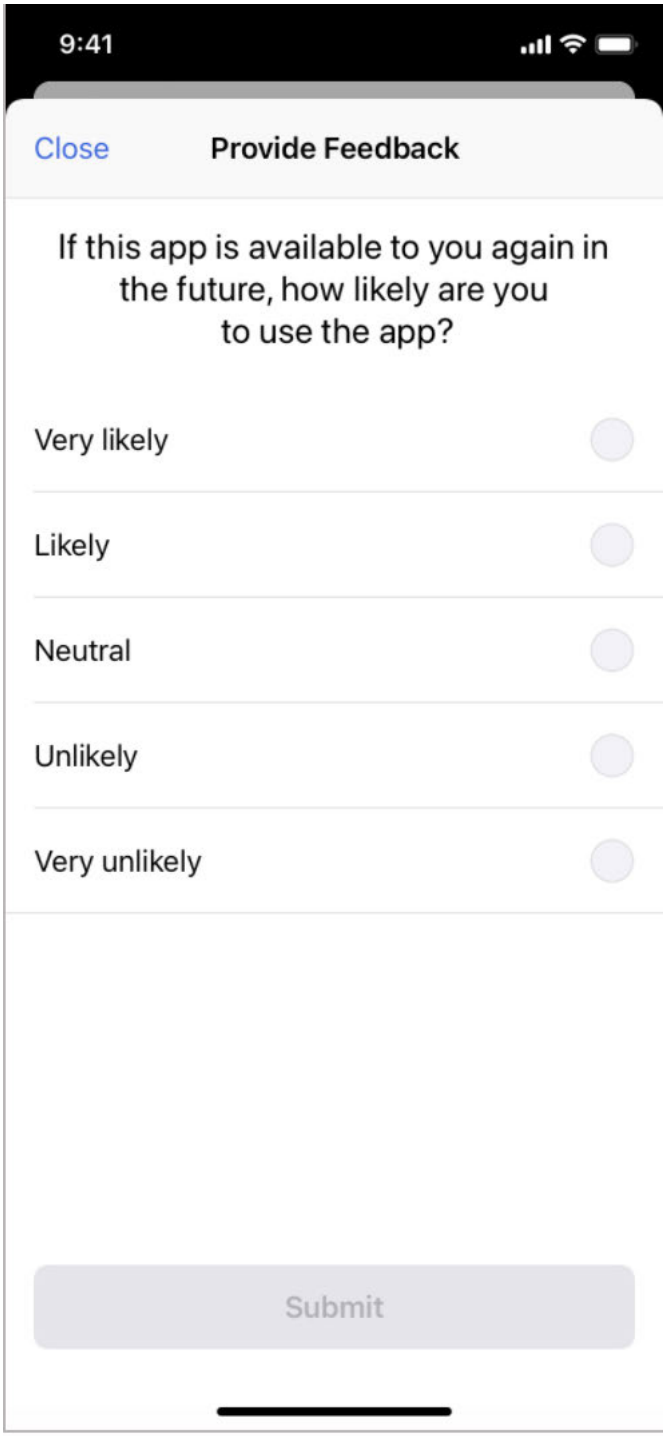



TestFlight
3:23 PM
Messages
Cancel
New Message
Send
To:
Subject:
Message
Disclaimer: Messages are not for medical emergencies. For medical emergencies, call 911 immediately.

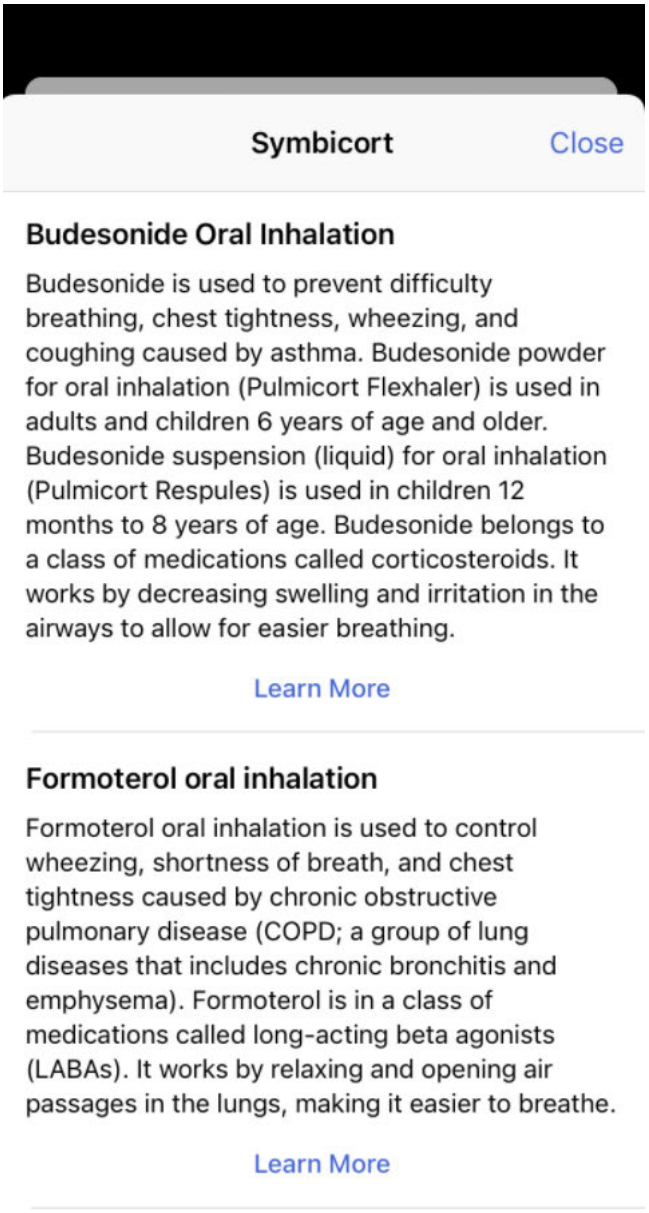

TestFlight
3:23 PM
Back
Choose Subject
Non-urgent medical question
Prescription question
Test results question
Visit follow-up question
Referral request

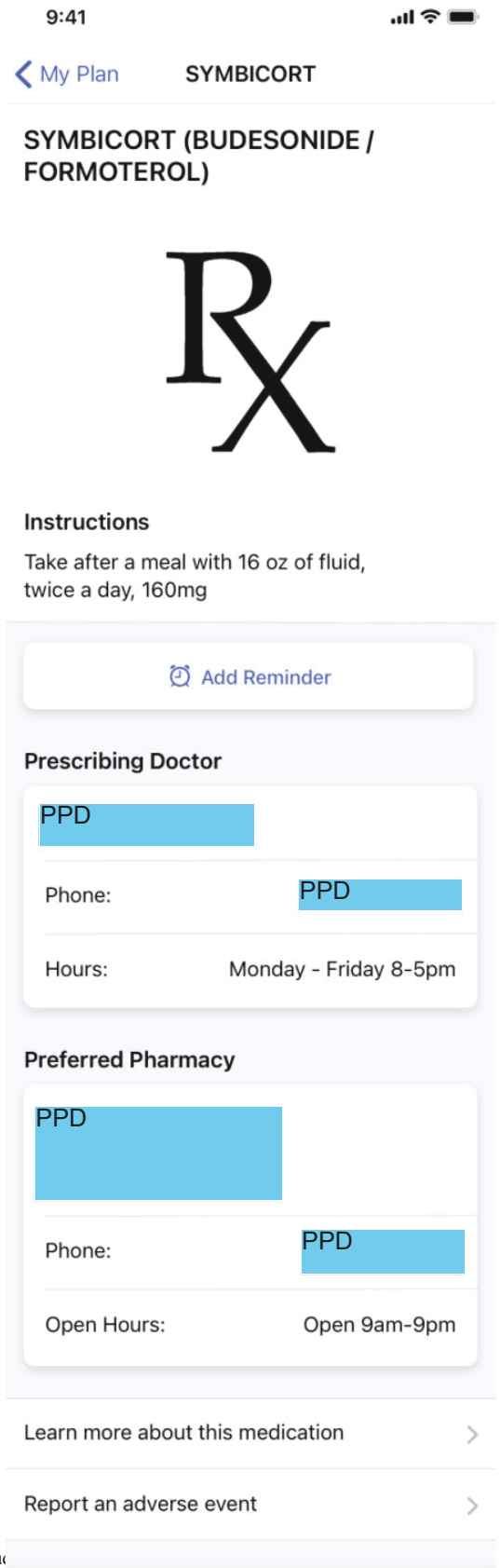

No SIM
10:07 AM
Messages
Inbox
Sent
New Message
My Asthma Care Team
November 20
Visit follow-up question
Test
My Asthma Care Team
November 20
Referral request
Test test
My Asthma Care Team
November 20
Prescription question
I have a question about my med...
Home
My plan
Trends
Messages
Settings

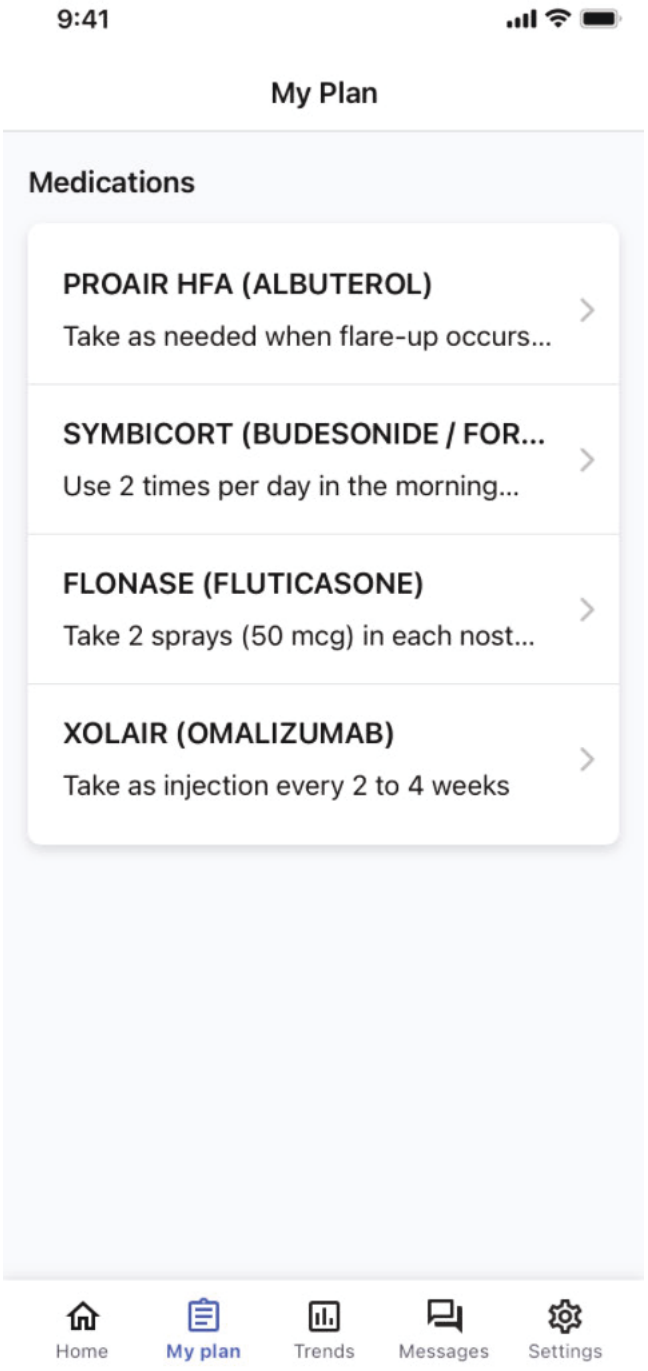
12.12 Feedback

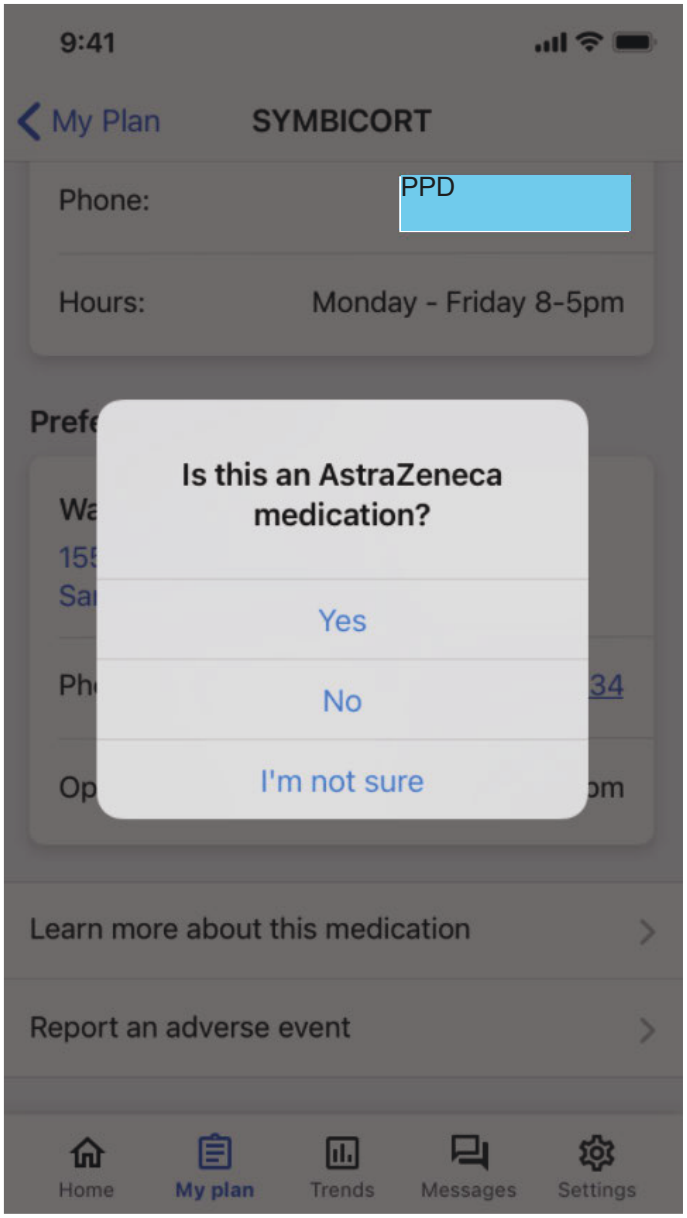


12.13 My Plan

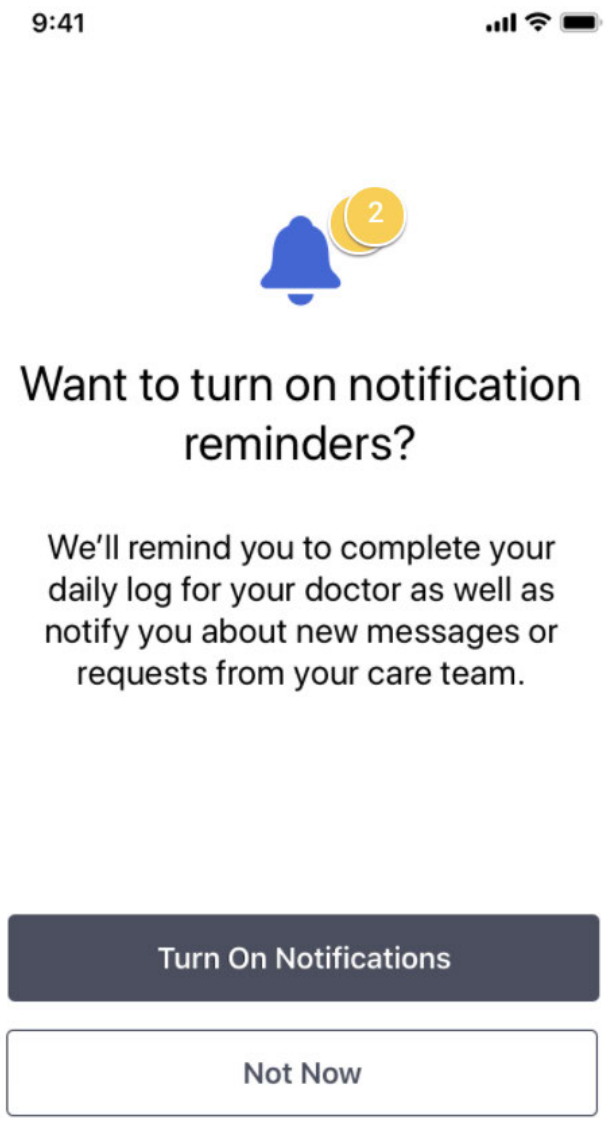

Symbicort
Close
Budesonide Oral Inhalation
Budesonide is used to prevent difficulty breathing, chest tightness, wheezing, and coughing caused by asthma. Budesonide powder for oral inhalation (Pulmicort Flexhaler) is used in adults and children 6 years of age and older. Budesonide suspension (liquid) for oral inhalation (Pulmicort Respules) is used in children 12 months to 8 years of age. Budesonide belongs to a class of medications called corticosteroids. It works by decreasing swelling and irritation in the airways to allow for easier breathing.
Learn More
Formoterol oral inhalation
Formoterol oral inhalation is used to control wheezing, shortness of breath, and chest tightness caused by chronic obstructive pulmonary disease (COPD; a group of lung diseases that includes chronic bronchitis and emphysema). Formoterol is in a class of medications called long-acting beta agonists (LABAs). It works by relaxing and opening air passages in the lungs, making it easier to breathe.
Learn More

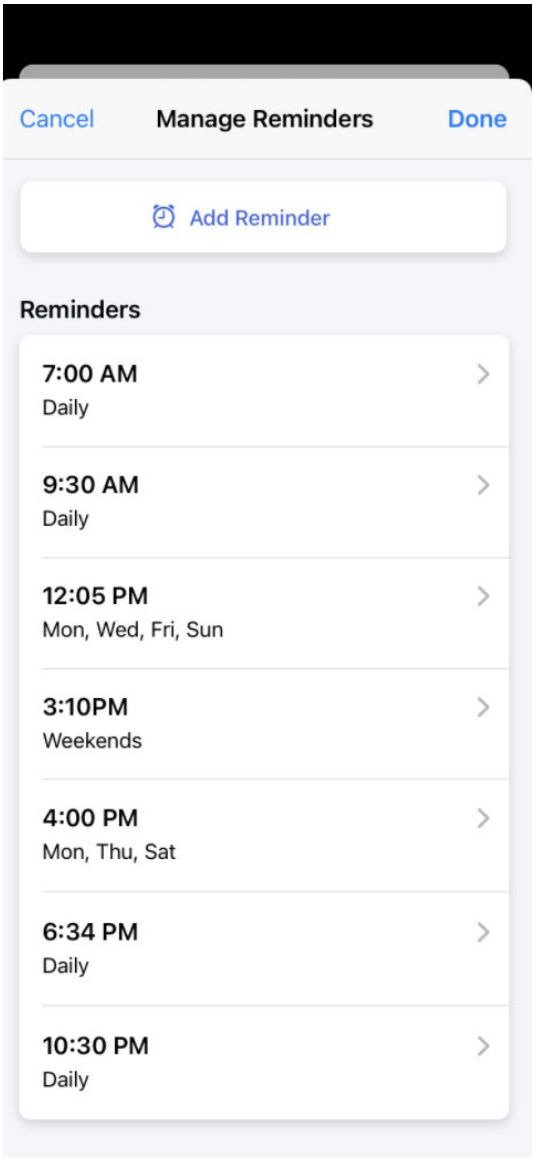

9:41
My Plan
SYMBICORT
SYMBICORT (BUDESONIDE / FORMOTEROL)
Rx
Instructions
Take after a meal with 16 oz of fluid, twice a day, 160mg
Add Reminder
Prescribing Doctor
PPD
Phone:
PPD
Hours:
Monday - Friday 8-5pm
Preferred Pharmacy
PPD
Phone:
PPD
Open Hours:
Open 9am-9pm
Learn more about this medication
Report an adverse event


9:41
My Plan
Medications
PROAIR HFA (ALBUTEROL)
Take as needed when flare-up occurs...
SYMBICORT (BUDESONIDE / FOR...
Use 2 times per day in the morning...
FLONASE (FLUTICASONE)
Take 2 sprays (50 mcg) in each nost...
XOLAIR (OMALIZUMAB)
Take as injection every 2 to 4 weeks
Home
My plan
Trends
Messages
Settings

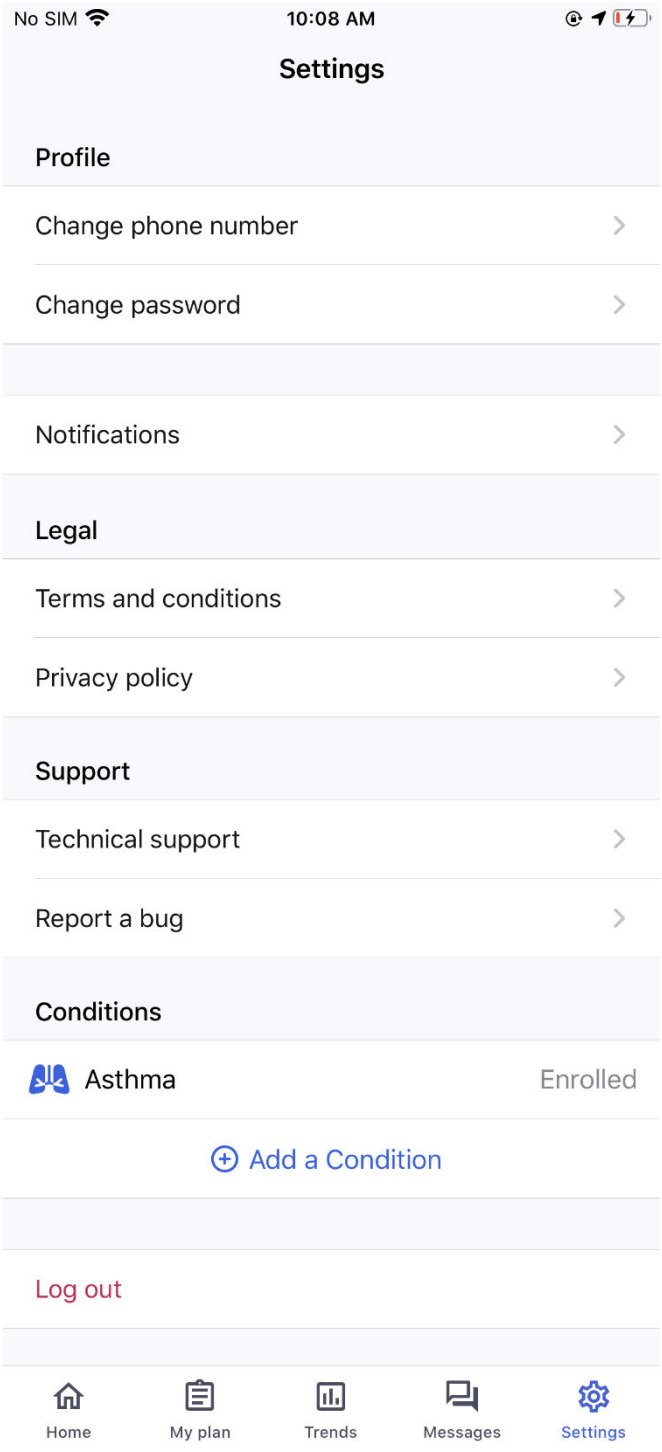

9:41
My Plan
SYMBICORT
Phone:
PPD
Hours:
Monday - Friday 8-5pm
Is this an AstraZeneca medication?
Yes
No
I'm not sure
Learn more about this medication
Report an adverse event
Home
My plan
Trends
Messages
Settings

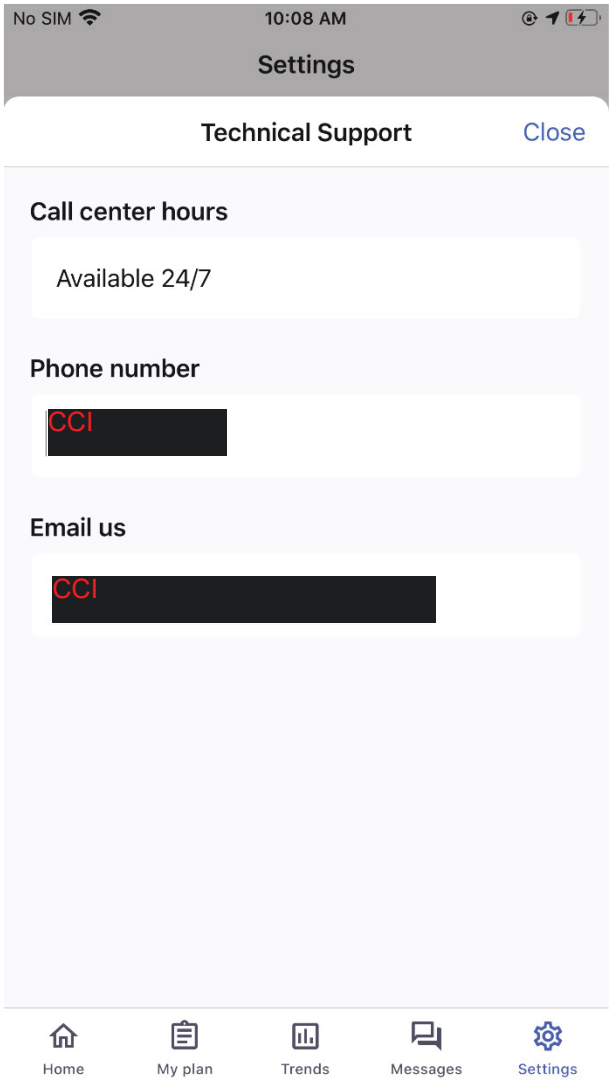
12.14 Notifications

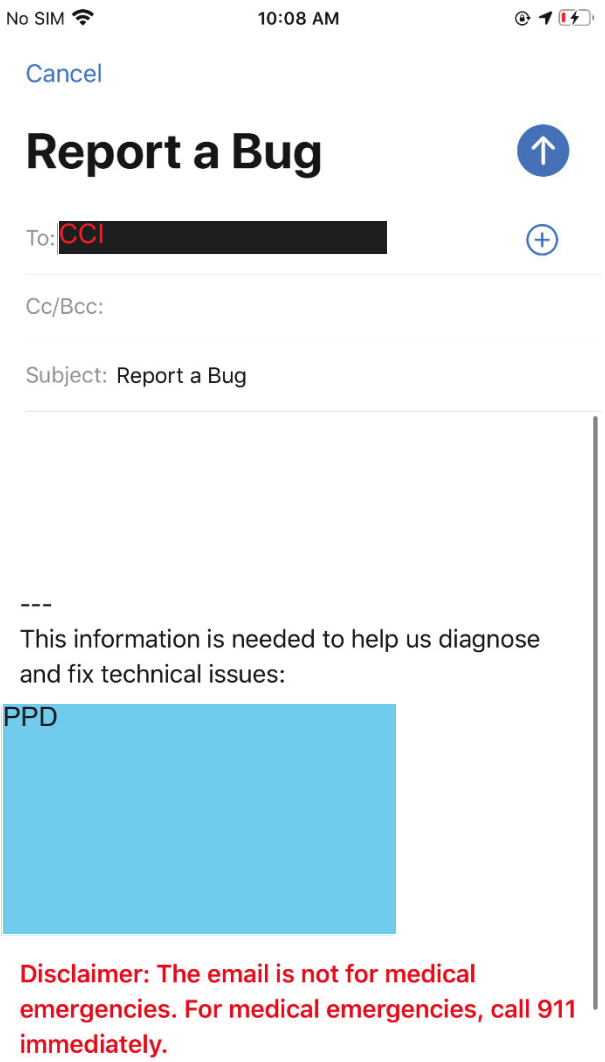




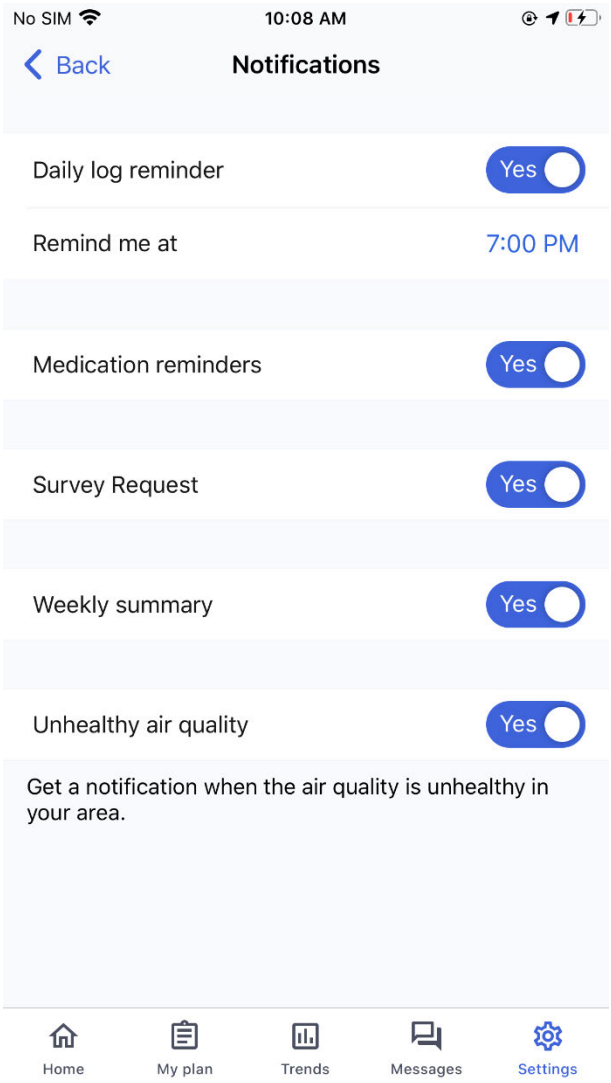
12.15 Settings

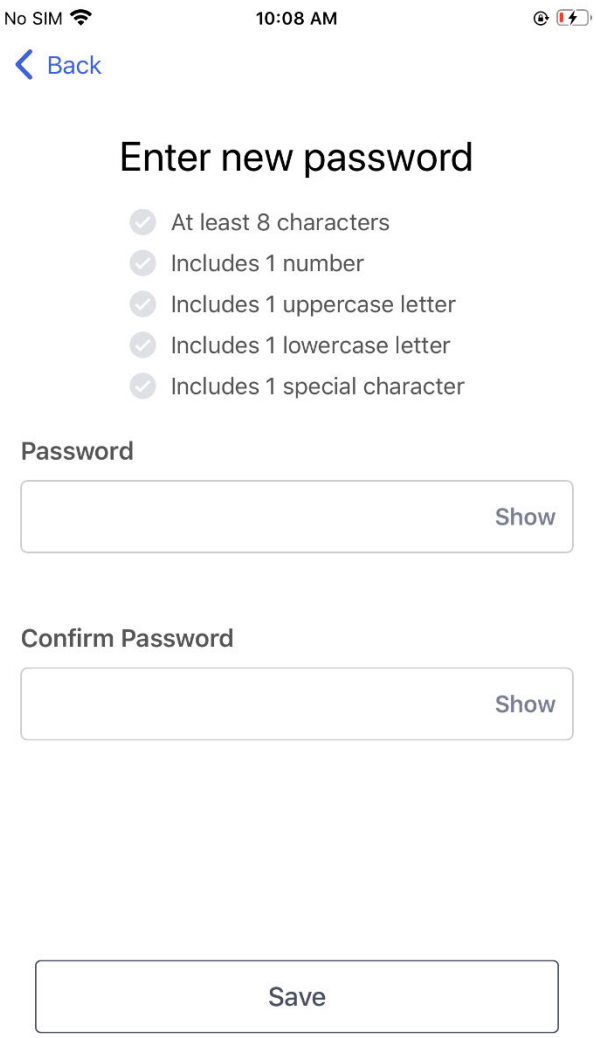


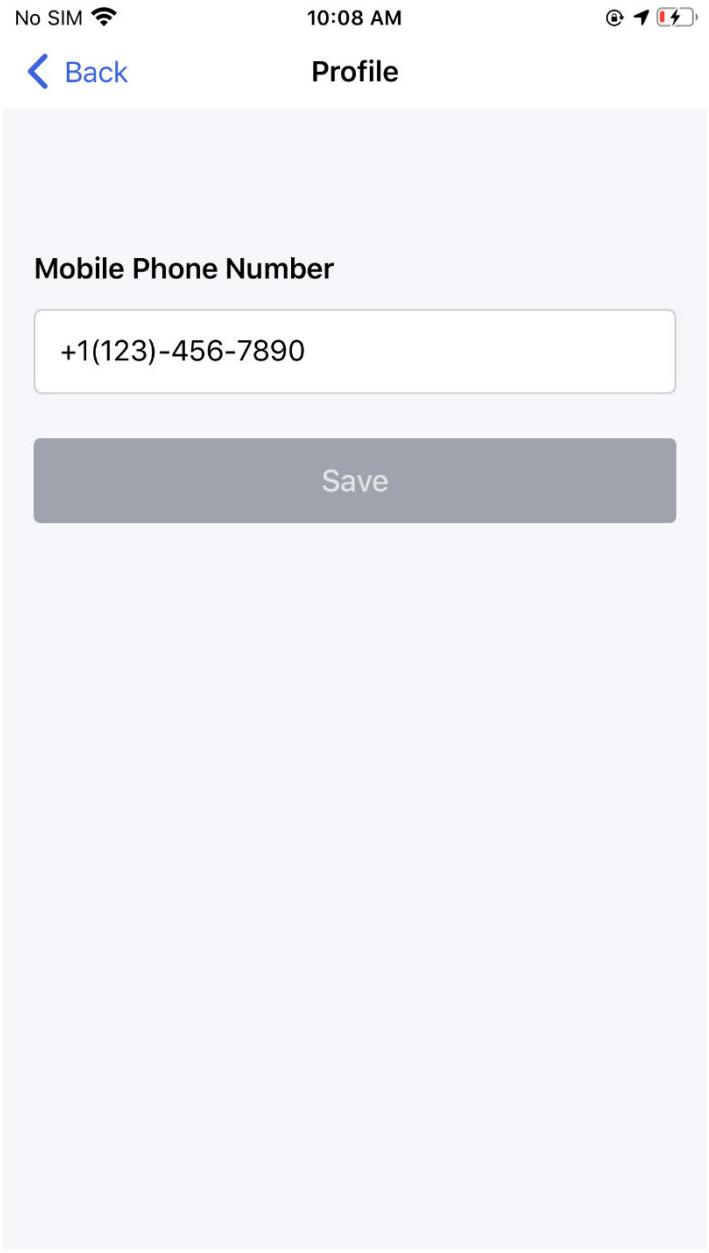

No SIM
10:08 AM
Settings
Technical Support
Close
Call center hours
Available 24/7
Phone number
CCI
Email us
CCI
Home
My plan
Trends
Messages
Settings


No SIM
10:08 AM
Cancel
Report a Bug
To: CCI
Cc/Bcc:
Subject: Report a Bug

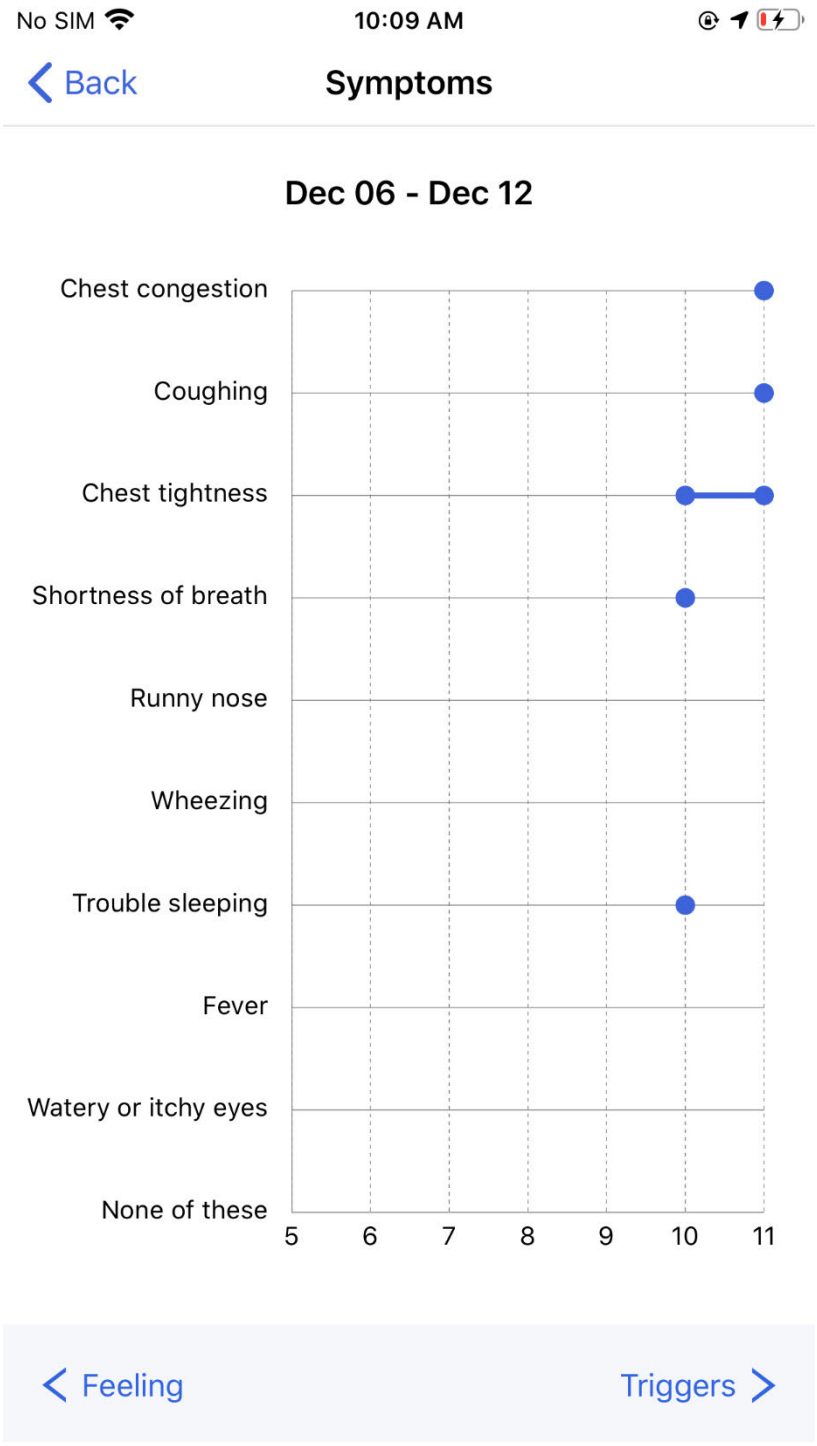
This information is needed to help us diagnose and fix technical issues:
PPD
Disclaimer: The email is not for medical emergencies. For medical emergencies, call 911 immediately.

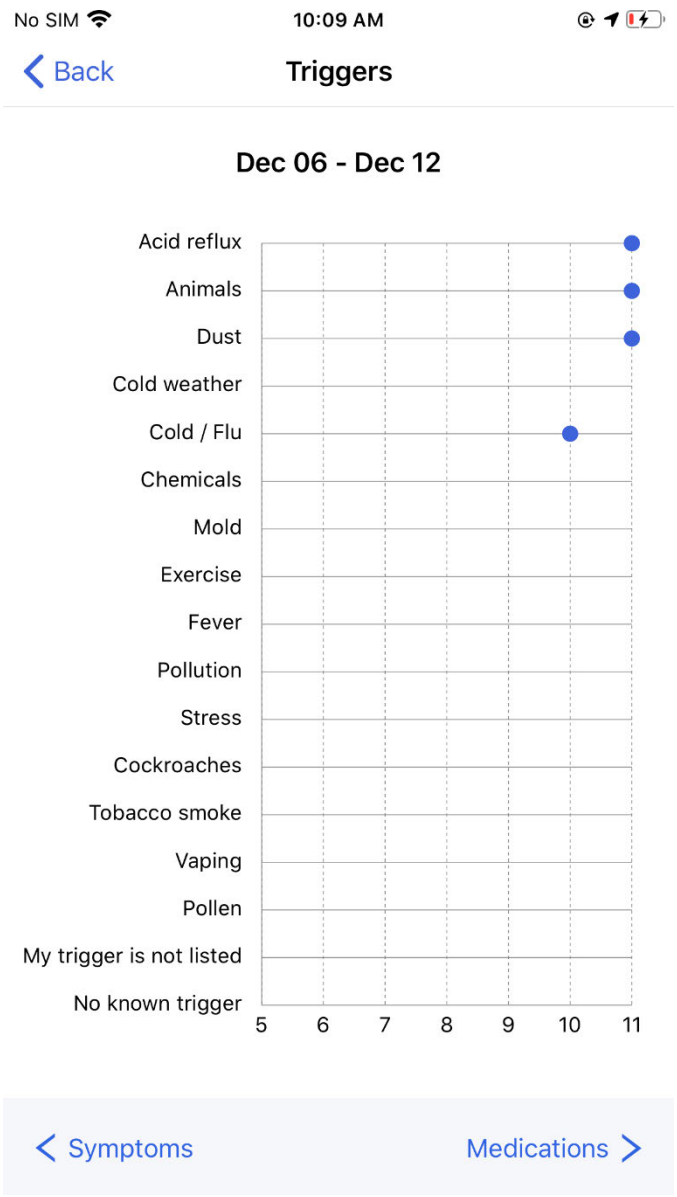

No SIM
10:08 AM
Back
Notifications
Daily log reminder
Yes
Remind me at
7:00 PM
Medication reminders
Yes
Survey Request
Yes
Weekly summary
Yes
Unhealthy air quality
Yes
Get a notification when the air quality is unhealthy in your area.
Home
My plan
Trends
Messages
Settings

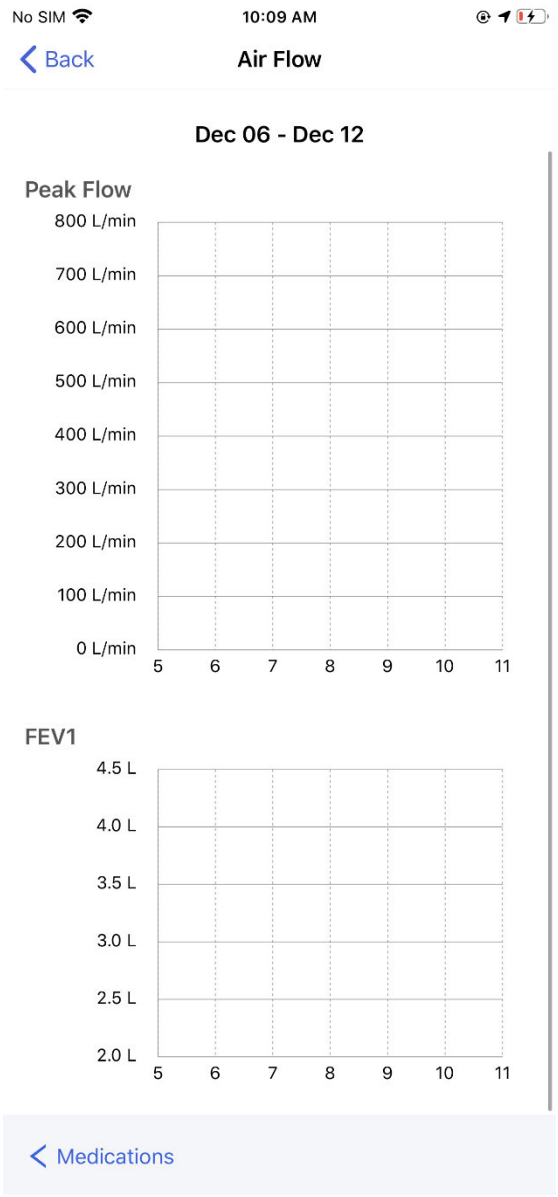

No SIM
10:08 AM
Back
Enter new password
At least 8 characters
Includes 1 number
Includes 1 uppercase letter
Includes 1 lowercase letter
Includes 1 special character
Password
Show
Confirm Password
Show
Save


No SIM
10:08 AM
Back
Profile
Mobile Phone Number
+1(123)-456-7890
Save

12.16 Trends

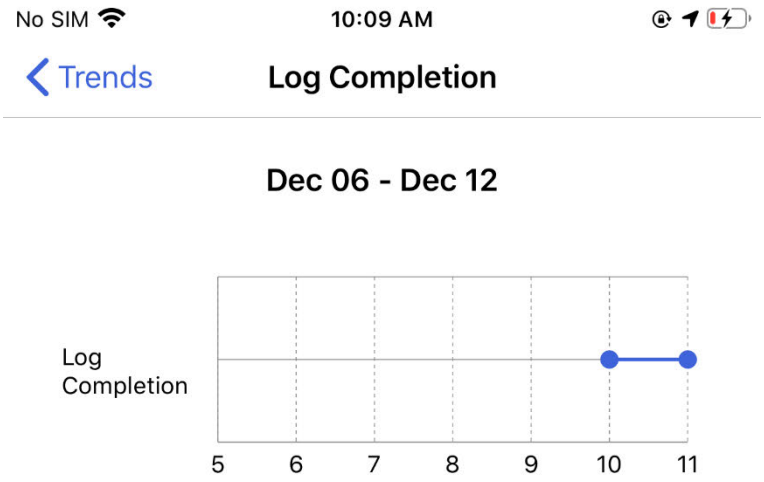

No SIM
10:09 AM
Back
Symptoms
Dec 06 - Dec 12
Chest congestion
Coughing
Chest tightness
Shortness of breath
Runny nose
Wheezing
Trouble sleeping
Fever
Watery or itchy eyes
None of these
5
6
7
8
9
10
11
Feeling
Triggers


No SIM
10:09 AM
Back
Triggers
Dec 06 - Dec 12
Acid reflux
Animals
Dust
Cold weather
Cold / Flu
Chemicals
Mold
Exercise
Fever
Pollution
Stress
Cockroaches
Tobacco smoke
Vaping
Pollen
My trigger is not listed
No known trigger
5
6
7
8
9
10
11
Symptoms
Medications

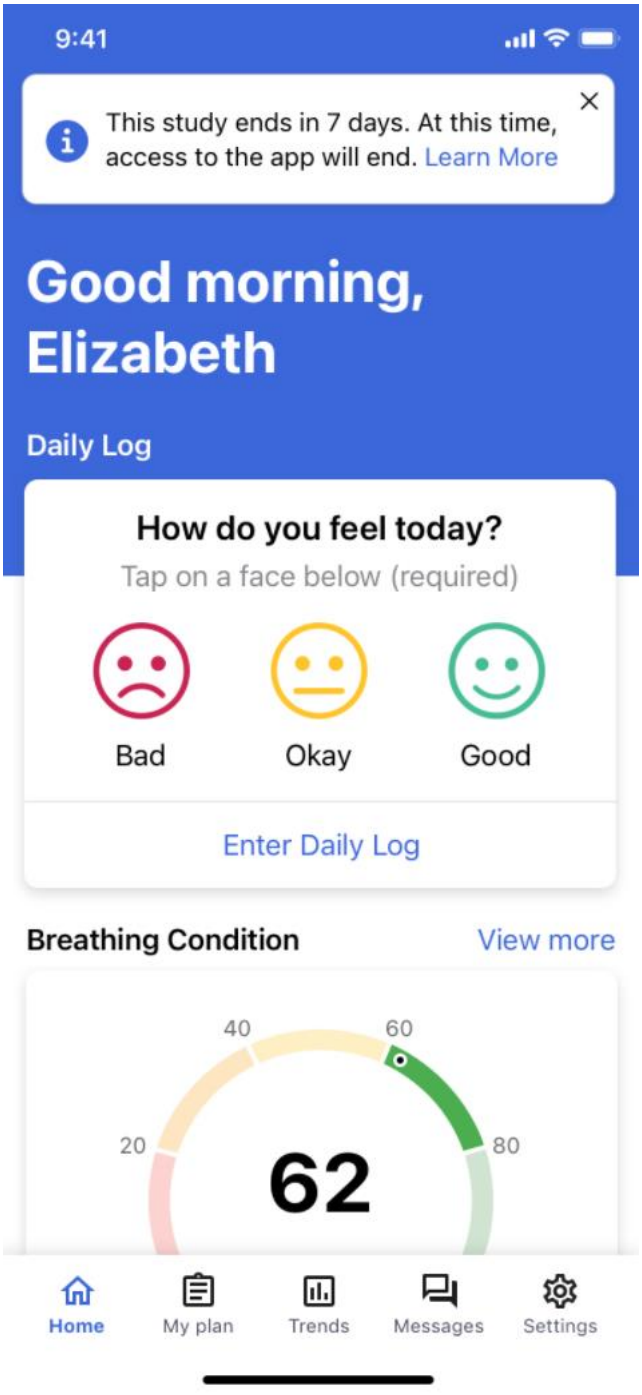

No SIM
10:09 AM
Back
Air Flow
Dec 06 - Dec 12
Peak Flow
800 L/min
700 L/min
600 L/min
500 L/min
400 L/min
300 L/min
200 L/min
100 L/min
0 L/min
5
6
7
8
9
10
11
FEV1
4.5 L
4.0 L
3.5 L
3.0 L
2.5 L
2.0 L
Medications

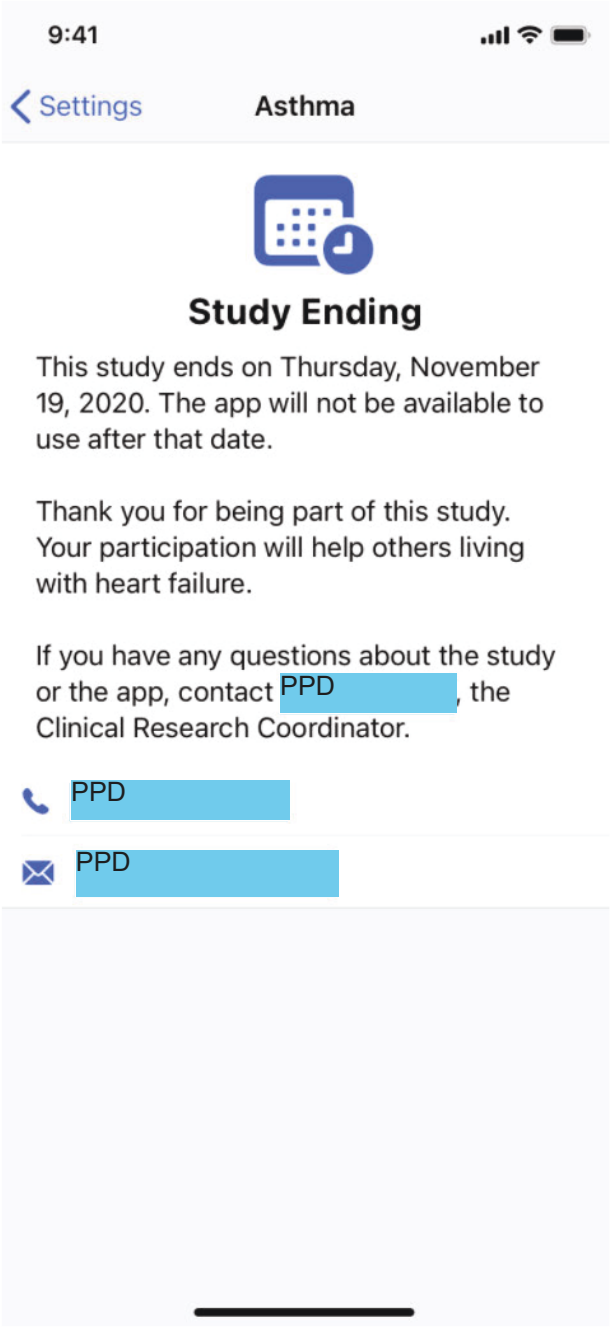

No SIM
10:09 AM
Back
Feeling
Dec 06 - Dec 12
Bad
Okay
Good
5
6
7
8
9
10
11
Log Completion
Symptoms

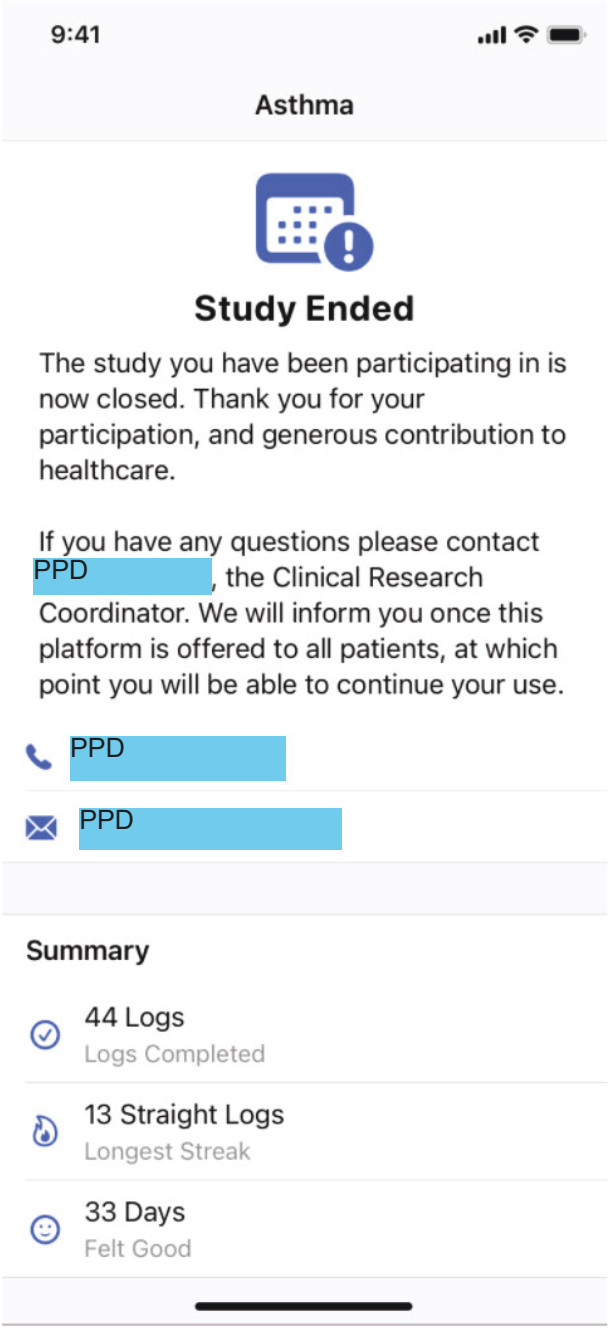

No SIM
10:09 AM
Back
Medications
Dec 06 - Dec 12
Asthma
Maintenance / daily
Oral steroids
Quick-relief / as-needed
5
6
7
8
9
10
11
Triggers
Air Flow


No SIM
10:09 AM
Trends
Log Completion
Dec 06 - Dec 12
Log Completion
5
6
7
8
9
10
11
Feeling

12.17 Study Ending




9:41
Settings
Asthma
Study Ending
This study ends on Thursday, November 19, 2020. The app will not be available to use after that date.
Thank you for being part of this study. Your participation will help others living with heart failure.
If you have any questions about the study or the app, contact PPD , the Clinical Research Coordinator.
PPD
PPD


9:41
Asthma
Study Ended
The study you have been participating in is now closed. Thank you for your participation, and generous contribution to healthcare.
If you have any questions please contact PPD , the Clinical Research Coordinator. We will inform you once this platform is offered to all patients, at which point you will be able to continue your use.
PPD
PPD
Summary
44 Logs
Logs Completed
13 Straight Logs
Longest Streak
33 Days
Felt Good

13. APPENDIX F. CLINICAL CASE REPORT FORM

Clinical Case Report Form

Screening ID

_____

Participant ID

_____

BI linked ID

_____

Date of Enrollment

_____

Confirmation of Eligibility Into the Study

Patient is ≥ 18 years of age at the time of enrollment?
Yes
No

Patient diagnosed with asthma?
Yes
No

Patient has access to smartphone with internet access with the following requirements: iOS (Operating System iOS 13 or newer and Devices iPhone 8 or newer) or Android (Operating System 8.0 or newer)?
Yes
No

Patient is able to understand and speak English sufficiently to be able to use the AMAZE™ patient app?
Yes
No

Patient provided consent to participate?
Yes
No

Does the patient have a cognitive impairment, hearing difficulty, visual impairment, acute psychopathology, medical condition, or insufficient knowledge of the English language that, in the opinion of the investigator or interviewer, would interfere with his or her ability to provide electronic consent and/or participate/complete the questionnaire?
Yes

No
(If yes - patient CANNOT be enrolled into the study)

Investigator/Coordinator Full Name

Dawei Jiang
Remona Kanyat
Dalton Lancaster
Peter Moschovis
Jehan Alladina

Investigator/Coordinator Signature: _____

Date: _____

Did the patient download the AMAZE DMP App? _____ *yes,* _____ *no*
IF YES, please record the BrightInsight ID Number: _____ (Add a comment if BI ID has not been provided yet.)

Patient Characteristics		
Sex: ☐ Male ☐ Female	Age (years): ___	Height: _____ ft ___ in; Weight: ____ lb
ASTHMA DIAGNOSIS		
Age when first diagnosed with asthma: _____(Years (if unknown, please mark the box below)) ☐ Unknown		
Duration patient seen by a health care provider for asthma: __ years __months		
Duration patient seen by a healthcare provider at MGH for asthma: __years __months		
Smoking status (tobacco products, electronic cigarettes, vaping, marijuana)		
Smoking Status ☐ Never smoked ☐ Previously Smoker ☐ Current Smoker		
Previously smoked ☐ Cigarettes ☐ Vaping ☐ Marijuana Number of years smoked _____ Average cigarette packs/vaping or marijuana times per day: _____ Choose an option to Record "Time Since Last Smoke" ☐ Weeks ☐ Months ☐ Years Time since last smoked: Weeks _____ (Weeks) Months _____ (Months) Years _____ (Years) Currently smoking ☐ Cigarettes ☐ Vaping ☐ Marijuana		

Number of years smoked _____ (Years)

Average cigarette packs/vaping or marijuana times per day: _____

Date last smoked: _____ (Date)

Time last smoked: _____ (Time)

Was spirometry lung function testing performed on this patient in the last 12 months?

☐ Yes ☐ No

Date of the most recent Spirometry test _____

FEV1: Liters _____ (Liters)
FEV1: % Predicted _____ (% Predicted)
FVC: Liters _____ (Liters)
FVC: % Predicted _____ (% Predicted)
FEV1:FVC: _____
FEV1/FVC: % Predicted _____ (% Predicted)

Was a test for eosinophil blood count performed on this patient in the last 12 months?

☐ Yes ☐ No

Date of highest Absolute Eosinophil Count Test _____
Absolute Eosinophil Count (Highest) _____ (Absolute Eosinophil Count)

How would you rate this patient's asthma severity?

☐ Intermittent
☐ Mild persistent
☐ Moderate persistent
☐ Severe persistent

At the last visit, do you think patient was:

☐ Well controlled (NO hospitalizations and NO ER visit and NO steroid prescriptions in the past 12 months)
☐ Not well controlled (NO hospitalizations, and 1 ER visit or 1 steroid prescription in the past 12 months)
☐ Very poorly controlled (1+ hospitalization, and/or 2+ ER visits, and/or 2+ steroid prescriptions in the past 12 months)

MAINTENANCE PHARMACOLOGIC THERAPY

*Please **only** include current medication the patient is **currently prescribed and taking**. Please check **all** that apply.*

ICS

☐ QVAR HFA/Redihaler (beclomethasone dipropionate)
☐ Beclovent HFA (beclomethasone dipropionate)
☐ Vanceril HFA) (beclomethasone dipropionate)
☐ Pulmicort Flexhaler/Respules (budesonide)
☐ Aerospan (flunisolide)
☐ Flunisolide
☐ Flovent HFA/Disc (fluticasone propionate)

LAMA

☐ Incruse Ellipta (Umeclidinium)
☐ Spiriva Respimat/Handihaler (tiotropium bromide)
☐ Tudorza/Aclidinium (aclidinium bromide)

Triple Therapy (fixed dose combination)

☐ Trelegy Ellipta (fluticasone/umeclidinium/vilanterol)

LTRA

☐ Singulair (Montelukast)
☐ Accolate (Zafirlukast)
☐ Zyflo (Zileuton)

MAINTENANCE PHARMACOLOGIC THERAPY

*Please **only** include current medication the patient is **currently prescribed and taking**. Please check **all** that apply.*

☐ Azmanex Twisthaler/HFA (mometasone furoate)
☐ Arnuity Ellipta (fluticasone furoate inhalation powder))
☐ Triamcinolbone Acetonide
☐ Alvesco

ICS/LABA

☐ Advair Diskus/HFA (fluticasone propionate and salmeterol)
☐ Wixela Inhub (fluticasone propionate and salmeterol)
☐ Airduo Respiclick (fluticasone propionate and salmeterol)
☐ Breo Ellipta (fluticasone furoate and vilanterol)
☐ Dulera HFA (mometasone furoate and formoterol fumarate dihydrate)
☐ Symbicort (budesonide/formoterol fumarate dihydrate)
☐ Budesonide/formoterol

LABA (Single inhaled medicine, *not* in a fixed dose combination with an ICS or ICS/LAMA)

☐ Serevent (Salmeterol xinafoate)
☐ Foradil (formoterol fumarate)
☐ Arcapta (Indacaterol)
☐ Brovana (arformoterol tartrate)
☐ Indacaterol
☐ Arformoterol
☐ Striverdi (Oldaterol)

Theophylline Preparations

☐ Theo-24 (Theophylline)
☐ Elixophylline (Theophylline)
☐ Theochron (Theophylline)

Chronic Add-on Therapy (Macrolides)

☐ Zithromax (Azithromycin)
☐ Biaxin (Clarithromycin)
☐ Erythromycin (Erythrocin)

Biologics

☐ Cinqair (reslizumab)
☐ Dupixent (dupilumab)
☐ Fasenra (benralizumab)
☐ Nucala (mepolizumab)
☐ Xolair (omalizumab)

SABA/Rescue Inhaler Use

☐ Daily Use (SABA)
☐ SABA alone
☐ SABA+ICS
☐ LABA+ICS
☐ Nebulizer
☐ SAMA

Nebulizer – Please Specify

_____

☐ Other – Please Specify

_____

Which of the following did you do to the patient's medication after their LAST visit? (Check all that apply)

☐ Step-down of controller medicines
☐ No change of controller medicines
☐ Step-up of controller medicines
☐ Prescribe a course of systemic corticosteroids

MAINTENANCE PHARMACOLOGIC THERAPY *Please **only** include current medication the patient is **currently prescribed and taking**. Please check **all** that apply.*
☐ Other: _____

Investigator Final Confirmation

Investigator/Coordinator Signature: _____

Date: _____

14. APPENDIX G. PATIENT DEMOGRAPHIC QUESTIONNAIRE

Demographic Questionnaire (AMAZE™ App)

Dear Research Participant,

Thank you for taking part of the AMAZE™ Asthma Research Study at Massachusetts General Hospital (MGH).

As part of the study procedure, please complete the survey below.

If you have any questions, please contact the Study Team at CCI [redacted].

Thank you!

What is your age? _____ (years)

What is your biological sex?

☐ Male
☐ Female

What is your ethnic background?

☐ Hispanic or Latino
☐ Not Hispanic or Latino
☐ Prefer not to say

What is your racial background?

☐ White
☐ Black or African American
☐ Asian
☐ Native Hawaiian or other Pacific Islander
☐ American Indian or Alaska Native
☐ Other (specify): _____
☐ Prefer not to say

What is your current living/domestic situation?

☐ Living alone
☐ Living with a spouse, partner, family, or friends
☐ Other (specify): _____

How would you describe your employment status?

☐ Employed, full-time
☐ Employed, part-time
☐ Homemaker
☐ Student
☐ Unemployed
☐ Retired
☐ Disabled
☐ Other (specify): _____

What is the highest level of education you have completed?
☐ Less than high school
☐ Secondary/high school
☐ Associate degree, technical or trade school
☐ College/university degree
☐ Postgraduate school
☐ Other (specify): _____

What is your household's total income from all sources over the past 12 months?

☐ Less than $15,000
☐ $15,000 to $29,999
☐ $30,000 to $44,999
☐ $45,000 to $59,999
☐ $60,000 to $74,999
☐ $75,000 to $99,999
☐ $100,000 or more
☐ Prefer not to answer

Age when you were first diagnosed with asthma? _____ (year-old)

How many years (and months) seen by a health care provider for asthma with asthma

_____ (years (and months))

How many years (and months) seen by a MGH provider for asthma with asthma

_____ (years (and months))

Do you currently smoke?

☐ Yes, smoker
☐ Not currently, but previous smoker
☐ No, never smoked

Do you currently vape?

☐ Yes, vaper
☐ Not currently, but previous vaper
☐ No, never vaped

Do you have any of the following health conditions? (Check all that apply)

☐ **No other health conditions**
☐ Allergy diagnosed by blood or skin testing
☐ Allergic rhinitis (nasal allergies, "hay fever")
☐ Heart disease (history of heart attack, heart failure or heart valve problems)
☐ Anxiety
☐ Anaphylaxis (severe allergic reaction to a food, bee sting, allergy shot, medication or other)
☐ Arthritis
☐ Aspirin sensitivity (aspirin causes hives, swelling or breathing problems)
☐ Atopic dermatitis/Eczema
☐ Chronic bronchitis
☐ Chronic Obstructive Pulmonary Disease (COPD)
☐ Chronic sinusitis
☐ Depression
☐ Diabetes
☐ Emphysema
☐ GERD (heartburn/reflux)
☐ Hypertension (high blood pressure)
☐ Nasal Polyps
☐ Sleep Apnea

☐ Stroke
☐ Other (specify): _____
☐ **Don't know**

Do you currently have health insurance?

☐ Yes
☐ No
☐ Prefer not to answer

[Programmer note: If answered "yes"] What type of health insurance coverage do you have? (Check all that apply)

☐ Third-party payer (for example, United Healthcare, Blue Cross/Blue Shield, Aetna.)
☐ Managed care organization
☐ Tricare (military health insurance)
☐ Medicare
☐ Medicaid (MassHealth)
☐ Self-pay
☐ Unsure
☐ Other (please specify): _____

15. APPENDIX H. PATIENT VISIT EXPERIENCE SURVEY

Visit Experience Survey (AMAZE™ App)

Dear Research Participant,

Thank you for taking part of the AMAZE™ Asthma Research Study at Massachusetts General Hospital (MGH).

As part of the study procedure, please complete the survey below.

If you have any questions, please contact the Study Team at CCI [redacted].

Thank you!

You've been using the AMAZE™ *App to track your asthma symptoms and find more information on asthma. Please answer the following questions, keeping in mind how the use of the* AMAZE™ *App may have affected your clinic experience you had recently.*

Your responses are strictly confidential and will not affect your clinical care in any way.

1) Was the visit initiated by (check one):

☐ Patient

☐ Healthcare Provider

		Strongly Agree	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
2) The AMAZE™ *App* helped me discuss my asthma with my healthcare provider(s) during my most recent visit	□ Not applicable	☐	☐	☐	☐	☐
3) I received information about my asthma that helped me better understand my condition during my most recent visit	□ Not applicable	☐	☐	☐	☐	☐
4) I received information about my asthma medications during my most recent visit	□ Not applicable	☐	☐	☐	☐	☐
5) I was given information about additional care that I	□ Not applicable	☐	☐	☐	☐	☐

need for my asthma during my most recent visit						
6) I was included in making decisions about my asthma treatment during my most recent visit	□ Not applicable	☐	☐	☐	☐	☐
7) The AMAZE™ *App* helped the appointment with my doctor go more smoothly.	□ Not applicable	☐	☐	☐	☐	☐
8) The time spent with my healthcare provider(s) discussing my asthma during my most recent visit was better compared to my last visit.	□ Not applicable	☐	☐	☐	☐	☐
9) I found it was easier to schedule an appointment with my doctor using the AMAZE™ *App*	□ Not applicable	☐	☐	☐	☐	☐
10) The visit helped avoid an ER or Urgent Care center visit or hospitalization	□ Not applicable	☐	☐	☐	☐	☐

16. APPENDIX I. POST-STUDY SURVEY (FOR HCPS)

Post-Study Survey (AMAZE™ App - Clinical Staff Research Participant)

Dear Clinical Staff Research Participant,

Thank you for taking part of the AMAZE™ Asthma Research Study at Massachusetts General Hospital (MGH).

As part of the study procedure, please complete the survey below.

If you have any questions, please contact the Study Team at CCI [redacted]. Thank you!

The purpose of this questionnaire is to obtain your feedback on the implementation of AMAZE™. This questionnaire should take approximately 10 minutes to complete. As an employee of MGH, your participation is completely voluntary and will not impact your job in a positive or negative manner. All information collected from you will be kept without any personal information. You will be identified in the research records by a code name or number. By completing this questionnaire, you are agreeing to participate in this study.

How would you rate the overall ease of implementing AMAZE™ on a platform into your clinical practice?

☐ Very easy
☐ Somewhat easy
☐ Not easy or difficult
☐ Difficult
☐ Very Difficult

Did the AMAZE™ help you manage your patients?

☐ Not at all
☐ Slightly
☐ Somewhat
☐ Moderately
☐ Very well

Regardless of intermittent or persistent, on average, what percentage of your asthma patients would you classify as:

___ % Mild asthma
___% Moderate asthma
___% Severe asthma
= 100%

On average, what percentage of your patients would you classify as:

___ % Well-controlled
___ % Not well-controlled
___ % Very poorly controlled
= 100%

On average, what percentage of your asthma patients do you feel are at (1) low, (2) medium, and (3) high risk for adverse outcomes from their asthma? Please fill out below.

___ % Low risk
___ % Medium risk
___ % High risk
= 100%

Did AMAZE™ help you identify patients who were at risk for adverse health outcome (e.g., hospitalizations, exacerbations, medication side effects) from their asthma that you would have otherwise missed?

☐ Yes
☐ No

What did you find most useful about the AMAZE™ platform? *Check all that apply*

☐ Ability to track symptoms
☐ Ability to asthma triggers
☐ Ability to track reliever medication use
☐ Ability track ER visits/ hospitalizations
☐ Ability to track air flow measurements
☐ Patient-HCP messaging feature
☐ Ability to assign another healthcare provider to a patient
☐ Integration of AMAZE™ platform with electronic health records
☐ Ability to track level of impairment through ACT™ scores
☐ Ability to receive alerts (flags) based on patient responses in the app
☐ Other: _____

What did you find least useful or cumbersome about AMAZE™ platform*? Check all that apply*

☐ Ability to track symptoms

☐ Ability to asthma triggers
☐ Ability to track reliever medication use
☐ Ability track ER visits/ hospitalizations
☐ Ability to track air flow measurements
☐ Patient-HCP messaging feature
☐ Ability to assign another healthcare provider to a patient
☐ Integration of AMAZE™ platform with electronic health records
☐ Ability to track level of impairment through ACT™ scores
☐ Ability to receive alerts (flags) based on patient responses in the app
☐ Other (Please Specify): _____

How frequently would you want to track the following for appropriate management of patients?

Symptoms	☐ Daily ☐ Weekly ☐ Monthly ☐ Other_____
Asthma triggers	☐ Daily ☐ Weekly ☐ Monthly ☐ Other_____
Rescue medication use	☐ Daily ☐ Weekly ☐ Monthly ☐ Other_____
Maintenance medication use	☐ Daily ☐ Weekly ☐ Monthly ☐ Other_____
Steroid medication use	☐ Daily ☐ Weekly ☐ Monthly ☐ Other_____
ER / Urgent Care visits	☐ Daily ☐ Weekly ☐ Monthly ☐ Other_____
Peak flow / FEV1	☐ Daily ☐ Weekly ☐ Monthly ☐ Other_____

Did AMAZE™ improve any of the following: *Check all that apply*

☐ Increased recognition of patients whose asthma placed their health at risk
☐ Increased recognition of conditions/risks, comorbidities driving poor asthma control
☐ Improved recognition of patient goals
☐ Improved patient engagement with their treatment, risk, or control
☐ Improved patient adherence with their treatment
☐ Improved efficiency of patient visit
☐ Increased educational efforts

While using AMAZE™ disease management platform (DMP), how often did you change treatment?

☐ No different than before using the AMAZE™
☐ More often than before
Was the treatment change more often a:
☐ Step down (for example: lower dose/fewer drugs)
☐ Step up (for example: higher dose/additional drugs)
☐ Same level (for example: similar class/level of treatment)
☐ Less often than before

What features of AMAZE™ do you think could be improved?

_____

_____

_____

What barriers did you encounter in implementing AMAZE™ into your clinical practice?

_____

_____

_____

Do you have any other comments or suggestion?

_____

_____

_____

17. APPENDIX J. PATIENT SATISFACTION QUESTIONNAIRE-18 (PSQ-18)

Participant Satisfaction Questionnaire-18 (PSQ-18)

Dear Research Participant,

Thank you for taking part of the AMAZE™ Asthma Research Study at Massachusetts General Hospital (MGH).

As part of the study procedure, please complete the survey below.

If you have any questions, please contact the Study Team at CCI [redacted].
Thank you!

In the table below are some things people say about medical care. Please read each one carefully, keeping in mind the medical care you are receiving now. (If you have not received care recently, think about what you would expect if you needed care today.) We are interested in your feelings, good and bad, about the medical care you have received.

SHORT-FORM PATIENT SATISFACTION QUESTIONNAIRE (PSQ-18)

These next questions are about how you feel about the medical care you receive.

On the following pages are some things people say about medical care. Please read each one carefully, keeping in mind the medical care you are receiving now. (If you have not received care recently, think about what you would expect if you needed care today.) We are interested in your feelings, good and bad, about the medical care you have received.

How strongly do you AGREE or DISAGREE with each of the following statements?

(Circle One Number on Each Line)

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
1. Doctors are good about explaining the reason for medical tests	1	2	3	4	5
2. I think my doctor's office has everything needed to provide complete medical care	1	2	3	4	5
3. The medical care I have been receiving is just about perfect	1	2	3	4	5
4. Sometimes doctors make me wonder if their diagnosis is correct	1	2	3	4	5
5. I feel confident that I can get the medical care I need without being set back financially	1	2	3	4	5
6. When I go for medical care, they are careful to check everything when treating and examining me	1	2	3	4	5
7. I have to pay for more of my medical care than I can afford	1	2	3	4	5
8. I have easy access to the medical specialists I need	1	2	3	4	5

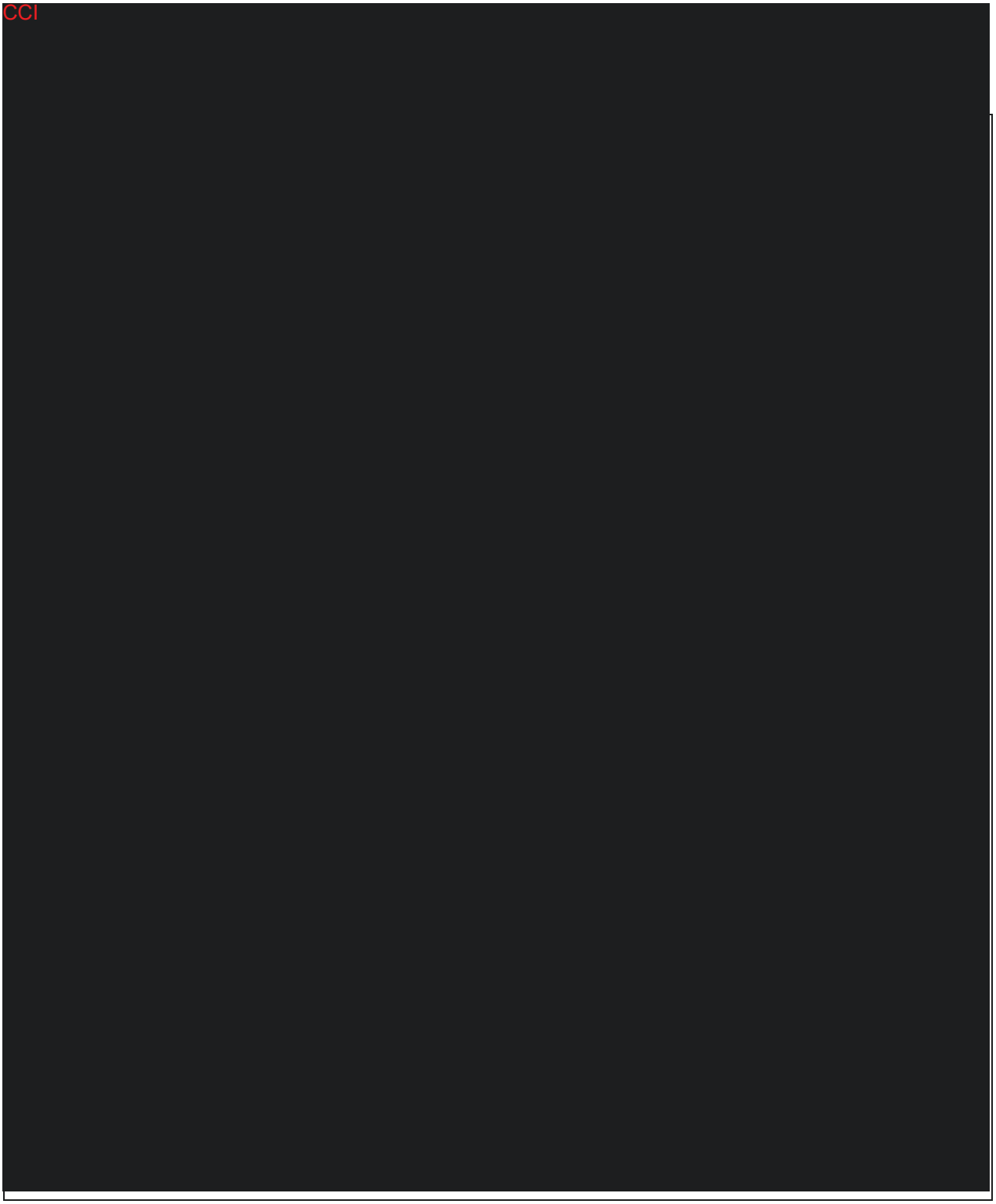
How strongly do you AGREE or DISAGREE with each of the following statements?

(Circle One Number on Each Line)

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
9. Where I get medical care, people have to wait too long for emergency treatment	1	2	3	4	5
10. Doctors act too businesslike and impersonal toward me	1	2	3	4	5
11. My doctors treat me in a very friendly and courteous manner	1	2	3	4	5
12. Those who provide my medical care sometimes hurry too much when they treat me	1	2	3	4	5
13. Doctors sometimes ignore what I tell them	1	2	3	4	5
14. I have some doubts about the ability of the doctors who treat me	1	2	3	4	5
15. Doctors usually spend plenty of time with me	1	2	3	4	5
16. I find it hard to get an appointment for medical care right away	1	2	3	4	5
17. I am dissatisfied with some things about the medical care I receive	1	2	3	4	5
18. I am able to get medical care whenever I need it	1	2	3	4	5

18. APPENDIX K. SIX-MONTH CHART REVIEW CASE REPORT FORM

CCI



New Medication/ Continued, Same Dose/ Continued, Increased Dose/ Continued, Decrease Dose/ Discontinued/ Not Applicable

ICS - Aerospan (flunisolide)
ICS - Alvesco (ciclesonide)
ICS - Arnuity Ellipta (fluticasone furoate inhalation powder)
ICS - Asmanex Twisthaler/HFA (mometasone furoate)
ICS - Beclovent HFA (beclomethasone dipropionate)
ICS - Flovent HFA/Disc (fluticasone propionate)
ICS - Flunisolide
ICS - Pulmicort Flexhaler/Respules (budesonide)
ICS - QVAR HFA/Redihaler (beclomethasone dipropionate)
ICS - Triamcinolone Acetonide
ICS - Vanceril HFA (beclomethasone dipropionate)
ICS/LABA - Advair Diskus/HFA (fluticasone propionate and salmeterol)
ICS/LABA - Airduo Respiclick (fluticasone propionate and salmeterol)
ICS/LABA - Breo Ellipta (fluticasone furoate and vilanterol)
ICS/LABA - IBCuSd/eLAsoBnAi d-e D/fuolremrao tHeFrAol (mometasone furoate and formoterol fumarate dihydrate)
ICS/LABA - Symbicort (budesonide/formoterol fumarate dihydrate)
ICS/LABA - Wixela Inhub (fluticasone propionate and salmeterol)
LABA - Arcapta (Indacaterol)
LABA - Arformoterol
LABA - Brovana (arformoterol tartrate)
LABA - Foradil (formoterol fumarate)
LABA - Indacaterol
LABA - Serevent (Salmeterol xinafoate)
LABA - Striverdi (Oldaterol)

LAMA - Incruse Ellipta (Umeclidinium)
LAMA - Spiriva Respimat/Handihaler (tiotropium bromide)
LAMA - Tudorza/Aclidinium (aclidinium bromide)
Triple Therapy (fixed dose combination) - Trelegy Ellipta (fluticasone furoate, umeclidinium, vilanterol)
LTRA - Accolate (Zafirlukast)
LTRA - Singulair (montelukast sodium)
LTRA - Zyflo (zileuton)
Theophylline Preparations - Elixophylline (Theophylline)
Theophylline Preparations - Theo-24 (Theophylline)
Theophylline Preparations - Theochron (Theophylline)
Chronic Add-on Therapy (Macrolides) - Zithromax (Azithromycin)
Chronic Add-on Therapy (Macrolides) - Biaxin (Clarithromycin)
Chronic Add-on Therapy (Macrolides) - Erythromycin (Erythrocin)
Biologics - Cinqair (reslizumab)
Biologics - Dupixent (dupilumab)
Biologics - Fasenra (benralizumab)
Biologics - Nucala (Bmioelopgoilcizsu -m Xaobla)ir (omalizumab)
Rescue Inhaler Use - Daily Use (SABA)
Rescue Inhaler Use - SABA alone
Rescue Inhaler Use - SABA+ICS
Rescue Inhaler Use - LABA+ICS
Rescue Inhaler Use - Nebulizer
Rescue Inhaler Use - SAMA
Other - Please specify
Name of Nebulizer

ASTHMA EXACERBATION HISTORY

An asthma exacerbation is defined by a change in asthma control requiring a course of oral steroids (i.e., at least 3 days with at least 10 days between each burst) and/or steroid injection and/or a hospitalization or emergency department visit for an asthma exacerbation.
Importantly, record only the highest utilization for each exacerbation, do not double count exacerbation episodes. If an OCS course was due to a hospitalization, do not record as OCS course but as the hospitalization

4. Number of times since enrollment asthma symptoms **required an emergency department or urgent care visit (but not an overnight stay in the hospital**):
   _____ ER/urgent care visits (with no overnight hospital stay)

5. Number of times since enrollment that there was a worsening in asthma symptoms that **required a hospital stay for greater than 24 hours**: _____ times admitted to hospital

6. Number of unplanned ambulatory clinic visits due to exacerbation in since enrollment:
   _____ unplanned visits

7. How many courses of oral corticosteroids (OCS) was the patient prescribed over the since enrollment for asthma exacerbations unrelated to emergency department, urgent care or, unplanned ambulatory clinic visits or hospitalizations? _____

Investigator Final Confirmation

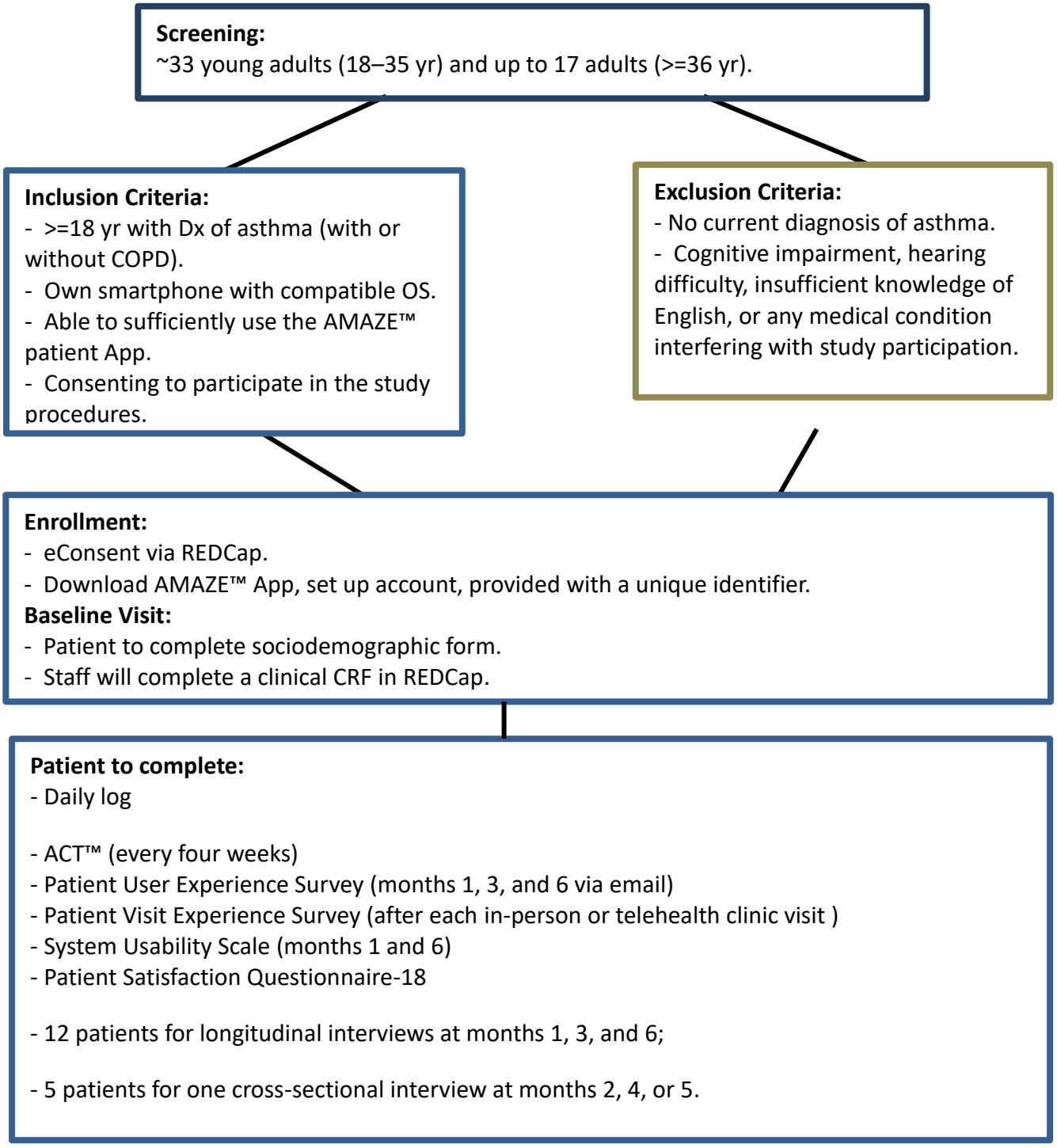
Investigator/Coordinator Full Name

Dawei Jiang
Remona Kanyat
Dalton Lancaster
Peter Moschovis
Jehan Alladina

Investigator/Coordinator Signature: _____

Date: _____

20. APPENDIX L. MGH WORKFLOW FOR IMPLEMENTATION OF DMP IN CLINICAL PRACTICE



MGH staff to complete:
- Clinical Case Report Form (initial visit)
- Chart Review Case Report Form (month 6)
- System Usability Scale (months 1 and 6)
- Follow-up Process Interviews (n=4, months 1, 3, and 6)

- Post-study Survey

Study monitoring:
- Nurse to monitor the patient dashboard twice a day

- Physician to review the dashboard during every clinical visit

Outcomes:
Primary Outcome: Feasibility, usability, perceived value, and potential benefits of the AMAZE™ implemented in clinical practice.

Process Outcomes: Evaluating the impact of AMAZE™ on clinical practice, including duration of patient visits and services, as well as responses to survey items on changes to timing of scheduling visits, communication during the visit, and satisfaction with medical care received.

Exploratory Clinical Outcomes: evaluate how AMAZE™ impacts key clinical outcomes including exacerbations, HCRU, change in therapy, and exposure to COVID-19

21. APPENDIX M. PATIENT USER EXPERIENCE SURVEY

User Experience Survey (AMAZE™ App)

Dear Research Participant,

Thank you for taking part of the AMAZE™ Asthma Research Study at Massachusetts General Hospital (MGH).

As part of the study procedure, please complete the survey below.

If you have any questions, please contact the Study Team at CCI .

Thank you!

In general, how would you describe your asthma in terms of severity?

A. Mild
B. Moderate
C. Severe
D. Other (Please specify): _____

Approximately, how many asthma flare-ups (also called exacerbations) did you have in the last 30 days?

_____ # of flare-ups

Who is your primary asthma doctor at Massachusetts General Hospital (MGH)?

PPD

PPD

Other (Please Specify) _____

Overall, how satisfied are you with your asthma care at MGH?

Very Unsatisfied
Unsatisfied
Neutral
Satisfied
Very Satisfied

Indicate your level of agreement with the following statement:

I have control over my asthma.

Strongly Agree
Agree
Neither
Disagree
Strongly disagree

I understand my asthma.

Strongly agree
Agree
Neither agree nor disagree
Disagree
Strongly disagree

Since the start of the study, use of the AMAZE™ app helped me avoid ER or Urgent Care center visit(s) or hospitalization(s).

A. Strongly agree
B. Agree
C. Neither agree nor disagree
D. Disagree
E. Strongly disagree
F. Not applicable – I did not use the app

Please **rate** the following features using a 5-point rating with 5 being the best possible score. If you do not use a given feature, you do not have to rate it.

1 (lowest score)
2
3
4
5 (highest score)
Did not use the feature

Daily log (where you track symptoms, etc.)
Messaging with MGH
Asthma education (articles, videos)
Air quality
My Plan (list of meds & reminders)
Trends (daily log summaries / graphs)
Appointments (viewing and scheduling)
Care Team Request (Asthma Control Test™ - monthly 5-question survey)

How frequently do you want to track the following for your doctor:

Symptoms Daily Weekly Monthly Other (Please Specify)_____

Asthma triggers Daily Weekly Monthly Other (Please Specify)_____

Rescue medication use Daily Weekly Monthly Other (Please Specify)_____

Maintenance medication use Daily Weekly Monthly Other (Please Specify)_____

Steroid medication use Daily Weekly Monthly Other (Please Specify)_____

ER / Urgent Care visits Daily Weekly Monthly Other (Please Specify)_____

Peak flow / FEV1 Daily Weekly Monthly Other (Please Specify)_____

What concerns if any do you have about the AMAZE^{TM} app? [Select all that apply]
Data / privacy concerns.
I do not find the app helpful.
I forget to use it.
There are things missing that I want in the app.
It is not fun to use.
It is not easy to use.
Other: _____
[radio button] I do not have any concerns.

Overall, how satisfied are you with the AMAZE^{TM} App?
Very Unsatisfied
Unsatisfied
Neutral
Satisfied
Very Satisfied

Why do you feel that way about the AMAZE^{TM} App?
_____

How likely are you to recommend the AMAZE™ App to another patient at MGH who has asthma?

Very Unlikely
Unlikely
Undecided
Likely
Very Likely

Please share any additional feedback you have about the app (suggested topics below):

- What you like vs do not like about the app
- What works well vs what does not
- Any issues / bugs you have found in the app
- Anything else you think we should know about the app

22. APPENDIX N.1 SYSTEM USABILITY SCALE (SUS) ADMINISTERED AT MONTHS 1 AND 6: Patients

System Usability Scale Survey (AMAZE™ App)

Dear Research Participant,

Thank you for taking part of the AMAZE™ Asthma Research Study at Massachusetts General Hospital (MGH).

As part of the study procedure, please complete the survey below.

If you have any questions, please contact the Study Team at CCI [redacted].

Thank you!

For each of the following statements, mark one box that best describes your reactions to the AMAZE™ Application (App).

	Strongly Agree	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
I think that I would like to use this app frequently.	☐	☐	☐	☐	☐
I found the app unnecessarily complex.	☐	☐	☐	☐	☐
I thought the app was easy to use.	☐	☐	☐	☐	☐
I think that I would need the support of a technical person to be able to use this app.	☐	☐	☐	☐	☐
I found the various functions in this app were well integrated.	☐	☐	☐	☐	☐
I thought there was too much inconsistency in this app.	☐	☐	☐	☐	☐
I would imagine that most people would learn to use this app very quickly.	☐	☐	☐	☐	☐
I found the app very cumbersome to use.	☐	☐	☐	☐	☐
I felt very confident using the app.	☐	☐	☐	☐	☐
I needed to learn a lot of things before I could get going with this app.	☐	☐	☐	☐	☐

23. APPENDIX N.2 SYSTEM USABILITY SCALE (SUS) ADMINISTERED AT MONTHS 1 AND 6: MGH Staff

System Usability Scale Survey (AMAZE™ App – Clinical Staff Research Participant)

Dear Clinical Staff Research Participant,

Thank you for taking part of the AMAZE™ Asthma Research Study at Massachusetts General Hospital (MGH).

As part of the study procedure, please complete the survey below.

If you have any questions, please contact the Study Team at CCI [redacted]. Thank you!

For each of the following statements, mark one box that best describes your reactions to the AMAZE™ clinician dashboard.

	Strongly Agree	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
I think that I would like to use this dashboard frequently.	☐	☐	☐	☐	☐
I found the dashboard unnecessarily complex.	☐	☐	☐	☐	☐
I thought the dashboard was easy to use.	☐	☐	☐	☐	☐
I think that I would need the support of a technical person to be able to use this dashboard.	☐	☐	☐	☐	☐
I found the various functions in this dashboard were well integrated.	☐	☐	☐	☐	☐
I thought there was too much inconsistency in this dashboard.	☐	☐	☐	☐	☐
I would imagine that most people would learn to use this dashboard very quickly.	☐	☐	☐	☐	☐
I found the dashboard very cumbersome to use.	☐	☐	☐	☐	☐
I felt very confident using the dashboard.	☐	☐	☐	☐	☐
I needed to learn a lot of things before I could get going with this dashboard.	☐	☐	☐	☐	☐

24. APPENDIX O. FOLLOW-UP SEMI-STRUCTURED INTERVIEW GUIDES

Longitudinal Follow-up Interview Guide [For months One, Three, and Six]

Hello, my name is [interviewer name] and I am working with [MGH] and AstraZeneca to see how well the new asthma app is working for you. You previously consented to participate in this study regarding the asthma app and you have been randomly selected to participate in up to three interviews periodically through the duration of the study (roughly 1, 3, and 6 months after you enrolled in the study). During each interview, we will ask for your feedback on the [MGH] asthma app that you have been using, including ease of use, suggestions for changes. There are no right or wrong answers; we'd like to hear your personal experience with the app.

I would like to have your permission to audio record this session. The recording will be used to help us improve the app and write a report about the things we talked about here today. The audio will be transcribed by a third-party vendor, TransPerfect, but any identifying information you say during the interview will be removed from the transcript. It will be kept confidential and your name will not be linked with your responses. If an adverse event (side effect) for an AstraZeneca product were to come up during the course of this interview, I am required to report that.

Begin Recorder: This is participant ID [Insert number here] for [month one/three/six] longitudinal follow-up interview of study EVA-28838. Do I have your permission to record this session? I want to confirm that you still consent to participate in the interview.

Thank you for completing the asthma app so far.

Introduction

First, we'll be going over a brief introduction to your experience with medical apps and your smartphone.

1. How long have you have been using the asthma app?
2. When you initially started the study, you had an [iPhone or Android]. Just to confirm, do you still have that phone?
3. Do you use any medical health apps beside the asthma app?
    a. [*If* needed]: If yes, what do you use and what do you use it for?

Asthma App – App Use and Experience

Now I'd like to ask you a few questions on your overall thoughts on the app and the notification/reminder system.

1. Overall, what do you think of the app?
    a. In what ways is it easy to use?
    b. In what ways is it hard to use?

2. [*For month 1 interview only*]: What did you think about the app when you were first contacted by [MGH]?
   a. Walk me through the process of finding, downloading, and using the app.
   b. Was there anything confusing or difficult for downloading the app and gaining access to the features?
3. Is there anything confusing about using the asthma app?
   a. [If yes]: What is confusing?
4. Do you have any trouble accessing any of the features in the app?
   a. [If yes]: Tell me more about that. What trouble do you have?
5. What notifications or reminders, if any, do you receive from the asthma app?
   a. Do you find the reminders helpful?
      i. Do you recall what time of day you set the reminders for? Why did you choose that time?
      ii. [Probe as needed]: Do you recall what you received a reminder for (i.e., medications, daily log, air quality alerts)?
   b. [*If no*]: Did you turn your notifications off? Would daily reminders have been helpful?
6. How often did you use the app? What time of day did you use it?
   a. [*If less than once a day*]: Why did you use it less than once a day? Is there anything missing that would have made you more likely to use the app every day?
7. How, if at all, did you report issues/problems that you found in the app? (*Note to interviewer: there is an option for participants to report bugs/issues in the app.*)

Features of the App

1. What features of the Asthma App (i.e., daily log, trends, messaging) do you use?

Now I'd like to go through each of the features with you. Feel free to open your app while we go through the sections. [Interviewer to wait for participant to open app if needed.]

a. Interviewer for each of the features go through the following probes:

i. Do you use this feature in the app? If yes, how often do you use the app? If no, why do you not use this feature?

ii. How helpful is the feature? Would you continue to use this feature to help monitor your asthma?

iii. Is there anything confusing or unclear about this feature? What ideas do you have to make the feature better?

iv. [For daily log only]: Have you ever had to change any of your answers for the daily log? If so, did you have any problems making changes?

v. [For daily log only]: What did you think about the amount of time it took you to complete the daily log? Was it too long, too short, or enough time?

Feature	Use	Helpfulness	Suggestions
Daily Log			
Air Quality			
Appointments			
ACT			
Education			
My Plan			
Trends			
Messaging			
Notifications			

Text and Image Size

4. Did you have any problems with the font size on any of the screens?
    a. Would you change anything about the way the text or images appear on any of the screens?

Using the App to Communicate with Doctor or During Visits

Now I'd like to discuss how you used the app to communicate with your doctor via the messaging feature or during a doctor's visit.

[Note to interviewer: the previous section probes on the messaging feature so use these probes if not fully addressed to this point.]

1. How do you typically communicate with your doctor outside of appointments?
2. Did you use the messaging feature to send communication to your doctor?
    a. If yes, what things did you discuss while messaging your doctor?
        i. Would you continue to use the messaging feature in the future? Why or why not?
        ii. How often did you send messages to your doctor through the app?
        iii. Which subject line did you typically use and why? [Note to interviewer: if needed explain that there is a forced choice for the subject line.]
    b. If no, why did you not use the messaging feature?

3. We noticed you had a doctor's visit on [insert date]. Did you and your doctor discuss anything regarding the app during the visit?
    a. If yes, what was discussed? Did you open the app during your visit and show any specific log or trends?
        i. How did the app change the communication with your doctor during the visit compared to previous visits?
    b. If no, do you think discussing the app or any feature of the app would have been helpful during your visit?

Long-Term Use

1. Would you consider using this app as a part of your long-term asthma care? Why or why not?
    a. If no, what would improve your experience with completing this app every day?
2. What do you hope to gain from the app? What do you think your doctor will gain from you using the app?
3. Do you feel like using the app has helped you avoid ER or hospital visits? Why or why not?
4. Are you likely to recommend this app to a person living with asthma? Why or why not?
5. What other feedback would you like to give us on this app today?

Thank you! We are all done with the interview. Interviewer should confirm the participant still has a ClinCard and let them know the $[insert payment] will be uploaded within 24 hours of the interview.

Cross-Sectional Patient Discussion Guide: AMAZE™ Asthma App

- **Purpose.** Hi, my name is [_____] and I'm a researcher with AstraZeneca, a pharmaceutical company. We wanted to speak with you today to get your feedback on the AMAZE™ asthma app that you have been using. We want to know what you think of the app so we can continue making this app better for people like you.
- **Anonymity / Confidentiality.** The research is all confidential and anonymous and none of your data will be directly paired to you. To keep things confidential, please never say your full name or any other identifiable information like your phone number or address, etc. We'll stick to first names only.
- **Honest Feedback.** Feel free to provide your honest feedback about the app today. Don't be afraid to share negative feedback, if you have any. I didn't personally create this so it won't hurt my feelings.
- **Adverse Events.** I'm not here to sell or market you any drug, but, if you should mention you had an adverse reaction come up on an AstraZeneca drug, I am required for

compliance reasons to report any details of that event you experienced.

- **Questions**. Do you have any questions for me before we get started?

Patient Intro

1. Tell me a little about yourself – what keeps you busy?
2. How long have you been living with asthma?
    a. How would you characterize it: mild, moderate, severe?
3. What are some of the biggest challenges you face living with asthma?

Phone Type + Health Apps

1. What type of phone do you have? I.e., Apple, Android?
2. How do you typically use your phone? What apps do you use the most?
3. Besides the asthma app, what kind of health apps/tools do you use or have you used in the past?
    a. Examples: Think AppleHealth, Fit Bit, Clinician portal, Headspace, etc.
4. Do you use MyChart? If so, how?

Experience with AMAZE™

App Introduction

1. How did you first learn about the asthma app?
    a. What was your reaction when you heard about it?
    b. Why do you think your clinician(s) wanted you to use the asthma app?
    c. What made you decide to join the asthma study?

Onboarding

2. Can you walk me through the process of finding and getting started with the app?
    a. Who, if anyone, helped you get started with the app? i.e., caregiver, staff, doctor
    b. How easy / difficult was it for you to find the app? How did you find it?
    c. How easy / difficult was it for you to create an account?
    d. What issues, if any, did you encounter with getting started with the app?
        i. I.e., finding it, downloading it, creating an account, etc.
3. Is there anything that could have been done differently to make onboarding to the app easier for you?

Overall

1. How have you been using the app? How often?
2. Have you encountered any issues / problems with the app?

    a. How did you resolve the issue, if at all?
3. Overall, what do you think of the asthma app?
    a. What parts are most / least useful?
4. Did it remind you of any other apps you've used before?

Specific Features

[Explore use and satisfaction of the following app features]

Questions for below:
-Did you use [feature]?
-How useful/helpful or not is [feature]?
-Any issues / problems with [feature]?
-What could be done to make this [feature] better?

Feature Set
Daily Log
Air Quality
Appointments
Asthma Control Test (ACT
Education
My Plan
Trends
Messaging
Notifications

[Additional questions to probe on when exploring a given feature]

1. **Daily log**
    a. How often do you typically fill out your log?
        i. What was your longest log streak?
    b. What time of day do you generally fill out the log? Why that time?
    c. Are there any questions in the daily log that are confusing? That do not apply to you?
        i. Do you own a peak flow meter? Ability to record FEV1?
    d. Were the symptoms you were experiencing always reflected in the list of symptom options?
        i. What about triggers?
    e. To what extent did the medication question make sense? Is 'Quick-relief / as-needed' a familiar term?
    f. How helpful was the review screen?
    g. How often did you go back and add a log for days that you missed?
    h. How often did you go back in and edit logs?
    i. How, if at all, do you know that a clinician is looking at your log data?
    j. Do you have any thoughts on how we can make filling out the log easier for you?
2. **Air Quality**
    a. How important is air quality to track for you?
    b. Is this something you tracked prior to the app?
    c. How else did you use this feature i.e., did you use it to track allergens like pollen, ragweed, etc.?
        i. If yes, how helpful? If no, why not?
3. **Appointments**
    a. How accurate was the information reflected in the appointments card? Anything unusual?
    b. How many appointment reminders did you receive?
    c. Did you use the link to schedule additional appointments? Why/why not?
4. **Asthma Control Test (ACT)**
    a. How was this different from the daily log for you?
    b. How easy / difficult were the questions?
    c. Have you ever taken this questionnaire before?
    d. Why do you think your clinicians wanted you to answer these questions?
5. **Education**
    a. Which articles did you explore if any?
        i. Asthma EDU? Depression EDU?
    b. What education is missing that would be important to have?
    c. What type of media format do you prefer: video, articles, podcasts, etc.?
6. **My Plan**
    a. How helpful was it to have your list of medications available? How did you use it?
        i. How accurate was the list of medications? How accurate were the images of your medications?
        ii. Was there anything confusing about the list?
    b. Did you use the medication reminder feature? If so, how helpful was that?
7. **Trends**

   a. How did you use Trends?
      i. To what extent did you use Trends in your appointment(s) with your doctor?
      ii. Which view (daily, weekly) did you use the most?
   b. What do you think is the purpose of Trends?
   c. To what extent is this the type of information you are interested in seeing?
   d. How easy/difficult were the graphs to understand and interpret?
   e. Did you use the 'share with caregiver' feature? If so, who did you share with and why?

8. **Messaging**
   a. What types of messages did you send to your clinician?
      i. Which subject line did you most commonly select?
   b. What was the response time like?
   c. How would you normally get in touch with your clinician before you had this app?
9. **Notifications**
   a. What types of notifications did you receive from the app?
   b. How helpful were those notifications?
   c. Did you turn on/off any notifications? What did you think of the frequency?

Bugs / Reporting

1. Have you encountered any bugs in the app?
   a. [if yes] were you able to report the bug?
2. Did you have to contact the support team at all?
   a. If so, how helpful were they?
   b. Were they able to resolve the issue you had?

Appointments with Doctor

1. Have you had any appointments with your doctor since you started using the app?
   a. If yes, how if at all was that appointment different than what you're used to?
   b. How if at all did they talk about the data that you put in the app?
   c. At any point during the appointment, did you pull up your app to show them anything you had recorded?

Value

1. What have you gained, if anything, from using this app?
2. If you had a magic wand, what would you change about this app?
3. On a scale of 1 to 5 (1=not at all; 5=extremely), how likely would you be to recommend this app to someone else living with asthma?
   a. Why a [#]?
   b. [if less than 5] What would bring your score closer to a 5?

What else do you think the team should know about the app that we haven't already discussed here today?

25. APPENDIX P. RECRUITMENT TRACKING LOG

RECRUITMENT TRACKING LOG (EVA-28838): SITE [XXX]

Please send the Recruitment Tracking Log to Evidera via SharePoint

Participant ID	BI Linked ID	Patient Age	Patient Sex	Recruitment Quotas	Phone Type (Operation System)	Outcome	Reason for Ineligible
			☒ Male ❑ Female	❑ New in practice (< 3 months) but uncontrolled ❑ ≥ one exacerbation in past 12 months ❑ Young adult ❑ Adult	❑ iOS (iOS 13 and iPhone 8 or newer) ❑ Android (OS 8.0 or newer) ❑ Other	☒ Eligible ❑ Ineligible ❑ Declined	
			❑ Male ❑ Female	❑ New in practice (< 3 months) but uncontrolled ❑ ≥ one exacerbation in past 12 months ❑ Young adult ❑ Adult	❑ iOS (iOS 13 and iPhone 8 or newer) ❑ Android (OS 8.0 or newer) ❑ Other	❑ Eligible ❑ Ineligible ❑ Declined	
			❑ Male ❑ Female	❑ New in practice (< 3 months) but uncontrolled ❑ ≥ one exacerbation in past 12 months ❑ Young adult ❑ Adult	❑ iOS (iOS 13 and iPhone 8 or newer) ❑ Android (OS 8.0 or newer) ❑ Other	❑ Eligible ❑ Ineligible ❑ Declined	
			❑ Male ❑ Female	❑ New in practice (< 3 months) but uncontrolled ❑ ≥ one exacerbation in past 12 months	❑ iOS (iOS 13 and iPhone 8 or newer) ❑ Android (OS 8.0 or newer) ❑ Other	❑ Eligible ❑ Ineligible ❑ Declined	

				❑ Young adult ❑ Adult			

26. SIGNATURES

ASTRAZENECA SIGNATURE(S)

AMAZE Asthma Implementation clinical pilot Study - MGH

This Interventional Study Protocol has been subjected to an internal AstraZeneca review. I agree to the terms of this Study protocol.

AstraZeneca representative

<<Name, title>> Date
(Day Month Year)

<<Email address and telephone number>>

AstraZeneca representative

<<Name, title>> Date
(Day Month Year)

<<Email address and telephone number>>