Statistical analysis plan	
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D2287R00166 Implementation Study:

AMAZE™ Asthma Implementation Clinical Pilots - Greater Austin Allergy (GAA) and Massachusetts General Hospital (MGH)

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AZ Study Statistician

TBD	Date

AMAZE™ Asthma Implementation Clinical Pilot - Greater Austin Allergy (GAA) and Massachusetts General Hospital (MGH)

Evidera Study Statistician

TBD	Date

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LIST OF ABBREVIATIONS

Abbreviations	Definitions
Abbreviation or special term	Explanation
ACT	Asthma Control Test
ANOVA	Analysis of variance
APP	Application
AZ	AstraZeneca
BI	BrightInsight
CRF	Case report form
DMP	Data Management Platform
FEV1	Forced expiratory volume in 1 second
GAA	Greater Austin Allergy
HCP	Healthcare practitioner
ID	Identifier
MGH	Massachusetts General Hospital
OCS	Oral corticosteroids
PCP	Primary care provider
PSQ-18	Patient Satisfaction Questionnaire-18
QI	Quality Improvement
REDCap	Research Electronic Data Capture
SAP	Statistical analysis plan
SD	Standard deviation
SUS	System Usability Scale
US	United States

AMENDMENT HISTORY

Date	Brief description of change

1 OBJECTIVES

The primary objective of this study 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 study is observational, 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 utilised, 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 Application (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?

The first exploratory objective is to assess the following clinical outcomes:

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

The second exploratory objective is to identify segments of patients that are most likely to benefit from using AMAZE™.

2 STUDY DESIGN AND SAMPLE SIZE

Study Design: This is an implementation study to assess the feasibility, usability, perceived value, and potential benefits of integrating the AMAZE™ Data Management Platform (DMP) at Greater Austin Allergy (GAA) and Massachusetts General Hospital (MGH). The AMAZE™ platform (developed by AstraZeneca/BrightInsight [BI]) consists of a clinician

dashboard to guide treatment and asthma management, and a patient App 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.

All study procedures for GAA are found in study protocol version 5.0; dated December 18th, 2020; study procedures for MGH are found in study protocol version 5.0; March 23rd, 2021.

Briefly, GAA will aim to recruit a diverse sample of asthma patients with varying disease severity and a maximum of 15 new patients to the GAA network will be included in the study. For MGH, 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). Eligible patients will be invited to participate in the study either in person on via telephone using a standardized recruitment script. For GAA, if interested, they will provide their email address to the site staff so that a consent form can be sent to them via email to sign via DocuSign, which is 21 CRF Part 11 compliant. For MGH, participants will be sent an email to consent via Research Electronic Data Capture (REDCap). The clinical site staff will review the consent with the patient either in person or via telephone and answer any questions they may have. This introductory email will also contain a link to a brief video describing the study.

After consenting to participate, patients will be sent an introductory email with link to download the App , 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 clinical site will complete a clinical case report form (CRF) to record baseline clinical information about the patient, while participants will be asked to complete a sociodemographic form via an emailed link. If 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. Additionally, the clinical sites may email reminders to complete the daily log to participants as needed.

After study launch, Evidera will conduct qualitative, longitudinal, follow-up interviews regarding process implementation with a random selection of patients and key clinical site personnel from GAA and MGH at months one, three, and six to gain a deeper understanding of the feasibility of implementing the asthma AMAZE™ platform. Patients from GAA (up to n=30) and MGH (up to n=15) will be randomly selected to participate in the qualitative interviews at 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. The follow-up interviews with site personnel (Up to n=6 at GAA and MGH) will elicit the advantages and disadvantages of implementing AMAZE™ in their clinic, their process for implementing these tools, what could be improved to facilitate

implementation, and any unforeseen potential effects of implementing these tools over time. An additional subset of MGH staff will be asked to complete the electronic staff surveys.

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 10 patients from GAA and MGH at each timepoint (excluding the patients who will be participating in the longitudinal interviews). The cross-sectional interviews are meant to help capture any new features or feedback from patients during the off-months in the longitudinal interviews and will be conducted on an as-needed basis.

In addition to the qualitative interviews, participants will be emailed a link to complete an electronic patient visit experience survey to evaluate their overall satisfaction with AMAZE™ and its impact on the visit. All participants will be asked to complete an electronic Patient User Experience survey at months 1, 3, and 6, sent via email, as well as the SUS at months 1 and 6. These surveys are meant to allow participants the opportunity to provide feedback on the App as they continue to interact with the App throughout the study. At the end of the study (approximately 3 months after completion of enrollment) prescribing providers and study coordinators at the clinical sites will complete a Post-study Survey and patients will complete the PSQ-18. The focus of these questionnaires will be to obtain additional feedback on the implementation of AMAZE™ and patient satisfaction with the medical care they receive, respectively. At Month six, clinical sites will also be asked to complete a chart review CRF for each patient. The patient App and/or clinician dashboard may be revised throughout the QI study based on feedback from patients and clinical staff.

A schedule of study Assessments is found below in Table A.

Table A. Schedule of Study Assessments

Procedures	Baseline	Month One	Month Two	Month Three	Month Four	Month Five	Month Six
Screen and Recruit[1]	S						
Consent via DocuSign	S/P						
Download App	P						
Completion of App	P	P	P	P	P	P	P
Monitor Clinician Dashboard	S	S	S	S	S	S	S
Clinical CRF	S						
Sociodemographic Form	P						
Patient User Experience Survey		P		P			P
System Usability Scale		P/S					P/S
Patient Visit Experience Survey[2]		P	P	P	P	P	P

Procedures	Baseline	Month One	Month Two	Month Three	Month Four	Month Five	Month Six
Patient Longitudinal Follow-up Interviews		P/E		P/E			P/E
Patient Cross-sectional Follow-up Interviews			P/AZ		P/AZ	P/AZ	
Clinical Site Staff Follow-up Interviews		S/E		S/E			S/E
Patient Satisfaction Questionnaire-18							P
Clinical Site Staff Post-Study Survey							S
Chart Review CRF							S

[1] For the QI full study, GAA sites will recruit a maximum of 60 patients each and MGH will target 50. 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 is sent within a week of a confirmed visit with their HCP at the site following baseline visit.

Abbreviation: AZ=AstraZeneca; DMP Product Team; CRF = case report form; E=Evidera; P=Patient; S=Clinical Site

Study Population: Participants will be recruited from GAA and MGH. GAA will attempt to recruit a diverse sample of asthma patients with varying severity and a maximum of 15 new patients to the GAA network. For MGH, approximately 10 patients who are new to the practice (less than 3-month history with the practice) and with uncontrolled asthma as well as patients experiencing at least 1 exacerbation in previous 12 months (n=approx. 40) will be recruited. Patients will be followed for up to six months while using the AMAZE™ App. Additional GAA patients beyond this maximum enrollment number who download and use the patient App will not be consented or included in the QI study.

Sample Size Estimations: 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. GAA site will target 120 patients and MGH will target 50. Implementing the AMAZE™ in this target sample of patients will provide sites 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.

3 ANALYSIS SETS

Analyses sets will include 1) all eligible patients successfully enrolled in the implementation study; and 2) Clinical site staff who utilized the AMAZE™ dashboard.

4 EXPOSURE(S) AND OUTCOMES

4.1 Exposures

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. 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 patient responds to questions in their daily log. The App allows participants to communicate with the GAA and MGH clinical site staff as well as see daily and weekly trends in their asthma. My plan, a component within the App, contains medications, air quality and upcoming appointments.

Every four weeks, the ACT™ will also be administered and completed by the patient.[1] The ACT™ consists of five items with the total score used to identify patients 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 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 QI study and completed the baseline survey will be emailed at months 1, 3, and 6 the patient user experience survey. The survey is meant to allow participants the opportunity to provide feedback 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 will be sent electronically any time a participant attends an in-person or telehealth clinic visit and has completed the baseline survey. 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 within a week of the visit. 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) will be sent electronically at months 1 and 6 for participants who completed the baseline survey 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.[2]

4.1.1.6 PSQ-18

At the end of the QI study (approximately 6 months), all participants who consented, completed the baseline survey, and participated in the QI study will be emailed a link to the Patient Satisfaction Questionnaire-18 (PSQ-18). The scoring manual can be found in APPENDIX A.

4.1.1.7 Follow-up Process Interviews with Patients

4.1.1.7.1 Longitudinal Interviews

A semi-structured interview guide 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.

4.1.1.7.2 Cross-Sectional Interviews

Semi-structured interview guides for months 2, 4, and 5 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 Clinical Site Completed

4.1.2.1 Clinical Case Report Form

For each participant, the clinical site will complete a paper CRF during the initial site visit after informed consent is obtained. The clinical CRF serves to characterise 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, the clinical site will complete a chart review clinical CRF 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 will be asked verbally to GAA clinical staff during the telephone interviews at months 1 and 6 to provide feedback on the clinical dashboard. For MGH, the SUS will be administered electronically.

4.1.2.4 Post-study Survey

All HCPs who participate will be asked to complete the Post-study Survey 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.

4.1.2.5 Follow-up Process Interviews with Clinical Site Staff

A semi-structured interview guide will also be used to obtain information from the same key clinical site study staff from each clinical site at months one, three, and six during 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 information on the process for implementing the AMAZE™ as part of clinical site visits and recommendations for improving processes related to implementation. Additional unscripted probes may also be used to gain further information or clarification. The interview guides may be modified as necessary during the study.

4.2 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:

1. **Technology Outcomes:** Technology outcomes will be assessed in a variety of ways throughout the QI 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 clinical sites. 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 qualitative interviews from key clinical site personnel at months one, three, and six will provide data regarding the usefulness and feasibility of implementing AMAZE™ into clinical practice.
- The monthly patient user experience surveys may be evaluated as well to determine how the platform is being utilized and the user friendliness of the App.

2. **Process Outcomes:** Similar to the technology outcomes described above, process outcomes will be evaluated using the patient and clinical site personnel 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™ 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(s)

There is no secondary outcomes in this study.

4.2.3 Exploratory Outcome(s)

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

- **Clinical Outcomes:** As part of AMAZE™, 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™ impacts key clinical outcomes of interest. Descriptive statistics (n, frequency, mean, and SD) will be utilized.

To address the second exploratory objective on identifying which segments of patients are most likely to benefit from using AMAZE™, 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.

Pending sample size, an additional exploratory regression analysis may be performed to analyze change in ACT score as the dependent variable, with the following possible independent variables: medication changes (i.e., step up, step down, no change), app engagement (i.e., engagement group), age, sex, attendance at a clinic visit, dashboard flags raised, and other possible clinical characteristics. All variables of interest will be evaluated within the ACT score timing (baseline completion and last ACT completion). Another parallel regression model may be conducted to evaluating PSQ-18 satisfaction score as the dependent variable, using similar independent variables as predictors.

4.3 Other Variables and Covariates

To be determined pending receipt of BrightInsight data.

5 ANALYSIS METHODS

5.1 General Aspects

All analyses will be conducted following the approved statistical analysis plan (SAP). The analyses detailed in the SAP will be conducted on a locked and clean data set. Table shells are located in APPENDIX B.

- Quantitative analyses will be performed using SAS version 9.4 and qualitative analyses will be performed using ATLAS.ti version 8.0 or higher.
- Descriptive statistics will be defined as follows:
    - For categorical variables: frequencies, percentages of each category with the number of patients with missing category data.
    - For continuous variables: frequencies, mean, standard deviation (SD), median, range (minimum [min]– maximum [max]).
- Descriptive statistics will be displayed with 1 decimal place.
- Analyses at the patient level will be calculated from the baseline date of enrollment, while analyses at the clinician level will be analyzed from the date the first patient is enrolled.
- No data imputations will occur in this analysis. All missing data will be tabulated and reported in the analysis tables.
- Weak, moderate, and strong Spearman correlations are defined as < 0.30, 0.30–0.60, and > 0.60 respectively.[3]
- All exploratory outcomes will be assessed with the total sample only;
- In the case of substantial deviations from data expectations, AZ and Evidera will work together to determine the necessary revisions in the analyses. Additional analyses,

deviations, and revisions will be summarized in a SAP amendment or memo-to-file and in the final report.

5.2 Disposition

A disposition table (Table 1; Figure 1) will be developed for the total sample and by site (GAA and MGH) to reflect study enrollment. The data disposition table will include:

- Number of patients enrolled from the GAA network and number of clinical site staff (medical doctor and support staff) from the GAA network who participated in the study
- Number of patients enrolled from the MGH network and number of clinical site staff (medical doctor and support staff) from the MGH network who participated in the study

5.3 Demographics and Clinical Characteristics

Descriptive statistics will be used to characterize the sample in terms of the duration enrolled in the study (in weeks), as well as sociodemographic and clinical characteristics (based on the patient demographic questionnaire, clinical CRF and six-month chart review case form) for the total sample and by site. The sociodemographic characteristics will be reported at the patient level (Table 2) and the clinical characteristics will be reported at both the patient and the physician levels (Table 3a series).

5.4 Primary Analyses: Generate Evidence on the Feasibility, Usability, Perceived Value, and Potential Benefits of the AMAZE™ Implemented in Clinical Practice

5.4.1 BrightInsight Usage Metrics Data

The frequency of use of the AMAZE™ App by patients and dashboard by clinical site staff during the study will be described using data collected by BI, pending data availability through BrightInsight. These analyses will be conducted for the total sample and by site:

- **Patient App Usage:** Descriptive statistics of the number of days per week that patient accessed the AMAZE™ App over the 6-month period and viewed the following tabs will be assessed (Table 4a.1 series). Weekly averages for each 4-week period will also be presented. If after the first month, App usage greatly decreases, descriptive statistics will be provided instead for the number of days per month that the patients accessed the App:
    - Home
    - Air quality
    - Appointments
    - Daily asthma log

- Educational material
- Messages
- My plan
- Notifications
- Settings
- Trends

- **Clinician Dashboard Usage:** Descriptive statistics of the number of days per week that clinical site staff accessed the AMAZE™ dashboard over the 6-month period (Table 4b.1 to Table 4b.3).

- **Patient Profiles of App Engagement and Agreement with Visit Survey Item 9 ("The visit helped avoid an ER or Urgent Care center visit or hospitalization"):** Patient engagement on the App will be defined as high (5-7 days per week), medium (3-4 days per week), or low (1-2 days per week) using completion of the daily asthma log as a measure of app usage. Specifically, patient engagement on the App (high, medium, low) will be described from Weeks 1-4 through Weeks 21-24 pending availability of data after Weeks 1-4 (Table 5a.1 to Table 5a.3). Patient profiles by agreement (agree/strongly agree) with visit survey item 9 ("The visit helped avoid an ER or Urgent Care center visit or hospitalization.") will also be explored (Table series 5b). In addition, patient engagement will be characterized by the following patient subgroups/segments from for the total sample and by site (Table series):

  - Age category (to be defined [TBD]);
  - Sex (Male, Female);
  - Level of education (Less than high school, Secondary/high school, Associate degree, technical or trade school, College/university degree, Postgraduate school, Other);
  - Ethnicity (Hispanic or Latino);
  - Race (White, Black or African American, Asian, Native Hawaiian or other Pacific Islander, American Indian or Alaska Native, Other);
  - Asthma severity (Intermittent, Mild persistent, Moderate persistent, Severe persistent).
  - Baseline ACT score category (Very Poorly controlled, Not well-controlled, Well-controlled)
  - GINA classification 1-5 (depending on sample size for each group a comparison between GINA 1-3 vs. GINA 4-5 may be conducted as well)

5.4.2 Other data

Descriptive statistics will be used to summarize the results of the following, for the total sample and by site:

- **Impact of AMAZE™ on patient visits:** Type of clinic visits will be shown descriptively Patient visit experience survey items from Weeks 1-4 through Weeks 24-24 (Table 6b.1 to Table 6b.3). In addition, Item 9: "The visit helped avoid an ER or Urgent Care center visit or hospitalization" will be described by the person that initiated a visit (either by the patient or the HCP) (Table 6c) and by visit type (Table 6d series). One visit type that will be reviewed is visits preceded by a flag in the prior 30 days.
- **Usability of mobile app:** SUS items for patients at Month 1 Survey and End of Study Survey (Table 7 series)
- **Usability of clinician dashboard:** SUS items for clinical site staff at Month 1 Survey and End of Study Survey (Table 8 series)
- **Evaluate feasibility and usability of AMAZE™ in clinical setting:** Post-study survey items for HCPs at End of Study Survey (Table 9 series)
- **Evaluate patient satisfaction with healthcare experience:** PSQ-18 items and subscale scores (General Satisfaction, Technical Quality, Interpersonal Manner, Communication, Financial Aspects, Time Spent with Doctor, Accessibility and Convenience) at End of Study Survey (Table 10 series)
- **Evaluate feasibility and usability of mobile app:** Patient user experience survey items at Month 1, Month 3 and End of Study Surveys (Table 11 series)

The following qualitative follow-up interviews (Appendix D) will be summarized and tabulated, reporting frequency counts and percentages, by month based on interviewers' notes:

- **Understand the long-term feasibility of the patient app:** Patient longitudinal interviews at Month 1, Month 3 and End of Study to gain a deeper understanding of the feasibility of implementing the AMAZE™ platform
- **Understand the feasibility and patient feedback on the app:** Patient cross-sectional interviews to Month 2, Month 4 and Month 5 with the AZ DMP Product team to gain a deeper understanding of the usability of the AMAZE™ platform
- **Understand the long-term feasibility of AMAZE™ in a clinical setting:** Clinical site staff interviews at Month 1, Month 3 and End of Study to gain a deeper understanding of the feasibility of implementing the AMAZE™ platform

Audio-recordings of interviews will be referred to as necessary to supplement interviewer notes. Qualitative results from the semi-structured interviews will be reviewed and grouped by theme to identify barriers, benefits, challenges, ease of implementation, and areas for improvement of the AMAZE™ from the patient's and the clinical site staff's perspective. Results will be presented for the total sample and by site.

5.5 First Exploratory Analysis: Assess the Impact of the AMAZE™ on Clinical Outcomes

Descriptive statistics will be used to summarize the results of the following, for the total sample and by site:

- Baseline clinical CRF: age (years) at asthma diagnosis, follow-up time (months) with an HCP for asthma, follow-up time with an HCP at GAA for asthma (months), smoking status, occurrence of spirometry lung function test in the last 12 months, occurrence of eosinophil blood count in the last 12 months, asthma severity, asthma control status, asthma medication in the last three months, health conditions other than asthma.

- Six-month chart review CRF for each patient: occurrence of in-person or telehealth clinic visits since study enrollment, change in patient's medication/testing since study enrollment, number of times of emergency department or urgent care visit (but not an overnight stay in the hospital) due to asthma symptoms since study enrollment, number of times of hospitalization (stay ≥ 24 hours) due to asthma symptom worsening since study enrollment, number of unplanned ambulatory clinic visits due to exacerbation since study enrollment, frequency of courses of oral corticosteroids (OCS) prescription, COVID-19 test and results in the past 12 months.

    - **Evaluating change in medication:** As a part of the descriptive analyses for clinical outcomes of interest, GINA medication class changes from baseline to six-month will be evaluated.

    - **Evaluating asthma control:** Asthma control was assessed by a clinician completed single item. Asthma control at baseline will be evaluated.

- **Evaluating asthma control:** AMAZE™ ACT: ACT scores will be presented by item, total and change score for baseline (defined as completed within 30 days after enrollment) and last completion (defined as final ACT completed at least 28 days after baseline ACT), and control level cut-off points (≤15 [poorly controlled], 16–19 [not well-controlled], and ≥20 [well-controlled]). Mean elapsed time between ACT administrations will be presented. In addition, key demographics will be presented by participants' change in ACT score category from baseline to last ACT score category (Table 12 series). The correlation between patient engagement and change in ACT scores will also be evaluated (Figure 11 series).

- AMAZE™ daily log:

1. **Daily Asthma status:** Patient daily asthma status (bad, okay, good) will be described per month from Weeks 1-4 through Weeks 21-24 pending availability of data after Weeks 1-4 (Table 13).

2. **Symptoms and Triggers:** Frequency of symptoms (Table 14 series) and frequency of triggers (for those that reported symptoms, Table 15 series) will be presented by asthma status (bad, okay, good) for the total sample and by site.

3. **Self-Reported Rescue Medication usage:** The number of times a patient used rescue medication as well as visited the emergency room or urgent care will be described by asthma status for the total sample and by site (Table 16 series).

- Trends in Clinical Outcomes Due to Clinical Visit(s) (if adequate data are present)
    - **Asthma status before clinical visit:** Bad days reported in the daily log up to two-weeks proceeding a clinical visit during the study period will be evaluated to assess trends in asthma status that may have triggered a visit (Table 17 series). Certain visits may be excluded depending on the type (e.g., allergy or biologic shots).
    - **Asthma symptoms before clinical visit:** Symptoms reported in the daily log up to a two-weeks preceding a clinical visit during the study period will be evaluated to assess trends in symptoms that may have triggered a visit (Table 18 series). Certain visits may be excluded depending on the type (e.g., allergy or biologic shots).
    - **Changes in medication after clinical visit:** Following a clinical visit any time during the study period, medication changes by class will be monitored to determine if any changes were prompted by the visit within two weeks (Figure 5a series). Certain visits may be excluded depending on the type (e.g., allergy or biologic shots).
    - C**hange in medications across study:** In addition to evaluating medication changes by class after clinical visits, overall medication changes by class throughout the study will be evaluated (Figure 4a series). Changes by GINA category will also be assessed.
- Flags generated by the clinician dashboard that initiate a clinic visit within 30 days: All flags generated during the study period will be assessed to see if a clinic visit was initiated within 30 days of the flag on the dashboard (Table 19 series). Clinic visits completed within the time frame will be presented by type of visit. Certain visits may be excluded from the analyses depending on the type (e.g., allergy or biologic shots).

The analyses will be descriptive in nature and no statistical inferences will be made from the above analyses. Additional analyses on the clinical outcomes may be performed should the results of the above initial analyses need to be further investigated.

5.6 Second Exploratory Analysis: Identify Subgroups of Patients who Benefit the Most from Using AMAZE™

To address the second exploratory objective on identifying which segments of patients are most likely to benefit from using AMAZE™, patient responses to item 9 on the visit survey, "The visit helped avoid an ER or Urgent Care center visit or hospitalization," will be assessed by engagement on the AMAZE™ platform as well as by the following patient subgroups/segments:

- Age category (to be defined [TBD]) (Figure 7a series);
- Sex (Male, Female) (Figure 8a series);
- Asthma severity (Intermittent, Mild persistent, Moderate persistent, Severe persistent) (Figure 9a series);
- Baseline ACT score category (Poorly controlled, Not well-controlled, Well-controlled) (Figure 10a series)

Any other relevant patient subgroups/segments may be considered after reviewing sample distribution.

6 BIAS

6.1 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.

7 INTERIM ANALYSES

The analyses for GAA only is considered an interim analysis; while, the combined results for GAA and MGH will be considered the final analysis.

8 REFERENCES

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2. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the system usability scale. *Intl Journal of Human–Computer Interaction.* 2008;24(6):574-594.
3. Hinkle DE, Wiersma W, Jurs SG. *Solutions Manual: Applied Statistics for the Behavioural Sciences.* Boston, MA: Houghton Mifflin; 1988.

9 APPENDICES

9.1 APPENDIX A. PSQ-18 SCORING MANUAL

PSQ-18 Manual.pdf

9.2 APPENDIX B. TABLE SHELLS

Table 1. Disposition Table (N=XXX) – Total and by Site Location

Variable	Total	GAA	MGH
Patients enrolled, n (%)			
Clinical site staff – Medical doctor, n (%)			
Clinical site staff – Support staff, n (%)			

Abbreviations: GAA = Greater Austin Allergy; MGH = Massachusetts General Hospital

Table 2. Patient-Reported Sociodemographic Characteristics (N=XXX) – Total and by Site

Variable	Total	GAA	MGH
Duration in Study, weeks			
Mean (SD)			
Median			
Range (min, max)			
Age, years			
n			
Mean (SD)			
Median			
Range (min, max)			
Sex, n (% female)			
Ethnicity, n (%)			
Not Hispanic or Latino			
Race, n (%)[1]			
American Indian or Alaska Native			
Asian			
Black or African American			
Native Hawaiian or Other Pacific Islander			
White			
Other[2]			
Current Living/Domestic Situation, n (%)			
Living alone			
Living with a spouse, partner, family, or friends			
Other[3]			
Employment, n (%)			
Employed, full-time			
Employed, part-time			
Homemaker			
Student			
Unemployed			
Retired			
Disabled			
Other[4]			
Education, n (%)			
Less than high school			
Secondary/high school			
Associate degree, technical or trade school			
College/university degree			
Postgraduate degree			
Other[5]			

Variable	Total	GAA	MGH
Household's total income over the past 12 months, n (%)			
Less than $15,000			
$15,000 to $29,999			
$30,000 to $44,999			
$45,000 to $59,999			
$60,00 to $74,999			
$75,000 to $99,999			
$100,000 or more			
Prefer not to answer			
Health insurance, n (%)			
Yes			
No			
If yes, type of health insurance coverage, n (%)			
Third-party payer (for example, United Healthcare, Blue Cross/Blue Shield, Aetna)			
Managed care organization			
Tricare (military health insurance)			
Medicare			
Medicaid			
Self-pay			
Other[6]			

Abbreviation: GAA = Greater Austin Allergy; MGH = Massachusetts General Hospital; SD = standard deviation

[1] Not mutually exclusive

[2] Other race includes:

[3] Other living situation includes:

[4] Other employment includes:

[5] Other education includes:

[6] Other health insurance coverage includes:

Table 3a. Patient-Reported Clinical Characteristics (N=XXX) – Total and by Site

Variable	Total	GAA	MGH
Age at asthma diagnosis, year			
n			
Mean (SD)			
Median			
Range (min, max)			
Current smoking status, n (%)			
Yes			
Not currently, but previous smoker			
No			
Co-morbid health conditions, n (%)[1]			
Don't know			
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[2]			

Abbreviation: GAA = Greater Austin Allergy; MGH = Massachusetts General Hospital; SD = standard deviation

[1] Not mutually exclusive

[2] Other comorbid condition includes:

Table 3b. Physician-Reported Clinical Characteristics from the Clinical CRF (N=XXX) – Total and by Site

Variable	Total	GAA	MGH
Age of asthma diagnosis, years			
n			
Mean (SD)			
Median			
Range (min, max)			
Height, in			
n			
Mean (SD)			
Median			
Range (min, max)			
Weight, lb			
n			
Mean (SD)			
Median			
Range (min, max)			
Duration of time with a HCP for asthma, months			
n			
Mean (SD)			
Median			
Range (min, max)			
Duration of time with a HCP at GAA or MGH for asthma, months			
n			
Mean (SD)			
Median			
Range (min, max)			
Smoking status, n (%)			
Never smoked			
Previous smoker			
Current smoker			
If previous smoker, smoking duration, years			
n			
Mean (SD)			
Median			
Range (min, max)			
If previous smoker, average packs per day			
n			
Mean (SD)			
Median			
Range (min, max)			

Variable	Total	GAA	MGH
If previous smoker, time since last smoked, weeks			
n			
Mean (SD)			
Median			
Range (min, max)			
If current smoker, smoking duration, years			
n			
Mean (SD)			
Median			
Range (min, max)			
If current smoker, average packs per day			
n			
Mean (SD)			
Median			
Range (min, max)			
If current smoker, time since last smoked, hours			
n			
Mean (SD)			
Median			
Range (min, max)			
Spirometry lung function testing performed in last 12 months, n (%)			
Yes			
Eosinophil blood count performed in last 12 months, n (%)			
Yes			
If yes, eosinophil blood count value[1]			
n	-	-	
Mean (SD)	-	-	
Median	-	-	
Range (min, max)	-	-	
Patient asthma severity, n (%)			
Intermittent			
Mild persistent			
Moderate persistent			
Severe persistent			
Patient asthma control status at last visit, n (%)			
Well-controlled			
Not well-controlled			
Very poorly controlled			
Current asthma medications, n (%)[2]			
Placeholder			
Placeholder			

Variable	Total	GAA	MGH
Placeholder			

Abbreviation: GAA = Greater Austin Allergy; MGH = Massachusetts General Hospital; SD = standard deviation

[1] Eosinophil blood count value is collected in the MGH network only

[2] Not mutually exclusive

Table 3c. Physician-Reported Clinical Characteristics from the End of Study Chart Review CRF (N=XXX) – Total and by Site

Variable	Total	GAA	MGH
In-person or telehealth clinic visits since enrollment, n (%)			
Yes			
Patient's medication/testing since enrollment			
Step-down of controller medicines			
No change of controller strength or class of controlled medication			
Step-up of controller medicines			
Order eosinophil blood count			
Order blood test for IgE			
Asthma medications for the past 3 months, n (%)[1]			
Placeholder			
Placeholder			
Placeholder			
EXACERBATIONS			
Number of times since enrollment asthma symptoms required an emergency room or urgent care visit (but not an overnight stay in the hospital)			
n			
Mean (SD)			
Median			
Range (min, max)			
Number of times since enrollment asthma symptoms required a hospital stay of at least 24 hours			
n			
Mean (SD)			
Median			
Range (min, max)			
Number of unplanned ambulatory clinic visits due to exacerbation since enrollment			
n			
Mean (SD)			
Median			
Range (min, max)			
Number of courses of oral corticosteroids (not associated with an emergency room, urgent care, or hospital visit) prescribed for worsening asthma since study enrollment			
n			
Mean (SD)			
Median			
Range (min, max)			
COVID-19 test in the past 12 months			

Variable	Total	GAA	MGH
Yes*			
No			
*If yes,			
Tested Positive			
Tested Negative			
Test Results Unknown			

Abbreviation: GAA = Greater Austin Allergy; MGH = Massachusetts General Hospital; SD = standard deviation

[1] Not mutually exclusive

Table 4a.1 AMAZE™ Patient Usage Metrics Data from BrightInsight From Weeks 1-4 to Weeks 21-24 (N=XXX) – Total

Variable	Weeks 1-4	Weeks 5-8	Weeks 9-12	Weeks 13-16	Weeks 17-20	Weeks 21-24
Number of days per 4-week period patient accessed 'Home'						
n						
Mean (SD)						
Median						
Range (min, max)						
Mean (SD) Weekly Average over 4-week period	Week 1:	Week 5:	Week 9:	Week 13:	Week 17:	Week 21:
	Week 2:	Week 6:	Week 10:	Week 14:	Week 18:	Week 22:
	Week 3:	Week 7:	Week 11:	Week 15:	Week 19:	Week 23:
	Week 4:	Week 8:	Week 12:	Week 16:	Week 20:	Week 24:
Number of days per month patient accessed 'Daily asthma log'						
n						
Mean (SD)						
Median						
Range (min, max)						
Mean (SD) Weekly Average over 4-week period	Week 1:	Week 5:	Week 9:	Week 13:	Week 17:	Week 21:
	Week 2:	Week 6:	Week 10:	Week 14:	Week 18:	Week 22:
	Week 3:	Week 7:	Week 11:	Week 15:	Week 19:	Week 23:
	Week 4:	Week 8:	Week 12:	Week 16:	Week 20:	Week 24:
Number of days per month patient accessed 'Air quality'						
n						
Mean (SD)						
Median						
Range (min, max)						
Mean (SD) Weekly Average over 4-week period	Week 1:	Week 5:	Week 9:	Week 13:	Week 17:	Week 21:
	Week 2:	Week 6:	Week 10:	Week 14:	Week 18:	Week 22:
	Week 3:	Week 7:	Week 11:	Week 15:	Week 19:	Week 23:
	Week 4:	Week 8:	Week 12:	Week 16:	Week 20:	Week 24:
Number of days per month patient accessed 'My plan'						
n						
Mean (SD)						
Median						
Range (min, max)						
Number of days per month patient accessed 'Trends'						
n						

Variable	**Weeks 1-4**	**Weeks 5-8**	**Weeks 9-12**	**Weeks 13-16**	**Weeks 17-20**	**Weeks 21-24**
Mean (SD)						
Median						
Range (min, max)						
Mean (SD) Weekly Average over 4-week period	Week 1:	Week 5:	Week 9:	Week 13:	Week 17:	Week 21:
	Week 2:	Week 6:	Week 10:	Week 14:	Week 18:	Week 22:
	Week 3:	Week 7:	Week 11:	Week 15:	Week 19:	Week 23:
	Week 4:	Week 8:	Week 12:	Week 16:	Week 20:	Week 24:
Number of days per month patient accessed 'Appointments'						
n						
Mean (SD)						
Median						
Range (min, max)						
Mean (SD) Weekly Average over 4-week period	Week 1:	Week 5:	Week 9:	Week 13:	Week 17:	Week 21:
	Week 2:	Week 6:	Week 10:	Week 14:	Week 18:	Week 22:
	Week 3:	Week 7:	Week 11:	Week 15:	Week 19:	Week 23:
	Week 4:	Week 8:	Week 12:	Week 16:	Week 20:	Week 24:
Number of days per month patient accessed educational material						
n						
Mean (SD)						
Median						
Range (min, max)						
Mean (SD) Weekly Average over 4-week period	Week 1:	Week 5:	Week 9:	Week 13:	Week 17:	Week 21:
	Week 2:	Week 6:	Week 10:	Week 14:	Week 18:	Week 22:
	Week 3:	Week 7:	Week 11:	Week 15:	Week 19:	Week 23:
	Week 4:	Week 8:	Week 12:	Week 16:	Week 20:	Week 24:
Number of days per month patient accessed 'Messages'						
n						
Mean (SD)						
Median						
Range (min, max)						
Mean (SD) Weekly Average over 4-week period	Week 1:	Week 5:	Week 9:	Week 13:	Week 17:	Week 21:
	Week 2:	Week 6:	Week 10:	Week 14:	Week 18:	Week 22:
	Week 3:	Week 7:	Week 11:	Week 15:	Week 19:	Week 23:
	Week 4:	Week 8:	Week 12:	Week 16:	Week 20:	Week 24:
Number of days per month patient accessed 'Settings'						
n						
Mean (SD)						

Variable	Weeks 1-4	Weeks 5-8	Weeks 9-12	Weeks 13-16	Weeks 17-20	Weeks 21-24
Median						
Range (min, max)						
Mean (SD) Weekly Average over 4-week period	Week 1:	Week 5:	Week 9:	Week 13:	Week 17:	Week 21:
	Week 2:	Week 6:	Week 10:	Week 14:	Week 18:	Week 22:
	Week 3:	Week 7:	Week 11:	Week 15:	Week 19:	Week 23:
	Week 4:	Week 8:	Week 12:	Week 16:	Week 20:	Week 24:
Number of days per month patient accessed 'Notifications'						
n						
Mean (SD)						
Median						
Range (min, max)						
Mean (SD) Weekly Average over 4-week period	Week 1:	Week 5:	Week 9:	Week 13:	Week 17:	Week 21:
	Week 2:	Week 6:	Week 10:	Week 14:	Week 18:	Week 22:
	Week 3:	Week 7:	Week 11:	Week 15:	Week 19:	Week 23:
	Week 4:	Week 8:	Week 12:	Week 16:	Week 20:	Week 24:

Abbreviation: SD = standard deviation

Table 4a.2 AMAZE™ Patient Usage Metrics Data from BrightInsight From Weeks 1-4 to Weeks 21-24 (N=XXX) – GAA

Table 4a.3 AMAZE™ Patient Usage Metrics Data from BrightInsight From Weeks 1-4 to Weeks 21-24 (N=XXX) – MGH

Table 4b.1 AMAZE™ Clinical Site Staff Usage Metrics Data from BrightInsight From Weeks 1-4 to Weeks 21-24 (N=XXX) – Total

Variable	Weeks 1-4	Weeks 5-8	Weeks 9-12	Weeks 13-16	Weeks 17-20	Weeks 21-24
Number of days per 4-week period clinical site staff accessed the dashboard						
n						
Mean (SD)						
Median						
Range (min, max)						
Mean (SD) Weekly Average over 4-week period	Week 1:	Week 5:	Week 9:	Week 13:	Week 17:	Week 21:
	Week 2:	Week 6:	Week 10:	Week 14:	Week 18:	Week 22:
	Week 3:	Week 7:	Week 11:	Week 15:	Week 19:	Week 23:
	Week 4:	Week 8:	Week 12:	Week 16:	Week 20:	Week 24:

Abbreviation: SD = standard deviation

Table 4b.2 AMAZE™ Clinical Site Staff Usage Metrics Data from BrightInsight From Weeks 1-4 to Weeks 21-24 (N=XXX) – GAA

Table 4b.3 AMAZE™ Clinical Site Staff Usage Metrics Data from BrightInsight From Weeks 1-4 to Weeks 21-24 (N=XXX) – MGH

Table 5a.1. AMAZE™ Patient Engagement Per 4-week Period (N=XXX) – Total

Variable	Weeks 1-4 (n)	Weeks 5-8 (n)	Weeks 9-12 (n)	Weeks 13-16 (n)	Weeks 17-20 (n)	Weeks 21-24 (n)
Patient engagement on App*, n (%)						
High (5-7 days per week)						
Medium (3-4 days per week)						
Low (1-2 days per week)						
Mean (SD) response per patient						

*Participants will be considered to have engaged with the app if they completed at least one daily asthma log per week.

Table 5a.2. AMAZE™ Patient Engagement Per 4-Week Period (N=XXX) – GAA

Table 5a.3. AMAZE™ Patient Engagement Per 4-Week Period (N=XXX) – MGH

Table 5b.4. AMAZE™ Patient Engagement Per 4-week Period by Participants Who Reported Agree or Strongly Agree with Visit Survey Item 9 (N=XXX) – Total

Variable	Weeks 1-4 (n)	Weeks 5-8 (n)	Weeks 9-12 (n)	Weeks 13-16 (n)	Weeks 17-20 (n)	Weeks 21-24 (n)
Patient engagement on App*, n (%)						
High (5-7 days per week)						
Medium (3-4 days per week)						
Low (1-2 days per week)						
Mean (SD) response per patient						

*Participants will be considered to have engaged with the app if they completed at least one daily asthma log per week.

Table 5b.5. AMAZE™ Patient Engagement Per 4-Week Period by Participants Who Reported Agree or Strongly Agree with Visit Survey Item 9 (N=XXX) – GAA

Table 5b.6. AMAZE™ Patient Engagement Per 4-Week Period by Participants Who Reported Agree or Strongly Agree with Visit Survey Item 9 (N=XXX) – MGH

Table 5c.1 AMAZE™ Patient Profiles of App Engagement (N=XXX) – Total

Variable	Overall	Patient Engagement on App		
		High (5-7 days per week) (n=XX)	Medium (3-4 days per week) (n=XX)	Low (1-2 days per week) (n=XX)
Age, n (%)				
Placeholder				

Variable	Overall	Patient Engagement on App		
		High (5-7 days per week) (n=XX)	Medium (3-4 days per week) (n=XX)	Low (1-2 days per week) (n=XX)
Sex, n (%)				
Male				
Female				
Ethnicity, n (%)				
Hispanic or Latino				
Not Hispanic or Latino				
Race, n (%)[1]				
American Indian or Alaska Native				
Asian				
Black or African American				
Native Hawaiian or Other Pacific Islander				
White				
Other[2]				
Level of education, n (%)				
Less than high school				
Secondary/high school				
Associate degree, technical or trade school				
College/university degree				
Postgraduate degree				
Other[3]				
Patient asthma severity, n (%)				
Intermittent				
Mild persistent				
Moderate persistent				
Severe persistent				
Baseline ACT score[4], n (%)				
Very Poorly Controlled (≤15)				
Not Well-Controlled (16-19)				
Well-Controlled (≥20)				
Asthma medications for the past 3 months, n (%)[1]				
Placeholder				
Placeholder				
Placeholder				
GINA Classification				

Variable	Overall	Patient Engagement on App		
		High (5-7 days per week) (n=XX)	Medium (3-4 days per week) (n=XX)	Low (1-2 days per week) (n=XX)
GINA 1				
GINA 2				
GINA 3				
GINA 4				
GINA 5				

Abbreviation: ACT = Asthma Control Test

[1] Not mutually exclusive

[2] Other race includes:

[3] Other education includes:

[4] Baseline is defined as completing the ACT within 30 days of enrollment.

Table 5c.2 AMAZE™ Patient Profiles of App Engagement (N=XXX) – GAA

Table 5c.3 AMAZE™ Patient Profiles of App Engagement (N=XXX) – MGH

Table 5d.4 AMAZE™ Patient Profiles of Participants Who Reported Agreement with Visit Survey Item 9 (N=XXX) – Total

Variable	Overall	Patient Agreement with Visit Survey Item 9	
		Agree/Strongly Agree (n=XX)	Neutral/Disagree/Strongly Disagree (n=XX)
Age, n (%)			
Placeholder			
Sex, n (%)			
Male			
Female			
Ethnicity, n (%)			
Hispanic or Latino			
Not Hispanic or Latino			
Race, n (%)[1]			
American Indian or Alaska Native			
Asian			
Black or African American			
Native Hawaiian or Other Pacific Islander			
White			
Other[2]			
Level of education, n (%)			
Less than high school			
Secondary/high school			

Variable	Overall	Patient Agreement with Visit Survey Item 9	
		Agree/Strongly Agree (n=XX)	Neutral/Disagree/Strongly Disagree (n=XX)
Associate degree, technical or trade school			
College/university degree			
Postgraduate degree			
Other[3]			
Patient asthma severity, n (%)			
Intermittent			
Mild persistent			
Moderate persistent			
Severe persistent			
Baseline ACT score[4], n (%)			
Very Poorly Controlled (≤15)			
Not Well-Controlled (16-19)			
Well-Controlled (≥20)			
Asthma medications for the past 3 months, n (%)[1]			
Placeholder			
Placeholder			
Placeholder			
GINA Classification			
GINA 1			
GINA 2			
GINA 3			
GINA 4			
GINA 5			

Abbreviation: ACT = Asthma Control Test

[1] Not mutually exclusive

[2] Other race includes:

[3] Other education includes:

[4] Baseline is defined as completing the ACT within 30 days of enrollment.

Table 5c.5 AMAZE™ Patient Profiles of App Engagement (N=XXX) – GAA

Table 5c.6 AMAZE™ Patient Profiles of App Engagement (N=XXX) – MGH

Table 6a. Types of Clinic Visits – Total and By Site

	Total (N=XXX)		GAA (N=XXX)		MGH (N=XXX)	
Type of Visit	**n**	**%**	**n**	**%**	**n**	**%**
Visit Type 1						
Visit Type 2						

	Total (N=XXX)		GAA (N=XXX)		MGH (N=XXX)	
Type of Visit	**n**	**%**	**n**	**%**	**n**	**%**
Visit Type 3						
Visit Type 4						
Visit Type 5						

Table 6b.1 Patient Visit Experience Survey Items (N=XXX) – Total

Variable	Strongly Agree, n (%)	Agree, n (%)	Neutral, n (%)	Disagree, n (%)	Strongly Disagree, n (%)	Not Applicable, n (%)
1. The GAA/MGH App helped me discuss my asthma with my healthcare provider(s) during my most recent visit						
2. I received information about my asthma that helped me better understand my condition during my most recent visit						
3. I received information about my asthma medications during my most recent visit						
4. I was given information about additional care that I need for my asthma during my most recent visit						
5. I was included in making decisions about my asthma treatment during my most recent visit						
6. The GAA/MGH App helped the appointment with my doctor go more smoothly.						
7. The time spent with my healthcare provider(s) discussing my asthma during my most recent visit was better compared to my last visit.						
8. I found it was easier to schedule an appointment with my doctor using the GAA/MGH App.						
9. The visit helped avoid an ER or Urgent Care center visit or hospitalization						

Table 6b.2 Patient Visit Experience Survey Items (N=XXX) – GAA

Table 6b.3 Patient Visit Experience Survey Items (N=XXX) – MGH

Table 6c. Patient Visit Experience Survey Item 9 by Visit Initiation (N=XXX)

	Person who initiated the visit					
	Total		GAA		MGH	
Variable	**Healthcare provider(s), n (%)**	**Patient, n (%)**	**Healthcare provider(s), n (%)**	**Patient, n (%)**	**Healthcare provider(s), n (%)**	**Patient, n (%)**
9. The visit helped avoid an ER or Urgent Care center visit or hospitalization, n (%)						
Strongly Agree						
Agree						
Neutral						
Disagree						
Strongly Disagree						

Table 6d.1. Patient Visit Experience Survey Item 9 by Type of Visit – Total (N=XXX)

	Type of Visit					
Variable	**Visit Type 1, n (%)**	**Visit Type 2, n (%)**	**Visit Type 3, n (%)**	**Visit Type 4, n (%)**	**Visit Type 5, n (%)**	**Visit Type 6, n (%)**
9. The visit helped avoid an ER or Urgent Care center visit or hospitalization, n (%)						
Strongly Agree						
Agree						
Neutral						
Disagree						
Strongly Disagree						

Table 6d.2. Patient Visit Experience Survey Item 9 by Type of Visit – GAA (N=XXX)

Table 6d.3. Patient Visit Experience Survey Item 9 by Type of Visit – MGH (N=XXX)

Table 7a.1 Patient-Reported System Usability Scale Items at Month 1 (N=XXX) – Total

Variable	Strongly Agree, n (%)	Agree, n (%)	Neutral, n (%)	Disagree, n (%)	Strongly Disagree, n (%)	Not Applicable, n (%)
1. I think that I would like to use this app frequently.						
2. I found the app unnecessarily complex.						
3. I thought the app was easy to use.						
4. I think that I would need the support of a technical person to be able to use this app.						
5. I found the various functions in this app were well integrated.						
6. I thought there was too much inconsistency in this app.						
7. I would imagine that most people would learn to use this app very quickly.						
8. I found the app very cumbersome to use.						
9. I felt very confident using the app.						
10. I needed to learn a lot of things before I could get going with this app.						

Table 7a.1 Patient-Reported System Usability Scale Items at End of Study (N=XXX) – Total

Table 7b.1 Patient-Reported System Usability Scale Items at Month 1 (N=XXX) – GAA

Table 7b.2 Patient-Reported System Usability Scale Items at End of Study (N=XXX) – GAA

Table 7c.1 Patient-Reported System Usability Scale Items at Month 1 (N=XXX) – MGH

Table 7c.2 Patient-Reported System Usability Scale Items at End of Study (N=XXX) – MGH

Table 8a.1 Clinical Site Staff-Reported System Usability Scale Items at Month 1 (N=XXX) – Total

Variable	Strongly Agree, n (%)	Agree, n (%)	Neutral, n (%)	Disagree, n (%)	Strongly Disagree, n (%)	Not Applicable, n (%)
1. I think that I would like to use this dashboard frequently.						
2. I found the dashboard unnecessarily complex.						
3. I thought the dashboard was easy to use.						
4. I think that I would need the support of a technical person to be able to use this dashboard.						
5. I found the various functions in this dashboard were well integrated.						
6. I thought there was too much inconsistency in this dashboard.						
7. I would imagine that most people would learn to use this dashboard very quickly.						
8. I found the dashboard very cumbersome to use.						
9. I felt very confident using the dashboard.						
10. I needed to learn a lot of things before I could get going with this dashboard.						

Table 8a.2 Clinical Site Staff -Reported System Usability Scale Items at End of Study (N=XXX) – Total

Table 8b.1 Clinical Site Staff-Reported System Usability Scale Items at Month 1 (N=XXX) – GAA

Table 8b.2 Clinical Site Staff -Reported System Usability Scale Items at End of Study (N=XXX) – GAA

Table 8c.1 Clinical Site Staff-Reported System Usability Scale Items at Month 1 (N=XXX) – MGH

Table 8c.2 Clinical Site Staff -Reported System Usability Scale Items at End of Study (N=XXX) – MGH

Table 9a. Post-study Survey Items for HCPs at End of Study (N=XXX) – Total

Variable	Total, n (%)				
1. 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					
2. Did the AMAZE™ help you manage your patients?					
Not at all					
Slightly					
Somewhat					
Moderately					
Very well					
3. Regardless of intermittent or persistent, on average, what percentage of your asthma patients would you classify as:		**n**	**Mean (SD)**	**Median**	**Range (Min - Max)**
Mild asthma					
Moderate asthma					
Severe asthma					
4. On average, what percentage of your patients would you classify as:		**n**	**Mean (SD)**	**Median**	**Range (Min - Max)**
Well-controlled					
Not well-controlled					
Very poorly controlled					
5. On average, what percentage of your asthma patients do you feel are at low, medium, and high risk for adverse outcomes from their asthma?		**n**	**Mean (SD)**	**Median**	**Range (Min - Max)**
Low risk					
Medium risk					
High risk					
6. Did AMAZE™ help you identify patients who were at risk for adverse health outcome (e.g., hospitalisations, exacerbations, medication side effects) from their asthma that you would have otherwise missed?					
Yes					

Variable	**Total, n (%)**				
No					
7. What did you find <u>most</u> useful about the AMAZE™ platform? [1]	**% yes**				
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[2]					
8. What did you find least useful or cumbersome about AMAZE™ platform? [1]					
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 cvx					
Other[3]					
9. How frequently would you want to track the following for appropriate management of patients?		**Daily, n (%)**	**Weekly (%), n (%)**	**Monthly, n (%)**	**Other, n (%)**

Variable	Total, n (%)				
Symptoms					
Asthma triggers					
Rescue medication use					
Maintenance medication use					
Steroid medication use					
ER / Urgent Care visits					
Peak flow / FEV_1					
10. Did AMAZE™ improve any of the following[1]					
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					
11. While using AMAZE™ disease management platform (DMP), how often did you change treatment?					
No different than before using the AMAZETM					
More often than before*					
Less often than before					
*If 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)					

[1] Not mutually exclusive

[2] Other most useful features about the AMAZE™ App includes:

[3] Other least useful features about the AMAZE™ App includes:

Table 9a. Post-study Survey Items for HCPs at End of Study (N=XXX) – GAA

Table 9b. Post-study Survey Items for HCPs at End of Study (N=XXX) – MGH

Table 10a.1 Patient Satisfaction Questionnaire-18 Items at End of Study (N=XXX) – Total

Variable	Strongly Agree, n (%)	Agree, n (%)	Neutral, n (%)	Disagree, n (%)	Strongly Disagree, n (%)	Missing, n (%)
1. Doctors are good about explaining the reason for medical tests.						
2. I think my doctor's office has everything needed to provide complete medical care						
3. The medical care I have been receiving is just about perfect						
4. Sometimes doctors make me wonder if their diagnosis is correct						
5. I feel confident that I can get the medical care I need without being set back financially						
6. When I go for medical care, they are careful to check everything when treating and examining me.						
7. I have to pay for more my medical care than I can afford						
8. I have easy access to the medical specialists I need						
9. Where I get medical care, people have to wait too long for emergency treatment						
10. Doctors act too business like and impersonal toward me						
11. My doctors treat me in a very friendly and courteous manner						
12. Those who provide my medical care sometimes hurry too much when they treat me						
13. Doctors sometimes ignore what I tell them						
14. I have some doubts about the ability of the doctors who treat me						
15. Doctors usually spend plenty of time with me						
16. I find it hard to get an appointment for medical care right away						
17. I am dissatisfied with some things about the medical care I receive						

Variable	Strongly Agree, n (%)	Agree, n (%)	Neutral, n (%)	Disagree, n (%)	Strongly Disagree, n (%)	Missing, n (%)
18. I am able to get medical care whenever I need it						

Table 10a.2 Patient Satisfaction Questionnaire-18 Items at End of Study (N=XXX) – GAA

Table 10a.3 Patient Satisfaction Questionnaire-18 Items at End of Study (N=XXX) – MGH

Table 10b.1 Patient Satisfaction Questionnaire-18 Subscale Scores at End of Study (N=XXX) – Total

Variable	n	Mean (SD)	Median	Range (Min-Max)
General Satisfaction				
Technical Quality				
Interpersonal Manner				
Communication				
Financial Aspects				
Time Spent with Doctor				
Accessibility and Convenience				

Table 10b.2 Patient Satisfaction Questionnaire-18 Subscale Scores at End of Study (N=XXX) – GAA

Table 10b.3 Patient Satisfaction Questionnaire-18 Subscale Scores at End of Study (N=XXX) – MGH

Table 11a.1 Patient User Experience Survey at Month 1 (N=XXX) – Total

Variable	Total, n (%)					
1. In general, how would you describe your asthma in terms of severity?						
A. Mild						
B. Moderate						
C. Severe						
2. Approximately, how many asthma flare-ups (also called exacerbations) did you have in the last 30 days						
n						
Mean (SD)						
Median						
Range (Min, Max)						
3. Who is your primary asthma doctor at GAA/MGH?						
A. GAA: PPD						
B. GAA:						
C. GAA:						
D. GAA:						
E. MGH:						
F. MGH:						
G. MGH:						
H. MGH:						
I. Other						
4. Overall, how satisfied are you with your asthma care at GAA/MGH?						
A. Very Unsatisfied						
B. Unsatisfied						
C. Neutral						
D. Satisfied						
E. Very Satisfied						
5. Indicate your level of agreement with the following statements:		**Strongly Agree, n (%)**	**Agree, n (%)**	**Neutral, n (%)**	**Disagree, n (%)**	**Strongly Disagree, n (%)**
5a. I have control over my asthma.						
5b. I understand my asthma						
6. Please rate the features of the GAA/MGH Asthma app using a 5-star rating. If you do not use a given feature, you do not have to rate it.		★ (1), **n (%)**	★★ (2), **n (%)**	★★★ (3), **n (%)**	★★★★ (4), **n (%)**	★★★★★ (5), **n (%)**

Variable	**Total, n (%)**					
A. Daily log (where you track symptoms, etc.)						
B. Messaging with GAA/MGH						
C. Asthma education (articles, videos)						
D. Air quality						
E. My Plan (list of meds & reminders)						
F. Trends (daily log summaries / graphs)						
G. Appointments (viewing and scheduling)						
H. Care Team Request[1] (monthly 5-question survey)						
7. How frequently do you want to track the following for your doctor?		**Daily, n (%)**	**Weekly (%), n (%)**	**Monthly, n (%)**	**Other, n (%)**	
Symptoms						
Asthma triggers						
Rescue medication use						
Maintenance medication use						
Steroid medication use						
ER / Urgent Care visits						
Peak flow / FEV_1						
8. What concerns if any do you have about the GAA Asthma app?[2]						
A. Data / privacy concerns.						
B. I do not find the app helpful.						
C. I forget to use it.						
D. There are things missing that I want in the app.						
E. It is not fun to use.						
F. It is not easy to use.						
G. Other3						
I do not have any concerns						
9. Overall, how satisfied are you with the GAA Asthma app?						
A. Very Unsatisfied						
B. Unsatisfied						
C. Neutral						
D. Satisfied						
E. Very Satisfied						

Variable	Total, n (%)					
10. Why do you feel that way about the GAA Asthma app?						
11. How likely are you to recommend the GAA Asthma app to another patient at GAA who has asthma?						
A. Very Unlikely						
B. Unlikely						
C. Undecided						
D. Likely						
E. Very Likely						
12. Please share any additional feedback you have about the app.						

[1] 'Care team request' corresponds to the ACT assessment

[2] Not mutually exclusive

[3] Other concerns about the AMAZE™ includes:

Table 11a.2 Patient User Experience Survey at Month 3 (N=XXX) – Total

Table 11a.3 Patient User Experience Survey at End of Study (N=XXX) – Total

Table 11b.1 Patient User Experience Survey at Month 1 (N=XXX) – GAA

Table 11b.2 Patient User Experience Survey at Month 3 (N=XXX) – GAA

Table 11b.3 Patient User Experience Survey at End of Study (N=XXX) – GAA

Table 11c.1 Patient User Experience Survey at Month 1 (N=XXX) – MGH

Table 11c.2 Patient User Experience Survey at Month 3 (N=XXX) – MGH

Table 11c.3 Patient User Experience Survey at End of Study (N=XXX) – MGH

Table 12a.1 AMAZE™ Asthma Control Test Item Scores at Baseline Completion and Last Completion (N=XXX) – Total

Variable	Baseline Completion[1]	Last Completion[2]	Change Score
Elapsed Time Between Study Enrollment and Baseline[1] ACT Completion			
n			
Mean (SD)			
Median			
Range (min, max)			
Elapsed Time Between Study Enrollment and Last ACT Completion[2]			
n			
Mean (SD)			
Median			
Range (min, max)			
Elapsed Time Between ACT Completions			
n			
Mean (SD)			
Median			
Range (min, max)			
Item 1 (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?)			
n			
Mean (SD)			
Median			
Range (min, max)			
Item 2 (During the past 4 weeks, how often have you had shortness of breath?)			
n			
Mean (SD)			
Median			
Range (min, max)			
Item 3 (During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?)			
n			
Mean (SD)			
Median			
Range (min, max)			
Item 4 (During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as Albuterol, Ventolin®, Proventil®, or Maxair®)?)			

Variable	Baseline Completion[1]	Last Completion[2]	Change Score
n			
Mean (SD)			
Median			
Range (min, max)			
Item 5 (How would you rate your asthma control during the past 4 weeks?)			
n			
Mean (SD)			
Median			
Range (min, max)			
Total score			
n			
Mean (SD)			
Median			
Range (min, max)			
Patients with total scores ≤15, n (%)			
Patients with total scores 16-19, n (%)			
Patients with total scores ≥20, n (%)			

[1]Baseline ACT completion is defined as completing the ACT within 30 days of enrollment.

[1]Last ACT completion is defined as completing a final ACT at least 28 days after the baseline ACT.

Table 12a.2 AMAZE™ Asthma Control Test Item Scores at Baseline Completion and Last Completion (N=XXX) – GAA

Table 12a.3 AMAZE™ Asthma Control Test Item Scores at Baseline Completion and Last Completion (N=XXX) – MGH

Table 12c.1 AMAZE™ Patient Profiles by Change in ACT Score Category (N=XXX) – Total

Variable	Overall	Change in ACT Score Category								
		WC-WC	WC-NWC	WC-VPC	NWC-WC	NWC-NWC	NWC-VPC	VPC-VPC	VPC-NWC	VPC-WC
Age, n (%)										
Placeholder										
Sex, n (%)										
Male										
Female										
Ethnicity, n (%)										
Hispanic or Latino										
Not Hispanic or Latino										
Race, n (%)[1]										
American Indian or Alaska Native										
Asian										
Black or African American										
Native Hawaiian or Other Pacific Islander										
White										
Other[2]										
Level of education, n (%)										
Less than high school										
Secondary/high school										

Variable	Overall	Change in ACT Score Category								
		WC-WC	WC-NWC	WC-VPC	NWC-WC	NWC-NWC	NWC-VPC	VPC-VPC	VPC-NWC	VPC-WC
Associate degree, technical or trade school										
College/university degree										
Postgraduate degree										
Other[3]										
Patient asthma severity, n (%)										
Intermittent										
Mild persistent										
Moderate persistent										
Severe persistent										
Baseline ACT score[4], n (%)										
Very Poorly Controlled (≤15)										
Not Well-Controlled (16-19)										
Well-Controlled (≥20)										
Asthma medications for the past 3 months, n (%)[1]										
Placeholder										

Variable	Overall	Change in ACT Score Category								
		WC-WC	WC-NWC	WC-VPC	NWC-WC	NWC-NWC	NWC-VPC	VPC-VPC	VPC-NWC	VPC-WC
Placeholder										
Placeholder										
GINA Classification										
GINA 1										
GINA 2										
GINA 3										
GINA 4										
GINA 5										

Abbreviation: ACT = Asthma Control Test, NWC=Not Well-Controlled, VPC= Very Poorly Controlled, WC=Well-Controlled; [1] Not mutually exclusive; [2] Other race includes:; [3] Other education includes:; [4] Baseline is defined as completing the ACT within 30 days of enrollment.

Table 12b.2 AMAZE™ Patient Profiles by Change in ACT Score Category (N=XXX) – GAA

Table 12b.3 AMAZE™ Patient Profiles by Change in ACT Score Category (N=XXX) – MGH

Table 12c.1 AMAZE™ Asthma Control Test Score Cut-offs (N=XXX) – Total

ACT	Weeks 1-4	Weeks 5-8	Weeks 9-12	Weeks 13-16	Weeks 17-20	Weeks 21-24
Very Poorly controlled, n (%)						
Not well-controlled, n (%)						
Well controlled, n (%)						

Table 12c.2 AMAZE™ Asthma Control Test Score Cut-offs (N=XXX) – GAA

Table 12c.3 AMAZE™ Asthma Control Test Score Cut-offs (N=XXX) – MGH

Table 13a. Summary of AMAZE™ Daily Log Per Week: Asthma Status (N=XXX) – Total

Variable	Weeks 1-4 (n)	Weeks 5-8 (n)	Weeks 9-12 (n)	Weeks 13-16 (n)	Weeks 17-20 (n)	Weeks 21-24 (n)
Total Patients Per Time Period With At Least One Daily Log, n (%)						
Total Diary Entries Per Time Period, n (%)						
Average Number of Daily Entries Per Patient						
Mean (SD)						
Asthma status, n (%)						
Bad						
Okay						
Good						

Table 13b. AMAZE™ Daily Log: Asthma Status (N=XXX) – GAA

Table 13c. AMAZE™ Daily Log: Asthma Status (N=XXX) – MGH

Table 14a. AMAZE™ Daily Log: Asthma Symptoms Overall and by Asthma Status – Total (N=XXX)

Variable	Overall	Asthma Status		
		Bad (n=XX, %)	Okay (n=XX, %)	Good (n=XX, %)
Chest congestion				
Mean (SD) number per person symptom reported				
Coughing per week				
Mean (SD) number per person symptom reported				
Chest tightness				
Mean (SD) number per person symptom reported				
Shortness of breath				
Mean (SD) number per person symptom reported				
Runny nose				
Mean (SD) number per person symptom reported				
Wheezing				
Mean (SD) number per person symptom reported				
Trouble sleeping				
Mean (SD) number per person symptom reported				
Fever				
Mean (SD) number per person symptom reported				
Watery or itchy eyes				
Mean (SD) number per person symptom reported				
None of these symptoms				
Mean (SD) number per person symptom reported				

Table 14b. AMAZE™ Daily Log: Asthma Symptoms Overall and by Asthma Status – GAA (N=XXX)

Table 14c. AMAZE™ Daily Log: Asthma Symptoms Overall and by Asthma Status – MGH (N=XXX)

Table 15a. AMAZE™ Daily Log: Symptom Triggers for Those who Reported Symptoms Overall and by Asthma Status – Total (N=XXX)

Variable	Overall	Asthma Status		
		Bad (n=XX, %)	Okay (n=XX, %)	Good (n=XX, %)
Acid reflux, n (%)				
Mean (SD) number per person trigger reported				
Animals, n (%)				
Mean (SD) number per person trigger reported patient				
Dust, n (%)				
Mean (SD) number per person trigger reported				
Cold weather, n (%)				
Mean (SD) number per person trigger reported				
Cold/Flu, n (%)				
Mean (SD) number per person trigger reported				
Chemicals, n (%)				
Mean (SD) number per person trigger reported				
Mold, n (%)				
Mean (SD) number per person trigger reported				
Exercise, n (%)				
Mean (SD) number per person trigger reported				
Fever, n (%)				
Mean (SD) number per person trigger reported				
Pollution, n (%)				
Mean (SD) number per person trigger reported				
Stress, n (%)				
Mean (SD) number per person trigger reported				
Cockroaches, n (%)				
Mean (SD) number per person trigger reported				
Tobacco smoke, n (%)				
Mean (SD) number per person trigger reported				

Variable	Overall	Asthma Status		
		Bad (n=XX, %)	Okay (n=XX, %)	Good (n=XX, %)
Vaping, n (%)				
Mean (SD) number per person trigger reported				
Pollen, n (%)				
Mean (SD) number per person trigger reported				
My trigger is not listed, n (%)				
Mean (SD) number per person trigger reported				
None of these triggers, n (%)				
Mean (SD) number per person trigger reported				

Table 15b. AMAZE™ Daily Log: Symptom Triggers for Those who Reported Symptoms Overall and by Asthma Status – GAA (N=XXX)

Table 15c. AMAZE™ Daily Log: Symptom Triggers for Those who Reported Symptoms Overall and by Asthma Status – MGH (N=XXX)

Table 16a. AMAZE™ Daily Log: Rescue Medication and Emergency Room / Urgent Care Visits Overall and by Asthma Status (N=XXX) – Total

Variable	Overall	Asthma Status		
		Bad (n=XX, %)	Okay (n=XX, %)	Good (n=XX, %)
In past 24 hours, have you taken any of these medications for asthma?				
Maintenance / daily				
Mean (SD) number per person response was yes				
Oral steroids				
Mean (SD) number per person response was yes				
Quick-relief / as-needed				
Mean (SD) number per person response was yes				
Number of patients visiting the emergency room per month				
n				
Mean (SD)				
Median				
Range (min, max)				
Number of patients visiting the urgent care per month				
n				
Mean (SD)				
Median				
Range (min, max)				

Table 16b. AMAZE™ Daily Log: Rescue Medication and Emergency Room / Urgent Care Visits Overall and by Asthma Status – GAA (N=XXX)

Table 16c. AMAZE™ Daily Log: Rescue Medication and Emergency Room / Urgent Care Visits Overall and by Asthma Status – MGH (N=XXX)

Table 17a. Asthma Status 2 Weeks Prior to Clinical Visit – Total (N=XXX)

Variable	Overall	Asthma Status		
		Bad (n=XX, %)	Okay (n=XX, %)	Good (n=XX, %)
Clinic Visit Within Next Two-Weeks				
Mean (SD) number per person a clinic visit occurred				

Table 17b. Asthma Status 2 Weeks Prior to Clinical Visit – GAA (N=XXX)

Table 17c. Asthma Status 2 Weeks Prior to Clinical Visit – MGH (N=XXX)

Table 18a. AMAZE™ Daily Log: Asthma Symptoms 2 Weeks Prior to a Visit – Total (N=XXX)

	Clinic Visit, n (%)
Symptoms Two-Weeks Prior to a Visit	
Chest congestion	
N	
Mean (SD) number of days log completed per patient over 2-week period	
Symptom reported, yes, n (%)	
Coughing per week	
N	
Mean (SD) number of days log completed per patient over 2-week period	
Symptom reported, yes, n (%)	
Chest tightness	
N	
Mean (SD) number of days log completed per patient over 2-week period	
Symptom reported, yes, n (%)	
Shortness of breath	
N	
Mean (SD) number of days log completed per patient over 2-week period	
Symptom reported, yes, n (%)	
Runny nose	
N	
Mean (SD) number of days log completed per patient over 2-week period	
Symptom reported, yes, n (%)	
Wheezing	
N	
Mean (SD) number of days log completed per patient over 2-week period	
Symptom reported, yes, n (%)	
Trouble sleeping	
N	
Mean (SD) number of days log completed per patient over 2-week period	
Symptom reported, yes, n (%)	
Fever	
N	
Mean (SD) number of days log completed per patient over 2-week period	
Symptom reported, yes, n (%)	
Watery or itchy eyes	
N	
Mean (SD) number of days log completed per patient over 2-week period	
Symptom reported, yes, n (%)	

	Clinic Visit, n (%)
None of these symptoms	
N	
Mean (SD) number of days log completed per patient over 2-week period	
Symptom reported, yes, n (%)	

Table 18b. AMAZE™ Daily Log: Asthma Symptoms 2 Weeks Prior to a Visit – GAA (N=XXX)

Table 18c. AMAZE™ Daily Log: Asthma Symptoms 2 Weeks Prior to a Visit – MGH (N=XXX)

Table 19a. Clinical Visits Initiated by Clinician Dashboard Flags Within 30 Days – Total (N=XXX)

	Type of Clinic Visit Initiated, n (%)			
Variable	**Clinic Visit Type 1**	**Clinic Visit Type 2**	**Clinic Visit Type 3**	**Clinic Visit Type 4**
Clinician Dashboard Flag				
Yes				
No				
Elapsed Time Between Flag and Visits in Days				
Mean (SD)				
Median				
Range (min, max)				

Table 19b. Clinical Visits Initiated by Clinician Dashboard Flags – GAA (N=XXX)

Table 19c. Clinical Visits Initiated by Clinician Dashboard Flags – MGH (N=XXX)

9.3 APPENDIX C. FIGURES

Figure 1. Patient Disposition - Total and By Site

Figure 2a. Total Number of AMAZE™ Users Per Month – Total (N=XXX)

Figure 2b. Total Number of AMAZE™ Users Per Month – GAA (N=XXX)

Figure 2c. Total Number of AMAZE™ Users Per Month – MGH (N=XXX)

Figure 3a. Patient Engagement Per Month – Total (N=XXX)

Figure 3b. Patient Engagement Per Month – GAA (N=XXX)

Figure 3c. Patient Engagement Per Month – MGH (N=XXX)

Figure 4a. Medication Changes Across the Study – Total (N=XXX)

Figure 4b. Medication Changes Across the Study – GAA (N=XXX)

Figure 4c. Medication Changes Across the Study – MGH (N=XXX)

Figure 5a. Medication Changes After Clinic Visits – Total (N=XXX)

Figure 5b. Medication Changes After Clinic Visits – GAA (N=XXX)

Figure 5c. Medication Changes After Clinic Visits – MGH (N=XXX)

Figure 6a. Patients Who Benefit From AMAZE™ Through ER/Hospital Avoidance – Total (N=XXX)

Figure 6b. Patients Who Benefit From AMAZE™ Through ER/Hospital Avoidance – GAA (N=XXX)

Figure 6c. Patients Who Benefit From AMAZE™ Through ER/Hospital Avoidance – MGH (N=XXX)

Figure 7a. Patients Who Benefit From AMAZE™ Through ER/Hospital Avoidance by Age – Total (N=XXX)

Figure 7b. Patients Who Benefit From AMAZE™ Through ER/Hospital Avoidance by Age – GAA (N=XXX)

Figure 7c. Patients Who Benefit From AMAZE™ Through ER/Hospital Avoidance by Age – MGH (N=XXX)

Figure 8a. Patients Who Benefit From AMAZE™ Through ER/Hospital Avoidance by Sex – Total (N=XXX)

Figure 8b. Patients Who Benefit From AMAZE™ Through ER/Hospital Avoidance by Sex – GAA (N=XXX)

Figure 8c. Patients Who Benefit From AMAZE™ Through ER/Hospital Avoidance by Sex – MGH (N=XXX)

Figure 9a. Patients Who Benefit From AMAZE™ Through ER/Hospital Avoidance by Asthma Severity – Total (N=XXX)

Figure 9b. Patients Who Benefit From AMAZE™ Through ER/Hospital Avoidance by Asthma Severity – GAA (N=XXX)

9.4 APPENDIX D. INTERVIEW GUIDES

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

Hello, my name is [interviewer name] and I am working with [GAA/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 [GAA/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. 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?
    4. [*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 [GAA/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?
   c. Did the reminders help you stay adherent with your medication?
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

5. Did you have any problems with the font size on any of the screens?
6. 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. Do you feel like the app helped improve your adherence to your asthma medication? Why or why not?
5. [End of study interview only]: How, if any, do you feel your use of the app has changed since the start of the study?
    a. Why do you think your use of the app has changed?
6. Are you likely to recommend this app to a person living with asthma? Why or why not?
7. 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.

CLINICIAN INTERVIEWS

Below is the discussion guide, it is to be used as a guide only. The actual areas of conversation are fluid and may be discussed at moments different from the order appearing below.

BACKGROUND FOR ALL INTERVIEWS

Great, thanks again for taking the time to speak with me today. As we discussed, the purpose of this interview is to gain a better understanding of what worked well, what did not work so well, and what could be improved upon with regard to implementing the Disease Management Platform and the asthma app in your clinical practice. This interview should take approximately 15 minutes to complete. As an employee of [clinical site] your participation is completely voluntary and will not impact your job in a positive or negative manner. There is no direct benefit to you for participating in this interview; however, information from this interview may help care providers improve the way they communicate with and treat asthma patients. 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. Would you like to continue to the interview now? [If no, thank clinical staff for their time and terminate interview. If yes, proceed.]

Great, thank you. Please feel free to answer honestly. We are really interested in your feedback and observations from implementing these tools in your clinical practice.

We'd like to audio-record this interview. Is it okay for me to record the conversation today?

INTERVIEW RULES FOR ALL INTERVIEWS

Begin Recorder: This is [interviewee's name] with [site] for Study EVA-28838 on [Date].

1. What are you overall thoughts on the DMP and asthma app?
2. Can you describe the process of monitoring the clinician dashboard in your practice?
    a. How many days on average in a week did you log in to the dashboard?
    b. (Probe as needed): Do you have a process in place for reviewing data from the app ahead of patient engagement? If yes, can you describe that process?
3. How useful was the DMP?
    a. How did you use the flags from the DMP in your clinical practice?
    b. Did the flags cause any changes to your care plan with patients?
    c. Can you describe the flags that were used during the study and if any changes were made through the study?
    d. How were ACT scores utilized in the management of asthma through the study?
4. Can you describe any examples or instances where you've felt the app has helped your patients avoid ER or hospital visits?
5. How useful was the messaging feature on the asthma portal?
    a. How did you use the messaging feature on the portal?
6. Did you use the DMP or asthma app during any follow-up visits with the patients?
    a. How did the DMP or asthma app change your communication with patients?
    b. Did the patients provide any feedback on the app during your visits?
7. What did you like about the DMP?
8. What did you not like about the DMP?

9. What are some recommendations for future improvement and implementation of the DMP?
    a. If these changes cannot be implemented, would this change your long-term engagement with the dashboard?
    b. (Probe as needed): What are critical improvements for you to continue to use the dashboard?
10. [End of study only]: How, if any, do you feel your expectations of the dashboard have changed since the start of the study?
11. With plans to roll the app out to more patients at [GAA/MGH] once the study is over, how do you feel your workflow or process with the dashboard will change, if any, as a result?

10 SIGNATURES

ASTRAZENECA SIGNATURE(S)

AMAZE Asthma Implementation QI Study - GAA

This Observational 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>>