Cover Page

Protocol title	Baseline Sleep Apnea #2
Protocol number	102033
Rev/Date	Rev B, IRB approved 05/31/2020
Sponsor Name	Verily Life Sciences LLC
NCT#	NCT04599803

Study Title	Baseline Sleep Apnea Study #2
Protocol Number	[redacted]
Version	[redacted]
Sponsor Name	Verily Life Sciences LLC
Sponsor Address	[redacted]
Sponsor Contacts	[redacted]

Protocol

Investigator's Agreement Signature Page

I, Principal Investigator, agree to conduct this study in accordance with the International Conference on Harmonisation (ICH) guideline for Good Clinical Practice (GCP), applicable legal and regulatory requirements, and in compliance with the provisions of this protocol.

I am responsible for ensuring that the investigation is conducted according to this protocol and for protecting the rights, safety, and welfare of the research subjects. All personnel involved in the conduct of this study will complete Human Subject Protection training.

I agree to ensure that all staff members involved in the conduct of this study are informed about their obligations in meeting the above commitments.

Principal Investigator	Signature	Date

Confidentiality Statement

The information in the following document is provided to you as an investigator, potential investigator, or consultant, for review by you, your staff, and applicable Institutional Review Board, and is considered confidential. It is understood that the information will not be disclosed to others without written authorization from Verily Life Sciences LLC, except to the extent necessary to obtain informed consent from those persons to whom the product may be administered.

Table of Contents

1. Protocol Summary

Study Sponsor	Verily Life Sciences LLC
Study Description	This study seeks to understand patient diagnostic and treatment journey and positive airway pressure (PAP) therapy compliance for Verily Sleep Apnea (VSA) program/app users. Participants will enroll remotely and may undergo a home sleep test (HST). Upon confirmation of obstructive sleep apnea (OSA) and prescription of PAP therapy, the participant will begin using the VSA app to supplement PAP treatment. After 90 days of active participation, the participant will be given instructions for follow-up care, as indicated. This study will take a decentralized approach. Recruitment, enrollment, consultation, testing, coaching and active participation with the VSA app will take place remotely.
Study Objectives	**Primary**: ● To assess and quantify patient journey (e.g., time to diagnosis, time to initiate therapy, patient satisfaction) for users of the VSA program **Secondary:** ● To assess patient journey completion rates for users of the VSA program ● To assess and quantify PAP compliance in users of the VSA program [redacted]
Study Endpoints	**Primary** ● Time (number of days) from when participant is told they may have OSA to OSA diagnosis ○ Time (number of days) from when participant is told they may have OSA to when they receive HST prescription ○ Time (number of days) from when participant receives HST prescription to when they receive their diagnosis ● Time (number of days) from OSA diagnosis to PAP therapy initiation ● Time (number of days) from therapy initiation to when 90-day compliance threshold is achieved **Secondary** ● Completion rates ○ Among individuals who had an HST ordered, % of individuals who completed the HST ○ Among individuals prescribed a PAP device, % of individuals who filled the order (PAP device delivered to them) ○ Among individuals prescribed a PAP device, % of individuals who used the PAP device at least once during the 90 days ● Compliance Metrics

	○ Percent of participants who meet 90 day compliance success criteria, as defined by: ■ ≥ 4 hours per night on 70% of nights during a consecutive 30 day period anytime during the first 90 days [redacted]
Study Type	This is a single group, unblinded, prospective clinical study
Regulatory Status/Trial Classification	Non-significant risk (NSR)
Study Population	Approximately 50-200 individuals who have been screened and diagnosed with Obstructive Sleep Apnea (OSA) during the study's initial screening and diagnostic process will be enrolled as participants in the study. This study will enroll remotely to participants across the United States. The number of individuals who will have to be screened will be greater than the number ultimately enrolled, i.e., greater than 50-200. The number of individuals who undergo the screening process will depend on how many must be screened in order to identify the requisite 50-200 subjects who meet the diagnostic and other criteria for enrollment.
Participant Duration	For participants who are diagnosed with OSA and prescribed a PAP device, active participation in the study after receiving the PAP device is expected to last approximately 3 months from receipt of the device. Active participation is defined as using the PAP device (PAP data collection) while completing the other study related activities (including VSA app and console use, surveys/questionnaires, and interacting with optional Health Coaches)

	For participants who are diagnosed with OSA and prescribed a PAP device, total participation may last for up to one (1) year, including screening, time to diagnosis, and PAP data collection after active participation in the study has been completed.
Inclusion Criteria	1. Ages 18 or older 2. Able to speak and read English 3. Legal United States Resident with a Government Issued ID 4. Participating in the Project Baseline Community Study 5. Demonstrates understanding of the study requirements and is able and willing to sign the informed consent form 6. Own a smartphone with a data plan and be the primary user of the smartphone; smartphone must use Android Lollipop (5.1+/ API 22+) or iOS 11.X+ 7. Own a computer with a web camera 8. Consistent access to electricity and wifi for the duration of the study 9. Have a high risk of OSA as determined by screening questionnaire 10. Good candidate for PAP therapy, in the opinion of the managing clinician 11. Without significant limitation in ability to participate in the study, in the opinion of the investigator.
Exclusion Criteria	1. Previously diagnosed with sleep apnea or other sleep disorders, that in the opinion of the investigator, makes the participant ineligible (e.g., Obstructive Sleep Apnea, Central Sleep Apnea, Complex Sleep Apnea, chronic insomnia) 2. Participant is a shift worker (indicated by having a night shift schedule on a regular basis, or a work shift that changes or rotates on a daily, weekly, or monthly basis) 3. Sponsor employees and individuals working on Project Baseline 4. Self reported to be pregnant or planning to become pregnant during the study period 5. Current use of home oxygenation devices, such as supplemental oxygen

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[redacted]	[redacted]	[redacted]	[redacted]

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7	[redacted]	[redacted]	[redacted]

3. Prior Experience

[redacted]

4. Study Background and Rationale

4.1. Background

Obstructive sleep apnea (OSA) is a sleep breathing disorder that affects an estimated 54 million Americans (calculated based on a 16-country prevalence data study),[1,2] and is associated with heart disease, stroke, type 2 diabetes and other life-threatening conditions. Despite the condition's high prevalence and increasing public awareness, past research has shown that approximately 80 percent of individuals with OSA are undiagnosed,[3] untreated and therefore unaware of their own risk and of the benefits that therapy could provide.

OSA presents to the patient most frequently as excessive daytime tiredness, increased lapses or micro-sleeps during important activities such as driving, nighttime disturbances to bed partners (largely through snoring or restlessness)[4], and perhaps most importantly significantly increased risk and severity of multiple comorbidities including but not limited to cardiovascular disease (CVD)[5-6], type 2 diabetes (T2D)[7], and mental health disorders[8].

The diagnosis pathway for patients with OSA is often complex and difficult for patients to navigate, involving interactions with many different parties such as a primary care provider, sleep labs, durable medical equipment companies, and insurance providers[9]. There exist opportunities for better coordinating care and improving the patient experience in the diagnostic and treatment pathways.

The gold standard treatment for OSA is the night-time use of a positive airway pressure (PAP) device. PAP provides positive pressure to support a patent airway for patients who experience clinically significant frequency of apneas and/or hypopneas[10]. The PAP device consists of a bedside powered device that pushes air through a flexible tube to a mask worn either over the mouth and nose or just the nose. This device is, as can readily be imagined, difficult to introduce into the patient's bedtime routine, life, travel, etc. No other treatment or therapy for OSA has been shown to be as effective as PAP[11]. Any method of increasing compliance with the patient's

prescribed therapy could thus decrease both the cost of care for relevant comorbidities as well as significantly improve the patient's quality of life.

4.2. Rationale

This study seeks to understand patient journey and PAP therapy compliance for Verily Sleep Apnea (VSA) program users.

The VSA app is intended to help individuals who may have OSA go through the complex diagnostic pathway more efficiently and virtually. The VSA app is also intended to help patients who have been diagnosed with OSA to manage their therapy and is intended to facilitate a program where users can possibly discover their potential risk for OSA through a clinically validated questionnaire screener and consult with a healthcare professional.

The VSA app will also allow participants to message with Health Coaches who will provide guidance related to sleep and OSA. Communication between the Health Coach and participant is important in enhancing and promoting motivation for PAP adherence. The motivational enhancement approach is a published behavioral intervention based on the principles of motivational interviewing[12]. Its fundamental premise is to honor the natural ambivalence that accompanies any change to behavior and to approach the patient in a thoughtful and empathetic manner that elicits critical thought - in order to maximize behavior change.

Technology, especially mobile technology, has the potential to provide new, easier to use, more timely, and more scalable methods for helping patients discover their OSA risk, onboarding patients with OSA to PAP treatment, as well as helping these patients to troubleshoot and make progress in their OSA treatment.

5. Study Design

5.1. Study Objectives and Endpoints

5.1.1. Objective(s)

Primary:

- To assess and quantify patient journey (e.g., time to diagnosis, time to initiate therapy, patient satisfaction) for users of the VSA program

Secondary:

- To assess patient journey completion rates for users of the VSA program
- To assess and quantify PAP compliance in users of the VSA program

[redacted]

5.1.2. Endpoint(s)

Primary

- Time (number of days) from when participant is told they may have OSA to OSA diagnosis

    - Time (number of days) from when participant is told they may have OSA to when they receive HST prescription
    - Time (number of days) from when participant receives HST prescription to when they receive diagnosis
- Time (number of days) from OSA diagnosis to PAP therapy initiation
- Time (number of days) from therapy initiation to when 90-day compliance threshold is achieved

Secondary

- Completion rates
    - Among individuals who had an HST ordered, % of individuals who completed the HST
    - Among individuals prescribed a PAP device, % of individuals who filled the order (PAP device delivered to them)
    - Among individuals prescribed a PAP device, % of individuals who used the PAP device at least once during the 90 days
- Compliance Metrics
    - Percent of participants who meet 90 day compliance success criteria, as defined by:
        - ≥ 4 hours per night on 70% of nights during a consecutive 30 day period anytime during the first 90 days

[redacted]

5.2. **Overview**

This is a single group, unblinded, prospective clinical study to understand the patient diagnostic and treatment journey and PAP therapy compliance for Verily Sleep Apnea (VSA) program users. Participants will enroll remotely and if deemed clinically appropriate will undergo a commercially available and approved home sleep test (HST). Upon confirmation of OSA, the participant will begin using the VSA app to supplement PAP treatment. After 90 days of active participation or in the event of earlier departure from the study, the participant will be given instructions for follow-up care, as indicated. Participants will lose access to the VSA app at the end of the 90 day period.

This study will take a decentralized approach. Recruitment, enrollment, consultation, coaching and active participation with the VSA app will take place remotely.

5.3. **Sample Size and Number of Participating Sites**

The study plans to enroll approximately 50-200 individuals that will be diagnosed with Obstructive Sleep Apnea (OSA) and begin PAP therapy, as part of the study procedures. This study will enroll remotely to participants across the United States.

5.4. **Inclusion Criteria**

1. Ages 18 or older
2. Able to speak and read English
3. Legal United States Resident with a Government Issued ID
4. Participating in the Project Baseline Community Study
5. Demonstrates understanding of the study requirements and is able and willing to sign the informed consent form
6. Own a smartphone with a data plan and be the primary user of the smartphone; smartphone must use Android Lollipop (5.1+/ API 22+) or iOS 11.X+
7. Own a computer with a web camera
8. Consistent access to electricity and wifi for the duration of the study
9. Have a high risk of OSA as determined by screening questionnaire
10. Good candidate for PAP therapy, in the opinion of the managing clinician
11. Without significant limitation in ability to participate in the study, in the opinion of the investigator.

5.5. **Exclusion Criteria**

1. Previously diagnosed with sleep apnea or other sleep disorders, that in the opinion of the investigator, makes the participant ineligible (e.g., Obstructive Sleep Apnea, Central Sleep Apnea, Complex Sleep Apnea, chronic insomnia)
2. Participant is a shift worker (indicated by having a night shift schedule on a regular basis, or a work shift that changes or rotates on a daily, weekly, or monthly basis).
3. Sponsor employees and individuals working on Project Baseline
4. Self reported to be pregnant or planning to become pregnant during the study period
5. Current use of home oxygenation devices, such as supplemental oxygen

5.6. **Discontinued/Withdrawal of Study Subjects**

Participation in this research study is voluntary and participants may withdraw at any time. In the event the participant chooses to withdraw, he/she will be instructed to contact the Investigator immediately and will be asked the reason for their withdrawal from the study.

The participant may also be discontinued from the research study at any time if the Investigator considers it to be in his/her best medical interest. The Investigator may withdraw the participant any time due to the non-compliance with respect to the provisions of the protocol. If a participant withdraws prior to study completion, no new health information identifying him/her will be gathered after that date. Information that has been gathered may still be used and given to others.

If an enrolled participant withdraws or is discontinued prior to completing all study activities, a new, qualified candidate may be enrolled in the study to compensate for the incomplete data set.

Participants will either satisfactorily complete all requirements set forth in the protocol or their participation in the clinical study will be prematurely terminated. The completion of a participant's participation in the study or early departure from the study, including reasons for early discontinuation, will be fully documented on the appropriate case report form and an effort will be made to connect them with a local clinician for post-study consultation, instructions and, if indicated, recommendations for follow-up care.

6. Study Assessment Plan and Methods

6.1. Schedule of Study Procedures Table

Table 1. *Schedule of Study Procedures*

Procedures	Remote Screening Activities	Self Complete Activities	Remote Clinician Consult 1	Remote Clinician Consult 2	Remote Health Coach Interactions	Remote Supplem-ental Visit(s)
Eligibility	✓					✓[a]
Informed Consent	✓					✓[a]
ID Verification	✓					✓[a]
Validated Tools		✓				
Non-Validated Surveys/ Questionnaires		✓				
Register for Verily Sleep Apnea (VSA) app/program		✓				
Medical and Sleep History Questionnaire		✓				
OSA Diagnostic Consult with Evaluating Clinician			✓			
Home Sleep Test (HST)		✓[b]	✓[b]			
Ship HST		✓				
PAP Therapy				✓		

Prescribed with Managing Clinician						
Verily Sleep Apnea (VSA) program PAP Therapy On-Boarding		✓				
Remote Interview					✓	✓
Compliance monitoring/outreach		✓			✓	✓
90-Day Compliance Check		✓			✓	
Adverse Event Evaluation	✓	✓	✓	✓	✓	✓
Protocol Deviation Assessment	✓	✓	✓	✓	✓	✓
Study Exit						✓

[a] Administered if new version of the Informed Consent Form is released that impacts currently enrolled participants
[b] HST may be administered more than once if test results are inconclusive

6.2. Study Conduct and Procedures

The study is conducted in accordance with this clinical investigational plan and ethical principles consistent with GCP and applicable regulatory requirements to protect the rights, safety, and well-being of the study participants.

Prior to any study-related procedures, informed consent must be obtained.

6.2.1. Recruitment

Participants will be recruited through a variety of methods such as IRB-approved advertisements, registries, care provider recommendation, and community events. All volunteers will be directed to visit the Project Baseline website or a study phone line to learn more about the study. Volunteers can express an interest in joining the Baseline Sleep Apnea Study #2 by visiting the Project Baseline website (www.projectbaseline.com) and enrolling in the Project Baseline Community Study. The study may also be referred to as “Baseline Sleep Apnea Study”, “Sleep Apnea Study #2”, or “Sleep Apnea Study” on some recruitment material and other participants facing material.

6.2.2. Screening/Screen Failures

Participants will be screened through the Project Baseline Community Study through data collection defined in that protocol. Participants enrolled in the Project Baseline Community Study will complete survey questions used to assist with screening and enrollment (such as demographics) into the Baseline Sleep Apnea Study #2.

Participants who consented to participate in the Baseline Remote Health Study but do not meet one or more criteria required for participation in the study during screening will be considered screen failures.

This data will be documented on the appropriate case report form.

6.2.3. Enrollment

Participants who are enrolled in the Project Baseline Community Study may be enrolled in the Baseline Sleep Apnea Study #2 based on an assessment of the study eligibility and selection criteria. Study personnel will be provided with guidance regarding participant eligibility for study enrollment. Target distribution will be based on demographics (e.g. age, gender, socioeconomic status).

Participants who qualify for the study will be notified via the Member Portal, Verily Sleep Apnea (VSA) app, email, mail, phone, text, or other methods that they are eligible to participate. Participants will be considered enrolled in the study when they have signed the IRB approved Informed Consent documents and are determined to meet all eligibility criteria.

6.2.4. Participant Compensation

Participants may be incentivized for enrolling in the study. Participants will be compensated as described in the IRB-approved Informed Consent Form.

6.2.5. Visit Schedule

The Baseline Sleep Apnea Study #2 participant journey includes:

- Remote Screening Activities
- Self Complete Activities

[redacted]

Remote Screening Activities
Participants that appear to qualify for the Baseline Sleep Apnea Study #2 will be invited to complete remote screening activities. Proof of identity will be required prior to enrollment. Before enrollment and engaging in any study activities, participants will be asked to sign the IRB-approved electronic Informed Consent Form. Consent will be obtained by the Investigator or his/her delegate, if applicable by state law. An individual is considered to be enrolled in the study upon signature of the consent and confirmation of all eligibility criteria. All participants will be given a signed copy of the consent, or sent one via the Member Portal, email, mail, or other methods.

All consented participants in the Baseline Sleep Apnea Study #2 will be asked to undergo the assessments outlined in the Schedule of Study Procedures Table(s) and Test Procedures sections of the protocol.

Self Complete Activities

All consented participants in the Baseline Sleep Apnea Study #2 will be asked to undergo the self-completed activities outlined in the Schedule of Study Procedures Table(s) and Test Procedures sections of the protocol.

Compliance with self-complete activities will be assessed throughout the study and participants will receive targeted reminders about activities that need to be completed.

[redacted]

Remote Supplemental Visit(s) and Study Exit

Participants who do not complete study activities within the requested time frame may be contacted throughout the study duration to attend a supplemental remote visit. During these visits, additional interviews/surveys may be deployed to help understand issues,

non-compliance and improve compliance moving forward. The study team may also review device/app setup and troubleshooting to help participants if they become stuck. Additionally, the study team may reach out to the participant throughout the duration of the study via phone or email for troubleshooting.

The study team reserves the right to update the VSA app as needed throughout the course of the study (e.g., to fix newly discovered bugs within the app). A supplemental visit may be scheduled to review changes associated with app updates.

Once a participant exits the study, either from early exit or completion of study-related activities, an effort will be made to connect them with a managing physician for post-study consultation, instructions and, if indicated, recommendations for follow-up care. The exit workflow will be designed in consultation with the Principal Investigator on this study and with the partnering physician based on clinical best practices. For example, the exit workflow includes an attempt by the managing physician to reach out to the participant's primary care provider to inform them of the study and to provide clinical recommendations. Upon exiting the study, participants will also be provided with key data collected during the study in an "Exit Packet", such as their Sleep Report and prescription for PAP therapy. A supplemental visit may be scheduled for final instruction and recommendations for follow-up care.

Participants will lose access to the VSA app after 90 days of active participation has ended.

6.3. Test Procedures and Data Collection

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7. Risk Analysis

7.1. Risk Analysis

Verily Life Sciences has conducted an analysis of the benefits and risks of the VSA app.

Verily Life Sciences has determined that this clinical investigation is justified as the overall potential benefit to the population outweighs its risks.

7.2. Benefits

Participants at risk of having OSA will have the opportunity to go through the OSA diagnostic pathway and use a PAP device (if prescribed) at no cost to them.

There are no other benefits to the participants for participating in this study, but the information obtained will be used in scientific research and may be helpful to others in the future.

7.3. Risks

The VSA app is intended to facilitate an Obstructive Sleep Apnea (OSA) management program. It is intended to improve the lives of patients who have been diagnosed with OSA to help manage their therapy and is intended to facilitate a program where users can possibly discover their potential risk for OSA.

The types of potential risk the volunteer research participants will encounter with the VSA app are related to risks for releasing participant/patient private health information. The participant profile in the VSA app will include personal information including name, contact information, and health information, including PAP usage data. All data sent from the VSA app are encrypted. Information collected during interviews from study participants will be kept confidential throughout the study. A unique subject identification code will be used when collecting data on standardized paper or electronic Case Report Forms (CRF/eCRF). Only study team members trained on the clinical study will have access to the study records. If a participant agrees to participate in the study, Verily will store the data collected on Google servers. This data will be restricted to authorized study personnel and access is audited to ensure the privacy of this data. All data used in the analysis and reporting of this study will be used in a manner without identifiable reference to the study participants.

Though PAP is part of the participants' clinical care prescribed by their clinician, for purposes of completeness, potential adverse effects of PAP follow.

1. Skin irritation or rashes
2. Feelings of claustrophobia when wearing mask
3. Dry mouth, throat, or nose after wearing the mask
4. Temporary marks on the skin
5. Difficulty sleeping in the first few weeks of treatment
6. Increased daytime sleepiness in the first few weeks of treatment
7. Bloating
8. Eye irritation
9. Ear or sinus discomfort

Adverse effects/discomfort associated with using PAP and related supplies are considered anticipated and will not be recorded as an adverse event.

Though the HST is part of the participants' clinical care prescribed by their clinician, for purposes of completeness, potential adverse effects of HST follow:

1. Skin irritation
2. Rash
3. Allergic reaction
4. Mild discomfort

Adverse effects/discomfort associated with using an HST and related supplies are considered anticipated and will not be recorded as an adverse event.

There may also be other side effects of participating in this study that are not known at this time.

8. Adverse Events (AE), Serious Adverse Events (SAE), and Unanticipated Problems

During and following a subject's participation in the study, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

In the event medical care to a subject is required, the medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician.

8.1. Adverse Events

An Adverse Event (AE) is defined as any untoward medical occurrence, unintended disease or injury in subjects, users or other persons, that is considered a change from baseline or pre-study status, whether or not related to the investigational medical device.

Any pre-existing medical conditions or symptoms present in a participant will not be considered an Adverse Event in this study, unless it worsens as a result of this study.

Only health events that are directly related to the VSA app or study procedures will be recorded as adverse events.

Adverse events related to commercially available FDA-regulated (i.e., cleared or approved) medical devices (such as PAP, HST and associated supplies) will not be recorded as adverse events. Anticipated AEs related to the commercially available FDA-regulated devices include the following:

1. Skin irritation or rashes
2. Feelings of claustrophobia when wearing mask
3. Dry mouth, throat, or nose after wearing the mask
4. Temporary marks on the skin
5. Difficulty sleeping in the first few weeks of treatment
6. Increased daytime sleepiness in the first few weeks of treatment
7. Bloating
8. Eye irritation
9. Ear or sinus discomfort
10. Allergic reaction
11. Mild discomfort

All Adverse Events (AEs) will be reported on an AE Case Report Form and will include the following: Date/time of onset, description of the event, the duration of the event, the severity of the event, assessment of the relation of the event to the study device and procedure, description of action taken (if any) and the event outcome.

In the event medical care to a subject is required, the medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician.

8.2. Serious Adverse Events

A Serious Adverse Event (SAE) is defined as an adverse event that is anticipated or unanticipated and which reasonably suggests that one of the manufacturers' devices has or may have caused or contributed to a death or serious injury.

A Serious Adverse Event is an Adverse Event that led to: (a) death, (b) serious deterioration in the health of the subject that either resulted in a (i) life-threatening illness or injury or (ii) permanent impairment of a body structure or a body function, or (iii) in-patient or prolonged hospitalization or (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function or (c) fetal distress, fetal death or a congenital abnormality or birth defect.

A planned hospitalization for a pre-existing condition is not considered a SAE.

These events are typically reportable to health authorities. Serious Adverse Events must be reported to the sponsor within 24 hours of knowledge of the event.

8.3. Unanticipated Adverse Device Effects (UADE)

An Unanticipated Adverse Device Effect (UADE) is a serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect or problem was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. Anticipated potential adverse device effects have been identified in the sponsor Risk Management files and/or product labeling.

The Principal Investigator will assure that all unanticipated adverse device effect (UADE) involving risk to subjects or others will be reported to the sponsor within 24 hours of knowledge of event. All UADE's will be evaluated and the results of such evaluation will be reported to the IRB within ten (10) working days after the event is reported by the study subjects. The sponsor will report all SAE's and UADE's to the appropriate regulatory authority. All Serious and Unanticipated Adverse Effects will be reviewed by a Medical Monitor.

9. Device Deficiencies

The VSA app is an NSR device, but since the device does not diagnose or provide therapy, no device deficiencies are anticipated.

Software bugs within the VSA app, either found by the study team or reported by the participant will not be considered a device deficiency.

If, at any time during the study, the participant's Smartphone (where the VSA app is installed) physically breaks, or malfunctions, or the VSA app ceases to function or gives unexpected or erroneous information, participants will be instructed to stop using the VSA app and contact the study team. If the participant has another compatible Smartphone, instructions on installing the VSA app on a different Smartphone will be provided and the participants will be instructed on how to remove the VSA app on the first Smartphone (if applicable).

If, at any time during the study, a commercially available (i.e., FDA cleared or approved) device (PAP and associated supplies) physically breaks, or malfunctions, or gives unexpected or erroneous information,

participants will be instructed to contact their DME provider. The DME provider may provide a replacement device or repairs at the sponsor's discretion. Alternatively, the sponsor may choose to exit the participant without providing a replacement device.

The sponsor will not provide maintenance or support for any commercially available (i.e., FDA cleared or approved) devices (PAP and associated supplies). If a participant reports a device malfunction and/or device complaint to the sponsor support team (Verily User Success), the participant will be instructed to contact their DME provider.

The sponsor support team may contact study participants during study participation in order to troubleshoot issues with the VSA app, such as issues logging in or the app crashing.

10. Investigational Products

10.1. Investigational Product Description

The VSA program/app, is an Obstructive Sleep Apnea (OSA) management platform.

[redacted]

10.2. Investigational Product Labeling & Accountability

The Investigator should take adequate precautions, including access to the Investigational product to prevent diversion of the VSA app into unauthorized channels of distribution.

The VSA app is classified as a Mobile Medical App (per FDA Guidance Policy for Device Software Functions and Mobile Medical Applications issued September 2019) under enforcement

discretion. The VSA appwill be labeled with the following: “CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use.”

Only Institutions/Investigators participating in the clinical study will be eligible to receive the VSA app and can be used only when the following has been received:

- Curriculum Vitae of the Investigator
- A signed Investigator Agreement
- Institutional Review Board (IRB) approval
- IRB-approved Informed Consent Form

11. Regulatory, Ethical and Study Oversight Considerations

11.1. Regulatory and Ethical Considerations

This study will be conducted in accordance with the protocol and with the following:

- Consensus ethical principles derived from international guidelines including the Declaration of Helsinki
- Applicable ICH Good Clinical Practice (GCP) Guidelines
- Applicable laws and regulations

The protocol, protocol amendments, ICF, and other relevant documents (eg, advertisements) must be submitted to an IRB/IEC by the investigator and reviewed and approved by the IRB/IEC before the study is initiated.

Any amendments to the protocol will require IRB/IEC approval before implementation of changes made to the study design, except for changes necessary to eliminate an immediate hazard to study participants.

The investigator will be responsible for the following:

- Providing written summaries of the status of the study to the IRB/IEC annually or more frequently in accordance with the requirements, policies, and procedures established by the IRB/IEC
- Notifying the IRB/IEC of SAEs or other significant safety findings as required by IRB/IEC procedures; and
- Providing oversight of the conduct of the study at the site and adherence to requirements of 21 CFR, ICH guidelines, the IRB and all other applicable local regulations

11.2. Financial Disclosure

Investigators and sub-investigators will provide the sponsor with sufficient, accurate financial information as requested to allow the sponsor to submit complete and accurate financial certification or disclosure statements to the appropriate regulatory authorities, as appropriate. Investigators are responsible for providing information on financial interests during the course of the study and for 1 year after completion of the study.

11.3. Informed Consent Process

Potential participants will be presented with the Baseline Sleep Apnea Study #2 eICF on the Baseline Sleep Apnea Study #2 Web Portal..

Participants must be informed that their participation is voluntary. Participants will be required to sign a statement of informed consent that meets the requirements of 21 CFR 50, local

regulations, ICH guidelines, Health Insurance Portability and Accountability Act (HIPAA) requirements, where applicable, and the IRB.

If the potential participant agrees to the terms described in the Baseline Sleep Apnea Study #2 eICF and provides consent, study eligibility will be further assessed.

11.4. **Data Protection**

Participants will be assigned a unique identifier by the sponsor. Any participant records or datasets that are transferred to the sponsor will contain the identifier only; participant names or any information which would make the participant identifiable will not be transferred.

The participant must be informed that his/her personal study-related data will be used by the sponsor in accordance with local data protection law. The level of disclosure must also be explained to the participant. All data used in the analysis and reporting of this evaluation will be used in a manner without identifiable reference to the study participant.

11.5. **Data Quality Assurance**

- All participant data relating to the study will be recorded on printed or electronic CRF unless transmitted to the sponsor or designee electronically (e.g. laboratory data). The Investigator (or designee) is responsible for verifying that data entries are accurate and correct by physically or electronically signing the CRF.
- The investigator must maintain accurate documentation (source data).
- The investigator must permit study-related monitoring, audits, IRB review, and regulatory agency inspections and provide direct access to source data.
- Monitoring details describing strategy (e.g. risk-based initiatives in operations and quality such as Risk Management and Mitigation Strategies and Analytical Risk-Based Monitoring), methods, responsibilities and requirements, including handling of noncompliance issues and monitoring techniques (central, remote, or on-site monitoring) are provided in the Monitoring Plan.
- The sponsor or designee is responsible for the data management of this study including quality checking of the data.
- The sponsor assumes accountability for actions delegated to other individuals (e.g. Contract Research Organizations).
- Records and documents, including signed ICFs, pertaining to the conduct of this study must be retained by the investigator for a minimum of [2] years after study completion unless local regulations or institutional policies require a longer retention period. No records may be destroyed during the retention period without the written approval of the sponsor. No records may be transferred to another location or party without written notification to the sponsor.

11.6. **Source Documents**

- Source documents provide evidence for the existence of the participant and substantiate the integrity of the data collected.
- If study data is recorded directly on the CRFs/eCRFs (i.e., no prior written or electronic record of data), it is considered to be source data.
- All data will be entered directly into the eCRF, ePRO, and eICF.
- Definition of what constitutes source data can be found in CRF completion guidelines.

11.7. **Study and Site Closure**

The sponsor designee reserves the right to close the study site (decentralized) or terminate the study at any time for any reason at the sole discretion of the sponsor. Study sites will be closed upon study completion. A study site is considered closed when all required documents and study supplies have been collected and a study-site closure visit has been performed.

The investigator may initiate study-site closure at any time, provided there is reasonable cause and sufficient notice is given in advance of the intended termination.

Reasons for the early closure of a study site by the sponsor or investigator may include but are not limited to:

- Failure of the investigator to comply with the protocol, the requirements of the IRB or local health authorities, the sponsor's procedures, or GCP guidelines
- Inadequate recruitment of participants by the investigator

11.8. **Publication Policy**

- The results of this study may be published or presented at scientific meetings. If this is foreseen, the investigator agrees to submit all manuscripts or abstracts to the sponsor before submission. This allows the sponsor to protect proprietary information and to provide comments.
- The sponsor will comply with the requirements for publication of study results. In accordance with standard editorial and ethical practice, the sponsor will generally support publication of multisite studies only in their entirety and not as individual site data. In this case, a coordinating investigator will be designated by mutual agreement.

12. Statistical Considerations

The study plans to enroll approximately 50-200 individuals that will be diagnosed with Obstructive Sleep Apnea (OSA) and begin PAP therapy, as part of the study procedures. It is recognized that the sample size achieved in this baseline study will likely be insufficient for statistical hypothesis testing, but it will still be useful for establishing a baseline understanding of the performance of the VSA program. The primary endpoints of interest are five timelines relating to the patient diagnostic and treatment journey:

- Time (number of days) from when participant is told they may have OSA to OSA diagnosis
  - Time (number of days) from when participant is told they may have OSA to when they receive HST prescription
  - Time (number of days) from when participant receives HST prescription to OSA diagnosis
- Time (number of days) from OSA diagnosis to PAP therapy initiation
- Time (number of days) from therapy initiation to when 90-day compliance threshold is achieved

Each of these will be reported as a point estimate accompanied by a confidence interval. These will be calculated from the average and standard deviation of these timeframes across all participants. [redacted]

- [redacted]

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14. Glossary

Term	Abbr.	Definition
Adverse Event	AE	Any untoward medical occurrence, unintended disease or injury in subjects, users or other persons, that is considered a change from baseline or pre-study status, whether or not related to the investigational medical device.
Case Report Form	CRF	A set of documents, designed for complete recording of all relevant participant and device related data, as required by the clinical investigation plan.
Clinical Investigation	N/A	Any controlled systematic study in human participants, undertaken to verify the safety and performance of a specific medical device, under normal conditions of use. This is also known as a Clinical Study or Clinical Trial.
Informed Consent	IC	A process by which a participant voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects that are relevant to the participant's decision, including potential risks and benefits to participate. Informed consent is documented by means of a written, signed, and dated informed consent form. Informed consent continues throughout the trial.
Investigational Device	N/A	Any medical device intended for use by an appropriately qualified practitioner when conducting clinical investigations in an adequate clinical environment.
Principal Investigator	PI	The investigator responsible for the conduct of a clinical investigation and who takes the clinical responsibility for the well being of the subjects/participants involved.
Serious Adverse Event	SAE	A Serious Adverse Event (also referred to as Adverse Incident) is defined as an adverse event that is anticipated or unanticipated and that reasonably suggests that one of the manufacturers devices has or may have caused or contributed to a death or serious injury. A Serious Adverse Event is an Adverse Event that led to: (a) death, (b) serious deterioration in the health of the subject that either resulted in a (i) life-threatening illness or injury or (ii) permanent impairment of a body structure or a body function, or (iii) in-patient or prolonged hospitalization or (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function or (c) fetal distress, fetal death or a congenital abnormality or birth defect. These events are typically reportable to health authorities.

Sponsor	N/A	An individual or an organization which takes responsibility for the initiation and/or implementation of a clinical investigation.
Sub-Investigator	Sub-I	A member of the clinical study team with appropriate credentials and is supervised by the Principal Investigator at a site and allowed to perform critical trial-related procedures and/or to make key trial-related decisions.
Participant (also referred to as "Subject")	N/A	A human being, either a patient or a non-patient volunteer, participating in a clinical investigation.
Unanticipated Adverse Device Effect	UADE	Serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect or problem was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.