Audible Health

Join us. Respiratory Research Study

Please join this Research Study and you could receive a \$50 gift card.

You will qualify for this study if you:

- Are 18 years of age or older
- ✓ You are the parent of a child between the ages of 5 and 17 and are willing to oversee this process on their behalf
- ✓ You or your child have received a positive test result for Flu, RSV, or Covid-19 in the past 48 hours
- You have a smart phone and internet access to complete the steps and submit your cough recordings

Because you have been tested for COVID-19, Flu, or RSV you may be eligible to participate in an ongoing clinical study. This study is designed to capture audio samples of cough sounds from people who tested positive for these conditions, to further develop a new kind of diagnostic test that uses only a person's cough sound to make a diagnosis.

Participating in this study is easy and convenient and takes a total of 10 to 15 minutes. You can participate using your mobile phone, and you can complete this process while safely staying at home if you wish. You do not need to participate in this study from your doctor's office, clinic, or hospital.

Step 1

We will send you an email with a link to our information and enrollment process. Once you get to that page, you will first digitally sign a document called Informed Consent that explains the study. After you've completed this online signature, you will be redirected to our information collection website.

Step 2

On the information collection website we'll ask you to answer a few questions about yourself and your current health.

Step 3

Once you've completed those questions, you'll get a link to download our free mobile app on your phone. This mobile app will guide you through the steps of coughing into the app so we can record your cough sounds for our study.

Step 4

After your cough submissions, you'll go to the page that lets you select the type of \$50 Gift Card you'd like to receive. You can choose an electronic Amazon Gift Card, or a \$50 VISA Gift Card that will be shipped to your home.

Thank you very much for your willingness to help us with this important research. Please be assured that your data is only being used to advance this scientific study. We do not store any personally identifiable information (such as your name, phone number or email address) after your study participation has been completed. We do not share the data we've collected from you with anyone outside this study. If you have any questions or concerns, please email us at CoughCollection@Raisonance.ai

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Fact Sheet for Participants

What is the Purpose of this Study?

• The purpose of this study is to collect cough sounds, also known as forced cough vocalizations (FCVs), to train the AudibleHealth Dx app to be able to detect COVID-19, Influenza, and RSV.

What is AudibleHealth Dx?

AudibleHealth Dx is an investigational diagnostic Software as a Medical Device (Dx SaMD). The intended use of this medical device is to diagnose respiratory illnesses. AudibleHealth Dx does this by analyzing your forced cough vocalization (FCV), the cough that you intentionally produce. Using an app that can be installed on any smartphone, the user submits an FCV and the AI/ML engines provide a diagnosis. Preliminary testing has shown that the investigational device will diagnose COVID-19 illness within minutes. "Investigational" means this device has not yet been approved by the FDA.

Will I be using the AudibleHealth Dx?

• No. This study will be using the Cough Collector app to obtain cough sounds.

How Do I Report an Adverse Event?

- Adverse event (AE) means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related.
- If at any time you think you may be having an adverse event, please contact one of the site principal investigators listed on your informed consent.

What are the Risks and Benefits of the Study?

- There are no major known risks associated with this study. It can be uncomfortable to cough many times in a row.
- The benefits of participating in this study are helping to create a technology that can diagnose COVID-19, Influenza, and RSV from a person's smartphone with only the sound of a cough, which will be faster and more cost-effective than current testing methods. You will also have the personal benefit of receiving a \$50 gift card.

Will I Receive a Test Result?

• No. This study is being used to train the investigational device, and no result will be created.

How long will the study last? How many people will be in the study?

- The study should take about 15-20 minutes to complete. The total time for the study is expected to be 2-4 weeks, but only requires one interaction with the smartphone app per person.
- More than 500 men and women are expected to participate in the study.

You will receive an email similar to the one below. When you follow the "ENTER THE RESEARCH STUDY" link, you will be taken to Adobe Sign to complete your informed consent. The informed consent is the

document that legally allows AudibleHealth Dx to enroll you in a study.



Dear {{NAME}},

Thank you for your interest in participating in our research study. This study will help us continue development of a new kind of test designed to diagnose COVID-19, Flu, and RSV using only the sound of your cough. You are under no obligation to join this study. Once you're ready to start, the entire process will take 10 to 15 minutes.

sent to the participant.

After provider enters a new subject in our system, the following email is

Please save this email for future use.

To participate, you'll go to our website to fill out some information about yourself. Next, we'll show you how to download our free cough collection mobile app. Once you've recorded your coughs in our mobile app, you'll be able to claim your \$50 gift card.

Here are all the details you'll need to participate:

- To start, click this link: ENTER THE RESEARCH STUDY
- This is your personal Participant ID: XXXXXXX. Please do not share this code with anyone else.
- We have attached some additional information about our project.
- · When it's time to download our mobile app, use these links on your mobile phone or scan the QR code to get the free download.



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This is some further basic information about the study in which you are agreeing to participate. You can choose "Continue" to move toward informed consent, or choose "I am not interested" if you do not wish to participate.

Confirm Enrollment (AdobeSign)
About This Clinical Research Study
You are invited to participate in a research study to assist in the continued development of a new kind of test that is designed to diagnose COVID 19, Flu, and RSV using only the sound of your cough. You are under no obligation to join this study. The entire process will take 10 to 15 minutes.
To participate you will fill out some additional information on this website. After that you will be provided with a link to download our free mobile app that works on both Android and Apple smart phones.
Once you download our free app, you will enter the Participant ID that your healthcare provider gave you, and you will be guided through a shor process to collect three audio recordings of you coughing. Be sure you have the Participant ID available before you continue with this process.
Once you have successfully completed submitting your cough recordings, you will be asked to complete a short survey. Once completed, you'll be able to obtain your \$50 gift card, to thank you for your participation in this study.
Click the continue button below to begin.
CONTINUE Lam not interested
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These lists explain the criteria for being included in the study. Some of these questions were likely asked at the clinic where you were recruited for the study, but please take a moment to review them. If you meet the criteria, choose "Continue." If you do not meet the criteria choose, "I do not qualify".

Eligibility Det	ails
(Adobe Sigr	n)
 You are unable to participate in this study if you: Were previously part of any prior AudibleHealth Dx trial Are under 5 years of age Are unable to produce a voluntary forced cough vocalization (FCV) Have experienced recent (within the last year) acute traumatic injury to the head, neck, throat, chest, abdomen, or trunk Have had a patent tracheostomy stoma Have had recent (within the last year) / abdomen / trunk trauma or surgery, recent/persistent neurovascular injury or recent intracranial surgery Have a history of cribriform plate injury or cribriform plate surgery, diaphragmatic hernia, external beam neck/throat / maxillofacial radiation, phrenic nerve injury/palsy, radical neck/throat/maxillofacial surgery, vocal cord trauma or nodules Have aphasia 	You qualify for this study if you are: 18 years of age or older, or, ages 5-17 and able to complete this study with your paren or guardian's approval and assistance Willing to comply with all study procedures and be available for the duration of the stud (your study time will end after you have completed your questionnaire) Able to complete this consent form and ent information on a cell phone app in English (translation to other languages is not available currently)

Then you will be taken to the informed consent, which must be signed and dated within Adobe Sign for you to participate in the study. Please read the informed consent carefully and direct any questions to the appropriate contact list on the consent form.

	Informed Consent (Adobe Sign)	
Please review and digitally sign this Informed Consent document	<text><text><text><text></text></text></text></text>	

After the informed consent is complete, you will be linked to an application where you can enter some basic demographic information and medical history. The first page is shown below. Log in using your participant ID and date of birth.

	Welcome
	Welcome!
To continue, please enter the birth. Your participant ID is a in our system.	e participant ID from your provider along with your date of Ilso in the email you received after your provider entered you
Please <u>note:</u> you must subm result.	it your cough samples within 24 hours of your positive test Enter Participant ID# Enter DOB

The starred fields are required. Use the drop-down menus to answer each question.

		About You	
BACK	Age* Gender* Smoker Status* Ethnicity (optional) Race (optional)	Ves No N/A Are you pregnant?	SAVE AND CONTINUE
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Please select each symptom that you are experiencing. For each symptom that you choose, you will be asked to provide the number of days you have been experiencing the symptom. If you are not currently having any of the listed symptoms, you may continue to the next question. You will then be asked about any prior testing you've received or exposure to others who have tested positive for an illness or had symptoms. Please answer yes or no for each. If the answer is yes, provide the approximate date of the test or exposure.

		Curre	ent Hea	Ith Status			
1. Are you currently experiencing any of the following? (Check all that apply):	2. Have you respiratory i	tested po liness with	sitive for a in the past	ny 14 days?	4. In the greater t	last 14 days, l han 15 minut	have you had close contact (for es, within 6 feet, without a masi
Cough	Test	Yes	No	If yes, approximate date	with som	eone who ha	d symptoms of a respiratory
Fever	COVID-19	0	0		illness?		
Chills	Influenza	0	0				
Nasal Congestion	RSV	0	0		Yes O	No O	lifuos, anoroximato dato
Chest Congestion	Other	0	0		103 0		II yes, approximate date
Shortness of Breath Loss of Taste/Smell Diant Pain Numbness Tingling	 In the last greater than with someor illness? 	14 days, 1 15 minut ne who te	have you h es, within t sted positiv	ad close contact (for feet, without a mask) se for a respiratory			MM-DD-YYYY
Rash	Test	Yes	No	If yes, approximate date		1.1.127	A 1997 1997 1997 1997
Biurred Vision	COVID-19	0	0			S	AVE AND
Dizziness	Influenza	0	0			C	ONTINUE
DNauroa	RSV	0	0				
Nomiting	Other	0	0				
Diarrhea							
K DOther							

This page will ask you some questions about what vaccinations you have received. Of note, you will not see subsequent questions if you select that you have not been vaccinated.

			Your Vaccination Status		
5. Have	you been vacc	inated for COVID-19?			
Yes O	No O				
6. Which	was your first	t vaccine?			
O	woderna	Johnson & Johnson			
0	0	0		Have you been vessioned a	as influenza des the current
7. Which	was your sec	ond vaccine?		flu season?	or induenza for the current
Pfizer	Moderna	I did not get a 2nd vaccine		Yes O No O	
0	0	0		If yes, date of vaccine:	MM-DD-YYYY
8. Have yo	u received a boos	ster in the last 6 months?			
Pfizer	Moderna	Johnson & Johnson			
0	0	0			
	I did not recei	ive a booster			CONTINUE
A CH	0				CONTINUE

This page will ask about medical diagnoses and surgeries you may have had. For each you select, you will be asked the approximate date of the diagnosis or surgery. Try to be as specific as possible with the month and year. If you do not remember, you can put the most specific information you have.

	Health History	
ВАСК	Have you experienced or been diagnosed with any of the following? (Check all that apply.) Asthma COPD – Chronic bronchitis COPD - Emphysema Pulmonary or cystic fibrosis Lung cancer Tuberculosis Long COVID Pneumonectomy Pneumothorax Major chest surgery or trauma Other	Approximate Date
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This page will help you determine the next steps. Choose whether you are completing the information on a smartphone or a laptop/tablet to continue.

Download A	Арр
Great! Thank you for y Let's get you set up on your fi	our information. ree Cough Collector app
If already using a smartphone:	If you've been using a laptop/tablet to this point:

If you are using a smartphone, follow these instructions to proceed:



1. Get your Apple or Android smartphone to complete the rest of the process.

If you've been using a laptop/tablet to this point:

- On your phone, go to your app store and search for "AudibleHealth Dx Cough Collector" (or scan the QR code below).
- 3. Download the free Cough Collector app.
- 4. To log into the app, enter your date of birth and the Participant ID # from your welcome email.
- 5. Follow the instructions to submit your coughs.
- 6. On the last screen, follow the link to the final step to receive your Gift Card.





After completing the download of the Cough Collector app from the Apple App Store or the Google Play Store, you will see the screens below. Use your Participant ID and Date of Birth, with a 4-digit year, to log in.



The next 2 screens provide some instructions and helpful tips to ensure that you have successful cough submissions. Please follow the instructions carefully. Listen to the cough example so that you understand what type of cough sound quality the device needs.



After you have read all instructions and tips, you will see the screen on the left. When you are ready to provide at least 10 coughs, choose "Start". Cough at least 10 times, and choose "Stop & Submit". If for some reason, there was a loud noise or you were unable to cough after selecting start, you may choose "Stop & Retry" to try again. After you submit, you will see the Analyzing screen.



After your first submission, you will see the "Great!" screen and be prompted through the same process for your second submission.



Once again, after the second submission, you will be prompted through the same process for your third submission.



If after your 3 submissions, the Cough Collector does not have enough coughs to use for training the new AI/ML, you will see this screen. If you receive this screen, you will be taken back through the process of submitting a cough. You may have to submit cough sounds up to 10 times although this is unlikely if you are following the helpful tips. If you complete 5 cough sound submissions, and there are still not enough coughs, you will be timed out for 30 minutes to prevent voice strain. (See the screen on the right.) When the 30 minutes are complete, you will be able to try your cough submission again and proceed to get your gift card.



Once enough high sound quality cough sounds have been collected, you will see the "Success!" screen. Choose "Continue" to proceed to receive your gift card. The next page will open in the web browser of your phone. If for some reason you need to come back to the app, you will see the screen on the right. You can choose "Continue" to re-launch the web browser or "Log Out" if you have already claimed your gift card.



The first screen in your browser will look like this. You will need to verify your Date of Birth and Participant ID one more time.

Verify Patient ID
nples! er your Participant ID below to access your Gift Card.
MM-DD-YYYY
SUBMIT

This is the screen where you can collect your gift card. If you choose Option 1, you will immediately receive an Amazon Gift Code to use. If you choose Option 2, a \$50 VISA Gift Card will be mailed to the address you provide. Your information will be removed from our secure cloud server after your gift card has been mailed.





When you see this screen, you have completed all components of the study and are officially discharged from the study.



Thank you! You have successfully completed your participation in our cough study.