Boston Scientific COVID-19 Heart Study

Information for Health Care Professionals

Cardiac patients are among those at highest risk for COVID-19. Boston Scientific and Yale/ Yale New Haven Hospital's Center for Outcomes Research & Evaluation (CORE) are working together to better understand how COVID-19 affects people with heart conditions, and whether we can leverage our implanted devices to improve care.

We are asking for your help in making your patients aware of this important study as quickly as possible.

What You Can Do

Inform patients about the opportunity to participate.
You can do this during routine in-person or virtual appointments, by email, phone, or other messaging means. You do not need to bring patients into the clinic as part of the study, nor do you need to identify specific patient who may have had COVID-19. Patients who choose to volunteer can enroll directly via the patient-facing web site **www.covid19heartstudy.com**.

Download and share the patient information sheet and post it visibly at your clinic.
Resources specifically designed for patients covering key information and questions about the study may be downloaded from **www.covid19heartstudy.com/hcp**.

Overview

Why are we building a registry of LATITUDE™ patients with COVID-19?
We have heard reports from some of you suggesting that some sensor data changed with COVID-19 onset. Since receiving these reports, we've been investigating how we might help you better remotely manage your patients in a COVID-19 and post-COVID-19 world. We believe we can help, but to do this we need data from a larger number of LATITUDE™ patients with COVID-19 to build and test our models.

How might this impact clinical care?
Patients with a history of cardiac issues and with multiple comorbidities are at higher risk of developing more serious complications associated with COVID-19, but not all COVID-19 cases are critical cases demanding ICU and other resources. Being able to detect COVID-19 sooner and to predict which patients will need critical resources may help us to reduce the burden on hospital systems while improving outcomes for at-risk patients.

Study Design

Who is leading this study?
The principal investigator is Dr. Harlan M. Krumholz, MD, SM from the Yale/Yale New Haven Hospital's Center for Outcomes Research & Evaluation (CORE). The CORE lab has partnered with Boston Scientific to design and launch the COVID-19 Heart Study.

How is this different from the AHA Registry or other COVID-19 registries?
This registry is specifically focused on patients with LATITUDE™ Remote Monitoring. We are in the unique position of having continuous sensor data from before, during, and after COVID-19 incidents, making it possible to develop detection tools where others can't.

Participation for Clinicians

Do I need my own IRB approval?
No. We will not be providing raw study data to you or asking you to provide data to us, so you will not be considered a collaborator for research purposes. We are simply asking you to share information about an ongoing study so that your patients can choose whether to participate. We do encourage you to consult with your local institution if you have any concerns about whether you can participate in this way.

Will I be paid for my time?
No. For compliance reasons and due to IRB restrictions, we cannot pay you for helping to promote the study. If you are interested, we will happily send email updates with access to study results as they are available. Please mention to your local Boston Scientific representative if you would like to receive these updates.

Is Boston Scientific asking me to work for free so you can charge me for the results?
No. Any COVID-19-related detection algorithms and tools will be made available to all monitoring clinics for applicable devices for no additional charge.

Will I be able to see my patient's responses?
No. In order to comply with IRB requirements, data will be de-identified after being matched to LATITUDE™ data. We will share results for regions and/or the entire U.S. as they are available, but you will not be able to see clinic specific data.

Do I need to interact with COVID-19 positive patients?
No. We are asking you to make patients aware of this study. You can do this by email, phone, or other messaging means. You do not need to bring patients into the clinic as part of the study.

Inclusion Criteria

How many patients are needed for the study?
The minimum target is 200 COVID-19 positive (or previously COVID-19 positive) LATITUDE™ patient respondents, with a stretch goal of 1000. To achieve this, we are asking clinicians across the U.S. to share this study with your patients.

Do patients need to actively have COVID-19?
No. The questionnaire will ask about date of diagnosis, symptoms, and treatment. Our target patient population is anyone who has ever tested positive for COVID-19 and who is currently monitored on LATITUDE™.

Inclusion Criteria (continued)

How will I know which patients to share this with? Do I need to check my EMR or contact patients to find out whether they have had COVID-19?
We have designed a patient-facing web site with inclusion/exclusion criteria and basic information about the study, so that you can share the study invitation with all LATITUDE™ patients, rather than needing to spend time identifying those who may have had COVID-19. Patients who choose to volunteer for the study can enroll directly via this website.

Can patients without HeartLogic™ participate?
Yes. Any patient with LATITUDE™ remote monitoring who has tested positive (or previously tested positive) for COVID-19 is invited to participate.

Patient Participation

What is involved to participate?
Patients can enroll in the study by completing a 15-minute enrollment to share information about their COVID-19 symptoms and testing, as well as some general health information. Patients who participate may elect to receive email updates from the study team, or to be contacted to provide feedback.

Will patients be compensated for participating?
No. Patients will have the opportunity to sign up for email updates on study progress but will not receive monetary compensation.

Will this impact patients' remote monitoring?
No. The study will not impact the remote monitoring or implanted devices in any way.

Will patient information be kept safe/secure/confidential?
We use industry standard security practices to protect data, including data encryption and access restrictions. Identifying data will be used only to match patient responses to LATITUDE™ data and will be removed before analysis.

Boston Scientific
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Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Cardiac Rhythm and
LATITUDE™ Support:
(800) CARDIAC (1-800-227-3422)

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