CHANGE AFib:

A Pragmatic Randomized Clinical Trial
of Early Dronedarone versus Usual Care to Change and Improve Outcomes in Persons with First-Detected Atrial Fibrillation

Fireside Chat – September 29, 2022

CHANGE AFib is a collaboration between the American Heart Association and the Duke Clinical Research Institute, with support from Sanofi US Services Inc.

Meeting Reminders

Please Note:

- All participants will be muted upon entry.
- Meeting is being recorded and will be archived on our trial website: www.changeafib.org

Questions?

- Please hold questions until our Q&A session at the end of the call.
- Feel free to submit questions in the chat throughout the call, knowing they will be addressed during the Q&A session.

If you are having issue with computer audio, please call in using the appropriate number below.

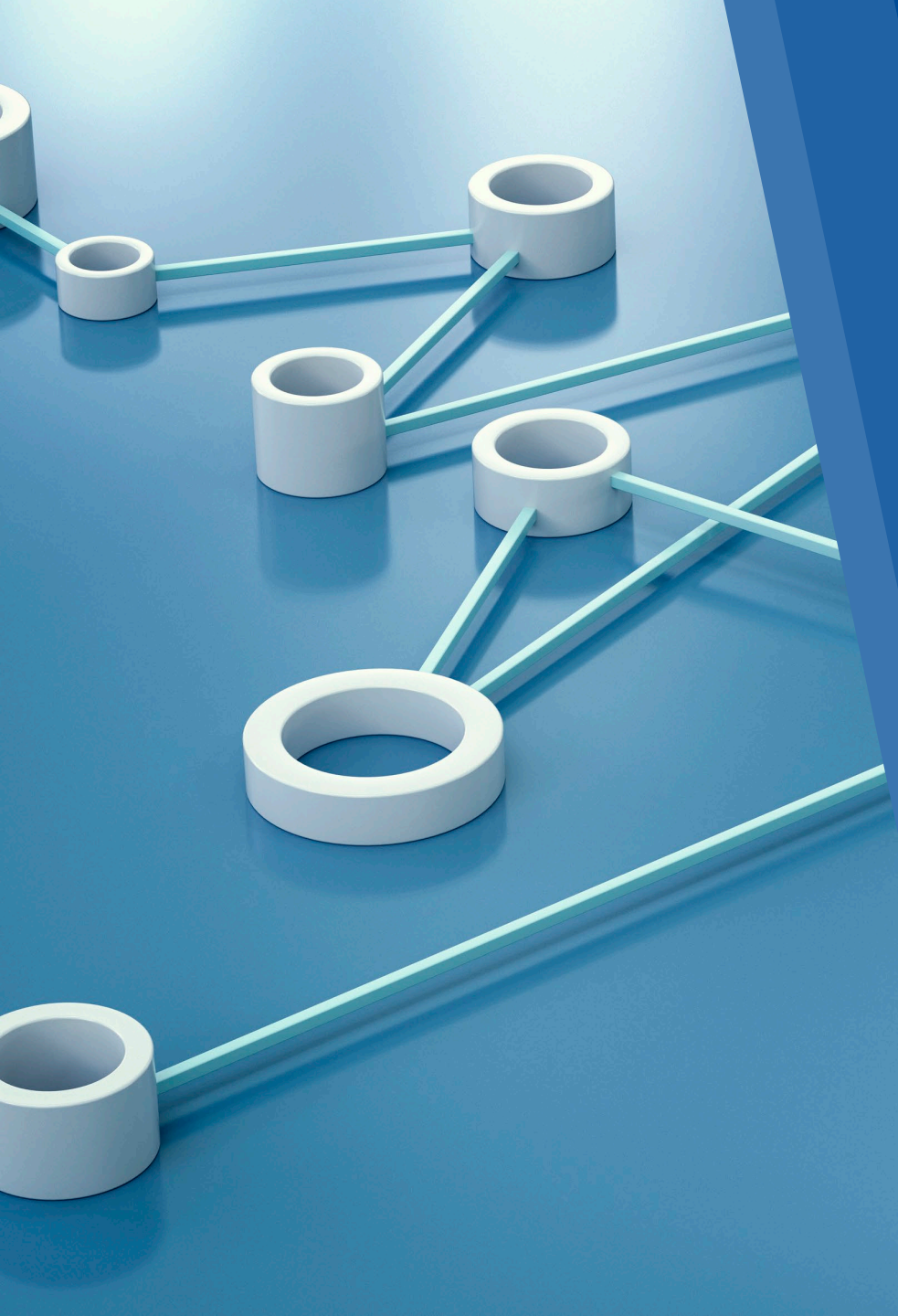
Dial by your location:

+1 (301) 715-8592	(Washington DC)
+1 (312) 626-6799	(Chicago)
+1 (646) 876-9923	(New York)
+1 (253) 215-8782	(Tacoma)
+1 (346) 248-7799	(Houston)
+1 (669) 900-6833	(San Jose)

Meeting ID: 834 6689 0261
Passcode: changeafib

Agenda:

- Welcome & Introductions – 5 mins
- Reviewing *Sanofi Patient Connection*® Information – 15 mins
- Q & A for Sanofi – 10 mins
- Trial Progress & FAQ Update – 10 mins
- Trial Q&A – 10 mins
- Trial Reminders & Closing – 5 mins



Reviewing *Sanofi Patient Connection®* Information

Michael Sanchez
Director, Patient Programs & Portfolio Leads

Hui Lui, PhD
Sr Director, US Value & Access, Cardiovascular and Transplant

www.sanofipatientconnection.com

Sanofi will review their publicly available medication resources. The information presented is available via Sanofi's Patient Connection website. Content provided is for informational purposes only and does not constitute an endorsement/support by the AHA.

Q&A for Sanofi

Trial Progress Update

Trial Progress – as of September 29, 2022

Site Status	Current Status	Trial GOAL!
Subject Enrollments	**16**	**3000**
Activated Sites	20	**200**
Sites in Onboarding	57	**-**
Sites Assessing Feasibility	30	**-**

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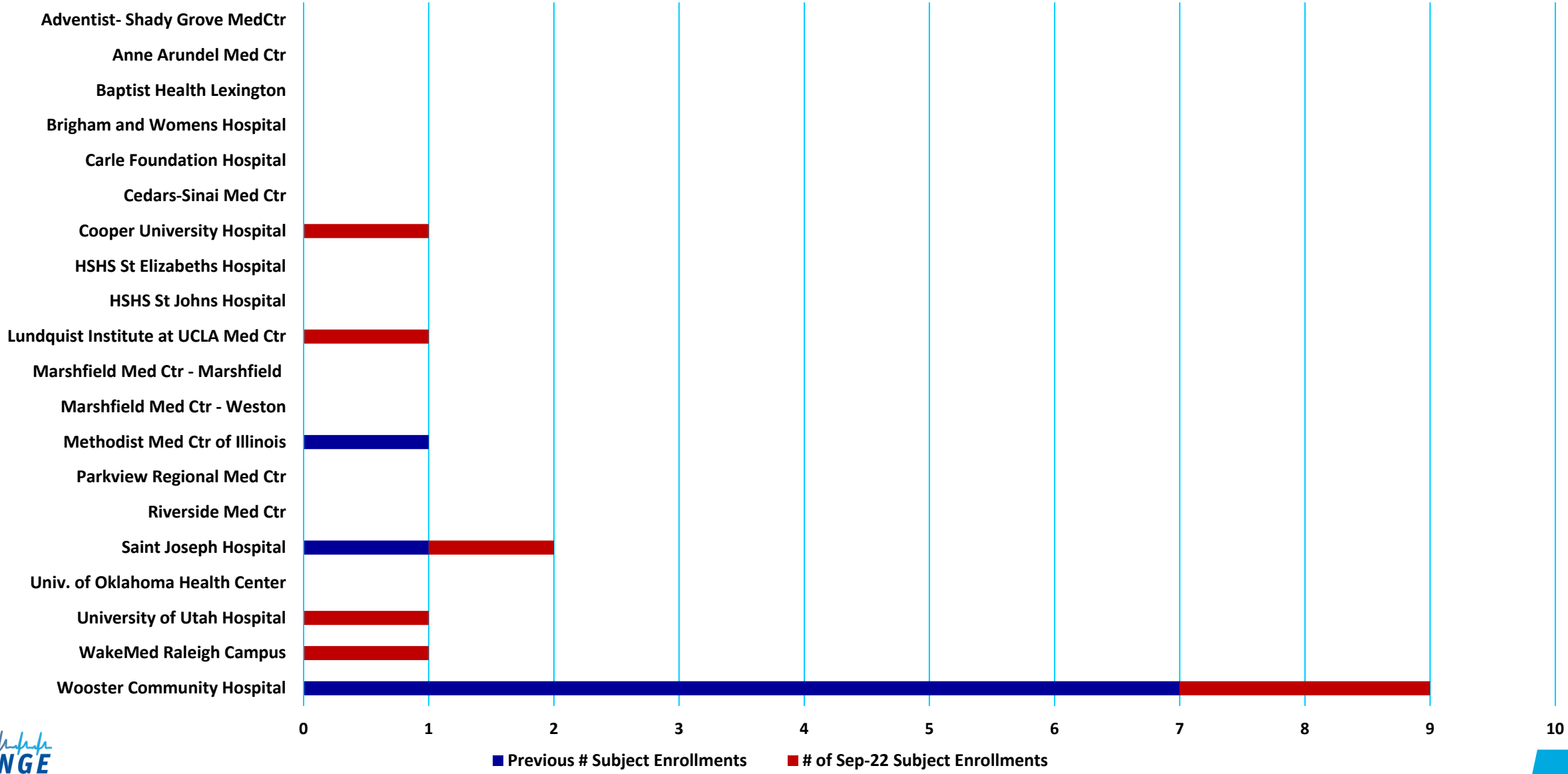
Subject Enrollments by Site

CHANGE AFib Subject Enrollments (16)



Above data current as of EOD on 27Sep2022

TRIAL ENROLLMENT GOAL

2022 YEAR END GOAL:

300 SUBJECTS

1 SUBJECT PER SITE PER WEEK

Our year-end goal can be achieved if all sites enroll at least 1-subject per week! As we are consistently activating new trial sites, we know can meet this 2022 goal together!!

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Updated FAQ Question (V5_15Sep2022)

Located HERE on the Trial Website

How should we approach concomitant antiarrhythmic drug therapy & CHANGE AFib enrollment?

- Beta-blockers (metoprolol, atenolol, carvedilol, propranolol, bisoprolol, etc) or calcium channel blockers (verapamil, diltiazem) are permitted in either arm.
- If a patient has short-term/IV antiarrhythmics in the ER or hospital (e.g. ibutilide, procainamide, amiodarone, etc as an inpatient) for cardioversion or acute control of AF only, they are eligible.
- If a patient has been on chronic antiarrhythmic drug therapy for AF or AFL they are not a candidate. Antiarrhythmics include class IC agents (flecainide, propafenone), class III agents (dofetilide, sotalol) or multichannel blockers (amiodarone, dronedarone).
- If a patient is failing therapy after enrollment and their provider wants to start an antiarrhythmic or stop dronedarone and switch to a different AAD then this is permissible as per protocol.

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Q&A

Trial Reminders

Continuing Review 2022

October 29, 2022

- All Central IRB sites will receive an email from Advarra notifying the request to submit for Continuing Review.

- Regardless of the date of your Initial Central IRB approval, all sites utilizing Advarra will require annual continuing review submission prior to our Master Protocol expiration date of 10/29/2022.

- Local/Institutional IRB sites are to follow the annual review date as indicated on their Local IRB Approval Letter.
  - *AHA Site Managers will work with Local IRB sites to track and manage upcoming Local IRB Continuing Review dates.*

- All sites, Central & Local, will receive the Master Protocol Continuing Review Approval Letter for your site records.
  - *Local IRB sites may need to provide this documentation to your IRBs. Check with your Institutional IRB policies.*

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EXAMPLE SITE EMAIL

IRB Continuing Review Notice

8/30/2022 10:10 PM

CIRBI Link: [redacted]

Protocol: American Heart Association-TX - 1.0

Protocol Title: Pragmatic Randomized Clinical Trial of Early Dronedarone versus Usual Care to Change and Improve Outcomes in Persons with First-Detected Atrial Fibrillation (CHANGE AFib).

From: Advarra IRB

Your site approval for the above referenced study will expire on 10/29/2022 . To ensure IRB review prior to your site approval expiring, please log into CIRBI using the link above to submit a Site Continuing Review Form at least 30 days prior to 10/29/2022. Failure to submit a timely Continuing Review Form could cause a lapse in approval.

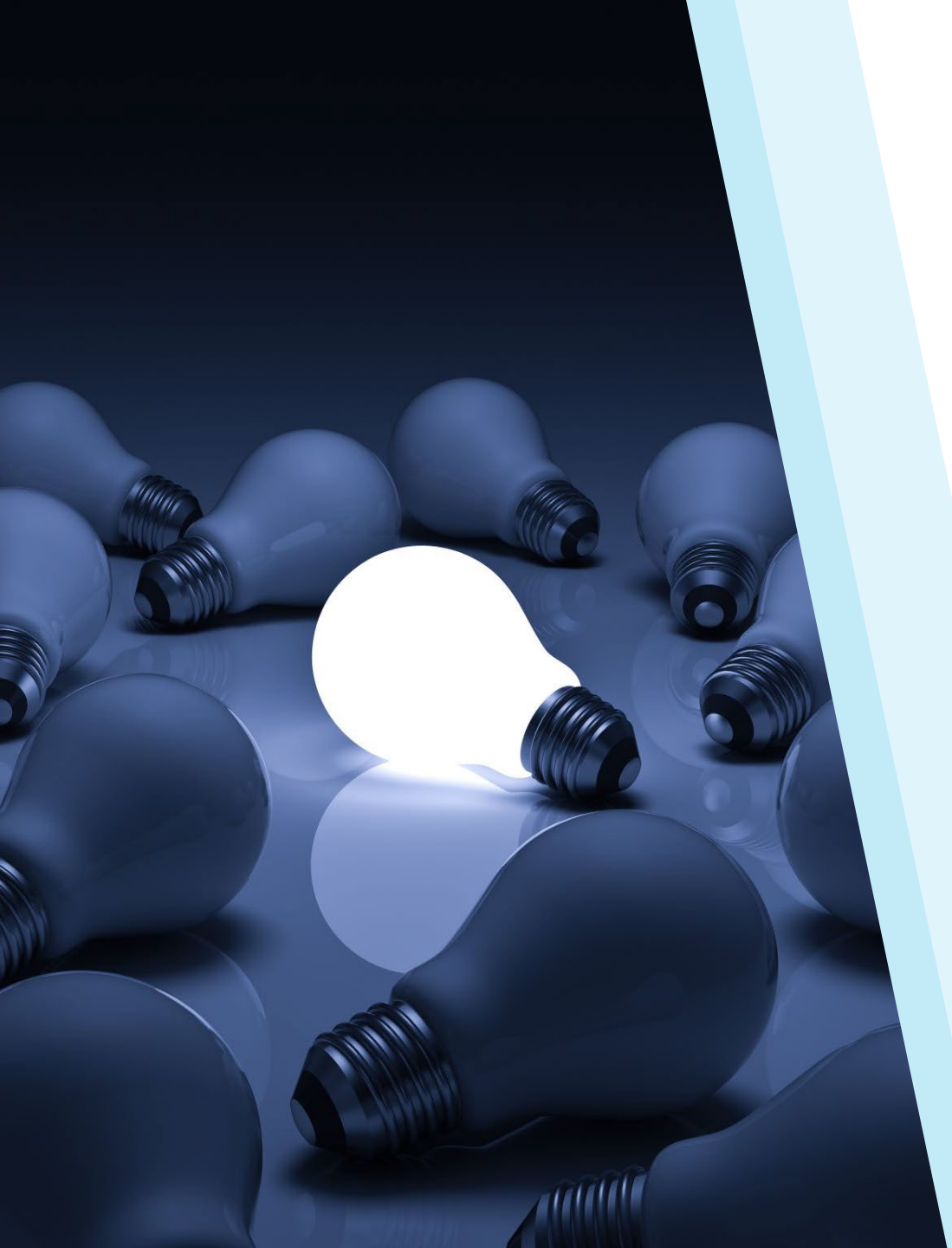
PLEASE NOTE: If enrollment for this study is closed and you expect that all subjects will have completed the study, please choose Termination as your report type when you create your Continuing Review Form.

Please click on the CIRBI link above and log into CIRBI to create and submit your Continuing Review report.

Your project coordinator is available to answer any questions that you may have as you complete this form. They can be reached by clicking the 'Contact IRB' activity or by calling the number listed on the workspace.

Continuing Review/Termination Reports received within two weeks of the expiration date will be subject to additional fees.

Thank you,
Advarra IRB



Trial Website Resources Review

Located Here: CHANGE AFib Trial Site Resources

Password: change2021!

Trial FAQ, Newsletters, & Fireside Chats

- FAQ
- Newsletters
- Fireside Chat Recordings and Handouts

- Website Resources: Routine monthly and real-time trial updates!
- FAQ Version Updates are posted in password-protected Resources section of website (in addition to trial email blast).
- Newsletters sent Monthly serve as a touch point in between Fireside Chats
  - Highlighting enrollment updates, trial site successes and best practices, Important upcoming trial dates, FAQs updates & other trial reminders
- Fireside Chat Recordings and Handouts posted for circulation amongst colleagues unable to join.

Mark Your Calendars!

Upcoming Fireside Chats

- **Thursday, October 27th 3-4pm ET** — Next Up
- **Monday, November 28th 3-4pm ET**
- **Monday, December 19th 3-4pm ET**

**Archived webinar recordings & handouts can be found HERE on the trial website.*

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Connect With Us!

How to reach the CHANGE AFib Team

AHA Site Managers:

Crystal.Glodek@heart.org

Jack.Goldberg@heart.org

Mariel.Dronson@heart.org

ChangeAFib@heart.org

Resources to Remember

For important trial information and today's meeting recording, go to the **Resources** page at **www.changeafib.org** or visit the QR Code to the left.