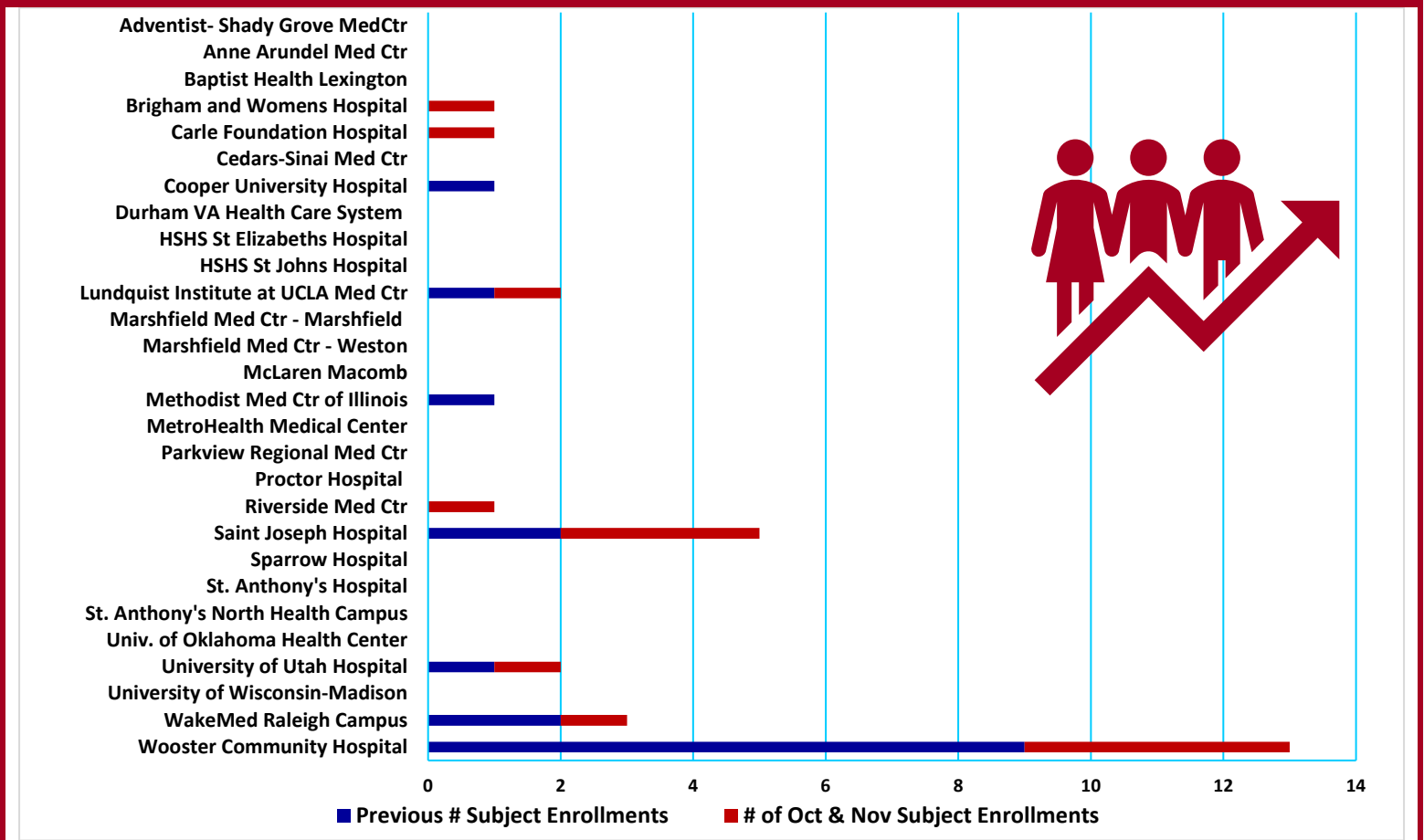


**MESSAGE FROM THE TRIAL TEAM**

During this holiday season, we reflect on how grateful we are for all CHANGE AFib trial team members who continue the commitment to advancing research and treatment options for our patients with newly diagnosed atrial fibrillation; we could not do it without you! We are happy to report the positive impact of Protocol V2.0 eligibility criteria on subject enrollments! We ask that all sites continue with this momentum as we close out the 2022 year! To meet our goal of 300 subjects by the end of the year, we are asking sites to enroll 3 subjects per week for the remainder of the year. To sites who are working towards activation, we encourage you to execute contracting and regulatory requirements quickly, in order to capitalize on our incentive program. Please reach out to your AHA site manager if there is anything we can do to assist in accomplishing these shared goals!

**TRIAL LEADERBOARD**



**WELCOME OCT & NOV ACTIVATED SITES!**

- St Anthony Hospital (Lakewood, CO)
- St Anthony North Health Campus (Westminster, CO)
- Durham VA Health Care System (Durham, NC)
- Proctor Hospital (Peoria, IL)
- Sparrow Hospital (Lansing, MI)
- McLaren Macomb (Mount Clemens, MI)
- MetroHealth Medical Center (Cleveland, OH)
- University of Wisconsin-Madison (Madison, WI)



**OCT & NOV TRIAL MILESTONES!**

**1<sup>st</sup> Randomization @ Site!**

- Brigham & Women's Hospital (Boston, MA)
- Riverside Medical Center (Kankakee, IL)
- Carle Foundation Hospital (Urbana, IL)



**Top Enrolling Sites!**

- 5 Subjects! - Saint Joseph Hospital (Lexington, KY)
- 13 Subjects! – Wooster Community Hospital (Wooster, OH)

## TRIAL UPDATES

### PROTOCOL VERSION 2.0:

Protocol V2.0 was officially approved 10/31/22. As outlined in Oct Newsletter & Nov Fireside Chat, Protocol V2.0 most pertinent updates were:

1. **Age:** Lowered to  $\geq 21$  years old
2. **First-detected AFib Diagnosis window:** Defined as atrial fibrillation diagnosed in the previous **120 days**
3. **Enrollment Setting Clarification:** Patients can be enrolled from the inpatient setting during this qualifying acute care encounter or afterwards in the outpatient setting, so long as the qualifying acute care event has occurred in the past 120 days. Acute care encounters are defined as a visit to an emergency department, observation unit, or hospital admission.
4. **Eligibility of consent by a Legally Authorized Representative**

### Updated Screening Log:

- All sites who are approved to recruit under Protocol V2.0, please be sure you are now using the updated screening log (Version 5.0 – 07Nov2022). This was sent with your site's Protocol V2.0 enrollment notice.
- New template can be found in the [Regulatory Binder Section](#) of the trial website.

### Update to Adverse Event Safety Reporting:

- Study teams are responsible for reporting any complaints or adverse events within three (3) business days after becoming aware of the complaint or adverse event.
- All AEs should be reported to:
  - **Email Sanofi PV:** [CL-CPV-Receipt@sanofi.com](mailto:CL-CPV-Receipt@sanofi.com)
  - **Fax Number** (to be used in the event e-mail failed): +33 1 6049 7070
- An update to the AE Reporting Form has been posted in the [Regulatory Binder Section](#) of the trial website.

### Protocol V2.0 Recruitment Materials:

- Updated materials are currently under production.
- Site mailings will be forthcoming ASAP!

## CALENDAR OF EVENTS

### FIRESIDE CHAT DATES:

- Mon, December 12th from 12-1pm ET
- 2023 Dates coming soon! Stay tuned!

*Please update your calendars!  
Don't Forget! Registration  
Required for ALL Fireside Chats!*

**END OF THE YEAR  
ENROLLMENT GOAL:  
300 SUBJECTS BY  
DECEMBER 31, 2022**

**CHANGE AFib  
INVESTIGATOR MEETING:  
March 3, 2023 in  
New Orleans, LA  
More details to come!  
Stay tuned!**



## IN CASE YOU MISSED IT!

- **November Fireside Chat** – Recordings and handouts from past Fireside chats can be found [on the trial website](#). If you were unable to attend the November Fireside Chat, please review the recording and slides for information regarding the recent protocol amendment: Protocol V2.0.
- **Call for new CHANGE AFib trial sites!** – As we work to reach our goal of activating 200 sites, we ask that you promote trial participation amongst your peer networks and connect us with any interested sites!
- **Site Invoicing** – Please remember to send your site's trial invoices to [CHANGEAFibInvoicing@heart.org](mailto:CHANGEAFibInvoicing@heart.org) for ALL trial payments, inclusive of incentive payments!

## ! IMPORTANT TRIAL CONTACTS !

General Trial Questions	<a href="mailto:CHANGEAFib@heart.org">CHANGEAFib@heart.org</a>
AHA Site Managers	<a href="mailto:Crystal.Glodek@heart.org">Crystal.Glodek@heart.org</a> ; <a href="mailto:Jack.Goldberg@heart.org">Jack.Goldberg@heart.org</a> ; <a href="mailto:Mariel.Dronson@heart.org">Mariel.Dronson@heart.org</a>
REDCap Questions	<a href="mailto:CHANGEAF@duke.edu">CHANGEAF@duke.edu</a> or Tel: 919-668-9339
GWTG-AFib (Trial EDC) Questions	Enrollment Site Managers or <a href="mailto:CHANGEAFib@heart.org">CHANGEAFib@heart.org</a>
Contracting Questions	<a href="mailto:CHANGEAFibContracting@heart.org">CHANGEAFibContracting@heart.org</a>
Invoicing Questions	<a href="mailto:CHANGEAFibInvoicing@heart.org">CHANGEAFibInvoicing@heart.org</a>
Adverse Event Reporting	Sanofi PV at <a href="mailto:CL-CPV-Receipt@sanofi.com">CL-CPV-Receipt@sanofi.com</a>