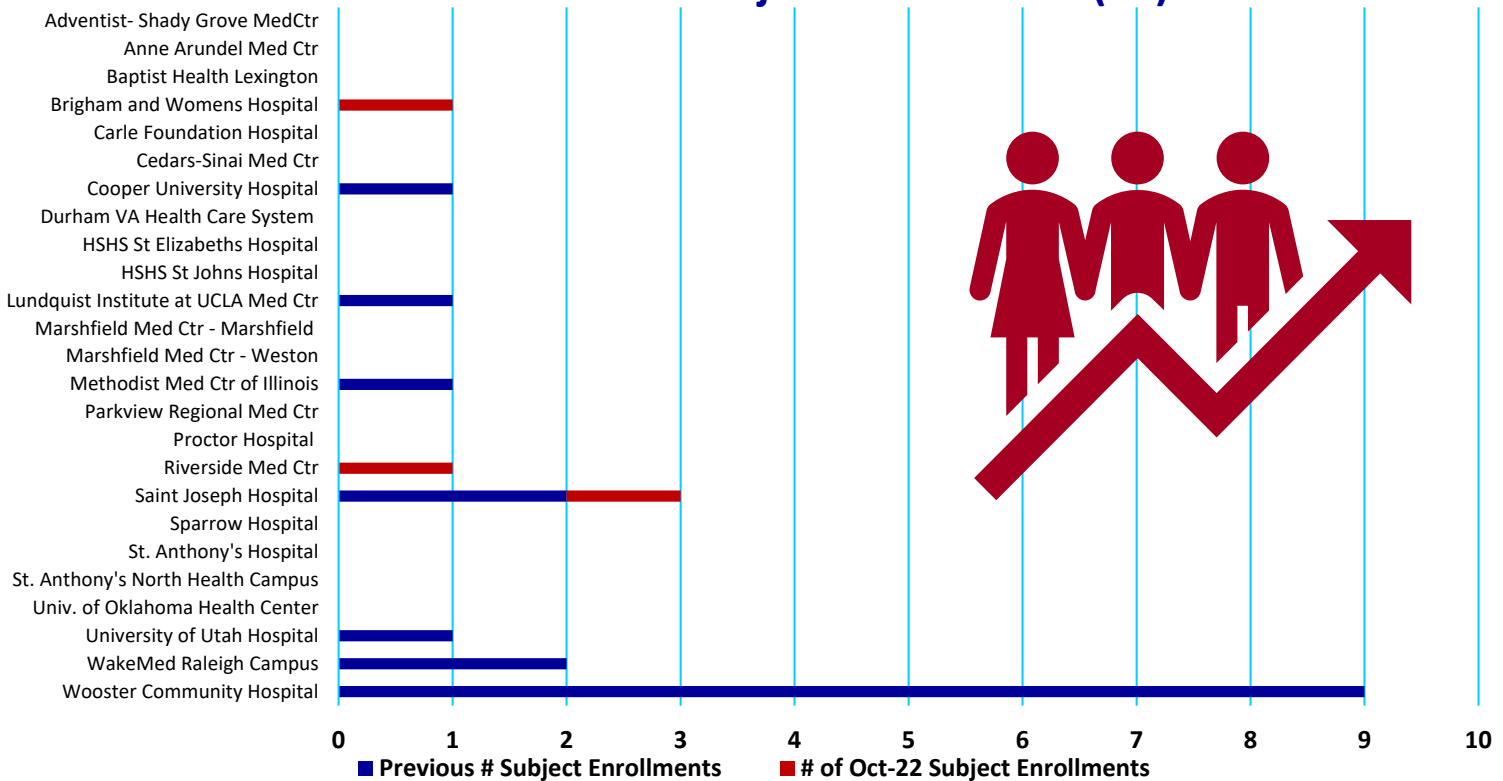


**MESSAGE FROM THE TRIAL TEAM**

Happy Fall, CHANGE AFib trial sites! We're focusing on meeting our year-end goal of 300 subject enrollments and need your help. We're asking that each site please focus on enrolling at least 1 subject per week through the rest of the year. If you're an activated site that has faced low enrollment challenges, we're looking to your site to help ramp up your screening efforts. Additionally, if your site is facing challenges enrolling your first subject, please don't hesitate to reach out to your AHA Site Manager (see down below) on how to best re-educate your team, fine-tune your screening approach, and best collaborate with your inpatient and outpatient colleagues. With your help we know we can meet this goal together! Thank you for all for your hard work in making the trial a success!

**TRIAL LEADERBOARD**

**CHANGE AFib Subject Enrollments (20)**



**WELCOME SEPTEMBER ACTIVATED SITES!**

- Adventist HealthCare Shady Grove Medical Center (Rockville, MD)
- Baptist Health Lexington (Lexington, KY)



**CONGRATULATIONS FOR SEPTEMBER FIRSTS!**

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

- WakeMed Raleigh Campus (Raleigh, NC)
- UCLA Med. Center-Harbor (Torrance, CA)
- Cooper University Hospital (Camden, NJ)
- Univ. of Utah Hospital (Salt Lake City, UT)



## MONTHLY SPOTLIGHT: PROTOCOL VERSION V2.0

**PROTOCOL VERSION 2.0 has been officially submitted for IRB Review.**

**We are expecting IRB Approval very soon! Stay tuned!**

The changes reflected in the upcoming Protocol V2.0 will positively expand upon the subject eligibility criteria which we anticipate will lead to increased enrollment opportunities for all sites. As you continue to screen potential CHANGE AFib subjects, please keep in mind the upcoming eligibility changes, as there may be some enrollment opportunities under Protocol V2.0 that were previously excluded.

### Protocol V2.0 Updates

1. **Age:** ≥ 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. **Orally administered antiarrhythmic drug for treatment of AFib definition**
  - a. Clarification: Antiarrhythmic drugs include Vaughan-Williams class I and III medications, including flecainide, propafenone, sotalol, dofetilide, dronedarone, and amiodarone. Note, beta-blockers (class II) and non-dihydropyridine calcium channel blockers (class IV) are not membrane active antiarrhythmic medications.
5. **Eligibility of consent by a Legally Authorized Representative**

### IRB Reminders

- **CENTRAL IRB:** Upon Master Protocol approval, all sites utilizing the central IRB will automatically be reviewed for Protocol V2.0 approval. Upon approval, Advarra will email out approval notifications and updated ICFs.
- **LOCAL IRB:** All pertinent regulatory material will be posted to [CHANGEAFib.org](http://CHANGEAFib.org) upon approval. Please adhere to Institutional IRB requirements in order to submit for IRB review and approval.
- **Protocol Signature Page:** All sites will be required to review the updated protocol in depth and return a signed protocol signature page for V2.0.

## CALENDAR OF EVENTS

### FIRESIDE CHAT DATES:

- **CANCELLED:**  
Thurs, October 27th 3-4pm ET
- Thurs, November 10th 1-2pm ET
- Mon, December 12th 12-1pm ET

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

### IRB CONTINUING REVIEW:

October 29<sup>th</sup> –  
**APPROVED 11Oct2022**

### CONFERENCES:

- Scientific Sessions:  
November 5-7<sup>th</sup> in Chicago, IL

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



## IN CASE YOU MISSED IT!

- **September Fireside Chat** – Recordings and handouts from past Fireside chats can be found [on the trial website](#).
  - If you were unable to attend the September Fireside chat, please review the recording and slides for information presented by Sanofi regarding drug access resources.
- **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 payment!

## ! 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 1-800-633-1610