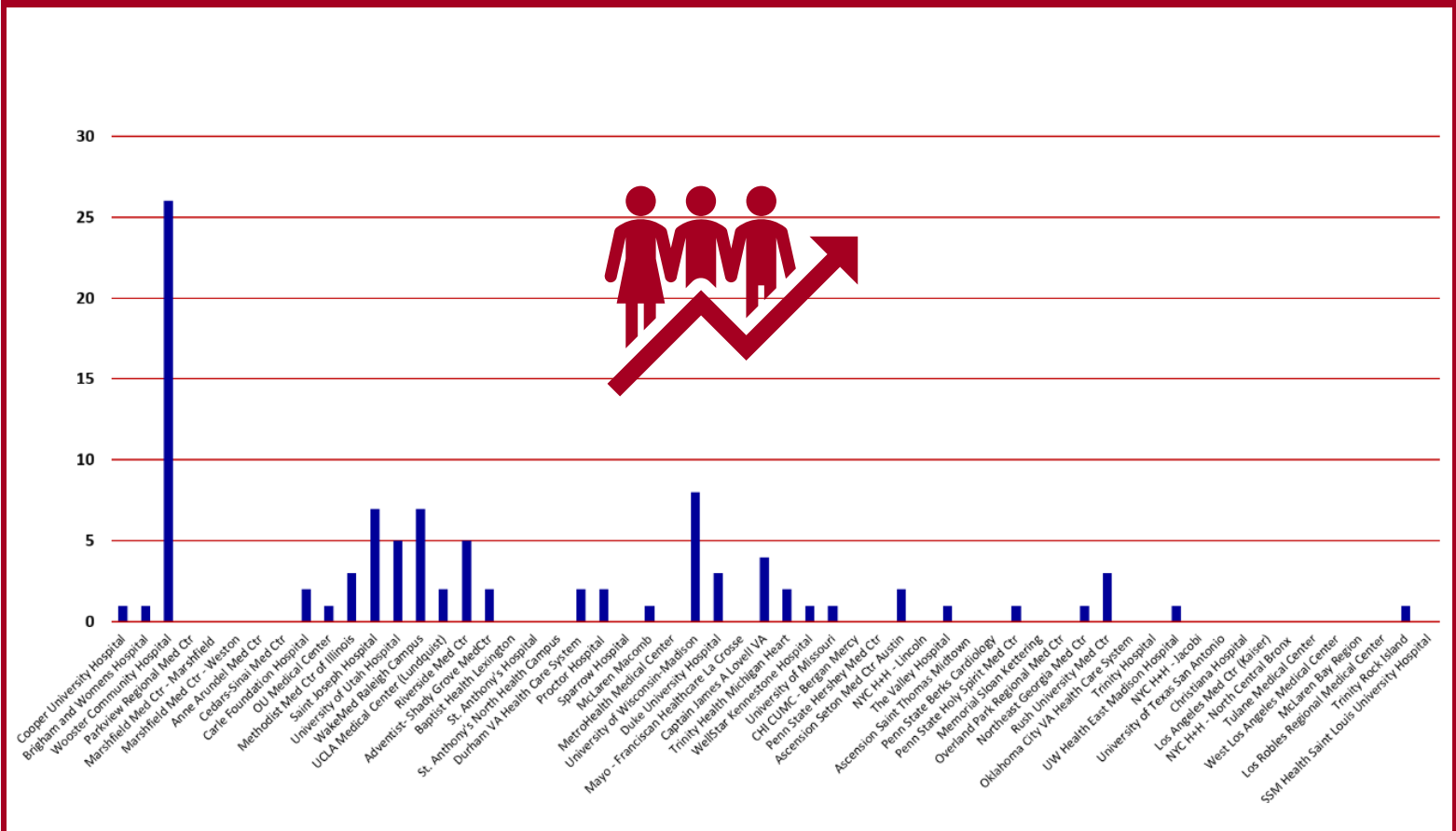


**A Pragmatic Randomized Clinical Trial of Early Dronedronone versus Usual Care to Change and Improve Outcomes in Persons with First-Detected Atrial Fibrillation**

**MESSAGE FROM THE TRIAL TEAM**

Thank you all for your recent efforts to get Protocol V3.0 off the ground! We trust drug provision will aid in your recruitment efforts and look forward to many more subject enrollments! As summer is approaching, we hope sites continue to keep an eye on our goal of **3 subjects per site, per month**. We've had a recent spike in enrollments, so thank you for picking up the pace! While we anticipate Protocol V4.0 to assist recruitment efforts, by removing the requirement for subjects to have an acute care encounter for the Dx of their first-detected AFib, we still need trial sites to monitor the above goal at their site. We look forward to our continued work together to increase enrollments!

**TRIAL LEADERBOARD – CHANGE AFIB SUBJECT ENROLLMENT**



**WELCOME MAY ACTIVATED SITES!**

- Christiana Hospital (Newark, DE)
- Los Angeles Medical Center- Kaiser Permanente (Los Angeles, CA)
- NYC Health and Hospitals – N. Central Bronx (Bronx, NY)
- Tulane Medical Center (New Orleans, LA)
- West Los Angeles Medical Center (Los Angeles, CA)
- McLaren Bay Region (Bay City, MI)
- Los Robles Health System – Los Robles Regional Medical Center (Thousand Oaks, CA)
- Trinity Rock Island (Rock Island, IL)
- SSM Health Saint Louis Hospital (Saint Louis, MO)



**MAY TRIAL MILESTONES!**

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

- Ascension Seton Medical Center Austin (Austin, TX) – 2 subjects this month!
- Penn State Health Holy Spirit Medical Center (Camp Hill, PA)
- Trinity Health Michigan Heart (Ypsilanti, MI) – 2 subjects this month!
- Trinity Rock Island (Rock Island, IL) – randomized within 6 days of activation!
- WellStar Kennestone Hospital (Marietta, GA)
- UW Health East Madison Hospital (Madison, WI)



## TRIAL UPDATES

### Protocol V4.0 Announcement:

- As mentioned at the Investigator Meeting and on the May Fireside Chat, Protocol V4.0 is being rolled out shortly! Subject Eligibility Changes are as follows:
  - **Removal of the Acute Care Encounter Inclusion Criteria.**
  - **Definition of ‘Electrocardiographic documentation of atrial fibrillation’.**
  - **Removal of Exclusion Criteria #2: Prior hospitalization for atrial fibrillation (other than the qualifying event).**
- **Next Steps:** We expect to receive Master Protocol V4.0 IRB Approval in the coming weeks. Immediately upon approval, Protocol V4.0 documents will be posted on the trial website to support your review and IRB submissions and a formal email will go out with more information.
  - **Central IRB Sites:**
    - All trial sites utilizing the Central IRB, Advarra, will automatically be reviewed for approval following the Master Trial Approval.
    - IRB approval emails will be sent to each individual site with site-specific approval notices and approved Informed Consent Forms (ICFs).
  - **Local/Institutional IRB Sites:**
    - All trial sites utilizing their Local/Institutional IRB will be required to submit an IRB Modification.
    - Site-Specific ICF edits are required to be sent to [CHANGEAFibContracting@heart.org](mailto:CHANGEAFibContracting@heart.org) for sponsor approval prior to Local IRB submission.
    - If your site has yet to submit to your IRB for the previous modification, please hold off and combine submissions for Protocol V4.0.

### Trial Invoices – Please submit all trial invoices by Thursday, June 15<sup>th</sup> 2023:

- Thank you to those who have already submitted their outstanding trial invoices! You should’ve already received a confirmation email from [changeafibinvoicing@heart.org](mailto:changeafibinvoicing@heart.org) or will receive one shortly! Please submit all invoices for start-up costs/annual site fees, enrollments, follow-up visits, and any incentives you qualified for.

## CALENDAR OF EVENTS

### **FIRESIDE CHAT DATES:**

- **Mon, June 12<sup>th</sup>** from 12-1pm ET
- *Stay tuned for remaining 2023 dates.*

*Don't Forget! Registration Required for ALL Fireside Chats!*

### **CONFERENCES:**

- Scientific Sessions: November 11-13<sup>th</sup> in Philadelphia, PA



**ENROLLMENT GOAL:**  
**3 SUBJECTS per SITE**  
**per MONTH**

## IN CASE YOU MISSED IT!

- **Fireside Chats, Prior Newsletters & Trial FAQ on our trial website** – Fireside chats [located HERE](#), Prior Newsletters [located HERE](#) and the Trial FAQ V7.0 is [located HERE](#).
- **Call for new CHANGE AFib trial sites!** – As we aim for 200 activated sites, we ask that you promote trial participation amongst your peer networks and connect us with any interested sites!
- **Site Invoicing** – Invoicing Template posted on the [trial website](#). Please remember to send your site’s trial invoices to [CHANGEAFibInvoicing@heart.org](mailto:CHANGEAFibInvoicing@heart.org) for ALL Trial Activities and Subject Payments.

## ! IMPORTANT TRIAL CONTACTS !

<b>General Trial Questions</b>	<a href="mailto:CHANGEAFib@heart.org">CHANGEAFib@heart.org</a>
<b>AHA Site Managers</b>	<a href="mailto:Jack.Goldberg@heart.org">Jack.Goldberg@heart.org</a> ; <a href="mailto:Mariel.Dronson@heart.org">Mariel.Dronson@heart.org</a>
<b>REDCap Questions</b>	<a href="mailto:CHANGEAF@duke.edu">CHANGEAF@duke.edu</a> or Tel: 919-668-9339
<b>GWTG-AFib (Trial EDC) Questions</b>	Above AHA Site Managers or <a href="mailto:CHANGEAFib@heart.org">CHANGEAFib@heart.org</a>
<b>Contracting Questions</b>	<a href="mailto:CHANGEAFibContracting@heart.org">CHANGEAFibContracting@heart.org</a>
<b>Invoicing Questions</b>	<a href="mailto:CHANGEAFibInvoicing@heart.org">CHANGEAFibInvoicing@heart.org</a>
<b>Adverse Event Reporting</b>	Sanofi PV at <a href="mailto:CL-CPV-Receipt@sanofi.com">CL-CPV-Receipt@sanofi.com</a>
<b>ALMAC IRT Questions</b>	<a href="mailto:irthelp@almacgroup.com">irthelp@almacgroup.com</a> or 1-877-738-8831 and press 0