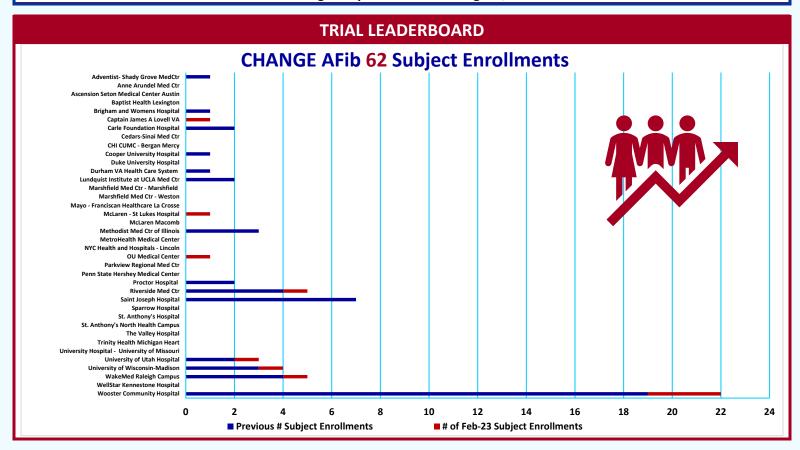


**Dronedarone versus Usual Care to Change and Improve Outcomes in Persons with First-Detected Atrial Fibrillation** 

# **MESSAGE FROM THE TRIAL TEAM: STUDY DRUG PROVISION!**

As recently announced, we are thrilled plans are underway for study drug to be provided to all current and future trial subjects in the intervention arm! Over the past few months, we have been diligently working to secure this benefit to overcome drug access and cost concerns, allowing more subject enrollments at each hospital. Our central pharmacy, The Almac Group, will be supplying direct-to-patient drug shipments reducing the need for any institutional pharmacy resources. A number of central pharmacy trainings are underway and we will provide more details as they become available. Stay tuned for more details on this exciting development! Additionally, sites will need to expedite a number of tasks surrounding clinical trial agreement amendments and IRB modifications, but please await instructions from our regulatory staff.

We look forward to discussing this change and trial progress with participating sites at our upcoming Investigator Meeting on April 25th in Washington, DC!



### **REMINDERS FOR SUCCESSFULLY ENROLLING IN 2023**

- Screening Strategies: Use a multi-pronged approach by manually reviewing inpatient and outpatient lists (ER, cardiology, etc.) then supplementing with EMR report reviews. There is no substitute for hands-on chart reviews compared to EMR reports reviews!
  - Ensure your site has a mechanism in place to screen patients admitted/discharged on weekends, holidays, etc.
- Outpatient Recruitment: Aim for trial introduction by clinical team and coordinator while inpatient. Review weekly clinic schedules.
- Trial Visibility: Promote trial regularly at departmental meetings and grand rounds using trial pitch deck, provider pocket cards & patient brochure. Collaborate with inpatient teams for referrals and patient management.
- Multi-disciplinary Teams: Ensure all high visibility areas have team representation, allowing for no eligible patient to be missed!

# **TRIAL UPDATES: December – February!**

### **WELCOME DEC, JAN & FEB ACTIVATED SITES:**

#### December

- Duke University Hospital (Durham, NC)
- Mayo Clinic Hospital Franciscan Healthcare La Crosse (La Crosse, WI)
- Captain James A Lovell Federal Health Care Center (North Chicago, IL)
- Trinity Health Michigan Heart (Ypsilanti, MI)

#### **January**

- WellStar Kennestone Hospital (Marietta, GA)
- University Hospital (Columbia, MO)



#### **February**

- CHI Health Creighton University Medical Center Bergan Mercy (Omaha, NE)
- Penn State Health Milton S Hershey Medical Center (Hershey, PA)
- McLaren St Lukes Hospital (Maumee, OH)
- NYC Health and Hospitals Lincoln (Bronx, NY)
- The Valley Hospital (Ridgewood, NJ)
- Ascension Seton Medical Center Austin (Austin, TX)

#### **DEC, JAN & FEB TRIAL MILESTONES:**

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



- Adventist Shady Grove Medical Center (Rockville, MD)
- University of Wisconsin- Madison (Madison, WI)
- Proctor Hospital (Peoria, IL)
- Durham VA Health Care System (Durham, NC)
- OU Medical Center (Oklahoma City, OK)
- McLaren St Lukes Hospital (Maumee, OH)
- Captain James A Lovell Federal Health Care Center (North Chicago, IL)

#### **Top Enrollers!**

- Wooster Community Hospital- 22 Subjects!
- Saint Joseph Hospital- 7 Subjects!

# Fastest Randomization Post Site Activation!

McLaren – St Lukes
Hospital (Maumee, OH)
randomized a subject just
4 days after site
activation!

# **CALENDAR OF EVENTS**

#### **FIRESIDE CHAT DATES:**

- Mon, March 27<sup>th</sup>
   from 3-4pm ET
- Tues, May 16<sup>th</sup> from 1-2pm ET
- o Mon, June 12<sup>th</sup> from 12-1pm ET

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

# CHANGE AFIB INVESTIGATOR MEETING:

April 25<sup>th</sup>, 2023 in Washington D.C.

RSVP HERE by March 10, 2023



# **IN CASE YOU MISSED IT!**

- 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! Keep in mind there are incentive payments for speedy CTA and IRB submissions, along with early subject enrollments!
- **Prior Fireside Chats** Recordings and handouts from past Fireside chats can be found on the trial website, if you were unable to attend live.
- **Site Invoicing** NEW Invoicing Template posted on the trial website. Please remember to send your site's trial invoices to CHANGEAFibInvoicing@heart.org for ALL trial payments (Start-Up Costs, Subject Enrollments, Screening Logs & Incentive Payments)!

	IMPORTANT TRIAL CONTACTS
General Trial Questions	CHANGEAFib@heart.org
AHA Site Managers	<u>Crystal.Glodek@heart.org</u> ; <u>Jack.Goldberg@heart.org</u> ; <u>Mariel.Dronson@heart.org</u>
REDCap Questions	CHANGEAF@duke.edu 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	CHANGEAFibContracting@heart.org
Invoicing Questions	CHANGEAFibInvoicing@heart.org
Adverse Event Reporting	Sanofi PV at <u>CL-CPV-Receipt@sanofi.com</u>