

NEWSLETTER

JULY 2023 | VOLUME 2, ISSUE 5

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

MESSAGE FROM THE TRIAL TEAM

We hope everyone had a great start to summer and enjoys the upcoming July 4th Holiday.

We understand summertime can be a busy time of year, so appreciate your teams' attention to the trial.

We are excited to announce the commencement of our

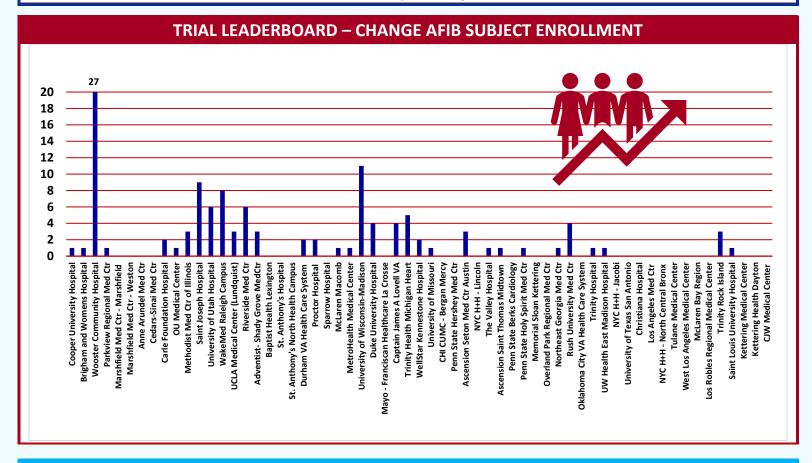


CHANGE AFib Summer Enrollment Olympics!

Let the games begin!

Details can be found on Page 2.





WELCOME TO OUR JUNE ACTIVATED SITES!

- Kettering Medical Center (Kettering, OH)
- Kettering Health Dayton (Dayton, OH)
- Chippenham and Johnston Willis Medical Center (Richmond, VA)
- Memorial Hermann Texas Medical Center (Houston, TX)

JUNE TRIAL MILESTONES!

Top Enroller for the Month of June! We have a TIE! Each site had 3 randomizations!

- Trinity Health Michigan Heart (Ypsilanti, MI) PI: Andrew Hughey, MD; PSC: Autumn Howe
- University of Wisconsin-Madison (Madison, WI) PI: Matthew Kalscheur, MD; PSC: Emily Sherrick

1st Randomization @ Site!

- MetroHealth Medical Center (Cleveland, OH) PI: Ohad Ziv, MD; PSC: Peter Leo
- SSM Health Saint Louis Hospital (Saint Louis, MO) PI: Philip Mar, MD, PharmD; PSC: Cheryl O'Shea
- Ascension Saint Thomas Midtown (Nashville, TN) PI: Robert Pickett, MD; PSC: Leslie Mosley
- Parkview Regional Medical Center (Fort Wayne, IN) PI: Roy Robertson, MD; PSC: Matthew Pyron
- Trinity Hospital (Minot, ND): PI: Samir Turk, MD; PSC: Natalie Quam

TRIAL UPDATES



CHANGE AFib Summer Enrollment Olympics

Sites enrolling a min of 4 subjects a month will begin to qualify for the monthly site prize competition being held for the months of July & August 2023.

For each month, sites that enroll the most subjects (\geq 4) by the end of the month will win the 1st place prize; sites enrolling the second-most subjects (\geq 4) will win the 2nd place price; and sites enrolling the third-most subjects (\geq 4) wins the 3rd place prize. *In the event of a tie, multiple sites will qualify for the corresponding tier.

Prize levels are as follows:

- 1st Place = Team Pizza Party (from your pizza parlor of choice!)
- 2nd Place = Cheryl's Cookies® Gift Box
- 3rd Place = SnackMagic® Gift Box



GWTG-AFIB (Trial EDC) Updates:

• Due to Protocol V4.0 and the removal of the acute care encounter requirement for trial eligibility, there are now 2 versions of the **Baseline Visit Coding Instructions**.

Reminder: Coding Instructions can be found in the GWTG-AFIB "Library".

- GWTG-AFib Coding Instructions (June 2023): To be utilized for subjects diagnosed with firstdetected AFib who had an acute care encounter.
- CHANGE AFib Outpatient (No Acute Care Encounter) Baseline Coding Instructions June
 2023: To be utilized for subjects diagnosed with first-detected AFib who did NOT have an acute care encounter.
- Data Field Clarifications from the June 2023 Coding Instructions!

Please go back and assess these fields for subjects already enrolled in the trial*

- <u>Discharge Tab:</u> Patient is currently enrolled in a clinical trial in which patients with the same condition as the measure set were being studied (i.e., AFib, STK, VTE)?
 - Select "Yes" for all subjects participating in the CHANGE AFib clinical trial.
- o Discharge Tab: Antiarrhythmic Prescribed?
 - If a trial subject is randomized in the outpatient setting to the intervention arm, select "Yes" for "Antiarrhythmic Prescribed?", select (dronedarone (Multaq)) medication, select (400mg) dosage, and select (2 times a day) frequency.
 - By selecting "Yes", 2 additional fields will populate on the discharge tab:
 - Date patient contacted to confirm dronedarone prescription was filled?
 - o Is patient taking dronedarone as prescribed?

CALENDAR OF EVENTS

FIRESIDE CHAT DATES:

- July- No Meeting
- August 3rd from 12-1pm ET
- September- TBD
- October 3rd from 12-1pm ET
- November 2nd from 12-1pm ET
- December 12th from 1-2pm ET

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



CONFERENCES:

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

SUBJECTS per SITE per MONTH

IN CASE YOU MISSED IT!

- Fireside Chats, Prior Newsletters & Trial FAQ Fireside chats <u>located HERE</u>, Prior Newsletters <u>located HERE</u> and the <u>Trial FAQ V8.0</u>
- 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! Don't forget, we are now expanding enrollment to outpatient facilities!
- **Site Invoicing** –Invoicing Template posted on the <u>trial website</u>. Please remember to send your site's trial invoices to <u>CHANGEAFibInvoicing@heart.org</u> for ALL trial activities and subject payments.

IMPORTANT TRIAL CONTACTS CHANGEAFib@heart.org **General Trial Questions AHA Site Managers** Jack.Goldberg@heart.org; Mariel.Dronson@heart.org; Cayla.Hadley@heart.org **REDCap Questions** CHANGEAF@duke.edu or Tel: 919-668-9339 Above AHA Trial Site Managers or CHANGEAFib@heart.org **GWTG-AFib (Trial EDC) Questions Contracting Questions** CHANGEAFibContracting@heart.org **Invoicing Questions** CHANGEAFibInvoicing@heart.org **Adverse Event Reporting** Sanofi PV at CL-CPV-Receipt@sanofi.com **ALMAC IRT Questions** irthelp@almacgroup.com or 1-877-738-8831 and press 0