



NEWSLETTER

MAY 2023 | VOLUME 2, ISSUE 3

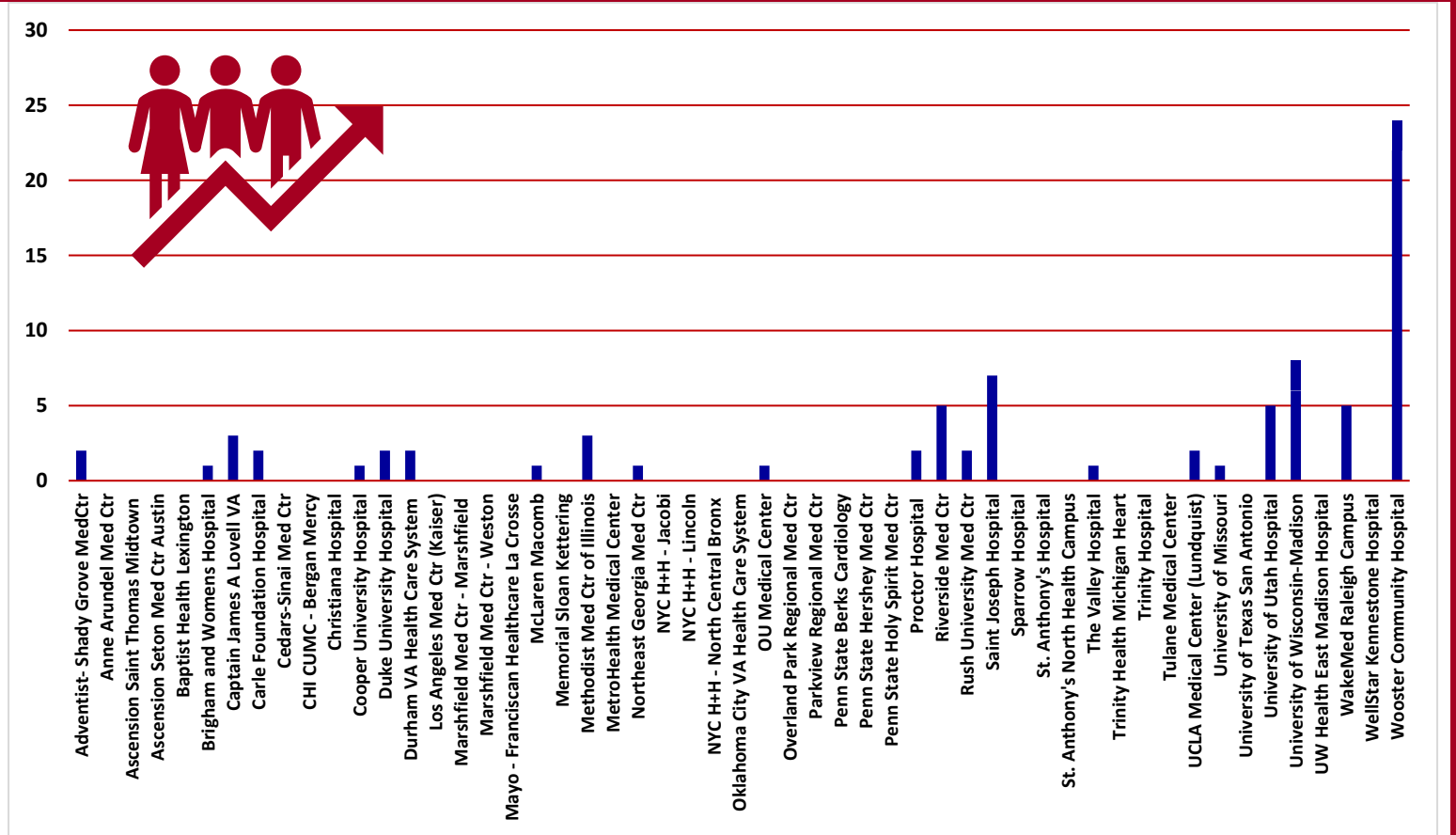
A Pragmatic Randomized Clinical Trial of Early Dronedronone versus Usual Care to Change and Improve Outcomes in Persons with First-Detected Atrial Fibrillation

MESSAGE FROM THE TRIAL TEAM

Thank you all for the great turnout at our recent Investigator Meeting held on April 25th! Present were 90 attendees representing 26 states across the US. To those who had conflicts, we are sorry we missed you but please know all materials and tools presented are on our trial [website](#). We trust the material presented will re-energize your trial teams to meet our trial-wide enrollment goals of 3 subjects per site, per month. As shared at the meeting, your teams are the faces of CHANGE AFib and are critical to helping identify treatment best practices for first-detected AFIB patients.

We look forward to our continued work together to increase enrollments!

TRIAL LEADERBOARD – CHANGE AFIB SUBJECT ENROLLMENT



WELCOME APRIL ACTIVATED SITES!

University Hospital at University of Texas San Antonio (San Antonio, TX)



1st Randomization @ Site!

- University Hospital (Columbia, MO)
- The Valley Hospital (Ridgewood, NJ)
- Rush University Medical Center (Chicago, IL)

Top Enrollers for Month!

- 2 Subjects! – Rush University (Chicago, IL)

APRIL TRIAL MILESTONES!

Multiple Randomizations in 1 Day

Congrats to the *Rush University* team who randomized 2 subjects in one day!



TRIAL UPDATES

Almac Simplify™ IXRS System (Trial Central Pharmacy):

- **Reminder:** All subjects randomized to the intervention must be entered in the Almac IRT System, Simplify™. This is NOT an automated process.
- **Study Drug Dispensation is a 2-step process:**
 1. Register the subject in the Simplify™ system.
 2. Complete the Drug Order Form and return via email to DrugtoPatient@AlmacGroup.com
- If you need assistance navigating timelines for subject visits and study drug dispensing events, please utilize the Subject Visit Tracker posted at the below Meeting Resources page of our trial website.

Review and Share Investigator Meeting Materials with Colleagues:

- **Meeting Resources:** All materials from the meeting are posted on our trial website <http://www.changeafib.org/private-resources>
Password: *change2021!*
- **Travel Expenses:** Please submit your completed Reimbursement Excel document and a PDF document of all receipts in a single email to CHANGEAFib@heart.org by Tuesday, May 9th

Protocol V3.0 Action Items:

- **Local IRB Approvals:** Trial sites utilizing their Local/Institutional IRB will be required to submit an IRB Modification. Please send any ICF edits to CHANGEAFibContracting@heart.org for sponsor review and approval prior to Local IRB submission.
- **Protocol Signature Page Submission:** Please be sure to have your Site PI review and sign-off on the Protocol V3.0 Protocol Signature Page and return to your AHA Site Manager.

NEW FAQ (V7.0 – 10Apr2023):

- New FAQ V7.0 is live on the trial website located [here](#). Password: *change2021!*

CALENDAR OF EVENTS

FIRESIDE CHAT DATES:

- **Tues, May 16th** from 1-2pm ET
- **Mon, June 12th** from 12-1pm ET

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

CONFERENCES:

- **Heart Rhythm Society (HRS):** May 19-21st in New Orleans, LA
- **Scientific Sessions:** November 11-13th in Philadelphia, PA



ENROLLMENT GOAL:
3 SUBJECTS per SITE
per MONTH

IN CASE YOU MISSED IT!

- **Prior Fireside Chats** – Presentations from past Fireside chats are posted to the [trial website](#) if you missed
- **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** – NEW Invoicing Template posted on the [trial website](#). Please remember to send your site's trial invoices to CHANGEAFibInvoicing@heart.org for ALL Trial Activities and Subject Payments.

! IMPORTANT TRIAL CONTACTS !

General Trial Questions	CHANGEAFib@heart.org
AHA Site Managers	Crystal.Glodek@heart.org ; Jack.Goldberg@heart.org ; Mariel.Dronson@heart.org
REDCap Questions	CHANGEAF@duke.edu or Tel: 919-668-9339
GWTG-AFib (Trial EDC) Questions	Above AHA Site Managers or CHANGEAFib@heart.org
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