

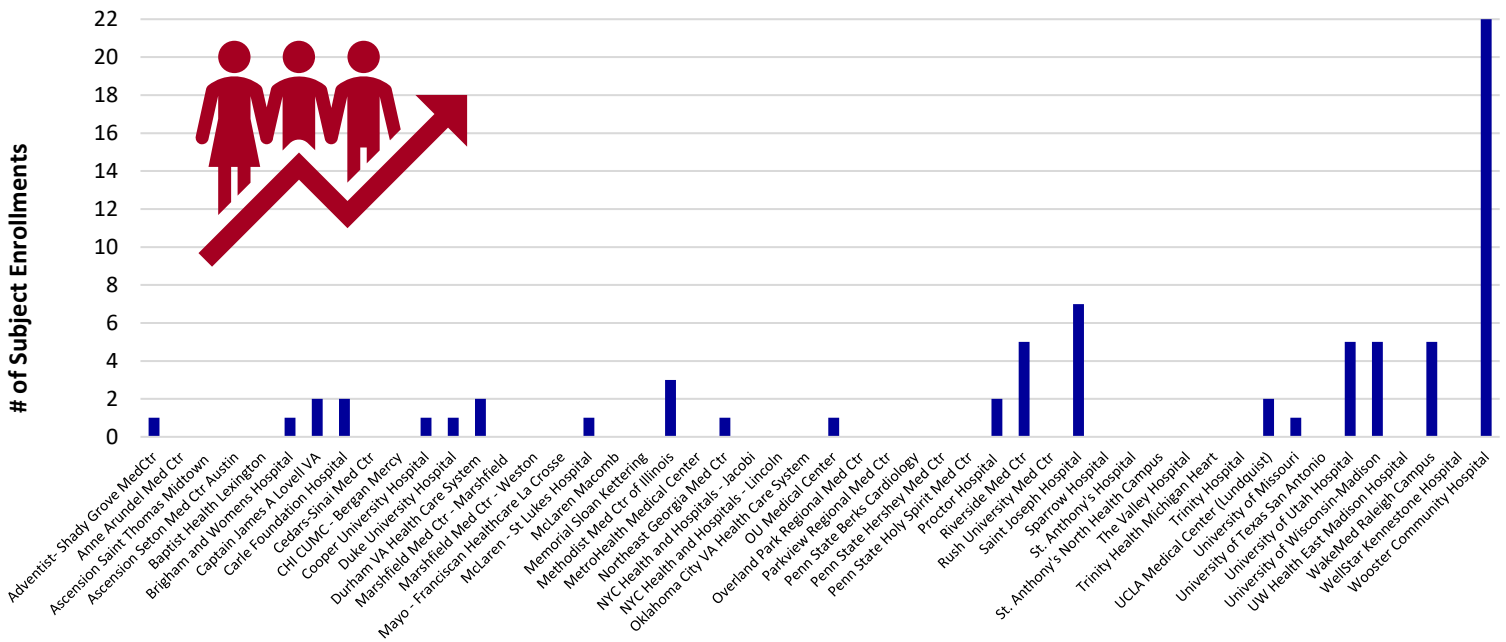
MESSAGE FROM THE TRIAL TEAM

All eyes are on STUDY DRUG PROVISION! In order to turn this plan into a reality for our current and future trial subjects, please be sure to read the 'Monthly Trial Updates & Reminders' section for an overview on all Protocol V3.0 updates, information and site requirements. We are so excited for this major change for CHANGE AFib!

We look forward to meeting our activated and contracted sites at the upcoming Investigator Meeting on April 25th in Washington, DC!

TRIAL LEADERBOARD

CHANGE AFib 70 Subject Enrollments from 20 Sites



WELCOME TO OUR MARCH ACTIVATED SITES!

- Penn State Health Holy Spirit Medical Center (Camp Hill, PA)
- Penn State Health St Joseph Medical Center- Main Campus (Reading, PA)
- Ascension Saint Thomas Midtown (Nashville, TN)
- Memorial Sloan Kettering (New York, NY)
- Overland Park Regional Medical Center (Overland Park, KS)
- Northeast Georgia Medical Center (Gainesville, GA)
- Rush University Medical Center (Chicago, IL)
- Trinity Hospital (Minot, ND)
- Oklahoma City VA Health Care System (Oklahoma City, OK)
- UW Health East Madison Hospital (Madison, WI)
- NYC Health and Hospitals – Jacobi (Bronx, NY)



CONGRATULATIONS FOR MARCH FIRSTS!

1st Randomization @ Site

- Duke University Hospital (Durham, NC)
- Northeast Georgia Medical Center (Gainesville, GA)



Subject Enrollment during 1st Month Activated!

- Northeast Georgia Medical Center (Gainesville, GA)

MONTHLY TRIAL UPDATES & REMINDERS

STUDY DRUG PROVISION PROTOCOL V3.0 GO LIVE ~ APRIL 18, 2023:

- **SUMMARY OF CHANGES:** Study Drug will be provided to all subjects. Please review Protocol V3.0 and the Summary of Changes found [HERE](#).
- **IRB DETAILS:**
 - **ALL SITES:** **Until your site has received a formal Protocol V3.0 activation notice from the AHA, please continue to enroll under Protocol V2.0. Formal Protocol V3.0 Site Activation emails will go out to all sites upon Protocol V3.0 REDCap programming, after receipt of IRB approval.**
 - **CENTRAL IRB SITES:** Central IRB approval emails are rolling in for Protocol V3.0 containing site-specific ICFs and approval letters. No further action is needed from Central IRB sites for Protocol V3.0. Please submit Protocol V3.0 approval documents to your local IRB for acknowledgement, if necessary.
 - **LOCAL IRB SITES:** Please submit any site-specific Protocol V3.0 ICF edits to changeafibcontracting@heart.org. Once approved for submission, proceed with local IRB submission, and provide the AHA confirmation of submission date.
- **CENTRAL PHARMACY INFO:** Our targeted go-live date for study drug provision is Tuesday, 4/18/23. Refer to 'IRB Details' as each site Protocol V3.0 activation date is contingent on REDCap programming and IRB approval. While we are working diligently to get all sites up and running on Protocol V3.0, there may be varying dates across sites due to site-specifics. As a reminder, Almac Clinical Services is the CHANGE AFib Central Pharmacy. Study drug will be provided to all intervention-arm subjects via *direct-to-patient* shipments, so there is no need to utilize site/institutional pharmacy services. **All Activated Sites are required to join our Almac IRT System training on 4/17 at 12pm ET.**
- **PROTOCOL V3.0 CONTRACT AMENDMENTS:** All sites who have previously executed a CHANGE AFib trial contract are required to execute a Protocol V3.0 trial agreement contract amendment. All contract amendments were sent to all sites in mid-March. Please continue to work with CHANGEAFibContracting@heart.org to finalize and execute your site's contract amendment.
- **PROTOCOL V3.0 PROTOCOL SIGNATURE PAGE:** Following Protocol V3.0 review, please complete and return the [Protocol Signature Page](#) to your AHA Site Manager.

INVESTIGATOR MEETING DETAILS:

- **Attendees:** Activated and Contracted Sites
- **Date:** Tuesday April 25th, 2023
- **Time:** 9:00am – 2:30pm ET
- **Location:** AC Hotel Washington DC Capitol Hill Navy Yard
- **Travel Accommodations:** Travel bookings are complete; Please contact Irene Redwine at AHA's Travel Desk – World Travel with any issues (1-800-251-9047 or t-irene.redwine@heart.org)
- **Lodging:** Hotel Confirmations emails sent out 04/13/23; Please contact CHANGEAFib@heart.org with any questions.
- **Expense Reimbursement:** Please review previously provided *AHA Volunteer and Expense Guidelines* for travel and reimbursement policies. Please submit your expenses and PDF of all receipts to CHANGEAFib@heart.org by Tuesday, May 9, 2023.



IN CASE YOU MISSED IT!

- Quarterly Performance Site Metrics**
 – Please be sure to review the Q1 2023 Site Performance Metrics that were sent to all of our activated trial sites on 4/10/23. Please revisit your screening strategy in light of study drug provision to increase and improve upon your site’s screening and enrollment efforts.
- 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)!
- 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!



CALENDAR OF EVENTS

CHANGE AFib INVESTIGATOR MEETING:

[April 25th, 2023 in
Washington D.C.](#)

FIRESIDE CHAT DATES:

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

*Please update your calendars!
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



! 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	Enrollment 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