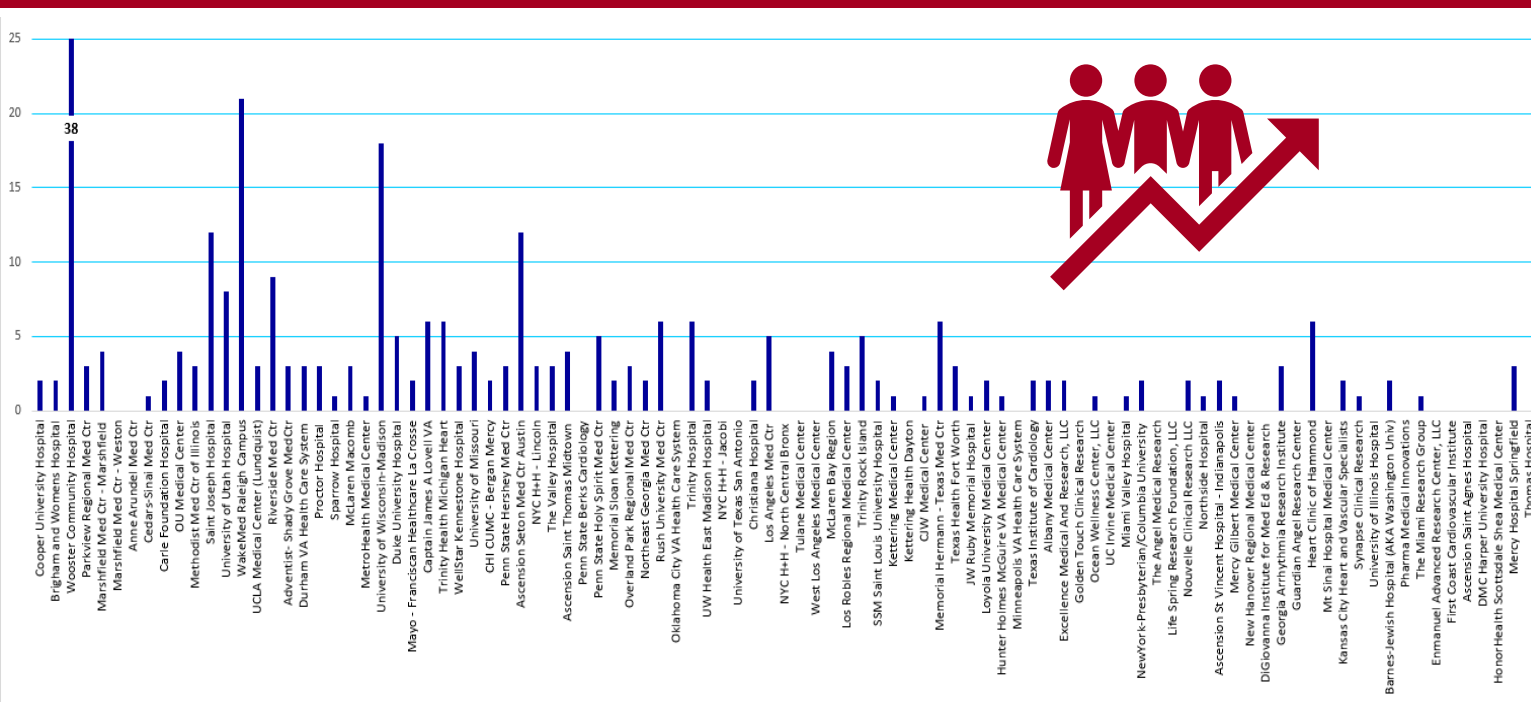


MESSAGE FROM THE TRIAL TEAM

As we transition into autumn, we'd like to thank all trial teams for another extraordinary month of engagement. ***In September 2023, we achieved our highest subject enrollment count to date and continue to be so appreciative of your dedication!*** We have seen a huge increase in subject enrollments from a variety of our trial sites! We are thrilled with the reinvigoration of some of our veteran sites as well as the new site engagement! We appreciate the dedication and efforts being made to help us towards our enrollment target and goal. ***We cannot thank you all enough for helping us CHANGE AFib!***

TRIAL LEADERBOARD – CHANGE AFIB SUBJECT ENROLLMENT



WELCOME TO OUR SEPTEMBER ACTIVATED SITES!

- Ascension Saint Agnes Hospital (Baltimore, MD)
- Barnes- Jewish Hospital (Saint Louis, MO)
- DMC Harper University Hospital (Detroit, MI)
- Enmanuel Advanced Research Center, LLC (Miami, FL)
- First Coast Cardiovascular Institute (Jacksonville, FL)
- HonorHealth Scottsdale Shea Medical Center (Scottsdale, AZ)
- Kanas City Heart and Vascular Specialist at Providence Medical Center (Kanas City, KS)
- Mercy Hospital Springfield (Springfield, MO)
- Pharma Medical Innovations (Miami Lakes, FL)
- Synapse Clinical Research (Missouri Lakes, TX)
- The Miami Research Group (Miami, FL)
- Thomas Hospital (Fairhope, AL)
- University of Illinois Hospital (Chicago, IL)



SEPTEMBER TRIAL MILESTONES!

1st Randomization @ Site!

- Georgia Arrhythmia Consultants and Research (Macon, GA) PI: Sogade
- New York Presbyterian/Columbia University (New York, NY) PI: Wan
- Marshfield Medical Center- Marshfield (Marshfield, WI) PI: Rezkalla
- The Miami Research Group (Miami, FL) PI: Franco
- Excellence Medical and Research, LLC (Miami, FL) PI: Bleicher
- Overland Park Regional Medical Center (Overland Park, KS) PI: Kabra
- Texas Institute of Cardiology (McKinney, TX) PI: Wahid
- Nouvelle Clinical Research (Miami, FL) PI: Haddad
- Albany Medical Center (Albany, NY) PI: Lyubarova
- Heart Clinic of Hammond (Hammond, LA) PI: Mikdadi
- CHI Health Creighton University Medical Center- Bergan Mercy (Omaha, NE) PI: Roka
- Kettering Medical Center (Kettering, OH) PI: Handel
- Northside Hospital (St Petersburg, FL) PI: Sheppard
- Synapse Clinical Research (Missouri Lakes, TX) PI: Khan



TRIAL UPDATES

September Enrollment Competition

- **1st Place Winner:** Congrats to **Heart Clinic of Hammond** for being the top enroller for September by enrolling 5 subjects!
 - *Principal Investigator: Ghiath Mikdadi, MD*
 - *Primary Study Coordinator: Issa Al-Ajlouni*
- **2nd Place Winners:** We have a tie! Congratulations to both sites below for enrolling 4 subjects!
 - **Ascension Seton Medical Center- Austin**
 - *Principal Investigators: Thomas Kurian, MD*
 - *Primary Study Coordinators: Teonna Piphus*
 - **Wooster Community Hospital**
 - *Principal Investigators: Cyril Ofori, MD*
 - *Primary Study Coordinators: Erica Stahl, MSN, RN*



Data Reminders

GWTG®-AFib (Trial EDC- Initial visit & Follow-up data):

- Reminder! Protocol V4.0 removed the acute care encounter inclusion criteria for subject eligibility.
- Subjects **WITHOUT an Acute Care Encounter**, meaning their first-detected AFIB was diagnosed in the outpatient setting, please utilize the “*Outpatient (No Acute Care Encounter) Baseline CRF*” and set of accompanying Coding Instructions (“*Outpatient (No Acute Encounter) Baseline Coding Instructions*” located in the GWTG-AFib Library).
- Subjects **WITH an Acute Care Encounter**, meaning their first-detected AFIB was diagnosed in-hospital, continue to use the standard CRF (“*Baseline CRF June 2023*”) and Coding Instructions (“*Coding Instructions August 2023*” located in the GWTG-AFib Library).

DCRI’s REDCap (Consent and Randomization System):

- **Regarding Screen Fails:** Subject eligibility should be confirmed prior to consent. Protocol eligibility should be assessed and confirmed PRIOR to consenting and registering subject in REDCap. While we understand that screen fails will occur, we would like to do our best to minimize this whenever possible.
- There were several very important REDCap reminders covered on our September 2023 Fireside Chat. Please refer to the PPT posted [HERE](#).

Almac Simplify™ IRT (Central Pharmacy for Intervention Arm Subjects):

- Please continue to ONLY enter intervention arm subjects into the Almac central pharmacy IRT for study drug dispensing and shipping. Upon consenting, registering and randomization assignment **TO THE TREATMENT ARM** the subject in REDCap, sites must manually register the subject in this IRT.
- For both new and older sites needing a refresher on this system, please view the recording from our [October 3, 2023 training](#).

Electrocardiographic Evidence Clarification

- Friendly reminder that Protocol V4.0 includes a definition for ECG evidence clarification. Several questions on this topic arose on the last Fireside chat, to which Dr. Piccini provided further guidance. Please listen to the [September Fireside Chat Recording](#) (Minute 6:50) to ensure your site is all set with this topic.

CALENDAR OF EVENTS

FIRESIDE CHAT DATES:

- **December 12th**
from 1pm-2pm EST

*Do not Forget!
Registration Required for
ALL Fireside Chats!*



CONFERENCES:

- **Scientific Sessions:**
November 11-14th in
Philadelphia, PA

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

Celebrating CHANGE AFib Spirit

Thank you to those who participated! We enjoyed seeing your smiling faces across the country while helping us **CHANGE AFib!**



Duke University in Durham, NC

Dr. Jonathan Piccini, MD & Meghan Pergola, CRC



The Valley Hospital in Ridgewood, NJ

Dr. Dan Musat, MD & Naomi Hatulan, RN



Sparrow Hospital in Lansing, MI

Top left to right: Sandra Mitchell, RN, Andrea Casler, RN, Lonna Blaske, RN, Samantha Verser, Kelli Wolf & Jennifer Boak, RN.



AHA Trial Team in Dallas, TX

Evelynn, 12 months old



IN CASE YOU MISSED IT!

- **Fireside Chats, Prior Newsletters & Trial FAQ** – Fireside chats [located HERE](#), prior Newsletters [located HERE](#) and the [Trial FAQ V8.0](#)
- **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! Do not forget, we are now expanding enrollment to outpatient/RO facilities!
- **Site Invoicing** –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	Cayla.Hadley@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 Trial 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