



CHANGE AFib:

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

Fireside Chat – August 3, 2023

CHANGE AFib is a collaboration between the American Heart Association and the Duke Clinical Research Institute, with support from Sanofi US Services Inc.



Meeting Reminders



Please Note:

- All participants will be muted upon entry.
- Meeting is being recorded and will be archived on our trial website:
www.changeafib.org

Questions?

- Please hold questions until our Q&A session at the end of the call.
- Feel free to submit questions in the chat throughout the call, knowing they will be addressed during the Q&A session.

If you are having issue with computer audio, please call in using the appropriate number below.

Dial by your location:

+1 (301) 715-8592	(Washington DC)
+1 (312) 626-6799	(Chicago)
+1 (646) 876-9923	(New York)
+1 (253) 215-8782	(Tacoma)
+1 (346) 248-7799	(Houston)
+1 (669) 900-6833	(San Jose)

Meeting ID: 816 9010 5654

Passcode: 982588



Agenda:



Welcome & Introductions



Trial Progress Update



Site Best Practices: *Identifying Subjects & Achieving Sustained Enrollment*



Next Steps & Trial Reminders



Q&A and Close

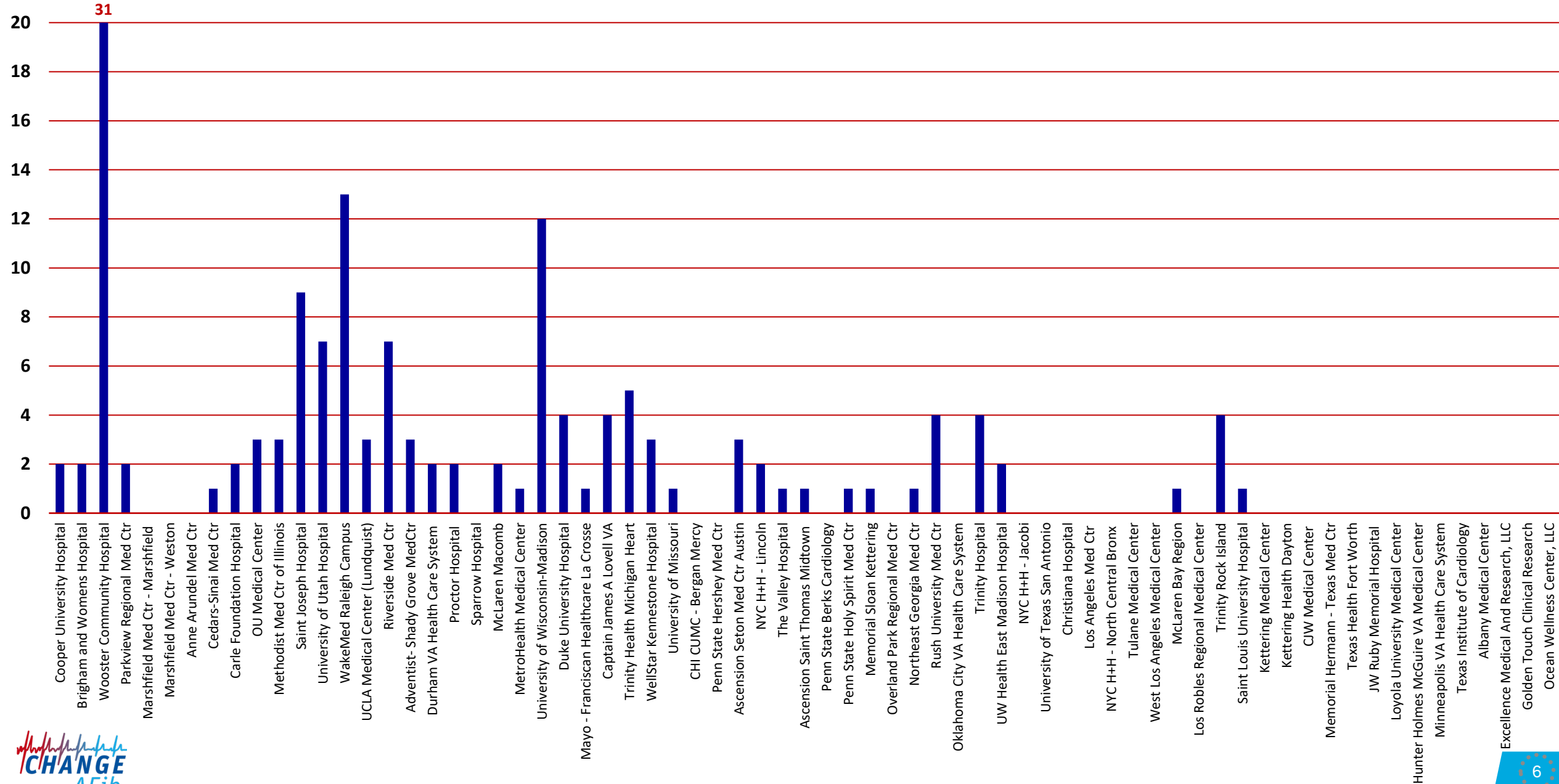


Trial Progress Update

Trial Progress – as of August 3, 2023

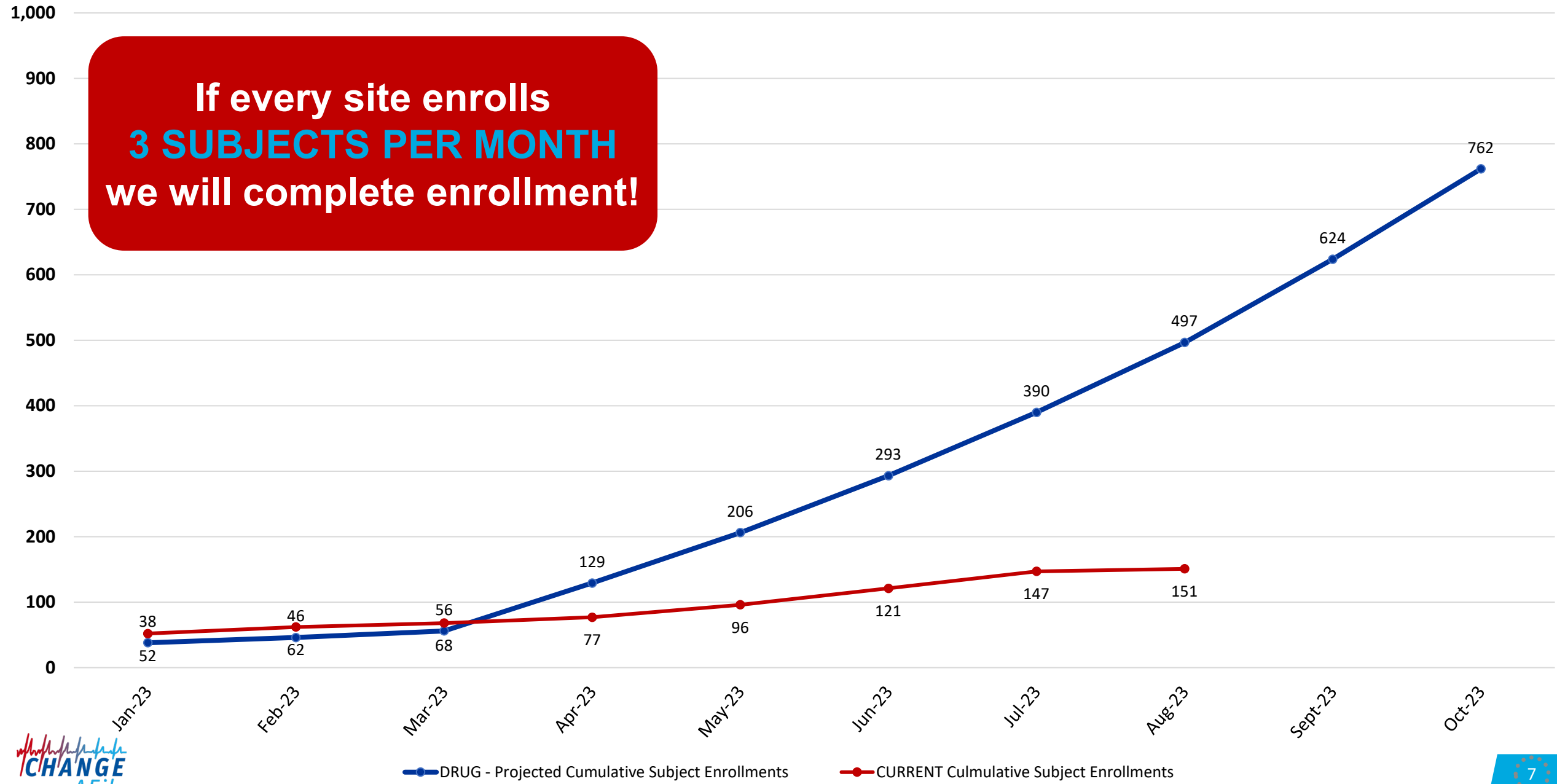
Site Status	Current Status	Trial GOAL!
Subject Enrollments	151	3000
Activated Sites	75	200
Sites in Onboarding	83	-
Sites Assessing Feasibility	32	-

CHANGE AFib 151 Subject Enrollments from 38 Sites



Monthly Subject Enrollment Projections

If every site enrolls
3 SUBJECTS PER MONTH
we will complete enrollment!



● DRUG - Projected Cumulative Subject Enrollments ● CURRENT Culmulative Subject Enrollments

Data as of 03AUG2023

TRIAL ENROLLMENT GOAL

2023 Enrollment Goal:

**3 SUBJECTS
PER SITE PER MONTH**

Thank you to all our CHANGE AFib trial teams on your hard work and dedication!

As the barrier of drug access has been removed, we encourage you to double down on your recruitment efforts to enroll 3 subjects per site per month!





CHANGE AFib Summer Enrollment Olympics



- Sites enrolling a **minimum of 4 subjects a month** will begin to qualify for the monthly site prize competition.
- For each month, sites that enroll the most subjects (≥ 4) by the end of the month will win the 1st place prize; sites enrolling the second-most subjects (≥ 4) will win the 2nd place prize; and sites enrolling the third-most subjects (≥ 4) wins the 3rd place prize.

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

Competition is Continuing Through 2023!

Summer Enrollment Olympics *1st Place Winner* July 2023

Congrats to WakeMed Raleigh Campus for being the top enroller for the month of July!

Principal Investigator: Kevin Manocha, MD
Primary Study Coordinator: Taylor Guidi, BSCR



Summer Enrollment Olympics

2nd Place Winner

July 2023

Congrats to Wooster Community Hospital for being the second highest enroller for the month of July!

Principal Investigator: Cyril Ofori, MD
Primary Study Coordinators: Erica Stahl, MSN, RN, APRN-AGCNS-BC & Michelle McConnell, MSPA-C



JULY MONTHLY ENROLLMENT LEADERBOARD

# of Monthly Enrollments	Trial Site Name (PI Name)
5 Subjects	WakeMed Raleigh Campus (PI: Manocha)
4 Subjects	Wooster Community Hospital (PI: Ofori)
3 Subjects	Trinity Hospital (PI: Turk)
2 Subjects	OU Medical Center (PI: Asad)
1 Subject	Brigham and Women’s Hospital (PI: Kapur) Cooper University Hospital (PI: Russo) Mayo Clinic Hospital - Franciscan Healthcare La Crosse (PI: Liu) McLaren Bay Region (PI: Salacata) McLaren Macomb (PI: Hunyadi) NYC Health & Hospitals- Lincoln (PI: Ong) Parkview Regional Medical Center (PI: Robertson) Trinity Rock Island (PI: Shen) University of Utah Hospital (PI: Steinberg) University of Wisconsin-Madison (PI: Kalscheur) UW Health East Madison Hospital (PI: Kalscheur) WellStar Kennestone Hospital (PI: Riley)



Goal Line



TRIAL ENROLLMENT LEADERBOARD

5 or More Subject Enrollments

- Wooster Community Hospital (PI: Ofori) – 31 Subjects!
- WakeMed Raleigh Campus (PI: Manocha) – 13 Subjects
- University of Wisconsin Madison (PI: Kalscheur) – 12 Subjects
- Saint Joseph Hospital (PI: Darrat) – 9 Subjects
- University of Utah Hospital (PI: Steinberg) – 7 Subjects
- Riverside Medical Center (PI: Beri)– 7 Subjects
- Trinity Health Michigan Heart (PI: Hughey) – 5 Subjects

4 Subject Enrollments

- Captain James A Lovell Federal Health Care Center (PI: Gazmuri)
- Duke University Hospital (PI: Pokorney)
- Rush University Medical Center (PI: Larsen)
- Trinity Hospital (PI: Turk)
- Trinity Rock Island (PI: Shen)

3 Subject Enrollments

- Adventist – Shady Grove Medical Center (PI: Shams)
- Ascension Seton Medical Center Austin (PI: Kurian)
- Lundquist – UCLA Medical Center – Harbor (PI: Khakpour)
- Methodist Medical Center of Illinois (PI: Adler)
- OU Medical Center (PI: Asad)
- WellStar Kennestone Hospital (PI: Riley)

2 Subject Enrollments

- Brigham & Women’s Hospital (PI: Kapur)
- Carle Foundation Hospital (PI: Mongwa)
- Cooper University Hospital (PI: Russo)
- Durham VA Health Care System (PI: Sun)
- McLaren Macomb (PI: Hunyadi)
- NYC Health and Hospitals– Lincoln (PI: Ong)
- Parkview Regional Medical Center (PI: Robertson)
- Proctor Hospital (PI: Adler)
- UW Health at the American Center (PI: Kalscheur)

1 Subject Enrollment

- Ascension Saint Thomas Midtown (PI: Pickett)
- Cedars Sinai Medical Center (PI: Albert)
- Mayo Clinic Hospital - Franciscan Healthcare La Crosse (PI: Liu)
- McLaren Bay Region (PI: Salacata)
- Memorial Sloan Kettering (PI: Kosmidou)
- MetroHealth Medical Center (PI: Ziv)
- Northeast Georgia Medical Center (PI: Ahn)
- Penn State Holy Spirit Medical Center (PI: Gassis)
- SSM Health Saint Louis University Hospital (PI: Mar)
- The Valley Hospital (PI: Musat)
- University Hospital – University of Missouri (PI: Gautman)

ACTIVATED SITES YET TO ENROLL

Anne Arundel Medical Center (PI: Beinert)	Memorial Hermann - Texas Medical Center (PI: Chiadika)
Ascension Saint Thomas Midtown (PI: Pickett)	NYC Health and Hospitals – Jacobi (PI: Grushko)
CHI Health Creighton University Med. Ctr. - Bergan Mercy (PI: Roka)	NYC Health and Hospitals - North Central Bronx (PI: Grushko)
Chippenham and Johnston Willis Medical Center (PI: Shah)	Oklahoma City VA Health Care System (PI: Thadani)
Christiana Hospital (PI: Kim)	Overland Park Regional Medical Center (PI: Kabra)
JW Ruby Memorial Hospital (PI: Schwartzman)	Penn State Milton S Hershey Medical Center (PI: Naccarelli)
Kettering Health Dayton (PI: Khouzam)	Penn State Berks Cardiology Group (PI: Rogers)
Kettering Medical Center (PI: Handel)	Sparrow Hospital (PI: Ip)
Los Angeles Medical Center (Kaiser Permanente) (PI: Gupta)	Texas Health Fort Worth Tulane Medical Center (PI: Kulkarni)
Los Robles Regional Medical Center (PI: Natale)	Tulane Medical Center (PI: Irimpen)
Loyola University Medical Center (PI: Kinno)	University Hospital at University of Texas San Antonio (PI: Nayak)
Marshfield Medical Center - Marshfield (PI: Rezkalla)	West Los Angeles Medical Center (PI: Gupta)
Marshfield Medical Center – Weston (PI: Kumar)	



Site Best Practice: *WakeMed Raleigh Campus*

*Taylor Guidi, BSCR
Research Coordinator,
WakeMed Clinical Research Institute*



Enrollment Review & Consent Conversations Best Practices



WakeMed Raleigh Campus in Raleigh, NC

CHANGE AFib Subject Cases

Subject Randomizations: 13

- Usual Care Alone: 7
- Dronedarone + Usual Care: 6

Activated on Protocol V4.0: June 27, 2023

- **6 Subject** enrollments since V4.0 activation!

PLEASE SEE NEXT SLIDE for full list of cases.

Eligibility & Enrollment Workflow

Screening

- EPIC report was built to capture patients with AFib/A flutter diagnosis
- Screen outpatient clinics: gen. cards, complex Arrhythmia, AFib Center. Outpatient providers send referrals to study team

PI Verification: PI reviews all cases for eligibility

- Inpatient: PI initiates conversation with patient
- Outpatient: PI or APPs will initiate conversations in clinic.

Coordinator Consents Patients

Consent Conversation Site Standards & Best Practices

The PI connects with the attending physician from the patient's care team for approval to approach patient for trial participation.

The PI approaches the potential subject **first!**

- Our team has found that patients are more receptive when they talk to the PI directly.
- The PI introduces the study with a brief overview and explains the randomization process including study medications and dosing details.

Once trial participation interest is established, the CRC approaches with the ICF. The trial and consent is then discussed in great depth.

- Trial purpose & Randomization process
- Dronedarone vs Usual Care Alone
- Study Requirements: 12mo participation w/ 2 FU visits at 6 & 12mo
- Risks/Benefits Profile highlighting study drug provision
- Voluntary nature and confidentiality

Common FAQs during Consent Convos

- What are the common side effects of Dronedarone?
- Will I be able to get Dronedarone after the trial is over?
- What is considered usual care?

Suggestions for Other Trial Sites

PI engagement is **KEY!**

Spread the Word!

Give pocket cards with the Inc/Exc criteria and brief study summary to the providers seeing these patients at follow-up and other colleagues.

Knowledge is Power!

Sanofi-hosted Lunch and Learn to provide clinicians further education on Dronedarone.

Contact Information

Principal Investigator: Kevin Mancoha, MD

Email: kmanocha@wakemed.org

Primary Study Coordinator: Taylor Guidi, BSCR

Email: tguidi@wakemed.org

Phone: 919-350-1198

CHANGE AFib Subject Enrollment Cases- Part 1 of 2

1. 61yr Male, PMHx of HTN, presented to ED w/ complaints of palpitations and elevated heart rate. Patient was admitted to hospital for observation and underwent DCCV with conversion back to NSR. Patient was enrolled in the inpatient setting.
2. 65yr Female, PMHx of obesity & heart mummer. Presented to the ED w/ complaints of SOB & palpitations x 9 days. Patient endorses intermittent, chest palpitations with some associated DOE. Patient was admitted to hospital for observation. Patient underwent DCCV with conversion back to NSR. Patient was enrolled in the inpatient setting.
3. 49yr Male, PMHx of HTN, Mild OSA non-compliant with CPAP. Presented to ED w/ complaints of concerns of atrial fibrillation shown on apple watch. Patients endorses associated palpitations, lightheadedness, and non-radiating sternal chest pressure. Patient was enrolled in the ED under observation. Spontaneously converted to NSR prior to cardioversion.
4. 43yr Female, PMHx of HTN, presented to ED for heart racing and shortness of breath. Patient was admitted to hospital for observation. Patient converted to NSR and did not require DCCV. Patient enrolled in inpatient setting.
5. 65yr Male, PMHx of HLD, DM type 2, HTN, tobacco abuse and recent COVID-19 infection. Patient presented due to having “cold-like symptoms” with cough congestion and fatigue. Patient was completely asymptomatic and no idea that he was in A. fib. Very active and exercises 4-5 times/week in home gym. Patient has no cardiac history and only family history of MI in grandfather in his 50’s. Was admitted to the hospital for observation and further workup. Patient underwent DCCV x1 with successful return of NSR. Patient was enrolled in outpatient setting.
6. 72yr Male, PMHx of HTN and GERD. Presented to the ED with nausea and vomiting. Patient denies any chest pain, SOB or dizziness. Patient was admitted for further workup of ongoing symptoms and found to have a small bowel obstruction along with new onset AFib. Patient underwent DCCV with successful conversion back to NSR. Patient was enrolled in the inpatient setting.
7. 45yr Female, PMHx of DM, obesity, and HTN. She presented to the ED with complaints of palpitations and SOB and was found to be in AFib. Patient converted to NSR after receiving a bolus of Cardizem and was discharged. Patient was enrolled in the outpatient setting.

CHANGE AFib Subject Enrollment Cases- Part 2 of 2

8. 60yr Male, PMHx of obesity, HTN and chronic back pain. Patient presented to the ED with complaints of palpitations that was associated with dyspnea, mild chest pressure, lightheadedness and dizziness. Patient was discharged in AFib and was scheduled for an outpatient DCCV. Patient presented for outpatient DCCV and was successfully converted back to NSR. Patient was enrolled in outpatient setting.
9. 58yr Male, PMHx of OSA on CPAP, HLD, DM, obesity with not prior cardiac history. Patient presented to the ED for AFib and patient had ongoing chest discomfort, SOB, and dizziness. Patient reported that the day prior to him coming to the ED he developed some chest tightness suddenly as well as palpitations and heart racing sensations. His heart rates were jumping up to the 180's at times but mainly around the 130's, per readings on his apple watch. Patient converted spontaneously to NSR and was discharged. Patient was enrolled in the inpatient setting.
10. 72yr Male, PMHx of HTN, HLD flutter and cancer. Patient presented to ED with complaints of palpitations and was found to be in AFib with RVR. Patient underwent a DCCV and was successfully converted back into NSR. Patient was approached in the ED for enrollment.
11. 63yr Male, PMHx of SSS s/p PPM, HTN, HLD, former smoker. Presented to the ED with complaints of fatigue, dizziness and shortness of breath. Patient spontaneously converted the in ED for NSR and was discharged with follow-up in the AFib Clinic. Patient was enrolled in the AFib clinic as an outpatient enrollment
12. 73yr Male, PMHx of HTN, HLD, OSA with use of CPAP, CAD, and DM type II. Patient presented to outside hospital with complaints of chest pain and found to be in AFib with RVR with heart rates in the 120s to 140s. Patient was converted to NSR with IV Cardizem drip and was discharged. Patient was approached and enrolled in the outpatient setting at the follow-up appointment from recent admission.
13. 65yr Male, PMHx HTN, DM, and peripheral vascular disease. Patient presented to the ED with symptoms of dizziness, and lightheadedness after working in the yard. He was found to be in rapid afib. Patient has never previously had any known cardiovascular issues. Patient was treated with Cardizem bolus and Cardizem and he converted in the NSR. Patient was enrolled in the outpatient setting with follow-up from admission.



Q&A With

*WakeMed Raleigh
Campus*



Site Best Practice: *University of Utah Hospital*

*Benjamin A. Steinberg, MD, MHS
Associate Professor of Medicine
Cardiovascular Medicine Division
University of Utah Hospital*



Enrollment Review & Consent Conversations

Best Practices

University of Utah Hospital in Salt Lake City, UT



CHANGE AFib Subject Cases

Subject Randomizations: 7

- Usual Care Alone: 3
- Dronedaron + Usual Care: 4

PLEASE SEE NEXT SLIDE for full list of cases

Eligibility & Enrollment Workflow

Screening

- Receives weekly list of patients with AFib on EMR “diagnosis list”
- Coordinator identifies eligible patients and sends to PI

PI Verification: PI reviews all cases for eligibility

- Once confirmed, Investigators or MA’s will schedule patient in PI’s clinic

Enrollment

- After discussion with Dr. Steinberg, coordinator meets with patient to consent and enroll

Consent Conversation Site Standards & Best Practices

A generated report is pulled for patients with AFib detected in their chart for the first time.

- Coordinator pre-screens the chart to verify first diagnosis and a true diagnosis.

PI verifies eligibility and schedules them for follow-up in the outpatient clinic.

- Most of our patients were seen in ED and/or discharged from inpatient.
- Have had more success enrolling in the outpatient setting, due to quick ER discharges.

PI and Coordinator meet to discuss study with patient

- Dronedaron education
- Risks/Benefits Profile highlighting study drug provision and confirming understanding of potential side effects
- Study Requirements: 12mo participation w/ 2 FU visits at 6 & 12mo
- Explain that despite being in this trial, if a patient requires escalation of care, they will be able to receive needed treatments and remain in the trial.

Suggestions for Other Trial Sites

Cast a Wide Net!

- Review all Cardiology clinic schedules. Many newly diagnosed AFib patients filter into our General Cardiology schedules and not EP.
- Generated lists are extremely helpful – even if they don’t generate 100% accurate “first diagnosis” it does capture a lot of potential patients.

Persistence is Key!

- The ‘younger’ population seem to decline at our site, but we still approach. Do not let declines discourage you, they are expected.

Contact Information

Principal Investigator: Benjamin Steinberg, MD, MHS, FACP, FACC, FHRS

Email: benjamin.steinberg@hsc.utah.edu

Primary Study Coordinator: Mija Wall, CCRP

Email: Mija.Wall@hsc.utah.edu

Change AFib Enrollment Subject Cases

All Subjects Enrolled in the Outpatient Setting

1. 81yr Male, presented to ED with fatigue and numbness. ECG's did not capture AFib at the time but MCT showed AFib during wear. During ED stay, patients HR fluctuated between NSR and Afib however patient did not want to stay or be admitted. Patient was discharged and agreed to follow-up with EP Clinic.
2. 68yr Female, no prior cardiac history, stated they had occasional palpitations her "whole life";, presented to ED as palpitations had lasted over an hour. Patient remained in ED and received Diltiazem infusion w/titration along with potassium and magnesium repletion. Was monitored for 2 hours and rhythm converted to normal sinus. Discharged and instructed to follow-up with Cardiology.
3. 76yr Female, PMH of HTN, HLD and T2DM. Patient was admitted with progressive DOE/fatigue/weight gain likely due to HFpEF (75%) exacerbation. On admission patient was in AFib and spontaneously converted back to normal rhythm. Patient follows with cardiology and EP.
4. 74yr Male, presented to ED after syncopal episode post-stroke eval. Admitted shortly after. During admit patient was in AFib – bolus of amiodarone was given and was converted back to NSR. Discharged and instructed to follow-up with EP clinic.
5. 56yr Male, presented to ED with complaints of SOB, chest pain, nausea, sweating and rapid HR. No cardiac history. Was given diltiazem drip and returned to NSR during ED visit. Was discharged with instructions to follow-up with Cardiology.
6. 76yo Female, with history of PH, which is thought to be secondary to both valvular disease and HFpEF (EF 63%) was seen in ED at an outside facility after having a clinic visit and experiencing chest pain/tightness. Dose of diltiazem was given during ED course as HR was 110+. Discharged after returned to NSR and was contacted to follow-up at UofU clinic with EP.
7. 56yo Male, with a history of hypertension, HFpEF (EF 60%), OSA on CPAP was seen in outside ED for chest pain. 5-day Holter was placed where the predominant rhythm was AFib. Underwent a successful cardioversion a few weeks after discharge. Was contacted to follow-up with EP clinic to establish care for AFib.



Q&A With

*University of Utah
Hospital*



Next Steps & Trial Reminders



GWTG[®]-AFIB Data Entry Reminders

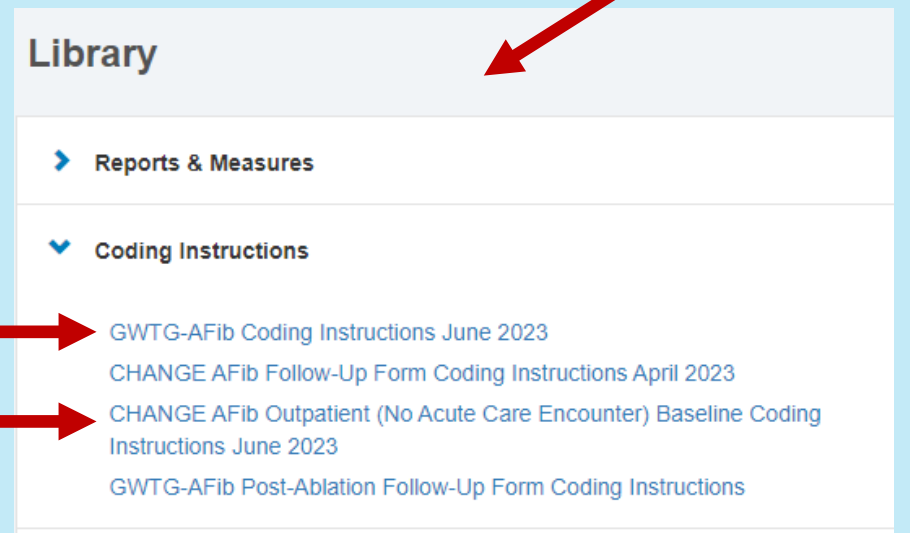
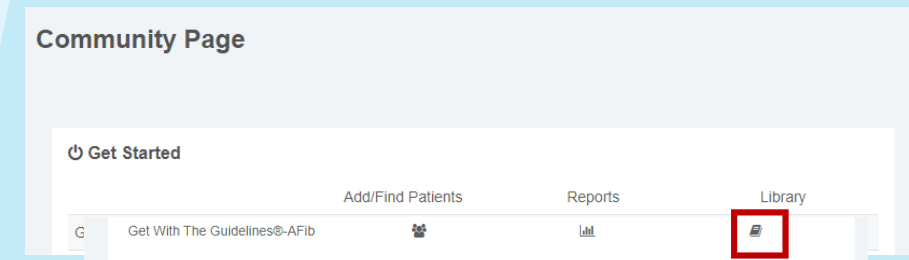
Separate Baseline Visit CRF & Coding Instructions for Protocol V4.0

REMEMBER to use Correct CRF for Subjects **WITHOUT** an Acute Care Encounter vs. Subjects **WITH** an Acute Care Encounter!

- As a reminder, Protocol V4.0 removed the acute care encounter inclusion criteria for subject eligibility.
- For Subjects **WITHOUT** an Acute Care Encounter, meaning their first-detected AFib was diagnosed in the outpatient setting, please utilize the “**No Acute Care Encounter**” baseline visit CRF and set of separate Coding Instructions.
- For 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 (**GWTC-AFIB Coding Instructions June 2023**).

REMINDER:

Coding Instructions can be found in the GWTC-AFIB “Library”



Baseline Data Field Clarifications

Please go back and assess these fields for existing trial subjects!

Discharge Tab:

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.

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?
 - Is patient taking dronedarone as prescribed?



Trial Payments: Please Submit Your Invoices!

- Trial sites are responsible for submitting invoices for **ALL TRIAL ACTIVITIES**
 - ✓ Invoiceable trial activities include:
 - Site Start-Up Payments
 - Subject Visits
 - Screening Log Payments
 - Site Incentive Payments (if applicable)
- Sites are instructed to submit their invoices to CHANGEAFibInvoicing@heart.org on a quarterly basis for all trial related activities (listed above).
- Trial Invoice Documentation Template can be found on the [‘Resources for Participating Hospitals’](#) page of our trial website.



Mark Your Calendars!



Upcoming Fireside Chats:

Mon, September 18th @ 11am-12pm EST

Tues, October 3rd @ 12-1pm EST

Thurs, November 2nd @ 12-1pm EST

Tues, December 12th @ 12-1pm EST

**Archived webinar recordings & handouts
can be found [HERE](#) on the trial website.*

Next Up

RECAP: Key Trial Contacts

General Trial Questions	Email your AHA trial site manager <i>OR</i> If you are a new site, email CHANGEAFib@heart.org
Invoicing Questions	CHANGEAFibInvoicing@heart.org
Contracting Questions	CHANGEAFibContracting@heart.org
Patient Consent & Randomization Questions	CHANGEAF@duke.edu or Tel: 919-668-9339
GWTG[®]-AFIB Questions <i>(GWTG[®]-AFIB is the trial EDC)</i>	Email your AHA trial site manager, <i>OR</i> If you are a new site, email CHANGEAFib@heart.org
sIRB Questions	CIRBI@advarra.com
AE Reporting	CL-CPV-Receipt@sanofi.com Fax Number <i>(to be used in the event e-mail failed)</i> : +33 1 6049 7070
ALMAC IRT Questions	irthelp@almacgroup.com OR 1-877-738-8831 and press '0

A detailed list of key trial contacts can continue to be found [HERE](#) on the trial website



Q&A & Close

Thank you & Connect With Us!

How to reach the CHANGE AFib Team



AHA Site Managers:

Cayla.Hadley@heart.org

Jack.Goldberg@heart.org

Mariel.Dronson@heart.org



Trial Email:

ChangeAFib@heart.org

Resources to Remember



For important trial information and today's meeting recording, go to the **Resources** page at www.changeafib.org or visit the QR Code to the left.

