



## **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 – September 18, 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](http://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: 895 2992 7623**

**Passcode: 072459**



# Agenda:



Welcome & Introductions



Trial Progress Update



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



Regulatory & Data Reminders



Q&A, Trial Reminders and Close

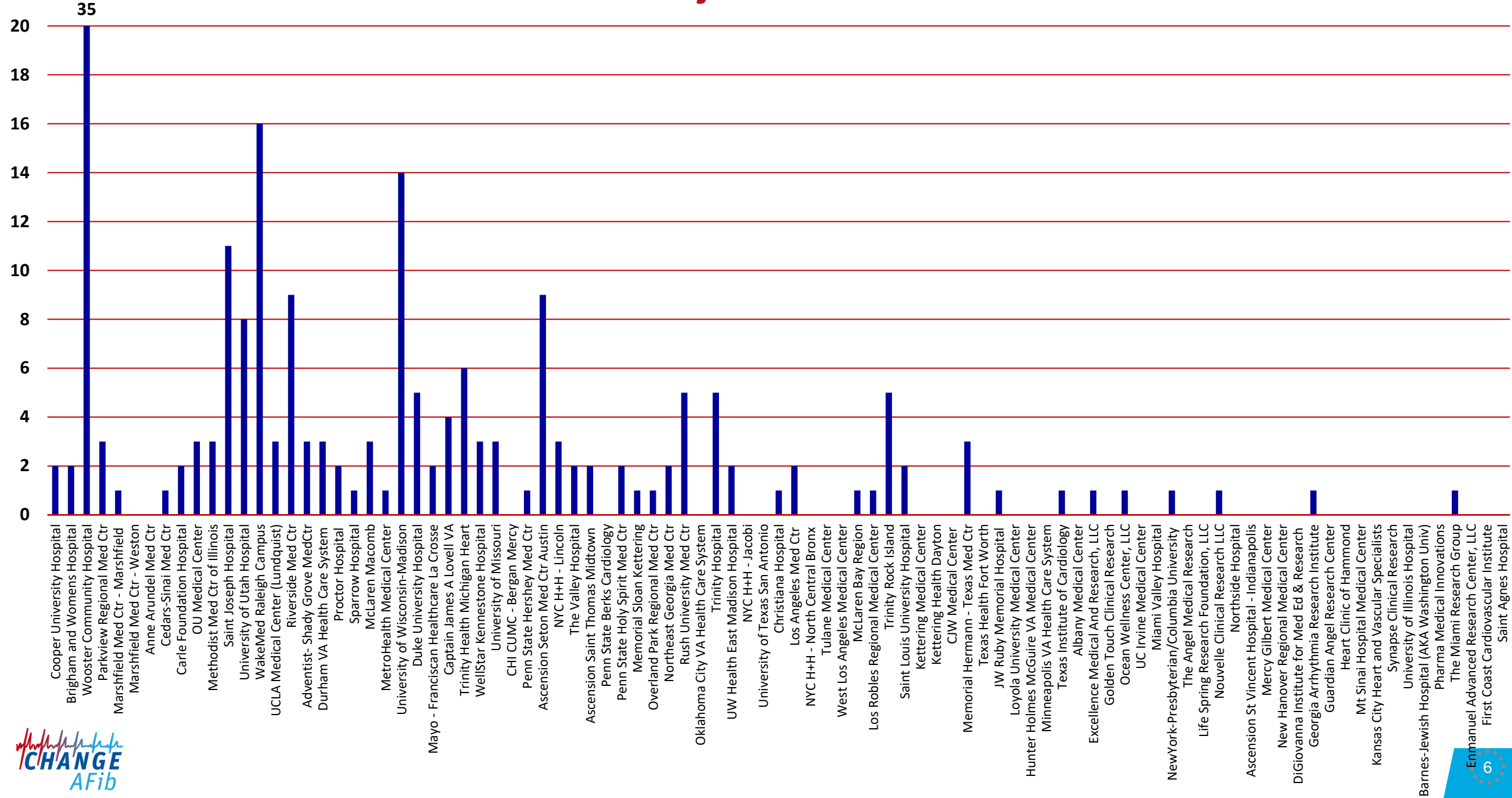


# Trial Progress Update

# Trial Progress – as of September 18, 2023

Site Status	Current Status	Trial GOAL!
Subject Enrollments	207	3000
Activated Sites	99	200
Sites in Onboarding	63	-
Sites Assessing Feasibility	23	-

# CHANGE AFib 207 Subject Enrollments from 54 Sites





# TRIAL ENROLLMENT GOAL

**2023 Enrollment Goal:**

**3 SUBJECTS**

**PER SITE PER MONTH**

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

**Protocol V4.0 has had the greatest impact to subject eligibility criteria to date!**

**As a result, we are confident all sites can be successful in enrolling 3 subjects per month!**



## REMINDER:

# What Is Considered ‘Prior Antiarrhythmic Drug Therapy’?

## And How Does This Relate To Exclusion Criteria #1?

- Antiarrhythmic drug therapy means chronic outpatient therapy (>7 days)
- One time dosing of an antiarrhythmic drug or pharmacologic cardioversion are not considered “prior AAD therapy” (*i.e., pill-in-pocket*)

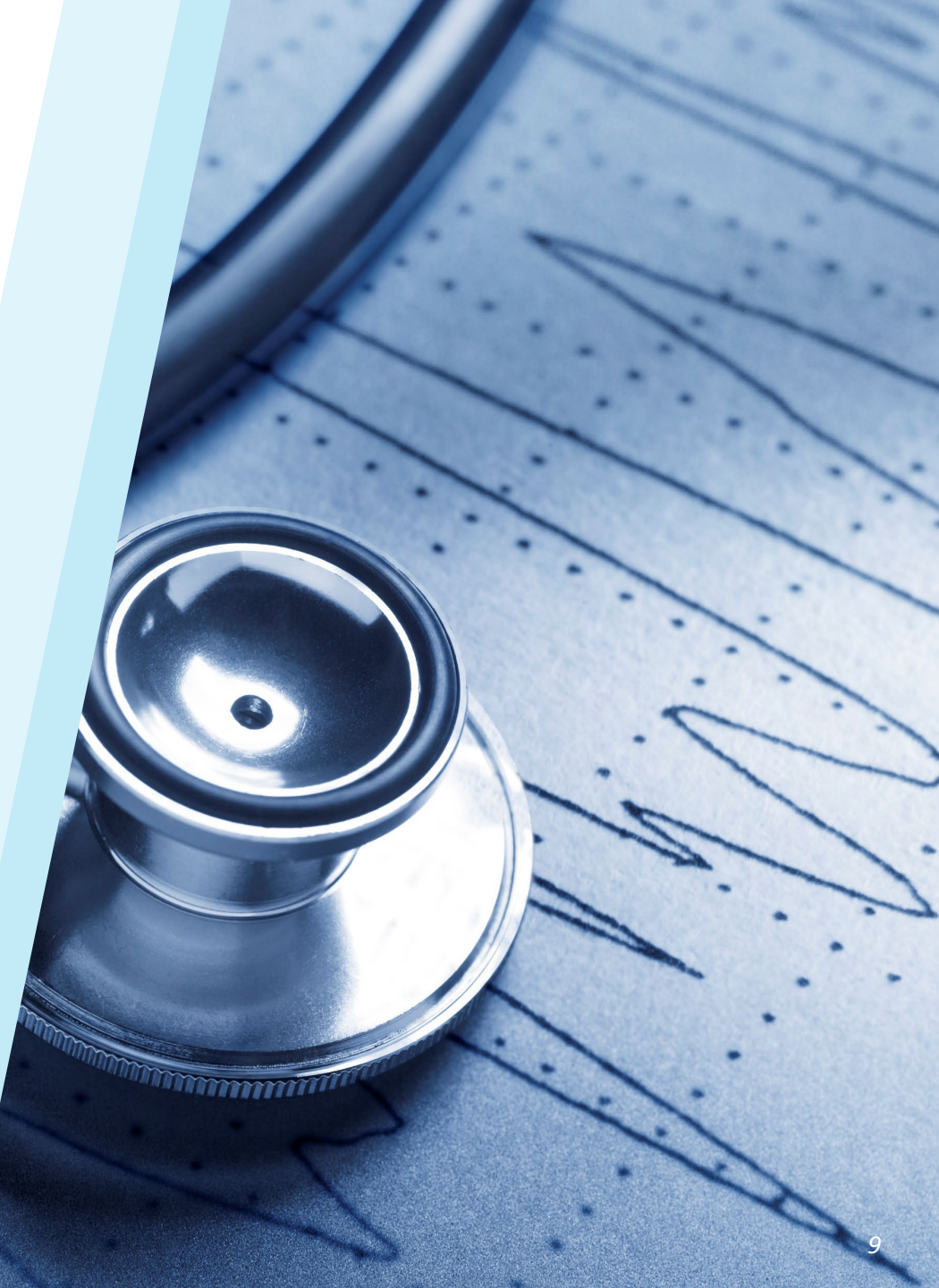




## REMINDER:

# Electrocardiographic Evidence Clarification

- AF documentation must be a tracing of sustained AF (>30 seconds) with an electrocardiographic tracing of some sort.
- Electrocardiographic evidence includes:
  - / Standard 12 lead electrocardiogram
  - / Mobile ECGs
  - / Ambulatory monitoring (e.g., Holter)
  - / Telemetry
  - / Electrograms from cardiac implanted electronic devices (i.e., pacemaker)
  - / Apple Watch EKG (NOT an irregular pulse check or PPG alert)





# CHANGE AFib

## September Enrollment Competition



- 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 ( $\geq 4$ ) 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 prize; and sites enrolling the third-most subjects ( $\geq 4$ ) 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** = Starbucks® Gift Cards

**Competition is Continuing Through 2023!**



# Summer Enrollment Olympics

## 1<sup>st</sup> Place Winner

### August 2023

Congrats to *Ascension Seton Medical Center- Austin* for being the top enroller for the month of August!

Principal Investigator: Thomas Kurian, MD  
Primary Study Coordinator: Teonna Piphus, MSc



# AUGUST MONTHLY ENROLLMENT LEADERBOARD

Goal  
Line

# of Monthly Enrollments	Trial Site Name (PI Name)
<b>4 Subjects</b>	Ascension Seton Medical Center Austin (PI: Kurian)
<b>3 Subjects</b>	Memorial Hermann – Texas Medical Center (PI: Chiadika)
<b>2 Subjects</b>	Los Angeles Medical Center (PI: Gupta) NYC H+H Lincoln (PI: Ong) Riverside Medical Center (PI: Beri) Saint Joseph Hospital (PI: Darrat) University of Wisconsin-Madison (PI: Kalscheur) WakeMed Raleigh Campus (PI: Manocha)
<b>1 Subject</b>	Ascension Saint Thomas Midtown (PI: Pickett) Cedars-Sinai Medical Center (PI: Albert) Christiana Hospital (PI: Kim) Duke University Hospital (PI: Pokorney) JW Ruby Memorial Hospital (PI: Schwartzman) Los Robles Health System - Los Robles Regional Medical Center (PI: Natale) Memorial Sloan Kettering (PI: Kosmidou) Northeast Georgia Medical Center (PI: Ahn) Ocean Wellness Center, LLC (PI: Bleicher) Penn State Health Milton S Hershey Medical Center (PI: Naccarelli) Sparrow Hospital (PI: Ip) SSM Health Saint Louis University Hospital (PI: Mar) St Joseph Mercy Ann Arbor Hospital (dba Trinity Health Michigan Heart) The Valley Hospital (PI: Musat) Trinity Hospital (PI: Turk) University Hospital (in MO) (PI: Gautman) University of Utah Hospital (PI: Steinberg) Wooster Community Hospital (PI: Ofori)



# TRIAL ENROLLMENT LEADERBOARD

## 10+ Enrollments

- Wooster Community Hospital – **35 Subjects!**
- WakeMed Raleigh Campus – **16 Subjects!**
- University of Wisconsin Madison – **14 Subjects!**
- Saint Joseph Hospital – **11 Subjects!**

## 4-9 Enrollments

- 9 Subjects –**
  - Ascension Seton Medical Center Austin
  - Riverside Medical Center
- 8 Subjects –**
  - University of Utah Hospital
- 6 Subjects –**
  - Trinity Health Michigan Heart
- 5 Subjects –**
  - Duke University Hospital
  - Rush University Medical Center
  - Trinity Hospital
  - Trinity Rock Island
- 4 Subjects –**
  - Captain James A Lovell VA

## 3 Enrollments

- Adventist- Shady Grove Medical Center
- Durham VA Health Care System
- McLaren Macomb
- Memorial Hermann - Texas Medical Center
- Methodist Medical Center of Illinois
- NYC H+H - Lincoln
- OU Medical Center
- Parkview Regional Med Ctr
- UCLA Medical Center (Lundquist)
- University of Missouri
- WellStar Kennestone Hospital

## 2 Enrollments

- Ascension Saint Thomas Midtown
- Brigham and Womens Hospital
- Carle Foundation Hospital
- Cooper University Hospital
- Los Angeles Med Ctr
- Mayo - Franciscan Healthcare La Crosse
- Northeast Georgia Med Ctr
- Penn State Holy Spirit Med Ctr
- Proctor Hospital
- Saint Louis University Hospital
- The Valley Hospital
- UW Health East Madison Hospital

## 1 Enrollment

- Cedars-Sinai Medical Center
- Christiana Hospital
- Excellence Medical & Research
- Georgia Arrhythmia Research Institute
- JW Ruby Memorial Hospital
- Los Robles Regional Medical Center
- Marshfield Med Ctr - Marshfield
- McLaren Bay Region
- Memorial Sloan Kettering
- MetroHealth Medical Center
- NewYork-Presbyterian/Columbia University
- Nouvelle Clinical Research LLC
- Ocean Wellness Center, LLC
- Overland Park Regional Med Ctr
- Penn State Hershey Med Ctr
- Sparrow Hospital
- Texas Institute of Cardiology
- The Miami Research Group



# ACTIVATED SITES YET TO ENROLL

Albany Medical Center (PI: Lyubarova)	Kettering Health Dayton (PI: Khouzam)	Oklahoma City VA Health Care System (PI: Thadani)
Anne Arundel Medical Center (PI: Beinert)	Kettering Medical Center (PI: Handel)	Penn State Health St Joseph Medical Center (PI: Rogers)
Ascension St Vincent Hospital –Indianapolis (PI: Patel)	Life Spring Research Foundation, LLC (PI: Rodriguez)	Pharma Medical Innovations (PI: Concepcion)
Barnes-Jewish Hospital (PI: Char)	Loyola University Medical Center (PI: Kinno)	Synapse Clinical Research (PI: Khan)
CHI Health Creighton University Med. Ctr. - Bergan Mercy (PI: Roka)	Marshfield Medical Center – Weston (PI: Kumar)	Texas Health Fort Worth Tulane Medical Center (PI: Kulkarni)
Chippenham and Johnston Willis Medical Center (PI: Shah)	Mercy Gilbert Medical Center	The Angel Medical Research (PI: Dyewski)
DiGiovanna Institute for Medical Education & Research (PI: DiGiovanna)	Miami Valley Hospital (PI: Singh)	Tulane Medical Center (PI: Irimpen)
Enmanuel Advanced Research Center, LLC (PI: Perdomo)	Minneapolis VA Health Care System (PI: Tholankanahalli)	UC Irvine Medical Center (PI: Rochon-Duck)
Golden Touch Clinical Research (PI: Yanez)	Mt Sinai Hospital Medical Center(PI: Khosla)	University Hospital at University of Texas San Antonio (PI: Nayak)
Guardian Angel Research Center (PI: Carballar)	New Hanover Regional Medical Center (PI: Rao)	University of Illinois Hospital (PI: Tofovic)
Heart Clinic of Hammond (PI: Mikdadi)	Northside Hospital (PI: Sheppard)	West Los Angeles Medical Center (PI: Gupta)
Hunter Holmes McGuire VA Medical Center (PI: Kaszala)	NYC Health and Hospitals – Jacobi (PI: Grushko)	
Kansas City Heart and Vascular Specialist at Providence Medical Center (PI: Katrapati)	NYC Health and Hospitals - North Central Bronx (PI: Grushko)	



# Site Best Practice: *Ascension Seton Medical Center Austin*

*Teonna Piphus, MSc.  
Clinical Research Coordinator  
Ascension Texas Cardiovascular*



# Enrollment Review & Consent Conversations Best Practices



Ascension Seton Austin, Texas

## CHANGE AFib Subject Cases

*\*9 total subjects enrolled; below are first 3 recaps*

1. **50 yr. old male, PMH:** Hypertension, diabetes. Initially presented to ED with rapid HR and chest tightness. Enrolled at follow up visit in clinic.
2. **61 yr. old female, PMH:** Hypothyroidism, low blood pressure, was sent to ED by cardiologist because heart monitor showed AF, PT CO flutter in chest and SOB.
3. **56 yr. old female, PMH:** Hypothyroidism, presented to ED w/ palpitations, dizziness, & SOB, converted on her own and referred to AF

## Eligibility & Enrollment Workflow

### Inpatient Enrollments:

1. PT presents to ED
2. Cardio consult; trial offered by clinician
3. Coordinator notified by provider involved in care to approach with consent

### Outpatient Enrollments:

1. Seen by EP; trial offered by clinician
2. Coordinator contacted by provider
3. Consent

## Consent Conversation Site Standards & Best Practices

### Physician covers all available treatment options.

- Cardioversion
- Antiarrhythmic drug therapy
  - Detailed discussion on **Change AFib** trial details including coverage of study medication.
- Ablation
- Monitor

### Coordinator approaches for consent and trial details.

- Highlight **Change AFib** is the first trial focusing on early intervention in newly diagnosed AFib patients.
  - If antiarrhythmics are introduced sooner, does it reduce cardiac events?
- Study Duration: 12 months
  - Only 2 FU visits (6M & 12M) which can be completed in-person or **virtually!**
- Study drug is **FDA approved!**
  - Study drug is **shipped directly** to the patient's home! Subjects can avoid trips to their pharmacy!
  - Study drug is free of charge to the patient.
- Safety Profile Reviewed: Main side effects < 5%

## Suggestions for Other Trial Sites

### Communication is Key!

**Form EP group chat:** Send weekly reminders!

**Resident Education:** Speak to hospital residents that rotate each week for referrals.

### PI Outreach!

PI emails **all** providers with brief Inc/Exc criteria.

### Screening!

Screen ED charts **daily!**

## Contact Information

### **Principal Investigator:**

**Thomas Kurian, MD**

Email: [Thomas.Kurian@ascension.org](mailto:Thomas.Kurian@ascension.org)

### **Primary Study Coordinator:**

**Teonna Piphus, MSc**

Email: [Teonna.Piphus@ascension.org](mailto:Teonna.Piphus@ascension.org)

Phone: 512-324-3434



**Q&A**

*Ascension Seton Medical  
Center Austin*



# Regulatory & Data Reminders



# Continuing Review 2023

October 11, 2023

- The **2023 Master Protocol Continuing Review** has been submitted to the Central IRB as of 11Sep2023.
- All sites, Central & Local, will receive the **2023 Master Protocol Continuing Review Approval Letter** for your site records.
- **Central IRB Sites:**
  - / All Central IRB sites have received emails from Advarra requesting the submission of their site-level Continuing Review application.
  - / Regardless of the date of your Initial Central IRB approval, all Central IRB sites are required to submit a continuing review application prior to the Master Protocol expiration date of 10/11/2023.
  - / ***If your site is listed on the following slide, your Continuing Review application has NOT YET been received and requires submission ASAP!***
  - / Thank you to those sites who have already completed their Continuing Review application!
- **Local/Institutional IRB Sites:**
  - / Please follow the annual review date as indicated on your most recent Local IRB Approval Letter and submit your Continuing Review accordingly.
  - / Local IRB sites may need to provide the Master Protocol Continuing Review Approval documentation to your IRBs. Please refer to your Institutional IRB policies.
  - / AHA Site Managers will work with Local IRB sites to track and manage upcoming Local IRB Continuing Review dates.



# Continuing Review 2023

## Outstanding CENTRAL IRB Site CR Applications



- Care Access Research, Baltimore (Jackson Booth)
- Care Access Research, Delray (Lipson)
- Care Access Research, Dorchester (Eaton)
- Care Access Research, Tamarac (Lipson)
- Enmanuel Advanced Research Center (Perdomo)
- Jamaica Hospital Medical Center (Keller)
- Lower Bucks Cardiology (Ahmed)
- Memorial Hermann-Texas Med. Ctr. (Chiadika)
- Mercy Hospital Springfield (Parvathaneni)
- Mt Sinai Hospital Medical Center (Khosla)
- NYC H+H Jacobi (Grushko)
- NYC H+H North Central Bronx (Grushko)
- Saint Joseph Hospital (Darrat)
- TBC Research (Streit)
- The Cardiovascular Center (Khan)
- The Valley Hospital (Musat)
- Trinity Rock Island (Shen)
- Univ. Hospital at Univ. of Texas San Antonio (Nayak)
- Univ. Hospitals Cleveland Med. Ctr. (Faryar)
- Wake Forest Baptist Medical Center (Mahler)
- WakeMed Raleigh Campus (Manocha)

**SAMPLE SITE EMAIL**

## IRB Continuing Review Notice

8/12/2023 10:01 PM

CIRBI Link: [SSU00196082](#)

Protocol: American Heart Association-TX -

Protocol Title: Pragmatic Randomized Clinical Trial of Early Dronedaronone versus Usual Care to Change and Improve Outcomes in Persons with First-Detected Atrial Fibrillation (CHANGE AFib).

From: Advarra IRB

**Your site approval for the above referenced study will expire on 10/11/2023 .** To ensure IRB review prior to your site approval expiring, please log into CIRBI using the link above to submit a Site Continuing Review Form at least 30 days prior to 10/11/2023. Failure to submit a timely Continuing Review Form could cause a lapse in approval.

**PLEASE NOTE:** If enrollment for this study is closed and you expect that all subjects will have completed the study, please choose Termination as your report type when you create your Continuing Review Form.

*Please click on the CIRBI link above and log into CIRBI to create and submit your Continuing Review report.*

Your project coordinator is available to answer any questions that you may have as you complete this form. They can be reached by clicking the 'Contact IRB' activity or by calling the number listed on the workspace.

**Continuing Review/Termination Reports received within two weeks of the expiration date will be subject to additional fees.**

Thank you,  
Advarra IRB



# DCRI REDCap Data Entry Reminders



# DCRI REDCap Reminders

## DCRI REDCAP Screen Fails –

- We highly encourage all protocol eligibility be assessed and confirmed PRIOR to consenting and registering subject in REDCap.
- Due to the pragmatic nature of this trial, **subject eligibility should be confirmed prior to consent.**
- Initiation of a REDCap subject record utilizes a trial subject ID#.
- If a potential subject's eligibility has NOT been confirmed prior to consent and REDCap record initiation, there is a greater likelihood of screen fail and resulting waste of subject ID #.
- While we understand that screen fails will occur, we would like to do our best to minimize this whenever possible.
- We understand this is cover on the REDCap training conducted by DCRI. Please ensure all site trial staff who will be registering subjects in REDCap have completed this training.





# DCRI REDCap Reminders

## DCRI REDCAP Accounts –

- All trial site staff in need of DCRI REDCap accounts **MUST** use a work email associated with their trial site when completing their Duke Sponsored Accounts / REDCap account registration!
- Due to the nature of the trial subject enrollment notifications, personal email accounts are NOT ACCEPTABLE.

## Site Delegation Log Changes/Updates–

After notifying your AHA Site Manager, please notify the DCRI REDCap team ([CHANGEAF@duke.edu](mailto:CHANGEAF@duke.edu)) when any changes in trial site staff occur.

- If new staff joins the trial site team that will be screening and randomizing trial subjects, they **MUST** be trained by the DCRI team for utilization and access to the trial REDCap!
- Additionally, if there are any site staff departures, please notify both your AHA Site Manager and the DCRI REDCap team ([CHANGEAF@duke.edu](mailto:CHANGEAF@duke.edu)) immediately upon departure so that the proper accesses can be revoked.
- As a reminder, it is against Good Clinical Practice to share logins amongst site staff!



# Troubleshooting in DCRI REDCap

**General DCRI REDCap Questions or Concerns** – Email [changeAF@duke.edu](mailto:changeAF@duke.edu)

- Routine/ Non-Urgent Emails –
  - All routine emails will be answered within 24 hours, from Monday to Friday.
- Immediate Attention Needed Emails –
  - Add **URGENT** in the email subject line and CC [Susana.Almeida-Peters@duke.edu](mailto:Susana.Almeida-Peters@duke.edu)
  - If the potential patient/subject is onsite and your concern needs immediate assistance, please call your DCRI Change AF Clinical Trials Coordinator, Susana Almeida-Peters @ 919-668-9339.

## **DCRI REDCAP LOGIN & PASSWORD Help** –

- For REDCap login/password issues, please call/message DUKE IT Department @ <https://oit.duke.edu/help> and click "START LIVE CHAT" or call 919-684-2200.
  - Inform the Duke IT staff: "I need to reset my password." or "I am having issues with my Duke sponsored account."
  - DO NOT mention REDCAP!
  - DUKE IT Office Hours:
    - Mon-Thurs 24-hours                      Fridays 12a-5p ET                      Sundays 3p-12a ET
- Reminder, the DCRI REDCap team cannot reset passwords for your Duke Sponsored Accounts!
- **DO NOT Click** on the DCRI REDCap Support on the Login Page on REDCap!

Please reach out to the DCRI CHANGE AFib team at [CHANGEAF@duke.edu](mailto:CHANGEAF@duke.edu) if you are not getting the assistance you need.



# GWTG<sup>®</sup>-AFIB Data Entry Reminders



# PROTOCOL V4.0: Acute Care Encounter Update

- Under Protocol V4.0, potential subjects are no longer required to have an acute care encounter for the diagnosis of their first-detected Atrial Fibrillation in order to be eligible for trial participation.
  - ✓ *To note, patients seen in the acute care setting (e.g., ER, Obs, Inpatient) where their first-detected AFib is diagnosed are still eligible under Protocol V4.0.*
- While you await IRB Approval for Protocol V4.0, please flag all future eligible subjects that do not have an acute care encounter for their first-detected AFib diagnosis. These patients will be eligible under Protocol V4.0 and can be enrolled within 120 days of their diagnosis.
- **REMINDER: Continue to screen and enroll subjects based on your current IRB approved protocol version. Enrollment following Protocol V4.0 should ONLY be conducted following receipt of your site's formal Protocol V4.0 Activation Notice.**





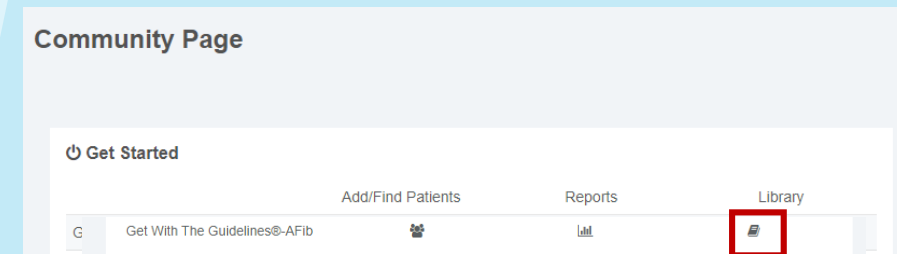
# Separate Baseline Visit CRF & Coding Instructions for Protocol V4.0

**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”*



## Library

Reports & Measures

Coding Instructions

GWTC-AFib Coding Instructions June 2023

CHANGE AFib Follow-Up Form Coding Instructions April 2023

CHANGE AFib Outpatient (No Acute Care Encounter) Baseline Coding Instructions June 2023

GWTC-AFib Post-Ablation Follow-Up Form Coding Instructions

# 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?





## REMINDER:

# Do Follow-Up Visits (6 & 12-months) Need to be Conducted in Person?

- **No.** In accordance with the pragmatic nature of the trial, follow-up visits can be conducted virtually, if necessary.
- To help align with SOC visits, the **6-month follow-up visit** has a window of  $\pm 3$  months and the **12-month follow-up visit** has a window of  $\pm 30$  days.
- Follow-up visit CRF data can be pulled from any SOC visit performed within the above window timeframes. The Protocol only requires that the PROs are completed (virtual or in-person) by a member on your DOA.
  - ✓ *This can be conducted at separate timepoints as long as both instances occur within the visit windows.*





# Q&A, Trial Reminders & Close



# Meet us at AHA's Scientific Sessions 2023!

Philadelphia, PA | November 11-13, 2023



## Visit the AHA Booth:

Staff are present to assist with trial questions and help prospective sites complete a site survey.

***Booth #: TBD***



## Trial Leadership *Meet & Greet* and Trial Site Poster Presentation:

Come network with trial leadership and peer trial sites, then vote for the submitted trial poster (more to come!).

***Saturday, November 11<sup>th</sup> 3:00-4:30pm EST***



# 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](mailto: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, October 30<sup>th</sup> @ 11am-12pm EST**

**Tues, December 12<sup>th</sup> @ 12-1pm EST**



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



# RECAP: Key Trial Contacts

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



# Thank you & Connect With Us!

## How to reach the CHANGE AFib Team



### AHA Site Managers:

[Cayla.Hadley@heart.org](mailto:Cayla.Hadley@heart.org)

[Jack.Goldberg@heart.org](mailto:Jack.Goldberg@heart.org)

[Mariel.Dronson@heart.org](mailto:Mariel.Dronson@heart.org)



### Trial Email:

[ChangeAFib@heart.org](mailto:ChangeAFib@heart.org)

## Resources to Remember



For important trial information and today's meeting recording, go to the **Resources** page at [www.changeafib.org](http://www.changeafib.org) or visit the QR Code to the left.

