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 – December 12, 2022

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: 860 0056 5378
Passcode: changeafib

Agenda:

- Welcome & Introductions
- Trial Progress Update
- Trial Site Best Practices
- Review of Trial Updates
- Q&A
- Trial Reminders & Closing
- Coordinator Office Hours, if Needed

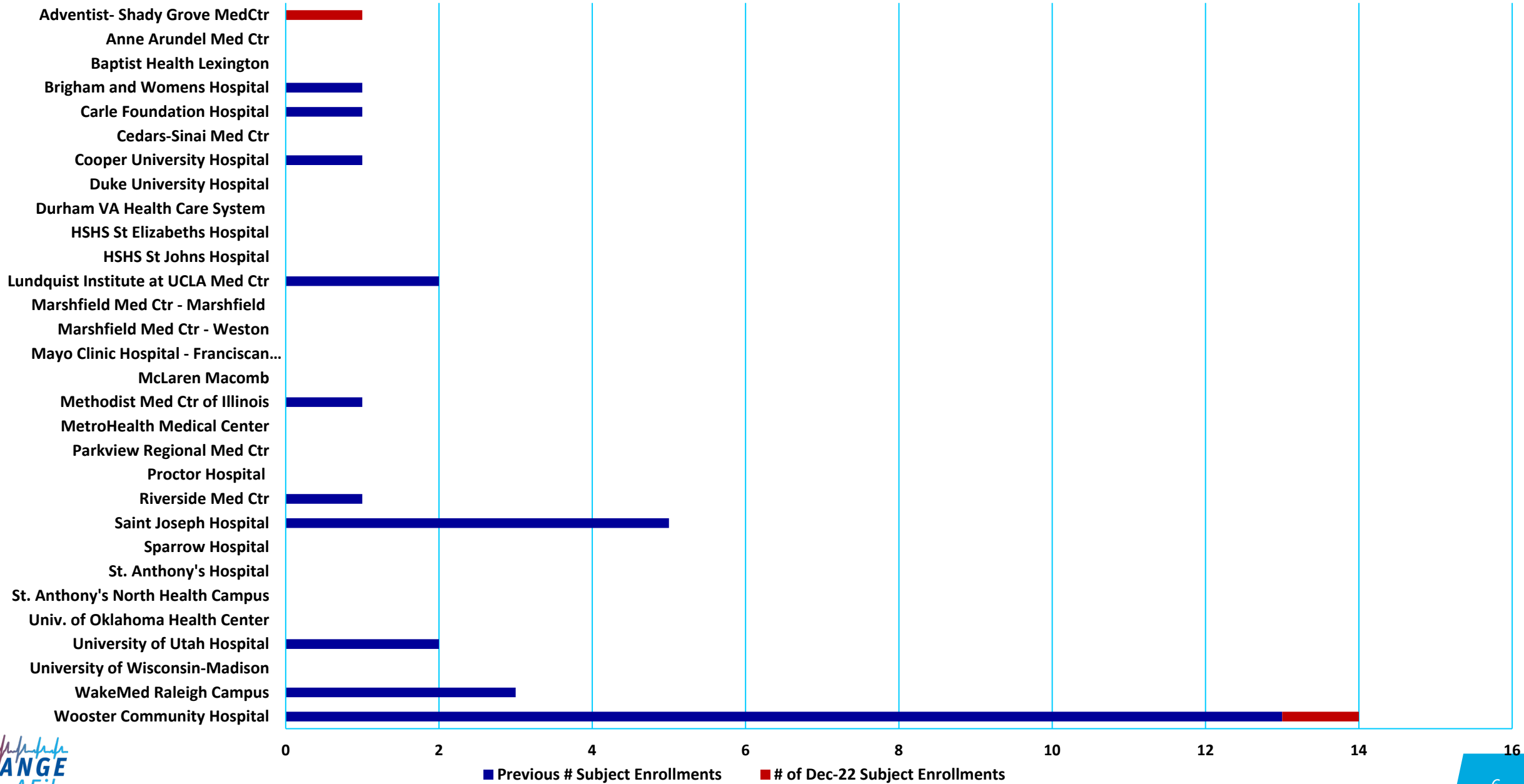
Trial Progress Update

Trial Progress – as of December 12, 2022

Site Status	Current Status	Trial GOAL!
Subject Enrollments	**32**	**3000**
Activated Sites	30	**200**
Sites in Onboarding	65	**-**
Sites Assessing Feasibility	43	**-**

CHANGE AFib

Subject Enrollments by Site (32)



Above data current as of 12Dec2022

TRIAL ENROLLMENT GOAL

2023 New Years Resolution:

2 SUBJECTS PER SITE PER WEEK

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

As we look forward to 2023, especially with sites now screening under Protocol V2.0 eligibility criteria, we hope to hit the ground running with

2 subject enrollments per site, per week!

Screening & Enrollment Requirements for Success

Tasks by End of Year 2022

- Screening Strategies
  - Manual Screening vs EMR Report reviews
  - Daily review of patients currently in ER or on cardiology floors/services
  - Daily collaboration with outpatient clinics and schedules for potential patients
  - Retroactive review of previously submitted screening logs due to increased diagnosis window (120-days)
    - Review diagnosis dates of subjects previously ineligible due to Protocol V1.0 60-day diagnosis window.
    - Review subjects previously listed as ‘planned for OP enrollment’
- Trial Visibility throughout the Site
  - Promote CHANGE AFib at routine departmental meetings or grand rounds
  - Identify a trial champion in various areas of your site (ER, OP clinics, etc.) & circulate provider pocket cards!

CHANGE AFib

Trial Site Best Practices

Enrollment Successes & Best Practices

Saint Joseph Hospital, Lexington, KY

CHANGE AFib Subject Cases

1. 74 y/o Male, Inpatient, 8/16/22
2. 73 y/o Female, Outpatient, 9/1/22
3. 62 y/o Male, Inpatient 10/21/22
4. 56 y/o Male, Outpatient, 11/16/22
5. 47 y/o Male, Outpatient, 11/22/22

Eligibility & Enrollment Workflow

Inpatient Enrollments:

1. MD identifies subject and contacts coordinator for screening
2. If subject meets criteria, MD discusses study with patient
3. If patient is receptive, study coordinator discusses study in-depth with patient and consents if patient agrees

Outpatient Enrollments:

1. Coordinator prescreens clinic schedules
2. Coordinator arrives before patient is seen to discuss study candidate with investigator
3. Investigator discusses study with patient at visit
4. If subject is receptive coordinator discusses study thoroughly with subject and consents if patient agrees

Consent Conversation Site Standards & Best Practices

1. Provider talks to patient about study. Informs patient that they will be seen by study coordinator to go over consent and study details.
2. Provider and coordinator stress to patient that the sponsor is the AHA and that the study has the potential to change treatment guidelines for future patients like themselves.
3. Consent is obtained as inpatient if patient agrees, if not then a follow up visit is scheduled, and the study is readdressed.
4. Coordinator comes to clinic for outpatient follow-up if subject did not consent in hospital and second attempt is made to enroll subject.

Suggestions for Other Trial Sites

1. Obtain consent as an inpatient/ during ER visit
2. Remind rounding cardiologist about study via text message or in person (done weekly)
3. Remind ER physicians about study
4. Use the good reputation of the AHA to your advantage when speaking with potential subjects

Contact Information

Yousef Darrat, MD

Principal Investigator

Tracie Carl-Nagel, RN, CCRC

Primary Study Coordinator

Email: Tracie.Nagel@commonspirit.org

Phone: 859-313-4459

Q&A

Saint Joseph Hospital

Trial Updates

NEW AE Reporting Process with Sanofi PV

- To comply with federal reporting, site trial teams must notify Sanofi US of any AEs (including SAEs) and complaints within three (3) business days after becoming aware of the AE or complaint.
  - The *Adverse Event Reporting Form* detailing the above is **HERE** on the trial website

- The PV reporting process has been updated from phone number to email- see below

  New Process:

  Email Sanofi PV: CL-CPV-Receipt@sanofi.com

  Fax Number (only use if above email failed): +33 1 6049 7070

  - As of now, no CRF was provided by Sanofi but should this change, we will update sites ASAP.
  - All trial clinical events, outcomes and endpoints will be captured on the CHANGE AFib follow-up CRF forms in GWTG-AFib *(e.g. the 6mth visit CRF will collect info from randomization to 6mths and the 12mth visit CRF will collect info from 6mths to 12mths- more to come on this shortly!).*

Subject Eligibility Deviation Form

Form Purpose & Location on Trial Website:

- This form was created to document patients that have a post-randomization Inclusion/Exclusion eligibility failure. While this situation should NOT be common, this form is available in case needed.
  - ***NOTE: This form only applies to enrolled subjects that were deemed ineligible at the time of consent/randomization and does NOT apply to subjects that become ineligible after their enrollment.***
  - This form is located in the 'Regulatory Binder Essentials' section of the Resource page of our trial website.

Directions on How to Submit:

- Email the completed & signed form to:
  - CHANGEAF@Duke.edu
  - CHANGEAFib@heart.org **AND**
  - **Your site-assigned AHA Site Manager**

CHANGE AFib

CHANGE AFib

Subject Eligibility Deviation Report Form

Site Number: _____ **Site Name:** _____

Date of Report: _____ **Site PI Name:** _____

Subject ID Number: CHGAF-_____ **Date of Randomization:** _____

Instructions: Complete this form upon confirmation of an ineligible subject enrollment and randomization. ***Check any/all of the inclusion and/or exclusion criteria the subject was found to not meet post-randomization.*** Sign/date this form and send to: DCRI Team CHANGEAF@Duke.edu, AHA Team CHANGEAFib@heart.org and your assigned AHA Site Manager.

Inclusion Criteria - Check any/all of the inclusion criteria the subject was found to NOT meet post-randomization.

☐	1. Age 21 years or older.
☐	2. First-detected atrial fibrillation (defined as atrial fibrillation diagnosed in the previous 120 days)
☐	3. Acute care encounter for evaluation or treatment of atrial fibrillation, within 120 days.
☐	4. Electrocardiographic documentation of atrial fibrillation.
☐	5. Estimated life expectancy of at least 1 year
☐	6. Patient or legal authorized representative capable of giving signed informed consent, which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.

Exclusion Criteria – Check any/all of the exclusion criteria the subject was found to meet post-randomization.

☐	1. Patients with prior or planned treatment with rhythm control, either catheter ablation or chronic (>7 days) antiarrhythmic drug therapy.
☐	2. Prior hospitalization for atrial fibrillation (other than the qualifying event).
☐	3. Planned cardiothoracic surgery
☐	4. New York Heart Association class III or IV heart failure or a hospitalization for heart failure in the last 4 weeks
☐	5. Patients with reduced ejection fraction (LVEF ≤40%)
☐	6. Permanent atrial fibrillation
☐	7. Ineligible for oral anticoagulation, unless CHA2DS2-VASc is less than 3 in women or 2 in men.
☐	8. Bradycardia with a resting heart rate < 50 bpm
☐	9. PR interval >280 msec or 2nd degree or 3rd degree atrioventricular block without a permanent pacemaker/cardiac implanted electronic device.
☐	10. Corrected QT interval ≥500 msec.
☐	11. Pregnancy or breast feeding
☐	12. Severe hepatic impairment in the opinion of the Investigator

Site Principal Investigator (**Name – printed**)	Reporting Site Coordinator (**Name – printed**)
Site Principal Investigator (**Signed**)	Reporting Site Coordinator (**Signed**)
Date	Date

Version 1.0_01Dec2022

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
    - Site Incentive Payments (if applicable)
    - Subject Visits
    - Screening Log Payments

- 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.

Regulatory Update

As of 12Dec2022- Activated Sites Approved to Enroll Under Protocol V2.0

(IRB Approved & REDCap Study Shell Update Complete)

- Adventist HealthCare Shady Grove Medical Center
- Anne Arundel Medical Center
- Baptist Health Lexington
- Brigham and Women's Hospital
- Carle Foundation Hospital
- Cedars-Sinai Medical Center
- Cooper University Hospital
- HSHS St Elizabeth's Hospital
- HSHS St John’s Hospital
- Marshfield Medical Center - Marshfield
- Marshfield Medical Center - Weston
- Mayo Clinic Hospital - Franciscan Healthcare La Crosse
- McLaren Macomb Methodist Hospital
- MetroHealth Medical Center
- Parkview Regional Medical Center
- Proctor Hospital
- Riverside Medical Center
- Saint Joseph Hospital
- Sparrow Hospital
- St Anthony Hospital
- St Anthony North Health Campus
- UCLA Medical Center - Harbor
- University Hospital - University of Wisconsin-Madison
- WakeMed Raleigh Campus
- Wooster Community Hospital

All above sites have received a formal enrollment approval email with the updated screening log template. If you are an activated site and not included above, please continue to work with your AHA Site Manager to complete the Protocol V2.0 activation requirements.

Q&A

Trial Reminders

RECAP: Key Trial Contacts

General Trial Questions	Email your AHA trial site manager *OR* 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 ***(GWTG®-AFIB is the trial EDC)***	Email your AHA trial site manager, *OR* If you are a new site, email CHANGEAFib@heart.org
sIRB Questions	CIRBI@advarra.com
AE Reporting	CL-CPV-Receipt@sanofi.com Fax Number *(to be used in the event e-mail failed)*: +33 1 6049 7070

A detailed list of key trial contacts can continue to be found HERE on the trial website

Mark Your Calendars!

Upcoming 2023 Fireside Chats

Tuesday, January 24th @ 2-3pm ET — Next Up

Monday, April 17th @ 2-3pm ET

Monday, May 8th @ 2-3pm ET

Tuesday, June 6th @ 2-3pm ET

CHANGE AFib Investigator Meeting

March 3, 2022 in New Orleans, LA

More details to come! Stay tuned!

CHANGE AFib /

Archived webinar recordings & handouts can be found HERE on the trial website.

2022 Holiday Closures

Please note the below AHA (trial sponsor) & DCRI closures for the current 2022 holiday season.

- **AHA** is closed Monday, 12/26 through Monday, 1/2, returning on Tuesday, 1/3

- **DCRI** is closed Friday, 12/23 through Monday, 1/2, returning on Tuesday, 1/3
  - **During this closure sites are welcome to continue randomizations, but enrolled subjects will NOT be uploaded to /created in GWTG®-AFIB from REDCap. This process will return on Tuesday, 1/3 so we appreciate your understanding during this time.**

CHANGE AFib

Connect With Us!

How to reach the CHANGE AFib Team

AHA Site Managers:

Crystal.Glodek@heart.org

Jack.Goldberg@heart.org

Mariel.Dronson@heart.org

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.

CHANGE AFib

On behalf of the CHANGE AFib Teams at the AHA & DCRI, we wish you and your families a wonderful and peaceful holiday season and Happy New Year! See you in 2023!

Coordinator Office Hours

Any Questions? Thank you and See You in 2023!