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 – June 12, 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: 831 3427 0402
Passcode: changeafib

Agenda:

- Welcome & Introductions
- Trial Progress Update
- Strategies from EMCREG
- Protocol V4.0 Next Steps & Trial Reminders
- Preparing for Protocol V4.0 GWTG-AFib Data Entry
- Q&A and Close

Trial Progress Update

We Did it: 100+ CHANGE AFib Subjects!

Congrats and Thank You
Saint Joseph's Team
for Enrolling the
100th Subject!

Principal Investigator: Yousef Darrat, MD

Co-Investigator: Samy Elayi, MD

Primary Study Coordinator: Tracie Carl-Nagel, RN, CCRC

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Trial Progress – as of June 12, 2023

Site Status	Current Status	Trial GOAL!
Subject Enrollments	**107**	**3000**
Activated Sites	62	**200**
Sites in Onboarding	61	**-**
Sites Assessing Feasibility	45	**-**

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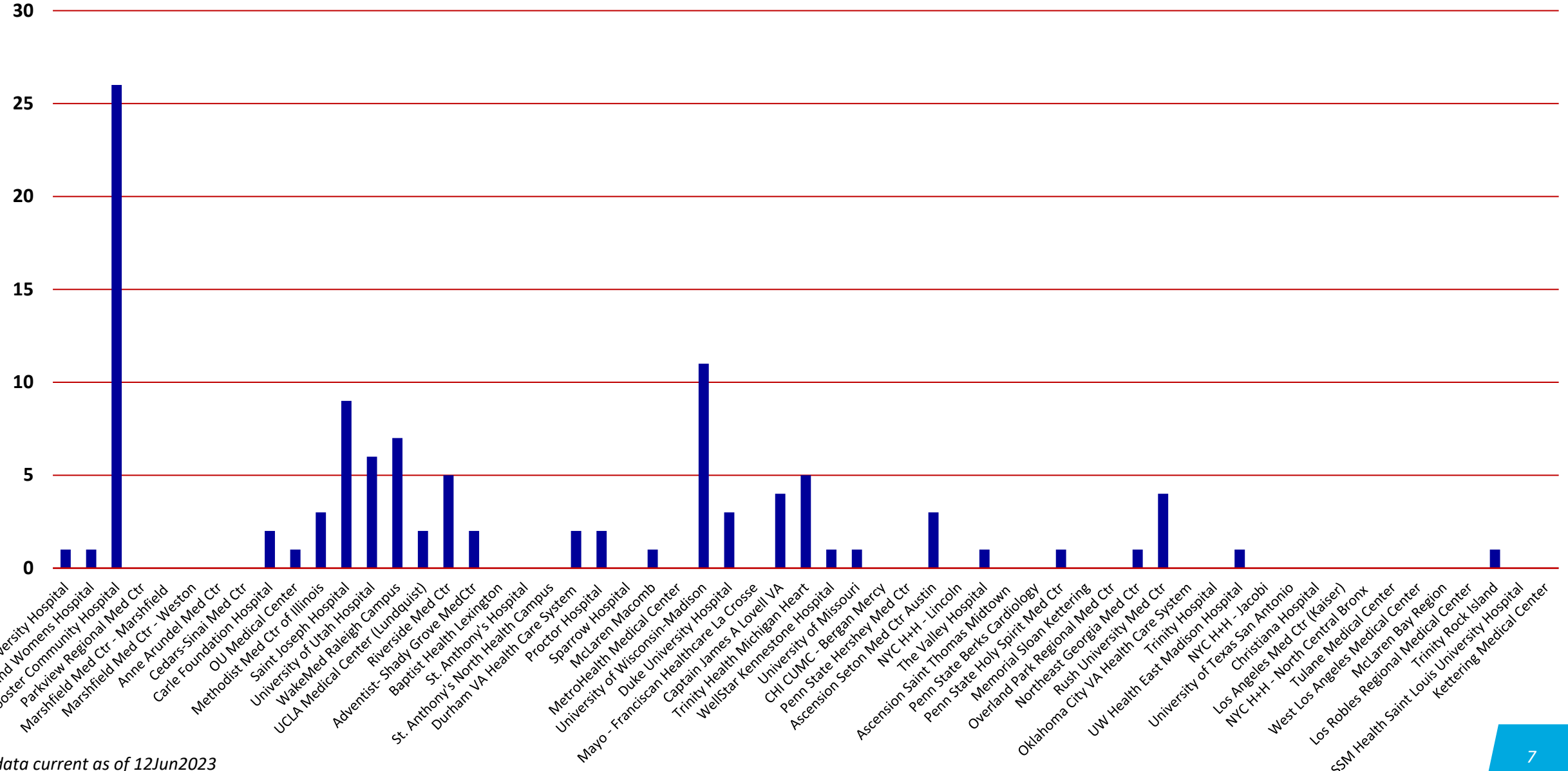
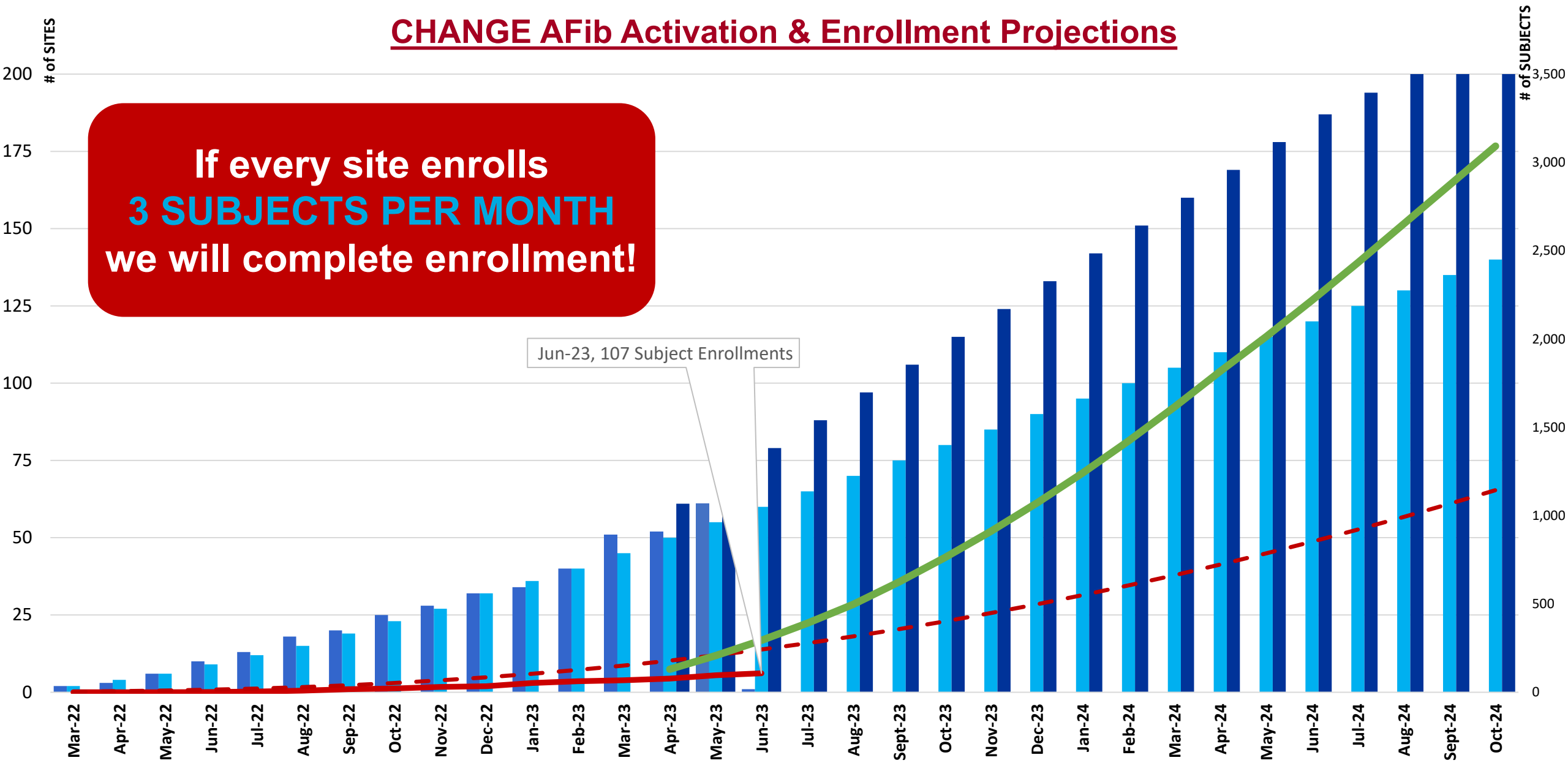
CHANGE AFib 107 Subject Enrollments from 28 Sites



Above data current as of 12Jun2023

CHANGE AFib Activation & Enrollment Projections



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!

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Strategies from EMCREG

THE EMERGENCY CARDIAC RESEARCH AND EDUCATION GROUP

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Liaising With Emergency Medicine Colleagues to Increase Subject Enrollment

Gregory J. Fermann, MD
EMCREG International
University of Cincinnati College of Medicine
Professor and Executive Vice Chairman
Department of Emergency Medicine

Agenda:

- Overview of EMCREG Partnership
- How to Engage ED Colleagues in CHANGE AFib
- Trial How to Increase Trial Visibility in the ED
- Additional Best Practices to Identify Eligible Patients for CHANGE AFib
- Q&A

Overview of EMCREG Partnership

- Dr Joe Miller, Research Director, Henry Ford Health System
- History of collaboration
  - Diagnostic studies
    - CPK-MB, myoglobin, troponin—POC, hs, novel ischemia markers
    - Extending lead ECG, cardiac mapping
    - Continuous ST segment monitoring
    - Wearable for HF monitoring (Medronic)
    - FLOOD-Lung ultrasound
  - Risk Stratification
    - STRATIFY
    - DECIDE
    - Six minute walk tests for AHF
- Therapeutic studies
  - Acute Heart Failure
    - Ularitide, nesiritide, tolvaptan
  - Acute coronary syndrome
    - Eptifibatide
- Registry
  - CRUSADE-acute coronary syndrome
  - REPORT HF
- Guideline implementation
  - GUIDED HF (PCORI)

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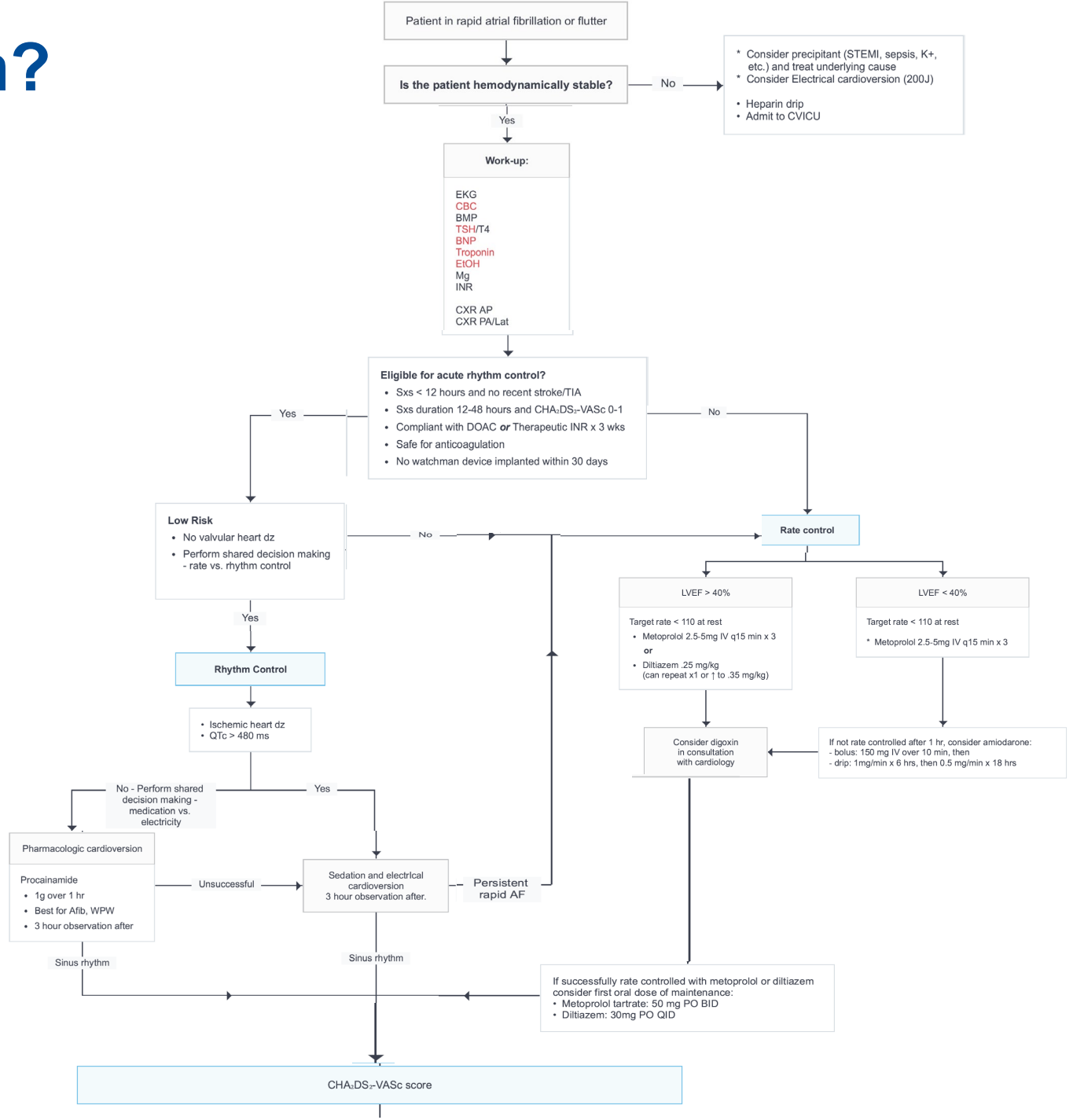
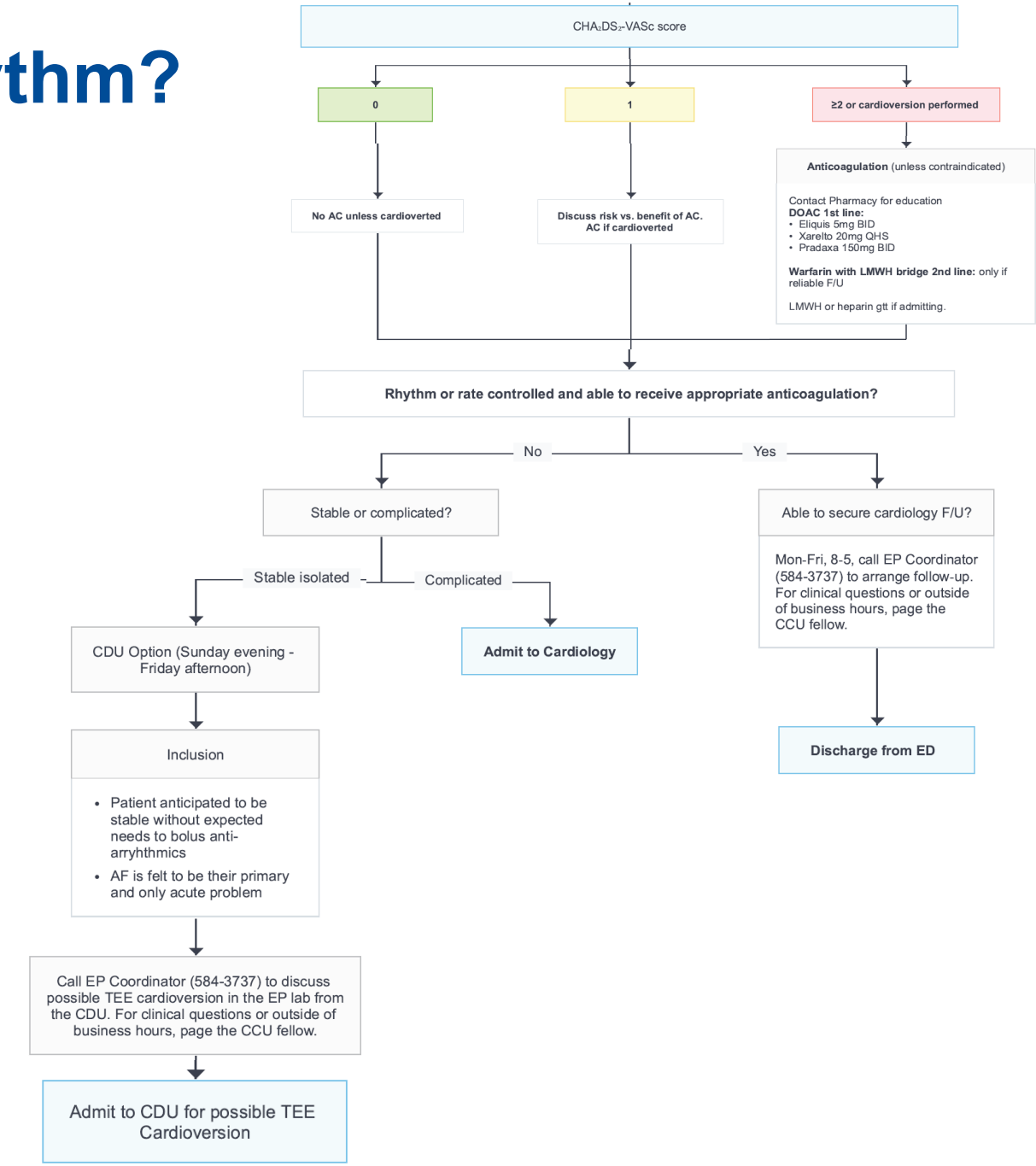
How to Engage ED Colleagues in CHANGE AFib

- Understand the setting
  - Academic Health Center—likely has a EM research infrastructure
    - Who is the Research Director (MD and non MD leader)?
    - How do they screen their ED subjects? Do they have a screening program for the EHR (Epic)?
    - Do they use student screeners? Have CRPs?
    - The “poster” approach is likely not a path forward
    - Can you support a portion of a CRP or screener with the comp
    - If you are a GWTG participant, is there someone in the data analyst side that can help?
  - Community setting
    - Get to know the Medical Director
    - What could motive them?
    - Discussion about finances and reimbursement for screening
    - Journal club
    - Engage on a clinical level
    - What do you do with AF now? Rate or Rhythm control

Rate or Rhythm?



Rate or Rhythm?
Continued



Trial How to Increase Trial Visibility in the ED

- Find a way to connect to ED
- Nurses-Inservice day, break room, lunches
- MDs-Journal club, M and M, Peer review
- Don’t ignore the APPs
- If a large CMG (USACS, Envision, Team Health)—they likely have an educator
- Daily drive by, in am
- Call Joe/Greg to set up a meeting

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Additional Best Practices to Identify Eligible Patients for CHANGE AFib

- Electronic screening of the track board
- Have analyst write for Afib+ED visit etc and have those patient's MRN directed to a research in basket for your research coordinator
- The coordinator screens chart
  - Inpatients—go see
  - Treated and released—see if they are eligible (have PI screen chart) and call them back!
- Call PMD if that is the culture of the organization
- Don't expect something for nothing
  - Partial compensation
  - If ED is really interested—Emergency Medicine Advisory Board

Q&A
For Dr. Fermann

Thank you

Contact Info:
Gregory J. Fermann, MD
gregory.fermann@uc.edu

Protocol V4.0 Next Steps & Trial Reminders

Protocol V4.0 Update

Master Trial IRB is Approved (details on next slide)!

Reminder- SUMMARY OF CHANGES

Subject Eligibility Changes:

- **Removal of the *Acute Care Encounter* Inclusion Criteria**
  - 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.
- **Definition of 'Electrocardiographic documentation of atrial fibrillation'**
  - Electrocardiographic documentation includes a standard 12 lead electrocardiogram, mobile ECGs, ambulatory monitoring (e.g., Holter), telemetry, or electrograms from cardiac implanted electronic devices (i.e., pacemaker).
- **Removal of Exclusion Criteria #2**
  - Prior hospitalization for atrial fibrillation (other than the qualifying event).

Protocol V4.0 Documentation

Main Trial IRB is APPROVED!

List of Updated Documents:

- Main Trial IRB Approval – 26May2023
- Protocol V4.0 – 12May2023
- Protocol V4.0 Tracked Changes – 12May2023
- Protocol V4.0 Summary of Changes – 12May2023
- Protocol V4.0 Signature Page – 12May2023
- Protocol V4.0 ICF Template – 26MAY2023
- Protocol V4.0 ICF Template_Tracked Changes – 26MAY2023
- Recruitment Materials V4.0
- Updated Protocol V4.0 Screening Log

CTA Amendments are forthcoming- thank you for your patience!

ALL above documents are located HERE on trial website.

- **Password** = change2021!

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Protocol V4.0 IRB Next Steps

CENTRAL IRB SITES:

- All trial sites utilizing the Central IRB, Advarra, are NOW automatically being reviewed for approval following our recent Master Trial Approval.
- IRB approval emails will be sent to each individual site with site-specific approval notices and approved Informed Consent Forms (ICFs).

LOCAL/INSTITUTIONAL IRB SITES:

- All trial sites utilizing their Local/Institutional IRB will be required to submit an IRB Modification.
- Site-Specific ICF edits are required to be sent to CHANGEAFibContracting@heart.org for sponsor approval prior to Local IRB submission.
- If your site has yet to submit to your IRB for the previous modification, please hold off and combine submissions for Protocol V4.0.

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Protocol V4.0 IRB Next Steps *continued*

For Both CENTRAL & LOCAL/INSTITUTIONAL IRB Sites:

You CAN NOT enroll under Protocol V4.0 until you receive a formal "Protocol V4.0 Activation" email from us (the AHA), the trial sponsor.

While you await IRB Approval on Protocol V4.0, please:

1. **Flag all future eligible subjects** that do NOT have an acute care encounter for their first-detected AFib diagnosis, as they will be eligible under Protocol V4.0 and can be enrolled within 120 days of their diagnosis.

2. **Continue to screen and enroll subjects based on your current IRB-approved protocol version.** Enrollment under Protocol V4.0 should ONLY be conducted following receipt of your site's formal Protocol V4.0 Activation Notice from the AHA.

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As of 12Jun2023- Sites Approved to Enroll Under Protocol V4.0

(IRB Approved & REDCap Study Shell Update Complete)

- Kettering Medical Center (Handel_21082)
- Los Angeles Medical Center (Gupta_42054)
- Trinity Hospital (Turk_52674)

Again, all sites will receive a formal Protocol V4.0 Activation email from the AHA once approved.

Preparing for Protocol V4.0 GWTG-AFIB Data Entry

Nadine Allyn, RD, MPH
Advisor, Quality Operations, AHA

Q&A & Close

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.

Mark Your Calendars!

Upcoming Fireside Chats:

Stay tuned for Summer 2023 dates

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

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
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

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Thank you & Connect With Us!

How to reach the CHANGE AFib Team

AHA Site Managers:

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.