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 – March 27, 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: 820 1442 7220
Passcode: changeafib

Agenda:

- Welcome & Introductions
- Trial Progress Update
- Refresher on Trial Justification & Study Medication
- Q&A on Trial Overview
- Site Best Practice
- Protocol V3.0 Next Steps & Trial Reminders
- Q&A and Close

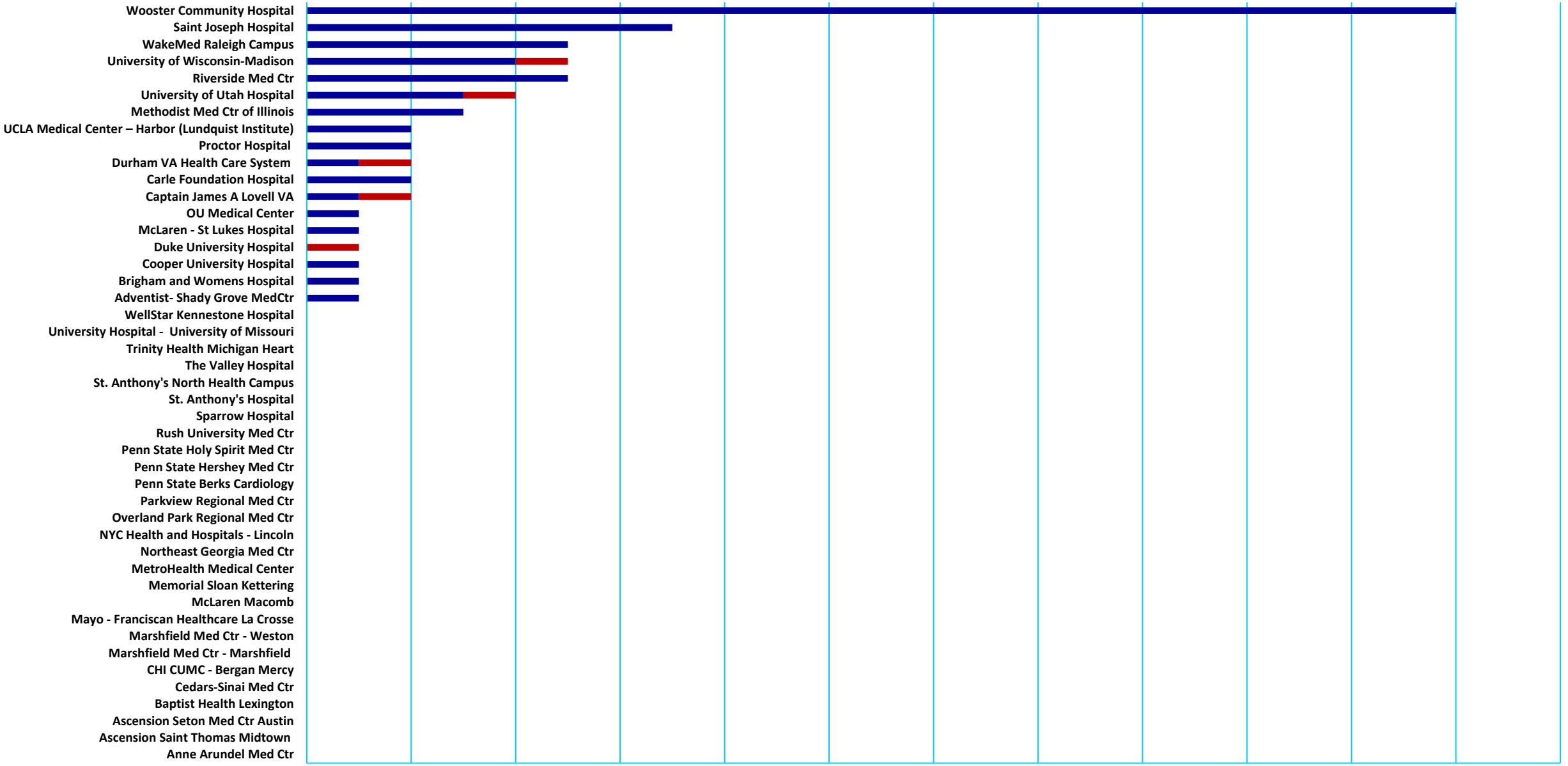
Trial Progress Update

Trial Progress – as of March 27, 2023

Site Status	Current Status	Trial GOAL!
Subject Enrollments	**67**	**3000**
Activated Sites	49	**200**
Sites in Onboarding	100	**-**
Sites Assessing Feasibility	95	**-**

CHANGE AFib

CHANGE AFib 67 Subjects from 18 Sites



Above data current as of 27Mar2023

Refresher on Trial Justification & Study Medication

Some Feedback from On-Site Visits

- In addition to weekly connects, the CHANGE AFib team has been conducting on-site visits with trial sites.
- Themes discussed included the following areas, that we plan to walk through in our following slides:
  - The case for dronedarone over other antiarrhythmics in newly-diagnosed AFIB patients
  - Trial PIs navigating established treatment patterns of peers and non-trial electrophysiologists, to consider patient for CHANGE AFib

Q&A on Trial Overview

Site Best Practice

Emily Wittrock, B.S., CMA (AAMA)

Clinical Research Coordinator

UW Madison School of Medicine and Public Health

Division of Cardiovascular Medicine

CHANGE AFib Recruitment at UW Health

Emily Wittrock, Dan Frost, Ann Wieben and Matthew Kalscheur, MD

CHANGE AFib Fireside Chat, 27Mar2023

CHANGE AFib Recruitment at UW Health

- UW Health – University Hospital is a 515 bed, academic hospital in Madison, WI
- Enrolling for CHANGE-AFib since November 23, 2022
- Recruitment includes some reminders / visits to our Emergency Medicine and Cardiology colleagues but relies heavily on an EMR based workflow

UW Health Workflow

- Potential patient identified via EMR logic with research team notified via an InBasket Message (Epic EMR)
- Research coordinator reviews and identifies potential patients – placed on a shared patient list in EMR
- PI confirms and then messages patient's provider and then patient if permission given
- If patient is interested, additional details given over MyChart or phone
- Research coordinator then follows up with patient to determine if patient wishes to proceed

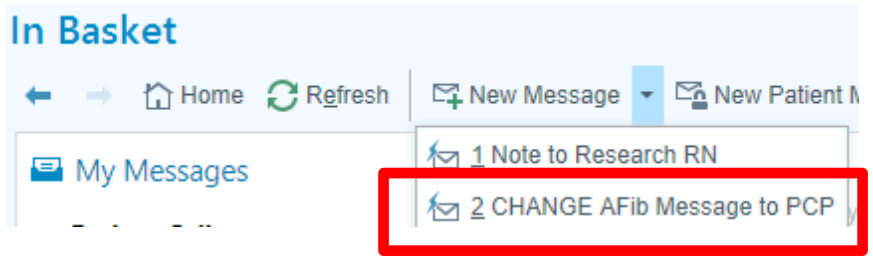
UW Health Workflow - BPA

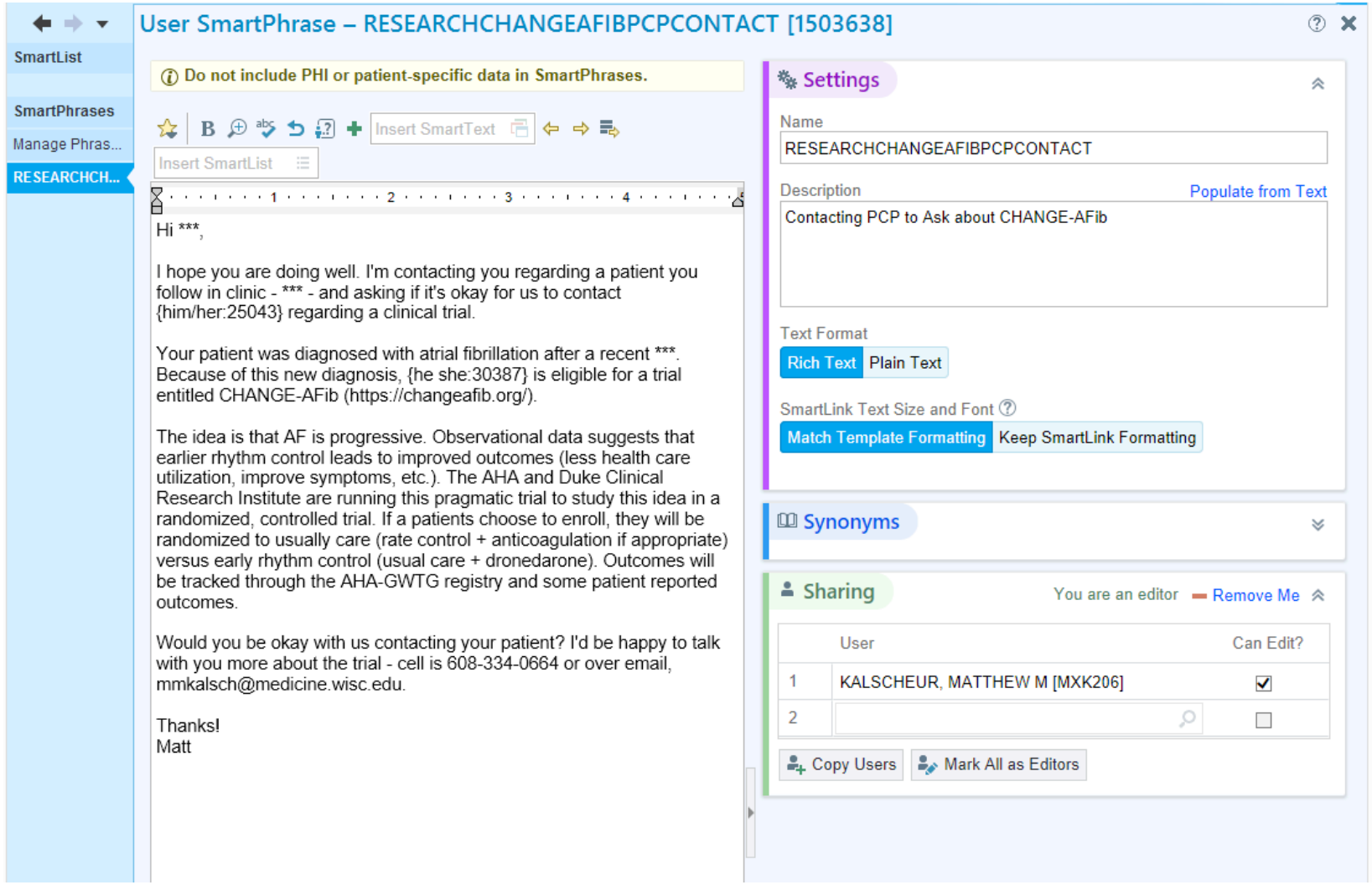
Logic:
(NOT 1 AND NOT 2 AND NOT 3) AND (4 AND
(5 AND 6 AND 7 AND 8) AND
((9 AND (10 OR 11)) OR (12 AND (10 OR 13)))

1. HAS FIRED AFTER GO LIVE [7000269]
2. PATIENT ALREADY ASSOCIATED WITH STUDY [7000272]
3. I48 DX PRIOR TO 90 DAYS AGO [7000265]
4. EXCLUDE WHEN STUDY IS NOT RECRUITING [7000271]
5. PATIENT IS ALIVE [4573]
6. AGE >= 21 [7000261]
7. PATIENT TYPE NOT DCFS DOC OR MMHI [7000210]
8. EJECTION FRACTION >40 OR NULL [7000263]
9. CURRENTLY ADMITTED TO UH OR EMH LESS THAN 7 DAYS [7000267]
10. I48 DX IN PAST 90 DAYS [7000264]
11. AFIB CONSULT OR ORDER SET USED IN PAST 6 DAYS [7000266]
12. ADMITTED IN PAST 90 DAYS TO UH OR EMH FOR LESS THAN 7 DAYS [7000268]
13. AFIB CONSULT OR ORDER SET USED IN PAST 41 DAYS [7000262]

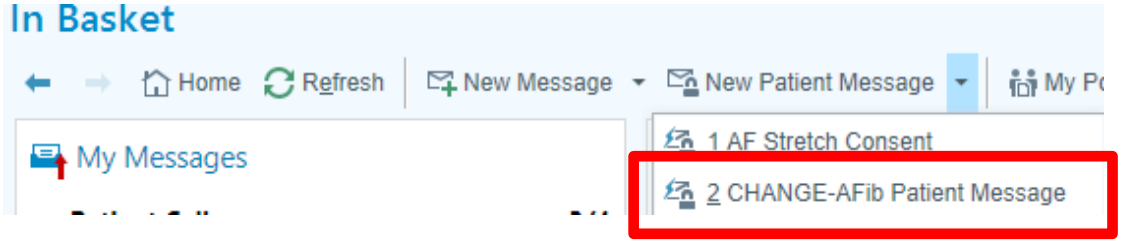
- Step 1: Patient has not been identified already and does not have diagnosis of AFib (I.48 in problem list or visit diagnosis)
- Step 2: Age and EF eligible
- Step 3: Acute care encounter and AFib identified (I.48 or certain orders placed)

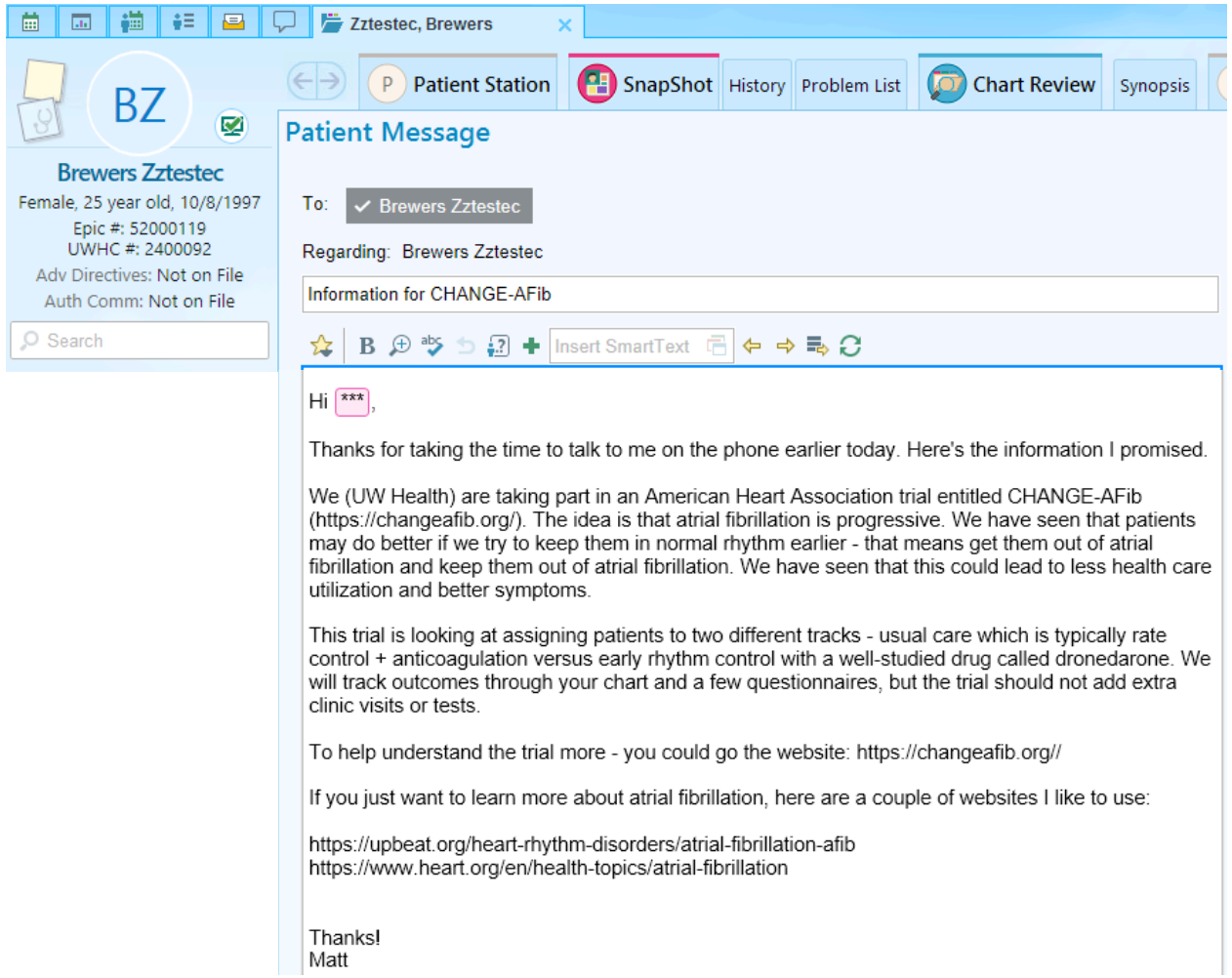
CHANGE AFib – Provider Message





CHANGE AFib – Patient Message





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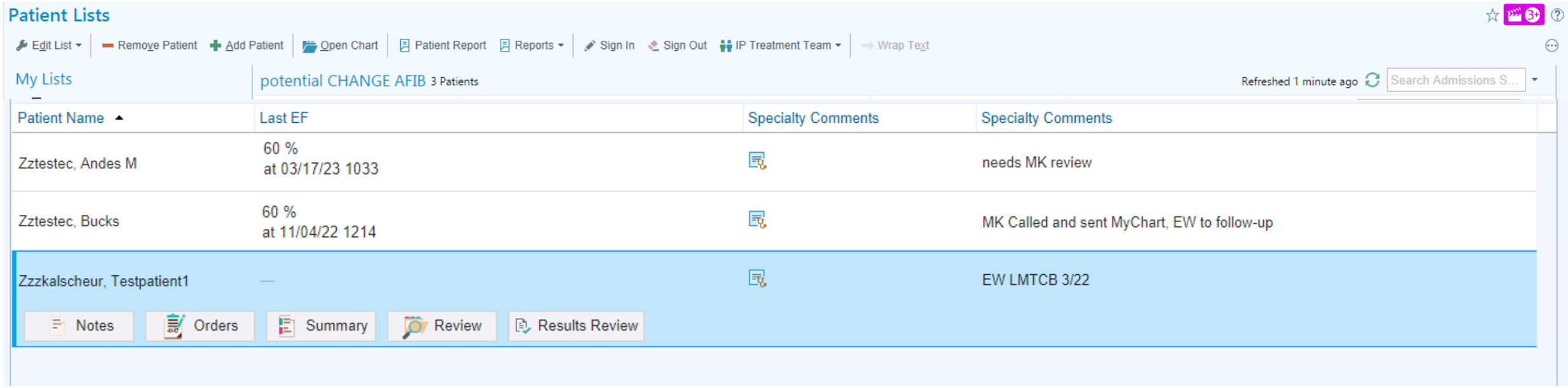
CHANGE AFib – Shared List



- Until patient enrolled, EW and MK communicate via Shared List

Lessons Learned

- UW Health recruitment workflow produces effective recruitment driven by EMR tools
  - Enhanced by reminders to our cardiology, hospital medicine and ED colleagues
  - Soon will be enrolling from a second hospital in our system using same tools
- BPA is helpful but there's room for improvement
  - Not very specific, requires a process for review / oversight
  - Working to improve sensitivity for ED patients as workflow / orders different than inpatient
- Workflow could be duplicated at other Epic sites – and hopefully lead to continued improvement / learning

Protocol V3.0
Next Steps

Protocol V3.0 Changes

- Changes accommodating provision of drug
  - *Direct-to-Patient* drug shipments via a third-party central pharmacy vendor, *Almac Clinical Services*
  - No services are needed from your Institutional or Research pharmacy services.
  - Formal education and training for drug order and shipment processes will be provided to all sites
  - More details to come at the Investigator Meeting!
- Minor Updates to Safety/PV Reporting
- No Inclusion/Exclusion Criteria Updates

Protocol V3.0 Next Steps

CLINICAL TRIAL AGREEMENT AMENDMENTS:

- Contract Amendments have been sent to all sites. Please expeditiously work with CHANGEAFibContracting@heart.org on contract amendment execution for your site.

PROTOCOL V3.0 & IRB REQUIRED UPDATES:

- Protocol V3.0 has been submitted to the Central IRB for Master Trial Approval.
- Immediately upon Master Trial IRB Approval receipt, Protocol V3.0 documents will be posted on the trial website to support your Protocol review and IRB submissions. A formal notice will be sent when these documents available.
- We are anticipating IRB Approval in <2 weeks

Protocol V3.0 IRB Next Steps *Continued*

CENTRAL IRB SITES:

- All trial sites utilizing the Central IRB, Advarra, will automatically be reviewed for approval following the 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.
- Please send any ICF edits to CHANGEAFibContracting@heart.org for sponsor approval prior to Local IRB submission.

Please Continue Enrolling Prior to Drug Provision

- We thank you all for your enthusiasm around provision of drug in the next month!
- While we await rollout of Protocol V3.0, please continue screening and enrolling eligible patients knowing drug provision is right around the corner.
- Again, all patients assigned to the treatment arm prior to and after drug provision will receive the study drug, dronedarone, free of charge.
- We also continue to encourage each site to follow up with previously approached patients who either declined participation due to drug provision or where unable to utilize any financial assistance programs to offset the medication cost, as this hurdle is now eliminated.

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Trial Reminders

Investigator Meeting Recap

April 25, 2023 in Washington, DC

TIME: 9:00AM – 2:30PM ET

LOCATION: **AC HOTEL WASHINGTON DC**
CAPITOL HILL NAVY YARD
67 NEW JERSEY AVE SE
WASHINGTON, DC 20003

- **Registration is now CLOSED! Should your site have ANY travel issues, please contact your AHA site manager immediately.**
- 50+ sites are sending representatives and we look forward to a lively discussion around drug provision!
- All materials will be posted on our trial website following the meeting stay tuned for the exact location.

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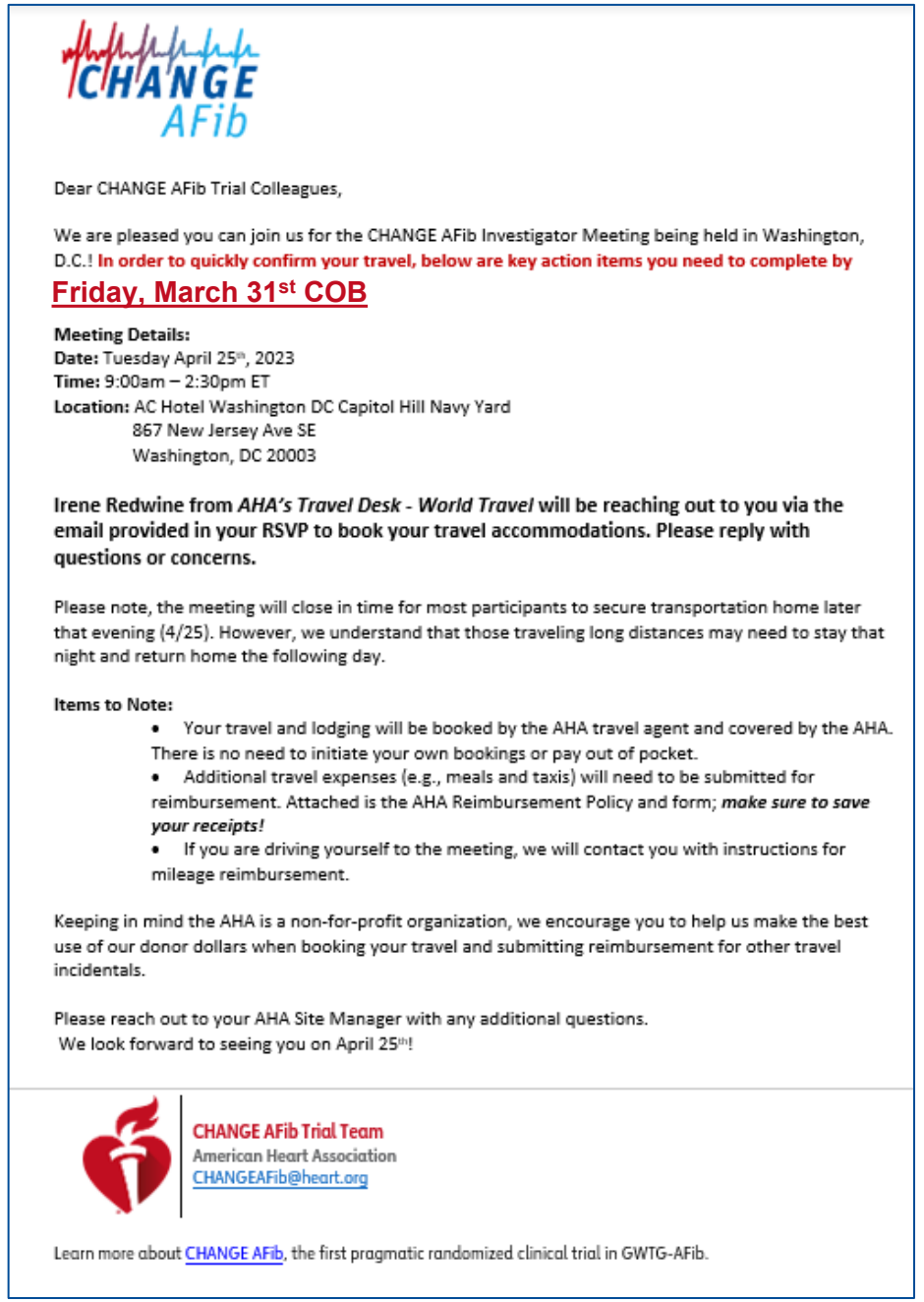
Investigator Meeting: Travel Arrangements

- **This information only pertains to confirmed IM attendees:**
  - You should've received an email from changeafib@heart.org confirming your attendance (*see right*)
  - Please refer to *Travel and Expense Guidelines and Volunteer Expense Reimbursement Form* on which expenses qualify and how to submit for reimbursement. Be sure to save your receipts!
  - Please do not initiate your own bookings or pay out of pocket. Your travel and lodging will be booked by the AHA travel agent and covered by the AHA.
    - **To book your travel:** Irene Redwine from AHA's Travel Desk-World Travel will email you at the email provided in your RSVP.
    - **To book your lodging:** you will receive an email once above travel is booked.

Please send all related questions to your AHA site manager.



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Dear CHANGE AFib Trial Colleagues,

We are pleased you can join us for the CHANGE AFib Investigator Meeting being held in Washington, D.C.! **In order to quickly confirm your travel, below are key action items you need to complete by**

Friday, March 31st COB

Meeting Details:
Date: Tuesday April 25th, 2023
Time: 9:00am – 2:30pm ET
Location: AC Hotel Washington DC Capitol Hill Navy Yard
867 New Jersey Ave SE
Washington, DC 20003

Irene Redwine from *AHA's Travel Desk - World Travel* will be reaching out to you via the email provided in your RSVP to book your travel accommodations. Please reply with questions or concerns.

Please note, the meeting will close in time for most participants to secure transportation home later that evening (4/25). However, we understand that those traveling long distances may need to stay that night and return home the following day.

Items to Note:

- Your travel and lodging will be booked by the AHA travel agent and covered by the AHA. There is no need to initiate your own bookings or pay out of pocket.
- Additional travel expenses (e.g., meals and taxis) will need to be submitted for reimbursement. Attached is the AHA Reimbursement Policy and form; ***make sure to save your receipts!***
- If you are driving yourself to the meeting, we will contact you with instructions for mileage reimbursement.

Keeping in mind the AHA is a non-for-profit organization, we encourage you to help us make the best use of our donor dollars when booking your travel and submitting reimbursement for other travel incidentals.

Please reach out to your AHA Site Manager with any additional questions.
We look forward to seeing you on April 25th!

CHANGE AFib Trial Team
American Heart Association
CHANGEAFib@heart.org

Learn more about CHANGE AFib, the first pragmatic randomized clinical trial in GWTG-AFib.

Mark Your Calendars!

CHANGE AFib Investigator Meeting

April 25, 2022 in Washington D.C.

Next Up

Upcoming Fireside Chats

Tuesday, May 16th @ 1-2pm ET

Monday, June 12th @ 12-1pm ET

CHANGE AFib /

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

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.

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

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Q&A

Thank you & 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.