



# Subject Enrollment Strategy Forum

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# Disclosures

- Cyril Ofori Disclosure:  
None
- Matthew Kalscheur Disclosure:  
None
- Sean Pokorney Disclosure:  
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# Key Objectives

1. Trial Site Characteristics
2. Enrollment Workflows
3. Patient Identification & Trial Engagement
4. Engaging Providers Across the Health System
5. Navigating Treatment Plans & Addressing Comorbidities
6. Subject & Study Drug Retention
7. Q&A





# **Trial Site Characteristics**

**Hospital:** Wooster Community Hospital

**Location:** Wooster, OH

**PI:** Dr. Cyril Ofori

**Study Coordinator:** Erica Stahl, MSN,  
RN, APRN-AGCNS-BC



## Site Characteristics:

- 172 bed, community hospital
- Activated in Trial = April 8, 2022
- DOA Composition: PI & 2 Study Coordinators
- 22 Enrolled Subjects; 68% from OP Setting

**Hospital:** University Hospital - University of Wisconsin-Madison

**Location:** Madison, WI

**PI:** Dr. Matthew Kalscheur

**Study Coordinator:** Emily Sherrick, BS, CMA (AAMA)



## Site Characteristics:

- 515 bed academic hospital
- Activated in Trial = November 22, 2023
- DOA Compositionn: PI, Sub-I and 2 Study Coordinators
- 6 Enrolled Subjects; 100% from OP Setting





# Enrollment Workflows

# Wooster Community Hospital Enrollment Workflows

- **Overall Tactics**

- / Daily Screening: *trial kept at forefront*
  - *AFIB census report of all AFIB Dx pts, RN documentation or AF telemetry rhythm*
- / Continuous team communication
- / Team approach: discuss/review subjects, consent conversations, etc.
- / Peer trial education to units with AFIB pt potential

- **Consent Conversations**

- / Building patient trust and rapport
- / Initial approach by RN
- / Stress medication history (FDA approved) and previous use in providers clinic
- / Involve Family/Spouse
- / Medication interactions and risk assessment





# University Hospital – University of Wisconsin-Madison Enrollment Workflows

- **Overall Tactics**

- / Screening conducted via EMR logic notifying research team via InBasket Message (EPIC EMR)
- / Potentially eligible patients are placed on a shared EMR list for PI review
- / PI confirmation of eligibility triggers message to patient's provider to discuss trial participation.
- / Upon provider permission, outreach to patient is conducted by PI.
- / Research team conducts follow-up to confirm potential study participation and provides additional study information.

- **Recruitment Strategies**

- / EMR Based Workflows
- / Trial visibility reminders and engagement with ED & Cardiology colleagues





# Patient Identification & Trial Engagement



# Patient Identification & Trial Engagement

- Catching ED patients prior to discharge
- Identifying inpatients prior to care plan establishment
  - ✓ Working in OP setting with general cardiology
- Identifying outpatients
- Manual screening practices & leveraging EMRs





# Engaging Providers Across the Health System

# Engaging Providers Across the Health System

- Increasing trial visibility and collaboration with other departments (ED, Outpatient, ICU, etc.)
- Familiarity with Dronedarone amongst non-trial colleagues
- Bi-directional communication between General Cardiology & EPs on treatment plans and subject identification
- Pharmacy Team engagement





# **Navigating Treatment Plans & Addressing Comorbidities**





# Navigating Treatment Plans & Addressing Comorbidities

- Study Drug Interactions, Contraindications & Adverse Reactions
- Renal Function
- Patient's Age
- Bradycardia
- Heart Failure Classifications & AFlutter

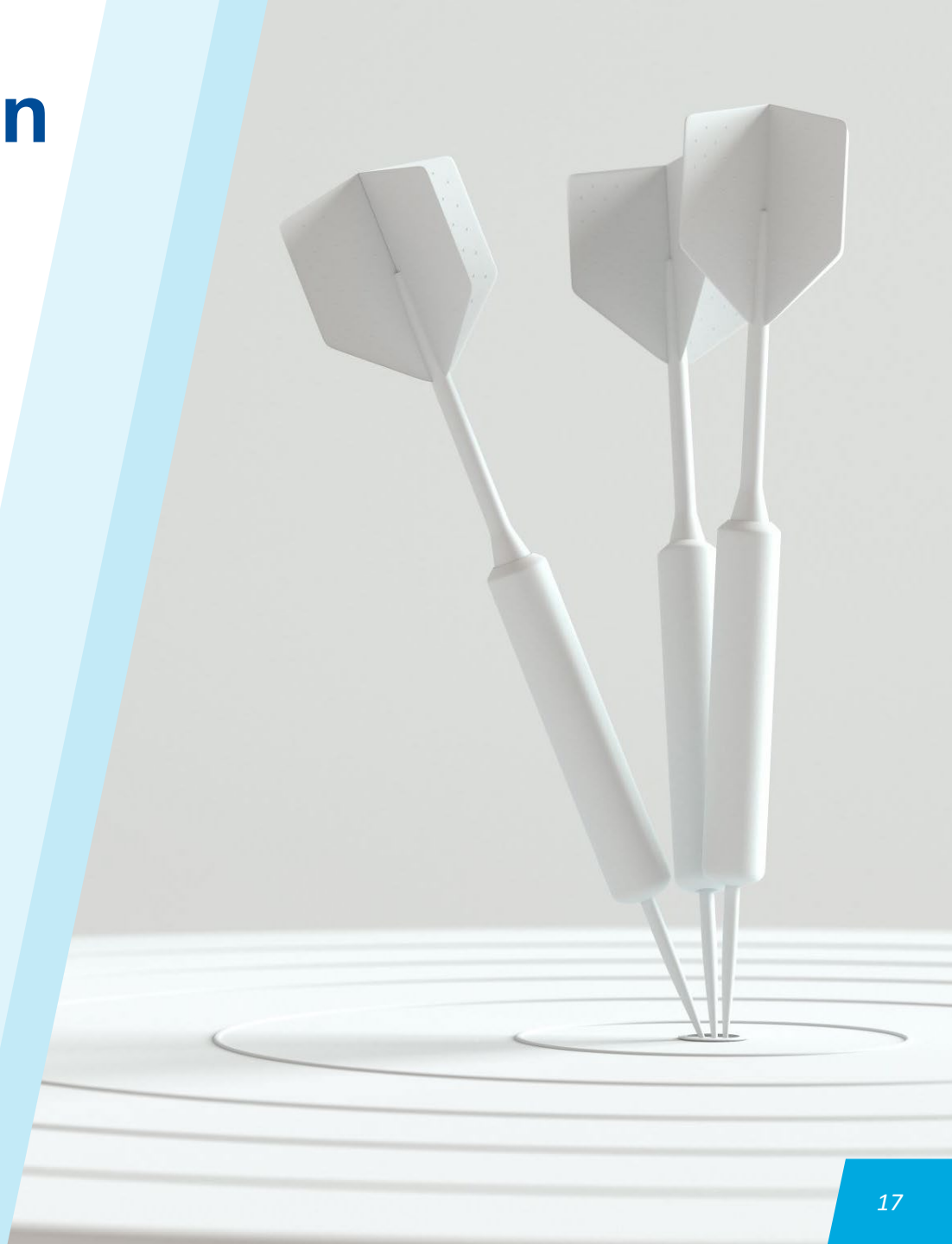




# **Subject & Study Drug Retention**

# Subject & Study Drug Retention

- Open line of communication between subject & research team
- Outreach to subject's treatment teams for continuity of care and study drug retention
- Organizational processes to prevent LTFUs







**Questions from  
the Group?**



## *AFib* / Contact

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**Thank You**





# Appendix

# UW Health: Workflow - BPA

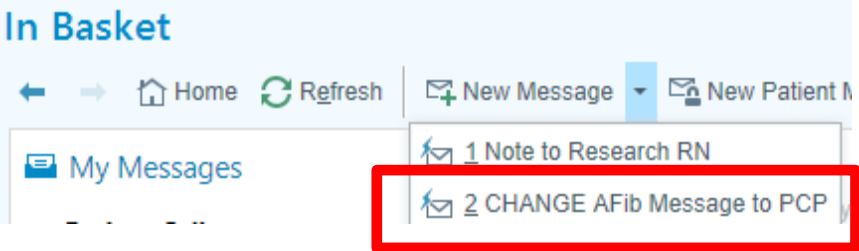
Logic:

(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)

# UW Health: CHANGE AFib – Provider Message



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SmartList

SmartPhrases

Manage Phras...

RESEARCHCH...

Do not include PHI or patient-specific data in SmartPhrases.

Insert SmartText

Insert SmartList

1

2

3

4

Hi \*\*\*,

I hope you are doing well. I'm contacting you regarding a patient you follow in clinic - \*\*\* - and asking if it's okay for us to contact {him/her:25043} regarding a clinical trial.

Your patient was diagnosed with atrial fibrillation after a recent \*\*\*. Because of this new diagnosis, {he/she:30387} is eligible for a trial entitled CHANGE-AFib (<https://changeafib.org/>).

The idea is that AF is progressive. Observational data suggests that earlier rhythm control leads to improved outcomes (less health care utilization, improve symptoms, etc.). The AHA and Duke Clinical Research Institute are running this pragmatic trial to study this idea in a randomized, controlled trial. If a patients choose to enroll, they will be randomized to usually care (rate control + anticoagulation if appropriate) versus early rhythm control (usual care + dronedarone). Outcomes will be tracked through the AHA-GWTG registry and some patient reported outcomes.

Would you be okay with us contacting your patient? I'd be happy to talk with you more about the trial - cell is 608-334-0664 or over email, [mmkalsch@medicine.wisc.edu](mailto:mmkalsch@medicine.wisc.edu).

Thanks!  
Matt

Settings

Name

RESEARCHCHANGEAFIBPCPCONTACT

Description

Populate from Text

Contacting PCP to Ask about CHANGE-AFib

Text Format

Rich Text

Plain Text

SmartLink Text Size and Font

Match Template Formatting

Keep SmartLink Formatting

Synonyms

Sharing

You are an editor

Remove Me

	User	Can Edit?
1	KALSCHUR, MATTHEW M [MXK206]	<input checked="" type="checkbox"/>
2		<input type="checkbox"/>

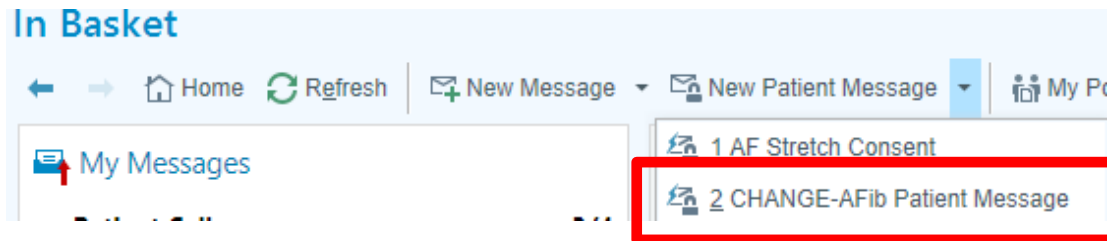
Copy Users

Mark All as Editors

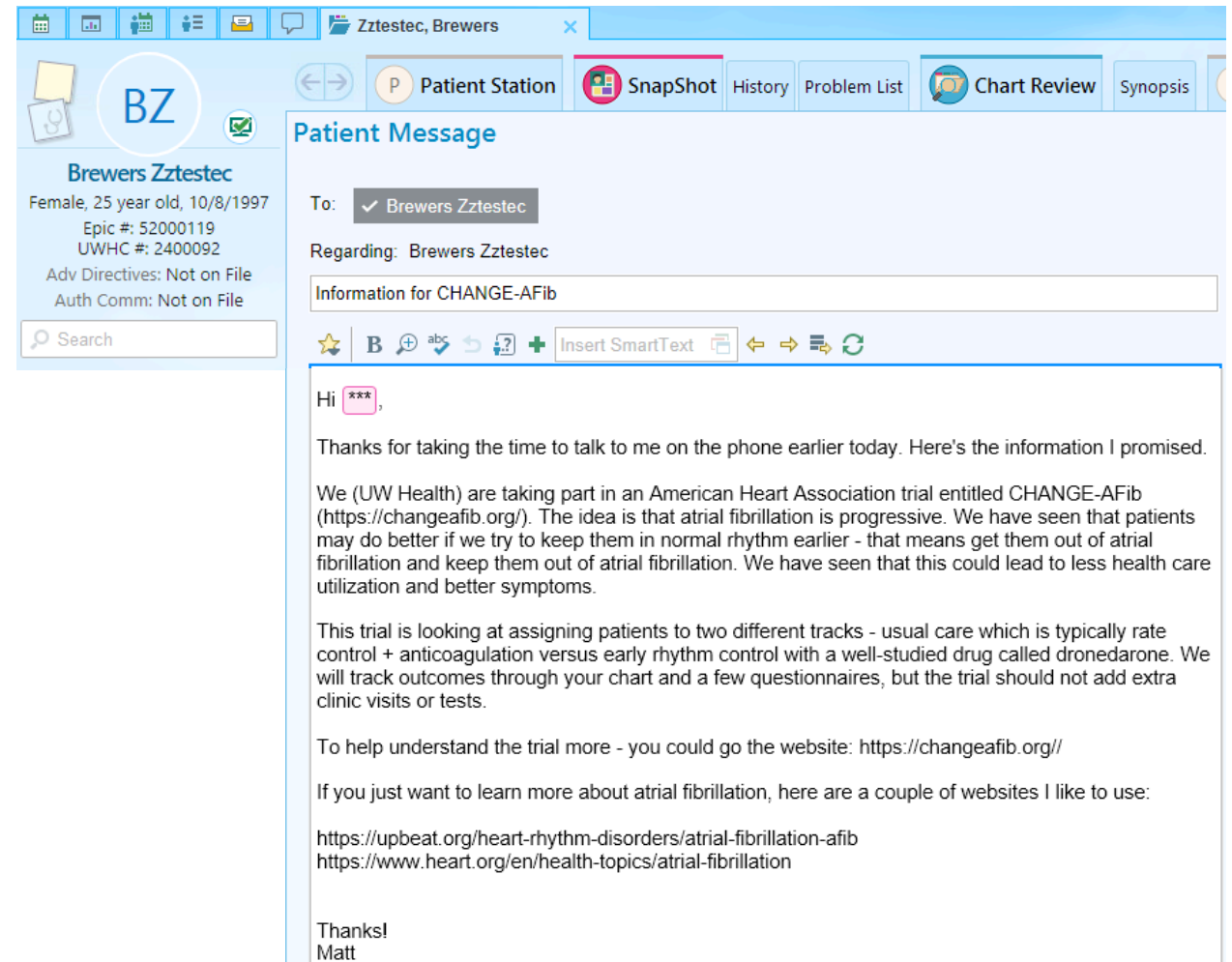




# UW Health: CHANGE AFib – Patient Message



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# UW Health: CHANGE AFib – Shared List



**Patient Lists**

Edit List | Remove Patient | Add Patient | Open Chart | Patient Report | Reports | Sign In | Sign Out | IP Treatment Team | Wrap Text

My Lists | potential CHANGE AFIB 3 Patients | Refreshed 1 minute ago | Search Admissions S...

Patient Name	Last EF	Specialty Comments	Specialty Comments
Zztestec, Andes M	60 % at 03/17/23 1033		needs MK review
Zztestec, Bucks	60 % at 11/04/22 1214		MK Called and sent MyChart, EW to follow-up
Zzzkalscheur, Testpatient1	—		EW LMTCB 3/22

Notes | Orders | Summary | Review | Results Review

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