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

Wooster Community Hospital
HEALTH SYSTEM

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

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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

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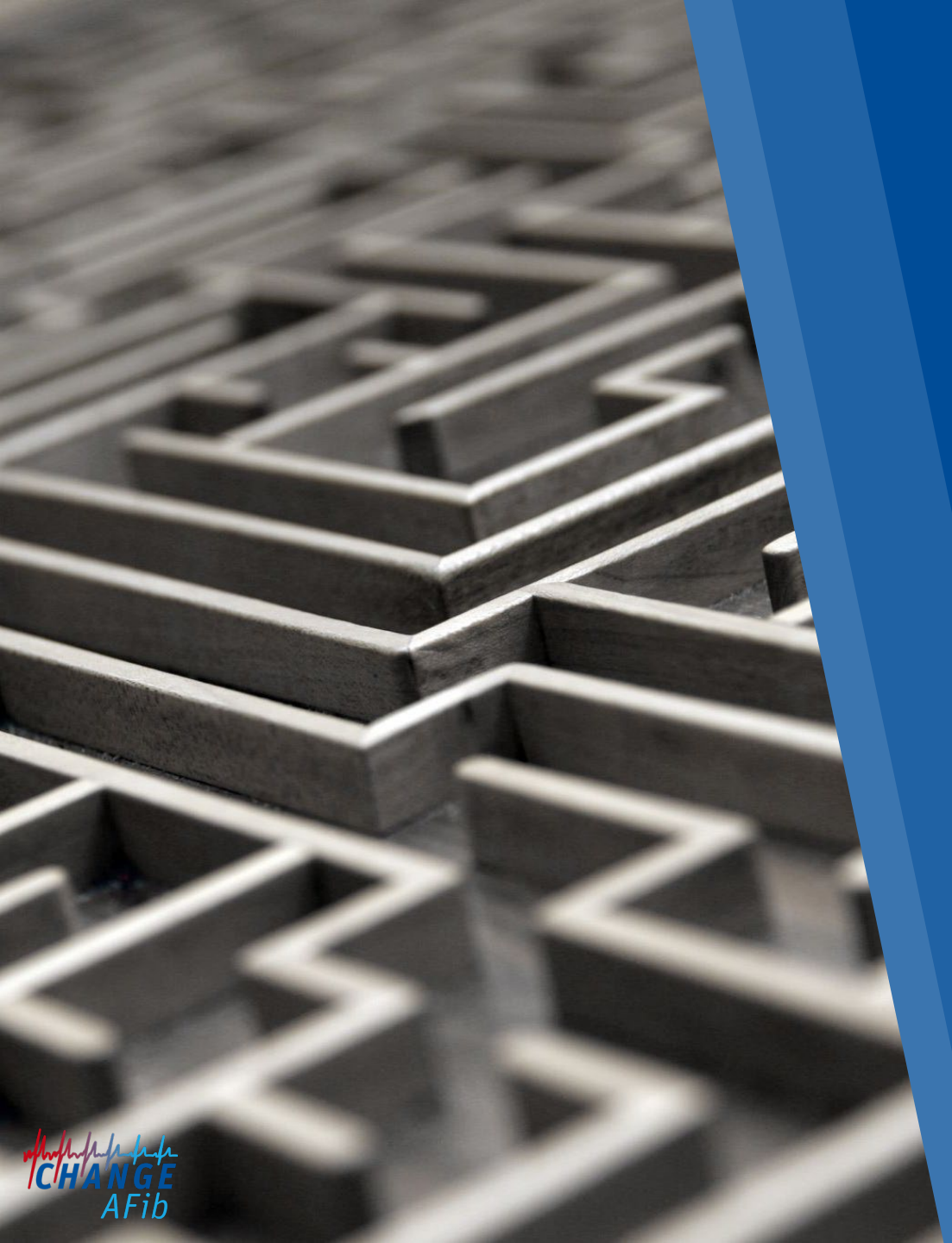
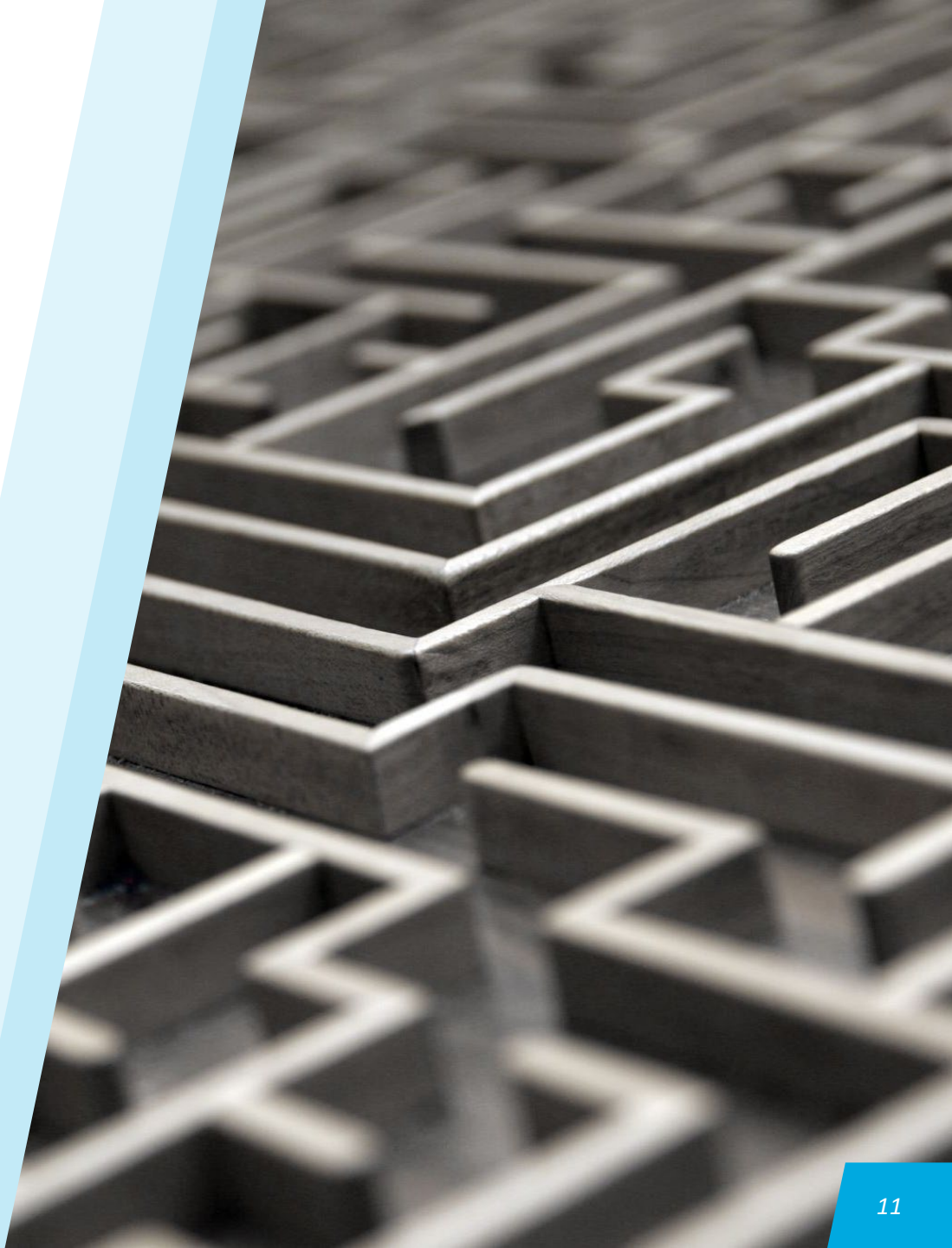


Patient Identification & Trial Engagement

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



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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

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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

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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

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Questions from the Group?

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/ Contact

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Thank You

Appendix

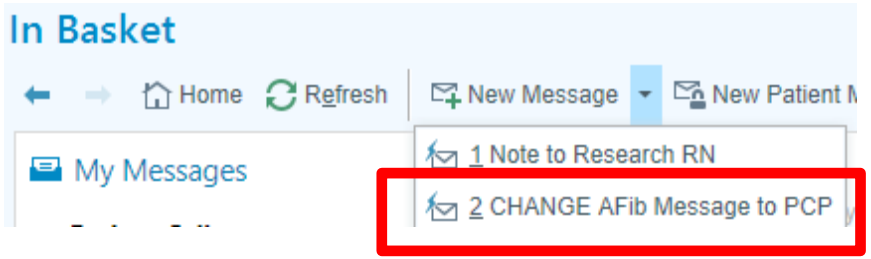
UW Health: Workflow - BPA

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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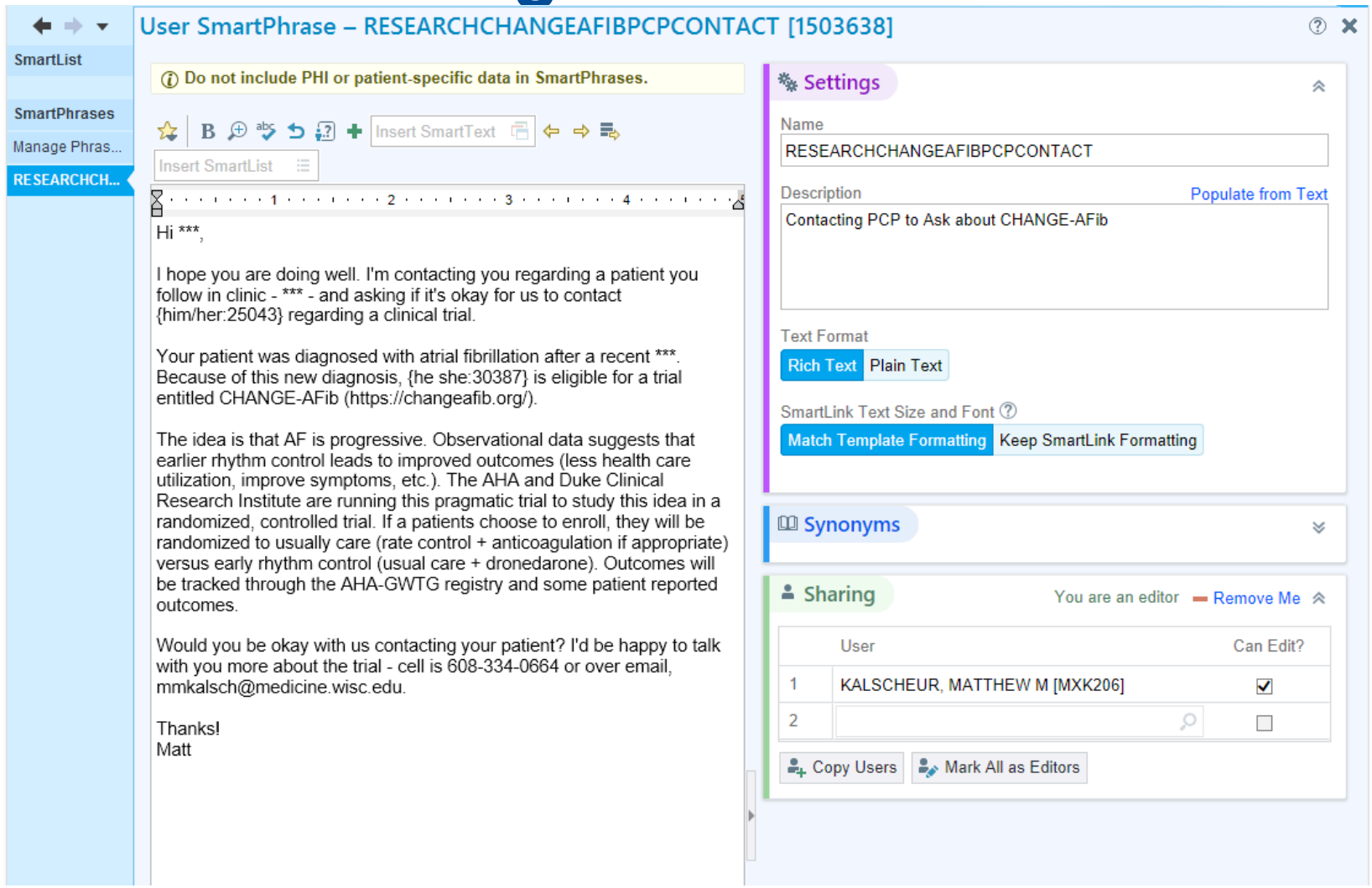

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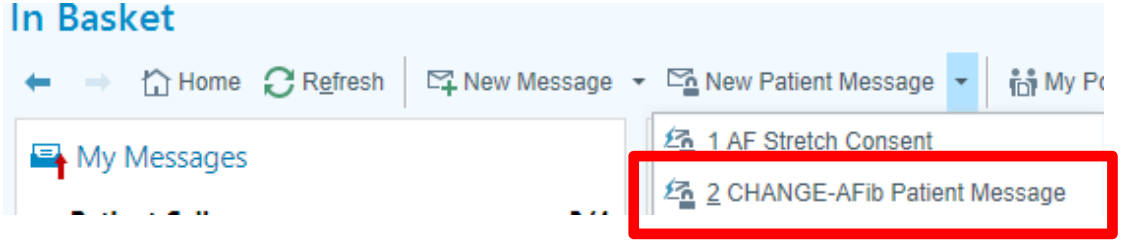
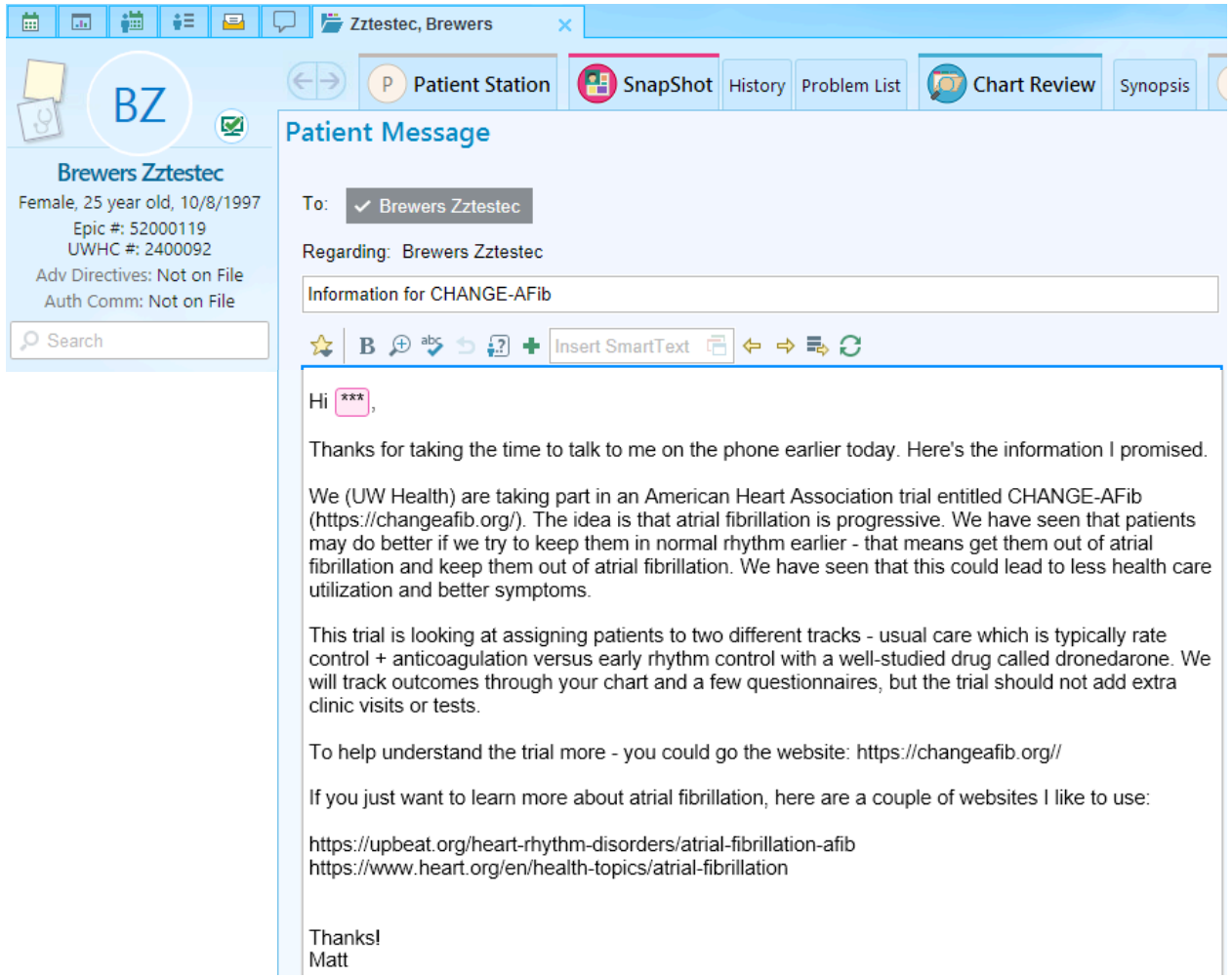
UW Health:
CHANGE AFib – Patient Message





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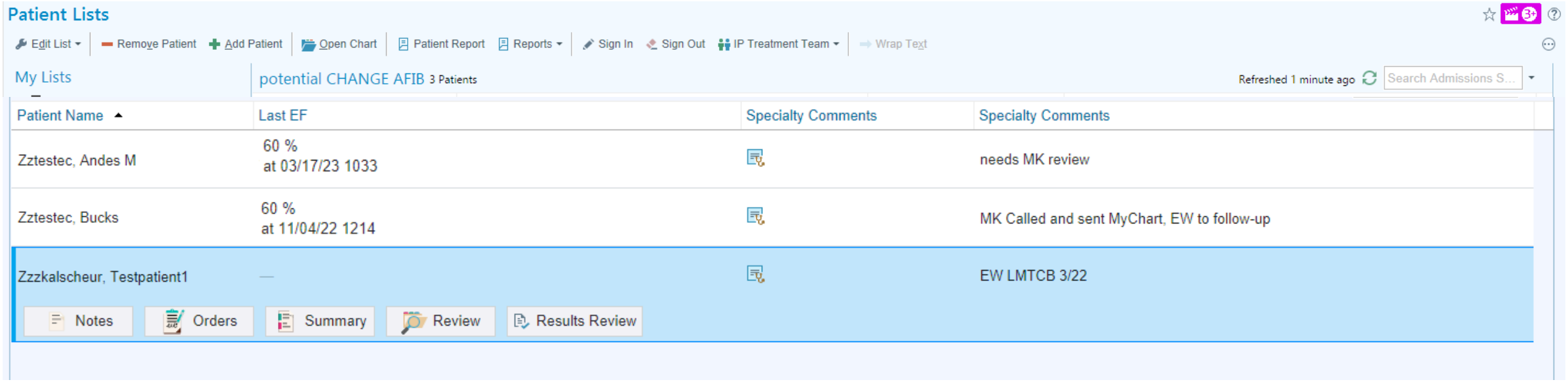
UW Health:
CHANGE AFib – Shared List



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

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