

Rhythm Evaluation for AntiCoagulaTion with Continuous Monitoring of Atrial Fibrillation (REACT-AF): Logistical Considerations for Wearable Device Trials



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MEDICINE

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BACKGROUND

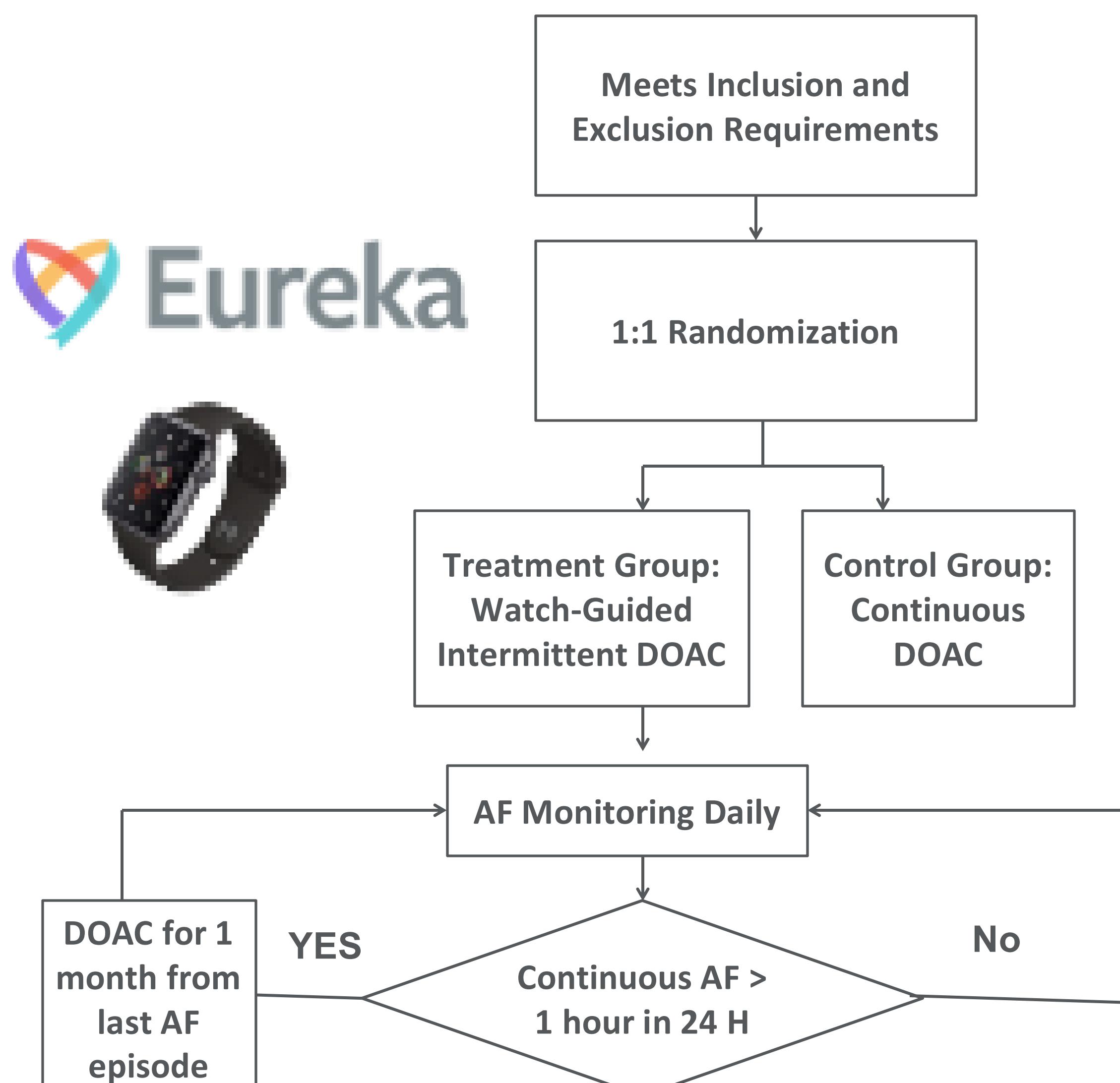
Atrial Fibrillation (AF) is a common cardiac arrhythmia characterized by irregular and rapid heart beats.

- Various factors contribute to the onset of AF.
- Higher incidence is observed in older adults with comorbid health conditions.
- AF significantly increases risk of blood clots and stroke.
- Standard of Care (SOC) for AF is to treat with Direct Oral Anticoagulants (DOACs), which reduce the likelihood of blood clotting. DOACs themselves incur risks, such as internal bleeding.
- Alternative 'pill-in-pocket' anticoagulation approach allows participants to initiate DOAC only when they have a detected episode of AF. DOAC is taken for 30 consecutive days per qualifying AF episode, as detected using Apple Watch and Eureka App.

REACT-AF aims to determine if this pill-in-pocket approach:

- Is non-inferior to the SOC therapy for key composite endpoints including:
 - 1) Stroke;
 - 2) Systemic Embolism; and
 - 3) All-cause mortality
- Reduces major bleeding events compared to the SOC.

STUDY DESIGN



CHALLENGES INVOLVED WITH IMPLEMENTATION

REACT-AF has 86 participating sites throughout the US. This large-scale clinical trial requires careful planning to ensure operations flow smoothly. Below are some challenges that these types of trials may face:

Device Distribution

- Secure storage considerations
- Considerations of insurance costs for study devices
- Timely watch restocks from supplier
- Receiving device attachments, such as charging cables and wall adaptors
- Receiving shipments on campus
- Shipment size (large crates or small, liftable boxes)
- Inventory tracking considerations
- Deciding what will happen with faulty devices - returned vs. disposed of

Device Setup

- Complex set up of Eureka investigational app on watch and iPhone
- Requires high degree of CRC tech-savviness
- Strong internet connection needed specifically where device setup takes place
- Instructions for device set up should be clear, and written for a naive audience
- Adequate budget considerations for tech support needs
- Eligibility requirement for participant to own compatible iPhone
- Planning for software updates

Table 1. Anticipated vs. Actual Time Spent per Week by CC Specialists on Eureka-Related Tasks

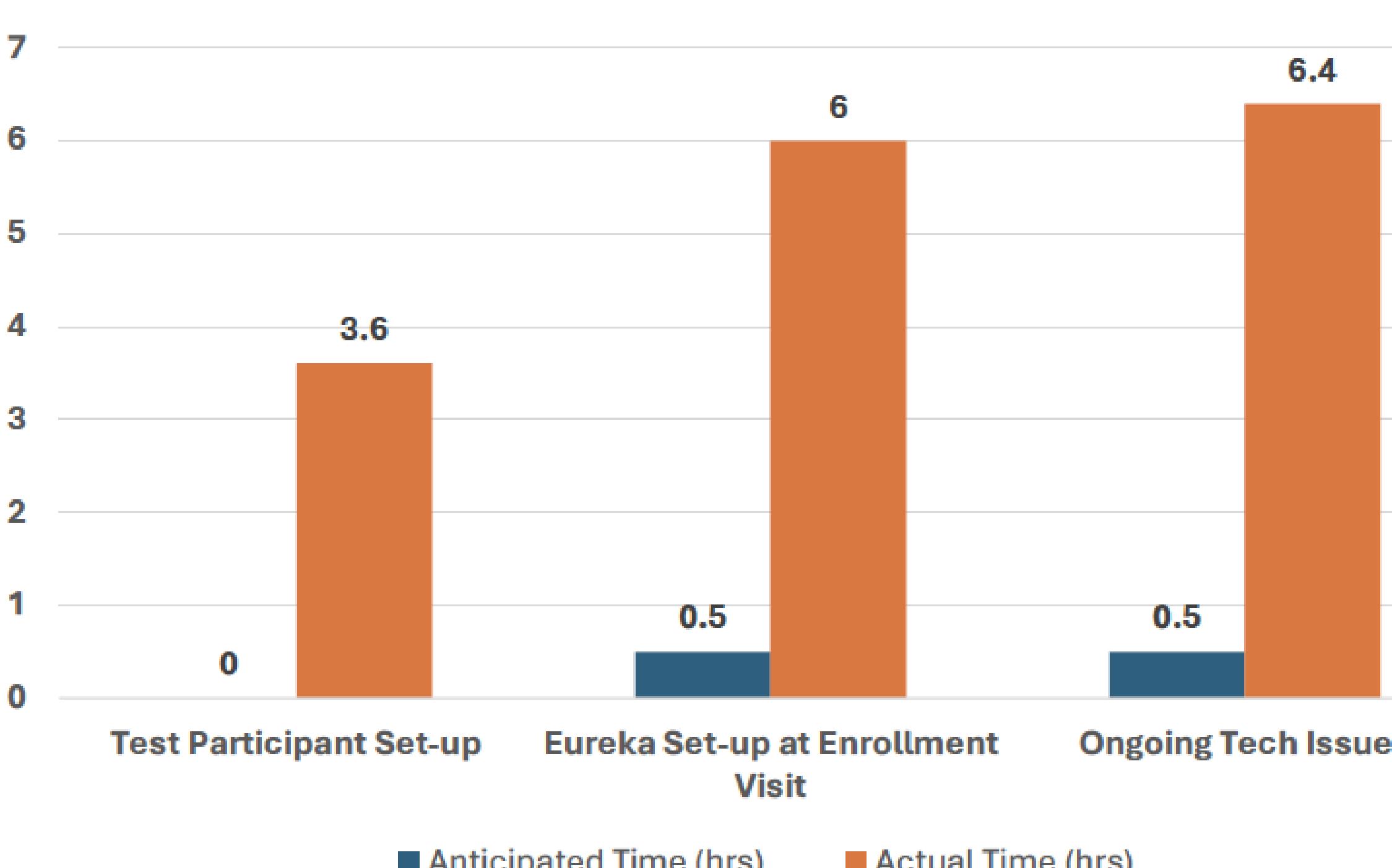
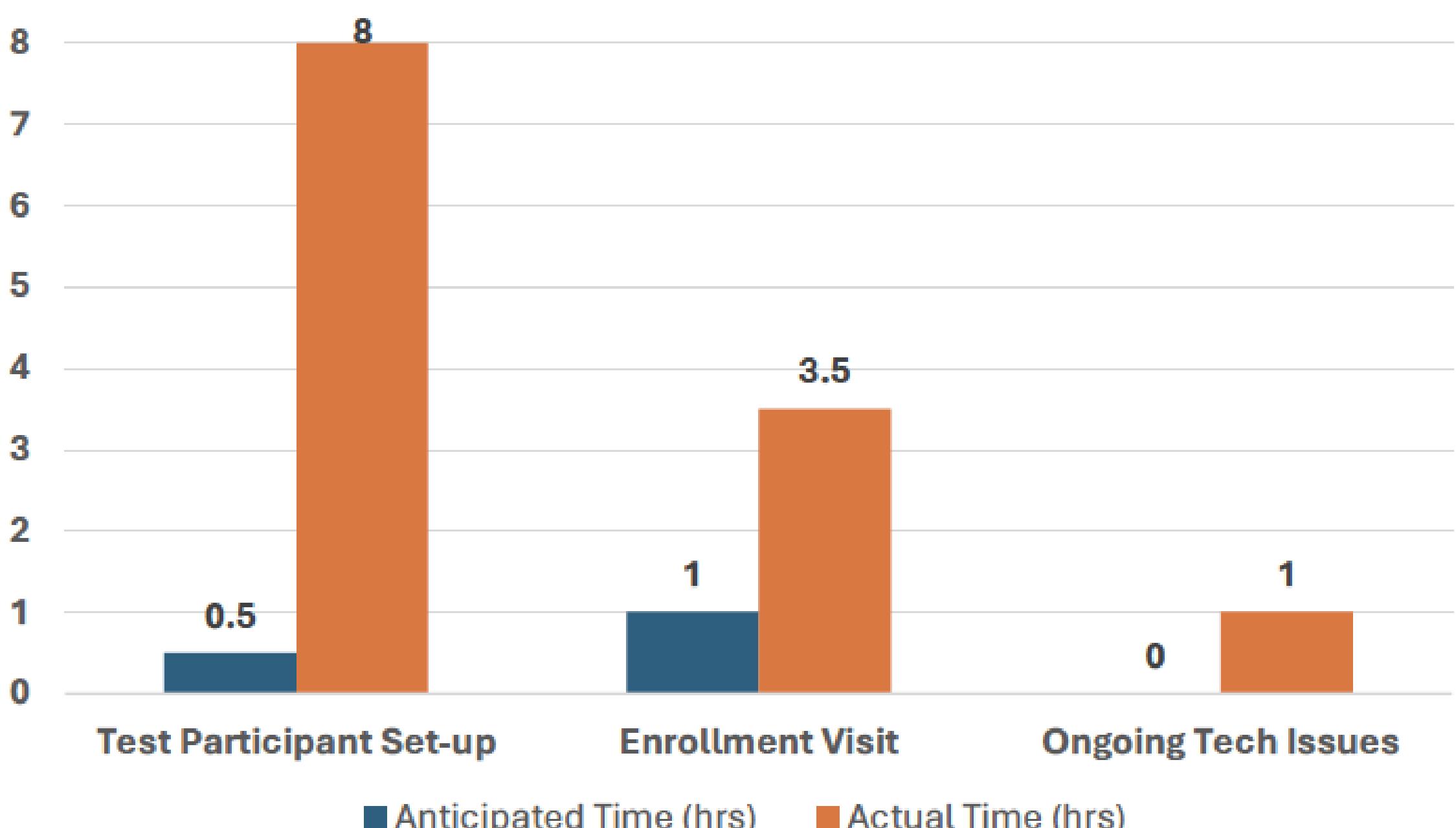


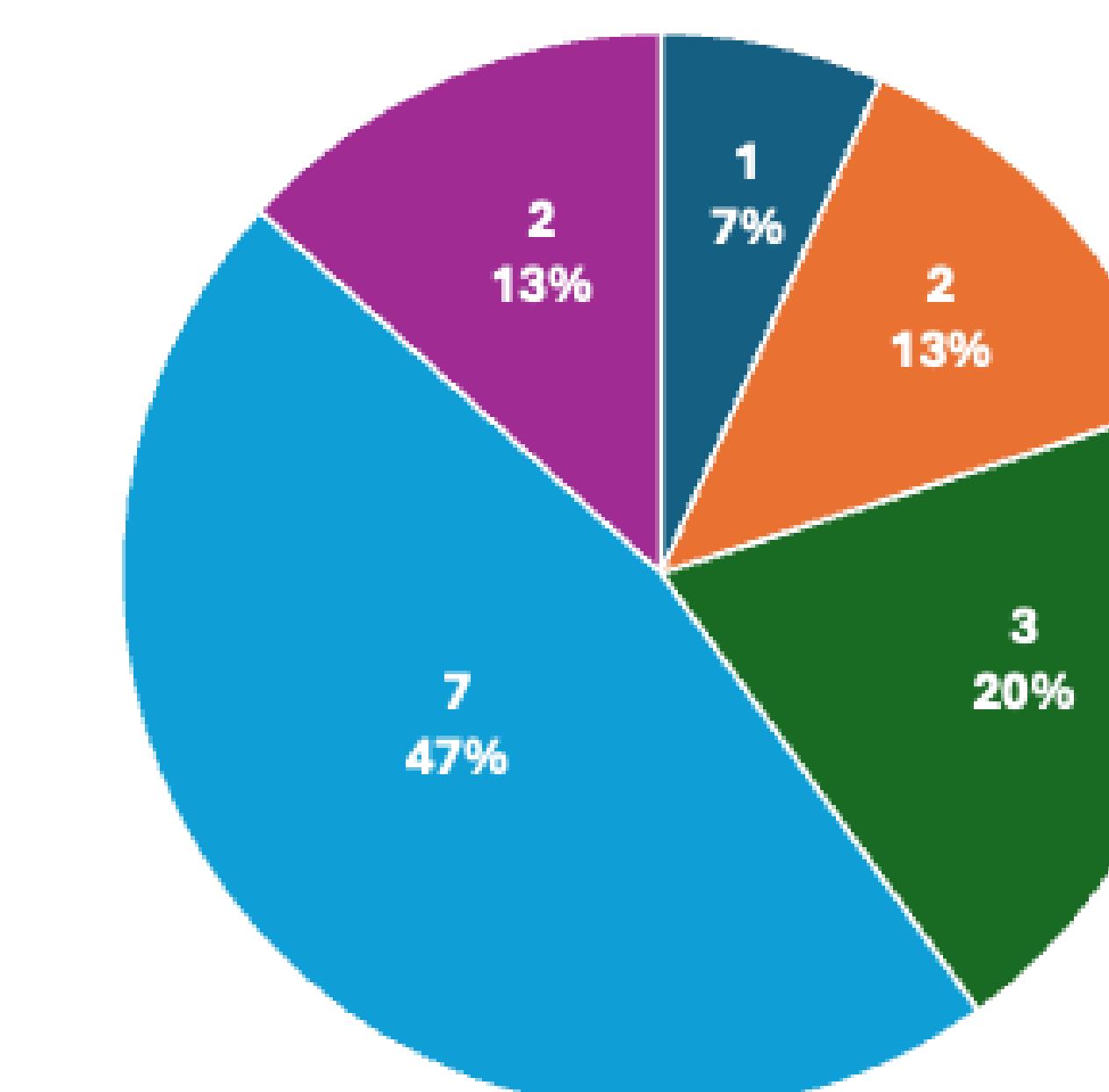
Table 2. Anticipated vs. Actual Time Spent per Week by Site CRCs on Eureka-Related Tasks



Participant Interest / Eligibility

- Challenge to retain participants if randomized to the control group
- Participant age vs. tech-savviness
- Candidates' trust in relying on technology to guide medication regimen
- Participants not having adequate iPhones for eligibility

Figure 1. Screen Failure Rates based on inclusion criteria



- History of non-permanent Afib
- Qualifying CHA2DS2-VASC score
- Participant on DOAC at the time of screening and willing to stay on DOAC for duration of study
- Possession of smartwatch-compatible smartphone
- Willing and able to discontinue DOAC

LESSONS LEARNED

- Establish a measure for tech-savviness for site staff and/or participants
- Funding needs targeted primarily for live tech support and patient education and resources.
- Ease of use for device and study application for patient compliance and trust.
- Use of non-manufacturer-specific devices (Apple and Android-compatible) when possible.
- Early identification and planning for potential technical roadblocks such as internet issues, software upgrades, device phaseout, and app/device troubleshooting support.

COLLABORATORS

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MORE INFORMATION

Curious to learn more?
• <https://reactaf.com>
• clinicaltrials.gov

