Trial Innovation Network Expression of Interest:
ASSERT-AF

Study Title	Insertable Cardiac Monitor for Primary Atrial Fibrillation Detection in High-Risk Heart Failure Patients (ASSERT-AF)
Funding I/C	**N/A, Industry**
Study Description	Patients with heart failure (HF) represent a large population of patients who are at high risk for complications related to undiagnosed atrial fibrillation (AF). However, currently there are limited modalities for early AF detection and subsequent stroke prevention in this high-risk population. An implantable cardiac monitor (ICM) is inserted subcutaneously and can provide long term arrhythmia information via remote monitoring. The ASSERT-AF study seeks to accurately define the burden of AF and other arrhythmias in high-risk HF patients using an ASSERT ICM.
Study Design	Study Type: Interventional, Primary Purpose: Prevention, Study Phase: N/A Interventional Study Model: Parallel Assignment, Subjects will be randomized in a 2:1 fashion to undergo implant of an ASSERT. ICM implant with remote monitoring and symptom-triggered mobile app transmissions versus conventional follow-up without an ICM. Randomization will be stratified by the degree of LV dysfunction to ensure balanced enrollment of HF subjects with mild LV dysfunction (LVEF = 36%-49%) and those with preserved LVEF (≥ 50% [i.e. heart failure with preserved ejection fraction -HFpEF]). Number of Arms: 2, Masking: Single (Outcomes Assessor), Events Review Committee: A blinded three-member Events Review Committee will review de-identified source documents obtained from each of the enrolling sites that will only be labelled with a subject ID. No data will be provided indicating the randomized treatment arm to the study and appropriately redacted with no ICM data provided. The information will be used to determine the nature of any clinical and adverse events. Available medical records and source documents will be used to determine cause-specific mortality.
IRB	The University of Rochester's Research Subjects Review Board (RSRB)
Coordinating Center	The University of Rochester
Study Length	5 years, participant duration 24 months
Study Enrollment #	477
Eligibility Criteria	**Inclusion Criteria** • Age ≥ 18 years (no upper age limit) • HF exacerbation requiring initiation or augmentation of decongestive therapy in a hospital setting (hospitalization or emergency department visits) during the past 24 calendar months prior to consent date OR current treatment with loop-diuretics (furosemide, bumetanide, or torsemide). • LVEF > 35% on a cardiac imaging study (echocardiogram, nuclear imaging, cardiac magnetic resonance imaging) performed during the past 24 calendar months prior to consent date • One or more FDA-approved indications for an Abbott ICM (unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias) • Willing to undergo an Abbott ICM implant and agree to remote ICM monitoring **Exclusion Criteria** Existing implantable cardioverter defibrillator or pacemaker • Known or documented history AF or atrial flutter any time in past • Has had a heart transplant. • Participation in other clinical trials (observational registries are allowed with approval from the Coordination Center) • Unable or unwilling to follow the study protocol • Unable or unwilling to sign the consent for participation
Total # of Sites	30

Site Requirements	<u>Study sites will need to have the following at their site to be considered:</u> • Age ≥ 18 years (no upper age limit) • HF exacerbation requiring initiation or augmentation of decongestive therapy in a hospital setting (hospitalization or emergency department visits) during the past 24 calendar months prior to consent date OR current treatment with loop-diuretics (furosemide, bumetanide, or torsemide). • LVEF > 35% on a cardiac imaging study (echocardiogram, nuclear imaging, cardiac magnetic resonance imaging) performed during the past 24 calendar months prior to consent date • One or more FDA-approved indications for an Abbott ICM (unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias) • Willing to undergo an Abbott ICM implant and agree to remote ICM Monitoring Additional: • Patient Population: The site should have access to a sufficient number of potential participants who meet the study's inclusion and exclusion criteria. • Adequate Facilities: The site should have the necessary facilities to conduct the study, including examination rooms, storage for study files, and ability to conduct remote visits. • Responsive Communication: The site should be responsive and maintain clear communication with the study's coordination center.
Site Invesitgator Qualifications	<u>Site Invesitigators should have the following:</u> • Research Staff: The PI should have a dedicated research team, including atleast 1 study coordinators. • Regulatory Knowledge and Compliance: The PI and their team should be trained in Good Clinical Practice (GCP) guidelines and be willing to adhere to regulatory requirements. • Communication and Collaboration: Prompt and clear communication with the ability to meet atleast 1x per month with the coordination center's staff to review site status. Willingness to collaborate and adhere to the protocol requirements and timelines.
Key Timeline Dates:	<u>The following dates are projections and subject to change:</u> **Site Selection Decisions**: August, 2024 **Site Selection Notifications:** August, 2024 **Enrollment begins: Ongoing-**The study is actively enrolling. The enrolling center may commence enrollment soon after they undergo and complete the onboarding process. **Last Patient/Last Visit:** Last Visit: 06/30/2025 **Study Closure:** 12/31/2025