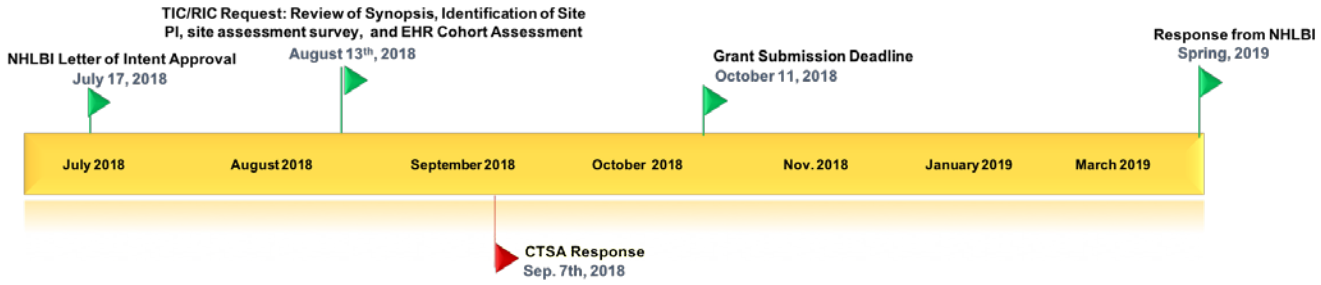
CTSA Engagement Packet

Study Title	Rhythm Evaluation for AntiCoagulaTion for Atrial Fibrillation (REACT-AF)
TIC POC	Johns Hopkins/Tufts Andrew Mould: wmould1@jhmi.edu
RIC POC	Sarah Nelson: Sarah.j.nelson@vumc.org
Date of Request	August 13, 2018
Requesting Institution/ Principal Investigator	Northwestern University Dr. Rodd Passman
Therapeutic Area	Cardiology
Funding Status	Pre-application
Project Status	Submission to NHLBI October 2018
Anticipated Number of Sites	100-120
Population Size	5000
Is there a proposal timeline available?	Yes
Does this packet include a request for **Site-level Investigator**?	Yes
Does this packet include a request for **Budget Review**?	No
Does this packet include an **EHR Based Cohort Assessment**?	Yes
What is the response **due date**?	September 7, 2018



RECRUITMENT INNOVATION CENTER

EHR-Based Cohort Assessment Request

General Information and Instruction Package
CTSA Liaison Teams and Informatics Representatives

Rhythm Evaluation for AntiCoagulaTion for Atrial Fibrillation (REACT-AF)

Protocol Summary	***Purpose.*** The purpose of the Rhythm Evaluation for Anticoagulation with Continuous moniToring of Atrial Fibrillation (REACT-AF) clinical trial is to compare continuous novel oral anticoagulation (NOAC) versus targeted NOAC using an AF-sensitive smartwatch to guide therapy for patients with non-continuous atrial fibrillation (AF). To assess the role of AFSM guidance in the use of NOAC in patients with infrequent AF episodes, the primary endpoints will measure the rate of stroke, arterial embolism, cardiovascular or unknown death, and major bleeding. If proven safe and beneficial, intermittent AFSM-guided NOAC treatment may reduce bleeding events and maintain stroke protection in AF patients compared with continuous NOAC. ***Design.*** REACT-AF is a prospective, unblinded, randomized (1:1 allocation), multi-center, investigational, clinical trial. Subjects randomized to the treatment arm (AFSM-guided NOAC) will take their NOAC for 30 consecutive days if a qualifying AF episode is detected by their device. A qualifying AF episode is defined as continuous AF ≥1 hour in duration. If a subject is already taking a 30-day course of NOAC and experiences a new qualifying AF episode, the NOAC course will be extended for an additional 30 days. Subjects randomized to the control arm (continuous NOAC) will continuously take their NOAC throughout the course of the study. All subjects will be followed for 30 months. Roughly 6,000 subjects will be enrolled in the study to ensure 5,260 randomized subjects.
Investigator Team Information	(PI) Dr. Rod Passman, Northwestern University
Project Status	Submission to NHLBI October 2018
Funding Status	Pre-application
Expected Number of Sites	100-120
Response deadline	**September 7, 2018**
General Contact Information for Study Related Questions	Andrew Mould | wmould1@jhmi.edu
Informatics Team Contact for EHR-based Cohort Assessment	Sarah Nelson | sarah.j.nelson@vanderbilt.edu
Instructions for EHR-based data interrogation	Please see included algorithm to be run at your site Respond at: https://redcap.vanderbilt.edu/surveys/?s=HJEF8NHP7T
Instructions for PI and Site Assessment Survey	If interested, please respond at: https://jhmi.co1.qualtrics.com/jfe/form/SV_6RynwaRmsQirmPX