Project Charter

ADVANCED CARDIAC THERAPIES IMPROVING OUTCOMES NETWORK

A. General Information	
Project Title & Project #:	"My ACTION Tracker" – Wearables in Pediatric Heart Failure
Department/Division/Team:	ACTION-Heart Failure
Population:	Pediatric heart failure patients Inclusion criteria: 1) ≥13 years old 2) Heart failure due to cardiomyopathy or congenital heart disease (1 or 2 ventricle), with or without VAD. 3) Enrolled in ACTION ADHF or VAD Registry 4) Patient owns iPhone to pair with ACTION-provided or personal Apple Watch. (If patient has an Android phone, they must have their own wearable device: Garmin, Fitbit or Google Pixel.) 5) Willing to wear wrist wearable for 4 weeks total while awake (charge while asleep). Exclusion criteria: 1) Unable to utilize wearable technology due to physical or cognitive impairment 2) Unable to ambulate independently 3) Patient does not own an iPhone or an Android + wearable. Enrollment target: 20 patients Cohort will be followed for 4 weeks.
Brief Project Description (AIM):	PRIMARY AIM: To evaluate the feasibility of collecting HR and activity data from pediatric patients with severe heart failure and/or VADs using a smart watch or activity tracking device. SECONDARY AIM: To establish the relationship between physiologic data collected by wearable smartwatches (total daily step count, resting heart rate, and heart rate variability) patient reported outcomes in pediatric heart failure patients. SECONDARY AIM: To establish the relationship between inter-individual differences in physiologic data collected by wearable smartwatches (total daily step count, resting heart rate, and heart rate variability) and adverse heart failure events in pediatric heart failure patients (ICU admission, need for inotropic support, VAD, transplant listing or death).
Measures:	Data collection: • Ensure patients are consented for ACTION, including initialing their agreement to participate in this specific project (included in the general ACTION consent). • Ensure patients are enrolled in ACTION ADHF and/or VAD registry.

	• Patients can use their own wrist wearable: Apple Watch, Garmin, Fitbit, or Google. • ACTION can provide Apple Watch for patients with an iPhone who do not have their own wearable. • Ensure wearable is paired with their smartphone. • Download the MyDataHelps app to their smartphone and follow prompts. • See the "Patient & Provider Handouts" for more information. Patient will wear wrist device 4 weeks continuously while awake (charge while asleep). Programmed alerts will encourage wearing of wearables. <u>Data Variables and Surveys:</u> • MyDataHelps will automatically collect daily steps, HR data and other available health data* from the wearable. • Participants will be prompted by the MyDataHelps app to complete the following surveys: 1. PROMIS 7+2 (at enrollment and weekly for 4 weeks – 5 surveys total). 2. Question regarding acceptability of wearable devices will be collected 7 days after enrollment and each week thereafter until the end of the study. 3. Visual Analog Scale (M, W, F = 12 total check-ins). If their response is ≤5, they will be prompted to fill out the HF Symptoms checklist. Sites should continue data entry in ACTION registries (per usual): ACTION ADHF project forms (REDCap) (or) ACTION VAD registry forms (Simplified Clinical) <u>Ending Data Collection & Study Participation:</u> • Wearable study will end after 4 weeks. • To **deactivate a patient** that is enrolled in the project after 4 weeks, or upon request from the patient prior to the completion of the 4 week period, complete the "Coordinator Withdrawal Survey" in MyDataHelps. This will stop the data collection and distribution of the surveys to the patient but will keep the data in the platform. **Other health data to include steps covered, distance walked/ran, running/walking speed, resting energy burned, number of times fallen, active energy burned, flights of stairs climbed, VO2 max, exercise time, stand hours, resting HR, walking HR average, HR variability, time in bed, time asleep, respiratory rate while asleep, number and duration of patient-initiated 'workouts' on the watch.*
Prepared By:	David Peng, Aine Lynch, & Lauren Smyth
Date:	February 20, 2025
B. Project Background:	

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Pediatric heart failure is a significant, burdensome, and complex condition associated with high morbidity and mortality. The estimated incidence of heart failure is 0.9-7.4 per 100,000 children.[1] Each year in the United States, tens of thousands of children are admitted for heart failure with an in-hospital mortality of 7%.[2, 3] In children with congenital heart disease admitted with severe heart failure requiring at least intravenous inotropes, in-hospital mortality climbs to 26%.[4] For the sickest children on the waiting list for a heart transplant, 22% will die before a donor organ becomes available.[5] Managing end-stage heart failure in children is particularly challenging due to the paucity of pediatric-specific data and evidence. There are limited tools and scoring systems available to monitor and assess disease severity and functional status in pediatric heart failure.[6, 7] Traditional practice is driven by brief, infrequent encounters and imprecise, biased recall that may not accurately or wholly reflect a patient's clinical status, trajectory, and risk. In order to improve quality of life and outcomes, it is important to better understand and characterize children in heart failure and in the hopes of earlier identification of, and intervention for, children at high or worsening risk of decompensation.

Adult heart failure studies have demonstrated that digital biomarkers from wearable or implantable sensor technologies may help identify patients at greater risk, predict clinical decompensation, and prevent heart failure exacerbations.[8-10] In adult heart failure patients, physical inactivity is associated with higher all-cause mortality and exercise-based cardiac rehabilitation may reduce hospital admissions and improve health-related quality of life.[11, 12] The ability to accurately, regularly, and closely monitor a child's physiologic and activity data may improve the assessment of the child's health status, adequacy of therapies, and identify areas of potential intervention and improvement.

Wearable technologies have rapidly advanced in recent years. On-person devices of reasonable cost and portability are now able to capture a significant amount of physiologic and activity data and may facilitate interventions, presenting opportunities to improve care in heart failure.[13, 14] However, we do not yet know if and how the technology can be optimally adopted and utilized in children with heart failure. We propose a novel prospective, observational, multi-center cohort study using a customized, smartphone app connected with wearable device to demonstrate feasibility of collecting biometric health data of children with severe heart failure and correlating the data with patient reported and overall heart failure outcomes.

D. High-Level Timeline/Schedule:

Pilot Project 2022-2024:

- The pilot project for wearable device data collection via Apple watches was conducted from 2022 to early 2024 (5 patients enrolled and studied during this time).
- Pilot included the build and use of ACTION's own App to sync with patients' Apple watches and collect data.
- Barriers/challenges identified and leadership decision to move platforms

MyDataHelps Launch 2025

- The MyDataHelps platform will launch early 2025 to all sites in ACTION with an active IRB/DUA.

E. Communication & Expectations:

ACTION sites will be invited to participate in the relaunch of this study. Training and onboarding sessions will be available to onboard teams and providers to the project, and materials will be distributed to help with onboarding, enrollment, and study facilitation. Baseline and follow-up clinical variables will be entered by sites into ACT-HF and ACT-VAD Registries and linked to MyDataHelps data by the DCC.

F. Project Risks & Mitigation:

Risk	Level (high/med/low)	Mitigation and Escalation Strategy
Workload burden for staff	Med	Simplify data collection on tool and minimize required data entry
Technical challenges of using and collecting patient data using Apple Watch & other wearable devices	Med	ACTON DCC monitor enrollment and data collection on a regular basis ensuring all processes are operating as planned

Patients not wearing device or forgetting to charge device	High	Weekly survey question will be sent to enrolled patients asking about their ability to wear the device over the previous week and patients will be reminded to charge their devices

G. Roles and Responsibilities	
Sponsor/Champion: Provides overall direction on the project.	
Name	**Title/Role**
Angela Lorts, MD	Sr. Leader Sponsorship of Project
Project Leader: Leads the team and provides guidance on scope of the project.	
Name	**Title/Role**
David Peng, MD	Project Leader
Aine Lynch, MD	Project Leader
Kevin Hall, MD	Project Advisor
Project Support (QIC/QOM/Data Analytics/Project Manager Support): Leads in the planning & development of the project; manages the project to scope and/or provides data analysis and reporting expertise for the project.	
Name	**Title/Role**
Lauren Smyth, MHA	Project Management & Support
Nikita Orwick, MHA	Project Support
Toni Duganiero, MPA	DCC Support
Harish Gureddygari, Developer II	DCC Support
Family/Patient Representative:	
Name	**Title/Role**
Melissa McQueen	Parent Leader
Joseph Hillenburg	Parent Leader

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