Wearables
For Providers

Heart Success Failure

Specific AIMS

Primary AIM

1. 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 AIMs

1. 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 and clinical status in pediatric heart failure patients.

2. 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).

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.

NOTE: Please make sure the patient you are enrolling is consented for ACTION, including their agreement to participate in the wearables project specifically.

Measures

Initial cohort will be followed for 4 weeks total.

The MyDataHelps platform will:

- Collect HR, activity and other available health data* from the wearable.

Prompt patient to complete three brief surveys:

- Weekly Check-in Survey (every Monday, Wednesday, Friday) – ~12 check-ins total, depending on the day of the week the patient is enrolled

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- PROMIS Survey (at enrollment and once a week) – 5 surveys total
- Weekly question regarding wear of the device (begins 7 days after enrollment) – 3 questions total

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-intiated 'workouts' on the watch.

Wearables Enrollment and Installation Guide

Fill out REDCap and fill in obtained ACTION ID below:

1. Open Heart Failure Registry within REDCap
2. Check to see if patient is already enrolled in the Registry
   - If yes, » find the patient and open the entry form
   - If no, » start a new patient record and open the entry form
3. Complete the form, including the Wearables section under **'ACTION Studies'**
   - If patient is a VAD patient, please still fill out the initial HF form to obtain the ACTION ID. All data will be subsequently entered into Simplified Clinical. Please keep Simplified Clinical up to date. You will receive a prompt at one month (the end of the Wearables study).

Participant Responsibilities

This study will last **4 weeks.** We ask that you/your patient follow these steps:

- Instruct your patient to fully charge their Apple Watch before pairing.
- Make sure to pair the Apple Watch to your patient's iPhone using the "Watch" app.

- Instruct patient to fully charge their Apple Watch while they sleep and put it on each morning. Remind them to wear it as much as possible. The data collected will automatically be sent to their heart team and ACTION.

- Please remind the patient to be connected to a WIFI network known to their phone at least every other day.

- The MyDataHelps platform will send them notifications for brief surveys about how they are feeling. Please ask them to answer those questions so their care team will receive their responses.

It is important to let your patients know that MyDataHelps does NOT alert your or their heart team automatically to changes in their health. If they have ANY questions or concerns, they need to contact you or their care team right away or go to their closest hospital.

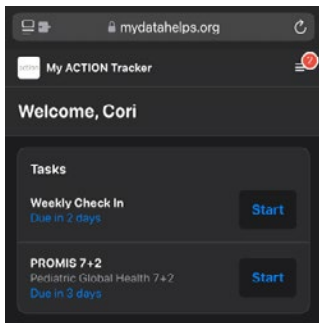## Enrolling Patients in the MyDataHelps Platform
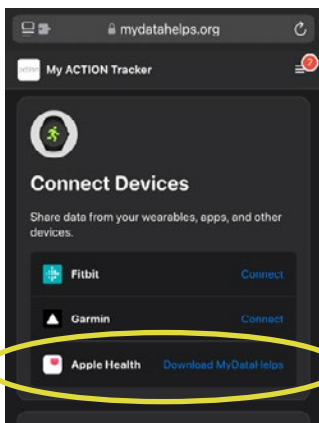
Instructions for Patients

Using the Patient's smartphone, have them scan the QR code to enroll.
https://mydatahelps.org/e/VHVVVK

Have your patient enter their **email** OR **phone number,** this will become their MyDataHelps Username.

Patients must complete their registration by entering their name, DOB, contact information, and hospital.
Next, click **'Done'.**
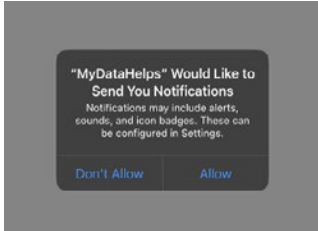
Have your patient complete the **'Tasks'.**
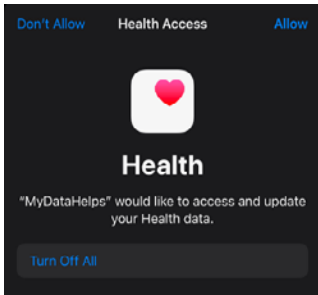
Download and Access MyDataHelps App

If using Apple Watch/IPhone—under Connect Devices, click **'Download MyDataHelps'** to connect to Apple Health or download the MyDataHelps app from the Apple App Store or Google Play Store.
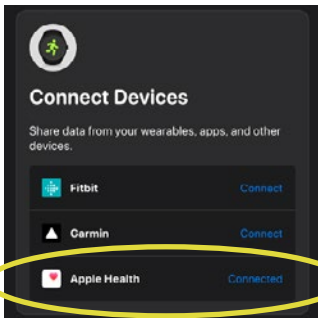
Open the MyDataHelps app on your iPhone and login to MyDataHelps (again) using your username and password (above).

On the Notifications screen, click **'OK'.**
In the 'Would Like To Send You Notifications' pop-up window, click **'Allow'.**

Allow 'MyDataHelps' to access and update your health data, Click **'Turn On All'.**
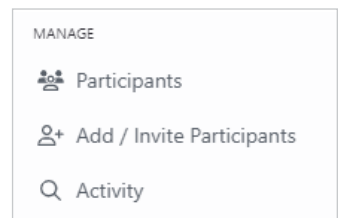Click **'Allow'** in the top right corner.

Make sure Apple Health is **Connected.**
*Note: If you are using Fitbit or Garmin instead of Apple Watch, click the link to **Connect** next to those apps.*

Accessing Your Patients' Data

For back-end user access to your center's *MyDataHelps™ Designer* platform, please contact ***ACTIONDCC@cchmc.org.***
You will be able to see your patients' data, but you will not be able to export and download it. ACTION DCC will download and share center-specific data on a regular basis.

Steps to View Survey Responses and Wearables Data for your Center

1. **Log in:** Open the *MyDataHelps™ Designer* platform *(designer.mydatahelps.org)* and log in using your credentials.

2. **Navigate to the Participants Section:** On the left sidebar, click on **'Participants'** to access the participant overview page.

3. **Review Participant Data:** The list displayed will automatically show participants associated with your center. Browse through the list to view the data of participants.
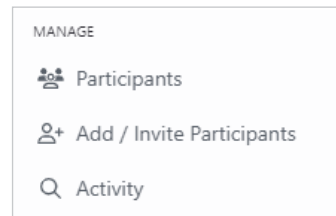

MANAGE

👥 Participants

👤+ Add / Invite Participants

🔍 Activity

Review Participant Data

4. **View Detailed Participant Information:** Click on any participant's record to see more detailed information specific to that individual.

5. **Export or Analyze Data:** If needed, use the available tools within *MyDataHelps™ Designer* to view **Task List, Survey Results,** or more.

⊕ Support	🗓 Task List	☰ Survey Results	📇 Participant Info	⬆ Auxiliary Data	📊 Reports	✉ Notifications

Steps to De-Activate a Patient/Caregiver

1. **Log in:** Open the *MyDataHelps™ Designer* platform *(designer.mydatahelps.org)* and log in using your credentials.

2. **Navigate to the Participants Section:** On the left sidebar, locate and click on **'Participants'** to access the list of all participants.

3. **Select the Participant:** From the list of participants, find and click on the record of the patient you wish to deactivate.

4. **Open the Withdrawal Survey:** At the top of the participant's record, click on **'Coordinator-Withdrawal - Wearables'** to open the withdrawal survey form.

	COORDINATOR SURVEY
☐	Coordinator-Withdrawal - Wearables (Coordinator-Withdrawal)

MANAGE

👥 Participants

👤+ Add / Invite Participants

🔍 Activity

Navigate to the Participants Section

5. **Complete and Submit the Survey:**
   Fill out the required details in the survey. Once completed, click **'Done'** to submit the survey.

Cancel

Withdrawal Participant

Submitting this form will immediately withdraw
<%= DemographicField.FirstName %> <%= DemographicField.LastName %>
from the study so that they no longer receive any notifications.

Date of Withdrawal   Date
_____

Reason for Withdrawal

Patient has reached 1 month of participating in the project   ○

Patient requests to end project participation   ○

Other   ○

_____

Done

Contact *info@actionlearningnetwork.org* with any questions.

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