

Enrolling Patients in MyDataHelps™



Before a patient or caregiver can be enrolled for VAD Patient Reported Outcomes, they must be consented for ACTION. Electronic consent is not implemented in MyDataHelps™ at this time. Please consent your patient/caregiver as you normally do for ACTION Inclusion Criteria.

Steps to Enroll

1. Consent the patient for ACTION.
2. Give the patient/caregiver the PRO handout. They will enroll in VAD PRO's by clicking the link or scanning the QR code to get to the MyDataHelps™ platform. A smartphone, tablet, or computer can be used to participate, and an email or phone number is needed to create an account where they will also receive notifications.
3. Assist the patient/caregiver with the enrollment survey and help them understand how PRO's will be completed (workflows outlined below).

TIP: We encourage you/your care team to try this process out *by creating an account.*

Workflows for Enrollment:

Based on the age and/or VAD implant date of the patient being enrolled in PRO's, the following options are available for enrollment, and they will be prompted for one of the following options during the enrollment survey. All options/possibilities for enrollment are listed below:

If patient is 18 or older and does not yet have a VAD:

If the patient/caregiver provides the date the patient is scheduled to receive a VAD, MyDataHelps™ will send them a survey on that date to confirm whether they received their VAD. Patients/caregivers can also log in to MyDataHelps™ at any time to note they have received their VAD. Once a VAD is in place, MyDataHelps™ will send periodic surveys with questions asking about the patient and their family's wellbeing.

If patient is under 18 and receiving a VAD today:

Starting today, MyDataHelps™ will send a series of surveys with questions to the caregiver about the child they care for and their family's wellbeing while their child is on the support of a VAD.

If patient is 18 or older and receiving a VAD today:

Starting today, MyDataHelps™ will send a series of surveys with questions to the patient about their, and their family's, wellbeing while they are on the support of a VAD.

If patient is under 18 and received a VAD in the past:

Based on when the caregiver's child received a VAD, MyDataHelps™ will send periodic surveys with questions about the child they care for and their family's wellbeing.

If patient is 18 or older and received a VAD in the past:

Based on when the patient received a VAD, MyDataHelps™ will send periodic surveys with questions about the patient and their family's wellbeing.

If patient is aged 12–17:

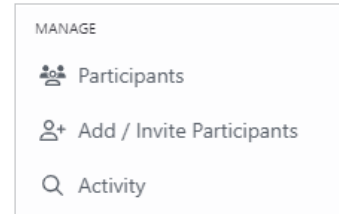
Since the caregiver's child is between the ages 12–17, the patient will also have the option to complete their own surveys to share how they are feeling.

Accessing Your Patients' Data

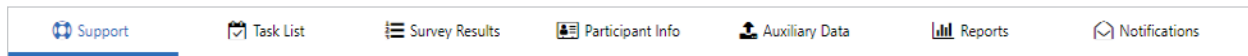
For backend user access to your center's MyDataHelps™ Designer platform, please contact ACTIONDCC@cchmc.org. Each site will have one PRO champion that receives email notifications when surveys are completed by patients. You will be able to see your patients' data, but you will not be able to export and download it. ACTION DCC will download and share center-specific data on a regular basis.

Steps to View PRO 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.
- 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.



Review Participant Data



Site Level Enrollment

How often will patients/caregivers complete PROs?

See chart to the right for PROs completion guidelines.

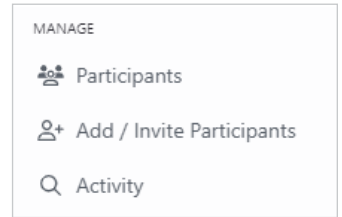
How long do they take?

Average of **5 minutes or less** per survey completion

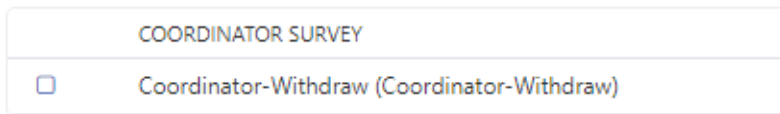
Patient Age	Who Completes PROs?	How are PROs Completed?	When are PROs Completed?	Which PROs to Complete?
0–1 years old	Parent Only	Text or Email	VAD Implant	Take ACTION
			Weekly for 1st Mo.	Take ACTION
			1 Mo. Post-Implant	Take ACTION
			3 Mo. Post-Implant	Take ACTION
			6 Mo. Post-Implant	Take ACTION
2–4 years old	Parent Only	Text or Email	VAD Implant	Take ACTION
			Weekly for 1st Mo.	Take ACTION
			1 Mo. Post-Implant	Take ACTION
			3 Mo. Post-Implant	Take ACTION
			6 Mo. Post-Implant	Take ACTION, PedsQL
5–11 years old	Parent Only	Text or Email	VAD Implant	Take ACTION, PROMIS
			Weekly for 1st Mo.	Take ACTION
			1 Mo. Post-Implant	Take ACTION, PROMIS
			3 Mo. Post-Implant	Take ACTION, PROMIS
			6 Mo. Post-Implant	Take ACTION, PROMIS, PedsQL
12–17 years old	Patient Only <i>OR</i> Parent Only <i>OR</i> Both Patient and Parent	Text or Email	VAD Implant	Take ACTION, PROMIS
			Weekly for 1st Mo.	Take ACTION
			1 Mo. Post-Implant	Take ACTION, PROMIS
			3 Mo. Post-Implant	Take ACTION, PROMIS
			6 Mo. Post-Implant	Take ACTION, PROMIS, PedsQL
18+ years old	Patient Only	Text or Email	VAD Implant	Take ACTION, PROMIS
			Weekly for 1st Mo.	Take ACTION
			1 Mo. Post-Implant	Take ACTION, PROMIS
			3 Mo. Post-Implant	Take ACTION, PROMIS
			6 Mo. Post-Implant	Take ACTION, PROMIS, PedsQL

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 Survey'** to open the withdrawal survey form.



Participants Section



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

[Save & Exit](#) [Cancel](#)

Withdrawal Participant

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

Date of Withdrawal Date

Reason for withdrawal (if provided):

Reason for withdrawal

Done

Reason for withdrawal

- Transplant
- Recovery
- Death
- Patient/Family requested to stop participation
- Transferred to another hospital
- Other