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| **A. General Information** |  |  | | | |  |  | | |  |  | | |  |
| ***Project Title*** | VAD Patient Reported Outcomes | | | | | | | | | | | | | |
| ***Department/Division/Team:*** | **ACTION Network** | | | | | | | | | | | | | |
| ***Population:*** | VAD Patients can be enrolled for Patient Reported Outcomes (PRO)s through the MyDataHelps platform via CareEvolution. | | | | | | | | | | | | | |
| ***Brief Project Description (AIM):*** | 1. A weekly assessment of patient symptoms and well-being, captured by the “Take ACTION Check-in” and a Visual Analog Scale (VAS). The results of these assessments can be used clinically by caregivers in real time, immediately after assessments are complete. 2. Validated longitudinal assessments of functional status, reflecting the changes before VAD, early after VAD implant, and later after VAD implant. These assessments will be captured by the PROMIS measures and the PedsQL. | | | | | | | | | | | | | |
| ***Measures:*** | 1. Proportion of all patients on VAD who are enrolled in the PRO initiative   Missing responses when the link to measures is sent out  Incomplete survey responses  Attrition of patients/families from PRO initiative | | | | | | | | | | | | | |
| ***Prepared By:*** | Melissa Cousino, PhD, Betsy Blume, MD, Andrea Fasbinder, RN, VAD Coord, & Lauren Smyth, MHA | | | | | | | | | | | | | |
| ***Dates & Timeline:*** | Tonic Phase 1: May 2021 – July 2024  MyDataHelps Phase 2 (testing): February 2025 – July 2025  MyDataHelps Phase 2 (launch): August 2025 | | | | | | | | | | | | | |
| **B. Project Background:** |  |  | | | |  |  | | |  |  | | |  |
| Comprehensive assessments of patient well-being (physical, social, and psychological) can help guide clinical care in both the short- and long-term. Given that there is no “gold standard” single assessment tool for young people on VAD support, ACTION is using a combination of tools to evaluate feasibility of PRO administration and evaluate the quality and relevance of the information PROs provide for our patients.  The ACTION Patient Reported Outcomes Committee launched an initial Phase 1 project pilot in May 2021 in partnership with Tonic Health. The project background is included in the timeline below:    In February 2025, we rebuilt the VAD PRO surveys and delivery system in MyDataHelps to improve patient/caregiver enrollment, data capture, and analysis. We tested the platform with 6 centers through July 2025. Network-wide launch of MyDataHelps is occurring August 2025. | | | | | | | | | | | | | | |
| **C. Project Scope**: | | | | | | | | | | | | | | |
| Sites with IRB/DUA approval are invited to join the PRO initiative in ACTION. PROs are available for VAD patients only at this time.  **Inclusion**: All VAD recipients and/or their caregivers are eligible for the PRO initiative. Patients must be consented for ACTION to be included in the PRO initiative.  **Exclusion**: Lack of consent for participation in ACTION. Non-English speaking patients and caregivers are excluded from PROs for this initial phase (survey translation is a next step).  Assessment tools will be administered to patients and/or their caregiver proxy at these intervals (see table included in the Provider Handout):   1. Time of VAD Implant: Take ACTION Check-In, Visual Analog Scale (VAS), and PROMIS 2. Weekly while on support for the first 3 weeks: Take ACTION Check-In and VAS 3. 1, 3, 6 months post-VAD implant while on support: Take ACTION Check-In, VAS, PROMIS, and at 6 months include Peds QL   See the [**Provider Handout**](https://public.3.basecamp.com/p/TsxiyGhJi9wjsB6uNGPg3QGw) for more detailed information.  See the [**Patient/Family Handout**](https://public.3.basecamp.com/p/WQQVJdystHZiTB5jFj49m9C2) for more detailed information. | | | | | | | | | | | | | | |
| **D. Project Participation & Access** | | | | | | | | | | | | | | |
| If your center is ready to enroll VAD patients in PRO’s, please email [Lauren.Smyth@cchmc.org](mailto:Lauren.Smyth@cchmc.org) to get started.  We will need to know the names and email addresses of your teammates that will need access to the completed surveys and platform.  It is also recommended to have 1 site champion that will be the point of contact for this project and will receive emails and notifications from MDH.    For Provider access to the *MyDataHelps Designer* backend, you will need a *MyDataHelps Designer* account. After setting your password and security questions during account registration, you'll be prompted to enable two-step verification. To enable two-step verification, install an authenticator app on your phone, then scan the QR code or enter the code from your *MyDataHelps Designer* profile page to complete setup. | | | | | | | | | | | | | | |
| **D. Roles and Responsibilities** | | |  |  | | | |  |  | | |  |  | |
| **Sponsor/Champion:** Provides overall direction on the project. | | | | | | | | | | | | | | |
| **Name** | | | | | **Title/Role** | | | | | | | | | |
| Angela Lorts, MD | | | | | ACTION Co-Executive Director | | | | | | | | | |
| **Team Leader:** Leads the team and provides guidance on scope of the project. | | | | | | | | | | | | | | |
| **Name** | | | | | **Title/Role** | | | | | | | | | |
| Melissa Cousino, PhD | | | | | PRO Committee Co-Leader | | | | | | | | | |
| Betsy Blume, MD | | | | | PRO Committee Co-Leader | | | | | | | | | |
| Andrea Fasbinder, RN, VAD Coord | | | | | PRO Committee Co-Leader | | | | | | | | | |
| **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 | | | | | Program Manager | | | | | | | | | |
| Harish Gureddygari | | | | | Developer II | | | | | | | | | |
| Toni Duganiero, MPA | | | | | Sr. Data Management Specialist | | | | | | | | | |
| **Team Members:** Works toward the deliverables of the project. | | | | | | | | | | | | | | |
| **Name** | | | | | **Title/Role** | | | | | | | | | |
| VAD Collaborative Projects Members | | | | |  | | | | | | | | | |
| **Family/Patient Representative:** | | | | | | | | | | | | | | |
| Melissa McQueen and FACT | | | | |  | | | | | | | | | |