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| **A. General Information** |  | |  | | | | | | |  |  | | | |  | |  | | | |  | |
| ***Project Title & Project #:*** | CardioMEMS Registry for Pediatric and Congenital Heart Disease Patients | | | | | | | | | | | | | | | | | | | | | |
| ***Department/Division/Team:*** | ***ACTION Network*** | | | | | | | | | | | | | | | | | | | | | |
| ***Population:*** | All patients who have a CardioMEMS device implantation (or attempted implantation) at an ACTION site with the following diagnoses will be approached to consent for project enrollment:   * Pediatric patients with congenital or acquired cardiomyopathy and evidence of heart failure * Pediatric patients with pulmonary hypertension (of any etiology) with established heart failure * Congenital heart disease patients of any age with evidence of heart failure * Heart transplant patients with graft dysfunction of any cause resulting in heart failure | | | | | | | | | | | | | | | | | | | | | |
| ***Brief Project Description (AIM):*** | This registry will act as a prospective database of all CardioMEMS device implantations in patients in the pediatric age range or with congenital heart disease who meet the above indications. The aim is to determine feasibility and safety of device implantation in this patient population and to identify factors associated with immediate, medium-term, and long-term procedural success and failure. | | | | | | | | | | | | | | | | | | | | | |
| ***Measures:*** | Patient characteristics, intra-procedural data regarding implantation and patient hemodynamics, and both short-term and long-term data regarding post-procedural transmissions, hemodynamics, and complications will be recorded. | | | | | | | | | | | | | | | | | | | | | |
| ***Prepared By:*** | Arash Salavitabar, M.D.; Jesse Esch, M.D.; David Peng, MD | | | | | | | | | | | | | | | | | | | | | |
| ***Date:*** | 5/18/21 | | | | | | | | | | | | | | | | | | | | | |
| **B. Project Background:** |  | |  | | | | | | |  |  | | | |  | |  | | | |  | |
| Implantable hemodynamic monitors (IHMs) have been studied to track ambulatory pulmonary artery pressures (PAP) in an effort to provide earlier detection of rising ventricular diastolic pressures before clinical acute decompensated heart failure ensues. The CardioMEMS™ HF System is a FDA-approved IHM for patients with New York Heart Association Functional Class III HF and at least 1 admission for acute decompensated HF in the year prior to implantation. The CHAMPION trial and the studies following that cohort have, thus far, excluded patients with CHD and of pediatric age from the initial investigations of feasibility of implantation, safety, and clinical outcomes. In non-CHD cohorts, adjustment of outpatient therapy based upon PAP recordings led to reduced heart failure-related hospital re-admissions and improved quality of life. Safety and accuracy of the device have been demonstrated in several studies in structurally normal hearts in adults, but substantial data in pediatric patients and those with complex CHD does not exist. Given the clear importance of understanding hemodynamic data in this patient population at future heart failure risk, the study of IHM use is crucial. | | | | | | | | | | | | | | | | | | | | | | |
| **C. Project Scope (and exclusions)**: | | | | | | | | | | | | | | | | | | | | | | |
| The scope of this project is broad, as the indications for IHMs in our target populations are heterogenous and evolving. The current dearth of knowledge on safety and efficacy in the pediatric/congenital sphere may be limiting more widespread use. Indeed, as we accumulate safety and feasibility data through this project, we anticipate increased IHM utilization over time (including through increasing numbers of implanting sites). Implantations at any given site are likely to remain relatively low in the short term, making this project ideally suited to a multi-center learning network approach.  As this database will include clinically diverse patients, we foresee the potential for multiple avenues of future inquiry and collaboration with other ACTION working groups (for example, the effect of CardioMEMS placement on heart failure admission rates or patient-reported outcomes may be of interest).  **There are no formal exclusion criteria for inclusion into this registry**, as we seek to learn from the broad experience of the ACTION community’s use of IHMs. However, decisions regarding indications and feasibility of implantation will remain at the discretion of the clinical care team based on patient characteristics. We intend to capture data on all attempted implantations, even if they are unsuccessful or do not adhere to the device’s Instructions for Use. The following are relative contraindications for implantation of the CardioMEMSTM system, but would not preclude enrollment in the database if chosen to proceed by the implantation center:   * Distal branch PA diameter <7mm or >10 mm at the target implantation site. * Chest asymmetry (pectus, scoliosis). * GFR <25 ml/min/1.73m2 * BMI >35 kg/m2 or chest circumference >165 cm. * History of non-adherence * Known coagulation disorder or inability to tolerate dual antiplatelet or anticoagulation therapy. * Patients with implantable loop recorder on the same side as the target vessel. * History of recurrent (>1) pulmonary embolism or deep vein thrombosis | | | | | | | | | | | | | | | | | | | | | | |
| **D. High Level Timeline/Schedule:** | | | | |  |  | |  | | | | |  | | |  | |  | | | |  |
| The goal is to launch data collection in May 2021.   |  |  | | --- | --- | | May 2021 | * Invite teams to participate in project at 5/20/21 ACTION for All meeting * ACTION Newsletter – will announce project in May newsletter * Teams commit to joining the project * Teams select, resource, and onboard team members * ACTION Operations team assigns team members to DAG’s in REDCap * Project kick-off meeting w/ participating teams | | May - June 2021 | * Participating sites begin data collection | | June – December 2021 | * Collect data and analyze first cohort after 6 months of data collection or 50 patients, whichever is achieved first | | | | | | | | | | | | | | | | | | | | | | | |
| **E. Communication & Expectations:** | | | | | |  | |  | | | | |  | | |  | |  | | | |  |
| **Participating Teams:**  All ACTION sites with a completed IRB/DUA are welcome to be involved in this project. Teams must complete this [**project commitment survey**](https://www.surveymonkey.com/r/H7PNYH7) **by 5/31/21.** We will ask each participating center to identify one point person for the project, but anyone on the project team can enter or view data in REDCap. To set up data access, we will need the following:**1.)** Name of person **2.)** Institutional affiliation **3.)** Email address, and **4.)** The level of permissions needed (i.e. entering data, viewing, etc.). Lastly, a REDCap account will need to be created prior to being able to enter data prospectively.  The designated data team members will need to be added to the IRB and study staff listing. Please email [Mary.Banks@cchmc.org](mailto:Mary.Banks@cchmc.org) to update your staff listing. **Patients will also be consented for prospective data entry**, so anyone consenting or interacting with the data will need to be listed on the ACTION IRB study staff listing.  Team members will be added to the ACTION Heart Failure Committee. We will use the monthly Heart Failure Committee meetings as a touchpoint to discuss any updates or questions about the data entry. The HF Committee meets the last Tuesday of each month from 12pm-1pm ET.  **Data Entry:**  The expectation is that all participating institutions will enter their data regarding implantation attempts, as well as the prompted follow-up data, in a timely manner. This data will eventually be used to educate centers regarding safety and feasibility of sensor implantation, as well as associated complications. This information will be communicated periodically amongst participating centers, as well as via future peer-reviewed publications. The patients will be prospectively enrolled from ACTION centers. Patients **must be consented for ACTION** to be enrolled in the data collection. Your site will use the general ACTION consent for this project.  Prospective data for CardioMEMS patients, will be collected via REDCap: <https://redcap.research.cchmc.org/> Once logged in, select the “ACTION Cardiomems” project.  The expectation is for patient data to be entered into REDCap once a CardioMEMS device has been implanted or attempted to be implanted (and patient is consented for ACTION!). You must have a login to the CCHMC REDCap in order to enter data for this project (per the emails that have been sent out). Please contact the [operations/data team](mailto:action.dcc@cchmc.org) if you are having trouble accessing this REDCap.  The REDCap survey asks for an “ACTION ID.” This ID allows for better tracking of patients between ACTION projects and will be more clear for data analytics on back end. The ACTION ID will be populated each time you enter data. The ID is comprised of the hospital number, the patient’s full name initials (First, Middle, Last - *\*use “x” if patient does not have middle initial*), and the patient’s DOB. This creates an ACTION ID with a mathematical equation that de-identifies the ID. For example, if the CCHMC site number was 10, using Lauren Elise Smyth, and DOB: 05/02/1988, the ID would be auto-generated as: **010-LES-5022010**. | | | | | | | | | | | | | | | | | | | | | | |
| **G. Project Risks & Mitigation**: | | | | | | | | | | | | | | | | | | | | | | |
| **Risk** | | **Level (high/med/low)** | | | | | | | | **Mitigation and Escalation Strategy** | | | | | | | | | | | | |
| Data breach | | low | | | | | | | | Sensitive patient information will be delivered via currently utilized, secure ACTION protocols and housed at the ACTION DCC. | | | | | | | | | | | | |
| **F. Roles and Responsibilities** | | | |  | | |  | | | | |  | |  | | | | |  |  | | |
| **Sponsor/Champion:** Provides overall direction on the project. | | | | | | | | | | | | | | | | | | | | | | |
| **Name** | | | | | | | | | **Title/Role** | | | | | | | | | | | | | |
| Angie Lorts | | | | | | | | | ACTION Executive Leader | | | | | | | | | | | | | |
| David Peng | | | | | | | | | ACTION Leader | | | | | | | | | | | | | |
| **Team Leader:** Leads the team and provides guidance on scope of the project. | | | | | | | | | | | | | | | | | | | | | | |
| **Name** | | | | | | | | | **Title/Role** | | | | | | | | | | | | | |
| Arash Salavitabar | | | | | | | | | Interventional Cardiologist | | | | | | | | | | | | | |
| Jesse Esch | | | | | | | | | Interventional Cardiologist | | | | | | | | | | | | | |
| **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 | | | | | | | | | Project Manager | | | | | | | | | | | | | |
| Paige Krack | | | | | | | | | Quality Improvement Consultant | | | | | | | | | | | | | |
| Karina Tabar | | | | | | | | | Specialist-Data Management | | | | | | | | | | | | | |
| Chloe Connelly | | | | | | | | | Data Analyst | | | | | | | | | | | | | |
| Kyle Werling | | | | | | | | | Developer I | | | | | | | | | | | | | |
| **Team Members:** Works toward the deliverables of the project. | | | | | | | | | | | | | | | | | | | | | | |
| **Name** | | | | | | | | | **Title/Role** | | | | | | | | | | | | | |
| Participating sites/members will be added to the ACTION Heart Failure Committee & CardioMEMS sub-group | | | | | | | | |  | | | | | | | | | | | | | |