AWARD NUMBER:	W81XWH-20-1-0272
TITLE:	A Phase 2B Multicenter Study of the Comparative Efficacy and Safety of Transendocardial Injection of MSC in Patients with Non-ischemic Dilated Cardiomyopathy.
PRINCIPAL INVESTIGATOR:	Dr. Joshua Hare, MD.
CONTRACTING ORGANIZATION:	University of Miami, Coral Gables, FL
REPORT DATE:	May 2021
TYPE OF REPORT:	Annual Report
PREPARED FOR:	U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012
DISTRIBUTION STATEMENT:	Approved for Public Release; Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
May 2021	Annual	01May2020-30Apr2021

4. TITLE AND SUBTITLE

A Phase 2B Multicenter Study of the Comparative Efficacy and Safety of Transendocardial Injection of MSC in Patients with Non-ischemic Dilated Cardiomyopathy.

5a. CONTRACT NUMBER
W81XWH-20-1-0272

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Aisha Khan

E-Mail: akhan@med.miami.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Miami, 1320 S Dixie Hwy., Ste. 650, Coral Gables, FL 33146-2919

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This proposal addresses the FY19 PRMRP Topic Area of Cardiomyopathy. Non-ischemic dilated cardiomyopathy (NIDCM) is one of the more common causes of heart failure in young adults, a leading cause of disability and death, and accounts for approximately 50% of heart transplants performed. As such this disorder is a lead candidate for cell-based therapy. Patients with NIDCM have an enlarged, structurally damaged heart muscle with reduced function. Our group and others have shown that cell-based therapy using mesenchymal stem cells (MSCs) holds great promise as a new approach to produce durable and sustainable improvements in heart function and structure in patients with heart failure due to NIDCM. If these effects can be clinically established and optimized, there is enormous potential for improving clinical outcomes for the many patients suffering from NIDCM. Our group has extensive experience with catheter delivery of bone marrow-derived MSCs in patients with heart failure due to heart attack as well as NIDCM. There is substantial scientific and public interest for cardiac regenerative cell therapy strategies, based on pre-clinical, translational, and early Phase I/II clinical studies. In the POSEIDON-DCM clinical trial, we identified a meaningful increase in cardiac function in a cohort of patients with NIDCM who received MSCs. One-third of the patients transitioned from heart failure with reduced cardiac function to heart failure with recovered function, which is associated with reductions in disease-related symptoms and complications as well as death. Since NIDCM is associated with genetic mutations in a significant proportion of patients, we hypothesized that NIDCM genotype influences patient responsiveness to MSC therapy. Accordingly, we conducted a sub study in the POSEIDON-DCM patients by performing a detailed genotyping using a comprehensive cardiomyopathy gene panel. Our novel preliminary findings show a benefit of MSC therapy, namely improvement in cardiac function, quality of life, major adverse cardiac events, and survival, in patients that lack a known pathogenic mutation, suggesting that patients devoid of pathogenic mutations represent a 'super-responder' group compared to those that have a pathogenic mutation. This Phase IIB clinical trial proposal will test whether MSC therapy is effective in improving cardiac function, as compared to placebo, in patients with NIDCM. Patients will be genotyped and the efficacy of MSC therapy will be compared to placebo in patients that lack a known disease-causing mutation (genotype A), patients with mutations of unknown significance (genotype B), and in those that have a known disease-causing mutation in NIDCM associated genes (genotype C). We expect that patients without a disease-causing mutation will respond better to MSC therapy than those with known mutations or mutations of unknown significance. The primary outcome will be assessed using cardiac magnetic resonance imaging to measure cardiac function at 12 months. This study is clinically important because it will help physicians determine which patients are more likely to respond to specific therapies and will help us develop more individualized therapies for patients with heart failure due to NIDCM. The proposed trial is currently approved by the FDA under IND BB-14419.

15. SUBJECT TERMS

None listed.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
					USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE	Unclassified	19	19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified			

TABLE OF CONTENTS

1. INTRODUCTION:

This clinical study will address a significant clinical need, namely the investigation of new and promising therapies for heart failure, one of the leading causes of cardiovascular death and disability. The proposed studies will elucidate new mechanisms of repair and regeneration of heart tissue. The goal of this study is to identify whether patient genotype determines the responsiveness to allogeneic mesenchymal stem cells (MSCs) administered by transendocardial injection in patients with non-ischemic dilated cardiomyopathy (NIDCM).

2. KEYWORDS:

Mesenchymal Stem Cell
Heart Failure
Non-ischemic dilated cardiomyopathy (NIDCM)
Genotype
Transendocardial injection
Cellular Therapy
Cardiovascular Disease
Current Good Manufacturing Practices

3. ACCOMPLISHMENTS:

- **What were the major goals of the project?**

Accomplished

Tasks	Timeline (Months)				
Major Task1 Subtask 1: Regulatory Documents		% of Completion	Initiated/ Work in Progress	Completed	Note
Finalize consent form & human subjects' protocol	1-3	100%		✓	Submitted to single IRB (BRANY IRB) and Masterfile approval received on 4/27/20.
Site submission to sIRB for initial approval	1-6	100%		✓	Final site approval on 10/26/2020
Submit Protocol to HRPO	3-6	100%		✓	Approval on 4/7/2021
Completion of regulatory approvals (FDA/DSMB)	3-6	98%	✓		DSMB membership has been secured. Charter document has been finalized. First meeting to review protocols/data table format is pending
Development and approval of CRFs	1-6	100%		✓	full set of CRFs has been developed and DCC programming has completed the electronic data capture system
Finalize MOP and eCRF users guide	1-12	100%		✓	MOP is completed and materials are posted in secured section of trial website. eCRF users guide of electronic database

Tasks	Timeline (Months)				
					capture system is also complete and available on website.
Submit amendments, adverse events and protocol deviations as needed	As Needed				An amendment to the protocol is planned in the coming weeks. This amendment is largely administrative in nature and will provide further clarification to the clinical sites. AEs and deviations are not applicable as trial has not yet initiated.
Continuing review (CR) submission by Sites to sIRB	Semi-Annually	100%		✓	CRs are occurring at regular intervals. All sites are up to date with submissions and approvals
Milestone Achieved: Local IRB approval at all sites	3	100%		✓	Final site approval on 10/26/2020
Milestone Achieved: HRPO approval for all protocols	3-6	100%		✓	Approval on 4/7/2021
Major Task 1 Subtask 2: Site Management		% of Completion	Initiated/ Work in Progress	Completed	Note
Contract with identified sites and core labs	1-6	95%	✓		All contracts are finalized except for the company to provide Noga catheter
Comprehensive lab plan/product SOP development	1-6	95%	✓		All lab SOPs and manual are completed, final training for sites is in progress.
Finalize data & safety monitoring and data management plan	1-6	100%		✓	DSMB charter is finalized. Medical Monitoring Plan is finalized
Finalize organization/communication and site performance plans	1-6	100%		✓	Site recruitment plans received and reviewed 01/25/2021. Study team meetings held 2x per month. Research Coordinator meeting to begin monthly once enrollment starts.
Finalize clinical trial management plan	1-6	100%		✓	• Manual of Operations (complete) • Clinical Research Monitoring Plan (complete) • Medical Monitoring Plan (complete) • Data and Safety Monitoring Plan. (complete) • Stat Analysis Plan (complete)
Finalize data completeness & quality monitoring plan	1-6	100%		✓	Clinical Research Monitoring Plan is finalized
Deploy secure website for sharing study materials	1-6	100%		✓	Web site is deployed. Training materials are posted.
Complete and deploy EDC-system set-up	6-12	100%		✓	Test and production databases complete. EDC training completed for coordinators and cell processors
Implement site training plan (including MRI, FMD, Cell processing)	1-6	85%	✓		
Activate initial site(s) (at least 2 sites out of 4)	1-12	50%	✓		2 sites Activated: University of Miami – 05/07/2021 Stanford University – 05/19/2021

Tasks	Timeline (Months)				
Design information to ClinicalTrials.gov	6-7	100%		✓	NCT04476901
Major Task 2 Subtask 1: Participant Recruitment –		% of Completion	Initiated/ Work in Progress	Completed	Note
Coordinate with Sites for flow chart for all study steps, web data collection and database requirements	4-8	100%		✓	Coordinator training was completed 11/18/2020 with training sessions completed for MOP, safety/event reporting, and electronic database
Deploy randomization system	6-12	100%		✓	System complete. Initiation pending first subject enrollment
Finalize assessment measurements	1-3	100%		✓	All clinical assessments (including core lab evaluations) finalized
Milestone Achieved: Study begins	6-12	50%			University of Miami – 05/07/2021 Stanford University – 05/19/2021
Major Task 2 Subtask 2: Genetic Screening and Randomization –		% of Completion	Initiated/ Work in Progress	Completed	Note
Genetic Screen	3-30	90%	✓		Testing and reporting processes established, webinar on collection held 1/26/2021. Sample collection kits provided to sites. Genotype classification SOP established. Testing to begin with enrollment.
Randomization	3-30	100%		✓	EDC access for entry of genetic info complete. Randomization scheme incorporates genotype. Will be deployed once enrollment starts
Milestone Achieved: Ongoing randomization during enrollment	3-30				Pending opening enrollment.
Major Task 3 Subtask 1: Allogeneic MSC manufacture		% of Completion	Initiated/ Work in Progress	Completed	Note
Donor recruitment	3-12	90%	✓		We are in process of recruiting last donor.
Cell manufacture and quality assessment	3-12	90%	✓		A total of 60 doses are manufactured.
Product shipment	6-12				This will start after patient recruitment.
Milestone achieved: Reach production requirement for the entire trial	3-12	90%	✓		A total of 60 doses are manufactured.
Major Task 3 Subtask 2: Therapy Implementation		% of Completion	Initiated/ Work in Progress	Completed	Note
Follow-up visit and assessment at 1 week and at months 1, 3, 6, and 12	3-42	N/A			This will start after patient recruitment.
Milestone Achieved: Perform blinded therapy and follow-up visits	3-30				This will start after patient recruitment.
Major Task 3 Subtask 3: Evaluation		% of Completion	Initiated/ Work in Progress	Completed	Note
Assessment of site protocol performance	3-42	100%		✓	This will start after patient recruitment. Recruitment action plan version 1 complete and tracking strategies in place.

- **What was accomplished under these goals?**

Category	*Item*	Actual Completion Date	% complete	UM Completion Date	UL Completion Date	THI Completion Date	ST Completion Date
Regulatory	*Finalize Protocol, IB, ICF for BRANY Masterfile submission*	4/27/2020	**100%**				
Regulatory	*Coordinate with sites for Permission to use BRANY and site submission materials in BRANY system*	8/18/2020	**100%**	7/24/2020	8/5/2020	8/18/2020	6/26/2020
Regulatory	*Obtain final approval by BRANY for DCC & sites*	10/26/2020	**100%**	9/24/2020	10/16/2020	10/26/2020	7/23/2020
Regulatory	*Submission to HRPO (protocol and IRB approval)*	overall approved 4/7/2021	**100%**	4/7/2021	4/8/2021	4/7/2021	4/8/2021
Regulatory	*Complete Regulatory Documentation (CVs, license, lab info, etc.) on file with Sponsor (UM)*	7/10/2020	**100%**				
Regulatory	*Submit current materials to FDA (protocol, IB, FDA 1572s, ICF template)*	9/30/2020	**100%**				
Finance	*Contract Agreements with identified. Sites, BDS and core labs*	11/19/2020	**100%**	n/a	10/29/2020	10/21/2020	8/31/2020
Finance	*CSA and contract for payment between Invitae, Cenetron lab*	*in progress*	95%				
Cell Manufacture	*Donor recruitment*	*ongoing*	90%				
Cell Manufacture	*Cell manufacture and qualityassessment*	*ongoing*	90%				
Cell Manufacture	*IP Preparation training at each site*	*in progress*	75%	n/a	QA and Technical SOP is completed on 4/26	Completed	Practice run and SOP is completed on 4/28
Cell Manufacture	*Product shipment to each site*	*projected May 2021*	0%				

Site Management	*Generate MOP and coordinator checklist*	8/6/2020	**100%**	
Site Management	*MLHFQ licensing agreement*	6/10/2020	**100%**	
Site Management	*Design information to ClinicalTrials.gov*	7/15/2020	**100%**	
Site Management	*Development of DSMB Charter/Identification of Members*	6/22/2020	**100%**	
Site Management	*Comprehensive lab plan/product SOP development*	7/30/2020	**100%**	
Site Management	*Genetic testing process document/SOP (Dr. Myerburg)*	10/8/2020	**100%**	
Site Management	*FMD equipment buildout*	11/16/2020	**100%**	
Site Management-Training	*Kick off Meeting/Webinar (trainingincluding MOP/safety/protocol)*	11/16/2020	**100%**	
Data	*Establish list of data deliverables from core labs*	*in progress*	75%	
Data	*Development and approval of CRFs*	6/29/2020	**100%**	
Data	*Development of EDC in test environment*	9/21/2020	**100%**	
Data	*Development of Clinical Monitoring Plan*	6/26/2020	**100%**	
Data Safety	*Development of Medical Monitoring Plan*	7/28/2020	**100%**	
Data Website	*Deploy secure website for sharing study materials*	9/21/2020	**100%**	
Data Training	*Generate eCRF User's Guide*	9/9/2020	**100%**	
Data	*EDC system testing and finalization at DCC*	9/30/2020	**100%**	
Data Training	*EDC Certification of sites (receive eCRF users guide)*	9/30/2020	**100%**	
Data	*Development of Statistical Analysis Plan*	1/30/2021	**100%**	
Core Training	*Manuals sent to sites/posted (MOP, Core Lab Procs)*	3/15/2021	**100%**	

- **What opportunities for training and professional development has the project provided?**

Nothing to Report

- **How were the results disseminated to communities of interest?**

Nothing to Report

- **What do you plan to do during the next reporting period to accomplish the goals?**

Tasks
Submit amendments, adverse events and protocol deviations as needed
Coordinate with Sites for annual IRB report for continuing review
Activate other 2 sites
Milestone Achieved: Study begins
Major Task 2 **Subtask 2: Genetic Screening and Randomization –**
Genetic Screen
Milestone Achieved: Ongoing randomization during enrollment
Major Task 3 **Subtask 1: Allogeneic MSC manufacture**
Complete donor recruitment
Complete cell manufacture and quality assessment
Initiate product shipment
Milestone achieved: Reach production requirement for the entire trial
Major Task 3 **Subtask 2: Therapy Implementation**
Follow-up visit and assessment at 1 week and at months 1, 3, 6, and 12
Milestone Achieved: Perform blinded therapy and follow-up visits

4. IMPACT:

- **What was the impact on the development of the principal discipline(s) of the project?**

Nothing to Report

- **What was the impact on other disciplines?**

Nothing to Report

- **What was the impact on technology transfer?**

Nothing to Report

- **What was the impact on society beyond science and technology?**

Nothing to Report

5. CHANGES/PROBLEMS:

- **Changes in approach and reasons for change**

Nothing to Report

- **Actual or anticipated problems or delays and actions or plans to resolve them**

Nothing to Report

- **Changes that had a significant impact on expenditures**

Nothing to Report

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
- **Significant changes in use or care of human subjects**

Nothing to Report

- **Significant changes in use or care of vertebrate animals.**

Nothing to Report

- **Significant changes in use of biohazards and/or select agents**

Nothing to Report

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Nothing to Report

Journal publications.

Nothing to Report

Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers, and presentations.

Nothing to Report

- **Website(s) or other Internet site(s)**

Public facing website is available (www.dcmii.org). Electronic data capture system is available via secured access from public facing website. Training modules from core lab training sessions are being added to secured website for new personnel/refresher training. Clinicaltrials.gov registry is available (NCT04476901).

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

The Data Coordinating Center (DCC) has developed and maintains a comprehensive, feature-rich framework of web-based applications that support data capture, data transfer and harmonization, randomization, specimen management, and reporting services for the DCMII trial. Adverse event reporting and MedDRA classification are supported as well. Clinical sites enter electronic case report forms data through a web interface provided by the secured electronic data capture (EDC) portal, where data checks are performed to validate all data before committing it to the EDC system. The DCC system also provides services for transferring core laboratory and specimen data from a variety of sources, and can accept files in a variety of standard formats; this data can then be merged with existing clinical data.

- *biospecimen collections; Nothing to Report*
- *audio or video products; Nothing to Report*
- *software; Nothing to Report*
- *models; Nothing to Report*
- *educational aids or curricula; Nothing to Report*
- *instruments or equipment; Flow Mediated Dilation (FMD) Testing System – System will be used to measure FMD of patients enrolled in the trial prior to treatment and then at 3, 6, and 12 months post-treatment time points.*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models); Nothing to Report*
- *clinical interventions; Nothing to Report*
- *new business creation; and Nothing to Report*
- *other. Nothing to Report*

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the**.

Name:	
Project Role:	
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	
Contribution to Project:	
Funding Support:	

Institution	Name	Project Role	Proposed Effort	Actual Effort	Person Months Worked	Contribution to Project
University of Miami	Joshua Hare	Principal Investigator (Contact)	15.00%	15%	0.45	Attending bi-weekly meetings (2x per week), protocol development, compliance review, report development
University of Miami	Dushyantha Jayaweera	Principal Investigator	8.00%	10%	0.29	Attending bi-weekly meetings (2x per week), protocol development, compliance review
University of Miami	Aisha Khan	Principal Investigator	20.00%	20%	0.60	Attending bi-weekly meetings (2x per week), protocol development, compliance review, report development and review, establishing contracts with collaborators
University of Miami	Raul Mitrani	Co-Investigator	10.00%	10%	0.30	Attending bi-weekly meetings (2x per week), protocol development, compliance review
University of Miami	Robert Myerburg	Co-Investigator	15.00%	15%	0.45	Attending bi-weekly meetings (2x per week), protocol development, compliance review
University of Miami	Antonio Izquierdo	Administrator	5.00%	5%	0.15	Attending bi-weekly meetings (2x per week), providing budgetary and resource guidance, compliance review
University of Miami	Andrew Sundin	Post Doctoral Fellow	30.00%	67%	2.00	Assisting with protocol development and compliance review.
University of Miami	Yee-Shuan Lee	Assist. Scientist	30.00%	26%	0.79	Attending bi-weekly meetings (2x per week), protocol development, compliance review
University of Miami	Ketty Bacallao	Assist. Scientist	30.00%	25%	0.75	Attending bi-weekly meetings (2x per week), protocol development, compliance review
University of Miami	Bangon Longsomboon	Manager, Quality Assurance	30.00%	26%	0.79	Attending bi-weekly meetings (2x per week), protocol development, compliance review
University of Miami	Lina Caceres	Manager, Quality Assurance	20.00%	23%	0.68	Attending bi-weekly meetings (2x per week), protocol development, compliance review
University of Miami	Yvenie Desire	Regulatory Analyst	20.00%	20%	0.60	Attending bi-weekly meetings (2x per week), protocol development, compliance review, report development and review
University of Miami	Varaporn Suwunrut	Sr. Clinical Trial Program Coordinator	20.00%	20%	0.60	Attending bi-weekly meetings (2x per week), protocol development, compliance review
University of Miami	Jehan Corpuz	Senior Project Coordinator	16.00%	16%	0.47	Overseeing bi-weekly meetings (2x per week) and administrative organization of the project.
University of Miami (Vascular Core)	Barry Hurwitz	Core Leader	5.00%	5%	0.15	Attending bi-weekly meetings (2x per week), protocol development, compliance review, building equipment required to carry out clinical component
University of Miami (Vascular Core)	Alex Gonzalez	Research Associate	5.00%	4%	0.11	Building equipment required to carry out clinical component

University of Miami (Vascular Core)	Meela Parker	Ultrasound Technician	25.00%	19%	0.56	Building equipment required to carry out clinical component
University of Texas Health	Barry Davis	Principal Investigator	15.00%	15%	0.45	Attending bi-weekly meetings (2x per week), protocol development, compliance review
University of Texas Health	Dejian Lai	Co-Investigator	10.00%	10%	0.30	Statistical analysis plan development, protocol amendment review, Investigator meeting attendance
University of Texas Health	Lara Simpson	Safety Officer	30.00%	11%	0.34	Statistical analysis plan development, protocol amendment review, Investigator meeting attendance
University of Texas Health	TBD	Graduate Student	6.00%	1%	0.03	Clinical endpoint adjudication definitions, protocol amendment review, testing of EDC system for event reporting/adjudication, Investigator meeting attendance
University of Texas Health	Judy Bettencourt	Clinical Trials Project Manager	30.00%	13%	0.38	Not utilized during this time
University of Texas Health	Shelly Sayre	Clinical Trials Project Manager	70.00%	30%	0.91	Updates to public facing website, Investigator meeting attendance, testing of the EDC system; EDC user account management; programming requests
University of Texas Health	Sibi Mathew	Clinical Research Monitor	6.00%	20%	0.59	IRB ongoing correspondence (continuing reviews), clinicaltrials.gov registry maintenance, bi-weekly Investigator meeting organization, EDC testing, posting of materials from trainings to website, finalization of trial documents
University of Texas Health	Gina DeWildt	Programmer Analysis	6.00%	14%	0.41	Recruitment action plan development, template recruitment plans, EDC testing, and meeting attendance, and generation of Investigator meeting minutes
Johns Hopkins	Joao Lima	Principal Investigator	8.33%	8%	0.24	provide scientific input in MR image data acquisition, develop the MRI protocol; participate in monthly investigator calls
Johns Hopkins	Bharath Ambale-Venkatesh	Co-Investigator	10.00%	10%	0.30	designed MRI protocol, trained technologists at each of the 4 sites; participated in data reporting template to the coordinating center; assist in regulatory activities
Johns Hopkins	Chikara Noda	Post-Doctoral Fellow	30.00%	12%	0.35	conducted certification quality control review of test cases and provided extensive feedback reports to sites; provide input to MRI protocol; participate in site training; assisted in generating MOP; assisted in setting up study database; participate in data reporting template to the coordinating center
Johns Hopkins	Ela Chamera	Technician	35.00%	8%	0.23	assisted in designing the MRI protocol and quality control review; generate MOP; participated in the site training and reader training activities; assisted in data reporting template to the Coordinating Center

Johns Hopkins	Jason Ortman	Technician	5.00%	3%	0.08	set up image transfer and storage solutions for each site to send data to JHU core lab
Univ. of Louisville	Roberto Bolli	Principal Investigator	10.00%	10%	0.30	Attending bi-weekly meetings (2x per week), protocol development, compliance review
Univ. of Louisville	Shari Williams	Clinical Research Coordinator	20.00%	0%	0.00	No effort because no clinical work was being done at this time.
Stanford University	Phillip Yang	Principal Investigator	8.33%	8%	0.24	Attending bi-weekly meetings (2x per week), protocol development, compliance review
Stanford University	Fouzia Khan	Clinical Research Coordinator	20.00%	0%	0.00	No effort because no clinical work was being done at this time.
Texas Heart	Emmerson Perin	Principal Investigator	10.00%	10%	0.30	Attendance of DCM II virtual meetings, Completion of all required regulatory documents for start-up and trainings, institutional operational management with James and team
Texas Heart	James Chen	Clinical Research Coordinator	20.00%	5%	0.15	Attendance of DCM II virtual meetings, Regulatory work (ie: IRB submission, site start-up requirements by U of Miami), institutional operational management (ie: coordinator huddles, meetings/discussions with local hospital departments)

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Nothing to Report

- **What other organizations were involved as partners?**

- **Organization Name:**

Site 1: **University of Miami, Miller School of Medicine**
Clinical Coordinating Center

Interdisciplinary Stem Cell Institute
Biomedical Research Building
1501 NW 10th Avenue, Room 903
Miami, Florida 33136

PIs: Joshua Hare, MD (JH); Ivonne Schulman, MD (IS); Aisha Khan, MSc, MBA. (AK)
Clinical Coordinator: Lina Caceres, MHS (LC)
Project Manager: Kevin Ramdas, MD. MPH (KR)

Site 2: **University of Louisville Research Foundation, Inc.**

Department of Medicine,
Institute of Molecular Cardiology
300 E. Market Street, Suite 300
Louisville, KY 40202

PI: Roberto Bolli, MD (RB)
Coordinator: Shari Williams, RN, BSN (SW)

Site 3: **Texas Heart Institute**

6770 Bertner Avenue, Houston TX 77225
PI: Emerson Perin, MD/PhD (EP)
Coordinator: Huang (James) Chen, RN, BSN (HC)

University of Texas, School of Public Health

1200 Pressler St. W-916, Houston, TX 77030
PI: Barry R Davis, MD/PhD (BD)
Co-I: Dejian Lai, PhD (DL); Lara Simpson, PhD (LS)
Project Manager: Judy Bettencourt, MPH (JB)

Site 4: **Stanford University School of Medicine Research Management Group**
3172 Porter Drive, Palo Alto, CA 94304-1212

PI: Phillip C. Yang, MD (PY)
Coordinator: Fouzia Khan, MBBS (FK)

Johns Hopkins University, MRI Core Center

600 N. Wolfe Street, Blalock 524, Baltimore, MD 21287

PI: Joan Lima, MD (JL)
Co-I: Bharath Ambale -Venkatesh (BA)

- **Location of Organization:** *(if foreign location list country)*
- **Partner's contribution to the projec**t *(identify one or more)*
  - **Financial support;**
  - **In-kind support** *(e.g., partner makes software, computers, equipment, etc., available to project staff)*;
  - **Facilities** *(e.g., project staff use the partner's facilities for project activities)*;
  - **Collaboration** *(e.g., partner's staff work with project staff on the project)*;
  - **Personnel exchanges** *(e.g., project staff and/or partner's staff use each other's facilities, work at each other's site)*; and
  - **Other.**

8. SPECIAL REPORTING REQUIREMENTS –

- **COLLABORATIVE AWARDS:**
- **QUAD CHARTS:**

9. APPENDICES: