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TITLE: Multicenter Randomized Trial of Everolimus in Pediatric Heart Transplantation

PRINCIPAL INVESTIGATOR: Lynn A Sleeper

CONTRACTING ORGANIZATION: Boston Children's Hospital, Boston, MA

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14. ABSTRACT

TEAMMATE is a multicenter randomized clinical trial of a novel immunosuppressive therapy that is studing children who have undergone recent heart transplantation. The primary goal is to determine whether a new rejection treatment (everolimus and low-dose tacrolimus) can reduce or prevent complications of transplant, including rejection, coronary artery disease, and kidney disease, when compared to usual care (tacrolimus and mycophenolate mofetil). The secondary goal is to acquire FDA approval of the first immunosuppression regimen for pediatric heart transplantation. The primary trial endpoint is a validated surrogate measure—the major adverse transplant event (MATE) score—which efficiently predicts long-term survival, and that has been accepted by the FDA (IND# 127980). The trial is being conducted at 25 centers, with leadership at Boston Children's Hospital (Data Coordinating Center) and Stanford University (Clinical Coordinating Center). At the time of this annual report, enrollment is complete and the target has been met, with 211 patients randomized and 170 have completed the trial (30 months follow-up). Additional accomplishments in Year 05 include the launch of a Trial Biobank and biospecimen collection (32 plasma samples to date); successful execution of two Data and Safety Monitoring Board meetings; submission of the Trial Design paper; a Continuing Medical Education feature on TEAMMATE (#PHTS Live); and the continuation of endpoint adjudication.

15. SUBJECT TERMS
Heart transplantation; children; immunosuppression; randomized clinical trial

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TEAMMATE is a multicenter randomized clinical trial of a novel immunosuppressive therapy that is studing children who have undergone recent heart transplantation. The primary goal is to determine whether a new rejection treatment (everolimus and low-dose tacrolimus) can reduce or prevent complications of transplant, including rejection, coronary artery disease, and kidney disease, when compared to usual care (tacrolimus and mycophenolate mofetil). The secondary goal is to acquire FDA approval of the first immunosuppression regimen for pediatric heart transplantation. The primary trial endpoint is a validated surrogate measure—the major adverse transplant event (MATE) score—which efficiently predicts long-term survival, and that has been accepted by the FDA (IND# 127980). The trial is being conducted at 25 centers, with leadership at Boston Children's Hospital (Data Coordinating Center) and Stanford University (Clinical Coordinating Center). At the time of this annual report, enrollment is complete and the target has been met, with 211 patients randomized and 170 have completed the trial (30 months follow-up). Additional accomplishments in Year 05 include the launch of a Trial Biobank and biospecimen collection (32 plasma samples to date); successful execution of two Data and Safety Monitoring Board meetings; submission of the Trial Design paper; a Continuing Medical Education feature on TEAMMATE (#PHTS Live); and the continuation of endpoint adjudication.

TABLE OF CONTENTS

1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Median survival after pediatric heart transplantation is only 15 years in the current era, due to the occurrence of late complications after heart transplant, most of which stem from the medications used to suppress the immune system in order to prevent graft rejection. While graft survival has improved significantly with the current standard of care, tacrolimus (TAC) and mycophenolate mofitil (MMF), most of the improvement has come from a reduction in early mortality. Preliminary studies suggest that everolimus in combination with low-dose TAC may prevent rejection, coronary artery disease, and kidney failure more effectively than TAC-MMF. However, these studies are limited by single-center design, inconsistent endpoint definitions and use of historical controls. In contrast to adults, children have a substantially longer *potential* life expectancy in the absence of late transplant complications, making the prevention of such complications an urgent priority for the pediatric heart transplant community

The research that is the subject of this report, the TEAMMATE trial, is a multicenter randomized clinical trial of a novel immunosuppressive therapy that is studying a target of 210 children who have undergone recent heart transplantation. The primary goal is to determine whether a new rejection treatment (everolimus and low-dose TAC) can reduce or prevent complications of transplant when compared to usual care (TAC-MMF). The secondary goal is to acquire FDA approval of the first immunosuppression regimen for pediatric heart transplantation. The primary trial endpoint is a validated surrogate measure—the major adverse transplant event (MATE) score—which efficiently predicts long-term survival, and that has been accepted by the FDA (IND# 127980). The trial is being conducted at 25 centers, with leadership at Boston Children's Hospital (Data Coordinating Center) and Stanford University (Clinical Coordinating Center).

This trial has high military relevance: 1) pediatric heart transplant is most often performed in those with congenital heart disease, which may be more common in military families due to *in utero* exposures such as hazardous chemicals, poor air quality, ground water contamination, and infectious diseases that may be more prevalent when serving abroad; 2) the evaluation of everolimus may have medical applications for treating military injuries that require a vascular composite allograft, such as hand transplantation; and 3) proliferation signal inhibitors (such as everolimus) are uniquely known for their ability to alter healing of human tissues, and therefore may provide insights into mechanistic pathways necessary to expedite wound healing.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

Children, heart transplant, immunosuppression, randomized clinical trial, everolimus

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The OVERALL AIM *of the research is to execute a multicenter randomized trial enrolling 210 pediatric heart transplant recipients from 25 sites to evaluate the efficacy, safety and tolerability of everolimus+low-dose tacrolimus and to secure its FDA approval.*

Major Tasks per SOW include:

1. *Regulatory & Contractual Activities required for Study Launch* — *Months -6 to 3*
2. *Prepare Study Staff and Systems to Execute Trial* — *Months 1 to 3*
3. *Participant Recruitment* — *Months 4 to 18*
4. *Participant Follow-up and Evaluation* — *Months 4 to 48*
5. *Study Closeout and Analysis* — *Months 36 to 48*

Shaded rows indicate tasks completed at time of last Annual Report.

Table 1. Statement of Work Tasks and Completion Status

Table 1. Progress Report based on Statement of Work for Major Tasks 1 to 5. Shaded rows indicate fully completed tasks.

Major Task 1: Regulatory & Contractual Activities required for Study Launch	Timeline (mo)	Status
Subtask 1: Obtain regulatory approvals for study protocol		
Submit final protocol to U.S. FDA for review and approval of amendments to Investigational New Drug (IND) application #127980	-6 to -3	✓ 11/20/17
Submit final protocol for Military IRB (ORP/HRPO) review and approval	-3 to 0	✓ 9/21/17 (v1)
Coordinate with Sites for IRB submission of protocol and ICF	1-3	✓ 25 fully approved, +2 terminated
DSMB organizational and protocol review meeting, arranged by DCC	2	✓ 11/01/17
Submit amendments, adverse events and protocol deviations as needed	As Needed	Amendment #28 approved 11/17/21

Submit annual single IRB report for continuing review	Annually	✓
Milestone Achieved: Approval by Military HRPO and FDA	1	✓
Milestone Achieved: Local IRB approval at Study Sites and Angio Core Laboratory	3	**COMPLETE**
Subtask 2: Execute financial agreements / subawards		
Coordinate with CCC, 25 Sites (22 original, 5 new, minus 2 terminated = 25 currently) and Core Lab to execute Subcontracts/ CTAs	1-3	✓ 26 fully executed, 2 terminated
Execute Consultant Agreements with Adjudication Committee members	1-3	✓
Milestone Achieved: All Subcontracts and Consultant Agreements executed	1-3	**COMPLETE**
Major Task 2: Prepare Study Staff and Systems to Execute Trial		
Subtask 1: Training of Research Staff		
DCC/CCC to conduct in-person training session for certification on study protocol	2-3	✓ 11/10/17 in Anaheim, CA; 7/19/18 in Palo Alto, CA 1/11/19 in Boston, MA
DCC/CCC to conduct webinars for SCs to review study protocol procedures	2-3	✓ (occurs monthly)
Angio Core Lab to conduct webinar with site angiographers and site study coordinators regarding data transfer and image acquisition	3	✓ (held 2/1/18)
Adjudication Committee webinar to standardize AE review procedures	3	✓ (calls held throughout 2018, 2019 & Feb 2020)
Retrain site study coordinators/Train new coordinators as needed via Webinar	As Needed	✓ 81 Study &

		Transplant Coords + 35 PIs trained
Milestone Achieved: Research staff trained	3	**COMPLETE**
Subtask 2: Build Trial materials and communications and database system		
Finalize case report forms, including pilot testing with core site SCs	1-3	✓ 53 CRFs finalized
Create Trial and Angio Core Lab Manuals of Operation (MOO)	2-3	✓
Develop Administrative website to post trial materials and secure documents	1-3	✓
Develop and test database management and randomization systems	2-3	✓ 53 of 53 CRFs in use (100%)
Angio Core Lab to obtain license from Ambra Health for secure image transfer	1	✓ 12/14/17
Milestone Achieved: Study systems developed and functional for trial launch	3	**COMPLETE**
Major Task 3: Participant Recruitment		
Site Study Coordinators screen records for eligibility and randomize consented patients; CCC on call for eligibility questions from sites	4-18	722 screened **Complete**- 211 randomized of 210 Target ✓
Teleconference with SCs every other week and site PIs monthly	4-18	✓
Milestone Achieved: Recruitment and randomization of 210 participants	18	**COMPLETE**
Major Task 4: Participant Follow-up and Evaluation (0,3,6,9,12,18,24,30 mo post-randomization)		
Subtask 1: Data collection - Complete participant study visits		
Complete required study visits, including QOL/functional status	4-48	Ongoing

assessments		
Obtain prescription records from local pharmacies to monitor compliance	4-48	Ongoing
Submit participant clinical data to DCC database management system	4-48	Ongoing
De-identify angiograms and submit to Angio Core Lab	4-48	Ongoing
Collect blood/urine samples for ancillary studies, if funded	4-48	Agreements in process to initiate collection (16 of 20 completed)
Submit adverse event reports to DCC and local IRB (if applicable) per required time frames	As needed	Ongoing
Milestone Achieved: Data collection complete	48	**CONTINUING**
Subtask 2: Event Reporting and Monitoring, Quality Assurance and Centralized Assessments		
DCC securely posts SAEs and Committee submits adjudications	7-30	Ongoing
DCC submits SAEs to DoD and DSMB per required time frames	7-30	Ongoing
DSMB reviews 6-mo outcomes of first 5 participants assigned to EVL/LDTAC	10	✓ Mtg held 10JAN2019
ACL performs angio readings and submits assessments to DCC	10-33	Ongoing
Site visits and data audits performed in person, 1 per site and for-cause;	12-40	✓ Completed
Ongoing monitoring of site and ACL data quality and completeness by DCC		Ongoing
Write and publish trial design manuscript prior to interim look	8-14	Submitted; Under review
DSMB meeting for one interim look at efficacy outcome (estimated timing)	30	Mtg held 11DEC2020
DCC coordinates DSMB meetings, prepares and securely post reports	10-43	Ongoing

Milestone Achieved: Standardized assessments and QA/QC measures executed	48	**CONTINUING**
Major Task 5: Study Closeout and Analysis		
Subtask 1: Study Closeout		
DCC collects all outstanding data & queries from Sites, ACL, Adjudication. Committee	42-48	
All trial parties request extension of protocol duration to local IRBs** to permit analyses in fifth year	45	Continuing review approved
Secure (Foundation, Industry) funds for extended analysis period	36-48	DoD IIR application FY21 not funded
Milestone Achieved: Complete high quality trial data from all sources	48	**CONTINUING**
Subtask 2: Analysis and Dissemination		
Statistical analysis for annual regulatory reports, investig & DSMB meetings	10-48	Ongoing
Statistical analysis programs developed for final results manuscript using dummy randomization and pre-specified table/figure shells from SAP	36-48	
Identify targets for dissemination of results (presentations, publications, web)	36-48	Ongoing
Milestone Achieved: Analyses performed and dissemination targets identified	48	
Major Task 6: Writing and publication of results manuscripts (extension year, post-Award end) with carryover and ancill. funding (Foundation, Industry)	(49-60)	

What was accomplished under these goals?

In this Reporting Period (Year 5), trial execution has proceeded successfully on many fronts.

Study Sites: Business agreements with all 24 (non-BCH) study sites and core laboratory are renewed each year. A Central IRB and full Reliance is in use for 24 of 25 sites.

Communications: Biweekly Operations Committee, semimonthly Executive Committee and semimonthly Steering Committee and Study Coordinator conference calls are held.

1. *Protocol Execution and Monitoring: The InForm database management system, randomization system, and core laboratory and event adjudication systems are in full use. Two DSMB meetings were held in Year 05 (Nov 2021 and May 2022), including* an interim look at treatment efficacy. *Qualifying SAEs are sent to the DSMB Chair in real time as needed. All 25 regulatory/data audit site visits have occurred.*

Trial Tools:
a) The informed consent videos produced in Y01 (English) and in Y02 (Spanish) as an informational tool for families, are described and available at http://med.stanford.edu/teammate.html, https://www.youtube.com/watch?v=KnWwkHUZCv8.
The informed consent videos in English and Spanish acquired over 500 hits during the recruitment period.

b) A video demonstrating the preparation procedure for liquid everolimus to be used by families with infants and young children randomized to everolimus (created in Y02):

https://www.youtube.com/watch?v=CO7VtATeofU&feature=youtu.be

This video had 73 hits. About 25% of the patients in the Everolimus treatment arm are infants/young children (i.e., approximately 30 patients).

Enrollment: Enrollment was completed for the trial in August 2020 (30 months duration). **The final total is 211 participants** (target of 210 (occurred on 31JUL2020), plus one patient who was consented prior to the 210th randomization, who was allowed to proceed to randomization (07AUG2020).

Trial Completion: As of 9/14/22, 170 patients (81%) have completed the trial.

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

March 2022: The TEAMMATE Trial was the focus of a Continuing Medical Education (CME) event with the Pediatric Heart Transplant Society, #PHTSLIVE : https://pediatricheartransplantsociety.org/phts-live/

How were the results disseminated to communities of interest?

Not applicable (trial not complete).

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

2. Continue follow-up of enrolled patients (51 of 211 remaining).
3. Collect and ship biospecimens (funded by Enduring Hearts organization).
4. Complete the baseline characteristics manuscript
5. Complete the Statistical Analysis Plan (SAP).
6. Continue Adjudication Committee case reviews and submission of scores.
7. Continue Angiography Core Laboratory image reviews and submission of data.
8. Conduct a DSMB meeting in late 2022 for assessment of data quality and patient safety.
9. Determine target Conference to present final trial results in 2023.

4. **IMPACT:**

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

This randomized trial has made an impact on the field of pediatric heart transplantation by demonstrating for the first time that a collaborative clinical research network specific to pediatric heart transplantation can be successfully formed to efficiently execute multicenter research studies to improve the management and outcomes of children who have undergone heart transplantation.

What was the impact on other disciplines?

The TEAMMATE Trial has demonstrated to other subspecialties within pediatric cardiology that with planning, collaboration and continued focus, rigorous multicenter research can be successfully executed even in relatively rare and fragile pediatric populations.

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

No changes in approach during the last reporting period.

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

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

The planned 15-month accrual (enrollment) period required almost 30 months to attain the target sample size. The follow-up period of 30 months per participant is fixed; therefore, the trial has extended into a second one-year no-cost extension period to complete patient follow-up. We received approval for the second NCE and advance payment of remaining funds.

While we have received a small amount of philanthropic funding to support a TEAMMATE Biobank, our CDMRP Investigator-Initiated Research Award application in September 2021, "*Correlative Studies of Immunophenotype and Memory in the DoD TEAMMATE Trial Cohort*", log PR210559 was not funded. Hence, resources for execution of correlative studies in the final trial period and *resources for analysis of final Trial results* have not yet been identified.

Changes that had a significant impact on expenditures

Enrollment for TEAMMATE required an additional 14-15 months; therefore, the expenditures to reimburse study sites for end-of-study milestone payments to sites planned for Y04 and Y05 as well as event adjudication costs will now occur in the recently approved second (final) no-cost extension year (Y06).

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

- The trial protocol has had 28 amendments approved and 1 withdrawn. Amendment #28 was approved by the single IRB at Boston Children's Hospital 11/17/21.
- The continuing review for Columbia University was approved by the DoD HRPO on 12/22/21.
- The continuing review for the main protocol was approved by the Central IRB (Boston Children's Hospital) on 1/24/22.
- The continuing review for the main protocol approved by the Central IRB (Boston Children's Hospital) was approved by the DoD HRPO on 09/14/21.

Significant changes in use or care of vertebrate animals

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

Publications, conference papers, and presentations

1. **"TEAMMATE, Trials, and Everolimus"**
   March 2, 2022
   Almond C, Barkoff L, Klein G, Daly KP
   Pediatric Heart Transplant Society, #PHTSLIVE

2. **Under journal review (submitted Aug 2022):**
   Almond CS, Sleeper LA, Rossano JW, Bock MJ, Pahl E, Auerbach S, Lal A, Hollander SA, Miyamoto SD, Castleberry C, Lee J, Barkoff LM, Gonzales S, Klein G, Daly KP. The TEAMMATE Trial: Study Design and Rationale. Under review, American Heart Journal.

See Appendix for published abstracts reported in prior Annual Reports.

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)

The following website went live in October 2018. Its purpose was to promote TEAMMATE Trial visibility and serve as an informational resource to patient families and study centers:

http://med.stanford.edu/teammate.html

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products (presented in past Annual Reports)**

  - **A Spanish language version informed consent video** was produced as an informational tool for families: : https://www.youtube.com/watch?v=KnWwkHUZCv8

  - **An instructional video on Preparation of Liquid Everolimus** was produced for use by families participating in the trial:

  https://www.youtube.com/watch?v=CO7VtATeofU&feature=youtu.be

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Name:	Lynn Sleeper, ScD
Project Role:	PD/PI, PI of DCC
Researcher Identifier (e.g. ORCID ID):	0000-0002-8055-768X
Nearest person month worked:	1.20
Contribution to Project:	No change.

Name:	Kevin Daly, MD
Project Role:	Co-Investigator, Co-PI of CCC
Researcher Identifier (e.g. ORCID ID):	0000-0003-4327-1532
Nearest person month worked:	1.80
Contribution to Project:	No change.

Name: Christopher Almond, MD, MPH
Project Role: Co-Investigator, Co-PI of CCC
Researcher Identifier (e.g. ORCID ID): 0000-0001-7136-8337
Nearest person month worked: 1.45
Contribution to Project: No change.

Name: Tajinder Pal Singh, MD, MSc
Project Role: Co-Investigator/Medical Monitor
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 0.60
Contribution to Project: No change.

Name: Shelley Miyamoto, MD
Project Role: Co-Investigator/Director of Angiography Core Laboratory
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 0.095
Contribution to Project: No change

Name: Gloria Klein, MS, RD
Project Role: Project Director of DCC
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 1.2
Contribution to Project: No change.

Name: JungWoo Lee
Project Role: Research Assistant
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 3.96
Contribution to Project: No change.

Name: Minmin Lu, MS
Project Role: Statistical Programmer
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 0.72
Contribution to Project: No change.

Name: Jane Messere, RN
Project Role: Clinical Research Associate
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 1.2
Contribution to Project: No change.

Name: Selena Gonzales, MPH
Project Role: Project Manager of the CCC
Researcher Identifier (e.g. ORCID ID): 0000-0003-3744-111X
Nearest person month worked: 3
Contribution to Project: No change.

Name: Joseph Rossano, MD
Project Role: Co-Investigator/Site PI
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 0.075
Contribution to Project: No change.

Name: Scott Auerbach, MD

Project Role:	Co-Investigator/Site PI
Researcher Identifier (e.g. ORCID ID):	0000-0002-2341-0913
Nearest person month worked:	0.075
Contribution to Project:	No change.

Name:	Seth Hollander, MD
Project Role:	Co-Investigator/Site PI
Researcher Identifier (e.g. ORCID ID):	0000-0002-0818-3150
Nearest person month worked:	0.075
Contribution to Project:	No change.

8.

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?

Nothing to Report.

9

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

10. APPENDICES:

Previously published/listed in past Annual Reports:

1. **The TEAMMATE Trial: An Update for Patients and Families**

Enduring Hearts Facebook Live!
April 22, 2021

Presenter: Kevin Daly, MD (Trial Co-Chair)

Assistant Professor of Pediatrics, Harvard Medical School
Advanced Cardiac Therapies Program
Dept of Cardiology, Boston Children's Hospital

TEAMMATE was featured in both of these invited talks:

2. **Proliferation Signal Inhibitor Avenue: Use of mTORi/PSI Immunosuppression in Pediatric Heart Transplantation**

Kevin P. Daly, MD
American Transplant Congress 2021: The Road Less Traveled:
Experience with Unique Immunosuppression in Pediatric Transplantation
June 6, 2021

3. ***Brayden Andrew Moore Transplant Educational Lecture***
Heart Transplant Immunosuppression and Steroid-Free Induction Therapy

Kevin P. Daly, MD (Trial Co-Chair)
Children's of Alabama, University of Alabama at Birmingham
August 10, 2021

4. Sleeper LA, Daly KP, Addonizio LJ, Alejos JC, Auberbach S, Bock MJ, Butto A, Carlo WF, Castleberry C, Dreyer WJ, Feingold B, Lamour J, Friedland-Little J, Hollander S, Klein G, Lal A, Pahl E, Peng D, Pietra B, Punnoose AR, Ryan TD, Su J, Sutcliffe DL, Zangwill S, Rossano JW, Almond CS. Recruitment in the TEAMMATE Trial: Observed vs. Expected. Select Abstracts From Cardiology 2020: 23rd Annual Update on Pediatric and Congenital Cardiovascular Disease. *World J Ped Congenit Heart Surg* 2020; 11(2), NP1–NP77. https://doi.org/10.1177/2150135120904324

5. Lee J, Castleberry C, Bock M, Auerbach SR, Rossano JW, Hollander SA, Lal AK, Pahl E, Barkoff L, Klein GL, Almond CS, Sleeper LA**,** Daly KP. Accuracy of Initial Everolimus Dosing in the TEAMMATE Trial: How Well Does It Work in Pediatric Heart Transplantation? *Circulation* 2019; Abstract 16528, Vol. 140, Suppl_1.

6. Almond, C., Sleeper, L.A., Rossano, J.W., Pahl, E., Lal, A.K., Castleberry, C.D., Lee, J., Hollander, S., Klein, G., Barkoff, L.M., Bock, M., Fenton, M., Daly, K.P. The TEAMMATE

Trial: Study Design and Rationale of the First Pediatric Heart Transplant Randomized Clinical Trial. *The Journal of Heart and Lung Transplantation 2020;* 39, S207–S208. https://doi.org/10.1016/j.healun.2020.01.825

7. Daly KP, Sleeper LA, Addonizio LJ, Alejos JC, Auerbach S, Bock MJ, Butto A, Carlo WF, Castleberry C, Dreyer WJ, Feingold B, Lamour JM, Albers EL, Hollander SA, Klein GL, Lal A, Pahl E, Peng D, Punnoose AR, Rossano JW, Ryan TD, Su J, Sutcliffe DL, Zangwill S, Almond CS. Recruitment in the Pediatric Heart Transplant TEAMMATE Trial: Observed vs. Expected [abstract]. *Am J Transplant*. 2020; 20 (suppl. 3). https://atcmeetingabstracts.com/abstract/recruitment-in-the-pediatric-heart-transplant-teammate-trial-observed-vs-expected/. Accessed June 18, 2020.

8. Bock MJ, Chau P, Kuhn MA, Martens T, Razzouk A, Chinnock RE. The Major Adverse Transplant Events (MATE) Score Applied to a Cohort of Pediatric Heart Transplant Recipients. *J Heart Lung Transpl* April 2019; 38(4), Supplement, S471-S472. DOI: https://doi.org/10.1016/j.healun.2019.01.1199

9. Sleeper LA, Daly KP, Rossano JW, Desai M, Auerbach S, Bock MJ, Castleberry CD, Fenton M, Hollander SA, Lal A, Pahl E, Almond CS. Design of the TEAMMATE Trial for children with heart transplant and development of a novel efficient endpoint. *Clinical Trials* 2018; 15:2 suppl. P79; p.183