Form Approved Through 09/30/2007

OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

# Grant Progress Report

| Review Group | Type | Activity | Grant Number |
|---|---|---|---|
| | 5 | U01 | U01 AT01156-04 |

Total Project Period
From: 08/15/2002 Through: 02/28/2007

Requested Budget Period
From: 03/01/2005 Through: 02/28/2006

1. TITLE OF PROJECT
Trial to Assess Chelation Therapy (TACT)

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Gervasio A. Lamas, MD
Mount Sinai Medical Center
4300 Alton Road; Butler Building
Miami Beach, FL 33140

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Mount Sinai Medical Center of Florida, Inc.
4300 Alton Road
Miami Beach, FL 33140

2007 DEC 30 11:37

2b. E-MAIL ADDRESS
TACTNIH@aol.com

4. FACILITY IDENTIFICATION NUMBER
EIN [redacted]

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Medicine

2d. MAJOR SUBDIVISION
Cardiology

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
William Abraham, Ph.D
Director of Research
4300 Alton Road
Miami Beach, FL 33140

E-MAIL: Abraham@msmc.com

2007 DEC 30 11:36

6. HUMAN SUBJECTS
☐ No ☒ Yes

6a. Research Exempt
☒ No ☐ Yes

6b. Human Subjects Assurance No.
FWAA00000176

If Exempt ("Yes" in 6a):
Exemption No.

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

If Not Exempt ("No" in 6a):
IRB approval date 3/22/2001
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $8,710,556 8b. TOTAL $8,951,920

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Mount Sinai Medical Center
4300 Alton Road
Miami Beach, FL 33140

Duke Clinical Research Institute
Box 3300
Durham, NC 27715

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 305-674-2162
FAX 305-674-3970

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
William Abraham, PhD
TEL 305-674-2790
FAX 305-674-2198

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Paul Katz, MD
TITLE Vice President
TEL 305-674-2633 FAX 305-674-2007
E-MAIL pkatz@msmc.com

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)*

DATE 12/28/04

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)*

DATE 12-28-04

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio A., MD

| DETAILED BUDGET FOR NEXT BUDGET PERIOD -- DIRECT COSTS ONLY | FROM 03/01/05 | THROUGH 02/28/06 | GRANT NUMBER 1 U01 AT01156-03 |
|---|---|---|---|

| PERSONNEL (Applicant organization only) | | TYPE APPT. (months) | % EFFORT ON PROJ. | DOLLAR AMOUNT REQUESTED (omit cents) | | |
|---|---|---|---|---|---|---|
| NAME | ROLE ON PROJECT | | | SALARY REQUESTED | FRINGE BENEFITS | TOTALS |
| Gervasio A. Lamas, MD | Principal Investigator | 12 | [redacted] | 64,480 | 0 | 64,480 |
| Jacqueline Arciniega, MPH | Project Director | 12 | | 73,388 | 0 | 73,388 |
| Kayvan Amini, DO | Clinical Manager | 12 | | 41,162 | 0 | 41,162 |
| Virginia Martini | Admin. Coordinator | 12 | | 28,323 | 0 | 28,323 |
| Renea L. Moss | Office Coordinator | 12 | | 40,299 | 0 | 40,299 |
| Parminder Singh, MD | Research Assistant | 12 | | 31,360 | 0 | 31,360 |
| Jewmaull Reed | Research Assistant | 12 | | 28,513 | 0 | 28,513 |
| **SUBTOTALS** → | | | | 307,525 | 0 | 307,525 |

| | |
|---|---|
| CONSULTANT COSTS<br>Chelation Consultants: Martin Dayton (3,744) Ted Rozema (3,744) Misc. Consultants: (7,512) | 15,000 |
| EQUIPMENT *(Itemize)*<br>Scanner/Color Printer | 500 |
| SUPPLIES *(Itemize by category)*<br>General Office: 7,000 FAX and copier: 1,000 Paper: 2,000 | 10,000 |
| TRAVEL<br>CCC Travel | 20,604 |
| PATIENT CARE COSTS — INPATIENT 0 | 0 |
| PATIENT CARE COSTS — OUTPATIENT 0 | 0 |
| ALTERATIONS AND RENOVATIONS *(Itemize by category)*<br>0 | 0 |
| OTHER EXPENSES *(Itemize by category)*<br>Telephone: 12,000 Pagers/Cellulars: 2,000 Postage: 4,160 Advertisement: 10,400 | 28,560 |
| **SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD** | $ 382,189 |
| CONSORTIUM/CONTRACTUAL COSTS — DIRECT COSTS | 8,328,367 |
| CONSORTIUM/CONTRACTUAL COSTS — FACILITIES AND ADMINISTRATIVE COSTS | 240,464 |
| **TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD** *(Item 8a, Face Page)* | $ 8,951,020 |

| BUDGET JUSTIFICATION | GRANT NUMBER |
|---|---|
| | 1 U01 AT01156-03 |

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

More study patients will be enrolled during year 4 than during year 3. Nonetheless we are requesting the same estimated number of personnel and costs for consortia. In addition, there has been sub-category rebudgeting among the following subcontractor:

Omnicomm: Omnicomm is receiving additional funding for covering costs related to the reprogramming the TrialMaster system for patient safety measures detailed in the progress report. These funds were taken from CCC Travel since all three required study meetings were completed by year 3.

| CURRENT BUDGET PERIOD | FROM | THROUGH |
|---|---|---|
| | 03/01/2004 | 02/28/2005 |

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget.

Consortium: Because of the modified patient enrollment curve, there have been less expenditures for central lab and clinical units as of December 2004. These expenses will be incurred during year 4 as the number of enrolled patients increases. A carryover request will be forthcoming.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

| NAME | POSITION TITLE |
|---|---|
| Arciniega, Jacqueline | Project Director |
| eRA COMMONS USER NAME | |

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Macalester College, St. Paul, MN | BA | 1992-1996 | Biology |
| Mailman School of Public Health Columbia University. New York. NY | MPH | 1998-2000 | Epidemiology |

**A. Positions and Honors.**

**Positions and Employment**

| | |
|---|---|
| Research Assistant, Sergievsky Center of Columbia University, New York, NY | 1999-2000 |
| Health Services Analyst, HIP Health Plan of New York, New York, NY | 2000-2001 |
| Manager, Health Services Analysis Unit, HIP Health Plan of New York, New York, NY | 2001-2002 |
| Assistant Director, HIP Health Plan of New York, New York, NY | 2002-2003 |
| Senior Consultant, Outcomes Research, NDCHealth, Yardley, PA | 2003-2004 |
| Research Associate/TACT Project Director, Mt. Sinai Medical Center, Miami Beach, FL | 2004-Present |

**Other Experience**

| | |
|---|---|
| Research Assistant, Biology Department, Macalester College, St. Paul, MN | 1993-1995 |
| Intern Research Assistant, Institute of Human Genetics, University of MN, Minneapolis, MN | 1995-1998 |

**Honors**

Midwest Chapter INROADS Scholar, 1994
Midwest Ronald E. McNair Scholar, 1995
Macalester College, Presidential Leadership Award, 1996
HIP Health Plan Team Player of the Year, 2002

**Selected peer-reviewed publications (in chronological order).**

Tilden AR, Becker MA, Amma LL, Arciniega J, McGaw AK. Melatonin Production in an Aerobic Photosynthetic Bacterium: An Evoluntionary Early Association with Darkness. Journal of Pineal Gland Research, 1997; 22: 102-106.

Reich L, Jaramillo B, Kaplan L, Arciniega J and Kolbasovsky A. Improving Continuity of Care: Success of a Behavioral Health Program. Journal for Health Care Quality, 2003; 25: 4-9.

**Research Support**

1 U01 AT01156-03 (Project Director) 7/26/2004-Present

TACT is a randomized clinical trial with a 2 X 2 factorial design to independently test the effects of the standard chelation solution recommended by the American College for Advancement in Medicine (ACAM) versus placebo solution, and the effects of a high-dose oral vitamin supplementation, versus a low dose regimen to simply replace chelation-related losses.

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

| NAME | POSITION TITLE |
|---|---|
| Kayvan Amini, DO | Clinical Trial Manager |
| eRA COMMONS USER NAME | |

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| University of Miami, FL | BS | 1992-1996 | Chemistry/Biology/Math |
| University of Miami, FL | Masters | 1997 | Masters of Chemistry Level |
| Nova Southeastern College of Osteopathic Medicine FL | DO | 1997-2001 | Doctor of Osteopathic Medicine |
| Mount Sinai School of Medicine, NY | Residency | 2002 | Internal Medicine Residency (PGYI) |
| University of Southern California and Los Angeles County Medical Center, CA | Residency | 2002-2004 | Internal Medicine Residency (PGYII – III) |
| Mount Sinai Medical Center, FL | Fellowship | 2004 | Cardiology Fellowship (PGYIV) |

**Positions and Honors**

**EXPERIENCE**

University of Miami Department of Chemistry, Teaching Assistant 1996-1997
University of Miami School of Medicine, Lab Assistant 1994-1995
University of Miami School of Medicine, Research Assistant Immunochemistry Lab 1994-1995
Keck School of Medicine, University of Southern California, Volunteer Faculty 2002-2204
Licensed by California Board of Osteopathic Medicine, 2003-Present
Board Certified in Internal Medicine, 2004-Present

**PROFESSIONAL AND HONORARY ORGANIZATIONS**

Recipient of University of Miami Grant A and B (1992-1996)
President of Chemistry Honor Society, and Chemistry Society at University of Miami (1994-96)
Award for Excellence in Student Involvement, University of Miami (1996)
American Chemical Society Award for Superior Achievements in Chemistry (1996)
2nd Place University of Miami Research Symposium (1996)
Florida Osteopathic Association Member since 2001
American College of Internists Member since 2001
American College of Cardiology Member since 2004
American Medical Association Member since 2001
American College of Physicians Member since 2001
American Osteopathic Association Member since 2001

**Research Support**

1 U01 AT01156-03 (Project Director) 7/26/2004-Present
TACT is a randomized clinical trial with a 2 X 2 factorial design to independently test the effects of the standard chelation solution recommended by the American College for Advancement in Medicine (ACAM) versus placebo solution, and the effects of a high-dose supplementation, versus a low dose regimen to simply replace chelation-related losses.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A, MD

| PROGRESS REPORT SUMMARY | GRANT NUMBER<br>1 U01 AT01156-03 | |
|---|---|---|
| | PERIOD COVERED BY THIS REPORT | |
| PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR<br>Gervasio A. Lamas, MD | FROM<br>03/01/2005 | THROUGH<br>02/28/2006 |

APPLICANT ORGANIZATION
Mount Sinai Medical Center

TITLE OF PROJECT (Repeat title shown in item 1 on first page)
Trial to Assess Chelation Therapy (TACT)

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

**WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.**

Has there been a change in the other support of key personnel since the last reporting period?
The following are organizational changes in the TACT CCC since the last reporting period (December 2003). All changes were made without a significant increase in total cost.
Danielle Hollar, PhD (Project Director): Dr. Hollar resigned from TACT.

Jaime Zimmerman, MPH (Research Assistant/Interim Project Director): Ms. Zimmerman took on the Project Director's responsibilities upon Danielle Hollar's resignation until a permanent Project Director was found. Ms. Zimmerman resigned from TACT.

Matt Shields (Research Assistant): Mr. Shields resigned from TACT.

Jacqueline Arciniega, MPH (Project Director): Ms. Arciniega has been added to the CCC as a full-time Project Director. She will spend [redacted] committed to TACT, with a base salary of $[Institutional Base Salary] increasing by 3% each year. Her TACT related duties are the following:

1. Maintaining the organization integrity of the Clinical Coordinating Center. The Project Director will assist the Principal Investigator in selecting personnel with scientific experience and clinical expertise to fill the funded positions in the CCC. All NIH hiring policies will be adhered to and any gaps in CCC personnel will be promptly filled.
2. Maintaining communication and cohesion among the organizational units of TACT. The Project Director will assist the Principal Investigator in maintaining open lines of communication with the organizational units of TACT. Scheduled conference calls will occur weekly to discuss the progress of the trial. The staffs at each of the organizational units will maintain close telephone and email contact.
3. Maintaining close contact and collaboration with the chelation medicine community. The Project Director will assist the Principal Investigator in devloping a liaison committee with the chelation community, educating the traditional medicine clinical investigators, presenting at annual meeting of ACAM when invited, and publishing methodological and other aspects of the study in the alternative medicine literature as well as in the traditional scientific literature.
4. Identify and recruit clincial units. The Project Director will assist the Prinicipal Investigator in recruiting

competent clinical units for study performance.
5. Setting standards of productivity and scientific performance for TACT clinical units. The Project Director will assist the Principal Investigator in developing and enforcing expectations of quality, safety, and productivity.
6. Developing contractual relationships with over 120 Clinical Units and with the organizational and performance units. The Project Director will assist the Principal Investigator in developing the clinical units' Memoranda of Agreement to formalize the scientific and economic relationships that will cement participation in the study.
7. Assisting clinical units to obtain OHRP clearance. The Project Director will lead the CCC staff in identifying those clinical units that do not carry MPA or FWA numbers. Those clinical units will be assisted in obtaining FWA numbers so the study can proceed rapidly.
8. Planning and directing training and yearly meetings. The Project Director will assist the Principal Investigator in deciding the timing, location, and content of the training meeting and of the subsequent yearly study meetings.
9. Maintain close interaction with the NCCAM and NHLBI Project Offices. The Project Director will assist the Principal Investigator in maintaining close contact with the Project Office, keeping it apprised of the progress of the trial. This includes participation in conference calls, active participation in meetings, and, when necessary, assisting in management of recruitment or quality control issues with the clinical units.
10. Coordinating the collection of regulatory documents from clinical units.
11. Coordinating yearly NCCAM Progress Report and non-competitive renewal applications.
12. Coordinating the Ancillary Studies applications.
13. Identifying, recruiting, and activating international sites. Submitting regulatory documentation to appropriate country agencies for International sites. The Project Director will assist the Principal Investigator in writing and submitting documents following each country's regulatory requirements when establishing International clinical sites.
14. Coordinate efforts for establishing International sites. The Project Director will assist the Principal Investigator in identifying and resolving any barriers and issues when establishing International clinical sites.
15. Develop and establish standard operating procedures for site activation process, annual IND submission process, informed consent process, site payment process..
16. Coordinate efforts with consortia: DCRI, Omnicomm, and Central Pharmacy.
The Project Director reports to the Principal Investigator.

Kayvan Amini, DO (Clinical Manager): Dr. Amini has been added to the CCC as a full-time Clinical Manager for one-year as part of his clinical research fellowship program. Dr. Amini will spend [redacted] time committed to TACT. His TACT related duties follow:
1. Training and assisting clinical units with the clinical management of TACT patients.
2. Training and assisting clinical units with patient recruitment strategies.
3. Training and assisting clinical units with patient retention strategies.
4. Responding to clinical inquires from clinical units.
5. Working with the DCC site monitors to assure a smooth operation of TACT.
6. Participating in weekly Operations Committee calls.
7. Participation in the Steering Committee as an ex-officio member.
8. Developing educational materials for TACT patients.
9. Developing educational materials for TACT clinical units.
10. Assist clinical sites in patient monitoring to ensure the safety of all TACT patients.

11. The Clinical Trial Manager will assist the Principal Investigator in reviewing and modifying (if necessary) the TACT protocol.
12. Assists Project Director in coordinating and managing study related tasks.
13. Manages, coordinates, and develops changes for Electronic Data Capture (EDC-TrialMaster) system with Omnicomm.
14. Involved in all management aspects of the Central Pharmacy.
15. Responsible for assisting clinical units with the clinical management of study patients.
16. Responsible for monitoring clinical units to assure the integrity and compliance to TACT protocol.
The Clinical Trial Manager reports to the Principal Investigator and Project Director.

Parminder Singh, MD (Research Assistant): Dr. Singh was added to the CCC as a full-time Research Assistant for one-year in Spring 2004. Dr. Singh will be with the TACT study until mid-Spring 2005. He will spend [redacted] time committed to TACT, with a base salary of [Institutional Base Salar] with an annual increase of 3%. His principal duties are:
1. Assist clinical units in submitting required regulatory documents required for study.
2. Assist in identifying new clinical sites.
3. Maintain and update contact information for clinical sites.
4. Assist in the development of study reports as directed by Project Director.
5. Serve as a liaison between study sites and the Clinical Coordinating Center.
6. Follow-up on site monitoring reports generated after each DCC site monitor visits.
7. Participate in weekly Operations call.
8. Assist in the yearly IRB re-review and re-approval process so sites are notified at least three (3) months prior to their IRB expiration date, and assist in yearly submissions.
9. Assist sites in obtaining FWA number.
10. Assist with IRB and OHRP submissions of individual clinical sites.
The Research Assistant reports to the Project Director and Clinical Trial Manager.

Jewmauil Reed, BA (Research Assistant): Mr. Reed was added to the CCC as a full-time Research Assistant for one-year in Spring 2004. Mr. Reed will be with the TACT study until mid-Spring 2005. He will spend [% Effort] time committed to TACT, with a base salary of [Institutional Base Salary] with an annual increase of 3%. His duties are as follows:
1. Assist clinical units in submitting required regulatory documents required for study.
2. Assist in identifying new clinical sites.
3. Maintain and update contact information for clinical sites.
4. Assist in the development of study reports as directed by Project Director.
5. Serve as a liaison between study sites and the Clinical Coordinating Center.
6. Submit and coordinate IRB submissions.
7. Participate in weekly Operations call.
8. Maintain site regulatory documents through regular auditing of clinical site files for expiration of IRB approval dates, change of staffing in clinical sites.
9. Assist in coordinating the distribution of study related materials to sites.
The Research Assistant reports to the Project Director and Clinical Trial Manager.

Renea Moss (Office Coordinator): Ms. Moss was promoted to an Office Coordinator position. She will spend [redacted] time committed to TACT, receiving a base salary of [redacted] with an annual increase of 3%. The Office Coordinator's duties are as follows:

1. Monitoring and maintaining the integrity of the TACT budget.
2. Process weekly clinical site payments. The Office coordinator is responsible for paying clinical units upon each patient randomization with a completed EQOL questionnaire.
3. Process consortium payments upon receipt. The Office coordinator is responsible for timely payment of all subcontractors in accordance with MOA: Accucare Pharmacy, Duke Clinical Research Institute, Omnicomm Systems, Brigham and Women's Hospital, Quest, and Pharmed.
3. Creates and maintains database for clinical sites to track site related expenses including patient lab procedures and other miscellaneous expenses.
4. Analyzes and updates current and projected expenditures of assigned projects.
5. Develops and maintains budgetary database for clinical units and consortia.
6. Reviews and verifies Notice of Grant Award reports from National Institute of Health.
7. Develops and submits Financial Status Reports to National Institute of Health.
8. Assists with budget aspects of TACT Progress Report to National Institute of Health.

The Office Coordinator reports to the Project Director.

Virginia Martini (Administrative Coordinator/International Coordinator): Ms. Martini has reduced her time commitment to TACT to [redacted] with a base salary of [redacted] Institutional Base Salary increasing by 3% each year. The Administrative Coordinator's duties are as follows:

1. Translating TACT protocol into Spanish.
2. Maintain and audit Memoranda of Agreement (MOA) for clinical sites and study subcontractors. The Administrative Coordinator is responsible for reviewing MOAs with the following subcontractors: Accucare Pharmacy, Omnicomm, Duke Clinical Research Institute, Pharmed, Quest, and Brigham and Women's Hospital.
3. Coordinates with Mount Sinai Medical Center Grants and Research Administration implementing MOAs for clinical sites and subcontractors.
4. Assists in identifying new clinical sites for the study.
5. Assists Project Director in coordinating submission of regulatory documents for international sites.
6. Translating TACT patient recruitment materials into Spanish.
7. Supports in the development of letters and reports.
8. Acts as a secondary liaison with international sites. The Administrative Coordinator will assist in the coordination of establishing international sites.
9. Assists Project Director in organizing conference calls.
10. Supports in the development of reports, charts, letters.

The Administrative Coordinator/International Coordinator reports to the Project Director.

Ingrid Bazin, BS (Administrative Assistant): Ms. Bazin has resigned from the study. The responsibilities for this position were divided between the coordinator positions.

**Will there be, in the next budget period, a significant change in the level of effort for the PI or other personnel designated on the Notice of Grant Award from what was approved for this project?**

**Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year's total budget?**
Administrative delays in receiving year 3's carryover may cause the prior year's carryover to be greater than 25% of the current year's total budget. The modified curve predicted fewer patients in year three, than anticipated leading to lower expenditures for central lab and clinical units. More expenses will be incurred during year 4 when the number of enrolled patients is predicted to be the highest. A carryover request will be forthcoming.

**Progress Report Summary**

**a. Specific Aims**

The specific aims of the Trial to Assess Chelation Therapy (TACT) remain the same as listed in the original award.

**b. Studies and Results**

No results have been obtained. This is a double-blind trial therefore results are not expected until completion of the study.

**c. Significance**

As mentioned above, no results have been obtained thus far. The trial, however, remains as significant as when it was conceived.

**d. Plans**

**Milestones accomplished:**

*Site Activation Process*

As of December 21, 2004, 105 clinical sites have completed the regulatory document process. Of these seventy-two clinical sites have randomized at least one patient in TACT. The overall average number of patients enrolled per site is 0.92. Enrollment at the site level has a wide range of variation (0 to 5.3 patients per month). Conference calls with sites that have not recruited patients has helped the Clinical Coordinating Center identify specific barriers faced by the sites. The CCC has been working with NCCAM to coordinate activities that will address barriers identified by sites. The number of enrolling sites will remain at approximately 120 sites at study completion by implementing two measures: all new sites (as of November 2004) are required to consent two patients prior to activation and all currently activated sites that have not randomized any patients for 3 months will be given 30-days to enroll a patient in order to retain their active status. These two efforts will help the CCC maintain the number of clinical sites at approximately 120 and only retain productive sites in the trial.

*Site Recruitment Efforts*

The aforementioned measures to maintain the number of sites to 120 require concentrated efforts in identifying more interested sites. We intend to have a continuous source of potential sites by the following efforts:
1. Duke University Cooperative Cardiovascular Studies (DUCCS) group fax: Letter from Drs. Lamas and Lee describing TACT to 2,400 cardiologists in DUCCS database. Number of DUCCS sites sent additional information on TACT: 3% (74/2500)
2. Distribution of TACT site recruitment brochure at recent American Heart Association (AHA) meeting at NHLBI booth.
3. Distribution of TACT study description at AHA meeting at DCRI booth.

4. Key cities targeted site recruitment: Site recruitment letters were sent to 98 cardiologist offices in Atlanta, GA.
5. General Clinical Research Center (GCRC) Site Recruitment: 50 letters were sent inviting GCRCs to become TACT sites.

The Clinical Coordinating Center is in process of contacting the following groups to invite to apply to become TACT sites:
1. ALLHAT sites
2. American Osteopathic Association 200/600 letters of invitations were sent to DO physicians identified as cardiologists. The other 400 letters will go out early January 2005.
3. Family practice and cardiology programs in osteopathic medical schools
4. Society of Cardiac Rehabilitation
5. Cardiologists in selected urban areas as listed in the American College of Cardiology directory to target minority enrollment.
6. The CCC is in the process of establishing sites in Canada and Argentina. Contact was established with cardiologists in each country who are willing to become country leaders to facilitate the coordination of TACT sites in their countries. The country leaders will help the CCC identify new clinical units in their country, facilitate regulatory document submission, clinical unit monitoring, and developing sensible logistical plans for clinical unit training and receipt of study materials. International sites will be directly managed by the CCC therefore will not incur any additional study costs, since the CCC would manage these sites in the same fashion as domestic (USA) sites. The addition of international sites only presents additional administrative time.

*Patient Safety*
The current calcium low normal range (9.0 mg/dL) in the protocol will be changed to 8.5 mg/dL. The decrease in calcium does not affect the specific aims of the study. This change was implemented to reflect the central laboratory (Quest) normal calcium lab values. A closer review of patient safety measures were conducted and led to the development of two additional patient safety measures focusing on improving the infusion times at each clinical site, correcting abnormal calcium levels based on albumin concentration, and notifying patients and primary care physicians of critical laboratory values. The following detail these processes:

1. Fast Infusions:
Current protocol allows for active infusion to occur over 3 hours, while below-normal calcium levels require the infusion to occur over a minimum of 4 hours. In order to ensure a safe infusion, the time and volume of the infusion given will be recorded via the TrialMaster®, allowing for proper rate calculations. The TrialMaster® will then automatically notify the CCC, DCRI, and the Site investigator of a fast infusion. Fast infusions will be addressed by the CCC following a specific process (diagram 1). A second mechanism of ensuring proper infusion rates is the incorporation of flowmeters.

2. Calcium Correction:
The standard measurement of serum calcium does not take into account patients with hypoalbuminemia. Since calcium is bound to albumin, patients with low albumin will have a different true value of serum calcium. In order to account for this, the serum calcium level must be corrected using the serum albumin. We will automate the process of calculating corrected calcium through TrialMaster®:
1) All serum calcium will require a calcium correction for albumin level.
corrected calcium = serum calcium + (0.8 x [normal serum albumin - patient's albumin]).
(Note: normal serum albumin is defined as the midpoint of the central lab normal albumin range 4.2 mg/dL)
2) If corrected calcium is **8 mg/dl to 8.4 mg/dl**, it will be considered a lab alert, hence will require a long infusion (4-5 hrs).
3) Any corrected calcium **below 8.0 mg/dl** will place the patient in Lab Delay. Therefore, patient will not receive an infusion and will be required to repeat lab draw in two weeks.

3. Laboratory Critical Values
Modifications have been made to ensure more clinically relevant ranges for the lab alert system. In addition, an automated alert and check system monitored by the CCC via TrialMaster® will be set up to notify the site to contact the patients' primary care physician (PCP) in case a critical lab value is reached (diagram 2).
EDTA can affect renal function. Lab alerts will be triggered when a decline in estimated creatinine clearance of 25% or greater occurs. This will be addressed by the CCC.

*Patient Enrollment Update*
Patient enrollment is closely monitored on a weekly basis to assess recruitment. Weekly site calls with the CCC help sites discuss barriers. These calls also serve to identify interventions that can address these site barriers. These calls also help foster interactions with sites and the CCC. The following list represents the CCC and NCCAM efforts to help site recruit patients:
1. Development of Patient Recruitment Toolkit that provides tips to help sites develop and implement their own patient recruitment action plan.
2. IRB approved fliers and brochures.
3. NCCAM website: http://nccam.nih.gov/chelation/
NCCAM clearinghouse number collects and disseminates patient contact information to sites.
Media training at last investigators' and coordinators' meeting addressed how to successfully approach local media to discuss TACT.
4. Weekly conference calls with Clinical Trial Manager and Research Assistants to sites with no patients to identify barriers in recruiting patients and propose solutions to help in their efforts. NCCAM Communications Specialist joins many calls to discuss patient recruitment toolkit.
5. Point-of-service displays are provided to sites upon request. These displays can be placed in physicians' waiting rooms.
6. Weekly site calls from TACT Principal Investigator to sites that have not enrolled any patients. These phone calls give sites an opportunity to talk directly with PI about barriers faced when recruiting patients:
7. Weekly site calls from TACT Principal Investigator to dormant sites (enrolled at least one patient but had no enrollment activity in the past three months).
8. Referring Cardiologist Program: Letter is sent from TACT PI to site-identified cardiologists requesting patient referrals to TACT site:
Mailed 484 letters to cardiologists for 9 sites.
9. General patient recruitment program: Letters were sent to 56 Cardiac Rehabilitation Centers across the United States referring them to call the Clinical Coordinating Center or the NCCAM clearinghouse number.

The Clinical Coordinating Center is in the process of implementing the following:
1. Patient Waiting Room Toolkit: This toolkit will provide sites with a poster board and patient information that they can place in their waiting room.
2. Patient Ambassador Program: This program recruits enthusiastic patients interested in passing on information of TACT to other patients.
3. Site Advertising Program: One of the barriers identified during site calls was funding for paid media. Many sites determined the best method of advertising in their local area were radio, newspaper, and other circulars. The vast majority of these media forms are not free. Through this program sites are asked to submit a proposal requesting extra funding for a paid advertisement. As part of the program the site is required to commit to tracking the number of patient responses to the advertisement.
4. Referring Cardiologist Program Phase 2: Revised referral letter, PI bio-sketch, and STEMI guidelines are sent to site-identified cardiologists requesting patient referrals (attachment 9).
5. TACT Teleconference Lunch: sites will host a lunch for interested cardiologists to hear a 20-30 minute teleconference by Dr. Lamas on the TACT study. This forum will allow sites to initiate and recruit local cardiologists to refer patients to their TACT site.
6. Targeted media outreach using NCCAM's IRB approved B-roll in cities with TACT sites: short video describing TACT profiling a TACT patient, TACT site investigator, and Dr. Lamas. Available in English and Spanish.

6. Targeted media outreach using NCCAM's IRB approved B-roll in cities with TACT sites: short video describing TACT profiling a TACT patient, TACT site investigator, and Dr. Lamas. Available in English and Spanish.
7. IRB approved article on TACT will be distributed through the North American Precis Syndicate (NAPS).

*Planned Activities to Improve Enrollment of Minorities and Women*

The CCC is in the process of implementing the following action plan to improve enrollment of minorities and women in the study:

1. Activation of clinical units in urban areas with denser populations of minorities.
2. The Mount Sinai Medical Center (MSMC) TACT clinical unit was activated, the medical center has a large pool of post-MI Hispanic patients which will be assessed for eligibility into the trial.
3. Pursuit of clinical sites in Puerto Rico. The CCC is in the process of identifying clinical units in Puerto Rico who had success in previous clinical trials like ALLHAT.
4. The CCC will begin, in February 2005, a campaign focused on increasing enrollment of women. This will be initiated via our study newsletter where sites with high proportions of women will be highlighted.

*Review and Approval of Site Informed Consent Forms*

A guideline was created to accurately audit and approval each site's informed consent forms. These guidelines include review of elements of each sites consent form prior to submission for IRB approval by site. A checklist detailing all the essential elements required on every consent form was developed and is used when reviewing all site consent forms.

Principal Investigator/Program Director (Last, first, middle): Lamas, Gervasio A., MD

GRANT NUMBER
1, U01AT01156-03

# CHECKLIST

**1. PROGRAM INCOME** ***(See Instructions.)***
All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

| Budget Period | Anticipated Amount | Source(s) |
|---|---|---|
| | | |

**2. ASSURANCES/CERTIFICATIONS** ***(See Instructions.)***
In signing the application Face Page, the authorized organizational representative agrees to comply with the following policies, assurances and/or certifications when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398. If unable to certify compliance, where applicable, provide an explanation and place it after this page.
• Human Subjects • Research Using Human Embryonic Stem Cells • Research on Transplantation of Human Fetal Tissue • Women and Minority Inclusion Policy • Inclusion of Children Policy • Vertebrate Animals

• Debarment and Suspension • Drug- Free Workplace *(applicable to new [Type 1] or revised [Type 1] applications only)*; • Lobbying • Non-Delinquency on Federal Debt • Research Misconduct • Civil Rights (Form HHS 441 or HHS 690); • Handicapped Individuals (Form HHS 641 or HHS 690) • Sex Discrimination (Form HHS 639-A or HHS 690) • Age Discrimination (Form HHS 680 or HHS 690); • Recombinant DNA Research, Including Human Gene Transfer Research • Financial Conflict of Interest (except Phase I SBIR/STTR) • Prohibited Research • Select Agents
• STTR ONLY: Certification of Research Institution Participation.

**3. FACILITIES AND ADMINSTRATIVE (F&A) COSTS**
Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will *not* be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

☒ DHHS Agreement dated: 12/21/2000 ☐ No Facilities and Administrative Costs Requested.

☐ No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base $ 381,689 x Rate applied 63.00 % = F&A costs $ 240,464

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

☐ Salary and wages base ☒ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.)*:

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio A., MD

## KEY PERSONNEL REPORT

Place this form at the end of the signed original copy of the application. Do not duplicate.

GRANT NUMBER
1 U01 AT01156-03

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

| Name | Degree(s) | SSN (last 4 digits) | Role on Project (e.g. PI, Res. Assoc.) | Date of Birth (MM/DD/YY) | Annual % Effort |
|---|---|---|---|---|---|
| Gervasio A. Lamas | MD | | PI | | [redacted] |
| Jacqueline Arciniega | MPH | | Project Director | | |
| Kayvan Amini | DO | | Clinical Manager | | |
| Kerry Lee | PhD | | Co-PI | | |
| Daniel Mark | MD | | Co-PI | | |

# Targeted/Planned Enrollment Table

**This report format should NOT be used for data collection from study participants.**

**Study Title:** Trial to Assess Chelation Therapy (TACT)

**Total Planned Enrollment:** 2,372

| TARGETED/PLANNED ENROLLMENT: Number of Subjects | | | |
|---|---|---|---|
| **Ethnic Category** | **Sex/Gender** | | |
| | **Females** | **Males** | **Total** |
| Hispanic or Latino | 57 | 133 | 190 |
| Not Hispanic or Latino | 655 | 1,528 | 2,182 |
| **Ethnic Category: Total of All Subjects *** | 712 | 1,660 | 2,372 |
| **Racial Categories** | | | |
| American Indian/Alaska Native | 7 | 17 | 24 |
| Asian | 14 | 33 | 47 |
| Native Hawaiian or Other Pacific Islander | 14 | 33 | 47 |
| Black or African American | 85 | 199 | 285 |
| White | 591 | 1,378 | 1,969 |
| **Racial Categories: Total of All Subjects *** | 712 | 1,660 | 2,372 |

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio A., MD

# Inclusion Enrollment Report

**This report format should NOT be used for data collection from study participants.**

**Study Title:** Trial to Assess Chelation Therapy (TACT)

**Total Enrollment:** 2,372 **Protocol Number:** 00-21-H-03

**Grant Number:** 1 U01 AT01156-03

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race**

| Ethnic Category | Sex/Gender | | | |
|---|---|---|---|---|
| | Females | Males | Unknown or Not Reported | Total |
| Hispanic or Latino | 2 | 10 | 0 | 12 ** |
| Not Hispanic or Latino | 72 | 366 | 0 | 438 |
| Unknown (individuals not reporting ethnicity) | 0 | 0 | 0 | 0 |
| **Ethnic Category: Total of All Subjects*** | 74 | 376 | 0 | 450 * |
| **Racial Categories** | | | | |
| American Indian/Alaska Native | 0 | 3 | 0 | 3 |
| Asian | 0 | 3 | 0 | 3 |
| Native Hawaiian or Other Pacific Islander | 0 | 2 | 0 | 2 |
| Black or African American | 8 | 11 | 0 | 19 |
| White | 66 | 359 | 0 | 425 |
| More Than One Race | 0 | 2 | 0 | 2 |
| Unknown or Not Reported | 0 | 0 | 0 | 0 |
| **Racial Categories: Total of All Subjects*** | 74 | 376 | 0 | 450 * |

**PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)**

| Racial Categories | Females | Males | Unknown or Not Reported | Total |
|---|---|---|---|---|
| American Indian or Alaska Native | 0 | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 | 0 |
| White | 2 | 10 | 0 | 12 |
| More Than One Race | 0 | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 | 0 |
| **Racial Categories: Total of Hispanics or Latinos**** | 2 | 10 | 0 | 12 ** |

* These totals must agree.
** These totals must agree.

## PHS 2590 OTHER SUPPORT

**Lamas, Gervasio A. MD**
ACTIVE

[redacted] (Lamas) 1/10/99 - present
$500,000

Advanced Elements of Pacing Trial (ADEPT)
The major goal is to determine how effective the dual sensor rate modulation and automatic mode switching features in the Kappa 400 are in improving patients' quality of life.
Overlap: None

105292 09/15/01 – 09/01/05
NIH/NHLBI $259,250.00
Heart Failure Home Care (HFHC)

The major goal is to compare enhanced heart failure follow-up with conventional care.
Overlap: None

RO1 HL 62509-01A1 (Hochman) 12/1/99 - 11/30/06
NIH/NHLBI $15,000,000
Occluded Artery Trial (OAT)
Co-Chairman
The major goal is to evaluate if the late reestablishment of blood flow to the artery that caused the heart attack will decrease clinical events and improve the quality of life.
Overlap: None

R01 HL 72906 (Rashba) 9/1/02 - 8/31/06
NIH/NHLBI $900,000
Electrophysiologic effects of late PCI (OAT-EP)
Co-Chairman
The major goal is to characterize the effects of late PCI of occluded IRAs on the most prognostically important and clinically relevant noninvasive markers of vulnerability to malignant ventricular arryhythmias: heart rate variability, T wave variability and signal averaged electrocardiography.
Overlap: None

U01HI49804 12/1/98 - 9/30/01
NIH/NHLBI $11,000,000
Mode Selection Trial (MOST)

Clinical benefits of dual versus single chamber pacing.

Overlap: None

1 U01 AT01156-01 (Lamas; PI) 08/15/2002-02/28/2007
NIH/NHLBI $30,000,000
Trial to Assess Chelation Therapy (TACT)

The major goal of the Trial to Assess Chelation Therapy is to determine whether an intensive course of EDTA chelation, will reduce major adverse coronary events in patients with coronary artery disease who have recovered from a prior myocardial infarction.
**Lee, Kerry L.**

**ACTIVE**

% Effort

HL55297(Lee) 5/1/97-4/30/04
NIH/NHLBI $5,085,587 (total costs)
Data Coordinating Center for the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)
The objective of this project is to provide the Statistical and Data Coordinating Center for the multicenter randomized clinical trial of prophylactic amiodarone or implantable defibrillator therapy versus conventional heart failure therapy in patients with Class II or Class III heart failure and a reduced ejection fraction.

(Lee) [redacted] 5/1/97-4/30/04 0%
$13,000,000
Data Coordinating Center for the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)
This grant provides additional support for the SCD-HeFT trial to cover study materials, expenses for investigator/coordinator meetings, and the payments to sites for enrolling and following the study patients.

1U01HL69015-01 (Lee) 1/1/02-12/31/08
NIH/NHLBI $2,965,075 (Total Direct Costs)
STICH (Surgical Treatment for Ischemic Heart Failure Trial)
This grant supports the Statistical and Data Coordinating Center for the STICH trial. The study is a multicenter, international, randomized trial in patients with clinical heart failure and left ventricular dysfunction who have coronary artery disease amenable to surgical revascularization.

1U01HL63747 (O'Connor, Christopher) 9/30/2002-9/29/2007
NIH/NHLBI $30,179,911 Total Direct Cost
HF-ACTION (A CHF Trial Investigating Outcomes of Exercise Training)
This grant supports the Coordinating Center for the multi-center HF-ACTION trial. The objective of this trial is to assess whether exercise training improves clinical outcomes for heart failure patients.

1 U01-AT01156 (Lamas, G.A.) 8/15/02 – 2/28/07
NIH/NCCAM/NHLBI/Mt Sinai $1,879,530 (Year 1 Total Costs)
Trial to Assess Chelation Therapy (TACT)
Duke Clinical Research Institute (under leadership of Dr. Lee) is a subcontractor to Mt. Sinai Medical Center to provide the Statistical and Data Coordinating Center for this trial. The study is a multicenter, randomized clinical trial of chelation therapy in patients with a prior myocardial infarction.

1 U01-HL67972 (Bardy, Gust) 9/30/02 – 8/31/07
NIH/NHLBI/Seattle Institute for Cardiac Research $430,245 (Year 1 Total Costs)
Home Automatic External Defibrillator Trial – H.A.T.
Duke Clinical Research Institute (under leadership of Dr. Lee) is a subcontractor to the Seattle Institute for Cardiac Research to provide statistical services and perform economic and quality of life analyses for this trial. The study is a multicenter, randomized clinical trial to assess the effects of home use of automatic external defibrillators in reducing mortality in patients with a prior anterior myocardial infarction.

**OVERLAP**
No overlap exists at this time.

**MARK, DANIEL B.**

ACTIVE

U01 HL62251 (Mark, Daniel B.; PI) 09/01/1999-08/31/2005
NIH/NHLBI $222,225
Economics and Quality of Life in the Occluded Artery Trial (OAT)
Role: Principal Investigator
The objective of this study is to establish an Economics and Quality of Life Coordinating Center for the Occluded Artery Trial, a multi-center, randomized trial of late (3-42 days) percutaneous revascularization versus standard medical therapy in 3200 asymptomatic high-risk acute myocardial infarction (MI) survivors and who are found at diagnostic catheterization to have an occluded infarct related artery. Cost, cost effectiveness, and health-related quality of life are secondary endpoints.

U01 HL69011 (Mark, Daniel B.; PI) 01/01/2002-12/31/2008
NIH/NHLBI $208,533
Economics and Quality of Life Core Laboratory in Surgical Treatment of Ischemic Heart Failure (STICH)
Role: Principal Investigator
The major goal of this substudy of the Surgical Treatment of Heart Failure Trial is to determine cost effectiveness and health-related quality of life of CABG +/- ventricular reconstruction versus medical therapy.

1R01 HL69081-01 (Newman, Mark; PI) 12/01/2001-11/30/2005
NIH $393,123
Peri-Operative Interventional Neuroprotection Trial: POINT
Role: Co-Investigator
The major goal of this project is to determine the impact of magnesium administration to therapeutic serum levels on short- and long-term neurocognitive function after cardiac surgery evaluated by preoperative and postoperative neurocognitive and neurologic testing.

R01 HS013345-01 (Eisenstein, Eric L.; PI) 09/12/2002-08/31/2005
AHRQ $227,777
Dialysis Facility Management
Role: Co-Investigator
The goal of this study is to define the impact of dialysis facility characteristics on dialysis patient mortality, morbidity, and total medical costs.

[redacted]

1U01 HL66530 (Mark, Daniel B.; PI) 08/15/2002-08/14/2007
NIH/NHLBI $86,478
Economics and Quality of Life in the Trial to Assess Chelation Therapy (TACT)
Role: Principal Investigator
The major goal of the Trial to Assess Chelation Therapy is to determine whether an intensive course of EDTA chelation, administered over 18 months, will reduce major adverse coronary events in patients with coronary artery disease who have recovered from a prior myocardial infarction. The objective of this project is to assess the secondary endpoints of cost effectiveness and health-related quality of life of the treatment strategies being tested in TACT.

[redacted] % Effort

U01 HL67972-01 (Bardy Gust; PI) 10/01/2002-08/30/2007
NIH/NHLBI $1,965,243
Home Automatic External Defibrillator Trial (HAT)
Role: Co-Investigator
The major objective of this study is to conduct a randomized clinical trial of automatic external defibrillator therapy, provided by spouses or other family members, superimposed on the local emergency medical system vs. the local emergency medical system in 3400 survivors of anterior myocardial infarction. Duke University will act as subcontractor to Seattle Institute for Cardiac Research for this trial. Duke will provide data management and statistical services for the trial, as well as performing economic and quality of life analyses.

[redacted] (Mark, Daniel B.; PI) 02/10/1998-12/31/2005
$335,460
Treating to New Targets (TNT) Economics Substudy
Role: Principal Investigator
The objective of this substudy of the TNT clinical trial is to determine cost effectiveness of lowering LDL-C beyond the currently accepted minimum targets for patients at high risk for developing coronary heart disease.

[redacted]

(Mark, Daniel B; PI) 01/01/2002 – 12/31/2004
Private Source [redacted] /Alexion $95,625
Economic Outcomes in Phase III of Pexelizumab in CABG (PRIMO CABG)
Role: Principal Investigator
The major goals of this substudy are to perform a detailed comparison of medical resource consumption and medical costs in the PRIMO-CABG trial; and to perform a series of cost-effectiveness analyses of the Pexelizumab arm versus placebo in CABG patients.

[redacted]

1U01-AR-052186-01 (Schulman,KA, PI) 09/01/04 – 08/31/09
NIH (NIH Roadmap PRO) $567,720
Dynamic Outcome Assessment in Multi Center Trials
Role: Co-Investigator
The goal of the Patient-Reported Outcomes Measurement Information System (PROMIS) Network is to develop a unified approach for assessing PROs using computerized adaptive testing (CAT).

[redacted]

(Mark, Daniel, PI) 03/01/2004 – 04/30/2006
Private Source [redacted] $126,054
APEX-MI EQOL
Role: Principal Investigator

The specific objectives of this study are to compare medical resource use patterns and associated medical costs for the Pexelizumab arm versus the control arm by intention-to-treat in patients randomized into APEX-MI; and to perform a cost-effectiveness analysis of Pexelizumab versus control using the empirical outcomes observed in overall APEX-MI and the Economic study to provide base case parameters for the model.

| TACT CLINICAL COORDINATING CENTER BUDGET | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Y2005-2006 | | | | | | | | | | |
| Year 4 | | | | | | | | Requested | Awarded | Needed from Carryover |
| | | | | | Salary | Fringe | Fringe | Salary | | |
| Name | Position | Appointment | Effort | Salary | Requested | Rate | Total | Total | | |
| Gervasio Lamas MD | Study Chairman | 12 | % | Institution | $64,480 | 0 | $0.00 | $64,480 | | |
| Jacqueline Arcintega, MPH | Project Director | 12 | Effort | al Base | $73,388 | 0 | $0.00 | $73,388 | | |
| Kayvan Anini, DO | Clinical Trial Manager | 12 | | Salary | $41,162 | 0 | $0.00 | $41,162 | | |
| Virginia Martini, BA | Admin Coordinator | 12 | | | $28,323 | 0 | $0.00 | $28,323 | | |
| Renea Moss | Office Coordinator | 12 | | | $40,299 | 0 | $0.00 | $40,299 | | |
| Parminder Singh | Research Assistant | 12 | | | $31,360 | 0 | $0.00 | $31,360 | | |
| Jewmauli Reed | Research Assistant | 12 | | | $28,513 | 0 | $0.00 | $28,513 | | |
| | | | | | | Total Salaries | | $307,525 | | |
| | | | | | | | | | | |
| Consultants | | | | Salary | | | | | | |
| | | | | | | | | | | |
| Martin Dayton DO | | | | $3,744 | | | | $15,000 | | |
| Theodore Rozsma | | | | $3,744 | | | | | | |
| Misc. Consultants | | | | $7,512 | | | | | | |
| | | | | | | | | | | |
| Equipment | | | | | | | | | | |
| Scanner / Color Printer | | $500 | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | Total equipment | | $500 | | |
| | | | | | | | | | | |
| Supplies | copier supplies | | | | | | | | | |
| | fax supplies | | | | | | | | | |
| | paper | | | | | Total supplies | | $10,000 | | |
| | | | | | | | | | | |
| Travel | Yearly meetings | $0 | | | | | | | | |
| | | | | | | | | | | |
| | CCC travel | $20,604 | | | | Total Travel | | $20,604 | | |
| | | | | | | | | | | |
| Patient care costs | | $0 | | | | | | | | |
| | | | | | | Total Patient Costs | | $0 | | |
| | | | | | | | | | | |
| Other expenses | Telephone | $12,000 | | | | | | | | |
| | Pagers | $2,000 | | | | | | | | |
| | Postage | $4,160 | | | | | | | | |
| | Advertisement | $10,400 | | | | Total other (A) | | $28,560 | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | Subtotal | | $382,189 | $230,740 | $25,659 |
| Consortium/ contractual costs | | | | | | | | | | |
| Direct costs | DCRI | $1,044,492 | | | | | | | | |
| | OmniComm | $120,200 | | | | | | | | |
| | Brigham and Women's | $42,203 | | | | | | | | |
| | Clinical units | $2,935,409 | | | | | | | | |
| | Central Pharmacy | $3,357,525 | | | | | | | | |
| | Central Lab | $161,569 | | | | | | | | |
| | Pharmed | $125,000 | | | | | | | | |
| | Total direct costs | $7,786,393 | | | | | | | | |
| | | | | | | | | | | |
| Indirect costs | DCRI | $331,423 | | | | | | | | |
| | | | | | | | | | | |
| | Brigham and Women's | $10,551 | | | | | | | | |
| | | | | | | | | | | |
| | Total indirect costs | $341,974 | | | | Total Consortium | | $8,128,367 | $4,605,794 | $3,722,573 |
| | | | | | | | | | | |
| | | | | TOTAL DIRECT COSTS YEAR 4 ==> | | | | $8,710,566 | $4,972,048 | $3,738,506 |
| | | | | | | | | | | |
| | | | | COST BASE FOR CALCULATING INDIRECT | | | | $381,689 | $368,254 | |
| | | | | INDIRECT COST | | | 0.63 | $240,464 | $230,740 | |
| | | | | TOTAL COST | | | | $8,951,030 | $5,202,788 | $3,748,232 |