Type 5

Activity Grant Number Review Group Type Department of Health and Human Services ₩U01 AT01156-03 Public Health Services **Total Project Period Grant Progress Report** From: 08/15/2002 Through: 02/28/2007 Requested Budget Period: From: 03/01/2004 Through: 02/28/2005 1. TITLE OF PROJECT Trial to Assess Chelation Therapy (TACT) 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR 3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) (Name and address, street, city, state, zip code) Mount Sinai Medical Center of Florida, Inc. Gervasio A. Lamas, MD 4300 Alton Road Mount Sinai Medical Center Miami Beach 4300 Alton Rd; Suite 207A Fi Miami Beach, FL 33140 33140 4. ENTITY DENTIFICATION NUMBER 26. E-MAIL ADDRESS TACTNIH@acl.com 2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT RESS OF ADMINISTRATIVE OFFICIAL William Abraham, Ph.D., Director of Research Medicine 2d. MAJOR SUBDIVISION 4300 Alton Road Cardiology Miami Beach, FL, 33140 E-MAIL: Abraham@msmc.com 6. HUMAN SUBJECTS 7. VERTEBRATE ÁNIMALS 7a. If "Yes," IACUC approval Date 6a. Research Exempt 6b. Human Subjects Assurance No. No KO No #A00000176 ☑ No ☐ Yes X Yes ☐ Yes If Exempt ("Yes" in 6a): 6c. NIH-Defined Phase III 7b. Animai Welfare Assurance No. Exemption No. Clinical Trial | No XYes X Full IRB or If Not Exempt ("No" in 6a): Expedited Review IRB approval date 9. INVENTIONS AND PATENTS 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD 8a. DIRECT 8b. TOTAL No Yes If "Yes," Previously Reported \$7,997,047 \$8,284,710 Not Previously Reported 11a. PRINCIPAL INVESTIGATOR 10. PERFORMANCE SITE(S) (Organizations and addresses) TEL 305-674-2162 OR PROGRAM DIRECTOR (Item 2s) FAX 305-674-3970 Gervasio A. Lamas, MD **Mount Sinal Medical Center** 11b. ADMINISTRATIVE OFFICIAL 4300 Alton Rd TEL 305-674-2790 NAME (Item 5) Miami Beach, FL 33140 FAX 305-674-2198 William Abraham, Ph.D. 11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT **Duke Clinical Research Institute** ORGANIZATION (Item 14) Box 3300 NAME Paul Katz, MD Durham, NC 27715 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 SIGNATURE OF PUPD NAMED IN 2a. DATE statements herein are true, complete and accurate to the best of my knowledge. I am aware that any fatee, lictitious, 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 regulated progress reports if a grant is awarded as a result of this application. well as SIGNATURE OF OFFICIAL NAMED IN DATE 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 11c. (In Ink. "Per" signature flot acceptable.) 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.

	CT COSTS ONLY	4	ROM 3/01/04	THROUGH 02/28/05	GRANT NUME 1 U01 AT011	
DEDCONNEL (Applicant		بر ا				
PERSONNEL (Applicant organization only) NAME POLE ON PROJECT		TYPE	EFFORT		MOUNT REQUESTE	
NAME	ROLE ON PROJECT	APPT. (months)	ON PROJ.	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Gervasio A. Lamas, MD	Principal Investigator	12	% Effort	64,480	0	64,480
Danielle Hollar, Ph.D.	Project Director	12		74,100	0	74.100
Steven Hussein, MD	Clinical Manager	12	15年	. 0	0	
Virginia Martini, BS	Admin. Coordinator	12		41,600	0	41,600
Matt Shields, BS	Research Assistant	12		28,500	Q	28,500
Jamie Zimmerman, MPH	Research Assistant	12		28,500	0	28,500
Renea Moss	Admin. Assistant	12		24,800	0	24,800
	SUBTOTALS				0	261,980
EQUIPMENT (Itemize)						
Copier						1,72
Copier SUPPLIES (Itemize by category) copier supplies fax supplies paper						
Copier SUPPLIES (Itemize by category) copier supplies fax supplies paper TRAVEL	000): CCC Travel	(\$26.134				10,000
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Copier SUPPLIES (Itemize by category) copier supplies fax supplies paper TRAVEL Yearly Meetings (\$125,0 PATIENT CARE COSTS ALTERATIONS AND RENOVATION OTHER EXPENSES (Itemize by category)	INPATIENT 0 OUTPATIENT 0 ONS (Hemize by category) 7,572.00)	0				10,00
Copier SUPPLIES (Itemize by category) copier supplies fax supplies paper TRAVEL Yearly Meetings (\$125,0	INPATIENT 0 OUTPATIENT 0 ONS (Hemize by category) 7,572.00) Ostage (\$6,490); A	dvertise				10,000 151,134 (
Copier  SUPPLIES (Itemize by category)  copier supplies  fax supplies  paper  TRAVEL  Yearly Meetings (\$125,0)  PATIENT CARE COSTS  ALTERATIONS AND RENOVATION  OTHER EXPENSES (Itemize by company)  Telecommunications (\$120,704); Person Principles (\$120,000)	INPATIENT 0 OUTPATIENT 0 ONS (Hemize by category) 7,572.00) Ostage (\$6,490); A	dvertise				10,000 151.13 ( 16,760 \$456,600
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#### **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,

There has been sub-category rebudgeting among the subcontractors described below.

Central Pharmacy: Specifically, the Central Pharmacy is receiving more funding to account for separate shipments of vitamin supplies to sites.

Omnicomm: Additional funds were added to the OmniComm budget line to cover costs related to the creation of a workflow system for shipping and tracking vitamins and vitamin placebos.

Central Lab: Additional funds were added to the Central Lab budget line to cover costs related to measuring high sensitivity C-reactive protein levels (Cardio-CRP) 3 times for each patient. The Cardio-CRP test is more expensive than general CRP test, but is required in order to be able to understand the effect of Chelation therapy, if any, on this important inflammatory marker, as specified in the original RFA.

# **CURRENT BUDGET PERIOD**

FROM 03/01/2003 THROUGH

/2003 02/29/2004

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

Consultant Costs: A pharmacy regulatory consultant has been added to the budget. This consultant will assist with ongoing regulatory requirements of the FDA Investigational New Drug Application (IND) and other pharmacy regulatory issues.

Equipment: Currently, computers and a printer are being purchased to meet the needs of the TACT CCC. Expenses will show up by the end of year 2.

Supplies: Expenditures of supplies are lower than expected due to delay in activating clinical sites.

Travel: The number of clinical sites that will attend the Second Investigators' Meeting, planned for Spring 2004, will be significantly higher than the number that attended the first meeting. Consequently, the budget category for this expense has been increased, and expenses will be deducted in 2004. A carryover request will be forthcoming.

Other expenses: Postage funds for Year 1 will be used as part of payment for the 2<sup>nd</sup> Investigators Meeting. Audiovisual expenses were incurred during the First Investigators Meeting and will be deducted in the near future. No advertisement funds were expended during Year 1 because clinical sites were not activated during this time. However, advertising will take place during the rest of Year 2 and throughout Year 3.

Consortium: Because patient enrollment has been slower than expected, there have been few expenditures for the central lab, clinical units, or the Clinical Events Committee (Brigham & Women's) as of November 2003. These expenses will be incurred during year 3 as the number of enrolled patients increases. A carryover request will be forthcoming.

Page 3

#### **BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel in the order listed for Form Page 2. Follow the sample format for each person. DO NOT EXCEED FOUR PAGES.

NAME		POSITION TITLE	POSITION TITLE			
EDUCATION	/TRAINING (Begin with baccalaureate or other initial pro	ofessional education, such DEGREE (if applicable)	h as nursing, and inclu YEAR(s)	de postdoctoral training.) FIELD OF STUDY		

NOTE: The Biographical Sketch may not exceed four pages. Items A and B (together) may not exceed two of the four-page limit. Follow the formats and instructions on the attached sample.

No new sketches are required at this time.

Page 4

Principal . . . jator: Lamas, Gervasio A.

DDOODEGG DEDOOT CHAMADY	GRANT NUMBER	Notation of the second
PROGRESS REPORT SUMMARY	1 U01 AT01156-0	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	PERIOD COVERED	THROUGH
Gervasio A. Lamas, MD	FROM 03/01/2003	02/29/2004
APPLICANT ORGANIZATION		
Mount Sinai Medical Center		
TITLE OF PROJECT (Repeat title shown in Item 1 on first pag	e)	
Trial to Assess Chelation Therapy (TACT)		
A. Human Subjects (Complete Item 6 on the Face Page) Involvement of Human Subjects No Change,S	Ince Previous Submission	Change
Vertebrate Animals (Complete Item 7 on the Face Page)     Use of Vertebrate Animals	Singe Previous Submission	Change
SEE PHS 2590 INSTRUCTIONS.  Has there been a change in the support of key pe	rsonnel since the la	st reporting period?
The following represent organizational changes in the	e TACT CCC since the	he last reporting period (July 2003)
Charles H. Hennekens, MD, DrPH (Co-Principal	Investigator): Dr. l	Hennekens resigned from TACT.
Jamie Zimmerman, MPH (Research Assistant): time Research Assistant (base salary of Research Assistant (base salary of Research Assistant (base salary of Research Assistant): time Research Assistant (base salary of Research Assistant): time Research Assistant (base salary of Research (base salary of Research (base salary of Research (bas	FTE). Her principle ions, FWA applications ory documents; assist CCC, and assisting w	e duties are to assist in identifying ons, and the completion of ing with literature searches and
Is it anticipated that an estimated unobligated bathan 25 percent of the current year's total budge		ior year carry over) will be greate
Yes, an unobligated balance (including prior year appropriate to slower will be forthcoming.	proved carry over) w than expected patient	ill be greater than 25% of the tenrollment. A carryover request
Progress Report Summary		
a. Specific Aims The specific aims of the Trial to Assess Chelation Thaward.	nerapy (TACT) remai	in the same as listed in the original
b. Studies and Results No results have been obtained because the study only	y began enrolling pat	ients in September 2003.
c. Significance As mentioned above, no results have been obtained to	thus far.	
d. Plans		

Page 5

# Milestones accomplished:

# d.I.IND Application Requirements

The TACT Clinical Coordinating Center (CCC) submitted 1572s and CVs for Site Investigators to the FDA according to IND Application requirements. A plan has been operationalized to ensure that subsequent submissions of these documents occur on a monthly basis.

In accordance with the IND Application requirements, the TACT Pharmacy submitted pharmaceutical samples of required study medications to Guidelines Laboratory, of Miramar, FL. Testing continues based on the laboratory schedule outlined in the IND Application, with results being maintained on site at the TACT Pharmacy.

#### d.2. Site Activation

Based on the current rate of patient enrollment per site, it is predicted that the number of clinical sites needed to meet TACT enrollment goals will be much higher than originally expected. Accordingly, clinical site recruitment continues. To date, four sets of clinical sites are in various stages of site activation. These sets of sites are described below.

#### First Set of Sites

As of November 27, 2003, 30 of 58 clinical sites that attended the First Investigators Meeting are regulatory compliant and approved to enroll. Six sites are located in academic centers, 9 are cardiology practices, 14 are chelation practices, and 1 is a research institute. These clinical sites are screening and enrolling patients at this time (patient enrollment is described later in this section of the report).

#### Second Set of Sites

During the fall of 2003, an additional 110 potential clinical sites were invited to begin the regulatory process for site activation. Clinical sites that complete the regulatory process by early February 2004 will be invited to attend the Second Investigators Meeting planned for Spring 2004.

#### Third Set of Sites

Also during the fall of 2003, approximately 25 potential clinical sites with experience in other cardiovascular clinical trials directed by Dr. Lamas were invited to begin the regulatory process for site activation. Clinical sites that complete the regulatory process by early February 2004 will be invited to attend the Second Investigators Meeting planned for Spring 2004.

# Fourth Set of Sites

Approximately 70 attendees of the American College for Advancement in Medicine (ACAM) visited the TACT information booth during the November 19-21, 2003 annual conference. Currently, approximately 12 of these attendees are completing the TACT application materials. Upon approval by the TACT Steering Committee, these sites will be invited to begin the final set of regulatory requirements for site activation and to attend the Spring 2004 meeting if their regulatory requirements are met.

Page_	6
ugc	

#### d.3. TACT Contractors

The Pharmed Group

On November 7, 2003 a contract was executed between the CCC and The Pharmed Group for the provision of vitamins at below production cost for the term of the trial.

# d.4. Clinical Site IRB Approvals

As mentioned in previous submissions, Sterling Institutional Review Board (IRB) serves as the central IRB for TACT. Thus far, 48clinical sites have received IRB approval.

#### Central IRB - Sterling Institutional Review Board

As of November 27, 2003, 30 clinical sites have been approved by Sterling Institutional Review Board.

#### Local IRBs

As of November 27, 2003, 18 clinical sites have been approved by local institutional review boards.

#### d.5. Enrollment Update

Patient randomization began September 10, 2003, and the first infusion occurred September 12, 2003. The table below presents the demographics of the patient population, as of November 27, 2003.

32 Patients (as of November 27, 2003)	University Center (n)	Cardiology Practice (n)	Chelation Practice (n)	Totals (n)
Gender:				
Female	1	3	4	8
Male	0	12	12	24
Race/Ethnicity:				
Asian		•		0
Black		-		0
Hawaii		• • • • • • • • • • • • • • • • • • •		0
White	1	15	16	32
Age:				
50-54		2	2	4
55-59		4	2	7
60-64		3	Ž	5
65-69			4	5
70-74			5	6
75-79	7000 E-01 - 201 -	1	2	3
80+ (oldest: 82)		2		2
State:				
CA			7	7
FL		2		2
LA		-	2	2
ME		5	- 1	5
NC		2		3
NY		6		6
SC			7	7

# Enrollment is slower than projected. The principal reasons for slower patient enrollment have been:

1] The final protocol was not approved until May 29, 2003.

2] The study binder and CRF's were approved June 27, 2003.

3] Vitamins and their placebos were received on September 3, 2003.

4] Regulatory approval for sites has been slower than anticipated. There are 9 specific regulatory steps required to be approved to enroll in TACT. Of 58 sites that attended the initial investigators' meeting in July 10-13, 2003, only 30 have completed regulatory requirements and are ready to enroll. Thus, the median time to gain approval for the group is 11 weeks and rising. The principal delays have been with IRBs, particularly local, University-based IRBs, and with the contract to carry out TACT.

5] Once sites are approved, they are finding that enrollment is more difficult than anticipated due to the patient burden required by the study.

6] The public relations campaign planned by the NCCAM Communications office has been delayed, of necessity, since not enough sites are ready, but this has compounded slow enrollment.

7] Enrollment is slower than projected. The principal reason, however, is delay in activating new sites. For example, the very first date that enrollment could occur, due to drug delivery, was September 3, or 3 months ago. If, to be realistic, we assume a 4-week lag after approval for screening, consent, and scheduling before the first enrollment, then the randomization rate is 0.9 patients per site per month, very similar to our original projections. Thus, CCC activities to improve enrollment are geared towards increasing site approval, as well as assisting sites with screening and enrollment advice.

# The TACT CCC expects that the following solutions put into place will speed enrollment:

- 1] An additional research assistant, Jamie Zimmerman, MPH, was employed to assist sites with fulfilling initial regulatory requirements, and an additional one will be employed within the month.
- 2] Dr. Lamas and colleagues have stepped up efforts to move sites through the regulatory process with frequent telephone and email contact with PIs.
- 3] Mount Sinai, the grantee institution, has provided more flexibility with contractual variations relating to levels of malpractice insurance coverage for subcontracting PIs.
- 4] Efforts to identify additional potential sites have been stepped up over 100 sites have expressed interest since the initial investigators' meeting and are beginning to move through the regulatory process.
- 5] Coordinators' conference calls have been instituted so that successful sites may speak with less successful ones to learn strategies for success.

As shown in the table above, the number of minority patients in the population is low. Sites that would be expected to have a high minority patient base, however, have not yet started enrolling, and the previously planned NCCAM public relations campaign in Spanish has not yet been launched. The trial management remains committed to enrolling an ethnically diverse population, and optimistic that we can do so.

	Principal i: Jator: Lamas, Gervasio A.		<u> </u>	
	A STANDARD CONTRACTOR OF THE STANDARD CONTRACTOR		NUMBER AT01158-03	
	Lawrence Consideration of the	1001	M101130-03	
	CHECKL	.IST		
PROGRAM INCOME (See in All applications must indicate what inticipated, use the formal below	structions.) nether program income is anticipated during the to reflect the amount and source(s).	e period(s) for which g	rant support is requested. I	f program income is
Budget Period	Anticipated Amount		Source(s)	
	ations are made and verified by the	new IType 1) or revise	ension •Drug-Free Workplace ed (Type 1) applications only);	·Lobbying ·Non-
of the application. Descriptions of provided in Section III of the PHS applicable, provide an explanation		(Form HHS 441 or HH 641 or HHS 690) •Sec •Age Discrimination (I	al Debt •Research Misconduct IS 690); •Handicapped Individe Discrimination (Form HHS 63 Form HHS 680 or HHS 690); •	uals (Form HHS 39-A or HHS 690) Recombinant DNA
<ul> <li>Human Subjects Research Using on Transplantation of Human Fet Policy Inclusion of Children Polic</li> </ul>	ng Human Embryonic Stem Cells •Research al Tissue •Women and Minority Inclusion by• Vertebrate Animals	(except Phase I SBIR	nsfer Research •Financial Cor 'STTR) :atton of Research Institution F	
with the appropriate DHHS R	RATIVE (F&A) COSTS  Ion's most recent F&A cost rate established eglonal Office, or, in the case of for-profit hed with the appropriate PHS Agency Cost	organizations, grants any additional instru- institutional National Innovation Research	pe paid on construction grant to individuals, and confere actions provided for Resear Research Service Award /Smail Business Technolog ectalized grant applications.	nce grants. Follow rch Career Awards, Is, Small Business
DHHS Agreement:	12/21/2000		to Facilities and Administrative	Costs Requested.
No DHHS Agreement, but	rate established with		Date	
CALCULATION*				
Entire proposed budget period:	Amount of base \$ 456,608  Add to total direct costs from F	x Rate applied 63		287,663 b.
*Check appropriate box(es):		CONTRACTOR OF THE PARTY OF THE	Other base (Explain)	
*Check appropriate box(es):  Salary and wages base	Modified total direct of	ost Dase	Other base (cxpam)	
	Modified total direct of or more than one rate involved (Explain)	ost Dase	Otre base (explain)	

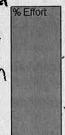
#### PERSONNEL REPORT

GRANT NUMBER 1 U01 AT01156-03

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

Senior Investigator	Participating Institution	Role	
Hollar, Danielle PhD (Replaced) by Jamie Zimmerman, Approved by RO. Hussein, Steven MD (Has replaced) Dr. Alan Ackerman	Mount Sinai Medical Center 4300 Alton Rd Miami Beach, FL 33140	Project Director	% Effort
Hussein, Steven MD (Has replaced Dr. Alan Ackerman	Mount Sinal Medical Center 4300 Alton Rd Miami Beach, FL 33140	Clinical Manager	
	Mount Sinai Medical Center 4300 Alton Rd Miarni Beach, FL 33140	Principal Investigator	
	Duke Clinical Research Institute Box 3300 Durham, NC 27715	Co-Principal Investigator	
	Duke Clinical Research Institute Box 3300 Durham, NC 27715	Co-Principal Investigator	

Changes in Personnel
Dr. Charles Hennekens
Dr. Rachel Eidelman
Or. Alan Achterman



-Resigned and will not be replaced

-Nolonger working on the growt

- Replaced by Or, Steven Husseln

Targeted/Planned Enrollment Table
This report format should NOT be used for data collection from study participants.

Study Title: Trial To Assess Chelation Therapy

**Total Planned Enrollment: 2372** 

Ethnic Cafegory	<u> </u>	r	
	Females	Males	Total
Hispanic or Latino	57	133	190
Not Hispanic or Latino	655	1528	2182
Ethnic Category Total of All Subjects*	712	1660	2372
Racial Categories			1
American Indian/Alaska Native	7	17	24
	7	17 33	24 47
Asian			
Asian Native Hawaiian or Other Pacific Islander	14	33	47
American Indian/Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White	14	33	47 47

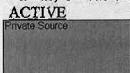
<sup>&</sup>quot;The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

# **PHS 2590 OTHER SUPPORT**

Provide active support for all key personnel. Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

There is no "form page" for other support, information on other support should be provided in the *format* shown below, using continuation pages as necessary. *Include the principal investigator's name at the top and number consecutively with the rest of the Grant Progress Report.* The sample below is intended to provide guidance regarding the type and extent of information requested. For information pertaining to the use of and policy for other support, see "Policy and Additional Guidance" in the PHS 398 instructions.

Lamas, Gervasio A. MD

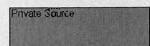


12/01/01 - 12/31/03

\$550,000



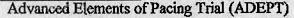
The major goal is to evaluate the effects of three different doses of Bayer aspirin on levels of C-Reactive Protein in Post-Menopausal women who initiate hormone replacement therapy.



(Lamas)

1/10/99 - present

\$500,000



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

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 NIH/NHLBI 12/1/98 - 9/30/01

\$11,000,000

Mode Selection Trial (MOST)

Clinical benefits of dual versus single chamber pacing.

Overlap: None

#### PHS 2590 OTHER SUPPORT (continued)

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

HL55297(Lee) NIH/NHLBI 5/1/97-4/30/03

\$3,856,583 (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) Private Source 5/1/97-4/30/03 \$3,400,000 18%

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.

1R01HL69015-01 (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.

1R01HL63747 (O'Connor, Christopher)

9/30/2002-9/29/2007

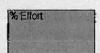
NIH/NHLBI

\$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.) NIH/NCCAM/NHLBI/Mt Sinai Trial to Assess Chelation Therapy (TACT) 8/15/02 - 2/28/07 \$1,879,530 (Year 1 Total Costs)



# PHS 2590 OTHER SUPPORT (continued)

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 HL55496 (Mark, Daniel B.; PI) NIHAHLBI

05/01/2003-04/30/2004

\$232,764

Economics & Quality of Life in SCD-HeFT (1-yr ext)

The objective of this project is to establish an Economics and Quality of Life Coordinating Center for SCD-HeFT, a multi-center clinical trial of prophylactic amiodarone or implantable defibrillator therapy versus conventional heart failure therapy in 2500 patients with Class III or Class III congestive heart failure (CHF) and an ejection fraction ≤35%. This is a one-year extension of the initial project.

U01 HL62257 (Mark, Daniel B.; PI)

09/01/1999-08/31/2004

NIH/NHLBI

\$222,225

Economics and Quality of Life in the Occluded Artery Trial (OAT)

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

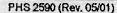
Economics and Quality of Life Core Laboratory in Surgical Treatment of Ischemic Heart Failure (STICH)

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.



% Effort

80 Tota



#### PHS 2590 OTHER SUPPORT (continued)

1R01 HL69081-01 (Newman, Mark; PI)

12/01/2001-11/30/2005

NIH

\$393,123

Peri-Operative Interventional Neuroprotection Trial: POINT



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.

1R01 HL54780 (Barefoot, John; PI)

08/01/2000-07/31/2004

NIH/NHLBI

\$225,000

Hostility, depression, social environment, and CHD risk

The major goal of this study is to identify interactions among psychosocial risk factors and demographic variables that affect the risk of cardiovascular disease

ROI HS013345-01 (Eisenstein, Eric L.; PI)

09/12/2002-08/31/2004

AHRO

\$227,777

Dialysis Facility Management

The goal of this study is to define the impact of dialysis facility characteristics on dialysis patient mortality, morbidity, and total medical costs.

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)

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.

U01 HL67972-01 (Bardy Gust; PI)

10/01/2002-08/30/2007

NIHNHLBI

\$1,965,243

Home Automatic External Defibrillator Trial (HAT)

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.



& Effort

<b>HS</b>	2590	OTHER SUPP	ORT	(continued)
PHS	2590	OTHER SUPP	OKI	(ContinueC

5 U18 HS10548-05 (Kramer, Judith; PI) NIH/AHCPR

09/30/2003-09/29/2007

\$519,480 DCRI Cardiovascular CERT Research Center

The main objective of this project is to investigate clinical therapeutics in cardiovascular medicine at Duke's DCRI by providing vision, leadership, and direction to translate clinical findings into improved medical practice.

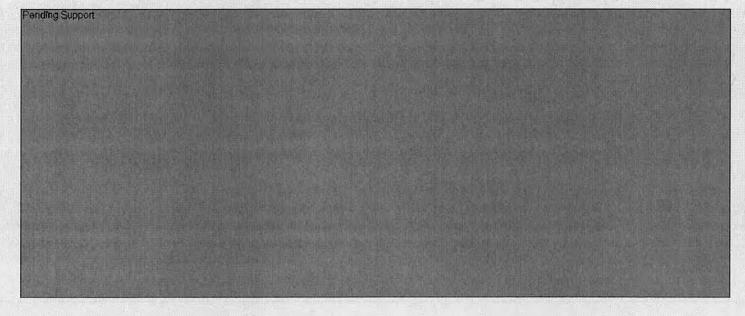
Private Source

(Mark, Daniel B.; PI)

02/10/1998-12/31/2005

Treating to New Targets (TNT) Economics Substudy

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.



# TACT CLINICAL COORDINATING CENTER BUDGET Y2006-2007

12000-2001											
Year 5					Calana	Colores	Frie		Salary		
			-11.4	Outers		Fringe	Tota		Total		
Name	Position		Effort % Effort	Salary Institutional	HEAVE THE PROPERTY OF	Rate				64 100	
Gervasio Lamas MD	Study Chairman	12	NO CHIAIL	Base Salary	\$64,480		0	\$0.00		64,480	
Charles Hennekens MD DrPH		12		Edge Certif	\$64,480		0	\$0.00		64,480	
Danielle Hollar PhD	Project Director	12			\$74,100		0	\$0.00		74,100	
TBN ,	Clinical Coordinator	12			\$38,995		0	\$0.00		38,995	
Virginia Martini BS	Admin Coordinator	12		FILE	\$41,600		0	\$0.00		41,600	
TBN	Research Assistant	12			\$28,500		0	\$0.00		28,500	
TBN	Research Assistant	12			\$28,500		0	\$0.00		28,500	
Ophelia Stephens	Admin Assistant	12			\$24,800		0	\$0.00	\$	24,800	
			(MINUTE)			Total Sa	larles			\$365,455	420017
Consultants				Salary							
Made Budes DO				\$3,000						\$6,000	6000
Martin Daylon DO				\$3,000							
Theodore Rozema MD				40,000							
Equipment						Valed a s				\$0	
District N						Total eq	uipanes			***	
Supplies	copier supplies										
	fax supplies										
	baber					Total su	pples			\$10,000	10000
Travel	Yearly meetings	\$0									
11819	radily moonings									Selection	
	CCC travel	\$20,171				Total Tr	ave)			\$20,171	20171
Patient care costs		\$0									
						Yotal Pa	tient C	osts		\$0	
04	Talashana	\$7,019									
Other expenses	Telephone										
	Pagers	\$1,170									
	Audiovisual	\$2,925									
	Postage	\$7,019					1.00			414.444	10400
	Advertisement	\$0				Total of	ner (A)			\$18,133	18133
Consortium/ contractual cos	ds										
Direct costs •	DCRI	\$1,107,018									
	OmniComm	\$60,200							16		
	Brigham and Women's	\$45,647									
	Clinical units	\$2,561,760						V.			
	Central Pharmacy	\$0									
	Central Lab	\$0									
	Pharmed	\$150,000									
	Total direct costs	\$3,924,525									
Indirect costs	DCRI	\$585,782									
	Brigham and Women's	\$11,412									
						Table A				+1 201 010	0070040
	Total indirect costs	\$597,194				Total C	ansom)	TILI		\$4,521,819	2679313
				TOTAL DIRE	CT COSTS Y	AR 5 ==	⇒			\$4,941,578	
			,		FOR CALCUI	ating i	NDIRE	- 1 Told 100 Co.		\$413,759	
				INDIRECT C TOTAL COS				0.63		\$260,668 \$5,202,246	