



# TACT Newsletter



**NCCAM** National Center for  
Complementary and Alternative Medicine

January 2004

## TACT Leaders

### *Message from the Principal Investigator – Gervasio A. Lamas, MD*

I hope that all of the you had a very happy new year. Since our last newsletter, several new sites have joined us, and I would like to take this opportunity to welcome all of you. You join us in an interesting and challenging trial. By participating in TACT, you join a distinguished group of CAM physicians and traditional cardiologists, who will help to answer an important clinical and public health question.

Although the study is challenging, many of our sites have been successful in recruiting patients. Congratulations to our top enrollers Dr. Shah, Dr. Golden, Dr. Rozema, and Dr. Silverman! We encourage all of you to challenge these top sites with your own enrollment. To date, we have 61 patients enrolled, but to reach our goal of 2,366 patents, we need everyone to step up recruiting efforts. We have included some enrollment tips in this newsletter to assist you.

We continue our efforts to get more sites approved. Since the last investigators' and coordinators' meeting, we trained seven additional sites via teleconference training. More sites will be trained at the second investigators and coordinators' meeting. This will be held March 25<sup>th</sup>-28<sup>th</sup> at the Marco Polo Beach Resort in North Miami Beach. To attend this meeting sites must submit regulatory documents by February 16th. You will be receiving information about the conference in the next few weeks. We look forward to meeting the new sites.

We do understand that this trial takes a lot of time and effort. Please remember that we are always here to help. Please call us anytime with any questions or issues you have. Let's work together to meet our enrollment goals!

### Enrollment

227 Sangeeta Shah/ Janet Dunbar	9
406 Patrick Golden/ Jeannie Buhler	8
220 Theodore Rozema/ Dolly Corbin	8
113 Russell Silverman/ Sherri Loucks	8
302 Greg Flaker/ Jamie Easley	5
212 Joseph O'Bryan/Mary Barr	5
115 Robert Weiss/ Diane Cass	5
223 Roy Heilbron/Celia Heilbron	4
407 Nampalli Vijay/Melinda Washam	3
217 James Carter/ David Maddox	2
216 Ricky Schneider/ Amy Abreu	2
221 Denis Weinberg/ Raquel Rojas	2
228 James Carter/ Jodie Ledbetter	1
224 Angelique Hart/Angelique Hart	1
107 Allan Magaziner/Betty Ann Persico	1
215 Shalendra Varma/Sharon Collins	1

Total 61



Try with all your might to start the  
New Year off right.

Don't let time get away. Enroll  
today!!



## TACT Newsletter Continued

### Trial Master(TM) TIPS

- Check the daily message for updates and tips
- Before adding any pull-in pages to the infusion visits, look first! The system may have already added the needed pages. When any of the safety labs (creatinine, ALT, AST, alkaline phosphatase, bilirubin, hematocrit, white blood count, neutrophils or platelet count) are abnormal, the system recognizes that repeat testing will be needed and will automatically add another lab page to that visit.
- TM has updated the laboratory page to make it easier to keep all lab results needed for infusion prescriptions on one page. You will now note that dates fields have been added to each laboratory value. When any tests are repeated, a new page will appear and all values will pre-populate. You will only need to go in to the one field with the repeat value, enter it and the new date that it was drawn. You will need to add two comments to each change.

### CHANGES IN THE TRIAL MASTER SYSTEM

- Unscheduled Lab Screen is no longer needed. Now, the Lab Results screen is used for both routine and repeat lab draws.
- Neutrophil measurements are to be recorded as Absolute neutrophils, indicated by cells/micro Liter. The results are generally a four-digit number.
- The LDL lab field may now be left blank. This helps when the LDL cholesterol can not be calculated because the Triglyceride value > 400 .
- Users in the E-mail Address Book will now be in alphabetical order by last name
- Subject Information Screen: The randomization date field will now auto fill as soon as the "Randomized?" question is answered "Yes".

### RECRUITMENT/RANDOMIZATION TIPS

- Ask, ask, ask every patient about participating in TACT
- Tell patients to call with any questions at all
- Emphasize the importance of participating in research
- Set a goal of enrolling patients (example, 3 per month)
- Emphasize that all patients receive vitamins
- Create a comfortable infusion environment ( easy chairs if you have them)
- Have the site investigator talk personally with potential TACT patients
- Target retirement communities
- Have short books on chelation therapy available for patients to take home to read. We will be happy to provide titles.

### Study Notes

As a reminder, Adverse Events are collected from the start of study drug, NOT from randomization.

### EQOL Update

Reminder: Baseline QOL Questionnaires must be **completed for every randomized patient** and should be **entered within 2 days of randomization.**

**Be careful not to enter data too quickly from dropdown boxes** as you can create blank data fields. Review that all data fields are filled in with the correct responses before signing the questionnaire form in TrialMaster.

Keep up the great work! Contact Diane Liu at 919-668-8221 or [minsh001@mc.duke.edu](mailto:minsh001@mc.duke.edu) with any EQOL questions.



### TACT Communication