



# TACT TALK

May/June 2005

TACT ENROLLMENT REACHES 657 AS OF May 31, 2005.

## In this Issue

- 1- Message from Dr. Lamas
- 2- Top Enrollers, Spotlight on Patient Recruitment, Reminder from Dr. Lamas, All Things Being EQOL, DCC Corner
- 3- More DCC Corner / Preparing for On-Site Monitor, Regulatory Binder Preparations
- 4- Recruitment TACTics

## Contacts

### Clinical Coordinating Center

Mount Sinai Medical Center

Email: [cccadmin@tactnih.com](mailto:cccadmin@tactnih.com)

Fax: (305) 674-2146

**Gervasio A. Lamas, MD, Principal Investigator**

Voice: (305) 674-2162

Email: [TACTNIH@aol.com](mailto:TACTNIH@aol.com)

**Jacqueline Arciniega, MPH, Project Director**

Voice: (305) 674-3948

Email: [jarcinie@msmc.com](mailto:jarcinie@msmc.com)

**Dr. Kayvan Amini, Clinical Trial Manager**

Voice: (305) 674-2049

Email: [kamini@msmc.com](mailto:kamini@msmc.com)

### Data Coordinating Center

Duke Clinical Research Institute

**Cresha Cianciolo, RN, Regional Coordinator**

Voice: (919) 668-8973

Email: [cianc001@dcri.duke.edu](mailto:cianc001@dcri.duke.edu)

**Mary Nahm, RN, MSN, Regional Coordinator**

Voice: (919) 668-8808

Email: [nahm0002@dcri.duke.edu](mailto:nahm0002@dcri.duke.edu)

### Economics and Quality of Life

Duke Clinical Research Institute

**Diane Minshall-Liu, CCRP, Coordinator**

Voice: (919) 668-8221

Fax: (919) 668-7054

Email: [dianem.liu@duke.edu](mailto:dianem.liu@duke.edu)

**Jason Blevins, Sr. Research Assistant/Analyst**

Voice: (919) 668-8640

Fax: (919) 668-7054

Email: [jason.blevins@duke.edu](mailto:jason.blevins@duke.edu)

### National Center for Complementary and

### Alternative Medicine (NIH)

**Alyssa Cotler, Communications Specialist**

Voice: (301) 451-3851

Fax: (301) 480-3519

Email: [cotlera@mail.nih.gov](mailto:cotlera@mail.nih.gov)

### Clearinghouse

1-888-644-6226 (for patient referrals and to order recruitment materials)

Web Address: <http://www.tactnih.com>

### Urgent Clinical Questions

Call TACT Helpline :

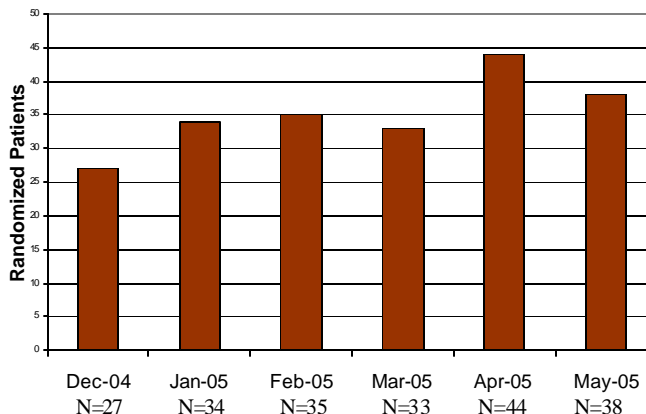
1-800-545-3853 (DUKE)

## Message from Dr. Lamas... A Focus on Safety

Over the last few months, all of you have been reading newsletter articles and receiving emails from me that enrollment, compliance, and safety are always the order of the day, every single day. Today, I want to take this newsletter opportunity to expand on patient safety as a goal, and make you aware of some issues and changes that will improve the TACT experience for all of our patients. As you know from my email of May 1, we have had a small number of heart failure events in patients whose weight has been increasing during the weekly infusion phase of the trial. I wanted to let you know the timeline for upcoming operational changes that will make it easier for you to detect and keep track of patients who may be developing heart failure. Heart failure (HF), in regulatory terms, is an "expected" side effect. This means that it is already reported in the package insert for EDTA infusions. "Expected", however, does not mean "okay", and each episode of HF leading to hospitalization, if it occurs during the weekly infusions, is carefully scrutinized. For now, we are asking you to practice good medicine and, **when patients have gained 3 or more pounds between infusions, or at least 5 pounds since baseline, the Coordinator must have the Site Investigator clinically evaluate the patient (history and exam), and then call us through the TACT (DCRI) Helpline [1-800-545-3853 (DUKE)] at the CCC to discuss whether the patient has any symptoms or signs of HF.** We will help you reach a decision as to whether you should infuse. But remember, we are not there with you, so the final decision will be yours! I know that all of us have a lot to think about in this study, so in order to put the weight algorithm on auto-pilot, we have asked OmniComm to re-program TrialMaster to include weight and heart failure symptoms at each and every infusion visit. This will be done by the end of May. In the meantime, stay alert to weight change, other signs of heart failure such as rales and pedal edema, and symptoms such as shortness of breath. Stay alert, and we'll make sure TACT is a rewarding, safe experience for our patients.

Thanks and keep enrolling.

TACT Enrollment over the Past Six Months



We'll meet our target enrollment of 2,372...

IF...each site enrolls an average 1 patient/month

IF...each site enrolls an average 12 patients/year

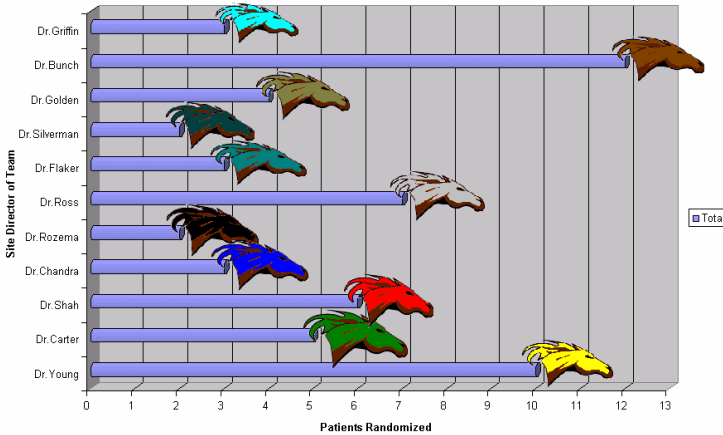
IF...each site averages 22 patients in 22 months!

Submitted by Jason Blevins



## TACT Site Team Derby Week 6 (May 24 – May 30)

TACT Derby Week 6



### ANOTHER EXCITING DAY AT THE RACES TRIAL FANS!!!

Dr. Bunch's Team leads for the fifth consecutive week. Dr. Young's Team holds onto second place with an iron grip. In a surprise move Dr. Ross's Team shoots into third place. And Dr. Shah's team slips into fourth place. *Submitted by Jewmaull Reed*

### All Things Being EQOL....

#### Patient Follow-up and Telephone Contacts

Patients who discontinue treatment or threaten to withdraw from the study are not only critical to retain in the study for the clinical follow-up and telephone contact in TACT, but they are also very important to the questions of the quality of living post chelation and vitamin treatments. **As with collecting CRF data, Jason Blevins, interviewer at the DCRI EQOL Core Lab will continue to phone these patients through their 24th month of follow-up.** We will call any of the Site Coordinators for whom we need help in facilitating calls with their patients. These patients pose unique challenges for us all to convert if refusing and to retain if threatening discontinuation. Our mantra is: continue to work very hard to enroll patients who are fully cognizant of the demands of the TACT study design.

*Submitted by Diane Minshall-Liu*

### In order to prevent heart failure hospitalizations in association with infusions and persistent weight gain, REMEMBER THE FOLLOWING:

1. The coordinator weighs the patient before each infusion
2. The pre-infusion weight is compared with the last infusion weight and with the baseline infusion weight.
3. If the weight is at least 3 lbs greater than during the last infusion, call the TACT (DCRI) Helpline prior to infusing.
4. If the weight is at least 5 lbs greater than baseline, call the TACT (DCRI) Helpline prior to infusing.

This is critical. Please make sure it is put into effect.

*Submitted by Dr. Tony Lamas*

## Spotlight on Patient Recruitment Highlights from NCCAM

Over the last several months, NCCAM has employed a range of communications activities in an effort to help recruit patients to TACT. With a limited budget, NCCAM's goal has been to implement outreach strategies designed to have a broad reach and affect as many sites as possible. In addition, NCCAM has trained and provided materials to study sites to implement their own customized patient recruitment campaigns. These local activities are absolutely vital to the success of the trial.

These centralized efforts are unprecedented within NCCAM; TACT reflects the first time that NCCAM has been directly involved in patient recruitment activities for any of its Phase III clinical trials, and reflects the Center's commitment to helping TACT reach its goals. This month, we'd like to highlight just a few of the centralized efforts and share some results.

*Submitted by Alyssa Cotler*

## DCC Corner

### Patient Visit WorkFlow Tips

The most important thing to remember is that the workflow is advanced in stages. If any of the stages are not completed or completed out of order then the workflow stops. The order is as follows.

1. Visit Status is "Awaiting Infusion Visit Scheduling".
2. The patient's visit is scheduled in the workflow.
3. Visit Status is "Awaiting Prescription Shipment".
4. The pharmacy ships the prescription.
5. Visit Status is "Awaiting Infusion Visit".
6. The patient's data is entered and the form is signed and if there are Labs at the visit the lab form is signed.
7. Visit Status is "Complete" for the visit and a new line appears for the next infusion visit.
8. The new line will say "Awaiting Infusion Visit Scheduling" and the process will repeat itself.

There are some exceptions to this. If the patient missed the visit or did not have the infusion then the visit status will go back to "Awaiting Infusion Visit Scheduling" and the patient's visit will need to be rescheduled for the visit that was missed. If there are labs at a visit and they have not yet been signed, the visit where the labs took place will go to a status of "Complete" and the new line for the next infusion visit will have a status of "Awaiting Lab Results" until the labs are signed.

*Submitted by Julie Glenn*

## Preparing for an On-Site Monitoring Visit

Study Coordinators are always busy--THIS IS A FACT. But, when a site visit by a monitor is scheduled, this is a way to validate one aspect of your work. The TACT Monitor would like to be efficient by completing all tasks in a timely manner. You should review your confirmation visit letter for the patients and documents to be monitored as well as the activities that will require your presence.

Here are some ways to help in the monitoring process at your site by having the following available:

- All source documents for the patients to be monitored (i.e. infusion visit worksheets, concomitant medication lists, urine dipstick results, Quest lab results, notes of adverse events, medical records relating to study)
- Sign TrialMaster® iCRFs where appropriate and respond to all queries
- Informed consents for all patients enrolled are available and completed using the current IRB approved version (*note: current version date for Sterling IRB is April 19, 2004*)

A designated area for the monitor to work that has access to the site's high speed internet, telephone and copier is a necessity.

**Remember that the monitor is there to support you and your site investigator.** A prepared study coordinator typically leads to a rewarding monitoring visit and a pleasant experience for all.

*Submitted by Wanda Parker*

**Regulatory Binder Preparations:** Prior to the site monitoring visit, review your regulatory binder for the following...

Tab	Document(s)	Where to Find on Study Web Page (*not applicable)
Protocol/Amendments	Protocols dated May 30, 2003 and February 17, 2004	Institutional Review Board Materials
Investigator Brochure	<ul style="list-style-type: none"> <li>▪ Version dated February 17, 2003</li> <li>▪ DSMB Letter dated May 26, 2004</li> <li>▪ Safety Alert #1 dated January 19, 2005 and #2 dated January 25, 2005</li> </ul>	-Institutional Review Board Materials -Alerts, Updates and Announcements -Same as above
Consent Forms	Blank copies of each version that has been approved by your IRB	Sent to site by the IRB
IRB Approvals	IRB approval letters for the study, informed consents, advertisements and recruitment materials	Sent to site by the IRB
IRB Communications	IRB memorandums of reports and acknowledgements	From IRB
Form 1572 and Site Signature and Responsibility Log	<ul style="list-style-type: none"> <li>▪ All signed 1572s</li> <li>▪ Updated signature log noting end dates for personnel no longer associated with the study</li> </ul>	N/A
Financial Disclosure and Conflict of Interest Forms	Completed and signed by site and sub-investigators. Each form is separate.	Regulatory Requirements
Curricula Vitae and Medical Licenses	<ul style="list-style-type: none"> <li>▪ Signed and dated by site and sub-investigators</li> <li>▪ Photocopy of current licenses</li> </ul>	N/A
Laboratory	<ul style="list-style-type: none"> <li>▪ Current CLIA and CAPS certificates of your local Quest Lab</li> <li>▪ Laboratory normal values</li> </ul>	Regulatory Requirements
Study Drug Documents	All of the Pharmacy Packing Slips received to date for infusions and vitamins	N/A
Training	<ul style="list-style-type: none"> <li>▪ Investigator meeting attendance certificates</li> <li>▪ EDC Training certificates</li> <li>▪ NIH Protection of Human Research Subjects certificate of completion</li> </ul>	N/A
Site Visit Log	This section will be empty until your first visit is completed	N/A
Correspondence	All communications regarding the study including emails, flyers and newsletters. If this is kept electronically, a note to file indicating the location of materials	Newsletters- Alerts, Updates and Announcements



## Recruitment TACTics

### Bites and B-roll Package

In December 2004, NCCAM released a “bites and b-roll” video package for media outlets to use in developing news stories about TACT. The video package included footage of TACT participants and investigators and interviews – in English and Spanish – with Dr. Lamas, Dr. Heilbron (site #223), and two TACT patients. To let media outlets know the package was available, NCCAM’s media consultant sent media advisories and personally phoned more than 400 media outlets nationwide. You can view the b-roll on the NCCAM website at <http://nccam.nih.gov/chelation/>.

*Result:* While it’s not possible to track all of the times the package was used, we know that at least 29 stations used the b-roll to develop stories, and we estimate that at least 4.5 million people saw a story. We saw a marked increase in coverage in those areas where sites also contacted their local TV news outlets to encourage them to use the b-roll. In some of those cases, local investigators were interviewed and provided a more local angle to the story.

In addition, AARP, the nation’s largest non-profit member organization, representing Americans over 50, used our package to create a “video news release” (VNR – a drop-in news segment made available to news stations nationwide). The VNR was also aired during dozens of newscasts.



### Drop-in Newspaper Article

Through the North American Precis Syndicate, NCCAM provided a drop-in newspaper article to community papers throughout the country.

*Result:* The article was placed in 220 newspapers in 20 different states with a readership of 7,376,768. For a detailed list of placements, visit [http://www.napsreport.com/2229\\_lange/62785.html](http://www.napsreport.com/2229_lange/62785.html).

### Advertising Campaign

While the activities we have highlighted above have generated good results, unfortunately, patient recruitment is behind schedule. NCCAM authorized a portion of TACT’s grant funding be redirected into paid advertising. As such, the CCC has implemented an aggressive campaign, involving newspapers and TV ads throughout the country.

*Result:* The results have been quite remarkable, with 777 calls coming to the NCCAM Clearinghouse in 1 week (this 40-times greater than our typical weekly total). We hope that this campaign, combined with your continued local efforts, will create a significant increase in enrollments.



### NCCAM Clearinghouse

The NCCAM Clearinghouse responds to all of NCCAM’s public inquiries regarding complementary and alternative medicine. TACT is the first clinical trial in which we’ve made the Clearinghouse available to field, screen, and refer callers to the 100+ clinical sites.

The Clearinghouse received its first TACT call in September 2003, and had taken 1,632 calls regarding TACT through the end of April 2005 (an average of 80 calls every month). From those calls, 1,200 callers have been pre-screened (74%) and 582 have been deemed eligible for further screening and either referred to a study site or placed on a waiting list for a site to open.

***During the advertising campaign in May, the Clearinghouse received more than 900 calls and provided more than 400 referrals to TACT sites.***

There are several benefits to the Clearinghouse service:

- Busy site coordinators do not spend time talking to callers who are not eligible for screening.
- Potential patients can call a toll-free number.
- Potential patients who are not close to a study site can be placed on a waiting list to be informed when a study site opens up near them.
- The Clearinghouse tracks every call and tries to assess how the caller heard about the study. This helps us evaluate which outreach strategies are effective.
- It’s beneficial for callers to engage in a dialog with a live person as the caller thinks through the decision process about participating. The Clearinghouse is able to act immediately on the caller’s decision to take the next step.

*Best practices:*

- Make sure you have someone available to answer the phone or use voice mail.
- Return patient calls within 24-48 hours.
- If your site is unable to accommodate an eligible patient, refer them back to the Clearinghouse to help find another convenient site.

Keep up the good work, and thanks to all of you who are working to bring patients into TACT. We know it is hard and time-consuming work and greatly appreciate your efforts.

For more information, or if you’d like to discuss outreach strategies, contact Alyssa Cotler at NCCAM at 301-451-3851 or [cotlera@mail.nih.gov](mailto:cotlera@mail.nih.gov).

*Submitted by Alyssa Cotler*

### 1st Randomized Patient? Fax the ICF.

TACT is auditing the Informed Consent Form on the first randomized patient at each new site. Diane Minshall Liu, the EQOL Coordinator, will contact you shortly after your first patient is randomized to review the procedures for obtaining EQOL data on your patients and to remind you to fax in the ICF. Please fax the entire signed ICF to the attention of TACT EQOL at fax number 919-668-7054.

*Submitted by Diane Minshall Liu*