



TACT ENROLLMENT REACHES **840** AS OF December 27, 2005.

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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 . . .

I write to you today to discuss the recent meeting and follow-up calls with the TACT Data and Safety Monitoring Board. These were critical meetings, and the final recommendations, which are not yet set in stone, affect all of us in our quest to determine whether EDTA chelation benefits patients with coronary heart disease.

The Investigative Team and the DSMB both noted that enrollment in TACT is low, and that we will not be able to complete the trial by 2007. In addition, our NIH sponsors made it very clear that no additional funds will be directed to the study. In fact, it was very clear that we are in danger of losing the study if, at any point, the NIH or the DSMB feel that we will not meet our revised enrollment goals.

In response, we developed a recruitment plan that would allow us to meet our goals with an extension of enrollment and follow-up, and no change in total budget. The essential elements of this recruitment plan, and what role you can play are:

- 1. Increase Efforts to Recruit US Sites:** We continue to approach US sites. Please refer any potential sites to us at the Clinical Coordinating Center.
- 2. Increase Reimbursement to Sites:** We have developed an enhanced reimbursement plan this quarter in order to recognize the level of work that screening for TACT requires. You can help by enrolling patients so we can deliver added reimbursement to your site. (For more information, see memo on page 3.)
- 3. US Study meeting First Quarter 2006:** A study meeting is the best way to re-energize a trial. Please come to Miami February 10th & 11th. Be ready to get RE-ENERGIZED!
- 4. Patient Ambassador Program:** We believe that happy patients may become our best recruiters. Keep checking your emails for the details. The program will be unveiled for all the Sterling IRB sites in the next few weeks.
- 5. Renewed Media Campaign:** We have updated the press releases, developed stories to place in minority-friendly media, and are updating the video clip. The program will be unveiled in January or February.
- 6. Expand Study to International Sites:** We are pursuing Canadian and Argentine approval, but this will not materialize until at least June 2006 or later because of regulatory hurdles.

Colleagues, we are doing everything possible to
increase our numbers. Please assist us.



Let your daily goals be:

- ✚ Screen,
- ✚ Consent,
- ✚ Randomize!



Memo from Dr. Lamas to TACT Sites Re: Intensified Screening and Additional Reimbursement

From my many calls to site PIs and coordinators, I have learned that screening for patients is very difficult and more time-consuming than anticipated. I agree. In our own Mount Sinai clinical site, many patients have to be screened before one is enrolled. In recognition of this fact, I have asked NIH to allow me to redistribute some funds, and they have agreed.

Therefore, for the next 3 months (Dec-Jan-Feb), we will reimburse for additional screening activity above and beyond the standard \$2300 enrollment fee as shown in the table.

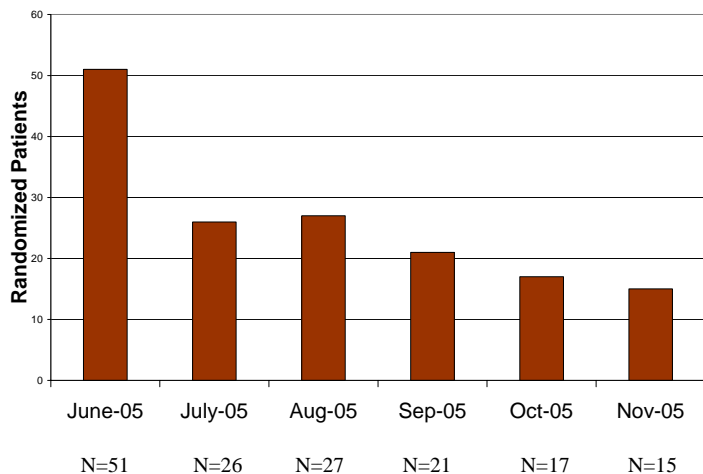
While I cannot guarantee that this program will be repeated, I can tell you that if it leads to increased screening and therefore enrollment, there is a good chance for repetition.

Patients enrolled in 3 months	Supplemental screening payment
1 patient	\$0
2 patients	\$1000
3 patients	\$1500
4 patients	\$2250
5 patients	\$3000
6 patients	\$3750
>6 patients	add \$750/pt

Let's show our NIH sponsors that we appreciate their flexibility in permitting this payment for increased screening activity.

Please screen and enroll!

TACT Enrollment over the Past Six Months



Submitted by Jason Blevins

CLINICAL **FLASH** MESSAGE

When patients have vague symptoms with a neurologic flavor, unexplained BP changes, or cardiac rhythm disturbances after receiving their study infusions, consider whether they may be having symptoms of hypocalcaemia, and check a calcium level if clinically indicated. Also, make sure that a calcium level is checked when patients are hospitalized or go to an ER with any of these symptoms.

Submitted by Dr. Lamas



CONGRATULATIONS

TO THE WINNERS OF A CHOCOLATE GIFT BASKET FOR ENROLLING TWO PATIENTS IN OCTOBER 2005:



- * Dr. Yulius Poplyansky and Marjorie Patino (SITE 126) in Roselle Park, New Jersey.
- * Dr. Jack Young and Estella Fransbergen (SITE 233) in Mount Dora, Florida.
- * Dr. Charles Adams, Jackie Miles, Judy Huskey, and Christina Griffin (SITE 262) in Ft. Oglethorpe, Georgia.

Submitted by Jacqueline Arciniega

SPOTLIGHT ON PATIENT RECRUITMENT

Optimizing the Web

A key source of health information for many Americans today is the Internet and use among people over the age of 50 is growing. According to the Pew Internet & American Life Project, 82 percent of Internet users between 50 and 64 years old and 66 percent of users above 65 have searched for health information online.

As a referral source for TACT, the Web consistently yields a large number of referrals. Are you taking advantage of this opportunity? Do you have TACT information on your Web site? The Internet is an important recruitment tool. Here are some easy ways to use the Internet to enhance recruitment:

- Review all of the TACT information you have developed and have available to you through the Clinical Coordinating Center. Recruitment materials can be found at http://www.tactnih.com/index_rec_tool.htm.
- Review the National Center for Complementary and Alternative Medicine's (NCCAM) Web site. It contains a wealth of information about TACT including facts sheet on chelation therapy and heart disease, a list of participating sites, downloadable video clips of physicians and participants in the study, and a national press release. <http://www.nccam.nih.gov/chelation>.
- Designate an area on your Web site for information about the study and post approved TACT information.
- Feature the study on your homepage with a link to more information. **Remember that any new content that you develop will need to be IRB-approved.**
- Be sure to link to NCCAM's Web site (<http://www.nccam.nih.gov/chelation>). Having many links to NCCAM's site will improve placement of this TACT information on search engines.
- Provide your and NCCAM's Web addresses to reporters, potential patients, colleagues, etc., so they may access the information available.
- Keep in mind that easy-to-use content is critical.
 - Avoid jargon.
 - Use many headings and keep paragraphs and sentences short.
 - Use visuals (like icons or small pictures) when possible.
 - Be sure all content is IRB-approved (for guidance, visit <http://www.hhs.gov/ohrp/policy/clinicaltrials.html>).

As always, thank you for your hard work.

Submitted by Alyssa Cotler and Amy Lange



Investigator and Coordinator Study Meeting February 10th & 11th Miami, Florida



<http://www.emarketing360.com/Hilton/FL/MIAf/index.html>

Attend our 4th Investigator’s and Coordinator’s Meeting at the Miami Airport Hilton in Miami, Florida on February 10th and 11th. This is a mandatory meeting to discuss the new patient and site recruitment plan and the trial’s overall progress. Every site investigator and coordinator is strongly encouraged to attend.

The trial will pay for your travel to and from Miami, hotel, room, and food.

Coordinators are scheduled to arrive on Thursday, February 9th for an all-day study meeting on Friday, February 10th focusing on patient recruitment and retainment, followed by TrialMaster® training.

Investigators are scheduled to arrive on Friday, February 10th for an all-day study meeting on Saturday, February 11th focusing on study’s progress, preliminary study results, and the new patient recruitment plan.

Contact Tristan Edwards at the CCC (305) 674-2703 (tedwards@msmc.com) or Stephanie Escalante (305) 674-2794 (escalan@msmc.com) to obtain booking information
or FAX back this sheet to (305) 674-3970

Site Number _____

Name _____ Investigator _____ Coordinator

Name _____ Investigator _____ Coordinator

YES, OUR SITE WILL ATTEND. SEND BOOKING INFORMATION.