



TACT TALK

December 2004

TACT ENROLLMENT REACHES 447 AS OF NOV. 30, 2004...

In this Issue

- 1- Inclusion/Exclusion Criteria
DSMB Update
Enrollment Graph
- 2- Top Enrollers
All Things Being EQOL...
DCC Corner
- 3- Site Interviews

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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)

A Closer Look at Patient Inclusion/Exclusion Criteria

During our last issue of TACT TALK, we discussed how if each site randomizes one patient each month, we will reach our goal of enrolling 2,372 patients by the end of the trial. Identifying potentially eligible patients for the trial should become a routine part of each sites' daily practice. Each time a patient chart is reviewed you should ask yourself if the patient is eligible for TACT. By incorporating this as part of your daily routine, you will be able to have more success finding patients. The TACT Team has worked hard on trying to come up with tools that help sites in their screening process. A quick reference tool available to help screen potential TACT patients is the "Study Pocket Card" available on the TACT website

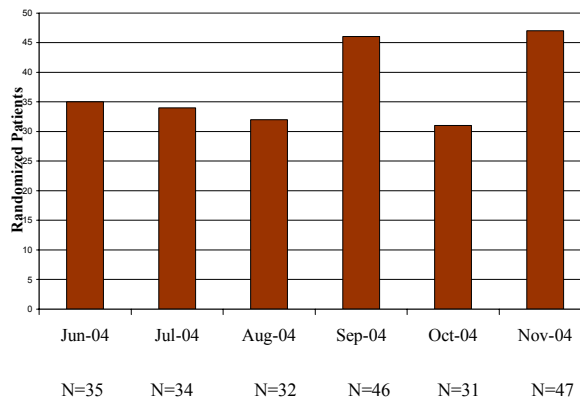
(http://www.tactnih.com/Study_Materials/Study_Tools/tact_pc%20revised%20for%20web.pdf). Even though the basic inclusion and exclusion criteria are clear, at times determining whether a patient has a chronic non-coronary condition that may limit survival beyond four years can present a challenge. Clearer definitions of conditions that fall under this category include: **severe aortic stenosis, severe valvular heart disease, severe COPD, cirrhosis, various cancers, or Alzheimer's.**

If you encounter any of these conditions in an otherwise eligible patient, **contact Dr. Kayvan Amini (305-674-2049) for help in determining whether the patient is truly eligible for TACT.**

Update on DSMB Meeting

The Data Safety and Monitoring Board (DSMB) meeting occurred earlier this month. The committee members were pleased with the trial's progress and strongly emphasized two areas: increased efforts to recruit patients for the trial and patient safety. The CCC and NCCAM are working on several initiatives to help sites in their patient recruitment efforts. Additionally, the CCC is working on identifying new sites for the trial. The TACT Team is also working on incorporating measures to ensure patient safety. One of these efforts aims to identify when a short infusion has occurred by reprogramming the TrialMaster system to immediately alert the TACT CCC and DCC when a short infusion has occurred at a site.

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!

Do you need promotional materials about TACT to help spread the word?
Call the NCCAM Clearinghouse at 888-644-6226 to order study brochures and flyers.





Congratulations To Our Top 5 Enrollers (as of 12/15/04):

Site	Investigator/ Coordinator	# of Patients
234	Dr. Rajiv Chandra/ Terry Murphy <i>Tru Med ED/Melbourne, FL</i>	40
220	Dr. Ted Rozema/ Dolly Corbin <i>Biogenesis Medical Center/Landrum, SC</i>	25
227	Dr. Sangeeta Shah/ Tracey Wilks <i>Wellness and Longevity Center of Louisiana/Lafayette, LA</i>	24
113	Dr. Russell Silverman/Sherri Loucks <i>Heart Care Center, East Syracuse, NY</i>	19
239	Dr. Randy Hartman/ Amy Heineman <i>Heart and Vascular Research Group/Sarasota, FL</i>	19

ALL THINGS BEING EQOL...

Tips to Avoid Calls from Diane or Jason at EQOL DCRI....

Responses to the **Baseline Questionnaire items 8, 9, 34 and 80 must be a number**. If you receive a validation message that includes the statement "...is not a valid integer", you have entered more than one number or added text to the response. Please **do not enter text** into the response area **and do not use bypass notes** for these questions. In cases where a patient does not have a steady number of work hours per week (Question 34), ask the patient for a best average. Any text or added numbers for only these questions convert to **blank fields** when they are **downloaded for analysis**.

Also remember that the **sum for Questions 8 and 9** (total number of days in bed and of reduced activity) **cannot total more than 42** (7 days x 6 weeks).

DCC Corner

All About TrialMaster® Notes:

Notes are user entered text that are attached to the answer of any question on any iCRFs. There are three basic types of notes:

- General
- Bypass
- Change

Notes are a way for users of the system to explain WHY he or she answered a question the way he did. They are also a way to provide further elaboration on ANY question. Notes also cover unexpected changes to available answers.

General Notes - provide a general text attachment for information purposes. Any question may have a general note attached, however, no general notes are mandatory.

Bypass Notes - Bypass notes are mandatory for answers that fail normal validation. They allow you to explain why there is an out-of-range value, for example. The form cannot be taken to a signed status until all failed questions have been explained with a bypass note.

Change Notes - Change notes are mandatory for questions whose answers changed after the form was originally signed. They allow you to explain why the answer changed (new information on a history of hypertension, for example). The form cannot be taken to a signed status again until all changed answers have a change note attached to them.

VERIFICATION OF REVASCULARIZATION AS AN ENDPOINT:

- The site is responsible for providing accurate data and for submitting source documents for TACT patients with revascularization procedures.
- Revascularization procedures include CABG and PCI (*PCI = Balloon angioplasty, atherectomy, stent, or any transcatheter attempt to open a coronary stenosis or occlusion. Diagnostic catheterization without intervention is not part of an endpoint and does not need to be reported.*)
- Any attempt at revascularization is considered revascularization.

Carefully review the following process for verifying revascularizations in TACT patients. Contact your DCRI Regional Site Coordinator if you have questions about the process. Contact the clinical manager at Mt Sinai if you have questions about specific patients.

Site responsibilities:

1. Collect source documents for all PCIs, CABGs and attempted revascularizations.
2. Review source documents for date and to assure revascularization was attempted or performed.
3. Enter procedure and date of procedure into appropriate iCRF (Next scheduled infusion visit, details page, telephone follow-up or clinic visit). Complete Adverse Event form if applicable.
4. Submit de-identified source documents for procedure to DCRI. Submit documents for patients who have revascularizations or attempted revascularizations only, not for every patient who goes to the cath lab for a diagnostic procedure.
5. Adhere SOURCE DOCUMENT LABELS provided in the TACT Starter Kit to each page of source documents submitted to prevent distribution of patient's Protected Health Information. The supply is limited, so do not use these labels for other purposes.

Expiration of Infusion Kits

- Infusion kit labels specify expiration dates for each component.
- The 500 ml solution bag expires 3 days (72 hours) after shipment date.
- The 2 syringes expire 7 days after shipment.
- Do not administer any solution after the expiration date on the bag.
- If mixed infusion cannot be administered to the patient within **24 hours**, it must be disposed of at the clinical site in accordance with the site policy for disposal of study drugs.

Missing Responses

Question #9 (intermittent claudication) on the Baseline iCRF is frequently not answered., possibly due to lack of understanding of the term. *Intermittent claudication* is a predictable pattern of lower leg pain that is:

- 1) brought on by exertion
- 2) relieved by rest
- 3) is reproducible.

This reference can be found in the Glossary of Clinical Terms in the Document section of TrialMaster® and in the iCRF Instructions. Be sure to ask your patients if they have lower leg pain so that this data can be provided.

Focus on Patient Recruitment

Contacting the media may seem like an ominous task, but the potential rewards are great. Ask Dr. Dantin at site #263. After her local paper in Baton Rouge printed a brief story about TACT, the NCCAM Clearinghouse received 21 calls and referred 13 potentially eligible patients to Dr. Dantin’s site. A few weeks later, the local television news reported on TACT and Dr. Dantin received another 7 referrals.

Not sure how to get started? **Simply visit www.tactnih.com and click on “TACT Recruitment Tools and Advertising.”** There you will find a customizable news release about TACT. Add your site’s information to this template, and you’re ready to send it out. Look up contact information for your local newspaper’s health reporter and health editor and send the news release to them either via e-mail or fax. In a day or two, call the reporters to follow up.

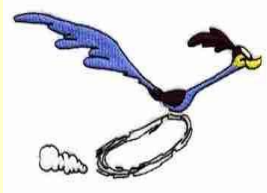
For more information and tips on contacting the media, turn to your patient recruitment toolkit. Can’t find it? **Go to www.tactnih.com and download it.** Any questions, please contact Alyssa Cotler at the NCCAM Office of Communications at 301-451-3851 or cotlera@mail.nih.gov.

Introduction to Site Interviews

One of the new programs presented in our last issue was award presentations to successful sites in the areas of regulatory document completion and patient enrollment and retention. This issue of TACT TALK highlights two of our award winners Dr. Tammy Born (a top enroller) and Dr. Eleanor Hynote (a new TACT site):



The “Aramis Award” for third top enroller present at the meeting (Aramis was the third member of the three Musketeers): Dr. Tammy Born and her coordinator Judy Schneider from Crossroads Clinic



Awarded the “Roadrunner Award” for the swift completion of the regulatory requirements (Beep-Beep): Dr. Eleanor Hynote and her coordinator Inna Goreva from Phoenix Wellness Group

Introduction:

Dr. Born is Site Investigator for Sites 312 and 332, located in Grand Rapids (MI) and Goshen (IN). Her practice encompasses family practice, chelation, and preventative medicine. Dr. Born has been consistently among the top 10 enrolling sites in TACT. She was the third top enroller at the meeting. Below are Dr. Born’s responses to our questions:

What is the reason for your success in enrolling patients in TACT?

I give the credit for the success of the trial to my staff especially my nurse, Judy. The whole office is extremely enthusiastic about TACT. We are determined to make the study successful and we encourage patients to participate.

Have you advertised for the trial? If yes, what venues did you contact?

Certainly, another big factor in my success has been media coverage. We have established relationships with local media. I have utilized almost every venue available for advertising and public relations. I have had a good response from advertising in newspapers and radio stations. Local TV stations have provided coverage for TACT as well. Local health and food storeowners are also eager to put the TACT flyers in their stores. I have contacted local cardiologists to refer eligible patients to my site, but this approach has not worked for our site.

How important do you feel this trial is?

I feel that TACT is extremely important as many of our future treatments may rely on studies like this. As we look to change the way healthcare is administered in the US, we must focus on prevention.

How many patients do you project to enroll?

Our clinic is well known in western Michigan for providing chelation therapy, so I feel we can realistically enroll 75-100 subjects in TACT, with increased awareness and advertising.



Dr. Tammy Born



Judy Schneider and Dr. Lamas

Introduction:

Dr. Hynote is the Site Investigator for site 421 located in Napa, CA. Her practice focuses on combining conventional and complementary medicine. Dr. Hynote submitted all her site’s regulatory documents in less than two weeks, had IRB approval in 30 days, thus completing the overall process to become a TACT site in approximately two months! Below are Dr. Hynote’s responses to our questions:

What would you say was the greatest factor in completing the regulatory process so quickly?

I kept on my staff about getting approved in the study, but I would have to say I have a good staff. I have an efficient staff and a quick administrative assistant.

How important do you think this study is?

I think it is of the highest importance, because we need this study to give us a final answer about chelation therapy. On account of this I am doing a lot of advertising. We advertise in the local Sunday paper. Also the local newspaper is doing an interview with us soon, which should prove very fruitful.

How many patients do you project your site will enroll?

We will enroll as many patients as possible.



Eleanor Hynote, M.D.

Merry Holidays from the TACT CCC, DCC, and EQOL CC!

