



# TACT TALK

January 2007

**Important news for TACT Site Investigators and Coordinators:  
FOCUS ON PATIENT RETENTION**

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# HAPPY NEW YEAR 2007

## CONTACTS

### Clinical Coordinating Center

Mount Sinai Medical Center

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

Fax: (305) 674-2146

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

Voice: (305) 674-2162

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

**Ana Mon, MPH, Project Director**

Voice: (305) 674-3936

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

**Faisal Shamshad, MD, Clinical Trial Manager**

Voice: (305) 674-2049

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

**Laura Davila, Research Assistant**

Voice: (305) 674-2703

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

**Rita Weber, RN, MSN, Regional Coordinator**

Voice: (919) 668-8173

Email: [rita.weber@duke.edu](mailto:rita.weber@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) 402-4741

[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>

2006 has come to a close, but I wanted to thank all of you again, as I do frequently, for all your efforts on this most interesting and most difficult clinical trial. This was a landmark year.

Just to give you 2006 in a nutshell:

- We randomized nearly 300 patients; the lead enrollers for the year were:
  - Site 220 Biogenesis Medical Center (Dr. Ted Rozema and Dolly Corbin),
  - Site 234 Tru Med Inc. (Dr. Rajiv Chandra, Jackie Strohfus and Linda Stevens),
  - Site 131 Celebration of Health Center (Dr. Terry Chappell and Marcia Arnold),
  - Site 239 Heart and Vascular Center for Research Inc. (Dr. Randy Hartman and Amy Heineman),
  - Site 227 Wellness and Longevity Center of Louisiana (Dr. Sangeeta Shah, and Debbie Vige).
- Jacqui Arciniega has moved to New York, and Ana Mon replaced her; Faisal replaced Pablo; Tristan left for Chicago, and Laura Davila is our new research assistant;
- Wanda Parker and her staff visited 154 sites;
- ...and surprisingly, Kerry Lee and I are still standing and in good humor.

There's more!

We surpassed 30,000 infusions throughout the study, and changed vitamin vendors. We survived an independent NHLBI review committee.

And there is even more! Finally, last week we found out that we have regulatory approval to do TACT in Canada, and 18 sites (15 CAM) applied to IRB.

Enough reminiscing, however, we have to think of 2007. For the beginning of 2007, we are back to the dual messages of recruitment and retention. We need to enroll 35 patients per month to finish the trial, and we are stuck way below this number. So screen and enroll. Take advantage of the enhanced reimbursement programs. We are really trying to pay you for the extra work TACT takes.

Now the hard work. Over the last year, the number of patients that have stopped their infusions and vitamins has increased dangerously. If our patients do not receive their treatments, then there is no chance that we could show a difference between groups. That is why this newsletter issue is devoted to patient retention. Please help TACT out.

GERVASIO A. LAMAS, MD  
TACT Principal Investigator

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## Critical Importance of Patient Retention and Complete Follow-up

There has been considerable emphasis thus far in TACT on recruiting patients, and this is appropriate because enrolling the number of patients required to answer the primary questions being addressed in the trial is critically important. However, it is of little value to enroll patients if those patients do not comply with the assigned interventions or if the important follow-up data are not adequately obtained.

**To adequately evaluate the benefits of chelation therapy and /or high-dose vitamin therapy (1) the interventions must be delivered, and (2) the outcome of the patients must be accurately ascertained.**

In TACT, delivering the interventions is not a trivial task. The effort required by personnel at the enrolling site and by the patients themselves over an extended period of time in order to deliver the 40 infusions and maintain compliance with the high dose/placebo vitamins is very significant. Even after completion of the infusion phase, regular follow-up of the patients must continue so that the clinical outcomes of the patients can be accurately assessed.

Some confusion may exist that discontinuation of infusions constitutes patient withdrawal from follow-up in the trial. **Patients are in the trial until either death or the until they have been in the study for 5 years, and should continue to be followed,** even if they have a valid reason to discontinue the intervention(s). If we take a genuine interest in these patients, it should be rare that a patient is unwilling to have a brief periodic follow-up call to check on their progress. Helpful hints for finding/following difficult patients are available from your Regional Coordinator.

**Remember that missing follow-up data in a relatively small number of patients with events can alter the outcome and interpretation of the study.** Failure to capture all events will not only reduce the statistical power, but could alter the interpretation of the trial. If the significance of the treatment effect is borderline, it takes only a few missing events to change a p-value from less than 0.05 to greater than 0.05.

TACT is a high-profile study that will be closely scrutinized, and critically judged based on the completeness of follow-up and compliance with the interventions. It is very unlikely that the study will ever be repeated. We have a unique window of opportunity to evaluate the interventions being studied in this trial. **Completeness of follow-up and compliance in delivering the intervention will distinguish TACT from simply a good study to a superb (landmark) study that will help improve the care of patients in the future.** With the great network of sites working together, a high level of scientific integrity can be achieved. May we all unite our efforts to achieve that worthy goal.

*Submitted by Kerry Lee, PhD, DCC Principal Investigator*



## Site Experience with Retention Strategies

The time and effort being devoted to patient retention at each TACT site is very special to the success of the study. We hear of many examples in our conversations with our sites of successful strategies used to encourage patients and support them through the entire length of the study. Because of your efforts, our campaign focusing on patient retention should be very successful as we begin the New Year.

Several of our study coordinators have shared their thoughts regarding what they feel has been successful at their site in retention efforts.

**Berni McClendon and Dr. Carol Roberts at Wellness Works in Bradenton, Florida** work hard to let the patients know that they truly have “the patient’s best interest at heart”. We let them know we understand and are empathetic to their needs.” Berni has found that providing the utmost flexibility in scheduling patients for their therapy has worked well at their site. Some of the difficulties encountered with patient’s work schedules can be overcome and “eventually just work themselves out if you are flexible”. Some patients may be discouraged by their non cardiac illnesses. Berni remains in frequent contact with these patients. It is not unusual to offer a brief interruption in therapy for some patients rather than to have them withdraw from the study.

**Helena Williams and Dr. Timothy Blend, Integrated Healing Arts, Bradenton, Florida** have had recent success in retaining a patient who was considering leaving the study. They met with the patient together, shared and discussed the literature available as a resource on the TACT Website. In addition, this site has formed a TACT support group. TACT patients receive therapy on the same day and Helena and Dr. Blend take advantage of this time to visit with the patients and discuss issues relevant to the study. They have found that patients support each other as well.

**Dolly Corbin and Dr. Ted Rozema at Biogenesis Medical Center, Landrum, South Carolina** places a great deal of emphasis on their accessibility for patients. Dolly leaves a message on her phone with instructions on how she can be reached after hours and the weekend to assist her in efforts following patients with difficult schedules. TACT patients at Dolly’s site receive a “miss you note”. The note provides patients with the dates they can expect a telephone follow up call, supplements to be mailed, etc. Patients are encouraged to call or drop in and say hello at any time.

*Submitted by Rita Weber, RN, MS*

**Kelly Odom and Dr. Allen Roberts, The Castle Clinic, Johnson City, Tennessee** also put their special touch regarding patient support. Kelly visits each patient during their treatment session to answer questions and reinforce their value to the study. Kelly feels this is especially important as the patient progresses further along in the study and may be questioning the value of their further participation. When TACT patients reach their 30<sup>th</sup> infusion a “Congratulations” banner is hung in the treatment room. The celebration sets the stage for continuing the study not only through infusion but telephone and clinic visit follow up as well.

## Retention Hints and Suggestions

Site coordinators must always be on the alert to issues that might affect the willingness of TACT patients to remain in the study. Admittedly, due to the long time commitment of the treatment and maintenance phases of the study, participants might become 'bored' with the routine. Extra attention and effort by the Site Investigator and Study Coordinators might well prevent participants from losing interest. Obviously, some exploration and review of the causes of a participant's discontent would be necessary to determine the best solution. Below are some suggestions that might assist you retain patients.

- While acknowledging that the patient has a right to discontinue any therapy, solicit the specific reasons for this decision. Based on this information, consider a plan to alleviate the patient's concerns.
- For patients experiencing transportation problems, consider offering to arrange a cab to transport them.
- For patients who wish to discontinue infusions, suggest that they at least stay on study drug for the remainder of the study. Explain that this would save them out-of-pocket expenses for a private vitamin supply.
- If a patient appears to be getting frustrated and 'needs' a break from therapy, consider a 'pause' in treatment and readjust schedule. Also possible, but less desirable, treatment visits can be accelerated for a quicker completion (discuss with Clinical Manager).
- For patients uncomfortable with vitamin therapy (due to possible side effects), consider multiple dosing adjustments. Scenarios can be discussed with Clinical Manager to accommodate each specific issue.
- Consider providing uninterrupted time for confidential communications with TACT patients. Site coordinators may identify potential problems (adherence, behavioral or psychosocial) during these one-on-one conversations and work quickly to address these issues.
- Be open to discussing other non-TACT issues that might affect patient's participation (family illness, job relocation, financial issues).
- Be open with information regarding potential site policies or staffing changes that might cause stress to the patient. Any potential changes that may affect patient's routine should be brought to their attention as soon as possible. This is not uncommon in a long-term study such as this.
- Ensure that any new TACT personnel are properly introduced to patient (and family, if applicable)
- Staff must be attentive to patients who require frequent rescheduling or miss several visits. This may be the patient's subtle way of indicating discontent with the study.
- Be alert to on-going problems in contacting the patient. Other contact information should be solicited to provide a back-up communication method.
- Pay attention to patient complaints about study procedures. Consistent comments about specific issues need to be addressed and remedied.
- Consider pill counts that indicate a lack of compliance and interest. Identify what can be done to encourage continued dosing.
- Remind patients of their importance to the TACT study.
- Be alert for lack of family support. Frank discussions with family members not familiar with benefits of the study might be helpful to alleviate non-support.
- Be alert for personality conflicts between staff members and patients. Ensure that patients are treated with respect and courtesy.
- Develop an open relationship with the patient. Consider placing calls outside of protocol requirements (every three months post last infusion). This can be very helpful in maintaining open communications.

*Submitted by Cresha Cianciolo, RN*

## Locating Missing Patients

With Focus on Patient Retention as the theme of this newsletter, let's review some means to find your wayward patients. **REMEMBER:** If a patient is temporarily or permanently discontinued from study medication (for any reason other than patient death or withdrawal of consent from follow-up), it is CRITICAL that the patient continue to be followed until study completion.

**MAINTAINING FOLLOW-UP:** Follow-up must be vigorously adopted in the TACT Trial. Be sure to document each patient contact attempt made. Copy and file any correspondence sent to a patient. For every scheduled visit a patient misses complete the following:

**1<sup>st</sup> Week** Call patient at different times of day, including week nights, and at different days of the week, including weekends. Make at least 6 phone calls.  
Refer to the Confidential Patient Information form. Call secondary and work numbers.  
Call friend or relative listed to verify patient contact numbers.

**2<sup>nd</sup> Week** Contact PCP or referring doctor's office and/or medical record to see if patient has been in for recent visits and to verify patient contact numbers.  
Check with the hospital and clinic billing offices for updated contact information.

**3<sup>rd</sup> Week** Send out a letter or card requesting that he/she contact your site.  
Search websites for current address and phone number. (list of websites below)

**4<sup>th</sup> Week** Send the patient a **Certified** letter requesting that he/she contact your site.  
Search the Social Security Death Index. (website address given below)

If you are unsuccessful in contacting a patient after attempting the steps above, please contact your DCRI Regional Coordinator.



### Helpful Websites for Finding Patients

*Free of Charge websites:* the following are like having each state's phone book at your disposal

**Anywho.com**

**Searchbug.com**

**Whitepages.com**

**Social Security Death Index** –<http://ssdi.genealogy.rootsweb.com/>

[This website will only search for deceased patients and is updated monthly.]

**People.Yahoo.com**

**Smartpages.com**

**Switchboard.com**

#### **Search Tips:**

- \* Try using the patient's first initial and last name, instead of the complete first name.
- \* Try using only the patient's last name, without first or middle names.
- \* Try searching both with and without the state, in case the patient has moved.
- \* Direct questions regarding the website resources to your DCRI Regional or EQOL Coordinators.