Welcome to our first edition of TACT TALK. This monthly newsletter for TACT sites addresses and highlights key messages and news from TACT’s Clinical Coordinating Center (CCC), Data Coordinating Center (DCC), EQOL Coordinating Center, NCCAM, NHLBI, and other TACT team members. We kick-off this newsletter edition after our Investigators’ and Coordinators’ Meeting held on October 22nd and 23rd at the Sheraton Biscayne Bay in Miami, Florida.

This meeting heavily emphasized patient recruitment. Attendees brainstormed a variety of innovative ideas, heard from successful sites, and received specialized media training. All of these topics will be highlighted in greater detail in subsequent newsletters and emails. In the meantime, if you’re not sure where to begin with your efforts, or if you think you’ve tried everything, we urge you to turn to your patient recruitment toolkit on the website or call us directly for help. Your toolkit includes a checklist to help you develop your action plan. Use it to help select a variety of strategies you feel comfortable undertaking. Create a timeline for implementing your plan. Then, get started with the first strategy, assess its effectiveness, repeat or move on. Alternatively, call us and we’ll help you get started.

A key message addressed at the meeting was “22 patients in 22 months.” If each current TACT site enrolls an average of one patient per month (12 patients per site per year) we can meet our recruitment goals! We have 22 months to go until the end of the study so enroll an average of at least one patient per month (22 patients within 22 months), and your site will help us meet our goals.

All of us at the CCC and DCC want to make sure you know that we are here to help you in becoming successful in recruiting, retaining, and managing your TACT patients. The CCC is currently holding weekly conference calls for site coordinators to call in and discuss any barriers they are encountering at their local TACT site. If you are interested in participating in these calls, please call Parm Singh at (305) 674 - 2703 or email him at pwsingh@msmc.com. We hope to hear from you!
Congratulations to our Top 5 Enrollers (as of 11/5/04):

<table>
<thead>
<tr>
<th>Site</th>
<th>Investigator/ Coordinator</th>
<th># of Patients</th>
</tr>
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<tbody>
<tr>
<td>234</td>
<td>Dr. Rajiv Chandra/Terry Murphy</td>
<td>39</td>
</tr>
<tr>
<td>227</td>
<td>Dr. Sangeeta Shah/Tracey Wilks</td>
<td>23</td>
</tr>
<tr>
<td>220</td>
<td>Dr. Ted Rozema/Dolly Corbin</td>
<td>21</td>
</tr>
<tr>
<td>239</td>
<td>Dr. Randy Hartman/Amy Heineman</td>
<td>18</td>
</tr>
<tr>
<td>312/322</td>
<td>Dr. Tammy Born/Judy Schneider</td>
<td>17</td>
</tr>
</tbody>
</table>

TACT Investigators’ Meeting

A key message at last month’s Investigators’ and Coordinators’ Meeting was our recognition of enrollment leaders. These successful TACT sites shared their secrets for success with the attendees, and received awards for their success. Your success is our success, and we want to recognize your efforts in helping TACT reach our patient enrollment targets each month.

Awards of Excellence for the top three enrollers who were present at the meeting:
1) Longevity and Wellness Center of Louisiana (Site#227)
   Dr. Sangeeta Shaah/Traci Wilkes received the “Sir Edmund Hillary” and “Tenzing Norgay” awards
2) Biogenesis Medical Center (Site#220)
   Dr. Ted Rozema/Dolly Corbin received the “Buzz Aldrin” and “Apollo 11 Eagle” awards
3) Crossroads Healing Arts (Site#311/312)
   Dr. Tammy Born/Judy Schneider received “Aramis” awards

In recognition of retaining a patient in the study: (Lasso Awards)
University of Missouri Hospital and Clinic (Site#302)
Dr. Greg Flaker/Dr. Duc Nguyen/Jamie-Lee Easley

In recognition of randomizing several patients shortly after becoming activated as a new TACT site: (SuperNova/Nova Awards)
Milwaukee Cardiovascular Research Foundation (Site#105)
Dr. Anita Arnold/Dana Kappel

In recognition of a speedy completion of the regulatory document process for becoming a TACT site: (Roadrunner Awards)
Phoenix Wellness Group (Site#421)
Dr. Eleanor Hynote/Inna Goreva

In recognition of enrolling patients after a few months of inactivity (Sleeping Beauty Awards)
Advantage Health Center, LLC (Site#226)
Donald Tice, DO/Samantha Edwards

Upcoming issues will have articles spotlighting these sites!

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Keep up the great work! “It’s that simple and that important…”

DCC (Data Coordinating Center) Corner

The TM system is being upgraded to incorporate new edit checks and other enhancements to the system. Changes will be implemented during November and December, 2004. Check the Tactnih.com website regularly for updates.

Important clarification of iCRF instructions:
PCI = Balloon angioplasty, atherectomy, stent, or any transcatheter attempt to open a coronary stenosis or occlusion. Unsuccessful PCI is still PCI, so it should be reported. Do not enter a diagnostic cath as a PCI unless there is an intervention as described above.

Study Coordinators!
Clear your TrialMaster® Task List of all ACTION queries at least weekly.

Source Document Label Clarification
The source document labels included in your TACT Starter Kit are to be adhered to source documents submitted to DCRI. Place the sticker over the patient information on the source document to help de-identify these documents. The supply is limited so please do not use these for any other purpose, e.g. labeling all of your other source documents that do not need to be submitted.

Use source document labels only for documents that are submitted to DCRI

TACT Newsletter Continued – page 2

Timely delivery of infusions:
To ensure delivery of infusions for patient visits for the upcoming week please schedule all patient visits in TrialMaster™ system by 5pm EST on Friday of the prior week. Scheduling patients after this deadline require verbal approval directly from Dr. Kayvan Amini the Clinical Trial Manager by calling (305) 674-2049.

Site Payments for Patient Randomization:
Sites receive payments for each patient randomized within three (3) to four (4) weeks, from date of patient randomization. Delays can result if EQOL questionnaire for each randomized patient is incomplete and/or the Memorandum of Agreement is not in proper order.

ALL THINGS BEING EQOL…

The completion and entry of the Baseline Quality of Life forms into TrialMaster are excellent! Thank you for your superb efforts.

Tips to Site Coordinators to avoid calls from Diane or Jason at EQOL DCRI….

• Remember it is protocol to administer the Baseline QOL form as close to the baseline labs and randomization as possible (prior to treatment assignment). If there are extenuating circumstances that need to be discussed, please call Diane or Jason.
• Be sure to complete the Confidential Patient Information form in its entirety at enrollment and update it in follow-up.
• Obtain all patient contact information, especially of a family member or friend who has a residence and phone number(s) different from the patient.
• Facilitate the EQOL phone (919-668-8221 or 919-668-8640) follow-ups by emphasizing…
  o the importance of understanding QOL for patients treated with chelation;
  o the opportunity the patient has to help the research effort by answering questions when the Duke Clinical Research Institute calls (at 6, 12 and 24 months after randomization)—only 3 calls over 2 years! It’s critical we follow both easy and difficult pts.

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MAXIMIZING RETENTION OF TACT PATIENTS

NOTE: This assumes the patient was informed of the necessary commitment to the trial and that careful review and explanation of the consent form occurred before enrollment.

(Prepared by EQOL Outcomes)

<table>
<thead>
<tr>
<th>C</th>
<th>CONFER WITH PATIENT</th>
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<tbody>
<tr>
<td>O</td>
<td>OBSERVE AND LISTEN</td>
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<tr>
<td>N</td>
<td>NEGOTIATE OPTIONS</td>
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<td>Q</td>
<td>QUESTION TO CONNECT</td>
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<td>U</td>
<td>UNDERSTAND “REFUSALS”</td>
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<tr>
<td>E</td>
<td>EMPATHIZE CONCERNS</td>
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<tr>
<td>R</td>
<td>REASSESS &amp; SUMMARIZE</td>
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What are the issues behind the patient’s wish to “refuse”/discontinue? Listen closely to your patients, as they often give clues for being upset that are hidden and not explicit.

Offer suggestions to address concerns, for example, schedule return visits at times convenient for the patient, or, if there are billing problems, offer to contact the patient accounts department. Make sure to update follow-up contact information at every visit.

Get to know your patients, their families and physicians; involve your site investigator with the discussions. Give them your business card so they know how to call you if hospitalized, etc.

“Refusals” are a challenge to be conquered rather than an “easy out” for the patients. Their follow–up is valuable and critical whether their outcome is positive or negative. Point out that the power to analyze the effectiveness of chelation in TACT is reduced by each patient who withdraws consent.

Acknowledge patients’ concerns or fears. Work with them to alleviate potential “refusal” situations.

Has the patient been “converted” to continue in TACT?, or will the patient discontinue: infusions? vitamins? post infusion follow-up? or completely withdraw consent? Please call the Clinical Coordinating Center to discuss any of these issues.