



Highlights from the February 2006 TACT Investigator Meeting

97 Sites were represented at the 4th TACT Investigator Meeting, February 10-11 in Miami, with 69 Investigators and 96 Coordinators participating.

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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)

FRIDAY SESSIONS

On Friday, study coordinators were divided into 4 groups that were comprised of new and old sites, high and low enrollers, chelation and academic sites. Each group was color coded. The groups stayed together for all of the Friday sessions. The sessions were as follows:

- How to Recruit and Enroll TACT Patients
- How to Manage Patients
- How to Ensure Patient Safety
- How to Retain and Follow Patients



TACT JEOPARDY



The TACT Jeopardy game premiered after dinner on Friday. The four teams competed to collect the most money. The game was comprised of 6 categories with nine questions. Unlike the Jeopardy game on TV, The TACT Dollars beheld the faces of Drs. Lamas and Lee.

Winning team: "The Yellow Sunsets"

- | | |
|-----------------------------------|-----------------------|
| Amanda Valeria site 102 | Charles Adams 262 |
| Betty Anne Persico 107 | Jackie Miles 262 |
| Debbie Truin 124 | Deborah Begnaud 263 |
| Nella Hamtil 128 | Karen Dantin 263 |
| Barb Casella 132 | Mitesh Matkar 277 |
| Sue Chipps 150 | Lorraine Christy 329 |
| Carol Strang 150 | Brenda Rowe 331 |
| Kaylynn LeBlanc 217 (team leader) | Samer Kurait 333 |
| Terry Murphy 234 | Zbigniew Grudzien 402 |
| Krista Fallin 237 | |

SATURDAY SESSIONS

For Investigators and Coordinators

- Study Status: Where Should We Be?
- Data Safety Monitoring Board's Comments and Recommendations
- Focus on Patient Recruitment: Available Resources and Study Wide Efforts
- Focus on Patient Recruitment: Conventional and Out-of-the Box Ideas
- Focus on Patient Retention: Impact on Overall Study
- Focus on Patient Retention: Accounts of Successful Patient Retention
- Focus on Medication Compliance
- Focus on Patient Safety



TrialMaster EDC Refresher and Advanced Training was also provided for all sites on Friday. New TrialMaster users practiced case study data entry in a computer lab staffed by DCRI on Saturday.



Sites Recognized for Significant Achievements

Site #	PI	SC
Superlative Medical Compliance		
108	Raymond Magorien, MD	Ovidu Adam
110	Pamela Ouyang, MD	Jeanne Wingo
208	Wade Aude, MD	Paige Barton
242	Miguel Trevino, MD	Kimberly Mai
Excellent Data Quality		
113	Russel Silverman, MD	Sherri Loucks
132	Ralph Miranda, MD	Barb Casella
212	Joseph O'Bryan, MD	
331	Timothy Logeman, MD	Brenda Rowe
Outstanding Patient Recruitment		
234	Rajiv Chandra, MD	Terry Murphy
220	Ted Rozema, MD	Dolly Corbin
227	Sangeeta Shah, MD	Lisa Boudreaux
239	Randy Hartman, MD	Lynn King
Exceptional Patient Retention		
131	Terry Chappell	Marcia Arnold
262	Charles Adams	Jackie Miles
310	Donald Riemer	Laura Sembach
255	John T Sullebarger	Marcie Terrana, Sally Robins
Honorable Mention		
407	Nampalli K. Vijay	Melinda Washam
416	William David Voss	Lorna Gordon
140	James Garofalo	Kathleen O'Neill
205	Lisa Merritt	Tunesia Lyons
208	Wade Aude	Paige Barton, Sharon Shuler
121	Charles Dennis	
129	Ronald Tatelbaum	Susan Rimmey
331	Timothy Logeman, MD	Brenda Rowe
Little Bo Peep		
217 and 228	KayLynn LeBlanc, SC for site 217 in Mandeville, LA and was the SC for site 228 in Metairie—after hurricane Katrina, KayLynn found 6 patients who had been lost to contact as a result of the storm.	

TAKE HOME POINTS

- ▶ Richard Nahin, PhD (NCCAM Project Officer) informed the group that the study may be stopped if we do not reach the quarterly recruitment milestones. Goal: 915 patients by the end of March 2006.
- ▶ Recruitment is likely to be extended through March 2008, with a goal of 1950 patients.
- ▶ A physician must be present during all patient infusions, or no more than 10 minutes away from the TACT site.
- ▶ During follow-up phase, after the study infusions, patients must not start open-label chelation therapy at the TACT site or at any other site.
- ▶ Offering free infusions after the end of the study as an inducement to recruitment is not recommended.
- ▶ Patients need to take high-dose vitamins/placebo after their final infusion until follow-up is completed (5 years after enrollment or in July 2009).
- ▶ Patients must not receive open-label chelation during their participation in TACT. (5 years after enrollment or in July 2009).
- ▶ All recruitment ads or changes to ad templates require Mt. Sinai and IRB approval.
- ▶ Study-wide safety alerts for SAEs at any site need to be submitted to Sterling IRB or their local IRB.
- ▶ Patients reported as “withdrawn consent” should be very rare. Encourage patients to receive telephone follow-up even if they have prematurely discontinued infusions and/or vitamins.
- ▶ Patients discontinuing infusions and/or vitamins early will be analyzed with the group (placebo or active) to which they were assigned according to the “intent to treat” principle. Make every effort to continue all treatments according to protocol, optimizing the ability to discern between the groups as the results are analyzed.
- ▶ TACT Infusions must be run for at least 3 hours, and 4-5 hours if calcium is low or glucose is high.
- ▶ Never share Trial Master passwords.
- ▶ TACT remains a unique trial, as important today as when it was conceived, but if we do not enroll, we will be terminated.