



TACT TIPS

Helpful Operational Hints
for TACT Coordinators

December 2005

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CONTACTS

Clinical Coordinating Center

Mount Sinai Medical Center
Email: ccadmin@tactnih.com
Fax: (305) 674-2146

Gervasio A. Lamas, MD, Principal Investigator

Voice: (305) 674-2162
Email: TACTNIH@aol.com

Jacqueline Arciniega, MPH, Project Director

Voice: (305) 674-3948
Email: jarcinie@msmc.com

Pablo Guala, MD, Clinical Trial Manager

Voice: (305) 674-2049
Email: pguala@msmc.com

Tristan Edwards, BS, Research Assistant

Voice: (305) 674-2703
Email: tedwards@msmc.com

Stephanie Escalante, Administrative Assistant

Voice: (305) 674-2794
Email: sescalane@msmc.com

Data Coordinating Center

Duke Clinical Research Institute
Cresha Cianciolo, RN, Regional Coordinator
Voice: (919) 668-8973

Email: cianc001@dcric.duke.edu

Mary Nahm, RN, MSN, Regional Coordinator

Voice: (919) 668-8808
Email: nahm0002@dcric.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

Jason Blevins, Sr. Research Assistant/Analyst

Voice: (919) 668-8640

Fax: (919) 668-7054

Email: jason.blevins@duke.edu

National Center for Complementary and Alternative Medicine (NIH)

Alyssa Cotler, Communications Specialist

Voice: (301) 451-3851

Fax: (301) 402-4741

Email: cotlera@mail.nih.gov

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)

Attention Study Coordinators!!

This is a view of the Patient Visit Workflow. Before you enter the date of the next infusion, MAKE SURE that the "Visit Status" column indicates **"AWAITING INFUSION VISIT SCHEDULING"** before entering the date for the next scheduled visit. If the "Visit Status" is displayed with any other status---STOP and call your Regional Coordinator! If another status is present, the system would use the previous EDTA prescription rather than updating it based on the most recent creatinine lab result.

Visit List

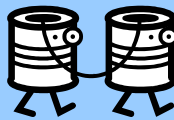
Search Again

Actions	Patient Number	Randomization Number	Visit Name	Visit Status	Schedule Status	Date Scheduled	Time Scheduled	Comment
	1079003	107-003	INF31	Awaiting Infusion Visit Scheduling	Awaiting Scheduling	[mm/dd/yyyy]	[hh:mm]	

Search Again

Submitted by Wanda Parker

ALL THINGS BEING EQOL...



The EQOL portion of the TACT Trial investigates the following question: What effect does chelation and/or vitamins have on the quality of living for the sub-randomized sample of TACT patients?

Retain Those Patients!

The message of the day is **ENROLL AND RETAIN YOUR PATIENTS!** Follow up with data is critical--missing data compromises our ability to answer our research questions. This makes your work as a site very important. Currently the withdrawal of consent rate for patients randomized to EQOL follow-up is nearly 6%, and the discontinuation rate of infusion therapy is 16%. We desperately need your help in working with patients in TACT overall as well as in EQOL to convince them how important they are to the study. Discontinuing therapy has shown itself to be a troublesome marker of withdrawing consent, of refusing telephone calls, or of pushing the window when the data are actually collected. "Converting" these patients will reduce our need to request your assistance when the patients return to clinic, and/or will permit measurement and comparison of the patients' QOL "snapshot" with their clinical "snapshot".




Keep in contact with your patients about changes in their contact information and listen for any early "red flags" that you might be able to convert before they become deleterious. Routinely ask them about upcoming vacations or plans to move. Update the Patient Contact Information form and fill in any missing information not obtained during screening. It is important to get information on family, neighbors or friends who can be contacted if you're unable to reach the patient.

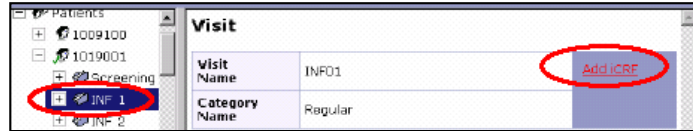
If you get "stuck", please contact Diane Minshall-Liu: 919-668-8221; dianem.liu@duke.edu

Submitted by Diane Minshall-Liu



Helpful hints on Adding Adverse Events

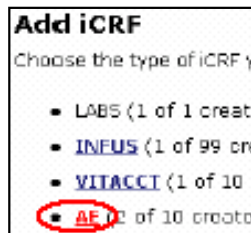
-  How to add an AE iCRF page
-  How to select or change an AE term
-  How to add your own AE term with free text



How to add an AE iCRF page

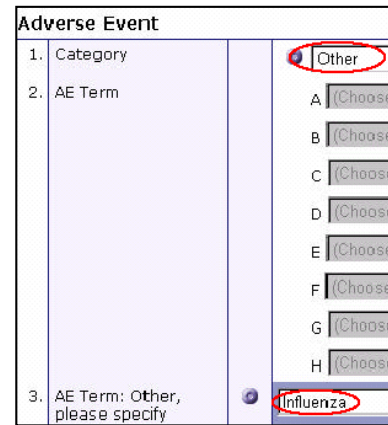
1. Click on the appropriate infusion folder. This brings you to a page titled "Visit". Once on the "Visit" page, click "Add iCRF".

2. When the "Add iCRF" page has loaded, click on "AE"

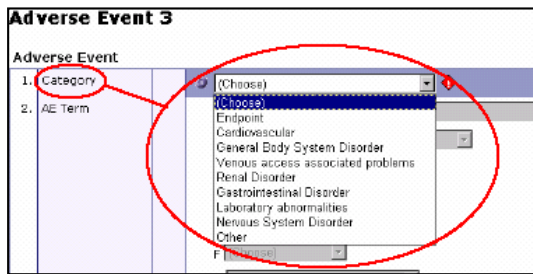


How to add your own AE term

If the most appropriate AE term is not present among the 88 pre-selected terms found in the 8 sorted categories, enter your own term by typing free text.

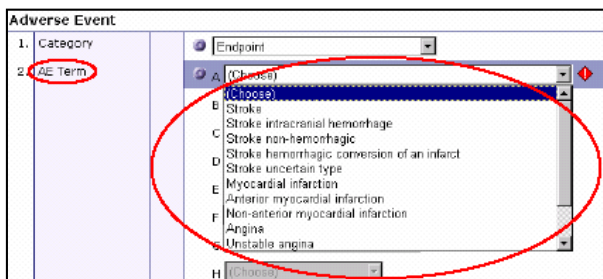


How to select or change an AE Term



1. First, you must choose a category. Select 1 of the 8 categories in the drop-down box.

2. Once a category is selected, only one pre-sorted list of AE Terms will become an active drop-down box. All other AE term lists are inactive, or "grayed out". Pre-sorted AE term lists are categorized A through H.



3. If the appropriate AE term is present, select it from the list. If the appropriate AE term is not present in the current list, select another category. Once a new category is selected, this will activate a different drop-down box.

To enter your own AE term, first select the category of "Other". Once the "Other" category is chosen, type the AE term in the field identified with the field identified as number 3, "AE Term: Other, please specify".

Reminders

- Always use a final medical diagnosis for the adverse event term. This is especially important if you identify your adverse event as serious
- DCRI Safety Surveillance is available to answer any questions, along with providing assistance to report deaths or other serious events.

Phone: 919-668-8624, Toll Free Phone: 866-668-7799
 Fax: 919-668-7138, Toll Free Fax: 866-668-713
 Email: safetysurveillance@dcri.duke.edu

Instructions for online TACT Initial Site Training / New Site Staff Training

TACT now offers on-line training for new sites entering the trial and all new investigators and coordinators joining an existing TACT site. The on-line training is available at your convenience. **On-line training must be completed within 2 weeks of your site activation and/or assignment of new personnel.** The appropriate documentation for completing the training must be submitted to the Clinical Coordinating Center as indicated below. If you have any questions please contact our Research Assistant, Tristan Edwards at (305) 674-2703 or at tedwards@msmc.com.

1. Log into TACT’s official website at: www.tactnih.com (username: infusion and password: tactnih).
2. Click on link entitled “TACT Study Materials.”
3. Click on link entitled “TACT Site Training and Refresher Courses.”
4. You will be directed to <http://www.realcastproductions.com/sinai> and asked to enter your site number, first name, last name and email address. *If you are viewing with more than one person, only enter one person’s contact information. You will have an opportunity to indicate others who view the session with you later.*
5. When you login, a table of contents listing the presentations will be displayed.
6. You are required to view the following presentations in their entirety:

Speaker	Subject
Gervasio A. Lamas, MD	TACT Principal Investigator – Study Overview
Kerry Lee, PhD.	TACT Statistical Considerations
Richard Nahin, MPH, PhD	Overview of CAM and the Mandate of NCCAM
Christine Goertz, DC, PhD	TACT Investigators’ and Coordinators’ Meeting
Lindsay Lambe	DCC and TACT
Wanda Parker, RN, MSN	Getting Started With TACT part 1
	Getting Started With TACT part 2 (slides only)
Jamie L. Gault, RAC	Good Clinical Practice and HIPAA Considerations
Lindsay Lambe	Clinical Endpoints & TACT Part I
Erin J. Cloherty	Clinical Endpoints & TACT Part II
Nancy Clapp-Channing, MPH	Economics and Quality of Life in TACT
Allan Magaziner, DC	Indications for and Contraindications to EDTA Chelation Therapy
Steven Hussein, MD	Evidence-based Concurrent Care

7. When viewing has been completed, download and complete the “Certificate of Completion”. Indicate others who viewed the presentation by name, role in the study, signature and date. FAX a copy to Tristan in the CCC at (305) 674-2146 and place original in the site regulatory binder “training” section.
8. All site personnel that view any of the above presentations should be documented on the “Certificate of Completion”. FAX the updated copy to the CCC.

Submitted by Jacqueline Arciniega



Essential Documents for Conducting a Clinical Trial (Regulatory Binder)

- ✚ 150 patients have completed infusion 40
- ✚ Over 33,807 iCRFs have been monitored
- ✚ 19,654 infusions have been completed



Essential documents are those *that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced* (ICH Guidelines 8.1, 2005). These documents are also usually audited by an inspector with regulatory authority to affirm the validity of a trial. All required documents should be in the appropriate section of the binder, in date order, and current. **Outdated or revised documents should be kept to indicate renewal and any changes.** When TACT is ready for close-out, a review of these essential documents will take place.

The site investigator ensures the up-keep of the site’s regulatory binder. The site investigator may delegate this task to trial personnel (noted on the Site Signature and Responsibility Log).

Submitted by Wanda Parker

SOURCE DOCUMENT ADVICE COLUMN


This is the first in a series of articles about TACT Source Documents

Part I: A General Source Document Question from a TACT Site


Dear DCRI,
During my last monitoring visit, I was told that I had missing source documents. What exactly does this mean?

This is an excellent question. If you are a new coordinator and still learning all of the jargon specific to clinical research, it is not always clear what source documentation really means. To answer your question about regarding missing sources, this means that data entered into Trial Master® could not be verified against the participant's original data. When a monitor is on-site, iCRF pages are reviewed and then compared to where the participant data was originally captured such as clinic notes, TACT visit worksheets, lab results...etc. It is an FDA requirement to maintain adequate and accurate case histories that support the iCRFs.*


Here is an example of how original data is documented at a TACT infusion visit and then entered into TrialMaster®.



Prior to the patient's arrival, the study coordinator pulls a blank Infusion Visit Worksheet from the TACT Study Manual. Using the source document worksheet and completing all fields ensures that the appropriate protocol assessments are completed and allows for easier data entry into Trial Master®.



During the participant's visit, the study coordinator performs the appropriate visit procedures, records data required by the protocol, and documents all observations. Any observations not recorded on the Infusion Visit Worksheet can be recorded in a progress note.



After the visit is complete, the study coordinator logs into TrialMaster® and enters data into each field on the iCRF page **exactly** as it appears on the source document (i.e. Infusion Visit Worksheet, clinic notes, lab results). Double-check all entries to prevent transcription errors.

Remember: To have complete source documents every piece of data entered into TrialMaster® must first be documented.

*The reference for maintaining case histories can be found in the Code of Federal Regulations: (21CFR 312.62 Investigator recordkeeping and record retention, (b) Case histories)

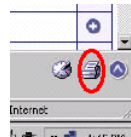
“An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurse's notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.”

Part II: Specific Question about Source Documents in TACT


Dear DCRI,
I need help with source documentation for the Concomitant Medication iCRF page. What do you suggest?

The easiest way to document the assessment of concomitant medications (commonly referred to as “conmeds”) is to create a tool so you can quickly review/document what the patient is taking at Baseline, Infusion 15, Infusion 30, Infusion 36, and Infusion 40. **See steps 1 through 3 below regarding how you can create your own tool.**

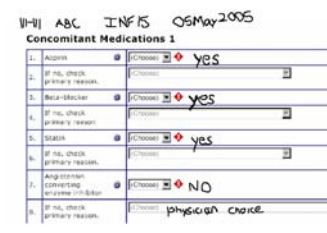
Once you have created copies of your new conmed assessment tool, don't forget to complete this assessment at the appropriate visits. If you prepare paperwork for TACT study visits prior to your patient's arrival, attach the conmed assessment tool to your Infusion Visit worksheet as a reminder. You also want to remind patients to bring their medication bottles to these visits for your review.



Step 1: Print a blank Concomitant Medications iCRF page from TrialMaster. *The easiest way to print in TrialMaster® is to click the printer icon located in the lower right hand corner of the screen.*



Step 2: Make copies so a blank tool is always available. Prior to making copies, make sure no patient numbers remain on printed page from TrialMaster® Write the words “TACT Source Document” in the header.



Step 3: Use this template during Baseline, Infusion 15, Infusion 30, Infusion 36, and Infusion 40 to document your conmed assessment. This is now your source document to use when entering data into the iCRF.

Please note that you are not required to use this tool for assessment of concomitant medications. If your site already has a medication list created, or you prefer to document the conmeds in a progress note, this is fine.

Look for more tips and guidance in upcoming issues of the *TACT Operations Bulletin*. If you have questions or general comments about source documents in TACT, contact Wanda Parker at the DCRI. Phone: 919-668-8589 Email: wanda.parker@duke.edu

Submitted by Rebecca DeWire and Anthony Wilson