



May 4, 2005

Subject: Patient Safety and Clinical Management

Dear TACT Sites:

Attached is a worksheet that must be implemented immediately for documenting the weight of TACT patients prior to each infusion. Print a copy for each patient, record the patient's weight at each visit (prior to the infusion) and file in the patient's study chart.

If a patient gains 3 lbs or more between visits, OR 5 lbs or more from the baseline weight, you should contact the CCC (305-674-2049) before proceeding with the infusion.

We appreciate your cooperation in implementing this safety change prior to the upcoming automated changes within TrialMaster®.

Dr. Kayvan Amini
TACT Clinical Trial Manager
Cardiovascular Research
Mount Sinai Medical Center
305-674-2049

TACT Subject Number: _____ - 9 _____

Baseline weight: _____ lb

| Infusion Visit | Date | Weight | Is weight gain \geq 3 lbs since last visit or \geq 5 lbs since baseline? |
|----------------|---------------|--------|--|
| 1 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 2 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 3 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 4 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 5 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 6 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 7 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 8 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 9 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 10 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 11 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 12 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 13 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 14 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 15 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 16 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 17 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 18 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 19 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 20 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |

* If Yes, contact the Clinical Manager at 305-674-2049 BEFORE administering the infusion.

TACT Subject Number: _____ - 9 _____

Baseline weight: _____ lb

| Infusion Visit | Date | Weight | Is weight gain \geq 3 lbs since last visit or \geq 5 lbs since baseline? |
|----------------|---------------|--------|--|
| 21 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 22 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 23 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 24 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 25 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 26 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 27 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 28 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 29 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 30 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 31 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 32 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 33 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 34 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 35 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 36 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 37 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 38 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 39 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |
| 40 | ___/___/_____ | lb | <input type="checkbox"/> No <input type="checkbox"/> Yes* |

* If Yes, contact the Clinical Manager at 305-674-2049 BEFORE administering the infusion.