



TO: TACT Site Investigators and Coordinators
FROM: Data Coordinating Center (DCRI)
DATE: June 7, 2005

This notice is to advise you of three (3) data reports now available within TrialMaster® using the *REPORT TAB on the Home Page*. These reports may be used to support you in your management of patient visit data. A brief description of each report is below. **More detailed information on how to use the Patient and Site Reports will be made available at a later. This optional training will be through WebEx. If you have questions, please call your Regional Clinical Coordinator.**

Report Name	Purpose	How can this report help with your work?
Patient Clinical Evaluation Report <i>(Usage Required)</i>	To provide a summary of your patient weights and renal function to help with clinical management of the patients during the infusion phase.	<ol style="list-style-type: none"> 1. Weight gain ≥ 3 lbs comparison between last two infusion visits 2. Weight gain ≥ 5 lbs since baseline 3. Site Investigator support in assessing the patient's clinical status for signs and symptoms of: new heart failure and/or fluid retention in existing heart failure 4. Use with the Patient Weight Log
Patient Report <i>(Usage Optional, at this time)</i>	To provide an overview of data entered and the iCRF status (<i>Incomplete, Complete, Signed and Monitored</i>) by patient.	<ol style="list-style-type: none"> 1. Allow you to determine a patient's iCRF progression 2. Assess what data is needed to complete the iCRF to reach <i>Signed</i> status
Site Report <i>(Usage Optional, at this time)</i>	To provide an overview of all the patients enrolled at the site, data entered, iCRF and Query status	<ol style="list-style-type: none"> 1. Assess your progress with entering and cleaning data for: <ul style="list-style-type: none"> • each patient • the entire study 2. Determine what needs to be done and where you need to put your efforts. 3. At the end of the study your site data will be complete when the totals indicate : <ul style="list-style-type: none"> • Screening - % of Screening data signed = 100% there are no action queries for site (only zeros under "S") • Infusion - every patient has completed 40 Infusions (unless discontinued or withdrawn) % of Infusion data signed = 100% there are no action queries for site (only zeros under "S") • Follow-up - % of Follow-up data signed = 100% there are no action queries for site (only zeros under "S") • Patient Clean = "Yes" for every patient; indicating all data is entered, signed and all queries closed