Volume 3, Chapter 9

Clinical Management Committee Chapter

Administrative Manual Volume 3, Chapter 9
Clinical Management Committee Chapter

Charge:

1. To ensure consistency of treatment regimens across Centers, the CMC will review and monitor:
   a. All clinical procedures described in protocol and Manual of Operations
   b. All dietary prescriptions described in protocol of Manual of Operations

   And will assist Clinical Centers in interpreting and implementing them.
2. The CMC will review and monitor:
   a. All intercurrent illnesses and adverse clinical events or outcomes including deaths
   b. All patients who reached Clinical Management "Safety Variables"
   c. All patients who reached stop points
   d. Any patients who are lost to follow-up
   e. All new problems related to patient safety
3. To ensure maintenance of patient safety, the CMC may:
   a. recommend modifications in clinical management procedures
   b. refer cases via the Study Chairman to the External Monitoring Committee (EMC) for additional evaluation.
4. The CMC will consider and approve:
   a. all drugs to implement the protocol; and especially to ensure that FDA requirements are met pertaining to IND-controlled drugs used in the study.
   b. add devices used to implement the protocol.

Charge No.	Input* From	Process	Output To
1	Queries in writing from DCC, NCC, EKG lab, GFR lab other study committees,	Written communications sent to CMC Chairman and logged in. Items logged out to one or more CMC members for processing; assign deadline. Items returned to Chairman logged in. Processed items reviewed by Chairman and, as appropriate, during CMC conference call or meeting. Items with CMC decision/recommendation logged out.	Appropriate format and means of communications; to originating source, and/or appropriate offices/committees for action, information, coordination.
2	Data files on each instance, from DCC. Telephone notifications of stop points from Clinical Center Principal Investigators.	As in Charge 1.	Reports forms recommendations to DCC, Operations committee, EMC via the Study Chairman as requested.
3	Queries, data files as in Charges 1 &2. As in Charge 1, listings of FDA controls and requirements and documentation reports from IND Investigators.	As in Charge 1 Review with recommendations approval at CMC meeting.	As in Charge 2

*Every 3 months for items deemed urgent by the originator.

Details:

Clinical Management Committee Safety Variables currently include the following:

Weight Loss Protocol Action Item #2

Persistent High Blood Pressure Action Item #6

Persistent Symptoms of Low Blood Pressure Action Item #8

Declining Albumin Protocol Action Item #9

Low Albumin Protocol Action Item #10

Declining Transferrin Protocol Action Item #11

High Serum Potassium Action Item #21 if patient is on ACE

Hospitalization (as determined by the committee chairperson)

Dialysis after a stop point

Transplant after a stop point

Future Safety Variables are likely to include two anthropometry values (1. Arm muscle area and 2. Percent body fat) and three amino acid values (1. sum of valine, leucine and isoleucine; 2. Essential to non-essential ratio; and 3. Methionine).

Data files from the DCC will include the following:

1) Key variables from the Demographic Form 4
2) The Biochemistry Flow Sheet (which includes blood pressure and edema data)
3) The Amino Acid Reports
4) Key variables from the "Unscheduled Medical Attention/Hospitalization Form 10"
5) Key variables from the Action Item Response Form 23 (for the first safety variables which are Protocol Action Items)
6) The following data from analyses of diet diaries:
   - Potassium from food
   - Potassium from supplements
   - Calories
   - Calories per kg standard body weight
   - Protein from food
   - Sodium from food
7) The Anthropometry Flow Sheet