

## **Change in CTSU Data Submission and Query Distribution Procedures Effective March 5, 2007**

Starting March 5, 2007, data submission and query/delinquency distribution procedures for a majority of CTSU menu trials (all trials except NCIC MA.27 and B.19, ECOG PACCT-1, NCCTG N0147, and ACOSOG Z1031 and Z4032) will change. Instead of sending data (i.e., CRFs) to CTSU Data Operations, sites will send data directly to the Cooperative Group leading each trial. In general, query and delinquency notices will come directly from the lead group, and sites will send their responses back to the lead group.

### **Regulatory Materials**

This does not change where you send your regulatory materials. Continue to send regulatory materials to the CTSU Central Regulatory Office in Philadelphia – except for the following studies SELECT (**S0000**) and any of the SELECT ancillary studies (**S0000A**, **S0000B** and **S0000C**), PCPT Long Term Follow-up (**S0437**), **S9808**, and **S0316**. For these studies, please submit your regulatory materials directly to the Operations Office by FAX at 210/677-0006.

### **Registration**

This does not change the registration process. If you are using the CTSU mechanism (i.e., are not a member of the Group leading a particular trial) continue to enroll patients onto CTSU trials via the CTSU Registrar Office.

### **Data submission**

Data submission procedures will depend on the Lead Group's data management system and preferences. As always, refer to each protocol document and CTSU appendix for instructions and addresses/fax numbers.

### **Queries**

In general, all query and delinquency notices will come to you directly from the Group leading each trial.

### **Protocols**

The CTSU has been working with the Groups to revise the CTSU appendices and bring them in line with these new procedures. In some cases, the amendments have already been approved and are posted on the CTSU web site. In the majority of cases, the amended protocols will not be approved or posted until after March 5, 2007 (the Groups have a grace period of four months following the March 5 transition date to complete the amendments). Regardless, please understand that the new procedures will commence on March 5, 2007, even if all protocol documents have not yet been updated.

For a limited period of time, while sites are adjusting to the new data submission procedures, the CTSU will forward all data and query responses that it receives after March 5 on to the Lead Group.

### **How do I submit data for the trials that are listed as exceptions above (NCIC MA.27 and B.19, ECOG PACCT-1, NCCTG N0147, and ACOSOG Z1031 and Z4032)?**

These trials are being conducted under the Comprehensive Service level of CTSU data management support. You should continue to send all data for these studies in the usual manner, as defined in the CTSU appendix of the protocol documents.

### **For more information**

Please see the CTSU Members' web site home page for more information, including a list of affected studies and a slide show on the transition. Also, feel free to contact the CTSU Help Desk (888-823-5923, [CTSUContakt@westat.com](mailto:CTSUContakt@westat.com)) with any questions. NOTE: At this time, please continue to submit data on your CTSU studies as always, this change does not go into effect until March 5, 2007.