

PREMIER Clinical Manual of Procedures

3.	TRIAL COMMUNICATIONS	3
	Importance of Trialwide Communications _____	3
	Principles of PREMIER Communications _____	3
	Electronic Communications _____	3
	Direct Delivery of Urgent Items _____	3
	Central Contact Person for Non-Urgent Items _____	4
	Rapid Turnaround of Minutes _____	4
	Rapid Turnaround of Queries _____	4
	Elements of Communications Network _____	4
	Internal Web Site _____	4
	National Recruitment Website _____	4
	Fax and Mail Delivery _____	5
	Site Computer Workstations _____	5
	Selection of Communication Method _____	5

PREMIER Clinical Manual of Procedures

Summary of Edits

New Changes in Version 1.1

- Added description of national recruitment website.

PREMIER Clinical Manual of Procedures

3. Trial Communications

Importance of Trialwide Communications

Maintaining lines of good communication is important to the successful operation of a long-term collaborative clinical trial. During the course of the PREMIER study the coordinating center will be responsible for the following tasks that depend heavily on effective communication channels and skills:

1. Arranging orientation and initial training of clinical center personnel
2. Monitoring project adherence
3. Reporting to the Project Office, committees, and DSMB
4. Responding to clinical center and Project Office requests,
5. Staffing trial committees, including logistic arrangements and distribution of meeting minutes

The tools of communications for PREMIER include: regular meetings of the Steering Committee and its subcommittees, conference calls, website and site workstation posting of study documents, e-mail, sequential memos, telephone calls, data edit reports, and routine trial monitoring reports.

This section summarizes the principles for PREMIER communications and describes the procedures for sending communications between participating institutions.

Principles of PREMIER Communications

Electronic Communications

A key component of the PREMIER communications protocol is that wherever possible, documents will be delivered electronically. The coordinating center will use e-mail and the PREMIER web site as the preferred delivery method for all study materials.

Direct Delivery of Urgent Items

Urgent communications (faxes and express mail) are normally sent directly to the recipient, rather than the contact person, to avoid any delays in delivery. However, if a staff member is out of town, the contact person is responsible for ensuring that their mail and incoming faxes are checked and re-routed if necessary.

E-mail messages are also normally sent directly to the addressee, rather than to the contact person. If the message requires urgent follow up, then the sender should copy the contact person so that the message will be handled even if the recipient is out of town or unable to check their e-mail. Some project staff do not have reliable e-mail access, so urgent information will be sent to them via fax or express mail.

PREMIER Clinical Manual of Procedures

Central Contact Person for Non-Urgent Items

For non-urgent documents and materials, each participating institution identifies a single person who serves as the contact person for that site. PREMIER communications directed to several people at a site should be sent to the contact person, who is then responsible for forwarding copies of the document as appropriate. In the event that this individual is not available, backup coverage is arranged at the clinical site so that someone else checks for incoming correspondence on a daily basis.

Rapid Turnaround of Minutes

Especially during the initial planning stages of a trial, the work of the trial is done by committees who meet to design the trial and work out the various procedures. For this process to proceed smoothly, it is critical that accurate minutes of committee meetings be taken and that they be distributed in a timely manner. The coordinating center takes notes during all PREMIER committee meetings and conference calls. If a non-coordinating center person takes minutes for a meeting, it is their responsibility to forward the minutes to the coordinating center secretary. Meeting minutes are posted weekly on the PREMIER website.

Rapid Turnaround of Queries

All participating institutions in the trial shall make every effort to promptly respond to queries. Phone messages, e-mail messages, or written queries should be answered within a maximum of five working days.

Elements of Communications Network

The coordinating center uses a variety of tools to facilitate study communications.

Internal Web Site

The coordinating center will use the PREMIER web site as the primary study communications tool. This allows maximum access to all study materials by all project staff, regardless of geographic location. While most of the documents on the site originate with the coordinating center, committee chairs can also submit documents to be posted on the web site. The web site is secured so that only project staff will have access.

National Recruitment Website

The coordinating center also maintains a website that is accessible to potential enrollees. It will convey general information about the study, including contact numbers for recruitment at each site.

PREMIER Clinical Manual of Procedures

Fax and Mail Delivery

For informal communications, and all documents that can not be posted to the web site, the coordinating center and sites use a combination of fax, e-mail, express mail, and regular mail to send written study communications and materials.

Site Computer Workstations

After the study is underway, an additional communications tool will be available. Each of the clinical centers will have a computer workstation on site as part of the PREMIER data management system. The workstation transmits study data to the coordinating center, and receives electronic copies of MOP chapters, forms, the protocol, and staff directories from the coordinating center. The clinical centers will also have a printer for their workstation, so that they can print master copies of these study documents in a consistent manner.

Selection of Communication Method

The coordinating center maintains a detailed document, the “Communications Flowsheet,” that describes which methods should be used for each type of communication. This ensures consistent, reliable, and efficient communications with all project staff.

The appropriate communication method is selected based on the information to be communicated, its format, the urgency of the message, the amount of information to be sent, and the location of the recipient.

The following table is a summarized version of the Communications Flowsheet:

Communication Method	When To Use
E-mail*	Informal communications, notifications of web postings, notifications of revisions to study documents on web/workstations
Phone	Informal communications
Web Site*	Minutes; packets of materials for committees to review; draft and final MOP chapters, forms, protocol; staff directory; conference call schedule; analysis guide; paper proposal and manuscript review materials/ballots
Fax	Short memos, short trial monitoring reports
Express Mail	Long memos, long trial monitoring reports, urgent supplies/materials, urgent bound reports/documents.
US Mail	Non-urgent supplies/materials, non-urgent bound reports/documents
Site Workstation Posting	Final MOP chapters, forms, protocol; staff directory

**Note: express mail or fax delivery may be used in cases of e-mail failure, or inability to access the web site.*