Title: Study Initiation Meeting

Document ID:	CP-CTNet SOP 01-02
Version:	1.0
Version Date:	August 05, 2020
Document Distribution:	Distribution of this document to persons or organizations outside of CP-CTNet without consent is strictly prohibited.

REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
1.0	AUG-17-2020	Original version of document

1. INTRODUCTION AND PURPOSE

It is the Lead Academic Organization's responsibility to conduct the study initiation meeting. The purpose of the study initiation meeting is to meet with DCP staff, and with key staff from each Affiliated Organization (AO) who will be conducting the study and:

1. Provide an orientation to the study and review study-specific details, such as the procedures for investigational agent management, reporting requirements, and data and specimen management;
2. Confirm all roles and responsibilities, and performance expectations;
3. Confirm staff have received the required systems (e.g., Medidata RAVE, enrollment) training confirmations from the Data Management, Auditing and Coordinating Center (DMACC);
4. Confirm that all regulatory requirements are complete for the AO(s);
5. Ensure that the AO(s) is/are ready to begin enrollment.

2. SCOPE

This document details the responsibilities of the LAO Investigators, Site Coordinators, and designees regarding the Study Initiation Meeting.

3. ROLES AND RESPONSIBILITIES OF LEAD ACADEMIC ORGANIZATIONS

1. The Lead Academic Organization (LAO) Investigator, Site Coordinator, and/or their designee(s) are responsible for conducting the study initiation meeting for each study.
2. Key staff members from the LAO and each AO are responsible for attending the study initiation meeting before consenting or enrolling participants.

4. PROCEDURES

The LAO Investigator, Site Coordinator, and/or their designees will:

1. Schedule the study initiation meeting:
   - 1.1. The meeting is typically scheduled after:
     - DCP issues a "Notice of Study Approved on Hold" letter to the LAO; and
     - The NCI Central Institutional Review Board (CIRB) has approved the protocol.
   - 1.2. The meeting should be scheduled as close to the study activation date as possible.
   - 1.3. The meeting may be held at the LAO site, AO site, other location, or remotely. If held on-site, remote conferencing for participants unable to attend in person may be scheduled.
   - 1.4. The meeting is typically accomplished in one business day.
   - 1.5. Schedule a meeting date that is mutually convenient for DCP staff, the LAO staff, and key staff from each AO. Consider the following list of key staff from the LAO and/or each AO, as applicable to the study:
     - Investigator(s) and Site Coordinators
     - Study pathologist
     - Study statistician
     - Study pharmacist
     - Data management team
     - Other staff with study responsibilities
   - 1.6. The DCP Medical Monitor, DCP Scientific Lead, DCP Nurse Consultant, and other DCP representatives, including Data Management, Auditing, and Coordinating Center (DMACC) staff, may also elect to attend the meeting and should be included during the scheduling

process.
Send an email confirmation of the meeting date to all participants, including the DMACC (Audit_CP-CTNet@frontierscience.org).

1.7. Schedule a separate meeting for AO(s) that are unable to attend or are added as a new enrolling site at a later date.

2. Prepare for a study initiation meeting:
   2.1. Prepare an agenda prior to the meeting determining all relevant discussion topics and designating a facilitator for each topic. Refer to the Study Initiation Meeting Report to review the list of topics that may be applicable.
   2.2. Prepare electronic meeting materials and distribute to participants.
   2.3. Confirm with the DCP Regulatory Contractor (regulatory@ccsainc.com) that all or most regulatory documents are on file and complete for each AO, including the final study approval letter from the Protocol Information Office (PIO).
3. Conduct a study initiation meeting:
   3.1. Complete an attendance record to document name/institutional affiliation/study role for all meeting participants. Maintain the original attendance record in the LAO study files and provide a copy to AO staff for their records.
   3.2. During the meeting, record items that are identified as action items or that require follow up. Review the action items with the meeting participants prior to concluding the meeting.
   3.3. Complete the Study Initiation Meeting Report, including a description of action items.
      - Distribute the completed report via email to the AO(s), DCP study representative(s), and the DMACC within 15 business days of the meeting date.
      - Document the resolution of all action items prior to participant enrollment, and forward the completed action item form to the AOs, DCP study representatives, and the DMACC.

5. DOCUMENTATION REQUIREMENTS

The LAO is responsible for maintaining the following documentation related to the study initiation meeting: attendance record, meeting agenda, study initiation meeting report, and any other related communications such as resolution of action items. This documentation should be readily accessible and may be requested by DCP, the DCP Regulatory Contractor, and/or the DMACC Audit Team at any time during the duration of the study. The AOs should file the Study Initiation Meeting Report in their Investigator Site Files/Regulatory binders.

6. ADDITIONAL INFORMATION

Refer to the CP-CTNet Acronym List to see the description of commonly used acronyms in this SOP.

Please send questions and comments to Audit_CP-CTNet@frontierscience.org.

7. REFERENCES

- None

8. APPENDICES

- None