## **I. Site Information**

|  |  |
| --- | --- |
| **Site Name:** |       |
| **NCI Protocol Number:** |       |
| **NCI Protocol Title:** |       |
| **NCI Protocol Version Number and Date:** |       |
| **Meeting Date:** | Enter a date.  |
| **Meeting Modality:** | Choose one. |
| **Meeting Conducted By:** |       |

## **II. Meeting Attendees**

|  |  |  |
| --- | --- | --- |
| **Name** | **Affiliation** | **Role or Title** |
|       |       |       |
|       |       |       |
|       |       |       |
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|       |       |       |

## **III. Definitions**

| **Term** | **Definition** |
| --- | --- |
| A | Auditor |
| AO | Affiliated Organization |
| AQuIP | Accrual Quality Improvement Program |
| CCSA | CCS Associates, Inc. (DCP Regulatory Contractor) |
| CTCAE | Common Terminology Criteria for Adverse Events |
| CIRB | Central Institutional Review Board |
| CMCTAU | Co-Manager of the Clinical Trials Auditing Unit |
| CMDMRU | Co-Manager of the Data Management and Reporting Unit |
| CP-CTNet | Cancer Prevention Clinical Trials Network |
| DCP | Division of Cancer Prevention |
| DM | Data Manager |
| DMACC | Data Management, Auditing, and Coordinating Center  |
| LAO | Lead Academic Organization |
| M-SOP | Manual of Standard Operating Procedures |
| MM | Medical Monitor |
| NC | Nurse Consultant |
| NCI | National Cancer Institute |
| PI | Principal Investigator |
| PIO | Protocol Information Office |
| SAE | Serious Adverse Event |
| SL | Scientific Lead |
| SOP | Standard Operating Procedure |
| SVAR | System Variable Attribute Report |
| TS | Training Specialist |

## **IV. Study Initiation Meeting Checklist**

**Completion Instructions for the LAO:** Indicate who is responsible for presenting each topic by selecting the appropriate presenter (e.g., ***AO,* *DCP Study Staff, DMACC, LAO,*** or ***Other***). If ***Other*** is selected, indicate the presenter in the Comments. Mark each item below as: ***Yes***, item verified and/or discussed; ***No***, unable to verify and/or discuss item; or ***Not Applicable***. For any item marked ***No*** or ***Not Applicable***, please provide a comment. For items marked ***Yes***, please provide a comment whenever necessary or helpful.

### **CP-CTNet Overview**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. CP-CTNet General Overview
 | DCP Study Staff | Choose one. |       |
| 1. DCP Staff Roles/Responsibilities (NC, MM, SL)
 | DCP Study Staff | Choose one. |       |
| 1. DMACC Staff Roles/Responsibilities (PI, CMDMRU, DM, CMCTAU, A, TS)
 | DMACC | Choose one. |       |
| 1. Support Contracts (MRIGlobal, CCSA, PIO, CIRB)
 | DCP Study Staff | Choose one. |       |
| 1. AQuIP Overview (including a description of pre-screening and screening)
 | DCP Study Staff | Choose one. |       |

### **Review of Study**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. Background and Purpose of Study
 | Choose one. | Choose one. |       |
| 1. Study Objectives, Endpoints, and Design
 | Choose one. | Choose one. |       |
| 1. Clinical and Laboratory Evaluations
 | Choose one. | Choose one. |       |
| 1. Schedule of Evaluations and Study Visit Windows
 | Choose one. | Choose one. |       |

### **Enrollment**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. Informed Consent Process
 | Choose one. | Choose one. |       |
| 1. Screening/Pre-Entry Period
 | Choose one. | Choose one. |       |
| 1. Protocol Audit Risk Level
 | Choose one. | Choose one. |       |
| 1. LAO Eligibility Verification
 | Choose one. | Choose one. |       |
| 1. No Eligibility Exceptions/Waivers Allowed
 | Choose one. | Choose one. |       |
| 1. Registration/Randomization (including AQuIP data in Rave)
 | DMACC | Choose one. |       |
| 1. Stars Registration/Randomization System
 | DMACC | Choose one. |       |
| 1. Recruitment/Retention/Adherence
 | Choose one. | Choose one. |       |
| 1. Anticipated Start of Enrollment
 | Choose one. | Choose one. |       |

### **Pharmacy**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. Study Drug Availability
 | Choose one. | Choose one. |       |
| 1. Study Drug Packaging and Labeling
 | Choose one. | Choose one. |       |
| 1. Study Drug Storage
 | Choose one. | Choose one. |       |
| 1. Study Drug Accountability and Use of DCP Investigational Agent Forms
 | Choose one. | Choose one. |       |
| 1. Treatment Assignments Module in Stars
 | DMACC | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. | Choose one. |       |

### **Specimen Management**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. Specimen Collection
 | Choose one. | Choose one. |       |
| 1. Specimen Labeling
 | Choose one. | Choose one. |       |
| 1. Specimen Processing and Shipping
 | Choose one. | Choose one. |       |
| 1. Specimen Storage and Disposition
 | Choose one. | Choose one. |       |
| 1. Specimen Tracking
 | Choose one. | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. | Choose one. |       |

### **Resources**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. CP-CTNet DMACC Public Website and Portal Gateway
 | DMACC | Choose one. |       |
| 1. CP-CTNet SOPs/Related Documents
 | DMACC | Choose one. |       |

### **Essential Documents**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. SOP 01-01 *Essential Documents Submission for Sponsor’s Record*
 | Choose one. | Choose one. |       |
| 1. Submission of Documents to LAO
 | Choose one. | Choose one. |       |
| 1. Protocol Amendment Process with LAO
 | Choose one. | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. | Choose one. |       |

### **Source Documentation**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. REFGD01 *Source Documentation Guide*
 | Choose one. | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. | Choose one. |       |

### **Study Start-up**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. Study Activation
 | DMACC | Choose one. |       |
| 1. Site Activation
 | DMACC | Choose one. |       |
| 1. Study Build
 | DMACC | Choose one. |       |

### **Data Collection**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. Procedures and Electronic Case Report Forms/SVARs
 | Choose one. | Choose one. |       |
| 1. Adverse Events (NCI CTCAE Version)
 | Choose one. | Choose one. |       |
| 1. Baseline Symptoms/Baseline and Adverse Event Reporting Guidelines
 | Choose one. | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. | Choose one. |       |

### **Database Management**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. Medidata Rave
 | DMACC | Choose one. |       |
| 1. Other DMACC System(s)
 | DMACC | Choose one. |       |
| 1. Data Management Quality Control Procedures
 | DMACC | Choose one. |       |
| 1. Data Management Quality Assurance Procedures
 | DMACC | Choose one. |       |
| 1. Data Queries and/or Discrepancy Management
 | DMACC | Choose one. |       |
| 1. Data Queries for Source Data Verification
 | DMACC | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | DMACC | Choose one. |       |

### **Site Auditing Visits**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. Audits - Purpose, Frequency, and Components
 | DMACC | Choose one. |       |
| 1. Accruing LAO and AO Responsibilities
 | DMACC | Choose one. |       |
| 1. Reports and Distribution
 | DMACC | Choose one. |       |
| 1. Action Items
 | DMACC | Choose one. |       |

### **DCP Reporting Requirements**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. SAE Reporting
 | Choose one. | Choose one. |       |
| 1. Protocol Deviations
 | Choose one. | Choose one. |       |

### **Record Keeping Requirements**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. Original Signed Informed Consent Forms
 | Choose one. | Choose one. |       |
| 1. Study Files and Source Documentation
 | Choose one. | Choose one. |       |

### **Communication with the LAO**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. Emails/Conference Calls/Meetings
 | Choose one. | Choose one. |       |

### **Additional Study Information**

| **TOPICS** | **Presenter** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- | --- |
|  | Choose one. | Choose one. |       |
|  | Choose one. | Choose one. |       |
|  | Choose one. | Choose one. |       |

|  |
| --- |
| **Additional Comments:** |
|       |

## **V. Recording the Study Initiation Meeting**

**Completion Instructions for the LAO:** Indicate the group that is responsible for each item by selecting the appropriate CP-CTNet group (e.g., ***AO,* *DCP Study Staff, DMACC, LAO,*** or***Other***). If ***Other*** is selected, indicate the CP-CTNet group in the Comments. Mark the status of each item below as: ***Complete***, item complete; ***Not Addressed***, item not yet addressed; or ***Not Applicable***. For any item marked ***Not Addressed*** or ***Not Applicable***, please provide a comment. For items marked ***Yes***, pleaseprovide a comment whenever necessary or helpful.

| **ITEMS to Address** | **Group** | **Status** | **COMMENTS** |
| --- | --- | --- | --- |
| 1. Record the Study Initiation Meeting
 | Choose one. | Choose one. |       |
| 1. Share the Recording with LAO and/or AO Staff
 | Choose one. | Choose one. |       |

## **VI. Action Items for Site**

**Completion Instructions for the LAO:** List meeting findings in the *Action Item Status* tablebelow in order of severity and mark Status as ***Resolved*** or ***Site* *follow-up of action items required***. Provide a comment whenever necessary or helpful. Sites should follow up on any item marked as ***Site* *follow-up of action items required*** and update the action item status in the table below. If site follow-up of action items is required, the updated Study Initiation Meeting Report must be returned to the LAO Coordinator within 30 business days upon receipt of the final meeting report. The LAO documents the resolution of all action items prior to participant enrollment and forwards the updated Study Initiation Meeting Report to the accruing LAOs and AOs, DCP study representative(s), and DMACC as per SOP 01-02 *Study Initiation Meeting*.

|  |  |  |
| --- | --- | --- |
| **Action Item(s)** | **Status** | **COMMENTS** |
| 1. |       | Choose one. |       |
| 2. |       | Choose one. |       |
| 3. |       | Choose one. |       |
| 4. |       | Choose one. |       |

**Completion Instructions for the LAO:** Select a response below to guide sites in updating the *Action Item Status* table.

\*Choose one.\*

**Report Prepared By:**

|  |  |  |
| --- | --- | --- |
| **Printed Name** | **Signature** | **Date** |
|       |       | Enter a date. |

## **VII. References**

**Note:** All CP-CTNet SOPs are included in the [*CP-CTNet Manual of Standard Operating Procedures (M-SOP)*](https://www.cp-ctnet-dmacc.org/static/resources/CP-CTNet_Manual_of_Standard_Operating_Procedures.pdf), which is available on the [CP-CTNet DMACC public website](https://www.cp-ctnet-dmacc.org/public/).

|  |  |  |
| --- | --- | --- |
| **Document** | **ID** | **Location** |
| Essential Documents Submission for Sponsor’s Record | SOP 01-01 | [Program Resources](https://www.cp-ctnet-dmacc.org/static/resources/CP-CTNet_Manual_of_Standard_Operating_Procedures.pdf) |
| Source Documentation Guide | REFGD01 | [Program Resources](https://www.cp-ctnet-dmacc.org/static/resources/CP-CTNet_REFGD01_Source_Documentation_Guide.pdf) |
| Study Initiation Meeting | SOP 01-02 | [Program Resources](https://www.cp-ctnet-dmacc.org/static/resources/CP-CTNet_Manual_of_Standard_Operating_Procedures.pdf) |