## **Study Initiation Meeting Report**

## **I. Site Information**

|  |  |
| --- | --- |
| **Site Name:** |       |
| **NCI Protocol Number:** |       |
| **NCI Protocol Title:** |       |
| **Meeting Date(s):** | **From:** Enter a date. **To:** Enter a date. |
| **Meeting Modality:** | Choose one. |
| **Meeting Conducted By:** |       |

## **II. Meeting Attendees:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Affiliation** | **Role or Title** |
|       |       |       |
|       |       |       |
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## **III. Study Initiation Meeting Checklist**

**Completion Instructions** Mark each item below as: ***Yes***, item verified and/or discussed; ***No***, unable to verify and/or discuss item; ***Not Applicable***; or, ***Not Reviewed***. Provide comments for items marked ***No***, or whenever necessary or helpful.

### **Review of Study**

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

### **Enrollment**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. Informed Consent Process
 | Choose one. |       |
| 1. Screening/Pre-Entry Period
 | Choose one. |       |
| 1. No Exemptions
 | Choose one. |       |
| 1. Registration/Randomization
 | Choose one. |       |
| 1. Recruitment/Retention
 | Choose one. |       |
| 1. Anticipated Start of Enrollment
 | Choose one. |       |

### **Pharmacy**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. Study Drug Availability
 | Choose one. |       |
| 1. Study Drug Packaging and Labeling
 | Choose one. |       |
| 1. Study Drug Storage
 | Choose one. |       |
| 1. Study Drug Accountability and Use of DARF
 | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. |       |

### **Specimen Management**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. Specimen Collection
 | Choose one. |       |
| 1. Specimen Processing and Shipping
 | Choose one. |       |
| 1. Specimen Storage and Disposition
 | Choose one. |       |
| 1. Specimen Tracking
 | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. |       |

### **DCP Resources**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. DCP Website
 | Choose one. |       |
| 1. Protocol Information Office
 | Choose one. |       |
| 1. DCP Consortia 2012 SOPs
 | Choose one. |       |
| 1. DCP Guidance Documents
 | Choose one. |       |

### **Regulatory Documents**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. DCP Consortia 2012 SOP 1 – Regulatory
 | Choose one. |       |
| 1. Submission of documents to CLO
 | Choose one. |       |
| 1. Protocol Amendment Process with CLO
 | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. |       |

### **Source Documentation**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. DCP Guidance Document on Source Documentation
 | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. |       |

### **Data Collection**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. Procedures and Case Report Forms
 | Choose one. |       |
| 1. Adverse Events (NCI CTCAE Version)
 | Choose one. |       |
| 1. Baseline Symptoms
 | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. |       |

### **Database Management**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. Database of Record
 | Choose one. |       |
| 1. Other system(s) to be Used
 | Choose one. |       |
| 1. Quality Assurance Procedures
 | Choose one. |       |
| 1. Data Queries and/or Discrepancy Management
 | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. |       |

### **Site Monitoring Visits**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. Purpose and Frequency
 | Choose one. |       |
| 1. DCP Consortia 2012 SOP 9 -Site Preparations
 | Choose one. |       |
| 1. CLO Monitor(s)
 | Choose one. |       |
| 1. Reports and Distribution
 | Choose one. |       |
| 1. Action Items
 | Choose one. |       |

### **DCP Reporting Requirements**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. SAE Reporting
 | Choose one. |       |
| 1. Protocol Deviations
 | Choose one. |       |
| 1. Minimum Data Set (MDS)
 | Choose one. |       |

### **Record Keeping Requirements**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. Participant Screening Log
 | Choose one. |       |
| 1. Original Signed Informed Consent Forms
 | Choose one. |       |
| 1. Study Files and Source Documentation
 | Choose one. |       |

### **Communication with the CLO**

| **ITEMS VERIFIED and/or DISCUSSED** | **RESPONSE** | **COMMENTS** |
| --- | --- | --- |
| 1. Emails/Conference Calls/Meetings
 | Choose one. |       |

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

## **IV. Action Items for Site**

**Completion Instructions for the CLO Monitor:** List visit findings below in order of severity and mark Status as ***Resolved*** or ***Site* *follow-up of action items required***. Complete an Action Item-Site Response Form for any item marked as ***Site* *follow-up of action items required***.

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

\*Choose one.\*

**Report Prepared By:**

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