## **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. |