1. Study Initiation Meeting Information:

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| **LAO Name(s):** |  |
| **Accruing LAO and/or AO Name(s):** |  |
| **NCI Protocol Number:** |  |
| **NCI Protocol Title:** |  |
| **Meeting Date:** | Enter a date. |
| **Meeting Time (in applicable time zones):** |  |
| **Meeting Modality:** | Choose one. |
| **Meeting Location (e.g., video-conference ID, link, address, etc.):** |  |
| **Meeting Moderator Name(s):** |  |

1. Expected Attendees:

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| **Name** | **Affiliation** | **Role or Title** | **Attended** | **Absent** |
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1. Agenda

| **Time (in applicable time zones)** | **Topic(s) with Suggested Timeframes** | **Suggested Presenter(s)**  **(based on the** [***CP-CTNet Study Initiation Meeting Report Template***](https://www.cp-ctnet-dmacc.org/static/resources/CP-CTNet_Study_Initiation_Meeting_Report.docx)**)** |
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|  | **Welcome and Brief Introductions (5 min.)** | LAO Leadership |
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|  | **CP-CTNet Overview (15 min.)**   * CP-CTNet General Overview * DCP Staff Roles/Responsibilities * DCP Support Contracts * AQuIP Overview | DCP Staff |
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|  | **Review of Study and Communication with the LAO(s) (30 min.)**   * Background and Purpose of Study * Study Objectives, Endpoints, and Design * Clinical and Laboratory Evaluations * Schedule of Evaluations and Study Visit Windows * Study Emails, Conference Calls, and Meetings | Study PI and LAO Staff |
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|  | **Specimen Management (10 min.)**   * Specimen Collection * Specimen Labeling * Specimen Processing and Shipping * Specimen Storage and Disposition * Specimen Tracking * Staff Roles and Responsibilities | LAO Staff/Specimen Management Staff |
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|  | **Enrollment (20 min.)**   * Informed Consent Process * AQuIP Pre-Screening and Screening * LAO Eligibility Verification * No Eligibility Exceptions/Waivers Allowed * Recruitment, Retention, and Adherence * Anticipated Start of Enrollment | LAO Staff |
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|  | **Pharmacy (10 min.)**   * Study Drug Availability * Study Drug Packaging and Labeling * Study Drug Storage * Study Drug Accountability and Use of DCP Investigational Agent Forms * Staff Roles and Responsibilities | LAO Staff/Pharmacy Staff |
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|  | **Break (10 min.)** |  |
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|  | **Essential Documents (10 min.)**   * SOP 01-01 *Essential Documents Submission to Sponsor’s Record* * Submission of Documents to LAO(s) * Protocol Amendment Process with LAO(s) * Staff Roles and Responsibilities | LAO Staff |
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|  | **Data Collection, Source Documentation, Reporting Requirements, and Record Keeping (15 min.)**   * [REFGD01 *Source Documentation*](https://www.cp-ctnet-dmacc.org/static/resources/CP-CTNet_REFGD01_Source_Documentation_Guide.pdf) * Adverse Events (NCI CTCAE Version) * Baseline Symptoms/Baseline and Adverse Event Reporting Guidelines * Serious Adverse Event Reporting * Protocol Deviation Reporting * Original Signed Informed Consent Forms * Study Files and Source Documentation * Staff Roles and Responsibilities | LAO Staff |
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|  | **Data Management and Auditing (40 min.)**   * DMACC Overview * Study Start-Up * [CP-CTNet DMACC Website](https://www.cp-ctnet-dmacc.org/) * Data Management and Quality Control with DMACC Systems * Auditing * SOPs and Related Documentation * Communication | DMACC Staff |
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|  | **Questions, Comments, and Action Items (10 min.)** | All Presenters |
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