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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* 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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