Clarification on Study Start Date and Reporting for clinicaltrials.gov

V 2.0 November 1, 2023

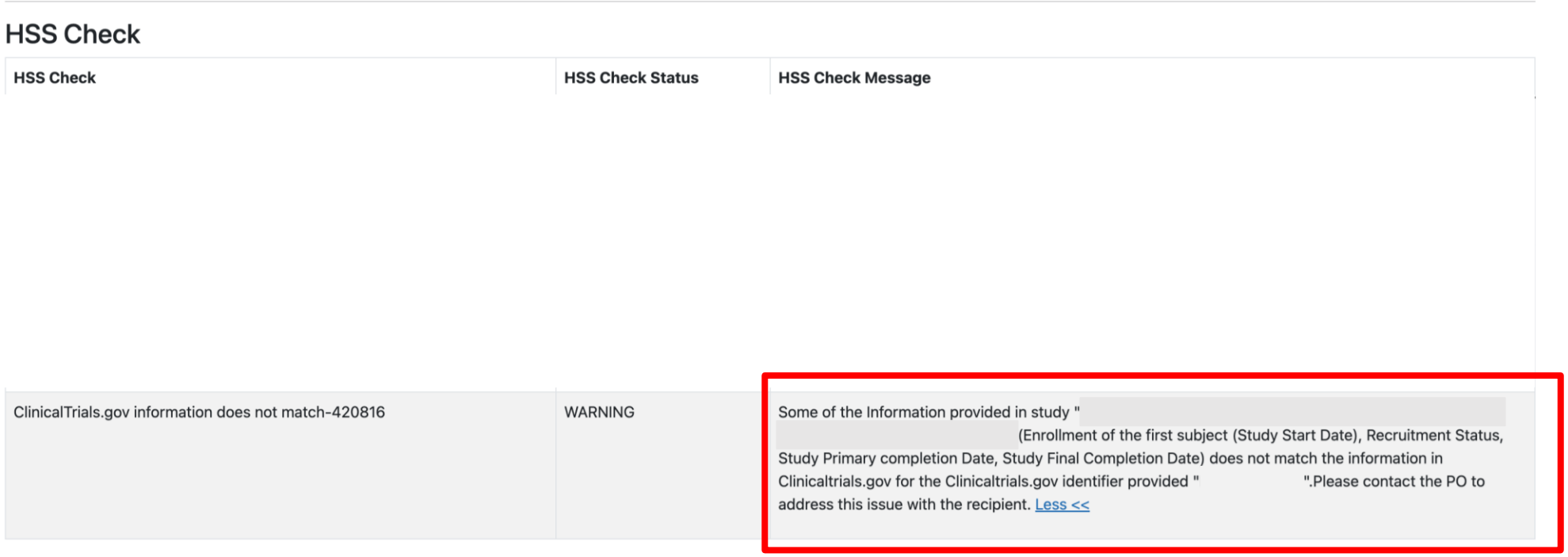
DCP Leadership, CP CTNet

Why this matters?

- CP CTNet is funded under a Grant Mechanism which requires correct entry of data between the Grant Human Subjects System (HSS) and clinicaltrials.gov
- Failure to have dates align properly will result in a “Yellow Bar” designation which impacts release of grant funds and must be addressed by the NCI DCP Program Officer

Yellow Bar

- Blocks Notice of Award (NOA) based on Human Subjects System (HSS) validations
- Recruitment status, Study Start Date, Study Primary Completion Date, and Study Final Completion Date are all validated
- An error message example is shown in the red box below with the CP CTNet trial name de-identified



HSS Check

HSS Check	HSS Check Status	HSS Check Message
ClinicalTrials.gov information does not match-420816	WARNING	Some of the Information provided in study " (Enrollment of the first subject (Study Start Date), Recruitment Status, Study Primary completion Date, Study Final Completion Date) does not match the information in Clinicaltrials.gov for the Clinicaltrials.gov identifier provided " ".Please contact the PO to address this issue with the recipient. Less <<

https://inside.era.nih.gov/files/hss_user_guide.pdf

Examples of Data Discrepancies which result in a Yellow Bar

Research Performance Progress Report (RPPR)/HSS and CT.gov that does not match*

Human Subject and Clinical Trials Form (RPPR)

6.1. Study Primary Completion Date	03/31/2026	Anticipated
6.2. Study Final Completion Date	03/31/2026	Anticipated
6.3. Enrollment and randomization Enrollment of the First Participant (Study Start Date)	09/30/2022	Anticipated
25% of planned enrollment recruited by	04/30/2023	Anticipated
50% of planned enrollment recruited by	11/30/2023	Anticipated
75% of planned enrollment recruited by	08/31/2024	Anticipated
100% of planned enrollment recruited by	06/30/2025	Anticipated
6.4. Completion of primary endpoint data analyses	03/31/2026	Anticipated
6.5. Reporting of results in ClinicalTrials.gov	02/28/2027	Anticipated
6.6. Is this an applicable clinical trial under FDAAA?	● Yes ○ No	

Clinicaltrials.gov

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	86 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Primary Purpose:	Prevention
Official Title:	M4OC-Prevent 2.0: Phase IIb Trial
Actual Study Start Date :	November 28, 2022
Estimated Primary Completion Date :	July 31, 2026
Estimated Study Completion Date :	July 31, 2026

Data Sources

Minimum Data Set - MDS

Informed Consent Date	Screen 1 Date	Screen 2 Date	Registration Date	Randomization Date	Eligibility Status	Participant Enrollment Date
12/08/2022	12/09/2022		01/12/2023	01/12/2023	Yes	01/12/2023

Protocol Submission Wksheet - PSW

Section 4a: Accrual Information

Projected Study Start Date: November 2022	Planned Sample Size (#Evaluable): 72 Target Enrollment: (Maximum #): 86	Projected Monthly Accrual Rate: 3-4 Projected completion date of accrual: October 2025
Expected # Subjects/Site: 9-12	# Case Report Forms per Participant:	Estimated # Participants Screened: 86

Anticipated Primary Completion Date: June 2026

Primary Completion Date: _____

Protocol Status Update Form

☒ **PRIMARY COMPLETION DATE**

Definition: The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated. The Primary Completion date must be on or after the Closed to Accrual and Treatment date and must be on or before the Completed date.

Required: Please choose either #1 or #2:

☒ **#1:** Anticipated primary completion date: 8/28/26

☐ **#2:** Actual primary completion date:

☒ **ACTIVE**

Date of status change: 11/28/22

* HSS updates are pulled into the RPPR

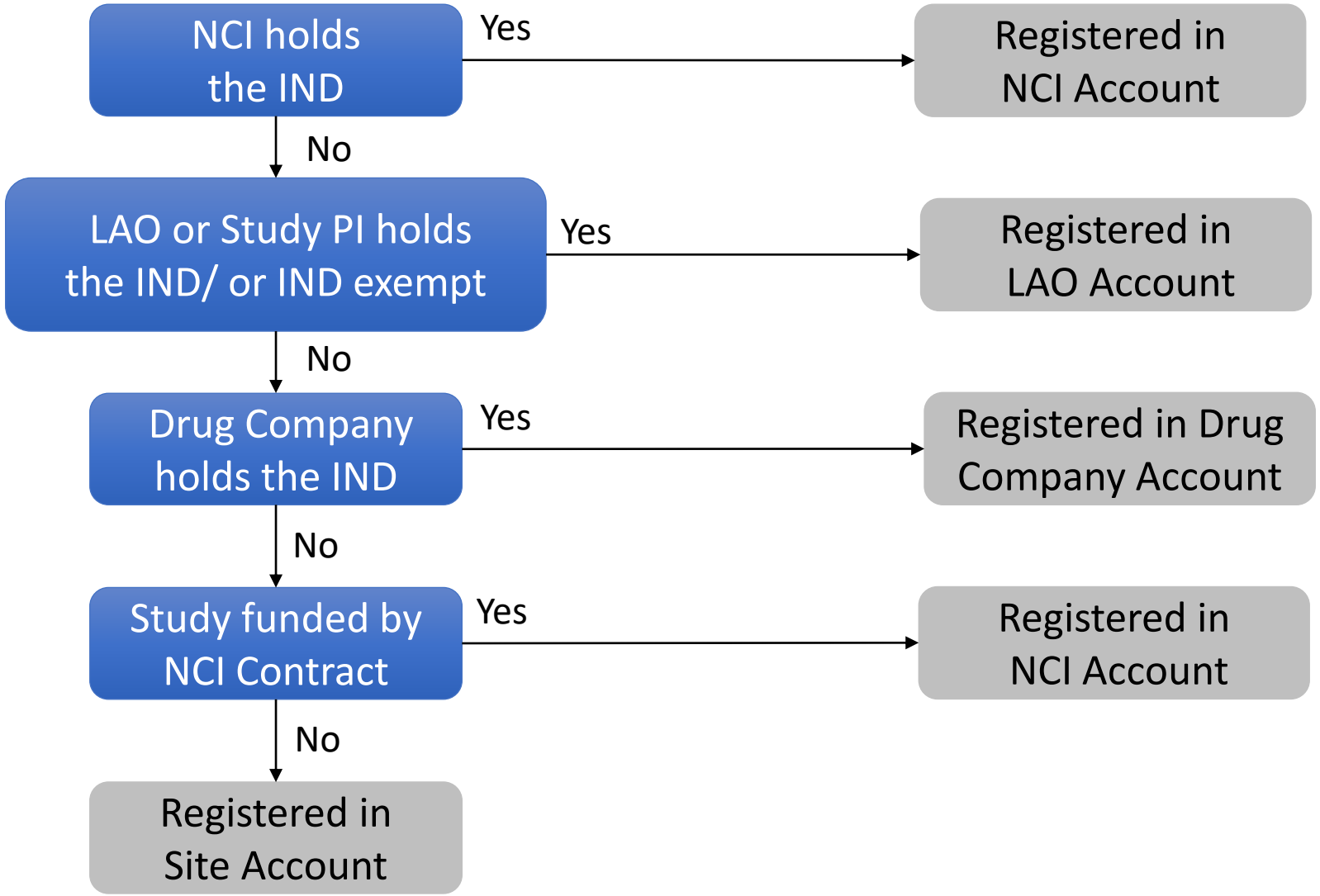
Current Guidance

- **Recruitment Status**
  - If study has enrolled a participant the Recruitment Status in ct.gov should show as “Recruiting” and the enrollment should be reported through HSS
- **Study Start Date**
  Definition: The estimated date on which the clinical study will be open for recruitment of participants, or the actual date on which the first participant was enrolled.
  - Use the **FIRST** MDS enrollment date
  - The MDS enrollment date comes from STARs defined as: The date the patient has successfully enrolled onto the study via the enrollment system and has been assign a participant ID (and treatment ID, if applicable). The enrollment date is considered the participants start date/on study date.
- **Status notice drives other dates**
  - Estimated (same as Anticipated) Primary Completion Date on status notice/PSW/CT.gov/HHS should all match
  - Estimated (same as Anticipated) Study Completion Date **must be on or after** the Estimated (Anticipated) Primary Completion Date

Data Needs to Match

- Data in CT.gov needs to match the data in the HSS
- Using the MDS enrollment date allows us to communicate clearly so it is consistent whether NCI enters the data or the site enters the data
- NCTN and NCORP use this same date
- LAOs should check the HSS before submitting their RPPR as HSS updates are pulled into the RPPR
- **If an LAO updates the PSW or Protocol Status Form they should update HSS and CT.gov if they are responsible for the record (see next slide)**

Who is responsible for registering trials?



Who is responsible for submitting results?

- Basic Results Reporting is due **one year after the Primary Completion Date** (PCD)
- **Primary Completion Date:** The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated. In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes.