Introduction

This document provides an overview of the enrollment process for Cancer Prevention Clinical Trials Network (CP-CTNet) studies, including the assignment of *Pre-Screen, Screening, Participant*, and *Treatment IDs*; the pre-screening, screening, and enrollment process within the Stars registration/randomization system (Stars) and the Medidata Rave electronic data capture system (Rave); and information on the Accrual Quality Improvement Program (AQuIP) recruitment journal, which is where study events that can affect recruitment (either positively or negatively) are documented. For more detailed information, see USRMAN01 *CP-CTNet Stars User Guide*.

Assignment of Participant IDs

After a study has received notification of Approval on Hold, Lead Academic Organizations (LAOs) may access the Reserve PIDs module in Stars to reserve *Participant IDs* (PIDs) by protocol and by accruing LAO and Affiliated Organization (AO), based on an institution's accrual projections. IDs consist of six digits. The same numeric ID for a participant carries across all phases of the enrollment process, with the leading prefix ("PS," "S") added to distinguish between pre-screening and screening.

Examples of Pre-Screen, Screening, and Participant IDs:

Study	Accruing LAO or AO	Pre-Screen ID	Screening ID	Participant ID
DEF20-03-04	YY444	PS100321	S100321	100321
DEF20-03-04	YY555	PS100422	S100422	100422

Assignment of Treatment IDs

When an accruing LAO or AO enrolls a participant in Stars, Stars assigns a *Participant ID*. If the study uses an intervention or investigational agent, Stars also assigns a unique *Treatment ID* for the participant. The *Treatment ID* corresponds to the treatment that is assigned to the participant based on the schema outlined in the protocol.

A set of *Treatment IDs* is allocated for each study and accruing LAO and AO by the Data Management, Auditing, and Coordinating Center (DMACC) prior to the opening of a study involving an intervention or investigational agent. The accruing LAO or AO pharmacist uses the Treatment Assignments module in Stars to view and/or download the *Treatment ID* list. This list maps the *Treatment ID* to the participant's assigned intervention or investigational agent to determine the treatment regimen that should be dispensed to the participant based on the *Treatment ID*.

Examples of Treatment IDs:

Study	Accruing LAO or AO	Treatment IDs
ABC02-01-02	YY444	ABC02-01-02 1001 through ABC02-01-02 1050
DEF02-01-02	YY555	DEF02-01-02 2176 through DEF02-01-02 2275

After receiving the assigned *Participant ID* and *Treatment ID* for a participant, the pharmacist uses the *Treatment ID* list to verify what treatment regimen to dispense. Then, the pharmacist pulls from inventory any bottle, package, or vial that corresponds to the assigned treatment regimen. The pharmacist selects the appropriate over-label (as applicable), writes the *Participant ID*, participant initials, and date on the label, and places it on the bottle, package, or vial of the study agent to be dispensed to the participant. The pharmacist dispenses the study agent. See QKREFGD08 *CP-CTNet Treatment ID Information* for more information.

Pre-Screening

During protocol development, the Principal Investigator (PI) and study team select a small subset of the protocol eligibility criteria to identify individuals for pre-screening via medical record review, which are included in the study-specific *Recruitment, Retention, and Adherence Plan* (RRA Plan, Section II.D). Once determined to be eligible for pre-screening, before the actual pre-screening activity (which is further medical record review to determine eligibility for contact) may take place, a *Pre-Screen ID* is obtained for those individuals within Stars as follows:

1. Select the Institution, Protocol, and Version in Stars.
2. Select the Pre-Screen Checklist.
3. Click Continue.
4. Enter the current date at the participant's Institution and the date the participant was pre-screened/recruited.
5. After completing all required information, click Continue.
6. After reviewing the entered responses on the Review page, click Submit.
7. A Summary page is displayed, which provides the results of the pre-screen submission and the assigned *Pre-Screen ID*. For successful submissions, an encrypted email message with the PDF confirmation file is also sent to the user and designated staff at the LAO.
8. Within two minutes, the pre-screen information that was entered into Stars is automatically data exchanged and is available in Rave.
9. Next, log into Rave and enter the remaining pre-screen information. This includes AQuIP-related data such as:
   - Recruitment strategies (e.g., staff recruitment, existing database, postal service/email, phone calls, referral, non-digital/digital/social media, community contacts, patient issues).
   - Pre-Screen outcome (e.g., eligible for contact or not eligible for contact).
   - Reason(s) not eligible for contact (if applicable).
   - Date of first contact.
   - Consent status (e.g., signed, pending, or not signed).
   - Reason(s) consent not signed (if applicable).

Screening

If it is indicated in Rave that the participant is eligible for contact and the informed consent document was signed, then the next step is to obtain a *Screening ID* for the participant. This is done within Stars.

1. Select the Institution, Protocol, and Version in Stars.
2. Select the Screening Checklist and enter the previously assigned *Pre-Screen ID* for the participant.
3. Click Continue.
4. Enter the current date at the participant's Institution, indicate if the participant was previously assigned a *Screening ID* for the protocol, enter the previously assigned *Screening ID* (as applicable), and confirm that the informed consent document was signed.
5. After completing all required information, click Continue.
6. After reviewing the entered responses on the Review page, click Submit.
7. A Summary page is displayed, which provides the results of the screening submission and the assigned *Screening ID*. For successful submissions, an encrypted email message with the PDF confirmation file is also sent to the user and designated staff at the LAO.
8. Within two minutes, the screening information that was entered into Stars is automatically data exchanged and is available in Rave. The *Subject ID* in Rave is changed from the *Pre-Screen ID* to the *Screening ID*.
9. Next, log into Rave and enter the remaining screening information (if applicable). This includes:

- Whether the participant declined to enroll even though consent was signed.
- Whether the participant meets the study-specific screening criteria.
- AQuIP-related data such as screening date(s).

Enrollment

If the participant is eligible to move on to enrollment, the next step is to obtain a *Participant ID* for the participant. This is done within Stars.

1. Select the Institution, Protocol, and Version in Stars.
2. Select the Enrollment Checklist and enter the previously assigned *Screening ID* for the participant.
3. Click Continue.
4. The Enrollment Checklist appears. This checklist contains the eligibility criteria for the study, a question to confirm that the informed consent document was signed, a question to confirm that the eligibility verification process for the participant is complete (see SOP 03-03 *Lead Academic Organization Oversight Activities* for more information), and questions that collect the names of the individuals that verified the participant's eligibility.
5. Select the appropriate answers for each question. If an answer disqualifies the participant for the study, the checklist cannot be completed, and the participant cannot be enrolled.
6. If the full checklist can be completed for the participant, click Continue.
7. After reviewing the entered responses on the Review page, click Submit.
8. A Summary page is displayed, which provides the results of the enrollment submission, the assigned *Participant ID*, and the assigned *Treatment ID*, if applicable. For successful submissions, an encrypted email message with the PDF confirmation file is also sent to the user and designated staff at the LAO.
9. Within two minutes, the enrollment information that was entered into Stars is automatically data exchanged and is available in Rave. The *Subject ID* in Rave is changed from the *Screening ID* to the *Participant ID*.
10. Next, log into Rave and enter all the study-specific data for the participant as the participant moves through the study.

AQuIP Recruitment Journal

The AQuIP recruitment journal is used to document study events that occur at the study or accruing LAO or AO level that may affect participant recruitment (e.g., drug not available, staff changes, local Institutional Review Board (IRB) issues, etc.). All AQuIP recruitment journaling is done within Rave. Once an accruing LAO or AO is activated to its first study, the staff at the accruing LAO or AO receive access to the Recruitment study in Rave, which holds the AQuIP recruitment journal. Each accruing LAO or AO has its own *AQuIP Recruitment Journal ID* for each study that it is participating in, which is formatted as Journal_Study Number_Site Code (e.g., Journal_ABC20-01-02_XY123).

Note: The *AQuIP Recruitment Journal ID* for a study does not appear in Rave until the accruing LAO or AO pre-screens its first participant for that study.

Examples of AQuIP Recruitment Journal IDs:

AQuIP Recruitment Journal ID	Description
Journal_**ABC02-01-01**_XY123	AQuIP recruitment journal for AO XY123 and study **ABC02-01-01**
Journal_**ABC02-01-02**_XY123	AQuIP recruitment journal for AO XY123 and study **ABC02-01-02**

On a monthly basis, under the *AQuIP Recruitment Journal ID* for each study, the accruing LAOs and AOs enter the **site-wide** AQuIP recruitment journal information. This includes the start date, end date, event, description, and affected accruing LAO or AO. DMACC enters **study-wide** AQuIP recruitment journal information, which the accruing LAOs and AOs can view.

References

Note: All CP-CTNet Standard Operating Procedures (SOPs) are included in the *CP-CTNet Manual of Standard Operating Procedures (M-SOP)*, which is available on the CP-CTNet DMACC public website.

Resource	ID	Location
CP-CTNet Stars User Guide	USRMAN01	Program Resources
CP-CTNet Treatment ID Information	QKREFGD08	Program Resources
Lead Academic Organization Oversight Activities	SOP 03-03	Program Resources
Recruitment, Retention, and Adherence Plan	Form	Program Resources