

Title: **Stars and Rave Data Flow Information**

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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
1.0	AUG-17-2020	Original version of document

1. INTRODUCTION

This document details the data flow in Stars and Medidata Rave (Rave) for the CP-CTNet project. Stars is the DMACC enrollment/registration/randomization system, used to obtain assignments of Pre-Screening, Screening, and/or Enrollment/Registration/Randomization IDs for participants. Rave is the electronic data capture (EDC) system that holds the clinical database. Data entered into Stars are automatically data exchanged into Rave within five minutes of entry, so there is no duplication of data entry and all data are held in one database.

Note that data related to the Accrual Quality Improvement Program (AQuIP) (including Recruitment Journaling) will be entered into Stars or Rave. This document describes the Pre-Screening, Screening, and/or Enrollment/Registration/Randomization process, as well as provides information regarding recording of AQuIP data.

2. RECRUITMENT JOURNALING

The Recruitment Journal is used to document study events that occur at the study or site level that may affect participant enrollment. All recruitment journaling is done within Rave. Once a site is approved to their first study, they receive access to the “Recruitment Study” in Rave, which holds the Recruitment Journal. Each study has its own Recruitment Journal ID, which is formatted as Journal_Study Number_Site Code (e.g., Journal_ABC20-01-02_YZ123).

On a monthly basis, under the Recruitment Journal ID for each study, the user will enter the Recruitment Journal information. This includes study event start date, study event end date, study event (study active, site open, protocol amendment approval: eligibility, accrual hold, site issues: local IRB/regulatory issues, staff issues: availability/change in PI, etc.), and study event description.

3. PARTICIPANT PRE-SCREENING

Once a participant is identified as a potential candidate for a study, the first step is to obtain a Pre-Screen ID for the participant. This is done within Stars:

1. Select the study in Stars.
2. Select and complete the “Pre-Screen Checklist”.
3. Enter current date at site.
4. Pre-Screen ID (e.g., PS100001) is assigned.

Within five minutes, the pre-screen information that was entered into Stars is automatically data exchanged into Rave under the study titled “Recruitment Study.” The user logs into Rave, clicks on the “Recruitment Study”, finds the assigned Pre-Screen ID for the participant, and enters the remaining pre-screen information. This includes AQuIP-related data such as pre-screen strategy(ies), pre-screen outcome (eligible for contact or not eligible for contact), and reasons not eligible for contact (if applicable).

4. PARTICIPANT SCREENING

If it is indicated that the participant was eligible for contact, then the next step is to obtain a Screening ID for the participant. This is done within Stars:

1. Select the study in Stars.
2. Select the “Screening Checklist”.
3. Enter previously assigned Pre-Screen ID.
4. Complete the “Screening Checklist”.
5. Answer “Did this participant have a previously expired Screening ID? If yes, please provide.”
6. Enter current date at site.
7. Screening ID (e.g., S600001) is assigned.

Within five minutes, the screening information that was entered into Stars is automatically data exchanged into Rave under the specific study name (for example, Study “ABC02-01-02”). The user

logs into Rave, clicks on the specific study, finds the assigned Screening ID for the participant, and enters the remaining screening information. This includes AQuIP-related data such as date of first contact, recruitment strategy(ies), consent date, consent status (signed, pending, or not signed), and reasons consent not signed/intervention not started (if applicable).

5. PARTICIPANT ENROLLMENT/REGISTRATION/RANDOMIZATION

If it is indicated that the participant signed consent, then the next step is to obtain a Participant ID for the participant. This is done within Stars:

1. Select the study in Stars.
2. Select the “Enrollment/Randomization Checklist”. This includes all of the protocol-specific eligibility questions.
3. Enter previously assigned Screening ID.
4. Complete the “Enrollment/Randomization Checklist”.
5. Enter current date at site.
6. Participant ID (e.g., 900001) and treatment arm (if applicable) are assigned.

Within five minutes, this enrollment/registration/randomization information that was entered into Stars is automatically data exchanged into Rave under the specific study name (for example, study “ABC02-01-02”). The Subject ID in Rave is changed from the Screening ID to the Participant ID. When the user logs into Rave, they can now click on the specific study, find the assigned Participant ID for the participant, and enter all of the protocol-specific data for the participant as the participant moves through the study.

Example of Subject IDs in Rave

Examples for Recruitment Study

The Recruitment Study contains the Recruitment Journals for the clinical studies that the site is participating in and the Pre-Screen IDs obtained from Stars. The Pre-Screen IDs in the Recruitment Study span across all clinical studies.

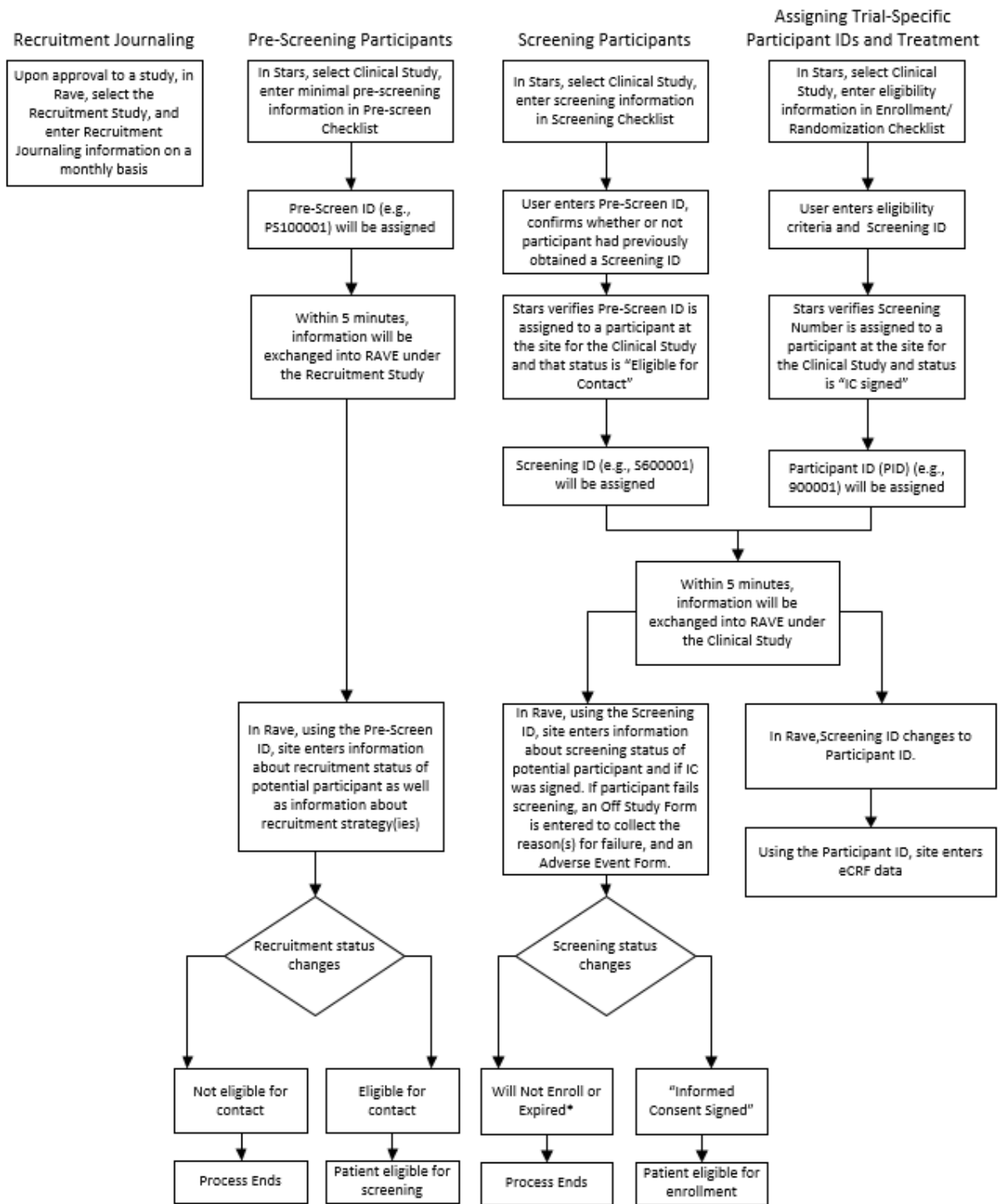
Example Subject ID	Description
Journal_ABC02-01-01_XY123	Recruitment Journal for Site XY123 and Study ABC02-01-01
Journal_ABC02-01-02_XY123	Recruitment Journal for the Site XY123 and Study ABC02-01-02
PS100341	Pre-Screen ID for Study ABC02-01-01
PS100403	Pre-Screen ID for Study ABC02-01-02
PS100456	Pre-Screen ID for Study ABC02-01-01

Examples for Clinical Study ABC02-01-02

Each clinical study contains the Screening IDs that were obtained in Stars. Once a Screening ID is used to enroll a participant onto the clinical study, the Screening ID is replaced with the Participant ID in Rave.

Example Subject ID	Description
S600002	Screening ID for ABC02-01-02 (screen failure or not yet enrolled)
S600088	Screening ID for ABC02-01-02 (screen failure or not yet enrolled)
902371	Participant ID for ABC02-01-02 . This Participant ID would replace the Screening ID upon enrollment.

CP-CTNet Enrollment Procedures



*If the Screening Number expires or the participant is found to be ineligible, participant may be screened again and receive a new Screening Number that is linked to the original Screening Number