Introduction

This document provides an overview of the treatment assignment process for Cancer Prevention Clinical Trials Network (CP-CTNet) studies that takes place within the Stars registration/randomization system (Stars). When an accruing Lead Academic Organization (LAO) or Affiliated Organization (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. 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*. Then, the pharmacist pulls from inventory any bottle, package, or vial that corresponds to the assigned treatment regimen. See USRMAN01 *CP-CTNet Stars User Guide* and QKREFGD02 *Summary of Enrollment Process* for more information about the Stars enrollment and treatment assignment processes.

Study Setup

1. DMASC generates a sequential list of *Treatment IDs* for each study and accruing LAO and AO.
2. The pharmacist accesses the Treatment Assignments module in Stars to view and/or download the *Treatment ID* list.
    - The pharmacist has access to the *Treatment ID* list for both non-blinded and blinded studies.

Ordering Study Agent

1. The pharmacist orders the study agent based on study guidelines and expected accrual at the accruing LAO or AO.
    - The pharmacist should be able to identify the contents of the received study agent even if the study is blinded.
    - The pharmacist should always have a supply of each possible study agent available in inventory. Failure to do so could result in the intervention being delayed until the assigned study agent is ordered and received.

Enrollment/Randomization

1. The accruing LAO or AO enrolls the participant using Stars.
2. Stars assigns a Participant ID and Treatment ID.
    - Participants are assigned a *Treatment ID* if the study is an intervention study regardless of whether the study is non-randomized single arm or randomized (non-blinded or blinded) and regardless of how the pharmacist orders and obtains the study agent.
    - If the study is non-randomized single arm or randomized and non-blinded, the treatment assignment is displayed to the accruing LAO or AO.
    - If the study is non-randomized single arm, *Treatment IDs* are assigned in sequential order for a given accruing LAO or AO. If the study is randomized, *Treatment IDs* are assigned in accordance with the treatment option that the participant is randomized to.
    - Once a participant is assigned a *Treatment ID*, that *Treatment ID* is never assigned again, even if treatment is not dispensed to the participant.

Dispensing Treatment

1. The accruing LAO or AO provides the *Participant ID* and *Treatment ID* to the pharmacist. In the case of a non-blinded study, the treatment assignment is also provided.

2. The pharmacist uses the *Treatment ID* list to verify what treatment assignment to dispense. The *Treatment ID* does not correspond to a specific bottle, package, or vial of the assigned treatment regimen. The pharmacist has three options for accessing the *Treatment ID* list associated with a study and accruing LAO or AO:
   - Each time a participant is enrolled, the pharmacist accesses the Treatment Assignments module in Stars and looks up the treatment assignment that should be dispensed to the participant based on the *Treatment ID*. The Treatment Assignments module enables the pharmacist to:
     - Verify that the participant was enrolled using Stars.
     - Verify the *Participant ID* and *Treatment ID* mapping provided by the accruing LAO or AO.
     - Verify the treatment assignment provided by the accruing LAO or AO (if non-blinded).
     - Obtain the treatment assignment (if blinded).
   - The pharmacist downloads the *Treatment ID* list from the Treatment Assignments module in Stars. Each time a participant is enrolled, the pharmacist uses the downloaded list to confirm that the *Treatment ID* is valid, and the treatment assignment provided by the accruing LAO or AO is correct (if non-blinded).
     Note: This option does not guarantee that the *Participant ID* and *Treatment ID* mapping is correct, but it does allow the pharmacist to confirm that the *Treatment ID* provided by the accruing LAO or AO is valid (which implies that the participant was enrolled using Stars) and (if non-blinded) that the treatment assignment provided by the accruing LAO or AO is correct.
   - A designee, who does not have any interaction with participants (even if the study is non-blinded), downloads the *Treatment ID* list from the Treatment Assignments module in Stars and provides it to the pharmacist. Each time a participant is enrolled, the pharmacist uses the list to confirm that the *Treatment ID* is valid, and the treatment assignment provided by the accruing LAO or AO is correct.
     Note: This option is discouraged as the pharmacist may not be able to reach the designee when a *Treatment ID* list needs to be downloaded. Also, this option does not guarantee that the *Participant ID* and *Treatment ID* mapping is correct, but it does allow the pharmacist to confirm that the *Treatment ID* provided by the accruing LAO or AO is valid (which implies that the participant was enrolled using Stars) and (if non-blinded) that the treatment assignment provided by the accruing LAO or AO is correct.
3. The pharmacist pulls from inventory any bottle, package, or vial that corresponds to the assigned treatment regimen.
   - If the study is randomized and blinded, the pharmacist ensures that the bottle, package, or vial does not have any information that reveals the identity of the assigned treatment regimen on the label.
4. 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.
5. The pharmacist dispenses the study agent.

Examples of Treatment IDs:

Study	Accruing LAO or AO	Treatment IDs
ABC02-01-02	YY444	ABC02-01-02 1001 through ABC02-01-02 1050
ABC02-01-02	YY555	ABC02-01-02 1051 through ABC02-01-02 1100
DEF02-01-02	YY555	DEF02-01-02 2176 through DEF02-01-02 2275

References

Resource	ID	Location
CP-CTNet Stars User Guide	USRMAN01	Program Resources
Summary of Enrollment Process	QKREFGD02	Program Resources