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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
6.1	24-Nov-2025	Updated the *Signing In* section to reflect the single sign-on process. Updated the Contact Us popup window screenshot to reflect the updated support schedule. Updated DMACC to DMASC and made minor editorial updates throughout the document.
6.0	28-Aug-2025	Made minor administrative updates to the cover page. Made minor editorial updates throughout the document.
5.0	24-Jan-2023	Updated screenshots to reflect the updated Stars homepage, removed references to *Screening ID* expiration, and made minor editorial updates.
4.0	06-Jul-2022	All screenshots and descriptions for pre-screening, screening, enrollment, reserve PIDs, treatment assignments, eligibility checklists, history and appendix sections were updated to reflect the most recent Stars update.
3.1	28-Jul-2021	The Treatment Assignments section was updated to be consistent with the *Summary of Enrollment Process* [CP-CTNet QKREFGD02] and *CP-CTNet Treatment ID Information* document.
3.0	08-Apr-2021	All screenshots and descriptions for pre-screening, screening, enrollment, eligibility checklists, history, and appendix sections were updated to reflect the most recent Stars update. Combined the Stars User Guide with the CP-CTNet Pre-Screen, Screen and Enrollment Procedures document. Added Reserve PIDs and Treatment Assignments Module sections.
2.0	08-Dec-2020	Section on participant ID assignment added. Screenshots of pre-screening, screening and enrollment removed. Changed timing of data exchange from five minutes to 2.
1.0	31-Jul-2020	Original version of the document.

CP-CTNet Stars User Guide

About Stars

Stars is the registration/randomization system used by sites to enroll participants onto studies and to obtain assignments of *Pre-Screen, Screening, Participant*, and *Treatment IDs* for participants. The application consists of a number of other modules pertaining to the enrollment process. The available modules are based on the project and user access. This user manual documents the Pre-Screening, Screening, and Enrollment process, including the assignment of *Pre-Screen, Screening, Participant*, and *Treatment IDs*.

Definitions

Term/Acronym	Definition
AO	Affiliated Organization
AQuIP	Accrual Quality Improvement Program
.csv	Comma-Separated Values
DCP	Division of Cancer Prevention
DM	Data Manager
DMASC	Data Management, Auditing, and Statistical Center
LAO	Lead Academic Organization
PI	Principal Investigator
PID	Participant Identification Number

Signing In

To access Stars:
1. Go to the CP-CTNet DMASC Portal Gateway.
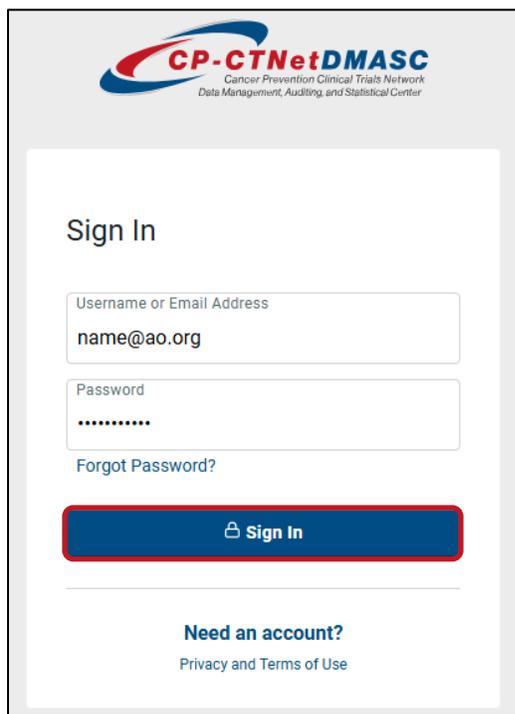2. Sign in with the user's CP-CTNet DMASC Portal Gateway username and password.

Figure 1: CP-CTNet DMASC Portal Gateway Sign In page.

3. Click **Open App** beneath the Stars tile on the dashboard.
    a. Click **More Details** beneath the Stars tile on the dashboard to see more information about Stars, Frequently Asked Questions, and Stars documentation and training materials (e.g., quick reference guides, video tutorials, etc.).
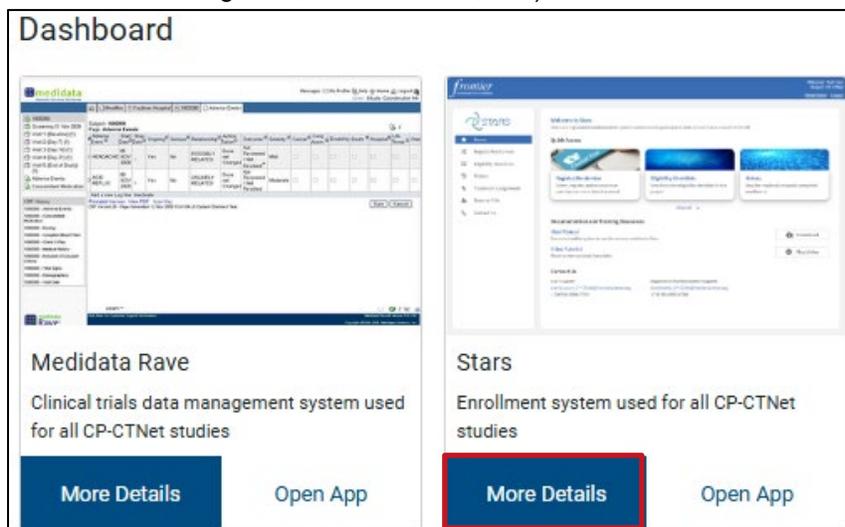

Figure 2: CP-CTNet DMASC Portal Gateway dashboard tiles.

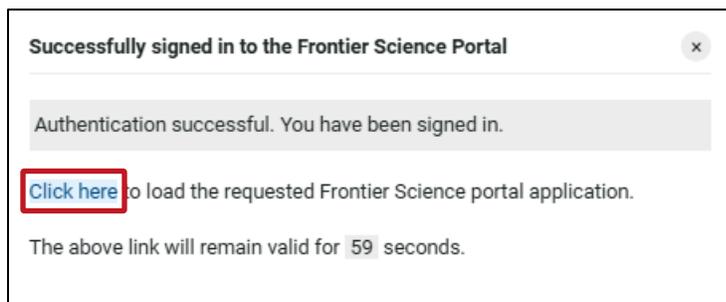4. Click the **Click here** link in the displayed single sign-on popup window to load Stars.

Figure 3: Single sign-on popup window.

Navigation

The Home screen contains Quick Access links to the modules that the user has approval for, along with documentation and training materials pertaining to Stars. Important announcements are displayed in a blue banner at the top of this page (when applicable). In addition to the Quick Access links, the user can also view and access each module that they are approved to access in the navigation menu on the left side of the Stars interface. This menu is always available and can be used to navigate between different steps during the enrollment process by clicking the name of the desired module.
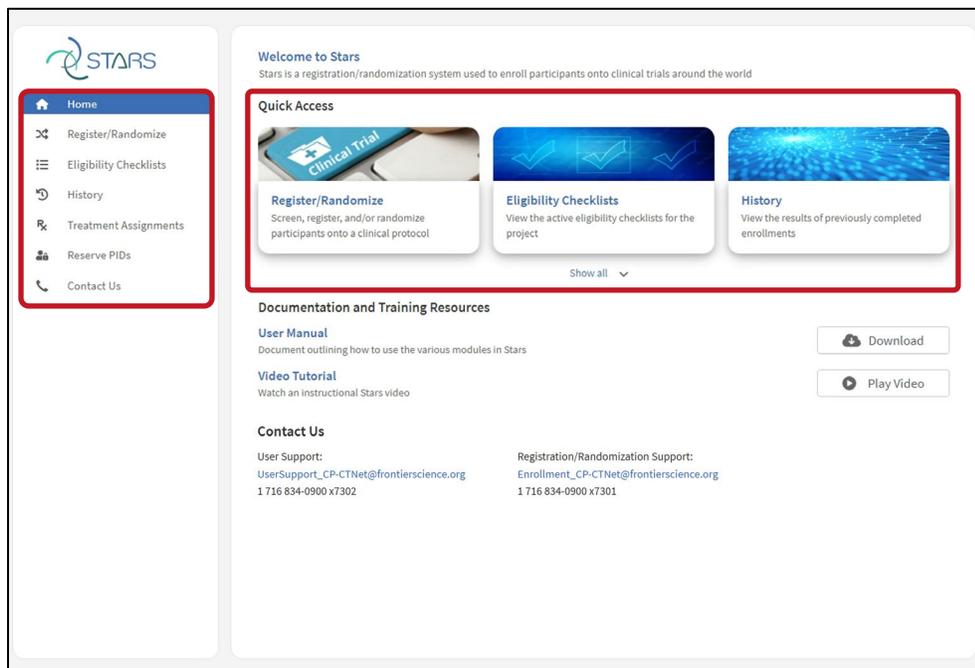
Figure 4: Stars homepage.

Register/Randomize Module

The Register/Randomize Module is used to pre-screen, screen, and enroll participants onto a study.

Getting Started page

The Getting Started page provides some basic information about the enrollment. Initially, the Institution (site) and Protocol (study) fields are displayed. Subsequent fields are dynamically displayed based on previous selections. When only one option is available, it is automatically pre-selected. All fields for the selected study must be completed before the **Continue** button will be enabled.

The Getting Started page uses the following fields, although certain fields may be omitted based on the configuration for a given project, protocol, and/or checklist:

Field	Usage
Institution	Select the site or institution.
Protocol	Select the study or protocol.
Version	Select the version of the protocol the institution is approved to enroll participants under.
Protocol Title	The Protocol Title is automatically displayed based on the protocol and version selections.
Checklist	Select the checklist to be completed (e.g., Pre-Screen, Screening, or Enrollment).
Checklist ID	Automatically displayed. This is a unique number used to identify the selected checklist. Subsequent updates to a checklist result in a new Checklist ID. This ID establishes a link between the specific checklist used for a given enrollment submission.
Pre-Screen	Enter the *Pre-Screen ID.*
Screening ID	Enter the *Screening ID.*

Figure 5: Register/Randomize, Getting Started page.

Note: Only the Institutions that the user is approved to enroll participants for are listed in the Institution dropdown menu.

Based on the Institution, the selections in the Protocol dropdown menu are populated based on the following criteria:

- User access

- Protocols currently open to accrual

- Protocols that the Institution received the necessary approvals to begin enrolling participants
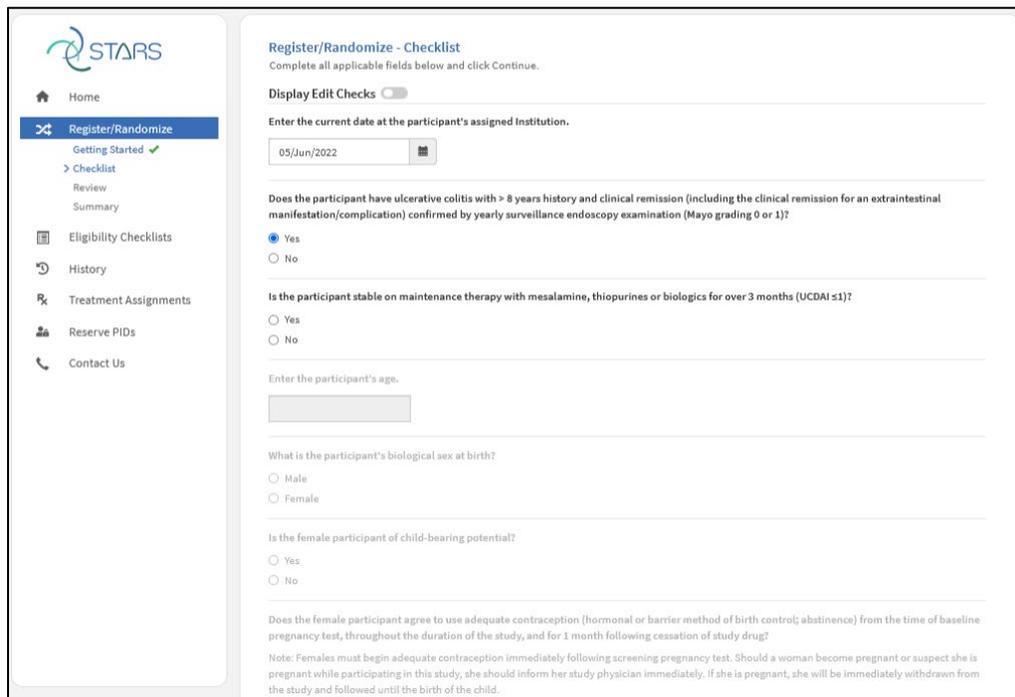
The Version dropdown menu displays the protocol versions that are currently active. If version control is enforced for the selected protocol, the version that the Institution is approved to is automatically displayed.

The checklists that are currently active are displayed in the dropdown menu.

Depending on the configuration for a given protocol and checklist, additional fields such as the Checklist ID, Participant ID, Pre-Screen ID, and/or Screening ID may also be displayed.

Checklist page

Checklists used in Stars are guided. Questions must be answered in order, and new questions are enabled as each question is answered.
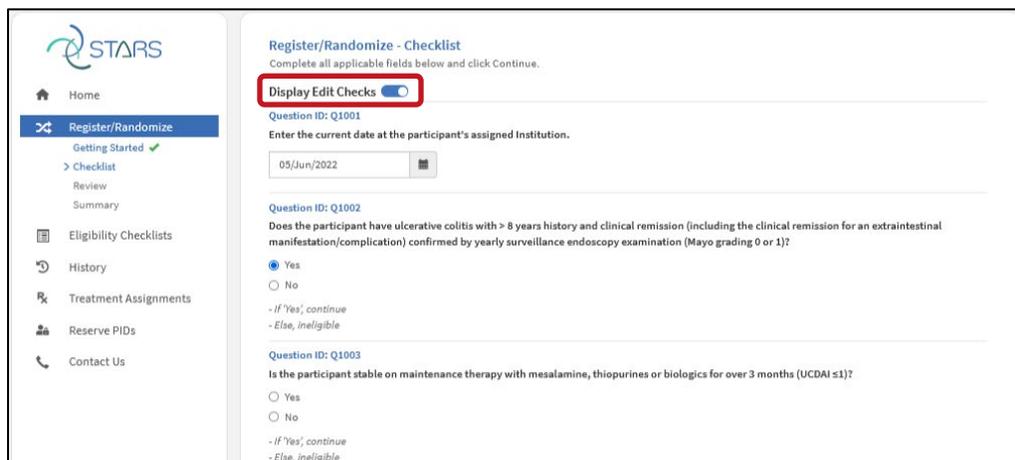

Figure 6: Register/Randomize, Checklist page.

Display Edit Checks

The Display Edit Checks toggle button, located at the top of the Checklist page, may be enabled to display the embedded edit checks within the checklist.

Figure 7: Register/Randomize, Checklist page, Display Edit Checks enabled.

Invalid responses are immediately reported

Stars shows an error for any answers that are not valid for the protocol. The error must be resolved before continuing with the checklist.

Figure 8: Register/Randomize, Checklist page, invalid response.

Responses may cause questions to be skipped

For some checklists, a specific response to a question may cause questions following it to be skipped. For example, if a question asks for the participant's biological sex at birth and Male is selected, subsequent questions relevant only to female participants are skipped. In these cases, the application automatically skips to the next appropriate question on the checklist.

Checklist must be completed

Incomplete checklists cannot be saved or submitted. All questions (not including optional and skipped questions) must be completed before a checklist can be submitted.

Review page

The Review page provides the user with the opportunity to review their selections/responses prior to submission. All the information should be verified for accuracy. Responses can be modified by clicking the Edit link for the applicable section.

Figure 9: Register/Randomize, Review page.

Summary page

The Summary page provides the results of the enrollment submission. The page also includes a copy of the checklist that was completed.

To download the confirmation file, click on the download (cloud) icon. An encrypted email message with the PDF confirmation file is also sent to the user for successful enrollments.

Figure 10: Register/Randomize, Summary page, enrollment success.

Note: If the enrollment was unsuccessful, the message at the top indicates the reason for the failure. The PDF confirmation file for an unsuccessful enrollment may also be downloaded.

Assignment and Reservation of Participant IDs

IDs consist of six digits starting at 1XXXXX and are increased sequentially as IDs are reserved by LAOs. This pool of IDs is shared across all accruing LAOs, AOs, and studies. Before a study opens and accruing LAOs and AOs enroll participants:

- LAOs use the Reserve PIDs Module in Stars to reserve IDs by study and accruing LAO or AO.

- LAOs specify the number of IDs they would like to reserve per accruing LAO and AO for a given study based on an accruing LAO's or AO's accrual projections.

- Stars allocates the IDs to the accruing LAO or AO and study, starting with the next available ID from the shared pool of IDs referenced above.

- Stars generates an Excel (.csv) file for the LAO containing the reserved IDs for the study and accruing LAO or AO.
  - The IDs in this file can be used for pre-generating labels.

Examples of ID Reservations:

LAO	Study	Accruing LAO or AO	# IDs Reserved	IDs
NWU	NWU20-01-02	XX111	40	100201 - 100240
NWU	NWU20-01-02	XX222	30	100241 - 100270

LAO	Study	Accruing LAO or AO	# IDs Reserved	IDs
NWU	NWU20-01-02	XX333	50	100271 - 100320
UAZ	UAZ20-03-04	YY444	100	100321 - 100420
UAZ	UAZ20-03-04	YY555	100	100421 - 100520
MDA	MDA20-01-02	ZZ666	15	100521 - 100535
MDA	MDA20-01-02	ZZ777	20	100536 - 100555
UAZ	UAZ20-03-04	YY444	10	100556 - 100565

Pre-Screen, Screening, and *Participant IDs* are assigned by Stars from the reserved pool of IDs for a given study and accruing LAO or AO. The same ID number for a participant carries over across all phases of the study, with the leading prefix ("PS" and "S") added to distinguish between *Pre-Screen* and *Screening IDs*.

Examples of ID Assignments:

Study	AO	Pre-Screen ID	Screening ID	Participant ID
UAZ20-03-04	YY555	PS100421	S100421, S100423 (re-screened)	100423
UAZ20-03-04	YY444	PS100321	S100321	100321
UAZ20-03-04	YY555	PS100422	S100422	100422
UAZ20-03-04	YY555	PS100424	S100424	100424
UAZ20-03-04	YY444	PS100322	S100322	100322

LAOs must reserve PIDs for each accruing LAO or AO before they can pre-screen, screen, or enroll participants for their site. If an accruing LAO or AO tries to enroll participants before PIDs are reserved, they receive an error message and cannot enroll participants until the LAO reserves PIDs for their site.

Once the study receives the DCP Approval on Hold letter, the LAO Coordinator or designee from the LAO is selected to reserve PIDs for the accruing LAO and AOs in the study. The LAO notifies the DMASC DMs (via DataManagement_CP-CTNet@frontierscience.org) of the designee's name and email.

Note: The LAO designee must have a CP-CTNet DMASC Portal Gateway account. DMASC then grants the LAO designee access to the Reserve PIDs Module in Stars. Once access is granted, the LAO designee:

1. Selects the Reserve PIDs Module from the Navigation Menu or Quick Access links.

2. Selects the protocol they are reserving PIDs for from the Protocol selection box.

   a. The LAO designee only has access to their specific CP-CTNet protocols.
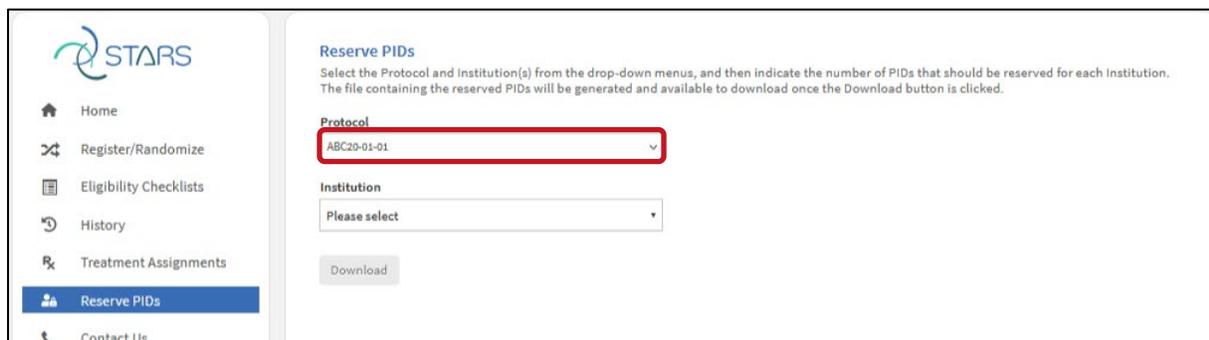

Figure 11: Select the protocol on the Reserve PIDs Module homepage.

3. Clicks the Institution selection box. A dropdown list of available accruing LAOs and AOs is displayed.

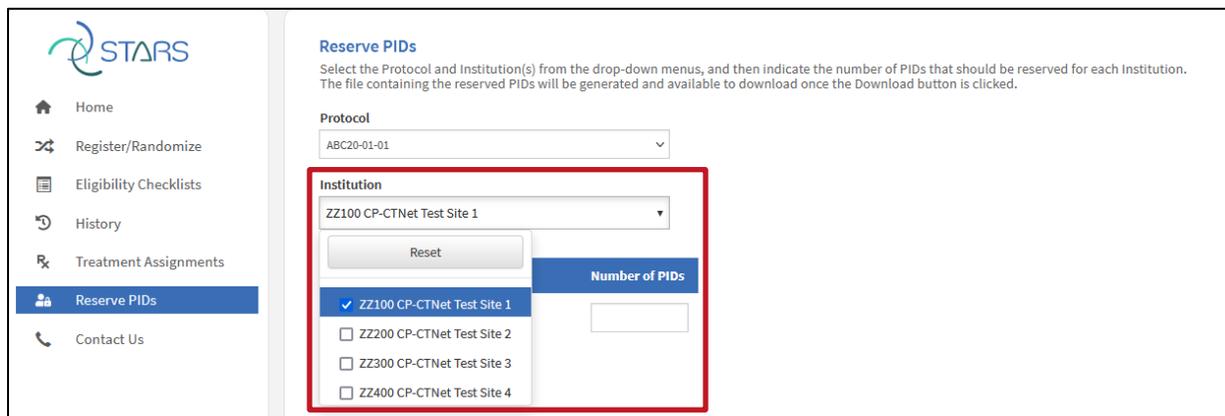4. Selects the desired site(s) from the Institution selection box.

Figure 12: Select the accruing LAO(s) and/or AO(s) that need PIDs reserved.

5. Clicks in the white space outside of the site dropdown list to refresh the page and complete the selection.

6. The accruing LAO and/or AO is displayed next to a field for entering the number of PIDs needed for each accruing LAO and/or AO.

    a. The LAO designee enters the number of PIDs to reserve for each accruing LAO and/or AO and clicks **Download**.
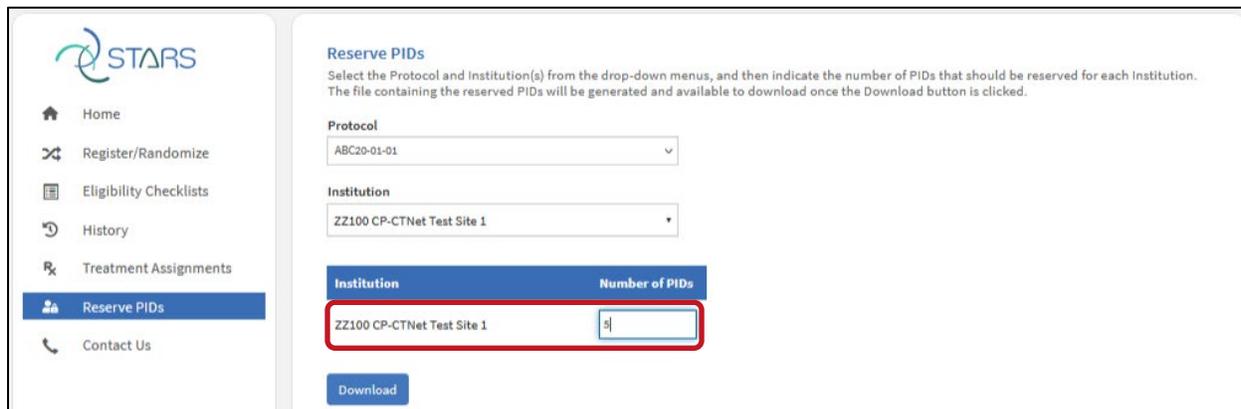
Figure 13: Enter the number of PIDs to reserve for the accruing LAO(s) and/or AO(s).

A message confirming the PIDs reservation is displayed and the associated .csv file is available to review. The .csv file is either downloaded automatically or the user is prompted to open or save the file. If the user's browser is configured to automatically download files, they can find the file in their browser-designated download folder. When opened, the .csv file displays three columns with the Protocol (study number), Institution (accruing LAO and/or AO), and PIDs that were reserved with the submission.

If the LAO designee is reserving PIDs for multiple sites, the first site (alphabetically) is listed with the associated PIDs (one row per PID). The next site is listed with the associated PIDs (one row per PID), and so on. When sites start the enrollment process in Stars, the IDs are assigned sequentially by Stars from this reserved pool of IDs for a given study and accruing LAO or AO.

Figure 14: Summary page and downloaded .csv file.

Treatment Assignments

When an accruing LAO or AO enrolls a participant, Stars assigns a *Participant ID*. If a 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 for the protocol.

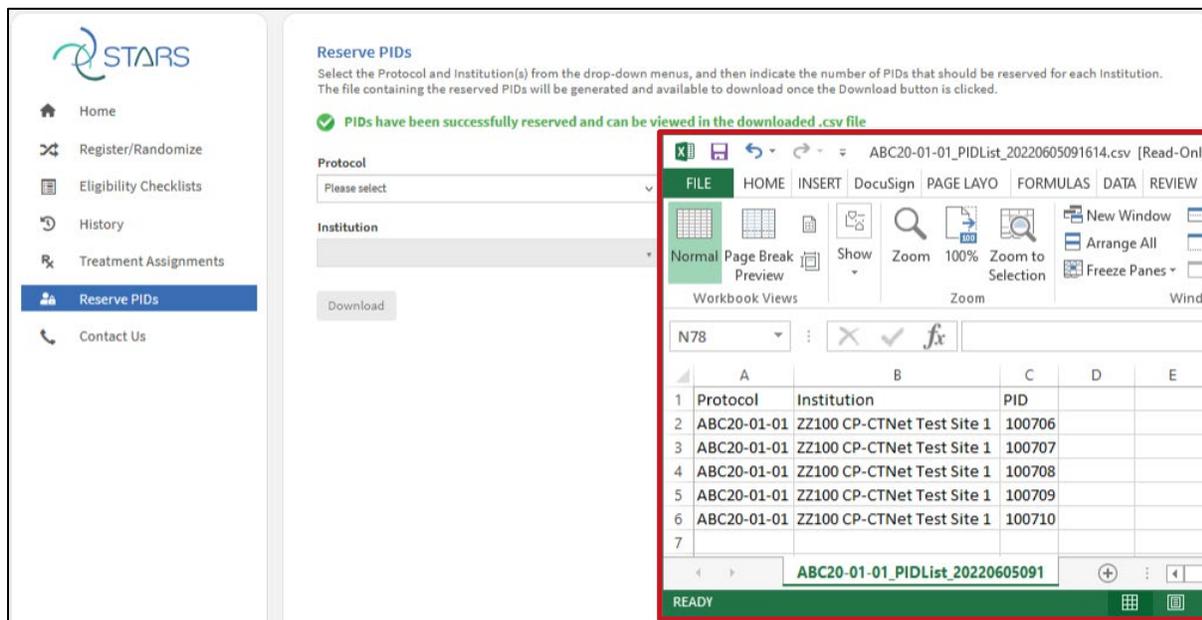A set of *Treatment IDs* is allocated for each study and accruing LAO and AO by DMASC prior to the opening of a study involving an intervention or investigational agent. The number of *Treatment IDs* that are allocated for a study and accruing LAO or AO varies depending on the projected accrual for a given study.

Examples of Allocated Treatment IDs:

Study	Site	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

Treatment IDs are assigned in a sequential order for a given study and accruing LAO or AO, only if the study is open-label, single arm. For randomized studies, *Treatment IDs* are assigned in accordance with the treatment option (intervention/investigational agent) that the participant is randomized to.

Before the sites begin enrolling, the LAO Coordinator or designee proxy requests access to the Stars Treatment Assignments Module on behalf of the site pharmacist(s) via the CP-CTNet DMASC Portal Gateway. The Treatment Assignments Module is used to verify what study agent to dispense. DMASC grants access to the Treatment Assignments Module in Stars. Once access is granted, the site pharmacist may determine the treatment assignments by viewing them in Stars. The site pharmacist may also download the entire Treatment Assignment File, or a sub-set of the list, by following the steps below:

1. Select the Treatment Assignments Module from the Navigation Menu or Quick Access links.

2. Select the desired Institution.
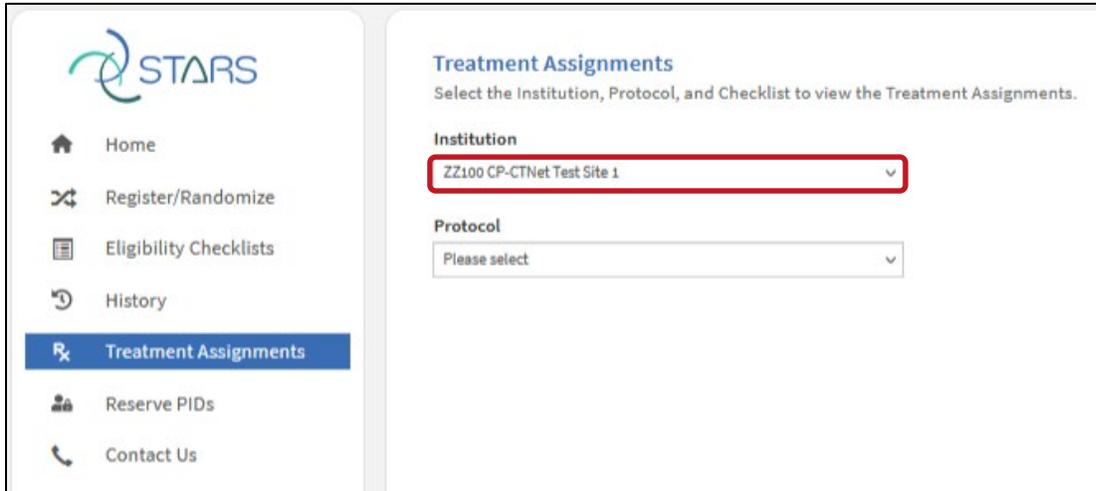
Figure 15: Treatment Assignments Module home page, Institution selected.

3. Select the desired protocol.
4. The treatment assignment list is automatically displayed based on the selections made above.
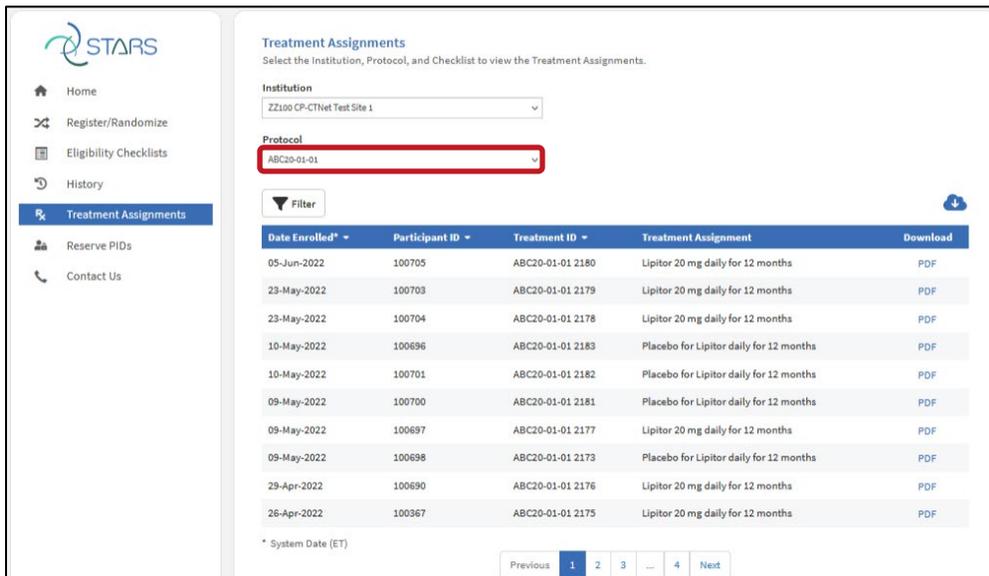
Figure 16: Treatment Assignments Module home page, Protocol selected.

Note: The displayed results may be narrowed by completing one or more of the available filter fields. Click the **Filter** button to display the available filter fields. The *Start Date* and *End Date* filters limit the displayed treatment assignments to participants that were enrolled within the specified date range. The *Participant ID* and *Treatment ID* fields may be used to search for a specific participant or treatment assignment. If filters are applied, the downloaded results are restricted to the filtered results.
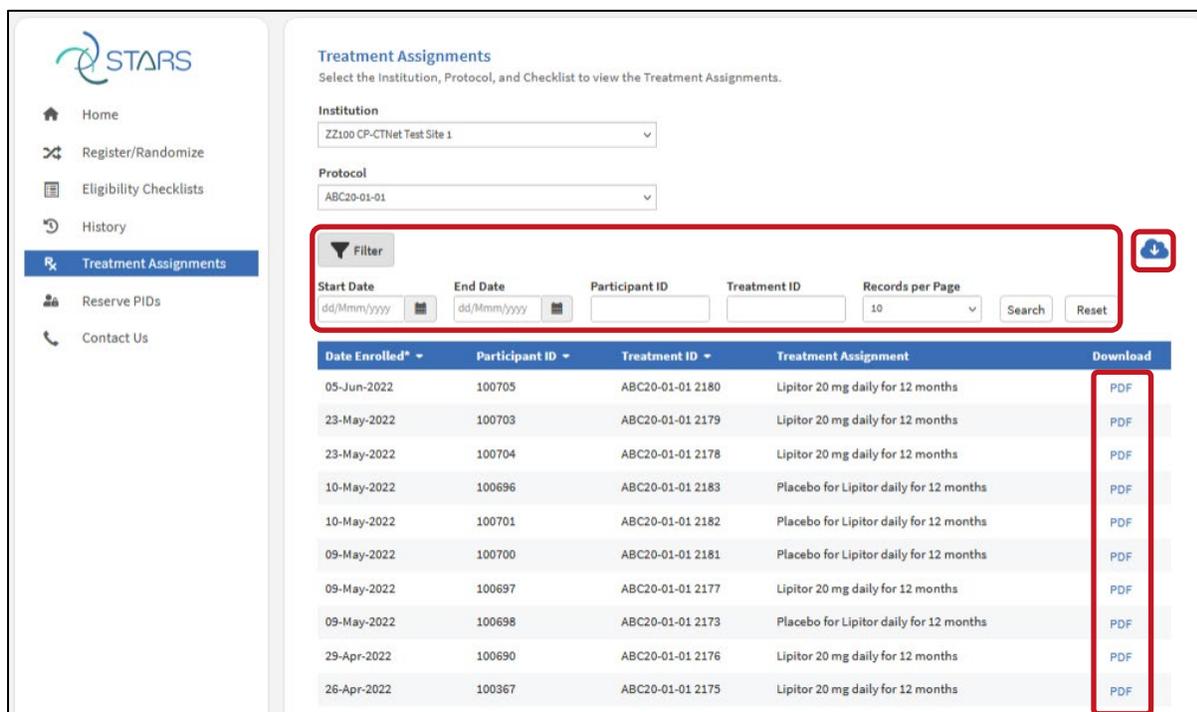
Figure 17: Treatment Assignments Module home page, Filters displayed.

5. Download individual participant results by clicking the *PDF* link beneath the *Download* column.

6. Download the Treatment Assignment File by clicking the download (cloud) icon.

The Treatment Assignment File maps *Treatment IDs* to the participant's assigned intervention. It includes *Treatment IDs* that have been assigned to a participant and *Treatment IDs* that have not yet been assigned to a participant. The interventions that have been assigned to a participant include the *Date Enrolled, Participant ID, Treatment ID,* and *Treatment Assignment*, whereas the interventions that have not yet been assigned only include the *Treatment ID* and *Treatment Assignment*.

As participants are enrolled or randomized onto a study involving an intervention or investigational agent, the accruing LAO or AO provides the *Participant ID* and *Treatment ID* to the site pharmacist. In the case of a non-blinded study, the treatment information is also provided.

The *Treatment ID* does not correspond to a specific bottle or package of study agent. The site pharmacist uses the Treatment Assignments Module in Stars to verify the study agent that should be dispensed to the participant based on the *Treatment ID*. Then, the site pharmacist pulls from inventory any bottle or package that corresponds to the assigned study agent, selects the appropriate over-label (as applicable), handwrites the *Participant ID*, participant initials, and date on the label, and places it on the bottle or package of study agent to be dispensed to the participant. If the study is randomized and blinded, the pharmacist ensures that the bottle or package does not have any information that reveals the identity of the assigned study agent on the label. The site pharmacist dispenses the study agent.

Note: Site pharmacists may log into Stars before the study starts and download all available treatment assignments on one list and then compare the list once the *Participant IDs* and *Treatment IDs* are sent by the accruing LAO or AO. Alternatively, they may log into Stars to verify what study agent to dispense once they receive the *Participant ID* and *Treatment ID*.

Pre-Screening

During protocol development, the PI and study team select a small subset of the protocol eligibility criteria to identify individuals for pre-screening via medical record review. Before the pre-screening activity (which is further medical record review to determine eligibility for contact) may take place, a *Pre-Screen ID* is obtained within Stars for individuals that are determined to be eligible for pre-screening.

Note: The pre-screening process that takes place within Stars and Rave relates to obtaining pre-screening data that are used for AQuIP reporting.

1. Select the Institution, Protocol, and Version in Stars. If the user only has access to one institution, protocol, and/or version, the associated fields are automatically pre-selected.

2. Select the Pre-Screen Checklist from the dropdown on the Getting Started page.

3. Click **Continue**.

Note: The Protocol dropdown menu only includes studies that are open to accrual and have been granted accruing LAO or AO enrollment access by DMASC.

Register/Randomize - Getting Started
To begin your submission, complete all fields below and click Continue. The active protocols that the selected Institution are approved to will be displayed in the Protocol field.

Institution
ZZ100 CP-CTNet Test Site 1

Protocol
ABC20-01-01

Version
1.0

Protocol Title
Demo study for CP-CTNet

Checklist
Pre-Screen

Checklist ID
ABC20-01-01-PS1001

Continue

Figure 18: Getting Started page, Pre-Screen.

4. Enter the current date and the date the participant was pre-screened.
5. Click **Continue**.

Register/Randomize - Checklist
Complete all applicable fields below and click Continue.

Display Edit Checks

Enter the current date at the participant's assigned Institution.

05/Jun/2022

Enter the date the participant was pre-screened/recruited for this protocol.

05/Jun/2022

Continue

Figure 19: Pre-Screen Checklist.

6. Review the entered responses on the Review page.
7. Click **Submit** to assign a *Pre-Screen ID*.

Register/Randomize - Review

Review the information below. Responses can be modified by clicking Edit for the applicable section. Once all information has been confirmed for accuracy, click the Submit button.

Getting Started Edit ✏

Protocol	ABC20-01-01
Version	1.0
Checklist	Pre-Screen
Checklist ID	ABC20-01-01-PS1001
Institution	ZZ100 CP-CTNet Test Site 1

Checklist Edit ✏

Enter the current date at the participant's assigned Institution.

05/Jun/2022 📅

Enter the date the participant was pre-screened/recruited for this protocol.

05/Jun/2022 📅

Submit

Figure 20: Review page.

Register/Randomize - Summary

The result of your submission is below, and a confirmation file has been sent to the email address linked to this account. You can also view or download the PDF confirmation file be clicking on the icon below. To start a new submission, click on the Register/Randomize link in the navigation pane.

✅ **Pre-Screen ID assigned**   ☁

Overview

Pre-Screen ID	PS100706
Protocol	ABC20-01-01
Version	1.0
Checklist	Pre-Screen
Checklist ID	ABC20-01-01-PS1001
Institution	ZZ100 CP-CTNet Test Site 1
User	krolikowski.alex
Date	05/Jun/2022 09:50:11 ET (GMT -04:00)
Confirmation Number	1154
Message	Please enter the remaining Pre-Screen information in Rave. Click here to access Rave

Checklist

Question ID: Q1001

Enter the current date at the participant's assigned Institution.

05/Jun/2022 📅

Figure 21: Pre-Screen Summary page.

The Summary page provides the results of the pre-screen submission and the assigned *Pre-Screen ID* (e.g., PS100706). The page also includes a copy of the checklist that was completed. To download the confirmation file, click on the download (cloud) icon. An encrypted email message with the PDF confirmation file is sent to the user and designated staff at the LAO for successful submissions. A link is provided at the bottom of the Overview section for the user to access Rave and enter the remaining pre-screen information.

Within two minutes, the pre-screen information that was entered into Stars is automatically data exchanged and is available in Rave under the specific study number (e.g., ABC20-01-01). The user logs into Rave, clicks on the study number, selects their site, finds the assigned *Pre-Screen ID* for the participant, and enters 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. If the user only has access to one institution, protocol, and/or version, the associated fields are automatically pre-selected.

2. Select the Screening Checklist from the dropdown on the Getting Started page.

3. Enter the previously assigned *Pre-Screen ID* for the participant.

4. Click **Continue**.

Register/Randomize - Getting Started
To begin your submission, complete all fields below and click Continue. The active protocols that the selected Institution are approved to will be displayed in the Protocol field.

Institution
ZZ100 CP-CTNet Test Site 1

Protocol
ABC20-01-01

Version
1.0

Protocol Title
Demo study for CP-CTNet

Checklist
Screening

Checklist ID
ABC20-01-01-S0001

Pre-Screen ID
PS100706

Continue

Figure 22: Getting Started page, Screening.

5. If the participant *was not* previously assigned a *Screening ID* for this study, select the radio button for **No** on the Checklist page for the question, "Was the participant previously assigned a *Screening ID* for this Protocol?"

If the participant *was* previously assigned a *Screening ID* for this study, select the radio button for **Yes** on the Checklist page for the question, "Was the participant previously assigned a *Screening ID* for this Protocol?" and enter the participant's previously assigned *Screening ID*.

Figure 23: Screening Checklist.

6. If the informed consent document was not signed, select the radio button for **No** on the Checklist page for the question, "Was the informed consent document signed?" If **No** is selected for this question, a red error message appears, and the checklist cannot be completed.

    If the informed consent document was signed, select the radio button for **Yes** on the Checklist page for the question, "Was the informed consent document signed?"

7. Click **Continue.**

8. Review the entered responses on the Review page.

9. Click **Submit** to assign a *Screening ID*.

Figure 24: Review page.

Figure 25: Screening Summary page.

The Summary page provides the results of the screening submission and the *Screening ID* (e.g., S100076). The page also includes a copy of the checklist that was completed. To download the confirmation file, click on the download (cloud) icon. An encrypted email message with the PDF confirmation file is sent to the user and designated staff at the LAO for successful submissions. A link is provided at the bottom of the Overview section for the user to access Rave and enter the remaining screening information.

Within two minutes, the screening information that was entered into Stars is automatically data exchanged and is available in Rave under the specific study number (e.g., ABC20-01-01). The *Patient ID* in Rave is changed from the *Pre-Screen ID* to the *Screening ID*. The user logs into Rave, clicks on the study, selects their site, finds the assigned *Screening ID* for the participant, and enters 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

  o AQuIP-related data such as screening date(s)

If the participant fails screening, the participant may be re-screened (as applicable). This involves obtaining another *Screening ID* for the participant. This is done by using the Screening Checklist again in Stars as outlined above.

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. If the user only has access to one institution, protocol, and/or version, the associated fields are automatically pre-selected.

2. Select the Enrollment Checklist from the dropdown on the Getting Started page.

3. Enter the previously assigned *Screening ID* for the participant.

4. Click **Continue**.

Figure 26: Getting Started page, Enrollment.

5. The Enrollment Checklist appears. This checklist contains the eligibility criteria for the study.
6. Select the appropriate radio buttons for each question. If an answer disqualifies the participant for the study, a red error message appears. If an error message appears, the checklist cannot be completed, and the participant cannot be enrolled.

Figure 27: Enrollment edit check.

7. If all eligibility criteria are met, provide a response to the question "Did two individuals sign and date the eligibility checklist with at least one of the two individuals being a registered investigator (IVR) or non-physician investigator (NPIVR)?"

    If **No** is selected for this question, a red error message appears, and the checklist cannot be completed.

    If **Yes** is selected for this question, proceed to the next checklist question.

Figure 28: Eligibility verification checklist question.

8. Enter the names of the registered IVR(s), NPIVR(s), and/or the individual that verified eligibility for this participant in the appropriate checklist response fields. A unique name must be provided in each field.

Question ID: Q1014

Enter the name of the registered investigator (IVR) or non-physician investigator (NPIVR) who signed and dated the eligibility checklist (wet or electronic) for this participant.

Note: If both individuals are a registered investigator (IVR) or a non-physician investigator (NPIVR), enter one name in this question and the other name in the question below.

Jane Smith

Question ID: Q1015

Enter the name of the other individual who signed and dated the eligibility checklist (wet or electronic) for this participant.

Sean Samuel

Figure 29: Names of the eligibility verification signatories.

9. If the full checklist can be completed for a participant, click **Continue**.

Question ID: Q1015

Enter the name of the other individual who signed and dated the eligibility checklist (wet or electronic) for this participant.

Sean Samuel

Continue

Figure 30: Continue button on the Enrollment checklist.

10. Review the entered responses on the Review page.

Register/Randomize - Review

Review the information below. Responses can be modified by clicking Edit for the applicable section. Once all information has been confirmed for accuracy, click the Submit button.

Getting Started Edit ✏

Protocol	ABC20-01-01
Version	1.0
Checklist	Enrollment
Checklist ID	ABC20-01-01-0101
Institution	ZZ100 CP-CTNet Test Site 1
Screening ID	S100706

Checklist Edit ✏

Enter the current date at the participant's assigned Institution.

05/Jun/2022

Does the participant have ulcerative colitis with > 8 years history and clinical remission (including the clinical remission for an extraintestinal manifestation/complication) confirmed by yearly surveillance endoscopy examination (Mayo grading 0 or 1)?

◉ Yes
○ No

Is the participant stable on maintenance therapy with mesalamine, thiopurines or biologics for over 3 months (UCDAI ≤1)?

◉ Yes
○ No

Figure 31: Review page.

11. Click **Submit**.

Enter the name of the registered investigator (IVR) or non-physician investigator (NPIVR) who signed and dated the eligibility checklist (wet or electronic) for this participant.

Note: If both individuals are a registered investigator (IVR) or a non-physician investigator (NPIVR), enter one name in this question and the other name in the question below.

Jane Smith

Enter the name of the other individual who signed and dated the eligibility checklist (wet or electronic) for this participant.

Sean Samuel

Submit

Figure 32: Submit button on the Review page.

The Summary page provides the results of the submission, the *Participant ID* (e.g., 100076), and the *Treatment ID* (e.g., ABC20-01-01 2184), if applicable. The page also includes a copy of the checklist that was completed. To download the confirmation file, click on the download (cloud) icon. An encrypted email message with the PDF confirmation file is sent to the user and designated staff at the LAO for successful submissions.

Register/Randomize - Summary

The result of your submission is below, and a confirmation file has been sent to the email address linked to this account. You can also view or download the PDF confirmation file be clicking on the icon below. To start a new submission, click on the Register/Randomize link in the navigation pane.

✅ **Participant successfully enrolled**

Overview

Participant ID	100706
Screening ID	S100706
Protocol	ABC20-01-01
Version	1.0
Checklist	Enrollment
Checklist ID	ABC20-01-01-0101
Institution	ZZ100 CP-CTNet Test Site 1
User	krolikowski.alex
Date	05/Jun/2022 10:28:24 ET (GMT -04:00)
Treatment ID	ABC20-01-01 2184
Treatment Regimen	Blinded. Provide the Participant ID and Treatment ID to your pharmacist.

Checklist

Question ID: Q1001

Enter the current date at the participant's assigned Institution.

05/Jun/2022

Question ID: Q1002

Does the participant have ulcerative colitis with > 8 years history and clinical remission (including the clinical remission for an extraintestinal manifestation/complication) confirmed by yearly surveillance endoscopy examination (Mayo grading 0 or 1)?

◉ Yes
○ No

Figure 33: Enrollment Summary page.

Within two minutes, the randomization information that was entered into Stars is automatically data exchanged and is available in Rave under the specific study number (e.g., ABC20-01-01). The *Patient 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, select their site, find the assigned *Participant ID* for the participant, and enter all the study-specific data for the participant as the participant moves through the study.

Eligibility Checklists

To download an eligibility checklist, click *Eligibility Checklists* on the sidebar. Active checklists are available based on the user's access, regardless of the site's current approval status for enrolling participants onto a study. Checklists include the questions and corresponding edit checks built into the checklist.

Figure 34: Eligibility Checklists Module.

History

The History Module shows a list of previously completed enrollments. Click the Filter button to display and use filters to find a specific enrollment. To view a PDF of the summary page, click the *PDF* link for the enrollment in the *Download* column.

Figure 35: History Module.

Contact Us

The Contact Us popup window is available to all users and is a quick reference guide to the schedule and contact information for Registration/Randomization Support and User Support.

Figure 36: Contact Us popup window.
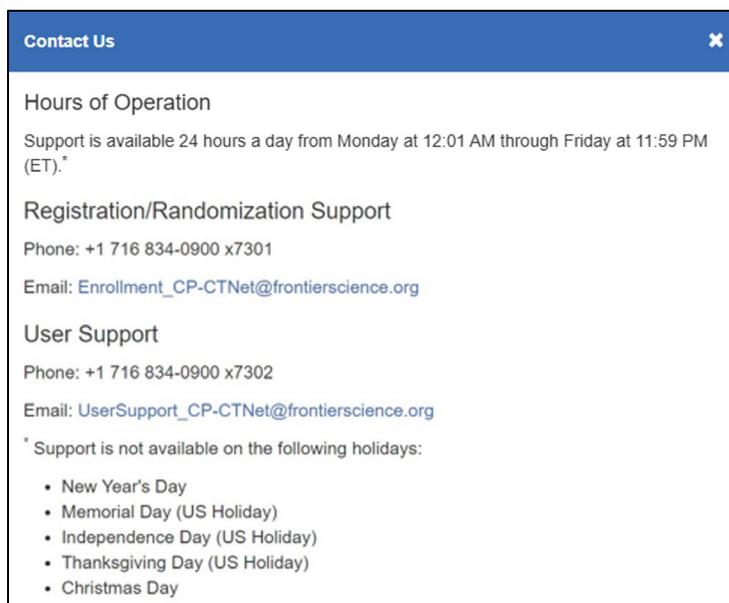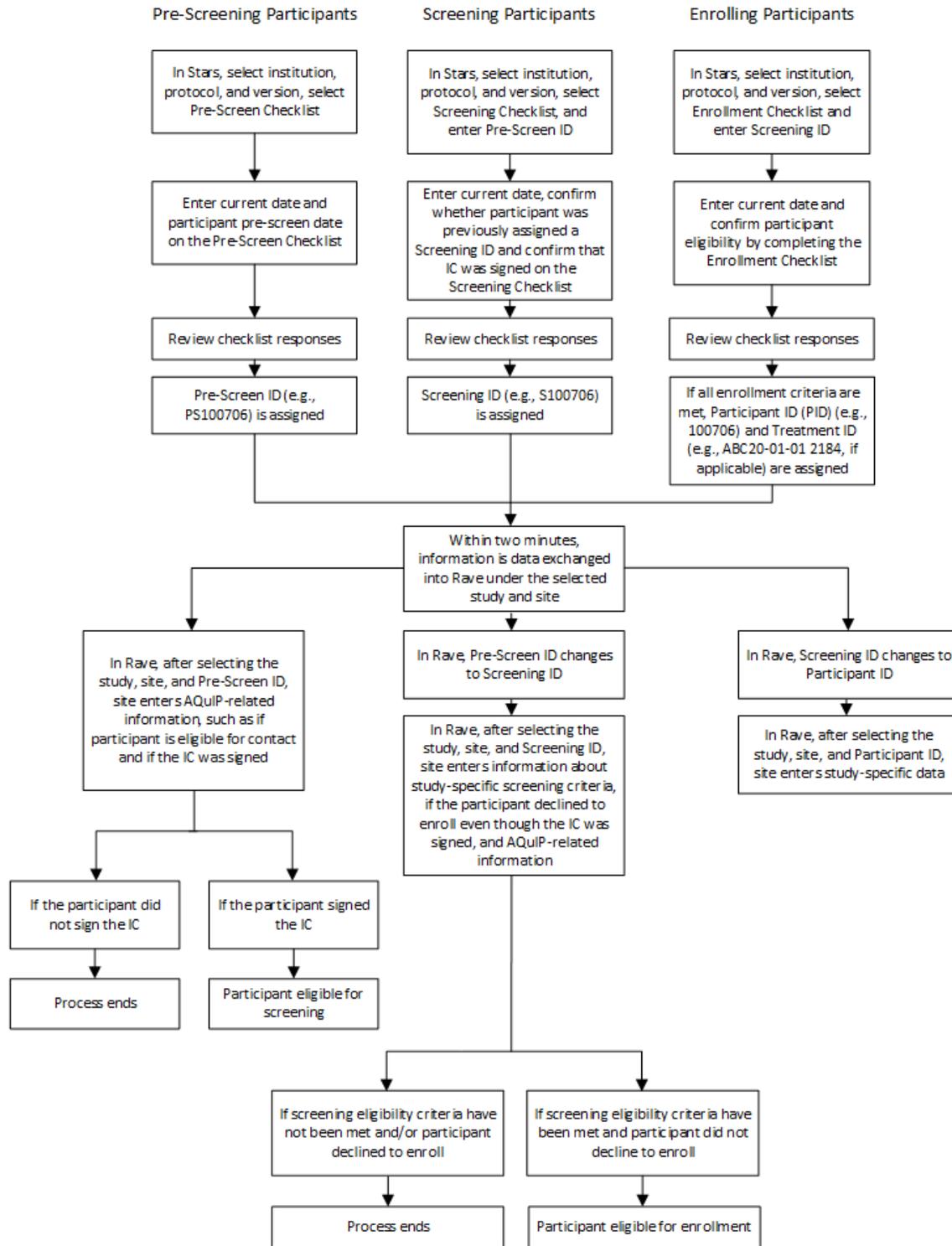
For assistance using Stars, contact *Registration/Randomization Support*.

- **Email:** Enrollment_CP-CTNet@frontierscience.org
- **Phone:** (716) 834-0900, extension 7301

For general assistance using the CP-CTNet DMASC Portal Gateway, including account and access issues, contact *User Support*.

- **Email:** UserSupport_CP-CTNet@frontierscience.org
- **Phone:** (716) 834-0900, extension 7302

Appendix I

CP-CTNet Pre-Screen, Screening, and Enrollment Procedures

Pre-Screening Participants	Screening Participants	Enrolling Participants
In Stars, select institution, protocol, and version, select Pre-Screen Checklist	In Stars, select institution, protocol, and version, select Screening Checklist, and enter Pre-Screen ID	In Stars, select institution, protocol, and version, select Enrollment Checklist and enter Screening ID
Enter current date and participant pre-screen date on the Pre-Screen Checklist	Enter current date, confirm whether participant was previously assigned a Screening ID and confirm that IC was signed on the Screening Checklist	Enter current date and confirm participant eligibility by completing the Enrollment Checklist
Review checklist responses	Review checklist responses	Review checklist responses
Pre-Screen ID (e.g., PS100706) is assigned	Screening ID (e.g., S100706) is assigned	If all enrollment criteria are met, Participant ID (PID) (e.g., 100706) and Treatment ID (e.g., ABC20-01-01 2184, if applicable) are assigned

Within two minutes, information is data exchanged into Rave under the selected study and site

In Rave, after selecting the study, site, and Pre-Screen ID, site enters AQuIP-related information, such as if participant is eligible for contact and if the IC was signed	In Rave, Pre-Screen ID changes to Screening ID	In Rave, Screening ID changes to Participant ID
	In Rave, after selecting the study, site, and Screening ID, site enters information about study-specific screening criteria, if the participant declined to enroll even though the IC was signed, and AQuIP-related information	In Rave, after selecting the study, site, and Participant ID, site enters study-specific data

If the participant did not sign the IC → Process ends

If the participant signed the IC → Participant eligible for screening

If screening eligibility criteria have not been met and/or participant declined to enroll → Process ends

If screening eligibility criteria have been met and participant did not decline to enroll → Participant eligible for enrollment

*If the participant is found to be ineligible, the participant may be screened again and, if screening criteria are met, receive a new Screening ID that is linked to the original Screening ID.

V9.0 24Jan23

CP-CTNet_USRMAN01 Stars User Guide_v6_1

Final Audit Report   2025-11-10

Created:	2025-11-10
By:	Alex Krolikowski (krolik@frontierscience.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAtIUdUiQwh7DavLZdOIGpwll-vJmqyaUu

"CP-CTNet_USRMAN01 Stars User Guide_v6_1" History

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