

Title: CP-CTNet Stars User Guide

Document ID: CP-CTNet USRMAN01

Version: 5.0

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Date Version is Effective: February 7, 2023

Date Reviewed: January 24, 2023

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Revision History

Version	Date	Summary
5.0	24 January 2023	Updated screenshots to reflect the updated Stars homepage, removed references to <i>Screening ID</i> expiration, and made minor editorial updates.
4.0	06 July 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 July 2021	The Treatment Assignments section was updated to be consistent with the <i>Summary of Enrollment Process</i> [CP-CTNet QKREFGD02] and <i>CP-CTNet Treatment ID Information</i> document.
3.0	08 April 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 December 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 July 2020	Original version of the document.

CP-CTNet Stars User Guide

About Stars.....	2
Definitions.....	2
Logging In.....	2
Navigation	4
Register/Randomize Module.....	4
Assignment and Reservation of Participant IDs.....	8
Treatment Assignments	11
Pre-Screening.....	14
Screening.....	16
Enrollment.....	18
Eligibility Checklists.....	23
History	23
Contact Us.....	24
Appendix I.....	25

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
AQulP	Accrual Quality Improvement Program
.csv	Comma-Separated Values
DCP	Division of Cancer Prevention
DM	Data Manager
LAO	Lead Academic Organization
PI	Principal Investigator
PID	Participant Identification Number

Logging In

To access Stars:

1. Go to the [CP-CTNet DMACC Portal Gateway](#).
2. Log in with user's Portal Gateway username and password.

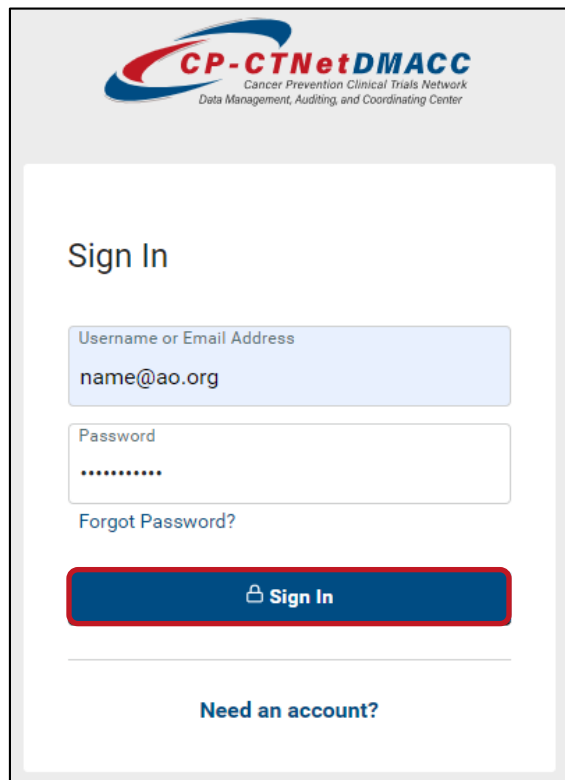


Figure 1: DMACC Portal Gateway Sign In page

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

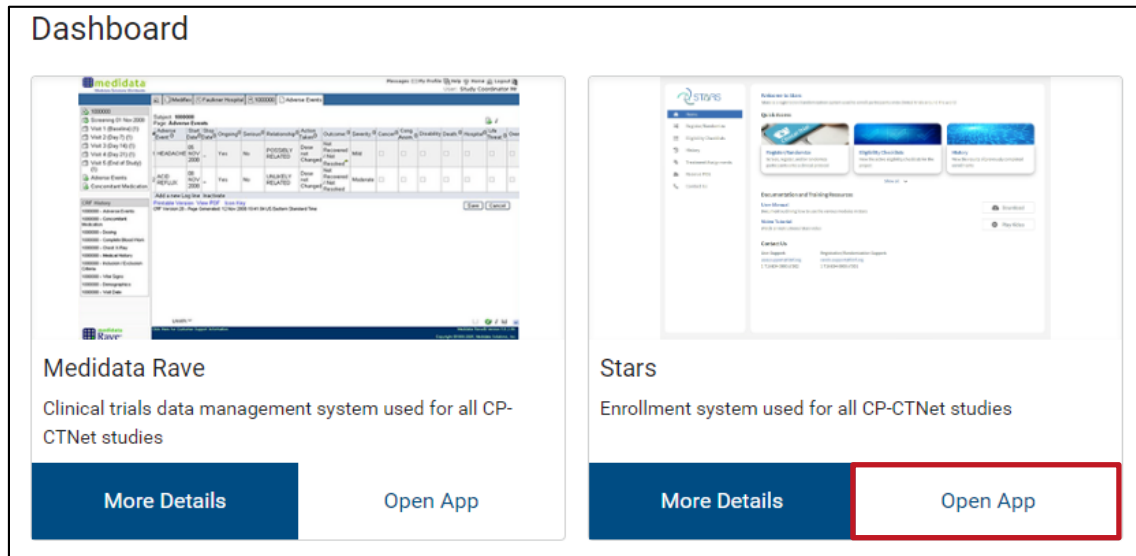


Figure 2: CP-CTNet DMACC Portal Gateway dashboard tiles

4. Log in to the Frontier Science Portal with user's Portal Gateway username and password.

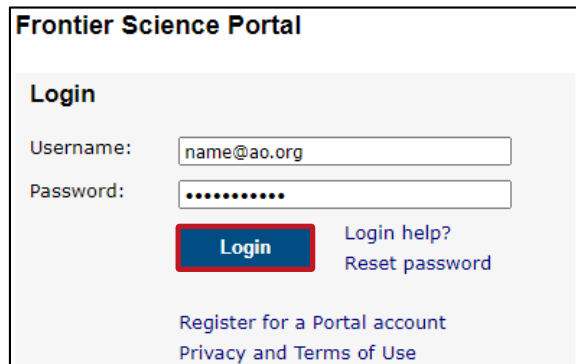


Figure 3: Frontier Science Portal Login page

5. Click the *Stars Registration/Randomization* link to open Stars.

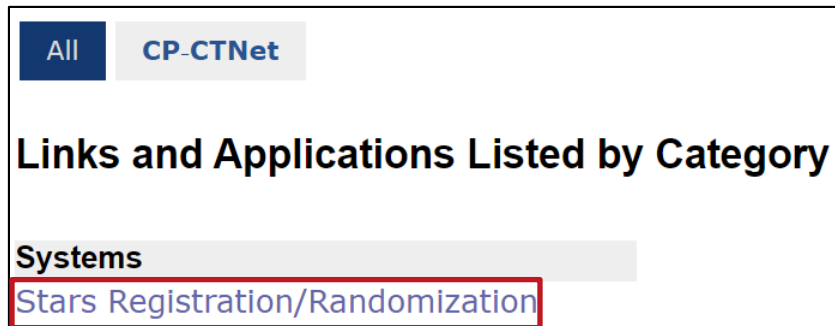


Figure 4: Stars Registration/Randomization under the CP-CTNet tab on the Frontier Science Portal

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.

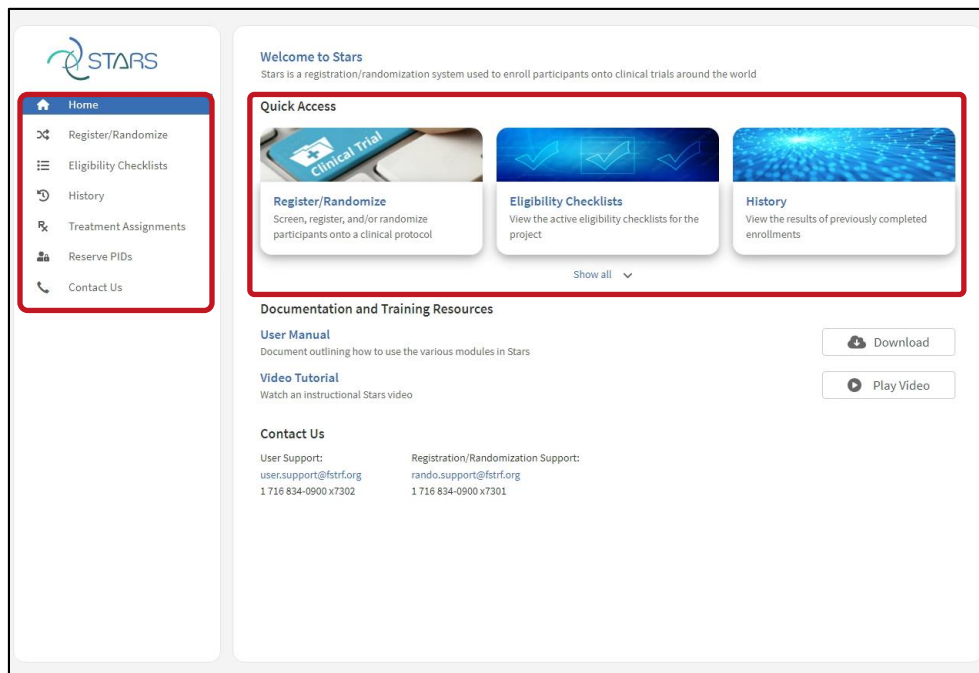


Figure 5: Stars Homepage

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).

Field	Usage
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 <i>Pre-Screen ID</i> .
Screening ID	Enter the <i>Screening ID</i> .

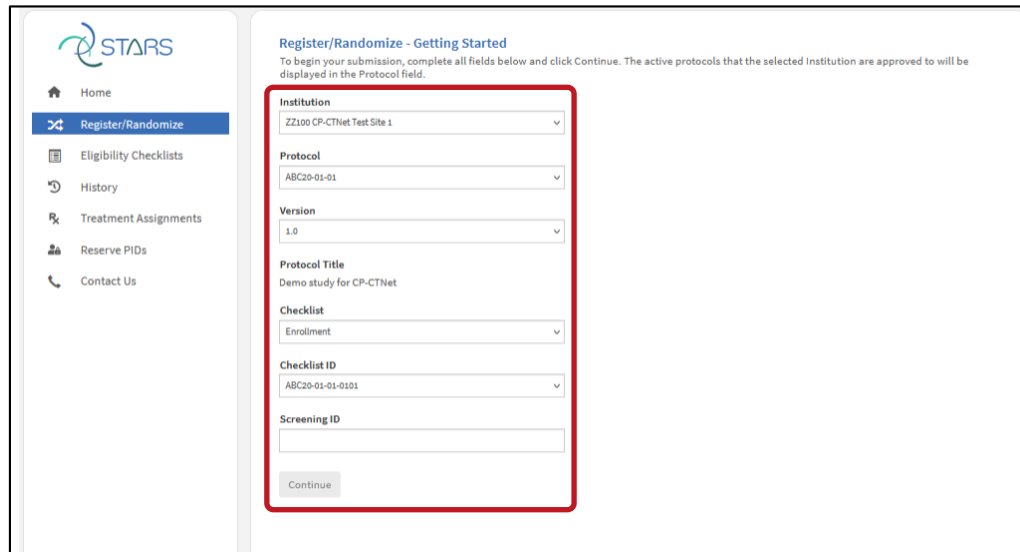


Figure 6: Register/Randomize, Getting Started page

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

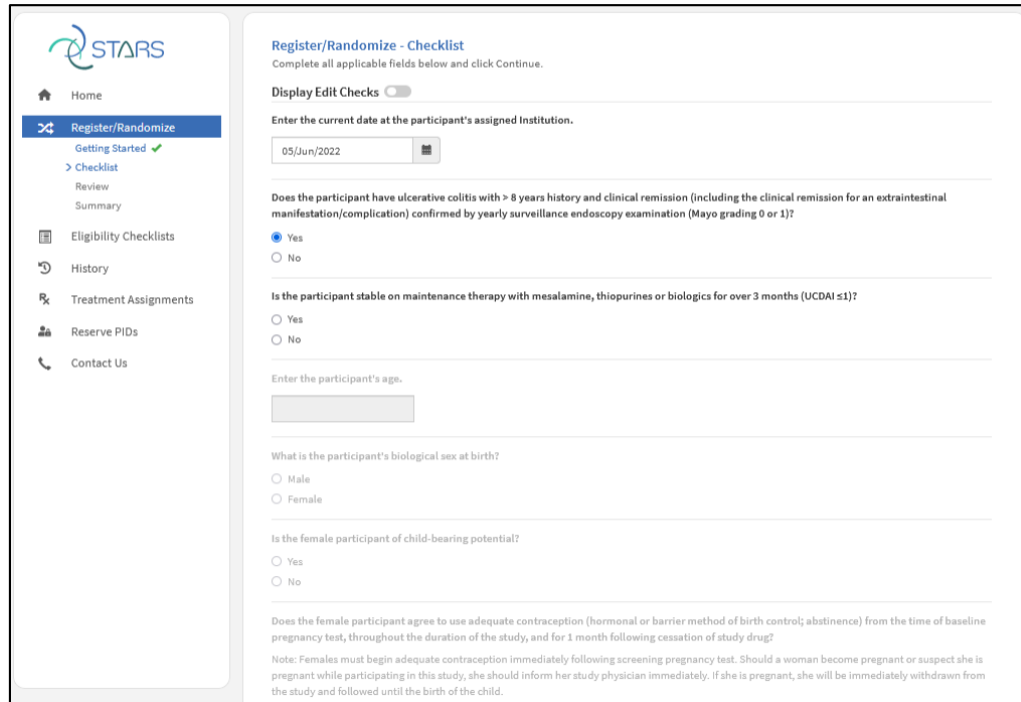
The Version dropdown menu displays the protocol versions that are currently active. If version control is enforced for the selected protocol, the version that the Institution is approved to is automatically displayed.

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.

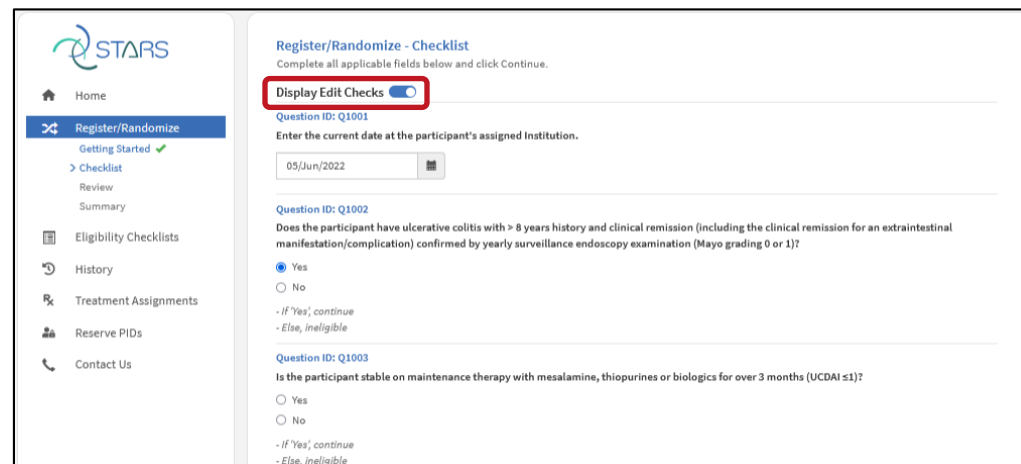


The screenshot shows the 'Register/Randomize - Checklist' page. The left sidebar contains navigation options: Home, Register/Randomize (selected), Getting Started, Checklist, Review, Summary, Eligibility Checklists, History, Treatment Assignments, Reserve PIDs, and Contact Us. The main content area is titled 'Register/Randomize - Checklist' and includes the instruction 'Complete all applicable fields below and click Continue.' Below this is a 'Display Edit Checks' toggle button, which is currently turned off. The checklist questions are: 'Enter the current date at the participant's assigned Institution.' (with a date field showing 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)?' (with 'Yes' selected), 'Is the participant stable on maintenance therapy with mesalamine, thiopurines or biologics for over 3 months (UCDAI ≤1)?' (with 'No' selected), 'Enter the participant's age.' (with an empty text field), 'What is the participant's biological sex at birth?' (with 'Male' and 'Female' radio buttons), and 'Is the female participant of child-bearing potential?' (with 'Yes' and 'No' radio buttons). A note at the bottom states: 'Does the female participant agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) from the time of baseline pregnancy test, throughout the duration of the study, and for 1 month following cessation of study drug? Note: Females must begin adequate contraception immediately following screening pregnancy test. Should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her study physician immediately. If she is pregnant, she will be immediately withdrawn from the study and followed until the birth of the child.'

Figure 7: 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.



This screenshot is identical to Figure 7, but the 'Display Edit Checks' toggle button is now turned on. The questions are the same, but the second question now includes conditional text: '- If 'Yes', continue' and '- Else, ineligible'. The third question also includes '- If 'Yes', continue' and '- Else, ineligible'.

Figure 8: 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.



Question ID: Q1004
Enter the participant's age.

Inclusion Criteria in Section 4.1.3 of the Protocol was not met

17

- If the response of Question ID: 1004 is ≥ 18 and ≤ 70 , continue
- Else, ineligible

Figure 9: Register/Randomize, Checklist page, invalid response

Responses may cause questions to be skipped

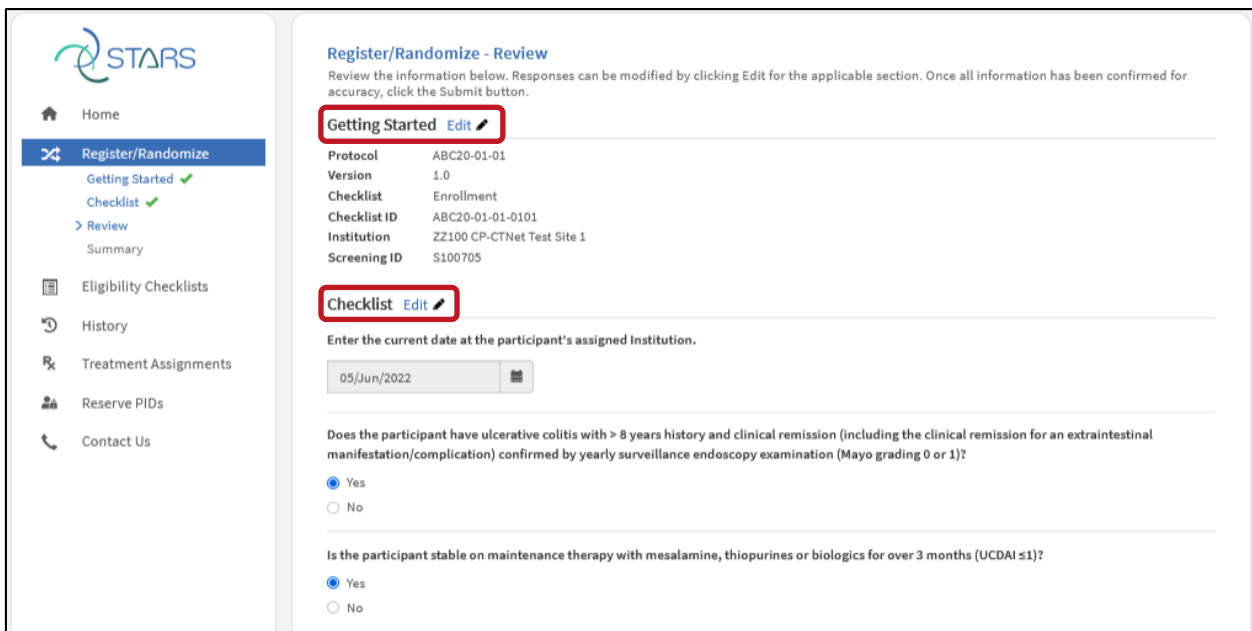
For some checklists, a specific response to a question may cause questions following it to be skipped. For example, if a question asks for the participant's biological sex at birth and Male is selected, subsequent questions relevant only to female participants are skipped. In these cases, the application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



STARS

Home

Register/Randomize

- Getting Started ✓
- Checklist ✓
- Review
- Summary

Eligibility Checklists

History

Treatment Assignments

Reserve PIDs

Contact Us

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	S100705

Checklist [Edit](#)

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

05/June/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 10: 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.

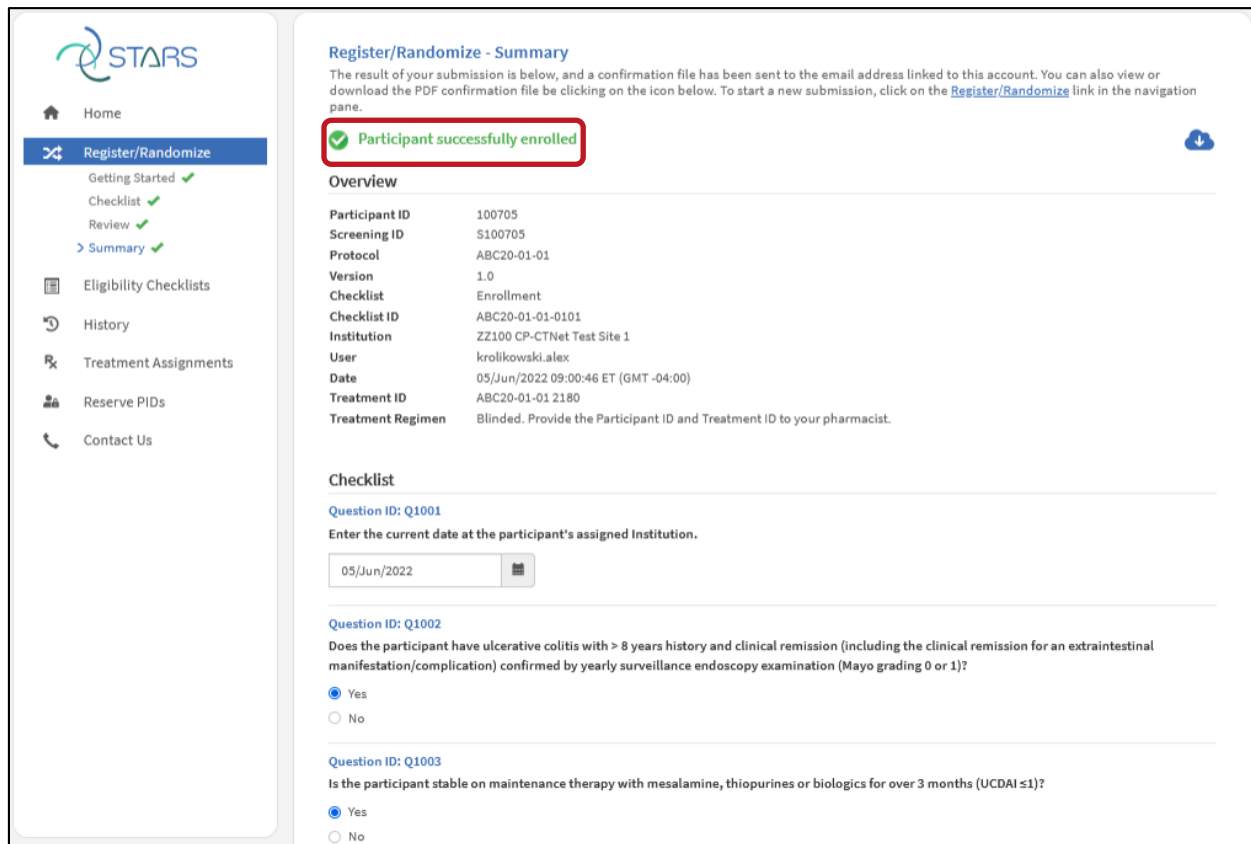


Figure 11: Register/Randomize, Summary page, enrollment success

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
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 DMACC DMs (via DataManagement_CP-CTNet@frontierscience.org) of the designee’s name and email.

Note: The LAO designee must have a CP-CTNet DMACC Portal Gateway account. DMACC 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.

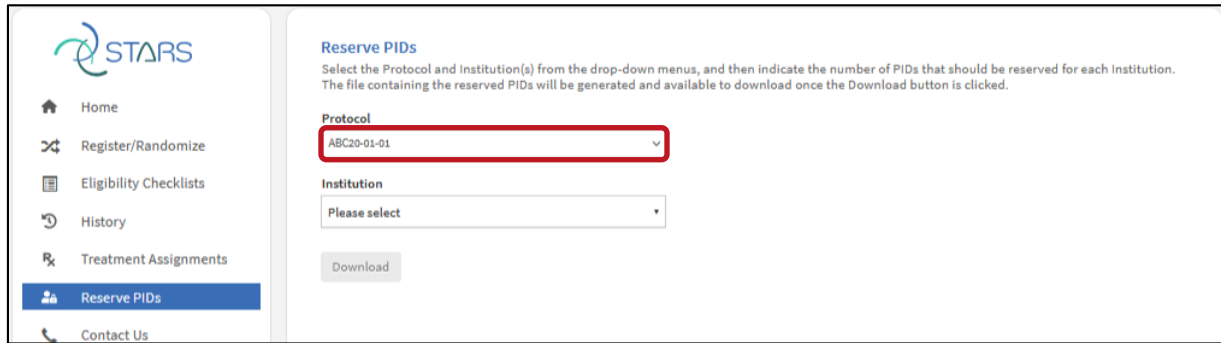


Figure 12: Select the protocol on the Reserve PIDs Module homepage

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.

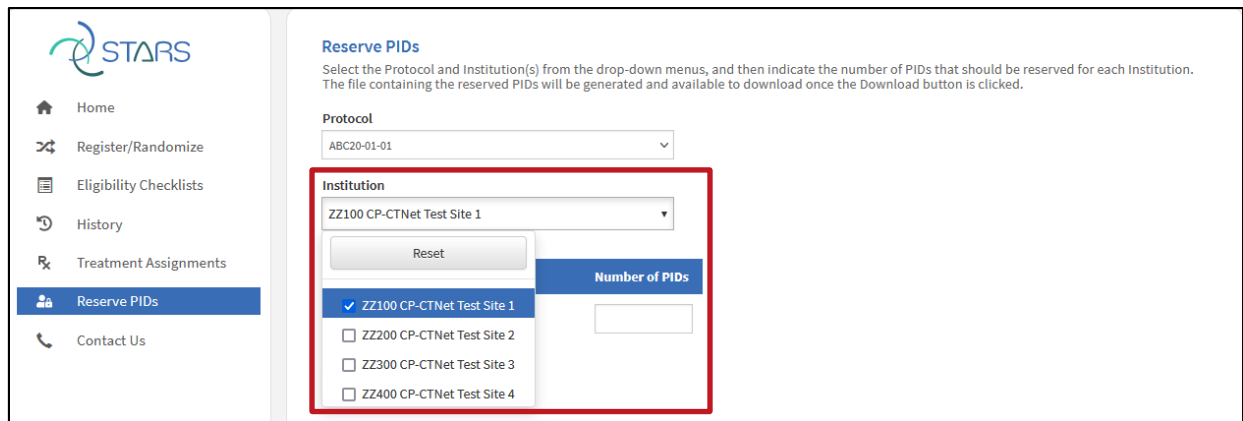


Figure 13: Select the accruing LAO(s) and/or AO(s) that need PIDs reserved

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**.

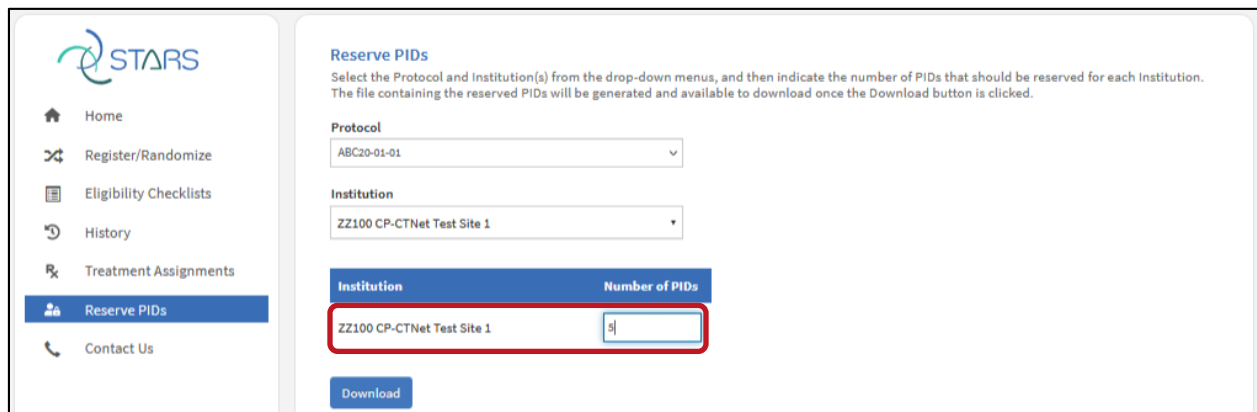


Figure 14: Enter the number of PIDs to reserve for the accruing LAO(s) and/or AO(s)

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.

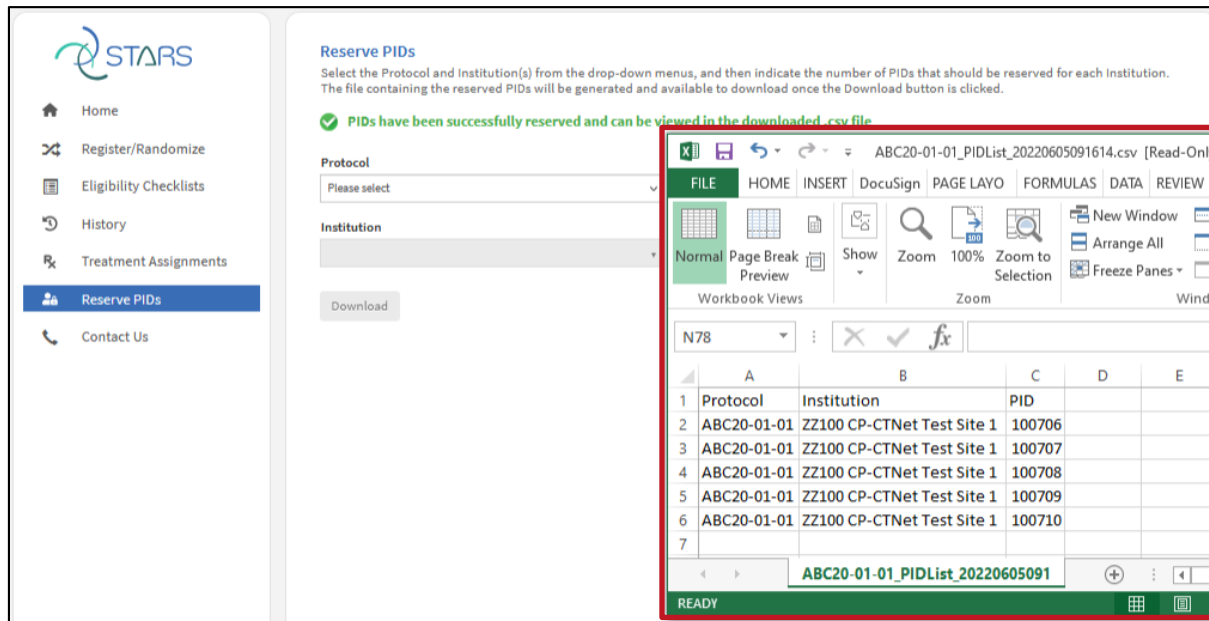


Figure 15: Summary page and downloaded .csv file

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 DMACC 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 DMACC Portal Gateway. The Treatment Assignments Module is used to verify what study agent to dispense. DMACC 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.

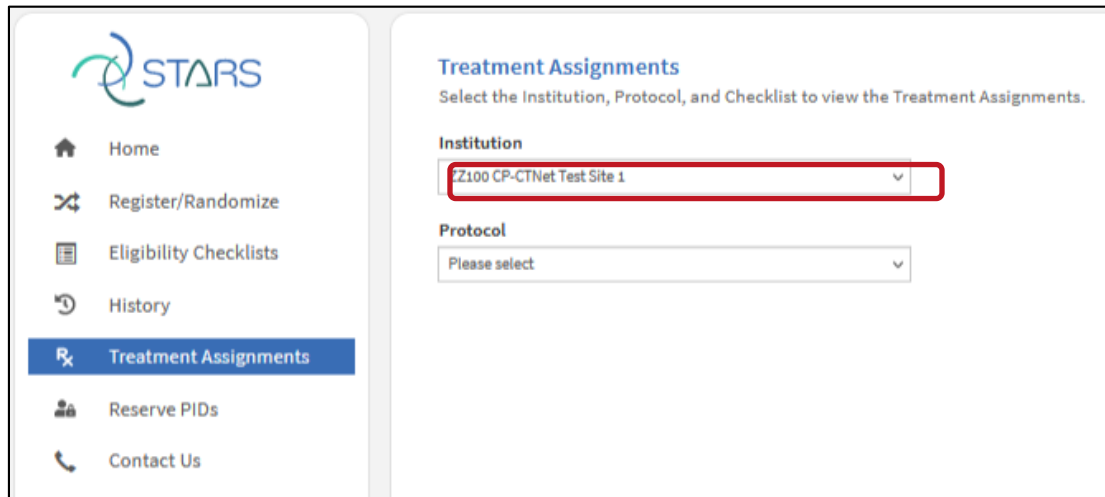


Figure 16: Treatment Assignments Module home page, Institution selected

3. Select the desired protocol.
4. The treatment assignment list is automatically displayed based on the selections made above.

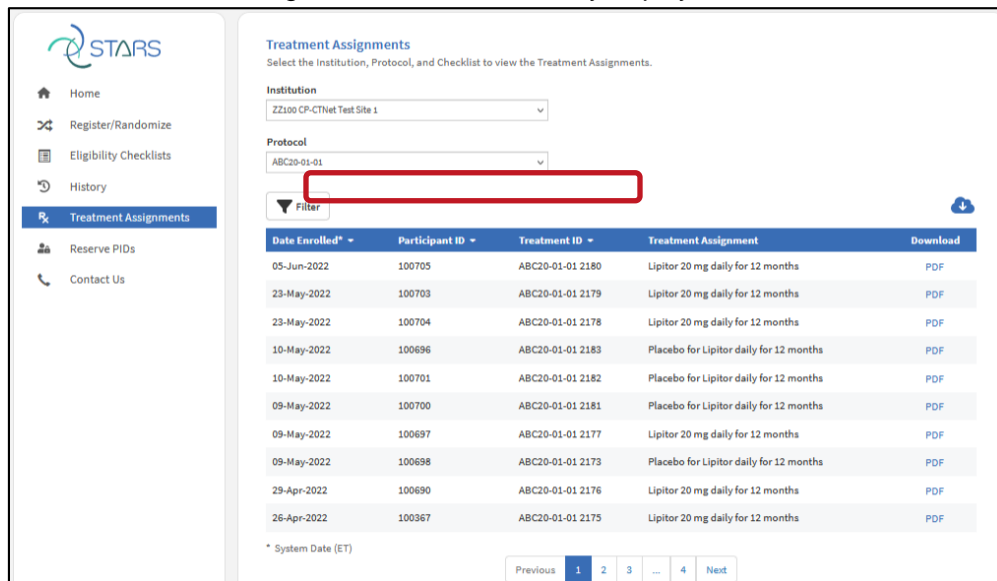


Figure 17: Treatment Assignments Module home page, Protocol selected

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.

Date Enrolled*	Participant ID	Treatment ID	Treatment Assignment	Download
05-Jun-2022	100705	ABC20-01-01 2180	Lipitor 20 mg daily for 12 months	PDF
23-May-2022	100703	ABC20-01-01 2179	Lipitor 20 mg daily for 12 months	PDF
23-May-2022	100704	ABC20-01-01 2178	Lipitor 20 mg daily for 12 months	PDF
10-May-2022	100696	ABC20-01-01 2183	Placebo for Lipitor daily for 12 months	PDF
10-May-2022	100701	ABC20-01-01 2182	Placebo for Lipitor daily for 12 months	PDF
09-May-2022	100700	ABC20-01-01 2181	Placebo for Lipitor daily for 12 months	PDF
09-May-2022	100697	ABC20-01-01 2177	Lipitor 20 mg daily for 12 months	PDF
09-May-2022	100698	ABC20-01-01 2173	Placebo for Lipitor daily for 12 months	PDF
29-Apr-2022	100690	ABC20-01-01 2176	Lipitor 20 mg daily for 12 months	PDF
26-Apr-2022	100367	ABC20-01-01 2175	Lipitor 20 mg daily for 12 months	PDF

Figure 18: Treatment Assignments Module home page, Filters displayed

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

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 19: 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/June/2022

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

05/June/2022

Continue

Figure 20: 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 21: 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 by 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 krolkowski.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 22: 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., Study 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
PS100708

Continue

Figure 23: 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 24: 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 25: 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 by clicking on the icon below. To start a new submission, click on the [Register/Randomize](#) link in the navigation pane.

Screening ID successfully assigned

Overview

Screening ID	S100706
Pre-Screen ID	PS100706
Protocol	ABC20-01-01
Version	1.0
Checklist	Screening
Checklist ID	ABC20-01-01-S0001
Institution	ZZ100 CP-CTNet Test Site 1
User	krolikowski.alex
Date	05/Jun/2022 10:04:38 ET (GMT -04:00)
Confirmation Number	1337

Message

Please enter the remaining Screening 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

Question ID: Q1002

Was the participant previously assigned a Screening ID for this Protocol?

Yes

No

Figure 26: 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., Study ABC20-01-01). The *Subject 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
 - 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**.

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
Enrollment

Checklist ID
ABC20-01-01-0101

Screening ID
S100708

Continue

Figure 27: 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.

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/June/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)?

Inclusion Criteria in Section 4.1.1 of the Protocol was not met

Yes
 No

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

Yes
 No

Figure 28: 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.

Question ID: Q1013
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)?

Note: See [CP-CTNet SOP 03-03: LAO Oversight Activities](#) for more information.

Yes
 No

- If 'Yes', continue
- Else, ineligible

Figure 29: 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 30: 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 31: 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 \leq 1)?

Yes
 No

Enter the participant's age.

56

What is the participant's biological sex at birth?

Male
 Female

Figure 32: 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 33: Review page, click Submit

The Summary page provides the results of the submission, the *Participant ID* (e.g., 100706), 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

The screenshot shows a web interface titled "Register/Randomize - Summary". At the top, there is a message: "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 by clicking on the icon below. To start a new submission, click on the Register/Randomize link in the navigation pane." Below this message is a green checkmark icon and the text "Participant successfully enrolled". To the right of this message is a blue cloud download icon. Underneath is an "Overview" section with a table of details:

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.

Below the overview is a "Checklist" section. The first question is "Question ID: Q1001" with the instruction "Enter the current date at the participant's assigned Institution." There is a date input field containing "05/Jun/2022" and a calendar icon. The second question is "Question ID: Q1002" with the instruction "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)?" There are two radio button options: "Yes" (which is selected) and "No".

Figure 34: 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., Study ABC20-01-01). 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, 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 35: 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.

Date *	PID	Protocol	Checklist	User	Institution	Download
05/Jun/2022	100706	ABC20-01-01	Enrollment	krolikowski.alex	ZZ100	PDF
05/Jun/2022	S100706	ABC20-01-01	Screening	krolikowski.alex	ZZ100	PDF
05/Jun/2022	PS100706	ABC20-01-01	Pre-Screen	krolikowski.alex	ZZ100	PDF
05/Jun/2022	100705	ABC20-01-01	Enrollment	krolikowski.alex	ZZ100	PDF
05/Jun/2022	S100705	ABC20-01-01	Screening	krolikowski.alex	ZZ100	PDF
05/Jun/2022	PS100705	ABC20-01-01	Pre-Screen	krolikowski.alex	ZZ100	PDF
23/May/2022	100703	ABC20-01-01	Enrollment	krolikowski.alex	ZZ100	PDF

Figure 36: History Module

Contact Us

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

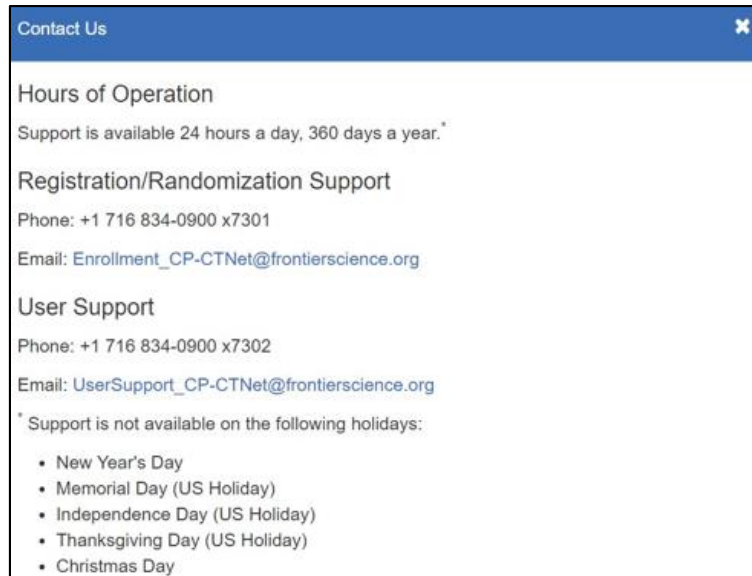


Figure 37: Contact Us Module

For assistance using Stars, contact *Registration/Randomization Support*.

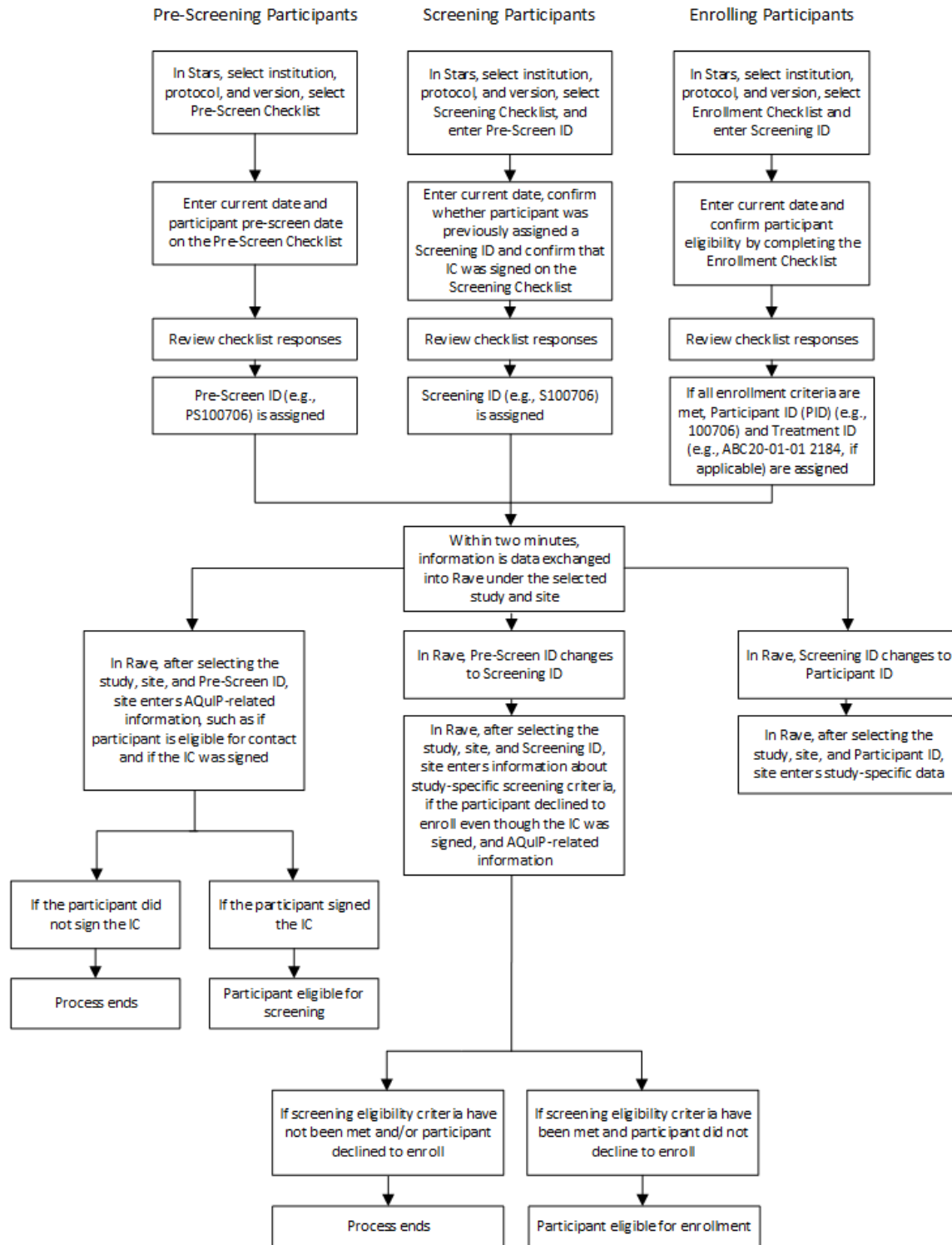
- **Email:** Enrollment_CP-CTNet@frontierscience.org
- **Phone:** (716) 834-0900, extension 7301

For general assistance using the CP-CTNet 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



*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