eCRF Completion Guidelines

Client: Connect Biopharma

Protocol: CBP-201-207

Clinical Data Management System (CDMS):
Medrio

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CCG APPROVAL

The signatures below indicate approval of the CCG file titled: Connect Biopharma eCRF Completion Guidelines_V2.0_20NOV2025.pdf

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Munim Saeed
Signer Name: Munim Saeed
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744C5F57974A4A0394AC786A59A34A62

Signature	Date
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Precision for Medicine

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Signing Time: 21-Nov-2025 | 9:28:33 AM PST
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Marisa Jones	Clinical Trials Associate Manager

Connect Biopharma

REVISION HISTORY

Version	Summary/Reason for changes	Revision Date
V1.0	Initial Approval	NA
V1.1	Eligibility CRF – Text added to clarify CRFs which will not appear in EDC if protocol version 2.0 was selected. 12 Lead eCRF – Text added for clarification on abnormally clinically significant findings Index COPD Exacerbation – question label updated to replace 'consent' with 'agree'- [Does the participant agree to having optional spirometry measurements taken on Day 2 and Day 3?]**,** Text added to Index COPD Exacerbation Follow-Up and Subsequent COPD Exacerbation Episode CRFs On Urgent Care and Emergency Room details Spirometry/FeNO - Text added to clarify row completion Concomitant Medications – Reminder added to separate steroid courses Accessing Your Project – Medrio e-Learning module (41.6) specified for site staff General eCRF Entry Guidelines – Specified that data entry is expected within 5 business days	
V1.2	Updates confirmed by the Sponsor	
V2.0	Final version	

TABLE OF CONTENTS

Overview

The purpose of the eCRF Completion Guidelines (CCGs) is to provide instructions on how to complete the eCRFs for the CBP-201-207 Connect Biopharma project, whereby Precision for Medicine (Precision) is contracted for data management services. It also provides some general overview information and instructions on how to use the Electronic Data Capture (EDC) used for collecting the participant data for this clinical trial. The EDC training set up for this project should be referenced for further instructions on how to use the database based on the user's assigned role.

DM Team Personnel

The primary data management team member(s) for this project are:

Name	Position	Responsibility
Munim Saeed Precision Phone: +1 (416) 799-3622 Email: munim.saeed@precisionformedicine.com	Lead Data Manager (LDM)	Data management activities from database open, conduct, through database lock.
Zachary Kaminski Precision Phone: +1 (585) 300-0057 Email: zachary.kaminski@precisionformedicine.com	Data Management Oversight (DMO)	Oversee data management activities from database open, conduct, through database lock. May serve as the back-up.

Medrio

Medrio is the web-based EDC database selected by the Sponsor to collect clinical data for this project. Designated project team members responsible for collecting, cleaning, and/or reviewing the data and project progress will have role-based access to the EDC (e.g. CRA, DM, Study Coordinator, PI, etc.).

Getting Started

Supported Browsers

This EDC supports all commonly used browsers e.g. Microsoft Edge (formerly Internet Explorer, Firefox (Mozilla), Chrome (Google), Safari (Apple). It is highly recommended that

the latest versions available are used and the browser software is up to date with any vendor updates, especially those concerning security.

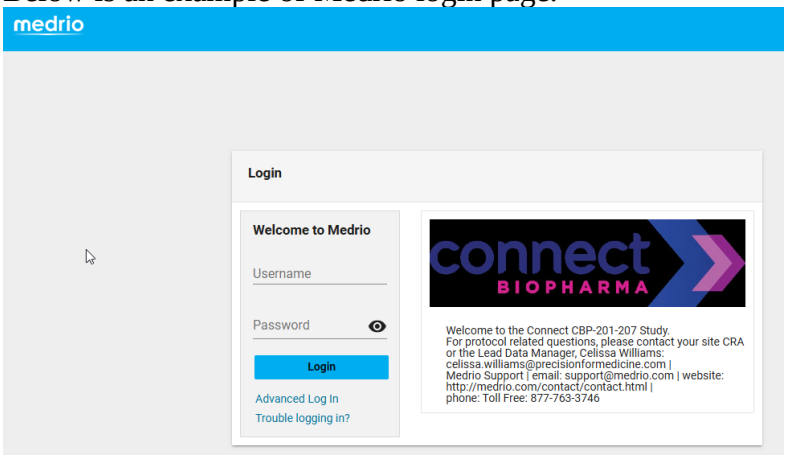
Browser	Version
Microsoft Edge	9 and later
Firefox (Mozilla)	27 and later
Chrome (Google)	30 and later
Safari	7 and later

Accessing Your Project

Study Database

Participant data for this study will be entered into the Medrio EDC application. This application is accessed using a web-based portal called Medrio. You will have access to this portal over the internet using a standard internet browser such as Google Chrome or Firefox. No software needs to be installed locally. The Medrio portal can be found at the following location: https://identity.medrio.com/identity/login?signin.

Below is an example of Medrio login page.

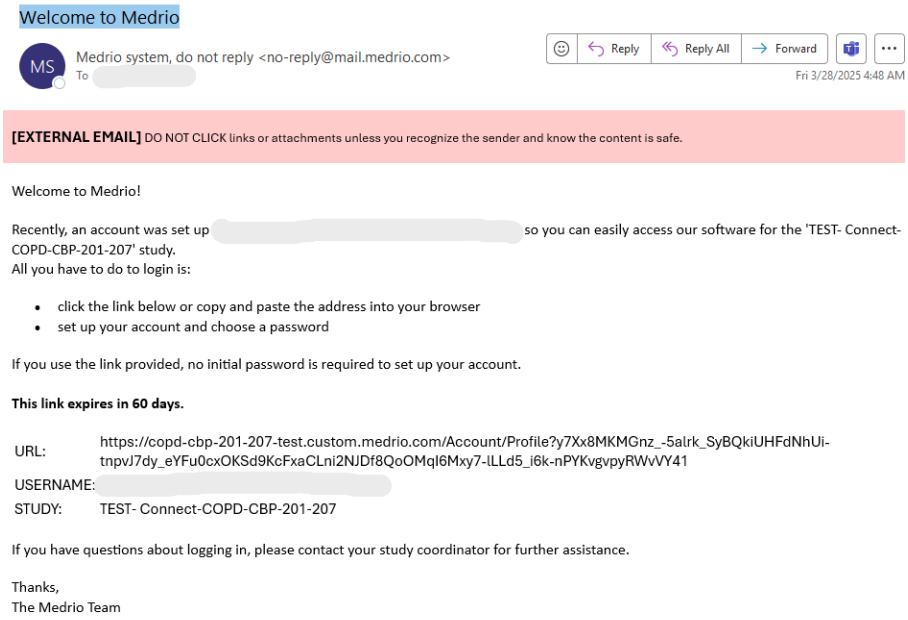


Tip: save the Medrio Internet address as a browser ‘Favorite’ or ‘Bookmark’ to keep it easily accessible throughout the study.

Permissions and project access to the EDC are granted by the Lead Data Manager (LDM) after EDC training is completed by the intended user and a Medrio training certificate has been returned to the LDM.

When access is granted to a project, the user will receive an automated email from “Database System Administrator (Medrio system)” with instructions on how to set up your account and profile. If the LDM has set up permissions and you did not receive the email, check your junk

and/or spam email folders in the event it routed there inadvertently. If you still have not received it, contact your CRA who will reach out to the project LDM for access request. The following is an example of the email you will receive:



Welcome to Medrio

MS Medrio system, do not reply <no-reply@mail.medrio.com>
To [redacted]

Reply | Reply All | Forward
Fri 3/28/2025 4:48 AM

[EXTERNAL EMAIL] DO NOT CLICK links or attachments unless you recognize the sender and know the content is safe.

Welcome to Medrio!

Recently, an account was set up [redacted] so you can easily access our software for the 'TEST- Connect-COPD-CBP-201-207' study.
All you have to do to login is:

- click the link below or copy and paste the address into your browser
- set up your account and choose a password

If you use the link provided, no initial password is required to set up your account.

This link expires in 60 days.

URL: https://copd-cbp-201-207-test.custom.medrio.com/Account/Profile?y7Xx8MKMGnz_-5alrk_SyBQkiUHFdNhUi-tnpvJ7dy_eYFu0cxOKSd9KcFxaCLni2NJDf8QoOMqI6Mxy7-lLLd5_i6k-nPYKvgvpyRWvVY41
USERNAME: [redacted]
STUDY: TEST- Connect-COPD-CBP-201-207

If you have questions about logging in, please contact your study coordinator for further assistance.

Thanks,
The Medrio Team

To access the EDC database, click on the link provided in the email and/or open a web browser and copy paste the link: https://copd-cbp-201-207-test.custom.medrio.com/Account/Profile?y7Xx8MKMGnz_-5alrk_SyBQkiUHFdNhUi-tnpvJ7dy_eYFu0cxOKSd9KcFxaCLni2NJDf8QoOMqI6Mxy7-lLLd5_i6k-nPYKvgvpyRWvVY41

Enter the username provided in the Welcome to Medrio email.

First Time Login

Access to Medrio is by invitation only set-up by Precision DM. As a new user, you cannot log in until you receive an email and click the link to accept the invitation to join Medrio. If you need access to the study, please contact your CRA to request user activation/invitation from Precision DM. Once Precision DM completes the user activation process, an e-mail invitation will be sent from the following e-mail address: Medrio system, no-reply@mail.medrio.com. You are then redirected to an activation web page where you create your username and password and register as a Medrio user. If the Precision DM has set up permissions and you did not receive the email, check your junk and/or spam email folders in the event it routed there inadvertently. If you still did not receive it, contact the study CRA who will follow-up the issue with the LDM to re-send the invitation email.

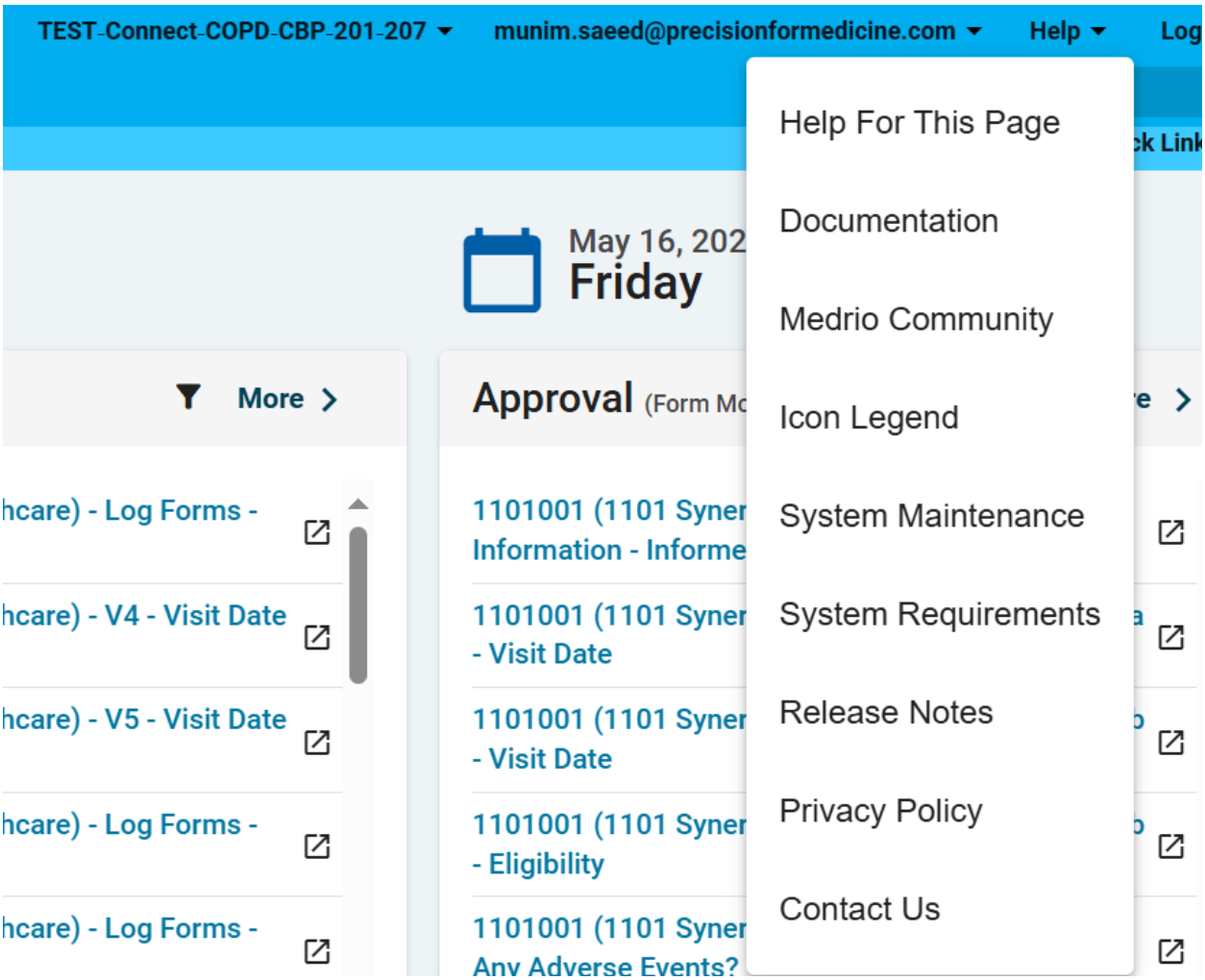
Activating your Medrio Account:

1. Open your invitation email.
2. Click the link or copy and paste the address into your browser.
3. Set up your account and choose a password.
   - Passwords must: be at least ten (10) characters in length,
   - contain at least three of the following four items: uppercase letter, one lowercase letter, one character and one number,

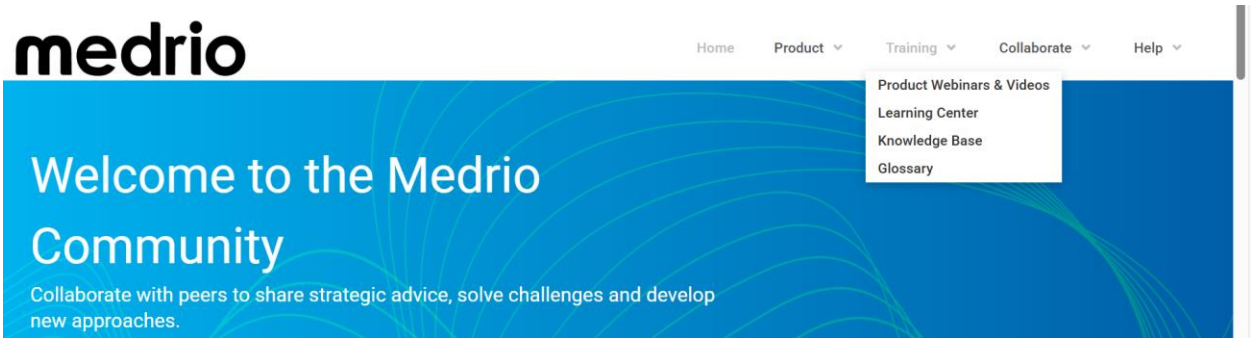
Complete all required fields on the activation page. E-learning needs to be completed (if not completed earlier) before access to the study EDC database can be granted.

Accessing eLearning in Medrio:

- Go to 'Help' tab on top left corner of Medrio
- Click on 'Medrio Community' from the drop down option



- Click on ‘Training’ and select ‘Learning Center’ from the drop down.
- Select role specific training from Medrio eLearning Home page.
    - Site staff should complete training module “Data Entry – EDC (R41.6)”.



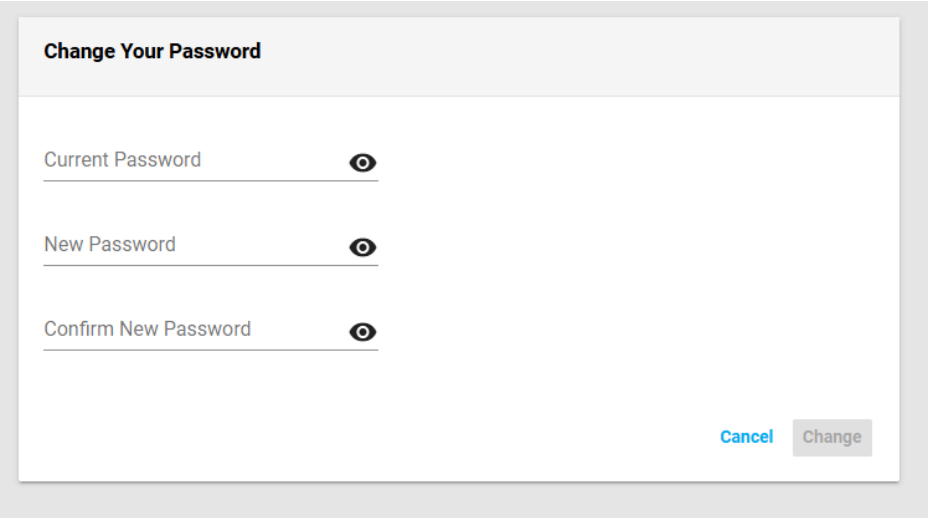
After elearning is completed, site staff should generate their training certificate (in pdf format) and send to Lead Data Manager for access request to EDC.

Subsequent Logins

Once you register as a Medrio user, log in by entering your username and password on https://medrio.com. You must accept the End User License Agreement (EULA) the first time you log in. All subsequent invitations and assignments appear on your Medrio home page.

Changing Your Password

To change your password, click on user’s name at the top right corner of the screen. Click ‘Change Your Password’. A pop-up window will appear.



Password Reset

Users can reset their own passwords by providing answers to security questions they set up upon account creation.

The user password automatically expires after 90 days. Users are notified of the expiration when they log into Medrio and are taken to a page to create a new password. The last two passwords may not be reused when resetting passwords.

EDC Support / Help

For protocol related questions, please contact your site CRA. For Medrio related questions, please contact the Lead Data Manager, Munim Saeed: Munim.Saeed@precisionformedicine.com

If your study administrator is unable to assist you, please submit a ticket to Medrio Support.

|Medrio Support | email: support@medrio.com | website: http://medrio.com/contact/contact.html | phone: Toll Free: 877-763-3746

Site-Level Access

Users are granted access to specific sites and participants based on their role and permissions in the project. If a user has access to only specific sites, then they can only access the forms (eCRFs) and data for the participants who are assigned to those specific sites. If they have permissions to run reports, the report output will only show the results of the participants and sites they have access to view as well.

Getting More Help

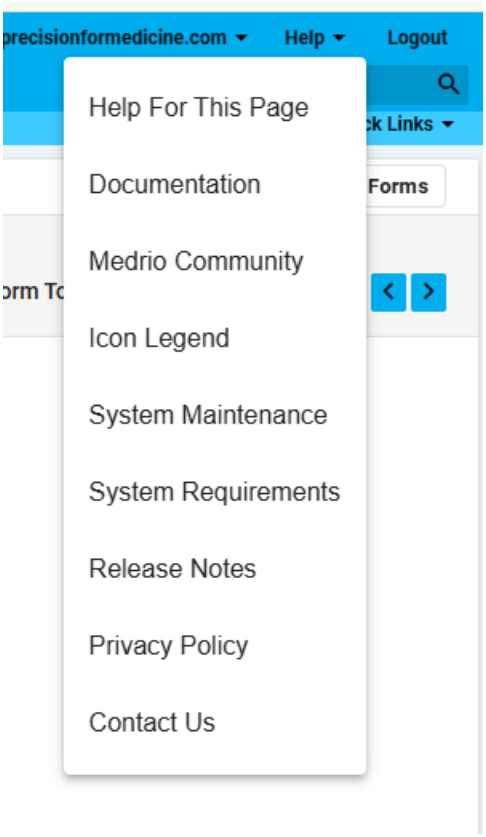
The 'Help' tab at the top right upper corner of the page is available to assist with any questions.

Alternatively, you may contact:

- Your Project Assigned CRA
- Lead Data Manager and Back up DM as noted in the DM Team Personnel section

These links are available on all pages within the database:

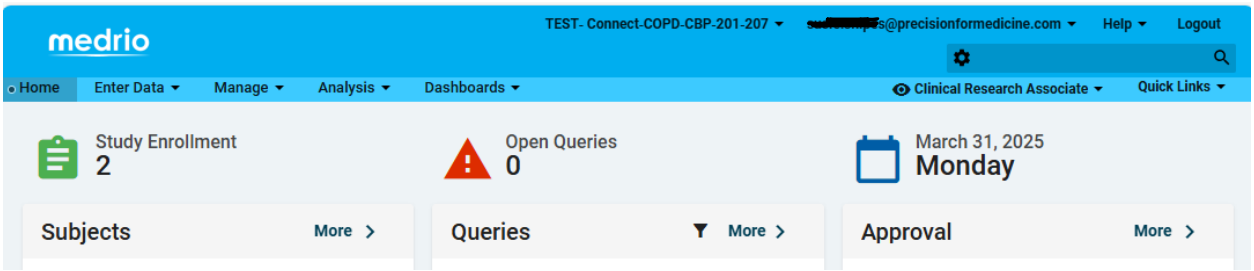
- Help for this page – provides help for the page you are currently on
- Documentation – opens a new page, providing access to the Medrio EDC Main User guide
- Medrio Community – opens a new page, providing access to Medrio discussion boards
- Icon Legend – explanation of system and display icons
- System Maintenance – opens a screen providing timing for upcoming scheduled maintenance
- System Requirements – software requirements to use Medrio
- Release Notes – opens a new page, provides information on Medrio release documentation
- Privacy Policy – opens a new page, provides access to the Medrio privacy policy statement
- Contact Us – provides contact information for support



The full list of system icons can be accessed by clicking Icon Legend in the screen shot above.

Home page

The Home page is the first page a user will see upon login. What appears on the Home page depends upon user permissions and roles. The Home page of a Clinical Research Associate (CRA) is displayed in the example below:



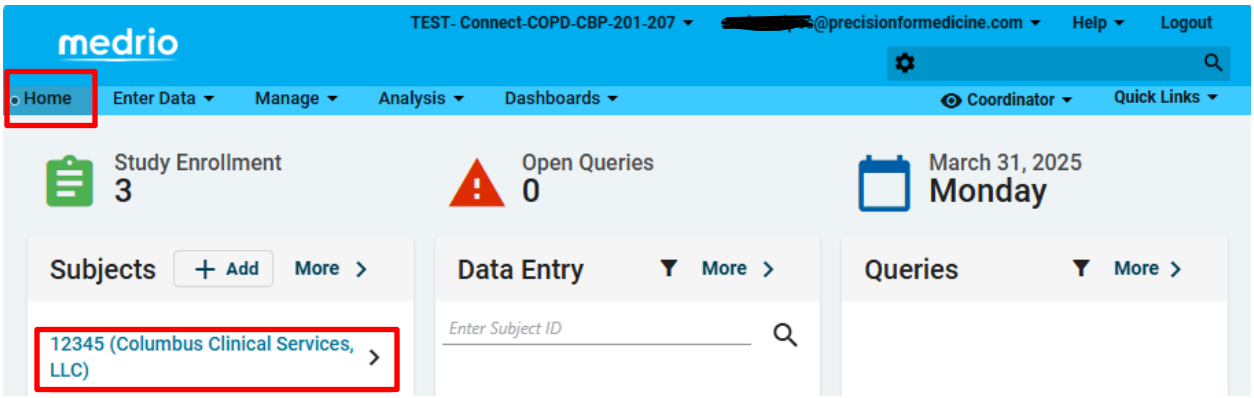
Creating a New Participant

Participant/Subject IDs will be automatically generated using the Interactive Response Technology (IRT).
Participant data will not be available for entry in EDC until they are enrolled through the IRT.

Accessing Participants

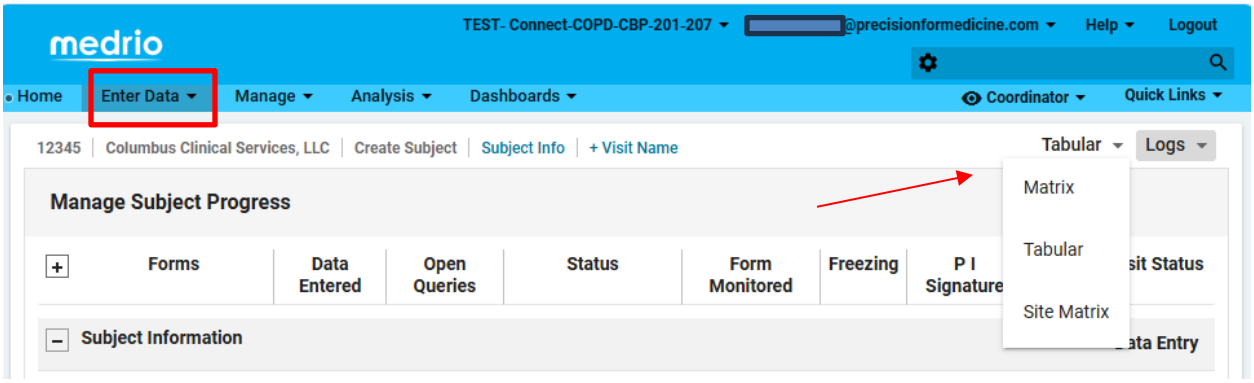
The 'Home' tab is a portal screen that gives information on Enrolled Subjects, Data Entry, and Queries. You can also access participant data from this screen by selecting the Participant/Subject ID.

Once the ID is selected, you can then begin to 'Enter Data'.

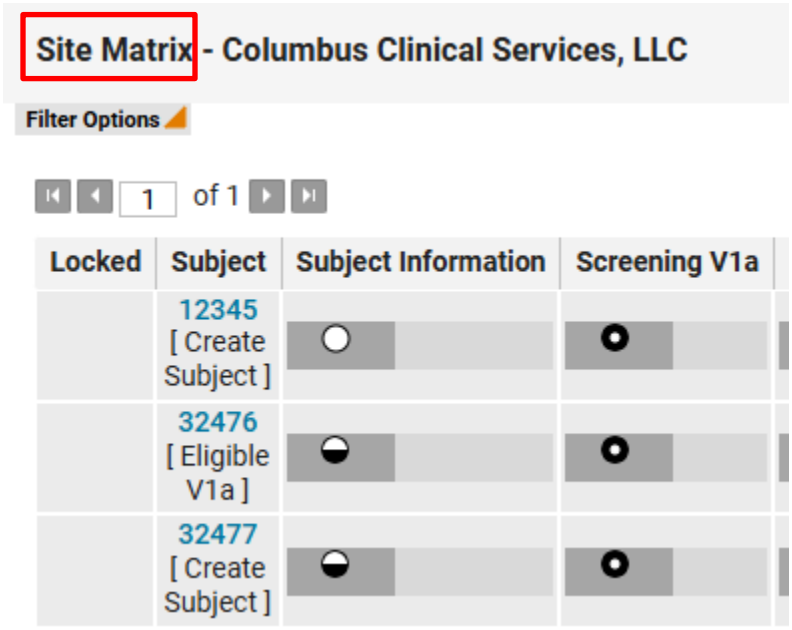


Enter Data Tab

The 'Enter Data' tab provides a Subject Listing (where you can click on a participant to go into the records for that participant) and 'Tabular' (where you can adjust data entry views). To begin data entry for a CRF, select that form.



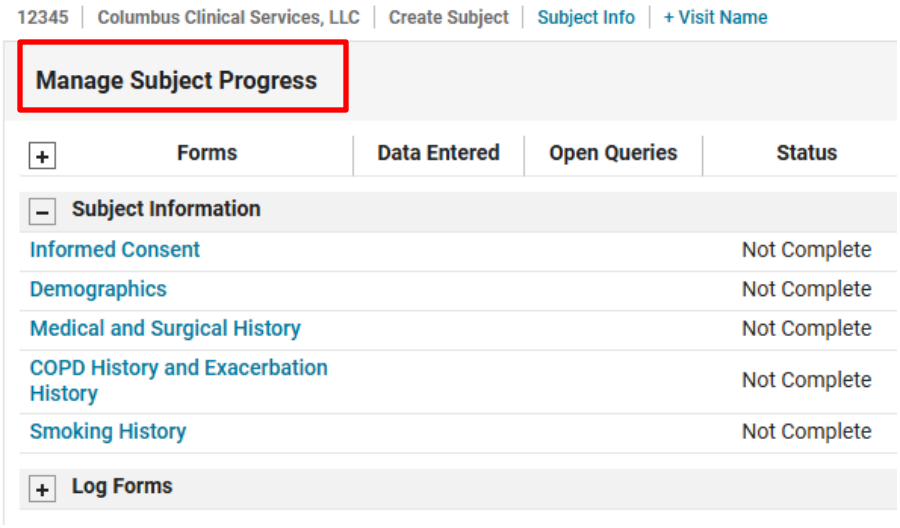
To view all participants data at your site use option 'Site Matrix':



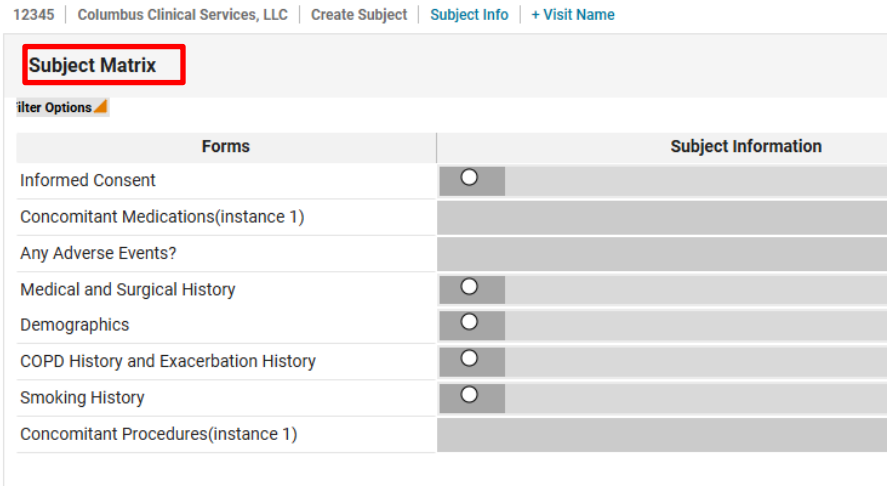
Matrix View Icons

Icon	Name	Description
●	Complete Final	In Forms Complete mode: All forms at the visit are in a complete status - either "Complete", "Complete – Final" or combination of "Complete", "Complete-Final" and "Not Expected". In Data Entered mode: All forms at the visit have data entered.
◉	Not Expected	All forms for the visit are marked "Not Expected".
◒	Partially Complete	In Forms Complete mode: Some forms at the visit have data entered, but not all forms are yet marked complete. In Data Entered mode: Some forms at the visit have data entered.
○	Not Entered	In Forms Complete mode: No forms have been marked complete or not expected. In Data Entered mode: No forms at the visit have data entered.

To view data entry status for a particular participant, select option ‘Tabular’:



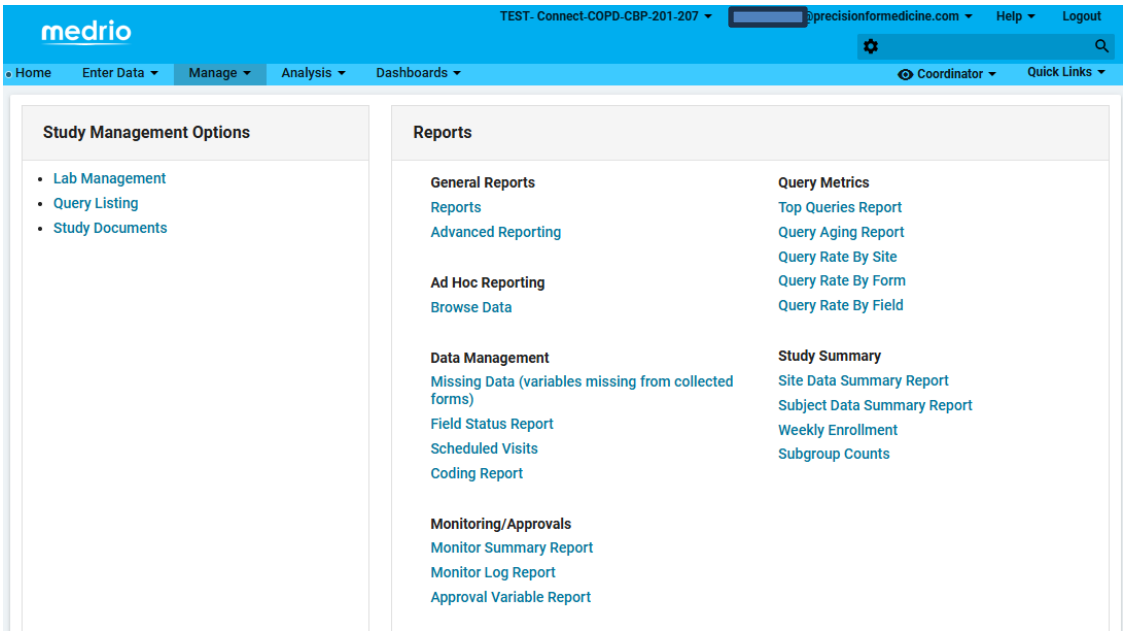
To view participants data use option 'Matrix':



Manage Tab

The 'Manage' tab provides Study Management Options and Reports.

The Study Coordinator view is below:



General eCRF Entry Guidelines

All requested fields on the eCRF should be completed within 5 business days of each visit. It is best practice to enter data in the order of the eCRF page from top to bottom. This can help avoid missing fields inadvertently. The eCRFs are designed with *skip logic*, meaning that as data is entered on the eCRF in order, subsequent data may grey out to be omitted from data entry. All requested data fields on the eCRF must be completed. Fields with a red asterisk * are required and must be entered before saving the eCRF.

All information must be entered in English. Attention to correct spelling and accurate information is important. Where appropriate, use clear and concise medical terminology. Do not use abbreviations. The TAB key may be used to advance to the next field. Answer every question as applicable. Do not leave spaces or blank boxes unless specified.

It is important to try to enter all data required on the page and address all queries as they arise. A page will only be saved with a [Complete] status when there are no missing data fields or there are no open queries on the eCRF. A page will reflect the status of Not Complete when the eCRF is partially completed or queries are pending.

Source Documentation

According to the Food and Drug Administration (FDA) regulations, all data entered on eCRFs must be verifiable in study participants medical records; therefore, detailed source

documentation is required. Source documentation may consist of progress notes, data collection worksheets, laboratory printouts, or additional records from which data are extracted at the study site and entered into the eCRF. Each participant's medical record must clearly indicate the date the participant gave his/her consent to participate in the study, including the study number. A dated entry must be made in the participant's medical record for each study visit, and accompanying source documentation must be maintained. Source documentation must be available to the CRA for inspection during monitoring visits to verify eCRF entries.

Leading Zeroes

If a leading zero is entered for a numeric field, once the page is saved the leading zero will be dropped. For instance, a Systolic Blood Pressure entry of [090] will be saved as [90]. Note for sites in Europe - numbers use a decimal point (.), not a comma (,) to separate the whole number from the fractional number, e.g., 27.6 kg. Use leading zero before decimal if number is lower than 1, e.g., 0.37.

Radio Buttons

eCRF fields are set up as Radio Buttons, these are designed typically for selecting from a list of choices. It can either be one choice or all that apply. If you would like to remove a selected choice, hold down the *Ctrl* key on your keyboard while clicking the selected value. This will deselect the previous choice entered.

Keyboard Shortcuts

There are two keyboard shortcuts for data entry; Ctrl+S for Save, and Ctrl+N for Save & Next. Buttons with keyboard shortcuts are indicated with an underscore beneath the shortcut letter (see Ctrl+S example below).

Dates

Complete dates are required on study expect where specified. The date format is DD/MMM/YYYY (e.g. 01/JAN/2025).

Certain date fields for this project have been configured to accept partial dates. These dates are noted within the CCG instructions for those particular eCRFs.

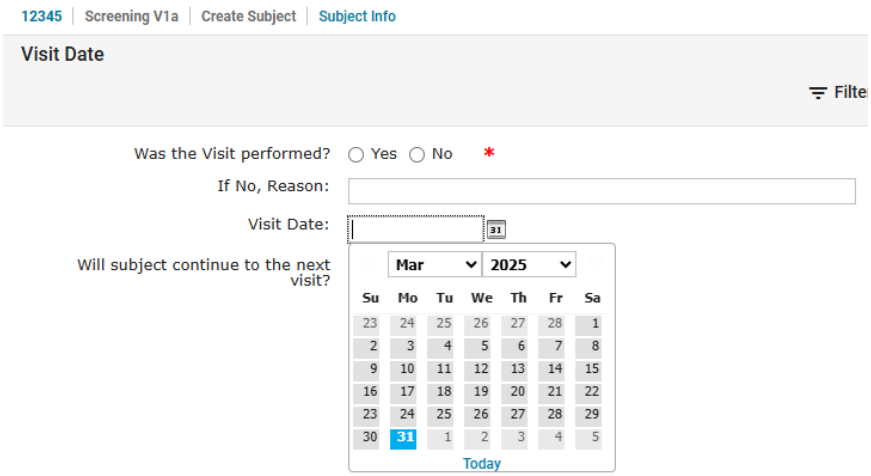
If part of a date is unknown, the Month and/or Day can be entered as [UN] or [UNK]. A minimum entry of Year is required.

Any date field that is not set-up to accept partial dates will fire a query when partial dates are entered. If the year is unknown and nothing is entered, a query will auto-fire. Respond to the query stating no information is known about the desired date.

To enter the date, you may either:

- Utilize the calendar icon next to each date field to select the date you wish to enter, and it will pre-fill the date
- Some date fields have a [Today] shortcut button. If selected, it will enter the current date at time of data entry.

Type the date in the form using DD/MMM/YYYY format.



Time Format

Times must be entered in a 24-hour clock format (00:00-23:59), see table below for conversions. If the time is unknown and nothing is entered, a query will auto-fire. Please respond to the query stating no information is known about the desired time.

AM TIME	24-Hour Time		PM TIME	24-Hour Time
12:00 AM	00:00		12:00 PM	12:00
1:00 AM	01:00		1:00 PM	13:00
2:00 AM	02:00		2:00 PM	14:00
3:00 AM	03:00		3:00 PM	15:00
4:00 AM	04:00		4:00 PM	16:00

5:00 AM	05:00		5:00 PM	17:00
6:00 AM	06:00		6:00 PM	18:00
7:00 AM	07:00		7:00 PM	19:00
8:00 AM	08:00		8:00 PM	20:00
9:00 AM	09:00		9:00 PM	21:00
10:00 AM	10:00		10:00 PM	22:00
11:00 AM	11:00		11:00 PM	23:00

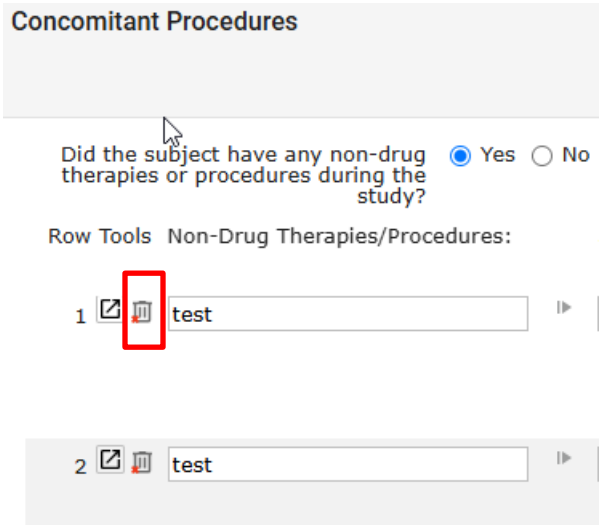
Log and Repeat eCRFs

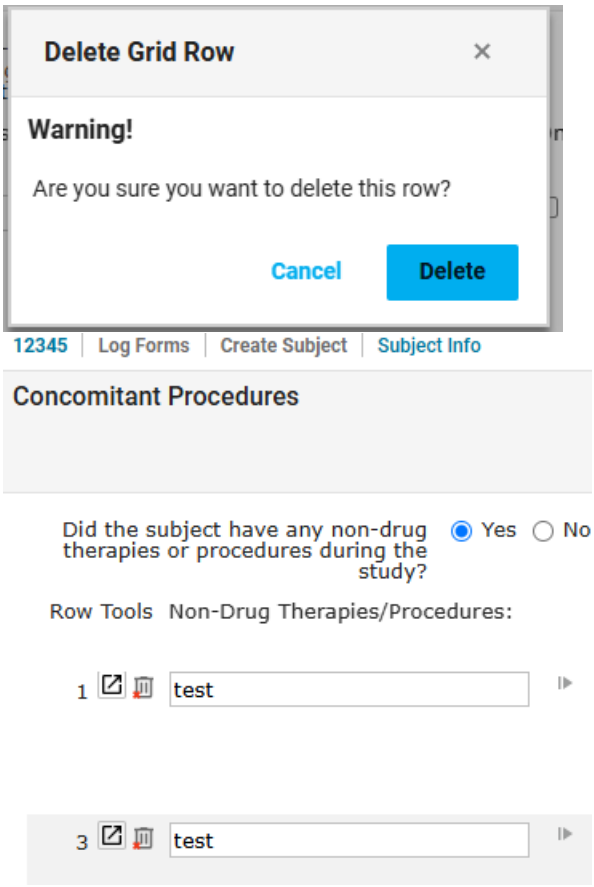
Logs are repeat style eCRFs that are typically not tied to a particular visit but can be added and updated as much as needed throughout the course of the project. Adverse Events, Concomitant Procedures and Concomitant Medications are common types of log (repeat) pages. Although these eCRFs are not tied to a particular visit, ensure these pages are up to date throughout the course of the project. If more log eCRFs are needed, you are to create as many repeat forms "pages" as needed for Adverse Events. See the section on Adverse Events for more information.

Inactivate/Reactivate Loglines

To **delete a record** on a log form if a line was added by mistake:

1. Click the trash can icon on the left of each log line
2. A warning box will appear asking you to confirm the deletion.
3. The record will be removed including the assigned log line identifier.





NOTE: Once a log line has been deleted, it cannot be retrieved. If deleted in error, you will need to re-enter the data in the eCRF.

Unscheduled eCRFs

The Unscheduled eCRFs should be used for data collected outside of the regular scheduled study visits per protocol. Select as many eCRFs as needed to capture the assessments performed at the Unscheduled Visit. The following eCRFs are available under the Unscheduled eCRFs Section:

- Unscheduled Visit
  - Enter this CRF first to trigger the applicable data collected within the Unscheduled visit from the below options:
    - 12-Lead ECG (Local Lab)
    - Biomarker Sample
    - Chemistry (Local Lab)
    - Chest X-ray or CT
    - Health Care Resource Utilization
    - Height

- Hematology (Local Lab)
- Immunogenicity Sample (ADA and NAb)
- Index COPD Exacerbation Follow-Up
- Injection Site Reaction (ISR)
- Laboratory Tests
- Physical Exam
- PK Sampling
- Pregnancy Test
- Smoking Status Changes
- Spirometry/FeNO
- Subsequent COPD Exacerbation Episode
- Urinalysis (Local Lab)
- Venous Blood Gas (VBG) Analysis
- Vital Signs

Other, Specify Fields / Yes/No Questions

Per EDC design, if you enter in an "Other, Specify" comment, but then select a corresponding response field is not "Other", the data entered in the "Other, Specify" comment field will be removed. Ensure you select the proper choice option before you enter comment text, this will prevent an entry error and inadvertently lose text entered in the other specify comment text field.

The same EDC design also applies to Yes/No and related questions. If you entered the date before you enter the initial yes/no question, then select No, the supporting data you entered will be removed. As noted in the general eCRF entry guidelines, it's best to enter data in order of the eCRF from top to bottom.

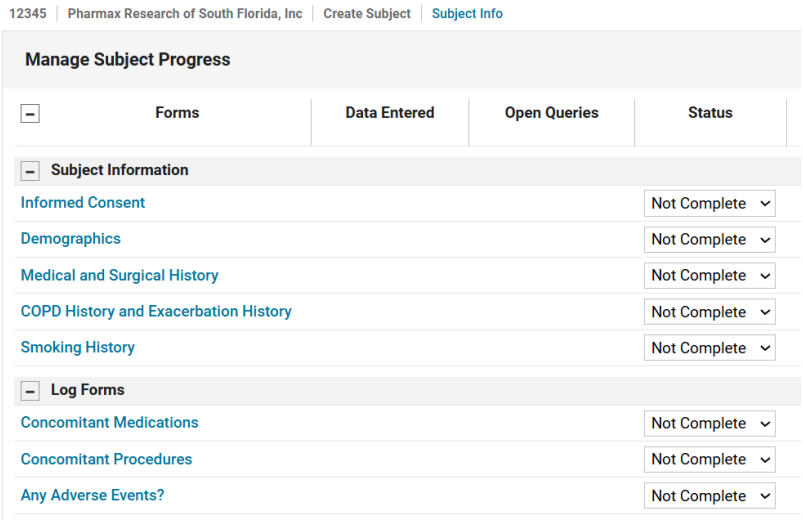
CRF Book / Visit Map

This EDC is integrated with the Suvoda IRT.
In order to enter a participant in EDC, the participant must first be registered through the IRT system.

Once a participant is created in IRT, the record will be automatically created in the Medrio EDC. Upon record creation, you will have access to enter data in the Subject Information and Log Forms folders. The IRT will automatically populate the following fields:

- Participant/Subject ID
- Randomization Date
- Randomization Number
- Age At Screening
- Sex
- Did the exacerbation result in a hospitalization at V2?

- Kit Number 1
- Kit Number 2
- Replacement Kit Number 1A (if applicable)
- Replacement Kit Number 2A (if applicable)
- Replacement Kit Number 1B (if applicable)
- Replacement Kit Number 2B (if applicable)
- Re-screen Participant ID #1 (if applicable)
- Re-screen Participant ID #2 (if applicable)

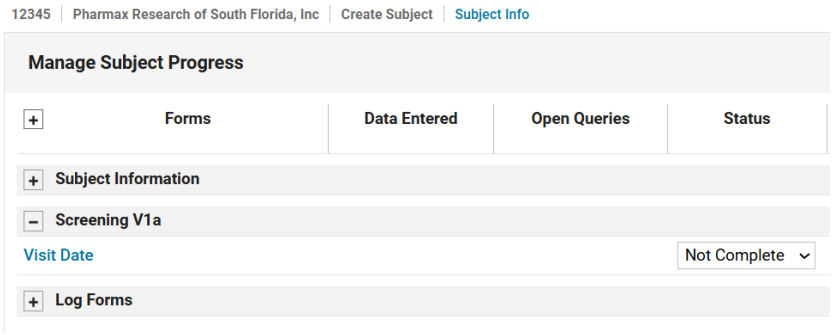


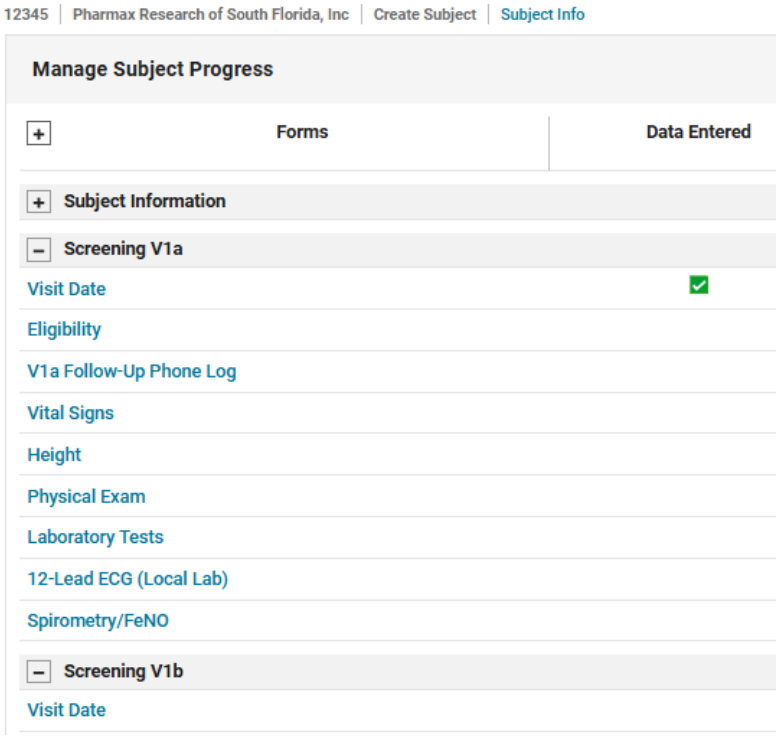
Enter all required fields on the [Informed Consent] eCRF to trigger the appropriate Screening Channel in the participant's schedule. If V1a is selected for [Screening Channel], the V1a visit folder will populate. If V1b is selected [Screening Channel], the V1a visit will be skipped in the participant's schedule and the V1b visit will appear next.

Enter all Subject Information eCRFs prior to populating data in the Screening V1a or V1b visit. Once a Screening channel is selected, Unscheduled Visits will be available for data entry.

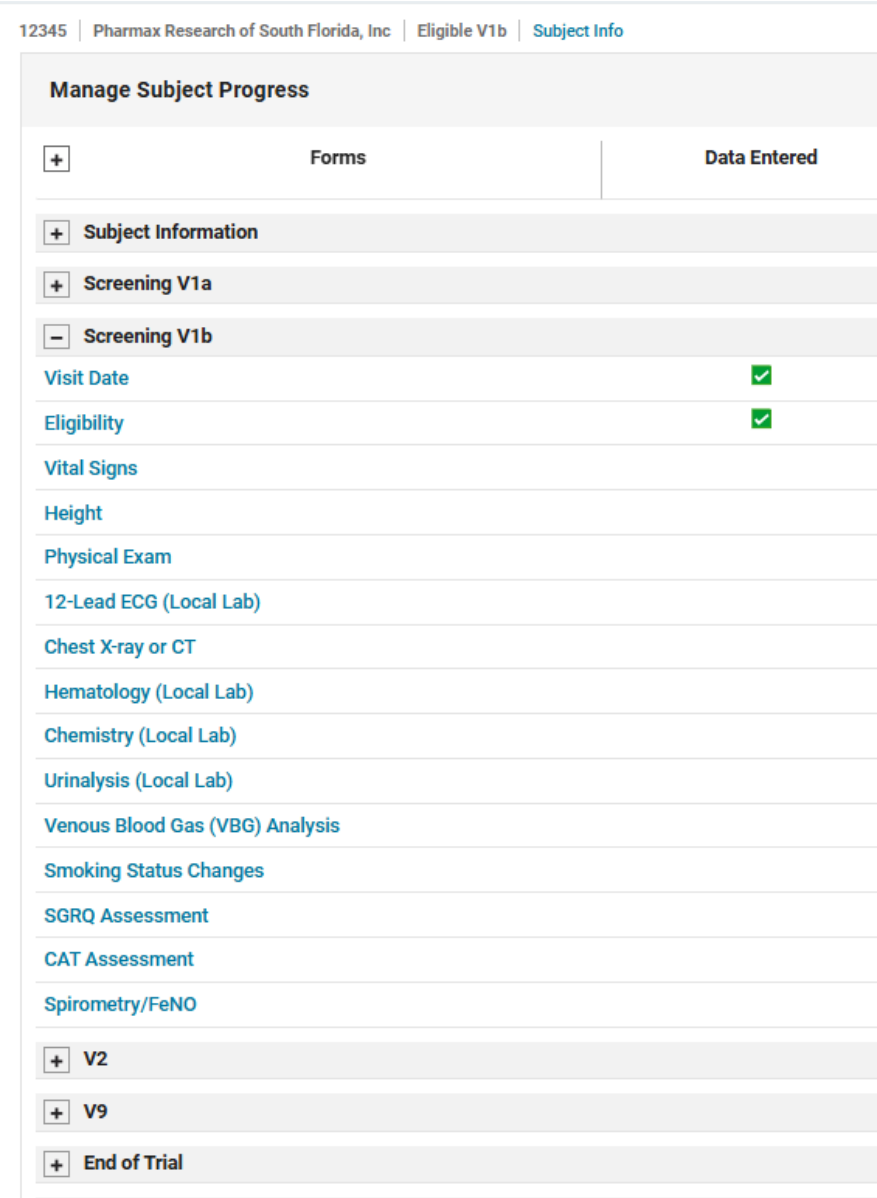
Within each participant schedule folder, first populate the [Visit Date] eCRF.

- Once confirmed that the visit occurred, add the [Visit Date:] and the remaining eCRFs for the visit will appear in the participant's schedule.
- Once confirmed that the participant will proceed to the next visit, the subsequent visit eCRFs will appear in the participant's schedule.

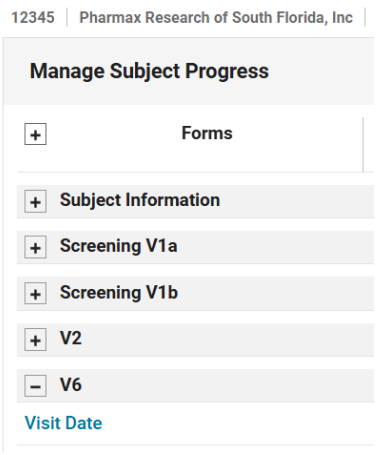




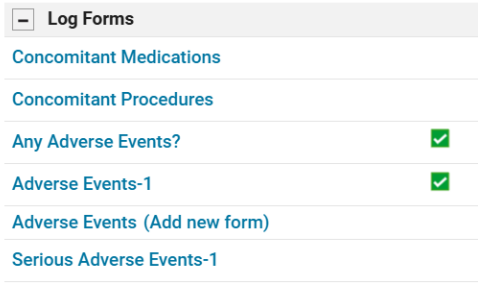
To trigger the V2 visit, both the [Visit Date] and [Eligibility] eCRF must be submitted at the Screening V1b visit. This will also trigger the V9 and End of Trial visits, as participants may withdraw consent from study visits at any time after V2.



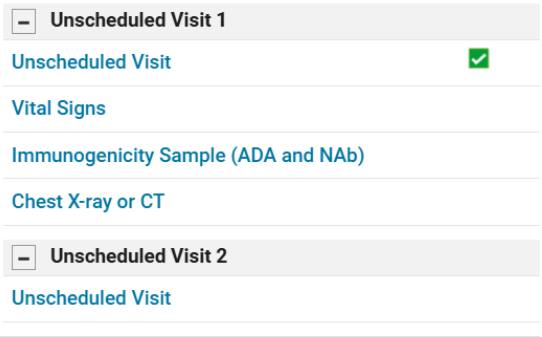
Within the V2 visit, enter [Visit Date] with same requirements as above. To trigger subsequent participant schedule visits, also populate the [Index COPD Exacerbation] eCRF. If [Did the exacerbation result in a hospitalization at V2?] is Yes or if [Does the participant consent to having optional spirometry measurements taken on Day 2 and Day 3?] is Yes, then visits V3 and V4 will appear in the participant's schedule. If [Did the exacerbation result in a hospitalization at V2?] is No or if [Does the participant consent to having optional spirometry measurements taken on Day 2 and Day 3?] is No, then V3 and V4 will be skipped and the V5 visit will appear as the next visit in the participant's schedule.



To enter Adverse Events, populate the [Any Adverse Events?] eCRF in the Log Forms folder. If yes is selected, the [Adverse Events] eCRF will appear in the folder for entry.
If an Adverse Event is indicated as 'Serious', the [Serious Adverse Event] eCRF will populate in this folder for entry.

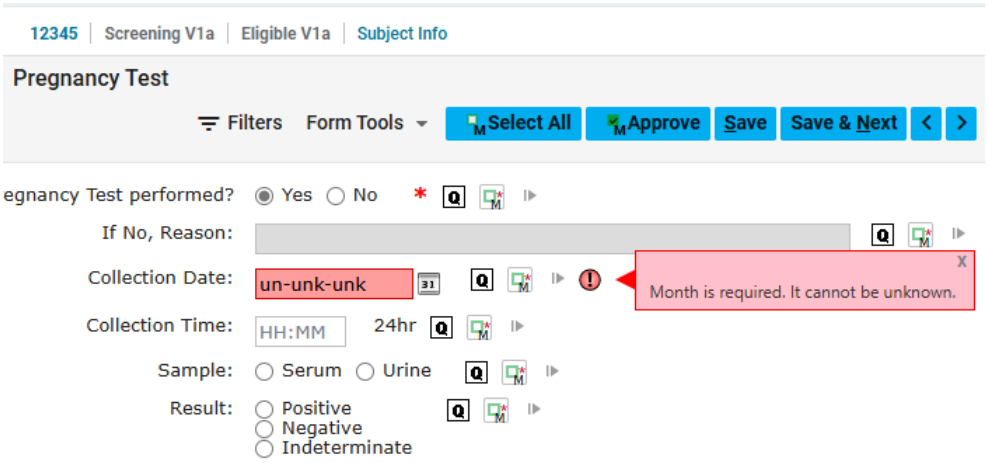


In the event a participant has an Unscheduled Visit, navigate to the bottom of the schedule to the [Unscheduled Visit 1] folder. First, populate the [Unscheduled Visit] eCRF to indicate the [Visit Date:] and select all assessments that occurred. These assessments will then populate within the [Unscheduled Visit] folder. In the event an additional Unscheduled Visit is conducted, answer 'Yes' to the [Did participant have an additional Unscheduled visit?] field on the [Unscheduled Visit] eCRF. This will trigger the next Unscheduled visit folder. This study was built to accommodate 10 Unscheduled Visits. In the event additional Unscheduled Visits are needed, contact your study DM.



Queries

Edit checks are programmed within the database to fire queries if the data entered does not satisfy the edit check customized for this project. They are triggered once the eCRF is saved and/or at the time data is entered in a field. The query icon is red exclamation point that is located next to the data field that needs to be addressed. This is an example of a query on the [Pregnancy Test Collection Date].



To review and address a query, open the query that has fired by selecting the Query Icon

Resolving Queries

There are three ways to resolve queries:

1) Changing the data
   - If data entered is not correct and data should be changed per source, click on the data field, update the data, then select the reason why data is changed. Note: Do not enter data to be updated in the query comments. All data should be updated on the eCRF field.
2) Respond to query (No data change)
   - If data is entered correctly as is, per source, respond to the query by entering a comment to confirm data is correct and/or add additional clarification.
   - Click the [Queries Icon], a field information page will pop up. Select the [Respond] button in the upper right corner, enter a Comment, then select Save. Note: Do not enter data in the query comments. All data should be updated on the eCRF.

3) Edit Form
    - If a field and/or form has already been SDV'd and there are queries to resolve post SDV, select [Edit Form] to enable the query to be addressed, select edit options and reason for change, then resolve query – either edit data or respond to query. See screenshots for examples:

Accessing CCGs

In the 'Manage' tab, under Study Management Options, under Study Documents, you will find the study specific CRF Completion Guidelines eCCGs.

Project Specific Information

Screen Failures/Enrolled Participants

Screen failures are defined as participants who signed the ICF to participate in the clinical trial but are not subsequently randomized. These participants are not required to complete the EOT visit assessments. Screen failures should be recorded in the Interactive Response Technology (IRT) according to instructions in the IRT manual.

Participants who initially screen fail for the trial solely due to the ineligible eosinophil count (i1. Eosinophil count of <300 cells/µL) at Screening Visit 1b, are allowed to re-screen no more than twice if they experience another COPD exacerbation, provided it is deemed appropriate by the Principal Investigator.

If re-screened, the participant should be assigned a new participant number in the IRT.

All participants meeting enrollment criteria will be randomized at baseline (V2) to receive treatment with either rademikibart 600 mg SC or volume-matched placebo.

As participants qualify for randomization, they will be assigned to treatment by the IRT System.

Minimum eCRFs required for Screen Failures include:

- Informed Consent
- Demographics
- Eligibility
- Serious Adverse Events, if applicable
- Adverse Events, if applicable

Guidelines -Per Project Specific eCRFs

Visit Date

Visit date is the date a visit occurred. If [Was the Visit performed?] is Yes, complete [Visit Date] and [Will participant continue to the next visit?]. If assessments for a scheduled visit occur over multiple dates, the date of the first assessment should be recorded.

If the visit was not performed, enter the reason. No further CRFs will populate for that visit.
If the participant continues to the next visit, indicating yes for this question will trigger the next visit in the participant schedule to be populated.

Informed Consent

[Participant Number] is an IRT integrated field and is read only.

For [Date Informed Consent Signed], enter the date the participant signed and consented to participate in the study. This date should be before all on-study procedures and dates.

[Informed Consent Version] should correspond to the current informed consent version the participant was consented to. Incremental versions should be rounded down to the whole number (ie Version 1.1 consented, select Version 1 in EDC).

Select the correct [Screening Channel] to populate the V1a or V1b screening. Screening Channel V1a is for participants who are consented while in a stable state. Screening Channel V1b is for participants who are consented after having experienced a qualifying exacerbation. This field will trigger the V1a or V1b visit in the participant schedule.

For [Was the participant re-consented?], enter Yes if a new consent has been obtained. Populate the date and informed re-consent version.

The [Participant Re-Screen #1 and #2] are auto generated by IRT in case a participant is re-screened.
These fields will be blank if the participant has not been rescreened.
Note: If the participant has been rescreened twice, Participant Re-Screen #1 will be the most recent prior participant number. If the participant has been rescreened once, Participant Re-Screen #1 will be their prior participant number.

Eligibility

[Protocol Version] should correspond to the protocol version that was effective at the time the participant was consented. Incremental versions should be rounded down to the whole number (ie Version 1.1 consented, select Version 1 in EDC).

Note: Protocol version selection with determine CRF availability according to the schedule of assessments for the following CRFs:

- Height/Weight
- 12 -Lead ECG
- Pregnancy Test only required if Pregnancy Test at Baseline Screening V1a and Screening V1b visit are not done on the same date.
- Health Care Utilization

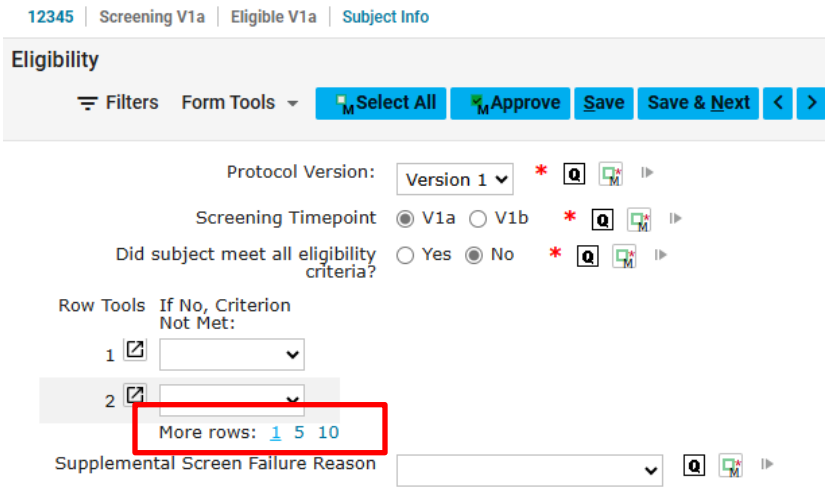
[Screening Timepoint] is required. Ensure this field matches the current visit where Eligibility is confirmed. Participants who enter the study via Channel V1a will have their eligibility confirmed at both V1a and V1b.

If response to [Did participant meet all eligibility criteria?] is Yes at the Screening V1b visit, the V2 visit in the participant schedule will appear for Randomization/Treatment information to be collected.

If response to [Did participant meet all eligibility criteria?] is No, then enter in the data for the Criterion not met.

For Criterion No, enter the number listed in protocol sections 7.1 Inclusion Criteria and 7.2 Exclusion Criteria.

The eCRF has pre-defined rows available to enter data for Criterion Not Met. If more rows are needed, select [More Rows] as applicable. If you select 1, then one row will be added to the eCRF, if you select 5 or 10, then that many respective additional rows will be added.



The [Supplemental Screen Failure Reason] field is intended for participants who screen fail for reasons other than, or in addition to, inclusion and exclusion criteria. Reasons such as lost to follow-up, withdrawal of consent, and physician decision can be found here.

Randomization

Eligible participants will be randomized to one of the 2 treatment arms using IRT. [Date of Randomization:] and [Randomization Number:] are IRT integrated fields and are read only.

Participants will be randomized at baseline (V2) to received treatment with either rademikibart 600 mg SC or volume-matched placebo.

Demographics

Enter all requested data fields.

[Date of Birth:] the participant must be greater than or equal to 40 years of age to participate in the study and no older than 80 years inclusive at the time of signing the informed consent form. Enter the participant's birth Mon (MMM) and year YYYY). UNK-YYYY may be entered if birth month is unknown or per local regulation.

[Age At Screening]: This is an IRT integration field and is Read-Only. Data will flow from IRT to EDC.

[Sex:] This is an IRT integration field and is Read-Only. Data will flow from IRT to EDC.
If Female, please indicate if the subject is of childbearing potential.

[If Female, is participant of childbearing potential?] Indicate if female subject is of childbearing potential. [Yes] will trigger the 'Pregnancy Test' CRF.

[Race (Mark all that apply):] select all race options that are applicable to the participant. If other is selected, enter in [Other Race, Specify] field.

The collection of race and ethnicity is based on the FDA Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials. Additional information on this guidance, can be obtained at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials-and-clinical-studies-fda-regulated-medical

Medical and Surgical History

Enter all requested data fields. This CRF is set up as log form. Add 1 row for each medical condition and/or surgery.

The medical history will collect all active conditions and any relevant clinically significant condition which was diagnosed prior to date of Informed Consent. Record the participant's medical history (excluding COPD medical history) including medical conditions, diagnostic results, (drug) allergies and relevant physical examination findings (if applicable). For history and treatment related to COPD, enter data on the 'COPD History and Exacerbation History' eCRF. Use standard medical terminology and only record one condition per line.

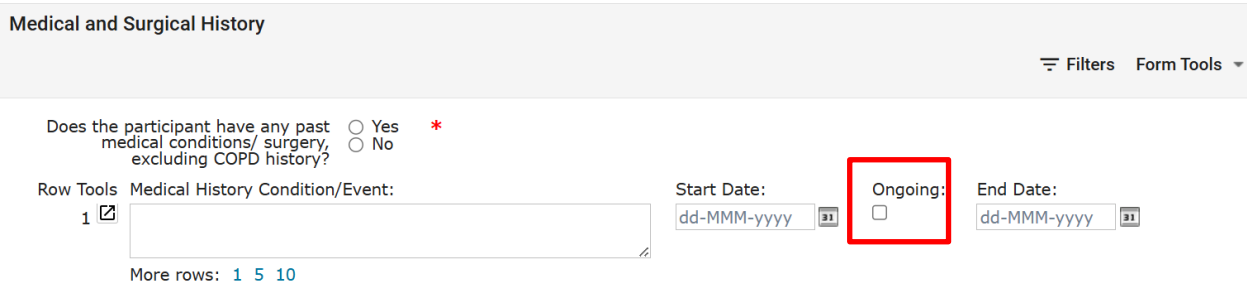
Any pre-existing condition present at the time the participant signs the ICF through the participant's last visit or 28 days post last dose, whichever is longer, that worsen during the study, should be entered as an adverse event on the Adverse Events eCRF.

Any new medical conditions that occur after signing of the ICF but prior to IP administration should be recorded on the Medical and Surgical History eCRF and considered adverse events. AEs reported during this time that are serious should also be reported as an SAE per protocol Section 11.6.

Any adverse event a participant may experience post signing of ICF that meets the definition of Serious Adverse Events (SAE) per protocol Section 11.7.1 must be reported as an SAE on the SAE eCRF.

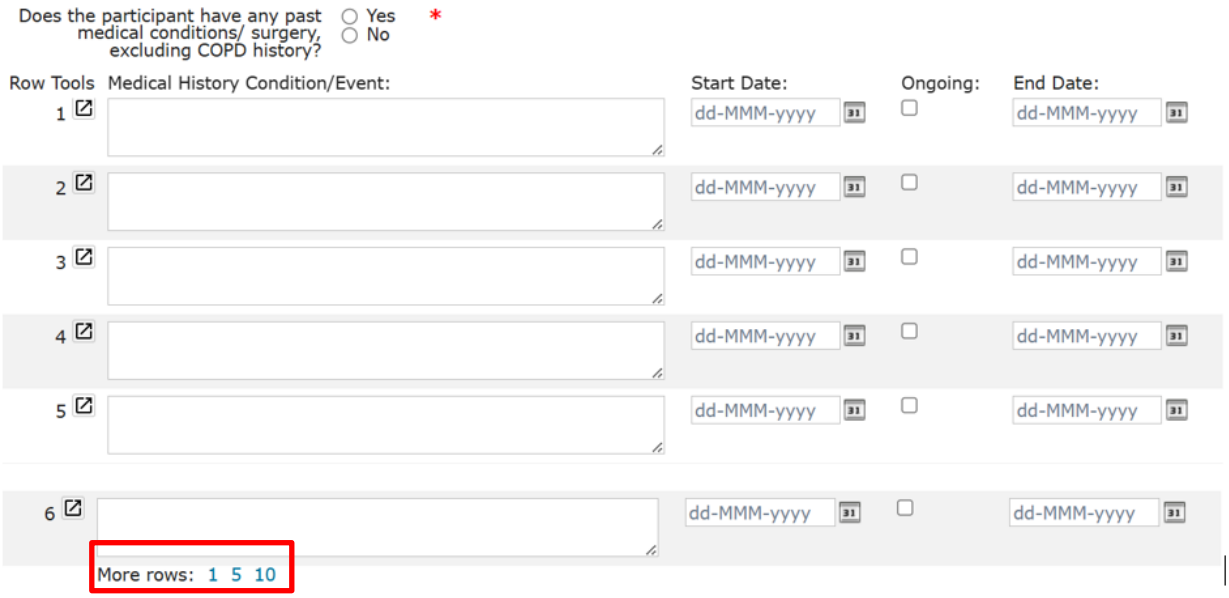
If response to [Does the participant have any past medical conditions/ surgery, excluding COPD history?] is No, then the rest of eCRF will be disabled for entry.

It is preferred that the complete date is provided as available; however, if the complete [Start Date] and/or [Stop Date] are not known for medical history, then at minimum, enter the Year. For unknown month enter UNK and unknown day enter UN.



Ongoing: Select [Ongoing], if the medical history condition is still present at the time the eCRF is being completed. If the medical condition resolves/ends during the course of the study, update the Medical History and enter the End Date.

The eCRF has pre-defined rows available for data entry. If more rows are needed, select [More Rows] at the bottom of the eCRF page as applicable. If you select 1, then one row will be added to the eCRF, if you select 5 or 10, then that many respective additional rows will be added.



COPD History and Exacerbation History

Record participant's COPD history from the [First appearance of COPD symptoms]. For both [First appearance of COPD symptoms] and [COPD Diagnosis Date], year must be known. For unknown month enter UNK and unknown day enter UN.

If [Has the participant ever received any biologic treatment for COPD, inluding during a clinical trial?] is yes, add the relevant biologic treatment information to the Concomitant Medications form. In the field [If yes, add the relevant biologic treatment information to the CM-Concomitant Medication form and enter the CM#] enter the CM number only (e.g. 1 or 2).

Record participant's COPD exacerbation history in the previous 12 months.

[Number of COPD exacerbations that resulted in hospitalization within the previous 12 months prior to screening] Hospitalization includes observation for over 24 hours in an ED or urgent healthcare facility, to collect how many severe COPD exacerbation in previous 12 month.

[Total number of COPD exacerbations that resulted in systemic corticosteroids treatment, antibiotics, or hospitalization in the last 12 months] This is all moderate and severe COPD exacerbation. Mild exacerbations will not be counted. Hospitalization includes observation for over 24 hours in an ED or urgent healthcare facility.

For the most recent historical COPD exacerbation that resulted in systemic corticosteroids treatment and/or hospitalization a complete [Event start date] and [Event end date] are required.

If [Did the exacerbation require treatment with systemic glucocorticosteroids?] is Yes, enter this information on the Concomitant Medications eCRF.

V1a Follow-Up Phone Log

Participants who consent to participate through Screening Channel V1a will be contacted by telephone approximately every 4 weeks after Screening V1a to collect any changes in concomitant medications and any SAEs.

If [Not Done] is selected, the row will grey out.

Add "More rows" as needed to complete additional phone contacts with participants.

Vital Signs

Enter all requested data fields. The vital signs assessment per each visit is defined per protocol schedule of events. Ensure the timing vital signs are collected as per protocol, section 11.2.1.

Any abnormal findings that are new or worsened in severity and clinically significant, in the opinion of the Investigator, will be recorded as an AE.

If response to [Were Vital Signs Collected?] is No, then the rest of eCRF will be disabled for entry. [If No, Reason:] should be completed.

If vital signs were conducted outside of an expected visit per schedule of events, enter the data on the Unscheduled Vital Signs eCRF.

If [Not Done] is selected for any parameter, the result field will grey out.

Please enter results in the unit specified on the eCRF.

Height/Weight

Height will only be measured at Screening Visit 1a or 1b. Select [Not required] for all subsequent visits. The participants' height must be measured without shoes.

Height will be recorded in centimeters (cm).

Enter unscheduled collections in the Unscheduled Visit section.

[Was Weight collected?] If Yes, record subject [Weight:] and [Collection Date:].

Note: Weight is defaulted to Kilogram (Kg)

[BMI]: this field is auto- calculated. Once weight and height are both entered click 'Update Value' to get the BMI. If weight or height changes value after the page has been saved, click 'Update Value' to re-calculate the BMI

Note: BMI will be calculated automatically to 1 decimal place. For purposes of inclusion criteria, round to the nearest whole number. (For example, participant with BMI of 35.4 rounds down to 35 and meets inclusion criteria #3)

Physical Exam

Complete and symptom-directed physical examinations will be performed at timepoints per the SoA (Table 5).

A complete physical examination will cover general appearance, dermatology, head, ears, eyes, nose, throat, respiratory, cardiovascular, abdominal, neurological, musculoskeletal, and lymphatic body systems.

Symptom-directed physical examinations can be performed at the Investigator's discretion at timepoints allowed per the SoA.

Findings from physical examinations will be documented in the appropriate sections of the eCRF. Abnormal findings identified during physical examination will be evaluated and documented by the Investigator as to whether the abnormality is an AE or medical history.

If [Was a Physical Exam performed?] is No, then complete [If No, reason].
Select [Not Required] when symptom-directed physical exam is not conducted per investigator discretion.
If Yes, complete all fields on the form.

Select [Complete] or [Symptom-directed] for the appropriate visit.

The [Date of the Examination] is required and cannot be left Unknown.

For each [Body System] select the appropriate [Interpretation]. The [Finding] field will populate in the event that the Interpretation is indicated as Abnormal. If Abnormal Clinically Significant, please enter adverse event or medical history number in the [Finding] field. [Body System Not Assessed] should be utilized for body systems not assessed.

Pregnancy Test

This form will be completed for all female participants recorded as 'Female' and if [If Female, is participant of childbearing potential?] is Yes on the Demographics CRF.

A complete [Collection Date:] is required.
Record [Collection Time:] in a 24 hour format.
Record [Sample] as "Serum" or "Urine". Note that per the Schedule of Assessments, serum pregnancy test must be conducted at V1a and V1b. A urine pregnancy test must be conducted at V2 (unless V1b and V2 are on the same day, then a urine pregnancy test is not required), V8, and V9. Both serum and urine pregnancy tests will be analyzed at the local lab.

The investigator must notify the Sponsor of any pregnancy by completing the Pregnancy Form and emailing it to the Sponsor **within 24 hours** after the Investigator becomes aware of the pregnancy. Email alerts will be disseminated to the Sponsor and safety representatives in the event of an on-study pregnancy.

Pregnancy is not considered to be an AE. Do not report as an SAE unless outcome of pregnancy meets SAE criteria (i.e. ectopic pregnancy, spontaneous abortion including miscarriage and missed abortion, intrauterine fetal demise, neonatal death, congenital anomaly).

Enter unscheduled collections in the Unscheduled Visit section.

Laboratory Test

Central lab tests for Hematology, Chemistry and Urinalysis sample(s) are collected on this eCRF. Indicate in all sections whether the sample was collected per protocol requirements.

Local lab tests for Hematology, Chemistry and Urinalysis sample(s) are collected on a separate eCRF at V1b.

A complete [Collection Date:] is required.
Record [Collection Time:] in a 24-hour format.

Enter unscheduled collections in the Unscheduled Visit section.

Clinically significant abnormal laboratory values should also be entered as an AE. Record the specific diagnosis rather than the abnormal result, see Adverse Events section for additional information.

Concomitant Medications

All medications taken from 3 months prior to the participant's initial Screening Visit 1a or Visit 1b through the end of the trial, including those given in the urgent healthcare setting to treat the index acute COPD exacerbation are captured on this log form.

If systemic steroids were discontinued and later restarted, each course should be entered as a separate entry with its respective start and end dates. This is critical to study endpoints.

Any medication or vaccine (including over-the-counter or prescription medications, vitamins and/or herbal supplements) received at Screening visits and throughout the trial must be recorded.

Any biologic drugs taken as treatment for COPD, including during a clinical trial, are to be entered in the Concomitant Medications form.

Oxygen therapy should also be included as a concomitant medication.

The [Start Date] and [End Date] allow for Unknown Day and Month. Year is required.

[Ongoing] is only selected in case there is no End Date. Ongoing status of all medications should be assessed at each visit and finally at the End of Trial visit for [End Date:] information. In the event a subject passes away on study, the date of death should be entered as the [End Date:] for all ongoing medications.

If [Unit] or [Dose Form] or [Route] or [Frequency] or [Prophylaxis, Specify] is "Other" complete the [Other, Specify] field accordingly.

If [Frequency] is pro re nata (PRN) and the medication is related to COPD treatment, please enter approximate actual frequency instead of selecting PRN. When the frequency changes, add a new entry to capture the intensification or reduction in pharmacological treatment.

> Note: the exception to the above is PRN rescue medication changes in frequency. This information will be reported by the participant in the daily e-Diary. PRN rescue medication use should only be captured once in the Concomitant Medications eCRF.

Depending on the selection for [Indication], populate the remaining fields. Select all that apply.

- Medical History: Refer to the Medical History (MH) eCRF for the corresponding MH and enter the MH number. If medication is related to MH and is ongoing at the time of ICF, leave End Date blank and check "ongoing". The medication will not need to be entered again for the duration of the study.
- COPD: Select COPD if medication is for treatment of COPD

- COPD Exacerbation: Select COPD Exacerbation if medication is for treatment of a COPD exacerbation. Check either Index or Subsequent for the question 'Is exacerbation an index or subsequent exacerbation?' If medication is for a subsequent COPD exacerbation, please provide the associated Subsequent Exacerbation number.
- Adverse Event: Select if medication is for treatment of an adverse event. Refer to the Adverse Event (AE) eCRF for the corresponding AE number.
- Procedures: Select Procedures if a medication is used for a procedure. *Refer* to the Concomitant Procedures eCRF for the corresponding Procedure number.
- Prophylaxis: Select if medication is used for prophylaxis of any condition. Please provide details on type of prophylaxis taken by the participant.
- "Other" is to be used if the reason for administration is *not* an Adverse Event, Medical History, COPD, COPD Exacerbation, or Prophylaxis. Please use this option and make your description as specific as possible.

Select [More rows] to add rows to this log form.

The Medical Monitor should be contacted if there are any questions regarding prior or concomitant medications.

Concomitant Procedures

[Non-Drug Therapies/Procedures]: Provide the procedure or non-medication the treatment name. Enter one term per line. Common procedures for COPD exacerbation may include invasive/non-invasive ventilation (Continuous Positive Airway Pressure [CPAP], Bilevel Positive Airway Pressure [BiPAP]), endotracheal intubation, and arterial blood gas (ABG) analysis, etc.

If ventilation was administered during COPD Exacerbation Episodes (Index or Subsequent), please record it in the Concomitant Procedure eCRF.

If [Did the participant have any non-drug therapies or procedures during the study?] is Yes, the form will generate fields to complete.

The [Start Date] and [End Date] allow for Unknown Day and Month. Year is required.

[Ongoing] is only selected in case there is no End Date. Ongoing status of all therapies should be assessed at each visit and finally at the End of Trial visit for [End Date:] information. In the event a participant subject passes away on study, the date of death should be entered as the [End Date:] for all ongoing therapies.

If [Frequency] is "Other, Specify", complete [Specify Other Frequency].

Depending on the selection for [Indication], populate the remaining fields. Select all that apply.

- Medical History: Refer to the Medical History (MH) eCRF for the corresponding MH and enter the MH number.
- COPD and COPD Exacerbation: Check either Index or Subsequent for the question 'Is exacerbation an index or subsequent exacerbation?' If COPD Exacerbation is subsequent, please provide Subsequent Exacerbation number.
- Adverse Event: Refer to the Adverse Event (AE) eCRF for the corresponding AE number
- Prophylaxis: Select if procedure is for the prophylaxis of any condition. Please provide details on type of prophylaxis taken by the participant.
- "Other" is to be used if the reason for procedure is *not* an Adverse Event, Medical History, COPD, COPD Exacerbation, or Prophylaxis. Please use this option and make your description as specific as possible.

Select [More rows] to add rows to this log form.

Any Adverse Events?

All AEs regardless of causality will be recorded. If [Has the participant experienced any Adverse Events?] is Yes and the eCRF is saved, the Adverse Events eCRF will populate to collect further information.

Adverse Events

This form is completed if the participant has experienced any Adverse Events. To add a new "Adverse Events" form, select "Adverse Events (add new form) from the Form View within the Log Forms folder.

[AE #]: This field should be unique and sequentially assigned. This is a manual field. Please check prior AE # added to assist with consistent numbering. This field will be utilized to reference AE as an Indication across other CRFs like Concomitant Medications/Procedures, Exacerbation History, etc.

[AETERM] list only one adverse event per log line. This field will be coded using the information provided verbatim.

- Record the specific diagnosis rather than abnormal results, e.g., "ALT 120 U/L" is not allowed.
- Record only one term per row, e.g., "Nausea and Vomiting", should be provided as "Nausea" and "Vomiting" separately.
- Do not use abbreviations, e.g., GERD should be spelled out as Gastroesophageal reflux disease.

- Please do not enter the Medications or Non-drug Treatments.
- If a pre-existing medical condition from the Medical History CRF worsens or increases in severity, record this change in condition as an Adverse Event. Use the same event term that was recorded in the Medical History CRF and modify it to note worsening.
- Avoid recording duplicate AEs if an ongoing AE or MH has already been entered.
- If applicable, organ or body part/system involved should be specified to allow for accurate coding. For example: "Neck Pain" and "Abdominal Pain".
- Do not record "pregnancy" as an Adverse Event.

[Start Date] and [End Date] of the AE must be a complete date. If an AE is serious, indicate the dates the AE becomes/is considered serious on the SAE CRF separately. Partial dates are not acceptable.
[Ongoing] is only selected in case there is no End Date. Ongoing status of all AEs should be assessed at each visit and finally at the End of Trial visit for [End Date:] information. In the event a participant passes away on study, the date of death should be entered as the [End Date:] for all ongoing AEs.

Select the appropriate [AE Category (Select all that apply)], this is a required field. "Not Applicable" should be selected in the event none of the categories apply.

[DILI] **Suspected Drug-induced Liver Injury (DILI)**
DILI refers to a liver injury induced by various chemical drugs, biological products, herbal medicines and their metabolites or even excipients. Hy's Law can facilitate assessment of severe liver injury predominated by hepatocellular injury. It specifically refers to cases that meet all of the following 3 criteria:
For participants with normal liver function tests at baseline:

1. ALT or AST ≥ 3× ULN during Treatment Assessment Period, and
2. Total bilirubin > 2× ULN during Treatment Assessment Period; without cholestasis at baseline (serum alkaline phosphatase [ALP] increased), and
3. No other identifiable causes explaining the simultaneous elevation of aminotransferases and total bilirubin, such as viral hepatitis A, B, C or E or other acute liver diseases, or concomitant use of other drugs that may induce liver injury.

[AESI] **Adverse Event of Special Interest (AESI)**
An AESI may be serious or non-serious and is one of scientific and medical concern specific to the Sponsor's product mechanism of action, for which ongoing monitoring may be appropriate. Such an event might warrant further investigation to characterize and understand it and rapid communication by the trial Sponsor to other regulatory authorities may also be warranted.
For this trial, AESIs shall include:

- Conjunctivitis

- Keratitis
- Severe injection site reactions persisting for more than 24 hours: defined as injection site reactions persisting for more than 24 hours and the severity is CTCAE Grade ≥3.
- Parasitic and opportunistic infections: whether the infection is classified as opportunistic infection will be determined after discussion with medical monitor. When reporting opportunistic infection, the Investigators will refer to protocol Appendix J Table 7.
- Anaphylaxis: defined according to the symptoms shown in protocol Appendix J Table 8.

[UADE] **Unanticipated Adverse Device Effect (UADE)**
According to 21 CFR 812.3(s), a UADE means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device (pre-filled syringe in this case), if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants.

[Severity] is important to distinguish between serious and severe AEs. The Investigator will use the CTCAE Version 5.0 to assist in the determination of severity and clinical significance. The following represents CTCAE grading of AE severity:

- Grade 1: asymptomatic or mild symptoms or clinical or diagnostic observations only or intervention not indicated.
- Grade 2: minimal, local or noninvasive intervention indicated or limiting age-appropriate instrumental activities of daily living (ADL). Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.
- Grade 3: hospitalization or prolongation of hospitalization indicated or disabling or limiting self-care ADLs. Self-care ADLs refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications and not bedridden.
- Grade 4: Life-threatening consequences with urgent intervention indicated.
- Grade 5: Death related to AE.

[Serious] An AE or suspected adverse reaction is considered “serious” if, in the view of either the Investigator or Sponsor, it results in any of the following outcomes:

- Death
- A life-threatening AE (ie, presented an immediate risk of death from the event as it occurred. This criterion is not intended to include an AE that, had it occurred in a more severe form, might have caused death.)
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity to conduct normal life functions
- A congenital anomaly/birth defect
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical

judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

The following events do not meet the definition of an SAE: hospitalization for elective treatment of a pre-existing condition that does not worsen from baseline, hospitalizations for a standard procedure for IP administration, routine monitoring of the studied indication not associated with any deterioration in condition, social or convenience admission to a hospital, prolongation of a hospitalization for social or convenience reasons not associated with the occurrence of an AE, or hospitalization or an emergency room visit that lasts less than 24 hours that does not meet the criteria of an important medical or a life-threatening event.

If [Serious:] is selected as Yes, the Serious Adverse Event eCRF will populate for entry in the Log Forms Subject Information folder to collect additional details.
Email alerts will be disseminated to the Sponsor and safety representatives when [Serious:] is selected as Yes.

[Serious Adverse Event #:] This field should be unique and sequentially assigned. This is a manual field. Please check prior SAE # added to assist with consistent numbering. This SAE # should match the number entered in the SAE CRF.

[Causality] relates to the IP administration according to the following guidelines.

- Possibly Related: the AE is known to occur with the IP, there is a reasonable possibility that the IP caused the AE, or there is a temporal relationship between IP and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the IP and the AE.
- Unlikely Related: there is not a reasonable possibility that the administration of the IP caused the event, there is no temporal relationship between the IPand event onset, or an alternate etiology has been established.

[Action Taken with Study Drug:] Select [Dose not changed] if full dose of study drug was already administered. Select [Dose Interrupted] if AE resulted in interruption of full dose during administration. Select Not Applicable if AE occurs prior to dosing.

[Outcome] Select outcome of the AE from the drop-down list: Resolved, resolved with sequalae, not resolved, unknown, and death. In the event a participant passes away on study, only the AE that is the primary reason for death should have an outcome of [death] and other AE in this case should be [not resolved].

Serious Adverse Events

This eCRF will be completed if [Serious] is Yes on the "Adverse Events" eCRF. Complete the SAE eCRF within 24 hours of awareness.

Only enter one SAE per eCRF, add a new instance of the SAE eCRF for additional SAEs.

Enter the [AE#] that corresponds to the event term reported from the "Adverse Events" eCRF.

[SAE #]: This field should be unique and sequentially assigned. This is a manual field. Please check prior SAE # added to assist with consistent numbering.

Mark all that apply when selecting the [Serious Criteria Met].

If the participant is hospitalized, complete the [Date of Inpatient Hospitalization] and [Date of Inpatient Hospitalization Discharge], partial dates are not acceptable.

> Note: If the SAE criteria is prolongation of existing hospitalization, then [Date of Inpatient Hospitalization] refers to the day when the inpatient must prolong the hospitalization due to SAE.

If the participant has a fatal outcome, complete if the redacted autopsy report has been emailed to: connectsafety.sm@thermofisher.com and PV@connectpharm.com.
[Date of First Dose of Study Drug:] is a derived field, populating from the Study Drug Administration eCRF.

Any updates saved to the SAE (or it's supporting parent AE) eCRF will result in an email alert to the Safety and Sponsor representatives.

To add a new "Serious Adverse Events" form, select the "Serious Adverse Events (add new form) from the Forms View.

12-Lead ECG (Local Lab)

Measurements will be performed with the participant resting in a supine position for approximately 5 minutes before each reading and should be carried out after measurement of vital signs and before spirometry. ECGs should be performed before blood is drawn during visits requiring blood draws.

If [Was a 12-Lead ECG performed?] is Yes, complete all fields on the form. Date Performed may not be Unknown.

Record the protocol defined assessments in the units specified.
The [QTcF] is a derived field and is read only.
If [Interpretation] is indicated as Abnormal , enter Adverse Event number or Medical History Number in the [If Abnormal, Specify:] field as applicable.

Enter unscheduled collections in the Unscheduled Visit section.

PK Sampling

If [Were PK sample(s) collected] is Yes, complete the [Timepoint] noting correctly if "Pre-Dose" or "Post-Dose".

A complete [Collection Date:] is required.
Record [Collection Time:] in a 24-hour format.

Enter unscheduled collections in the Unscheduled Visit section.

Biomarker Sample

If [Were biomarker sample(s) collected?] is Yes, complete the [Collection Date] and [Collection Time].

A complete [Collection Date:] is required.
Record [Collection Time:] in a 24-hour format.

Enter unscheduled collections in the Unscheduled Visit section.

Immunogenicity Sample (ADA and Nab)

If [Were Immunogenicity (ADA and Nab) sample(s) collected?] is Yes, complete the [Collection Date] and [Collection Time].

A complete [Collection Date:] is required.
Record [Collection Time:] in a 24-hour format.

Enter unscheduled collections in the Unscheduled Visit section.

Chest X-ray or CT

A chest X-ray (or CT scan), for purposes of determining participant eligibility, will be performed only at Screening Visit 1b.

If [Was the Chest X-ray/CT performed?] is Yes, complete [Date Performed] which is performed up to 48 hours after Screening.

Additional information is requested when [Interpretation:] is Abnormal.

Enter unscheduled collections in the Unscheduled Visit section.

Hematology (Local Lab)

Local Labs will be collected during Screening Visit 1b to expedite eligibility. At other visits, labs will be collected centrally on the "Laboratory Test" eCRF.

Enter the results in the corresponding units available. Note that you will need to manually enter the lab normal ranges.

Clinically Significant is only entered when the result is not within the laboratory normal ranges. Otherwise, it should be blank.

Enter unscheduled collections in the Unscheduled Visit section.

Chemistry (Local Lab)

Local Labs will be collected during Screening Visit 1b to expedite eligibility. At other visits, labs will be collected centrally on the "Laboratory Test" eCRF.

Enter the results in the corresponding units available. Note that you will need to manually enter the lab normal ranges.

Clinically Significant is only entered when the result is not within the laboratory normal ranges. Otherwise, it should be blank.
Enter unscheduled collections in the Unscheduled Visit section.

Urinalysis (Local Lab)

Local Labs will be collected during Screening Visit 1b to expedite eligibility. At other visits, labs will be collected centrally on the "Laboratory Test" eCRF.

Enter the results in the corresponding units available. Note that you will need to manually enter the lab normal ranges.

Clinically Significant is only entered when the result is not within the laboratory normal ranges. Otherwise, it should be blank.
Enter unscheduled collections in the Unscheduled Visit section.

Venous Blood Gas (VBG) Analysis

Enter the results in the corresponding units available.

Clinically Significant is only entered when the result is not within the laboratory normal ranges. Otherwise, it should be blank.
Enter unscheduled collections in the Unscheduled Visit section.

Smoking History

If [Was the Smoking History collected?] is Yes, complete the [Approximate Smoking Start Date] and [Approximate Smoking Cessation Date]. The approximate date will allow an Unknown entry for Day and Month. The Year is required. Use the format UN-UNK-YYYY for unknown day and month. Use the format UN-MMM-YYYY for unknown day.

[What is the participant's Smoking History?] Former smokers are defined as individuals who have stopped smoking for at least 6 months prior to Screening (Visit 1b).

[Estimated Number of Pack-Years] should be calculated as defined in Protocol Section 11.1.2. Number of pack-years = (number of cigarettes per day / 20) × number of years smoked) (eg, 20 cigarettes per day for 10 years, or 10 cigarettes per day for 20 years both equal 10 pack-years)

One pack of cigarettes a day for 1 year is equivalent to:

- 1 cigar or pipe per day for 1 year
- Smoked hookah or shisha =1 session per day for 1 year
- Vaped e-cigarettes =0.5 mL e-liquid per day for 1 year, or =1 cartridge/tank/pod per day for 1 year
- 1 use of marijuana per day for 1 year

Smoking Status Changes

Changes in smoking status are captured for consented participants through EOT visit. Pharmacological smoking cessation therapies will be recorded on Concomitant Medication eCRF.

[Smoking Start Date] and [Smoking Cessation Date] allow for Unknown day. Month and Year are required. Use the format UN-MMM-YYYY for unknown day.

Enter unscheduled collections in the Unscheduled Visit section.

Index COPD Exacerbation

This eCRF indicates the baseline exacerbation of the participant at the V2 visit.

Complete dates are required throughout the eCRF.
Times are to be reported in 24-hour format.

[Did the exacerbation result in a hospitalization at V2?] is an IRT integrated field and is read only. Based on the response to this question in IRT, the participants' schedule will trigger visits V3 and V4 if it is Yes. If [Did the exacerbation result in hospitalization at V2?] is No, but [Does the participant agree to having optional spirometry measurements taken on Day 2 and Day 3?] is Yes, this will also trigger V3 and V4. If [Did the exacerbation result in hospitalization at V2?] is No, and [Does the participant consent to having optional spirometry measurements taken on Day and Day 3?] is No, then the system will skip these visits and populate the next as the V5 visit.

If ventilation was administered, please record it in the Concomitant Procedure eCRF.

In the event the Index COPD Exacerbation requires hospitalizations/interventions which are ongoing beyond the V2 visit, the exacerbation information should be followed to completion and entered on the 'Index COPD Exacerbation Follow-Up' eCRF.

The index COPD exacerbation should also be entered as an SAE if the event is considered serious.

Index COPD Exacerbation Follow-Up

This eCRF is utilized to follow any hospitalizations/interventions which were ongoing from the V2 'Index COPD Exacerbation' eCRF or to capture any new treatment visits related to the index exacerbation.

Complete dates are required throughout the eCRF.
Times are to be reported in 24-hour format.

All Urgent Care and Emergency Room details are to be entered in the CRF as applicable.

[Did the exacerbation result in an Urgent Care (re)visit?]: Mark YES if the participant had a new, distinct urgent care visit after V2 and within 14 days of onset of the index exacerbation for the original exacerbation.

[Did the exacerbation result in an ER (re)visit?]: Mark YES only if the participant had a new, distinct emergency room/department after V2 and within 14 days of onset of the index exacerbation.
[Did the index exacerbation require (re)hospitalization?]: Mark YES only if the participant had a new, distinct hospitalization after V2 and within 14 days of onset of the index exacerbation.

If ventilation was administered, please record it in the Concomitant Procedure eCRF.

An Unscheduled Visit should be utilized to complete this form if:

- Participant becomes hospitalized or re-hospitalized for the index exacerbation after V2 and within 14 days of onset or
- Participant visits or re-visits the ED for the index exacerbation after V2 and within 14 days of onset
- Participant visits or re-visits Urgent Care for the index exacerbation after V2 and within 14 days of onset

After 14 days the Subsequent COPD Exacerbation CRF should be utilized for new exacerbations. The protocol states that for both moderate and severe events to be counted as separate events, they must be separated by at least 14 days.

Subsequent COPD Exacerbation Episode

Enter 1 eCRF for each subsequent COPD Exacerbation Episode after the Index COPD Exacerbation resolves.

An exacerbation should be considered subsequent if it occurs on or after Day 14, unless the Index COPD exacerbation is still ongoing. The subsequent exacerbation CRF appears starting on Visit 7 (Day 14).

Complete dates are required throughout the eCRF.
Times are to be reported in 24-hour format.
All Urgent Care and Emergency Room details are to be entered in the eCRF, as applicable.

Exacerbation severity: mild, moderate, or severe
Exacerbations of COPD are defined as clinically significant worsening of COPD symptoms, including increases in dyspnea, wheezing, cough, sputum volume, and/or increase in sputum purulence. Exacerbation severity is further defined as moderate if treatment with systemic corticosteroids and/or antibiotics was required, or severe if they resulted in hospitalization or observation for over 24 hours in an ED or urgent healthcare facility.

All other exacerbations will be classified as “mild.”

For both moderate and severe events to be counted as separate events, they must be separated by at least 14 days.

If ventilation was administered, please record it in the Concomitant Procedure eCRF.

Complete the SAE CRF if the exacerbation meets SAE criteria.

Enter unscheduled collections in the Unscheduled Visit section.

Health Care Resource Utilization

Complete dates are required throughout the eCRF.
Times are to be reported in 24 hr format.

Enter unscheduled collections in the Unscheduled Visit section.

Injection Day Vital Signs

Utilize this eCRF to record vital signs at the V2 visit.
Enter all requested data fields. Injection day vital signs are to be collected at timepoints specified in protocol section 11.2.1. Fields are available in the eCRF for any other timepoints that may be collected.

Any abnormal findings that are new or worsened in severity and clinically significant, in the opinion of the Investigator, will be recorded as an AE.

If response to [Were Vital Signs Collected?] is No, then the rest of eCRF will be disabled for entry. [If No, Reason:] should be completed.

If [Not Done] is selected for any parameter, the result field will grey out. Please enter results in the unit specified on the eCRF.

Study Drug Administration

Utilize this eCRF to record information relating to IP Administration at the V2 visit.

The following fields on this eCRF are IRT integrated and are read only. In the event that a kit is not replaced, the replacement fields will appear blank.

[Kit Number 1:]
[Kit Number 2:]
[Replacement Kit Number 1A:]
[Replacement Kit Number 2A:]
[Replacement Kit Number 1B:]
[Replacement Kit Number 2B:]

A complete [Date Administered:] is required.
Record [Start Time of Injection:] and [End Time of Injection:] in a 24-hour format.

[Start Time of Injection:] should indicate the time the first injection began.
[End Time of Injection:] should indicate the time the last injection was completed.

In the event that a participant does not receive all four injections, indicate 'Not Done' in the corresponding [Anatomical Location:] field which correlates with doses not received.

Injection Site Reaction Assessment

For assessments conducted after V2, select 'Not applicable' for the [Injection Day Timepoint] field.

A complete [Collection Date:] is required.
Record [Collection Time:] in a 24-hour format.

Report clinically significant findings on the Adverse Event eCRF.

Enter unscheduled collections in the Unscheduled Visit section.

SGRQ Assessment

A complete [Collection Date:] is required.

CAT Assessment

A complete [Collection Date:] is required.
Record [Collection Time:] in a 24-hour format.

Spirometry/FeNo

If [Was the Spirometry assessment completed?] is No, complete [If No, Reason].

If Yes, complete the [Timepoint], [Collection Date:] and [Collection Time:].
A complete [Collection Date:] is required.
Enter one row for each spirometry session. For example, the pre-BD session should be entered as one line, and the post-BD session should be entered as one line.

There are more rows than required per protocol in case of unscheduled sessions. Mark No to [Was the Spirometry assessment completed] for unnecessary rows. [If No, Reason] can indicate "Not required per protocol" or similar text.

Record [Collection Time:] in a 24-hour format.

If [Was the FeNo assessment completed] is No, complete [If No, Reason]. If Yes, complete the [Collection Date and Time].
Note: in the event a FeNo assessment is Not Required at the time of Spirometry Assessment, select [Not Required] for this section.

Enter unscheduled collections in the Unscheduled Visit section.

End of Trial

This eCRF is required for all participants who received IP administration on V2.

A complete date is required for [Date of Trial Completion/Termination:]. In the event a patient passes away after V2 visit, populate the date of death in this field.

If [Reason for Trial Completion/Termination:] is Adverse Event, ensure this information is entered on the corresponding AE eCRF.

If [Reason for Trial Completion/Termination:] is Death, ensure all ongoing log form entries are updated with an [End Date:] consistent with the date of death.

If [Death Details:] is checked as 'Not Due to COPD', add details on cause of death in [Specify Cause of Death:]

Investigator Signatures

Principal Investigators are required to review and apply an electronic signature for each participant's CRF. Applying this signature is the Investigator's attestation that the data entered in the database is complete and accurate. The CRA informs the Investigator when the CRFs are ready for review and signature. This notification occurs after the CRFs have been cleaned, verified against the source documents, and frozen. Investigators may be informed to sign eCRFs prior to freezing the database. Re-signing may be required if eCRFs have been updated due to new information or query response.

The Investigator Signature may be applied to an individual form, or the Investigator may batch sign the entire casebook.

To Sign an individual form, navigate to that form and review the data entered. At the bottom of the form, click on the Sign button to apply your credentials. A popup window will appear. Add your username and password. You will see that your signature has been applied.

To Batch sign a participant's casebook after the Investigator has reviewed the data entered, click the Sign Subject actions button on the participant's home page. This is located at the top of the home page. A popup window will appear. Add your username and password. You will see that your signature has been applied to the participant's entire casebook.

Certificate Of Completion

Envelope Id: B02950CB-1CDA-4D75-BA3F-BC3CE15DDEF1
Status: Completed
Subject: Complete with Docusign: CBP-201-207_eCRF Completion Guidelines_eCCGs_v2.0_20Nov2025.docx
GRC:
Vendor Name:
Practice Area:
Source Envelope:
Document Pages: 52
Signatures: 2
Certificate Pages: 5
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Disabled
Time Zone: (UTC-08:00) Pacific Time (US & Canada)

Envelope Originator:
Munim Saeed
2 Bethesda Metro Center
Suite 850
Bethesda, MD 20814
Munim.Saeed@precisionformedicine.com
IP Address: 165.225.208.181

Record Tracking

Status: Original
11/21/2025 9:20:46 AM
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Signer Events	Signature	Timestamp
Marisa Jones mjones@connectpharm.com Clinical Trials Associate Manager Connect Biopharma Security Level: Email, Account Authentication (Required), Login with SSO	Marisa Jones Signature Adoption: Pre-selected Style Signature ID: DA7DCEFC-9A1D-4049-B0A8-4A836FEDFF75 Using IP Address: 70.95.41.115 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 11/21/2025 9:22:38 AM Viewed: 11/21/2025 9:28:20 AM Signed: 11/21/2025 9:28:55 AM
Electronic Record and Signature Disclosure: Accepted: 11/21/2025 9:28:20 AM ID: 65caf7be-8e8e-46c4-aaa6-640141aad99b		
Munim Saeed Munim.Saeed@precisionformedicine.com Lead Clinical Data Manager Precision for Medicine - Part 11 Security Level: Email, Account Authentication (Required)	Munim Saeed Signature Adoption: Pre-selected Style Signature ID: 744C5F57-974A-4A03-94AC-786A59A34A62 Using IP Address: 165.225.208.181 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 11/21/2025 9:22:38 AM Viewed: 11/21/2025 10:29:39 AM Signed: 11/21/2025 10:30:29 AM
Electronic Record and Signature Disclosure: Accepted: 11/21/2025 10:29:39 AM ID: 59af3ddc-4441-446d-bed8-5a1f29829bf4		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	11/21/2025 9:22:38 AM
Certified Delivered	Security Checked	11/21/2025 10:29:39 AM
Signing Complete	Security Checked	11/21/2025 10:30:29 AM
Completed	Security Checked	11/21/2025 10:30:29 AM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

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