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WELCOME

Advancing Care, One Breath at a Time

Seabreeze STAT Trials Investigator Meeting

San Diego, CA | Friday, September 12, 2025

Investigator Meeting Agenda | San Diego, CA

Seabreeze STAT Trials - ***Advancing Care, One Breath at a Time***

Time (PT)	Session Title	Speaker(s)
08:30–08:40	**Welcome to Seabreeze STAT Trials:** Why This Program Matters	Dr. Barry Quart (Connect)
08:40–08:55	**Meet the Minds Behind the Mission (Introductions & Team Overview)** 🎉 *Trivia Showdown - Compete for prizes while mastering the protocols*	Dr. Raul Collazo, Master of Ceremonies (Connect)
08:55–09:10	**Tech Check:** iPad Setup & Interactive Tools Demo	Turner Papke (Array)
09:10–09:45	🎉 **Rademikibart Revealed:** The Science Driving the Trials + Live Q&A	Dr. Cristian Rodriguez (Connect)
09:45–10:00	🎉 **Safety Snapshot & Reporting**	Kimberly Manhard (Connect)
10:00–10:20	-- *Break & Take a Breather*	—
10:20–11:20	🎉 **Protocol Power Hour:** Asthma & COPD Essentials + Live Q&A	Dr. Marisa “MJ” Jones, Guy Boccia (Connect)
11:20–12:00	**Breath by Breath:** Spirometry & FeNO in Action	Dr. Erin Lennox (ZEPHYRx)
12:00–01:30	-- **Lunch & Learning Stations** • Spirometry Demo • Study Start-Up Station	All
01:30-01:40	**Diving into Labs:** Navigating Blood and the Lab Workflow	Guy Boccia (Connect)
01:40–01:50	🎉 **Behind the Scenes:** How Safety Committees Keep Trials on Course	Radha Adivikolanu (Connect)
01:50–02:50	**Recruitment That Works:** • Top Tips from an Expert • Table Talk / Voicing Innovative Recruitment	 Dr. Sanjay Ramakrishnan (ABRA Lead Investigator) All
02:50–03:10	**Tech at the Core:** Randomization Meets Data	Guy Boccia (Connect)
03:10–03:25	-- *Break & Moment to Breathe*	—
03:25–04:10	🎉 **Study Expectations & Monitoring with Meaning:** Oversight to Drive Quality	Aubree Malan (ProPharma Group)
04:10–04:30	**Closing Notes and Winning Moments (Trivia Champions!)**	All

🎉 **Trivia Tip:** Watch for this symbol on the agenda - fastest correct responders have a shot at *prizes*.

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Lunch and Learning – Return at **01:30 pm PT**

Let’s Lunch in the Atrium!

– Fuel up, mingle, and enjoy the break.

ZEPHYRx Spirometry Demo Station

– Hands-on experience with the device — come see it in action!

Study Start-Up Station

– Get prepped and ready — all the essentials in one spot!

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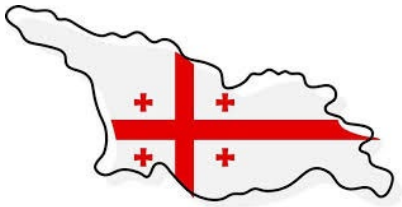
Diving into Labs

Navigating Blood and Lab Workflow

Guy Boccia, MA
Sr Director, Clinical Development Strategic Operations

LabConnect Locations

- LabConnect Cleveland
  - USA
- LabConnect Miami
  - Argentina
- LabConnect Australia Pty Ltd
  - Australia
- LabConnect GmbH Horbeller Straβe
  - Georgia
  - Serbia
  - United Kingdom



LabConnect Responsibilities

- ***Initial shipment of supplies***
- ***Queries related to requisitions***
- Issue queries to sites and receiving labs to resolve:
  - discrepancies related to information on the completed requisition forms
  - any uncertainty associated with collection and/or shipment of samples

- ***Fulfill Resupply Order Requests*** (submitted by sites)
  - Complete LabConnect Supply Reorder Form found in Lab Manual
    - Email request to workorders@labconnect.com

Site Responsibilities

Manage inventory of kits, shippers and additional supplies

Timely response to queries

Ship samples according to the detailed instructions in the Central Lab Manual

Adhere to the guidelines specified by the central lab manual

LabConnect Event Schedule and Visit Setup

	Phase	Screening	Randomization /Baseline	Post-IP Treatment Assessment			Follow-up	Unscheduled	Early Termination
	Visit	V1a	V2[1]	V5	V6	V8	V9	UNS	ET
	Day	Up to 26 Weeks to D-1	0	3	7 (Week 1)	28 (Week 4)	56 (EOT/Week 8)		
	Window				±2 days	±3 days	±3 days		
Lab Assessments	Draw Volume (mL)								
Chemistry[2]	12.0	A	A[3]		A	A	A	A	A
Hematology[2]	3.0	A	A[3]		A	A	A	A	A
Urinalysis[2]		A	A[3]		A	A	A	A	A
Total IgE[4]	3.5		B		B	B	B	B	B
PK[4]	2.0		C	C	C	C	C	C	C
ADA/nAb[4]	3.0		D			D	D	D	D
Biomarker Sample[4]	6.0		E		E	E	E	E	E
Total Blood Draw Per Visit (mL)		**15.0**	**29.5**	**2.0**	**26.5**	**29.5**	**29.5**	**29.5**	**29.5**
On Site Testing									
Urine Pregnancy			X[5]			X	X		

Kit Letter	Kit Name
A	Safety(AM)
B	IgE(AM)
C	PK(AM)
D	ADA/nAb(AM)
E	Biomarker Sample(AM)

Kit name abbreviation will be different per region. Example shown is for US.

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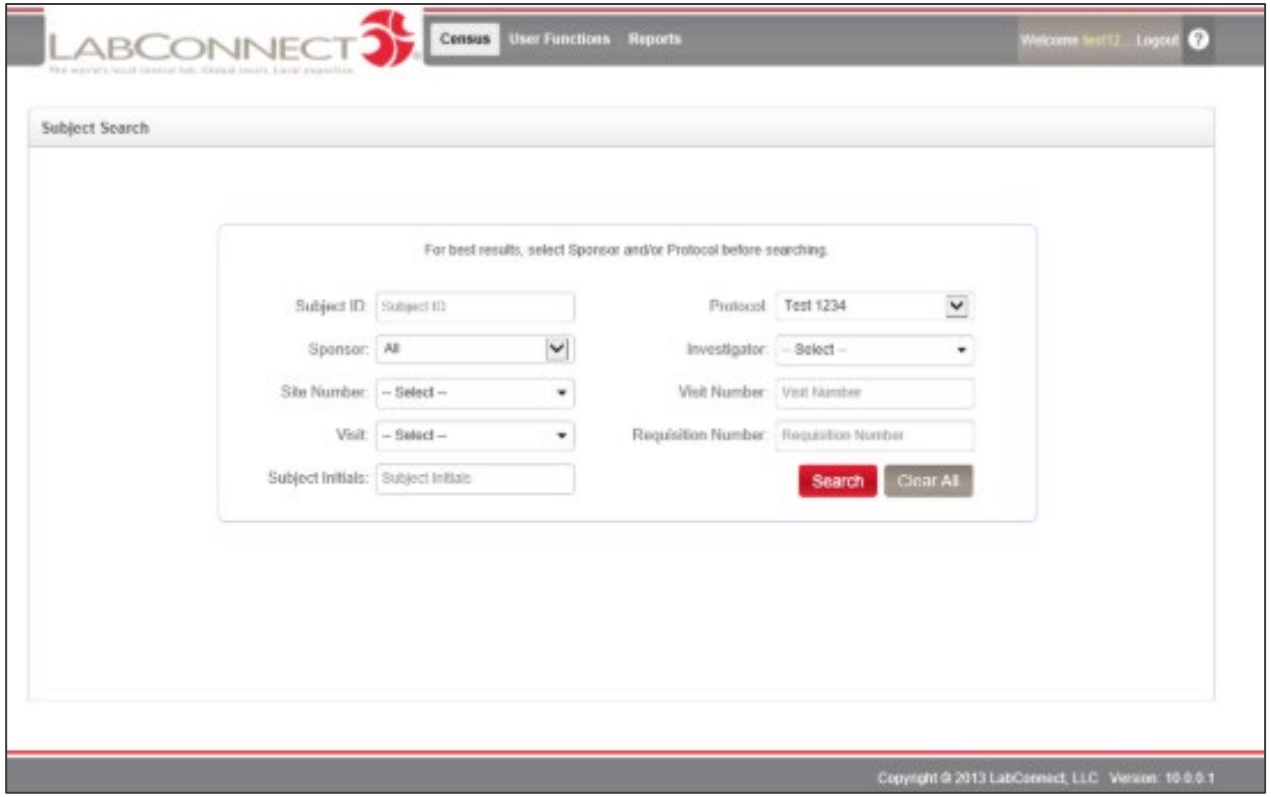
LabConnect Portal

- **Login Page**
  - Enter the base URL (https://labconnect.com/). It will open the Home page of the LabConnect website. Click on ‘Client Login’ button at the top right of the page.
- **User Login**
  - Enter the credentials (username and password) of the user, and complete the verification “captcha” before clicking LOGIN
- **Subject Search (Landing Page)**
  - In top right corner click the ‘?’ button to open the User Manual for SponsorREACH Module guide.



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Questions?

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Behind the Scenes: How Safety Committees Keep Trials on Course

Radha Adivikolanu, MSPH
Sr Manager, Clinical Operations

Data Monitoring Committee (DMC) Seabreeze STAT Trials

- Monitor participant safety in clinical trials
  - Independent of the trial's Investigators and Sponsor to ensure objective decision making
  - Reviews unblinded data on an ongoing basis
- Rationale
  - Seabreeze STAT Asthma: first trial to include adolescents outside of China
  - Seabreeze STAT COPD: first trial in this disease setting
  - Seabreeze STAT trials: first trials when rademikibart is administered during an acute exacerbation
- Membership
  - 5 physicians
    - 1 - General Medicine, Pharmacovigilance and Medical Governance
    - 2 - Internal Medicine
    - 2 - Pulmonology and Critical Care
  - Biostatistician
- Responsibilities
  - Evaluate Safety data, ultimately deciding if the trial should continue, change or terminate early based on cumulative findings
    - Connect or ProPharma Group (PPG) to communicate any DMC recommendations/requests to IRBs/IECs for changes in study
  - Review Interim Analysis (IA) results from each trial to review for potential adjustment of sample size
    - IA performed when half of participants in each trial complete Week 4 visit

Cardiovascular Events Adjudication Committee (CEAC)

*Seabreeze STAT COPD

- Provide external, systematic and unbiased review of all deaths and potential Cardiovascular (CV) treatment emergent adverse events
  - Independent of the trial's Investigators and Sponsor to ensure objective decision making
  - Adjudicates CV events in a blinded manner

- Rationale
  - COPD patients have higher risk of developing heart disease, stroke, heart failure and arrhythmias, this risk is increased following an acute COPD exacerbation

- Membership
  - 3 Cardiologists
    - Professor of Cardiovascular Medicine
    - Professor of Medical Cardiology
    - Distinguished Teaching Professor with Tenure: Internal Medicine/Cardiology

- Responsibilities
  - Assess the incidence of CV deaths and non-fatal CV events of myocardial infarction, stroke, AF/atrial flutter (AFI), and Heart Failure

Question

- Is there a Cardiovascular Adjudication Events Committee (CEAC) for both Seabreeze STAT studies?
  A. Yes
  B. No
  C. Depends on data outcome

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Recruitment That Works

Top Tips from and Expert

Sanjay Ramakrishnan, MD
ABRA Lead Investigator

Table Talk

ALL

Top Tips from an Expert
Dr. Sanjay Ramakrishnan (ABRA Lead Investigator)

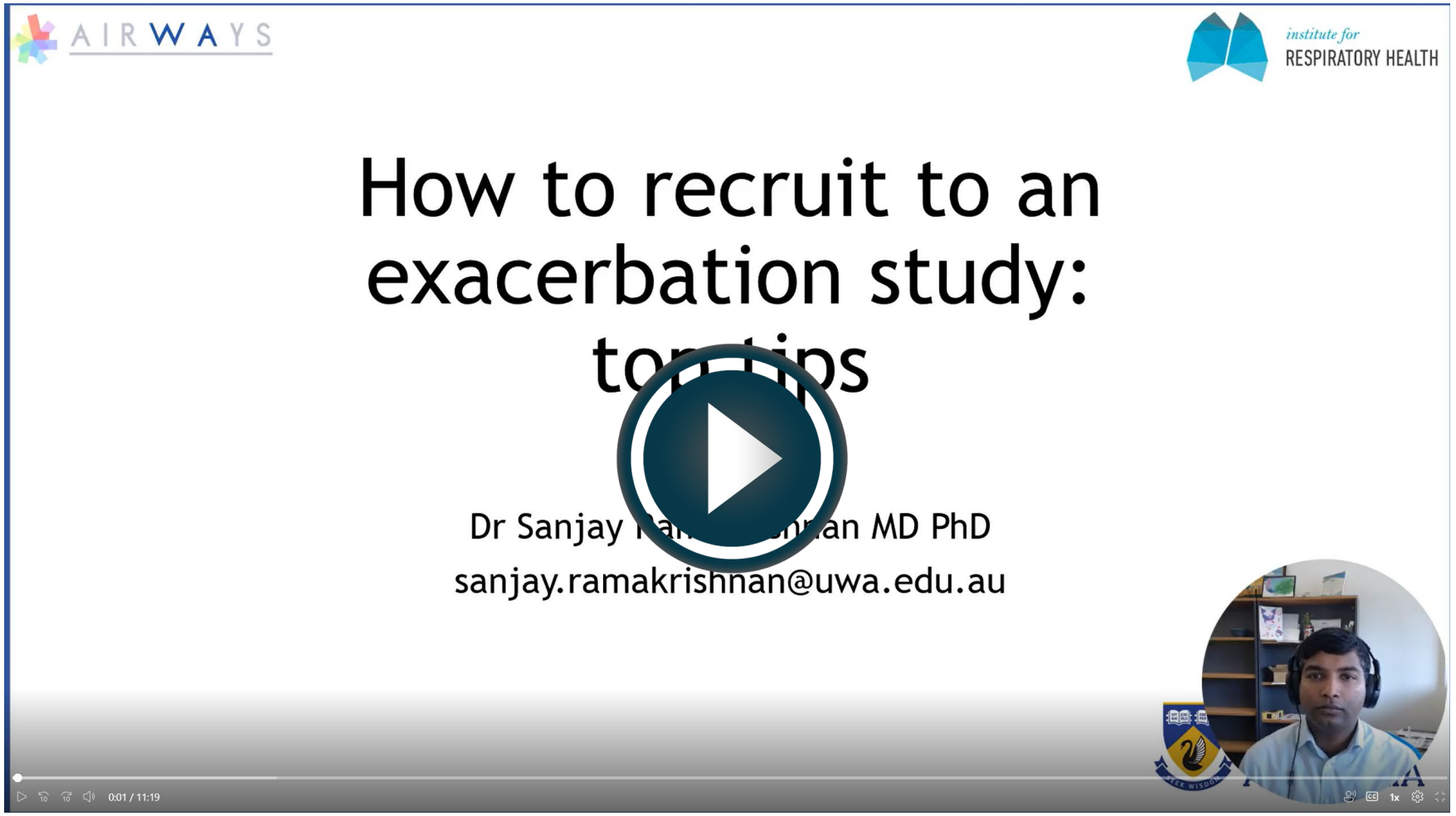


Table Talk: Voicing Innovative Recruitment

💡 Spark Something New!

– Gather with your table crew and brainstorm bold, brilliant recruitment ideas.

– 🔪 Be ready to share at least one standout concept with the room!

Tech at the Core

Randomization Meets Data

Guy Boccia, MA
Sr Director, Clinical Development Strategic Operations

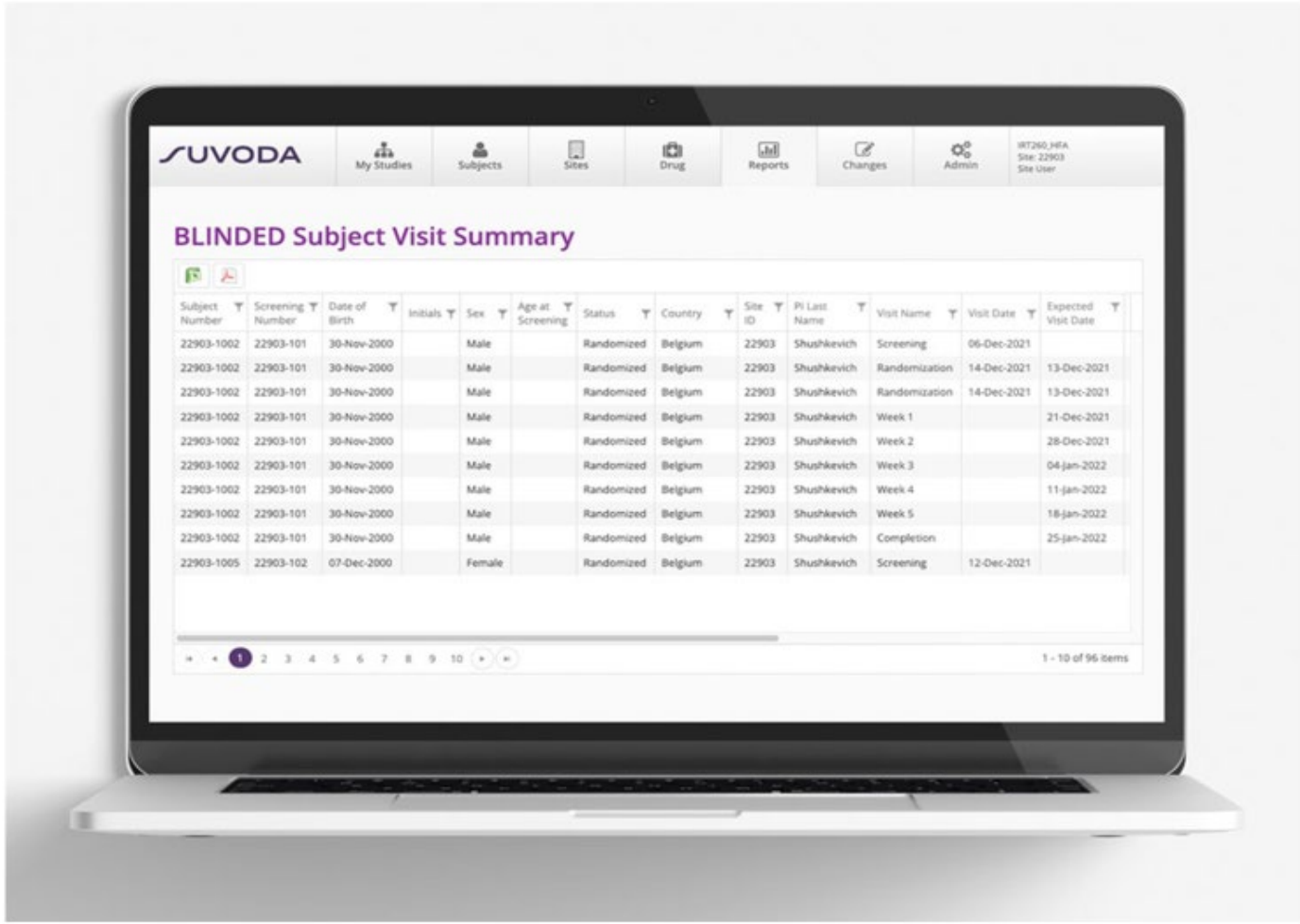
SUVODA SITE USER TRAINING

What is Suvoda?

Suvoda Interactive Response Technology (IRT)

Navigating the Suvoda Platform

- Investigative site users will use Sovoda IRT to register subject screening, enrollment, and drug-dispensing visits
- Suvoda is separate from the Electroninc Data Capture (EDC) system used to capture study subject data



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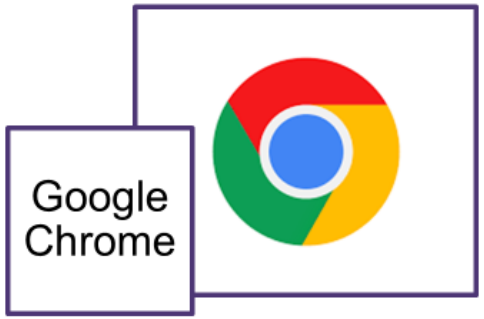
SUVODA SITE USER TRAINING

How will I be accessing Suvoda?

You will be accessing Suvoda through an Internet browser

Recommended Browsers:



Internet Explorer users may need to turn off Compatibility Mode before accessing the system.

I. Suvoda Self-Registration

Users will create their own Suvoda account via a self-registration process and request access to the study-level system.

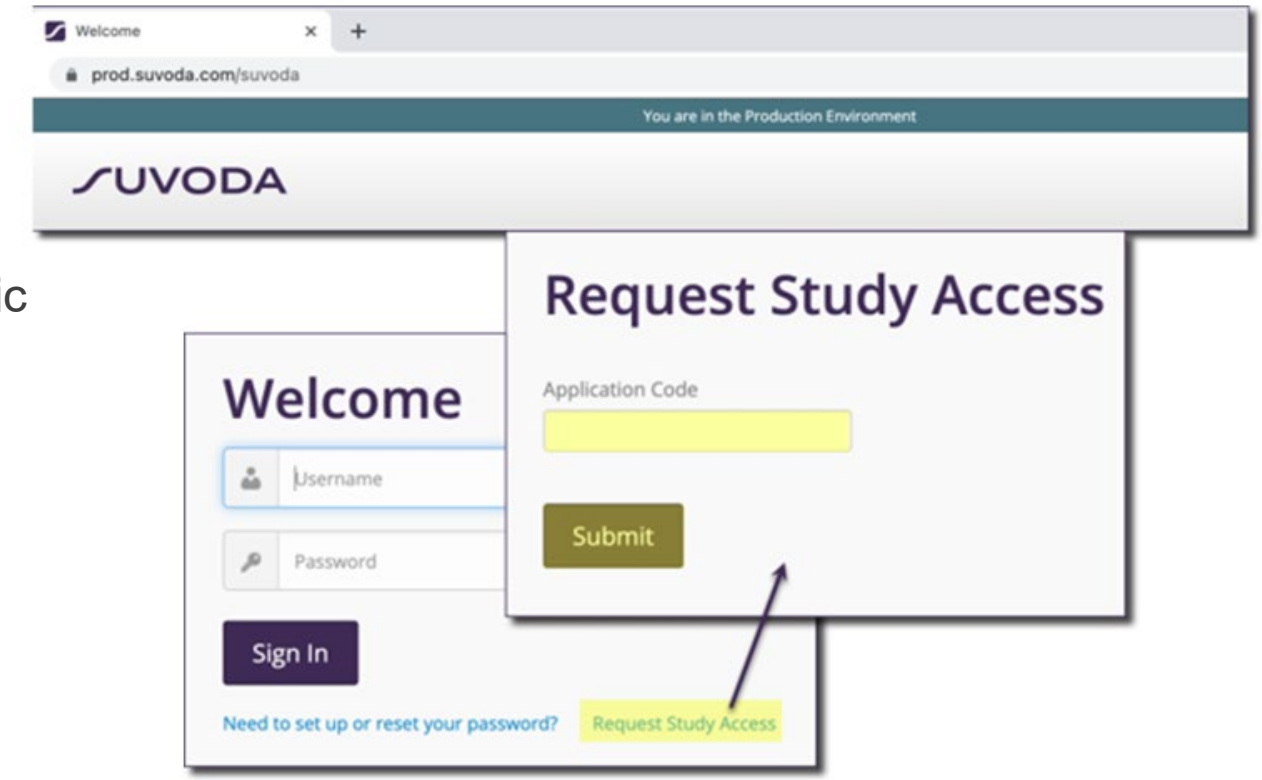
SUVODA SITE USER TRAINING

Requesting Study Access

Users create their own Suvoda account and request access to the study-level system

How To Request Study Access

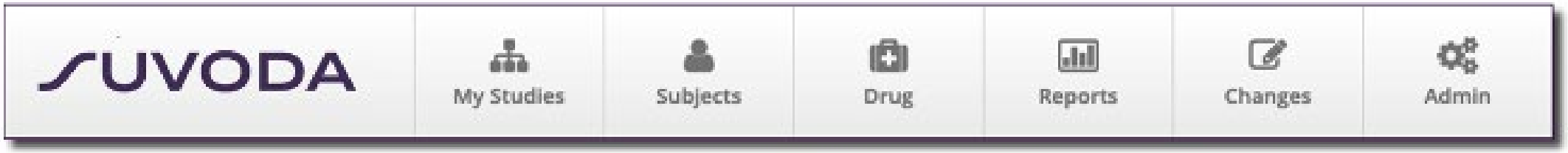
- Navigate to prod.suvoda.com/suvoda
- Click Request Study Access
- Enter Study Code
  - Find your study code in your protocol-specific summary sheet or user manual



Study Codes:

- Connect-CBP-201-206
- Connect-CBP-201-207

Suvoda - IRT

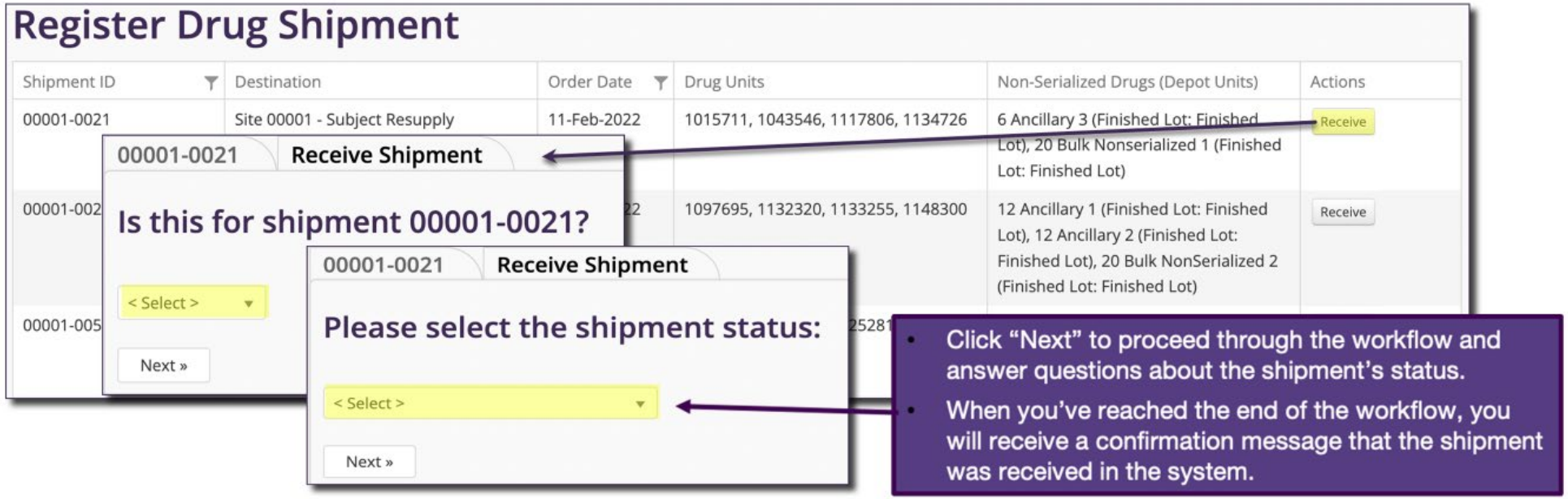


- My Studies – view protocols you can access with your account
- Subjects – perform subject-specific function (e.g. subject visits, drug dispensing)
- Drug – receive shipments at site, update site inventory, and perform drug reconciliation steps
- Reports – access IRT reports and export functionality
- Changes – correct subject demographic data
- Admin – access notifications

Register Receipt of Study Investigation Product Shipments

Register Drug Shipment

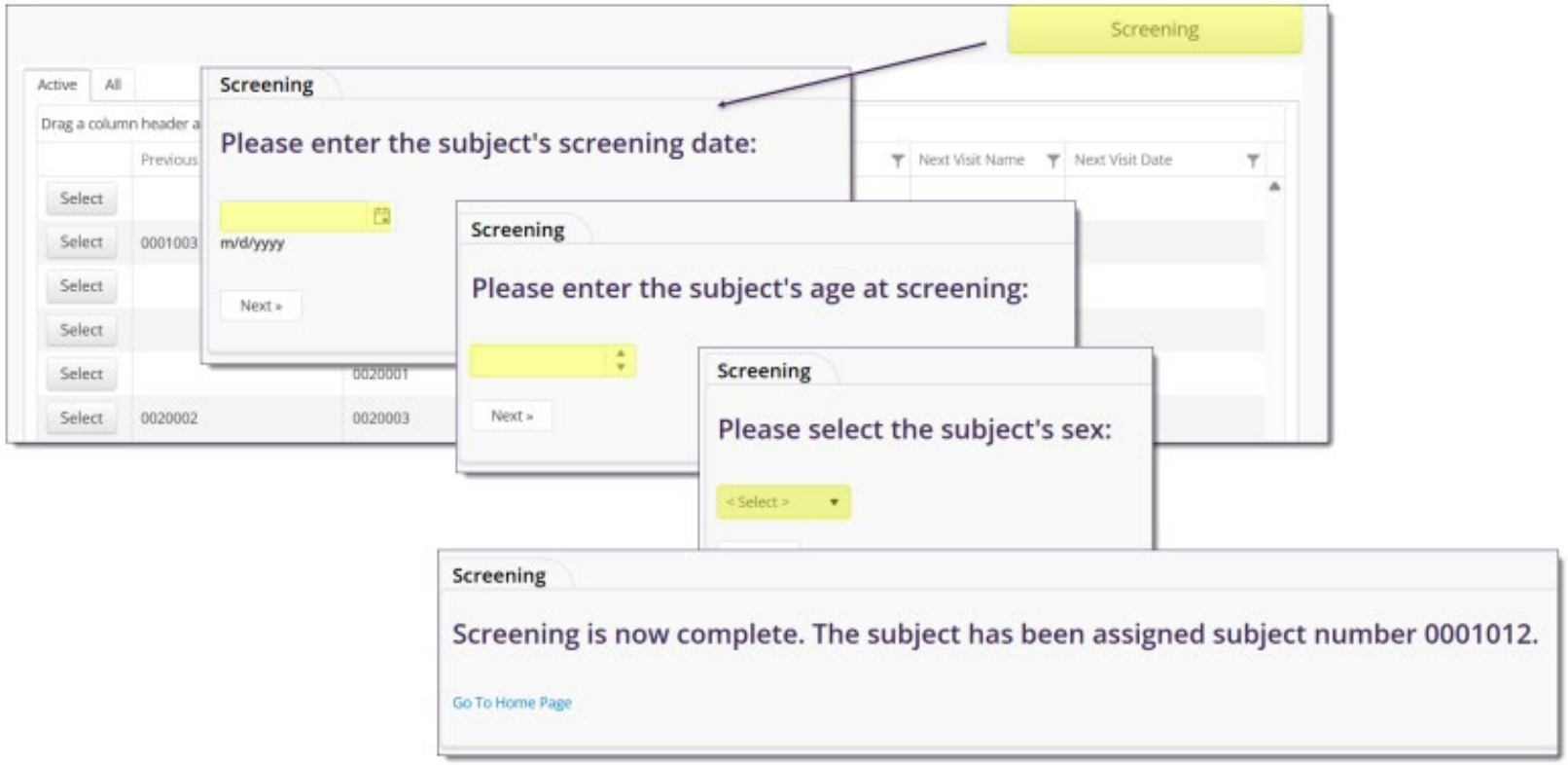
To register shipments in the IRT system, select the "***Register Drug Shipment***" function > Click the "***Receive***" button to the right of the shipment you wish to register.



Enter a New Participant in Suvoda

- **Important Note:** Subjects created in Interactive Response Technology (IRT) will automatically generate the subject in Electronic Data Capture System (EDC) (within 10 minutes). Subjects cannot be created in EDC.

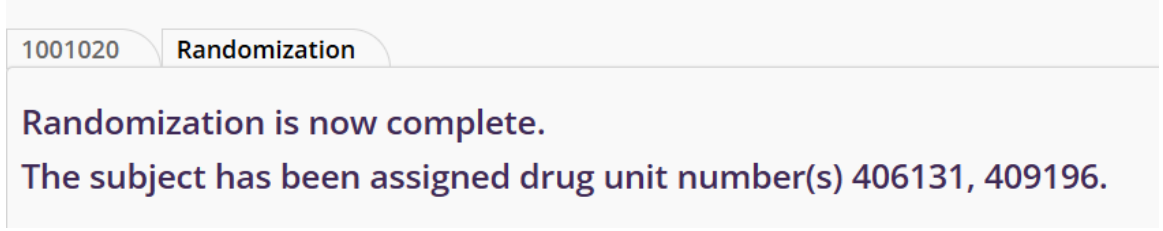
1. Click the “Screening” button (at the top of the Subjects tab)
2. Select the site at which you wish to screen the subject (if applicable) and confirm
3. Enter screening and demographic information, as applicable (e.g., Screening Date, Age at Screening, Subject’s Sex)
4. At the close of the workflow, the subject will be assigned a new Subject Number

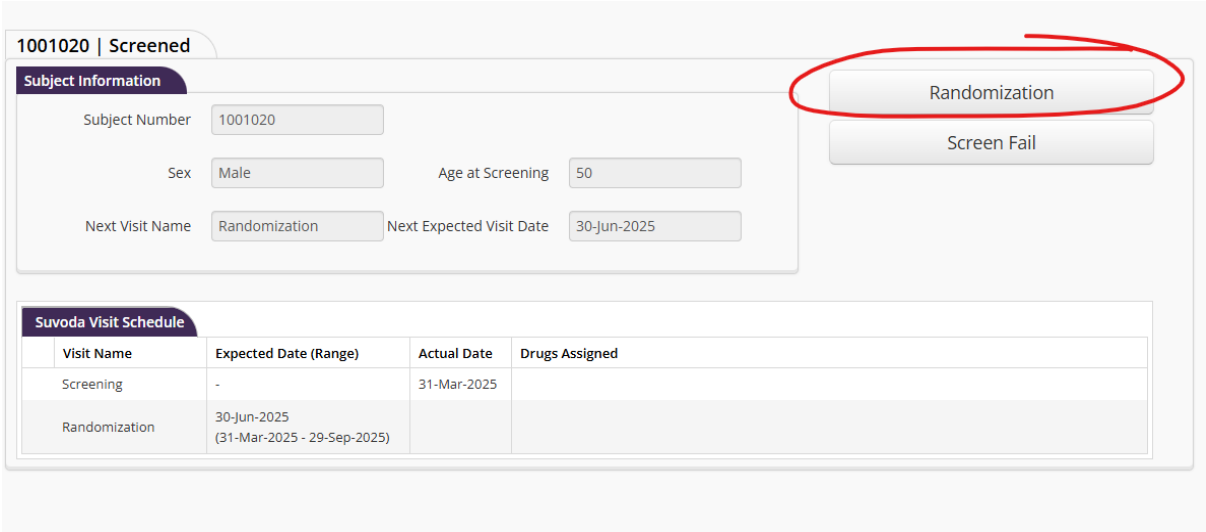


Randomize A Participant in Suvoda

1. Locate the screed subject for which you would like to perform a visit and click on the “Select” button to the left of that subject’s row on the Subjects tab
2. Click the “Randomization” function
3. Confirm the subject’s demographic information
4. Enter information required to enroll/randomize the subject, as prompted by the system (does/does not require hospitalization, baseline smoking status – former or current)
5. At the close of the workflow, the subject will be marked as randomized and the drug assigned to the subject will be displayed in the final prompt

- Two drug unit numbers will be generated for each subject randomized.
- IRT drug unit number = medication number on IP carton label





Suvoda - IRT

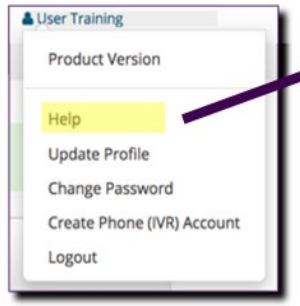
SUVODA SITE USER TRAINING

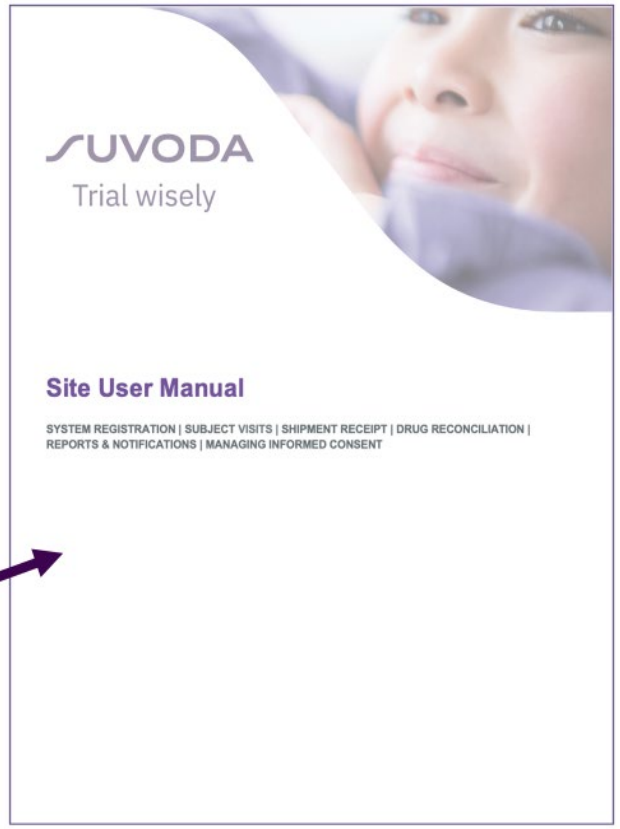
Additional Questions?

Access the Site User Manual in the “help” section of Suvoda IRT

How To Access the Site User Manual

- Log into the Suvoda IRT
- Click your name in the upper-right hand corner of the application
- Click “Help”
- View and download the user manual





Contact Suvoda

- Support@suvoda.com

USA
1-858-788-6321

Argentina
08006662236

Country Specific Toll Free Numbers
www.suvoda.com/toll-free-numbers

SUVODA

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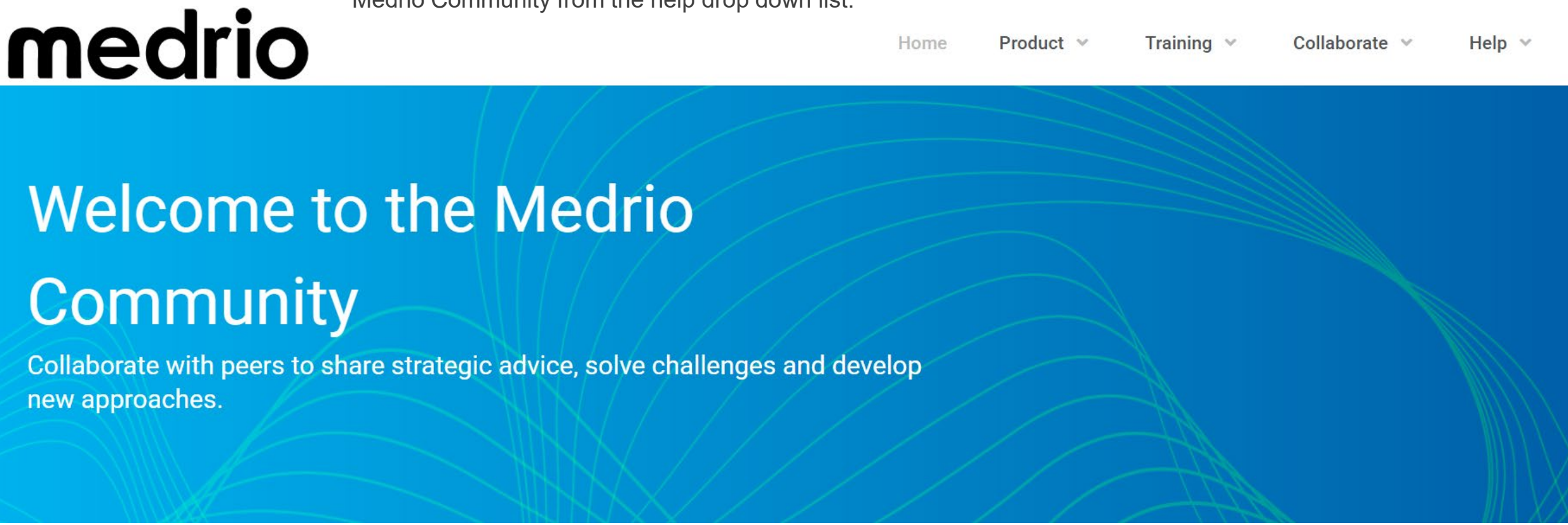
EDC System

Medrio Community:

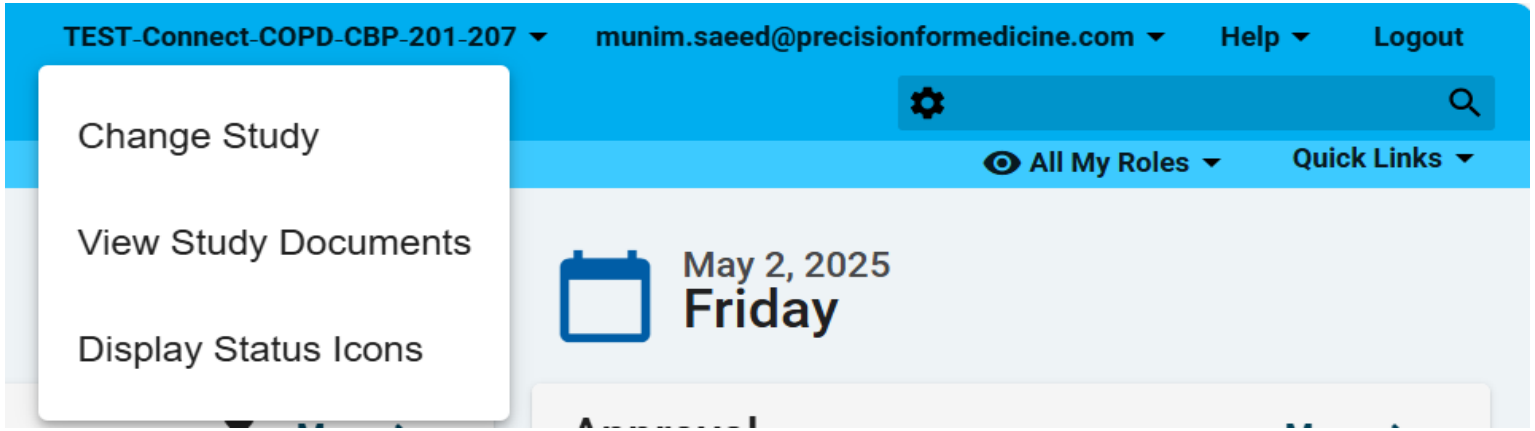
User can learn about announcements, latest updates and medical dictionary upgrades by clicking on Medrio Community from the help drop down list.



Medrio EDC

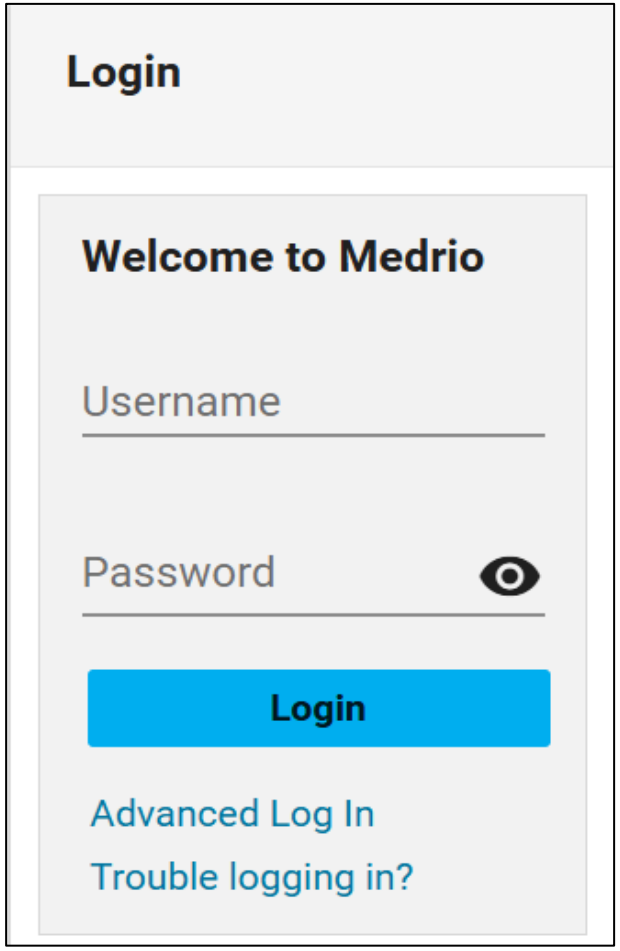
- First Time Log-In
  - Link on Medrio email will take you to Set-Up profile page to set-up your account.
  - Complete requested information including fields with asterisk* and click submit

- Users with Access to Multiple Studies
  - If you have access to more than one study in Medrio, it will log you into the last study you were logged into. To change your study, go to study on the upper right hand of the screen, then select “Change Study”.



Logging On

- Medrio login URL: Medrio Login
- User will receive email (slide 2) from Medrio after study access is granted
- Commonly used browsers for Medrio
  - Recommended to use Microsoft Edge, Google Chrome, Mozilla Firefox and Apple Safari

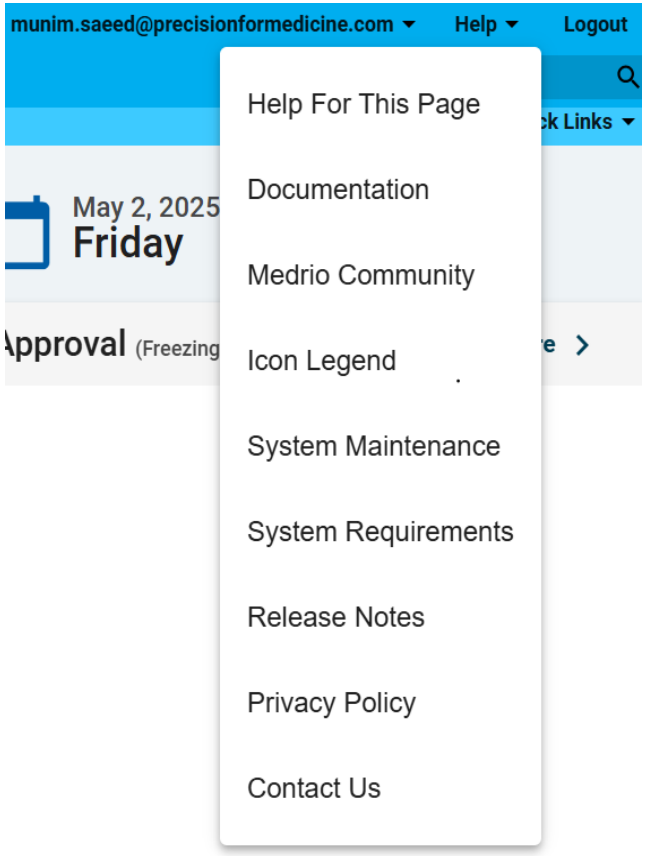


Medrio EDC Contact Information

Precision Lead DM
Munim Saeed | munim.saeed@precisionformedicine.com

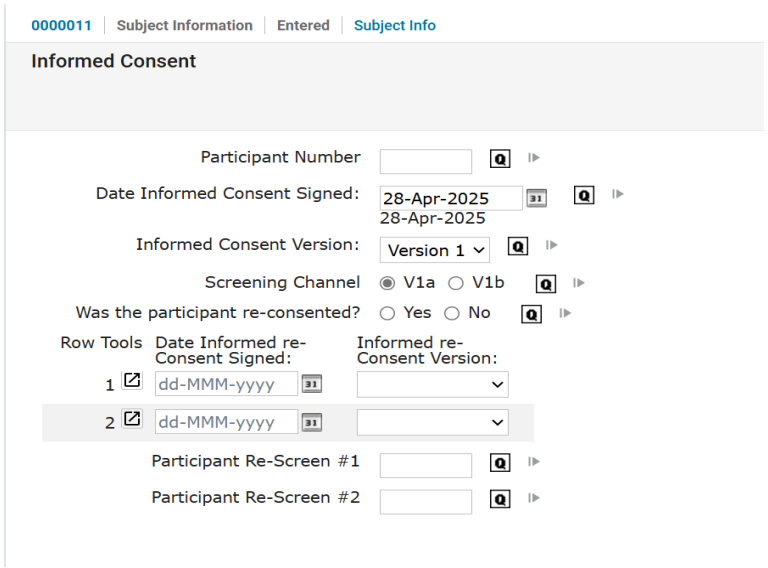
Medrio Support / Help
support@medrio.com | +1 877.763.3746 |
http://www.medrio.com/contact/contact.html

Getting More Help
In the upper right-hand corner of the Medrio screen, there is a “Help” drop-down list



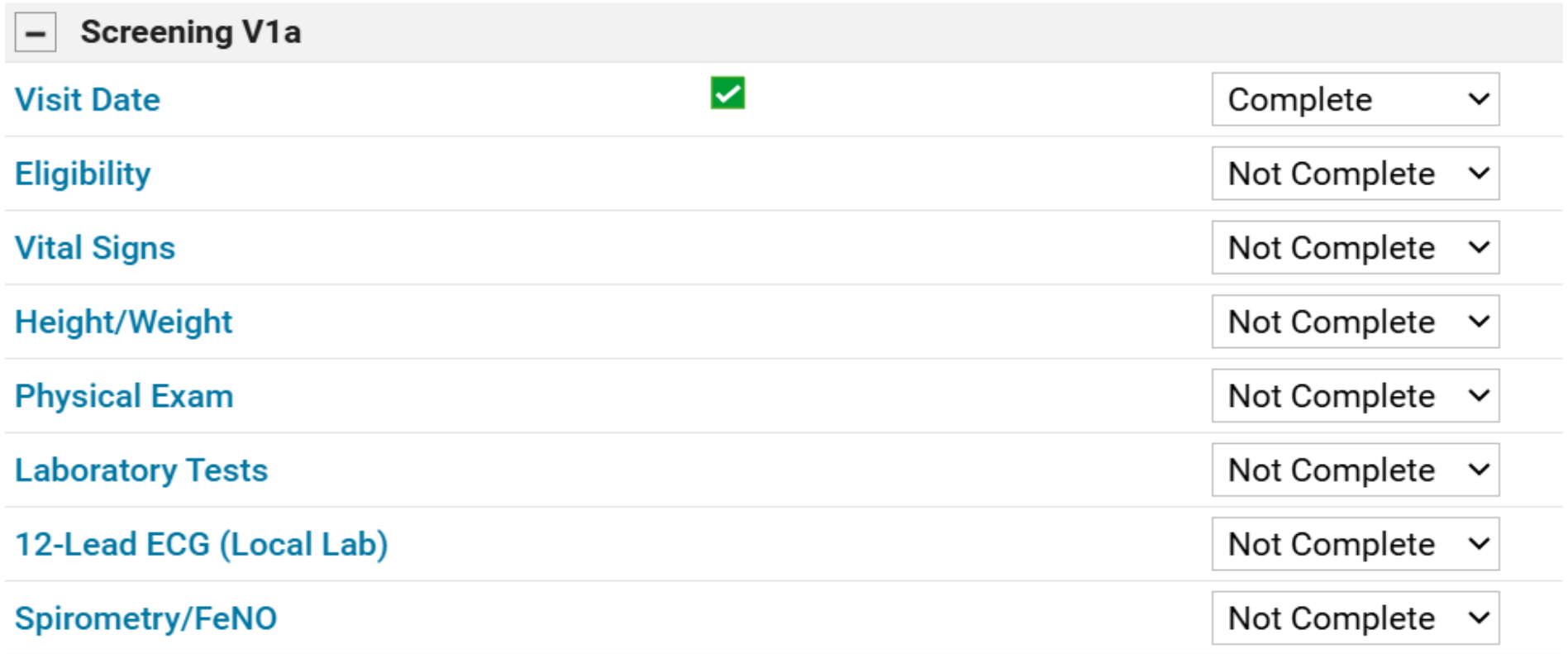
Medrio - EDC

- **Dynamic Visits:**
  - Visits or “Folders” dynamically become available for entry based on data entry progress.
    - If the folder is active, it’s due to entered results, and forms are expected to be completed in all active folders.
  - Folder: Subject Information
    - Informed Consent – Based on Screening Channel selected for a participant, subsequent visit folders/CRFs appear



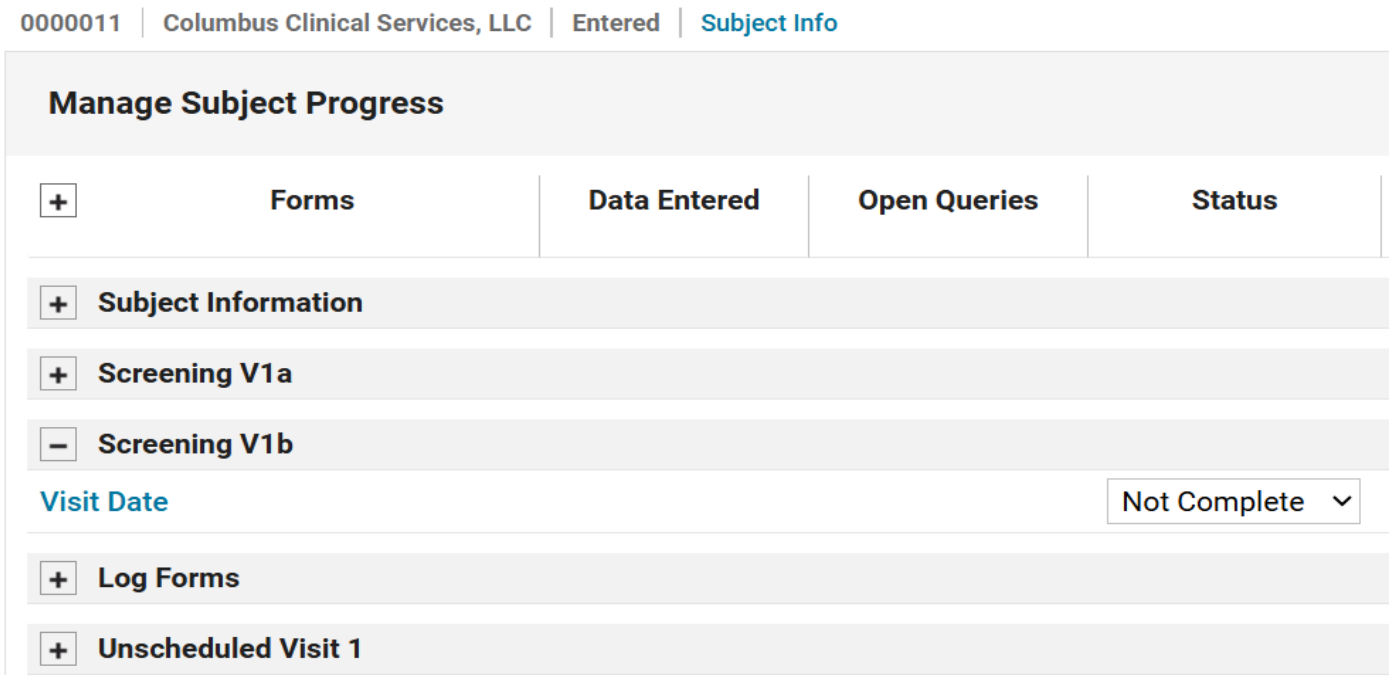
Medrio - EDC

- **Dynamic Visits:**
  - Screening Visit 1a: Upon completion of Visit Date CRF, all other CRFs within that visit appears.



Medrio - EDC

- **Dynamic Visits:**
  - Screening Visit 1b: Upon completion of Visit Date CRF, all other CRFs within that visit appears.
    - Note: Visit Date CRF appears by default in each visit folder except log forms. This form must be completed for other CRF to appear within that folder.



Reporting SAEs, AESI, DILI, UADE & Pregnancies

How to report:

- Enter into EDC within timeframe
  - SAEs, Serious AESI, DILI, UADE & Pregnancies **within 24 hours**
  - Non-serious AESI **within 72 hours**

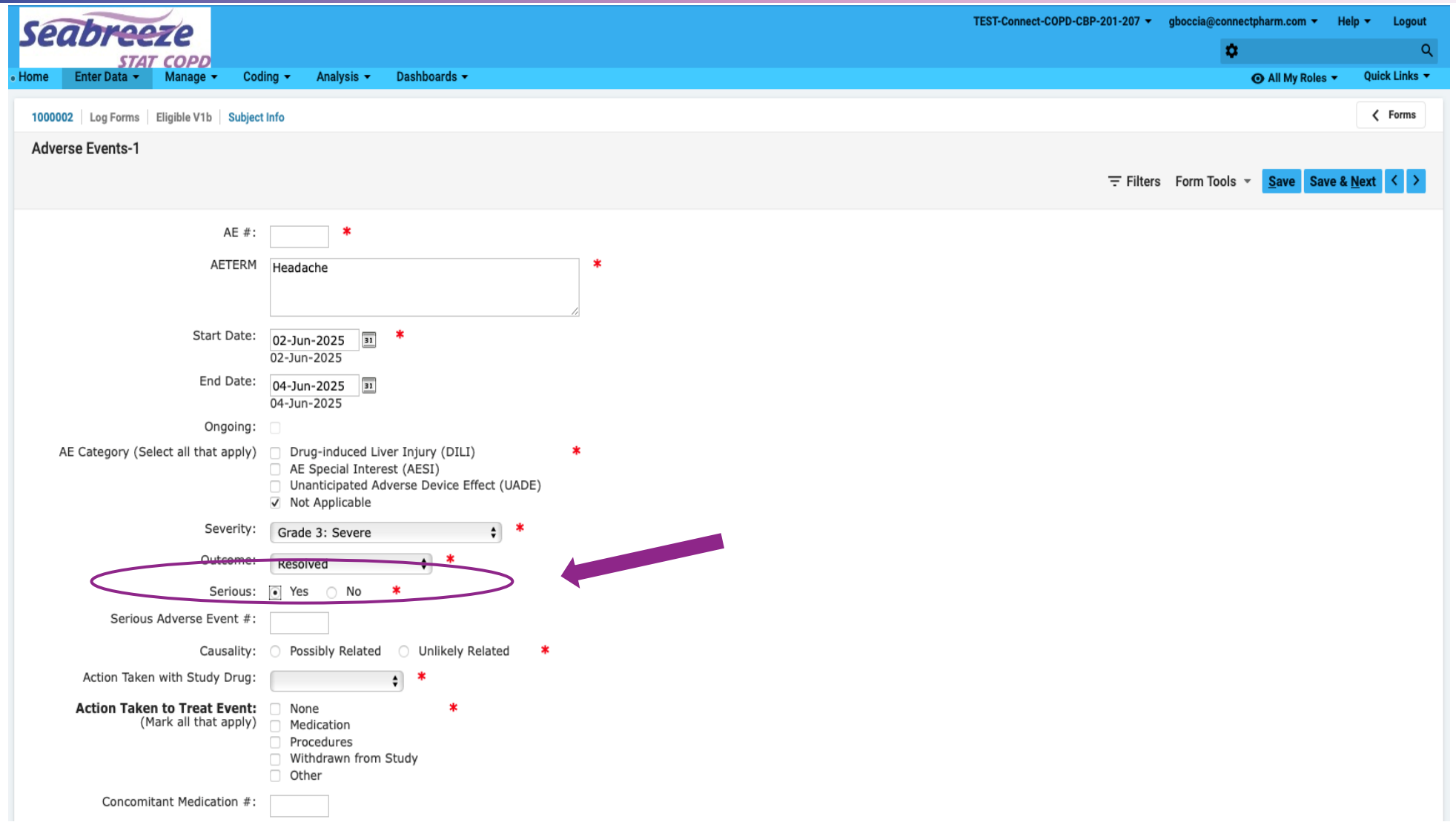
- If EDC is unavailable, download and complete the appropriate form and submit via email or fax to the Sponsor Safety Reporting Email address: **connectsafety.sm@thermofisher.com**

https://www.seabreezestatasthma.com/ **https://www.seabreezestatcopd.com/**

Password: seabreeze2025

- Acute Exacerbations should be entered as an SAE if they meet the criteria
- Safety Reporting Forms (for SAEs, AESIs and DILI cases) and Pregnancy Forms need to be sent to same email.
  - The site should enter the SAE information into the eCRF as soon as possible thereafter.

Entering SAE into EDC



Question

When should an SAE be reported to the Sponsor?

A. Within 48 hours of becoming aware of the event
B. Once you have all the information
C. It doesn't need to be reported
D. Within 24 hours of becoming aware of the event
E. Determined by the IRB/EC

Question

Should an exacerbation be reported as an SAE?

A. Yes
B. No
C. **If it meets SAE Criteria**

Questions??

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Break – Return at **03:35 pm PT**

A Moment to Breathe 

- Step into the foyer for light bites and a refreshing pause.