

connect
BIOPHARMA



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) 🎉 <i>Trivia Showdown - Compete for prizes while mastering the protocols</i>	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	-- <i>Break & Take a Breather</i>	—
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	-- <i>Break & Moment to Breathe</i>	—
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.

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!



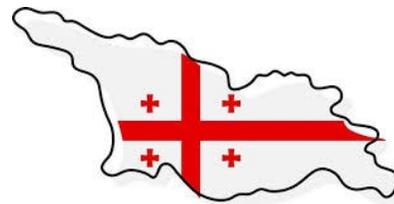
Diving into Labs

Navigating Blood and Lab Workflow

Guy Boccia, MA
Sr Director, Clinical Development Strategic Operations

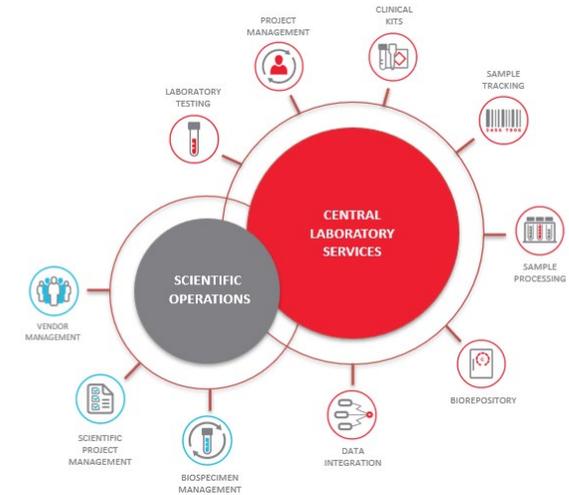
LabConnect Locations

- LabConnect Cleveland
 - USA
- LabConnect Miami
 - Argentina
- LabConnect Australia Pty Ltd
 - Australia
- LabConnect GmbH Horbeller Straße
 - 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.

- **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.



Questions?





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



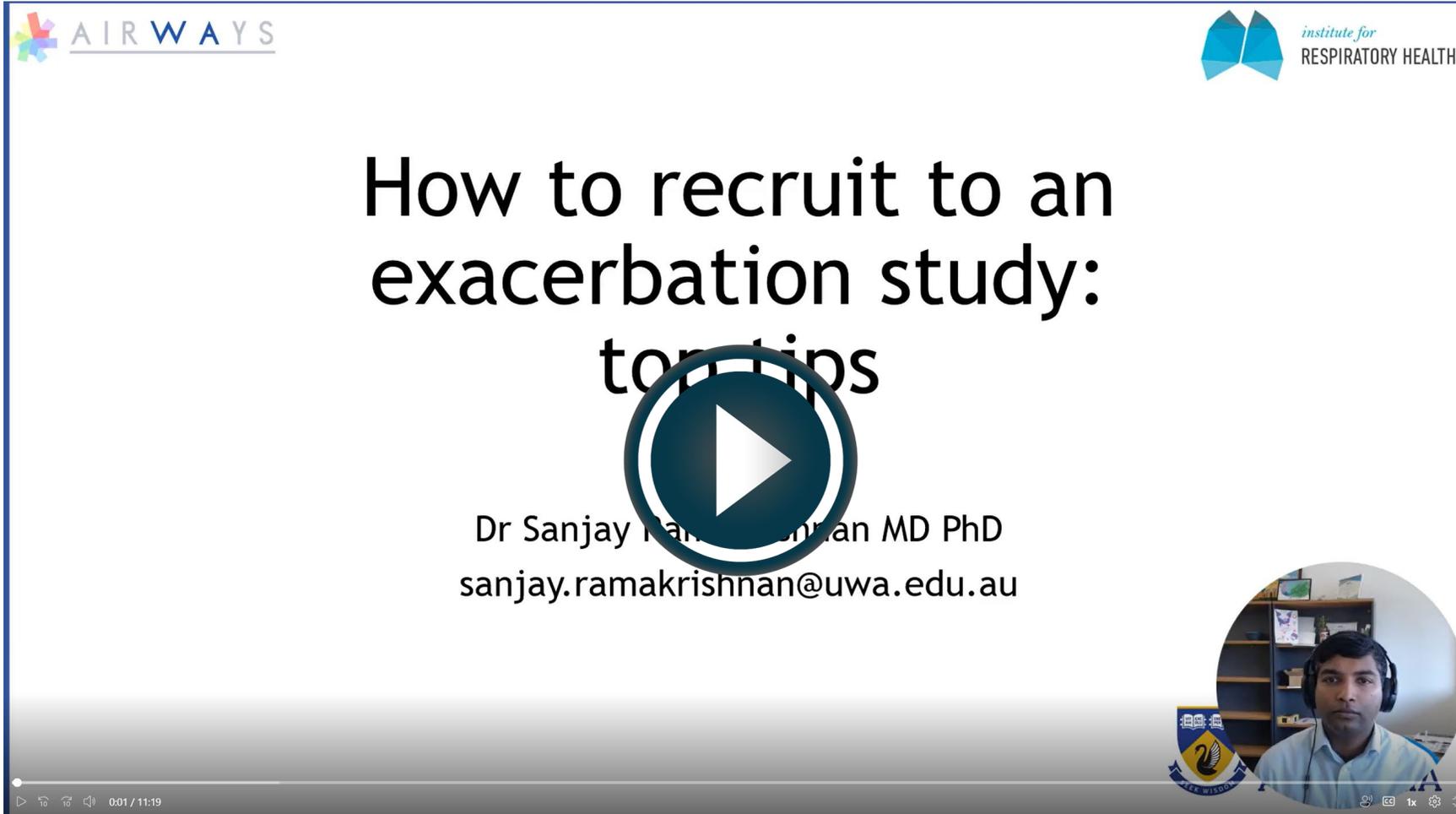
Recruitment That Works

Top Tips from and Expert

Sanjay Ramakrishnan, MD
ABRA Lead Investigator

Table Talk

ALL

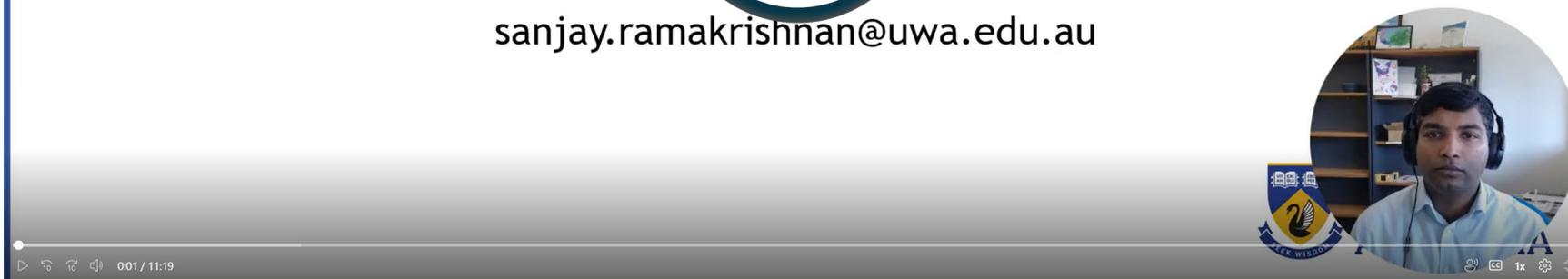


AIRWAYS

institute for
RESPIRATORY HEALTH

How to recruit to an exacerbation study: top tips

Dr Sanjay Ramakrishnan MD PhD
sanjay.ramakrishnan@uwa.edu.au



0:01 / 11:19

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The image shows a video player interface. At the top left is the 'AIRWAYS' logo. At the top right is the 'institute for RESPIRATORY HEALTH' logo. The main content is a slide with the title 'How to recruit to an exacerbation study: top tips' and the speaker's name and email: 'Dr Sanjay Ramakrishnan MD PhD sanjay.ramakrishnan@uwa.edu.au'. A large play button is centered over the text. In the bottom right corner, there is a circular video inset showing Dr. Sanjay Ramakrishnan wearing a headset. At the bottom left of the video player, there are playback controls and a progress bar showing '0:01 / 11:19'. At the bottom right of the slide, there is the 'connect BIOPHARMA' logo.

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

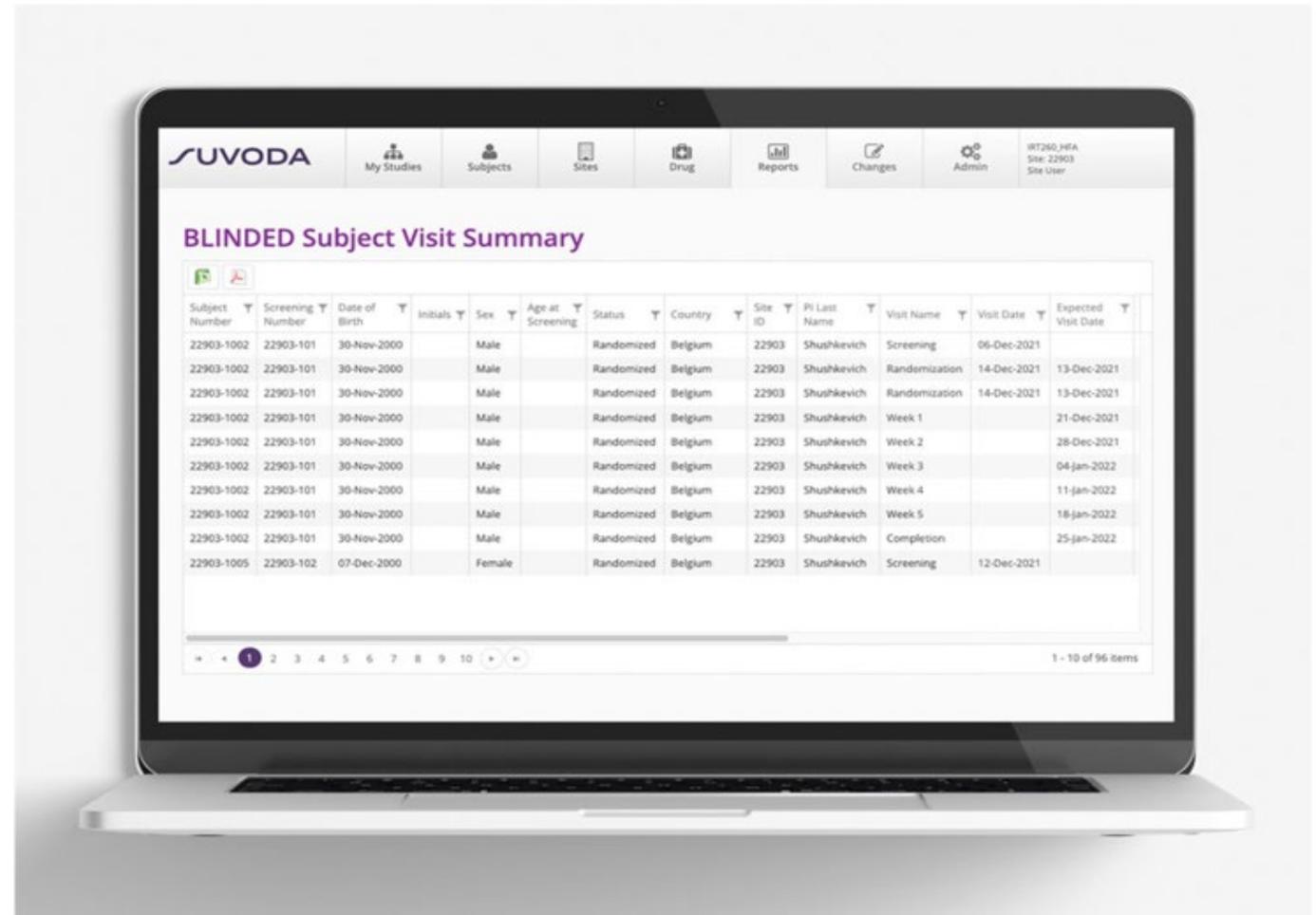
SUVODA SITE USER TRAINING

What is Suvoda?

Suvoda Interactive Response Technology (IRT)

Navigating the Suvoda Platform

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



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

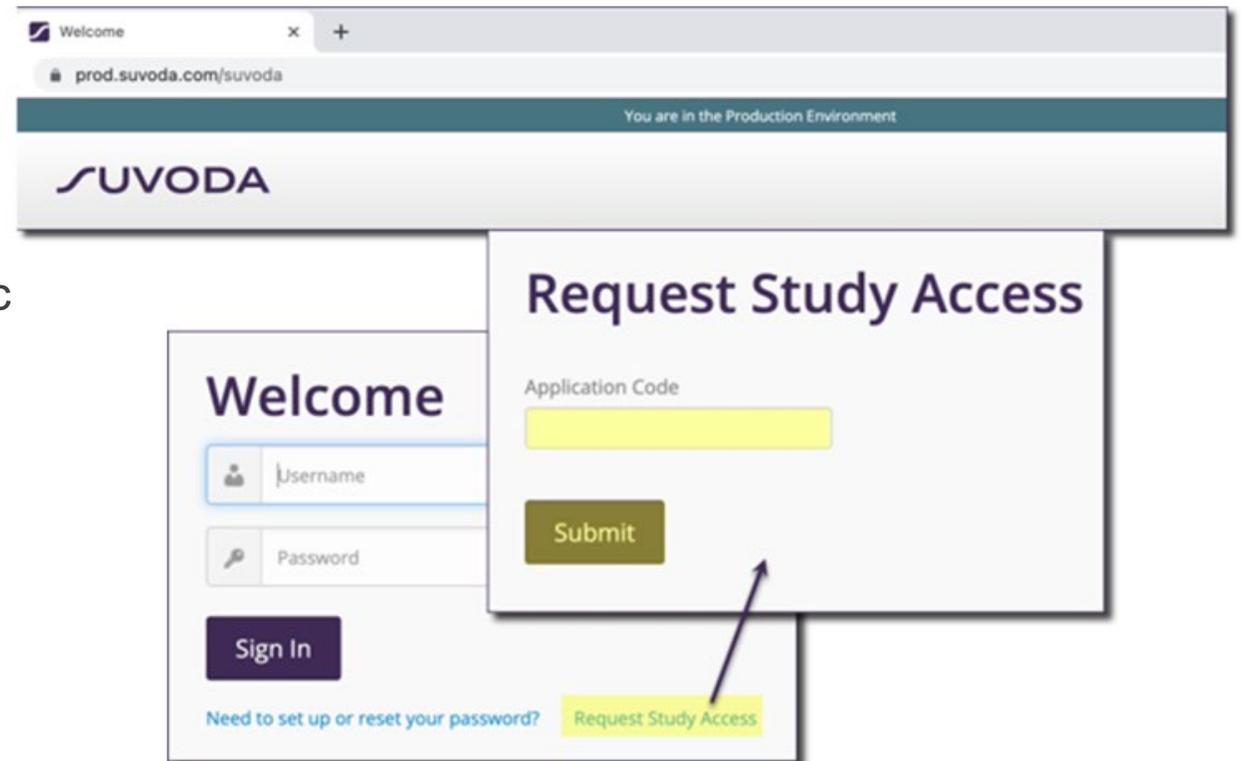
Users create their own Suvoda account and request access to the study-level system

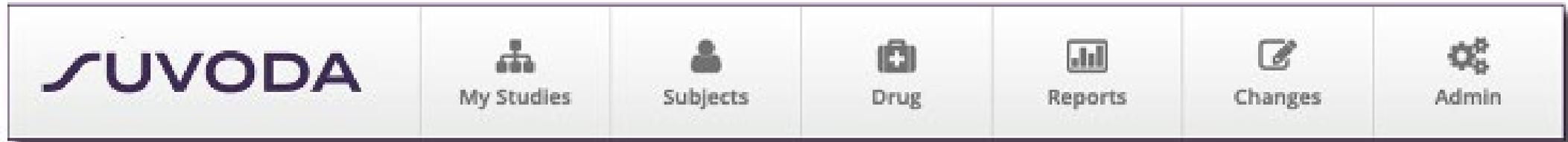
How To Request Study Access

- 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





- 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 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.

The screenshot displays the 'Register Drug Shipment' interface. It features a table with columns: Shipment ID, Destination, Order Date, Drug Units, Non-Serialized Drugs (Depot Units), and Actions. The first row shows shipment 00001-0021 with a 'Receive' button. Two modal windows are overlaid on the table. The first modal asks 'Is this for shipment 00001-0021?' and has a 'Next »' button. The second modal asks 'Please select the shipment status:' and has a dropdown menu and a 'Next »' button. A callout box on the right provides instructions: 'Click "Next" to proceed through the workflow and answer questions about the shipment's status.' and 'When you've reached the end of the workflow, you will receive a confirmation message that the shipment was received in the system.'

Shipment ID	Destination	Order Date	Drug Units	Non-Serialized Drugs (Depot Units)	Actions
00001-0021	Site 00001 - Subject Resupply	11-Feb-2022	1015711, 1043546, 1117806, 1134726	6 Ancillary 3 (Finished Lot: Finished Lot), 20 Bulk Nonserialized 1 (Finished Lot: Finished Lot)	Receive
00001-002		22	1097695, 1132320, 1133255, 1148300	12 Ancillary 1 (Finished Lot: Finished Lot), 12 Ancillary 2 (Finished Lot: Finished Lot), 20 Bulk NonSerialized 2 (Finished Lot: Finished Lot)	Receive
00001-005					

00001-0021 Receive Shipment

Is this for shipment 00001-0021?

< Select >

Next »

00001-0021 Receive Shipment

Please select the shipment status:

< Select >

Next »

- Click "Next" to proceed through the workflow and answer questions about the shipment's status.
- When you've reached the end of the workflow, you will receive a confirmation message that the shipment was received in the system.

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

The screenshot illustrates the screening workflow in Suvoda. It shows a sequence of steps:

- Step 1:** A table with columns for "Next Visit Name" and "Next Visit Date". A "Screening" button is highlighted in yellow at the top right.
- Step 2:** A modal window titled "Screening" with the prompt "Please enter the subject's screening date:". It features a date input field with a calendar icon and a "Next >" button.
- Step 3:** A modal window titled "Screening" with the prompt "Please enter the subject's age at screening:". It features a numeric input field and a "Next >" button.
- Step 4:** A modal window titled "Screening" with the prompt "Please select the subject's sex:". It features a dropdown menu with "< Select >" and a "Next >" button.
- Step 5:** A final modal window titled "Screening" with the message "Screening is now complete. The subject has been assigned subject number 0001012." and a "Go To Home Page" link.

Randomize A Participant in Suvoda

1. Locate the screened 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

1001020 | Screened

Subject Information

Subject Number: 1001020

Sex: Male Age at Screening: 50

Next Visit Name: Randomization Next Expected Visit Date: 30-Jun-2025

Randomization

Screen Fail

Suvoda Visit Schedule

Visit Name	Expected Date (Range)	Actual Date	Drugs Assigned
Screening	-	31-Mar-2025	
Randomization	30-Jun-2025 (31-Mar-2025 - 29-Sep-2025)		

1001020 Randomization

Randomization is now complete.
The subject has been assigned drug unit number(s) 406131, 409196.

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

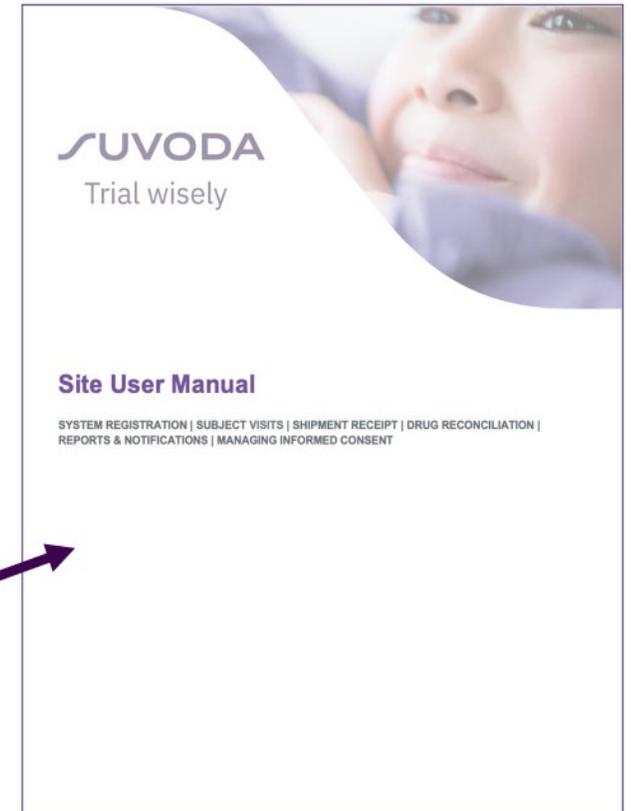
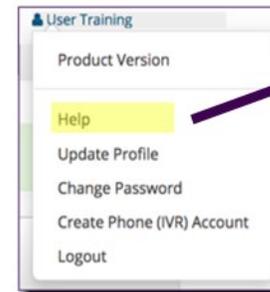
1-858-788-6321

Argentina

08006662236

Country Specific Toll Free Numbers

www.suvoda.com/toll-free-numbers



SUVODA



Medrio Community:

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

The logo for Medrio, featuring the word "medrio" in a bold, lowercase, sans-serif font.

[Home](#)

[Product](#) ▾

[Training](#) ▾

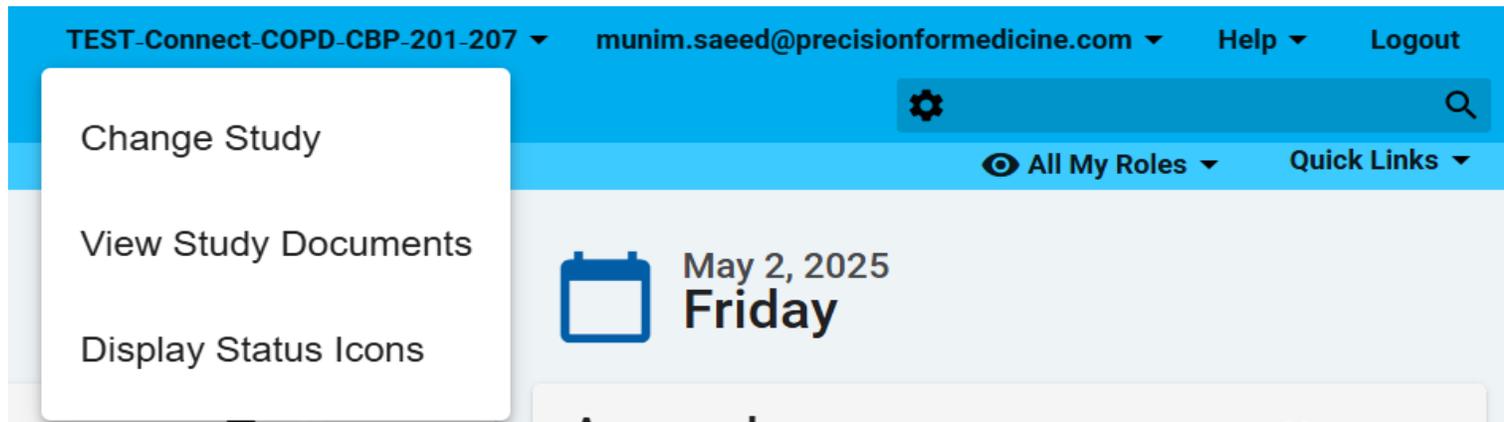
[Collaborate](#) ▾

[Help](#) ▾

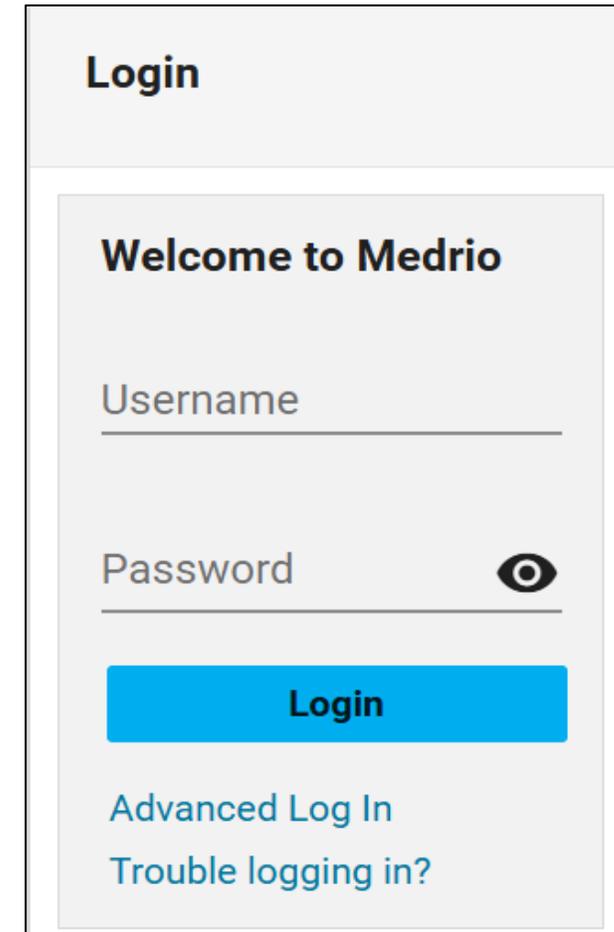
Welcome to the Medrio Community

Collaborate with peers to share strategic advice, solve challenges and develop new approaches.

- 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”.



- 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



The screenshot shows a web browser window with a light gray background. At the top, the word "Login" is displayed in a bold, black font. Below this, a white box contains the text "Welcome to Medrio" in bold black font. Underneath, there are two input fields: "Username" and "Password". The "Password" field has a blue eye icon to its right, indicating a toggle for password visibility. A prominent blue button with the word "Login" in white text is positioned below the input fields. At the bottom of the white box, there are two links: "Advanced Log In" and "Trouble logging in?", both in a blue font.

Medrio EDC Contact Information

Precision Lead DM

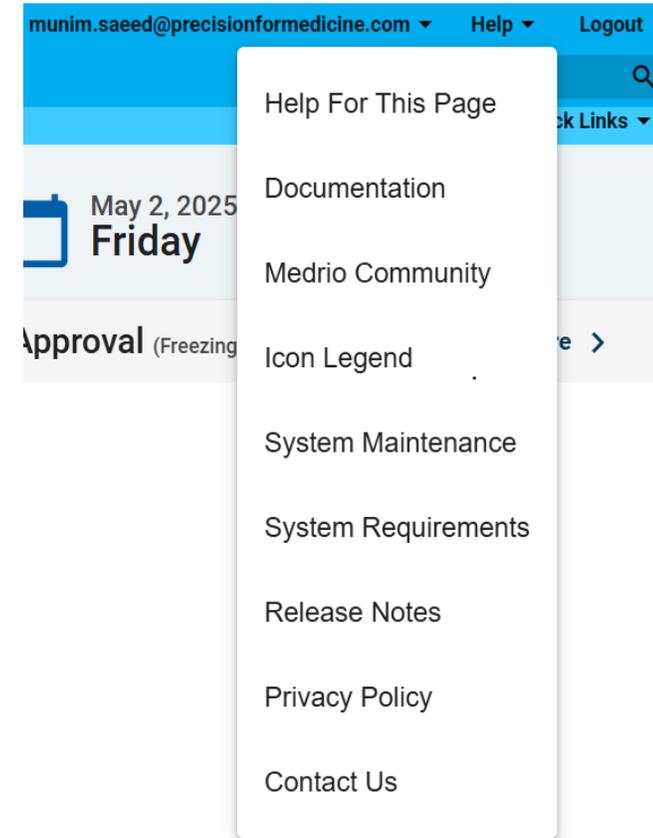
Munim Saeed | munim.saeed@precisionformedicine.com

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 



- **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

0000011 | Subject Information | Entered | [Subject Info](#)

Informed Consent

Participant Number  

Date Informed Consent Signed: 28-Apr-2025  
28-Apr-2025

Informed Consent Version: Version 1  

Screening Channel V1a V1b  

Was the participant re-consented? Yes No  

Row Tools	Date Informed re-Consent Signed:	Informed re-Consent Version:
1  	<input type="text" value="dd-MMM-yyyy"/> 	<input type="text"/>
2  	<input type="text" value="dd-MMM-yyyy"/> 	<input type="text"/>

Participant Re-Screen #1  

Participant Re-Screen #2  

- **Dynamic Visits:**

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

- Screening V1a		
Visit Date	✓	Complete ▾
Eligibility		Not Complete ▾
Vital Signs		Not Complete ▾
Height/Weight		Not Complete ▾
Physical Exam		Not Complete ▾
Laboratory Tests		Not Complete ▾
12-Lead ECG (Local Lab)		Not Complete ▾
Spirometry/FeNO		Not Complete ▾

- **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.

0000011 | Columbus Clinical Services, LLC | Entered | [Subject Info](#)

Manage Subject Progress

<input type="checkbox"/>	Forms	Data Entered	Open Queries	Status
<input type="checkbox"/>	Subject Information			
<input type="checkbox"/>	Screening V1a			
<input type="checkbox"/>	Screening V1b			
	Visit Date			Not Complete <input type="button" value="v"/>
<input type="checkbox"/>	Log Forms			
<input type="checkbox"/>	Unscheduled Visit 1			

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.seabreezestatsthma.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

Seabreeze STAT COPD
TEST-Connect-COPD-CBP-201-207 | gboccia@connectpharm.com | Help | Logout

Home | Enter Data | Manage | Coding | Analysis | Dashboards | All My Roles | Quick Links

1000002 | Log Forms | Eligible V1b | Subject Info | Forms

Adverse Events-1

Filters | Form Tools | Save | Save & Next | < | >

AE #: *

AETERM: *

Start Date: 31 *
02-Jun-2025

End Date: 31 *
04-Jun-2025

Ongoing:

AE Category (Select all that apply):
 Drug-induced Liver Injury (DILI) *
 AE Special Interest (AESI)
 Unanticipated Adverse Device Effect (UADE)
 Not Applicable

Severity: *

Outcome: *

Serious: Yes No *

Serious Adverse Event #:

Causality: Possibly Related Unlikely Related *

Action Taken with Study Drug:

Action Taken to Treat Event: (Mark all that apply)
 None *
 Medication
 Procedures
 Withdrawn from Study
 Other

Concomitant Medication #:

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

Should an exacerbation be reported as an SAE?

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

Questions??



Break – Return at 03:35 pm PT

40

A Moment to Breathe

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