CBP-201-206 and CPB-201-207
Quick Access Guide v3.0
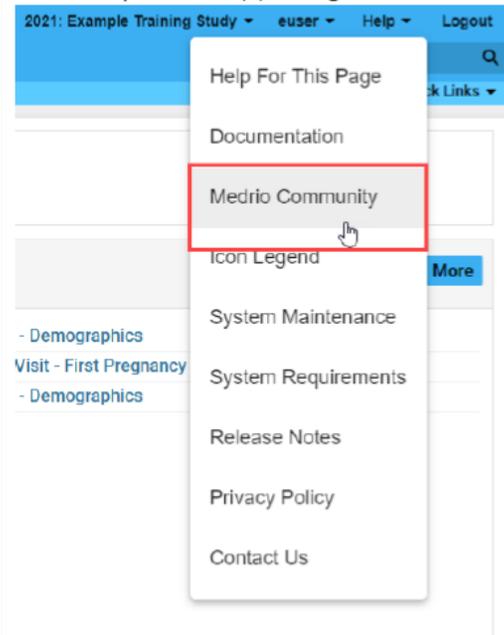
Resource	Vendor Name	Access Information
Operational Manual	-	www.SeabreezeSTATasthma.com www.SeabreezeSTATCOPD.com [For Investigators] Navigate to the "For Investigators" button on the top right. Password: seabreeze2025 For any issues contact the Sponsor at: clinical206@connectpharm.com or clinical207@connectpharm.com Documents available: • Protocol • Investigator's Brochure • IRT manual • Laboratory manual • Pharmacy manual • CRF completion guidelines • SIV slides • Safety reporting forms • Medical monitor contact information • Investigator meeting slides & recording • Monthly newsletters
IRT	Suvoda	https://prod.suvoda.com/suvoda Click "Request Study Access". Enter the study code: **Connect-CBP-201-206** or **Connect-CBP-201-207** **Include your Site# with the request.**

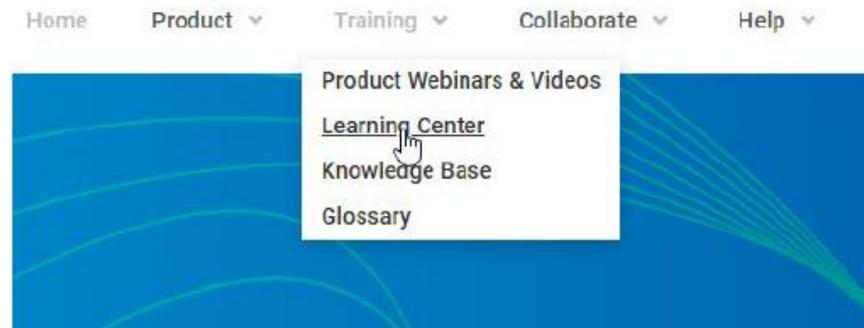|		If you have a Suvoda account with another study, you can select to "Use Existing Account". Repeat requesting access for the other study, if applicable.
		To create a new account, select "Create New Account". You will be prompted to create a username. *NOTE: For users creating a new account, <u>access must be approved for one study before access to the second study can be requested</u>.*
		Upon submission of access request, a member of the study team at Connect Biopharma will review and approve study access. You will receive an email from suvodaIRT@suvoda.com detailing whether your access request was approved/rejected.
		Suvoda Support For urgent issues, we recommend contact through phone. Phone: 1-855-788-6321 (US toll free) International Toll-Free Numbers: http://www.suvoda.com/toll-free-numbers Email: support@suvoda.com Suvoda Customer Care will need the following information: your Suvoda username, the sponsor (Connect), the protocol, and any datapoints relevant to the situation (e.g., subject number, shipment number). Translation services are available, if needed. If you need to be connected to a translator, please provide your name, protocol, and language.

EDC	Medrio (managed by Precision for Medicine)	https://identity.medrio.com/identity/login?signin
		
		 Please contact your CRA to request access to Medrio.
		
		 The CRA will complete the "Database Site and User Management Tracker" on the ProPharma Sharepoint and notify data management that the tracker was updated.
		
		 Data Management Contacts:
		     o Lindsey Falor Lindsey.Falor@precisionformedicine.com (lead data manager)
		     o Nikola Jovanovic Nikola.Jovanovic@precisionformedicine.com (for user access)
		
		 When access is granted to a project, the user will receive an automated email from no-reply@mail.medrio.com with instructions on how to set up account and profile.

E-Learning

E-learning required training needs to be completed before full access is granted.

Click Help in the upper-right corner of the study, then select Medrio Community.

In the Medrio Community, click Training > Learning Center.

For site staff: Click Site User > Data Entry – EDC (R41.6) > Register

Data Entry - EDC (R41.6)

Data entry for Site Users using Medrio EDC as of version R41.6

REGISTER (FREE!)   MORE INFORMATION

.

For investigators: Click Site User > Investigator Sign-Off (R41) > Register

Investigator Sign-Off (R41)

This course is for learners who need to sign off on eCRFs that have patient data awaiting review. In the Medrio EDC system, you can view a list of forms awaiting your approval and approve forms in bulk.

REGISTER (FREE!)   MORE INFORMATION

Complete registration then Click View Course to complete the training. After you complete the required videos and quizzes for the course, you can download your certificate by clicking View/Print Your Certificate next to the Certificate module in the course.

		medrio ✓ **Certificate of Completion** This acknowledges that **Marisa Jones** has successfully completed Medrio EDC: **Data Entry - EDC (R41.6)** [or R41 for investigators] _signature_ Tamika Davis Learning Organization Manager Date of Completion: **May 22, 2025**

<div style="color:red; text-align:center">

IMPORTANT!!!!

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Site staff should generate their training certificate (in pdf format) for Medrio trainings and email it to:
- Your CRA for filing in the Trial Master File
- Data management **– required for full study access**
  - Lindsey Falor   Lindsey.Falor@precisionformedicine.com
  - Nikola Jovanovic   Nikola.Jovanovic@precisionformedicine.com

Full study access will be granted within 2 business days.

EDC Support
Lead Data Manager:
  - Lindsey Falor   Lindsey.Falor@precisionformedicine.com

If the data management lead is unable to assist you, notify your CRA or submit a ticket to Medrio Support:
email: support@medrio.com
http://medrio.com/contact/contact.html
phone: Toll Free: 877-763-3746

Central lab	LabConnect	https://portal.labconnect.com/ Contacts provided to LabConnect for kit shipment will automatically receive a Lab Report Access request form (usually the study coordinator). For additional staff, please request portal access from PC@labconnect.com. In the subject line enter: "CONN1206: Portal Access Needed - Site [#]" for study CBP-201-206 and/or "CONN1207: Portal Access Needed - Site [#]" for study CBP-201-207 You will receive an Access Form by email from remote@labconnect.com. Note: *Each individual requesting access must sign a personal Lab Report Access Form*. If more than one individual is requesting access, please contact LabConnect for additional forms. Complete all fields, sign via a wet or 21CFR11 compliant electronic signature, and return to: PC@labconnect.com.

Laboratory Report Access Form Example

Complete all fields on the form, sign, and return completed form to PC@labconnect.com.

LabConnect Support
If you need help logging in, please send a username or password problem request to: pc@labconnect.com

For other issues, notify your CRA or contact the LabConnect project manager Lauren Scerbo
lscerbo@labconnect.com

ZEPHYRx Provider Dashboard	ZEPHYRx	- ZEPHYRx is providing spirometry, FeNO, PEF (asthma only), e-Diary, and in-clinic questionnaires (eCOAs) - The provider dashboard can be used to: - Create participants for spirometry, eCOAs, e-Diary, etc

		o View results o Clear spirometry safety alerts o Monitor at-home task compliance o Tag questionnaires (eCOAs) and spirometry sessions with visit labels (mandatory) ZEPHYRx Provider Dashboard: https://dashboard.zephyrx.com/login **Access to the Provider Dashboard will be provided to site staff during the 1-hour ZephyrX virtual training**. • ZEPHYRx will email site staff with a scheduling calendar link • Please have all spirometry and FeNO equipment charged and available for training • ZEPHYRx provides one training for all site staff who will be performing spirometry/FeNO For any **new** site staff that require access, submit a support request at www.zephyrx.com/seabreeze. Select the applicable study (Asthma or COPD) and then fill in the requested info. In the ticket description section note that you are requesting dashboard access. If you are requesting access to both the asthma and the COPD study, select either study and note in the ticket description section that the request is for both studies. **ZEPHYRx Support** For any ZEPHYRx issues (spirometry, FeNO, PEF, questionnaires, e-Diary, provider dashboard), submit a support request at: https://www.zephyrx.com/seabreeze For urgent matters, call (24/7 support hours) +1 (888) 452-6269

Change Table	
Version 3.0	• Updated Precision for Medicine and LabConnect contacts • Added investigator specific training for Medrio • Added detail on ZEPHYRx training process • Removed ZEPHYRx app registration instructions since this detail can be found in the Platform User Guide