CBP-201-206 and CPB-201-207
Quick Access Guide

Resource	Vendor Name	Access Information
Operational Manual (Protocol, manuals, and forms)	-	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
IRT	Suvoda	https://prod.suvoda.com/suvoda Click "Request Study Access". Enter the study code: **Connect-CBP-201-206** or **Connect-CBP-201-207** 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: CBP-201-206: Celissa Williams Celissa.Williams@precisionformedicine.com CBP-201-207: Munim Saeed Munim.Saeed@precisionformedicine.com 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.
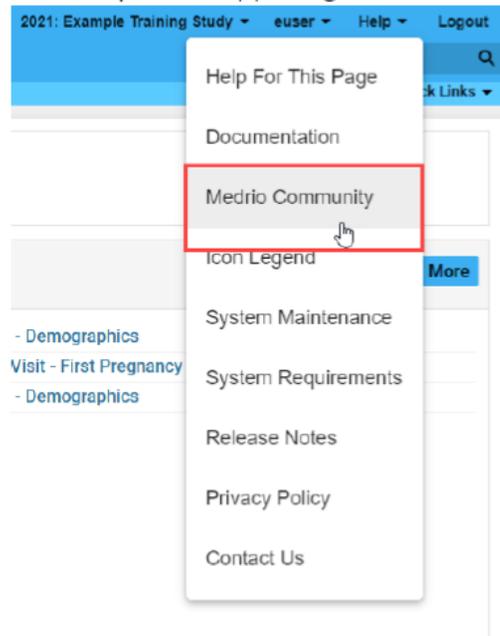
In the Medrio Community, click Training > Learning Center.
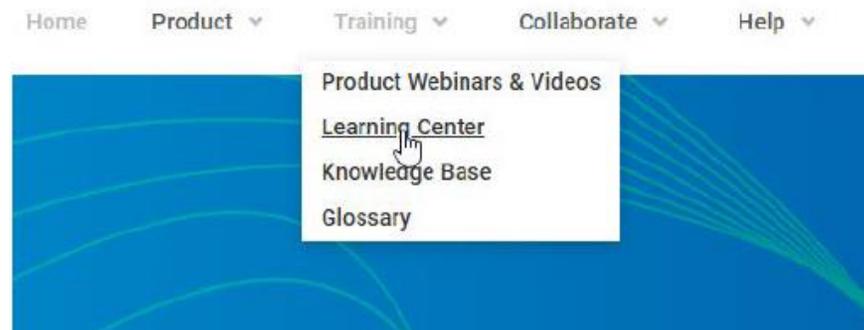
Click Site User > Data Entry – EDC (R41.6) > Register

Data Entry - EDC (R41.6)

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

REGISTER (FREE!)   **MORE INFORMATION**

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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

Elearning User

has successfully completed

Data Entry - ePRO Remote and In-Clinic ePRO Web (R41.7)

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Tamika Davis
Learning Organization Manager

Date of Completion: **July 6, 2022**

Site staff should generate their training certificate (in pdf format) for Medrio trainings and email it to:
- Data management – **required for full study access**
  - CBP-201-206: Celissa Williams Celissa.Williams@precisionformedicine.com
  - CBP-201-207: Munim Saeed Munim.Saeed@precisionformedicine.com
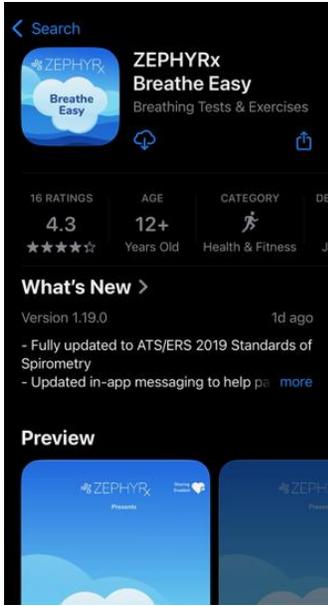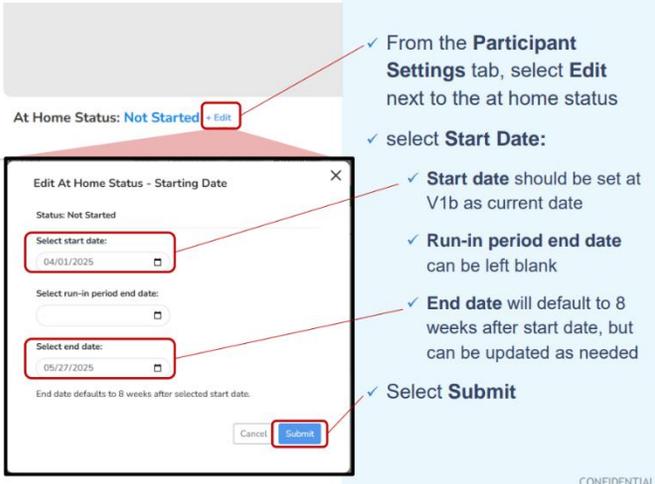- Also email to your CRA for filing in the Trial Master File

		EDC Support Data Management Contacts: CBP-201-206: Celissa Williams Celissa.Williams@precisionformedicine.com CBP-201-207: Munim Saeed Munim.Saeed@precisionformedicine.com If the data management lead is unable to assist you, please 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 Kaitlyn Hill at khill@labconnect.com with Mary Mays in cc at MMays@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, contact Project Manager Mary Mays
Phone: +1 423-670-6556
mmays@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: |

		o 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) 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**. 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
Spirometry	ZephyrX	

		1. Power on the Spirobank Smart II spirometer and provided Samsung Galaxy A9+ Tablet 2. Swipe up to open the tablet 3. Go to Settings and connect to WIFI 4. Note: the tablet is SIM enabled in case WIFI is not available. 5. Open the **Kiosk app** 6. Enter email and password you created for the Provider Dashboard 7. Follow full instructions in the Platform User Guide located in the Operational Manual.
FeNO	ZephyrX	 1. Power on the NiOX FeNO Device and the provided Windows Surface Tablet 2. Tablet Password: 5023 3. Go to Settings and connect to WIFI 4. Note: the tablet is SIM enabled in case WIFI is not available. 5. Open **NiOX Panel app** 6. App will connect to the FeNO device 7. Follow full instructions in the Platform User Guide located in the Operational Manual.
In-clinic questionnaires (eCOA)	ZephyrX	1. Log in to the **Kiosk App** on the provided Samsung Tablet. 2. Enter email and password you created for the Provider Dashboard 3. Select your Participant or Create a new participant 4. Select the desired eCOA

		5. Full instructions can be found in the ZephyrX Platform User Guide located in the Operational Manual.
e-diary app	ZephyrX	 for iPhone for Android 1. Download the **Breathe Easy App** to the participant's phone. 2. Link the app to the participant according to the ZephyrX Platform User Guide located in the Operational Manual. 3. Change the language of the app if applicable. 4. Set the at-home task start date from the Zephyrx provider dashboard: https://dashboard.zephyrx.com/login 5. Follow full instructions in the Platform User Guide located in the Operational Manual.

Peak Flow (asthma only)	ZephyrX	

		1. MIR Spirobank Smart spirometer setup
		    a. Insert batteries into the spirometer
		    b. Attach the turbine and mouthpiece
		2. Pair home spirometer in the Provider Dashboard
		    a. Prior to distributing the spirometer to the participant, go to the Participant Settings Tab on the Provider Dashboard https://dashboard.zephyrx.com/login
		    b. Select "Edit"
		    c. Enter the 6 Digit spirometer ID: e.g. A23-Z133977
		3. Connect spirometer to Breathe Easy App
		    a. Download the **Breathe Easy App** to the participant's phone
		    b. The spirometer's ID number will pop up on screen, select the ID to connect device
		4. Follow full instructions in the Platform User Guide located in the Operational Manual.