




**MODIUS Study: Clinical Site's Workflow
Guide**

Version: 1.1

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Date: 14 April 2026

	MODIUS Study: Clinical Site's Workflow Guide
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Participant Onboarding Process

1. Pre-Enrollment: LibreView Account Assessment

To connect the participant to the system, the process begins with the LibreView account setup. Please follow these steps in sequence:

Participants With an Existing Personal LibreView Account

If the participant confirms they have an active personal LibreView account, no additional account should be created.

The staff member shall verify that the participant remembers their login credentials, as these credentials will be required once for the initial connection to endo.digital.

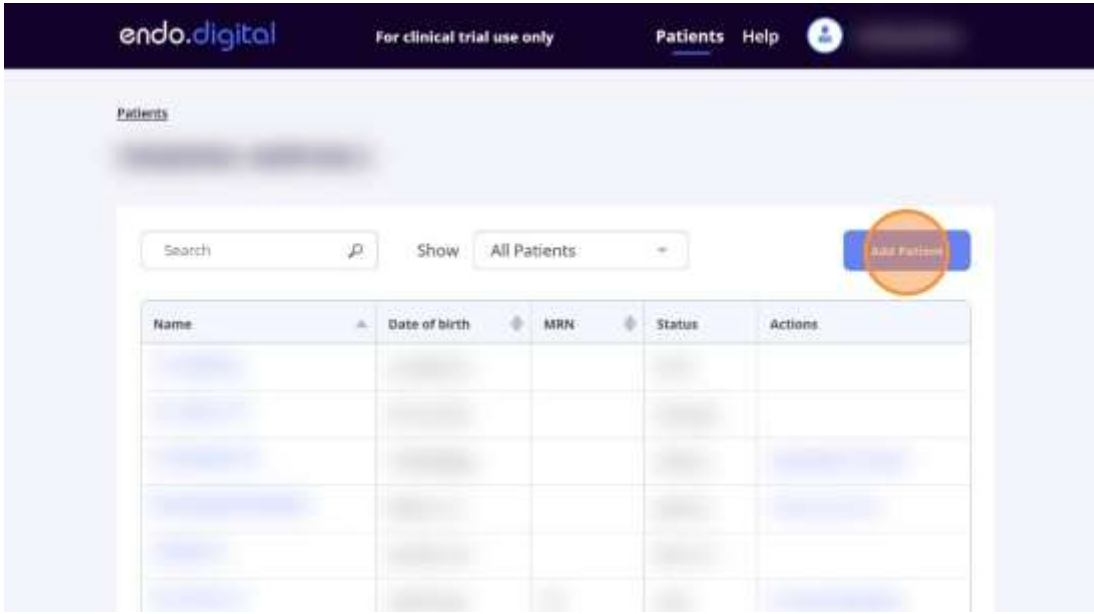
Note: Inform the participant that using their personal account will avoid having two separate data streams to reconcile with their provider after the study.


Participants Without a Personal Account or Who Prefer Not to Use Their Personal Account

If the participant does not have a personal LibreView account or chooses not to use their existing one for the study, a study-specific LibreView account may be assigned. These accounts may be pre-generated to facilitate enrollment.

2. Adding participant to endo.digital

2.1 Click the “Add Patient” button to begin patient enrollment



	MODIUS Study: Clinical Site's Workflow Guide
	Version: 1.1

2.2 Complete the required fields and click "Add Patient" to finalize

When completing the "Add Patient" form", the following fields must be entered according to the JCHR patient-ID convention:

First Name: Enter the site-level study ID

Last Name: Enter the participant sequence number

Example:

First Name: MODIUS-005

Last Name: 002

This corresponds to JCHR PtID: MODIUS-005-002

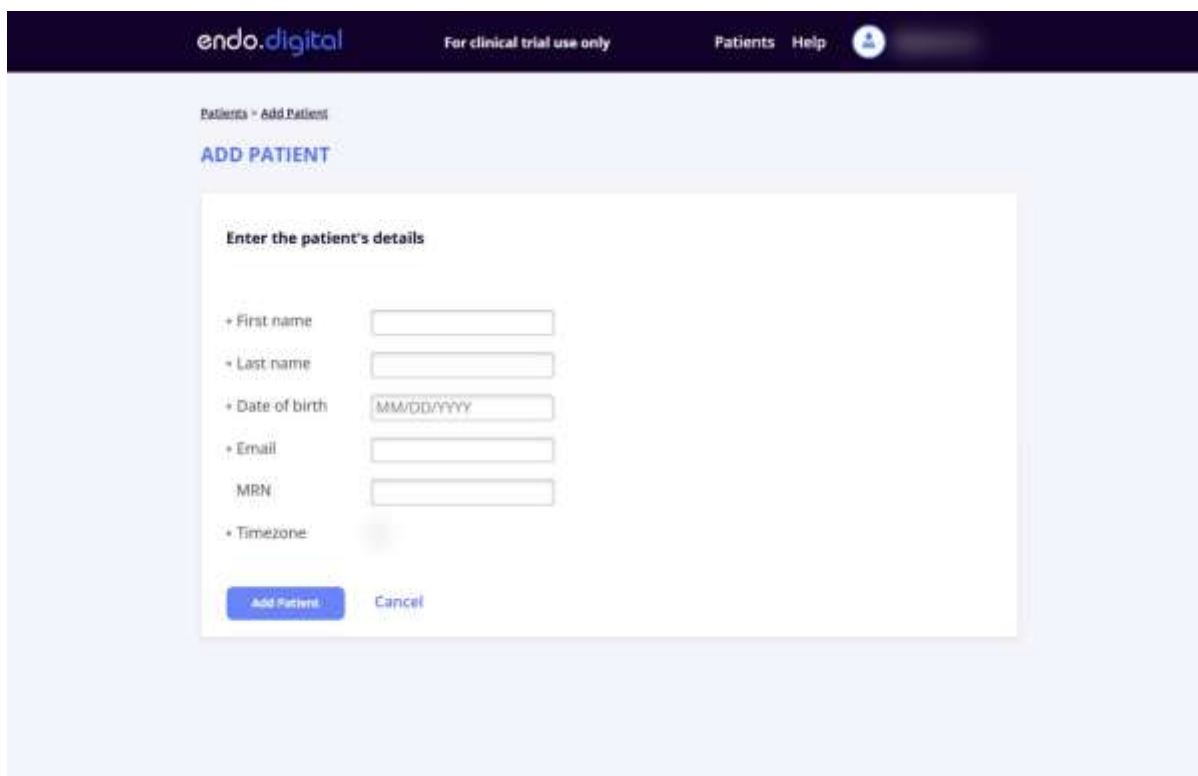
Additionally:

Date of Birth (DOB): Enter the participant's real date of birth

Email: Enter the participant's *real* email address to ensure they receive the invitation

MRN: Enter the participant's study sequence number


The First Name/Last Name convention must be used consistently for all participants to ensure accurate identification throughout the study.



The screenshot shows the 'Add Patient' form in the endo.digital system. The form is titled 'Enter the patient's details' and includes the following fields:

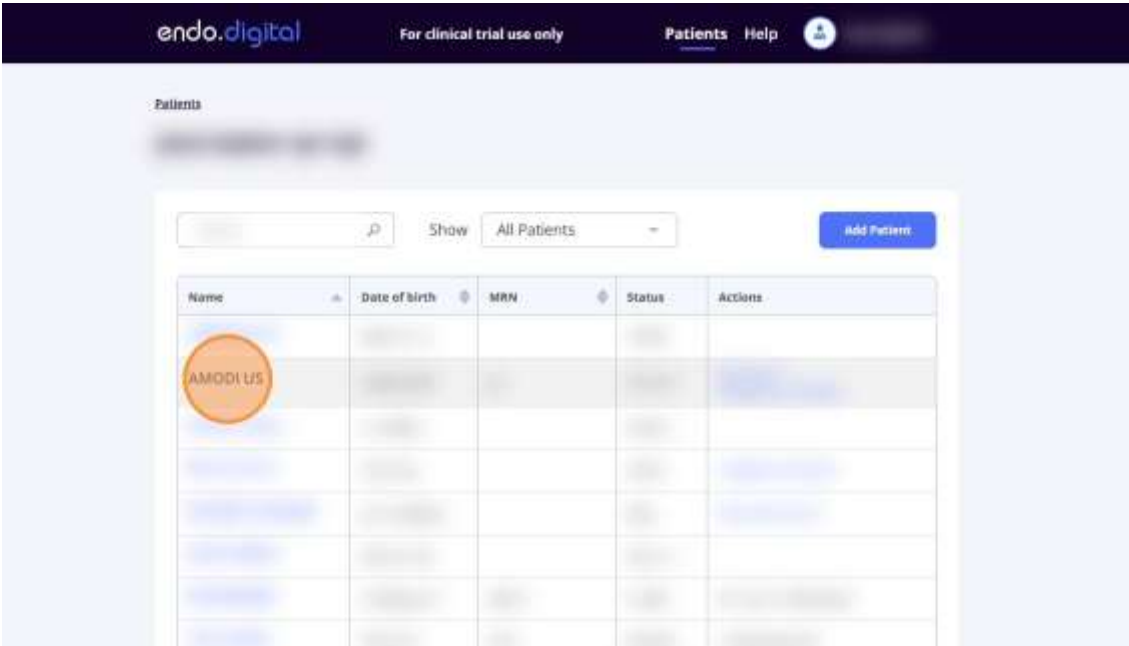
- First name
- Last name
- Date of birth (MM/DD/YYYY)
- Email
- MRN
- Timezone

At the bottom of the form, there are two buttons: 'Add Patients' and 'Cancel'.

	MODIUS Study: Clinical Site's Workflow Guide
	Version: 1.1


3. Connecting the Participant's LibreView Account to endo.digital

Select the Participant Name from list or search for it.

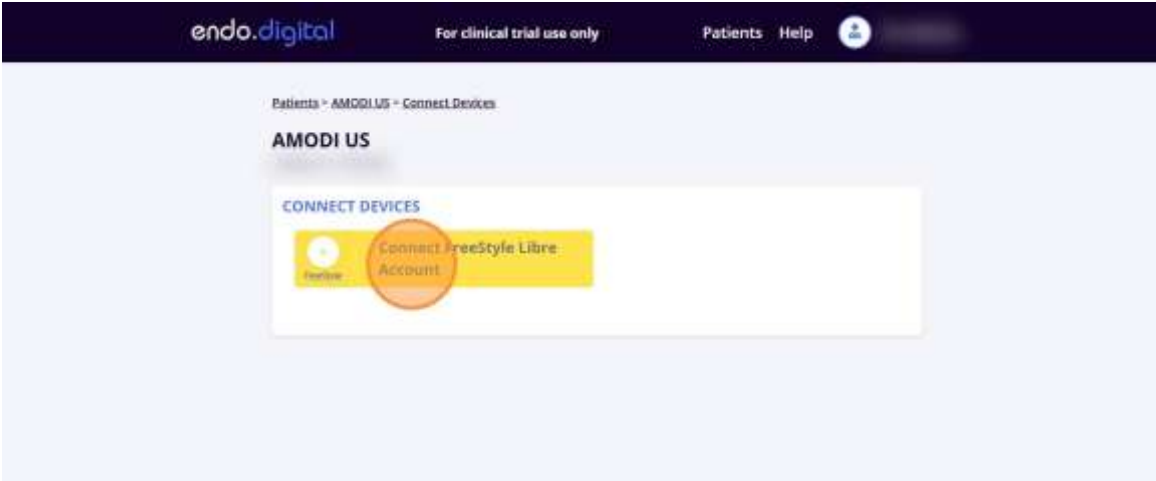


Click "Connect Devices"




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	Version: 1.1

Click "Connect FreeStyle Libre Account"



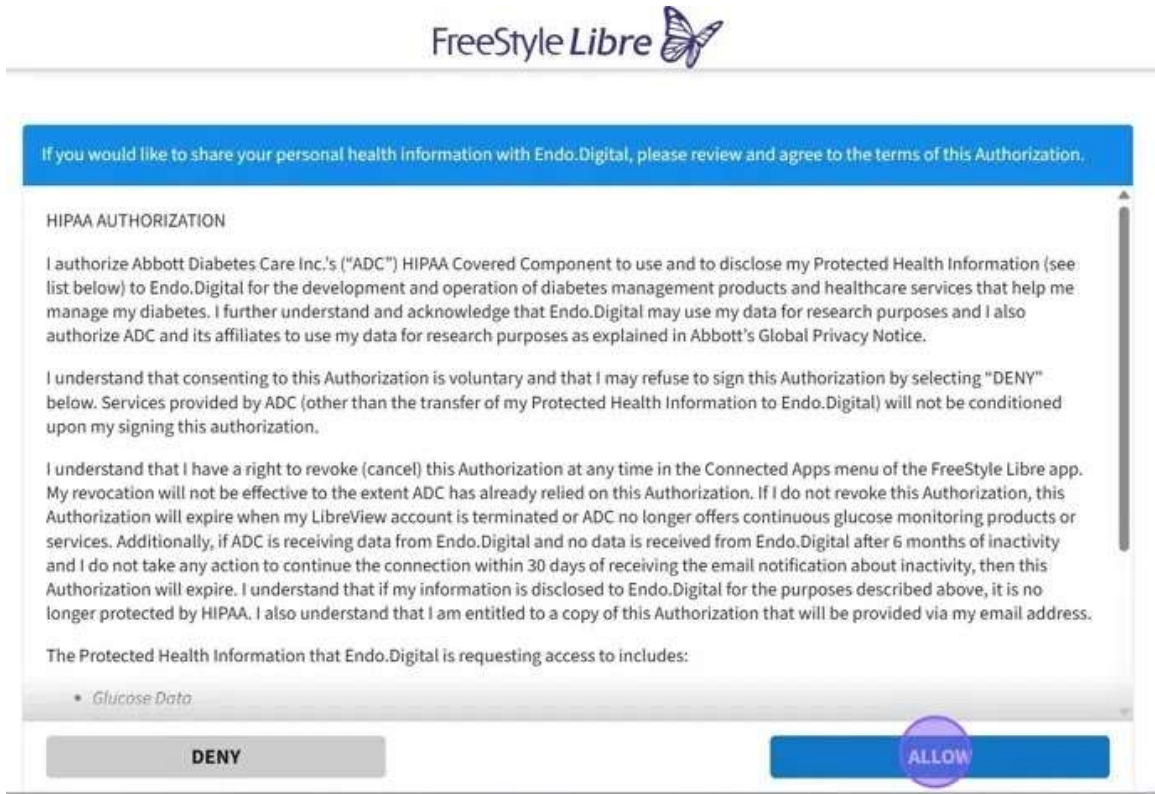
Enter Participant's LibreView Credentials and click "SIGN IN"



	MODIUS Study: Clinical Site's Workflow Guide
	Version: 1.1

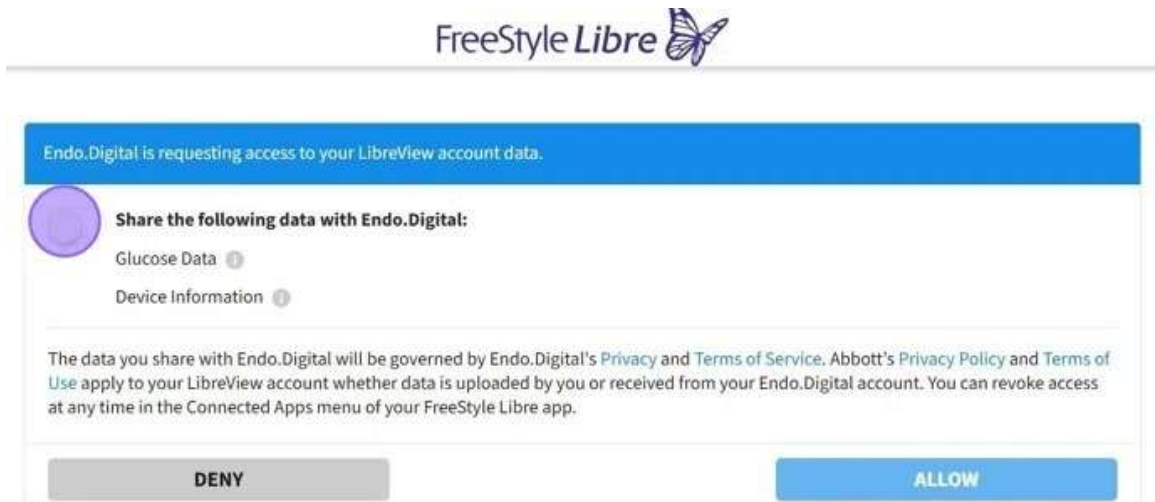
Complete HIPAA Authorization

Finalize the privacy and data-sharing consent by clicking “Allow”, followed by “Agree”




Authorize Data Sharing

Enable data transfer by switching the “Share the following data” toggle to blue and confirming with “Allow”



Confirm Successful Linkage

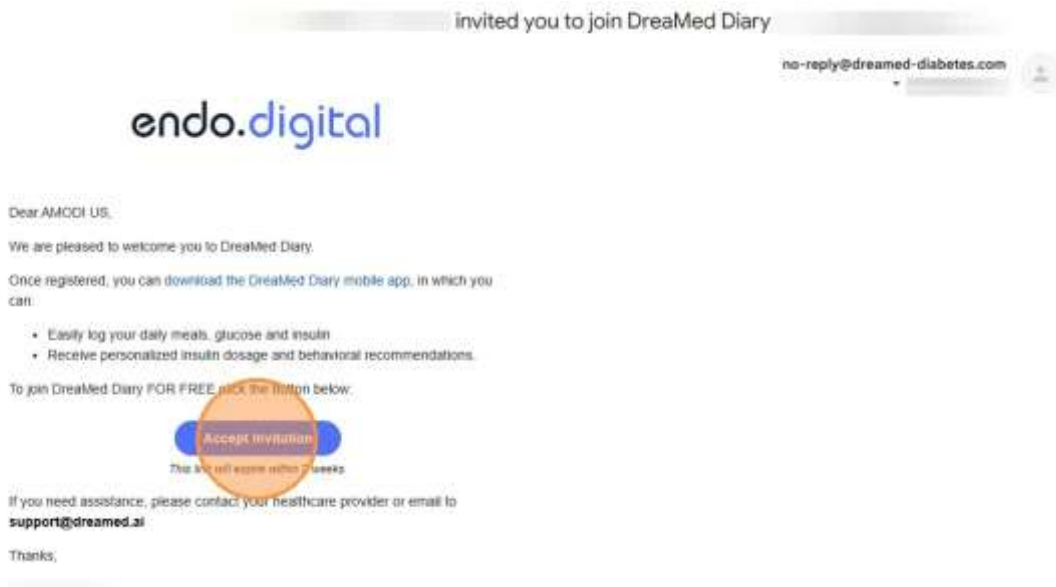
A confirmation message will appear. Select “OK” to complete the process.

	MODIUS Study: Clinical Site's Workflow Guide
	Version: 1.1

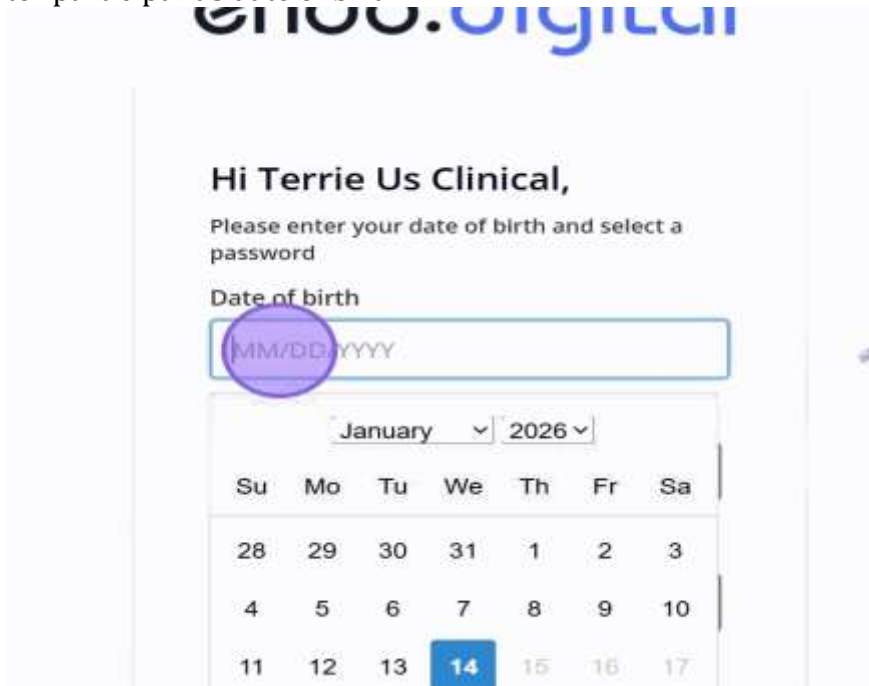
4. Participant Onboarding on the Diary App


4.1. Email Invitation Acceptance & Registration

- a) Participant should receive an email invitation from: no-reply@dreadmed-diabetes.com
- b) Click 'Accept the Invitation' in the email



- c) Enter participant's date of birth



	MODIUS Study: Clinical Site's Workflow Guide
	Version: 1.1

d) Create and Confirm Password

Type a password in the "Password" field that meets all listed criteria, then re-enter it in "Confirm Password."

As you type, each criterion will change from a red X to a green ✓ once satisfied



Hi Terrie Us Clinical,
Please enter your date of birth and select a password

Date of birth
03/04/1995

Password

Confirm Password

- ✗ Minimum of 8 characters
- ✗ Upper case & lower case letters
- ✗ Number
- ✗ Symbol

e) Accept Privacy Policy and Terms and click "Sign Up"



Date of birth
03/04/1995

Password
.....

Confirm Password
.....


- ✓ Minimum of 8 characters
- ✓ Upper case & lower case letters
- ✓ Number
- ✓ Symbol

I have read and agreed to Advisor Pro Privacy Policy and Terms of Use

Sign Up

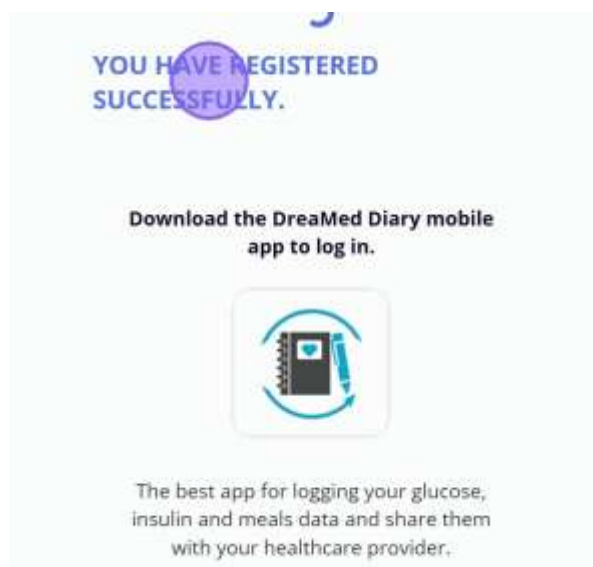
I have read and agreed to Advisor Pro Privacy Policy and Terms of Use

Sign Up

	MODIUS Study: Clinical Site's Workflow Guide
	Version: 1.1


4.2. Download the DreaMed Diary App

- a) Download the app from the appropriate store and complete installation on the device:
Google Play (Android) / Apple App Store (iOS)



- b) Login to the DreaMed Diary app by entering the participant's email in the username field and the password as created.

From this point **the participant will go through the self-onboarding process.**

	MODIUS Study: Clinical Site's Workflow Guide
	Version: 1.1

4.1 Carbs Counting Participants - Special Onboarding Instructions:

Participants who usually count carbs but the participant and investigator agree they can switch to meal size bolusing, should do the following:

Complete the full onboarding workflow in the Diary app with Meal Size boluses:

- Acknowledge the dosing warning
- Enter weight
- Complete long-acting insulin setup
- Complete rapid-acting (mealtime) insulin setup
- Enter Meal Size Plan values (Small / Medium / Large) based on the average amount of carbs per meal. *

**** If the participant has different Small/Medium/Large doses for each meal of the day: (1) the participant should enter the Small / Medium / Large values for the breakfast meal at the app onboarding. (2) after onboarding is complete, the site should instruct the participant how to proceed with entering the additional meal doses – see below**.***

- Complete the onboarding

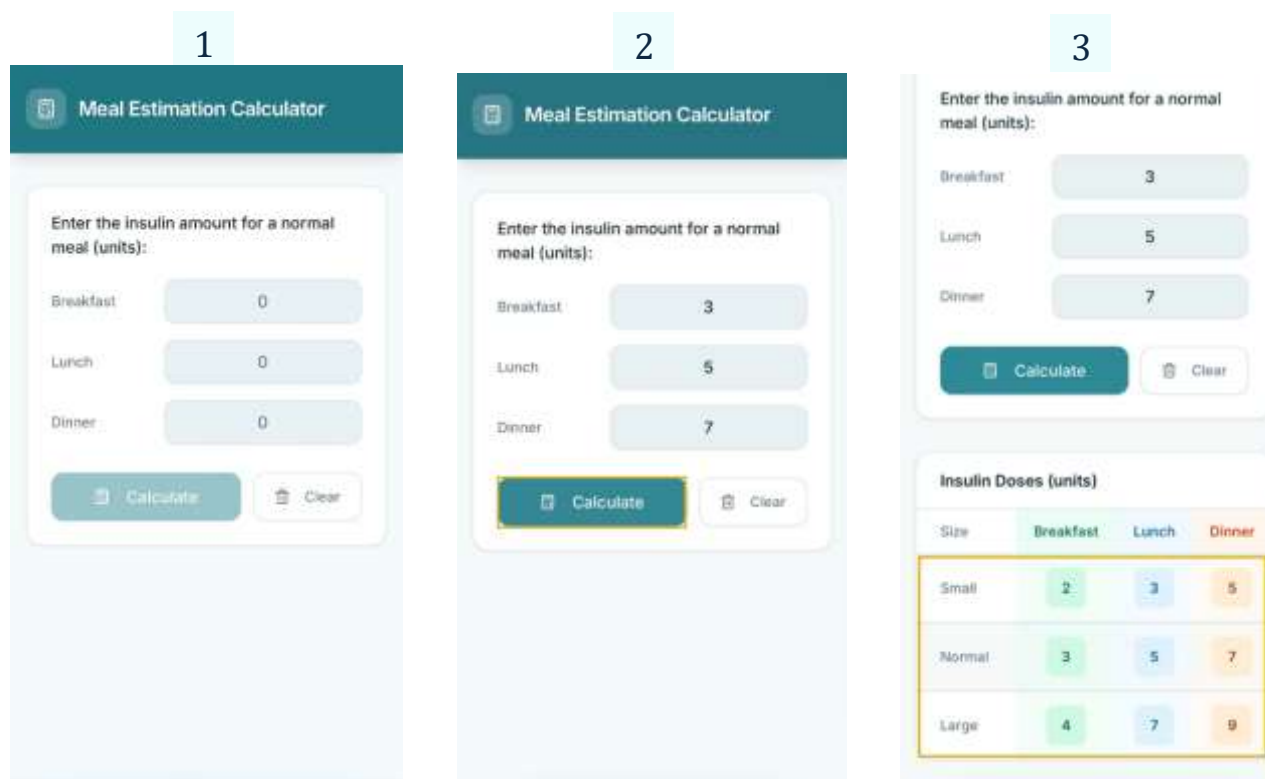
Important:

The participant must complete the entire onboarding workflow.

**** From here forward, proceed only for carbs counting participants who have different doses for each meal.**

Once onboarding is completed:

1. Open the external Meal Size Calculator webpage:
<https://insulin-sync-cd8db0db.base44.app>
The calculator will be used to calculate meal size insulin doses for each meal (Breakfast, Lunch, Dinner) based on the average amount of insulin the participant takes per meal.
2. Enter the normal insulin amount for each meal and click calculate.
3. A table will appear showing calculated doses for **Small, Normal, and Large** meals.

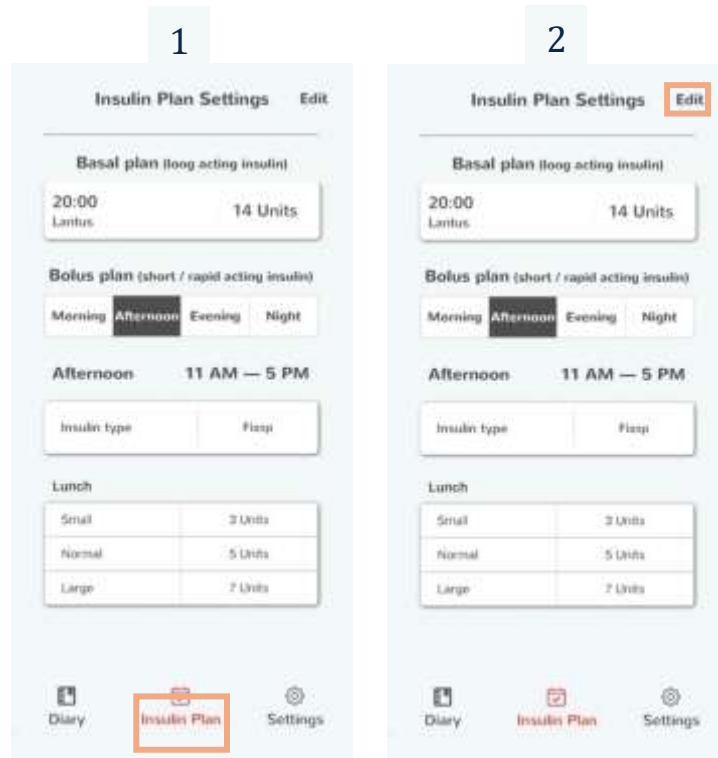


- **Action Required:** Save or record this table (e.g., take a screenshot).

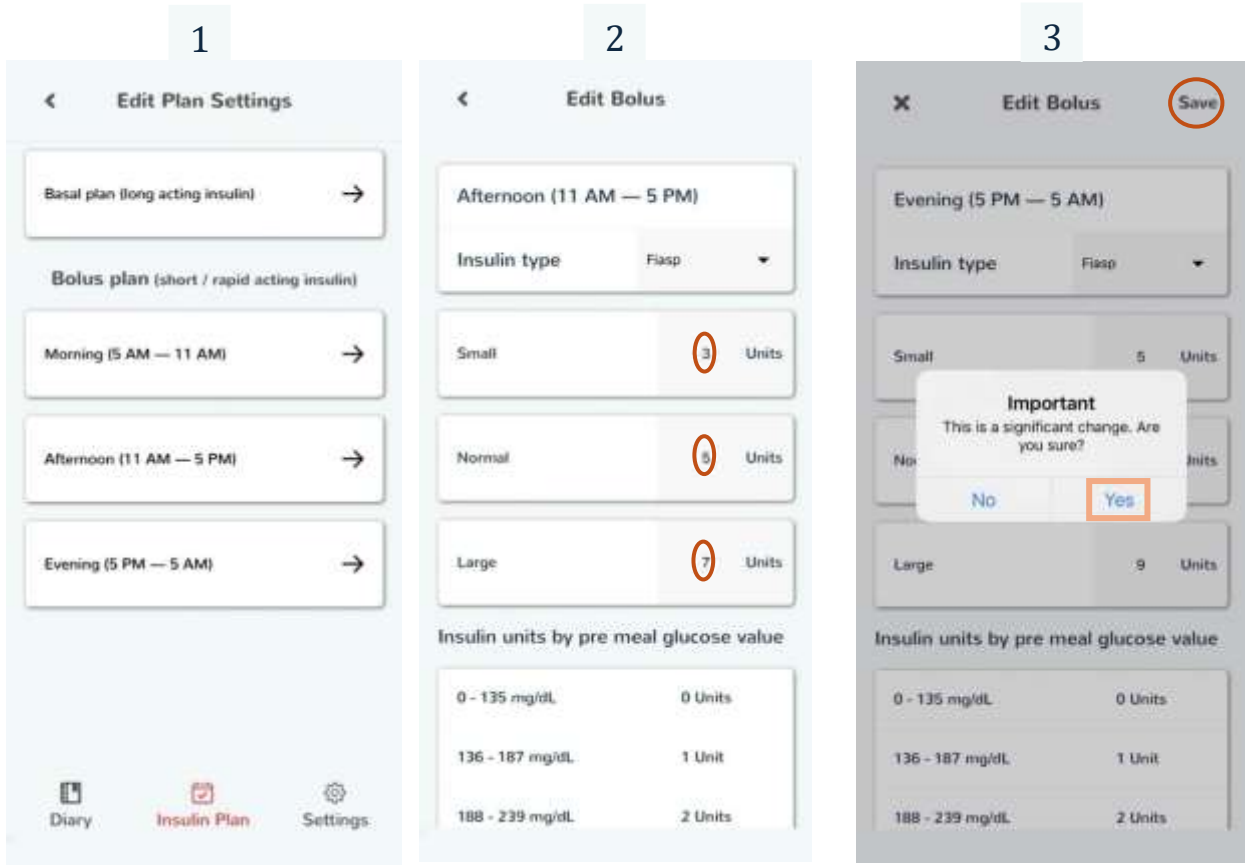
Note: The participant should use these values for prandial insulin dosing, based on their meal sizes.

After receiving the table from the external calculator, the participant should enter these values in the Diary app treatment plan:

1. Navigate to the treatment plan by selecting “Insulin Plan”
2. Click “Edit”




- Update the Small, Medium, and Large insulin values for Morning, Afternoon, and Evening according to the calculator results.
 - Make sure the values are entered correctly.
 - After updating the values, click "Save".
- A message may appear that this is a significant change. If you validated the numbers are entered correctly, click Yes.



Note: Once the changes have been saved and applied, review the full daily meal plan to verify that all Small, Medium, and Large insulin values are correctly populated for Morning, Afternoon, and Evening.

This process will only be done on the first time onboarding. From this point forward the participant will receive updated treatment plans for each part of the day.

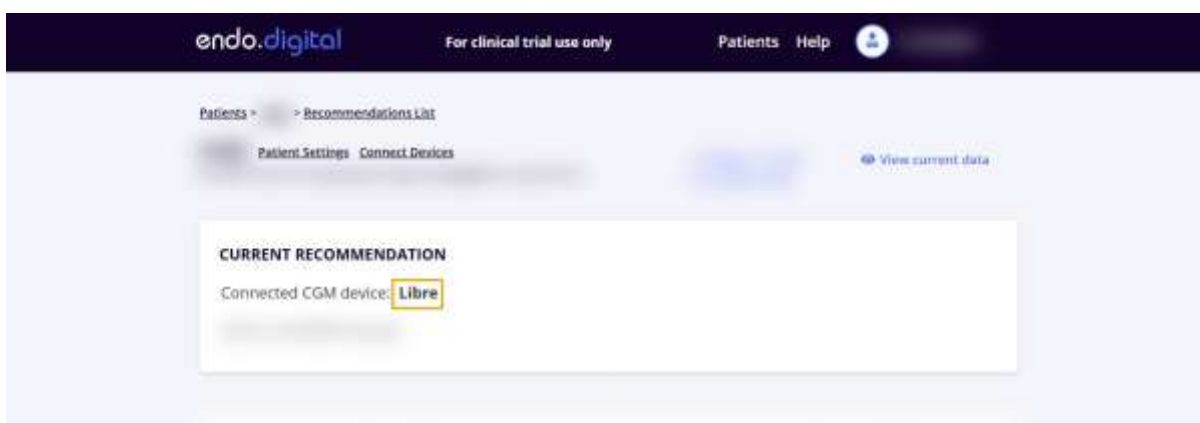
	MODIUS Study: Clinical Site's Workflow Guide
	Version: 1.1

Site Staff Patient Monitoring and Study Management

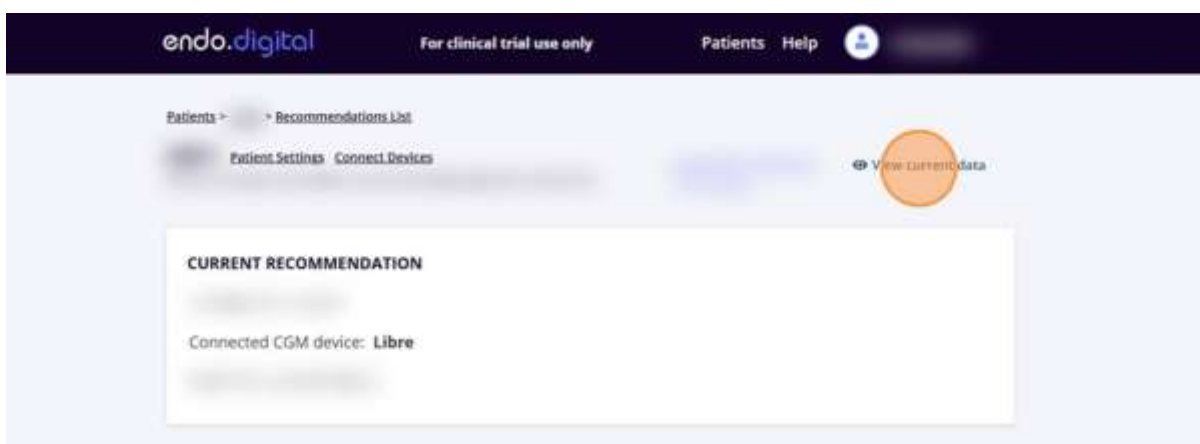
1. Verify Account Connection and View Data

Site staff should first verify that the participant's CGM device is connected:

- Select the Participant Name from list or search for it.
- Confirm that the Connected CGM device field displays “Libre”.



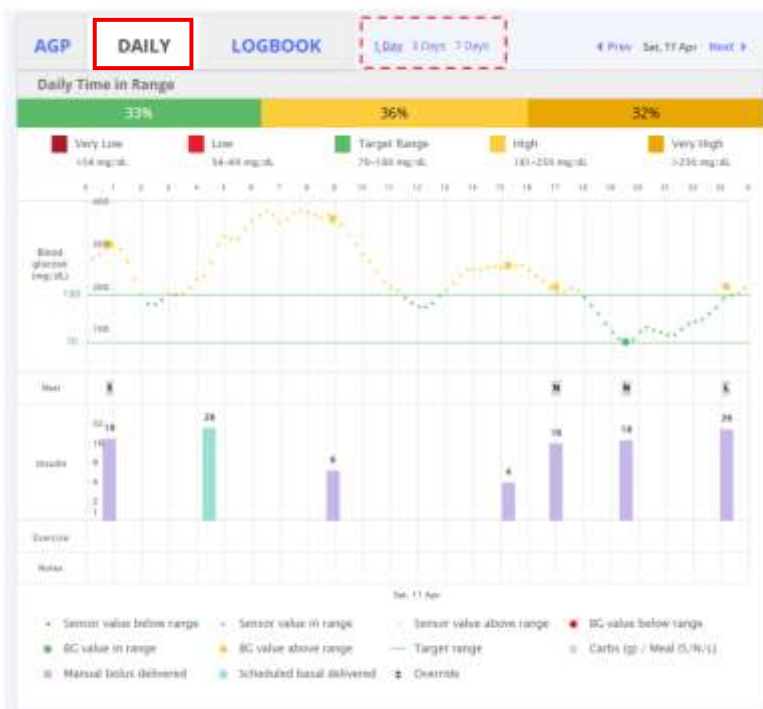
- Select “View current data” and view participant’s data:



Review in AGP:


%CGM wear (should be >70%)

Insulin statistics



Review in Daily report:

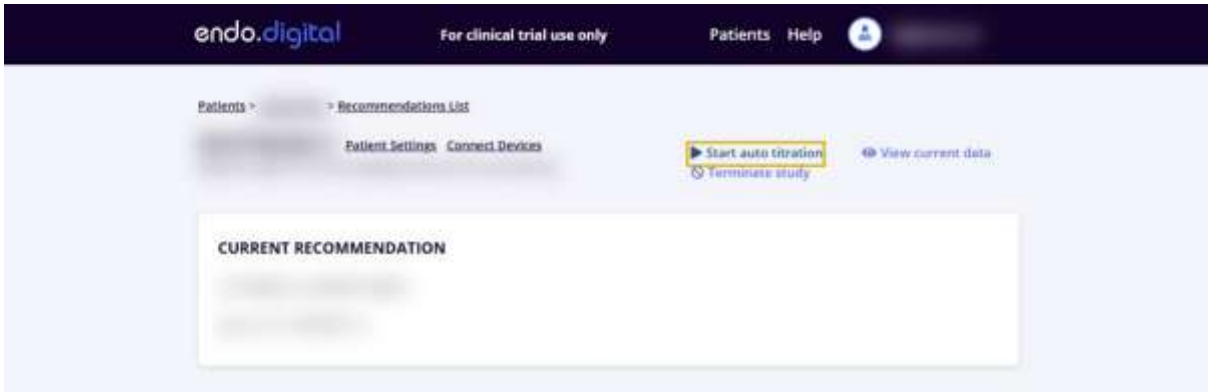
- Basal insulin records (1 per day)
- Bolus insulin records using the bolus calculator

	MODIUS Study: Clinical Site's Workflow Guide
	Version: 1.1

2. Initiating Auto-Titration


Start auto-titration if the participant:

- Completed 7 days of data collection
- Has >67% CGM wear
- Has at least 5 days with basal records
- Has at least 15 bolus records



Stop Auto Titration (**Only if needed**):



	MODIUS Study: Clinical Site's Workflow Guide
	Version: 1.1

3. Terminating a Participant from the Study

At the end of the study, clinic visit week 12 or early termination visit, click the 'Terminate study' link to disconnect the participant's LibreView account and disconnect their Diary app user.

Also be sure the participant uninstalls the DreaMed Diary app from their phone.

