



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

Version: 1.0- DRAFT

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Version 1.0 - *draft*

Date:

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Patient 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.

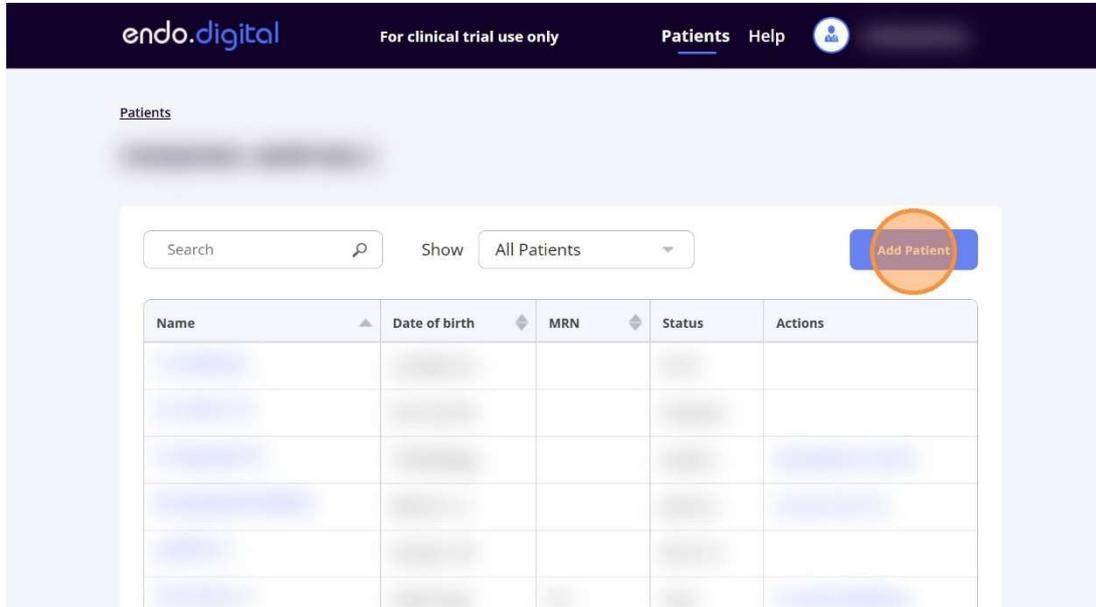
Note: Inform the participant that using their personal account will avoid having two separate data streams to reconcile with their provider after the study.

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. endo.digital Patient Enrollment

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



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

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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

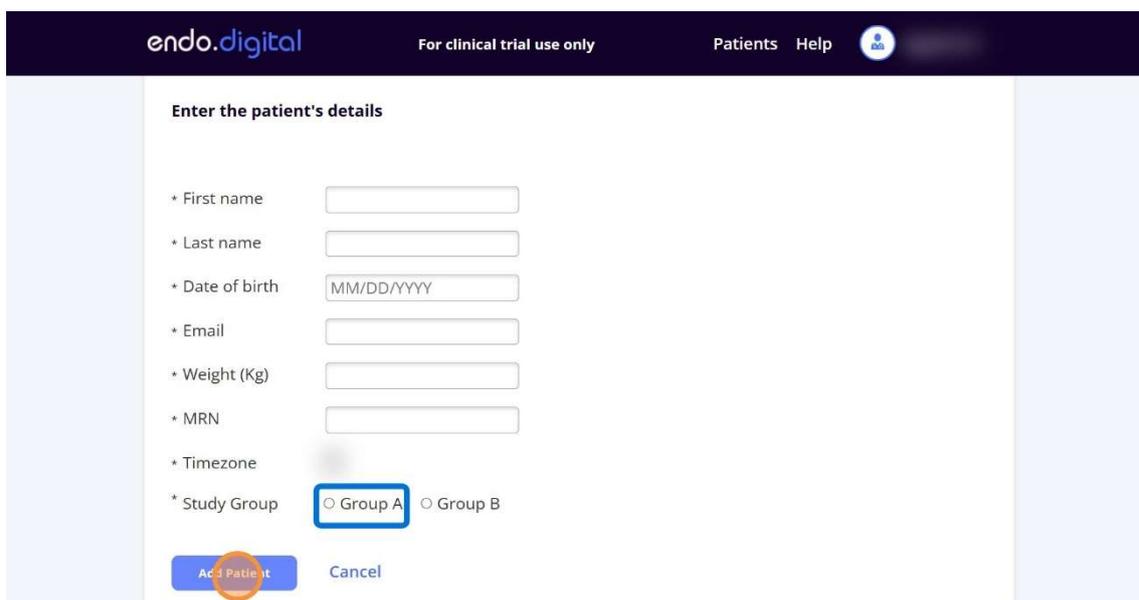
Additionally:

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 a web form titled "Enter the patient's details" on the endo.digital platform. The form contains the following fields and options:

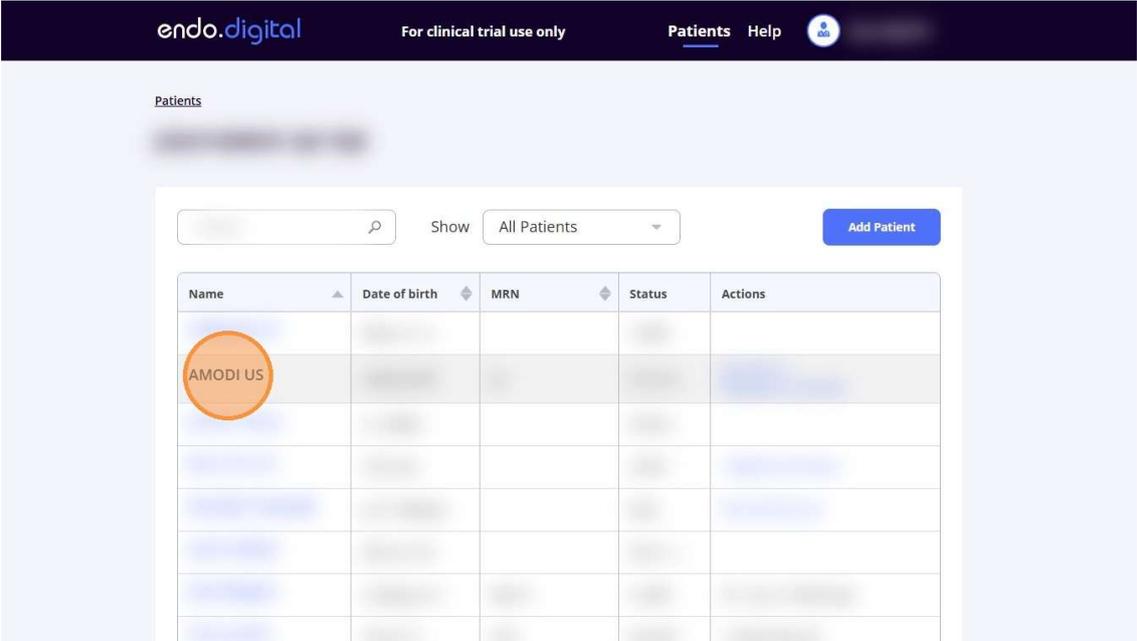
- * First name: Text input field
- * Last name: Text input field
- * Date of birth: Text input field with placeholder "MM/DD/YYYY"
- * Email: Text input field
- * Weight (Kg): Text input field
- * MRN: Text input field
- * Timezone: Dropdown menu (partially obscured)
- * Study Group: Radio button selection for "Group A" (which is selected and highlighted with a blue box) and "Group B"

At the bottom of the form, there are two buttons: "Add Patient" (highlighted with an orange circle) and "Cancel".

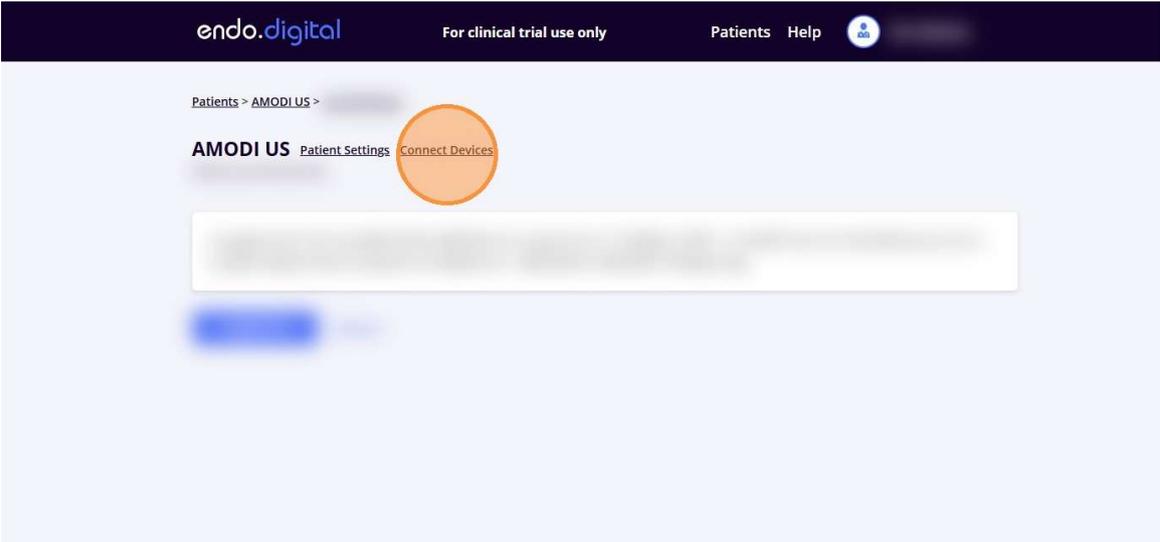
***Before finalizing the form, ensure that the Study Group selection is set to "Group A"**

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

Select the Participant Name from list or search for it

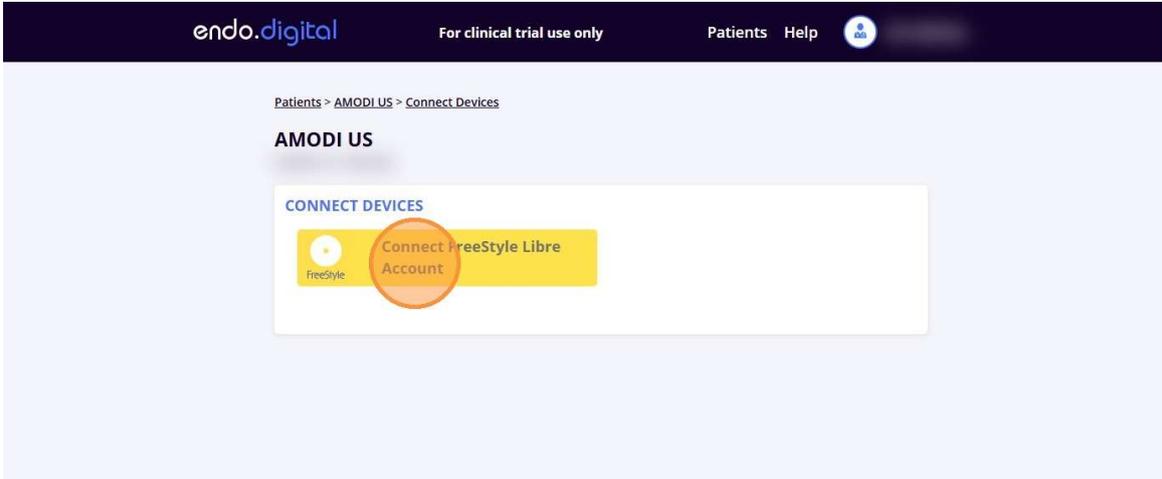


Click "Connect Devices"



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Click "Connect FreeStyle Libre Account"



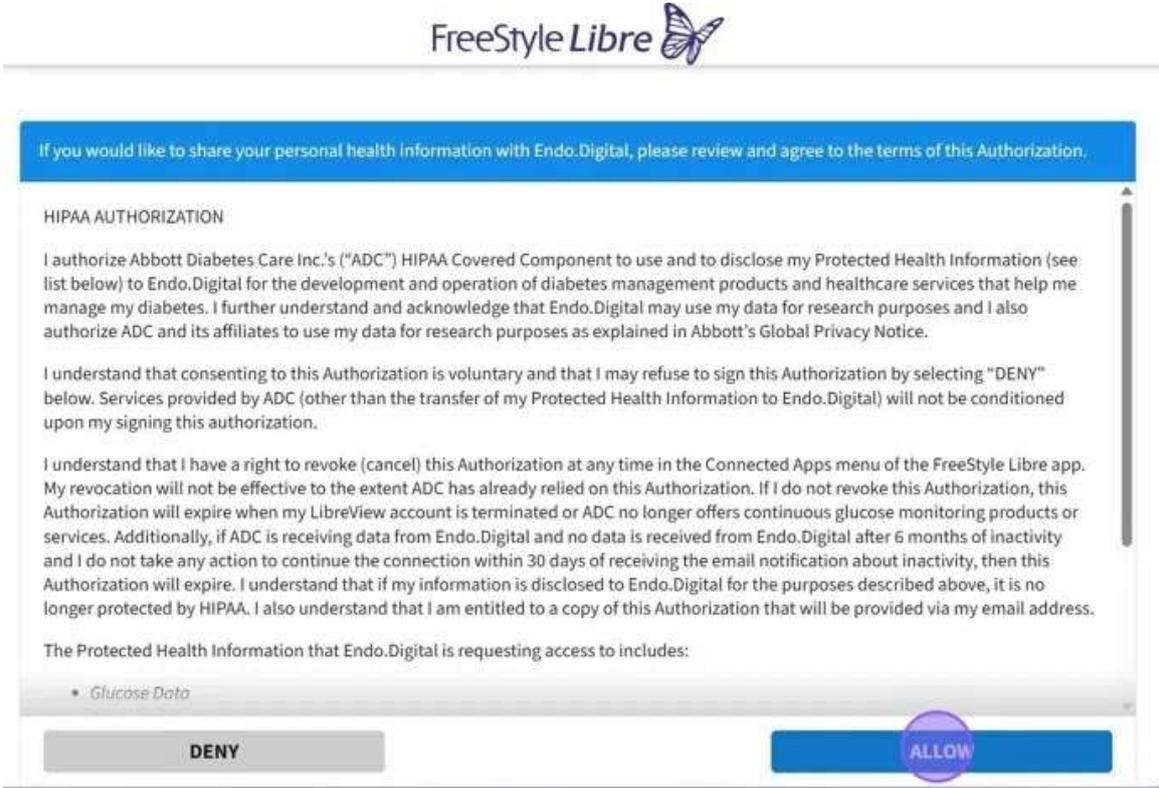
Enter Participant's LibreView Credentials and click "SIGN IN"



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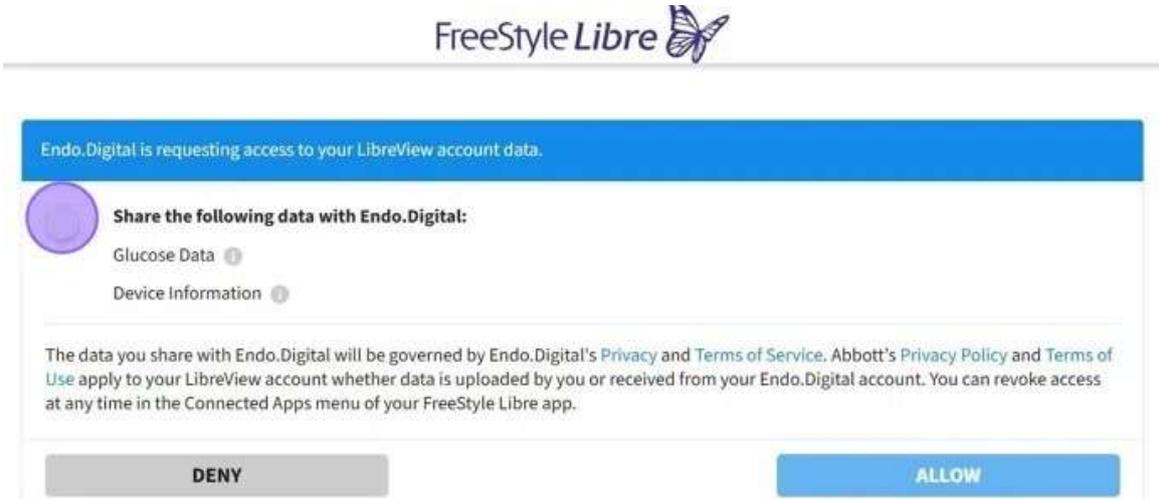
Complete HIPAA Authorization

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

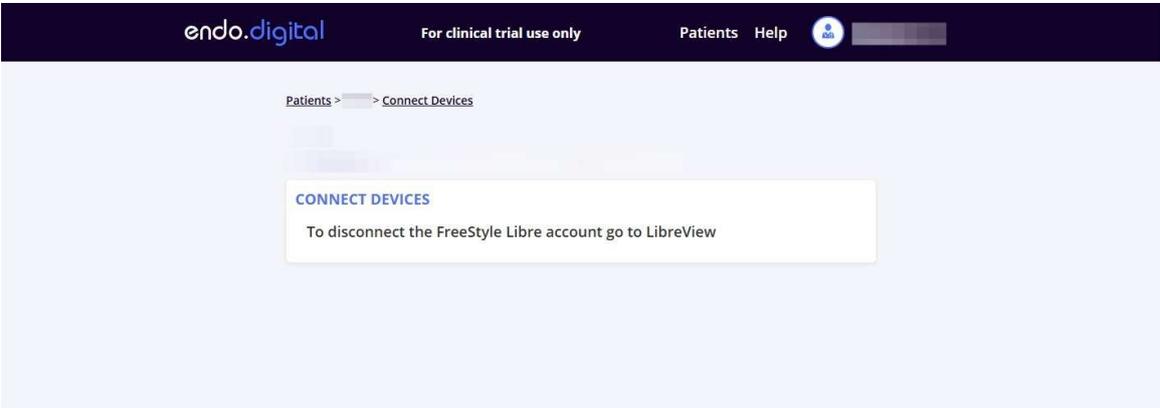
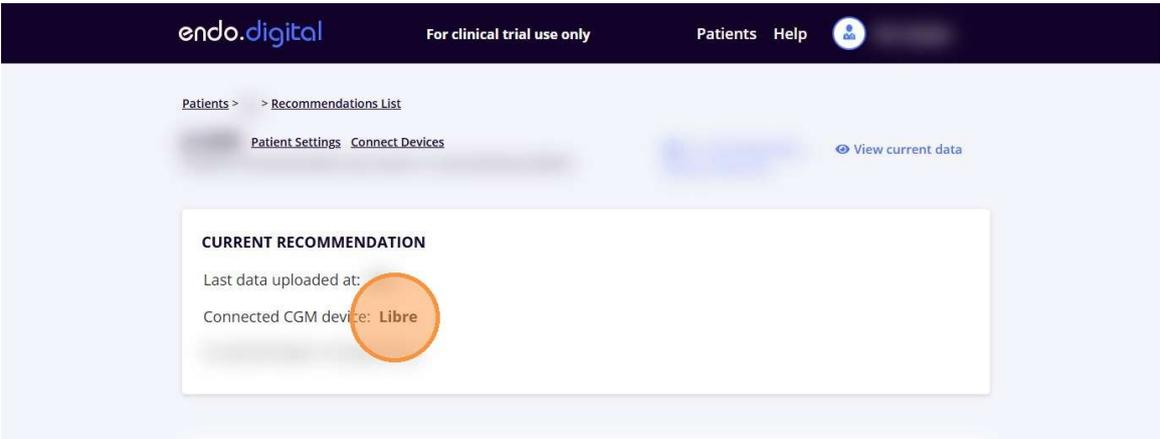
A confirmation message will appear. Select “OK” to complete the process.

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Verify Active Sync Status

There are two ways to confirm that the participant's Libre device is successfully connected:

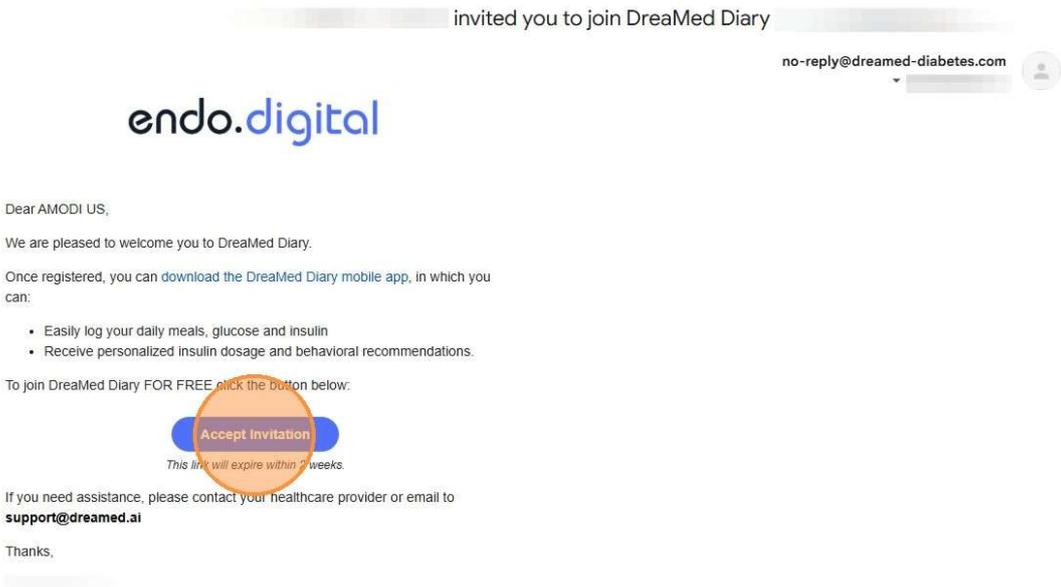
- 1. The "Connected CGM device" section on the patient dashboard displays "Libre".
- 2. The yellow "Connect Your Freestyle Libre" button disappears on the Connect Devices page.



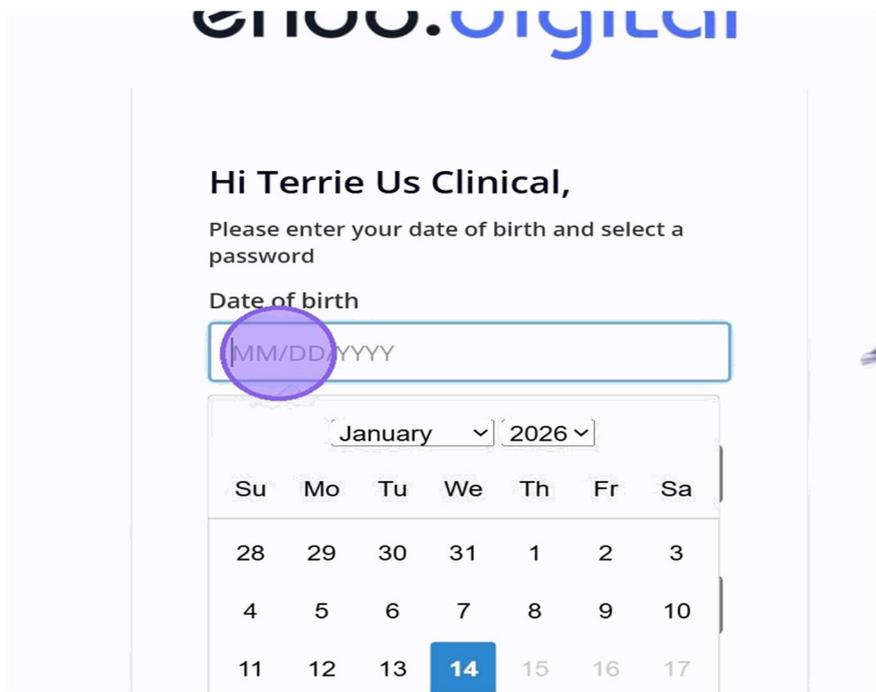
3. Participant Onboarding

3.1. Email Invitation Acceptance & Registration

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



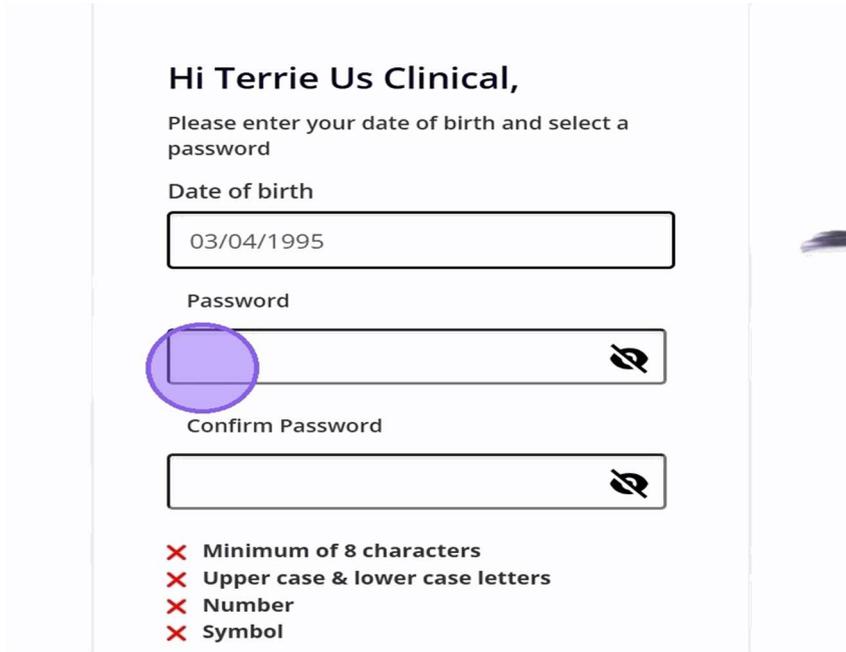
- Enter participant's date of birth



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

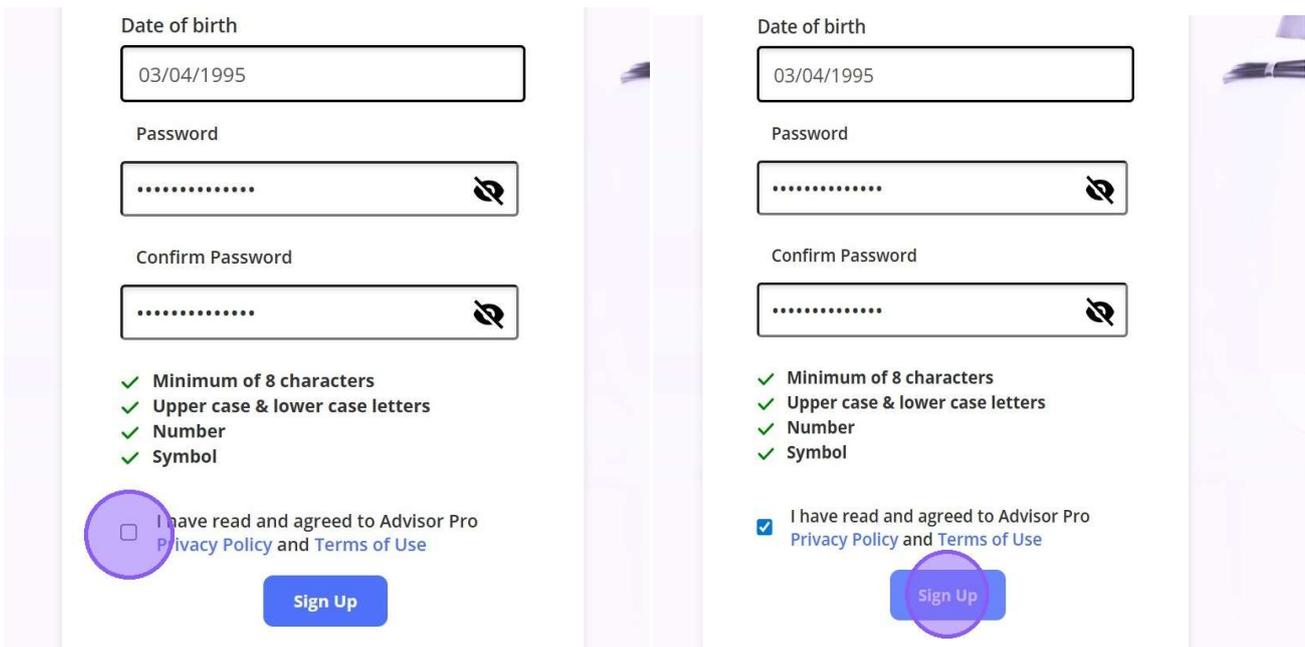
Date of birth
03/04/1995

Password
[Redacted]

Confirm Password
[Redacted]

- ✗ 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
[Redacted]

Confirm Password
[Redacted]

- ✓ 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

Date of birth
03/04/1995

Password
[Redacted]

Confirm Password
[Redacted]

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

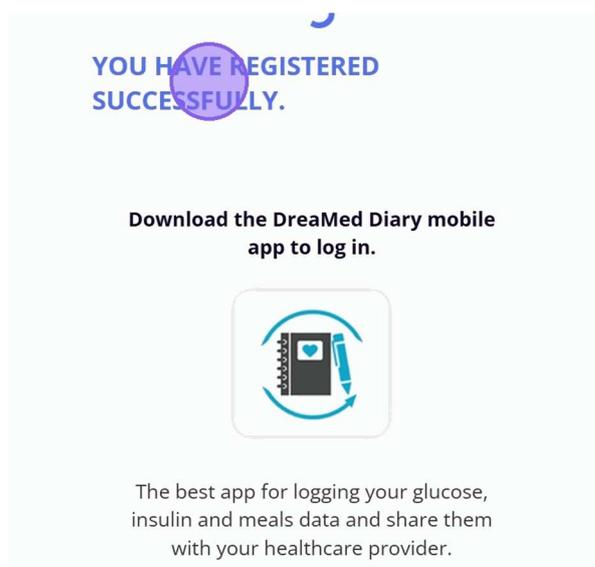
I have read and agreed to Advisor Pro Privacy Policy and Terms of Use

Sign Up

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3.2. 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)



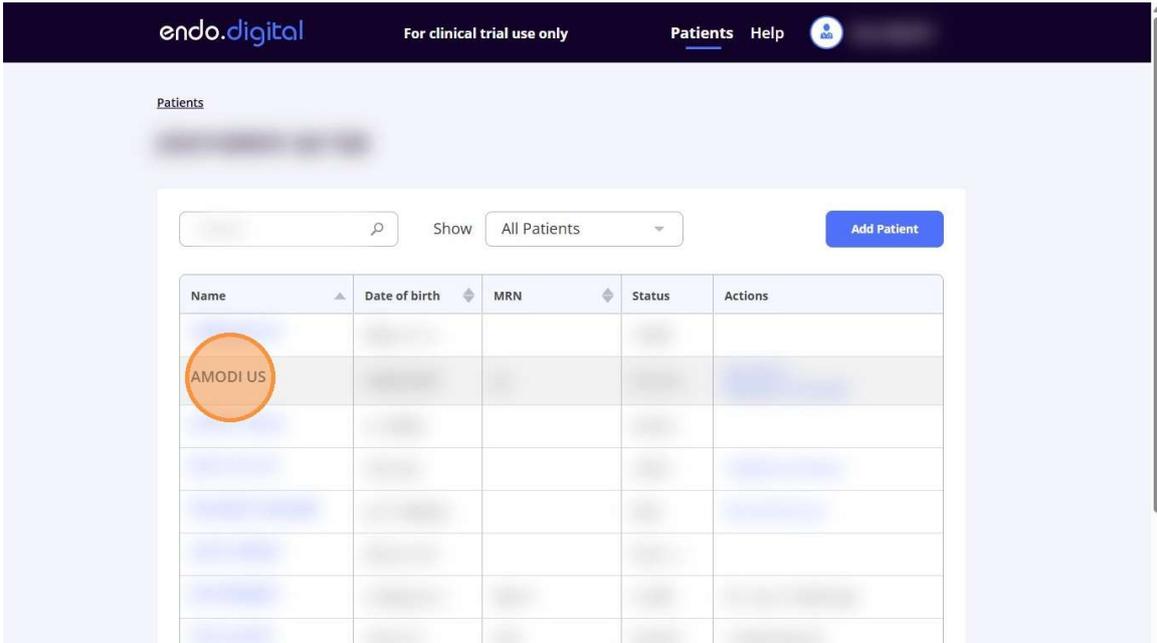
- b) Login to the DreaMed Diary app by entering the participant's email in the username field and the password as created.

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

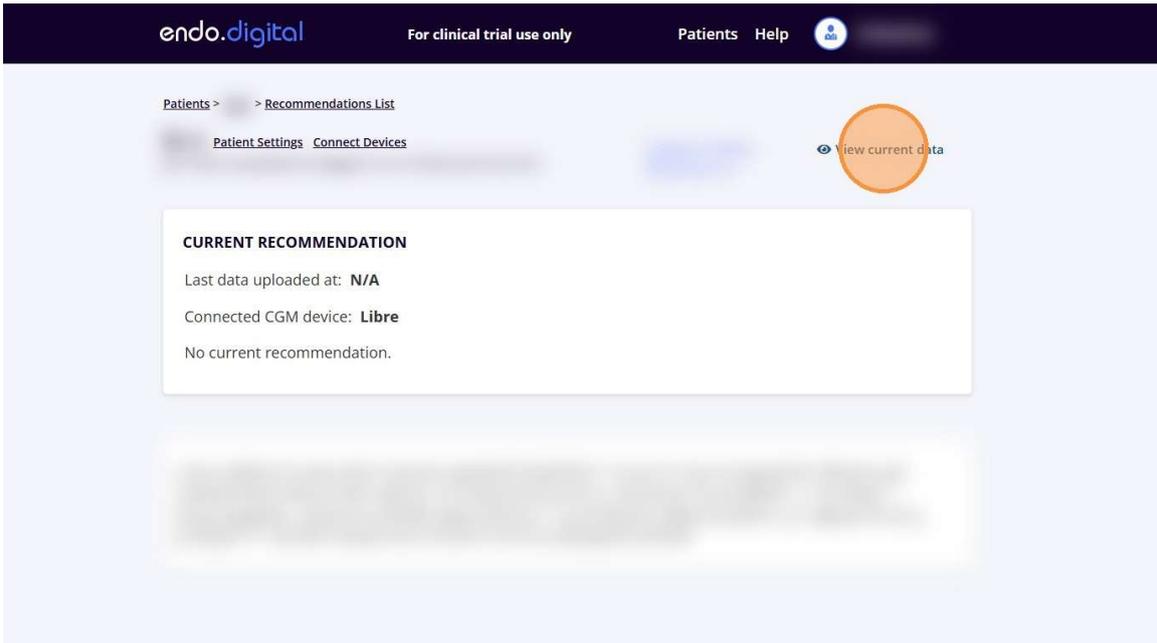
4. Clinical Data Review & Study Management

4.1 Reviewing CGM Usage and Insulin Logging in endo.digital

Select the Participant Name from list or search for it



Click "View current data"



Scroll to the bottom of the page

The screenshot shows the 'endo.digital' interface with a dark blue header containing the logo, 'For clinical trial use only', and navigation links for 'Patients' and 'Help'. Below the header, the breadcrumb trail reads 'Patients > Recommendations List > Current Data'. The main content area is divided into sections for 'CURRENT PLAN', 'BASAL PLAN', and 'BOLUS PLAN'. The 'BASAL PLAN' section contains a table with columns for 'Time', 'Amount', and 'Insulin type'. The 'BOLUS PLAN' and 'MEAL' sections are partially visible below.

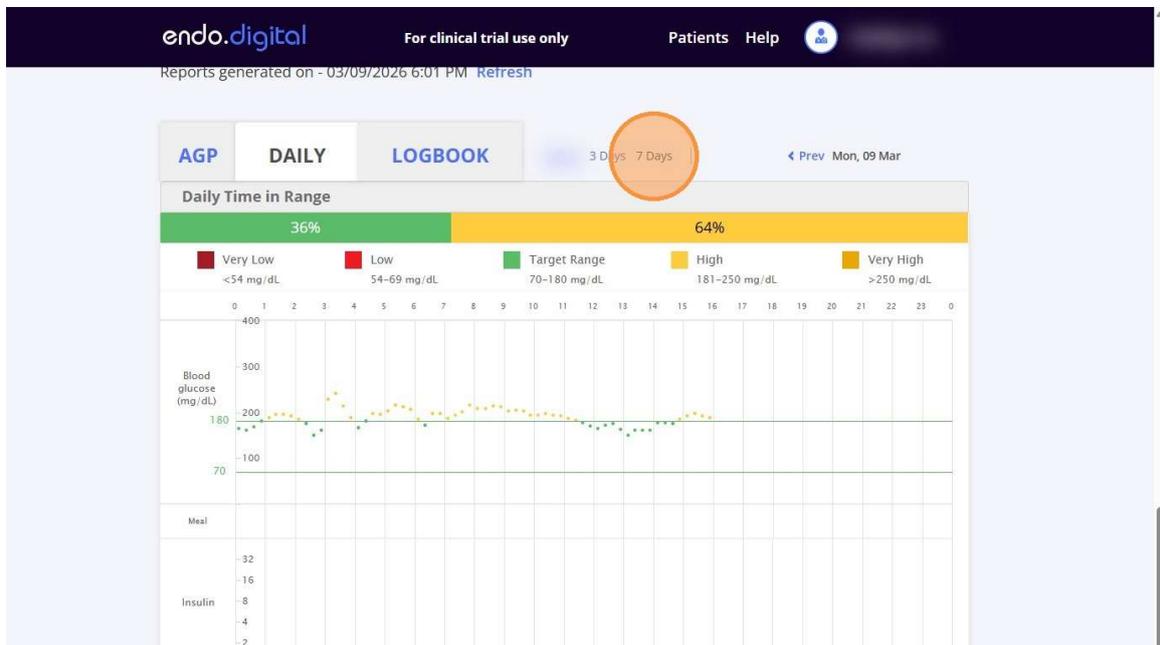
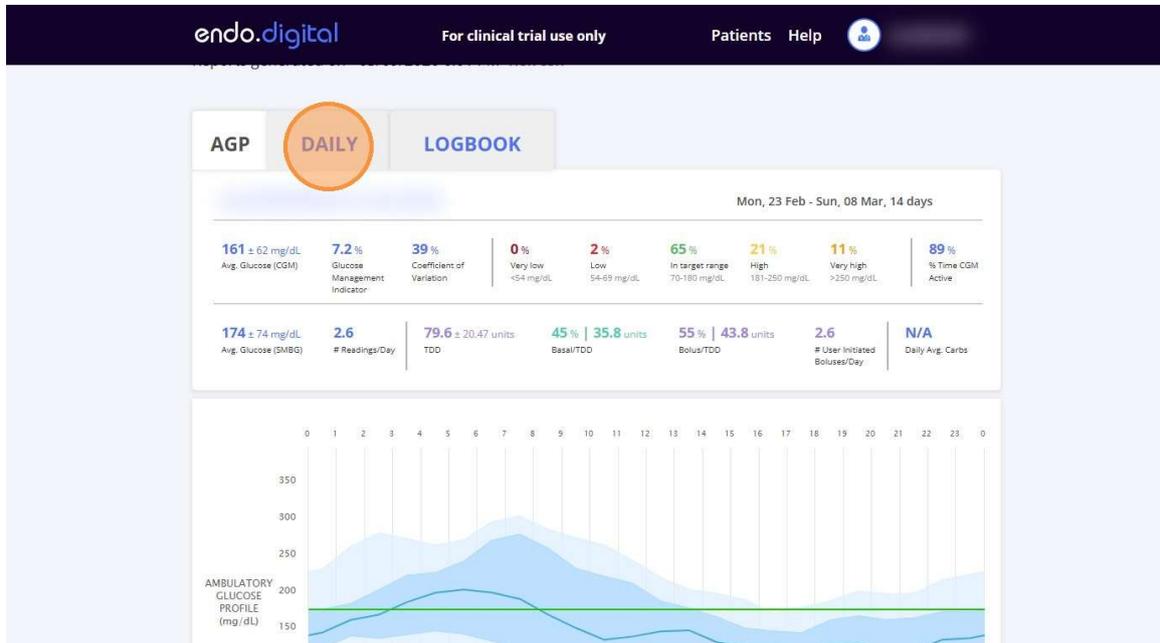
Confirm that the participant's CGM active wear percentage is at least 70%

The screenshot displays the 'endo.digital' interface with a dark blue header. The main content area has tabs for 'AGP', 'DAILY', and 'LOGBOOK', with 'AGP' selected. The date range is 'Mon, 23 Feb - Sun, 08 Mar, 14 days'. A summary of CGM metrics is shown in a grid:

161 ± 62 mg/dL Avg. Glucose (CGM)	7.2 % Glucose Management Indicator	39 % Coefficient of Variation	0 % Very low <54 mg/dL	2 % Low 54-69 mg/dL	65 % In target range 70-180 mg/dL	21 % High 181-250 mg/dL	11 % Very high >250 mg/dL	89 % % Time CGM Active
174 ± 74 mg/dL Avg. Glucose (PMBG)	2.6 # Readings/Day	79.6 ± 20.47 units TDD	45 % 35.8 units Basal/TDD	55 % 43.8 units Bolus/TDD	2.6 # User Initiated Boluses/Day	N/A Daily Avg. Carbs		

Below the metrics is an 'AMBULATORY GLUCOSE PROFILE (mg/dL)' graph showing a 24-hour cycle with a shaded area representing the range and a line for the average glucose level.

Switch to Daily View and Select 7 Days



Review Bolus Logging for the Last 7 Days

Target: At least 70% of expected bolus injections must be logged in the app.

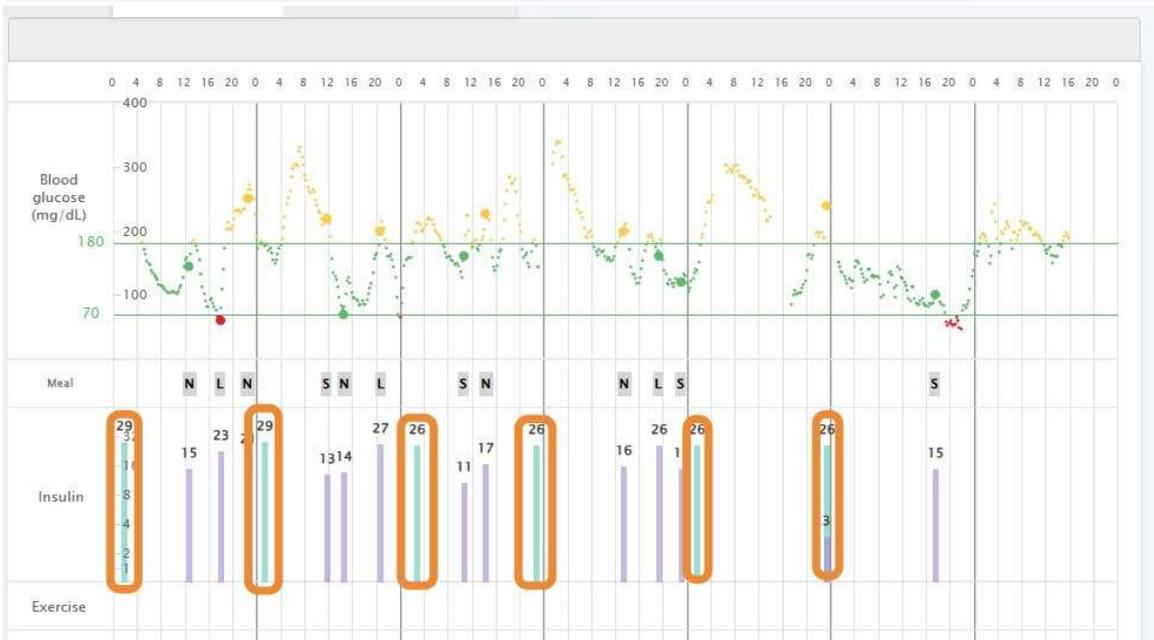
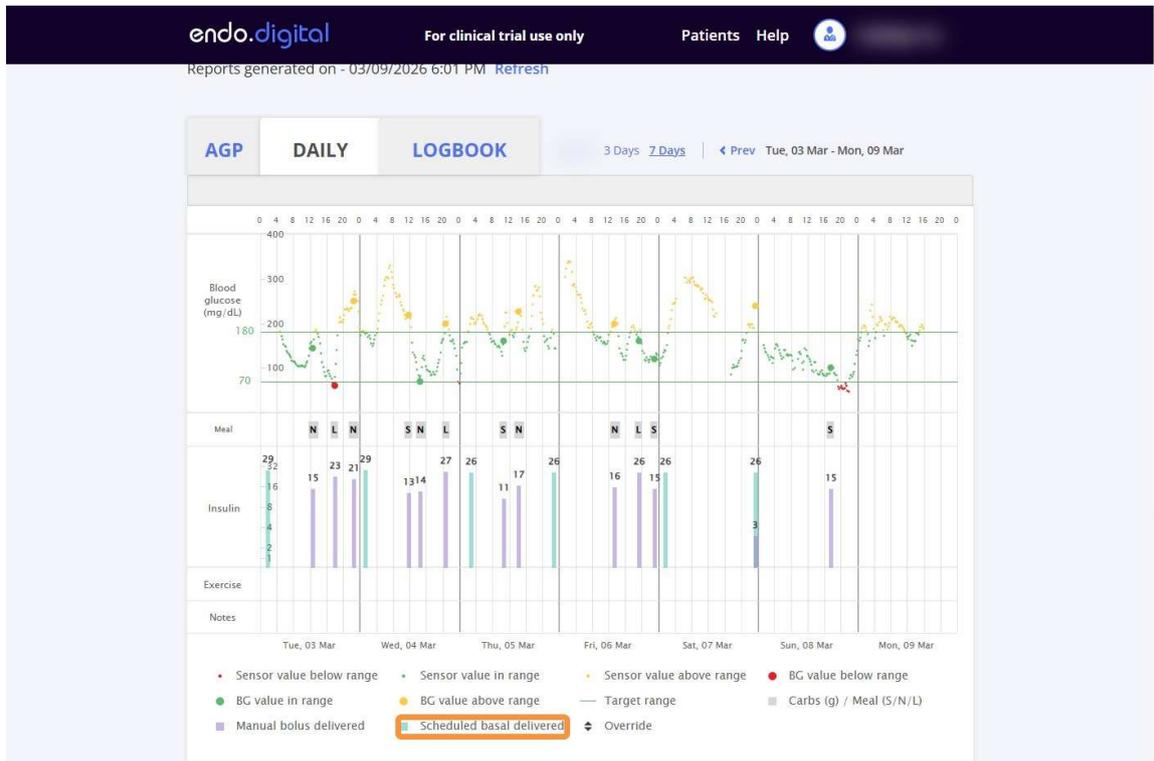
Example: A participant taking ~3 boluses/day should have ≥ 15 of 21 boluses logged over a week (15/21).

Look for gaps (days without entries, long periods with no bolus logs)



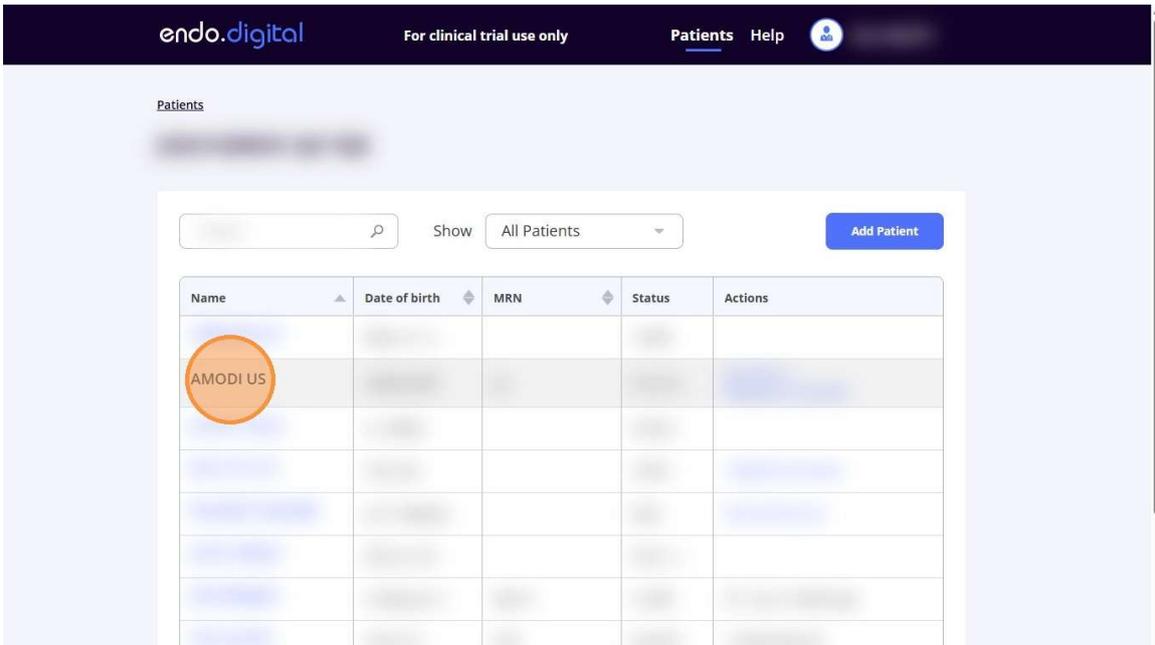
Review Basal Logging for the Last 7 Days

Verify there is at least one basal dose logged per day within the same 7-day period, consistent with the participant's Basal plan

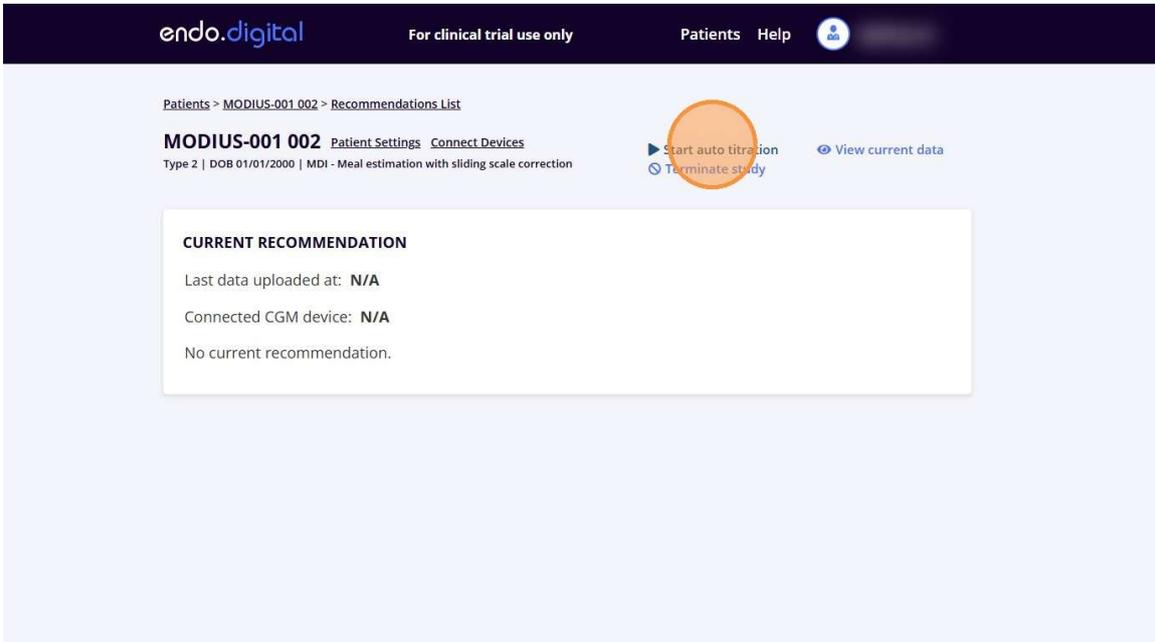


4.2 Starting MODI Auto-Titration

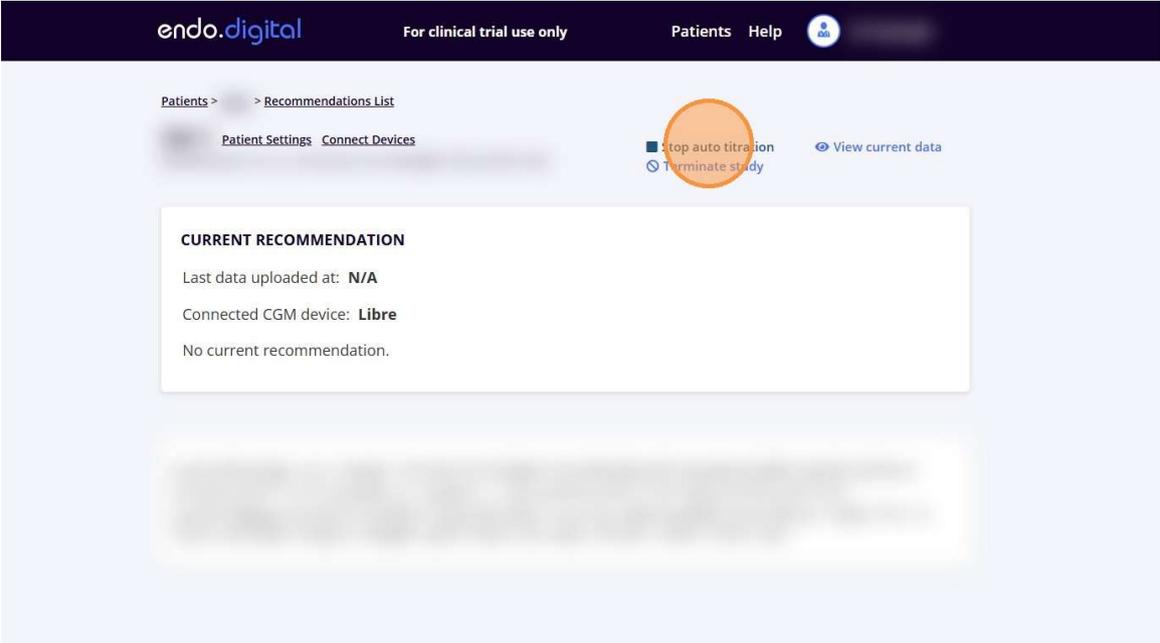
Select the Participant Name from list or search for it



Click Start Auto Titration

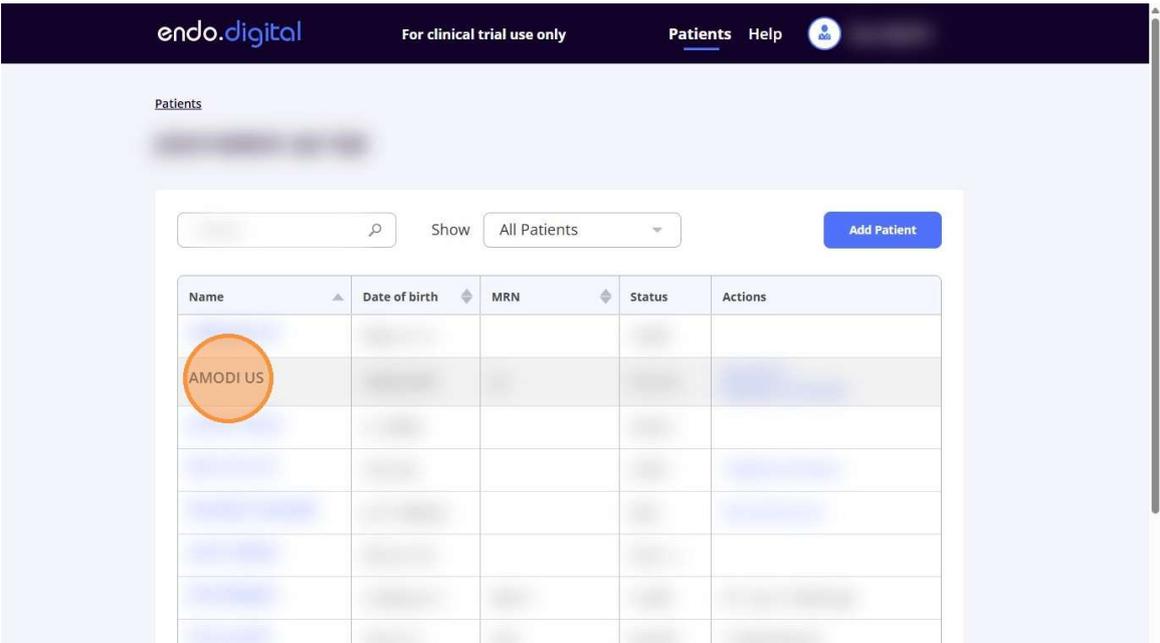


Once activated, the participant's dashboard will display an Auto-Titration active status indicator



4.3 Terminating the Study

Select the Participant Name from list or search for it





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Select "Terminate Study"

The screenshot shows a web interface for a clinical study. At the top, there is a breadcrumb trail: "Patients > > Recommendations List". Below this, there are two tabs: "Patient Settings" and "Connect Devices". To the right of these tabs, there are two buttons: "Stop auto titration" (with a blue square icon) and "View current data" (with a blue eye icon). The "Terminate study" button, which has a red circle with a white 'X' icon, is highlighted with an orange border. Below the navigation area, there is a white box titled "CURRENT RECOMMENDATION" containing the following text: "Last data uploaded at: N/A", "Connected CGM device: Libre", and "No current recommendation." Below this box, there is a blurred area that appears to be a list of recommendations.



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FAQ – Frequently Asked Questions