

Regulora[®]

Instructions for Use for Patients and Physicians

R_x Only

US federal law restricts this mobile application to sale by
or on the order of a physician

Prescription mobile application for the treatment of abdominal
pain due to adult Irritable Bowel Syndrome (IBS)



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DESCRIPTION OF SYMBOLS



Catalog number



CAUTION: Pay special attention to instructions



Consult instructions for use



Lot number



Manufacturer



Prescription medical device



Reference part number



CAUTIONS AND NOTES



Regulora is intended for patients who speak and read English.

Regulora may not be appropriate for patients with mental or physical impairment that would prevent interacting with a mobile video application. Patients should consult their healthcare provider.

Regulora may not be appropriate for patients with evidence of intestinal illness that better explain IBS symptoms such as celiac disease or inflammatory bowel disease. Patients should consult their healthcare provider.

If you experience feelings or thoughts of harming yourself or others, contact your healthcare provider.

If you experience worsening of your IBS symptoms during or after *Regulora* treatment, contact your healthcare provider.

If you experience headache or fatigue during or after *Regulora* treatment, contact your healthcare provider.

The *Regulora* app is downloaded onto your mobile device. Follow all the manufacturer's instructions for the safe operation of the mobile device.

R_x Only

Regulora is a prescription mobile application for the treatment of adult abdominal pain due to IBS. US federal law restricts this mobile application device to sale by or on the order of a physician.

CAUTIONS AND NOTES



Caution

Regulora should not be used in lieu of your current IBS medication or therapy.

Not all patients will achieve relief from their IBS symptoms. If your IBS symptoms persist or worsen, contact your health care provider.

Note

To minimize distraction during treatment, switch your charged mobile device to **“Do Not Disturb mode”** when using *Regulora* and find a quiet place with a good network connection where for 30 minutes you won’t be disturbed. Never view your sessions in a car, even if it is stationary.

- We recommend using headphones, earbuds, or quality speakers.
- Choose a place you can adjust the lights so that they are not too bright.

After completing your *Regulora* treatment, you should discuss your results with your healthcare provider. She or he can further advise you on how to best manage your IBS.

INDICATIONS FOR USE AND SIDE EFFECTS

Indications for Use

Regulora® is a prescription-only digital therapeutic device intended to provide behavioral therapy through gut-directed hypnotherapy for adults 22 years of age and older who have been diagnosed with Irritable Bowel Syndrome (IBS). *Regulora* is indicated as a 3-month treatment for patients with abdominal pain due to IBS and is intended to be used together with other IBS treatments.



Side Effects

In a clinical trial of *Regulora* side effects were low. About 1% of patients experienced abdominal pain, constipation, fatigue, or headache which was thought to be related to using *Regulora*.

IBS AND *REGULORA*

IBS

Irritable Bowel Syndrome (IBS) is a common disorder, affecting approximately 10% of the US adult population. IBS is characterized by abdominal pain that is often severe, with an onset that is unpredictable. Episodes of pain are associated with altered bowel habits, all of which have significant impact on quality of life, work performance, and work attendance.

Regulora

Regulora is a digital therapeutic mobile app that is downloaded onto your mobile device. *Regulora* provides for 12 weeks of remote behavioral therapy based on Gut-Directed Hypnotherapy (GDH). Prior to *Regulora*, GDH therapy would be provided via a trained clinician in a medical clinic. With *Regulora*, pre-recorded GDH treatment sessions are presented on your mobile device online.

GDH provided in the clinic by trained therapists has been shown to help patients with their IBS symptoms. According to the International Foundation for Gastrointestinal Disorders, therapist-administered GDH helps patients with IBS with their abdominal pain, constipation, diarrhea, and bloating. Remote *Regulora*-administered GDH has also been studied in a clinical trial and has been shown to improve the abdominal pain due to IBS in adults.

Using *REGULORA*

Getting Started

The *Regulora* app will provide you with 7 online streamed GDH sessions over the next 3 months. Each treatment session takes approximately 30 minutes. There are also 15-minute practice sessions that you can take between treatment sessions.

After your healthcare provider writes you a prescription for *Regulora*, you will be provided an “**Access Code.**”

Once you have your access code, go ahead and search for “***Regulora***” from **metaMe Health** on the Apple App Store or Google Play Store.

Download and install *Regulora* onto your mobile device. Once *Regulora* is installed on your mobile device you will be able to watch a video within the app that further explains the *Regulora* program.

Open the *Regulora* App on your mobile device and follow the steps described on the following pages to:

- Setup your account with metaMe Health
- Schedule your *Regulora* treatment sessions
- Start your *Regulora* treatment
- Your prescription provides for 3 months of access to *Regulora* which is enough time to complete the treatment regimen

After you complete your 7 treatment sessions with *Regulora* over the 3 months you should discuss your results with your healthcare provider. She or he can further advise you on how to best manage your IBS.

1: Create Account

First you'll need to sign up to receive *Regulora* with your access code.

[< HOME](#)

Signup

FIRST NAME

First name

LAST NAME

Last name

EMAIL

Email

A confirmation link will be sent to this address, so you must be able to check email at the address you enter.

CONFIRM EMAIL

Confirm email

ACCESS CODE

Access code

Submit

[Already have an account?](#)

2: Treatment Schedule

After being prompted to confirm your email and update your password, it's time to schedule your 7 treatment sessions over the next 3 months.

Treatment Preferences

DAY OF THE WEEK

Select the Day of the Week that is generally best for your sessions over the next three months. (many people choose a weekend day)

TIME OF THE DAY

Select the Time of Day on the day you picked above that is generally best for your sessions over the next three months.

TIMEZONE

Select your Time Zone

PHONE NUMBER

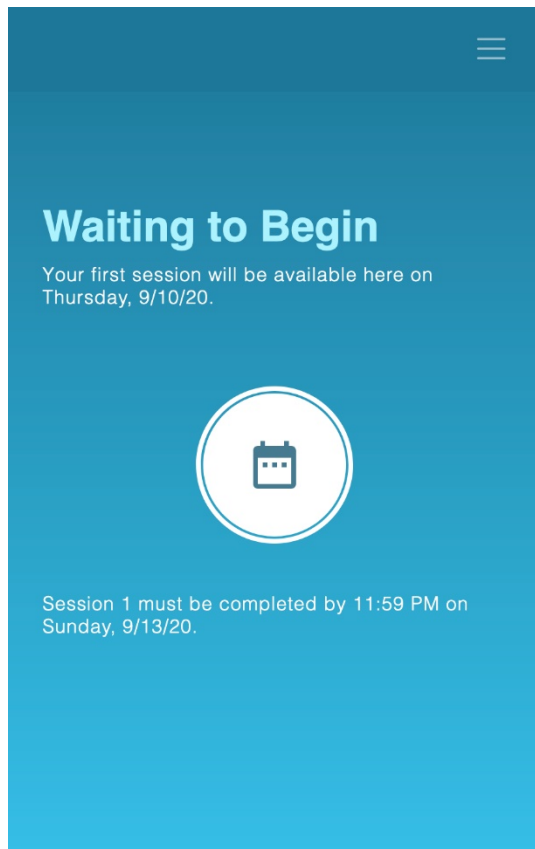
Phone number

Enter your Mobile Phone Number. We will use your mobile phone number to send you text reminders of your sessions. It will not be shared or used for any other purpose.

Submit

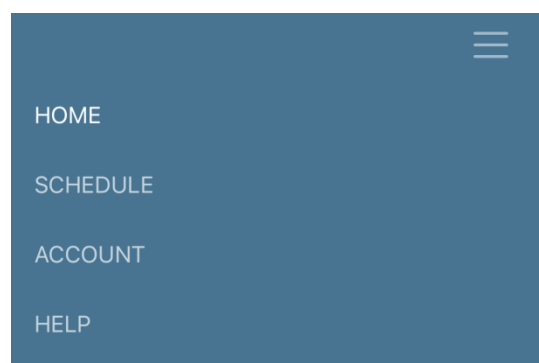
3: Treatment Confirmation

After scheduling your treatment sessions *Regulora* will display your first treatment confirmation.



4: Navigation Menu

This is the *Regulora* main menu. From here you can initiate your treatment sessions, see your upcoming treatments (reschedule if needed), and manage your account. Check out the help tab for tips (including the best way to set up Do Not Disturb mode) and how to contact us for technical support.

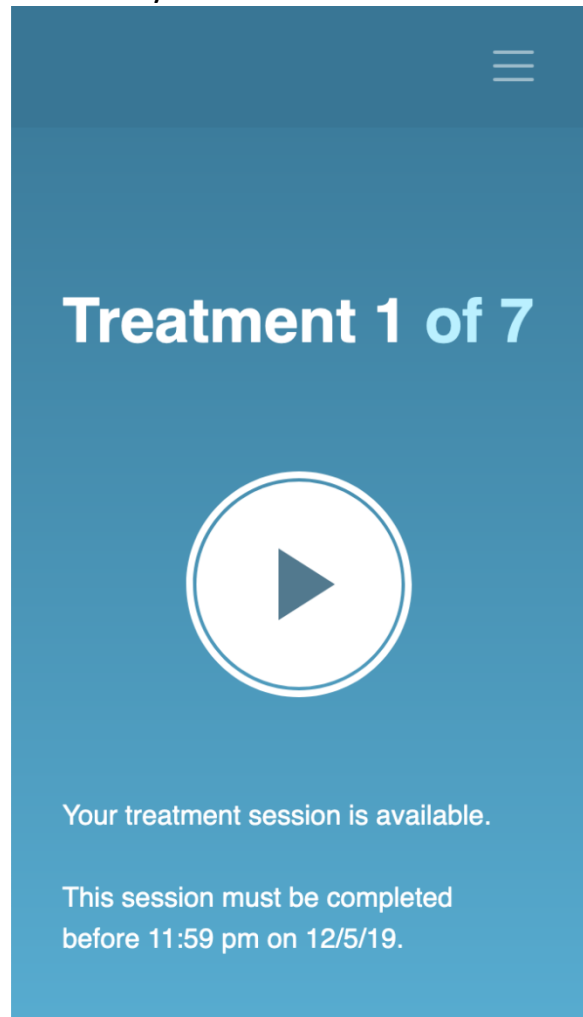


5: Treatment Day

It's time for treatment! Make sure your mobile device is set to "Do Not Disturb."

A Regulora treatment session takes about 30 minutes, so find a quiet place where you won't be disturbed.

You can take your treatment any time of the day, but you must take it within 3 days of when you scheduled it. So why not take it now...



6: Tips

Here are some helpful tips to get the most out of *Regulora*.

Try hard to complete your treatment session on the scheduled day. If you miss it, the session is only available for three days.

Remember to set your device to "Do Not Disturb" and find a quiet place for the next 30 minutes where you won't be interrupted. Never take your sessions in a car, even if it is stationary.

You should use your earbuds, headphones, or high-quality speakers.

Choose a place you can adjust the lights so that they are not too bright.

Unfortunately, interruptions happen. If you miss any part of the session you should press "Begin Again", and the session will replay from the beginning.

It's good to stay tuned up. You'll see access to 15-minute practice sessions. Try to complete at least 3 of these in the days between your treatment sessions.

7: Interruptions

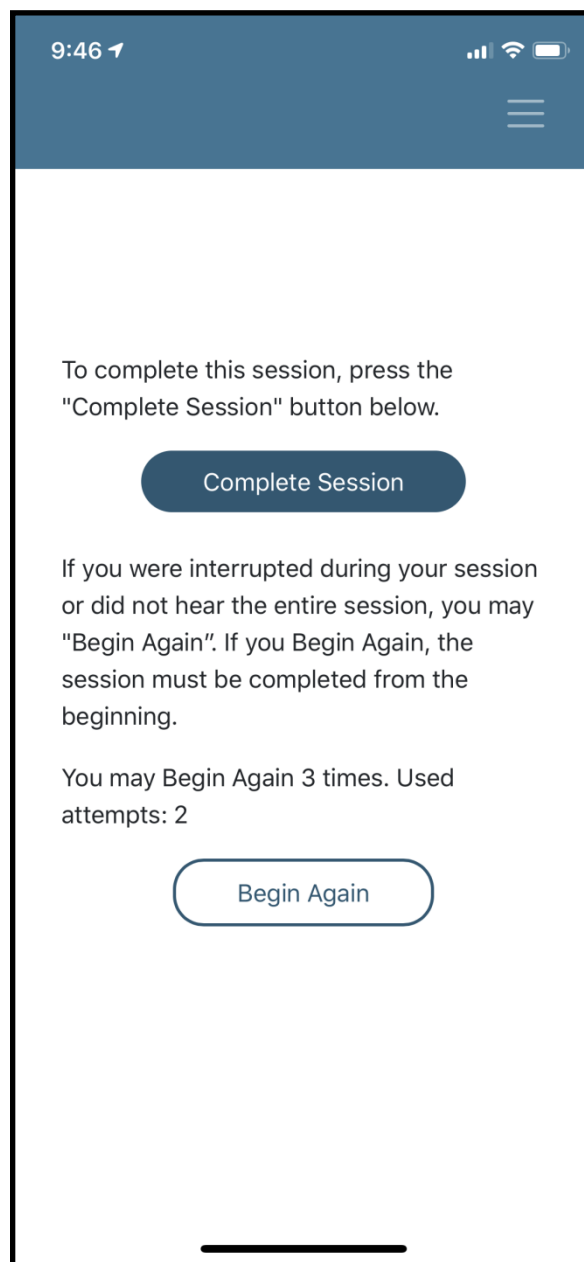
Interruptions are a part of life (such as phone calls or loud music playing). To avoid being interrupted during your treatment session it is essential that you place your device in “Do Not Disturb” mode and that your settings for Do Not Disturb are set correctly. **Please see the “Help” page from the main menu for more instruction on setting this up.**

If you receive a call (even if you don’t answer it), answer an email or text, or leave the app for any reason during a session, when you come back to the app your session will be reset and you will have to begin again. Remember to choose a room or location where you can hear the audio modules clearly and can focus on the instructions.

8: End of session

You just finished a treatment session. Nice work!

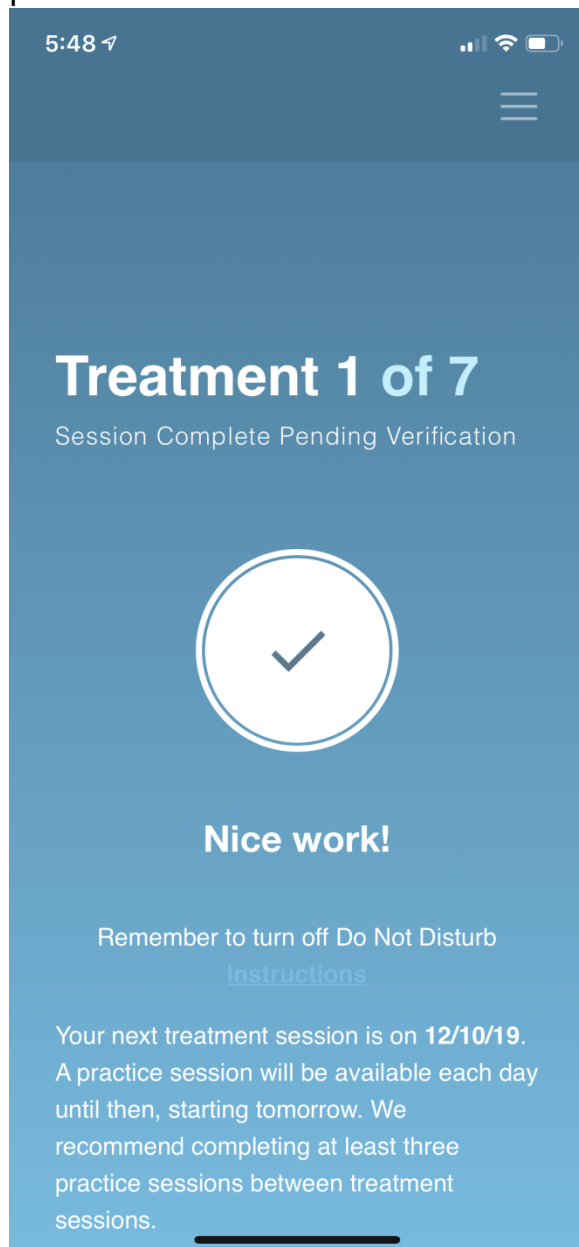
If you were interrupted during treatment, you should select “Begin Again” to restart it. If not, Select “Complete Session”



9: Completed Session

Congratulations you just completed a session!

You won't see another session until your next scheduled one. But in the meantime, be sure to take your practice sessions.

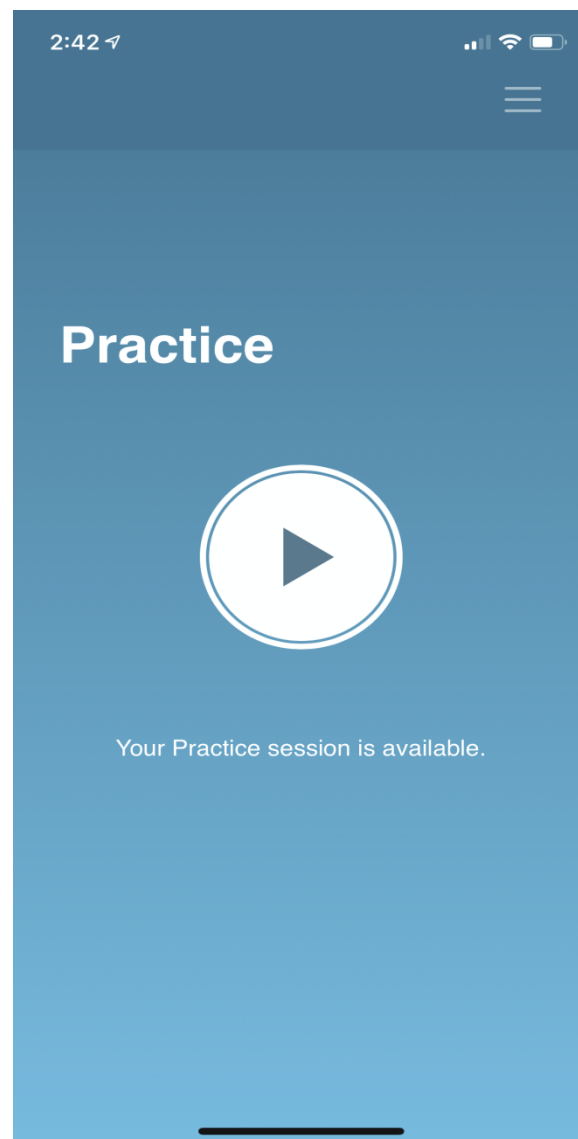


10: Practice Session

Stay tuned up! Practice sessions are a short 15-minute session.

The day after your first treatment session you'll have access to your first practice session.

You should try to do at least three practice sessions between your treatment sessions.



11: Symptoms

Periodically, *Regulora* may request that you describe the severity of your symptoms. This is to help you in your communications with your healthcare provider.



Symptom Severity Scale

To access your treatment session, please answer the following questions about your gut health.

DO YOU CURRENTLY (IN THE PAST 10 DAYS) SUFFER FROM ABDOMINAL (STOMACH) PAIN?

Yes

HOW SEVERE WAS YOUR ABDOMINAL (STOMACH) PAIN IN THE PAST 10 DAYS?

Choose one

Please indicate a number from 0 to 100, with 0 meaning "no pain" and 100 meaning "very severe pain".

PLEASE ENTER THE NUMBER OF DAYS YOU HAD THE ABDOMINAL PAIN IN THE PAST 10 DAYS.

Choose one

For example, if you enter 4 it means that you had pain 4 out of 10 days. If you have pain every day, enter 10.

DO YOU CURRENTLY (IN THE PAST 10 DAYS) SUFFER FROM ABDOMINAL DISTENTION (BLOATING, SWOLLEN OR TIGHT STOMACH)?

Yes

Women: Please ignore distention related to your period when answering this question.

HOW DISSATISFIED ARE YOU WITH YOUR BOWEL FUNCTIONING IN THE PAST 10 DAYS?

Choose one

Please indicate a number from 0 to 100, with 0 meaning "Not dissatisfied" and 100 meaning "very dissatisfied".

HOW MUCH DID ABDOMINAL PAIN OR DISCOMFORT OR ALTERED BOWEL FUNCTIONING AFFECT OR INTERFERE WITH YOUR LIFE IN GENERAL IN THE PAST 10 DAYS?

Choose one

Please indicate a number from 0 to 100, with 0 meaning "Not at all" and 100 meaning "completely".

HOW OFTEN WERE YOUR STOOLS IN THE PAST 10 DAYS HARD OR LUMPY?

Choose one

Please indicate a number from 0 to 100, with 0 meaning "never" and 100 meaning "always".

HOW OFTEN WERE YOUR STOOLS IN THE PAST 10 DAYS MUSHY OR WATERY?

Choose one

Please indicate a number from 0 to 100, with 0 meaning "never" and 100 meaning "always".

Submit

MOBILE DEVICE SECURITY

The design of *Regulora* incorporates industry recommendations and the FDA's guidance for cybersecurity. Maintaining the security of your personal data is important to us at metaMe Health. Please follow the cybersecurity recommendations below:

- Password/PIN protect your mobile device.
- Never share your mobile device or Regulora login information (account or password). metaMe will never request your password; notify us immediately if you receive an email or phone call requesting your *Regulora* login information.
- After several minutes of inactivity, your mobile device should be set to automatically lock.
- Avoid connecting to untrusted and/or unsecure WIFI networks.
- Regularly install the periodic updates to your mobile device operating system to ensure latest malware / antivirus protection.
- "Jail-broken" mobile devices should not be used.
- Notify metaMe if you suspect any type of cybersecurity incident related to *Regulora*.

COMPATIBLE DEVICES AND TROUBLESHOOTING

Compatible Devices

Regulora is compatible with smartphones, tablets, and other mobile devices that are connected to the internet. Specifically:

iOS devices

- Operating System: iOS 12 or later
- Processor: 1.4 GHz minimum
- Memory (RAM): 1 GB minimum
- Examples of minimally compatible models: iPhone 6 or later, iPad Air 2, and iPad Mini 4 or later

Android devices

- Operating System: Android 9 or later
- Processor: 1.8 GHz minimum
- Memory (RAM): 2 GB minimum
- Examples of minimally compatible models: Samsung Galaxy 8, Motorola Moto G7, or later

Network Connection and Speed

- Wi-Fi network or cellular data network
- Minimum 2 Mbps (megabits per second; for example 3G)
- Recommended 5 Mbps or greater (for example 4G/LTE, 5G, or Wi-Fi)

Troubleshooting

Regulora app won't start

- Ensure your mobile device is connected to internet
- Ensure your mobile device meets minimum requirements above

Login / password isn't accepted, or password forgotten

- Ensure your mobile device is connected to internet
- Double check that you are entering credentials correctly
- Reset your password using the link provided on the login page.
- Contact Customer Service

Regulora unexpectedly crashes / freezes

- Follow your mobile device instructions to force a quit of *Regulora*; then restart the app
- Re-install *Regulora* on your mobile device

You may also contact Regulora support at help@regulora.com or 1-888-463-8263.

REGULORA CLINICAL FINDINGS

(For Physicians and Healthcare Professionals)

Indications for Use

Regulora® is a prescription-only digital therapeutic device intended to provide behavioral therapy through gut-directed hypnotherapy for adults 22 years of age and older who have been diagnosed with Irritable Bowel Syndrome (IBS). *Regulora* is indicated as a 3-month treatment for patients with abdominal pain due to IBS and is intended to be used together with other IBS treatments.

Clinical Efficacy

Regulora was evaluated in a multi-site, randomized, controlled, and blinded clinical trial of 362 evaluable subjects¹. Subjects were randomized 1:1 to receive either 12 weeks of *Regulora* digital therapy (n=181) or a digital control (n=181). Assessed at a 4-week off-treatment period following the *Regulora* program, 30.4% of subjects in the *Regulora* group and 27.1% of the subjects in the control group experienced at least a clinically meaningful 30% reduction in abdominal pain intensity scores as measured on a 0–10-point scale. Analysis of this off-treatment period (the primary outcome) did not exhibit statistical separation between the groups, however statistical separation was observed in two analyses of on-treatment periods.

During the final 4 weeks on-treatment, 30.9% of subjects in the GDH (*Regulora*) group and 21.5% of the subjects in the control group experienced at least a clinically meaningful 30% reduction in abdominal pain intensity scores.

Throughout the on-treatment period (weeks 1-12), 29.3% of subjects in the *Regulora* group and 18.8% of the subjects in the control group experienced at least a clinically meaningful 30% reduction in abdominal pain intensity scores.

Abdominal Pain is a primary component of IBS and is the most common symptom prompting clinical consultation². *Regulora* is intended to be used together with other IBS treatments.

Following 12 weeks of treatment, subjects experienced clinically meaningful improvement in IBS symptoms and other measures, although these measures did not show statistically significant separation from control and therefore the associated endpoints were not met. As measured using clinically validated instruments over a 4-week post-treatment period:

- 44.9% experienced at least a 30% improvement in the proportion of stools with normal consistency, based on BSFS (Bristol Stool Form Scale) definitions.
- 50.3% were either a pain or stool responder as defined above.
- 48.2% of participants in the IBS-D subgroup (n=56) experienced at least a 50% reduction in days with loose or watery stools.

- 39.7% of participants in the IBS-C subgroup (n=58) experienced at least 1 increased bowel movement per week.

Additionally, 64.0% reported Adequate Relief and 67.7% of subjects reported overall satisfaction with the Regulora treatment.

Study subjects were able to execute the program in the intended use environment by downloading, installing, and executing Regulora on their mobile device at home. Further, 87.2% of subjects would recommend *Regulora* to someone else with IBS, indicating satisfaction with the Regulora App user experience.



Side Effects

From the EASITx trial of *Regulora*, there were no treatment-related serious adverse events. Non-serious adverse events possibly related to treatment included headache (0.5%, n=1), fatigue (0.5%, n=1), abdominal pain (0.5%, n=1), and constipation (0.5%, n=1).

¹Efficacy and Safety of IBS Digital GDH Treatment (EASITx) - NCT04133519

²Hungin AP, Chang L, Locke GR, Dennis EH, Barghout V. Irritable bowel syndrome in the United States: prevalence, symptom patterns and impact. *Aliment Pharmacol Ther.* 2005 Jun 1;21(11):1365-75. doi: 10.1111/j.1365-2036.2005.02463.x. PMID: 15932367

MEDICAL DEVICE LABEL

Regulora[®]

Model: GDH-1

CAT

60005-97020

LOT

Software 2.0
March 18, 2022



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REF

Part: IFU-001 Ver. 7