Gastrointestinal Symptoms

A brief guide to the PROMIS® Gastrointestinal Symptom Scales:

ADULT
PROMIS Scale v1.0 – Gastrointestinal Belly Pain 5a
PROMIS Scale v1.0 – Gastrointestinal Bowel Incontinence 4a
PROMIS Scale v1.0 – Gastrointestinal Constipation 9a
PROMIS Scale v1.0 – Gastrointestinal Diarrhea 6a
PROMIS Scale v1.0 – Gastrointestinal Disrupted Swallowing 7a
PROMIS Scale v1.0 – Gastrointestinal Gas and Bloating 13a*
PROMIS Scale v1.1 – Gastrointestinal Gas and Bloating 13a
PROMIS Scale v1.0 – Gastrointestinal Nausea and Vomiting 4a
PROMIS Scale v1.0 – Gastrointestinal Reflux 13a
PROMIS Scale v1.1 – Gastrointestinal Reflux 13a

*retired measure

ABOUT GASTROINTESTINAL SYMPTOMS

The PROMIS Gastrointestinal Belly Pain Scale assesses the severity of belly pain in adult (18 years+) populations over the past 7 days. The Gastrointestinal Belly Pain Scale is not disease-specific and is multifaceted, thus is able to measure belly pain as it varies in location, intensity, and quality. The intensity, nature (sharp vs. dull), frequency, bothersomeness, and predictability (e.g. ability to tell in advance when a pain episode would occur) all contribute towards belly pain severity. Involvement of more abdominal regions is related to higher pain severity.

The PROMIS Gastrointestinal Bowel Incontinence Scale includes 4 items that assess the frequency of bowel incontinence, soiling, and gas incontinence (i.e. stool leakage while passing gas) over the past 7 days. The measure is not disease specific and is intended for adult respondents (18+).

The PROMIS Gastrointestinal Constipation Scale assesses the frequency and intensity of incomplete evacuation, rectal pain, straining, and hard stools, as well as the need for manual extraction of stool. This scale also assesses the degree of bother and interference from these symptoms. All items use a 7 day reporting period. The measure is not disease specific and is intended for adult respondents (18+).

The PROMIS Gastrointestinal Diarrhea Scale contains items focused on capturing the frequency, form, bothersomeness, impact, controllability, and predictability of bowel urgency during the past 7 days. Diarrhea refers to loose, watery stools, urgency, and frequent bowel movements. The measure is not disease specific and is intended for adult respondents (18+).

The PROMIS Gastrointestinal Disrupted Swallowing Scale includes 7 items that assess difficulty swallowing solid and soft foods, liquids, and pills as well as throat/chest pain and the sensation of food being stuck in the throat/chest. The PROMIS Gastrointestinal Disrupted Swallowing Scale assesses the frequency of these swallowing-related symptoms during the past 7 days. The measure is not disease specific and is intended for adult respondents (18+).

The PROMIS Gastrointestinal Gas and Bloating Scale assesses the frequency and intensity/severity of bloating (i.e. feeling pressure or fullness), bloating appearance (i.e. belly swollen or larger than usual size), flatulence (i.e. passing gas), and abdominal sounds (i.e. gurgling or rumbling). The scale also assesses the degree of bother and interference with daily activities resulting from bloating and swelling. All items assess these experiences over the past 7 days. The measure is not disease specific and is intended for adult respondents (18+).

The PROMIS Gastrointestinal Nausea and Vomiting Scale includes 4 items that assess the frequency of vomiting, nausea, and poor appetite, as well as the predictability of nausea over the past 7 days. The measure is not disease specific and is intended for adult respondents (18+).

The PROMIS Gastrointestinal Gastroesophageal Reflux Scale assesses symptoms associated with stomach contents leaking backwards from the stomach into the esophagus. The scale assesses the frequency of regurgitation, experience of burning or a lump in the throat, burping, hiccupping, and excessive saliva production in the past 7 days. The scale also assesses the amount of regurgitation experienced as well as the degree of bother from burping or experiencing a lump in the throat, also reported over the past 7 days. The measure is not disease specific and is intended for adult respondents (18+).

INTRODUCTION TO ASSESSMENT OPTIONS

There is one administration option for assessing adult PROMIS Gastrointestinal Symptoms (GI): fixed length scales. No computer adaptive test (CAT) is available. When administering a scale, instruct respondents to following the administration instructions in the scale. Some GI scales include instructions to skip non-relevant items (i.e., questions or statements).

SCORING THE MEASURES

All PROMIS GI measures with the exception of Bowel Incontinence use T-scores, a type of scale score. Measures are scored using item-level calibrations. This means that the most accurate way to score a PROMIS measure is to use the HealthMeasures Scoring Service (https://www.assessmentcenter.net/ac_scoringservice) or a data collection tool that automatically calculates scores (e.g., Assessment Center, REDCap auto-score). This method of scoring uses responses to each item for each participant. We refer to this as "response pattern scoring." Because response pattern scoring is more accurate than the use of raw sum score/scale score look up tables included in this manual, it is preferred. Response pattern scoring is especially useful when there is missing data (i.e., a respondent skipped an item without an instruction to skip), different groups of participants responded to different items, or you have created a new questionnaire using a subset of items from a PROMIS measure.

If scoring with the HealthMeasures Scoring Service or the data collection tool is not possible, you can follow the instructions in this manual. It describes how to obtain T-scores from participants' responses on these scales by evaluating the items with missing data, calculating a summed score, and using a look up table.

PROMIS Gastrointestinal Measures with NO Instructions to Skip Items

Measure Name	T-Score available (calibrated)	Number of screening questions
PROMIS Scale v1.0 – Gastrointestinal Bowel Incontinence 4a	No	0
PROMIS Scale v1.0 – Gastrointestinal Disrupted Swallowing 7a	Yes	0

Bowel Incontinence
The PROMIS Scale v1.0 – Gastrointestinal Bowel Incontinence 4a includes 4 items. All items are to be answered by all respondents. The measure does *not* produce an item-response theory based T-score. Instead, the raw responses should be used in analyses.

Disrupted Swallowing
The PROMIS Scale v1.0 – Gastrointestinal Disrupted Swallowing 7a includes 7 items. All items are to be answered by all respondents. The measure utilizes item-level calibrations to produce a T-score. Some data collection systems will automatically produce a T-score (e.g., REDCap "auto-scored"). You can also utilize the HealthMeasures Scoring Service to transform raw responses into a T-score. If there is no missing data, you can use the table included in this manual. For each respondent, calculate the sum of all response scores (range 7 to 35). Use the Disrupted Swallowing table in the Appendix to find the T-score that corresponds to the summed score. For example, a summed score of 21 equates to a T-score of 65.7 (SE = 2.4).

PROMIS Gastrointestinal Measures with Instructions to Skip Items

Six PROMIS GI scales feature screening questions which instruct participants to skip subsequent items that are not relevant to their experiences. For example, for the item "How often did you have belly pain?" participants are instructed, "If Never, go to #5." The following chart summarizes the number of screening questions by measure.

PROMIS Gastrointestinal Measures with Skip Instructions

Instrument Name	T-Score available (calibrated)	Number of screening questions	Possible number of items that can be skipped correctly	Possible number of items answered by following skip logic
PROMIS Scale v1.0 – Gastrointestinal Belly Pain 5a	Yes	1	0, 3	5, 2
PROMIS Scale v1.0 – Gastrointestinal Constipation 9a	Yes	3	0, 1, 2, 3, 4	9, 8, 7, 6, 5
PROMIS Scale v1.0 – Gastrointestinal Diarrhea 6a	Yes	2	0, 2, 4	6, 4, 2
PROMIS Scale v1.1 – Gastrointestinal Gas and Bloating 13a	Yes	2	0, 3, 6, 9	13, 10, 7, 4
PROMIS Scale v1.0 – Gastrointestinal Nausea and Vomiting 4a	Yes	1	0, 1	4, 3
PROMIS Scale v1.0 – Gastrointestinal Reflux 13a	Yes	3	0, 1, 2, 3, 4, 5	13, 12, 11, 10, 9, 8
PROMIS Scale v1.1 – Gastrointestinal Reflux 13a	Yes	2	0, 3, 6, 9	13, 10, 7, 4

Preferred Scoring Options

These six measures use item-level calibrations to produce T-scores. Some data collection systems will automatically produce a T-score (e.g., REDCap "auto-scored"). If you are collecting data on paper or in a different system, please use the HealthMeasures Scoring Service to transform raw responses to T-scores.

Given the skip patterns in these instruments, we strongly encourage you to score these instruments with one of the above methods. However, if these methods are not an option for your data, you can use the tables in this manuals as an alternative, provided there are no unusual patterns of missing data.

How to Score a Scale Manually When Items are Skipped Correctly

Before scoring these measures, it is important that you inspect the data to ensure that participants have followed the skipping logic. Provided participants have followed the skipping instructions as indicated (e.g., "If Never, go to #5"), please follow these steps to score your data:

1. Count the number of items skipped for each participant.

2. Sum the item scores of all items answered. That is, sum the numerical value assigned to each response of the participant's answer. These values range from 1 to 5 (or 4) for each item. NOTE: the first item in Gas & Bloating is an unscored item (GISX94). Its response options are "A" and "B" and do not contribute to the summed score.

3. Find the correct look-up table in the Appendix. This is the table that matches the number of items a respondent correctly answered. NOTE: some scales will have complex patterns of missing responses. For example, for Gastrointestinal Reflux, a person could correctly skip 0, 1, 2, 3, or 4 of the 9 total items.

4. Find the participant's raw summed score in the correct table and its corresponding T-score value. These T-scores are based on a general population sample, where 50 is an estimate of the general population mean (and 10 is the standard deviation).

How to Score When Participants have NOT Followed the Skipping Instructions Correctly
If participants have not followed the skip logic correctly, it is still possible to assign T-scores to the data, but the circumstances are limited. Please consider these circumstances:

Inconsistency between Screener Answer and the Subsequent Answers

As noted above, some of these measures have "screener" questions which allow participants to skip items that are not applicable to them. If there is an inconsistency between the screener response and the subsequent items, the screener response should be interpreted as correct. For example, a participant answers "Never" to "How often did you have belly pain?" and, ignoring the skip rule, answers "a little bit" to "How much did belly pain interfere with your day-to-day activities?" In that case, we recommend excluding the answers in the to-be-skipped items as if they were in fact skipped and only summing the screener question when computing the summed score.

Items that are Incorrectly Skipped

If a participant skips an item(s) that may not be skipped according to the skip instructions, we do not recommend scoring these scales using this manual. Instead, we recommend using the HealthMeasures Scoring Service as it is able to handle missing data appropriately. The skip instructions permit substantial amounts of missing data; with additional or unusual patterns of missing data, the final scale scores are problematic.

Meaning of Scores

The PROMIS GI measures use a T-score centered on the U.S. General Population. This means that a score of 50 represents the average of the general population (and that 10 represents the standard deviation).

Important: *A higher PROMIS T-score represents more of the concept being measured.* For negatively-worded concepts like belly pain, bowel incontinence, constipation, diarrhea, disrupted swallowing, gas & bloating, nausea & vomiting, and reflux, a T-score of 60 is one SD worse than average. By comparison, a gastrointestinal symptom T-score of 40 is one SD better than average.

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Statistical Characteristics

There are four key features of the score for GI measures:

- **Reliability**: The degree to which a measure is free of error. It can be estimated by the internal consistency of the responses to the measure, or by correlating total scores on the measure from two time points when there has been no true change in what is being measured (for z-scores, reliability = $1 - SE^2$).
- **Precision**: The consistency of the estimated score (reciprocal of error variance).
- **Information:** The precision of an item or multiple items at different levels of the underlying continuum (for z-scores, information = $1/SE^2$).
- **Standard Error (SE):** The possible range of the actual final score based upon the scaled T-score. For example, with a T-score of 52 and a SE of 2, the 95% confidence interval around the actual final score ranges from 48.1 to 55.9 (T-score $\pm$ (1.96*SE) = 52 $\pm$ 3.9 = 48.1 to 55.9).

The final score is represented by the T-score, a standardized score with a mean of 50 and a standard deviation (SD) of 10. More information is available at HealthMeasures.net.

Preview of Sample Item

Figure 1 is an excerpt from the paper version of the seven-item Gastrointestinal Disrupted Swallowing Scale. This is the paper version format used for some of the Gastrointestinal Symptoms instruments.

	In the past 7 days…	Never	Rarely	Sometimes	Often	Always
GISX31	How often did food get stuck in your <u>chest</u> when you were eating?....................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
GISX32	How often did food get stuck in your <u>throat</u> when you were eating?...................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Figure 1

Version Differences

The PROMIS Gastrointestinal measures available at www.HealthMeasures.net, Assessment Center, the Assessment Center API (used by REDCap, Epic, and other 3rd party vendors) have slight modifications from the versions included in the Corrigendum in *The American Journal of Gastroenterology*. (Spiegel BMR, Hays RD, Bolus R, Melmed GY, Chang L, Whitman C, Khanna PP, Paz SH, Hays T, Reise S, Khanna D (2015). Corrigendum: Development of the NIH Patient-Reported Outcomes Measurement Information System (PROMIS) gastrointestinal symptom scales. *American Journal of Gastroenterology, 110*: 608. Doi:10.1038/ajg.2015.62).

The AJG scoring tables are different from the HealthMeasures' versions in this manual. AJG published a single summed score to scale score look-up table for each scale. Using a single look-up table provides a convenient best estimate for summed scores. But respondents who

answered 5, 6, 7, 8, and 9 items (as might happen with the Constipation measure) could have the same summed score, but by means of different patterns. Consequently, this HealthMeasures manual includes additional tables for when a respondent correctly skipped items. This approach, while less convenient, provides an improvement in the T-score estimate relative to a single table.

The *AJG* summed score to scale score look-up tables start with sums of 0. As the lowest response score for any item is 1, it is not possible to produce a sum of 0. The HealthMeasures versions of scoring tables match the summed response scores possible from the print-ready versions of measures.

Belly Pain: The *AJG* version of the Belly Pain measure includes one item that is an image of a belly with lines mapping out 9 areas. The image is interactive; the respondent is to select all of the areas of the belly that have pain. The number of areas is summed. Item-level parameters are then assigned to that summed value. The item thus contributes to the final T-score for Belly Pain. The version of Belly Pain available from HealthMeasures does not include this item. This item was removed due to the significant technology demands for implementing this idiosyncratic administration and scoring protocol in multiple data collection platforms, browsers, and apps. Additionally, APIs used to access to HealthMeasures in 3rd party data collection systems cannot control the respondent's user interface. This means that the largest distributors of PROMIS measures – REDCap and Epic – will not support this item. Consequently, the item was removed. The remaining 5 items were recalibrated and made available as a 5-item scale.

Bowel Incontinence: The *AJG* version of Bowel Incontinence included an IRT-based T-score. The HealthMeasures version of the measure does not produce an IRT-based T-score. While the model fit was good, one of the items showed an extremely high discrimination parameter; for this reason, we are currently promoting simple summed scores for this measure. Further study to refine IRT-based scoring is welcome.

Gas and Bloating: In the *AJG* version of Gas and Bloating, a screener item (GISX94) has response scores of "1" and "2". These responses are not intended to be included in the summed score. To reduce the likelihood that users would add these responses in the summed score, they were modified to "A" and "B" in the versions distributed by HealthMeasures.net.

The HealthMeasures version of Gas and Bloating also has item 12 (GISX105) use "If Never, you are finished" and skip item 13. This skip logic is not included in the *AJG* version of the measure.

PROMIS Scale v1.1 – Gastrointestinal Gas and Bloating 13a replaced PROMIS Scale v1.0 – Gastrointestinal Gas and Bloating 13a. The v1.0 measure included an incorrect instruction with item GISX105 to skip the following question (GISX109) if a respondent selected "Never." This error was removed in v1.1. Use the scoring tables (v1.0 or v1.1) that correspond to the version of the measure used.

Reflux: The *AJG* version of Reflux includes one static image of the chest with a red area for the item "Look at the picture below. In the past 7 days, how often did you feel burning in the red area shown in the picture – that is, behind the breastbone?" The HealthMeasures version of Reflux includes slightly different wording to support interfaces in which the image is not below,

but next to the item, or not shown at all. We needed to make this modification, APIs used to access to HealthMeasures in 3rd party data collection systems (e.g., REDCap) do not support images. The instruction before the item reads: "Think of the area behind your breastbone (the area extending from the base of your throat to mid-chest." The item reads "In the past 7 days, how often did you feel burning in the red area shown in the picture – that is, behind the breastbone?" The image is included in the print-ready version of the scale at HealthMeasures.net and in Assessment Center. The image is excluded from systems using the Assessment Center API (e.g., REDCap). The version of the scale without the image is named "PROMIS Scale v1.0 – GI Reflux no image 13a". If possible, use a version of the measure with the image. All versions use the same scoring.

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FREQUENTLY ASKED QUESTIONS (FAQs)

Q: I am interested in learning more. Where can I do that?

Review the HealthMeasures website at www.healthmeasures.net.

Q: Do I need to register with PROMIS to use these instruments?

No.

Q: Are these instruments available in other languages?

These instruments are currently not available in other languages. The HealthMeasures website (www.healthmeasures.net) has current information on PROMIS translations.

Q: Can I make my own short form?

Yes, custom short forms can be made by selecting any items from a scale. This can be scored using the HealthMeasures Scoring Service.

Q: How do I handle multiple responses when administering a short form on paper?

Guidelines on how to deal with multiple responses have been established. Resolution depends on the responses noted by the research participant.

- If two or more responses are marked by the respondent, and they are next to one another, then a data entry specialist will be responsible for randomly selecting one of them to be entered and will write down on the form which answer was selected. Note: To randomly select one of two responses, the data entry specialist will flip a coin (heads - higher number will be entered; tails – lower number will be entered).To randomly select one of three (or more) responses, a table of random numbers should be used with a statistician's assistance.
- If two or more responses are marked, and they are NOT all next to one another, the response will be considered missing.

Q: What is the minimum change on a PROMIS instrument that represents a clinically meaningful difference?

To learn more about research on the meaning of a change in scores, we suggest conducting a literature review to identify the most current information. The HealthMeasures website http://www.healthmeasures.net/score-and-interpret/interpret-scores/promis) has additional information on interpreting scores.

APPENDIX

PROMIS Scale v1.0 – Gastrointestinal Belly Pain 5a (1 of 2 tables)

Participant answered all items		
Summed Score	**T-score**	**SE**
6	39.3	4.4
7	43.3	3.8
8	47.0	3.3
9	49.9	3.1
10	52.3	3.0
11	54.4	3.0
12	56.5	3.0
13	58.4	2.9
14	60.2	2.8
15	61.9	2.8
16	63.5	2.8
17	65.0	2.8
18	66.6	2.8
19	68.1	2.7
20	69.6	2.7
21	71.1	2.8
22	72.8	2.8
23	74.7	3.0
24	76.8	3.1
25	80.0	3.7

PROMIS Scale v1.0 – Gastrointestinal Belly Pain 5a (2 of 2 tables)

Participant skipped 3 items, answered 2 items		
Summed Score	**T-score**	**SE**
2	33.9	6.2
3	42.2	5.9
4	48.3	5.6
5	54.0	5.5
6	58.6	5.3

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PROMIS Scale v1.0 – Gastrointestinal Bowel Incontinence 4a

This is a 4-item measure that is scored by summing the items (score range is 4 to 20). The scores are not based on item response theory models; therefore, there is no T-score.

PROMIS Scale v1.0 – Gastrointestinal Constipation 9a (1 of 5 tables)

Participant answered all items		
Summed Score	T-score	SE
12	44.4	3.4
13	46.1	3.1
14	47.7	2.8
15	49.0	2.6
16	50.2	2.5
17	51.3	2.4
18	52.3	2.4
19	53.3	2.3
20	54.3	2.3
21	55.2	2.3
22	56.2	2.3
23	57.1	2.3
24	57.9	2.2
25	58.8	2.2
26	59.6	2.2
27	60.4	2.2
28	61.3	2.2
29	62.1	2.2
30	62.9	2.2
31	63.7	2.3
32	64.6	2.3
33	65.4	2.3
34	66.3	2.4
35	67.2	2.5
36	68.2	2.6
37	69.2	2.7
38	70.3	2.8
39	71.4	3
40	72.6	3.2
41	73.9	3.4
42	75.3	3.6
43	76.9	3.9
44	78.7	4.1
45	80.8	4.2

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PROMIS

PROMIS Scale v1.0 – Gastrointestinal Constipation 9a (2 of 5 tables)

Participant skipped 1 item, answered 8 items		
Summed Score	**T-score**	**SE**
10	42.7	4.0
11	45.0	3.5
12	46.8	3.2
13	48.5	2.9
14	49.9	2.7
15	51.2	2.6
16	52.3	2.6
17	53.4	2.5
18	54.5	2.5
19	55.5	2.5
20	56.6	2.5
21	57.6	2.4
22	58.5	2.4
23	59.5	2.4
24	60.4	2.4
25	61.3	2.4
26	62.3	2.4
27	63.2	2.4
28	64.2	2.4
29	65.1	2.5
30	66.1	2.6
31	67.1	2.7
32	68.2	2.8
33	69.4	2.9
34	70.6	3.1
35	71.8	3.3
36	73.2	3.5
37	74.6	3.7
38	76.2	4.0
39	78.1	4.2
40	80.3	4.4

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PROMIS Scale v1.0 – Gastrointestinal Constipation 9a (3 of 5 tables)

Participant skipped 2 items, answered 7 items		
Summed Score	**T-score**	**SE**
8	40.6	4.5
9	43.2	4.2
10	45.6	3.7
11	47.6	3.5
12	49.4	3.2
13	50.9	3.0
14	52.3	2.9
15	53.6	2.9
16	54.9	2.9
17	56.1	2.8
18	57.3	2.8
19	58.4	2.8
20	59.6	2.8
21	60.6	2.8
22	61.8	2.8
23	62.9	2.8
24	63.9	2.8
25	65.1	2.9
26	66.3	2.9
27	67.5	3.1
28	68.7	3.2
29	70.0	3.3
30	71.4	3.5
31	72.9	3.7
32	74.4	3.8
33	76.0	4.1
34	77.9	4.3
35	80.2	4.5

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PROMIS Scale v1.0 – Gastrointestinal Constipation 9a (4 of 5 tables)

Participant skipped 3 items, answered 6 items		
Summed Score	**T-score**	**SE**
7	41.1	4.7
8	43.9	4.5
9	46.5	4.1
10	48.6	3.8
11	50.5	3.6
12	52.2	3.5
13	53.8	3.4
14	55.3	3.4
15	56.8	3.4
16	58.2	3.4
17	59.5	3.4
18	60.9	3.4
19	62.3	3.4
20	63.6	3.4
21	64.9	3.4
22	66.3	3.5
23	67.8	3.6
24	69.2	3.7
25	70.7	3.8
26	72.4	3.9
27	74.0	4.1
28	75.8	4.2
29	77.8	4.4
30	80.1	4.5

Participant skipped 4 items, answered 5 items		
Summed Score	T-score	SE
5	36.6	6.0
6	41.8	4.9
7	44.9	4.7
8	47.6	4.3
9	49.9	4.1
10	52.1	4.0
11	54.0	3.9
12	55.8	3.8
13	57.5	3.8
14	59.2	3.8
15	60.8	3.8
16	62.4	3.9
17	64.1	3.9
18	65.7	4.0
19	67.4	4.0
20	69.1	4.1
21	70.9	4.2
22	72.7	4.3
23	74.7	4.5
24	76.8	4.6
25	79.3	4.8

PROMIS Scale v1.0 – Gastrointestinal Diarrhea 6a (1 of 3 tables)

Participant answered all items		
Summed Score	**T-score**	**SE**
8	45.9	4.12
9	48.2	3.69
10	50.1	3.33
11	51.9	2.65
12	53.3	2.35
13	54.5	2.25
14	55.6	2.20
15	56.7	2.16
16	57.8	2.10
17	58.8	2.05
18	59.8	2.00
19	60.7	1.98
20	61.6	1.98
21	62.5	1.98
22	63.5	2.01
23	64.4	2.07
24	65.5	2.18
25	66.6	2.34
26	67.9	2.63
27	69.2	2.90
28	70.8	3.22
29	72.3	3.50
30	75.2	4.32

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PROMIS

PROMIS Scale v1.0 – Gastrointestinal Diarrhea 6a (2 of 3 tables)

Participant skipped 2 items, answered 4 items		
Summed Score	T-score	SE
5	44.1	4.9
6	47.2	4.6
7	50.0	4.3
8	52.2	4.0
9	54.3	3.5
10	56.1	3.2
11	57.7	3.1
12	59.4	3.0
13	61.0	2.9
14	62.5	3.0
15	64.0	3.0
16	65.7	3.2

PROMIS Scale v1.0 – Gastrointestinal Diarrhea 6a (3 of 3 tables)

Participant skipped 4 items, answered 2 items		
Summed Score	T-score	SE
2	39.9	7.1

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PROMIS Scale v1.0 – Gastrointestinal Disrupted Swallowing 7a

Participant answered all items		
Summed Score	**T-score**	**SE**
7	40.3	6.5
8	46.0	5.0
9	49.0	4.5
10	51.6	3.8
11	53.5	3.5
12	55.3	2.9
13	56.7	2.7
14	58.0	2.6
15	59.2	2.5
16	60.4	2.5
17	61.5	2.4
18	62.6	2.4
19	63.6	2.4
20	64.6	2.4
21	65.7	2.4
22	66.7	2.4
23	67.7	2.4
24	68.8	2.4
25	69.8	2.4
26	70.8	2.4
27	71.9	2.4
28	73.0	2.4
29	74.1	2.5
30	75.3	2.5
31	76.6	2.6
32	78.0	2.8
33	79.6	3.0
34	81.4	3.2
35	84.1	3.8

Patient-Reported Outcomes Measurement Information System
Dynamic Tools to Measure Health Outcomes From the Patient Perspective

PROMIS

PROMIS Scale versions 1.0 and v1.1 – Gastrointestinal Gas and Bloating 13a (1 of 8 tables)

Participant answered all items					
Summed Score	**T-score**	**SE**	**Summed Score**	**T-score**	**SE**
14	41.6	4.9	37	62.2	1.3
15	44.3	4.4	38	62.6	1.3
16	46.6	3.7	39	63.1	1.3
17	48.6	3.0	40	63.6	1.3
18	50.2	2.4	41	64.1	1.3
19	51.3	2.0	42	64.6	1.3
20	52.2	1.8	43	65.1	1.3
21	53.1	1.7	44	65.5	1.3
22	53.8	1.6	45	66.0	1.3
23	54.6	1.5	46	66.5	1.4
24	55.2	1.5	47	67.0	1.4
25	55.9	1.5	48	67.5	1.4
26	56.5	1.4	49	68.1	1.4
27	57.0	1.4	50	68.7	1.5
28	57.6	1.4	51	69.3	1.6
29	58.1	1.4	52	70.0	1.7
30	58.7	1.4	53	70.8	1.8
31	59.2	1.4	54	71.7	2.1
32	59.7	1.4	55	72.7	2.4
33	60.2	1.3	56	73.9	2.7
34	60.7	1.3	57	75.3	3.1
35	61.2	1.3	58	76.9	3.5
36	61.7	1.3	59	79.0	4.0

Patient-Reported Outcomes Measurement Information System
Dynamic Tools to Measure Health Outcomes From the Patient Perspective

PROMIS

PROMIS Scale versions 1.0 and v1.1 – Gastrointestinal Gas and Bloating 13a (2 of 8 tables)

Participant skipped 1 item, answered 12 items					
Summed Score	**T-score**	**SE**	**Summed Score**	**T-score**	**SE**
12	39.7	5.7	32	61.3	1.3
13	44.5	4.4	33	61.7	1.3
14	46.8	3.9	34	62.2	1.3
15	49.4	2.4	35	62.7	1.3
16	50.7	2.0	36	63.2	1.3
17	51.8	1.7	37	63.7	1.3
18	52.7	1.6	38	64.2	1.3
19	53.5	1.5	39	64.7	1.3
20	54.3	1.5	40	65.2	1.3
21	55.0	1.4	41	65.7	1.3
22	55.7	1.4	42	66.2	1.3
23	56.3	1.4	43	66.7	1.3
24	56.9	1.4	44	67.3	1.3
25	57.5	1.4	45	67.8	1.4
26	58.1	1.3	46	68.4	1.4
27	58.6	1.3	47	69.0	1.5
28	59.2	1.3	48	69.7	1.6
29	59.7	1.3	49	70.5	1.7
30	60.2	1.3	50	71.4	1.9
31	60.8	1.3	51	72.5	2.2

Participant skipped 3 items, answered 10 items		
Summed Score	T-score	SE
11	42.1	5.1
12	44.9	4.6
13	47.5	4.0
14	49.6	3.2
15	51.3	2.6
16	52.6	2.2
17	53.7	2.0
18	54.7	1.9
19	55.6	1.8
20	56.4	1.7
21	57.1	1.7
22	57.9	1.6
23	58.6	1.6
24	59.3	1.6
25	60.0	1.6
26	60.7	1.6
27	61.4	1.5
28	62.0	1.5
29	62.7	1.6
30	63.4	1.6
31	64.0	1.6
32	64.7	1.6
33	65.4	1.6
34	66.1	1.6
35	66.8	1.6
36	67.5	1.7
37	68.4	1.8
38	69.3	2.0
39	70.4	2.2
40	71.5	2.5
41	72.8	2.9
42	74.3	3.2
43	76.0	3.7
44	78.1	4.2

Participant skipped 4 items, answered 9 items		
Summed Score	T-score	SE
10	45.3	4.6
11	47.8	4.1
12	50.5	2.5
13	52.0	2.1
14	53.2	1.9
15	54.3	1.8
16	55.3	1.7
17	56.2	1.6
18	57.0	1.6
19	57.8	1.6
20	58.5	1.5
21	59.3	1.5
22	60.0	1.5
23	60.8	1.5
24	61.5	1.5
25	62.1	1.5
26	62.8	1.5
27	63.5	1.5
28	64.2	1.5
29	65.0	1.5
30	65.7	1.5
31	66.4	1.5
32	67.1	1.6
33	67.9	1.6
34	68.9	1.8
35	70.0	2.0
36	71.2	2.3

PROMIS Scale versions 1.0 and v1.1 – Gastrointestinal Gas and Bloating 13a (5 of 8 tables)

Participant skipped 6 items, answered 7 items		
Summed Score	T-score	SE
7	38.3	6.2
8	42.3	5.2
9	45.4	4.8
10	48.2	4.2
11	50.7	3.6
12	52.7	3.1
13	54.3	2.9
14	55.8	2.7
15	57.2	2.6
16	58.5	2.6
17	59.7	2.5
18	60.9	2.5
19	62.1	2.4
20	63.2	2.4
21	64.4	2.4
22	65.5	2.4
23	66.7	2.5
24	68.0	2.6
25	69.5	2.8

PROMIS Scale versions 1.0 and v1.1 – Gastrointestinal Gas and Bloating 13a (6 of 8 tables)

Participant skipped 7 items, answered 6 items		
Summed Score	T-score	SE
5	36.7	7.1
6	40.4	5.9
7	45.9	4.7
8	48.7	4.3
9	51.8	3.0
10	53.7	2.7
11	55.4	2.6
12	56.9	2.5
13	58.4	2.5
14	59.7	2.4
15	61.1	2.4
16	62.3	2.4
17	63.6	2.3

PROMIS Scale versions 1.0 and v1.1 – Gastrointestinal Gas and Bloating 13a (7 of 8 tables)

Participant skipped 9 items, answered 4 items		
Summed Score	T-score	SE
3	34.7	7.4
4	39.1	6.6
5	43.8	5.9
6	47.7	5.7
7	51.3	5.4
8	54.6	5.2
9	57.6	5.0
10	60.4	5.0

PROMIS Scale versions 1.0 and v1.1 – Gastrointestinal Gas and Bloating 13a (8 of 8 tables)

Participant skipped 10 items, answered 3 items		
Summed Score	T-score	SE
2	37.6	7.6

PROMIS Scale v1.0 – Gastrointestinal Nausea and Vomiting 4a (1 of 2 tables)

Participant answered all items		
Summed Score	T-score	SE
5	45.0	6.3
6	49.3	5.8
7	52.9	5.3
8	55.9	4.8
9	58.7	4.0
10	60.9	3.8
11	62.8	3.7
12	64.6	3.6
13	66.4	3.6
14	68.1	3.6
15	69.8	3.6
16	71.6	3.7
17	73.5	3.8
18	75.6	3.9
19	77.9	4.1
20	80.1	4.1

PROMIS Scale v1.0 – Gastrointestinal Nausea and Vomiting 4a (2 of 2 tables)

Participant skipped 1 item, answered 3 items		
Summed Score	T-score	SE
3	40.6	7.3
4	45.6	6.6
5	50.4	6.3
6	54.2	5.9
7	57.5	5.5
8	60.7	4.9
9	63.5	4.6
10	65.9	4.6
11	68.2	4.6

PROMIS Scale v1.0 – Gastrointestinal Reflux 13a (1 of 6 tables)

Participant answered all items					
Summed Score	T-score	SE	Summed Score	T-score	SE
16	38.7	5.1	41	65.1	2.8
17	40.8	4.7	42	65.9	2.8
18	42.7	4.4	43	66.6	2.8
19	44.4	4.1	44	67.3	2.8
20	46.0	3.9	45	68.1	2.8
21	47.4	3.7	46	68.8	2.8
22	48.7	3.5	47	69.6	2.8
23	49.9	3.4	48	70.3	2.8
24	51.1	3.2	49	71.1	2.8
25	52.1	3.1	50	71.9	2.8
26	53.1	3.0	51	72.7	2.8
27	54.1	3.0	52	73.5	2.9
28	55.0	2.9	53	74.3	2.9
29	55.8	2.9	54	75.2	3.0
30	56.7	2.9	55	76.1	3.1
31	57.5	2.8	56	77.0	3.1
32	58.3	2.8	57	78.0	3.2
33	59.1	2.8	58	79.1	3.3
34	59.9	2.8	59	80.1	3.4
35	60.7	2.8	60	81.2	3.4
36	61.4	2.8	61	82.4	3.4
37	62.2	2.8	62	83.4	3.3
38	62.9	2.8	63	84.4	3.2
39	63.7	2.8	64	85.3	3.0
40	64.4	2.8			

Patient-Reported Outcomes Measurement Information System
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PROMIS

PROMIS Scale v1.0 – Gastrointestinal Reflux 13a (2 of 6 tables)

Participant skipped 1 item, answered 12 items					
Summed Score	**T-score**	**SE**	**Summed Score**	**T-score**	**SE**
14	36.8	5.5	36	63.6	2.9
15	39.2	5.2	37	64.4	2.9
16	41.3	4.8	38	65.1	2.9
17	43.3	4.5	39	65.9	2.9
18	45.0	4.2	40	66.7	2.9
19	46.6	4.0	41	67.5	2.9
20	48.1	3.8	42	68.3	2.9
21	49.5	3.6	43	69.1	2.9
22	50.7	3.5	44	70.0	2.9
23	51.9	3.3	45	70.8	2.9
24	53.0	3.2	46	71.7	2.9
25	54.0	3.1	47	72.5	3.0
26	55.0	3.1	48	73.4	3.0
27	55.9	3.0	49	74.3	3.1
28	56.8	3.0	50	75.2	3.2
29	57.7	3.0	51	76.2	3.2
30	58.6	3.0	52	77.2	3.3
31	59.4	2.9	53	78.3	3.4
32	60.3	2.9	54	79.5	3.5
33	61.1	2.9	55	80.6	3.5
34	61.9	2.9	56	81.8	3.5
35	62.8	2.9			

Patient-Reported Outcomes Measurement Information System
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PROMIS Scale v1.0 – Gastrointestinal Reflux 13a (3 of 6 tables)

Summed Score	T-score	SE	Summed Score	T-score	SE
Participant skipped 2 items, answered 11 items					
12	34.5	5.9	30	60.7	3.0
13	37.3	5.6	31	61.6	3.0
14	39.6	5.2	32	62.5	3.0
15	41.8	4.9	33	63.4	3.0
16	43.8	4.5	34	64.2	3.0
17	45.6	4.3	35	65.1	3.0
18	47.3	4.0	36	66.0	3.0
19	48.8	3.8	37	66.8	3.0
20	50.2	3.6	38	67.7	3.0
21	51.5	3.5	39	68.6	3.0
22	52.8	3.3	40	69.5	3.0
23	53.9	3.2	41	70.4	3.0
24	55.0	3.2	42	71.3	3.0
25	56.0	3.1	43	72.3	3.1
26	57.0	3.1	44	73.2	3.1
27	57.9	3.1	45	74.2	3.2
28	58.9	3.0	46	75.3	3.3
29	59.8	3.0	47	76.4	3.3

PROMIS Scale v1.0 – Gastrointestinal Reflux 13a (4 of 6 tables)

Participant skipped 3 items, answered 10 items					
Summed Score	T-score	SE	Summed Score	T-score	SE
12	38.5	5.6	29	62.3	3.1
13	40.9	5.3	30	63.2	3.1
14	43.2	4.9	31	64.2	3.1
15	45.2	4.5	32	65.1	3.1
16	47.1	4.2	33	66.0	3.1
17	48.7	4.0	34	66.9	3.1
18	50.3	3.8	35	67.9	3.1
19	51.7	3.6	36	68.8	3.1
20	53.0	3.5	37	69.8	3.1
21	54.2	3.4	38	70.8	3.1
22	55.3	3.3	39	71.8	3.2
23	56.4	3.3	40	72.8	3.2
24	57.4	3.2	41	73.9	3.3
25	58.4	3.2	42	75.0	3.4
26	59.4	3.2	43	76.2	3.5
27	60.4	3.1	44	77.4	3.6
28	61.4	3.1	45	78.7	3.7

Participant skipped 4 items, answered 9 items		
Summed Score	**T-score**	**SE**
10	36.5	6.1
11	39.1	5.7
12	41.5	5.4
13	43.9	5.0
14	46.0	4.6
15	47.9	4.4
16	49.7	4.1
17	51.3	3.9
18	52.8	3.7
19	54.1	3.6
20	55.3	3.5
21	56.5	3.4
22	57.7	3.4
23	58.8	3.4
24	59.9	3.3
25	60.9	3.3
26	62.0	3.3
27	63.0	3.3
28	64.1	3.3
29	65.1	3.3
30	66.1	3.3
31	67.1	3.3
32	68.2	3.3
33	69.3	3.3
34	70.4	3.3
35	71.5	3.4
36	72.6	3.4
37	73.8	3.5

PROMIS Scale v1.0 – Gastrointestinal Reflux 13a (6 of 6 tables)

Participant skipped 5 items, answered 8 items		
Summed Score	**T-score**	**SE**
8	33.8	6.7
9	37.1	6.2
10	39.8	5.8
11	42.2	5.5
12	44.6	5.1
13	46.9	4.7
14	48.9	4.4
15	50.8	4.2
16	52.4	3.9
17	53.9	3.8
18	55.4	3.6
19	56.7	3.6
20	58.0	3.5
21	59.2	3.5
22	60.4	3.4
23	61.6	3.4
24	62.7	3.4
25	63.9	3.4
26	65.1	3.4
27	66.2	3.4
28	67.4	3.4