APRON

AE - Adverse Event Report

Purpose: To document an adverse event that threatens the integrity of the APRON trial or well-being of a study participant that includes, but not limited to:

(1) events that impact the patient's treatment or participation in APRON
(2) adverse events that may or may not be related to study drug
(3) other events that clinical center staff feel should be reported
(4) when a follow-up report is needed for a previously completed AE form

As defined by Title 21 Code of Federal Regulations Part 312.32 *IND Safety Reporting*:
Adverse event means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, "reasonable possibility" means there is evidence to suggest a causal relationship between the drug and the adverse event. Suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any adverse event caused by a drug.

Serious adverse event or serious suspected adverse reaction. An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Other medical events may be considered serious when, based upon appropriate medical judgement, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Life-threatening adverse event or *life-threatening suspected adverse reaction.* An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the investigator or sponsor, its occurrence places the patient or subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

When: All visits after randomization. Use visit code if reporting an event discovered during a regular follow-up visit. Use visit code n if event is discovered between study visits. Adverse events that are serious, unexpected and have evidence of being caused by APRON study drug should also be recorded on the Serious Adverse Event/IND Safety Report (SR) form.

Completed by: Study Physician and Clinical Coordinator.

Instructions: Complete and key this form for every visit. The category (item 17), short name (item 18) and the severity grade (item 19) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v3.0 (CTCAE). The CTCAE document is available at www.gpcrc.us. Click on Studies and then APRON. Fax the DCC (Fax 410-955-0932; Attention: Milana Isaacson) a copy of this form if severity grade is 3 or higher within 2 working days for further review by Dr. Linda Lee, the GPCRC Safety Officer. For more information, see APRON protocol section 6 and SOP I section 6.26.

Follow-up report: A follow-up report should be filed (use this form) when the adverse event is resolved or if there has been a significant change in the patient's condition or in the physician's judgment about the event since the previous report was filed.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of report:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____
if report not associated with a visit, fill in "n"

6. Form & revision: a e 1

7. Study: APRON 4

B. Visit interval identification

8. Since the last visit, has the patient had a reportable event:

(Yes 1) (No 2)

32. ____

9. Is this a regularly scheduled visit:

(Yes 1) (No 2)

11. ____

10. Most recently completed visit prior to adverse event

a. Date: ____ ____–____ ____ ____–____ ____
day mon year

b. Visit code: ____ ____

11. Since the last visit, has the patient had ER visits or hospitalizations:

(Yes 1) (No 2)

12. ____

If Yes, specify reason and list dates:

_____

_____

If none for items 11a or 11b, enter "00".

a. Number of hospitalizations: ____ ____
hospitalizations

b. Number of Emergency Room visits:

____ ____
visits

12. Since the last visit, has the patient had any health problems not already reported:

(Yes 1) (No 2)

If Yes, specify health problem and list dates:

_____

_____

C. Event description

13. Is this the first report or a followup report for this adverse event:

First report (1)
Followup report (2)

14. Date event started:

____ ____–____ ____ ____–____ ____
day mon year

15. Nature of event *(check all that apply)*

a. Drug dispensing mixup: (1)
b. Study procedure related event: (1)
c. Severe allergic reaction: (1)
d. Drug interactions: (1)
e. Worsening of a co-morbid illness: (1)
f. Pregnancy *(patient):* (*1)
g. Other *(specify):* (1)

_____

_____

**APRON study drug will be discontinued if a patient becomes pregnant. Contact the GPCRC Data Coordinating Center to unmask the study drug.*

16. Describe event:

_____

_____

_____

_____

_____

_____

For items 17, 18, and 19, please refer to CTCAE v3.0 available at www.gpcrc.us; click on Studies and then APRON.

17. CTCAE category *(check all that apply)*

a. Auditory/ear: (1)
b. Allergy/immunology: (1)
c. Ocular/visual: (1)
d. Hepatobiliary/pancreas: (1)
e. Infection: (1)
f. Cardiac general: (1)
g. Cardiac arrhythmia: (1)
h. Dermatology/skin: (1)
i. Endocrine: (1)
j. Gastrointestinal: (1)
k. Lymphatics: (1)
l. Musculoskeletal/soft tissue: (1)
m. Neurology: (1)
n. Pulmonary/upper respiratory: (1)
o. Renal/genitourinary: (1)
p. Sexual/reproductive function: (1)
q. Blood/bone marrow: (1)
r. Coagulation: (1)
s. Constitutional symptoms: (1)
t. Hemorrhage/bleeding: (1)
u. Metabolic/laboratory: (1)
v. Pain: (1)
w. Secondary malignancy: (1)
x. Surgery/intraoperative injury: (1)
y. Syndromes: (1)
z. Vascular: (1)
aa. Other *(specify):* (1)

_____
specify other body system

18. CTCAE short name for event:

_____

_____

19. Severity grade:

Grade 1 - Mild (1)
Grade 2 - Moderate (2)
Grade 3 - Severe (3)
Grade 4 - Life threatening or disabling (4)
Grade 5 - Death (*5)

**Complete and key Death Report (DR) form.*

20. Randomization in APRON

a. Has patient been randomized in APRON:

Yes (1) No (2)

28. ___

b. Date randomized in APRON:

____ ____–____ ____ ____–____ ____
day mon year

21. Is the patient currently receiving the APRON study drug:

Yes (1) No (2)

22. Patient's history of treatment with APRON study drug

a. How long has patient been on study drug:

_____

b. Have there been any treatment interruptions or restarts:

Yes (1) No (2)

Include stop/restart dates and reasons:

_____

_____

_____

23. Is there evidence to suggest a causal relationship between the APRON study drug and the adverse event:

Definitely yes (1)
Probably yes (2)
Possibly yes (3)
Probably no (4)
Definitely no (5)

24. Is this a serious adverse event:

Yes (1) No (2)

25.

If Yes, then select all the reasons that apply:

a. Required inpatient hospitalization or prolonged existing hospitalization: (1)

b. Persistent or significant incapacity or substantial disruption of ability to conduct normal life functions: (1)

c. Jeopardized patient and required medical or surgical intervention to prevent a serious event: (1)

d. Congenital anomaly or birth defect: (1)

e. Death: (1)

f. Life threatening: (1)

25. Is this an unexpected adverse event:

Yes (1) No (2)

27.

26. Reason the adverse event was unexpected:

Not listed in the aprepitant investigator's brochure (1)

Listed in the aprepitant investigator's brochure, but not at the specificity or severity that has been observed (2)

Listed in the aprepitant investigator's brochure as anticipated from the pharmacological properties of the study drug, but is not specifically mentioned as occurring with previous experience of aprepitant (3)

27. Did you select "Yes" for items 23 (definitely, probably, or possibly), 24, and 25:

Yes (*1) No (2)

**If Yes, please also complete a Serious Adverse Event/IND Safety Report (SR) form and follow instructions.*

28. Current status of adverse event *(check only one):*

Resolved (1)

Active (2)

30.

Unknown (3)

30.

29. Date adverse event resolved:

____ ____–____ ____ ____–____ ____
day mon year

30. What action was taken:

31. Other comments on event:

D. Administrative information

32. Clinical Coordinator PIN: ____ ____ ____

33. Clinical Coordinator signature:

34. Study Physician PIN: ____ ____ ____

35. Study Physician signature:

36. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

Key this form and fax the DCC (Attention: Milana Isaacson) a copy of this form in 2 days if severity grade is 3 or higher. We are asking for copies of these reports on serious adverse events so that we assure appropriate and timely NIDDK review. The serious adverse event reports will be reviewed by Dr. Linda Lee, the Safety Officer.

APRON

BD - Beck Depression Inventory

Purpose: To collect data on the psychosocial aspects of gastroparesis in the APRON trial.
When: Screening visit s and follow-up visit f4.
Administered by: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed questionnaire.
Respondent: Patient.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to each of pages 2-9. The patient should meet with the Clinical Coordinator, be trained in completion of the questionnaire, and then should complete pages 2-9. Page 1 should be reattached to pages 2-9 and the Clinical Coordinator should review the completed questionnaire for missing responses, complete sections B and C and resolve any problems before the patient leaves the clinical center.
Follow-up: At the follow-up visit, special attention should be paid to statements 16 (changes in sleeping pattern) and 18 (changes in appetite) , where there are seven answer options (see SOP I). If the patient indicates a different answer for either of these as compared to when they last completed the form, the presence of an increase or decrease in either of these statements could be of clinical significance, please follow your clinical center's guidelines for patient care.
Scoring: If the patient has made more than one choice for an item, use the highest scoring item. In statements 16 and 18, where there are seven answer options (0, 1a, 1b, 2a, 2b, 3a, 3b), a and b options are given the same weight. Only items on page 1 are keyed to the database.

A. Center, visit, and patient identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Visit date:

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____

6. Form & revision: b d 1

7. Study: APRON 4

B. Scoring information

(To be filled out by clinical center staff after survey is completed.)

8. Sum of all 21 statements: _____ _____
(0-63)

9. Is the sum greater than 28: Yes (*1) No (2)

10. Did the patient respond with a 2 or a 3 in statement 2: Yes (*1) No (2)

11. Did the patient respond with a 2 or a 3 in statement 9: Yes (*1) No (2)

** If "Yes" is checked for items 9, or 10, or 11, this suggests that the patient may be severely depressed; please follow your clinical center's guidelines for patient care.*

C. Administrative information

12. Clinical Coordinator PIN: _____ _____ _____

13. Clinical Coordinator signature:

_____

14. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Beck Depression Inventory - II

Date: _____

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out **one statement** in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

Circle One

1. Sadness

I do not feel sad 0

I feel sad much of the time 1

I am sad all the time 2

I am so sad or unhappy that I can't stand it 3

2. Pessimism

I am not discouraged about my future 0

I feel more discouraged about the future than I used to be 1

I do not expect things to work out for me 2

I feel my future is hopeless and will only get worse 3

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Circle One

3. Past Failure

I do not feel like a failure 0

I have failed more than I should have 1

As I look back, I see a lot of failures 2

I feel I am a total failure as a person 3

4. Loss of Pleasure

I get as much pleasure as I ever did from the things I enjoy 0

I don't enjoy things as much as I used to 1

I get very little pleasure from the things I used to enjoy 2

I can't get any pleasure from the things I used to enjoy 3

5. Guilty Feelings

I don't feel particularly guilty 0

I feel guilty over many things I have done or should have done 1

I feel quite guilty most of the time 2

I feel guilty all of the time 3

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Circle One

6. Punishment Feelings

I don't feel I am being punished 0

I feel I may be punished 1

I expect to be punished 2

I feel I am being punished 3

7. Self-Dislike

I feel the same about myself as ever 0

I have lost confidence in myself 1

I am disappointed in myself 2

I dislike myself 3

8. Self-Criticalness

I don't criticize or blame myself more than usual 0

I am more critical of myself than I used to be 1

I criticize myself for all my faults 2

I blame myself for everything bad that happens 3

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Circle One

9. Suicidal Thoughts or Wishes

I don't have any thoughts of killing myself 0

I have thoughts of killing myself, but I would not carry them out 1

I would like to kill myself 2

I would kill myself if I had the chance 3

10. Crying

I don't cry anymore than I used to 0

I cry more than I used to 1

I cry over every little thing 2

I feel like crying, but I can't 3

11. Agitation

I am no more restless or wound up than usual 0

I feel more restless or wound up than usual 1

I am so restless or agitated that it's hard to stay still 2

I am so restless or agitated that I have to keep moving or doing something 3

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Circle One

12. Loss of Interest

I have not lost interest in other people or activities 0

I am less interested in other people or things than before 1

I have lost most of my interest in other people or things 2

It's hard to get interested in anything 3

13. Indecisiveness

I make decisions about as well as ever 0

I find it more difficult to make decisions than usual 1

I have much greater difficulty in making decisions than I used to 2

I have trouble making any decisions 3

14. Worthlessness

I do not feel I am worthless 0

I don't consider myself as worthwhile and useful as I used to 1

I feel more worthless as compared to other people 2

I feel utterly worthless 3

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Circle One

15. Loss of energy

I have as much energy as ever 0

I have less energy than I used to have 1

I don't have enough energy to do very much 2

I don't have enough energy to do anything 3

16. Changes in Sleeping Pattern

I have not experienced any change in my sleeping pattern 0

I sleep somewhat more than usual 1a

I sleep somewhat less than usual 1b

I sleep a lot more than usual 2a

I sleep a lot less than usual 2b

I sleep most of the day 3a

I wake up 1-2 hours early and can't get back to sleep 3b

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Circle One

17. Irritability

I am no more irritable than usual 0

I am more irritable than usual 1

I am much more irritable than usual 2

I am irritable all the time 3

18. Changes in Appetite *(check only one)*:

I have not experienced any change in my appetite 0

My appetite is somewhat less than usual 1a

My appetite is somewhat greater than usual 1b

My appetite is much less than before 2a

My appetite is much greater than usual 2b

I have no appetite at all 3a

I crave food all the time 3b

19. Concentration Difficulty

I can concentrate as well as ever 0

I can't concentrate as well as usual 1

It's hard to keep my mind on anything for very long 2

I find I can't concentrate on anything 3

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Circle One

20. Tiredness or Fatigue

I am no more tired or fatigued than usual 0

I get more tired or fatigued more easily than usual 1

I am too tired or fatigued to do a lot of the things I used to do 2

I am too tired or fatigued to do most of the things I used to do 3

21. Loss of Interest in Sex

I have not noticed any recent change in my interest in sex 0

I am less interested in sex than I used to be 1

I am much less interested in sex now 2

I have lost interest in sex completely 3

APRON

BH - Baseline Medical History

Purpose: To collect baseline history information about the patient.

When: Screening visit s.

Administered by: Clinical Coordinator, reviewed by Study Physician.

Respondent: Patient.

Instructions: The Clinical Coordinator should collect the information by either interview or chart review necessary to complete sections A-D. Use flash cards as instructed. If a C is checked for any item, further review is necessary by the study physician who will determine whether the diagnosis or condition in the **Caution** item renders the patient ineligible for the APRON trial. If a STOP or Elig is checked for any item, the patient is ineligible for the APRON trial unless the item can be resolved within the 28 day allowed screening window between registration and randomization. The BH form can not be keyed to the data system if there are any **Stop** or **Ineligible** items present. The form should be retained in a study file for further evaluation as appropriate.

A. Center, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date *(date this form is initiated):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: s ____

6. Form & revision: b h 1

7. Study: APRON 4

B. Medical history

(C means Caution; condition is exclusionary if study physician agrees with diagnosis)

8. Does the patient report symptoms of gastroparesis or related disorder with presumed gastric origin of at least 6 months duration *(do not have to be contiguous)* with varying degrees of nausea, vomiting, abdominal pain, early satiety, or post-prandial fullness:

(Yes 1) (No 2) C

9. Has the patient ever been diagnosed with or treated for any of the following *(check all that apply; source of information can be interview or chart review)*

a. Diabetes type 1 or 2: (1)

b. Pyloric obstruction: (1) C

c. Intestinal obstruction: (1) C

d. Advanced liver disease *(CPT score of ≥ 10):* (1) C

e. Inflammatory bowel disease: (1)

f. Thyroid disease *(hormonal abnormality):* (1)

g. Peptic ulcer disease: (1)

h. GERD: Gastroesophageal reflux disease: (1)

i. Interstitial cystitis: (1)

j. Bladder dysfunction: (1)

k. Diverticulosis: (1)

l. Endometriosis: (1)

m. Blood clots: (1)

n. Hemophilia *(bleeding disorder):* (1)

o. Systemic lupus erythematosus (SLE) or collagen vascular disease: (1)

p. Rheumatoid arthritis: (1)

q. Fibromyalgia: (1)

r. Scleroderma: (1)

s. Malignancy *(cancer):* (1)

t. Migraine headaches: (1)

u. Hypertension: (1)

v. Coronary artery disease: (1)

w. Cerebrovascular disease: (1)

x. Hyperlipidemia *(high cholesterol, high triglycerides):* (1)

y. Myocardial infarction: (1)

z. Pancreatitis: (1)

aa. Cholelithiasis: (1)

ab. Gall bladder disease including chronic cholecystitis, gall bladder dyskinesia: (1)

ac. Polycystic ovary syndrome: (1)

ad. Myopathy: (1)

ae. Multiple sclerosis: (1)

af. Eating disorders *(anorexia, bulimia):* (1)

ag. Major depression: (1)

ah. Schizophrenia: (1)

ai. Bipolar disorder: (1)

aj. Obsessive compulsive disorder: (1)

ak. Severe anxiety or personality disorder: (1)

al. Dyslexia or learning problems including ADHD (attention deficit hyperactivity disorder): (1)

am. Other diagnosis #1 *(specify):* (1)

_____
specify

an. Other diagnosis #2 *(specify):* (1)

_____
specify

ao. Other diagnosis #3 *(specify):* (1)

_____
specify

ap. None of the above: (1)

C. Medication use

10. Is the patient currently taking or has the patient used any proton pump inhibitors, histamine H2 receptor antagonists or other similar medications in the past month:

Yes (1) No (2)

11.

(If yes, check all that apply):

a. Antacids, *(specify):* (1)

_____
specify

b. Cimetidine (Tagamet): (1)

c. Dexlansoprazole (Dexilant): (1)

d. Esomeprazole (Nexium): (1)

e. Famotidine (Pepcid): (1)

f. Lansoprazole (Prevacid): (1)

g. Nizatidine (Axid): (1)

h. Omeprazole (Prilosec, Zegerid): (1)

i. Pantoprazole (Protonix): (1)

j. Rabeprazole (Aciphex): (1)

k. Ranitidine (Zantac): (1)

l. Other *(specify):* (1)

_____
specify

11. Is the patient currently taking or has the patient used any benzodiazepines/anti-anxiety medications in the past month:

( ) Yes (1) ( ) No (2)

12.

(If yes, check all that apply):

a. Alprazolam (Xanax): ( ) (1)

b. Buspirone (BuSpar): ( ) (1)

c. Chlordiazepoxide (Librax): ( ) (1)

d. Clonazepam (Klonopin): ( ) (1)

e. Diazepam (Valium): ( ) (1)

f. Flurazepam (Dalmane): ( ) (1)

g. Lorazepam (Ativan): ( ) (1)

h. Midazolam (Versed): ( ) (1)

i. Oxazepam (Serax): ( ) (1)

j. Quazepam (Doral): ( ) (1)

k. Quetiapine fumarate (Seroquel): ( ) (1)

l. Temazepam (Restoril): ( ) (1)

m. Triazolam (Halcon): ( ) (1)

n. Other *(specify):* ( ) (1)

_____
specify

12. Has the patient taken cisapride, warfarin, pimozide, terfenadine, or astemizole in the past month:

( ) Yes (*1) ( ) No (2)

STOP

**Patient must be off these medications for 1 week prior to randomization. Use of these medications is not permitted during the APRON trial.*

13. Is the patient currently taking or has the patient used any prokinetic medications in the past month:

( ) Yes (1) ( ) No (2)

14.

(If yes, check all that apply)

a. Azithromycin (Zithromax): ( ) (1)

b. Bethanechol (Duvoid, Urecholine): ( ) (1)

c. Botulinum toxin (Botox): ( ) (1)

d. Clarithromycin (Biaxin): ( ) (1)

e. Domperidone (Motilium): ( ) (1)

f. Erythromycin: ( ) (1)

g. Metoclopramide (Reglan, Metozolv): ( ) (1)

h. Other *(specify):* ( ) (1)

_____
specify

14. Is the patient currently taking or has the patient used any antiemetic medications in the past month:

( ) Yes (1) ( ) No (2)

15.

a. Aprepitant (Emend): ( ) (1)

STOP

b. Dolasetron (Anzemet): ( ) (1)

c. Dronabinol (Marinol): ( ) (1)

d. Granisetron (Kytril, Sancuso): ( ) (1)

e. Meclizine (Antivert): ( ) (1)

f. Ondansetron (Zofran, Zuplenz): ( ) (1)

g. Palonosetron (Aloxi): ( ) (1)

h. Prochlorperazine (Compazine): ( ) (1)

i. Promethazine (Pentazine, Phenergan): ( ) (1)

j. Tetrahydrocannabinol (THC, marijuana): ( ) (1)

k. Trimethobenzamide (Benzacot, Stemetic, Tigan): ( ) (1)

l. Tropisetron (Navoban): ( ) (1)

m. Other *(specify):* ( ) (1)

_____
specify

15. Is the patient currently taking or has the patient used any selective serotonin reuptake inhibitors (SSRIs) in the past month:

Yes (1) No (2) → **16.**

(If yes, check all that apply):

a. Citalopram (Celexa): (1)

b. Escitalopram (Lexapro): (1)

c. Fluoxetine (Prozac): (1)

d. Fluvoxamine (Luvox): (1)

e. Paroxetine (Paxil): (1)

f. Sertraline (Zoloft): (1)

g. Other *(specify):* (1)

_____
specify

16. Has the patient taken any tricyclic antidepressants for refractory symptoms of gastroparesis in the past month:

Yes (1) No (2) → **17.**

a. Amitriptyline (Elavil): (1)

b. Amoxapine (Asendin): (1)

c. Clomipramine (Anafranil): (1)

d. Desipramine (Norpramin): (1)

e. Doxein (Sinequan): (1)

f. Imipramine (Tofranil): (1)

g. Nortriptyline (Pamelor): (1)

h. Trimipramine (Surmontil): (1)

i. Protriptyline (Pliva, Vivactil): (1)

j. Other tricyclic antidepressants *(specify):* (1)

_____
specify

17. Currently or during the past month, has the patient taken narcotic pain medications on a daily basis or more than 3 times per week:

Yes (*1) No (2) → **C** **18.**

a. Buprenorphine (Butrans patch): (1)

b. Butalbital combinations (Fioricet, Esgic-Plus): (1)

c. Codeine combinations (Tylenol #3, #4): (1)

d. Fentanyl (Abstral, Actiq, Fentora): (1)

e. Fentanyl patch (Duragesic patch): (1)

f. Hydrocodone combinations (Lorcet, Lortab): (1)

g. Hydromorphone (Dilaudid): (1)

h. Methadone: (1)

i. Morphine sulfate: (1)

j. Oxycodone combinations (Percocet, Percodan, Oxycontin, Tylox, Vicodin): (1)

k. Pentazocine (Talacen): (1)

l. Propoxyphene combinations (Darvocet, Wygesic): (1)

m. Tapentadol (Nucynta): (1)

n. Tramadol (Ultram, Ultracet): (1)

o. Other narcotic pain medications *(specify):* (1)

_____
specify

Use of narcotics* **more than 3 days per week *is not permitted during the APRON trial.*

18. Is the patient currently taking or has the patient used any of the following medications in the past month:

	Yes	No
	(1)	(2)
19.		

(If yes, check all that apply):

a. Aripiprazole (Abilify): (1)

b. Bupropion (Wellbutrin): (1)

c. Divalproex sodium (Depakote): (1)

d. Duloxetine (Cymbalta): (1)

e. Gabapentin (Neurontin): (1)

f. Haloperidol (Haldol): (1)

g. Lamotrigine (Lamictal): (1)

h. Maprotiline (Ludiomil): (1)

i. Mirtazapine (Remeron): (1)

j. Olanzapine (Zyprexa): (1)

k. Pregabalin (Lyrica): (1)

l. Venlafaxine (Effexor): (1)

m. Ziprasidone (Geodon): (1)

n. Other medication #1 *(specify):* (1)

_____
specify

o. Other medication #2 *(specify):* (1)

_____
specify

p. Other medication #3 *(specify):* (1)

_____
specify

19. Does the patient have a hypersensitivity or allergy to aprepitant:

Yes	No
(1)	(2)
Elig	

D. Clinical Global Patient Impression

20. Patient's rating of relief of symptoms during the past week compared to the way the patient usually feels *(show the patient Flash Card #7 and ask to pick the category that describes his/her relief of symptoms; check only one):*

Very considerably worse (1)

Considerably worse (2)

Somewhat worse (3)

Unchanged (4)

Somewhat better (5)

Considerably better (6)

Completely better (7)

E. Administrative information

21. Study Physician PIN: ____ ____ ____

22. Study Physician signature:

_____

23. Clinical Coordinator PIN: ____ ____ ____

24. Clinical Coordinator signature:

_____

25. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

Flash Card # 7	**Please consider how you felt this past week in regard to your stomach symptoms. Compared to the way you usually feel, how would you rate your relief of symptoms during the past week?**

1	**Very considerably worse**
2	**Considerably worse**
3	**Somewhat worse**
4	**Unchanged**
5	**Somewhat better**
6	**Considerably better**
7	**Completely better**

APRON

DD – Daily Diary (Follow-up visits)

Purpose: To assess daily symptom severity in patients with gastroparesis in the APRON trial.
When: Visits rz and f2.
Administered by: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed questionnaire.
Respondent: Patient will respond to symptom evaluations on a daily basis before bed.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to pages 2-15 before giving the daily diary to the patient for completion. The nausea visual analog scales should be measured from left to right with a metric ruler, to the closest millimeter (0-100mm). Enter the value closest to the patient's vertical line. Page 1 should be attached to each set of reports and the Clinical Coordinator should complete sections B and C. This form allows up to 14 diaries. If more than 14 diaries are completed at a time, complete a second form (using visit code "n") to record more information.

A. Center, patient, and visit identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date of visit :

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____

6. Form & revision: **d d 1**

7. Study: APRON 4

B. Calibration measurements

8. Number of diaries completed:

_____ _____
(00-30)

9. Measure the length of the calibration line below and enter the total length in millimeters: _____ _____ _____
mm

10. Is this a second form for returning additional diaries: Yes (1) No (2)

C. Administrative information

(To be completed by clinical center staff after survey is completed.)

11. Clinical Coordinator

a. PIN: _____ _____ _____

b. Signature: _____

12. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

D. Daily Diary - Day 1

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

13. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
13a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
13b.	Vomiting	0	1	2	3	4
13c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
13d.	Feeling excessively full after meals	0	1	2	3	4
13e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
13f.	Upper abdominal pain (above the navel)	0	1	2	3	4

13g. During the past 24 hours, how many episodes of vomiting did you have: __ __

13h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

13i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
13j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

13k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

13l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 2

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

14. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
14a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
14b.	Vomiting	0	1	2	3	4
14c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
14d.	Feeling excessively full after meals	0	1	2	3	4
14e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
14f.	Upper abdominal pain (above the navel)	0	1	2	3	4

14g. During the past 24 hours, how many episodes of vomiting did you have: __ __

14h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

14i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
14j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

14k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

14l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 3

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

15. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
15a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
15b.	Vomiting	0	1	2	3	4
15c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
15d.	Feeling excessively full after meals	0	1	2	3	4
15e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
15f.	Upper abdominal pain (above the navel)	0	1	2	3	4

15g. During the past 24 hours, how many episodes of vomiting did you have: __ __

15h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

15i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
15j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

15k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

15l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 4

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

16. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
16a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
16b.	Vomiting	0	1	2	3	4
16c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
16d.	Feeling excessively full after meals	0	1	2	3	4
16e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
16f.	Upper abdominal pain (above the navel)	0	1	2	3	4

16g. During the past 24 hours, how many episodes of vomiting did you have: __ __

16h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

16i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
16j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

16k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

16l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 5

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

17. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
17a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
17b.	Vomiting	0	1	2	3	4
17c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
17d.	Feeling excessively full after meals	0	1	2	3	4
17e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
17f.	Upper abdominal pain (above the navel)	0	1	2	3	4

17g. During the past 24 hours, how many episodes of vomiting did you have: __ __

17h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

17i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
17j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

17k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

17l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 6

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

18. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
18a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
18b.	Vomiting	0	1	2	3	4
18c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
18d.	Feeling excessively full after meals	0	1	2	3	4
18e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
18f.	Upper abdominal pain (above the navel)	0	1	2	3	4

18g. During the past 24 hours, how many episodes of vomiting did you have: __ __

18h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

18i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
18j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

18k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

18l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 7

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

19. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
19a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
19b.	Vomiting	0	1	2	3	4
19c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
19d.	Feeling excessively full after meals	0	1	2	3	4
19e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
19f.	Upper abdominal pain (above the navel)	0	1	2	3	4

19g. During the past 24 hours, how many episodes of vomiting did you have: __ __

19h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

19i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
19j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

19k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

19l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 8

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

20. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
20a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
20b.	Vomiting	0	1	2	3	4
20c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
20d.	Feeling excessively full after meals	0	1	2	3	4
20e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
20f.	Upper abdominal pain (above the navel)	0	1	2	3	4

20g. During the past 24 hours, how many episodes of vomiting did you have: __ __

20h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

20i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
20j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

20k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

20l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 9

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

21. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
21a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
21b.	Vomiting	0	1	2	3	4
21c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
21d.	Feeling excessively full after meals	0	1	2	3	4
21e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
21f.	Upper abdominal pain (above the navel)	0	1	2	3	4

21g. During the past 24 hours, how many episodes of vomiting did you have: __ __

21h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

21i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
21j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

21k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

21l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 10

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

22. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
22a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
22b.	Vomiting	0	1	2	3	4
22c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
22d.	Feeling excessively full after meals	0	1	2	3	4
22e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
22f.	Upper abdominal pain (above the navel)	0	1	2	3	4

22g. During the past 24 hours, how many episodes of vomiting did you have: __ __

22h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

22i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
22j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

22k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

22l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 11

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

23. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
23a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
23b.	Vomiting	0	1	2	3	4
23c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
23d.	Feeling excessively full after meals	0	1	2	3	4
23e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
23f.	Upper abdominal pain (above the navel)	0	1	2	3	4

23g. During the past 24 hours, how many episodes of vomiting did you have: __ __

23h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

23i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
23j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

23k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

23l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 12

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

24. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
24a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
24b.	Vomiting	0	1	2	3	4
24c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
24d.	Feeling excessively full after meals	0	1	2	3	4
24e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
24f.	Upper abdominal pain (above the navel)	0	1	2	3	4

24g. During the past 24 hours, how many episodes of vomiting did you have: __ __

24h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

24i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
24j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

24k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

24l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 13

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

25. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
25a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
25b.	Vomiting	0	1	2	3	4
25c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
25d.	Feeling excessively full after meals	0	1	2	3	4
25e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
25f.	Upper abdominal pain (above the navel)	0	1	2	3	4

25g. During the past 24 hours, how many episodes of vomiting did you have: __ __

25h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

25i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
25j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

25k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

25l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 14

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

26. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
26a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
26b.	Vomiting	0	1	2	3	4
26c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
26d.	Feeling excessively full after meals	0	1	2	3	4
26e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
26f.	Upper abdominal pain (above the navel)	0	1	2	3	4

26g. During the past 24 hours, how many episodes of vomiting did you have: __ __

26h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

26i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
26j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

26k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

26l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

APRON

DD – Daily Diary (Follow-up visits)

Purpose: To assess daily symptom severity in patients with gastroparesis in the APRON trial.
When: Visits rz and f2.
Administered by: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed questionnaire.
Respondent: Patient will respond to symptom evaluations on a daily basis before bed.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to pages 2-22 before giving the daily diary to the patient for completion. The nausea visual analog scales should be measured from left to right with a metric ruler, to the closest millimeter (0-100mm). Enter the value closest to the patient's vertical line. Page 1 should be attached to each set of reports and the Clinical Coordinator should complete sections B and C. This form allows up to 21 diaries.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit :

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: ____ ____

6. Form & revision: **d d 2**

7. Study: APRON 4

B. Calibration measurements

8. Number of diaries completed:

____ ____
(00-21)

9. Measure the length of the calibration line below and enter the total length in millimeters: ____ ____ ____
mm

C. Administrative information

(To be completed by clinical center staff after survey is completed.)

10. Clinical Coordinator PIN: ____ ____ ____

11. Clinical Coordinator signature:

_____

12. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

D. Daily Diary - Day 1

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

13. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
13a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
13b.	Vomiting	0	1	2	3	4
13c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
13d.	Feeling excessively full after meals	0	1	2	3	4
13e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
13f.	Upper abdominal pain (above the navel)	0	1	2	3	4

13g. During the past 24 hours, how many episodes of vomiting did you have: __ __

13h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

13i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
13j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

13k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

13l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 2

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

14. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
14a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
14b.	Vomiting	0	1	2	3	4
14c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
14d.	Feeling excessively full after meals	0	1	2	3	4
14e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
14f.	Upper abdominal pain (above the navel)	0	1	2	3	4

14g. During the past 24 hours, how many episodes of vomiting did you have: __ __

14h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

14i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
14j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

14k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

14l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 3

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

15. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
15a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
15b.	Vomiting	0	1	2	3	4
15c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
15d.	Feeling excessively full after meals	0	1	2	3	4
15e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
15f.	Upper abdominal pain (above the navel)	0	1	2	3	4

15g. During the past 24 hours, how many episodes of vomiting did you have: __ __

15h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

15i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
15j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

15k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

15l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 4

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

16. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
16a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
16b.	Vomiting	0	1	2	3	4
16c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
16d.	Feeling excessively full after meals	0	1	2	3	4
16e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
16f.	Upper abdominal pain (above the navel)	0	1	2	3	4

16g. During the past 24 hours, how many episodes of vomiting did you have: __ __

16h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

16i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
16j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

16k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

16l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 5

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

17. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
17a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
17b.	Vomiting	0	1	2	3	4
17c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
17d.	Feeling excessively full after meals	0	1	2	3	4
17e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
17f.	Upper abdominal pain (above the navel)	0	1	2	3	4

17g. During the past 24 hours, how many episodes of vomiting did you have: __ __

17h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

17i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
17j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

17k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

17l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 6

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

18. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
18a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
18b.	Vomiting	0	1	2	3	4
18c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
18d.	Feeling excessively full after meals	0	1	2	3	4
18e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
18f.	Upper abdominal pain (above the navel)	0	1	2	3	4

18g. During the past 24 hours, how many episodes of vomiting did you have: __ __

18h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

18i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
18j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

18k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

18l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 7

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

19. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
19a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
19b.	Vomiting	0	1	2	3	4
19c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
19d.	Feeling excessively full after meals	0	1	2	3	4
19e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
19f.	Upper abdominal pain (above the navel)	0	1	2	3	4

19g. During the past 24 hours, how many episodes of vomiting did you have: __ __

19h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

19i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
19j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

19k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

19l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 8

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

20. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
20a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
20b.	Vomiting	0	1	2	3	4
20c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
20d.	Feeling excessively full after meals	0	1	2	3	4
20e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
20f.	Upper abdominal pain (above the navel)	0	1	2	3	4

20g. During the past 24 hours, how many episodes of vomiting did you have: __ __

20h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

20i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
20j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

20k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

20l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 9

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

21. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
21a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
21b.	Vomiting	0	1	2	3	4
21c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
21d.	Feeling excessively full after meals	0	1	2	3	4
21e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
21f.	Upper abdominal pain (above the navel)	0	1	2	3	4

21g. During the past 24 hours, how many episodes of vomiting did you have: __ __

21h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

21i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
21j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

21k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

21l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 10

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

22. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
22a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
22b.	Vomiting	0	1	2	3	4
22c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
22d.	Feeling excessively full after meals	0	1	2	3	4
22e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
22f.	Upper abdominal pain (above the navel)	0	1	2	3	4

22g. During the past 24 hours, how many episodes of vomiting did you have: __ __

22h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

22i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
22j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

22k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

22l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 11

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

23. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
23a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
23b.	Vomiting	0	1	2	3	4
23c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
23d.	Feeling excessively full after meals	0	1	2	3	4
23e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
23f.	Upper abdominal pain (above the navel)	0	1	2	3	4

23g. During the past 24 hours, how many episodes of vomiting did you have: __ __

23h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

23i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
23j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

23k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

23l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 12

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

24. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
24a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
24b.	Vomiting	0	1	2	3	4
24c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
24d.	Feeling excessively full after meals	0	1	2	3	4
24e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
24f.	Upper abdominal pain (above the navel)	0	1	2	3	4

24g. During the past 24 hours, how many episodes of vomiting did you have: __ __

24h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

24i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
24j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

24k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

24l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 13

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

25. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
25a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
25b.	Vomiting	0	1	2	3	4
25c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
25d.	Feeling excessively full after meals	0	1	2	3	4
25e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
25f.	Upper abdominal pain (above the navel)	0	1	2	3	4

25g. During the past 24 hours, how many episodes of vomiting did you have: __ __

25h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

25i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
25j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

25k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

25l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 14

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

26. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
26a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
26b.	Vomiting	0	1	2	3	4
26c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
26d.	Feeling excessively full after meals	0	1	2	3	4
26e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
26f.	Upper abdominal pain (above the navel)	0	1	2	3	4

26g. During the past 24 hours, how many episodes of vomiting did you have: __ __

26h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

26i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
26j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

26k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

26l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 15

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

27. __ __ __ mm

NONE ——————————————— SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
27a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
27b.	Vomiting	0	1	2	3	4
27c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
27d.	Feeling excessively full after meals	0	1	2	3	4
27e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
27f.	Upper abdominal pain (above the navel)	0	1	2	3	4

27g. During the past 24 hours, how many episodes of vomiting did you have: __ __

27h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

27i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
27j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

27k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

27l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 16

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

28. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
28a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
28b.	Vomiting	0	1	2	3	4
28c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
28d.	Feeling excessively full after meals	0	1	2	3	4
28e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
28f.	Upper abdominal pain (above the navel)	0	1	2	3	4

28g. During the past 24 hours, how many episodes of vomiting did you have: __ __

28h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

28i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
28j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

28k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

28l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 17

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

29. __ __ __ mm

NONE ——————————————— SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
29a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
29b.	Vomiting	0	1	2	3	4
29c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
29d.	Feeling excessively full after meals	0	1	2	3	4
29e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
29f.	Upper abdominal pain (above the navel)	0	1	2	3	4

29g. During the past 24 hours, how many episodes of vomiting did you have: __ __

29h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

29i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
29j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

29k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

29l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 18

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

30. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
30a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
30b.	Vomiting	0	1	2	3	4
30c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
30d.	Feeling excessively full after meals	0	1	2	3	4
30e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
30f.	Upper abdominal pain (above the navel)	0	1	2	3	4

30g. During the past 24 hours, how many episodes of vomiting did you have: __ __

30h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

30i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
30j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

30k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

30l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3)

Date: _____

D. Daily Diary - Day 19

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

31. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
31a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
31b.	Vomiting	0	1	2	3	4
31c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
31d.	Feeling excessively full after meals	0	1	2	3	4
31e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
31f.	Upper abdominal pain (above the navel)	0	1	2	3	4

31g. During the past 24 hours, how many episodes of vomiting did you have: __ __

31h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

31i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
31j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

31k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

31l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 20

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

32. __ __ __ mm

NONE ——————————————————— SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
32a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
32b.	Vomiting	0	1	2	3	4
32c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
32d.	Feeling excessively full after meals	0	1	2	3	4
32e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
32f.	Upper abdominal pain (above the navel)	0	1	2	3	4

32g. During the past 24 hours, how many episodes of vomiting did you have: __ __

32h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

32i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
32j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

32k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

32l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

D. Daily Diary - Day 21

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

33. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
33a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
33b.	Vomiting	0	1	2	3	4
33c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
33d.	Feeling excessively full after meals	0	1	2	3	4
33e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
33f.	Upper abdominal pain (above the navel)	0	1	2	3	4

33g. During the past 24 hours, how many episodes of vomiting did you have: __ __

33h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

33i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
33j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

33k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

33l. Did you take the study drug today:

Yes, during lunch: (1)

Yes, at some other time: (2)

No, not taken: (3) Date: _____

APRON

DS – Daily Diary (Screening visit)

Purpose: To assess daily symptom severity in patients with gastroparesis in the APRON trial.
When: Screening visit s.
Administered by: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed questionnaires.
Respondent: Patient will respond to symptom evaluations on a daily basis before bed for 7 days.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to pages 2-8 before giving the daily diary to the patient for completion. The nausea visual analog scales in items 13, 14, 15, 16, 17, 18, and 19 should be measured from left to right with a metric ruler, to the closest millimeter (0-100 mm). Enter the value closest to the patient's vertical line. Page 1 should be attached to each set of reports and the Clinical Coordinator should complete sections B and C. This form allows up to 7 diaries. If Elig is reached, the patient is NOT eligible and this form should not be keyed.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit :

____ ____ - ____ ____ ____ - ____ ____
day mon year

5. Visit code: ____ s

6. Form & revision: **d s 1**

7. Study: APRON 4

B. Calibration measuerments

8. Number of diaries completed: ____ ____
(00-07)

a. Were 7 daily diaries completed: Yes (1) No (2) Elig

9. Measure the length of the calibration line below and enter the total length in millimeters:

____ ____ ____
mm

C. Administrative information

(To be completed by clinical center staff after survey is completed.)

10. Calculate the mean nausea visual analog scale (VAS) score

a. Subtotal of daily nausea VAS scores (sum of items 13, 14, 15, 16, 17, 18, and 19):

____ ____ ____
mm

b. Mean nausea VAS scores (divide subtotal in item 10a by 7):

____ ____ ____
mm

c. Is the mean nausea VAS score in item 10b greater than or equal to 25mm:

Yes (1) No (2) Elig

11. Clinical Coordinator

a. PIN: ____ ____ ____

b. Signature: _____

12. Date form reviewed:

____ ____ - ____ ____ ____ - ____ ____
day mon year

D. Daily Diary - Day 1

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ s

Instructions: Complete one page of the Daily Diary each evening before bed.

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

13. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
13a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
13b.	Vomiting	0	1	2	3	4
13c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
13d.	Feeling excessively full after meals	0	1	2	3	4
13e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
13f.	Upper abdominal pain (above the navel)	0	1	2	3	4

13g. During the past 24 hours, how many episodes of vomiting did you have: __ __

13h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

13i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
13j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

13k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

Date: _____

D. Daily Diary - Day 2

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ s

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

14. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
14a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
14b.	Vomiting	0	1	2	3	4
14c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
14d.	Feeling excessively full after meals	0	1	2	3	4
14e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
14f.	Upper abdominal pain (above the navel)	0	1	2	3	4

14g. During the past 24 hours, how many episodes of vomiting did you have: __ __

14h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

14i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
14j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

14k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

Date: _____

D. Daily Diary - Day 3

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ s

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

15. __ __ __ mm

NONE ——————————————— SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
15a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
15b.	Vomiting	0	1	2	3	4
15c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
15d.	Feeling excessively full after meals	0	1	2	3	4
15e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
15f.	Upper abdominal pain (above the navel)	0	1	2	3	4

15g. During the past 24 hours, how many episodes of vomiting did you have: __ __

15h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

15i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
15j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

15k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

Date: _____

D. Daily Diary - Day 4

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: ___ ___ ___ ___

Patient code: ___ ___ ___

Visit code: ___ s

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

16. ___ ___ ___ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
16a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
16b.	Vomiting	0	1	2	3	4
16c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
16d.	Feeling excessively full after meals	0	1	2	3	4
16e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
16f.	Upper abdominal pain (above the navel)	0	1	2	3	4

16g. During the past 24 hours, how many episodes of vomiting did you have: ___ ___

16h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: ___ ___

16i. During the past 24 hours, how many hours of nausea did you have: ___ ___

During the past 24 hours		None	Mild	Moderate	Severe	Very Severe
16j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

16k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

Date: _____

D. Daily Diary - Day 5

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ s

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

17. __ __ __ mm

NONE ——————————————— SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
17a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
17b.	Vomiting	0	1	2	3	4
17c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
17d.	Feeling excessively full after meals	0	1	2	3	4
17e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
17f.	Upper abdominal pain (above the navel)	0	1	2	3	4

17g. During the past 24 hours, how many episodes of vomiting did you have: __ __

17h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

17i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
17j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

17k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

Date: _____

D. Daily Diary - Day 6

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ s

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

18. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
18a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
18b.	Vomiting	0	1	2	3	4
18c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
18d.	Feeling excessively full after meals	0	1	2	3	4
18e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
18f.	Upper abdominal pain (above the navel)	0	1	2	3	4

18g. During the past 24 hours, how many episodes of vomiting did you have: __ __

18h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

18i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
18j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

18k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

Date: _____

D. Daily Diary - Day 7

Instructions: Complete one page of the Daily Diary each evening before bed.

Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ s

Daily Nausea Visual Analog Scale

Instructions: Mark your severity of nausea with a vertical line where you believe best describes how you currently feel.

NAUSEA

19. __ __ __ mm

NONE ---------- SEVERE

Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)

Please circle the number that best describes the worst severity of each symptom during the past 24 hours. Please be sure to answer each question.

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
19a.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4
19b.	Vomiting	0	1	2	3	4
19c.	Not able to finish a normal-sized meal (for a healthy person)	0	1	2	3	4
19d.	Feeling excessively full after meals	0	1	2	3	4
19e.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4
19f.	Upper abdominal pain (above the navel)	0	1	2	3	4

19g. During the past 24 hours, how many episodes of vomiting did you have: __ __

19h. During the past 24 hours, how many episodes of retching (heaving as if to vomit, but nothing comes up) did you have: __ __

19i. During the past 24 hours, how many hours of nausea did you have: __ __

During the past 24 hours		**None**	**Mild**	**Moderate**	**Severe**	**Very Severe**
19j.	What was the overall severity of your gastroparesis symptoms today (during the past 24 hours)	0	1	2	3	4

19k. When did you complete this form:

Before bed: (1)

Other, *(specify)*: (2) _____

Date: _____

APRON

EG - Upper Endoscopy Documentation

Purpose: To document the results of the upper gastrointestinal endoscopy (EGD) to determine patient eligibility for the APRON trial.

When: Screening visit **s**. The screening upper gastrointestinal endoscopy procedure must have been performed within 2 years prior to registration into APRON Trial.

Administered by: Study Physician and Clinical Coordinator.

Screening visit instructions: This form should be completed using the available reports of the upper gastrointestinal endoscopy procedure. Upper gastrointestinal and Endoscopy with Ultrasound (EUS) reports may be used if all of the required components of the EGD are available. Attach a copy of the available GI procedure reports as the source document. If a STOP or Elig is checked for any item, the patient is ineligible for the APRON trial unless the item can be resolved within the 28 day screening window. The EG form can not be keyed to the data system if there are any **Stop** or **Ineligible** items present. The form should be retained in a study file for further evaluation as appropriate or in the file for ineligible patients.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form is initiated:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____

6. Form & revision: e g 1

7. Study: APRON 4

B. Upper endoscopy information

8. Date of upper endoscopy:

____ ____–____ ____ ____–____ ____
day mon year

a. Is date of upper endoscopy within 2 years prior to the APRON registration date: Yes ( ) 1 No (*) 2 → STOP

**(If STOP, then do not key form. The upper endoscopy must be scheduled).*

C. Eligibility check

9. Were there any surgical changes, endoscopic or histologic findings observed that in the opinion of the Study Physician would characterize the patient as ineligible for participation in APRON:

Yes (*) 1 No ( ) 2 → Elig

**If Yes, specify:*

_____

_____

_____

D. Administrative information

10. Study Physician PIN: ____ ____ ____

11. Study Physician signature:

_____

12. Clinical Coordinator PIN: ____ ____ ____

13. Clinical Coordinator signature:

_____

14. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

APRON

FH - Follow-up Medical History

Purpose: To collect follow-up medical history information about the patient.
When: Follow-up visits f2, f4, f6.
Administered by: Clinical Coordinator, reviewed by Study Physician.
Respondent: Patient.
Instructions: The Clinical Coordinator should collect the information by either interview or chart review to complete sections A-D. Use flash cards as instructed.

A. Center, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date *(date this form is initiated):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____

6. Form & revision: f h 1

7. Study: APRON 4

B. Medical history

8. Date of last Follow-up Medical History form *(if this is f02, then date of randomization):*

____ ____–____ ____ ____–____ ____
day mon year

9. Since the date in item 8, has the patient been diagnosed with or treated for any of the following *(check all that apply; source of information can be interview or chart review)*

a. Diabetes type 1 or 2: (1)
b. Pyloric obstruction: (1)
c. Intestinal obstruction: (1)
d. Advanced liver disease *(CPT score of ≥ 10):* (1)
e. Inflammatory bowel disease: (1)
f. Thyroid disease *(hormonal abnormality):* (1)
g. Peptic ulcer disease: (1)
h. GERD: Gastroesophageal reflux disease: (1)
i. Interstitial cystitis: (1)
j. Bladder dysfunction: (1)
k. Diverticulosis: (1)
l. Endometriosis: (1)
m. Blood clots: (1)
n. Hemophilia *(bleeding disorder):* (1)
o. Systemic lupus erythematosus (SLE) or collagen vascular disease: (1)
p. Rheumatoid arthritis: (1)
q. Fibromyalgia: (1)
r. Scleroderma: (1)

s. Malignancy *(cancer):* (1)

t. Migraine headaches: (1)

u. Hypertension: (1)

v. Coronary artery disease: (1)

w. Cerebrovascular disease: (1)

x. Hyperlipidemia *(high cholesterol, high triglycerides):* (1)

y. Myocardial infarction: (1)

z. Pancreatitis: (1)

aa. Cholelithiasis: (1)

ab. Gall bladder disease including chronic cholecystitis, gall bladder dyskinesia: (1)

ac. Polycystic ovary syndrome: (1)

ad. Myopathy: (1)

ae. Multiple sclerosis: (1)

af. Eating disorders *(anorexia, bulimia):* (1)

ag. Major depression: (1)

ah. Schizophrenia: (1)

ai. Bipolar disorder: (1)

aj. Obsessive compulsive disorder: (1)

ak. Severe anxiety or personality disorder: (1)

al. Dyslexia or learning problems including ADHD (attention deficit hyperactivity disorder): (1)

am. Other diagnosis #1 *(specify):* (1)

_____
specify

an. Other diagnosis #2 *(specify):* (1)

_____
specify

ao. Other diagnosis #3 *(specify):* (1)

_____
specify

ap. None of the above: (1)

C. Medication use

10. Since the date in item 8, has the patient used any proton pump inhibitors, histamine H2 receptor antagonists or other similar medications:

Yes (1) No (2)

11. ____

(If yes, check all that apply):

a. Antacids, *(specify):* (1)

_____
specify

b. Cimetidine (Tagamet): (1)

c. Dexlansoprazole (Dexilant): (1)

d. Esomeprazole (Nexium): (1)

e. Famotidine (Pepcid): (1)

f. Lansoprazole (Prevacid): (1)

g. Nizatidine (Axid): (1)

h. Omeprazole (Prilosec, Zegerid): (1)

i. Pantoprazole (Protonix): (1)

j. Rabeprazole (Aciphex): (1)

k. Ranitidine (Zantac): (1)

l. Other *(specify):* (1)

_____
specify

11. Since the date in item 8, has the patient used any benzodiazepines/anti-anxiety medications:

Yes (1) No (2) **12.**

(If yes, check all that apply):

a. Alprazolam (Xanax): (1)
b. Buspirone (BuSpar): (1)
c. Chlordiazepoxide (Librax): (1)
d. Clonazepam (Klonopin): (1)
e. Diazepam (Valium): (1)
f. Flurazepam (Dalmane): (1)
g. Lorazepam (Ativan): (1)
h. Midazolam (Versed): (1)
i. Oxazepam (Serax): (1)
j. Quazepam (Doral): (1)
k. Quetiapine fumarate (Seroquel): (1)
l. Temazepam (Restoril): (1)
m. Triazolam (Halcon): (1)
n. Other *(specify):* (1)

_____
specify

12. Since the date in item 8, has the patient taken cisapride, warfarin, pimozide, terfenadine, or astemizole:

Yes (*1) No (2)

**Use of these medications is not permitted during the APRON trial.*

13. Since the date in item 8, has the patient used any prokinetic medications:

Yes (1) No (2) **14.**

(If yes, check all that apply)

a. Azithromycin (Zithromax): (1)
b. Bethanechol (Duvoid, Urecholine): (1)
c. Botulinum toxin (Botox): (1)
d. Clarithromycin (Biaxin): (1)
e. Domperidone (Motilium): (1)
f. Erythromycin: (1)
g. Metoclopramide (Reglan, Metozolv): (1)
h. Other *(specify):* (1)

_____
specify

14. Since the date in item 8, has the patient used any antiemetic medications:

Yes (1) No (2) **15.**

a. Dolasetron (Anzemet): (1)
b. Dronabinol (Marinol): (1)
c. Granisetron (Kytril, Sancuso): (1)
d. Meclizine (Antivert): (1)
e. Ondansetron (Zofran, Zuplenz): (1)
f. Palonosetron (Aloxi): (1)
g. Prochlorperazine (Compazine): (1)
h. Promethazine (Pentazine, Phenergan): (1)
i. Tetrahydrocannabinol (THC, marijuana): (1)
j. Trimethobenzamide (Benzacot, Stemetic, Tigan): (1)
k. Tropisetron (Navoban): (1)
l. Other *(specify):* (1)

_____
specify

15. Since the date in item 8, has the patient used any selective serotonin reuptake inhibitors (SSRIs):

Yes (1) No (2) **16.**

(If yes, check all that apply):

a. Citalopram (Celexa): (1)

b. Escitalopram (Lexapro): (1)

c. Fluoxetine (Prozac): (1)

d. Fluvoxamine (Luvox): (1)

e. Paroxetine (Paxil): (1)

f. Sertraline (Zoloft): (1)

g. Other *(specify):* (1)

_____
specify

16. Since the date in item 8, has the patient taken any tricyclic antidepressants for refractory symptoms of gastroparesis:

Yes (1) No (2) **17.**

a. Amitriptyline (Elavil): (1)

b. Amoxapine (Asendin): (1)

c. Clomipramine (Anafranil): (1)

d. Desipramine (Norpramin): (1)

e. Doxein (Sinequan): (1)

f. Imipramine (Tofranil): (1)

g. Nortriptyline (Pamelor): (1)

h. Trimipramine (Surmontil): (1)

i. Protriptyline (Pliva, Vivactil): (1)

j. Other tricyclic antidepressants *(specify):* (1)

_____
specify

17. Since the date in item 8, has the patient taken narcotic pain medications on a daily basis or more than 3 times per week:

Yes (*1) No (2) **18.**

a. Buprenorphine (Butrans patch): (1)

b. Butalbital combinations (Fioricet, Esgic-Plus): (1)

c. Codeine combinations (Tylenol #3, #4): (1)

d. Fentanyl (Abstral, Actiq, Fentora): (1)

e. Fentanyl patch (Duragesic patch): (1)

f. Hydrocodone combinations (Lorcet, Lortab): (1)

g. Hydromorphone (Dilaudid): (1)

h. Methadone: (1)

i. Morphine sulfate: (1)

j. Oxycodone combinations (Percocet, Percodan, Oxycontin, Tylox, Vicodin): (1)

k. Pentazocine (Talacen): (1)

l. Propoxyphene combinations (Darvocet, Wygesic): (1)

m. Tapentadol (Nucynta): (1)

n. Tramadol (Ultram, Ultracet): (1)

o. Other narcotic pain medications *(specify):* (1)

_____
specify

Use of narcotics* **more than 3 days per week *is not permitted during the APRON trial.*

18. Since the date in item 8, has the patient used any of the following medications:

	Yes	No
	(1)	(2)

19. ____

(If yes, check all that apply):

a. Aripiprazole (Abilify): (1)

b. Bupropion (Wellbutrin): (1)

c. Divalproex sodium (Depakote): (1)

d. Duloxetine (Cymbalta): (1)

e. Gabapentin (Neurontin): (1)

f. Haloperidol (Haldol): (1)

g. Lamotrigine (Lamictal): (1)

h. Maprotiline (Ludiomil): (1)

i. Mirtazapine (Remeron): (1)

j. Olanzapine (Zyprexa): (1)

k. Pregabalin (Lyrica): (1)

l. Venlafaxine (Effexor): (1)

m. Ziprasidone (Geodon): (1)

n. Other medication #1 *(specify):* (1)

_____
specify

o. Other medication #2 *(specify):* (1)

_____
specify

p. Other medication #3 *(specify):* (1)

_____
specify

D. Clinical Global Patient Impression

19. Patient's rating of relief of symptoms during the past week compared to the way the patient usually feels *(show the patient Flash Card #7 and ask to pick the category that describes his/her relief of symptoms; check only one):*

Very considerably worse (1)

Considerably worse (2)

Somewhat worse (3)

Unchanged (4)

Somewhat better (5)

Considerably better (6)

Completely better (7)

E. Administrative information

20. Study Physician PIN: ____ ____ ____

21. Study Physician signature:

_____

22. Clinical Coordinator PIN: ____ ____ ____

23. Clinical Coordinator signature:

_____

24. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

Flash Card # 7	**Please consider how you felt this past week in regard to your stomach symptoms. Compared to the way you usually feel, how would you rate your relief of symptoms during the past week?**

1	**Very considerably worse**
2	**Considerably worse**
3	**Somewhat worse**
4	**Unchanged**
5	**Somewhat better**
6	**Considerably better**
7	**Completely better**

Keyed: ( )

APRON

GD – Assessment of Gastrointestinal Disorders

Purpose: To assess symptom severity in patients with gastroparesis in the APRON trial.
When: Screening visit s and follow-up visits f2 and f4.
Administered by: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed forms.
Respondent: Patient.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to pages 2-4 before giving the questionnaire to the patient for completion. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-4 and the Clinical Coordinator should complete sections B and C. If patient is EMG at this visit, do not key the form in the data system. File this form in file for ineligible APRON patients. The patient may be re-screened at a later visit using a new GD form.

A. Center, patient, and visit identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date of visit *(date patient completed the form)*:

_____ _____ - _____ _____ _____ - _____ _____
day mon year

5. Visit code: _____ _____

6. Form & revision: **g d 1**

7. Study: APRON 4

B. Gastroparesis Cardinal Symptom Index (GCSI)

Scoring *(To be filled out by clinical staff after survey is completed.)*

8. Nausea subscore
Sum of items 15, 16, and 17 from page 2:

_____ _____
(00-15)

9. Fullness/Satiety subscore
Sum of items 18, 19, 20, and 21 from page 2:

_____ _____
(00-20)

10. Bloating subscore
Sum of items 22 and 23 from page 2:

_____ _____
(00-10)

11. Total GCSI score
Sum of subscores in Section B, items 8, 9, and 10:

_____ _____
(00-45)

12. Is this a screening visit and the total GCSI score in item 11 is less than 21:

Yes (*1) No (2)

EMG 5

** The patient is ineligible and cannot be randomized in APRON. This form should not be keyed to the data system but retained by the study site. The patient may be re-screened at a later visit using a new GD form.*

C. Administrative information

(To be completed by clinical center staff after survey is completed.)

13. Clinical Coordinator
a. PIN: _____ _____ _____
b. Signature:

_____

14. Date form reviewed:

_____ _____ - _____ _____ _____ - _____ _____
day mon year

D. Patient Assessment of Upper Gastrointestinal Symptoms

Affix label here

Patient ID: ___ ___ ___ ___

Patient code: ___ ___ ___

Visit code: ___ ___

PAGI - SYM©

Instructions: This questionnaire asks you about the severity of symptoms you may have related to your gastrointestinal problem. There are no right or wrong answers. Please answer each question as accurately as possible.

For each symptom, please *circle the number* that best describes how *severe* the symptom has been during the past 2 weeks. If you have not experienced this symptom, circle 0. If the symptom has been very mild, circle 1. If the symptom has been mild, circle 2. If it has been moderate, circle 3. If it has been severe, circle 4. If it has been very severe, circle 5. Please be sure to answer every question.

(Items 1-14 are reserved for clinical center use.)

Please rate the severity of the following symptoms during the past 2 weeks.

		None	Very Mild	Mild	Moderate	Severe	Very Severe
15.	**Nausea (feeling sick to your stomach as if you were going to vomit or throw up)**	0	1	2	3	4	5
16.	**Retching (heaving as if to vomit, but nothing comes up)**	0	1	2	3	4	5
17.	**Vomiting**	0	1	2	3	4	5
18.	**Stomach fullness**	0	1	2	3	4	5
19.	**Not able to finish a normal-sized meal**	0	1	2	3	4	5
20.	**Feeling excessively full after meals**	0	1	2	3	4	5
21.	**Loss of appetite**	0	1	2	3	4	5
22.	**Bloating (feeling like you need to loosen your clothes)**	0	1	2	3	4	5
23.	**Stomach or belly visibly larger**	0	1	2	3	4	5
24.	**Upper abdominal pain (above the navel)**	0	1	2	3	4	5
25.	**Upper abdominal discomfort (above the navel)**	0	1	2	3	4	5

Affix label here

Patient ID: ___ ___ ___ ___

Patient code: ___ ___ ___

Visit code: ___ ___

Please rate the severity of the following symptoms during the past 2 weeks.

		None	Very Mild	Mild	Moderate	Severe	Very Severe
26.	**Lower abdominal pain (below the navel)**	0	1	2	3	4	5
27.	**Lower abdominal discomfort (below the navel)**	0	1	2	3	4	5
28.	**Heartburn (burning pain rising in your chest or throat) during the day**	0	1	2	3	4	5
29.	**Heartburn (burning pain rising in your chest or throat) when lying down**	0	1	2	3	4	5
30.	**Feeling of discomfort inside your chest during the day**	0	1	2	3	4	5
31.	**Feeling of discomfort inside your chest at night (during sleep time)**	0	1	2	3	4	5
32.	**Regurgitation or reflux (fluid or liquid from your stomach coming up into your throat) during the day**	0	1	2	3	4	5
33.	**Regurgitation or reflux (fluid or liquid from your stomach coming up into your throat) when lying down**	0	1	2	3	4	5
34.	**Bitter, acid or sour taste in your mouth**	0	1	2	3	4	5

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

E. Additional gastrointestinal symptoms

In addition to the previous symptoms, please rate the severity of the following two symptoms:

		None	Very Mild	Mild	Moderate	Severe	Very Severe
35.	**Constipation**	0	1	2	3	4	5
36.	**Diarrhea**	0	1	2	3	4	5

37. Of the symptoms on these three pages, which one is the predominant symptom *(items 15-36)*: __ __ (15-36)

38. Date form completed: _____ _____-_____ _____ _____-_____ _____ day mon year

Keyed: ( )

APRON

GE - Gastric Emptying Scintigraphy Documentation

Purpose: Record results of gastric emptying scintigraphy test to determine eligibility for the APRON trial.

When: Screening visit s. The gastric emptying scintigraphy must have been performed as a 4 hour per protocol test. The baseline scintigraphy must be within 2 years prior to registration.

Administered by: Study Physician and Clinical Coordinator.

Instructions: The Study Physician should complete this form using the report generated by the gastric emptying scintigraphy. If STOP is reached for any item, then STOP filling out form and do not data enter the form. If C is checked for any item, further review is necessary to determine eligibility status. Information not included in the report should be gathered directly from the patient after the test, if possible.

A. Identifying information

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of form:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code
If report not associated with a visit, fill in "n." ____ ____

6. Form & revision: g e 1

7. Study: APRON 4

B. Gastric Emptying Scintigraphy Test

8. Date of gastric emptying scintigraphy:

____ ____–____ ____ ____–____ ____
day mon year

9. Is this date within 2 years prior to APRON registration:

( ) Yes (1) (*) No (2) STOP

**Test must be rescheduled.*

10. Meal given for test:

Egg Beaters with two pieces of bread/toast and 1 oz of jam (1)

Generic low-fat egg whites with two pieces of bread/toast and 1 oz of jam (2)

Other *(specify)* (* 3) C

_____
specify

**Caution: Test may have to be repeated depending on the meal.*

11. Amount of meal and water consumed

a. Meal *(check only one):*

100%	(1)
90%	(2)
75%	(3)
50%	(4)
33%	(5)
25%	(6)
10%	(7)
0%	(8)
Unknown	(9)

b. Water *(check only one):*

100%	(1)
90%	(2)
75%	(3)
50%	(4)
33%	(5)
25%	(6)
10%	(7)
0%	(8)
Unknown	(9)

12. Did the patient vomit the meal at any time during the tests:

None	(1)
Small	(2)
Moderate	(3)
Large	(*4)

**Caution: Test may not be clinically diagnostic if the amount of meal vomited is large.*

C. Scintigraphy results

13. Percent gastric retention
(Analysis is performed using the geometric mean of the anterior and posterior images for each time point which are then corrected for decay. Results expressed as percent remaining in the stomach.)

a. 0 minutes: ____ ____ ____ • ____ ____ %

b. 30 minutes*: ____ ____ ____ • ____ ____ %

c. 1 hour: ____ ____ ____ • ____ ____ %

d. 2 hours: ____ ____ ____ • ____ ____ %

e. 3 hours*: ____ ____ ____ • ____ ____ %

f. 4 hours: ____ ____ ____ • ____ ____ %

**The 30 minute and 3 hour time points are optional, but should be obtained if possible. The 0 minutes, 1, 2, and 4 hour time points are required.*

14. Interpretation of gastric emptying scintigraphy:

_____

_____

_____

15. Comments on the gastric emptying scintigraphy:

_____

_____

_____

_____

D. Results summary

16. Results of gastric emptying scintigraphy

a. Was the patient able to complete gastric emptying scintigraphy test:

Yes (1) No (2) → Elig

b. Did patient have abnormal 2-hour or 4-hour values on the gastric emptying of solids scintigraphy:

Yes (1) No (2)

c. Was 2-hour value greater than 60%:

Yes (1) No (2)

d. Was 4-hour value greater than 10%:

Yes (1) No (2)

E. Data Coordinating Center use

17. Study Physician PIN: ____ ____ ____

18. Study Physician signature:

_____

19. Clinical Coordinator PIN: ____ ____ ____

20. Clinical Coordinator signature:

_____

21. Date reviewed:

____ ____–____ ____ ____–____ ____
day mon year

APRON

GS - Gastrointestinal Symptom Rating Scale (GSRS)

Purpose: To collect data on the symptoms the patient has been experiencing in the APRON trial.
When: Screening visit s and follow-up visit f4.
Administered by: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed form.
Respondent: Patient.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to each of pages 2-7 before giving the questionnaire to the patient for completion. The Clinical Coordinator should review the completed questionnaire for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-7 and the Clinical Coordinator should complete section B.

A. Center, visit, and patient identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Visit date:

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____

6. Form & revision: g s 1

7. Study: APRON 4

B. Administrative information
(To be completed by clinical center staff after questionnaire is completed.)

8. Clinical Coordinator PIN: _____ _____ _____

9. Clinical Coordinator signature:

_____

10. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

DIRECTIONS: This survey contains questions about how you have been feeling and what it has been like DURING THE PAST WEEK. Mark the choice that best applies to you and your situation.

11. Have you been bothered by PAIN OR DISCOMFORT IN YOU UPPER ABDOMEN OR THE PIT OF YOUR STOMACH during the past week:

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

12. Have you been bothered by HEARTBURN during the past week? (By heartburn we mean an unpleasant stinging or burning sensation in the chest.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

Affix label here

Patient ID: ___ ___ ___ ___

Patient code: ___ ___ ___

Visit code: ___ ___

13. Have you been bothered by ACID REFLUX during the past week? (By acid reflux we mean, the sensation of regurgitating small quantities of acid or flow of sour or bitter fluid from the stomach up to the throat.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

14. Have you been bothered by HUNGER PAINS in the stomach during the past week? (This hollow feeling in the stomach is associated with the need to eat between meals.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

15. Have you been bothered by NAUSEA during the past week? (By nausea we mean a feeling of wanting to throw up or vomit.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

16. Have you been bothered by RUMBLING in your stomach during the past week? (Rumbling refers to vibrations or noise in the stomach.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

17. Has your stomach felt BLOATED during the past week? (Feeling bloated refers to swelling often associated with a sensation of gas or air in the stomach.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

18. Have you been bothered by BURPING during the past week? (Burping refers to bringing up air or gas from the stomach via the mouth, often associated with easing a bloated feeling.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

19. Have you been bothered by PASSING GAS OR FLATUS during the past week? (Passing gas or flatus refers to, the need to release air or gas from the bowel often associated with easing a bloated feeling.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

20. Have you been bothered by CONSTIPATION during the past week? (Constipation refers to a reduced ability to empty the bowels.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

21. Have you been bothered by DIARRHEA during the past week? (Diarrhea refers to a too frequent emptying of the bowels.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

22. Have you been bothered by LOOSE STOOLS during the past week? (If your stools (motions) have been alternately hard and loose, this question only refers to the extent you have been bothered by the stools being loose.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

23. Have you been bothered by HARD STOOLS during the past week? (If your stools (motions) have been alternately hard and loose, this question only refers to the extent you have been bothered by the stools being hard.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

24. Have you been bothered by an URGENT NEED TO HAVE A BOWEL MOVEMENT during the past week? (This urgent need to go to the toilet is often associated with a feeling that you are not in full control.):

Circle one

No discomfort at all 1

Minor discomfort 2

Mild discomfort 3

Moderate discomfort 4

Moderately severe discomfort 5

Severe discomfort 6

Very severe discomfort 7

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

25. When going to the toilet during the past week, have you had the SENSATION OF NOT COMPLETELY EMPTYING YOUR BOWELS? (The feeling of incomplete emptying means that you still feel a need to pass more stool despite having exerted yourself.):

Circle one

No discomfort at all	1
Minor discomfort	2
Mild discomfort	3
Moderate discomfort	4
Moderately severe discomfort	5
Severe discomfort	6
Very severe discomfort	7

Thank you. Please return this questionnaire to the coordinator.

APRON

LR - Laboratory Results

Purpose: To record laboratory results for tests done during screening and follow-up in the APRON trial.

When: Required at screening (s) and follow-up visit f4.

Administered by: Study Physician and Clinical Coordinator.

Instructions: Laboratory test results may be obtained from chart review. Complete tests as needed (repeat test if results are not within the required time window). The window for each test is specified next to the date of blood draw. Use a calculator if you need to convert units to match the units specified on this form. Please note that the units 10^3 cells/mL, 1000 cells/mL, and 10^6 cells/L are equivalent. Call the DCC if you have a question about conversion or how to record a value. Staple the laboratory report to the back of this form. If your laboratory reports are reported electronically, print a copy of the results and staple the report to the back of this form. If EMR is reached in item 34 or 35, the patient is NOT eligible and cannot be randomized in the APRON trial. The form should not be keyed to the data system.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit *(date form was initiated):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____

6. Form & revision: l r 1

7. Study: APRON 4

B. Hematology

Required at screening and f4

8. Date of blood draw for complete blood count:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within 90 days of registration or in the time window for the 4 week follow-up visit. Check the patient's APRON visit window schedule.

9. Hemoglobin: ____ ____ • ____ ____
g/dL

10. Hematocrit: ____ ____ • ____ ____
%

11. White blood cell count (WBC):

____ ____ ____ • ____ ____
10^3 cells/ µL or 10^9 cells/L

12. Red blood cell count (RBC):

____ ____ ____ • ____ ____
10^6 cells/ µL (million cells/ µL)

13. Platelet count: ____ ____ ____, ____ ____ ____
cells/ µL

C. Complete metabolic panel

Required at screening and f4

14. Date of blood draw for complete metabolic panel:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within 90 days of registration or in the time window for the 4 week follow-up visit. Check the patient's APRON visit window schedule.

15. Carbon dioxide: ____ ____ • ____ ____
mEq/L

16. Chloride: ____ ____ ____
mEq/L

17. Sodium: ____ ____ ____
mEq/L

18. Potassium: ____ ____ • ____ ____
mEq/L

19. Glucose: ____ ____ ____
mg/dL

20. Calcium: ____ ____ • ____ ____
mg/dL

21. Magnesium: ____ • ____ ____ ____
mg/dL

22. Blood urea nitrogen (BUN): ____ ____
mg/dL

23. Creatinine: ____ ____ • ____ ____
mg/dL

24. Total protein: ____ ____ • ____ ____
g/dL

25. Albumin: ____ ____ • ____ ____
g/dL

26. Alanine aminotransferase (ALT):
____ ____ ____
U/L

27. Upper limit of normal of ALT: ____ ____ ____
U/L

28. Aspartate aminotransferase (AST):
____ ____ ____
U/L

29. Upper limit of normal of AST: ____ ____ ____
U/L

D. Hemoglogin A1c

30. Are HbA1c result required at this visit:

Yes, diabetic visit	(1)
No, not required but result is available	(2)
No, not required at this visit	(3)

33.

** This test is required at screening visit for diabetic patients. Please record any available HbA1c results for non-diabetic patients.*

31. Date of blood draw for HbA1c:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window: within 90 days of registration or in the window for the follow-up visit.

32. HbA1c: ____ ____ • ____ ____
%

E. Eligibility check

Required at screening visit

33. Is this a screening visit s:

Yes (1) No (2)

36.

34. Are all screening laboratory results completed on this form:

Yes (1) No (* 2)

Elig

** If no, the patient is ineligible and cannot be randomized into APRON until all required screening laboratory results are obtained.*

35. Are the patient's ALT and AST results greater than 2x the upper limit of normal (ULN):

Yes (1) No (2)

Elig

** If yes, the patient is ineligible and cannot be randomized into APRON. This form should not be keyed into the data system retained by the study site.*

F. Administrative information

36. Study Physician PIN: ____ ____ ____

37. Study Physician signature:

_____

38. Clinical Coordinator PIN: ____ ____ ____

39. Clinical Coordinator signature:

_____

40. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

APRON

NP – Nausea Profile

Purpose: To obtain the patient's frequency and intensity of symptoms due to nausea.
When: At screening visit s and follow-up visits f2 and f4.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and to review completed form.
Respondent: Patient.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to page 2 before giving the questionnaire to the patient for completion. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to page 2, and the Clinical Coordinator should complete section B.

A. Center, patient, and visit identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date of visit *(date patient completed the form)*:

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____

6. Form & revision: n p 1

7. Study: APRON **4**

B. Administrative information
(To be completed by clinical center staff after questionnaire is completed)

8. Clinical Coordinator

a. PIN: _____ _____ _____

b. Signature:

_____

9. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

NP - Nausea Profile

Affix label here

Patient ID: __ __ __ __

Pt code: __ __ __

Visit code: __ __

(Items 1-9 are reserved for clinic use)

Rate the degree to which each of the following statements describes how you feel when you experience nausea. Please circle the appropriate number for each description on the scale below with 0=not at all and 9=severely.

		0=Not at All									9= Severely
10.	I feel shaky:	0	1	2	3	4	5	6	7	8	9
11.	I feel upset:	0	1	2	3	4	5	6	7	8	9
12.	I feel lightheaded:	0	1	2	3	4	5	6	7	8	9
13.	I feel sick:	0	1	2	3	4	5	6	7	8	9
14.	I feel sweaty:	0	1	2	3	4	5	6	7	8	9
15.	I feel queasy:	0	1	2	3	4	5	6	7	8	9
16.	I feel worried:	0	1	2	3	4	5	6	7	8	9
17.	I feel hopeless:	0	1	2	3	4	5	6	7	8	9
18.	I feel fatigued/tired:	0	1	2	3	4	5	6	7	8	9
19.	I feel panicked:	0	1	2	3	4	5	6	7	8	9
20.	I feel nervous:	0	1	2	3	4	5	6	7	8	9
21.	I feel scared/afraid:	0	1	2	3	4	5	6	7	8	9
22.	I feel ill:	0	1	2	3	4	5	6	7	8	9
23.	I feel awareness/discomfort in my stomach:	0	1	2	3	4	5	6	7	8	9
24.	I feel as if I might vomit:	0	1	2	3	4	5	6	7	8	9
25.	I feel weak:	0	1	2	3	4	5	6	7	8	9
26.	I feel hot/warm:	0	1	2	3	4	5	6	7	8	9

27. Today's date: _____

APRON

PE - Physical Examination

Purpose: Record physical exam findings in the APRON trial.

When: Screening visit s and follow-up visit f4.

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient.

Instructions: Standardized procedures for height, weight, waist and hip measurements are found in APRON SOP I. In brief: Height, weight, waist and hip circumferences should all be measured with the patient standing and wearing light clothing. Shoes should be removed for height and weight measures. Measure the waist around the abdomen horizontally at the midpoint between the highest point of the iliac crest and the lowest part of the costal margin in the mid axillary line. Measure the hips at the fullest part.
Note: ECG is <u>required</u> at screening visit s.

Screening visit instructions: The ECG is required during screening.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date: ____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: ____ ____

6. Form & revision: p e 1

7. Study: APRON 4

B. Vital status

8. Temperature *(oral)*

a. Degrees: ____ ____ ____ • ____

b. Scale:
Fahrenheit (1)
Centigrade (2)

9. Blood pressure

a. Systolic: ____ ____ ____
mmHg

b. Diastolic: ____ ____ ____
mmHg

10. Resting radial pulse: ____ ____ ____
beats/minute

11. Respiratory rate: ____ ____
breaths/minute

C. Measurements

12. Height *(shoes off)*

a. Height: ____ ____ ____ • ____

b. Units:
Inches (1)
Centimeters (2)

13. Weight *(shoes off)*

a. Weight: ____ ____ ____ • ____

b. Units:
Pounds (1)
Kilograms (2)

14. Waist *(standing, at midpoint between highest point of iliac crest and lowest part of costal margin)*

a. Circumference: ____ ____ ____ • ____

b. Units:

Inches (1)

Centimeters (2)

15. Hip circumference *(standing, at fullest part of the hips)*

a. Circumference: ____ ____ ____ • ____

b. Units:

Inches (1)

Centimeters (2)

D. Examination findings

16. Chest and lungs:

Normal (1)

17. ____

Abnormal (2)

_____
specify

17. Heart:

Normal (1)

18. ____

Abnormal (2)

_____
specify

_____
specify

18. Abdomen:

Normal (1)

20. ____

Abnormal (2)

19. Abdomen abnormality *(check all that apply)*

a. Distention: (1)

b. Tympany: (1)

c. Succussion splash: (1)

d. Tenderness: (1)

e. Organomegaly: (1)

f. Other *(specify):* (1)

_____
specify

_____
specify

20. Liver and spleen:

Normal (1)

21. ____

Abnormal (2)

_____
specify

_____
specify

21. Nervous system:

Not performed (0)

22. ____

Normal (1)

22. ____

Abnormal (2)

_____
specify

_____
specify

22. Other abnormalities noted:

Yes (1) No (2)

23. ____

_____
specify other abnormalities

_____
specify other abnormalities

E. Resting Electrocardiogram
(Required at visit s only)

23. Date electrocardiogram obtained:

____ ____–____ ____ ____–____ ____
day mon year

24. Record the QTc interval: ____ ____ ____
milliseconds

F. Administrative information

25. Study Physician PIN: ____ ____ ____

26. Study Physician signature:

_____

27. Clinical Coordinator PIN: ____ ____ ____

28. Clinical Coordinator signature:

_____

29. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

APRON

PI – Brief Pain Inventory (BPI)

Purpose: To assess the severity and impact on daily functions of the patient's pain in the APRON trial.
When: At screening visit s and follow-up visits f2 and f4.
Administered by: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed form.
Respondent: Patient.
Instructions: The Clinical Coordinator should complete section A and attach a pre-printed MACO label to pages 2-4 before giving the questionnaire to the patient for completion. The Clinical Coordinator should review the completed questionnaire for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-4 and the Clinical Coordinator should complete section B.

A. Center, patient, and visit identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date of visit *(date patient completed the form)*:

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____

6. Form & revision: p i 1

7. Study: APRON 4

B. Administrative information
(To be completed by clinical center staff after questionnaire is completed.)

8. Clinical Coordinator

a. PIN: _____ _____ _____

b. Signature:

_____

9. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

Affix label here	
Patient ID:	__ __ __ __
Patient code:	__ __ __
Visit code:	__ __

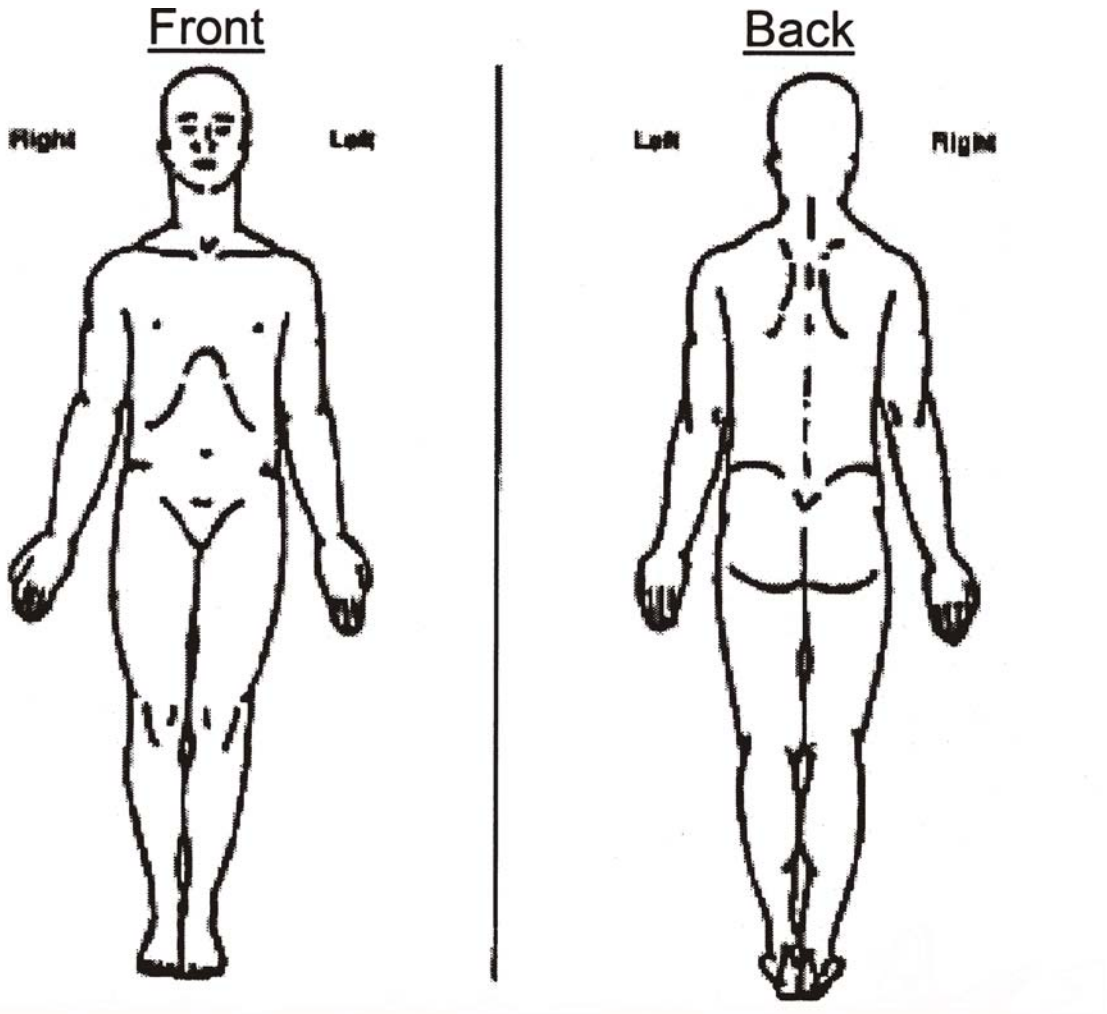
(Items 1-9 are reserved for clinical center use.)

Brief Pain Inventory

10. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

1. Yes 2. No → *If No, skip to question 19*

On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

Please circle the number that best describes your pain with "**0**" being "**No pain**" and "**10**" being "**Pain bad as you can imagine**".

		No pain										Pain as bad as you can imagine
11.	Rate your pain at its **worst** in the last 24 hours.	0	1	2	3	4	5	6	7	8	9	10
12.	Rate your pain at its **least** in the last 24 hours.	0	1	2	3	4	5	6	7	8	9	10
13.	Rate your pain on the **average**.	0	1	2	3	4	5	6	7	8	9	10
14.	Rate how much pain you have **right now**.	0	1	2	3	4	5	6	7	8	9	10

15. Are you receiving treatment or medications for your pain?

Yes (1) No (2) *If No, go to item 18.*

16. What treatment or medications are you receiving for your pain?

_____

_____

_____

17. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the percentage that most shows how much **relief** you have received.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

No Relief — Complete Relief

Affix label here	
Patient ID:	__ __ __ __
Patient code:	__ __ __
Visit code:	__ __

Please circle the number that best describes your pain with "**0**" being "**Does not interfere**" and "**10**" being "**Completely interferes**".

18. Circle the number that describes how, during the past 24 hours, pain has interfered with your:

		Does not interfere									**Completely interferes**
a.	General activity	0	1	2	3	4	5	6	7	8	9	10
b.	Mood	0	1	2	3	4	5	6	7	8	9	10
c.	Walking ability	0	1	2	3	4	5	6	7	8	9	10
d.	Normal work (includes both work outside the home and housework)	0	1	2	3	4	5	6	7	8	9	10
e.	Relations with other people	0	1	2	3	4	5	6	7	8	9	10
f.	Sleep	0	1	2	3	4	5	6	7	8	9	10
g.	Enjoyment of life	0	1	2	3	4	5	6	7	8	9	10

19. Date form completed: _____

APRON

PQ – Patient Health Questionnaire (PHQ-15)

Purpose: To obtain the patient's views of his/her health in the APRON trial.
When: At screening visit s and follow-up visit f4.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and to review completed form.
Respondent: Patient.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to page 2 before giving the questionnaire to the patient for completion. The Clinical Coordinator should review the completed form questionnaire for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to page 2, and the Clinical Coordinator should complete section B.

A. Center, patient, and visit identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date of visit *(date patient completed the form)*:

_____ _____ - _____ _____ _____ - _____ _____
day mon year

5. Visit code: _____ _____

6. Form & revision: p q 1

7. Study: APRON 4

B. Administrative information
(To be completed by clinical center staff after questionnaire is completed)

8. Clinical Coordinator

a. PIN: _____ _____ _____

b. Signature:

_____

9. Date form reviewed:

_____ _____ - _____ _____ _____ - _____ _____
day mon year

Affix label here

Patient ID: __ __ __ __

Pt code: __ __ __

Visit code: __ __

PQ - Patient Health Questionnaire

A 15-Item Somatic Symptom Severity Scale

(Items 1-9 are reserved for clinic use)

10. During the past 4 weeks, how much have you been bothered by any of the following problems?

	Not bothered at all	**Bothered a little**	**Bothered a lot**
a. Stomach pain	(1)	(2)	(3)
b. Back pain	(1)	(2)	(3)
c. Pain in your arms, legs, or joints *(knees, hips, etc)*	(1)	(2)	(3)
d. Menstrual cramps or other problems with your periods *[Women only; record "n" if male]*	(1)	(2)	(3)
e. Headaches	(1)	(2)	(3)
f. Chest pain	(1)	(2)	(3)
g. Dizziness	(1)	(2)	(3)
h. Fainting spells	(1)	(2)	(3)
i. Feeling your heart pound or race	(1)	(2)	(3)
j. Shortness of breath	(1)	(2)	(3)
k. Pain or problems during sexual intercourse	(1)	(2)	(3)
l. Constipation, loose bowels, or diarrhea	(1)	(2)	(3)
m. Nausea, gas, or indigestion	(1)	(2)	(3)
n. Feeling tired or having low energy	(1)	(2)	(3)
o. Trouble sleeping	(1)	(2)	(3)

Thank you. Please return this questionnaire to the Clinical Coordinator.

APRON

QF - SF–36v2 Health Survey

Purpose: To obtain the patient's views of his/her health.
When: Screening visit s and follow-up visit f4.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and to review completed forms.
Respondent: Patient without help from spouse or family.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to each of pages 2-7. The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-7. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-7 and the Clinical Coordinator should complete section B.

A. Center, patient, and visit identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date of visit *(date patient completed the form)*:

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____

6. Form & revision: **q f 1**

7. Study: APRON 4

B. Administrative information

(To be completed by clinical center staff after survey is completed.)

8. Clinical Coordinator
- **a**. PIN: _____ _____ _____
- **b**. Signature: _____

9. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

SF-36v2 Health Survey

Instructions: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

(Items 1-9 are reserved for clinical center use.)

10. In general, would you say your health is:

Circle one

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

11. Compared to one year ago, how would you rate your health in general now?

Circle one

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same as one year ago	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

12. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Activities	Circle one		
	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports:	1	2	3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:	1	2	3
c. Lifting or carrying groceries:	1	2	3
d. Climbing several flights of stairs:	1	2	3
e. Climbing one flight of stairs:	1	2	3
f. Bending, kneeling, or stooping:	1	2	3
g. Walking more than a mile:	1	2	3
h. Walking several hundred yards:	1	2	3
i. Walking one hundred yards:	1	2	3
j. Bathing or dressing yourself:	1	2	3

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

13. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Circle one				
	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Cut down on the amount of time you spent on work or other activities:	1	2	3	4	5
b. Accomplished less than you would like:	1	2	3	4	5
c. Were limited in the kind of work or other activities:	1	2	3	4	5
d. Had difficulty performing the work or other activities (for example, it took extra effort):	1	2	3	4	5

14. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Circle one				
	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Cut down on the amount of time you spent on work or other activities:	1	2	3	4	5
b. Accomplished less than you would like:	1	2	3	4	5
c. Did work of other activities less carefully than usual:	1	2	3	4	5

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

15. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Circle one

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

16. How much bodily pain have you had during the past 4 weeks?

Circle one

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

17. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Circle one

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

18. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks:

	Circle one				
	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Did you feel full of life?	1	2	3	4	5
b. Have you been very nervous?	1	2	3	4	5
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
d. Have you felt calm and peaceful?	1	2	3	4	5
e. Did you have a lot of energy?	1	2	3	4	5
f. Have you felt downhearted and depressed?	1	2	3	4	5
g. Did you feel worn out?	1	2	3	4	5
h. Have you been happy?	1	2	3	4	5
i. Did you feel tired?	1	2	3	4	5

19. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

Circle one

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __

20. How TRUE or FALSE is <u>each</u> of the following statements for you:

	Circle one				
	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

21. Today's date:

_____

Thank you for completing this survey. Please return this questionnaire to the coordinator.

APRON

RD – Study Drug Dispensing and Return

Purpose: To record dispensing and return of APRON study drug.
When: Visits rz and f4. Use visit code "n" if study drug is dispensed or returned at a time other than a regular study visit.
Administered by: Pharmacist or Clinical Coordinator, reviewed by Study Physician.
Instructions: This form documents dispensing of study drug, return of unused study drug, and return of study drug bottle. This form is required at visit rz and follow-up visit f4; it may be used at unscheduled visits as needed (use visit code n). If additional study drug is needed after randomization, contact the DCC.
At the Randomization visit (rz): dispense one bottle of study drug labeled "***Aprepitant (125 mg) or Placebo***" to the patient with instructions to take one capsule each day with lunch. The patient should be instructed to return the study drug bottle at the f4 follow-up visit. Affix the tear-off label from the study drug bottle in item 9 of this form.
Follow-up visit: The clinical coordinator (or pharmacist) should record the bottle number being returned and the number of capsules remaining in the study drug bottle in item 12 of this form.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: ____ ____

6. Form & revision: r d 1

7. Study: APRON 4

B. Study drug dispensing

8. Are drugs being dispensed at this visit:

Yes (1) No (2)

11.

Bottle tear-off label

9.

Affix label here

10. How was the study drug dispensed to the patient *(check only one)* :

In person (1)
Mail (2)
Other *(specify)* (3)

_____
specify

C. Study drug return

11. Was a study drug bottle returned at this visit:

Yes (1) No (2)

13.

	a. Bottle No.	**b. Number of capsules returned**
12.	A ____ ____ ____	____ ____ (00-35)

D. Administrative information

13. Clinical Coordinator PIN: ____ ____ ____

14. Clinical Coordinator signature:

_____

15. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

APRON

RG - Registration

Purpose: To register a patient as a candidate for randomization in the Aprepitant for the Relief of Nausea (APRON) Trial and to assign a patient ID number. This is the first form completed for a patient. The Registration Form must be the first form keyed, before any other forms.

When: At first screening visit **s**.

Administered by: Clinical Coordinator.

Respondent: Patient.

Instructions: Use Flash Cards as instructed. If a STOP condition was checked in Sections B or C, the patient is ineligible and a patient ID should not be assigned and the form should not be keyed. If the patient was previously registered in a GpCRC study, **a new ID number should not be assigned.**

A. Center, patient and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code ____ ____ ____

4. Visit date:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ s

6. Form & revision: r g 1

7. Study: APRON 4

B. Consent

8. Has the patient signed the APRON informed consent statement:

( ) Yes (1) ( ) No (*2) STOP

**Patient must sign the consent prior to continuing with screening.*

9. Has the clinical coordinator or study physician signed the consent form:

( ) Yes (1) ( ) No (2) STOP

C. Information about patient

10. Date of birth:

____ ____–____ ____ ____–____ ____ ____ ____
day month year

Record 4-digit year for the date of birth.

11. Age at last birthday: ____ ____ years

12. Is the patient at least 18 years old:

( ) Yes (1) ( ) No (2) STOP

13. Gender:

Male ( ) (1)
Female ( ) (2)

14. Ethnic category *(show the patient Flash Card #1 and ask to pick the category that describes him/her best; check only one):*

Hispanic or Latino ( ) (1)
Not Hispanic, not Latino ( ) (2)

15. Racial category *(show the patient Flash Card #2 and ask him/her to pick the category or categories that describe him/her best; check all that apply)*

a. American Indian or Alaska Native: ( ) (1)
b. Asian: ( ) (1)
c. Black or African American: ( ) (1)
d. Native Hawaiian or other Pacific Islander: ( ) (1)
e. White: ( ) (1)
f. Patient refused: ( ) (1)

16. Highest educational level achieved by patient *(show the patient Flash Card #3 and ask him/her to pick the category that describes him/her best; check only one):*

Never attended school ( ) (0)
Did not complete high school ( ) (1)
Completed high school ( ) (2)
Some college or post high school education or training ( ) (3)
Bachelor's degree or higher ( ) (4)

17. Which of the following categories best characterizes the patient's occupational history *(show patient Flash Card #4 and ask him/her to pick the category that describes him/her best; check only one):*

Never employed	(0)
Laborer	(1)
Clerical	(2)
Professional	(3)
Homemaker	(4)
Other, *(specify):*	(5)

_____
specify

18. Marital status of the patient *(show patient Flash Card #5 and ask to pick the category that describes him/her best; check only one):*

Single, never married	(1)
Married or living in marriage-like relationship	(2)
Separated, divorced, or annulled	(3)
Widowed	(4)

19. Combined annual income before taxes of all members of patient's household *(show the patient Flash Card #6 and ask to pick the category that describes his/her combined household income best; check only one):*

Less than $15,000	(1)
$15,000 - $29,999	(2)
$30,000 - $49,999	(3)
$50,000 or more	(4)
Refused	(5)

D. Previous registration in a GpCRC study

20. Has the patient previously been registered in any GpCRC study:

Yes (1) No (2)

24.

21. In which GpCRC studies has the patient previously been registered *(check all that apply)*

a. Gastroparesis Registry:	(1)
b. Gastroparesis Registry 2:	(1)
c. NORIG:	(1)
d. GLUMIT-DG:	(1)
e. Other, *(specify):*	(5)

_____
specify

22. ID number previously assigned to patient *(record patient ID in item 2):*

___ ___ ___ ___

23. Code previously assigned to patient *(record patient code in item 3):*

___ ___ ___

25.

E. ID assignment

(If a STOP condition was checked in sections B or C, the patient is ineligible and a patient ID should not be assigned. If the patient was previously registered in a GpCRC study, a new ID number should not be assigned.)

24. Place ID label below and record patient ID in item 2 and patient code in item 3.

CCCC ####, zzz

F. Administrative information

25. Clinical Coordinator PIN: ___ ___ ___

26. Clinical Coordinator signature:

_____

27. Date form reviewed:

___ ___–___ ___ ___–___ ___
day mon year

APRON

SE - State-Trait Anxiety Inventory (STAI)

Purpose: To collect data on the psychosocial aspects of gastroparesis in the APRON trial.
When: Screening visit s and follow-up visit f4.
Administered by: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed form.
Respondent: Patient, without help from spouse or family.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to each of pages 2-4. The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-3. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Pages 1 and 4 should be reattached to pages 2-3 and the Clinical Coordinator should complete section B.
Scoring: The Y-1 and Y-2 scores should be calculated using the scoring key on page 4. Only the items on page 1 are keyed to the APRON trial data system. Staple pages 1-4 together at the close of the assessment.

A. Clinic, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code ____ ____

6. Form & revision: **s** **e** **1**

7. Study: APRON 4

B. Administrative information

(To be completed by clinic center staff after survey is completed.)

8. Scoring

a. Form Y-1 *(sum of weights for items 1-20)*

____ ____
(20-80)

b. Form Y-2 *(sum of weights for items 21-40)*

____ ____
(20-80)

9. Clinical Coordinator

a. PIN: ____ ____ ____

b. Signature:

_____

10. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

Affix label here	
Pt ID:	___ ___ ___ ___
Patient code:	___ ___ ___
Visit code:	___ ___

SELF-EVALUATION QUESTIONNAIRE - STAI Form Y-1

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feeling best.

1. I feel calm	**1**	**2**	**3**	**4**
2. I feel secure	**1**	**2**	**3**	**4**
3. I am tense	**1**	**2**	**3**	**4**
4. I am strained	**1**	**2**	**3**	**4**
5. I feel at ease	**1**	**2**	**3**	**4**
6. I feel upset	**1**	**2**	**3**	**4**
7. I am presently worrying over possible misfortunes	**1**	**2**	**3**	**4**
8. I feel satisfied	**1**	**2**	**3**	**4**
9. I feel frightened	**1**	**2**	**3**	**4**
10. I feel comfortable	**1**	**2**	**3**	**4**
11. I feel self-confident	**1**	**2**	**3**	**4**
12. I feel nervous	**1**	**2**	**3**	**4**
13. I am jittery	**1**	**2**	**3**	**4**
14. I feel indecisive	**1**	**2**	**3**	**4**
15. I am relaxed	**1**	**2**	**3**	**4**
16. I feel content	**1**	**2**	**3**	**4**
17. I am worried	**1**	**2**	**3**	**4**
18. I feel confused	**1**	**2**	**3**	**4**
19. I feel steady	**1**	**2**	**3**	**4**
20. I feel pleasant	**1**	**2**	**3**	**4**

 STAIP-AD Test Form Y

Affix label here

Pt ID: ___ ___ ___ ___

Patient code: ___ ___ ___

Visit code: ___ ___

SELF-EVALUATION QUESTIONNAIRE - STAI Form Y-2

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally* feel.

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
21. I feel pleasant	1	2	3	4
22. I feel nervous and restless	1	2	3	4
23. I feel satisfied with myself	1	2	3	4
24. I wish I could be as happy as others seem to be	1	2	3	4
25. I feel like a failure	1	2	3	4
26. I feel rested	1	2	3	4
27. I am “calm, cool, and collected”	1	2	3	4
28. I feel that difficulties are piling up so that I cannot overcome them	1	2	3	4
29. I worry too much over something that really doesn’t matter	1	2	3	4
30. I am happy	1	2	3	4
31. I have disturbing thoughts	1	2	3	4
32. I lack self-confidence	1	2	3	4
33. I feel secure	1	2	3	4
34. I make decisions easily	1	2	3	4
35. I feel inadequate	1	2	3	4
36. I am content	1	2	3	4
37. Some unimportant thought runs through my mind and bothers me	1	2	3	4
38. I take disappointments so keenly that I can’t put them out of my mind	1	2	3	4
39. I am a steady person	1	2	3	4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

 STAIP-AD Test Form Y

Affix label here

Pt ID: ___ ___ ___ ___

Patient code: ___ ___ ___

Visit code: ___ ___

SELF-EVALUATION QUESTIONNAIRE SCORING KEY (Form Y-1, Y-2)

DIRECTIONS:

To use this stencil, fold this sheet in half and line up with the appropriate test page, either Form Y-1 or Form Y-2. Simply total the scoring **weights** shown on the stencil for each response category. For example, for question #1, if the respondent marked 3, then the **weight** would be 2.

Form Y-1

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
1.	**4**	**3**	**2**	**1**
2.	**4**	**3**	**2**	**1**
3.	**1**	**2**	**3**	**4**
4.	**1**	**2**	**3**	**4**
5.	**4**	**3**	**2**	**1**
6.	**1**	**2**	**3**	**4**
7.	**1**	**2**	**3**	**4**
8.	**4**	**3**	**2**	**1**
9.	**1**	**2**	**3**	**4**
10.	**4**	**3**	**2**	**1**
11.	**4**	**3**	**2**	**1**
12.	**1**	**2**	**3**	**4**
13.	**1**	**2**	**3**	**4**
14.	**1**	**2**	**3**	**4**
15.	**4**	**3**	**2**	**1**
16.	**4**	**3**	**2**	**1**
17.	**1**	**2**	**3**	**4**
18.	**1**	**2**	**3**	**4**
19.	**4**	**3**	**2**	**1**
20.	**4**	**3**	**2**	**1**

Form Y-2

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
21.	**4**	**3**	**2**	**1**
22.	**1**	**2**	**3**	**4**
23.	**4**	**3**	**2**	**1**
24.	**1**	**2**	**3**	**4**
25.	**1**	**2**	**3**	**4**
26.	**4**	**3**	**2**	**1**
27.	**4**	**3**	**2**	**1**
28.	**1**	**2**	**3**	**4**
29.	**1**	**2**	**3**	**4**
30.	**4**	**3**	**2**	**1**
31.	**1**	**2**	**3**	**4**
32.	**1**	**2**	**3**	**4**
33.	**4**	**3**	**2**	**1**
34.	**4**	**3**	**2**	**1**
35.	**1**	**2**	**3**	**4**
36.	**4**	**3**	**2**	**1**
37.	**1**	**2**	**3**	**4**
38.	**1**	**2**	**3**	**4**
39.	**4**	**3**	**2**	**1**
40.	**1**	**2**	**3**	**4**

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 STAID-AD Scoring Key

ST - EGG and Satiety Test

Purpose: To document symptoms and results of the satiety test and electrogastrogram in patients with gastroparesis.
When: Screening visit and follow-up visit f4.
Administered by: Study Physician and Clinical Coordinator.
Respondent: Patient will respond to symptom evaluations on pages 2-7.
Instructions: The Clinical Coordinator should complete section A. The Clinical Coordinator will use pages 2-7 to obtain patient's responses during the test procedure. The visual analog scales on pages 2, 3, 5, 6, and 7 should be measured from left to right with a metric (SI) ruler. Enter the value closest to the patient's vertical line in millimeters (0-100 mm) in items 14, 15, 19, 20, and 21. **Choose only whole minutes. Do not select more than 15 minutes for any EGG recording period.** Using the EGG report, complete section E. The Study Physician and Clinical Coordinator should complete Section F. Attach a copy of the EGG report to this form. Save the raw digital EGG data to a USB flash drive.

A. Clinic, visit, and patient identification

1. Center ID: ___ ___ ___ ___

2. Patient ID: ___ ___ ___ ___

3. Patient code: ___ ___ ___

4. Date of form:

___ ___-___ ___ ___-___ ___
day mon year

5. Visit code: ___ ___
(If report not associated with a visit, fill in "n".)

6. Form & revision: s t 1

7. Study: APRON 4

8. Has the patient fasted since midnight:

Yes (1) No (* 2) → Stop

* *Patient must be fasting; test must be rescheduled.*

9. Is the patient diabetic:

Yes (1) No (2) → 13.

10. Is the patient blood glucose between 60 and 275 mg/dL:

Yes (1) No (* 2) → Stop

* *Test must be rescheduled*

11. Patient's blood glucose level: ___ ___ ___ mg/dL

12. Does the patient have any other symptoms suggesting hypoglycemia or hyperglycemia:

Yes (* 1) No (2) → Stop

* *Test must be rescheduled*

B. Calibration

13. Measure the length of the line below and enter the total length in millimeters: ___ ___ ___ mm

C. Baseline Symptom Scores

14. BASELINE SYMPTOMS - - at the START of the 15 minute baseline EGG recording

__ __ __ __ __ __ __

□□ : □□

(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS __ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER __ __ __ mm

NONE — EXTREME

c. NAUSEA __ __ __ mm

NONE — SEVERE

d. BLOATING __ __ __ mm

NONE — SEVERE

e. ABDOMINAL DISCOMFORT __ __ __ mm

NONE — SEVERE

15. BASELINE SYMPTOMS - - AFTER baseline EGG but just BEFORE satiety test begins

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS __ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER __ __ __ mm

NONE — EXTREME

c. NAUSEA __ __ __ mm

NONE — SEVERE

d. BLOATING __ __ __ mm

NONE — SEVERE

e. ABDOMINAL DISCOMFORT __ __ __ mm

NONE — SEVERE

D. SATIETY TEST VOLUMES

Instructions for patients for the Satiety Test

"You will be given a cup of Ensure to drink every 5 minutes until you feel completely full. You will have up to 5 minutes to drink each cup. You may use all of this time, if needed. After each drink, we will ask about your feeling of fullness on a five-point scale, that is 0, 1, 2, 3, 4, 5 where 0 is not full at all and 5 is completely full. You will stop drinking when you become completely full from the Ensure. This is not a test to see how much you can drink, but simply to have you drink until you feel completely full."

16. Time Satiety Test Started: __ __ : __ __
(24-hour)

Do not key data recorded in this box.

Subject drinks Ensure 150 mL from a cup every 5 minutes until he/she is completely full.

After each cup, record amount ingested, wait 15 seconds, then ask the subject to rate their feeling of fullness on a 0, 1, 2, 3, 4, 5 scale. 0 = not full at all and 5 is completely full. The satiety test ends when the patient is completely full.

__ 1	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____
__ 2	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____
__ 3	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____
__ 4	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____
__ 5	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____
__ 6	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____
__ 7	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____
__ 8	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____
__ 9	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____
__ 10	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____
__ 11	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____
__ 12	Start Time: __ __ : __ __	Completed: _____	mL: _____	Fullness: _____

17. Time Satiety Test Ended: __ __ : __ __ **18.** Total Ensure Volume Consumed: __ __ __ __
(24-hour) *mL*

E. Post prandial Symptom Scores

19. POST PRANDIAL SYMPTOMS -- IMMEDIATELY AFTER finishing Ensure

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS __ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER __ __ __ mm

NONE — EXTREME

c. NAUSEA __ __ __ mm

NONE — SEVERE

d. BLOATING __ __ __ mm

NONE — SEVERE

e. ABDOMINAL DISCOMFORT __ __ __ mm

NONE — SEVERE

20. POST PRANDIAL SYMPTOMS -- 15 MINUTES AFTER finishing Ensure

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __
mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __
mm

NONE — EXTREME

c. NAUSEA

__ __ __
mm

NONE — SEVERE

d. BLOATING

__ __ __
mm

NONE — SEVERE

e. ABDOMINAL DISCOMFORT

__ __ __
mm

NONE — SEVERE

21. POST PRANDIAL SYMPTOMS -- 30 MINUTES AFTER finishing Ensure (At end of EGG)

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS __ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER __ __ __ mm

NONE — EXTREME

c. NAUSEA __ __ __ mm

NONE — SEVERE

d. BLOATING __ __ __ mm

NONE — SEVERE

e. ABDOMINAL DISCOMFORT __ __ __ mm

NONE — SEVERE

F. EGG data: ***(Note: The EGG signal analysis must be performed on a minimum of 4 consecutive, artifact-free minutes per 15 minute period.)***

22. What was the duration of the baseline 0-15 minute time period analyzed: __ __ *(min)*

23. What was the duration of the post satiety test 0-15 minute time period analyzed: __ __ *(min)*

24. What was the duration of the post satiety test 16-30 minute time period analyzed: __ __ *(min)*

25. Distribution of average power by frequency region (as % of power in the 0-15 cpm range) *(do not round the numbers; record as they appear on the report)*:

Period (minutes)	Bradygastria (1 - <2.5 cpm)	Normal (2.5 - <3.8 cpm)	Tachygastria (3.8-10 cpm)	Duodenal (>10-15 cpm)
Baseline:	**a.** _ _ _ . _ _ %	**b.** _ _ _ . _ _ %	**c.** _ _ _ . _ _ %	**d.** _ _ _ . _ _ %
0-15 post satiety:	**e.** _ _ _ . _ _ %	**f.** _ _ _ . _ _ %	**g.** _ _ _ . _ _ %	**h.** _ _ _ . _ _ %
16-30 post satiety:	**i.** _ _ _ . _ _ %	**j.** _ _ _ . _ _ %	**k.** _ _ _ . _ _ %	**l.** _ _ _ . _ _ %

26. Ratios of average power (POSTprandial/PREprandial) by frequency range *(do not round the numbers; record as they appear on the report)*:

Period (minutes)	Bradygastria (1 - <2.5 cpm)	Normal (2.5 - <3.8 cpm)	Tachygastria (3.8-10 cpm)	Duodenal (>10-15 cpm)
0-15 post satiety:	**a.** _ _ _ . _ _	**b.** _ _ _ . _ _	**c.** _ _ _ . _ _	**d.** _ _ _ . _ _
16-30 post satiety:	**e.** _ _ _ . _ _	**f.** _ _ _ . _ _	**g.** _ _ _ . _ _	**h.** _ _ _ . _ _

Data rounding rules for 27:

To round data, examine the digits following the last position required on the form:

· If the first digit following the last data position required for the response is less that 5, leave the digit in the last data position required for the response unchanged, e.g., if you need to round to _._ _ , then 1.4232 to 1.42 and 1.443 rounds to 1.44

· If the first digit following the last data position required for the response is 5 or more, round up the digit in the last data position required for the response, e.g., if you need to round to _._ _ , then 1.4252 to 1.43 and 4.756 rounds to 4.76

27. Distribution of average power by frequency range:

Period (minutes)	Bradygastria (1 - <2.5 cpm)	Normal (2.5 - <3.8 cpm)	Tachygastria (3.8-10 cpm)	Duodenal (>10-15 cpm)
Baseline:	**a.** _._ _e+_ _ _	**b.** _._ _e+_ _ _	**c.** _._ _e+_ _ _	**d.** _._ _e+_ _ _
0-15 post satiety:	**e.** _._ _e+_ _ _	**f.** _._ _e+_ _ _	**g.** _._ _e+_ _ _	**h.** _._ _e+_ _ _
16-30 post satiety:	**i.** _._ _e+_ _ _	**j.** _._ _e+_ _ _	**k.** _._ _e+_ _ _	**l.** _._ _e+_ _ _

28. Average dominant frequency *(do not round the numbers; record as they appear on the report)*:

a. Baseline: __ __ . __ __ cpm

b. 0-15 post satiety: __ __ . __ __ cpm

c. 16-30 post satiety: __ __ . __ __ cpm

29. Percentage of time with the dominant EGG frequencies in the four frequency ranges:

Period (minutes)	Bradygastria (1 - <2.5 cpm)	Normal (2.5 - <3.8 cpm)	Tachygastria (3.8-10 cpm)	Duodenal (>10-15 cpm)
Baseline:	**a.** __ __ __ %	**b.** __ __ __ %	**c.** __ __ __ %	**d.** __ __ __ %
0-15 post satiety:	**e.** __ __ __ %	**f.** __ __ __ %	**g.** __ __ __ %	**h.** __ __ __ %
16-30 post satiety:	**i.** __ __ __ %	**j.** __ __ __ %	**k.** __ __ __ %	**l.** __ __ __ %

G. Administrative information

30. Study Physician PIN: __ __ __

31. Study Physician signature:

_____

32. Clinical Coordinator PIN: __ __ __

33. Clinical Coordinator signature:

_____

34. Date form reviewed:

__ __-__ __ __-__ __
day mon year