GLUMIT-DG

BH - Baseline Medical History

Purpose: To collect baseline history information about the patient.

When: Screening visit.

Administered by: Clinical Coordinator, reviewed by Study Physician.

Respondent: Patient.

Instructions: The Clinical Coordinator should collect the information necessary to complete sections A-C by either interview or chart review. If △C is checked for any item, further review is necessary by the study physician to determine whether the diagnosis or condition in the **Caution** item renders the patient ineligible or unlikely to comply with the requirements of the GLUMIT-DG study. If Elig is checked for any item, the patient is ineligible for the GLUMIT-DG study unless the item can be resolved within the screening window. The BH form can not be keyed to the data system if there are any **Ineligible** conditions 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: GLUMIT-DG 3

B. Medical history

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

8. Has the patient had diabetes Type 1 or Type 2 for at least 2 years:

( ) Yes 1 — Elig
( ) No 2

9. Which form of diabetes has the patient been diagnosed with:

Type 1 (1)
Type 2 (2)

10. What is the total number of years the patient has had a diagnosis of Type 1 or Type 2 diabetes:

____ ____
years

11. Has the patient had prior gastric surgery including fundoplication:

( ) Yes 1 — Elig
( ) No 2

12. Does the patient report symptoms of gastroparesis of at least 12 months duration *(do not have to be contiguous)* with varying degrees of nausea, vomiting, early satiety, or post-prandial fullness:

( ) Yes 1 — Elig
( ) No 2

13. Is the patient currently taking insulin to manage his/her diabetes:

( ) Yes 1
( ) No 2 — 17.

14. What type of insulin is the patient currently using *(check all that apply)*

a. Insulin glargine (Lantus): (1)
b. Insulin glulisine (Apidra): (1)
c. Insulin detemir (Levemir): (1)
d. Insulin lispro (Humalog): (1)
e. Insulin aspart (Novolog): (1)
f. NPH (Humulin): (1)
g. NPH (Novolin): (1)
h. Other *(specify):* (1)

_____
specify

15. Is the patient currently wearing an insulin pump for insulin administration:

Yes (1) No (2)

17.

16. What type of insulin pump is the patient currently using

a. Minimed Paradigm REAL-Time insulin pump: (1)

b. One Touch Ping: (1)

c. ACCU-CHEK Spirit: (1)

d. OmniPod: (1)

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

_____
specify

17. Currently, the patients clinical metabolic pattern is characterized by *(check all that apply)*

a. Tendency to have ketoacidosis episodes: (1)

b. Stable using current insulin treatment: (1)

c. Stable using oral agents: (1)

d. Stable on a diet/exercise alone: (1)

e. Tendency to have ketoacidosis episodes during severe stress only: (1)

f. None of the above: (1)

18. 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. Pyloric obstruction: (1) C

b. Intestinal obstruction: (1) C

c. Inflammatory bowel disease: (1) C

d. Renal insufficiency: (1) C

e. Diabetic ketoacidosis: (1)

f. Diabetic hyperosmolarity (coma): (1)

g. Retinopathy: (1)

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

i. Major depression: (1)

j. Advanced liver disease: (1)

k. Peptic ulcer disease: (1)

l. GERD: Gastroesophageal reflux disease: (1)

m. Interstitial cystitis: (1)

n. Bladder dysfunction: (1)

o. Diverticulosis: (1)

p. Endometriosis: (1)

q. Blood clots: (1)

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

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

t. Rheumatoid arthritis: (1)

u. Fibromyalgia: (1)

v. Scleroderma: (1)

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

x. Migraine headaches: (1)

y. Hypertension: (1)

z. Coronary artery disease: (1)

aa. Cerebrovascular disease: (1)

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

ac. Pancreatitis: (1)

ad. Cholelithiasis: (1)

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

af. Polycystic ovary syndrome: (1)

ag. Myopathy: (1)

ah. Multiple sclerosis: (1)

ai. Eating disorders *(anorexia, bulimia):* (1) C

aj. Schizophrenia: (1)

ak. Bipolar disorder: (1)

al. Obsessive compulsive disorder: (1)

am. Severe anxiety or personality disorder: (1)

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

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

specify

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

specify

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

specify

ar. None of the above: (1)

C. Medication use

19. Has the patient used any of the following medications to treat diabetes in the past month:

Yes (1) No (2) → 20.

(If yes or unsure, check all that apply):

a. Acarbose (Precose): (1)

b. Acetohexamide (Dymelor): (1)

c. Chlorpropamide (Diabinese): (1)

d. Exenatide (Byetta): (1)

e. Glimepiride (Amaryl): (1)

f. Glipizide (Glucotrol): (1)

g. Glyburide (Micronase, Diabeta, Glynase): (1)

h. Metformin (Glucophage): (1)

i. Miglitol (Glyset): (1)

j. Nateglinide (Starlix): (1)

k. Pioglitazone (Actos): (1)

l. Repaglinide (Prandin): (1)

m. Rosiglitazone (Avandia): (1)

n. Saxagliptin (Onglyza): (1)

o. Sitagliptin (Januvia): (1)

p. Tolazamide (Tolinase): (1)

q. Tolbutamide (Orinase): (1)

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

specify

specify

20. Has the patient used any proton pump inhibitors, histamine H2 receptor antagonists or other similar medications in the past month:

Yes (1) No (2) → 21.

(If yes, check all that apply):

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

specify

b. Cimetidine (Tagamet): (1)

c. Esomeprazole (Nexium): (1)

d. Famotidine (Pepcid): (1)

e. Lansoprazole (Prevacid): (1)

f. Nizatidine (Axid): (1)

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

h. Pantoprazole (Protonix): (1)

i. Rabeprazole (Aciphex): (1)

j. Ranitidine (Zantac): (1)

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

specify

21. Has the patient used any prokinetic medications in the past month:

Yes (1) No (2) → 22.

(If yes, check all that apply)

a. Azithromycin (Zithromax): (1)

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

c. Botulinum toxin (Botox): (1)

d. Cisapride (Propulsid): (1)

e. Clarithromycin (Biaxin): (1)

f. Domperidone (Motilium): (1)

g. Metoclopramide (Reglan): (1)

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

specify

22. Has the patient used any antiemetic medications in the past month:

(Yes 1) (No 2)

23.

(If yes, check all that apply):

a. Aprepitant (Emend): (1)

b. Dolasetron (Anzemet): (1)

c. Dronabinol (Marinol): (1)

d. Granisetron (Kytril): (1)

e. Meclizine (Antivert): (1)

f. Ondansetron (Zofran): (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

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

(Yes 1) (No 2)

24.

(If yes, check all that apply):

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

24. Has the patient taken any other medications or over-the-counter supplements in the past month:

(Yes 1) (No 2)

25.

(If yes, specify):

a. Medication/supplement #1:

_____
specify

b. Medication/supplement #2:

_____
specify

c. Medication/supplement #3:

_____
specify

d. Medication/supplement #4:

_____
specify

D. 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

GLUMIT-DG

EG - Upper Endoscopy Documentation

Purpose: To document the results of the upper gastrointestinal endoscopy (EGD) to determine patient eligibility for the GLUMIT-DG study during screening and to document other findings if any, during follow-up.

When: Screening visit and if available during follow-up. The screening upper gastrointestinal endoscopy procedure must have been performed within 1 year prior to registration.

Administered by: Study Physician and Clinical Coordinator.

Instructions: This form should be completed using the available reports of the upper gastrointestinal endoscopy procedure. Upper gastrointestinal (upper GI) 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 reports as the source document. If  is checked for item 13, then STOP filling out the form and do not data enter the form. File the partially completed form 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: GLUMIT-DG 3

B. Upper endoscopy information

8. Date of upper endoscopy:

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

a. Is this a screening visit: Yes (1) No (2)

9. ____

b. Is date of upper endoscopy within 1 year prior to the GLUMIT-DG registration date: Yes (1) No (2)

STOP ____

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

9. Reason(s) for the procedure *(check all that apply):*

a. Gastroparesis symptoms/rule out obstruction: (1)

b. Anemia: (1)

c. Abdominal pain: (1)

d. Gastrostomy tube: (1)

e. GERD: (1)

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

_____
specify

C. Endoscopic findings

10. Normal stomach: Yes (1) No (2)

11. ____

(If no, check all that apply):

a. Gastritis: (1)

b. Ulcer: (1)

c. Gastrostomy tube: (1)

d. Pyloric stenosis: (1)

e. Bezoar: (1)

f. Other gastric findings, excluding any gastric surgery *(specify):* (1)

_____
specify

D. Other comments

11. Other comments concerning upper endoscopy procedure or results:

(Yes 1) (No 2)

12. ___

a. Specify:

_____

_____

_____

F. Eligibility check

12. Is this a screening visit:

(Yes 1) (No 2)

14. ___

13. Were there any other endoscopic or histologic findings not recorded above that in the opinion of the Study Physician would characterize the patient as ineligible:

(Yes * 1) (No 2)

Elig ___

**If Yes, specify:*

_____

specify

E. Administrative information

14. Study Physician PIN: ___ ___ ___

15. Study Physician signature:

_____

16. Clinical Coordinator PIN: ___ ___ ___

17. Clinical Coordinator signature:

_____

18. Date form reviewed:

___ ___ – ___ ___ ___ – ___ ___

day mon year

GLUMIT-DG

FH - Follow-up Medical History

Purpose: To collect follow-up medical information about the patient.
When: Follow-up visits f04, f08, f12, f16, f20 and f24.
Administered by: Clinical Coordinator, reviewed by Study Physician.
Respondent: Patient.
Instructions: The Clinical Coordinator should collect information by interview and chart review to complete sections A-D.

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: f ____ ____

6. Form & revision: f h 1

7. Study: GLUMIT-DG 3

B. Interval identification

8. Date of last Follow-up Medical History form *(if this is f04, then date of enrollment):*

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

9. Visit code of last Follow-up Medical History (FH) form *(if this is visit f04, then en):*

____ ____ ____

C. Medical history

10. 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. Complete the Interim Event Report (IE) form if thought to be associated with GLUMIT-DG study participation.)*

a. Pyloric obstruction: (1)
b. Intestinal obstruction: (1)
c. Inflammatory bowel disease: (1)
d. Renal insufficiency: (1)
e. Diabetic ketoacidosis: (1)
f. Diabetic hyperosmolarity (coma): (1)
g. Retinopathy: (1)
h. Thyroid disease *(hormonal abnormality):* (1)
i. Major depression: (1)
j. Advanced liver disease: (1)
k. Peptic ulcer disease: (1)
l. GERD: Gastroesophageal reflux disease: (1)
m. Interstitial cystitis: (1)
n. Bladder dysfunction: (1)
o. Diverticulosis: (1)
p. Endometriosis: (1)
q. Blood clots: (1)
r. Hemophilia *(bleeding disorder):* (1)
s. Systemic lupus erythematosus (SLE) or collagen vascular disease: (1)
t. Rheumatoid arthritis: (1)
u. Fibromyalgia: (1)
v. Scleroderma: (1)
w. Malignancy *(cancer):* (1)

x. Migraine headaches: (1)

y. Hypertension: (1)

z. Coronary artery disease: (1)

aa. Cerebrovascular disease: (1)

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

ac. Pancreatitis: (1)

ad. Cholelithiasis: (1)

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

af. Polycystic ovary syndrome: (1)

ag. Myopathy: (1)

ah. Multiple sclerosis: (1)

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

aj. Schizophrenia: (1)

ak. Bipolar disorder: (1)

al. Obsessive compulsive disorder: (1)

am. Severe anxiety or personality disorder: (1)

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

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

_____
specify

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

_____
specify

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

_____
specify

ar. None of the above: (1)

11. Since the date in item 8, has the patient had exacerbations of symptoms of gastroparesis or diabetes:

Yes (*1) No (2)

12.

a. Number of Emergency Room visits *(enter ''00'' if none):*

____ ____

**Complete the Interim Event Report (IE) form if thought to be associated with GLUMIT-DG study participation.*

12. Since the date in item 8, has the patient been hospitalized:

Yes (*1) No (2)

13.

a. Number of hospitalizations:

____ ____

**Complete the Interim Event Report (IE) form if thought to be associated with GLUMIT-DG study participation.*

D. Medication history

13. What type of insulin is the patient currently using *(check all that apply):*

a. Insulin glargine (Lantus): (1)

b. Insulin glulisone (Apidra): (1)

c. Insulin detemir (Levemir): (1)

d. Insulin lispro (Humalog): (1)

e. Insulin aspart (Novolog): (1)

f. NPH (Humulin): (1)

g. NPH (Novolin): (1)

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

_____
specify

14. Since the date in item 8, has the patient taken any of the following to treat diabetes *(check all that apply):*

a. Acarbose (Precose): (1)
b. Acetohexamide (Dymelor): (1)
c. Chlorpropamide (Diabinese): (1)
d. Exenatide (Byletta): (1)
e. Glimepiride (Amaryl): (1)
f. Glipizide (Glucotrol): (1)
g. Glyburide (Micronase, DiaBeta, Glynase): (1)
h. Metformin (Glucophage): (1)
i. Miglitol (Glycet): (1)
j. Nateglinide (Starlix): (1)
k. Pioglitazone (Actos): (1)
l. Repaglinide (Prandin): (1)
m. Rosiglitazone (Avandia): (1)
n. Saxagliptin (Onglyza): (1)
o. Sitagliptin (Januvia): (1)
p. Tolazamide (Tolinase): (1)
q. Tolbutamide (Orinase): (1)
r. Other *(specify):* (1)

_____
specify

_____
specify

s. None of the above: (1)

15. 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)

16. ____

(If yes, check all that apply):

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

_____
specify

b. Cimetidine (Tagamet): (1)
c. Esomeprazole (Nexium): (1)
d. Famotidine (Pepcid): (1)
e. Lansoprazole (Prevacid): (1)
f. Nizatidine (Axid): (1)
g. Omeprazole (Prilosec, Zegerid): (1)
h. Pantoprazole (Protonix): (1)
i. Rabeprazole (Aciphex): (1)
j. Ranitidine (Zantac): (1)
k. Other *(specify):* (1)

_____
specify

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

Yes (1) No (2)

17. ____

(If yes, check all that apply)

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

_____
specify

17. Since the date in item 9, has the patient used any antiemetic medications:

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

(If yes, check all that apply):

a. Aprepitant (Emend): (1)
b. Dolasetron (Anzemet): (1)
c. Dronabinol (Marinol): (1)
d. Granisetron (Kytril): (1)
e. Meclizine (Antivert): (1)
f. Ondansetron (Zofran): (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

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

Yes (1) No (2) **19.**

(If yes, check all that apply):

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

E. Administrative information

19. Has the patient taken any other medications or over-the-counter supplements in the past month:

Yes (1) No (2) **20.**

(If yes, specify):

a. Medication/supplement #1:

_____
specify

b. Medication/supplement #2:

_____
specify

c. Medication/supplement #3:

_____
specify

d. Medication/supplement #4:

_____
specify

20. Study Physician PIN: ____ ____ ____

21. Study Physician signature:

_____

22. Clinical Coordinator PIN: ____ ____ ____

23. Clinical Coordinator signature:

_____

24. Date form reviewed:

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

GLUMIT-DG GE - Gastric Emptying Scintigraphy Documentation

Purpose: Record results of gastric emptying scintigraphy to determine eligibility.

When: Screening visit or as needed. If patient has an additional gastric emptying scintigraphy during study participation, results should be recorded on this form. The gastric emptying scintigraphy must have been performed at a GpCRC clinical center. The baseline scintigraphy must be within 12 months of 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: GLUMIT-DG 3

B. Gastric Emptying Scintigraphy Test

8. Date of gastric emptying scintigraphy:

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

9. Is this a screening visit:

( ) Yes ( ) No

No → 11.

10. Is this date within 12 months of registration:

( ) Yes ( ) No

No → STOP

**Test must be rescheduled.*

11. Meal given for test:

Egg Beaters: ( )
Generic low-fat egg whites: ( )
Other *(specify)* ( )

C

specify

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

12. Amount of meal and water consumed

a. Meal *(check only one):*

100% ( )
90% ( )
75% ( )
50% ( )
33% ( )
25% ( )
10% ( )
0% ( )
Unknown ( )

b. Water *(check only one):*

100% ( )
90% ( )
75% ( )
50% ( )
33% ( )
25% ( )
10% ( )
0% ( )
Unknown ( )

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:

_____

_____

_____

_____

C. Eligibility check

16. Is this a screening visit:

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

18.

17. Do the results documented from the gastric emptying scintigraphy qualify this patient for enrollment in GLUMIT-DG *(Patients must have abnormal 2 hour (>60% retention) or 4 hour (>10% retention) gastric emptying to be classified as definite gastroparesis):*

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

Elig

D. Data Coordinating Center use

18. Study Physician PIN: ____ ____ ____

19. Study Physician signature:

_____

20. Clinical Coordinator PIN: ____ ____ ____

21. Clinical Coordinator signature:

_____

22. Date reviewed:

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

GLUMIT-DG

LR - Laboratory Results

Purpose: To record laboratory test results for tests done during screening and follow-up.

When: Screening visit and follow-up visits f12 and f24.

Administered by: Study Physician and Clinical Coordinator.

Instructions: Laboratory test results may be obtained from chart review. Complete tests as needed (repeat test if test 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 10^9cells/L are equivalent. Call the DCC if you have a question about conversion or how to record a value. If STOP is reached, the patient is NOT eligible and cannot enroll in the GLUMIT-DG study at this time. The form should not be keyed to the data system. 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.

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: GLUMIT-DG 3

B. Hematology

Required at screening, f12, and f24

8. Date of blood draw for hemoglogin A1c:

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

Date must be within 16 weeks of registration, or in the time window for the 12 week and 24 week follow-up visit. Check the patient's GLUMIT-DG visit window.

9. Hemoglobin A1c: ____ ____ • ____ ____
%

a. Is this a screening visit:

( ) Yes (1) ( ) No (2) → **11.**

10. Is hemoglobin A1c greater than or equal to 8.0%:

( ) Yes (1) (*) No (2) → STOP

** The patient is ineligible and cannot be enrolled into GLUMIT-DG if hemoglobin A1c is less than 8.0%.*

11. Date of blood draw for complete blood count:

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

Date must be within 16 weeks of registration, or in the time window for the 12 week and 24 week follow-up visit.

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

13. Hematocrit: ____ ____ • ____ ____
%

14. Red blood cell count:

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

15. White blood cell count:

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

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

C. Metabolic panel

Required at screening, f12, and f24

17. Date of blood draw for metabolic panel:

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

Date must be within 16 weeks of registration, or in the time window for the 12 week and 24 week follow-up visit.

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

19. Chloride: ____ ____ ____ mEq/L

20. Sodium: ____ ____ ____ mEq/L

21. Potassium: ____ ____ • ____ mEq/L

22. Glucose:* ____ ____ ____ mg/dL

**(If >300 mg/dL; check for ketones)*

23. Calcium: ____ ____ • ____ mg/dL

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

25. Creatinine: ____ ____ • ____ mg/dL

26. Bilirubin (total): ____ ____ • ____ mg/dL

27. Aspartate aminotransferase (AST):

____ ____ ____ U/L

28. Alanine aminotransferase (ALT):

____ ____ ____ U/L

29. Albumin: ____ • ____ g/dL

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

31. Is the patient's blood glucose >300 mg/dL:

Yes (1) No (2)

→ **34.**

32. Are ketones present *(check only one):*

Positive (*1) Negative (2)

→ **34.**

**If positive, complete either a or b for test method used*

a. Blood (1)

b. Urine (1)

→ **34.**

33. Blood ketone level: ____ • ____ ____ mmol/L

D. Thyroid stimulating hormone

34. Is this a screening visit:

Yes (1) No (2)

→ **39.**

35. Date of blood draw for TSH level:

____ ____–____ ____ ____–____ ____

day mon year

36. Thyroid stimulating hormone:

____ • ____ ____ µIU/mL or mIU/L

E. Eligibility check

Required before enrollment into GLUMIT-DG study

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

Yes (1) No (*2)

STOP

** The patient is ineligible and cannot be enrolled into GLUMIT-DG until all laboratory test results are obtained.*

38. Is the creatinine level >1.5 mg/dL:

Yes (*1) No (2)

STOP

** The patient is ineligible and cannot be enrolled into GLUMIT-DG if the creatinine level is >1.5 mg/dL*

F. Administrative information

39. Study Physician PIN: ____ ____ ____

40. Study Physician signature:

_____

41. Clinical Coordinator PIN: ____ ____ ____

42. Clinical Coordinator signature:

_____

43. Date form reviewed:

____ ____–____ ____ ____–____ ____

day mon year

GLUMIT-DG

PE - Physical Examination

Purpose: Record physical exam findings.

When: Screening visit and follow-up visits f12 and f24.

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient.

Instructions: Standardized procedures for height, weight, waist and hip measurements are found in GLUMIT-DG SOP I. In brief: Shoes should be removed for height and weight measures. Height, weight, waist and hips all should be measured with the patient standing and wearing light clothing. 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.

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: GLUMIT-DG 3

B. Vital status

8. Temperature *(oral)*

a. Degrees: ____ ____ ____ • ____

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

9. Blood pressure *(sitting)*

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)

Abnormal (2) **17.**

specify

17. Oropharynx:

Normal (1)

Abnormal (2) **18.**

specify

18. Trachea:

Normal (1)

Abnormal (2) **19.**

specify

19. Thyroid:

Normal (1)

Abnormal (2) **20.**

specify

20. Heart:

Normal (1)

Abnormal (2) **21.**

specify

21. Abdomen:

Normal (1)

Abnormal (2) **23.**

22. 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

23. Liver and spleen:

Normal (1)

Abnormal (2) **24.**

specify

24. Nervous system:

Not performed (0)

Normal (1) **25.**

Abnormal (2) **25.**

specify

25. Pupil reflexes:

Normal (1)

Abnormal (2) **26.**

specify

26. Eye fundus:

Normal (1)

Abnormal (2) **27.**

specify

27. Extraocular movements:

Normal (1)

28. ___

Abnormal (2)

_____
specify

28. Dentition *(appearance of teeth)*:

Normal (1)

29. ___

Abnormal (2)

_____
specify

29. Lymph nodes:

Normal (1)

30. ___

Abnormal (2)

_____
specify

30. Extremities: Is edema present:

Yes (1)

31. ___

No (2)

_____
specify

31. Other abnormalities noted:

Yes (1) No (2)

32. ___

_____
specify other abnormalities

E. Electrocardiogram and autonomic function assessment

(Required during screening and at follow-up visits f12 and f24)

32. Date electrocardiogram obtained:

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

33. Is normal sinus rhythm present:

Yes (1) No (2)

a. Resting heart rate:

____ ____ ____
beats/minute

b. Systolic blood pressure:

____ ____ ____
mmHg

c. Diastolic blood pressure:

____ ____ ____
mmHg

d. R-R interval:

____ ____ ____
milliseconds

34. Paced breathing *(have the patient take regular, deep breaths at a rate of 5-6 breaths per minute):*

a. Heart rate:

____ ____ ____
beats/minute

b. Systolic blood pressure:

____ ____ ____
mmHg

c. Diastolic blood pressure:

____ ____ ____
mmHg

d. R-R interval:

____ ____ ____
milliseconds

35. Valsalva maneuver *(have the patient forcibly exhale into a manometer to maintain a pressure of 40 mmHg for 15 seconds):*

a. Fastest heart rate during the Valsalva:

____ ____ ____
beats/minute

b. Systolic blood pressure:

____ ____ ____
mmHg

c. Diastolic blood pressure:

____ ____ ____
mmHg

d. R-R interval:

____ ____ ____
milliseconds

(allow the patient to breathe normally)

e. Heart rate after Valsalva maneuver:

____ ____ ____
beats/minute

f. Systolic blood pressure:

____ ____ ____
mmHg

g. Diastolic blood pressure:

____ ____ ____
mmHg

h. R-R interval:

____ ____ ____
milliseconds

F. Neuropathy foot exam

Complete the Neuropathy Foot Exam worksheet on pages 5 and 6 before completing items 36-39.

36. Right foot total score: ____ • ____
total

37. Left foot total score: ____ • ____
total

38. Grand total (items 36 and 37 combined):

____ ____ • ____
total

39. Has the diagnosis of neuropathy been made:

Yes (1)
No (2)
Unable to determine (3)

G. Administrative information

40. Study Physician PIN: ____ ____ ____

41. Study Physician signature:

_____

42. Clinical Coordinator PIN: ____ ____ ____

43. Clinical Coordinator signature:

_____

44. Date form reviewed:

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

Neuropathy Foot Exam

Instructions: A neuropathy foot exam should be completed as a part of the physical exam. Specific instruction on completion and scoring of the neuropathy foot exam can be found in GULMIT-DG SOP I: Clinical Center Operations. In brief, the right and left foot should be examined for the presence of deformity, ulceration, ankle reflex, vibration and monofilament. A score will be derived for each of these elements for both the right and left foot and will be combined to receive a total score. Calculate scores for the right foot and left foot separately. There are 5-points possible per foot.

Scoring the Neuropathy Screening Instrument.

For each foot, scoring should be completed as follows:

Appearance of foot (deformity)*:	Normal= 0	Abnormal= 1	
Ulceration*:	Absent= 0	Present= 1	
Ankle Reflexes:	Present= 0	Present with Reinforcement= 0.5	Absent= 1
Vibration Perception:	Present= 0	Decreased= 0.5	Absent=1
Monofilament (10-gram):	8-10 Correct= 0	1-7 Correct=0.5	None Correct=1

*Includes any excessively dry skin, callus formation, fissures, frank ulceration, flat feet, hammertoes, overlapping toes, hallux valgus, joint subluxation, prominent metatarsal head, medial convexity (Charcot foot), ulceration, and amputation.

Appearance of foot	**Right foot**			**Score**
Deformity *	Normal= 0	Abnormal= 1		
Ulceration*	Present= 1	Absent= 0		
Ankle Reflex	Present= 0	Present with reinforcement= 0.5	Absent= 1	
Vibration	Present= 0	Decreased= 0.5	Absent= 1	
Monofilament	8-10 correct= 0	1-7 correct= 0.5	None correct= 1	

A. Right foot total score (record score on item 36 of this form): __ . __

Appearance of foot	Left foot			Score
Deformity *	Normal= 0	Abnormal= 1		
Ulceration*	Present= 1	Absent= 0		
Ankle Reflex	Present= 0	Present with reinforcement= 0.5	Absent= 1	
Vibration	Present= 0	Decreased= 0.5	Absent= 1	
Monofilament	8-10 correct= 0	1-7 correct= 0.5	None correct= 1	

B. Left foot total score (record score on item 37 of this form): __ . __

C. Grand total score (record score on item 38 of this form): __ __ . __

Interpretation of Scoring

The following total score scale (combination of right and left foot scores) from the clinical neuropathy foot exam would denote presence or absence of neuropathy:

Total score of 0 to 2 = Neuropathy not present

Total score of 2.5 to 10 = Neuroapthy present

An increase of 1-point over time denotes progression toward neuropathy.

GLUMIT-DG

PE - Physical Examination

Purpose: Record physical exam findings.

When: Screening visit and follow-up visits f12 and f24.

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient.

Instructions: Standardized procedures for height, weight, waist and hip measurements are found in GLUMIT-DG SOP I. In brief: Shoes should be removed for height and weight measures. Height, weight, waist and hips all should be measured with the patient standing and wearing light clothing. 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.

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 2

7. Study: GLUMIT-DG 3

B. Vital status

8. Temperature *(oral)*

a. Degrees: ____ ____ ____ • ____

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

9. Blood pressure *(sitting)*

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)
Abnormal (2)
→ **17.**

specify

17. Oropharynx:

Normal (1)
Abnormal (2)
→ **18.**

specify

18. Trachea:

Normal (1)
Abnormal (2)
→ **19.**

specify

19. Thyroid:

Normal (1)
Abnormal (2)
→ **20.**

specify

20. Heart:

Normal (1)
Abnormal (2)
→ **21.**

specify

21. Abdomen:

Normal (1)
Abnormal (2)
→ **23.**

22. 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

23. Liver and spleen:

Normal (1)
Abnormal (2)
→ **24.**

specify

24. Nervous system:

Not performed (0)
Normal (1)
Abnormal (2)
→ **25.**

specify

25. Pupil reflexes:

Normal (1)
Abnormal (2)
→ **26.**

specify

26. Eye fundus:

Normal (1)
Abnormal (2)
→ **27.**

specify

27. Extraocular movements:

Normal (1)
Abnormal (2)

28. ___

_____
specify

28. Dentition *(appearance of teeth)*:

Normal (1)
Abnormal (2)

29. ___

_____
specify

29. Lymph nodes:

Normal (1)
Abnormal (2)

30. ___

_____
specify

30. Extremities: Is edema present:

Yes (1)
No (2)

31. ___

_____
specify

31. Other abnormalities noted:

Yes (1) No (2)

32. ___

_____
specify other abnormalities

E. Electrocardiogram and autonomic function assessment

(Required during screening and at follow-up visits f12 and f24)

32. Date resting electrocardiogram obtained:

__ __ – __ __ __ – __ __
day mon year

33. Is normal sinus rhythm present:

Yes (1) No (2)

a. Resting heart rate:

___ ___ ___
beats/minute

b. Systolic blood pressure:

___ ___ ___
mmHg

c. Diastolic blood pressure:

___ ___ ___
mmHg

34. Paced breathing *(have the patient take regular, deep breaths at a rate of 5-6 breaths per minute):*

a. Heart rate:

___ ___ ___
beats/minute

b. Systolic blood pressure:

___ ___ ___
mmHg

c. Diastolic blood pressure:

___ ___ ___
mmHg

35. Valsalva maneuver *(have the patient forcibly exhale into a manometer to maintain a pressure of 40 mmHg for 15 seconds):*

a. Fastest heart rate during the Valsalva:

___ ___ ___
beats/minute

b. Systolic blood pressure:

___ ___ ___
mmHg

c. Diastolic blood pressure:

___ ___ ___
mmHg

(allow the patient to breathe normally)

d. Heart rate after Valsalva maneuver:

___ ___ ___
beats/minute

e. Systolic blood pressure:

___ ___ ___
mmHg

f. Diastolic blood pressure:

___ ___ ___
mmHg

F. Neuropathy foot exam

Complete the Neuropathy Foot Exam worksheet on pages 5 and 6 before completing items 36-39.

36. Right foot total score: ___ • ___
total

37. Left foot total score: ___ • ___
total

38. Grand total (items 36 and 37 combined):

___ ___ • ___
total

39. Has the diagnosis of neuropathy been made:

Yes (1)
No (2)
Unable to determine (3)

G. Administrative information

40. Study Physician PIN: ___ ___ ___

41. Study Physician signature:

_____

42. Clinical Coordinator PIN: ___ ___ ___

43. Clinical Coordinator signature:

_____

44. Date form reviewed:

___ ___ – ___ ___ – ___ ___
day mon year

Neuropathy Foot Exam

Instructions: A neuropathy foot exam should be completed as a part of the physical exam. Specific instruction on completion and scoring of the neuropathy foot exam can be found in GULMIT-DG SOP I: Clinical Center Operations. In brief, the right and left foot should be examined for the presence of deformity, ulceration, ankle reflex, vibration and monofilament. A score will be derived for each of these elements for both the right and left foot and will be combined to receive a total score. Calculate scores for the right foot and left foot separately. There are 5-points possible per foot.

Scoring the Neuropathy Screening Instrument.

For each foot, scoring should be completed as follows:

Appearance of foot (deformity)*:	Normal= 0	Abnormal= 1	
Ulceration*:	Absent= 0	Present= 1	
Ankle Reflexes:	Present= 0	Present with Reinforcement= 0.5	Absent= 1
Vibration Perception:	Present= 0	Decreased= 0.5	Absent=1
Monofilament (10-gram):	8-10 Correct= 0	1-7 Correct=0.5	None Correct=1

*Includes any excessively dry skin, callus formation, fissures, frank ulceration, flat feet, hammertoes, overlapping toes, hallux valgus, joint subluxation, prominent metatarsal head, medial convexity (Charcot foot), ulceration, and amputation.

Appearance of foot	**Right foot**			**Score**
Deformity *	Normal= 0	Abnormal= 1		
Ulceration*	Present= 1	Absent= 0		
Ankle Reflex	Present= 0	Present with reinforcement= 0.5	Absent= 1	
Vibration	Present= 0	Decreased= 0.5	Absent= 1	
Monofilament	8-10 correct= 0	1-7 correct= 0.5	None correct= 1	

A. Right foot total score (record score on item 36 of this form): __ . __

Appearance of foot	Left foot			Score
Deformity *	Normal= 0	Abnormal= 1		
Ulceration*	Present= 1	Absent= 0		
Ankle Reflex	Present= 0	Present with reinforcement= 0.5	Absent= 1	
Vibration	Present= 0	Decreased= 0.5	Absent= 1	
Monofilament	8-10 correct= 0	1-7 correct= 0.5	None correct= 1	

B. Left foot total score (record score on item 37 of this form): __ . __

C. Grand total score (record score on item 38 of this form): __ __ . __

Interpretation of Scoring

The following total score scale (combination of right and left foot scores) from the clinical neuropathy foot exam would denote presence or absence of neuropathy:

Total score of 0 to 2 = Neuropathy not present

Total score of 2.5 to 10 = Neuropathy present

An increase of 1-point over time denotes progression toward neuropathy.

GLUMIT-DG

RG - Registration

Purpose: To register patients as candidates for enrollment in the Continuous Glucose Monitoring and Insulin Pump Therapy in Diabetic Gastroparesis (GLUMIT-DG) study 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.

Administered by: Clinical Coordinator.

Respondent: Patient.

Instructions: Use Flash Cards as instructed.

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: GLUMIT-DG 3

B. Consent

8. Has the patient signed the GLUMIT-DG informed consent statement:

Yes (1) No (2) STOP

Patient must sign the consent prior to continuing with screening.

9. Has the consentor 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 date of birth.

11. Age at last birthday: ____ ____
years

12. Is the patient at least 18 and less than 71 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)

D. Previous registration in a GpCRC study

17. Has the patient previously been registered in a GpCRC study:

Yes (1) No (2)

20. ___

18. ID Number previously assigned to patient *(record patient ID in item 2):*

___ ___ ___ ___

19. Code previously assigned to patient *(record patient code in item 3):*

___ ___ ___

21. ___

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.)

20. Place ID label below and record Patient ID in item 2 and patient code in item 3.

CCCC ####, zzz

F. Administrative information

21. Clinical Coordinator PIN: ___ ___ ___

22. Clinical Coordinator signature:

_____

23. Date form reviewed:

___ ___ – ___ ___ ___ – ___ ___

day mon year

ST - EGG and Caloric Satiety Test

Purpose: To document symptoms and results of the caloric satiety test and electrogastrogram in patients with gastroparesis.
When: Screening visit and follow-up visits f12 and f24.
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, 4, 5, 6, and 7 are 100 mm in length and 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 9, 13, 14, 15, and 16. **Choose only whole minutes and do not select more than 15 minutes for the baseline period. Do not select more than 10 minutes for any post-satiety recording period.** Using the EGG report, complete section F. The Study Physician and Clinical Coordinator should complete Section G. 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: GLUMIT-DG 3

8. Has the patient fasted since midnight:

Yes	No
(1)	(* 2)
	Stop

* *Patient must be fasting; test must be re-scheduled.*

8a. Is the patient's blood glucose level <270 mg/dL:

Yes	No
(1)	(* 2)
	Stop

** Glucose must be less than 270 mg/dL; test must be rescheduled.*

B. Baseline Symptom Scores

9. 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

NOT FULL AT ALL — COMPLETELY FULL

__ __ __ mm

b. HUNGER

NONE — EXTREME

__ __ __ mm

c. NAUSEA

NONE — SEVERE

__ __ __ mm

d. BLOATING

NONE — SEVERE

__ __ __ mm

e. ABDOMINAL DISCOMFORT

NONE — SEVERE

__ __ __ mm

C. SATIETY TEST VOLUMES

10. Satiety Test Started: __ __ : __ __

(24-hour)

Do not key data recorded in this box.

Subject drinks 150 mL of chilled Ensure® from a cup every 5 minutes until he/she feels 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: _____

11. Time Satiety Test Ended: __ __ : __ __ *(24-hour)*

12. Total Ensure Volume Consumed: __ __ __ __ *mL*

D. Post prandial Symptom Scores

13. SYMPTOMS -- 10 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

14. SYMPTOMS -- 20 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

15. SYMPTOMS -- 30 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

16. SYMPTOMS -- 60 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

E. Calibration

17. Measure the length of the line below and enter the total length in millimeters: __ __ __ mm

F. EGG Data (Note: The EGG signal analysis must be performed on a minimum of 4 consecutive, artifact-free minutes per period)

18. What was the duration of the baseline 0-15 minute time period analyzed: __ __ (min)

19. What was the duration of the post satiety test 0-10 minute time period analyzed: __ __ (min)

20. What was the duration of the post satiety 11-20 minute time period analyzed: __ __ (min)

21. What was the duration of the post satiety 21-30 minute time period analyzed: __ __ (min)

22. What was the duration of the post satiety 31-40 minute time period analyzed: __ __ (min)

23. What was the duration of the post satiety 41-50 minute time period analyzed: __ __ (min)

24. What was the duration of the post satiety 51-60 minute time period analyzed: __ __ (min)

25. Distribution of average power by frequency region (as % of power in the 0-15 cpm range):

Period (minutes)	**Bradygastria (1- <2.5 cpm)**	**Normal (2.5 - <3.8 cpm)**	**Tachygastria (3.8-10 cpm)**	**Duodenal (>10-15 cpm)**
Baseline (15):	**a.** _ _ _ . _ _%	**b.** _ _ _ . _ _%	**c**. _ _ _ . _ _%	**d.** _ _ _ . _ _%
0-10 post:	**e.** _ _ _ . _ _%	**f.** _ _ _ . _ _ %	**g.** _ _ _ . _ _%	**h.** _ _ _ . _ _%
11-20 post:	**i.** _ _ _ . _ _%	**j.** _ _ _ . _ _ %	**k.** _ _ _ . _ _%	**l.** _ _ _ . _ _%
21-30 post:	**m.** _ _ _ . _ _%	**n.** _ _ _ . _ _ %	**o.** _ _ _ . _ _%	**p.** _ _ _ . _ _%
31-40 post:	**q.** _ _ _ . _ _%	**r.** _ _ _ . _ _ %	**s.** _ _ _ . _ _%	**t.** _ _ _ . _ _%
41-50 post:	**u.** _ _ _ . _ _%	**v.** _ _ _ . _ _ %	**w.** _ _ _ . _ _%	**x.** _ _ _ . _ _%
51-60 post:	**y.** _ _ _ . _ _%	**z.** _ _ _ . _ _ %	**aa.** _ _ _ . _ _%	**ab.** _ _ _ . _ _%

26. Ratios of average powers (POSTprandial/PREprandial) 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)
0-10 post satiety:	**a.** _ _ . _ _	**b.** _ _ . _ _	**c.** _ _ . _ _	**d.** _ _ . _ _
11-20 post satiety:	**e.** _ _ . _ _	**f.** _ _ . _ _	**g.** _ _ . _ _	**h.** _ _ . _ _
21-30 post satiety:	**i.** _ _ . _ _	**j.** _ _ . _ _	**k.** _ _ . _ _	**l.** _ _ . _ _
31-40 post satiety:	**m.** _ _ . _ _	**n.** _ _ . _ _	**o.** _ _ . _ _	**p.** _ _ . _ _
41-50 post satiety:	**q.** _ _ . _ _	**r.** _ _ . _ _	**s.** _ _ . _ _	**t.** _ _ . _ _
51-60 post satiety:	**u.** _ _ . _ _	**v.** _ _ . _ _	**w.** _ _ . _ _	**x.** _ _ . _ _

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+_ _ _
0-10 post:	**e.** _ . _ _e+ _ _ _	**f.** _ . _ _ e+ _ _ _	**g.** _ . _ _ e+ _ _ _	**h.** _ . _ _e+ _ _ _
11-20 post:	**i.** _ . _ _e+ _ _ _	**j.** _ . _ _ e+ _ _ _	**k.** _ . _ _ e+ _ _ _	**l.** _ . _ _ e+ _ _ _
21-30 post:	**m.** _ . _ _e+ _ _ _	**n.** _ . _ _ e+ _ _ _	**o.** _ . _ _ e+ _ _ _	**p.** _ . _ _ e+ _ _ _
31-40 post:	**q.** _ . _ _e+ _ _ _	**r.** _ . _ _ e+ _ _ _	**s.** _ . _ _ e+ _ _ _	**t.** _ . _ _ e+ _ _ _
41-50 post:	**u.** _ . _ _e+ _ _ _	**v.** _ . _ _ e+ _ _ _	**w.** _ . _ _ e+ _ _ _	**x.** _ . _ _ e+ _ _ _
51-60 post:	**y.** _ . _ _e+ _ _ _	**z.** _ . _ _ e+ _ _ _ _	**aa.** _ . _ _ e+ _ _ _	**ab.** _ . _ _ e+ _ _

28. Average dominant frequency:

a. Baseline: _ _. _ _ cpm

b. 0-10 post: _ _. _ _ cpm

c. 11 -20 post: _ _. _ _ cpm

d. 21 -30 post: _ _. _ _ cpm

e. 31 -40 post: _ _. _ _ cpm

f. 41 -50 post: _ _. _ _ cpm

g. 51 -60 post: _ _. _ _ 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.** _ _ _ %
0-10 post :	**e.** _ _ _ %	**f.** _ _ _ %	**g.** _ _ _ %	**h.** _ _ _ %
11-20 post:	**i.** _ _ _ %	**j.** _ _ _ %	**k.** _ _ _ %	**l.** _ _ _ %
21-30 post:	**m.** _ _ _ %	**n.** _ _ _ %	**o.** _ _ _ %	**p.** _ _ _ %
31-40 post:	**q.** _ _ _ %	**r.** _ _ _ %	**s.** _ _ _ %	**t.** _ _ _ %
41-50 post:	**u.** _ _ _ %	**v.** _ _ _ %	**w.** _ _ _ %	**x.** _ _ _ %
51-60 post:	**y.** _ _ _ %	**z.** _ _ _ %	**aa.** _ _ _ %	**ab.** _ _ _ %

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

WL - EGG and Water Load Satiety Test

Purpose: To document symptoms and results of the water load satiety test and electrogastrogram in patients with gastroparesis.
When: Screening visit and follow-up visits f12 and f24.
Administered by: Study Physician and Clinical Coordinator.
Respondent: Patient will respond to symptom evaluations on pages 2, 4-6.
Instructions: The Clinical Coordinator should complete section A. The Clinical Coordinator will use pages 2-6 to obtain patient's responses during the test procedure. The visual analog scales on pages 2, 4, 5, and 6 are 100 mm in length and 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 10, 14, 15, and 16. **Choose only whole numbers. Do not select more than 15 minutes for the baseline period. Do not select more than 10 minutes for any post water-load satiety recording period.** Using the EGG report, complete section F. The Study Physician and Clinical Coordinator should complete Section G. 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: w 1 1

7. Study: GLUMIT-DG 3

8. Has the patient fasted since midnight:

Yes	No
(1)	(* 2)

Stop

* *Patient must be fasting; test must be rescheduled.*

9. Is the patient's blood glucose level <270 mg/dL:

Yes	No
(1)	(* 2)

Stop

** Glucose must be less than 270 mg/dL; test must be rescheduled.*

B. Baseline Symptom Scores

10. 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

NOT FULL AT ALL — COMPLETELY FULL

__ __ __ mm

b. HUNGER

NONE — EXTREME

__ __ __ mm

c. NAUSEA

NONE — SEVERE

__ __ __ mm

d. BLOATING

NONE — SEVERE

__ __ __ mm

e. ABDOMINAL DISCOMFORT

NONE — SEVERE

__ __ __ mm

C. NON-CALORIC WATER LOAD SATIETY TEST VOLUME

Subject drinks spring water, refrigerated at 4 degrees C, from a 16 ounce cup over a 5 minute period until he/she feels completely full.

11. Time Non-Caloric Water Load Satiety Test Started: __ __ : __ __
(24-hour)

12. Time Satiety Test Ended: __ __ : __ __
(24-hour)

13. Total Volume of Water Consumed: __ __ __ __
mL

D. Post Water Load Satiety Symptom Scores

14. SYMPTOMS -- 10 minutes AFTER finishing water

□□ : □□
(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

NOT FULL AT ALL — COMPLETELY FULL

__ __ __ mm

b. HUNGER

NONE — EXTREME

__ __ __ mm

c. NAUSEA

NONE — SEVERE

__ __ __ mm

d. BLOATING

NONE — SEVERE

__ __ __ mm

e. ABDOMINAL DISCOMFORT

NONE — SEVERE

__ __ __ mm

15. SYMPTOMS -- 20 MINUTES AFTER finishing water

□□ : □□
(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

16. SYMPTOMS -- 30 MINUTES AFTER finishing water (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

E. Calibration

17. Measure the length of the line below and enter the total length in millimeters: __ __ __ mm

F. EGG data: *(Note: The EGG signal analysis must be performed on a minimum of 6 consecutive, artifact-free minutes per period.)*

18. What was the duration of the baseline 0-15 minute time period analyzed: __ __ *(min)*

19. What was the duration of the post satiety test 0-10 minute time period analyzed: __ __ *(min)*

20. What was the duration of the post satiety test 11-20 minute time period analyzed: __ __ *(min)*

21. What was the duration of the post satiety test 21-30 minute time period analyzed: __ __ *(min)*

22. Distribution of average power by frequency region (as % of power in the 0-15 cpm 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.** _ _ _ . _ _ %	**b.** _ _ _ . _ _ %	**c.** _ _ _ . _ _ %	**d.** _ _ _ . _ _ %
0-10 post satiety:	**e.** _ _ _ . _ _ %	**f.** _ _ _ . _ _ %	**g.** _ _ _ . _ _ %	**h.** _ _ _ . _ _ %
11-20 post satiety:	**i.** _ _ _ . _ _ %	**j.** _ _ _ . _ _ %	**k.** _ _ _ . _ _ %	**l.** _ _ _ . _ _ %
21-30 post satiety:	**m.** _ _ _ . _ _ %	**n.** _ _ _ . _ _ %	**o.** _ _ _ . _ _ %	**p.** _ _ _ . _ _ %

23. Ratios of average power (POSTsatiety/PREsatiety) 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)
0-10 post satiety:	**a.** _ _ . _ _	**b.** _ _ . _ _	**c.** _ _ . _ _	**d.** _ _ . _ _
11-20 post satiety:	**e.** _ _ . _ _	**f.** _ _ . _ _	**g.** _ _ . _ _	**h.** _ _ . _ _
21-30 post satiety:	**i.** _ _ . _ _	**j.** _ _ . _ _	**k.** _ _ . _ _	**l.** _ _ . _ _

24. 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+__ __ __
0-10 post satiety:	**e.** __.__ __e+__ __ __	**f.** __.__ __e+__ __ __	**g.** __.__ __e+__ __ __	**h.** __.__ __e+__ __ __
11-20 post satiety:	**i.** __.__ __e+__ __ __	**j.** __.__ __e+__ __ __	**k.** __.__ __e+__ __ __	**l.** __.__ __e+__ __ __
21-30 post satiety:	**m.** __.__ __e+__ __ __	**n.** __.__ __e+__ __ __	**o.** __.__ __e+__ __ __	**p.** __.__ __e+__ __ __

25. Average dominant frequency:

a. Baseline: __ __ . __ __ cpm

b. 0-10 post satiety: __ __ . __ __ cpm

c. 11-20 post satiety: __ __ . __ __ cpm

d. 21-30 post satiety: __ __ . __ __ cpm

26. 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.** __ __ __ %
0-10 post satiety:	**e.** __ __ __ %	**f.** __ __ __ %	**g.** __ __ __ %	**h.** __ __ __ %
11-20 post satiety:	**i.** __ __ __ %	**j.** __ __ __ %	**k.** __ __ __ %	**l.** __ __ __ %
21-30 post satiety:	**m.** __ __ __ %	**n.** __ __ __ %	**o.** __ __ __ %	**p.** __ __ __ %

G. Administrative information

27. Study Physician PIN: __ __ __

28. Study Physician signature:

_____

29. Clinical Coordinator PIN: __ __ __

30. Clinical Coordinator signature:

_____

31. Date form reviewed:

___ ___-___ ___ ___-___ ___
day mon year