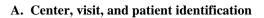
GLUMIT-DG

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 *w* 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.

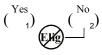


- 1. Center ID:
- **2.** Patient ID:
- 3. Patient code:
- **4.** Visit date (*date this form is initiated*):

day	mon year
5. Visit code:	_ <u>S</u>
6. Form & revision:	<u>b h 1</u>
7. Study:	GLUMIT-DG_3_

B. Medical history

- (<u>c</u> 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:



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

Type 1	(1)
Type 2	(2)

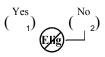
10. What is the total number of years the patient has had a diagnosis of Type 1 or Type 2 diabetes:

years

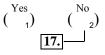
11. Has the patient had prior gastric surgery including fundoplication:



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:



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



- **14.** What type of insulin is the patient currently using *(check all that apply)*
 - a. Insulin glargine (Lantus): $\begin{pmatrix} & & & \\ & & & \end{pmatrix}$ b. Insulin glulisine (Apidra): $\begin{pmatrix} & & & \\ & & & \end{pmatrix}$ c. Insulin detemir (Levemir): $\begin{pmatrix} & & & \\ & & & \end{pmatrix}$ d. Insulin lispro (Humalog): $\begin{pmatrix} & & & \\ & & & \end{pmatrix}$ e. Insulin aspart (Novolog): $\begin{pmatrix} & & & \\ & & & \end{pmatrix}$ f. NPH (Humulin): $\begin{pmatrix} & & & \\ & & & \end{pmatrix}$ g. NPH (Novolin): $\begin{pmatrix} & & & \\ & & & \end{pmatrix}$ h. Other (specify): $\begin{pmatrix} & & & \\ & & & \end{pmatrix}$

specify

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

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

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:	$\operatorname{A}^{(-1)}$
b. Intestinal obstruction:	$\mathbf{r}^{(1)}$
c. Inflammatory bowel disease:	$\underline{\mathbf{C}}^{(1)}$
d. Renal insufficiency:	$\mathbf{r}^{(1)}$
e. Diabetic ketoacidosis:	(₁)
f. Diabetic hyperosmolarity (coma):	(₁)
g. Retinopathy:	(₁)
h. Thyroid disease <i>(hormonal abnormality):</i>	(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)

Patient ID: _____

ao. Other diagnosis #1 (specify): $\begin{pmatrix} 1 \\ 1 \end{pmatrix}$ specify ap. Other diagnosis #2 (specify): $\begin{pmatrix} 1 \\ 1 \end{pmatrix}$ specify aq. Other diagnosis #3 (specify): $\begin{pmatrix} 1 \\ 1 \end{pmatrix}$ specify ar. None of the above: $\begin{pmatrix} 1 \\ 1 \end{pmatrix}$

C. Medication use

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

Yes	(^N	10)
	0. 	ر ₂ ا
(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 <i>(specify)</i> :	(1)

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

in the pust month.		
	(Yes)	$\binom{No}{2}$
	V 17	(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 <i>(specify):</i>	(1)

specify

(Yes

 $\binom{No}{2}$

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

	V 17	(27
	22	2. —	J
(If yes, check all that apply)		_	
a. Azithromycin (Zithromax):		(1)
b. Bethanechol (Duvoid, Urech	noline):	(1)
c. Botulinum toxin (Botox):		(1)
d. Cisapride (Propulsid):		(1)
e. Clarithromycin (Biaxin):		(1)
f. Domperidone (Motilium):		(1)
g. Metoclopramide (Reglan):		(1)
h. Other <i>(specify):</i>		(1)

specify

specify

specify

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

r (^{Ye}	$\binom{N}{1}$	0 2)
	23.	J
(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, Phenerg	gan): (1)
j. Tetrahydrocannabinol (THC, marijuana):	(1)
k. Trimethobenzamide (Benzacot,	(``
Stemetic, Tigan):	(1)
l. Tropisetron (Navoban):	(1)
m. Other <i>(specify)</i> :	(1)

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

Yes _) (

(If yes, specify):

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:

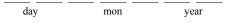
specify

- 23. Has the patient taken any tricyclic antidepressants for refractory symptoms of gastroparesis in the past month:
 - (Yes 24. (If yes, check all that apply): a. Amitriptyline (Elavil): 1) ,) **b.** Amoxapine (Asendin) c. Clomipramine (Anafranil) (₁) d. Desipramine (Norpramin) 1) e. Doxein (Sinequan) ₁) **f.** Imipramine (Tofranil) ,) g. Nortriptyline (Pamelor) 1) ₁) h. Trimipramine (Surmontil) i. Protriptyline (Pliva, Vivactil) ,) j. Other tricyclic antidepressants (specify): (1)

27. Clinical Coordinator PIN:

28. Clinical Coordinator signature:

29. Date form reviewed:



specify

No

GLUMIT-DG

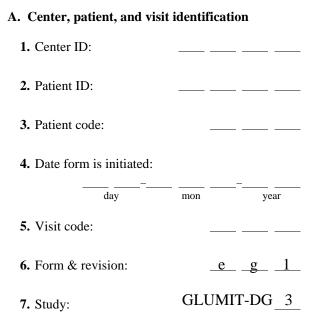
EG - Upper Endoscopy Documentation

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.

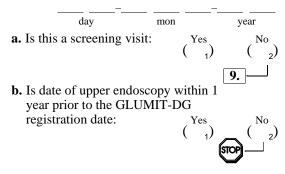
Administered by: Study Physician and Clinical Coordinator.

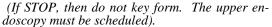
Instructions: This form should be completed using the available reports of the upper gastrointestinal endoscopy procedure. Upper gastrointestinal (upper GI) and Endoscopy with Ultrasound (EUS) reports may be used if all of the required components of the EGD are available. Attach a copy of the available 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.



B. Upper endoscopy information

8. Date of upper endoscopy:





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 (<i>specify</i>):	(₁)

specify

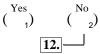
C. Endoscopic findings

10. Normal stomach: Yes	s (^N	° 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 gastric surgery (<i>specify</i>):	any (1)

specify

D. Other comments

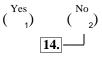
11. Other comments concerning upper endoscopy procedure or results:



a. Specify:

F. Eligibility check

12. Is this a screening visit:



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:

$$\underbrace{(\overset{\mathrm{Yes}}{\underset{1}{\overset{1}{\overset{1}}}}}_{1}) \qquad (\overset{\mathrm{No}}{\underset{2}{\overset{2}{\overset{1}{\overset{1}}}}})$$

*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	ye	ar
5. Visit code:	f		
6. Form & revision:	f	h_	_1_
7. Study:	GLUMI	T-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.	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 <i>(hormonal abnormality):</i>	(1)		
	i. Major depression:	(1)		
	j. Advanced liver disease:	(1)		
	k. Peptic ulcer disease:	(1)		
	I. 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)		

 $\binom{\text{Yes}}{*}$

No 2)

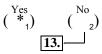
x. Migraine headaches:	(1)
y. Hypertension:	(1)
z. Coronary artery disease:	(1)
aa. Cerebrovascular disease:	(1)
ab. Hyperlipidemia <i>(high cholesterol, high triglycerides):</i>	(1)
ac. Pancreatitis:	(1)
ad. Cholelithiasis:	(1)
ae. Gall bladder disease including chronic cholecystitis, gall bladder dyskinesia:	(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:

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:



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) 1) **b.** Acetohexamide (Dymelor): 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) 1) k. Pioglitazone (Actos): I. Repaglinide (Prandin): ₁) m. Rosiglitazone (Avandia): ₁) **n.** Saxagliptin (Onglyza): ₁) o. Sitagliptin (Januvia): 1) p. Tolazamide (Tolinase): ₁) (1) q. Tolbutamide (Orinase): (**r.** Other (specify): ₁)

specify

specify

 $\begin{pmatrix} 1 \end{pmatrix}$

s. None of the above:

- 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)16. (If yes, check all that apply): a. Antacids, (specify): 1) specify **b.** Cimetidine (Tagamet): _) 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: $\begin{pmatrix} Yes \\ (\end{pmatrix}$

	(1)		(2)
			17.		J
(If yes, check all that apply)					
a. Azithromycin (Zithromax):				(1)
b. Bethanechol (Duvoid, Urech	olin	e):		(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

 $\binom{No}{}$

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

$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix}$	(No 2)
11	8. —	<u>ן</u>
(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 <i>(specify):</i>	(1)

E. Administrative information

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

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

(If yes, specify):

a. Medication/supplement #1:

specify

b. Medication/supplement #2:

specify

c. Medication/supplement #3:

specify

d. Medication/supplement #4:

specify

specify

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

Yes
(1)No
(2)19.19.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) j. Other tricyclic antidepressants (specify): (1)

22. Clinical Coordinator PIN:

- 23. Clinical Coordinator signature:
- **24.** Date form reviewed:

20. Study Physician PIN:

21. Study Physician signature:



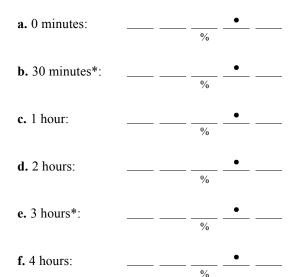
specify

GL

scintigraphy. If <i>w</i> is reached for any item then ST	s form using the report generated by the gastric emptying OP filling out form and do not data enter the form. If c o determine eligibility status. Information not included in the form the test if possible
A. Identifying information	11. Meal given for test:
	Egg Beaters: (
1. Center ID:	_ Generic low-fat egg whites: (
2. Patient ID:	- Other (specify)
3. Patient code:	
	specify
4. Date of form:	*Caution: Test may have to be repeated dependi on the meal.
day mon year	 12. Amount of meal and water consumed
5. Visit code	- a. Meal (check only one):
If report not associated with a visit, fill in "n."	100%
5 · F	90%
6. Form & revision: <u>g</u> <u>e</u> <u>1</u>	- 75% (
	50%
7. Study: GLUMIT-DG 3	33%
	25%
B. Gastric Emptying Scintigraphy Test	10%
b. Gastric Emptying Schugraphy Test	0%
8. Date of gastric emptying scintigraphy:	
	Unknown (
day mon year	b. Water (check only one):
	100% (
9. Is this a screening visit:	90%
$\begin{pmatrix} Yes \\ 1 \end{pmatrix}$ $\begin{pmatrix} No \\ 2 \end{pmatrix}$	75%
	50% (
11.	33%
10 In this data within 10 months of	25% (
10. Is this date within 12 months of	10% (
registration:	0% (
	2) 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.)



*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:

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):



D. Data Coordinating Center use18. Study Physician PIN: _____

- 19. Study Physician signature:
- **20.** Clinical Coordinator PIN:
- **21.** Clinical Coordinator signature:
- 22. Date reviewed:

day mon year

15. Comments on the gastric emptying scintigraphy:

C. Eligibility check

16. Is this a screening visit:

 $\binom{\text{Yes}}{1}$ 18.

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.

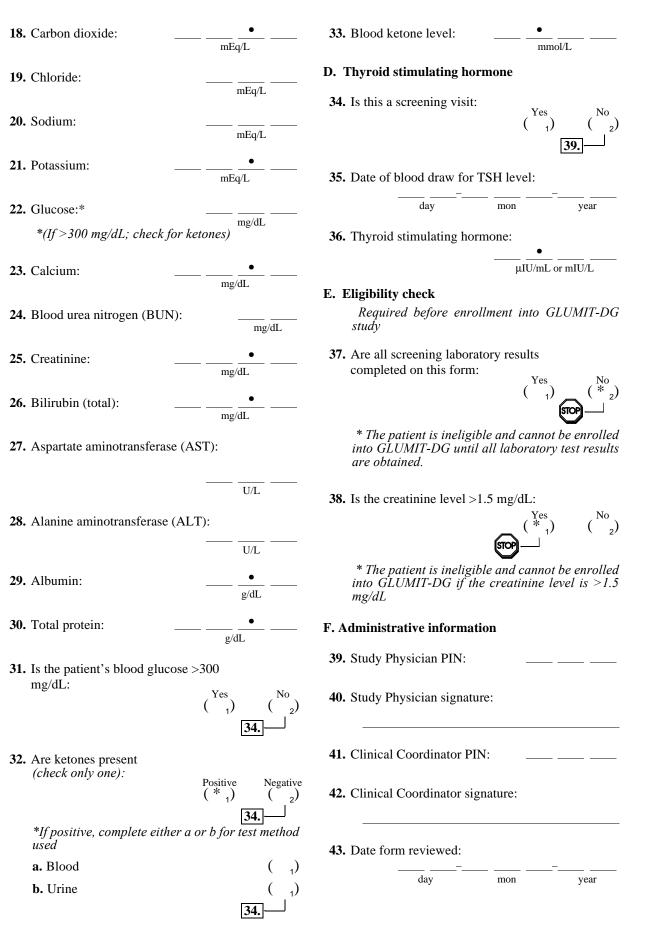
Instructions: Laboratory test results may be obtained from chart review. Complete tests as needed (repeat test if test results are not within the required time window). The window for each test is specified next to the date of blood draw. Use a calculator if you need to convert units to match the units specified on this form. Please note that the units 10³ cells/mL, 1000 cells/mL, and 10⁹ cells/L are equivalent. Call the DCC if you have a question about conversion or how to record a value. If 💬 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.

ple the report to the back of this form.	
A. Center, patient, and visit identification	10. Is hemoglobin A1c greater than or equal to 8.0%:
1. Center ID:	
2. Patient ID:	* The patient is ineligible and cannot be enrolled into GLUMIT-DG if hemoglobin A1c is less than 8.0%.
3. Patient code:	0.070.
4. Date of visit (date form was initiated):	11. Date of blood draw for complete blood count:
day mon year	day mon year
5. Visit code:	Date must be within 16 weeks of registration, or in the time window for the 12 week and 24 week follow-up visit.
6. Form & revision: $1 r 1$	12. Hemoglobin: $\underline{\qquad} \underbrace{\qquad}_{g/dL} \underline{\qquad} \underbrace{\qquad}_{g/dL}$
7. Study:GLUMIT-DG 3	13. Hematocrit:
B. Hematology	
Required at screening, f12, and f24	14. Red blood cell count:
8. Date of blood draw for hemoglogin A1c:	$\frac{\bullet}{10^6} \text{ cells/ } \mu \text{L (million cells/ } \mu \text{L)}$
day mon year	15. White blood cell count:
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	$\frac{\bullet}{10^3 \text{ cells/} \mu \text{L or } 10^9 \text{ cells/L}}$
visit window.	16. Platelet count:,,,
9. Hemoglobin A1c:	
%	C. Metabolic panel
a. Is this a screening visit:	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

follow-up visit.

in the time window for the 12 week and 24 week

Patient ID: _



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 i	dentification	11. Respiratory rate:	breaths/minute
1. Center ID:		C. Measurements	breatils/ fillitute
2. Patient ID:		12. Height (shoes off)	
		a. Height:	•
3. Patient code:		b. Units:	
		Inches	()
4. Visit date:		Centimeters	$\begin{pmatrix} & \\ & 2 \end{pmatrix}$
day	mon year	13. Weight (shoes off)	
5. Visit code:		a. Weight:	•
		b. Units:	
6. Form & revision:	<u>p e 1</u>	Pounds	()
7. Study:	GLUMIT-DG <u>3</u>	Kilograms	(₂)
B. Vital status		14. Waist (standing, at midpoint bet of iliac crest and lowest part of	ween highest point `costal margin)
8. Temperature (oral)		a. Circumference:	•
I man (I my		b. Units:	
a. Degrees:	•	Inches	()
		Centimeters	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
b. Scale:			
Fahrenheit	$\begin{pmatrix} & & \\ & & \end{pmatrix}$	15. Hip circumference (<i>standing</i> , <i>at hips</i>)	fullest part of the
Centigrade	(₂)	a. Circumference:	•
9. Blood pressure <i>(sitting)</i>			
st Brood pressure (straing)		b. Units: Inches	()
a. Systolic:	mmHg	Centimeters	$\begin{pmatrix} & 1 \end{pmatrix}$
	mmHg		× 2/
b. Diastolic:	mmHg		
10. Resting radial pulse:	beats/minute		

22. Abdomen abnormality *(check all that apply)* **D.** Examination findings 16. Chest and lungs: ₁) **a.** Distention: (Normal 1) (**b.** Tympany: 1) (17. c. Succussion splash: 1) Abnormal **d.** Tenderness: 1) e. Organomegaly: 1) specify f. Other (specify): ,) 17. Oropharynx: specify Normal 18. 23. Liver and spleen: Abnormal Normal specify Abnormal 18. Trachea: specify Normal 24. Nervous system: Abnormal Not performed specify Normal 19. Thyroid: Abnormal Normal 1) (20. specify Abnormal 25. Pupil reflexes: specify Normal 1) (**20.** Heart: 26. Abnormal 1) Normal (21 specify Abnormal **26.** Eye fundus: specify Normal 1) **21.** Abdomen: 27 Abnormal 1) Normal specify Abnormal

27. Extraocular movements: E. Electrocardiogram and autonomic function assessment Normal ₁) ((Required during screening and at follow-up visits f12 and f24) Abnormal 32. Date electrocardiogram obtained: specify day mon year **28.** Dentition (appearance of teeth): **33.** Is normal sinus rhythm present: ₁) Normal Yes No ₁) 2) Abnormal a. Resting heart rate: specify beats/minute **b.** Systolic blood pressure: 29. Lymph nodes: Normal ₁) mmHg 30. c. Diastolic blood pressure: Abnormal mmHg d. R-R interval: specify milliseconds **30.** Extremities: Is edema present: **34.** Paced breathing (have the patient take regular, deep breaths at a rate of 5-6 breaths per minute): Yes ₁) No **a.** Heart rate: beats/minute specify **b.** Systolic blood pressure: **31.** Other abnormalities noted: mmHg Yes c. Diastolic blood pressure: mmHg d. R-R interval: specify other abnormalities

milliseconds

			Patient ID):
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:		G. Administrative inform40. Study Physician PIN:		
		41. Study Physician signa	iture:	
	beats/minute			
b. Systolic blood pressure:	mmHg	42. Clinical Coordinator I	PIN:	
c. Diastolic blood pressure:		43. Clinical Coordinator s	signature:	
d. R-R interval:	mmHg			
(allow the patient to brea	milliseconds	44. Date form reviewed:		
e. Heart rate after Valsalva n	• /	day	mon	year
	beats/minute			
f. Systolic blood pressure:				
	mmHg			
g. Diastolic blood pressure:				
h. R-R interval:	mmHg			
	milliseconds			
F. Neuropathy foot exam Complete the Neuropathy F on pages 5 and 6 before com	Foot Exam worksheet pleting 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 neuropa made:	thy been			
Yes	(₁)			
No	(₂)			
Unable to determine	(3)			

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	Ri	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): ____.

GLUMIT-DG

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

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 identifica	tion	C. Measurements	
1. Center ID:		12. Height (shoes off)	
		a. Height:	•
2. Patient ID:		b. Units:	
		Inches	()
3. Patient code:		Centimeters	(₂)
4. Visit date:		13. Weight (shoes off)	
day	year	a. Weight:	•
	year	b. Units:	
5. Visit code:		Pounds	(₁)
		Kilograms	(₂)
6. Form & revision:p	<u>e</u> 2	14. Waist (standing, at midpoint be	tween highest point
		of iliac crest and lowest part of	f costal margin)
7. Study: GLUMI	T-DG <u>3</u>		•
B. Vital status		a. Circumference:	
		b. Units:	
8. Temperature (oral)		Inches	$\begin{pmatrix} & 1 \end{pmatrix}$
	•	Centimeters	(₂)
a. Degrees:		15. Hip circumference (standing, a	nt fullest part of the
b. Scale:		hips)	
Fahrenheit	(₁)	a. Circumference:	•
Centigrade	$\begin{pmatrix} & \\ & 2 \end{pmatrix}$	b. Units:	
		Inches	(₁)
9. Blood pressure <i>(sitting)</i>		Centimeters	(₂)
a. Systolic:			
	mmHg		
b. Diastolic:			
	mmHg		
10. Resting radial pulse:			
	beats/minute		
11. Respiratory rate:			
	breaths/minute		GLU
			GLU

Patient ID: ____ ___

D. Examination findings	22. Abdomen abnormality <i>(check all that apply)</i>	
16. Chest and lungs:	a. Distention:	()
Normal (1)	b. Tympany:	$\begin{pmatrix} 1 \\ -1 \end{pmatrix}$
[17.]	c. Succussion splash:	$\begin{pmatrix} 1 \\ -1 \end{pmatrix}$
Abnormal (2)	d. Tenderness:	$\begin{pmatrix} 1 \\ 1 \end{pmatrix}$
	e. Organomegaly:	$\begin{pmatrix} & 1 \end{pmatrix}$
specify	f. Other <i>(specify):</i>	$\begin{pmatrix} & 1 \end{pmatrix}$
17. Oropharynx:	i oner (specify).	(1)
Normal ()	specify	
Abnormal (2)	23. Liver and spleen:	
	Normal	()
specify	Abnormal	
18. Trachea:	Abhormar	(2)
Normal (1)	specify	
[19.]		
Abnormal (₂)	24. Nervous system:	
	Not performed	()
specify	Nerveral	25.
19. Thyroid:	Normal	
Normal (1)	Abnormal	
		2/
Abnormal (2)	specify	
	25 D - 1 - 0	
specify	25. Pupil reflexes:	
20. Heart:	Normal	
Normal (1)	Abnormal	
		~ 2/
Abnormal (2)	specify	
	26 Even from duras	
specify	26. Eye fundus:	
21. Abdomen:	Normal	
Normal (1)	Abnormal	<u>[27.]</u>
		× 2/
Abnormal	specify	

year

beats/minute

mmHg

mmHg

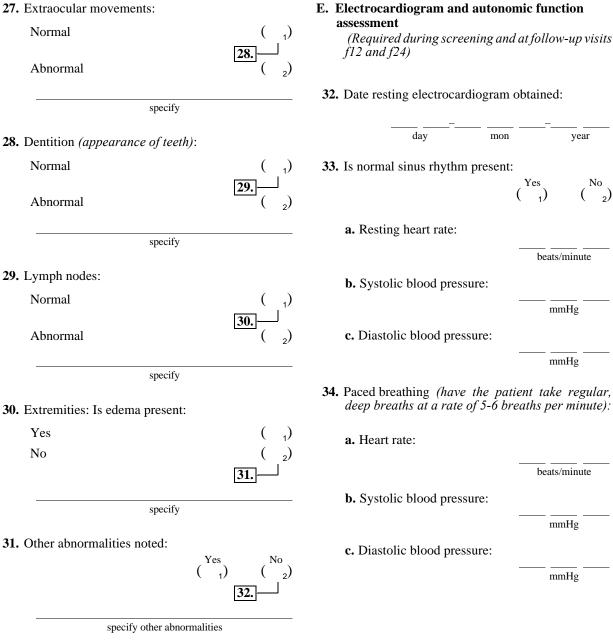
beats/minute

mmHg

mmHg

No

27. Extraocular movements:



Patient ID: _____ ____

_ ___ _

G. Administrative information

40. Study Physician PIN:

- **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:

a. Pastest heart fate during the valsarva.		41. Study Physician signature:		
	beats/minute			
b. Systolic blood pressure:				
	mmHg	42. Clinical Coordinator	PIN:	
c. Diastolic blood pressure:		43. Clinical Coordinator	signature:	
	mmHg			
(allow the patient to brea	athe normally)			
d. Heart rate after Valsalva	maneuver:	44. Date form reviewed:		
	beats/minute	day	mon	year
e. Systolic blood pressure:		-		2
	mmHg			
f. Diastolic blood pressure:				
	mmHg			
F. Neuropathy foot exam Complete the Neuropathy I on pages 5 and 6 before con	Foot Exam worksheet npleting 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 neuropa made:	athy been			
Yes	(₁)			
No	(₂)			
Unable to determine	(3)			

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): ____.

GLUMIT-DG

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

- 3. Patient code
- 4. Visit date:

day	mon year
5. Visit code:	_S
6. Form & revision:	<u>r g 1</u>
7. Study:	GLUMIT-DG 3

B. Consent

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



Patient must sign the consent prior to continuing with screening.

9. Has the consentor or study physician signed the consent form:



C. Information about patient

10. Date of birth:

daymonthyearRecord 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: 13. Gender: Male Female 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: 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 Did not complete high school Completed high school
 - Completed high school(2)Some college or post high schooleducation or trainingBachelor's degree or higher(4)

Patient ID: _____

D. Previous registration in a GpCRC study

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

- **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):



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.

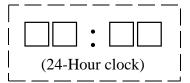
A. Clinic, visit, and patient identification

1. Center ID: 2. Patient ID: **3.** Patient code: **4.** Date of form: dav mon vear 5. Visit code: (If report not associated with a visit, fill in "n".) **6.** Form & revision: <u>s t 1</u> GLUMIT-DG 3 7. Study: 8. Has the patient fasted since midnight: Yes No (1) $(*_2)$ * Patient must be fasting; test must be re-scheduled. **8a.** Is the patient's blood glucose level <270 mg/dL: Yes No (1) $(*_2)$

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

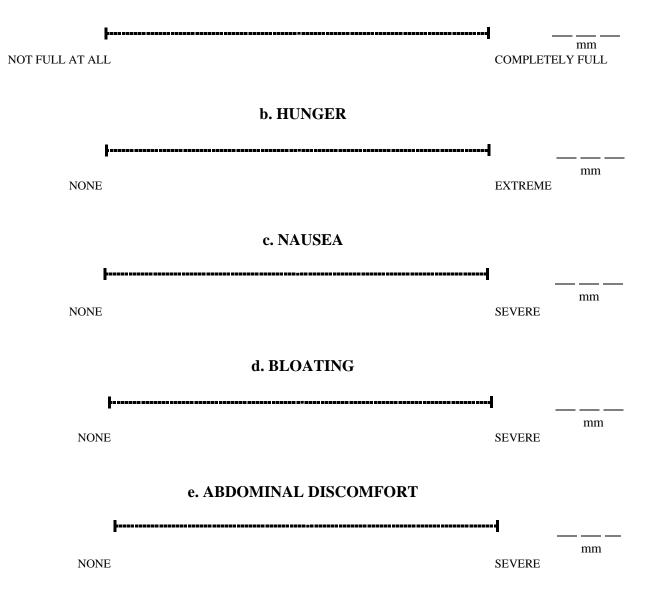
B. Baseline Symptom Scores

9. BASELINE SYMPTOMS - - at the START of the 15 minute baseline EGG recording



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



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.

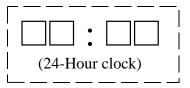
After each cup, record amount ingested, wait 15 seconds, then ask the subject to rate their feeling of fullness on a 0, 1, 2, 3, 4, 5 scale. 0 = not full at all and 5 is completely full. The satiety test ends when the patient is completely full.

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 Sa	atiety Test Ended:	:	12. Total Ensure Volume Consumed:	
		(24-hour)		mL

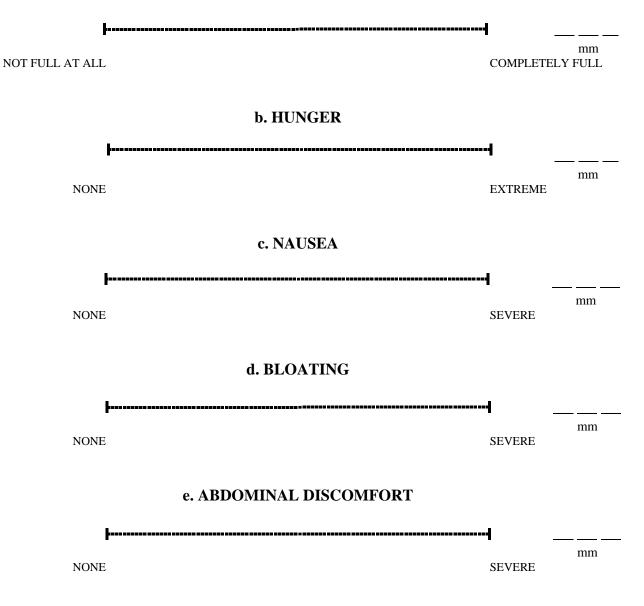
D. Post prandial Symptom Scores

13. SYMPTOMS -- 10 minutes AFTER finishing Ensure®

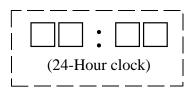


Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

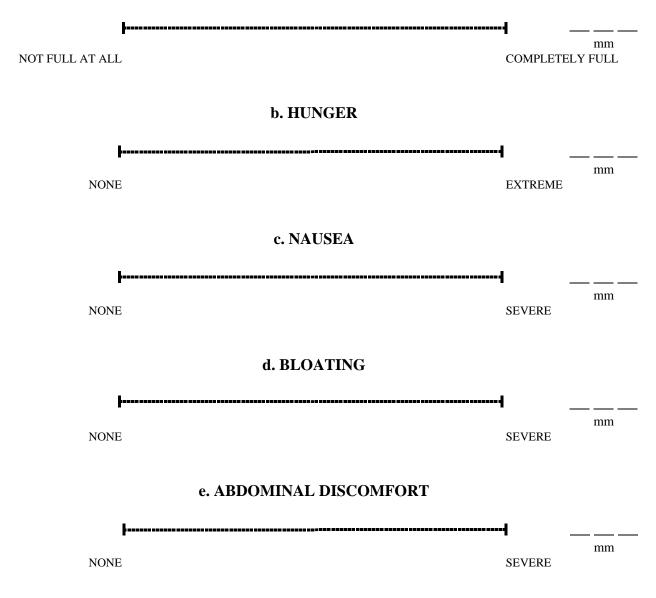
a. STOMACH FULLNESS



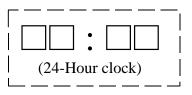
14. SYMPTOMS -- 20 MINUTES AFTER finishing Ensure®

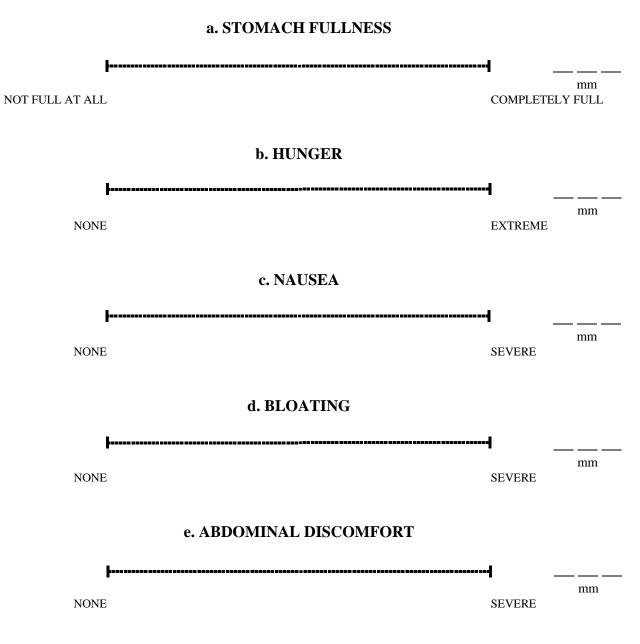




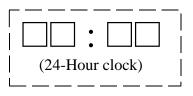


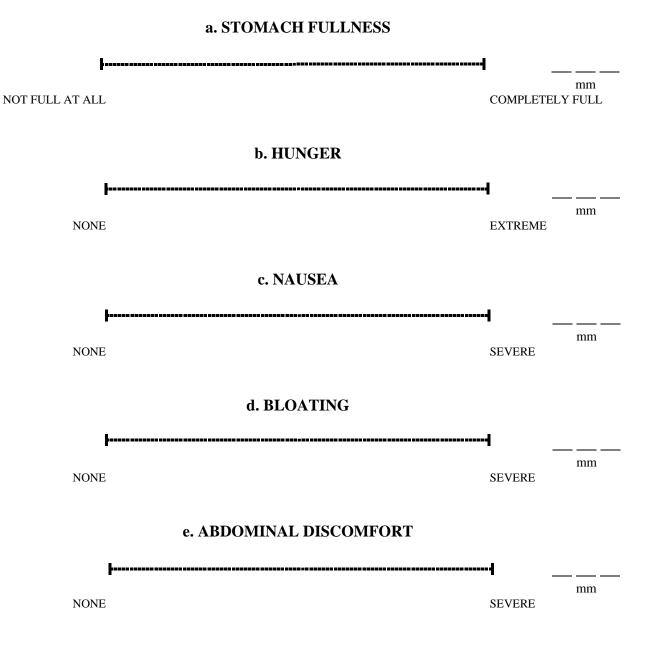
15. SYMPTOMS -- 30 MINUTES AFTER finishing Ensure®





16. SYMPTOMS -- 60 MINUTES AFTER finishing Ensure®





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. %	0%	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	0	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+	0. 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

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. %	0%	p. %
31-40 post:	q. %	r %	s. %	t. %
41-50 post:	u. %	v. %	w. %	X. %
51-60 post:	y. %	Z. %	aa %	ab %

29. Percentage of time with the dominant EGG frequencies in the four frequency ranges:

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 <u>USB flash drive</u>.

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 <u>3</u>
- **8.** Has the patient fasted since midnight:

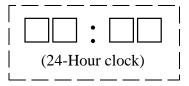
Yes No
$$(1)$$
 $(*_2)$
Stop \checkmark

- * Patient must be fasting; test must be rescheduled.
- **9.** Is the patient's blood glucose level <270 mg/dL:

Yes No
$$(1)$$
 (1)

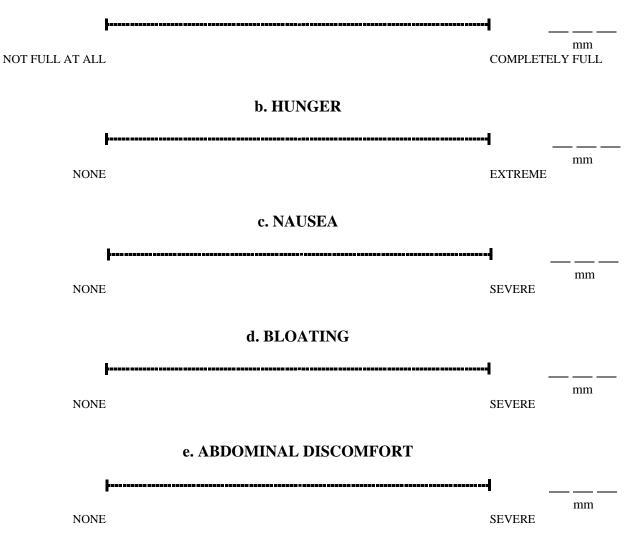
* Glucose must be less than 270 mg/dL; test must be rescheduled.

10. BASELINE SYMPTOMS - - at the START of the 15 minute baseline EGG recording



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



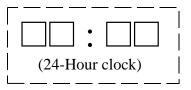
C. NON-CALORIC WATER LOAD SATIETY TEST VOLUME

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.

13. Total Volume of Water Consumed: $\underline{\qquad}_{mL}$

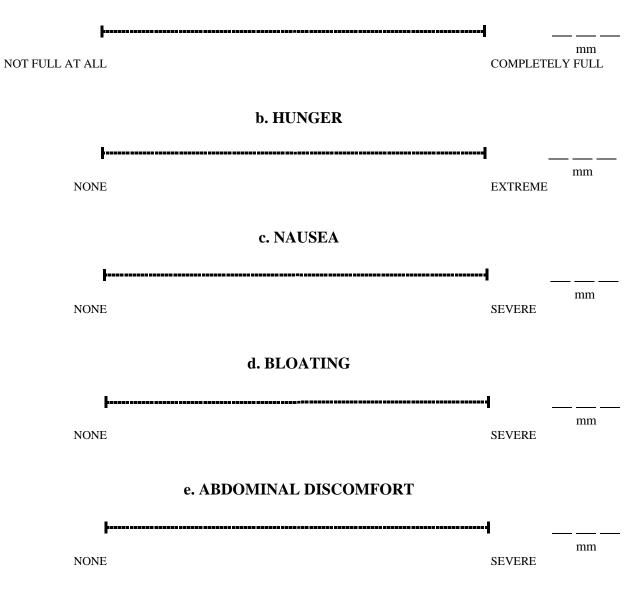
D. Post Water Load Satiety Symptom Scores

14. SYMPTOMS -- 10 minutes AFTER finishing water

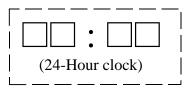


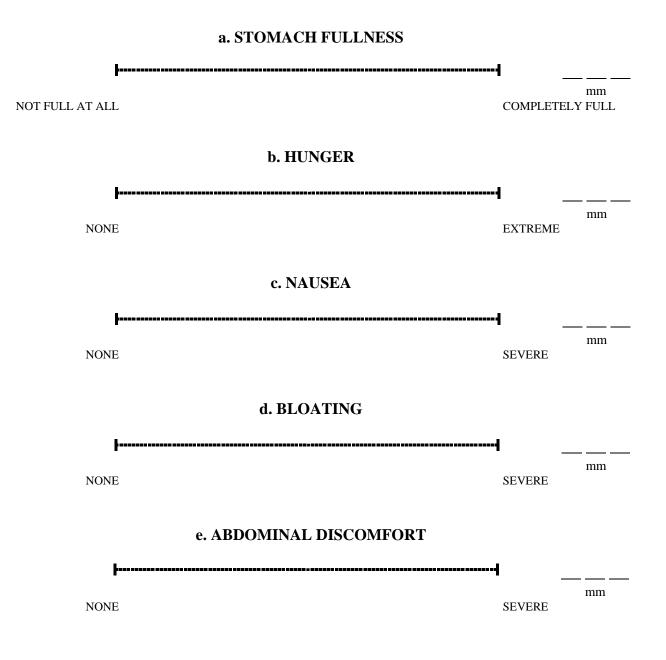
Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

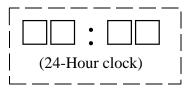


15. SYMPTOMS -- 20 MINUTES AFTER finishing water





16. SYMPTOMS -- 30 MINUTES AFTER finishing water (At end of EGG)



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	mm 7 FULL
	b. HUNGER		
NONE		EXTREME	mm
L	c. NAUSEA		
NONE		SEVERE	 mm
	d. BLOATING		
NONE		SEVERE	 mm
	e. ABDOMINAL DISCOMFORT		
NONE		SEVERE	mm

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 satiet	ty: i.	%	j. %	k. %	l%
21-30 post satiet	ty: m	_ %	6 n. %	0. %	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+	ge+	h. e+
11-20 post satiet	y: i. e+	j.	k e+	le+
21-30 post satiet	y: m. e+	e+	0. 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. %	0. %	p. %

G. Administrative information

27. Study Physician PIN:

28. Study Physician signature:

29. Clinical Coordinator PIN:

30. Clinical Coordinator signature:

31. Date form reviewed:

