



DataFax #001

Plate 001

Visit 000

Patient ID Patient Initials Prescreen Date
 Hospital Patient F M L month day year

Age: years Sex: male female

Race: White Not Hispanic Black Not Hispanic Hispanic
 Asian or Pacific Islander American Indian or Alaskan Native Other

Source of Patient: Hospital Survey Physician Referral Other (list) _____

FAILURE CHECKOFF: Using the information you have available now, mark if you know that patient FAILS for any of the following reasons (STOP at FIRST FAIL).

<input type="checkbox"/> EF too high - list EF: <input type="text"/> <input type="text"/> %	<input type="checkbox"/> MI in the past 6 months
<input type="checkbox"/> Class I or II NYHA - mark: <input type="checkbox"/> I <input type="checkbox"/> II	<input type="checkbox"/> Unstable angina
<input type="checkbox"/> Cardiac surgery /procedure within last 60 days, or anticipated (list) _____	<input type="checkbox"/> Age < 18 years
<input type="checkbox"/> Comorbid disease (list) _____	<input type="checkbox"/> Listed for cardiac transplant or will be listed within 6 months
<input type="checkbox"/> Pregnant or no reliable contraception	<input type="checkbox"/> Not on optimal therapy
<input type="checkbox"/> Excluded etiology for CHF (list) _____	<input type="checkbox"/> High grade AV block
<input type="checkbox"/> Excluded meds (list) _____	<input type="checkbox"/> Life threatening disease (list) _____
<input type="checkbox"/> Contra-indication to beta-blockers (list) _____	<input type="checkbox"/> Other Disqualification (list) _____

BASED ON THE ABOVE, CHOOSE ONE:

Disqualify patient Contact Physician and Patient for screening Review Patient in _____ days

Use other side for Identifiers, including Name, Address, Tel #, Spouse, etc.



7 id	8 init	9 vdate
10 ppage	11 psex	
12 pcrace		
13 pcsource	14 s_other	
15 pcef	16 pcef_per	17 pcmihx
18 pnyha	19 pcclass	20 pcangina
21 pproc60	22 lsturg	23 pc18yrs
24 pccomorb	25 lstcomor	26 pctransp
27 pcpregnt		28 pcnottx
29 pcetchf	30 lsetiol	31 pcavblk
32 pcxmeds	33 lstexmed	34 pcthdis
36 pccontra	37 lstcontr	35 lstthrt
38 pcodisq	39 lstother	
40 pcoutcom	41 review	
		42 staff

PCSF Dataset, Plate 1
 Preliminary Contact Screening (Prescreening)

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
visit	Visit Number	= 0
* vdays	Number of days to visit, from Baseline	<= 0
* race4	Patient race (in 4 groups)	1=white, 2=black, 3=hispanic, 4=other
pcage	Patient age in years	18+
pcsex	Patient sex	1=male, 2=female
pcsource	Source of patient	1=Hospital survey, 2=Physician referral, 3=other
s_other	Source other	
pcef	EF too high	yes=present, no=absent
pcef_per	EF percentage	
pcmihx	MI in past 6 months	yes=present, no=absent
pcnyha	Class I or II NYHA	yes=present, no=absent
pcclass	Class I or II	1=Class I, 2=Class II
pcangina	Unstable angina	yes=present, no=absent
pcproc60	Cardiac proc in 60 days	yes=present, no=absent
lsturg	List surgery/procedure	
pc18yrs	Age less than 18 years	yes=present, no=absent
pccomorb	Comorbid disease	yes=present, no=absent
lstcomor	List comorbid disease	
pctransp	Transplant in 6 months	yes=present, no=absent
pcpregnt	Pregnant/no contraception	yes=present, no=absent
pcnottx	Not on optimal therapy	yes=present, no=absent
pcetchf	Excluded etiology for CHF	yes=present, no=absent
lsetiol	List excluded etiology	
pcavblk	High grade AV block	yes=present, no=absent
pcxmeds	Excluded medications	yes=present, no=absent
lstexmed	List excluded meds.	

* Recoded/new variable, per patient confidentiality guidelines.

PCSF Dataset, Plate 1
Preliminary Contact Screening (Prescreening)

Variable Name	Description	Coding
pcthdisc	Life threatening disease	yes=present, no=absent
lstthrt	List life threatening	
pccontra	Contraindication Beta-Blk	yes=present, no=absent
lstcontr	List contraindication	
pcodisq	Other disqualification	yes=present, no=absent
lstother	List other disqualification	
pcoutcom	PCSF screening outcome	1=disqualify, 2=contact physician, 3=review patient
review	Review pt. no. days	

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 002

Visit Number

Patient ID
Hospital Patient

Patient Initials
F M L

Visit Date
month day year

Please choose one box for each question, and mark each choice with an "X".

- | | | | | | | | | | | | |
|--|--|---|---|---|---|---|---|---|---|---|----|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|--|--|---|---|---|---|---|---|---|---|---|----|
- On a scale from 1-10 (1 being WORST) how would you characterize your well-being right now compared to 3-4 months ago?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<i>much worse</i>		<i>a little worse</i>		<i>same as before</i>		<i>a little better</i>		<i>much better</i>		
 - Walking on level ground, do you get short of breath when you go: (average block = 100 yards):

<input type="checkbox"/>	<i>more than 5 blocks</i>	<input type="checkbox"/>	<i>up to 5 blocks</i>	<input type="checkbox"/>	<i>1-2 blocks</i>	<input type="checkbox"/>	<i>less than 1 block</i>
--------------------------	---------------------------	--------------------------	-----------------------	--------------------------	-------------------	--------------------------	--------------------------
 - Walking on level ground, do you become fatigued after:

<input type="checkbox"/>	<i>more than 5 blocks</i>	<input type="checkbox"/>	<i>up to 5 blocks</i>	<input type="checkbox"/>	<i>1-2 blocks</i>	<input type="checkbox"/>	<i>less than 1 block</i>
--------------------------	---------------------------	--------------------------	-----------------------	--------------------------	-------------------	--------------------------	--------------------------
 - Do you characterize your walking as:

<input type="checkbox"/>	<i>brisk</i>	<input type="checkbox"/>	<i>normal</i>	<input type="checkbox"/>	<i>slow</i>
--------------------------	--------------	--------------------------	---------------	--------------------------	-------------
 - How many flights of stairs can you comfortably climb?

<input type="checkbox"/>	<i>more than 2</i>	<input type="checkbox"/>	<i>2</i>	<input type="checkbox"/>	<i>1</i>	<input type="checkbox"/>	<i>less than 1</i>
--------------------------	--------------------	--------------------------	----------	--------------------------	----------	--------------------------	--------------------
 - Can you do housework?

<input type="checkbox"/>	<i>heavy (moving furniture)</i>	<input type="checkbox"/>	<i>medium (vacuuming)</i>	<input type="checkbox"/>	<i>light (dusting)</i>	<input type="checkbox"/>	<i>none</i>
--------------------------	---------------------------------	--------------------------	---------------------------	--------------------------	------------------------	--------------------------	-------------
 - Can you do occupational work?

<input type="checkbox"/>	<i>normal pace</i>	<input type="checkbox"/>	<i>reduced pace</i>	<input type="checkbox"/>	<i>had to change job</i>	<input type="checkbox"/>	<i>had to stop</i>
--------------------------	--------------------	--------------------------	---------------------	--------------------------	--------------------------	--------------------------	--------------------
 - Can you engage in recreational activities?

<input type="checkbox"/>	<i>normal pace</i>	<input type="checkbox"/>	<i>reduced pace</i>	<input type="checkbox"/>	<i>had to change activities</i>	<input type="checkbox"/>	<i>had to stop</i>
--------------------------	--------------------	--------------------------	---------------------	--------------------------	---------------------------------	--------------------------	--------------------
 - Are you unable/or do you find it difficult to do grocery shopping (including carrying packages)?

<input type="checkbox"/>	<i>yes</i>	<input type="checkbox"/>	<i>no</i>
--------------------------	------------	--------------------------	-----------
 - Are you short of breath when you are at rest (e.g. in a chair or on the sofa or bed)?.....

<input type="checkbox"/>	<i>yes</i>	<input type="checkbox"/>	<i>no</i>
--------------------------	------------	--------------------------	-----------
 - Do you awaken during the night because of shortness of breath?

<input type="checkbox"/>	<i>yes</i>	<input type="checkbox"/>	<i>no</i>
--------------------------	------------	--------------------------	-----------
 - To avoid shortness of breath in bed, do you need to sleep propped up on 3 or more pillows, or do you spend part of the night out of bed in a chair?

<input type="checkbox"/>	<i>yes</i>	<input type="checkbox"/>	<i>no</i>
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 - In the last 3-4 months, what changes have you noticed in your ability to exercise?

<input type="checkbox"/>	<i>improved</i>	<input type="checkbox"/>	<i>no change</i>	<input type="checkbox"/>	<i>deteriorated</i>
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Please go on to the second page!

QOL_1 Dataset, Plate 2
 Quality of Life Questionnaire, pg 1 (San Diego Heart Failure)

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
qo_1	Q1: On a scale from 1-10, current well-being compared to 3-4 months ago	1=much worse, [2-4], 5=same as before, [6-9], 10=much better
qo_2	Q2: Walking on level ground, SOB after:	1=more than 5 blocks, 2=up to 5 blocks, 3=1-2 blocks, 4=less than 1 block
qo_3	Q3: Walking on level ground, fatigue after:	1=more than 5 blocks, 2=up to 5 blocks, 3=1-2 blocks, 4=less than 1 block
qo_4	Q4: Do you characterize your walking as:	1=brisk, 2=normal, 3=slow
qo_5	Q5: How many flights of stairs can you comfortably climb?	1=more than 2, 2=two, 3=one, 4=less than 1
qo_6	Q6: Can you do housework?	1=heavy, 2=medium, 3=light, 4=none
qo_7	Q7: Can you do occupational work?	1=normal pace, 2=reduced pace, 3=had to change job, 4=had to stop
qo_8	Q8: Can you engage in recreational activities?	1=normal pace, 2=reduced pace, 3=had to change activities, 4=had to stop
qo_9	Q9: Are you unable/or do you find it difficult to do grocery shopping?	1=yes, 2=no
qo_10	Q10: Do you have SOB at rest?	1=yes, 2=no
qo_11	Q11: Do you awaken during night due to SOB?	1=yes, 2=no
qo_12	Q12: To avoid SOB in bed, do you sleep propped on 3+ pillows, or spend part of the night in a chair?	1=yes, 2=no
qo_13	Q13: In the last 3-4 months, what changes have you noticed in your in exercise ability?	1=improved, 2=no change, 3=deteriorated

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 003

Visit Number

Patient ID
 Hospital Patient

Patient Initials
 F M L

Visit Date
 month day year

These questions concern how your heart failure (heart condition) has prevented you from living as you wanted during the last month. These items listed below describe different ways some people are affected. If you are sure an item does not apply to you or is not related to your heart failure, then put an X in the box marked 0, (No) and go on to the next item. If an item does apply to you, then put an X in the box with the the number rating of how much it prevented you from living as you wanted. Remember to think about **ONLY THE LAST MONTH.**

Did your heart failure prevent you from living as you wanted during the last month by

	<i>no</i>	<i>very little</i>				<i>very much</i>
1. causing swelling in your ankles, legs, etc?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
2. making your working around the house or yard difficult?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
3. making your relating to or doing things with your friends or family difficult?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4. making you sit or lie down to rest during the day?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
5. making you tired, fatigued, or low on energy?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6. making your working to earn a living difficult?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
7. making your walking about or climbing stairs difficult?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
8. making you short of breath?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
9. making your sleeping well at night difficult?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
10. making you eat less of the foods you like?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
11. making your going places away from home difficult?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
12. making your sexual activities difficult?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Please go on to the third page!



QOL_2 Dataset, Plate 3

Quality of Life Questionnaire, pg 2 (Minnesota Living with Heart Failure, pg. 1)

[All questions ask "Did your heart failure prevent you from living as you wanted during the last month by:]

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
ql_1	Q1: Causing swelling in ankles, legs etc.?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_2	Q2: Making your working around the house or yard difficult?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_3	Q3: Making your relating to or doing things with friends/family difficult?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_4	Q4: Making you sit or lie down to rest during the day?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_5	Q5: Making you tired, fatigued?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_6	Q6: Making your working to earn a living difficult?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_7	Q7: Making your walking about or climbing stairs difficult?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_8	Q8: Making you short of breath?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_9	Q9: Making it difficult to sleep well at night?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_10	Q10: Making you eat less?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_11	Q11: Making your going places away from home difficult?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_12	Q12: Making your sexual activities difficult?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 004

Visit Number

Patient ID
Hospital Patient

Patient Initials
F M L

Visit Date
month day year

Did your heart failure prevent you from living as you wanted during the last month by

	<i>no</i>	<i>very little</i>				<i>very much</i>
13. making your recreational pastimes, sports, or hobbies difficult?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
14. making it difficult for you to concentrate or remember things?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
15. giving you side effects from medication?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
16. making you worry?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
17. making you feel depressed?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
18. costing you money for medical care?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
19. making you feel a loss of self-control in your life?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
20. making you stay in a hospital?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
21. making you feel you are a burden to your family and friends?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5



QOL_3 Dataset, Plate 4

Quality of Life Questionnaire, pg 3 (Minnesota Living with Heart Failure, pg. 2)

[All questions ask "Did your heart failure prevent you from living as you wanted during the last month by:]

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
ql_13	Q13: Making your recreational pastimes difficult?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_14	Q14: Making it difficult to concentrate or remember things?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_15	Q15: Giving you side effects from medication?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_16	Q16: Making you worry?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_17	Q17: Making you feel depressed?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_18	Q18: Costing you money for medical care?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_19	Q19: Making you feel a loss of self-control in life?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_20	Q20: Making you stay in a hospital?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much
ql_21	Q21: Making you feel you are a burden to your family/friends?	1=no, 2=very little, 3=3, 4=4, 5=5, 6=very much

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 005

Visit Number

Three empty boxes for visit number

Patient ID

Three empty boxes for hospital ID

Hospital

Three empty boxes for patient ID

Patient

Patient Initials

Three empty boxes for initials (F, M, L)

F M L

Visit Date

Two empty boxes for month

month

Two empty boxes for day

day

Two empty boxes for year

year

1. Vital Signs:

Heart Rate (sitting):

Three empty boxes for heart rate

beats per minute

Blood Pressure (sitting):

Three empty boxes for systolic

systolic

Three empty boxes for diastolic

diastolic

mm Hg

Weight:

Three empty boxes for weight

pounds

Height (first visit only):

Two empty boxes for height

inches

2. Cardiovascular Exam

S3 gallop:

Yes checkbox

yes

No checkbox

no

S4 gallop:

Yes checkbox

yes

No checkbox

no

Systolic murmur:

Yes checkbox

yes

No checkbox

no

Diastolic murmur:

Yes checkbox

yes

No checkbox

no

JVD at 30°:

Not present checkbox

not present

Base of neck checkbox

base of neck

Halfway up checkbox

halfway up

Angle of mandible checkbox

angle of mandible

Edema:

None checkbox

none

Feet alone checkbox

feet alone

Feet and ankles checkbox

feet and ankles

Pre-tibial checkbox

pre-tibial

Above the knee checkbox

above the knee

Hepatomegaly:

Yes checkbox

yes

No checkbox

no

Rales:

None checkbox

none

Bases only checkbox

bases only

Halfway up checkbox

halfway up

Entire lung field checkbox

entire lung field

Wheezes:

Yes checkbox

yes

No checkbox

no

Three empty boxes for staff initials (F, M, L)



PE Dataset, Plate 5
 Physical Exam

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
pehr	Heart Rate bpm	
pebps	Systolic BP mm Hg	
pebpd	Diastolic BP mm Hg	
pewt	Weight in pounds	
peht	Height in inches	
pes3	S3 gallop	1=yes, 2=no
pes4	S4 gallop	1=yes, 2=no
pesmr	Systolic murmur	1=yes, 2=no
pedmr	Diastolic murmur	1=yes, 2=no
pejvd	JVD at 30 degrees	1=not present, 2=base of neck, 3=halfway up, 4=angle of mandible
peedm	Edema	1=none, 2=feet alone, 3=feet and ankles, 4=pre-tibial, 5=above the knee
pehep	Hepatomegaly	1=yes, 2=no
perls	Rales	1=none, 2=bases only, 3=halfway up, 4=entire lung field
pewhz	Wheezes	1=yes, 2=no

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 006

Visit Number: [][][]

Patient ID [][][] [][][][]
Hospital Patient

Patient Initials [][][]
F M L

Visit Date: [][] [][] [][][]
month day year

Patient Hospitalized for CHF since last visit? yes no

If yes, fill out AME, SAE MedWatch 3500, and Hospitalization forms.

NYHA Class: I II III IV

SAS Class: I II III IV

NYHA Functional Classification

- I No limitations:** Ordinary physical activity does not cause undue fatigue, dyspnea, or palpitation.
- II Slight Limitation of physical activity:** Such patients are comfortable at rest, ordinary physical activity results in fatigue, palpitation, dyspnea, or angina.
- III Marked limitation of physical activity:** Although patients are comfortable at rest, less than ordinary activity will lead to symptoms.
- IV Inability to carry on any physical activity without discomfort:** Symptoms of congestive failure are present even at rest. With any physical activity, increased discomfort is experienced.

Specific Activity Scale (SAS)

1. Could the patient walk down a flight of stairs without stopping? If yes, go to 2, if no, go to 4
2. Could the patient carry anything up a flight of stairs without stopping? **Or** can the patient ..
 - a) have sexual intercourse without stopping
 - b) garden, rake or weed
 - c) rollerskate, dance foxtrot
 - d) walk at at 4 mph rate on level groundIf yes, go to 3, if no, **patient is class III.**
3. Could the patient carry at least 24 lbs up a flight of 8 steps? **Or** can the patient
 - a) carry objects weighing at least 80 lbs.?
 - b) perform outdoor work (e.g. shovel snow, spade soil)
 - c) participate in recreational activities such as skiing, basketball, touch football squash, handball
 - d) jog/walk 5 mph.....If yes, **patient is class I**, if no, **patient is class II.**
4. Could the patient shower without stopping? **Or** can the patient
 - a) change bed linen
 - b) mop floors
 - c) hang washed clothes
 - d) clean windows
 - e) walk 2.5 mph
 - f) bowl
 - g) play golf (walk and carry clubs)
 - h) push lawnmower.....If yes, the **patient is class III**, if no, go to 5
5. Can the patient dress without stopping because of symptoms? If yes, **patient is class III**, if no, **patient is Class IV**



CVS Dataset, Plate 6
Cardiovascular Symptoms

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
cvhhf	Hospitalized for CHF since last visit?	1=yes, 2=no
cvnyh	NYHA class	1=I, 2=II, 3=III, 4=IV
cvsas	SAS class	1=I, 2=II, 3=III, 4=IV

* Recoded/new variable, per patient confidentiality guidelines.

7 id

8 init

9 vdate

10 scdrug1	11 sccode1	12 scdose1	13 scunit1	14 sccat1	15 scrou1
16 scdrug2	17 sccode2	18 scdose2	19 scunit2	20 sccat2	21 scrou2
22 scdrug3	23 sccode3	24 scdose3	25 scunit3	26 sccat3	27 scrou3
28 scdrug4	29 sccode4	30 scdose4	31 scunit4	32 sccat4	33 scrou4
34 scdrug5	35 sccode5	36 scdose5	37 scunit5	38 sccat5	39 scrou5
40 scdrug6	41 sccode6	42 scdose6	43 scunit6	44 sccat6	45 scrou6
46 scdrug7	47 sccode7	48 scdose7	49 scunit7	50 sccat7	51 scrou7
52 scdrug8	53 sccode8	54 scdose8	55 scunit8	56 sccat8	57 scrou8
58 scdrug9	59 sccode9	60 scdose9	61 scunit9	62 sccat9	63 scrou9
64 scdrug10	65 sccode10	66 scdose10	67 scunit10	68 sccat10	69 scrou10
70 scdrug11	71 sccode11	72 scdose11	73 scunit11	74 sccat11	75 scrou11
76 scdrug12	77 sccode12	78 scdose12	79 scunit12	80 sccat12	81 scrou12
82 scdrug13	83 sccode13	84 scdose13	85 scunit13	86 sccat13	87 scrou13
88 scdrug14	89 sccode14	90 scdose14	91 scunit14	92 sccat14	93 scrou14

94 staff

SCT_1 Dataset, Plate 7
 Screening Cotherapy, pg. 1

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
visit	Visit Number	1
* vdays	Number of days to visit, from Baseline	
scdrug1	SCT #1 Drug Name	
sccode1	SCT #1 Drug Code	
scdose1	SCT #1 Total Daily Dose	
scunit1	SCT #1 Units	1=mg, 2=other
sccat1	SCT #1 Category	
scrout1	SCT #1 Route	
scdrug2	SCT #2 Drug Name	
sccode2	SCT #2 Drug Code	
scdose2	SCT #2 Total Daily Dose	
scunit2	SCT #2 Units	1=mg, 2=other
sccat2	SCT #2 Category	
scrout2	SCT #2 Route	
scdrug3	SCT #3 Drug Name	
sccode3	SCT #3 Drug Code	
scdose3	SCT #3 Total Daily Dose	
scunit3	SCT#3 Units	1=mg, 2=other
sccat3	SCT #3 Category	
scrout3	SCT #3 Route	
scdrug4	SCT #4 Drug Name	

* Recoded/new variable, per patient confidentiality guidelines.

SCT_1 Dataset, Plate 7
 Screening Cotherapy, pg. 1

Variable Name	Description	Coding
sccode4	SCT #4 Drug Code	
scdose4	SCT #4 Total Daily Dose	
scunit4	SCT #4 Units	1=mg, 2=other
sccat4	SCT #4 Category	
scrout4	SCT #4 Route	
scdrug5	SCT #5 Drug Name	
sccode5	SCT #5 Drug Code	
scdose5	SCT #5 Total Daily Dose	
scunit5	SCT #5 Units	1=mg, 2=other
sccat5	SCT #5 Category	
scrout5	SCT #5 Route	
scdrug6	SCT #6 Drug Name	
sccode6	SCT #6 Drug Code	
scdose6	SCT #6 Total Daily Dose	
scunit6	SCT #6 Units	1=mg, 2=other
sccat6	SCT #6 Category	
scrout6	SCT #6 Route	
scdrug7	SCT #7 Drug Name	
sccode7	SCT #7 Drug Code	
scdose7	SCT #7 Total Daily Dose	
scunit7	SCT #7 Units	1=mg, 2=other
sccat7	SCT #7 Category	

* Recoded/new variable, per patient confidentiality guidelines.

SCT_1 Dataset, Plate 7
 Screening Cotherapy, pg. 1

Variable Name	Description	Coding
scrout7	SCT #7 Route	
scdrug8	SCT #8 Drug Name	
sccode8	SCT #8 Drug Code	
scdose8	SCT #8 Total Daily Dose	
scunit8	SCT #8 Units	1=mg, 2=other
sccat8	SCT #8 Category	
scrout8	SCT #8 Route	
scdrug9	SCT #9 Drug Name	
sccode9	SCT #9 Drug Code	
scdose9	SCT #9 Total Daily Dose	
scunit9	SCT #9 Units	1=mg, 2=other
sccat9	SCT #9 Category	
scrout9	SCT #9 Route	
scdrug10	SCT #10 Drug Name	
sccode10	SCT #10 Drug Code	
scdose10	SCT #10 Total Daily Dose	
scunit10	SCT #10 Units	1=mg, 2=other
sccat10	SCT #10 Category	
scrout10	SCT #10 Route	
scdrug11	SCT #11 Drug Name	
sccode11	SCT #11 Drug Code	
scdose11	SCT #11 Total Daily Dose	

* Recoded/new variable, per patient confidentiality guidelines.

SCT_1 Dataset, Plate 7
 Screening Cotherapy, pg. 1

Variable Name	Description	Coding
scunit11	SCT #11 Units	1=mg, 2=other
sccat11	SCT #11 Category	
scrout11	SCT #11 Route	
scdrug12	SCT #12 Drug Name	
sccode12	SCT #12 Drug Code	
scdose12	SCT #12 Total Daily Dose	
scunit12	SCT #12 Units	1=mg, 2=other
sccat12	SCT #12 Category	
scrout12	SCT #12 Route	
scdrug13	SCT #13 Drug Name	
sccode13	SCT #13 Drug Code	
scdose13	SCT #13 Total Daily Dose	
scunit13	SCT #13 Units	1=mg, 2=other
sccat13	SCT #13 Category	
scrout13	SCT #13 Route	
scdrug14	SCT #14 Drug Name	
sccode14	SCT #14 Drug Code	
scdose14	SCT #14 Total Daily Dose	
scunit14	SCT #14 Units	1=mg, 2=other
sccat14	SCT #14 Category	
scrout14	SCT #14 Route	

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 008

Visit 001

Patient ID
 Patient Initials
 Screening Date

Hospital Patient F M L month day year

DRUG	CODE	TOTAL DAILY DOSE	UNITS	CATEGORY	ROUTE
15. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>
16. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>
17. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>
18. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>
19. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>
20. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>
21. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>
22. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>
23. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>
24. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>
25. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>
26. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> mg <input type="text"/> other	<input type="text"/>	<input type="text"/>

CATEGORIES:

- 1=Diuretic
- 2=ACEI
- 3=Vasodilator (non-ACEI)
- 4=Inotrope
- 5=Digitalis
- 6=Anti-arrhythmic
- 7=Anti-coagulant
- 8=Other cardiac
- 9=Non-cardiac

ROUTES:

- 1=PO
- 2=IV
- 3=Subcutaneous
- 4=Topical
- 5=Sublingual
- 6=Intramuscular
- 7=Suppository
- 8=Inhaler



7 id

8 init

9 vdate

10 scdrug15	11 sccode15	12 scdose15	13 scunit15	14 sccat15	15 scrout15
16 scdrug16	17 sccode16	18 scdose16	19 scunit16	20 sccat16	21 scrout16
22 scdrug17	23 sccode17	24 scdose17	25 scunit17	26 sccat17	27 scrout17
28 scdrug18	29 sccode18	30 scdose18	31 scunit18	32 sccat18	33 scrout18
34 scdrug19	35 sccode19	36 scdose19	37 scunit19	38 sccat19	39 scrout19
40 scdrug20	41 sccode20	42 scdose20	43 scunit20	44 sccat20	45 scrout20
46 scdrug21	47 sccode21	48 scdose21	49 scunit21	50 sccat21	51 scrout21
52 scdrug22	53 sccode22	54 scdose22	55 scunit22	56 sccat22	57 scrout22
58 scdrug23	59 sccode23	60 scdose23	61 scunit23	62 sccat23	63 scrout23
64 scdrug24	65 sccode24	66 scdose24	67 scunit24	68 sccat24	69 scrout24
70 scdrug25	71 sccode25	72 scdose25	73 scunit25	74 sccat25	75 scrout25
76 scdrug26	77 sccode26	78 scdose26	79 scunit26	80 sccat26	81 scrout26

82 staff

SCT_2 Dataset, Plate 8
 Screening Cotherapy, pg. 2

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
visit	Visit Number	1
* vdays	Number of days to visit, from Baseline	
scdrug15	SCT #15 Drug Name	
sccode15	SCT #15 Drug Code	
scdose15	SCT #15 Total Daily Dose	
scunit15	SCT #15 Units	1=mg, 2=other
sccat15	SCT #15 Category	
scrout15	SCT #15 Route	
scdrug16	SCT #16 Drug Name	
sccode16	SCT #16 Drug Code	
scdose16	SCT #16 Total Daily Dose	
scunit16	SCT #16 Units	1=mg, 2=other
sccat16	SCT #16 Category	
scrout16	SCT #16 Route	
scdrug17	SCT #17 Drug Name	
sccode17	SCT #17 Drug Code	
scdose17	SCT #17 Total Daily Dose	
scunit17	SCT #17 Units	1=mg, 2=other
sccat17	SCT #17 Category	
scrout17	SCT #17 Route	
scdrug18	SCT #18 Drug Name	
sccode18	SCT #18 Drug Code	
scdose18	SCT #18 Total Daily Dose	
scunit18	SCT #18 Units	1=mg, 2=other
sccat18	SCT #18 Category	
scrout18	SCT #18 Route	
scdrug19	SCT #19 Drug Name	

* Recoded/new variable, per patient confidentiality guidelines.

SCT_2 Dataset, Plate 8
 Screening Cotherapy, pg. 2

Variable Name	Description	Coding
sccode19	SCT #19 Drug Code	
scdose19	SCT #19 Total Daily Dose	
scunit19	SCT #19 Units	1=mg, 2=other
sccat19	SCT #19 Category	
scrout19	SCT #19 Route	
sdrug20	SCT #20 Drug Name	
sccode20	SCT #20 Drug Code	
scdose20	SCT #20 Total Daily Dose	
scunit20	SCT #20 Units	1=mg, 2=other
sccat20	SCT #20 Category	
scrout20	SCT #20 Route	
sdrug21	SCT #21 Drug Name	
sccode21	SCT #21 Drug Code	
scdose21	SCT #21 Total Daily Dose	
scunit21	SCT #21 Units	1=mg, 2=other
sccat21	SCT #21 Category	
scrout21	SCT #21 Route	
sdrug22	SCT #22 Drug Name	
sccode22	SCT #22 Drug Code	
scdose22	SCT #22 Total Daily Dose	
scunit22	SCT #22 Units	1=mg, 2=other
sccat22	SCT #22 Category	
scrout22	SCT #22 Route	
sdrug23	SCT #23 Drug Name	
sccode23	SCT #23 Drug Code	
scdose23	SCT #23 Total Daily Dose	
scunit23	SCT #23 Units	1=mg, 2=other
sccat23	SCT #23 Category	

* Recoded/new variable, per patient confidentiality guidelines.

SCT_2 Dataset, Plate 8
 Screening Cotherapy, pg. 2

Variable Name	Description	Coding
scrout23	SCT #23 Route	
sdrug24	SCT #24 Drug Name	
scode24	SCT #24 Drug Code	
sdose24	SCT #24 Total Daily Dose	
scunit24	SCT #24 Units	1=mg, 2=other
sccat24	SCT #24 Category	
scrout24	SCT #24 Route	
sdrug25	SCT #25 Drug Name	
scode25	SCT #25 Drug Code	
sdose25	SCT #25 Total Daily Dose	
scunit25	SCT #25 Units	1=mg, 2=other
sccat25	SCT #25 Category	
scrout25	SCT #25 Route	
sdrug26	SCT #26 Drug Name	
scode26	SCT #26 Drug Code	
sdose26	SCT #26 Total Daily Dose	
scunit26	SCT #26 Units	1=mg, 2=other
sccat26	SCT #26 Category	
scrout26	SCT #26 Route	

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 009

Visit Number

Three empty boxes for visit number

Patient ID

Three empty boxes for hospital part of patient ID

Hospital

Three empty boxes for patient part of patient ID

Patient

Patient Initials

Three empty boxes for patient initials

F M L

Visit Date

Two empty boxes for month

month

Two empty boxes for day

day

Two empty boxes for year

year

Use at every post-screening visit to record changes in current co-therapy.

Did patient require IV inotropes since last visit? ... yes no

Did patient require IV diuretics since last visit? ... yes no

Did patient require increase in PRN oral diuretics since last visit? yes no

No changes in any routine medication (if so, STOP)

Record changes in routine medications comparing last visit to this visit. A discontinued medication should be recorded as zero dose. If dosage changes from day to day, then list average daily dose in the following.

ORAL MEDICATIONS

Table with 5 columns: DRUG NAME, DRUG CODE, TOTAL DAILY DOSE, UNITS, CATEGORY. Includes 12 numbered rows for medication entry and a legend for categories 1-9.

Continue Co-Therapy form.....



				6 visit
7 id		8 init		9 vdate
				10 coino
				11 codui
				12 coprn
13 comed				
14 con1	15 coo1	16 cod1	17 cou1	18 cpt1
19 con2	20 coo2	21 cod2	22 cou2	23 cpt2
24 con3	25 coo3	26 cod3	27 cou3	28 cpt3
29 con4	30 coo4	31 cod4	32 cou4	33 cpt4
34 con5	35 coo5	36 cod5	37 cou5	38 cpt5
39 con6	40 coo6	41 cod6	42 cou6	43 cpt6
44 con7	45 coo7	46 cod7	47 cou7	48 cpt7
49 con8	50 coo8	51 cod8	52 cou8	53 cpt8
54 con9	55 coo9	56 cod9	57 cou9	58 cpt9
59 con10	60 coo10	61 cod10	62 cou10	63 cpt10
64 con11	65 coo11	66 cod11	67 cou11	68 cpt11
69 con12	70 coo12	71 cod12	72 cou12	73 cpt12
				74 staff

COTX_1 Dataset, Plate 9
 Cotherapy, pg. 1

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
coino	Did pt require IV inotrop	1=yes, 2=no
codui	Did pt require IV diuret	1=yes, 2=no
coprn	Did pt require increase	1=yes, 2=no
comed	No changes in any routine	yes=present, no=absent
con1	Oral #1 Drug Name	
coo1	Oral #1 Drug Code	
cod1	Oral #1 Total Daily Dose	
cou1	Oral #1 Units	1=mg, 2=other
cot1	Oral #1 Category	
con2	Oral #2 Drug Name	
coo2	Oral #2 Drug Code	
cod2	Oral #2 Total Daily Dose	
cou2	Oral #2 Units	1=mg, 2=other
cot2	Oral #2 Category	
con3	Oral #3 Drug Name	
coo3	Oral #3 Drug Code	
cod3	Oral #3 Total Daily Dose	
cou3	Oral #3 Units	1=mg, 2=other
cot3	Oral #3 Category	
con4	Oral #4 Drug Name	
coo4	Oral #4 Drug Code	
cod4	Oral #4 Total Daily Dose	

* Recoded/new variable, per patient confidentiality guidelines.

COTX_1 Dataset, Plate 9
 Cotherapy, pg. 1

Variable Name	Description	Coding
cou4	Oral #4 Units	1=mg, 2=other
cot4	Oral #4 Category	
con5	Oral #5 Drug Name	
coo5	Oral #5 Drug Code	
cod5	Oral #5 Total Daily Dose	
cou5	Oral #5 Units	1=mg, 2=other
cot5	Oral #5 Category	
con6	Oral #6 Drug Name	
coo6	Oral #6 Drug Code	
cod6	Oral #6 Total Daily Dose	
cou6	Oral #6 Units	1=mg, 2=other
cot6	Oral #6 Category	
con7	Oral #7 Drug Name	
coo7	Oral #7 Drug Code	
cod7	Oral #7 Total Daily Dose	
cou7	Oral #7 Units	1=mg, 2=other
cot7	Oral #7 Category	
con8	Oral #8 Drug Name	
coo8	Oral #8 Drug Code	
cod8	Oral #8 Total Daily Dose	
cou8	Oral #8 Units	1=mg, 2=other
cot8	Oral #8 Category	
con9	Oral #9 Drug Name	
coo9	Oral #9 Drug Code	
cod9	Oral #9 Total Daily Dose	

* Recoded/new variable, per patient confidentiality guidelines.

COTX_1 Dataset, Plate 9
Cotherapy, pg. 1

Variable Name	Description	Coding
cou9	Oral #9 Units	1=mg, 2=other
cot9	Oral #9 Category	
con10	Oral #10 Drug Name	
coo10	Oral #10 Drug Code	
cod10	Oral #10 Total Daily Dose	
cou10	Oral #10 Units	1=mg, 2=other
cot10	Oral #10 Category	
con11	Oral #11 Drug Name	
coo11	Oral #11 Drug Code	
cod11	Oral #11 Total Daily Dose	
cou11	Oral #11 Units	1=mg, 2=other
cot11	Oral #11 Category	
con12	Oral #12 Drug Name	
coo12	Oral #12 Drug Code	
cod12	Oral #12 Total Daily Dose	
cou12	Oral #12 Units	1=mg, 2=other
cot12	Oral #12 Category	

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 010

Visit Number

Three empty boxes for visit number.

(must match first page of form)

Patient ID

Three empty boxes for hospital part of patient ID.

Hospital

Three empty boxes for patient part of patient ID.

Patient

Patient Initials

Three empty boxes for patient initials labeled F, M, L.

F M L

Visit Date

Two empty boxes for month.

month

Two empty boxes for day.

day

Two empty boxes for year.

year

IV MEDICATIONS

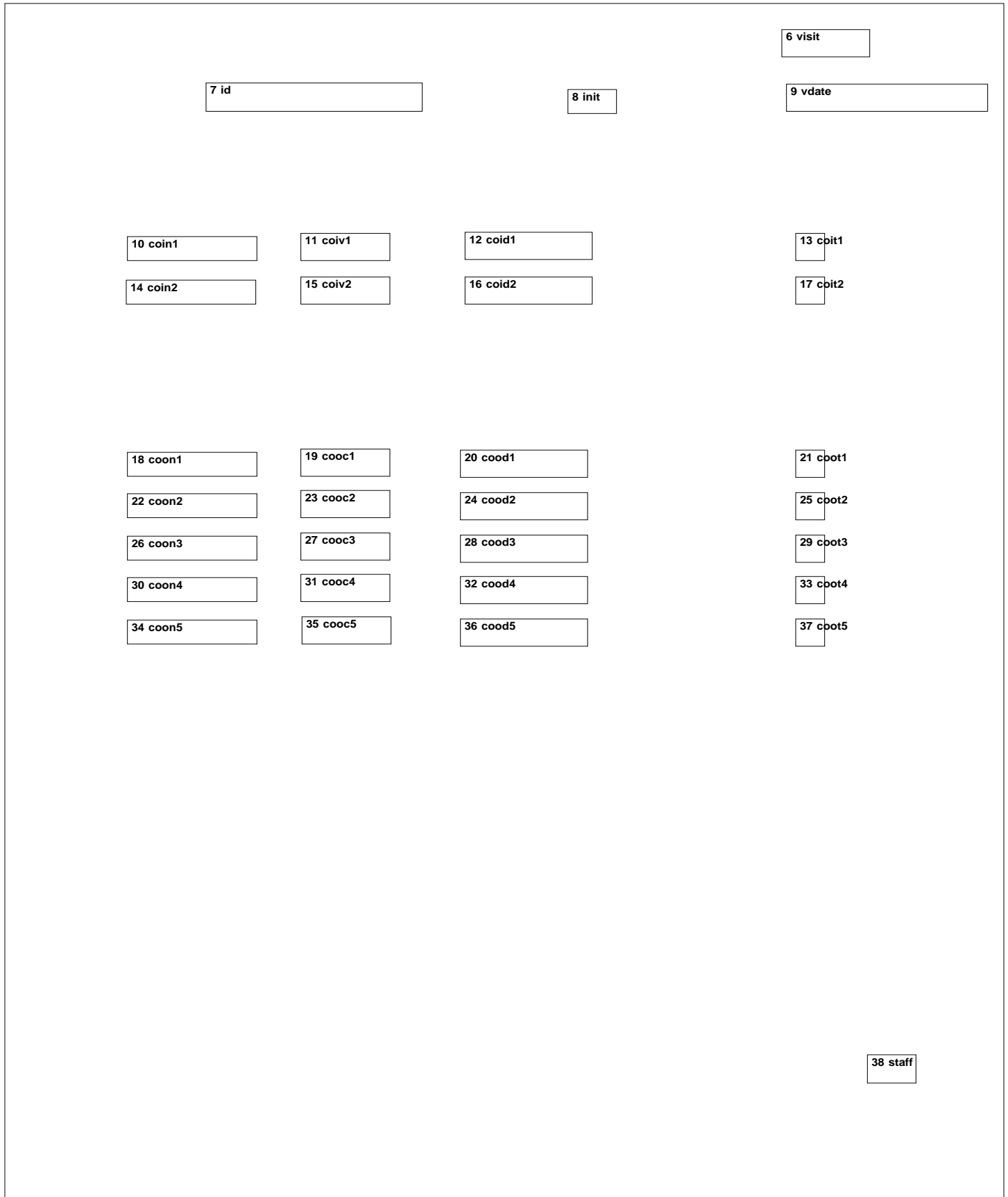
DRUG	CODE	DOSE	CATEGORY
1. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/> mcg/kg/min	<input type="checkbox"/>
2. _____	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/> mcg/kg/min	<input type="checkbox"/>

1=Diuretic
 2=ACEI
 3=Vasodilator (non-ACEI)
 4=Inotrope
 5=Digitalis
 6=Anti-arrhythmic
 7=Anti-coagulant
 8=Other cardiac
 9=Non-cardiac

MEDICATIONS DELIVERED BY OTHER ROUTES (SUB-Q, PATCH, PASTE, ETC.)

DRUG	CODE	TOTAL DAILY DOSE	CATEGORY
1. _____	<input type="text"/> <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>
2. _____	<input type="text"/> <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>
3. _____	<input type="text"/> <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>
4. _____	<input type="text"/> <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>
5. _____	<input type="text"/> <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>





COTX_2 Dataset, Plate 10
 Cotherapy, pg. 2

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
coin1	IV #1 Drug Name	
coiv1	IV #1 Drug Code	
coid1	IV #1 Total Daily Dose	
coit1	IV #1 Category	
coin2	IV #2 Drug Name	
coiv2	IV #2 Drug Code	
coid2	IV #2 Total Daily Dose	
coit2	IV #2 Category	
coon1	Other #1 Drug Name	
cooc1	Other #1 Drug Code	
cood1	Other #1 Total Daily Dose	
coot1	Other #1 Category	
coon2	Other #2 Drug Name	
cooc2	Other #2 Drug Code	
cood2	Other #2 Total Daily Dose	
coot2	Other #2 Category	
coon3	Other #3 Drug Name	
cooc3	Other #3 Drug Code	
cood3	Other #3 Total Daily Dose	
coot3	Other #3 Category	
coon4	Other #4 Drug Name	

* Recoded/new variable, per patient confidentiality guidelines.

COTX_2 Dataset, Plate 10
Cotherapy, pg. 2

Variable Name	Description	Coding
cooc4	Other #4 Drug Code	
cod4	Other #4 Total Daily Dose	
coot4	Other #4 Category	
coon5	Other #5 Drug Name	
cooc5	Other #5 Drug Code	
cod5	Other #5 Total Daily Dose	
coot5	Other #5 Category	

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 011

Visit 001

Patient ID

Hospital Patient

Patient Initials

F M L

Visit Date

month day year

Cardiac History

- Duration of CHF: *months*
- Atrial fibrillation/flutter *yes* *no*
- Ventricular fibrillation, sustained VT, or resuscitated cardiac arrest *yes* *no*
- Peripheral vascular disease *yes* *no*
- Thromboembolic disease *yes* *no*
- Angina: *yes* *no*
- Current smoker *yes* *no*
- Number of years smoked *years*
- Premature CHF (< age 65) in parents or siblings *yes* *no*

Prior Surgery/Procedure

- Coronary bypass surgery: *yes* *no*
- Coronary angioplasty, PTCA/DCA/stent/rotablator, etc: ... *yes* *no*
- Valvular replacement (list valve replaced) _____ *yes* *no*
- Valvuloplasty (list valve opened) _____ *yes* *no*
- Pacemaker *yes* *no*
- Ablation *yes* *no*
- Implanted Cardio defibrillator *yes* *no*
- Aneurismectomy *yes* *no*
- Congenital heart disease surgery (ASD, VSD, etc.) *yes* *no*

Continue form.....

Staff Initials

F M L



7 id

8 init

9 vdate

10 cvduratn

11 cvafib

12 cvvfib

13 cvpvd

14 cvthrom

15 cvang

16 cvsmoker

17 cvyrsmok

18 cvprechf

19 cvbypas

20 cvangiop

21 cvvalrep

22 cvvalvul

23 cvpacemk

24 cvblatn

25 cvdefibr

26 cvaneur

27 cvcongen

28 staff

CVH_1 Dataset, Plate 11
 Cardiovascular History, pg. 1

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
visit	Visit Number	1
cvduratn	Duration of CHF (months)	
cvafib	Atrial fibrillation or flutter	1=yes, 2=no
cvvfib	Ventricular fib, sustained VT, resuscitated cardiac arrest	1=yes, 2=no
cvpvd	Peripheral vascular disease	1=yes, 2=no
cvthrom	Thromboembolic disease	1=yes, 2=no
cvang	Angina	1=yes, 2=no
cvsmoker	Current smoker	1=yes, 2=no
cvyrsmok	Number of years smoked	
cvprechf	Premature CHF (< age 65) parents/siblings	1=yes, 2=no
cvbypas	Coronary bypass surgery	1=yes, 2=no
cvangiop	Coronary angioplasty, PTCA/DCA/stent/rotablator, etc.	1=yes, 2=no
cvvalrep	Valvular replacement	1=yes, 2=no
cvvalvul	Valvuloplasty	1=yes, 2=no
cvpacemk	Pacemaker	1=yes, 2=no
cvblatn	Ablation	1=yes, 2=no
cvdefibr	Implanted Cardio defibrillator	1=yes, 2=no
cvaneur	Aneurismectomy	1=yes, 2=no
cvcongen	Congenital heart disease surgery (ASD, VSD, etc.)	1=yes, 2=no

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 012

Visit 001

Patient ID Patient Initials Visit Date

Hospital Patient F M L month day year

History of related illness, requiring medical treatment:

Hypertension *yes* *no*

Diabetes mellitus *yes* *no*

Hyperlipidemia *yes* *no*

Ischemic CHF Etiology

Prior MI diagnosed by Q-waves: *yes* *no*

Prior MI diagnosed by Cardiac Enzymes: *yes* *no*

Greater than 70% stenosis with corresponding wall motion abnormality, by coronary angiography: *yes* *no*

Positive stress perfusion study: *yes* *no*

Positive exercise test with interpretable baseline ECG: *yes* *no*

CAD etiology (any of above etiologies marked "yes"): *yes* *no*

If no CAD etiology, complete all items below for Non-Ischemic Etiology:

Mitral Valvular disease *yes* *no*

Aortic Valvular disease *yes* *no*

Alcoholic cardiomyopathy *yes* *no*

Drug-induced *yes* *no*

Hypertension induced *yes* *no*

Familial *yes* *no*

Viral *yes* *no*

Idiopathic *yes* *no*

Other (Chagas', myocarditis) *yes* *no*



7 id

8 init

9 vdate

10 cvhxhtxn

11 cvhxdiab

12 cvhxlip

13 cvowave

14 cvenzyme

15 cvgt70

16 cvstress

17 cvexercs

18 cvcad

19 cvmitral

20 cvaortic

21 cvetoh

22 cvdrug

23 cvhyprin

24 cvfamil

25 cvviral

26 cvidiop

27 cvother

28 staff

CVH_2 Dataset, Plate 12
 Cardiovascular History, pg. 2

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
visit	Visit Number	1
cvhxhtxn	History of Hypertension	1=yes, 2=no
cvhxdiab	History of Diabetes Mellitus	1=yes, 2=no
cvhxlip	History of Hyperlipidemia	1=yes, 2=no
cvowave	Prior MI diagnosed by Q waves	1=yes, 2=no
cvenzyme	Prior MI diagnosed by cardiac enzymes	1=yes, 2=no
cvgt70	Greater than 70% stenosis w/ wall motion abn, by coronary angiography	1=yes, 2=no
cvstress	Positive stress perfusion study	1=yes, 2=no
cvexercs	Positive exercise test w/ interpretable baseline ECG	1=yes, 2=no
cvcad	CAD etiology	1=yes, 2=no
cvmitral	Mitral valvular disease	1=yes, 2=no
cvaortic	Aortic valvular disease	1=yes, 2=no
cvetoh	Alcoholic cardiomyopathy	1=yes, 2=no
cvdrug	Drug induced etiology	1=yes, 2=no
cvhyprin	Hypertension induced etiology	1=yes, 2=no
cvfamil	Familial etiology	1=yes, 2=no
cvviral	Viral etiology	1=yes, 2=no
cvidiop	Idiopathic etiology	1=yes, 2=no
cvother	Other (Chagas', myocarditis) etiology	1=yes, 2=no

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 013

Visit Number

Three empty boxes for Visit Number

Patient ID

Three empty boxes for Hospital part of Patient ID

Hospital

Three empty boxes for Patient part of Patient ID

Patient

Patient Initials

Three empty boxes for Patient Initials labeled F, M, L

F M L

Visit Date

Two empty boxes for month

month

Two empty boxes for day

day

Two empty boxes for year

year

Date of MUGA:

Two empty boxes for month

month

Two empty boxes for day

day

Two empty boxes for year

year

Avg HR during MUGA

Three empty boxes for Avg HR

bpm

Avg BP during MUGA

Three empty boxes for Avg BP (systolic)

/

Three empty boxes for Avg BP (diastolic)

mmHg

Atrial fibrillation during MUGA

Yes checkbox

yes

No checkbox

no

LVEF

Two empty boxes for LVEF

%

RVEF equilibrium

Two empty boxes for RVEF

%

LAO with caudal angulation

Yes checkbox

yes

No checkbox

no

Regional wall motion abnormality

Yes checkbox

yes

No checkbox

no

Diffuse Global wall motion abnormality

Yes checkbox

yes

No checkbox

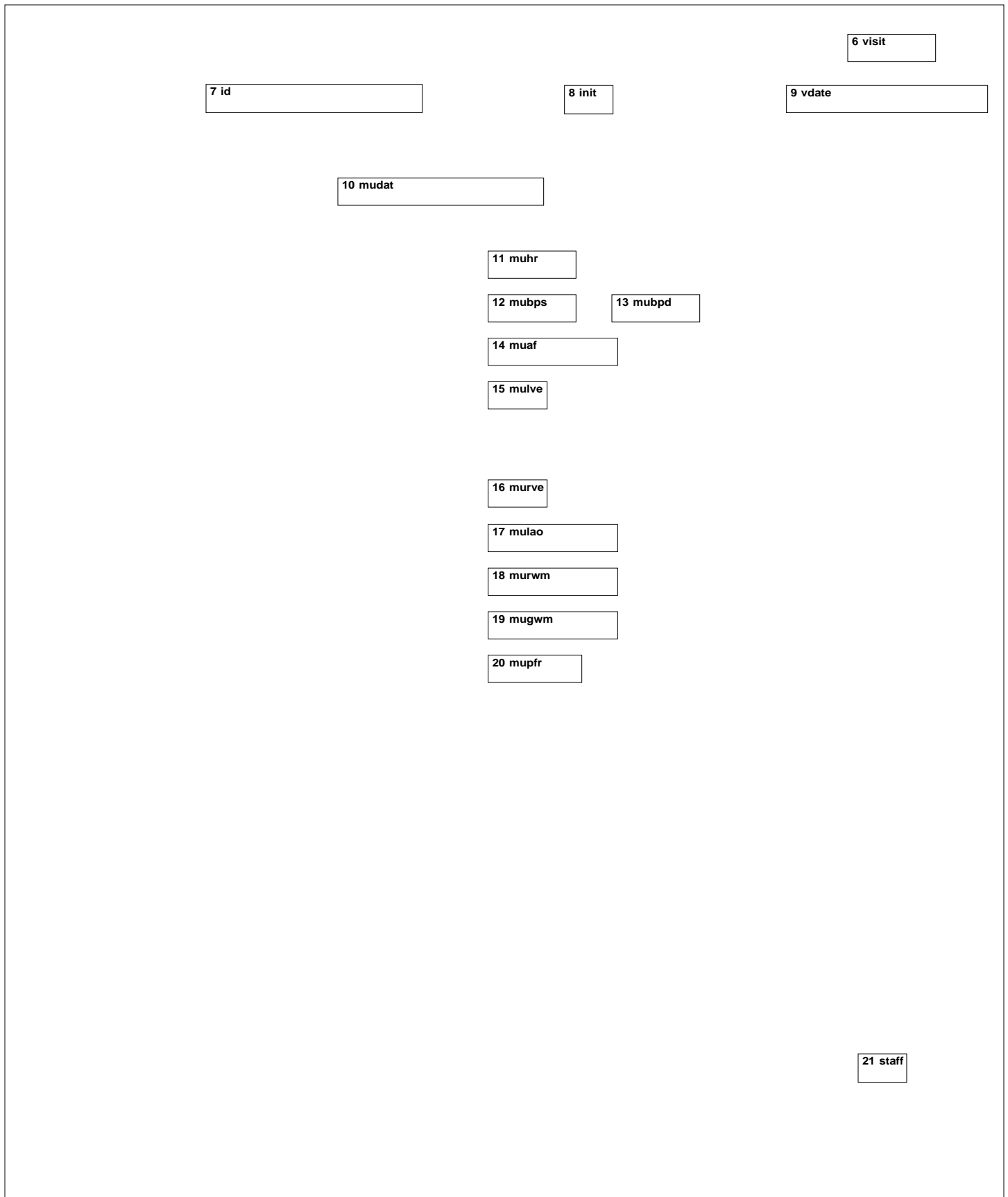
no

Peak filling rate

Two empty boxes for Peak filling rate with a decimal point

EDV/sec





MUGA Dataset, Plate 13
 Radionuclide Angiography

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
* mugadays	Number of days to MUGA, from Baseline	
muhr	Avg HR during MUGA (bpm)	
mubps	Systolic BP during MUGA (mm Hg)	
mubpd	Diastolic BP during MUGA (mm Hg)	
muaf	Atrial fibrillation during MUGA	1=yes, 2=no
mulve	LVEF (%)	
murve	RVEF equilibrium (%)	
mulao	LAO with caudal angulation	1=yes, 2=no
murwm	Regional wall motion abnormality	1=yes, 2=no
mugwm	Diffuse global wall motion abnormality	1=yes, 2=no
mupfr	Peak filling rate (EDV/sec)	

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 014

Visit Number

Three empty boxes for Visit Number

Patient ID

Three empty boxes for Hospital part of Patient ID

Hospital

Three empty boxes for Patient part of Patient ID

Patient

Patient Initials

Three empty boxes for Patient Initials labeled F, M, L

F M L

Visit Date

Three pairs of empty boxes for Visit Date

month day year

Date of Sample:

Three pairs of empty boxes for Date of Sample

month day year

Hematology

Mark if clinically significant abnormality (fill out AME form)

1. Hct

Two boxes, a decimal point, one box, a percent sign, and an empty box for abnormality

%

2. Hgb

Two boxes, a decimal point, one box, and an empty box for abnormality

g/dL

3. Platelet count

Four empty boxes, a $10^3/mm^3$ unit, and an empty box for abnormality

$10^3/mm^3$

4. WBC's

Two boxes, a decimal point, one box, and an empty box for abnormality

$10^3/mm^3$

Chemistry

5. Glucose

Three empty boxes, a mg/dL unit, and an empty box for abnormality

mg/dL

6. Sodium

Three empty boxes, a mEq/L unit, and an empty box for abnormality

mEq/L

7. Potassium

One box, a decimal point, one box, a mEq/L unit, and an empty box for abnormality

mEq/L

8. Chloride

Three empty boxes, a mEq/L unit, and an empty box for abnormality

mEq/L

9. Bicarbonate

Two boxes, a decimal point, one box, a mEq/L unit, and an empty box for abnormality

mEq/L

10. BUN

Three empty boxes, a mg/dL unit, and an empty box for abnormality

mg/dL

11. Creatinine

Two boxes, a decimal point, one box, a mg/dL unit, and an empty box for abnormality

mg/dL

12. Calcium

Two boxes, a decimal point, one box, a mg/dL unit, and an empty box for abnormality

mg/dL

13. Magnesium

One box, a decimal point, one box, a mEq/L unit, and an empty box for abnormality

mEq/L

14. Total bilirubin

Two boxes, a decimal point, one box, a mg/dL unit, and an empty box for abnormality

mg/dL

Continue on next page.....



LAB_1 Dataset, Plate 14
 Laboratory Results, pg. 1

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
* labdays	Number of days to Lab Exam, from Baseline	
lahct	Hct (%)	
lahcs	Hct - clinically significant abnormality	yes=present, no=absent
lahgb	Hgb (g/dL)	
lahgs	Hgb - clinically significant abnormality	yes=present, no=absent
lapc	Platelet count	
laps	Platelet count - clinically significant abnormality	yes=present, no=absent
lawbc	WBC	
lawbs	WBC - clinically significant abnormality	yes=present, no=absent
laglu	Glucose (mg/dL)	
lagls	Glucose - clinically significant abnormality	yes=present, no=absent
lasdm	Sodium (mEq/L)	
lasds	Sodium - clinically significant abnormality	yes=present, no=absent
lapot	Potassium (mEq/L)	
lapos	Potassium - clinically significant abnormality	yes=present, no=absent
lachl	Chloride (mEq/L)	
lachs	Chloride - clinically significant abnormality	yes=present, no=absent
labic	Bicarbonate (mEq/L)	
labis	Bicarbonate - clinically significant abnormality	yes=present, no=absent
labun	BUN (mg/dL)	
labus	BUN - clinically significant abnormality	yes=present, no=absent

* Recoded/new variable, per patient confidentiality guidelines.

LAB_1 Dataset, Plate 14
Laboratory Results, pg. 1

Variable Name	Description	Coding
lacre	Creatinine (mg/dL)	
lacrs	Creatinine - clinically significant abnormality	yes=present, no=absent
lacial	Calcium (mg/dL)	
lacas	Calcium - clinically significant abnormality	yes=present, no=absent
lamag	Magnesium (mEq/L)	
lamas	Magnesium clinically significant abnormality	yes=present, no=absent
labil	Total bilirubin (mg/dL)	
latbs	Total bilirubin - clinically significant abnormality	yes=present, no=absent

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 015

Visit Number (must match first page!)

Patient ID Patient Initials
Hospital Patient F M L

Visit Date
month day year

Chemistry, continued....

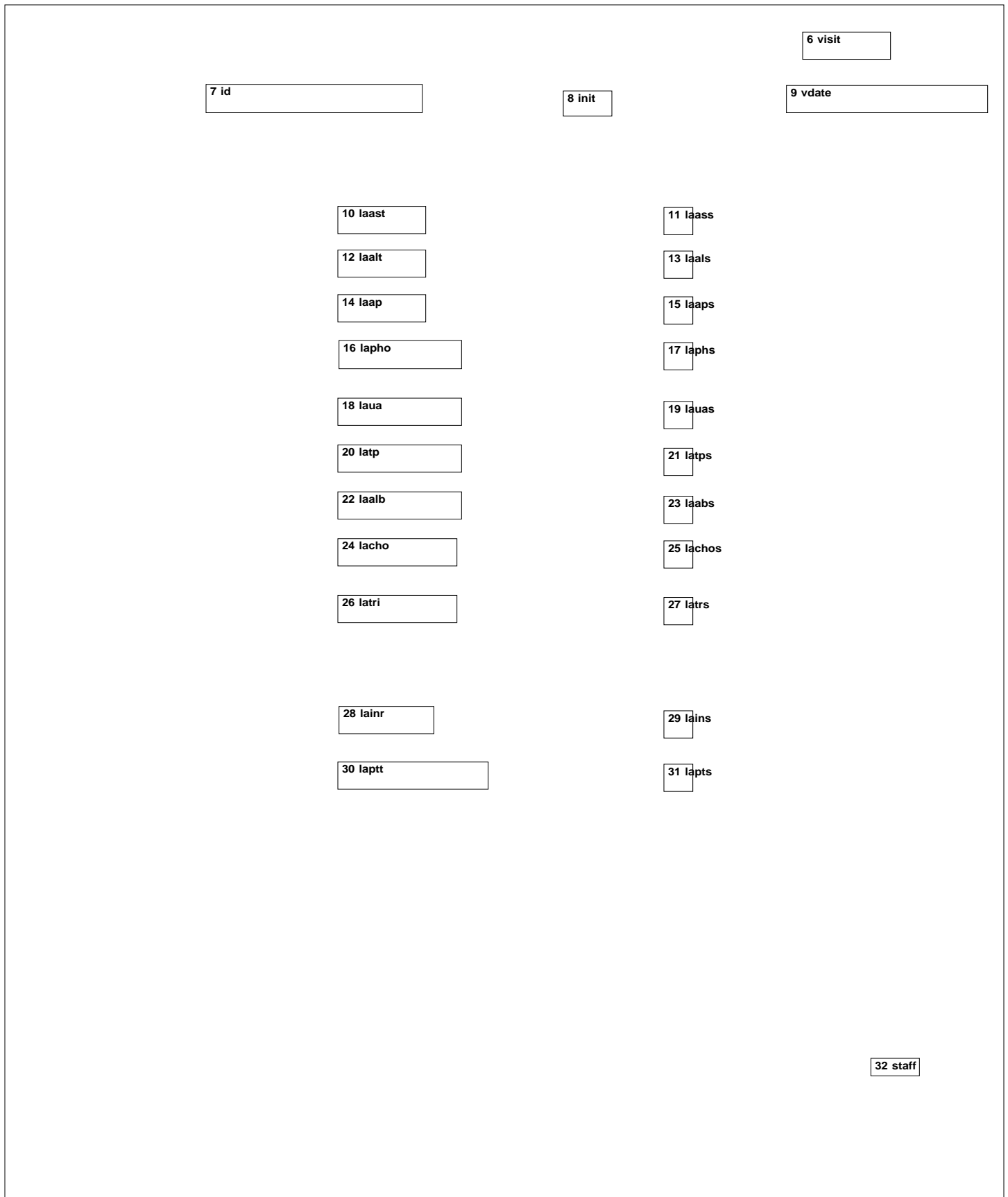
Mark if clinically significant abnormality (fill out AME form)

- 15. AST/SGOT U/L
- 16. ALT/SGPT U/L
- 17. Alkaline phosphatase U/L
- 18. Phosphorus . mg/dL
- 19. Uric acid . mg/dL
- 20. Total protein . g/dL
- 21. Albumin . g/dL
- 22. Cholesterol mg/dL
- 23. Triglycerides mg/dL

Coagulation

- 24. INR .
- 25. Activated partial thromboplastin time . sec





LAB_2 Dataset, Plate 15
 Laboratory Results, pg. 2

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
laast	AST/SGOT (U/L)	
laass	AST/SGOT - clinically significant abnormality	yes=present, no=absent
laalt	ALT/SGPT (U/L)	
laals	ALT/SGPT - clinically significant abnormality	yes=present, no=absent
laap	Alkaline phosphatase U/L	
laaps	Alkaline phosphatase - clinically significant abnormality	yes=present, no=absent
lapho	Phosphorus (mg/dL)	
laphs	Phosphorus - clinically significant abnormality	yes=present, no=absent
laua	Uric acid (mg/dL)	
lauas	Uric acid - clinically significant abnormality	yes=present, no=absent
latp	Total protein (g/dL)	
latps	Total protein - clinically significant abnormality	yes=present, no=absent
laalb	Albumin (g/dL)	
laabs	Albumin- clinically significant abnormality	yes=present, no=absent
lacho	Cholesterol (mg/dL)	
lachos	Cholesterol - clinically significant abnormality	yes=present, no=absent
latri	Triglycerides (mg/dL)	
latrs	Triglycerides - clinically significant abnormality	yes=present, no=absent

* Recoded/new variable, per patient confidentiality guidelines.

LAB_2 Dataset, Plate 15
Laboratory Results, pg. 2

Variable Name	Description	Coding
lainr	INR	
lains	INR - clinically significant abnormality	yes=present, no=absent
laptt	Activated PTT (sec)	
laptt	Activated PTT - clinically significant abnormality	yes=present, no=absent

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 016

Visit Number

Patient ID

Hospital

Patient

Patient Initials

F M L

Visit Date

month

day

year

Date of X-ray:

month

day

year

Cardio/Thoracic Ratio:

0.

Pulmonary Edema:

none

old

new

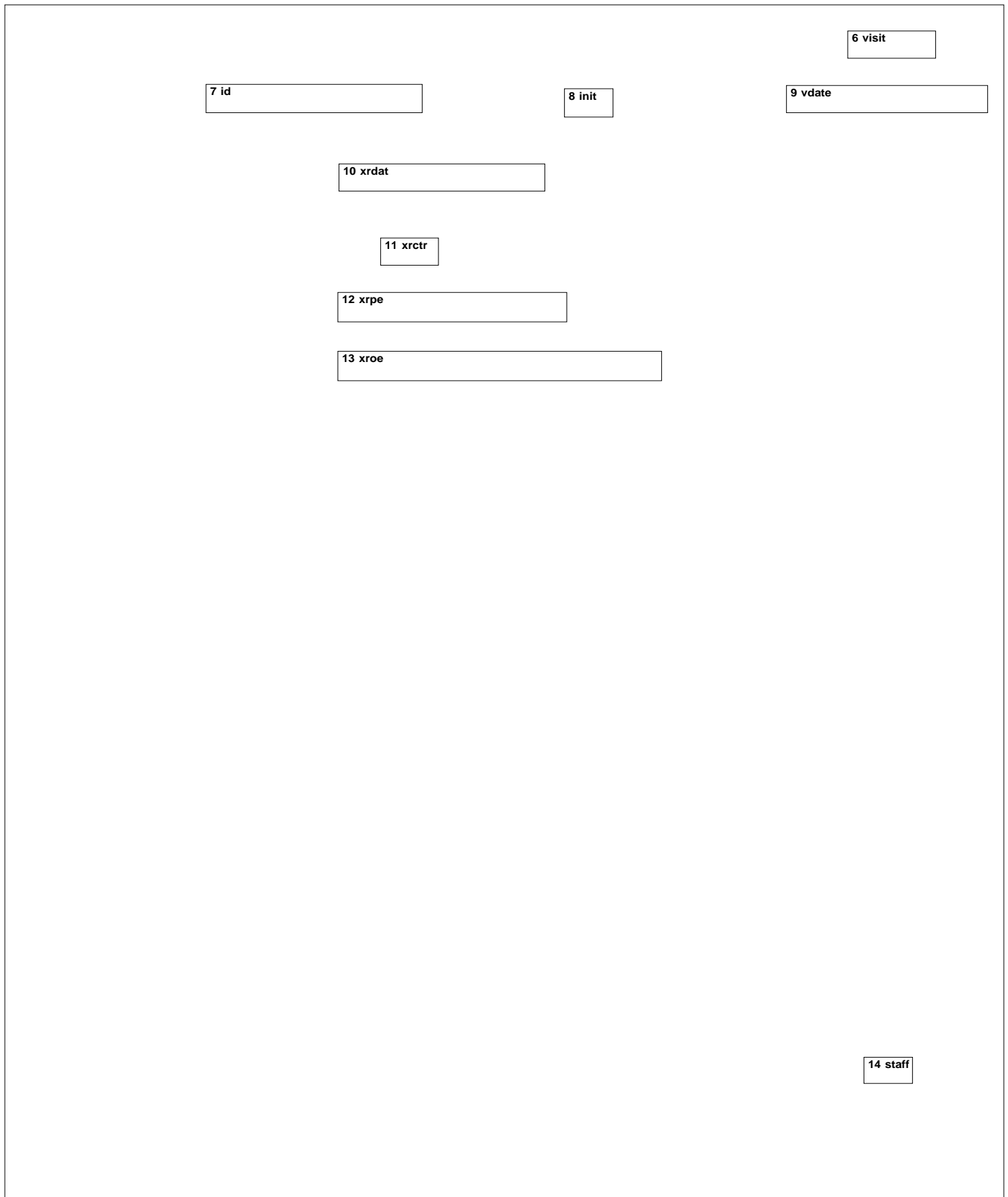
If old edema:

no change

worsened

improved





XRAY Dataset, Plate 16
Chest X-Ray

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
* xrdays	Number of days to X-ray, from Baseline	
xrctr	Cardio/thoracic ratio	
xrpe	Pulmonary edema	1=none, 2=old, 3=new
xroe	If old edema,	1=no change, 2=worsened, 3=improved

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 017

Visit Number

Patient ID Patient Initials
Hospital Patient F M L

Visit Date
month day year

Date of ECG:
month day year

Rate and intervals

Average ventricular rate: bpm

Rhythm: (choose one) Normal sinus Sinus tachycardia Sinus bradycardia

PR interval: 0. sec

Atrial fibrillation Atrial flutter Paced rhythm

QRS duration: 0. sec

Wandering atrial pacemaker Other

QTc interval: 0. sec

Hypertrophy

Left ventricular hypertrophy: yes no

Right ventricular hypertrophy: yes no

Infarction

Evidence of previous Q-wave MI: yes no

If yes, Location: anterior lateral infero-posterior

Conduction (mark all that apply)

normal 1° AV block 2° AV block Mobitz I 2° AV block Mobitz II 2° AV block Uncertain 2° AV block 2:1
 AV Dissociation 3° AV block LBBB RBBB Hemiblock Anterior Hemiblock Posterior
 Pre-excitation Other intraventricular conduction block



ECG Dataset, Plate 17
 Electrocardiogram

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
* ecdays	Number of days to ECG, from Baseline	
ecvr	Average ventricular rate	
ecrh	Rhythm	1=normal sinus, 2=sinus tachycardia, 3=sinus bradycardia, 4=atrial fibrillation, 5=atrial flutter, 6=paced, 7=wandering atrial pacemaker, 8=other
ecpr	PR interval (sec)	
ecqr	QRS interval (sec)	
ecqt	QTc interval (sec)	
eclvh	Left ventricular hypertrophy	1=yes, 2=no
ecrvh	Right ventricular hypertrophy	1=yes, 2=no
ecpmi	Evidence of previous Q-wave MI	1=yes, 2=no
ecmia	Location of MI: anterior	yes=present, no=absent
ecmil	Location of MI: lateral	yes=present, no=absent
ecmip	Location of MI: infero-posterior	yes=present, no=absent
ecnor	Normal conduction	yes=present, no=absent
ec1av	Cond 1st deg AV blk	yes=present, no=absent
ec2m1	Cond 2nd degree AV blk Mobitz I	yes=present, no=absent
ec2m2	Cond 2nd degree AV blk Mobitz II	yes=present, no=absent
ec2un	Cond 2nd degree AV blk uncertain	yes=present, no=absent
ec221	Cond 2nd degree AV blk 2:1	yes=present, no=absent

* Recoded/new variable, per patient confidentiality guidelines.

ECG Dataset, Plate 17
Electrocardiogram

Variable Name	Description	Coding
ecdis	Cond AV Dissociation	yes=present, no=absent
ec3av	Cond 3rd degree AV block	yes=present, no=absent
eclbb	Conduction LBBB	yes=present, no=absent
ecrbb	Conduction RBBB	yes=present, no=absent
echa	Cond Hemiblock Anterior	yes=present, no=absent
echp	Cond Hemiblock Posterior	yes=present, no=absent
ecpre	Conduction Pre-excitation	yes=present, no=absent
ecoht	Conduction - other intraventricular block	yes=present, no=absent

* Recoded/new variable, per patient confidentiality guidelines.

7 id

8 init

9 vdate

10 br18

11 brnyha34

12 brcomp

13 breftt35

14 brscons

15 bropt

16 brexetio

17 brdecomp

18 brmi6

19 brabuse

21 brxplant

20 brnoncom

23 bsurg

22 bricdf

24 brang

25 brhgav

26 brcontra

27 brothdis

28 brexmed

29 brexcomo

30 bpreg

31 brodisq

32 brcad

33 brefstr

34 brrace

35 brsex

36 brrandn

38 vest

37 staff

BR Dataset, Plate 19
 Baseline Randomization

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
* randays	Number of days to visit, from Baseline	0
visit	Visit Number	2
br18	At least 18 years old	1=yes, 2=no
brnyha34	NYHA Class III or IV	1=yes, 2=no
brcomp	Competent to consent	1=yes, 2=no
breft35	EF less or equal 35%	1=yes, 2=no
brscons	Signed consent form	1=yes, 2=no
bropt	Receiving optimal therapy	1=yes, 2=no
brexetio	Excluded etiology of HF	1=yes, 2=no
brdecomp	Unstable decompensated HF	1=yes, 2=no
brmi6	MI within past 6 months	1=yes, 2=no
brabuse	ETOH/drug abuse	1=yes, 2=no
brnoncom	History of noncompliance	1=yes, 2=no
brxplant	Anticipated/listed: transplant	1=yes, 2=no
bricdf	PCD/AICD fired - last 3 months	1=yes, 2=no
brsurg	Excluded cardiac surgery	1=yes, 2=no
brang	Severe/unstable angina	1=yes, 2=no
brhgav	High grade AV block	1=yes, 2=no
brcontra	Contraindication to beta-blockade	1=yes, 2=no
brothdis	Other life-threatening disease	1=yes, 2=no
brexmed	Excluded meds	1=yes, 2=no
brexcomo	Excluded comorbid disease	1=yes, 2=no
brpreg	Pregnant/no contraception	1=yes, 2=no

* Recoded/new variable, per patient confidentiality guidelines.

BR Dataset, Plate 19
Baseline Randomization

Variable Name	Description	Coding
brodisq	Other disqualification	1=yes, 2=no
brcad	CAD stratum	1=yes, 2=no
brefstr	EF stratum	1= $\leq 20\%$, 2= $> 20\%$
brrace	Race stratum	1=black, 2=other
brsex	Sex stratum	1=male, 2=female
brrandn	Randomization number	
vest	Former Vest patient	yes=present, no=absent

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 020

Visit Number

Three empty boxes for visit number

Patient ID

Three empty boxes for hospital part of patient ID

Hospital

Three empty boxes for patient part of patient ID

Patient

Patient Initials

Three empty boxes for patient initials labeled F, M, L

F M L

Visit Date

Two empty boxes for month

month

Two empty boxes for day

day

Two empty boxes for year

year

Date of Sample:

Two empty boxes for month

month

Two empty boxes for day

day

Two empty boxes for year

year

Norepinephrine Sample

Was sample spun down and plasma frozen?

yes

no

Any problems drawing sample?

yes

no

If yes,

Hemolysis

yes

no

Inadequate sample volume

yes

no

Three empty boxes for staff initials labeled F, M, L



NE Dataset, Plate 20
 Norepinephrine

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
* nedays	Number of days to PNE sample, from Baseline	
nespn	NE sample spun and frozen	1=yes, 2=no
neprb	Any problem drawing sample?	1=yes, 2=no
nehem	Hemolysis	1=yes, 2=no
nevol	Inadequate sample volume	1=yes, 2=no
noresult	Sample lost, no result	1=Sample taken, lost at site 2=Sample taken, other problem at site 3=Sample sent to corelab, lost 4=No result, circumstances unknown

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 021

Visit Number: [][][]

Patient ID [][][] [][][][]
Hospital Patient

Patient Initials [][][]
F M L

Visit Date: [][][] [][][] [][][]
month day year

Type of contact: initial challenge titration regular follow-up special change between visit dispensation

Is this an up-titration visit? yes no

If yes, test vital signs 1 and 2 hours after challenge dose. If no, skip to Study Drugs Returned.

Challenge dose: [][][] . [][][] mg

Vital signs one hour after challenge dose:

HR (sitting): [][][] beats/min BP(sitting): [][][] / [][][] mmHg

Vital signs two hours after challenge dose:

HR (sitting): [][][] beats/min BP(sitting): [][][] / [][][] mmHg

Tolerance: tolerated not tolerated, will rechallenge not tolerated, will NOT rechallenge **If not tolerated fill out AME**

Symptoms _____

Study drugs returned:

Did the patient return study drug from previous visit? yes no

Study drug returned (number of caps):	Study drug dispensed (number of caps):	Capsules/dose	doses/day
3.0 mg [][][]	3.0 mg [][][]	[]	[]
6.25 mg [][][]	6.25 mg [][][]	[]	[]
12.5 mg [][][]	12.5 mg [][][]	[]	[]
25 mg [][][]	25 mg [][][]	[]	[]
50 mg [][][]	50 mg [][][]	[]	[]
100 mg [][][]	100 mg [][][]	[]	[]

IMPORTANT

Adverse event since last visit?

yes no

**IF YES.....
Fill out AME form**

Is patient currently taking study medication? yes no

If no, is d/c expected to be permanent? yes no

Reasons for discontinuation (Notify Study Co-Chair at initial discontinuation): _____

Staff Initials [][][]
F M L



SMED Dataset, Plate 21
 Study Medication / Dose Titration

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
smtyp	Type of contact	1=initial challenge 2=titration 3=regular follow-up 4=special change 5=between visit dispensation
smupt	Is this an up-titr visit?	1=Yes, 2=No
smchd	Challenge dose	
smhr1	Heart rate after 1 hour	
smsb1	Systolic BP after 1 hr	
smdb1	Diastolic BP after 1 hr	
smhr2	Heart rate after 2 hours	
smsb2	Systolic BP after 2 hr	
smdb2	Diastolic BP after 2 hr	
smtol	tolerance	1=tolerated 2=not tolerated, will rechallnge 3=not tolerated, won't rechallenge
smsym	symptoms	
smret	Did pt ret. study drug?	1=Yes, 2=No
smr3	Returned 3.0 mg caps	

* Recoded/new variable, per patient confidentiality guidelines.

SMED Dataset, Plate 21
 Study Medication / Dose Titration

Variable Name	Description	Coding
smp3	Dispensed 3.0 mg caps	
smc3	Capsules per dose 3 mg	
smd3	Doses per day 3 mg	
smr6	Returned 6.25 mg caps	
smp6	Dispensed 6.25 mg caps	
smc6	Capsules per dose 6.25 mg	
smd6	Doses per day 6.25 mg	
smr12	Returned 12.5 mg caps	
smp12	Dispensed 12.5 mg caps	
smc12	Capsules per dose 12.5 mg	
smd12	Doses per day 12.5 mg	
smr25	Returned 25 mg caps	
smp25	Dispensed 25 mg caps	
smc25	Capsules per dose 25 mg	
smd25	Doses per day 25 mg	
smr50	Returned 50 mg caps	
smp50	Dispensed 50 mg caps	
smc50	Capsules per dose 50 mg	
smd50	Doses per day 50 mg	
smr10	Returned 100 mg caps	
smp10	Dispensed 100 mg caps	
smc10	Capsules per dose 100 mg	

* Recoded/new variable, per patient confidentiality guidelines.

SMED Dataset, Plate 21
Study Medication / Dose Titration

Variable Name	Description	Coding
smd10	Doses per day 100 mg	
smame	Adverse event since last visit?	1=Yes, 2=No
smsmd	Is pt taking study med?	1=Yes, 2=No
smdcp	Is d/c expt'd to be permanent?	1=Yes, 2=No
smdis	Discontinuation reasons	

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 023

Adverse Event Report Number 6

Patient ID Hospital Patient Patient Initials F M L

Form Date month day year

Date of hospital or ER visit: month day year

Type: hospital ER

Visit due to worsening heart failure yes no (Answer "yes" only if the admission/visit is due to decompensated heart failure.)

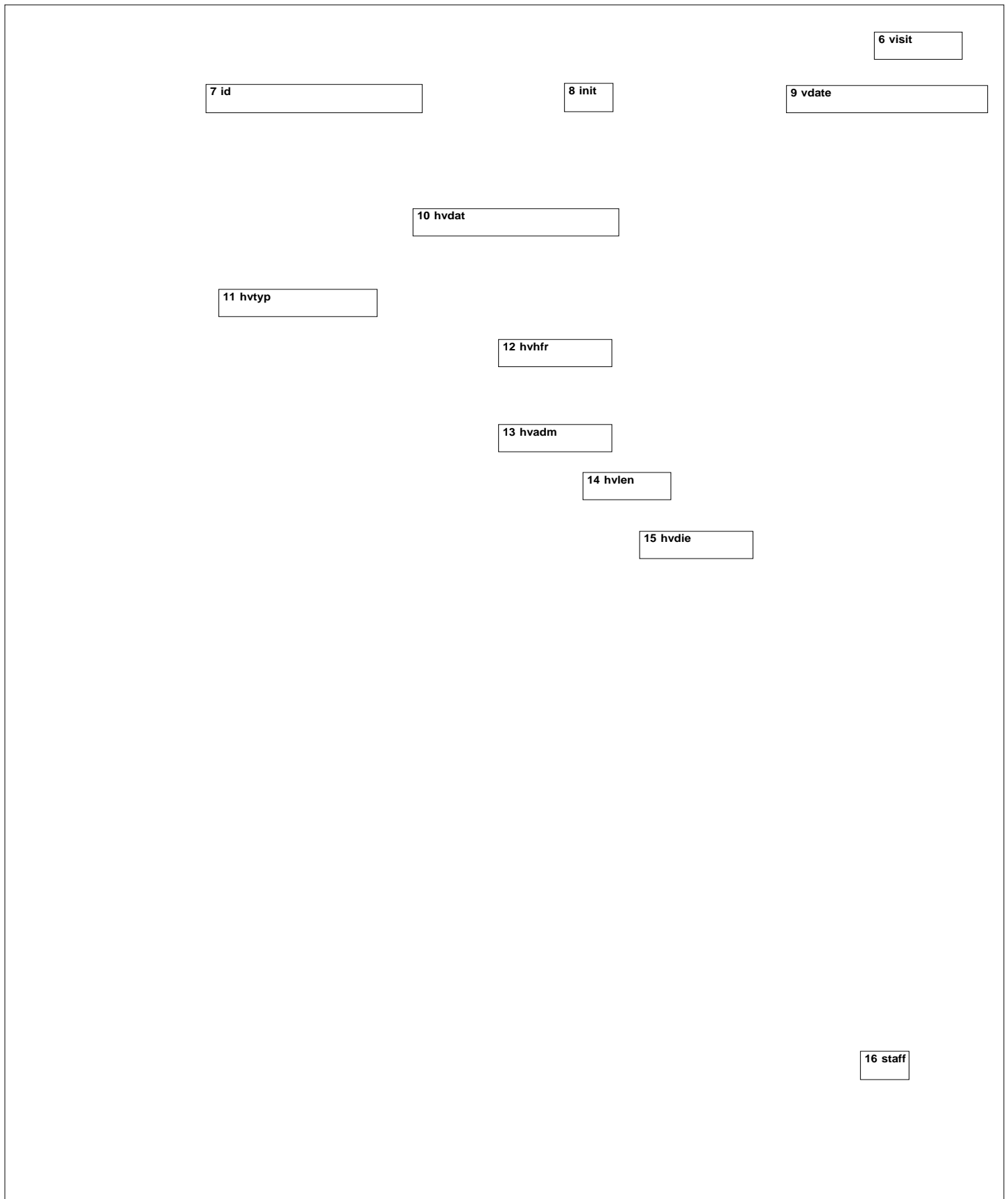
Was the patient admitted to hospital? yes no

If yes, how long was the hospital stay? days

Did patient die during this ER visit or hospitalization? yes no

Note: Fill out Adverse Medical Events Form and FDA Form 3500 (MedWatch) and obtain Discharge Summary for your files.





HV Dataset, Plate 23
Hospitalization or Emergency Room Visit

Variable Name	Description	Coding
visit	Adverse Event Report Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to report date, from Baseline	
* hvdays	Number of days to Hosp/ER visit, from Baseline	
hvtyp	Type	1=hospital, 2=ER
hvhfr	Visit due to HF related illness?	1=yes, 2=no
hvadm	Was patient admitted to the hospital?	1=yes, 2=no
hvlcn	How long was hospital stay?	
hvdie	Did patient die during visit?	1=yes, 2=no

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 024

Adverse Event Report Number

Patient ID
Hospital Patient

Patient Initials
F M L

Form Date:
month day year

Fill out if you have evidence that the patient has had a NEW MI (AME form required)

Date of suspected MI:
month day year

Q waves? *yes* *no* *unknown*

Evidence of MI (at least 2 must be answered yes for documented MI):

Enzymes: *yes* *no*

ECG: *yes* *no*

Clinical: *yes* *no* If YES, give details:

Note: Fill out Adverse Medical Events Form, Hospitalization Form (if necessary) and FDA Form 3500 (MedWatch)



6 visit

7 id

8 init

9 vdate

10 mida

11 miqw

12 mienz

13 miecg

14 micln

15 mi_dtls

16 staff

MI Dataset, Plate 24
Myocardial Infarction

Variable Name	Description	Coding
visit	Adverse Event Report Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to report date, from Baseline	
* midays	Number of days to MI, from Baseline	
miqw	Q waves?	1=yes, 2=no, 3=unknown
mienz	Enzyme evidence?	1=yes, 2=no
miecg	ECG evidence?	1=yes, 2=no
micln	Clinical evidence?	1=yes, 2=no
mi_dtls	MI clinical details	

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 025

XP Number:

Patient ID
Hospital Patient

Patient Initials
F M L

Form Date
month day year

Date of change in status:
month day year

New transplant status: *listed* *transplanted*



6 xpnum

7 id

8 init

9 vdate

10 xpdat

11 xpsta

12 staff

XP Dataset, Plate 25
Transplant Status

Variable Name	Description	Coding
xpnum	Transplant Number	551-559
* best_id	Patient ID	1-2708
* vdays	Number of days to report date, from Baseline	
* xpdays	Number of days to change in status, from Baseline	
xpsta	New transplant status	1=listed, 2=transplanted

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 026

Adverse Event Report Number 6

Patient ID Hospital Patient

Patient Initials F M L

Form Date: month day year

Date death pronounced: month day year

Autopsy performed? yes no

Documentation of death

Hospital record yes no

Death certificate yes no

Verbal report of family or friend yes no

Other report yes no

Death witnessed yes no

Location of death In ER in hospital out of hospital

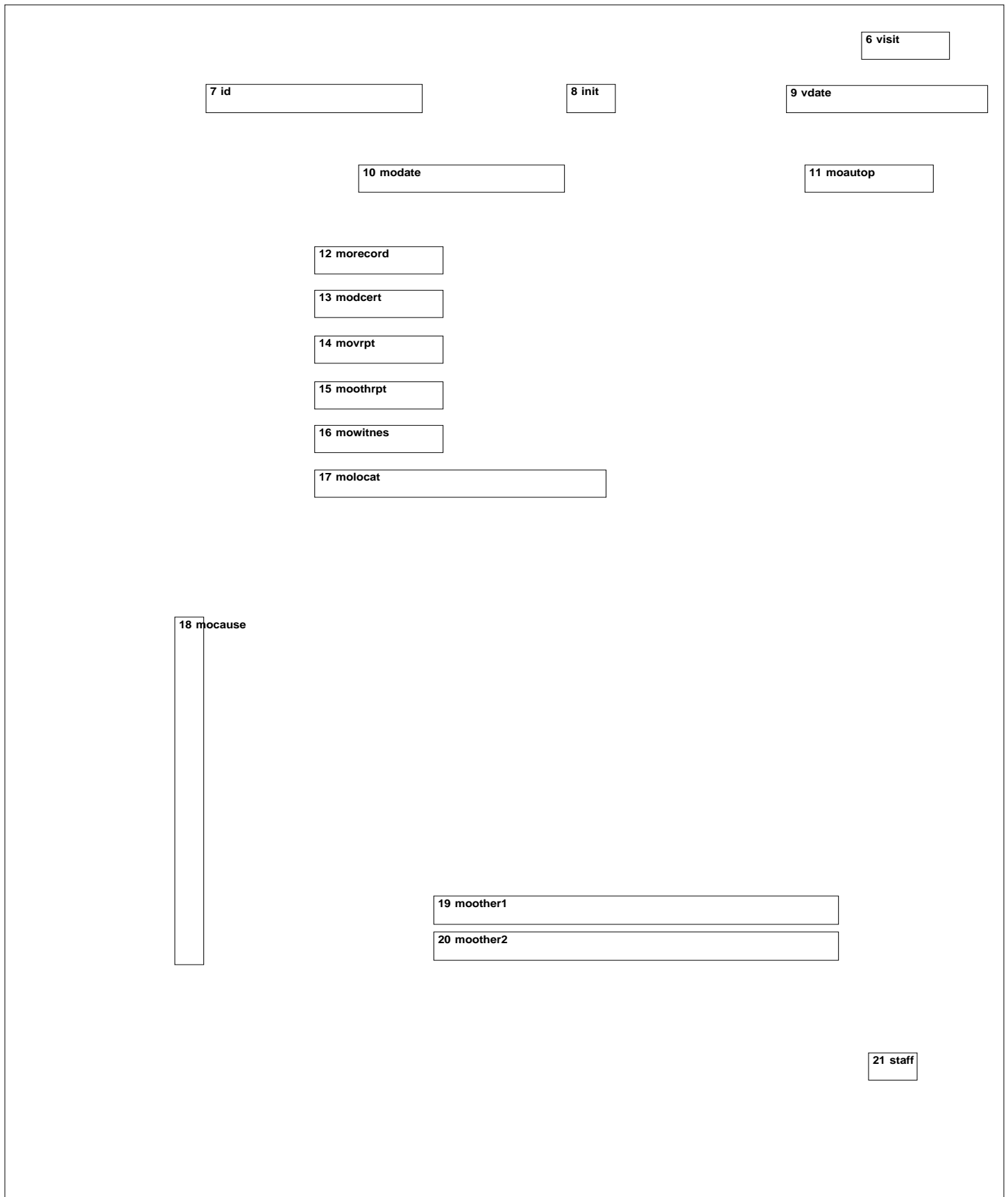
Cause of death:

Check one and only one of the following suspected causes of death

- Sudden Unexpected Death without change in CV symptoms, in NYHA class I or II patient.
Sudden Unexpected Death preceded by change in CV symptoms, in NYHA class I or II patient.
Sudden death without change in CV symptoms in NYHA class III or IV patient.
Sudden death preceded by change in CV symptoms, in NYHA class III or IV patient.
Pump failure with or without secondary arrhythmic death.
Myocardial Infarction
Cerebrovascular
Other Cardiovascular death
Non-Cardiovascular death

Continued.....





MORT_1 Dataset, Plate 26
 Mortality Form, pg. 1

Variable Name	Description	Coding
visit	Adverse Event Rpt. No.	
* best_id	Patient ID	1-2708
* vdays	Number of days to report date, from Baseline	
* modays	Number of days to death, from Baseline	
moautop	Autopsy performed	1=yes, 2=no
morecord	Hospital record	1=yes, 2=no
modcert	Death certificate	1=yes, 2=no
movrpt	Verbal report of family	1=yes, 2=no
moothrpt	Other report	1=yes, 2=no
mowitnes	Death witnessed	1=yes, 2=no
molocat	Location of death	1=in ER, 2=in hospital, 3=out of hospital
mocause	Cause of death	1 = Sudden unexpected death, without change in CV symptoms, in NYHA Class I or II pt. 2 = Sudden unexpected death, preceded by change in CV symptoms, in NYHA Class I or II pt. 3 = Sudden death, without change in CV symptoms, in NYHA Class III or IV patient 4 = Sudden death, preceded by change in CV symptoms, in NYHA Class III or IV patient 5 = Pump failure with or without secondary arrhythmic death 6 = Myocardial infarction 7 = Cerebrovascular 8 = Other cardiovascular death 9 = Non-cardiovascular death
mooother1	Other CV death (list)	
mooother2	Non-CV death (list)	

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 027

Adverse Event Report Number 6

Patient ID Hospital Patient Patient Initials F M L

Form Date: month day year

Last date study med taken: month day year

(Date and number must match page 1)

Medication use during week before death from one week to one month before death

Table with medication categories (Oral diuretic, IV diuretic, Digoxin, etc.) and response options (yes, no, unknown) for two time periods.

Note: Fill out Adverse Medical Events Form, FDA Form 3500 (MedWatch), Withdrawal Form, and prepare Long Form Mortality Report.



		6 visit
7 id	8 init	9 vdate
	10 momeddat	
11 moral_wk		12 moral_mo
13 moiv_wk		14 moiv_mo
15 modig_wk		16 modig_mo
17 moace_wk		18 moace_mo
19 monon_wk		20 monon_mo
21 mopho_wk		22 mopho_mo
23 mocal_wk		24 mocal_mo
25 moant_wk		26 moant_mo
27 moino_wk		28 moino_mo
29 moksu_wk		30 moksu_mo
31 mokdi_wk		32 mokdi_mo
33 moasp_wk		34 moasp_mo
		35 staff

MORT_2 Dataset, Plate 27
 Mortality Form, pg. 2

Variable Name	Description	Coding
visit	Adverse Event Rpt. Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to report date, from Baseline	
* momedays	Days to meds last taken, from Baseline	
moral_wk	Oral diuretic week before death	1=yes, 2=no, 3=unknown
moral_mo	Oral diuretic month before death	1=yes, 2=no, 3=unknown
moiv_wk	IV diuretic week before death	1=yes, 2=no, 3=unknown
moiv_mo	IV diuretic month before death	1=yes, 2=no, 3=unknown
modig_wk	Digoxin week before death	1=yes, 2=no, 3=unknown
modig_mo	Digoxin month before death	1=yes, 2=no, 3=unknown
moace_wk	ACEI week before death	1=yes, 2=no, 3=unknown
moace_mo	ACEI month before death	1=yes, 2=no, 3=unknown
monon_wk	Non-ACEI week before death	1=yes, 2=no, 3=unknown
monon_mo	Non-ACEI month before death	1=yes, 2=no, 3=unknown
mopho_wk	Phospho week before death	1=yes, 2=no, 3=unknown
mopho_mo	Phospho month before death	1=yes, 2=no, 3=unknown
mocal_wk	Calc. ch. blocker week before death	1=yes, 2=no, 3=unknown
mocal_mo	Calc. ch. blocker month before death	1=yes, 2=no, 3=unknown
moant_wk	Anti-arr. week before death	1=yes, 2=no, 3=unknown
moant_mo	Anti-arr month before death	1=yes, 2=no, 3=unknown
moino_wk	Inotrope week before death	1=yes, 2=no, 3=unknown

* Recoded/new variable, per patient confidentiality guidelines.

MORT_2 Dataset, Plate 27
Mortality Form, pg. 2

Variable Name	Description	Coding
moino_mo	Inotrope month before death	1=yes, 2=no, 3=unknown
moksu_wk	K suppl week before death	1=yes, 2=no, 3=unknown
moksu_mo	K suppl month before death	1=yes, 2=no, 3=unknown
mokdi_wk	K diuretic week before death	1=yes, 2=no, 3=unknown
mokdi_mo	K diuretic month before death	1=yes, 2=no, 3=unknown
moasp_wk	Aspirin week before death	1=yes, 2=no, 3=unknown
moasp_mo	Aspirin month before death	1=yes, 2=no, 3=unknown

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 028

Adverse Event Report Number

6

Patient ID

Hospital

Patient

Patient Initials

F M L

Form Date

month

day

year

Description:

AME code

New onset of an AME? yes no if yes, Onset date

month day year

Is this AME over? yes no if yes, End date

month day year

Greatest severity since last report of this AME mild moderate severe

Related to study medication? no possibly probably

Action taken since the last report of this AME:

Study drug: increased unchanged reduced interrupted discontinued

Treatment: none outpatient hospitalization

Outcome: resolved ongoing patient died

Is a Special Adverse Medical Event Report (FDA Form 3500) required? yes no (see note below)

Severity Classification:

Mild: Does not interfere with normal activity.
Moderate: Interferes with normal activity to some extent.
Severe: Interferes significantly with normal activity.

Criteria for relation to study medication:

No: Definitely not related to study medication.
Possibly: Known to occur. The temporal relationship is not clear, and other causes are also possible.
Probably: Commonly known to occur. Clear temporal relationship is noted or improvement is seen upon withdrawal of drug.

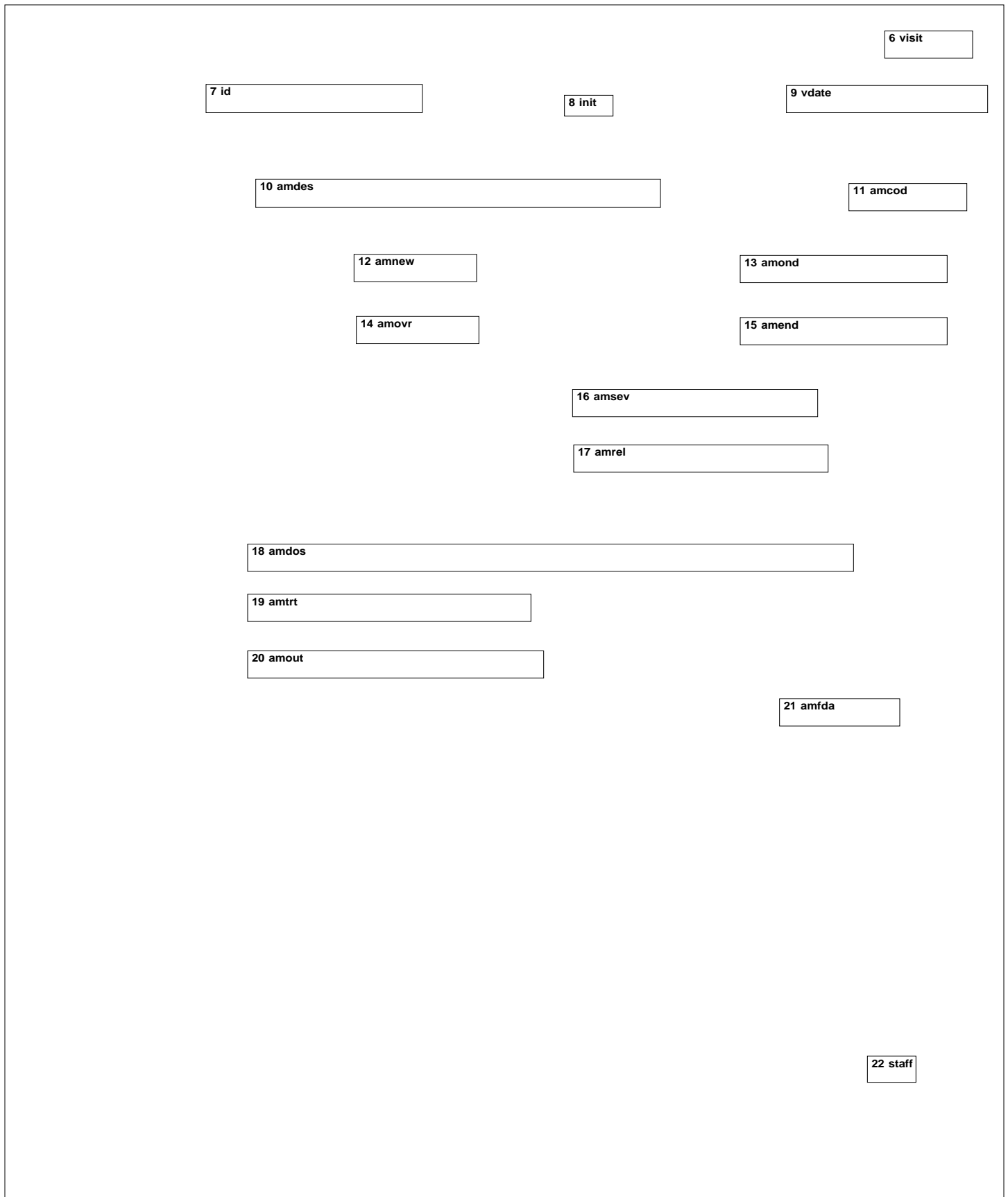
An event is serious when the outcome is:

- Death
Life-threatening (real risk of dying)
Hospitalization (initial or prolonged)
Disability (significant, persistent or prolonged)
Congenital anomaly
Required intervention to prevent permanent impairment or damage

Note: A Special Adverse Medical Event Report (FDA 3500) must be completed within 72 hours for any event reasonably attributable to the drug and is either 1) serious OR 2) unexpected or previously unreported. If the event is fatal or life-threatening, immediately report to the PCC in Albuquerque by telephone, followed by a written report within 72 hours to PCC with a copy to both study Co-Chairmen.

Staff Initials F M L





AME Dataset, Plate 28
 Adverse Medical Event

Variable Name	Description	Coding
visit	Adverse Event Report Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to report date, from Baseline	
amdes	Description	
amcod	AME code	
amnew	New onset of an AME?	1=yes, 2=no
* amondays	Days to AME onset, from Baseline	
amovr	Is this AME over?	1=yes, 2=no
* amendays	Days to AME end, from Baseline	
amsev	Greatest severity since last report of this AME	1=mild, 2=moderate, 3=severe
amrel	Related to study med?	1=no, 2=possibly, 3=probably
amdos	Study drug action taken since last report of this AME	1=increased, 2=unchanged, 3=reduced, 4=interrupted, 5=discontinued
amtrt	Treatment action taken since last report of this AME	1=none, 2=outpatient, 3=hospitalization
amout	Outcome	1=resolved, 2=ongoing, 3=patient died
amfda	Special AME report reqd?	1=yes, 2=no

* Recoded/new variable, per patient confidentiality guidelines.

7 id

8 init

9 vdate

10 wdreport

11 wddate

12 wdr1

13 wdr2

14 wdr3

15 wdr4

16 wdothor1

17 wdothor2

18 wdrecon

19 staff

WD Dataset, Plate 29
 Withdrawal

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
* vdays	Number of days to report date, from Baseline	
wdreport	WD report type	1=inactive, 2=death
* wddays	Days to Withdrawal (non-death), from Baseline	
wdr1	Judgement of PI	1=yes, 2=no
wdr2	Catastrophic injury/illness	1=yes, 2=no
wdr3	Complete inaccessibility	1=yes, 2=no
wdr4	Patient has withdrawn consent	1=yes, 2=no
wdother1	Other reason (text)	
wdother2	Other reason (yes/no)	1=yes, 2=no
wdrecon	Any chance of recontact?	1=yes, 2=no

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 030

EOS

9 0 9

Patient ID

Hospital

Patient

Hospital

Patient

Patient Initials

F M L

F M L

Status Date

month

month

day

day

year

year

Fill out for any randomized patient who has reached the end of scheduled follow-up without an early withdrawal or death.

Status of patient at the time this form completed:

known alive and on study medication

known alive and NOT on study medication

Vital status UNKNOWN



6 eosnum

7 id

8 init

9 vdate

10 ebstatus

11 staff

EOS Dataset, Plate 30
End of Study

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
* vdays	Number of days to report date, from Baseline	
eostatus	Status of Patient	1=alive, on meds 2=alive, off meds

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 031

Visit Number

Patient ID
Hospital Patient

Patient Initials
F M L

Visit Date
month day year

How do you feel today as compared to how you felt before taking this medication?
Please mark one box below.

Markedly improved

Moderately improved

Mild improvement

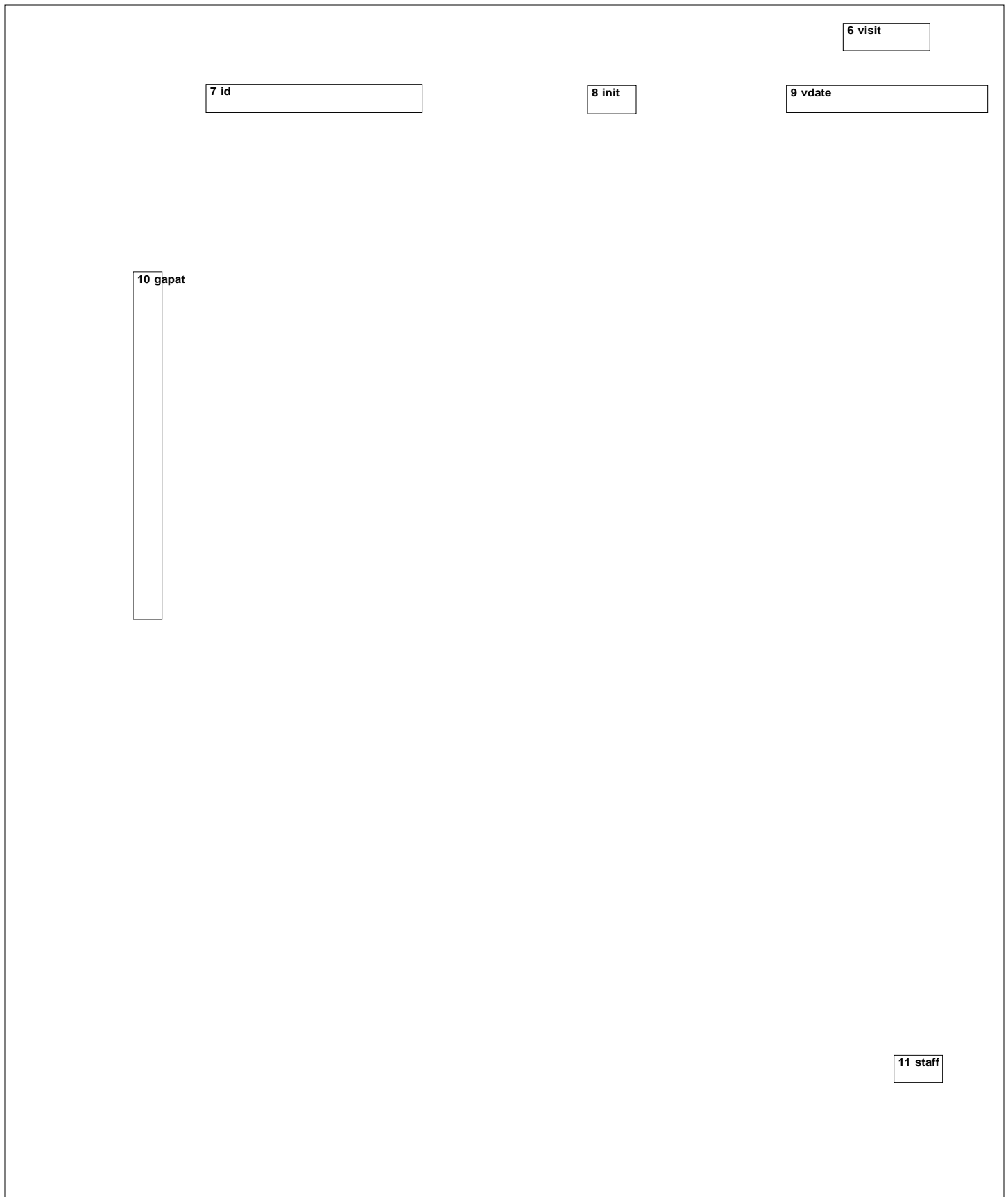
No change

Slightly worse

Moderately worse

Markedly worse





PTGA Dataset, Plate 31
Patient's Global Assessment

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
gapat	Patient Global Assessment	1=Markedly improved 2=Moderately improved 3=Mild improvement 4=No change 5=Slightly worse 6=Moderately worse 7=Markedly worse

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 032

Visit Number

Patient ID
Hospital Patient

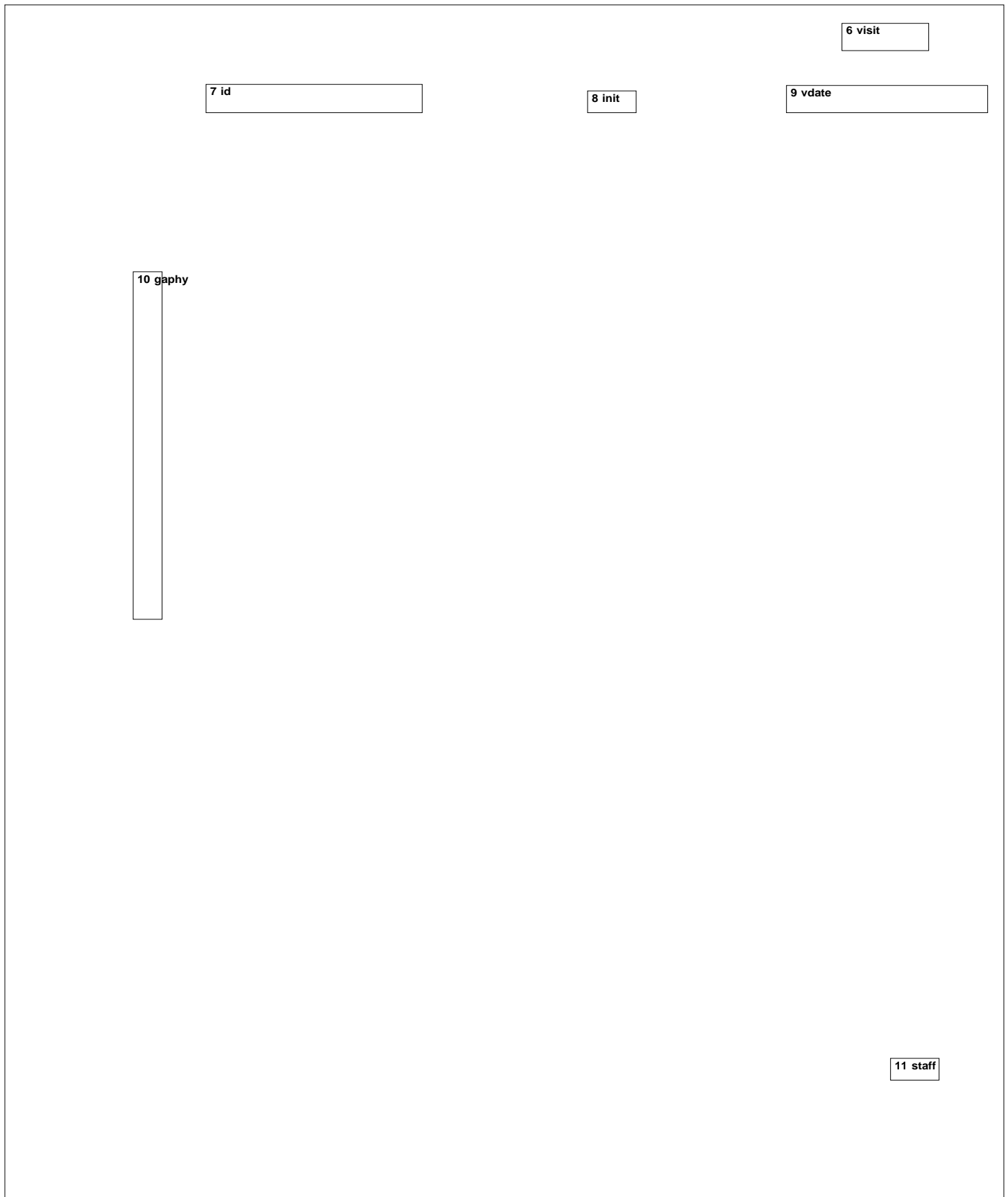
Patient Initials
F M L

Visit Date
month day year

How does the patient's clinical status today compare to his or her status prior to taking study medication?

- Marked improvement
- Moderate improvement
- Mild improvement
- No change
- Slight worsening
- Moderate worsening
- Marked worsening





PHYGA Dataset, Plate 32
Physician's Global Assessment

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
gaphy	Physician Global Assessment	1=Marked improvement 2=Moderate improvement 3=Mild improvement 4=No change 5=Slight worsening 6=Moderate worsening 7=Marked worsening

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate #035

Visit Number

Three empty boxes for visit number

Patient ID

Three empty boxes for hospital part of patient ID

Hospital

Three empty boxes for patient part of patient ID

Patient

Patient Initials

Three empty boxes for patient initials labeled F, M, L

F M L

Visit Date

Two empty boxes for month

month

Two empty boxes for day

day

Two empty boxes for year

year

Date of Sample:

Two empty boxes for month

month

Two empty boxes for day

day

Two empty boxes for year

year

Hematology

Mark if clinically significant abnormality (fill out AME form)

1. Hct

Box for Hct value followed by %

%

Box for clinical significance

2. Hgb

Three boxes for Hgb value followed by g/dL

g/dL

Box for clinical significance

3. Platelet count

Four boxes for platelet count followed by 10⁹/L

10⁹/L

Box for clinical significance

4. WBC's

Three boxes for WBC count followed by 10⁹/L

10⁹/L

Box for clinical significance

Chemistry

5. Glucose

Three boxes for glucose value followed by mmol/L

mmol/L

Box for clinical significance

6. Sodium

Three boxes for sodium value followed by mmol/L

mmol/L

Box for clinical significance

7. Potassium

Two boxes for potassium value followed by mmol/L

mmol/L

Box for clinical significance

8. Chloride

Three boxes for chloride value followed by mmol/L

mmol/L

Box for clinical significance

9. Bicarbonate

Three boxes for bicarbonate value followed by mmol/L

mmol/L

Box for clinical significance

10. BUN

Three boxes for BUN value followed by mmol/L

mmol/L

Box for clinical significance

11. Creatinine

Three boxes for creatinine value followed by umol/L

umol/L

Box for clinical significance

12. Calcium

Two boxes for calcium value followed by mmol/L

mmol/L

Box for clinical significance

13. Magnesium

Two boxes for magnesium value followed by mmol/L

mmol/L

Box for clinical significance

14. Total bilirubin

Three boxes for total bilirubin value followed by umol/L

umol/L

Box for clinical significance

Continue on next page.....



			6 visit
7 id		8 init	9 vdate
	10 cladat		
	11 clahct	12 clahcs	
	13 clahgb	14 clahgs	
	15 clapc	16 claps	
	17 clawbc	18 clawbs	
	19 claglu	20 clagls	
	21 clasdm	22 clasds	
	23 clapot	24 clapos	
	25 clachl	26 clachs	
	27 clabic	28 clabis	
	29 clabun	30 clabus	
	31 clacre	32 clacrs	
	33 clacal	34 clacas	
	35 clamag	36 clamas	
	37 clabil	38 clatbs	
			39 staff

CLAB_1 Dataset, Plate 35
 Canadian Laboratory Results, pg. 1

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
* clabdays	Days to Lab Exam, from Baseline	
clahct	Hct (%)	
clahctx	Hct (%) [conversion]	
clahcs	Hct-clin sign abnormality	yes=present, no=absent
clahgb	Hgb (g/L)	
clahgbx	Hgb (g/dL) [conversion]	
clahgs	Hgb clin sign abnormality	yes=present, no=absent
clapc	Platelet count	
claps	Platlet count - clinically significant abnormality	yes=present, no=absent
clawbc	WBC	
clawbs	WBC clin sign abnormality	yes=present, no=absent
claglu	Glucose (mmol/L)	
clagluc	Glucose (mg/dL) [conversion]	
clagls	Glucose clin sign abnormality	yes=present, no=absent
clasdm	Sodium (mmol/L)	
clasds	Sodium clin sign abnormality	yes=present, no=absent
clapot	Potassium (mmol/L)	
clapos	Potassium clin sig abnormality	yes=present, no=absent
clachl	Chloride (mmol/L)	
clachs	Chloride clin sign abnormality	yes=present, no=absent
clabic	Bicarbonate (mmol/L)	
clabis	Bicarbonate clin sign abnormality	yes=present, no=absent
clabun	BUN (mmol/L)	
clabunx	BUN (mg/dL) [conversion]	
clabus	BUN clin sign abnormality	yes=present, no=absent
clacre	Creatinine (umol/L)	
clacrex	Creatinine (mg/dL) [conversion]	

* Recoded/new variable, per patient confidentiality guidelines.

CLAB_1 Dataset, Plate 35
Canadian Laboratory Results, pg. 1

Variable Name	Description	Coding
clacrs	Creatinine clin sign abnormality	yes=present, no=absent
clacal	Calcium (mmol/L)	
clacalx	Calcium (mdl/dL) [conversion]	
clacas	Calcium clin sign abnormality	yes=present, no=absent
clamag	Magnesium (mmol/L)	
clamas	Magnesium clin sign abnormality	yes=present, no=absent
clabil	Total bilirubin (umol/L)	
clabilx	Total bilirubin (mg/dL) [conversion]	
clatbs	Total bilirubin clin sign abnormality	yes=present, no=absent

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate #036

Visit Number

Three empty boxes for visit number

(must match first page!)

Patient ID

Three empty boxes for hospital part of patient ID

Hospital

Three empty boxes for patient part of patient ID

Patient

Patient Initials

Three empty boxes for patient initials

F M L

Visit Date

Two empty boxes for month

month

Two empty boxes for day

day

Two empty boxes for year

year

Chemistry, continued....

Mark if clinically significant abnormality (fill out AME form)

15. AST/SGOT [][][] U/L []

16. ALT/SGPT [][][] U/L []

17. Alkaline phosphatase [][][] U/L []

18. Phosphorus [] . [][] mmol/L []

19. Uric acid [][][] umol/L []

20. Total protein [][][] . [] g/L []

21. Albumin [][][] . [] g/L []

22. Cholesterol [][] . [][] mmol/L []

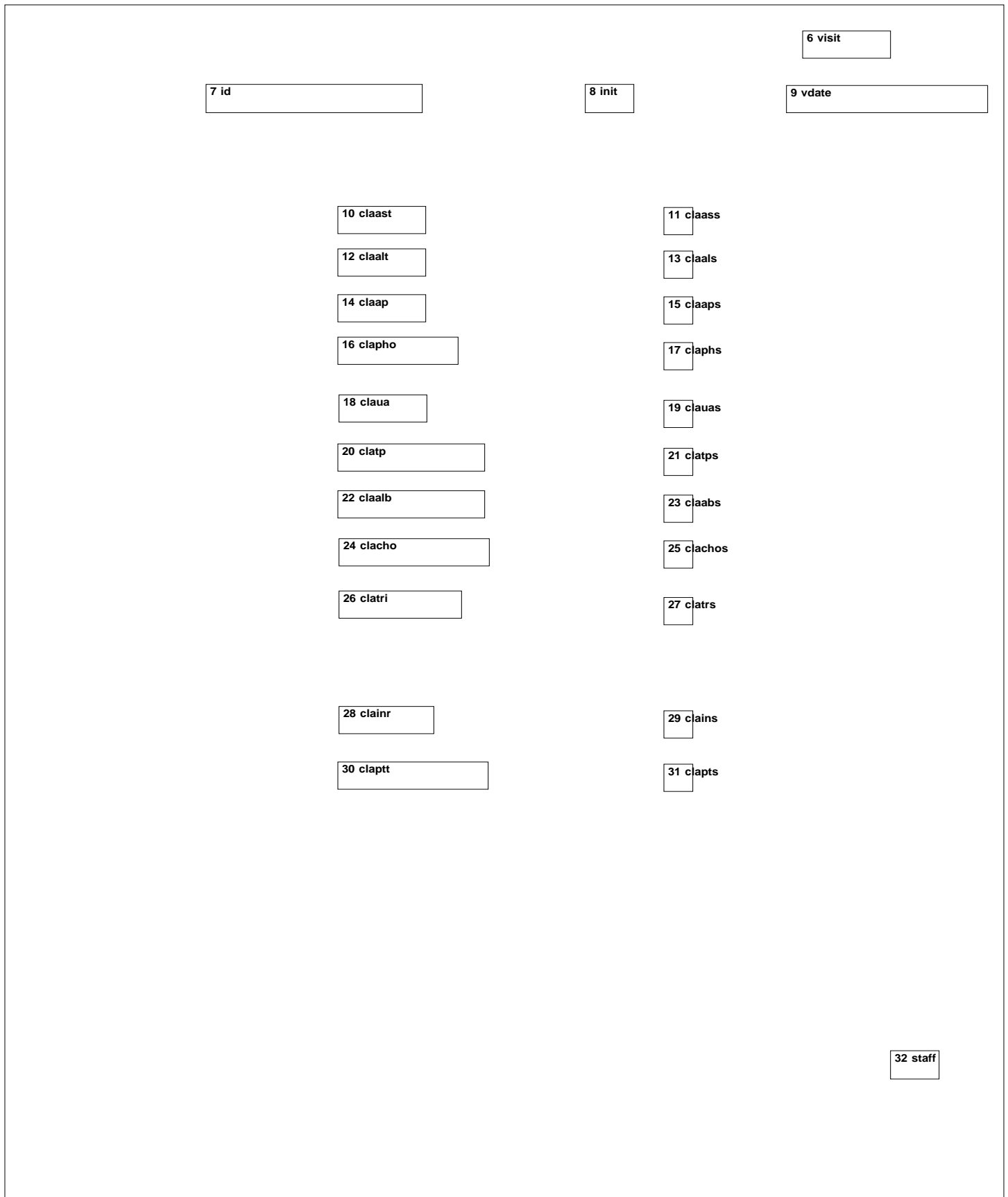
23. Triglycerides [] . [][] mmol/L []

Coagulation

24. INR [] . [] []

25. Activated partial thromboplastin time [][][] . [] sec []





CLAB_2 Dataset, Plate 36
 Canadian Laboratory Results, pg. 2

Variable Name	Description	Coding
visit	Visit Number	
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
claast	AST/SGOT (U/L)	
claass	AST/SGOT clin sign abnormality	yes=present, no=absent
claalt	ALT/SGPT (U/L)	
claals	ALT/SGPT clin sign abnormality	yes=present, no=absent
claap	Alkaline phosphatase-U/L	
claaps	Alkaline Phosp-clin sign abnormality	yes=present, no=absent
clapho	Phosphorus (mmol/L)	
claphox	Phosphorus (mg/dL) [conversion]	
claphs	Phosphorus clin sign abnormality	yes=present, no=absent
claua	Uric acid (umol/L)	
clauax	Uric acid (mg/dL) [conversion]	
clauas	Uric acid clin sign abnormality	yes=present, no=absent
clatp	Total Protein (g/L)	
clatpx	Total Protein (g/dL) [conversion]	
clatps	Total protein clin sign abnormality	yes=present, no=absent
claalb	Albumin (g/L)	
claalbx	Albumin (g/dL) [conversion]	
claabs	Albumin clin sign abnormality	yes=present, no=absent
clacho	Cholesterol (mmol/L)	
clachox	Cholesterol (mg/dL) [conversion]	
clachos	Cholesterol clin sign abnormality	yes=present, no=absent
clatri	Triglycerides (mmol/L)	

* Recoded/new variable, per patient confidentiality guidelines.

CLAB_2 Dataset, Plate 36
Canadian Laboratory Results, pg. 2

Variable Name	Description	Coding
clatrix	Triglycerides (mg/dL) [conversion]	
clatrs	Triglycerides clin sign abnormality	yes=present, no=absent
clainr	INR	
clains	INR clinically significant abnormality	yes=present, no=absent
clppt	Activated PTT (sec)	
clapts	Activated PTT clin sign abnormality	yes=present, no=absent

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate #045

Visit Number

0 0 1

Patient ID

Hospital

Patient

Patient Initials

F M L

Visit Date

month

day

year

Does the patient have a documented history of Diabetes Mellitus at baseline (prior to randomization)?

yes no

If yes, continue:

Mark one:

- Childhood onset (<18 years) - insulin therapy
Childhood onset (<18 years) - oral hypoglycemic therapy
Adult onset - insulin therapy
Adult onset - concurrent insulin and oral hypoglycemic therapy
Adult onset - oral hypoglycemic therapy
Adult onset - dietary treatment only

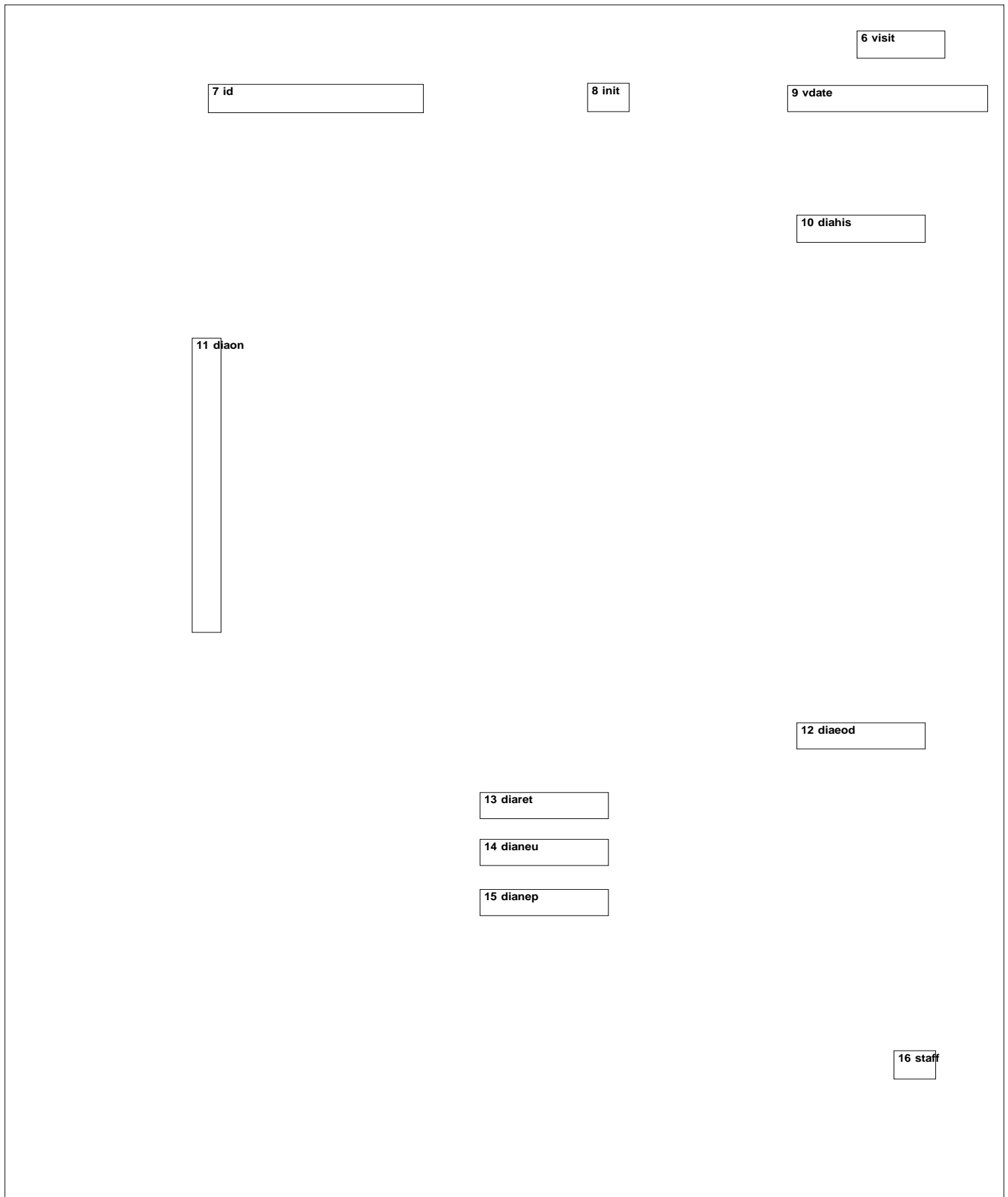
Does the patient have documented diabetic end organ disease at baseline (prior to randomization)?

yes no

If yes, answer each of the following:

- Retinopathy: yes no
Neuropathy: yes no
Nephropathy: yes no





DIAB Dataset, Plate 45
 Diabetes History

Variable Name	Description	Coding
visit	Visit Number	1
* best_id	Patient ID	1-2708
* vdays	Number of days to visit, from Baseline	
diahis	History of Diabetes?	1=yes, 2=no
diaon	Mark onset and therapy	1=Childhood onset - insulin 2=Childhood onset - oral hypoglycemic 3=Adult onset - insulin 4=Adult onset - concurrent insulin and oral hypoglycemic 5=Adult onset - oral hypoglycemic 6=Adult onset - dietary treatment only
diaeod	Documented end organ disease at baseline?	1=yes, 2=no
diaret	Retinopathy:	1=yes, 2=no
dianeu	Neuropathy:	1=yes, 2=no
dianep	Nephropathy	1=yes, 2=no

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate #048

Visit #500

Patient ID
Hospital Patient

Case Number

ADJ Date
month day year

Date death pronounced
month day year

Date patient last observed
month day year

Time of death known *yes* *no* *estimate*

Time of death :
hour min

Documentation reviewed:

Discharge summary *yes* *no*
 Death certificate *yes* *no*
 Autopsy report *yes* *no*

Cardiovascular symptoms:

NYHA class prior to terminal event
I II III IV

Cause of death:

Sudden death not preceded by change in CHF symptoms
 Sudden death preceded by change in CHF symptoms
 Pump failure with or without secondary arrhythmic death
 Myocardial Infarction
 Cardiac procedure _____
 Other cardiovascular death (e.g. cerebrovascular accident, pulmonary embolus, aortic dissection)

 Non-cardiovascular death _____
 No information

Chest pain? (24 hours prior to death):
 yes *no* *unknown*

Comments: _____

Signature: Primary Reviewer _____

DCC Initials
F M L



7 id

8 adcase

9 adjdate

10 addate

11 adlstob

12 adtimekn

13 adtime

14 addcsum

17 adnyha

15 addcert

16 adautop

18 adcause

19 adcpain

20 adcproc

21 adothcv

22 adnoncv

23 adcom

ADJU Dataset, Plate 48
 Mortality Adjudication

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
adcase	Case Number	
* adjdays	Days to adjudication, from Baseline	
* addays	Days to death, from Baseline	
* alldays	Days to date pt. last observed, from Baseline	
adtimekn	Time of death known	1=yes, 2=no, 3=estimate
adtime	Time of death	
addcsum	Discharge summary	1=yes, 2=no
addcert	Death certificate	1=yes, 2=no
adautop	Autopsy report	1=yes, 2=no
adnyha	NYHA class prior to death	1=I, 2=II, 3=III, 4=IV
adcause	Cause of death	1=Sudden death not preceded by change in CHF symptoms 2=Sudden death preceded by change in CHF symptoms 3=Pump failure with or without secondary arrhythmic death 4=Myocardial Infarction 5=Cardiac Procedure 6=Other cardiovascular death 7=Non-cardiovascular death 8=No information
adcpain	Chest pain?	1=yes, 2=no, 3=unknown
adcproc	List cardiac procedure	
adothcv	List other cardiovascular cause of death	
adnoncv	List non-cardiovascular cause of death	
adcom	Comments:	

* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 058

MI Number: 5 0 5

Patient ID Hospital Patient

Case Number

ADJ Date month day year

Date of MI: month day year

Did this MI meet the trial criteria? yes no If no, ACS other

Was it a procedurally-related MI? yes no

If yes, describe:

Evidence of MI: (documented by autopsy evidence or 2 of the other criteria, one of which must be enzymes)

Autopsy evidence: yes no unknown

Elevated enzymes: yes no unknown

If yes, check all that apply: CK > 1.5 UNL with CKMB > 2xUNL CK > 1.5 UNL with cardiac troponin I or T > 2xUNL Other:

ECG evidence: yes no unknown

If yes, check all that apply: new Q waves present new ST segment elevation > 1mm on 2 or more contiguous leads 1mm depression on v1 and v2

Clinical evidence: yes no unknown

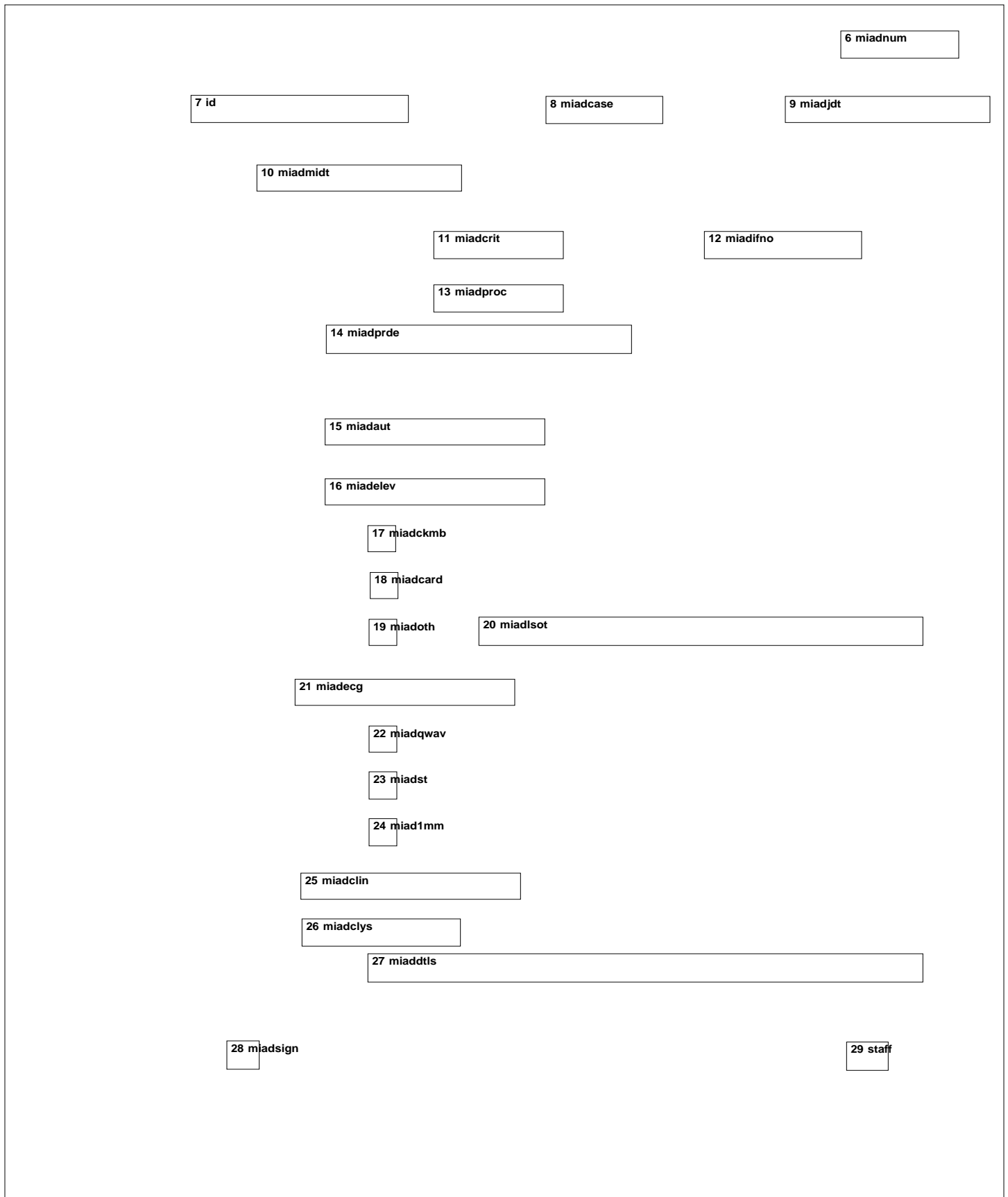
If yes, typical consistent

details:

Signature: Primary Reviewer

DCC Initials F M L





MIADJU Dataset, Plate 58
 Myocardial Infarction Adjudication

Variable Name	Description	Coding
miadnum	MI Number	
* best_id	Patient ID	1-2708
miadcase	MI Case Number	
* miadjday	Days to MI adjudication, from Baseline	
* miadays	Days to MI, from Baseline	
miadcrit	Did this MI meet criteria	1=yes, 2=no
miadifno	If no	1=ACS, 2=other
miadproc	Procedurally-related MI?	1=yes, 2=no
miadprde	If yes, describe	
miadaut	Autopsy evidence	1=yes, 2=no, 3=unknown
miadelev	Elevated enzymes	1=yes, 2=no, 3=unknown
miadckmb	CK > 1.5 UNL with CKMB > 2xUNL	yes=present, no=absent
miadcard	CK > 1.5 UNL with cardiac troponin I or T > 2xUNL	yes=present, no=absent
miadoth	Elev. enzymes, other	yes=present, no=absent
miadlsot	List other	
miadecg	ECG evidence	1=yes, 2=no, 3=unknown
miadqwav	New Q-waves present	yes=present, no=absent
miadst	New ST segment elevation	yes=present, no=absent
miad1mm	1mm depression on v1/v2	yes=present, no=absent
miadclin	Clinical evidence	1=yes, 2=no, 3=unknown
miadclys	Clinical evid., if yes	1=typical, 2=consistent
miaddtls	Clinical evid., details	
miadsign	Signature, primary reviewer	yes=present, no=absent

* Recoded/new variable, per patient confidentiality guidelines.

PERMDC Dataset
Permanent Discontinuation from Study Medication

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
* dcdays	Days to D/C, from Baseline	
reason	Reason for discontinuation	

* Recoded/new variable, per patient confidentiality guidelines.

PNELAB Dataset
PNE Lab Results from PNE Core Lab

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
pne	PNE Level (pg/ml)	
visit	Visit Number	

* Recoded/new variable, per patient confidentiality guidelines.

T Dataset
Treatment Assignment and Time in Study

Variable Name	Description	Coding
* best_id	Patient ID	1-2708
days	Days in study	Days calculated from baseline randomization date to date of withdrawal (non-death), date of death, or date of study termination.
* sitegrp	Clinical site type (VA/Non-VA)	VA=VA, NONVA=Non-VA
group	Treatment Group	1=Placebo, 2=Bucindolol

* Recoded/new variable, per patient confidentiality guidelines.