



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).

- EF too high - list EF:  %
- Class I or II NYHA - mark:  I  II
- Cardiac surgery /procedure within last 60 days, or anticipated (list) \_\_\_\_\_
- Comorbid disease (list) \_\_\_\_\_
- Pregnant or no reliable contraception
- Excluded etiology for CHF (list) \_\_\_\_\_
- Excluded meds (list) \_\_\_\_\_
- Contra-indication to beta-blockers (list) \_\_\_\_\_
- MI in the past 6 months
- Unstable angina
- Age < 18 years
- Listed for cardiac transplant or will be listed within 6 months
- Not on optimal therapy
- High grade AV block
- Life threatening disease (list) \_\_\_\_\_
- 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  |
|---------------|-----------------------------|---|
| pcthdis       | 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. On a scale from 1-10 (1 being WORST) how would you characterize your well-being right now compared to 3-4 months ago?  1  2  3  4  5  6  7  8  9  10  
*much worse a little worse same as before a little better much better*
2. Walking on level ground, do you get short of breath when you go: (average block = 100 yards):  *more than 5 blocks*  *up to 5 blocks*  *1-2 blocks*  *less than 1 block*
3. Walking on level ground, do you become fatigued after:  *more than 5 blocks*  *up to 5 blocks*  *1-2 blocks*  *less than 1 block*
4. Do you characterize your walking as:  *brisk*  *normal*  *slow*
5. How many flights of stairs can you comfortably climb?  *more than 2*  *2*  *1*  *less than 1*
6. Can you do housework?  *heavy (moving furniture)*  *medium (vacuuming)*  *light (dusting)*  *none*
7. Can you do occupational work?  *normal pace*  *reduced pace*  *had to change job*  *had to stop*
8. Can you engage in recreational activities?  *normal pace*  *reduced pace*  *had to change activities*  *had to stop*
9. Are you unable/or do you find it difficult to do grocery shopping (including carrying packages)?  *yes*  *no*
10. Are you short of breath when you are at rest (e.g. in a chair or on the sofa or bed)?.....  *yes*  *no*
11. Do you awaken during the night because of shortness of breath?  *yes*  *no*
12. 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?  *yes*  *no*
13. In the last 3-4 months, what changes have you noticed in your ability to exercise?  *improved*  *no change*  *deteriorated*

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



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 ground .....If 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.



DataFax #001

Plate 007

Visit 001

Patient ID      
 Patient Initials   
 Screening Date

Hospital Patient F M L month day year

Record all routine medications taken by patient at **Screening Visit only**.  
 If dosage changes from day to day, then list average daily dose in the following.

| DRUG      | CODE   | TOTAL DAILY DOSE  | UNITS  | CATEGORY             | ROUTE                |
|-----------|--|---|--|----------------------|----------------------|
| 1. _____  | <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"/> |
| 2. _____  | <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"/> |
| 3. _____  | <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"/> |
| 4. _____  | <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"/> |
| 5. _____  | <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"/> |
| 6. _____  | <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"/> |
| 7. _____  | <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"/> |
| 8. _____  | <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"/> |
| 9. _____  | <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"/> |
| 10. _____ | <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"/> |
| 11. _____ | <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"/> |
| 12. _____ | <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"/> |
| 13. _____ | <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"/> |
| 14. _____ | <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 scdrug1  | 11 sccode1  | 12 scdose1  | 13 scunit1  | 14 sccat1  | 15 scROUT1  |
| 16 scdrug2  | 17 sccode2  | 18 scdose2  | 19 scunit2  | 20 sccat2  | 21 scROUT2  |
| 22 scdrug3  | 23 sccode3  | 24 scdose3  | 25 scunit3  | 26 sccat3  | 27 scROUT3  |
| 28 scdrug4  | 29 sccode4  | 30 scdose4  | 31 scunit4  | 32 sccat4  | 33 scROUT4  |
| 34 scdrug5  | 35 sccode5  | 36 scdose5  | 37 scunit5  | 38 sccat5  | 39 scROUT5  |
| 40 scdrug6  | 41 sccode6  | 42 scdose6  | 43 scunit6  | 44 sccat6  | 45 scROUT6  |
| 46 scdrug7  | 47 sccode7  | 48 scdose7  | 49 scunit7  | 50 sccat7  | 51 scROUT7  |
| 52 scdrug8  | 53 sccode8  | 54 scdose8  | 55 scunit8  | 56 sccat8  | 57 scROUT8  |
| 58 scdrug9  | 59 sccode9  | 60 scdose9  | 61 scunit9  | 62 sccat9  | 63 scROUT9  |
| 64 scdrug10 | 65 sccode10 | 66 scdose10 | 67 scunit10 | 68 sccat10 | 69 scROUT10 |
| 70 scdrug11 | 71 sccode11 | 72 scdose11 | 73 scunit11 | 74 sccat11 | 75 scROUT11 |
| 76 scdrug12 | 77 sccode12 | 78 scdose12 | 79 scunit12 | 80 sccat12 | 81 scROUT12 |
| 82 scdrug13 | 83 sccode13 | 84 scdose13 | 85 scunit13 | 86 sccat13 | 87 scROUT13 |
| 88 scdrug14 | 89 sccode14 | 90 scdose14 | 91 scunit14 | 92 sccat14 | 93 scROUT14 |

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            |               |
| sdrug5        | 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            |               |
| sdrug6        | 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            |               |
| sdrug7        | 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 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

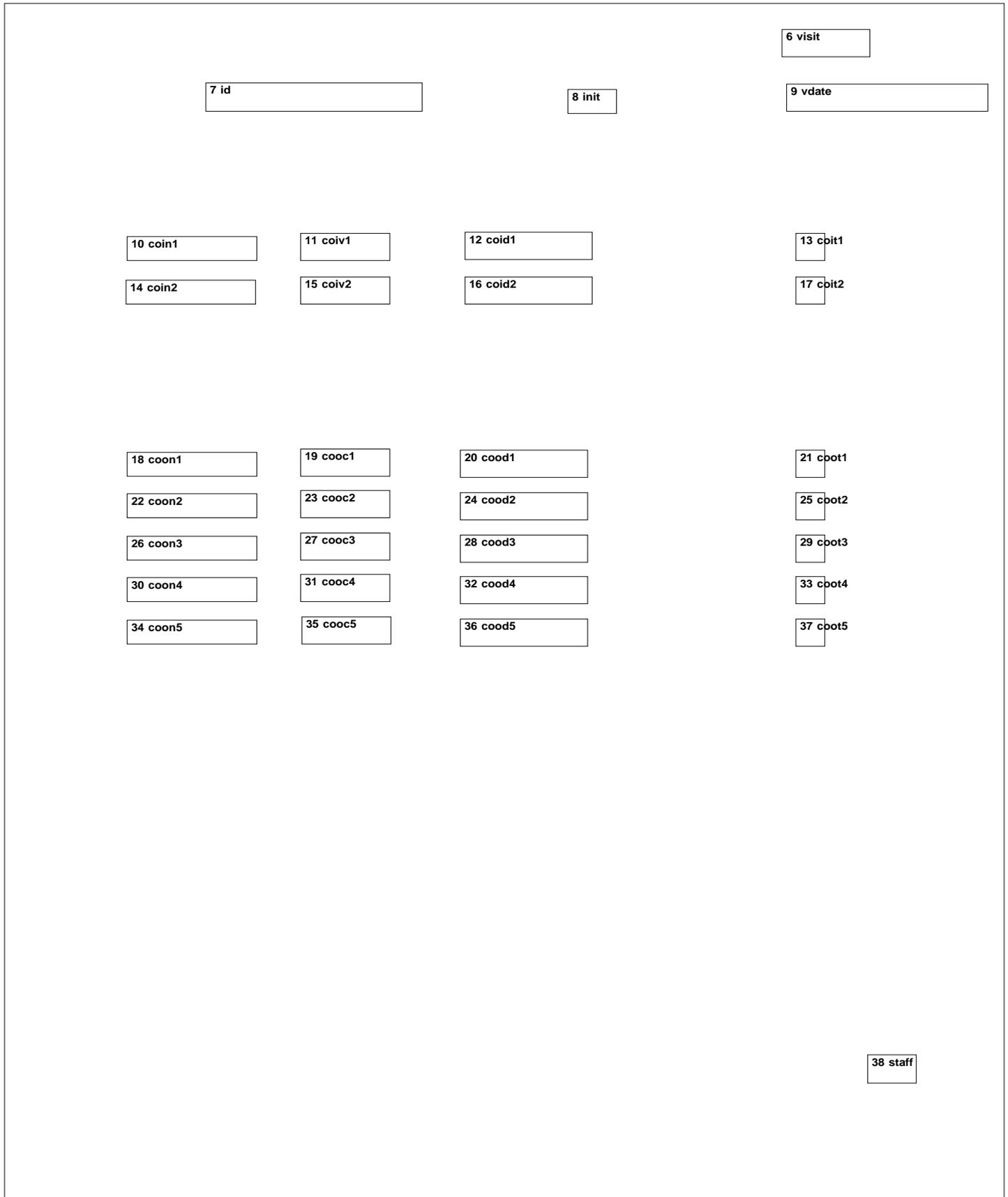
| DRUG     | CODE   | DOSE  | CATEGORY                 |
|----------|--|---|--------------------------|
| 1. _____ | <input type="text"/> <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> . <input type="text"/> mcg/kg/min | <input type="checkbox"/> |
| 2. _____ | 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

□ □ □

Patient ID

□ □ □

Hospital

□ □ □ □

Patient

Patient Initials

□ □ □ □

F M L

Visit Date

□ □

month

□ □

day

□ □

year

Date of MUGA:

□ □

month

□ □

day

□ □

year

Avg HR during MUGA

□ □ □

bpm

Avg BP during MUGA

□ □ □

/

□ □ □

mmHg

Atrial fibrillation during MUGA

yes

no

LVEF

□ □

%

RVEF equilibrium

□ □

%

LAO with caudal angulation

yes

no

Regional wall motion abnormality

yes

no

Diffuse Global wall motion abnormality

yes

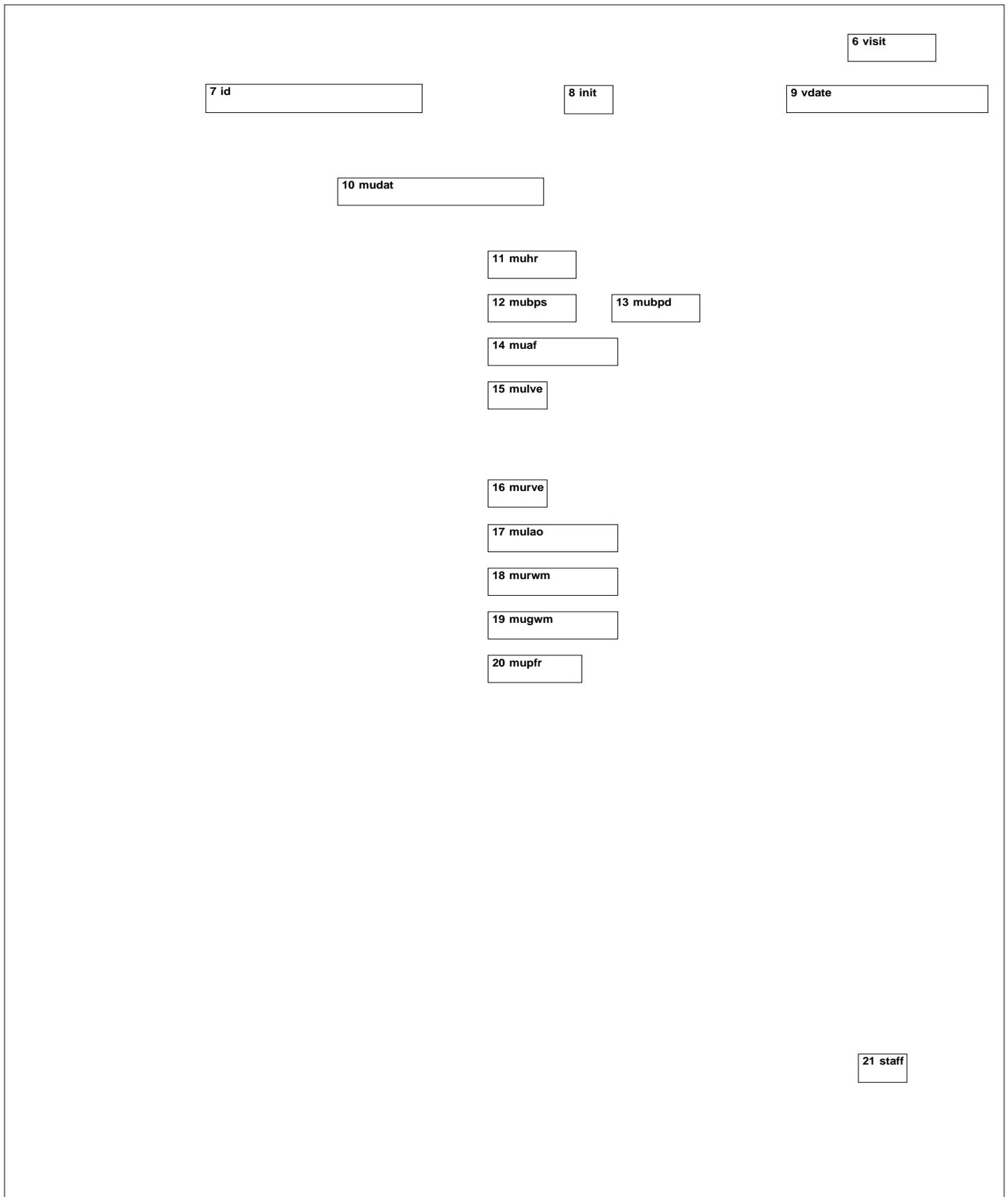
no

Peak filling rate

□ . □

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

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

Two empty boxes for Hct value.

. [ ] %

Empty box for abnormality.

2. Hgb

Two empty boxes for Hgb value.

. [ ] g/dL

Empty box for abnormality.

3. Platelet count

Four empty boxes for platelet count.

$10^3/mm^3$

Empty box for abnormality.

4. WBC's

Two empty boxes for WBC count.

. [ ]  $10^3/mm^3$

Empty box for abnormality.

Chemistry

5. Glucose

Three empty boxes for glucose value.

mg/dL

Empty box for abnormality.

6. Sodium

Three empty boxes for sodium value.

mEq/L

Empty box for abnormality.

7. Potassium

One empty box for potassium value.

. [ ] mEq/L

Empty box for abnormality.

8. Chloride

Three empty boxes for chloride value.

mEq/L

Empty box for abnormality.

9. Bicarbonate

Two empty boxes for bicarbonate value.

. [ ] mEq/L

Empty box for abnormality.

10. BUN

Three empty boxes for BUN value.

mg/dL

Empty box for abnormality.

11. Creatinine

Two empty boxes for creatinine value.

. [ ] mg/dL

Empty box for abnormality.

12. Calcium

Two empty boxes for calcium value.

. [ ] mg/dL

Empty box for abnormality.

13. Magnesium

One empty box for magnesium value.

. [ ] mEq/L

Empty box for abnormality.

14. Total bilirubin

Two empty boxes for total bilirubin value.

. [ ] mg/dL

Empty box for abnormality.

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 |
| laca          | Calcium (mg/dL)                                      |                        |
| lacas         | Calcium - clinically significant abnormality         | yes=present, no=absent |
| lamag         | Magnesium (mEq/L)                                    |                        |
| lomas         | 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   
Hospital Patient

Patient Initials   
F M L

Visit Date   
month day year

Chemistry, continued....

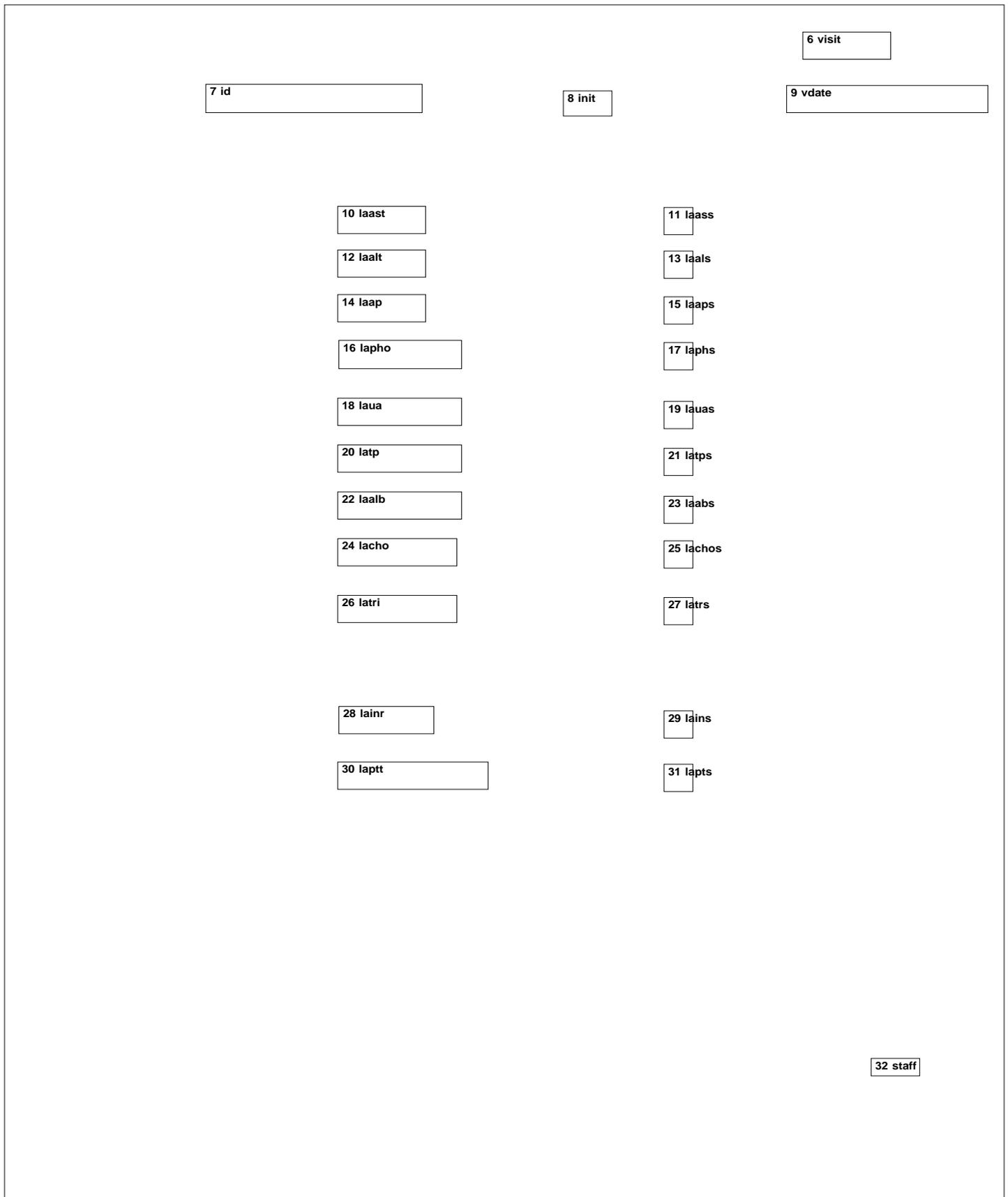
Mark if clinically significant abnormality (fill out AME form)

- 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

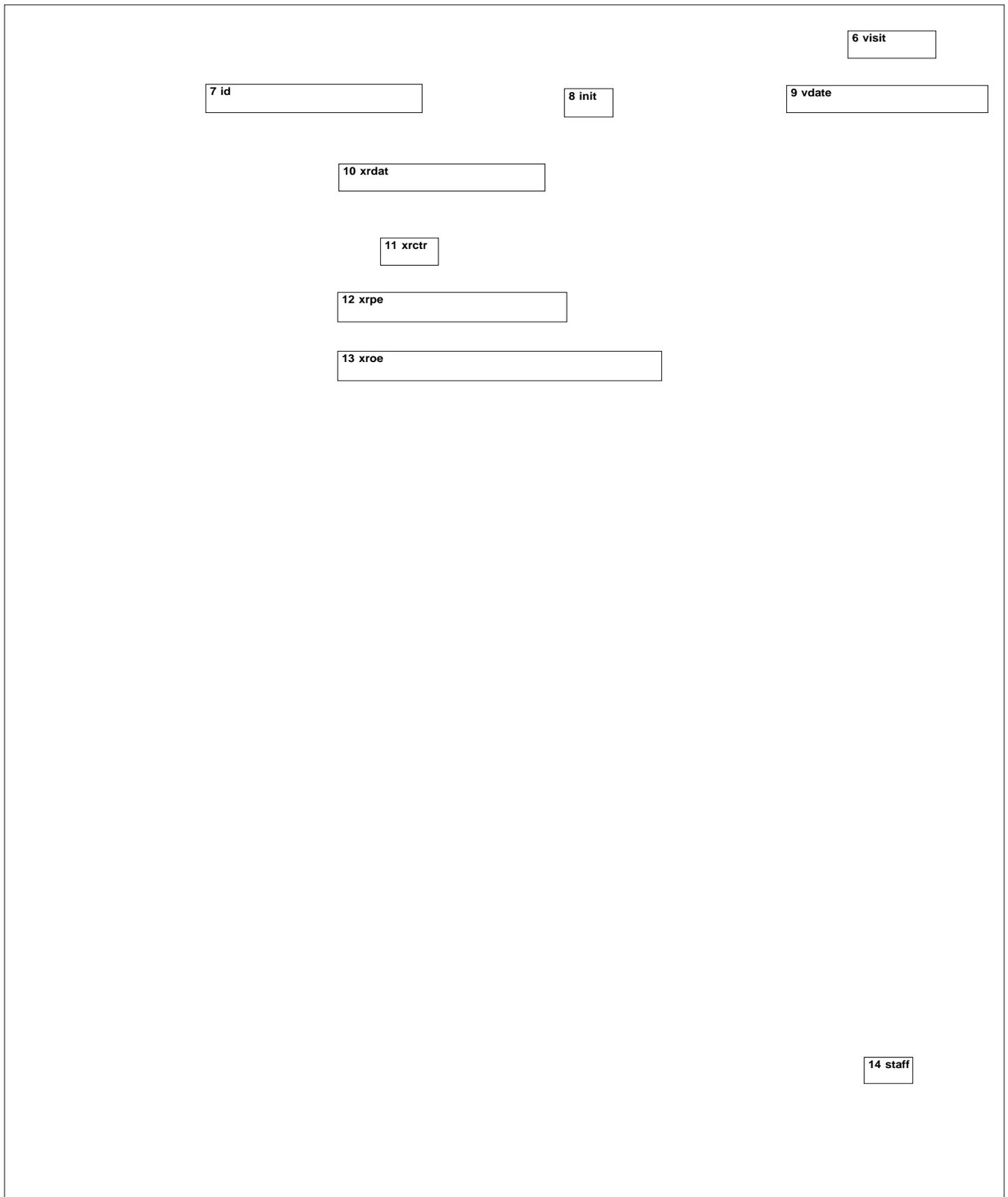
If old edema:

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 brsurg

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<br>2=Sample taken, other problem at site<br>3=Sample sent to corelab, lost<br>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<br>2=titration<br>3=regular follow-up<br>4=special change<br>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<br>2=not tolerated, will rechallnge<br>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?

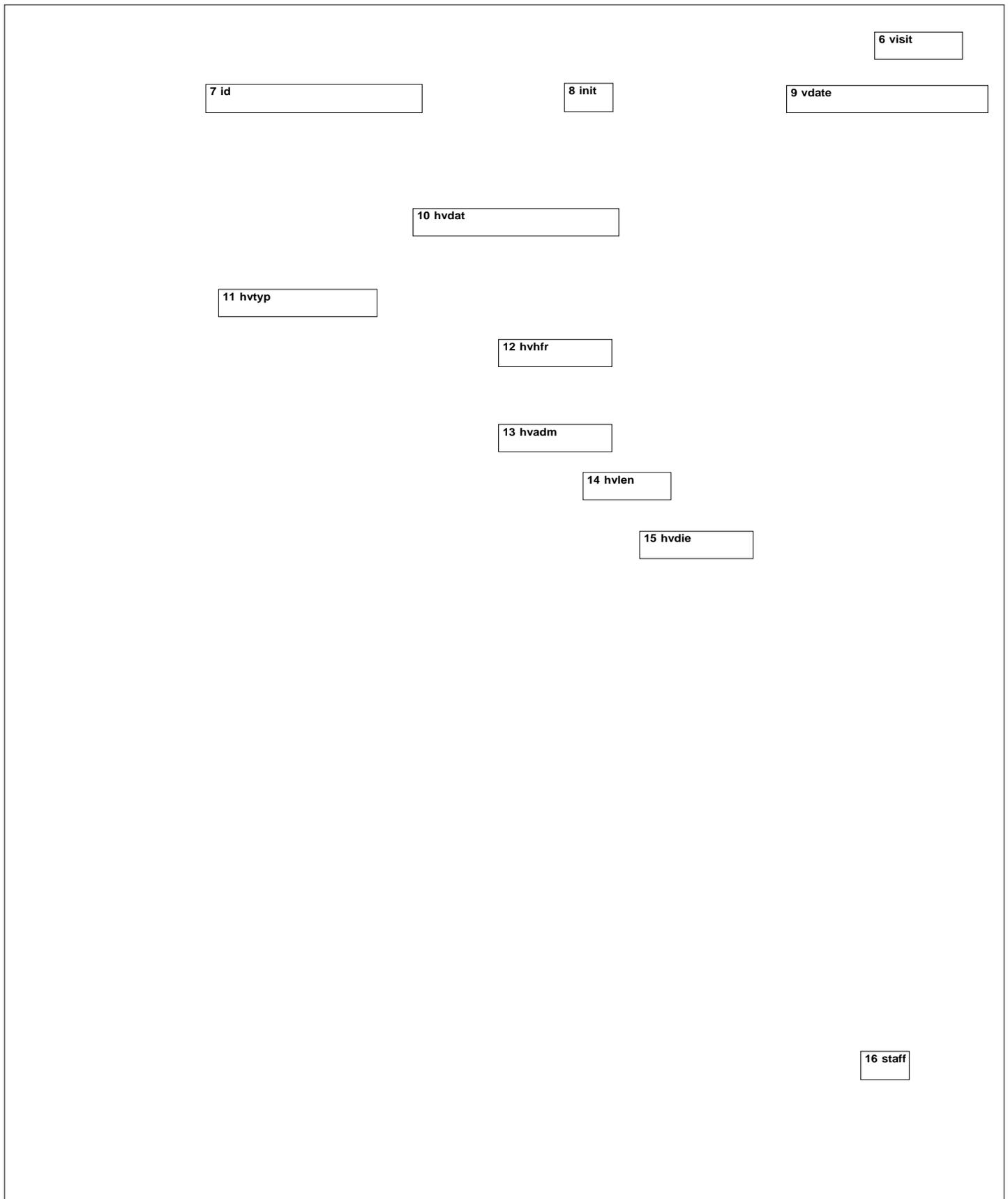
yes

no

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

F M L





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

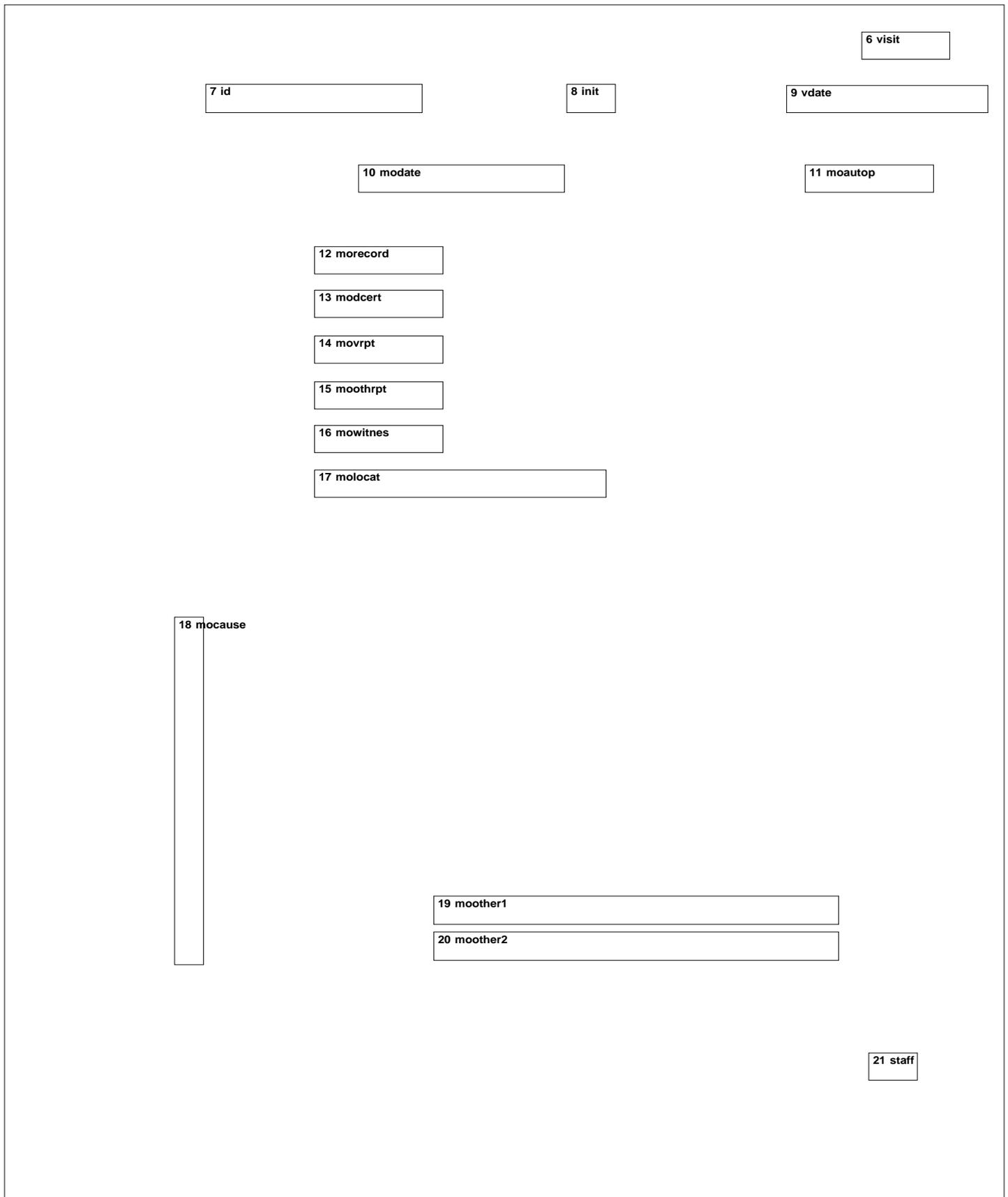
Cause of death:

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.<br>2 = Sudden unexpected death, preceded by change in CV symptoms, in NYHA Class I or II pt.<br>3 = Sudden death, without change in CV symptoms, in NYHA Class III or IV patient<br>4 = Sudden death, preceded by change in CV symptoms, in NYHA Class III or IV patient<br>5 = Pump failure with or without secondary arrhythmic death<br>6 = Myocardial infarction<br>7 = Cerebrovascular<br>8 = Other cardiovascular death<br>9 = Non-cardiovascular death |
| moother1      | Other CV death (list)                        |   |
| moother2      | 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? (see note below)

yes

no

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:

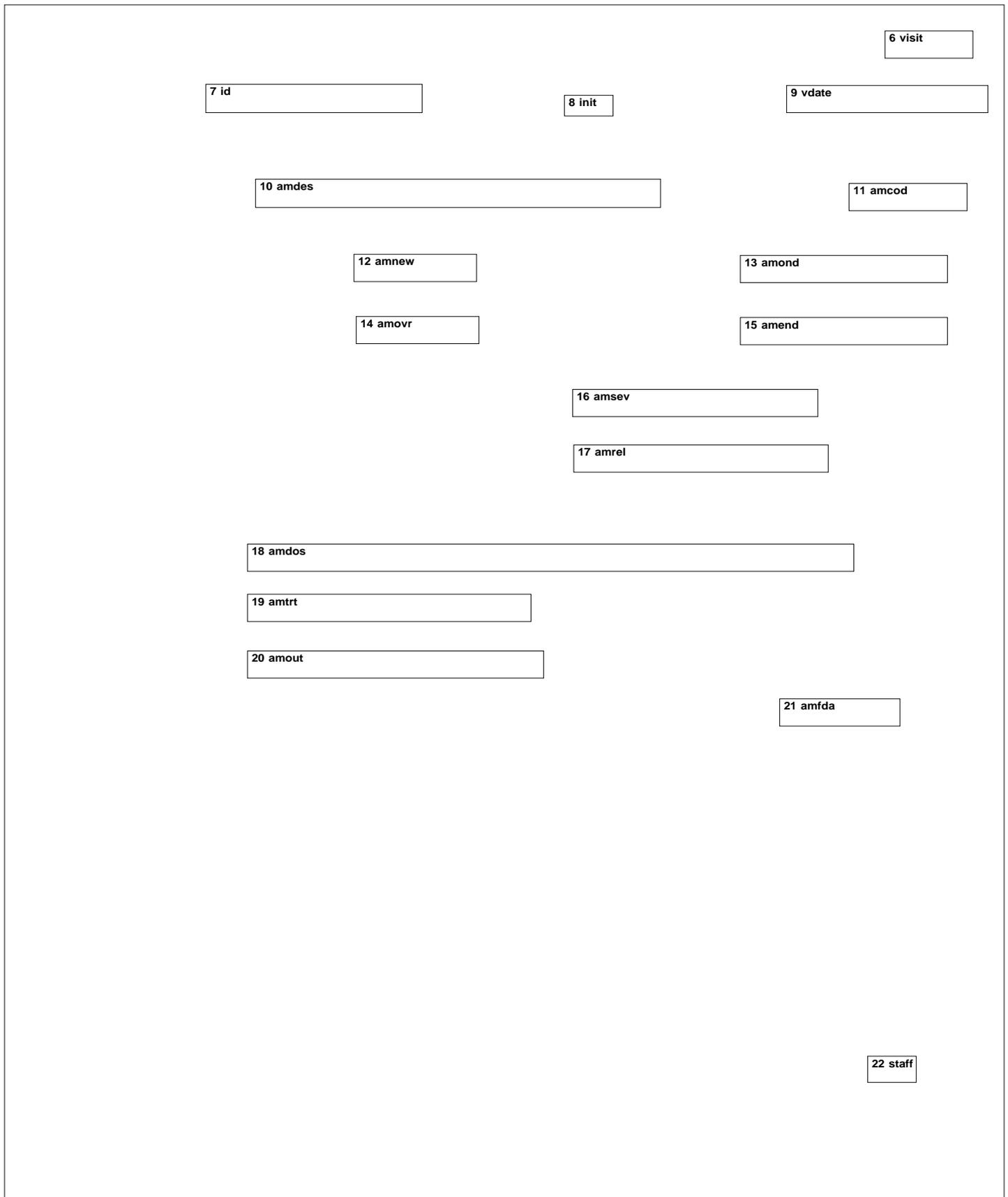
- Death
Life-threatening (real risk of dying)
Hospitalization (initial or prolonged)
Disability (significant, persistent or prolonged)
Congenital anomaly
Required intervention to prevent permanent impairment or damage

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<br>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

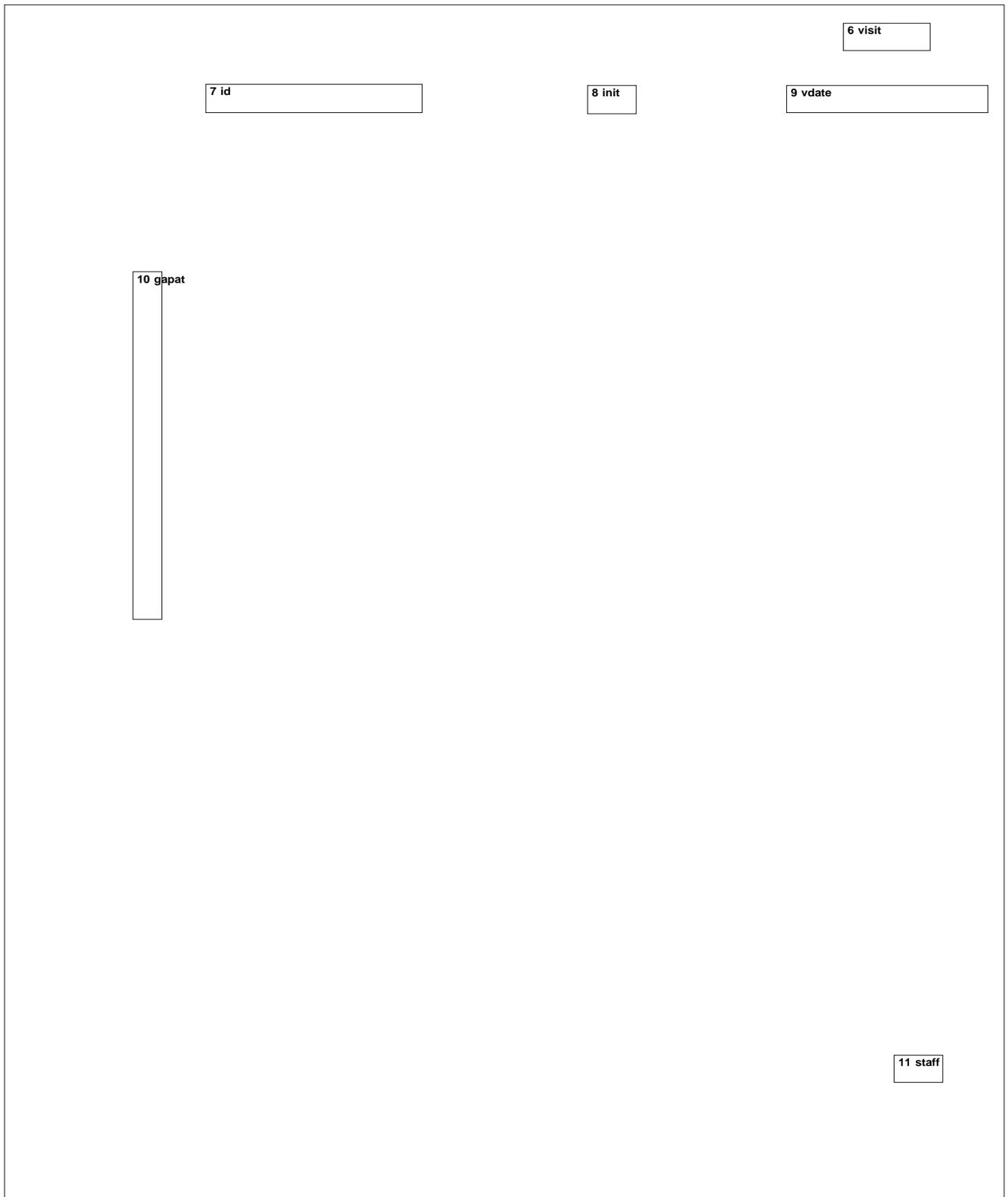
No change

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<br>2=Moderately improved<br>3=Mild improvement<br>4=No change<br>5=Slightly worse<br>6=Moderately worse<br>7=Markedly worse |

\* Recoded/new variable, per patient confidentiality guidelines.



DataFax #001

Plate 032

Visit Number

Patient ID    
*Hospital Patient*

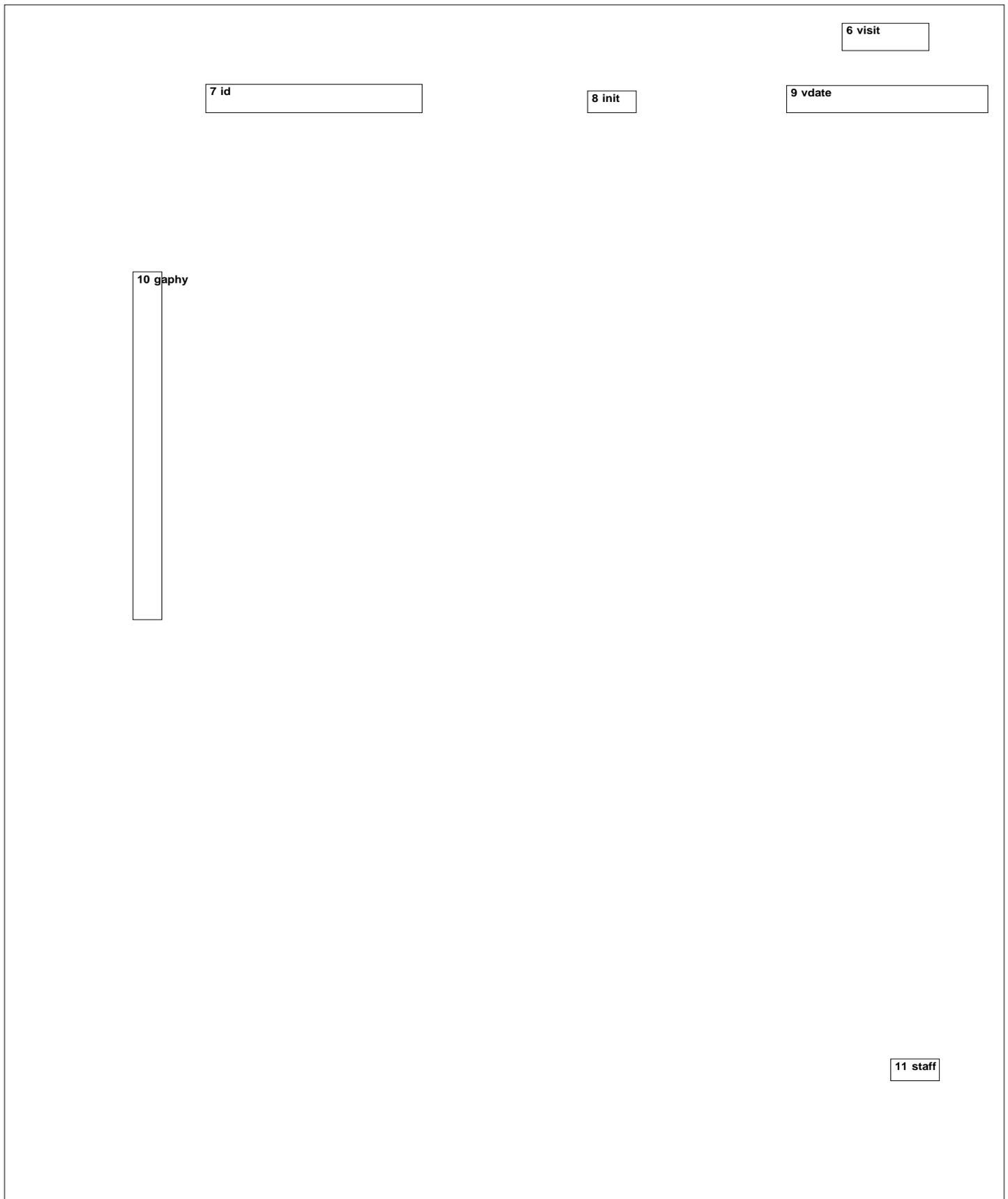
Patient Initials   
*F M L*

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<br>2=Moderate improvement<br>3=Mild improvement<br>4=No change<br>5=Slight worsening<br>6=Moderate worsening<br>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 value followed by 10<sup>9</sup>/L

10<sup>9</sup>/L

Box for clinical significance

4. WBC's

Three boxes for WBC value followed by 10<sup>9</sup>/L

10<sup>9</sup>/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

Three empty boxes for AST/SGOT value

U/L

Empty box for abnormality

16. ALT/SGPT

Three empty boxes for ALT/SGPT value

U/L

Empty box for abnormality

17. Alkaline phosphatase

Three empty boxes for alkaline phosphatase value

U/L

Empty box for abnormality

18. Phosphorus

One empty box before decimal, two empty boxes after decimal for phosphorus value

mmol/L

Empty box for abnormality

19. Uric acid

Three empty boxes for uric acid value

umol/L

Empty box for abnormality

20. Total protein

Three empty boxes before decimal, one empty box after decimal for total protein value

g/L

Empty box for abnormality

21. Albumin

Three empty boxes before decimal, one empty box after decimal for albumin value

g/L

Empty box for abnormality

22. Cholesterol

Two empty boxes before decimal, two empty boxes after decimal for cholesterol value

mmol/L

Empty box for abnormality

23. Triglycerides

One empty box before decimal, two empty boxes after decimal for triglycerides value

mmol/L

Empty box for abnormality

Coagulation

24. INR

One empty box before decimal, one empty box after decimal for INR value

Empty box for abnormality

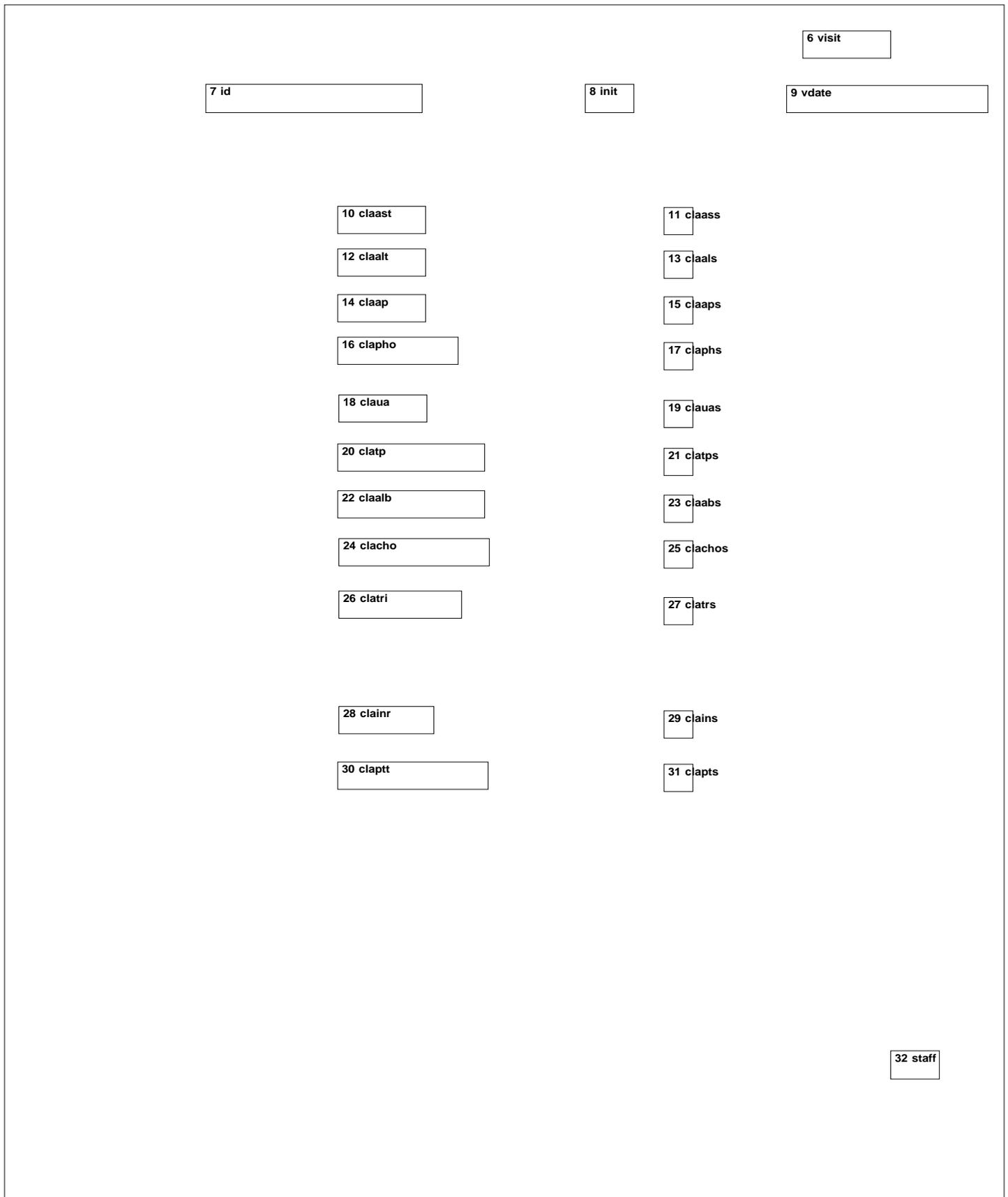
25. Activated partial thromboplastin time

Three empty boxes before decimal, one empty box after decimal for activated partial thromboplastin time value

sec

Empty box for abnormality





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

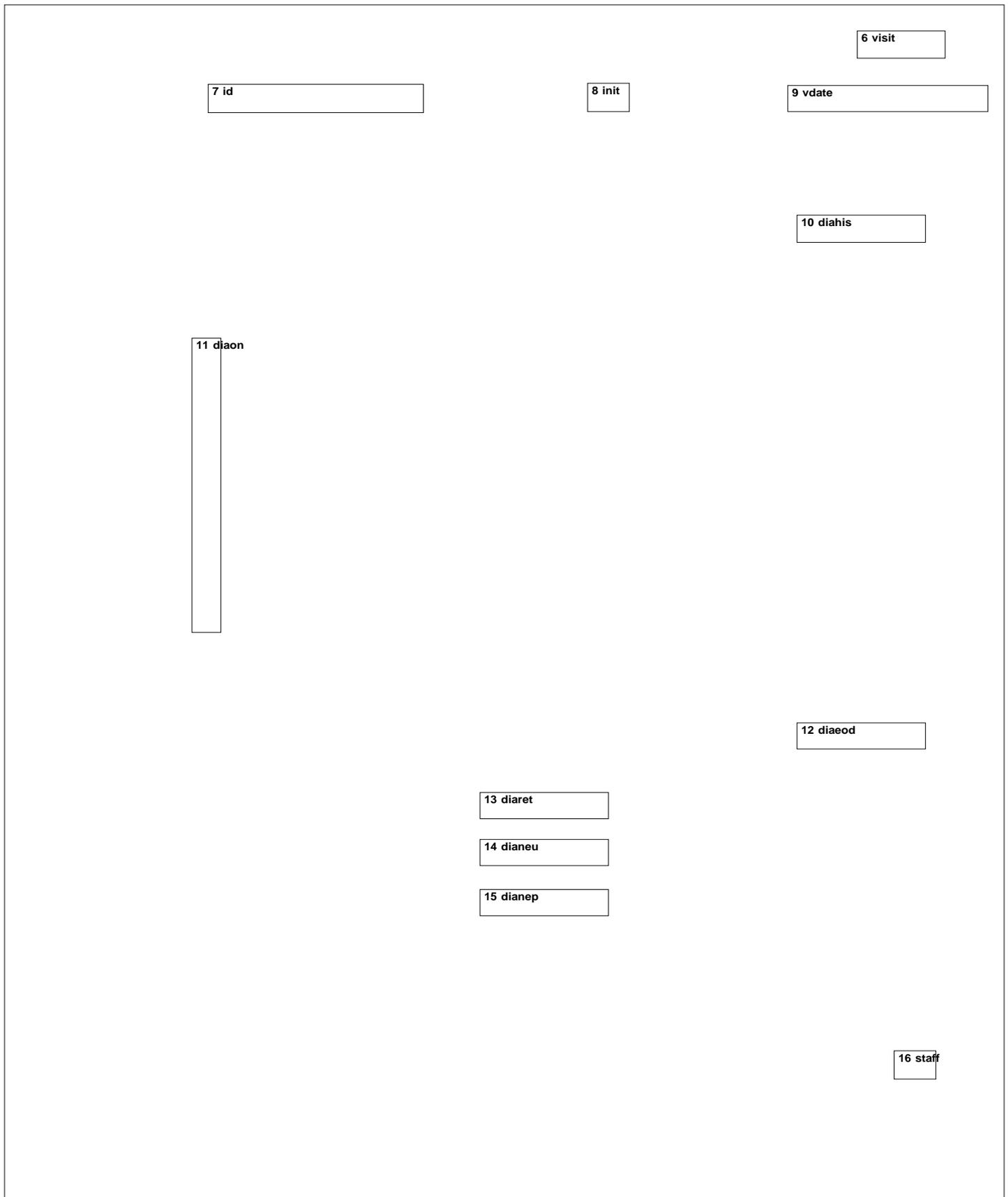
Does the patient have documented diabetic end organ disease at baseline (prior to randomization)?

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<br>2=Childhood onset - oral hypoglycemic<br>3=Adult onset - insulin<br>4=Adult onset - concurrent insulin and oral hypoglycemic<br>5=Adult onset - oral hypoglycemic<br>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 adnya

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<br>2=Sudden death preceded by change in CHF symptoms<br>3=Pump failure with or without secondary arrhythmic death<br>4=Myocardial Infarction<br>5=Cardiac Procedure<br>6=Other cardiovascular death<br>7=Non-cardiovascular death<br>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

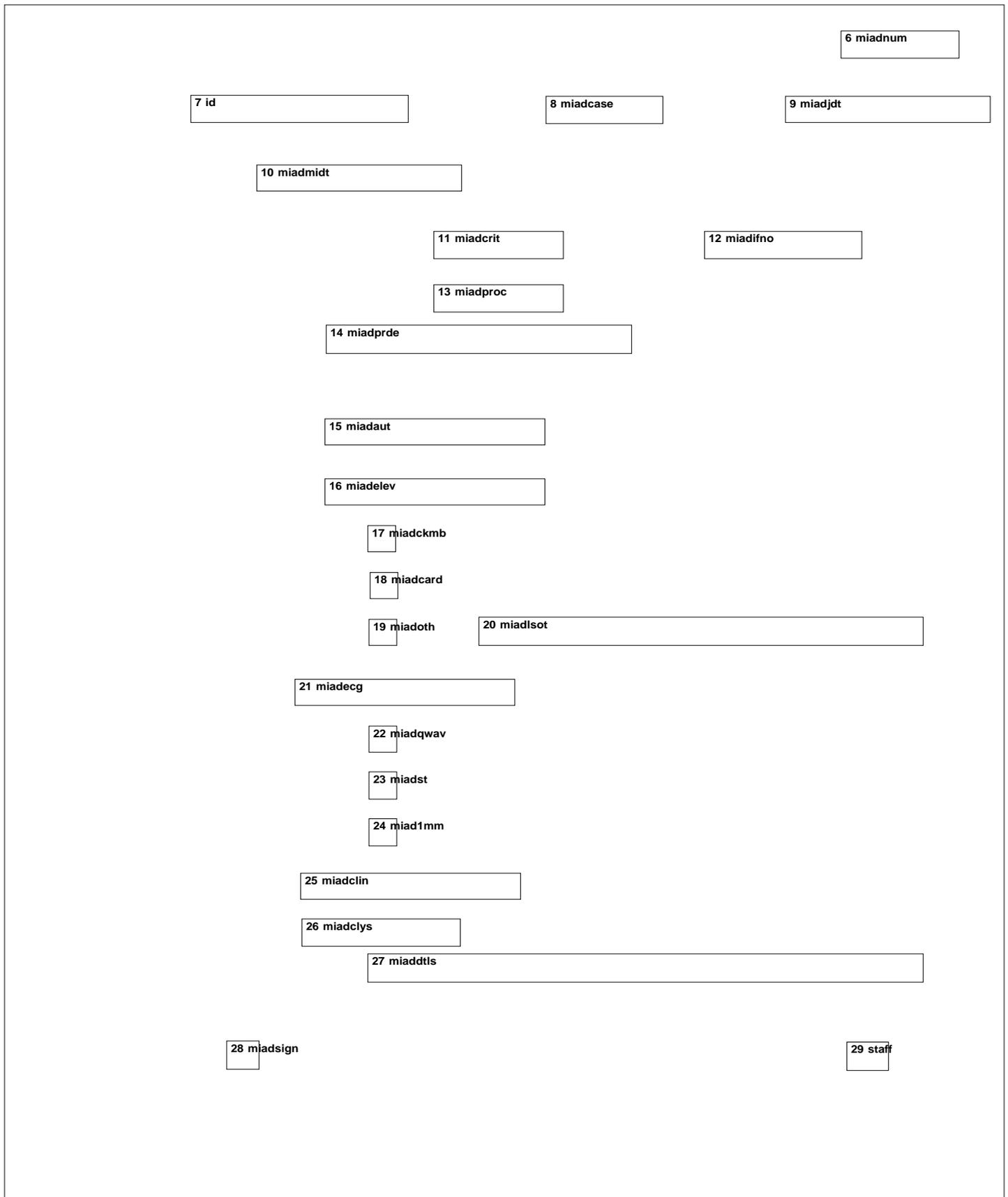
If yes, typical consistent

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.