Guide to SOLVD Data Set Structure and Variable Modification

Created for SOLVD Limited Access Database, Version 2.0, August 2004

General notes:

- Variables not listed here remain in their original form.
- ID_SOL is a transformed participant ID, with values that range from SOL001 through SOL6797.
- HOSPCODE contains codes for clinic/hospital combinations. Original variables CLINIC and HOSPITAL have been dropped.
- TRIAL contains value P for Prevention Trial participants and value T for Treatment Trial participants.

Definitions:

Modified variable	A variable that has been dropped or transformed in some way.
Standard date transformation	Subtract date of randomization from original date, resulting in the number of days since randomization.

1. **Data set name:** **SBF_LAD2**
   Description: **SOLVD Baseline Visit Form (SBF)**
   Form versions: **A, B, C**
   Number of observations: **6795**
   Visit range: **3**
   Structure: **One observation for each ID_SOL**
   Sort order (unique keys): **ID_SOL**

Variable	Description	Modification/Comment
SBF1	Date form completed	Standard date transformation
SBF2Z1	Participant's last name	Dropped, personal information
SBF2Z2	Participant's first name	Dropped, personal information
SBF2Z3	Participant's middle name	Dropped, personal information
SBF3Z3A	# of most important inclusion criteria not met	Versions B, C only
SBF4	Initials of person completing this form	Dropped, personal information
SBF4A	Participant given 2nd chance at placebo adherence	Versions B, C only
SBF9Z3	How many months ago did participant stop smoking	Top/bottom coding: Values above 600 recoded to 600.
SBF10	Avg # of alcoholic drinks/wk in last 2 yrs	Top/bottom coding: Values above 70 recoded to 70.
SBF11Z2	Date of most recent MI	Standard date transformation
SBF13Z1	Previous cardiac surgery	Version A only
SBF13Z2	Date of most recent cardiac surgery (Ver A)	Standard date transformation
SBF13Z3	Type of cardiac surgery	Version A only
SBF13A	Previous cardiac surgery/PTCA	Versions B, C only
SBF13B	Date of prev cardiac surgery/PTCA (Ver B,C)	Standard date transformation
SBF13C	Type of cardiac surgery/PTCA	Versions B, C only
SBF14Z9	History of atrial fib./flutter or supr. tachyarrythmia	Version C only
SBF21Z1	Currently on vasodilator (Ver A,B) – on vasodilator/ACE inhibitor (Ver C)	Version-specific
SBF21Z2	Currently on long-acting nitrate	Versions A, C only
SBF21Z2A	Currently on oral nitrate (Ver B)	Renamed to SBF21Z2

SBF21Z3	Currently on other vasodilator	Versions A, B only
SBF21Z3A	Currently on captopril (Ver C)	Dropped, count too low 5 Yes, 1635 No
SBF21Z4	Currently on enalapril (Ver C)	Dropped, count too low 2 Yes, 1636 No
SBF21Z5	Currently on other ACE inhibitor (Ver C)	Dropped, count too low 1 Yes, 1637 No
SBF22Z1	Currently on other vasodilator	Version C only
SBF26	Participant using non-ACE vasodilators	Version C only
SBF26Z2	Indication for stopping non-ACE vasodilators	Dropped, long text field
SBF27Z1	EF (ejection fraction) percentage	Top/bottom coding: Values below 10 set to 10.
SBF27Z2	Date of obtaining EF %	Standard date transformation
SBF28	Electrocardiogram: normal	Version A only
SBF28A	Atrial fibrillation	Versions B, C only
SBF28B	P wave terminal force in V1 (Ver B)	Top/bottom coding: Values above 0.50 set to 0.50.
SBF28C	QRS delay <= 120 ms	Versions B, C only
SBF28D	Amplitude of R wave in V5 or V6 (Ver B)	Top/bottom coding: Values above 4.0 set to 4.0.
SBF28E	Amplitude of R wave in AVL (Ver B)	Top/bottom coding: Values above 4.0 set to 4.0.
SBF28F	Amplitude of R wave in II, III, or AVF (Ver B)	Top/bottom coding: Values above 4.0 set to 4.0.
SBF28G	Amplitude of S wave in V1 (Ver B)	Top/bottom coding: Values above 4.0 set to 4.0.
SBF28H	Amplitude of S wave in V3 (Ver B)	Top/bottom coding: Values above 4.0 set to 4.0.
SBF28I	ST segment depression in inferior leads of V5 and V6 (Ver B)	Top/bottom coding: Values above 0.30 set to 0.30.
SBF28J	Left ventricular hypertrophy	Version C only
SBF28K	Q wave MI	Version C only
SBF28L	Location of MI	Version C only
SBF29	Atrial fibrillation/flutter	Version A only
SBF30	QRS delay >= 120 ms	Version A only
SBF31Z1	Left ventricular hypertrophy	Version A only
SBF31Z2	P wave	Version A only
SBF31Z3	Amplitude V3 in S & R wave	Version A only
SBF31Z4	ST segment	Version A only
SBF32Z1	Cardiac-thoracic ratio	Top/bottom coding: Values above 0.70 set to 0.70.
SBF33Z1	Weight (to nearest lb)	Top/bottom coding: Values below 100 set to 100. Values above 300 set to 300.
SBF33Z2	Weight (to nearest kg) Note: When weight is available in both lb and kg, the value is lb is generally more trustworthy.	Top/bottom coding: Values below 45 set to 45. Values above 136 set to 136.
SBF34	Heart rate (sitting)	Top/bottom coding: Values below 45 set to 45. Values above 120 set to 120.

SBF35Z1	Systolic BP (sitting)	Top/bottom coding: Values below 85 set to 85. Values above 180 set to 180.
SBF35Z2	Diastolic BP (sitting)	Top/bottom coding: Values below 50 set to 50. Values above 110 set to 110.
SBF36Z4	S3 gallop (Ver A,B) – S3 (Ver C)	Version-specific
SBF37Z2	Description of primary cause of CHF if "other"	Dropped, long text field
SBF38A	Participant still eligible for randomization	Versions B, C only
SBF38B	Reason for ineligibility for randomization	Versions B, C only
SBF39	Trial: Prevention/Treatment	Dropped, use the variable TRIAL
SBF41	Randomization number	Dropped, NHLBI guidelines
SBF43	Date of next scheduled visit	Dropped, available in follow-up form files

2. Data set name: **SDC_LAD2**
Description: **SOLVD Alteration in Study Drug Dosage Form (SDC)**
Form versions: **A, B**
Number of observations: **8329**
Visit range: **3-19**
Structure: **Multiple observations for each ID_SOL and possibly for each ID_SOL and VISIT**
Sort order (unique keys): **ID_SOL VISIT VISSEQ**

Variable	Description	Modification/Comment
SDC1	Date form completed	Standard date transformation
SDC2Z1	Participant's last name	Dropped, personal information
SDC2Z2	Participant's first name	Dropped, personal information
SDC2Z3	Participant's middle name	Dropped, personal information
SDC3	Initials of person completing this form	Dropped, personal information
SDC5Z1	Is more study drug needed at the new, altered dose?	Version B only
SDC6	Type of dose change: Increase/decrease (Ver A), Increase/decrease/stopping (Ver B)	Version-specific
SDC7Z3S	Increasing dose: Specify other reason	Dropped, long text field
SDC8Z3	Decreasing dose, due to taste abnormalities (Ver A) / Altered taste (Ver B)	Version-specific
SDC8Z4A	Decreasing dose, due to dizziness/fainting	Version B only
SDC8Z4B	Decreasing dose, due to fatigue	Version B only
SDC8Z4C	Decreasing dose, due to nausea	Version B only
SDC8Z4D	Decreasing dose, due to angioneurotic edema (Ver B)	Dropped, collapsed into SDC8Z6X
SDC8Z4E	Decreasing dose, due to cough	Version B only
SDC8Z6	Decreasing dose, due to other side effect	Dropped, see SDC8Z6X
SDC8Z6X	Decreasing dose, due to angioneurotic edema or other side effect	Combination of original SDC8Z6 and SDC8Z4D
SDC8Z6S	Decreasing dose: Specify other side effect	Coded into side effect categories summarized below this table.
SDC10Z2	Specify cardiac surgery other than transplant	Dropped, long text field
SDC16S	Specify other reason	Dropped, long text field – About 100 entries, only, contain useful information

Side effect and Reason categories used for SDC8Z6S:

1 = Side effects: Symptomatic hypotension
2 = Side effects: Taste / smell disturbance
3 = Side effects: Skin Rash/pruritis/flushing, Itching/ urticaria/ hives/gingivitis/ incr. eosinophils
4 = Side effects: Dizziness/Fainting (Light Headed, near syncope), Syncope, Ataxia, vertigo, Hypotension

5 = Side effects: Fatigue, drowsiness, lethargy
6 = Side effects: Nausea/indigestion
7 = Side effects: Possible angioedema
8 = Side effects: Cough
9 = Side effects: Azotemia (incr. creatinine or BUN), renal failure, Hyperkalemia, Proteinuria
10 = Side effects: Leg pain/weakness/claudication/PVD, Raynaud's
11 = Side effects: Chest pain/angina, worsening or unstable angina
12 = Side effects: Diarrhea, Constipation, Stomach / abdominal pain, Loss of appetite/ weight loss, anorexia
13 = Side effects: Headache
14 = Side effects: Heart irregularity-arrhythmia
15 = Side effects: Impotence, sexual dysfunction, decreased libido
16 = Side effects: CNS symptoms: Sleep disturbance, Numbness/tingling/parasthesia / shingles, Ear problem/tinitus/hearing loss, Irritable /nervous /anxiety /tension / personality chg., Backache, Depression, Tremor
17 = Side effects: Sweating/diaphoresis
18 = Side effects: Dryness in mouth/thirst
19 = Side effects: Arthritis, carpal tunnel
20 = Side effects: Stroke/TIA, subdural hematoma, CVA
21 = Side effects: Hyponatremia
22 = Side effects: Easy bruising, decreased platelets, ecchymosis
23 = Other side effects: Blurred vision, Forgetfulness, confusion, slow thinking, memory dec., Vision problem/eye aches, Leukocytosis, Chills/cold,flu,fever/nasal discharge/mucus prod./sore throat, Leukopenia, Nose bleed, epistaxsis, Hemoptysis, Hyperglycemia, increased glucose, Hair loss, alopecia, Miscellaneous GI symptoms / bowel obstruct./ bile duct obstruction/ esophageal tumor, gastric ulcer bleeding, Musculoskeletal problems, , aching all over, Menopausal symptoms, vaginal bleeding, Hypertension, Hypothyroidism, Seizures, Gynecomastia, tender breasts, Pleuritic pain, wheezing, pneumonia, pulmon. Embolus, Hypokalemia, Other miscellaneous

24 = MI/ R/O MI (myocardial infarction)
25 = Cardiac surgery
26 = cardiac transplant, awaiting heart transplant
27 = Noncardiac surgery
28 = CHF Symptoms (SOB), edema, congestion, PND, Taking Captopril/Vasotec/Other ACE-I
29 = SOLVD MD decreased dose/SOLVD RN
30 = Requested by participant
31 = Other reasons: Cancer; No show, non-compliant, participant stopped on own, ran out of meds, drug not available, moved out of country, dispensing error, house staff error, requested by wife, self unblinding, dosing error/ too sick to come, Hospitalization; Increased Triglyceride, asculitis, arteritis, phlebitis

Note: categories 7, 10, 11, 17-22, and text descriptions that indicated “Urinary problem, Nocturia, urinary freq, L. flank pain, hematuria” were collapsed into category 23 (Other side effects), due to sparseness of counts in each category. Categories 24-27 and 29-30 were collapsed into category 31 (Other reasons), due to sparseness of counts in each category.

3. Data set name: **SEF_LAD2**
Description: **SOLVD Eligibility Visit Form (SEF)**
Form versions: **A, B, C**
Number of observations: **6797**
Visit range: **1**
Structure: **One observation for each ID_SOL**
Sort order (unique keys): **ID_SOL**

Variable	Description	Modification/Comment
SEF_AGE	Participant's age at eligibility visit	Calculated as floor(date form completed – date of birth, or sef1-sef11)/365.25 Hard-coded in 11 cases. Top/bottom coding: Values below 27 recoded to 27.
SEF1	Date form completed	Standard date transformation
SEF2Z1	Participant's last name	Dropped, personal information
SEF2Z2	Participant's first name	Dropped, personal information
SEF2Z3	Participant's middle name	Dropped, personal information
SEF2Z4	Participant's third name (maiden, initial, etc.)	Dropped, personal information
SEF3Z1A	Street address – line #1	Dropped, personal information
SEF3Z1B	Street address – line #2	Dropped, personal information
SEF3Z2	City	Dropped, personal information
SEF3Z3	State/province	Dropped, personal information
SEF3Z4	Country	Dropped, personal information
SEF3Z5	Zip code/Canadian or European postal code	Dropped, personal information
SEF3Z5A	Zip code/Canadian or European postal code – part A (Ver C)	Dropped, personal information
SEF3Z5B	Zip code/Canadian or European postal code – part B (Ver C)	Dropped, personal information
SEF4	Telephone number (home)	Dropped, personal information
SEF5Z1	Hospital: Name	Dropped, personal information
SEF5Z2A	Hospital: Street address – line #1	Dropped, personal information
SEF5Z2B	Hospital: Street address – line #2	Dropped, personal information
SEF5Z3	Hospital: City	Dropped, personal information
SEF5Z4	Hospital: State/province	Dropped, personal information
SEF5Z5	Hospital: Country	Dropped, personal information
SEF5Z6	Hospital: Zip code/Canadian or European postal code	Dropped, personal information
SEF5Z7	Participant hospital ID number	Dropped, personal information
SEF6Z1	Private physician: Last name	Dropped, personal information
SEF6Z2	Private physician: First name	Dropped, personal information
SEF6Z3A	Private physician: Street address – line #1	Dropped, personal information
SEF6Z3B	Private physician: Street address – line #2	Dropped, personal information
SEF6Z4	Private physician: City	Dropped, personal information
SEF6Z5	Private physician: State/province	Dropped, personal information
SEF6Z6	Private physician: Country	Dropped, personal information

SEF6Z7	Private physician: Zip code/Canadian or European postal code	Dropped, personal information
SEF6Z8	Private physician: Telephone number	Dropped, personal information
SEF7Z1	Relative/friend: Last name	Dropped, personal information
SEF7Z2	Relative/friend: First name	Dropped, personal information
SEF7Z3	Relative/friend: Relationship	Dropped, personal information
SEF7Z4A	Relative/friend: Street address – line #1	Dropped, personal information
SEF7Z4B	Relative/friend: Street address – line #2	Dropped, personal information
SEF7Z5	Relative/friend: City	Dropped, personal information
SEF7Z6	Relative/friend: State/province	Dropped, personal information
SEF7Z7	Relative/friend: Country	Dropped, personal information
SEF7Z8	Relative/friend: Zip code/Canadian or European postal code	Dropped, personal information
SEF7Z9	Relative/friend: Telephone number –	Dropped, personal information
SEF8Z1	Employer: Name or Status	Dropped, personal information
SEF8Z2	Participant's Job title	Dropped, personal information
SEF8Z3A	Employer: Street address – line #	Dropped, personal information
SEF8Z3B	Employer: Street address – line #2	Dropped, personal information
SEF8Z4	Employer: City	Dropped, personal information
SEF8Z5	Employer: State/province	Dropped, personal information
SEF8Z6	Employer: Country	Dropped, personal information
SEF8Z7	Employer: Zip code/Canadian or European postal code	Dropped, personal information
SEF8Z8	Employer: Telephone number	Dropped, personal information
SEF10	Ethnic identity (1-6 = Am.Indian, Asian, Black, Caucasian, Hispanic, Other)	Collapsed into W=White, B=Black, O=Other, where O includes Am. Indian, Asian, Hispanic, and Other
SEF11	Date of birth	Dropped after use in SEF_AGE calculation
SEF11Z1	Marital status (1-4 = married, divorced/separated, widowed, never married) (Ver C)	Collapsed into M (married), D_S (divorced/separated), W_N (widowed or never married)
SEF12	Social security number	Dropped, personal information
SEF13Z1	Qualifying ejection fraction (%)	Top/bottom coding: Values below 10 recoded to 10. Values above 35 recoded to 35.
SEF13Z2	Date of ejection fraction measurement	Standard date transformation
SEF14Z1	Most recent ejection fraction (%)	Dropped, count too low
SEF14Z2	Date of most recent EF measurement	Dropped, see SEF14Z1
SEF15 (all variables)	Exclusion criteria	Dropped, not relevant for randomized participants
SEF16	Initials of person completing this form	Dropped, personal information
SEF18Z1	Systolic blood pressure – supine (mm Hg)	Top/bottom coding: Values below 85 recoded to 85. Values above 180 recoded to 180.
SEF18Z2	Diastolic blood pressure – supine (mm Hg)	Top/bottom coding: Values below 50 recoded to 50. Values above 110 recoded to 110.
SEF19Z1	Systolic blood pressure – sitting (mm Hg)	Top/bottom coding: Values below 90 recoded to 90.

		Values above 180 recoded to 180.
SEF19Z2	Diastolic blood pressure – sitting (mm Hg)	Top/bottom coding: Values below 50 recoded to 50. Values above 110 recoded to 110.
SEF20Z1	Heart rate – supine (beats per minute)	Top/bottom coding: Values below 47 recoded to 47. Values above 120 recoded to 120.
SEF20Z2	Heart rate – sitting (beats per minute)	Top/bottom coding: Values below 47 recoded to 47. Values above 120 recoded to 120.
SEF21	Hematocrit (HCT) (%)	Top/bottom coding: Values below 28 recoded to 28. Values above 55 recoded to 55.
SEF22Z1	Total white bood count (WBC x 1000)	Top/bottom coding: Values below 3 recoded to 3. Values above 16 recoded to 16.
SEF22Z2	Percent neutrophils	Top/bottom coding: Values below 26 recoded to 26. Values above 86 recoded to 86.
SEF22Z3	Percent lymphocytes	Top/bottom coding: Values below 5 recoded to 5. Values above 60 recoded to 60.
SEF23	Sodium (Na) (meq/l)	Top/bottom coding: Values below 129 recoded to 129. Values above 149 recoded to 149.
SEF24	Potassium (K) (meq/l)	Top/bottom coding: Values below 3.1 recoded to 3.1. Values above 5.9 recoded to 5.9.
SEF25	Blood urea nitrogen (BUN) (mg/dl)	Top/bottom coding: Values below 5 recoded to 5. Values above 49 recoded to 49.
SEF26	Creatinine (mg/dl)	Top/bottom coding: Values below 0.5 recoded to 0.5. Values above 2.4 recoded to 2.4.
SEF27	Proteinurea (0-4) (1="+") (Ver A)	Collapsed into C0 (0), C1 (1), C2 (2), C3_4 (3, 4).
SEF27A	Proteinurea (0-4) (1="trace or +") (Ver B,C)	Collapsed into C0 (0), C1 (1), C2 (2), C3_4 (3, 4).
SEF28Z1	Participant taking isosorbide med?	Version A only
SEF28Z2	Daily dose (mg) of isosorbide med (Ver A)	Dropped, dropped all dosages for sparseness of data
SEF28AA	Participant taking vasodilators?	Version C only
SEF28A	Participant taking oral nitrate? (Ver B), long acting nitrate? (Ver C)	Version-specific
SEF28B	Participant taking isosorbide med?	Versions B, C only
SEF28C	Participant stopping use of oral nitrate? (Ver B), long acting nitrate? (Ver C)	Dropped, count too low
SEF28D	Indication for continuing use of oral nitrate (Ver B), long acting nitrate (Ver C)	Dropped, long text field
SEF29Z1	Participant taking any vasodilator other than isosorbide?	Version A
SEF29Z2B	Total daily dose of prazosin (mg) (Ver	Dropped, count too low

	A)	
SEF29ZB2	Will prazosin be discontinued? (Ver B,C)	Dropped, count too low
SEF29Z2C	Indication for continuing prazosin (Ver B,C)	Dropped, long text field
SEF29Z3B	Total daily dose of hydralazine (mg) (Ver A)	Dropped, count too low
SEF29ZB3	Will hydralazine be discontinued? (Ver B,C)	Dropped, count too low
SEF29Z3C	Indication for continuing hydralazine (Ver B,C)	Dropped, long text field
SEF29Z4A	Participant taking nifedipine? (Ver A) calcium channel blocker? (Ver B,C)	Version-specific
SEF29Z4B	Total daily dose of nifedipine (mg) (Ver A)	Dropped, count too low
SEF29ZB4	Will calcium channel blocker be discontinued? (Ver B,C)	Dropped, count too low
SEF29Z4C	Indication for continuing calcium channel blocker (Ver B,C)	Dropped, long text field
SEF29Z5	Participant taking other vasodilator?	Version A only
SEF29Z5A	Participant taking other vasodilator (other than oral nitrate)? (Ver B), (other than long acting nitrate)? (Ver C)	Version-specific
SEF29Z5B	Will other vasodilator (other than oral nitrate - Ver B) (other than long acting nitrate – Ver C) be discontinued?	Dropped, count too low
SEF29Z5C	Indication for continuing other vasodilator (other than oral nitrate) (Ver B) (other than long acting nitrate) (Ver C)	Dropped, long text field
SEF30Z1	Participant discontinuing all non-ACE vasodilators? (Ver A)	Dropped, count too low
SEF30Z2	Indication for continuing non-ACE vasodilators (Ver A)	Dropped, long text field
SEF32Z1	For which trial is participant eligible? (P,T)	Version C only
SEF33Z1	Participant not taking hydralazine or isosorbide medication?	Version A only
SEF33Z1A	Participant taking hydralazine or isosorbide medication?	Versions B, C only

4. Data set name: **SEP_LAD2**
Description: **SOLVD Endpoints (Derived) File**
Form versions: **Not applicable**
Number of observations: **6797**
Visit range: **Not applicable**
Structure: **One observation for each ID_SOL**
Sort order (unique keys): **ID_SOL**

Variable	Description
DDATE	For deceased participants, number of days from randomization to date of death
EP1	All-cause mortality, indicated by the presence of form SFN (the SOLVD First Notification of Death form) or form SFD (the SOLVD Final Designation of Death form). There are 1,609 participants who have EP1=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP2	All-cause mortality, indicated by the presence of form SFD, the SOLVD Final Designation of Death form. There are 1,599 participants who have EP2=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP3	Cardiovascular death, indicated by the response 'C' to item SFD5 of the SOLVD Final Designation of Death form. There are 1,413 participants who have EP3=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP4	Cardiac death, indicated by the response 'C' to item SFD6Z1 (for versions A, B) or SFD6Z1A (for version C) of the SOLVD Final Designation of Death form. There are 1,326 participants who have EP4=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP5	Cardiac death, with the most likely terminal event being probable arrhythmia without preceding worsening symptoms of CHF -- indicated by the response '1' to item SFD6Z2 of the SOLVD Final Designation of Death form. There are 424 participants who have EP5=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP6	Cardiac death, with the most likely terminal event being probable arrhythmia with some preceding worsening symptoms of CHF -- indicated by the response '2' to item SFD6Z2 of the SOLVD Final Designation of Death form. There are 193 participants who have EP6=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP7	Cardiac death, with the most likely terminal event being primarily related to pump failure, even if terminal event was an arrhythmia -- indicated by the response '3' to item SFD6Z2 of the SOLVD Final Designation of Death form. There are 469 participants who have EP7=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP8	Cardiac death, with the most likely terminal event being probable myocardial infarction -- indicated by the response '5' to item SFD6Z2 of the SOLVD Final Designation of Death form. There are 205 participants who have EP8=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP9	Cardiac death, with the most likely terminal event being "Other" -- indicated by the response '4' to item SFD6Z2 of the SOLVD Final Designation of Death form. There are 35 participants who have EP9=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP10	Death due to stroke, indicated by the response 'S' to item SFD6Z1 (for

	versions A, B) or SFD6Z1A (for version C) of the SOLVD Final Designation of Death form. There are 45 participants who have EP10=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP11_12	Death due to pulmonary embolism or other vascular or unknown cardiovascular cause, indicated by the re-coded response 'X' to item SFD6Z1A of the SOLVD Final Designation of Death form. There are 42 participants who have EP11_12=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP13	Non-cardiovascular death, indicated by the response 'N' to item SFD5 of the SOLVD Final Designation of Death form. There are 186 participants who have EP13=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP14	Non-cardiovascular death: Type of death is a secondary complication of heart failure -- indicated by the response '1' to item SFD7Z1 of the SOLVD Final Designation of Death form. There are 30 participants who have EP14=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP15	Non-cardiovascular death: Type of death is a primary event independent of heart failure -- indicated by the response '2' to item SFD7Z1 of the SOLVD Final Designation of Death form. There are 123 participants who have EP15=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP16	Non-cardiovascular death due to cancer -- indicated by the response 'Y' to item SFD7Z2 of the SOLVD Final Designation of Death form. There are 84 participants who have EP16=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP17	Non-cardiovascular non-cancer death -- indicated by the response 'N' to item SFD7Z2 of the SOLVD Final Designation of Death form. There are 40 participants who have EP17=1. Use the variable FUTIME, described below, for follow-up time for this event.
EP18	Non-cardiovascular death: Type of death is neither a secondary complication of heart failure nor a primary event independent of heart failure -- indicated by the response '3' to item SFD7Z1 of the SOLVD Final Designation of Death form. There are 33 participants who have EP18=1. Use the variable FUTIME, described below, for follow-up time for this event.
EPA	This indicator has the value of 1 when either EPY=1 or EPZ=1 (see below), and 0 otherwise. There are 2,472 participants who have EPA=1.Use the variable EPATIME, described below, for follow-up time for this event.
EPATIME	Follow-up time in days for endpoint EPA (which is 1 (Yes) if EPY=1 or EPZ=1). It is the minimum of EPYTIME and EPZTIME (see below).
EPB	This indicator has the value of 1 when either EPA=1 (see above) or EP1=1 (all-cause mortality – see earlier), and 0 otherwise. There are 3,225 participants who have EPB=1. Use the variable EPBTIME, described below, for follow-up time for this event.
EPBTIME	Follow-up time in days for endpoint EPB (which is 1 (Yes) if EPA=1 or EP1=1). It is the minimum of EPATIME (see above) and FUTIME (see below).
EPT	This 0/1 indicator has the value of 1 for participants who have been randomized into the Prevention Trial arm of SOLVD, only. Additionally, it has a value of 1 when the endpoint EPA is 1, only. Now, EPA=1 when either EPY=1 or EPZ=1, that is, when there is a first instance of new or worsening CHF detected at a hospitalization or at a SOLVD follow-up visit. When EPA=1 for Prevention Trial participants, the endpoint EPT has the

	value of 1 if the participant was using digitalis, another inotropic agent, a diuretic, or a vasodilator at baseline ("Y" to items SBF15, SBF16, SBF17Z1, or SBF21Z1, respectively), and has discontinued the use of that medication (not "Y" for items SFE11, SFE12, SFE13Z1, or SFE17Z1, respectively), at some follow-up visit that is before or at most 1 visit after the visit corresponding to the occurrence of the endpoint EPA. The endpoint EPT is briefly described as "Development of CHF and the need for antifailure therapy" or (per Prevention Trial paper) as "Development of CHF and anti-CHF therapy". There are 770 participants who have EPT=1. Use the variable EPTTIME, described below, for follow-up time for this event.
EPTTIME	Follow-up time in days for endpoint EPT. When EPT=1, EPTTIME is the same as EPATIME. When EPT=0, EPTTIME is the same as FUTIME.
EPX	This indicator has the value of 1 when either EPY=1 (see below) or EP1=1 (all-cause mortality – see earlier), and 0 otherwise. There are 2,302 participants who have EPX=1. Use the variable EPXTIME, described below, for follow-up time for this event.
EPXTIME	Follow-up time in days for endpoint EPX. When EPX=1 (that is, EPY=1 or EP1=1: CHF hospitalization or all-cause mortality), EPXTIME is the number of days from the earlier of the cardiovascular hospitalization date and the date of death, to the date of randomization. When EPX=0, EPXTIME is the same as FUTIME.
EPY	First CHF hospitalization (after randomization) for new or worsening CHF (new CHF: SHF7=B; worsening CHF: SHF7=A). There are 1,260 participants who have EPY=1. Use the variable EPYTIME, described below, for follow-up time for this event.
EPYTIME	For EPY=1 (Yes), EPYTIME is the number of days between the first hospitalization for condition EPY (obtained from the date SHF4Z1 of that hospitalization) and date of randomization. When EPY=0, EPYTIME is the same as FUTIME.
EPZ	This 0/1 indicator is derived from the SOLVD follow-up form SFE. It designates the first follow-up physician's examination of the participant in which there is evidence that CHF has developed since last follow-up visit (SFE29Z1=Y), or that a previously symptomatic participant's CHF severity has worsened since last follow-up visit (SFE31=W). There are 2,217 participants who have EPZ=1. Use the variable EPZTIME, described below, for follow-up time for this event.
EPZTIME	For EPZ=1 (Yes), EPZTIME is the number of days between the first follow-up visit at which the participant is deemed to have the condition EPZ (obtained from the date SFE1 of that follow-up visit) and the date of randomization. When EPZ=0, EPZTIME is the same as FUTIME.
FUTIME	For endpoints EP1-EP18: When the endpoint is 1 (Yes), FUTIME is the number of days between DDATE (date of death) and date of randomization. When the endpoint is 0 (No), FUTIME is the number of days between the end of the study and date of randomization. End of study is taken to be January 31, 1991 for the Treatment Trial, and August 31, 1991 for the Prevention Trial.
HOSPCODE	Code for clinic/hospital combination
ID_SOL	Participant ID for SOLVD LAD data
RDATE	Date of randomization for each randomized participant. Set to 0 to serve as a reference point for all other dates in the SOLVD LAD data sets.
TRIAL	Indicator of SOLVD trial to which participant belongs. T=Treatment Trial, P=Prevention Trial.
TRTMENT	Treatment assignment of each randomized participant. PLAC=Placebo, ENAL=Enalapril.

5. Data set name: **SFD_LAD2**
Description: **SOLVD Final Designation of Death Form (SFD)**
Form versions: **A, B, C**
Number of observations: **1599**
Visit range: **3-20**
Structure: **One observation for each ID_SOL**
Sort order (unique keys): **ID_SOL**

Variable	Description	Modification/Comment
SFD1	Date form completed	Standard date transformation
SFD2	Date of death	Standard date transformation
SFD2AT	Time of death : Hours/minutes	Version C only
SFD2AH	Time of death : Hours	Version C only
SFD2AM	Time of death : Minutes	Version C only
SFD2B	Time of death : AM/PM	Version C only
SFD3Z1	Participant's last name	Dropped, personal information
SFD3Z2	Participant's first name	Dropped, personal information
SFD3Z3	Participant's middle name	Dropped, personal information
SFD4Z3	Condition of death: Traumatic	Dropped, count too low
SFD4Z4	Condition of death: Suicide	Dropped, count too low
SFD4Z6	Condition of death: Within 7 days of cardiac surgery	Dropped, collapsed into SFD4Z6_7 (original count too low)
SFD4Z7	Condition of death: Within 7 days of non-cardiac surgery	Dropped, collapsed into SFD4Z6_7 (original count too low)
SFD4Z6_7	Condition of death: Within 7 days of surgery	Y if either SFD4Z6 or SFD4Z7 is Y, N if both are N
SFD6Z1	Cardiovascular death: Type (Ver A,B)	Dropped, collapsed into SFD6Z1A (original count too low)
SFD6Z1A	Cardiovascular death: Type (Ver C)	Includes non-missing value from SFD6Z1 if original value of SFD6Z1A was missing. Values V,O,P collapsed into X.
SFD6Z3A	Describe "other" most likely terminal event for cardiac death: Line #1 (Ver A,B)	Dropped, long text field
SFD6Z3B	Describe "other" most likely terminal event for cardiac death: Line #2 (Ver A,B)	Dropped, long text field
SFD6Z3C	Describe "other" most likely terminal event for cardiac death: Line #3 (Ver A,B)	Dropped, long text field
SFD6Z3D	Describe "other" most likely terminal event for cardiac death: Line #4 (Ver A,B)	Dropped, long text field
SFD6Z3	Describe "other" most likely terminal event for cardiac death: Line #1 (Ver C)	Dropped, long text field
SFD6Z3S	Describe "other" most likely terminal event for cardiac death: Line #2 (Ver C)	Dropped, long text field
SFD6Z3S1	Describe "other" most likely terminal event for cardiac death: Line #3 (Ver	Dropped, long text field

	C)	
SFD6Z3S2	Describe “other” most likely terminal event for cardiac death: Line #4 (Ver C)	Dropped, long text field
SFD7Z3	Specify primary cancer site	Dropped, long text field
SFD7Z4	Specify type of non-cardio death if neither a primary event nor a secondary complication of heart failure	Dropped, long text field
SFD8	Initials of person completing this form	Dropped, personal information

6. Data set name: **SFE_LAD2**
Description: **SOLVD Follow-up Interview/Exam Form (SFE)**
Form versions: **A, B, C**
Number of observations: **65,158**
Visit range: **4-20**
Structure: **Multiple observations for each ID_SOL**
Sort order (unique keys): **ID_SOL VISIT**

Variable	Description	Modification/Comment
SFE1	Date of this interview/exam	Standard date transformation
SFE2	Date of last SOLVD interview/exam	Standard date transformation
SFE3Z1	Participant's last name	Dropped, personal information
SFE3Z2	Participant's first name	Dropped, personal information
SFE3Z3	Participant's middle name	Dropped, personal information
SFE4Z1	Participant's address and/or telephone # same as before?	Dropped, personal information
SFE4Z2A	Street address – line #1	Dropped, personal information
SFE4Z2B	Street address – line #2	Dropped, personal information
SFE4Z3	City	Dropped, personal information
SFE4Z4	State/province	Dropped, personal information
SFE4Z5	Country	Dropped, personal information
SFE4Z6	Zip code/Canadian or European postal code	Dropped, personal information
SFE4Z7	Telephone number (home)	Dropped, personal information
SFE5Z1	Participant's private physician (name, address, telephone #) same as before?	Dropped, personal information
SFE5Z2	Private physician: Last name	Dropped, personal information
SFE5Z3	Private physician: First name	Dropped, personal information
SFE5Z4A	Private physician: Street address – line #1	Dropped, personal information
SFE5Z4B	Private physician: Street address – line #2	Dropped, personal information
SFE5Z5	Private physician: City	Dropped, personal information
SFE5Z6	Private physician: State/province	Dropped, personal information
SFE5Z7	Private physician: Country	Dropped, personal information
SFE5Z8	Private physician: Zip code/Canadian or European postal code	Dropped, personal information
SFE5Z9	Private physician: Telephone number	Dropped, personal information
SFE6Z1	Participant's employment (name, title, address, telephone #) same as before?	Dropped, personal information
SFE6Z2	Employer: Name or status	Dropped, personal information
SFE6Z3	Participant's job title	Dropped, personal information
SFE6Z4A	Employer: Street address – line #1	Dropped, personal information
SFE6Z4B	Employer: Street address – line #2	Dropped, personal information
SFE6Z5	Employer: City	Dropped, personal information
SFE6Z6	Employer: State/province	Dropped, personal information
SFE6Z7	Employer: Country	Dropped, personal information
SFE6Z8	Employer: Zip code/Canadian or European postal code	Dropped, personal information
SFE6Z9	Employer: Telephone number	Dropped, personal information

SFE6Z10	Participant's nearest relative or friend's address and phone # same as before? (Ver C)	Dropped, personal information
SFE7Z2	Average # of angina attacks per week	Top/bottom coding: Values above 35 recoded to 35.
SFE17Z2	Currently on long-acting nitrate	Versions A only
SFE17Z2A	Currently on oral nitrate (Ver B), on long-acting nitrate (Ver C)	Renamed to SFE17Z2
SFE18Z1	Currently on other vasodilator	Version C only
SFE23Z3	Taste disturbance (Ver A,B) – Altered taste (Ver C) since last visit	Version-specific
SFE23Z6A	Angioneurotic edema since last visit	Version C only
SFE23Z6B	Cough since last visit	Version C only
SFE23Z8S	Specify other symptoms since last visit	Recoded into symptom categories. See note below this table.
SFE24Z1	Weight (to nearest lb)	Top/bottom coding: Values below 100 recoded to 100. Values above 300 recoded to 300.
SFE24Z2	Weight (to nearest kg) Note: When weight is available in both lb and kg, the value is lb is generally more trustworthy	Top/bottom coding: Values below 45 recoded to 45. Values above 136 recoded to 136.
SFE25	Heart rate (sitting) (beats per minute)	Top/bottom coding: Values below 40 recoded to 40. Values above 130 recoded to 130.
SFE26Z1	Systolic BP (sitting) (mm Hg)	Top/bottom coding: Values below 70 recoded to 70. Values above 200 recoded to 200.
SFE26Z2	Diastolic BP (sitting) (mm Hg)	Top/bottom coding: Values below 40 recoded to 40. Values above 120 recoded to 120.
SFE30Z4	Sign of CHF: S3 gallop (Ver A,B) – S3 (Ver C)	Version-specific
SFE32	Hematocrit (HCT) (%)	Top/bottom coding: Values below 15 recoded to 15. Values above 55 recoded to 55.
SFE33Z1	Total white blood count (WBC x 1000)	Top/bottom coding: Values below 3 recoded to 3. Values above 20 recoded to 20.
SFE33Z2	Percent neutrophils	Top/bottom coding: Values below 20 recoded to 20. Values above 90 recoded to 90.
SFE33Z3	Percent lymphocytes	Top/bottom coding: Values below 3 recoded to 3. Values above 65 recoded to 65.
SFE34	Sodium (Na) (meq/l)	Top/bottom coding: Values below 125 recoded to 125. Values above 150 recoded to 150.
SFE35	Potassium (K) (meq/l)	Top/bottom coding: Values below 2.7 recoded to 2.7. Values above 6.5 recoded to 6.5.
SFE36	Blood urea nitrogen (BUN) (mg/dl)	Top/bottom coding: Values below 5 recoded to 5. Values above 61 recoded to 61.

SFE37	Creatinine (mg/dl)	Top/bottom coding: Values below 0.4 recoded to 0.4. Values above 3.5 recoded to 3.5.
SFE38	Proteinurea (0-4) (1="+") (Ver A)	Collapsed into C0 (0), C1 (1), C2 (2), C3_4 (3, 4).
SFE38A	Proteinurea (0-4) (1="trace or +") (Ver B,C)	Collapsed into C0 (0), C1 (1), C2 (2), C3_4 (3, 4).
SFE41	Type of change in dosage: Increase/decrease	Versions A, B only
SFE42Z1	Increase toward prescribed maintenance dose following dose reduction	Versions A, B only
SFE42Z2	Increase toward prescribed maintenance dose by protocol	Versions A, B only
SFE42Z3	Other reason for increasing dose (Ver A,B)	Dropped, count too low
SFE42Z3S	Describe other reason for increasing dose (Ver A,B)	Dropped, count too low
SFE43Z1	Decreasing dose, due to side effects (Ver A,B)	Low count: 341 responses of Yes, only. So, all variables from SFE43Z2 to SFE51S are dropped
SFE43Z2	Decreasing dose, due to symptomatic hypotension (Ver A,B)	Dropped, count too low
SFE43Z3	Decreasing dose, due to taste abnormalities (Ver A,B)	Dropped, count too low
SFE43Z4	Decreasing dose, due to skin rash (Ver A,B)	Dropped, count too low
SFE43Z5	Decreasing dose, due to azotemia (Ver A,B)	Dropped, count too low
SFE43Z6	Decreasing dose, due to Other Reason (Ver A,B)	Dropped, count too low
SFE43Z6S	Decreasing dose: Specify other reason (Ver A,B)	Dropped, long text field
SFE44	Myocardial infarction (Ver A,B)	Dropped, count too low
SFE45Z1	Cardiac surgery other than transplant (Ver A,B)	Dropped, count too low
SFE45Z2	Specify cardiac surgery other than transplant (Ver A,B)	Dropped, long text field
SFE46	Cardiac transplant (Ver A,B)	Dropped, count too low
SFE47	Noncardiac surgery (Ver A,B)	Dropped, count too low
SFE48	Worsening CHF: needs study drug or similar medication (Ver A,B)	Dropped, count too low
SFE49	Requested by referring physician (Ver A,B)	Dropped, count too low
SFE50	Requested by participant (Ver A,B)	Dropped, count too low
SFE51	"Other" (Ver A,B)	Dropped, count too low
SFE51S	Specify "other" (Ver A,B)	Dropped, long text field
SFE52	Date of next visit	Dropped, no longer relevant
SFE53	Form completed at clinic or by telephone (Ver A,B) - at clinic or by telephone or at hospital (Ver C)	Version-specific
SFE54	Initials of person completing this form	Dropped, personal information

Symptom categories used for variable SFE23Z8S:

1 = Dizziness/Fainting (Light Headed, near syncope)/orthostatic symptoms, Syncope, Ataxia, vertigo, Hypotension
2 = Skin Rash/pruritis, Itching/urticaria/hives/gingivitis/dry skin/nail changes
3 = Taste/smell disturbance
4 = Blurred vision, Vision problem/eye aches/ eye floater/ watery eyes/ conjunctivitis
5 = Fatigue, drowsiness, lethargy, malaise, weakness, heat intolerance
6 = Nausea/indigestion/epigastric pain/bloating
7 = Forgetfulness, confusion, slow thought
8 = Headache
9 = Cough
10 = Chest pain/angina, worsening or unstable angina
11 = GI symptoms: Diarrhea, Constipation, Stomach pain/abdominal pain, Loss of appetite/weight loss
12 = Heart irregularity-arrhythmia, palpitations
13 = Azotemia (incr. creatinine or BUN), renal failure, Hyperkalemia, Proteinuria
14 = Urinary problem, Nocturia, urinary freq.
15 = CNS symptoms: Sleep disturbance, Numbness/tingling/parasthesia, Ear problem /tinitus/hearing loss, Irritable/nervous/anxiety/tension/personality change/dementia, Backache, Depression, Tremor
16 = Leg pain/weakness/claudication/PVD, cold feet, Raynaud's
17 = Sweating/diaphoresis
18 = Dryness in mouth/thirst
19 = Arthritis, carpal tunnel, gout, joint pain
20 = Possible angioedema
21 = Stroke/TIA, subdural hematoma
22 = Hyponatremia
23 =Easy bruising, decreased platelets, ecchymosis, decreased Hematocrit

24 = Other symptoms: Impotence, sexual dysfunction, decreased libido, Leukocytosis, Chills/cold, flu, fever/nasal discharge/throat irritation/bronchitis/dry mouth, Leukopenia, Nose bleed, epistaxsis, Hemoptysis, Hyperglycemia (incr. glucose), hair loss, alopecia, Cancer, Miscellaneous GI symptoms/ gastritis/ difficulty swallowing, Musculoskeletal problems, Menopausal symptoms, vaginal bleeding, Hypertension, Hypothyroidism, Seizures, Gynecomastia, tender breasts, Pleuritic pain, wheezing, Hypokalemia, Hair on abdomen, Hiccoughs, Other miscellaneous

25 = Not given – set to missing
26 = CHF Symptoms, include: Pedal Edema, orthopnea/lung congestion; SOB, Weight gain, Acute dyspnea

Note: categories 13 (Azotemia, etc.) and 23 (Easy bruising, etc.) were collapsed into category 24=Other symptoms, due to sparseness of counts.

7. Data set name: **SFN_LAD2**
Description: **SOLVD First Notification of Death Form (SFN)**
Form versions: **A**
Number of observations: **1591**
Visit range: **3-20**
Structure: **One observation for each ID_SOL**
Sort order (unique keys): **ID_SOL**

Variable	Description	Modification/Comment
SFN1	Date form completed	Standard date transformation
SFN2Z1	Participant's last name	Dropped, personal information
SFN2Z2	Participant's first name	Dropped, personal information
SFN2Z3	Participant's middle name	Dropped, personal information
SFN3	Date of death (to the best of informant's knowledge)	Standard date transformation
SFN4	Initials of person completing this form	Dropped, personal information

8. Data set name: **SHF_LAD2**
Description: **SOLVD Hospitalization Form (SHF)**
Form versions: **A, B**
Number of observations: **10,773**
Visit range: **2-19**
Structure: **Multiple observations for each ID_SOL and possibly for each ID_SOL and VISIT**
Sort order (unique keys): **ID_SOL VISIT VISSEQ**

Variable	Description	Modification/Comment
SHF1	Date form completed	Standard date transformation
SHF2Z1	Participant's last name	Dropped, personal information
SHF2Z2	Participant's first name	Dropped, personal information
SHF2Z3	Participant's middle name	Dropped, personal information
SHF3	Hospital name	Dropped, personal information
SHF4Z1	Date of admission	Standard date transformation
SHF4Z2	Date of discharge	Standard date transformation
SHF6A	Primary reason for hosp is non-CV: Specify: Line #1	Text in variables SHF6A and SHF6B was used for developing a single ICD9 code according to standard 3-digit ICD9 categories as summarized below this table
SHF6B	Primary reason for hosp is non-CV: Specify: Line #2	(See variable SHF6A). Dropped (long text field), after developing ICD9 code
SHF7	Primary reason for hosp is CV: Code for primary reason	Sparse levels K, L, M, N, O collapsed into level X
SHF7A	Primary reason for hosp is MI: Date of MI (Ver B)	Standard date transformation
SHF7B	Primary reason for hosp is MI: Time of MI	Version B only
SHF7BH	Primary reason for hosp is MI: Time of MI: Hour	Version B only
SHF7BM	Primary reason for hosp is MI: Time of MI: Minute	Version B only
SHF7C	Primary reason for hosp is MI: Time of MI: AM/PM	Version B only
SHF9Z1	Primary reason for hosp is cardiac surgery: Type of cardiac surgery	Sparse levels B, T, V, O collapsed into level X
SHF9Z2	Primary reason for hosp is cardiac surgery: Specify other cardiac surgery	Dropped, long text field
SHF10	Primary reason for hosp is any other major event: Specify	Codes 1-40 were developed from text. and are explained below this table.
SHF12A	Secondary reason for hosp is non-CV: Specify: Line #1	Dropped, long text field
SHF12B	Secondary reason for hosp is non-CV: Specify: Line #2	Dropped, long text field
SHF16Z1A	Secondary reason for hosp is MI: Date of MI (Ver B)	Standard date transformation
SHF16Z1B	Secondary reason for hosp is MI: Time of MI	Version B only

SHF16BH	Secondary reason for hosp is MI: Time of MI: Hour	Version B only
SHF16BM	Secondary reason for hosp is MI: Time of MI: Minute	Version B only
SHF16Z1C	Secondary reason for hosp is MI: Time of MI: AM/PM	Version B only
SHF22Z2	Secondary reason for hosp is cardiac surgery: Type of cardiac surgery	Sparse levels B, T, V, O collapsed into level X
SHF22Z3	Secondary reason for hosp is cardiac surgery: Specify other cardiac surgery	Dropped, long text field
SHF23	Secondary reason for hosp is pulmonary embolism	Collapsed into SHF27Z1X and then dropped
SHF24	Secondary reason for hosp is peripheral embolism	Collapsed into SHF27Z1X and then dropped
SHF25	Secondary reason for hosp is hypotension	Collapsed into SHF27Z1X and then dropped
SHF26	Secondary reason for hosp is azotemia	Collapsed into SHF27Z1X and then dropped
SHF27Z1	Secondary reason for hosp is any other major event	Collapsed into SHF27Z1X and then dropped
SHF27Z1X	Secondary reason for hosp is SHF23-26 or SHF27Z1	Recoded to include information from SHF23, SHF24, SHF25, SHF26, and SHF27Z1
SHF27Z2	Secondary reason for hosp is any other major event: Specify	Dropped, long text field
SHF28	Initials of person completing this form	Dropped, personal information

ICD9 categories for variable SHF6a:

. = Blank
1 = Infectious and Parasitic Diseases (001-139)
2 = Neoplasms (140-239)
3 = Endocrine, Nutritional, and Metabolic Diseases and Immunity Disorders (240-279)
4 = Diseases of the Blood and Blood-Forming Organs (280-289)
5 = Mental Disorders (290-319)
6 = Diseases of the Nervous System and Sense Organs (320-389)
7 = Diseases of the Circulatory System (390-459)
8 = Diseases of the Respiratory System (460-519)
9 = Diseases of the Digestive System (520-579)
10 = Diseases of the Genitourinary System (580-629)
11 = Complications of Pregnancy, Childbirth, and the Puerperium (630-676)
12 = Diseases of the Skin and Subcutaneous Tissue (680-709)
13 = Diseases of the Musculoskeletal System and Connective Tissue (710-739)
14 = Congenital Anomalies (740-759)
15 = Certain Conditions Originating in the Perinatal Period (760-779)
16 = Symptoms, Signs, and Ill-Defined Conditions (780-799)
17 = Injury and Poisoning (800-999)
18 = External Causes of Injury and Poisoning (E800 - E999)
19 = Supplementary Codes (V01 - V82)
20 = Other ICD9 Code

Note: categories 7 (Diseases of the Circulatory System) and 14 (Congenital Anomalies) were recoded into category 20 (Other ICD9 codes), due to sparseness of counts. Sparse counts were expected for category 7, as variables SHF6A-B are text descriptions of non-cardiovascular hospitalizations.

Categories for variable SHF10:

1 = Worsening or new CHF, Pulmonary Edema
2 = Worsening or new angina/ASHD/SOB
3 = Myocardial infarction
4 = Cardiac arrest
5 = Supraventricular tachycardia
6 = Uncertain tachycardia
7 = Other arrhythmias + (Bradycardia, Atrial node dysfunction)
8 = Stroke
9 = Cardiac surgery
10 = Cardiac surgery - graft
11 = Cardiac surgery - valve
12 = Cardiac surgery - transplantation
13 = Cardiac surgery - graft and valve
14 = Cardiac surgery - other
(Other cardiac surgery includes pacemaker replacement & adjustment and AV node ablation, AICD placement-revision, Cardiac Aneurysm (pseudo or real), Sympathomectomy)
15 = Pulmonary embolism/Infarction
16 = Peripheral embolism
17 = Hypotension
18 = Azotemia/Renal Failure/Uremia
19 = Syncope, dizziness / Vertigo/ Fainting/ Near Syncope
20 = TIA
21 = Cardiac/Coronary angiography/ rt or lf cather.
22 = Chest pain R/O MI, evaluation /Substudy Control
23 = Transplant evaluation
24 = Peripheral vasc. eval/surgery, BKA, ASHD, Carotid Arterial Stenosis, PVD, Angiogram, AAA / Peripheral vascular PTCA
25 = Pericarditis/pleuritis/SBE / Pleural Effusion / Post thoracotomy Syndrome
26 = Electrophysiologic testing/ Holter monitoring (EP Studies)
27 = Thrombophlebitis / DVT
28 = Coronary angioplasty, PTCA
29 = Atrial fibrillation/ flutter
30 = Hypokalemia/dehydration, Electrolyte imbalance
31 = Hypertension/ ASHD, HTN
32 = Hyperkalemia
33 = Digoxin toxicity
34 = CV medication adjustment
35 = Ruptured aneurysm
36 = Venous insufficiency / Bilateral leg swelling
37 = Subdurnal Hemorrhage
38 = TP Rejection
39 = Valvular Heart Disease
40 = Other cardiovascular reason

Note: categories 1-14 are redundant with levels A-J of variable SHF7 and with the levels of variable SHF9Z1, and so they contained sparse counts. Therefore, they were blanked out. Categories 29-39 also contained small counts, and were collapsed into category 40 (Other cardiovascular reason).

9. Data set name: **SMT_LAD2**
Description: **SOLVD Medication Tolerance Visit Form (SMT)**
Form versions: **A, B, C**
Number of observations: **6796**
Visit range: **2**
Structure: **One observation for each ID_SOL**
Sort order (unique keys): **ID_SOL**

Variable	Description	Modification/Comment
SMT1	Date form completed	Standard date transformation
SMT2Z1	Participant's last name	Dropped, personal information
SMT2Z2	Participant's first name	Dropped, personal information
SMT2Z3	Participant's middle name	Dropped, personal information
SMT3Z1	Systolic blood pressure – sitting (mm Hg)	Top/bottom coding: Values below 80 recoded to 80. Values above 180 recoded to 180.
SMT3Z2	Diastolic blood pressure – sitting (mm Hg)	Top/bottom coding: Values below 50 recoded to 50. Values above 110 recoded to 110.
SMT4	Heart rate – sitting (beats per minute)	Top/bottom coding: Values below 46 recoded to 46. Values above 112 recoded to 112.
SMT5A	Participant given 2nd chance for med tolerance?	Versions B, C only
SMT5B	Participant using non-ACE vasodilators?	Version C only
SMT6Z2	Indication for continuing use of all non-ACE vasodilators	Dropped, long text field
SMT7Z4	Not tolerated med – skin rash	Collapsed into variable SMT7Z6X and then dropped
SMT7Z4A	Not tolerated med – dizziness/fainting	Version C only
SMT7Z4B	Not tolerated med – fatigue	Version C only
SMT7Z4C	Not tolerated med – nausea (Ver C)	Collapsed into variable SMT7Z6X and then dropped
SMT7Z4D	Not tolerated med – angioneurotic edema (Ver C)	Collapsed into variable SMT7Z6X and then dropped
SMT7Z4E	Not tolerated med – cough (Ver C)	Collapsed into variable SMT7Z6X and then dropped
SMT7Z5	Not tolerated med – did not take med	Collapsed into variable SMT7Z6X and then dropped
SMT7Z6	Not tolerated med – other reason	Collapsed into variable SMT7Z6X and then dropped
SMT7Z6X	Not tolerated med – reason from SMT7Z4, SMT7Z4C, SMT7Z4D, SMT7Z4E, SMT7Z5, and SMT7Z6	Includes information from SMT7Z4, SMT7Z4C, SMT7Z4D, SMT7Z4E, SMT7Z5, and SMT7Z6
SMT7Z6S	Not tolerated med – specify other reason	Dropped, long text field, counts too low in categories and overall
SMT7Z7	Participant willing to continue on med despite side effects?	Dropped, not relevant for randomized participants
SMT7Z7A	Does participant still meet inclusion criteria? (Ver B,C)	Dropped, not relevant for randomized participants
SMT7Z7B	# of most important inclusion criteria not met (Ver B,C)	Dropped, not relevant for randomized participants

SMT8	Initials of person completing this form	Dropped, personal information
SMT9	Participant still eligible to continue in SOLVD?	Dropped, not relevant for randomized participants
SMT10	Hematocrit (HCT) (%)	Top/bottom coding: Values below 29 recoded to 29. Values above 54 recoded to 54.
SMT11Z1	Total white blood count (WBC x 1000)	Top/bottom coding: Values below 3 recoded to 3. Values above 15 recoded to 15.
SMT11Z2	Percent neutrophils	Top/bottom coding: Values below 29 recoded to 29. Values above 86 recoded to 86.
SMT11Z3	Percent lymphocytes	Top/bottom coding: Values below 6 recoded to 6. Values above 60 recoded to 60.
SMT12	Sodium (Na) (meq/l)	Top/bottom coding: Values below 129 recoded to 129. Values above 148 recoded to 148.
SMT13	Potassium (K) (meq/l)	Top/bottom coding: Values below 3.2 recoded to 3.2. Values above 5.9 recoded to 5.9.
SMT14	Blood urea nitrogen (BUN) (mg/dl)	Top/bottom coding: Values below 6 recoded to 6. Values above 50 recoded to 50.
SMT15	Creatinine (mg/dl)	Top/bottom coding: Values below 0.5 recoded to 0.5. Values above 2.5 recoded to 2.5.
SMT16	Proteinurea (0-4) (1="+") (Ver A)	Collapsed into C0 (0), C1 (1), C2 (2), C3_4 (3, 4).
SMT16A	Proteinurea (0-4) (1="trace or +") (Ver B,C)	Collapsed into C0 (0), C1 (1), C2 (2), C3_4 (3, 4).
SMT17Z1	Participant still suitable to continue?	Dropped, not relevant for randomized participants
SMT17Z2	Specify reason(s) for participant not suitable to continue	Dropped, not relevant for randomized participants
SMT17Z3	Scheduled date of baseline visit 3 (randomization)	Standard date transformation

10. Data set name: **SQL_LAD2**
Description: **SOLVD Quality of Life Form (SQL)**
Form versions: **A, B**
Number of observations: **17,522**
Visit range: **3-20**
Structure: **Multiple observations for each ID_SOL**
Sort order (unique keys): **ID_SOL VISIT**

Variable	Description	Modification/Comment
SQLA	Date form completed	Standard date transformation
SQLB	Participant's last name	Dropped, personal information
SQLC	Participant's first name	Dropped, personal information
SQLD	Participant's middle name	Dropped, personal information
SQLE	Initials of person completing this form	Dropped, personal information
SQL22CA	During last month, how difficult was it for participant to walk 1 block or climb 1 flight of stairs?	Version B only
SQL23A	Describe current work (or last job) of participant, if 'other'	Dropped, long text field
SQL30S	Describe reason for participant being forced to retire, when it is 'other'	Dropped, long text field
SQL32	Participant is retired: Participant's age at retirement	Top/bottom coding: Values below 40 recoded to 40. Values above 75 recoded to 75.
SQL36	Participant's gender	Dropped, use SEF9
SQL37	Participant's age	Dropped, use SEF_AGE
SQL38	Highest grade participant completed in school	Top/bottom coding: Values below 2 recoded to 2. Values above 22 recoded to 22.

11. Data set name: **SRF_LAD2**
Description: **SOLVD Randomization Form (SRF)**
Form versions: **A, B**
Number of observations: **6797**
Visit range: **3**
Structure: **One observation for each ID_SOL**
Sort order (unique keys): **ID_SOL**

Variable	Description	Modification/Comment
RDATE	Randomization date	Standard date transformation (resulting in value of 0 for all participants)
SRF1	Date form completed	Standard date transformation
SRF2	Date of last SOLVD Visit (Visit 2)	Standard date transformation
SRF3Z1	Participant's last name	Dropped, personal information
SRF3Z2	Participant's first name	Dropped, personal information
SRF3Z3	Participant's middle name	Dropped, personal information
SRF4	Initials of person completing this form	Dropped, personal information
SRF5Z1	NYHA CHF classification (Ver B)	Dropped, no information for 50% of participants
SRF5Z2	Participant taking digitalis ? (Ver B)	Dropped, no information for 50% of participants
SRF5Z3	Is the indication of use of digitalis for treatment of supraventricular arrhythmias ? (Ver B)	Dropped, no information for 88% of participants
SRF5Z4	Participant currently on diuretic therapy ? (Ver B)	Dropped, no information for 50% of participants
SRF5Z5	Is the indication of use of diuretic therapy for treatment of CHF ? (Ver B)	Dropped, no information for 85% of participants
SRF5Z6Z1	Reason for diuretic therapy: Hypertension (Ver B)	Dropped, no information for 94% of participants
SRF5Z62A	Reason for diuretic therapy: Peripheral edema – lymphatic disorders (Ver B)	Dropped, count too low
SRF5Z62B	Reason for diuretic therapy: Peripheral edema – venous insufficiency (Ver B)	Dropped, count too low
SRF5Z62C	Reason for diuretic therapy: Peripheral edema – nifedipine (Ver B)	Dropped, count too low
SRF5Z62D	Reason for diuretic therapy: Peripheral edema – perimenstrual (Ver B)	Dropped, count too low
SRF6Z3	Number of days since Visit 2	Top/bottom coding: Values above 21 recoded to 21. (Only 1 value (25) affected).
SRF6Z4	Adherence	Top/bottom coding: Values below 84 recoded to 84. Values above 105 recoded to 105.