

INSTRUCTIONS: This form should be completed and entered into ADEPT for all fully eligible participants who are more than 18 months post baseline echo date except for those who were withdrawn because of death or heart transplant. To enter this form in ADEPT, please select “VVV Final Status Event” from the “Category of Data” drop down menu at the bottom of the Summary of VVV Study Events screen for the patient. The DCC will provide sites with an individualized form for each subject that will substitute specific dates for the YELLOW-shaded generic “dates” that are listed on this form.

Section A: KEY IDENTIFYING INFORMATION

- A1. Study Identification Number _____ - _____ - _____ **REMOVED**
BLIND_ID
- A2. Acrostic Identifier _____ **REMOVED**
- A3. 18-month window close date <<baseline echo date + 18 months >> **REMOVED**
AGE_M18DATE
- A4. Date of form completion _____ / _____ / _____ **REMOVED**
M M D D Y Y Y Y AGE_COMP
- A5. Name of person completing form _____ **REMOVED** _____
PRINT FULL NAME INITIALS

Section B: INTERVENTIONS, CHF CLASSIFICATION, AND VITAL STATUS

B1. Did the subject have any of the following interventions between <<last VVV echo date>> and <<18-month window close date >>?

	YES	NO	UNKNOWN	1. If YES, date of intervention [if intervention occurred more than once, enter date of first occurrence]
a. ECMO XECMO	1	2	-8	_____/_____/_____ M M D D Y Y Y Y REMOVED AGE_XECMO_D
b. LVAD XLVAD	1	2	-8	_____/_____/_____ M M D D Y Y Y Y REMOVED AGE_XLVAD_D
c. BiVAD XBIVAD	1	2	-8	_____/_____/_____ M M D D Y Y Y Y REMOVED AGE_XBIVA_D
d. LV Reduction Surgery XLVRED	1	2	-8	_____/_____/_____ M M D D Y Y Y Y REMOVED AGE_XLVRED_D
e. Heart Transplant XTRANS	1	2	-8	_____/_____/_____ M M D D Y Y Y Y REMOVED AGE_XTRANS_D

B2. Date of last clinical visit prior to <<18-month window close date >> _____ / _____ / _____
 M M D D Y Y Y Y
 REMOVED AGE_XLASTCLIN D

B3. Age of patient at time of clinical visit on B2 date. XLASTCLINAGE
 < 5 YEARS..... 1 (B4) ≥ 5 YEARS 2 (B5)

B4. Ross Classification of Congestive Heart Failure on B2. date (Circle one) XROSCLAS
 COMPLETE IF AGE ON B2 DATE ABOVE IS < 5 YEARS
CLASS I (NO LIMITATIONS OR SYMPTOMS) 1 (B6)
CLASS II (SYMPTOMS BUT NO GROWTH FAILURE*)..... 2 (B4a)
CLASS III (GROWTH FAILURE* AND PROLONGED FEEDING TIME IN INFANTS) 3 (B4b)
CLASS IV (GROWTH FAILURE* AND SYMPTOMATIC AT REST 4 (B4c)
 WITH ≥1 SYMPTOM LISTED IN B4c BELOW)
CANNOT DETERMINE BASED ON NOTES IN RECORDS.....-8 (B6)

* Growth failure is defined as weight-for-age < 5th percentile

a. If Class II, indicate signs and symptoms present (Answer ALL questions 1-3)

		YES	NO	NA
1.	Mild tachypnea with feeds in infants XR2TACHY	1	2	-1
2.	Mild diaphoresis with feeds in infants XR2DIAPH	1	2	-1
3.	Dyspnea on exercise in older children XR2DYSPEX	1	2	-1
GO TO B6				

b. If Class III, indicate signs and symptoms present (Answer ALL questions 1-2)

		YES	NO
1.	Marked tachypnea with feeds or exertion XR3TACHY	1	2
2.	Marked diaphoresis with feeds or exertion XR3DIAPH	1	2
GO TO B6			

c. If Class IV, indicate signs and symptoms present (Answer ALL questions 1-4)

		YES	NO
1.	Tachypnea XR4TACHY	1	2
2.	Retractions XR4RETRC	1	2

3.	Grunting XR4GRUNT	1	2
4.	Diaphoresis XR4DIAPH	1	2
GO TO B6			

B5. New York Heart Association (NYHA) Classification of Congestive Heart Failure on B2. date COMPLETE IF AGE ON B2 DATE ABOVE IS \geq 5 YEARS XNYHCLAS

CLASS I (NO LIMITATION OF ACTIVITIES; NO SYMPTOMS FROM ORDINARY ACTIVITIES)..... 1

CLASS II (SLIGHT, MILD LIMITATION OF ACTIVITY; COMFORTABLE WITH REST OR WITH MILD EXERTION).....2

CLASS III (MARKED LIMITATION OF ACTIVITY; COMFORTABLE ONLY AT REST)3

CLASS IV (SHOULD BE AT COMPLETE REST, CONFINED TO BED OR CHAIR; ANY PHYSICAL ACTIVITY BRINGS ON DISCOMFORT AND SYMPTOMS OCCUR AT REST)4

CANNOT DETERMINE BASED ON NOTES IN RECORDS.....-8

B6. Was the patient on a heart transplant waiting list as of <<18-month window close date>>? XTRNWAIT

YES 1 NO.....2 (B7) UNKNOWN.. -8 (B7)

a. Status XTRNSTAT

1A (US) / 2, 3, 3.5, 4 (Canada)..... 1

1B (US)..... 2

2 (US) / 1 (Canada)..... 3

7 (US) / 0 (Canada)..... 4

UNKNOWN.....-8

b. Date listed
 REMOVED AGE_XTRN_D _____ / _____ / _____
 M M D D Y Y Y Y

B7. Is the patient known to have died? XDEAD

YES..... 1

a. Date of death _____ / _____ / _____ (C1)
 M M D D Y Y Y Y
 REMOVED AGE_XDEAD_D

NO..... 2

b. Date last known alive _____ / _____ / _____
 M M D D Y Y Y Y
 REMOVED AGE_XLIVE_D

Section C: STATUS OF COMPLETION OF A "1-YEAR" VVV STUDY ECHO

C1. Was a **VVV study echo** completed between <<baseline echo date + 11 months >> and <<18-month window close date >>? **X1YEAR**

YES..... 1 (END)

NO..... 2

a. Did the subject have an outpatient **clinical echo** completed between <<baseline echo date + 11 months>> and <<18-month window close date >>? **XCLINEECHO**

YES.....1

NO..... 2 (END)

UNKNOWN -8 (END)

C2. Reason **VVV study echo** not completed at time of clinical echo performed between <<baseline echo date + 11 months>> and <<18-month window close date >>

[Enter the first applicable choice from the list below] **REMOVED**

SUBJECT WITHDREW PRIOR TO <<baseline echo date + 11 months>>..... 1
[If Form V202 was NOT completed, please complete and enter into ADEPT]

LAST VVV STUDY ECHO < 3 MONTHS BEFORE2

SITE OVERSIGHT3

PRIMARY ULTRASONOGRAPHER UNAVAILABLE 4

TECHNICAL DIFFICULTY OR PATIENT COOPERATION PROBLEM.....5

CLINICAL ECHO PERFORMED AT NON-PHN SITE6

COMPLETED > 13 MONTHS AFTER BASELINE ECHO PRIOR TO EXTENSION OF WINDOW TO 18 MONTHS..... 7

OTHER99

a. Specify OTHER **REMOVED**
