

**INSTRUCTIONS: This form must be completed for all screened patients.**

**Section A: KEY IDENTIFYING INFORMATION**

A1. Study Identification Number \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**Replaced by blinded subject ID**

blind_id	Blinded ID
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A2. Acrostic Identifier \_\_\_\_\_

**Removed to protect privacy**

A3. Date of form completion \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
M M / D D / Y Y Y Y

**Replaced by age at form completion**

comp_age	A3. <created var>Age at completion of form, days
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A4. Name of person completing form \_\_\_\_\_  
PRINT FULL NAME INITIALS

**Removed to protect privacy**

**Section B: DIAGNOSIS AND SURGICAL HISTORY**

B1. Most recent single ventricle anatomic diagnosis

**Single Ventricle Anatomic Diagnosis Code**  
**(See Code List A)**  
 [code required for data entry]

- a. Level 1 \_\_\_\_\_
- b. Level 2 \_\_\_\_\_
- c. Level 3 \_\_\_\_\_
- d. Level 4 \_\_\_\_\_
- e. Level 5 \_\_\_\_\_

<b>Anatomic Diagnosis Name Worksheet</b>
If coding = <u>A4</u> you <b>must</b> specify here: a1.
b1.
If coding = <u>A1-06-03</u> you <b>must</b> specify here: c1.
d1.
e1.

banatdx	<created var> Most recent SV Anatomic Diagnosis (Code List A)
BANDX_S	B1c1. Single Ventricle Anatomic Diagnosis Code: specify
adxcat	<created var> Most recent SV anatomic diagnosis category

f. Any associated anatomic diagnoses? YES ..... 1 NO ..... 2 **(B2)**

ASSOCDX	[Added Version B] B1f. Any associated anatomic diagnoses?
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Form S101: Baseline Characteristics Form

Code associated anatomic diagnoses **(See Code List I)**

- 1) \_\_\_-\_\_\_-\_\_\_ 2) \_\_\_-\_\_\_-\_\_\_ 3) \_\_\_-\_\_\_-\_\_\_ 4) \_\_\_-\_\_\_-\_\_\_ 5) \_\_\_-\_\_\_-\_\_\_  
 6) \_\_\_-\_\_\_-\_\_\_ 7) \_\_\_-\_\_\_-\_\_\_ 8) \_\_\_-\_\_\_-\_\_\_ 9) \_\_\_-\_\_\_-\_\_\_ 10) \_\_\_-\_\_\_-\_\_\_

f.i. If Other, specify \_\_\_\_\_

asdxcode	<created var> All associated anatomic diagnoses (Code List I)
ASDXCODE_0 - ASDXCODE_9	[Added Version B] B1f.a. Associated anatomic diagnosis (Code List I) (0-9)
ASDX_S_0 - ASDX_S_9	[Added Version B] B1f.i. Specify other associated anatomic diagnosis (0-9)

B2. Cardiac surgical procedure(s) either prior to single ventricle palliative surgery, or if no surgery, prior to the end of screening YES ..... 1 NO .....2 **(B3)**

BNUMPSV	B2. Cardiac surgical procedures prior to palliative surgery
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	YES	NO
a. Atrial septectomy	1	2
b. Coarctation of aortic repair	1	2
c. Aortic valvotomy	1	2
d. Other	1	2
1. Specify:		

BATRSEPT	B2a. Atrial septectomy
BCOARCT	B2b. Coarctation of aortic repair
BAVALVOT	B2c. Aortic valvotomy
BOTHSURG	B2d. Other
BOSURG_S	B2d1. If other, specify

B3. Single ventricle palliative surgery prior to the end of screening? YES..... 1 NO.....2 **(B7)**

PALSURG	[Added Version C] B3. Single ventricle palliative surgery prior to the end of screen?
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a. Date of single ventricle palliative surgery       /       /            

M M D D Y Y Y Y

**Replaced with age at surgery**

palsrg_age	B3a. <created var>Age at single ventricle palliative surgery, days
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B4. Type of single ventricle palliative surgery

**Surgical Procedure Code**  
(See Code List B)  
[code required for data entry]

- a. Level 1 **B 1**
- b. Level 2
- c. Level 3
- d. Level 4

Surgical Procedure Name Worksheet
a1.
b1.
If coding = <u>B1-01-06</u> , you <b>must</b> specify here:
c1.
d1.

bproc	<created var> Single ventricle palliative surgery (Code List B)
BPROC_S	B4c1. Type of most recent Fontan procedure level: specify

B5. Number of other surgical procedures concurrent with single ventricle palliative surgery       (0-5) (If 0, skip to **B6**)

BNUMCON	B5. Number procedures concurrent w/single ventricle palliative
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Concurrent Surgical Procedures			
Code	Procedure Name	Code	Procedure Name
01	Aortic arch repair*	11	Repair of totally anomalous pulmonary venous connection
02	Atrial septectomy*		
03	Atrioventricular valve oversewn		
04	Atrioventricular valve replacement	14	Semilunar valve replacement
06	Division of main pulmonary artery*	16	Subaortic stenosis surgery
07	Ligation of main pulmonary artery		
08	Pacemaker insertion		
09	Patch repair of pulmonary artery stenosis		
10	Repair of atrioventricular valve regurgitation	99	Other

**\*DO NOT SELECT IF CODING FOR QUESTION B4 IS B1-05.**

**Concurrent Surgical Code (See codes above)**

- a. \_\_\_ \_\_\_ 1. If Other (99), specify: \_\_\_\_\_
- b. \_\_\_ \_\_\_ 1. If Other (99), specify: \_\_\_\_\_
- c. \_\_\_ \_\_\_ 1. If Other (99), specify: \_\_\_\_\_
- d. \_\_\_ \_\_\_ 1. If Other (99), specify: \_\_\_\_\_
- e. \_\_\_ \_\_\_ 1. If Other (99), specify: \_\_\_\_\_

bconcode	<created var> All concurrent surgical procedures
BCONCOD_0 - BCONCOD_4	B5a-B5e. Concurrent surgical code (0-4)
BCON_S_0 - BCON_S_4	B5a1-B5e1. Specify other concurrent surgical code (0-4)

B6. Number of other cardiac surgical procedures performed post-palliative surgery \_\_\_\_\_ (0-5) (If 0, skip to **B7**)

**[DO NOT include palliative surgery, cardiac surgical procedures listed in B2 or interventional cardiac catheterization procedures listed in B7]**

BNUMSURG	B6. Number of other cardiac surgical procedures
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Cardiac Surgical Procedures	
Code	Procedure Name
01	Chest closure
02	Chest exploration without intervention
03	Diaphragm plication
04	Pacemaker insertion
05	Percutaneous enteral gastrostomy
07	Pleurodesis
08	Pulmonary artery band revision
09	Pulmonary artery plasty
10	Shunt revision or thrombectomy
11	Thoroцентesis
12	Thoracic duct ligation
13	Thoracostomy tube
99	Other

**Cardiac Surgical Code (See codes above)**

- a.    \_\_\_ \_\_\_       1. If Other (99), specify: \_\_\_\_\_
- b.    \_\_\_ \_\_\_       1. If Other (99), specify: \_\_\_\_\_
- c.    \_\_\_ \_\_\_       1. If Other (99), specify: \_\_\_\_\_
- d.    \_\_\_ \_\_\_       1. If Other (99), specify: \_\_\_\_\_
- e.    \_\_\_ \_\_\_       1. If Other (99), specify: \_\_\_\_\_

bsurgcode	<created var> All other cardiac surgeries post-palliative to screening
BSURGCOD_0 - BSURGCOD_8	B6a-B6e. Other cardiac surgical procedure, post-palliative surgery to screening (0-8)
BSURG_S_0 - BSURG_S_8	B6a1-B6e1. Specify other surgical procedure post-palliative surgery to screening (0-8)

B7. Number of interventional cardiac catheterizations from birth to the end of screening \_\_\_\_\_ (0-5) (If 0, **END**)

[DO NOT include diagnostic catheterizations]

BNUMCATH	B7. Number of interventional cardiac catheterizations
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Cardiac Catheterization Intervention Code (See Code List F) [code required for data entry]						6. Date of Interventional Cardiac Catheterization
1. Level 1	2. Level 2	3. Level 3	4. Level 4	5. Level 5		
a.	_____ - _____ - _____ - _____ - _____					_____ / _____ / _____ / _____ / _____ / _____ / _____ / _____ M M D D Y Y Y Y Name of intervention
b.	_____ - _____ - _____ - _____ - _____					_____ / _____ / _____ / _____ / _____ / _____ / _____ / _____ M M D D Y Y Y Y Name of intervention
c.	_____ - _____ - _____ - _____ - _____					_____ / _____ / _____ / _____ / _____ / _____ / _____ / _____ M M D D Y Y Y Y Name of intervention
d.	_____ - _____ - _____ - _____ - _____					_____ / _____ / _____ / _____ / _____ / _____ / _____ / _____ M M D D Y Y Y Y Name of intervention
e.	_____ - _____ - _____ - _____ - _____					_____ / _____ / _____ / _____ / _____ / _____ / _____ / _____ M M D D Y Y Y Y Name of intervention

bcath	<created var> All Pre-Screening Cardiac Catheterization Code (Code List F)
bcath_0 - bcath_4	<created var> Interventional cardiac catheterization code (Code List F) (0-4)
bcath_0_age - bcath_4_age	B7a6. <created var>Age at interventional cardiac catheterization, days (0-4)
BCATHNAM_0 – BCATHNAM_4	B7.6a. Pre-Screening Cardiac Catheterization: specify (0-4)