

**Section A: KEY IDENTIFYING INFORMATION**

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

**Replaced by blinded ID**

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

**Removed to protect privacy**

A3. Restart number \_\_\_\_\_ (This Restart Number must match the Stop Number recorded on the S117 that necessitated this study drug restart)

DRSTARTN	[Added Version C] A3. Stop Number
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A4. Date of form completion \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
M M D D Y Y Y Y

**Replaced by age at form completion**

comp_age	A4. <created var>Age at form completion, days
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A5. Name of person completing form \_\_\_\_\_  
PRINT FULL NAME INITIALS

**Removed to protect privacy**

**Section B: STUDY DRUG AND ADMINISTRATION**

B1. Was the study drug stopped temporarily because of the Glenn shunt surgery? YES ..... 1 (B3) NO..... 2

**Vital signs do not need to be recorded, SKIP B6, B9 and B10**

RSRTGLEN	B1. Study drug stopped because of Glenn?
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B2. Will Study Visit 4 be scheduled based on this study drug restart date (B3)? YES ..... 1 NO..... 2

SCHEDV4	[Added Version E] B2. Will Study Visit 4 be scheduled based on this study drug restart date (B3)
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B3. Date study drug restarted \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
M M D D Y Y Y Y

**Replaced by age when study drug restarted**

restar_age	B3. <created var>Age when study drug is restarted, days
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Form S112: Study Drug Restart Form

B4. Weight \_\_\_\_\_ . \_\_\_\_\_ kg

WT_R	B4. Weight, kg
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B5. Restart dose of study drug prescribed \_\_\_\_\_ . \_\_\_\_\_ mg/kg/dose

RDOSEX	B5. Restart dose of study drug prescribed
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B6. Use the table below to record the patient's vital signs **before** administration of study drug.

Vital Signs	Immediately <b>before</b> dose
a. Heart rate	_____ bpm
b. Systolic BP	_____ mmHg
c. Diastolic BP	_____ mmHg
d. Mean BP	_____ mmHg
e. Oxygen Saturation	_____ %

RHRBEF	B6a. Heart rate (before dose), bpm
RSBPBEF	B6b. Systolic BP (before dose), mmHg
RDBPBEF	B6c. Diastolic BP (before dose), mmHg
RMBPBEF	B6d. Mean BP (before dose), mmHg
RO2SBEF	B6e. Oxygen saturation (before dose), %

B7. Restart dose of study drug administered \_\_\_\_\_ . \_\_\_\_\_ mg bid

RDOSEADM	B7. Restart dose of study drug administered, mg bid
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B8. Time study drug administered \_\_\_\_\_ : \_\_\_\_\_

a. Units AM..... 1 PM..... 2 24-HOUR..... 3

RDOSE_T	B8. Time study drug administered
RDOSETU	B8a. Units
rdose24	<created var> Time study drug administered (24-hour time)

B9. Use the table below to record the patient's vital signs for **240 minutes** after administration of study drug.  
 (NOTE: Only the vital signs at 120 and 240 minutes will be data entered.)

Vital Signs	a. 30 minutes	b. 60 minutes	c. 90 minutes	d. 120 minutes	e. 150 minutes	f. 180 minutes	g. 210 minutes	h. 240 minutes
1. HR (bpm)	_____	_____	_____	_____	_____	_____	_____	_____

RHR120	B9d1. Heart rate (120 min. after dose), bpm
RHR240	[Added Version C] B9h1. Heart Rate (240 min. after dose), bpm

Vital Signs	a. 30 minutes	b. 60 minutes	c. 90 minutes	d. 120 minutes	e. 150 minutes	f. 180 minutes	g. 210 minutes	h. 240 minutes
2. SBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____

RSBP120	B9d2. Systolic BP (120 min. after dose), mmHg
RSBP240	[Added Version C] B9h2. Systolic BP (240 min. after dose), mmHg

Vital Signs	a. 30 minutes	b. 60 minutes	c. 90 minutes	d. 120 minutes	e. 150 minutes	f. 180 minutes	g. 210 minutes	h. 240 minutes
3. DBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____

RDBP120	B9d3. Diastolic BP (120 min. after dose), mmHg
RDBP240	[Added Version C] B9h3. Diastolic BP (240 min. after dose), mmHg

Vital Signs	a. 30 minutes	b. 60 minutes	c. 90 minutes	d. 120 minutes	e. 150 minutes	f. 180 minutes	g. 210 minutes	h. 240 minutes
4. MBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____

RMBP120	B9d4. Mean BP (120 min. after dose)
RMBP240	[Added Version C] B9h4. Mean BP (240 min. after dose), mmHg

Vital Signs	a. 30 minutes	b. 60 minutes	c. 90 minutes	d. 120 minutes	e. 150 minutes	f. 180 minutes	g. 210 minutes	h. 240 minutes
5. O <sub>2</sub> Sat (%)								

RO2S120	B9d5. Oxygen saturation (120 min. after dose), %
RO2S240	[Added Version C] B9h5. Oxygen saturation (240 min. after dose), %

B10. a. **Lowest** systolic BP measured within                mmHg  
**240** minutes post-dose

Complete Form S200 if patient is not stable after **120** minutes, e.g., sustained SBP <70 mmHg

RLWSBP	B10a. Lowest systolic BP measured, mmHg
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b. Time lowest systolic BP measurement taken           :          

1. Units                      AM..... 1                      PM.....2                      24-HOUR ..... 3

RLWSBP_T	B10b. Time lowest systolic BP measurement taken
RLWSBPTU	B10b1. Units
rlwsbp24	<created var> Time lowest systolic BP measurement taken (24-hour time)

**Section C: RESULT OF STUDY DRUG RESTART**

C1. Was restart dose of study drug tolerated?      YES..... 1      NO .....2

a. Study drug dose prescribed           .                mg/kg/dose

RDOSETOL	C1. Was restart dose of study drug tolerated
RNEWDOSE	C1a. Study drug dose prescribed, mm/kg/dose