

INSTRUCTIONS: Complete this form only if the patient misses >6 consecutive doses of study drug or when the study drug is stopped prior to the Glenn surgery.

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. 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 form completion, days
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A4. Name of person completing form

PRINT FULL NAME INITIALS

Removed to protect privacy

A5. Stop number _____ (Enter number of times patient has temporarily stopped study drug: first stop=1, second stop=2...)

DRSTOPN	A5. Stop Number
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Section B: STUDY DRUG AND ADMINISTRATION

B1. Date study drug stopped temporarily
 _____ / _____ / _____
M M D D Y Y Y Y

Replaced by age when drug stopped temporarily

drstop_age	B1. <created var>Age at temporary stop of study drug, days
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Form S117: Study Drug Temporary Stop Form

- B2. Primary reason study drug stopped temporarily
- GLENN SHUNT SURGERY 1
 - HYPOTENSION 2
 - HYPOXIA 3
 - VOMITING 4
 - ACUTE ILLNESS 5
 - NPO STATUS 6
 - RENAL DYSFUNCTION 7
 - OTHER 99

STOPREAS	B2. Primary reason study drug stopped temporarily
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a. Specify other _____

STPRSN_S	B2a. Specify other
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B3. Last study drug dose prescribed ____ . ____ ____ mg/kg/dose

LDOSERX	B3. Last study drug dose prescribed, mg/kg/dose
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B4. Last study drug dose administered ____ . ____ ____ mg bid

LDOSEADM	B4. Last study drug dose administered, mg bid
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