

INSTRUCTIONS: Complete a new block (B1-B7) each time a dose adjustment or uptitration is attempted. If more adjustments or uptitrations are made than can be recorded on this form, make a photocopy of page 3, affix a study ID label to it and record the data.

Complete Form S200 (Adverse Event Form) for each adjustment or uptitration where the patient is not stable after 120-minutes of monitoring.

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 form initiated _____ / _____ / _____

Replaced by age at form initiation

init_age	A3. <created var>Age at form initiation, days
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A4. Name of person initiating form _____ PRINT FULL NAME _____ INITIALS _____

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A5. Date of **FIRST** adjustment or uptitration _____ / _____ / _____ / _____ / _____ / _____ / _____
(This is the date recorded in question B1a on this form)

Replaced by age at first adjustment or uptration

adjupf_age	A5. <created var>Age at first adjustment or uptitration, days
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A6. Date of **LAST** adjustment or uptitration _____ / _____ / _____ / _____ / _____ / _____ / _____
(This should be the last date that a dose adjustment or uptitration was attempted, i.e., the date recorded in the last block, B1, B2, B3, etc., for question a.)

Replaced by age at last adjustment or uptitration

adjupl_age	A6. <created var>Age at last adjustment or uptitration, days
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B1. Dose Adjustment/Uptitration 1

a. Date of adjustment or uptitration $\frac{\text{M}}{\text{M}} / \frac{\text{D}}{\text{D}} / \frac{\text{Y}}{\text{Y}} \frac{\text{Y}}{\text{Y}}$

Replaced by age at adjustment or uptitration

adjup_age_0 B1a <created var>Age at 1st adjustment/uptitration, days

b. Weight _____ . _____ kg

WT_ADJUP_0 B1b. Weight (kg) at adjustment/uptitration (0)

c. New dose prescribed _____ . _____ mg/kg/dose

ADOSERX_0 B1c. New dose prescribed (mg/kg/dose) (0)

d. Use table below to record vital signs **before** administration of study drug

Vital Signs	Before dose
1. Heart rate	_____ bpm
2. Systolic BP	_____ mmHg
3. Diastolic BP	_____ mmHg
4. Mean BP	_____ mmHg
5. O ₂ Saturation	_____ %

AHRBEF_0 B1d1. Heart rate (bpm) before dose (0)

ASBPBEF_0 B1d2. Systolic BP (mmHg) before dose (0)

ADBPBEF_0 B1d3. Systolic BP (mmHg) before dose (0)

AMBPBEF_0 B1d4. Mean BP (mmHg) before dose (0)

AOSATBEF_0 B1d5. O₂ Sat (%) before dose (0)

e. New dose administered _____ . _____ mg bid

ADOSEADM_0 B1e. New dose administered (mg bid) (0)

f. Time administered

___ : ___

1. Units

AM..... 1 PM2 24-HOUR3

ADOSE_T_0	B1f. Time new dose administered, __:__(0)
ADOSETU_0	B1f1. Units of time new dose administered (am/pm/24-hour) (0)
adose24_0	<created var> Time new dose administered, __:__(24-hour) (0)

g. Use table below to record vital signs after administration of study drug

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

AHR120_0	B1g1d. Heart rate (bpm) 120 minutes post-dose (0)
AHR240_0	[Added Version B] B1g1h. Heart rate (bpm) 240 minutes post-dose (0)

2. SBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ASBP120_0	B1g2d. Systolic BP (mmHg) 120 minutes post-dose (0)
ASBP240_0	[Added Version B] B1g2h. Systolic BP (mmHg) 240 minutes post-dose (0)

3. DBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ADBP120_0	B1g3d. Diastolic BP (mmHg) 120 minutes post-dose (0)
ADBP240_0	[Added Version B] B1g3h. Diastolic BP (mmHg) 240 minutes post-dose (0)

4. MBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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AMBP120_0	B1g4d. Mean BP (mmHg) 120 minutes post-dose (0)
AMBP240_0	[Added Version B] B1g4h. Mean BP (mmHg) 240 minutes post-dose (0)

5. O ₂ Sat (%)								
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AOSAT120_0	B1g5d. O2 Sat (%) 120 minutes post-dose (0)
AOSAT240_0	[Added Version B] B1g5h. O2 Sat (%) 240 minutes post-dose (0)

h. **Lowest** SBP during post-dose monitoring ___ ___ ___ mmHg

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

1. Time lowest SBP taken ___ ___ : ___ ___

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

ALWSBP_0	B1h. Lowest SBP within 120 minutes post-dose (0)
ALWSBP_T_0	B1h1. Time lowest SBP taken, __:__(0)
ALWSBPTU_0	B1h2. Units of time lowest SBP taken (am/pm/24-hour) (0)
alwsbp24_0	<created var> Time lowest SBP taken, __:__(24-hour) (0)

B2. Dose Adjustment/Uptitration 2

a. Date of adjustment or uptitration $\frac{\text{M}}{\text{M}} / \frac{\text{D}}{\text{D}} / \frac{\text{Y}}{\text{Y}} \frac{\text{Y}}{\text{Y}}$

Replaced by age at adjustment or uptitration

adjup_age_1 B1a <created var>Age at 2nd adjustment/uptitration, days

b. Weight $\text{---} \text{---} . \text{---} \text{---}$ kg

WT_ADJUP_1 B1b. Weight (kg) at adjustment/uptitration (1)

c. New dose prescribed $\text{---} . \text{---} \text{---} \text{---}$ mg/kg/dose

ADOSERX_1 B1c. New dose prescribed (mg/kg/dose) (1)

d. Use table below to record vital signs **before** administration of study drug

Vital Signs	Before dose
1. Heart rate	$\text{---} \text{---} \text{---}$ bpm
2. Systolic BP	$\text{---} \text{---} \text{---}$ mmHg
3. Diastolic BP	$\text{---} \text{---} \text{---}$ mmHg
4. Mean BP	$\text{---} \text{---} \text{---}$ mmHg
5. O ₂ Saturation	$\text{---} \text{---} \text{---}$ %

AHRBEF_1 B1d1. Heart rate (bpm) before dose (1)

ASBPBEF_1 B1d2. Systolic BP (mmHg) before dose (1)

ADBPBEF_1 B1d3. Systolic BP (mmHg) before dose (1)

AMBPBEF_1 B1d4. Mean BP (mmHg) before dose (1)

AOSATBEF_1 B1d5. O₂ Sat (%) before dose (1)

e. New dose administered $\text{---} . \text{---} \text{---}$ mg bid

ADOSEADM_1 B1e. New dose administered (mg bid) (1)

f. Time administered $\text{---} \text{---} : \text{---} \text{---}$

1. Units AM..... 1 PM2 24-HOUR3

Form S104: Dose Adjustment/Uptitration Log

ADOSE_T_1	B1f. Time new dose administered, __:__(1)
ADOSETU_1	B1f1. Units of time new dose administered (am/pm/24-hour) (1)
adose24_1	<created var> Time new dose administered, __:__(24-hour) (1)

g. Use table below to record vital signs after administration of study drug

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

AHR120_1	B1g1d. Heart rate (bpm) 120 minutes post-dose (1)
AHR240_1	[Added Version B] B1g1h. Heart rate (bpm) 240 minutes post-dose (1)

2. SBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ASBP120_1	B1g2d. Systolic BP (mmHg) 120 minutes post-dose (1)
ASBP240_1	[Added Version B] B1g2h. Systolic BP (mmHg) 240 minutes post-dose (1)

3. DBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ADBP120_1	B1g3d. Diastolic BP (mmHg) 120 minutes post-dose (1)
ADBP240_1	[Added Version B] B1g3h. Diastolic BP (mmHg) 240 minutes post-dose (1)

4. MBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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AMBP120_1	B1g4d. Mean BP (mmHg) 120 minutes post-dose (1)
AMBP240_1	[Added Version B] B1g4h. Mean BP (mmHg) 240 minutes post-dose (1)

5. O ₂ Sat (%)								
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AOSAT120_1	B1g5d. O2 Sat (%) 120 minutes post-dose (1)
AOSAT240_1	[Added Version B] B1g5h. O2 Sat (%) 240 minutes post-dose (1)

h. **Lowest** SBP during post-dose monitoring ___ ___ ___ mmHg

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

1. Time lowest SBP taken ___ ___ : ___ ___

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

ALWSBP_1	B1h. Lowest SBP within 120 minutes post-dose (1)
ALWSBP_T_1	B1h1. Time lowest SBP taken, ___:___ (1)
ALWSBPTU_1	B1h2. Units of time lowest SBP taken (am/pm/24-hour) (1)
alwsbp24_1	<created var> Time lowest SBP taken, ___:___ (24-hour) (1)

B3. Dose Adjustment/Uptitration 3

a. Date of adjustment or uptitration

 / /
M M D D Y Y Y Y

Replaced by age at adjustment or uptitration

adjup_age_2	B1a <created var>Age at 3rd adjustment/uptitration, days
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b. Weight

 . kg

WT_ADJUP_2	B1b. Weight (kg) at adjustment/uptitration (2)
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c. New dose prescribed

 . mg/kg/dose

ADOSERX_2	B1c. New dose prescribed (mg/kg/dose) (2)
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d. Use table below to record vital signs **before** administration of study drug

Vital Signs	Before dose
1. Heart rate	<u> </u> <u> </u> <u> </u> bpm
2. Systolic BP	<u> </u> <u> </u> <u> </u> mmHg
3. Diastolic BP	<u> </u> <u> </u> <u> </u> mmHg
4. Mean BP	<u> </u> <u> </u> <u> </u> mmHg
5. O ₂ Saturation	<u> </u> <u> </u> <u> </u> %

AHRBEF_2	B1d1. Heart rate (bpm) before dose (2)
ASBPBEF_2	B1d2. Systolic BP (mmHg) before dose (2)
ADBPBEF_2	B1d3. Systolic BP (mmHg) before dose (2)
AMBPBEF_2	B1d4. Mean BP (mmHg) before dose (2)
AOSATBEF_2	B1d5. O ₂ Sat (%) before dose (2)

e. New dose administered

 . mg bid

ADOSEADM_2	B1e. New dose administered (mg bid) (2)
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f. Time administered

___ : ___

1. Units

AM..... 1 PM2 24-HOUR.....3

ADOSE_T_2	B1f. Time new dose administered, __:__(2)
ADOSETU_2	B1f1. Units of time new dose administered (am/pm/24-hour) (2)
adose24_2	<created var> Time new dose administered, __:__(24-hour) (2)

g. Use table below to record vital signs after administration of study drug

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

AHR120_2	B1g1d. Heart rate (bpm) 120 minutes post-dose (2)
AHR240_2	[Added Version B] B1g1h. Heart rate (bpm) 240 minutes post-dose (2)

2. SBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ASBP120_2	B1g2d. Systolic BP (mmHg) 120 minutes post-dose (2)
ASBP240_2	[Added Version B] B1g2h. Systolic BP (mmHg) 240 minutes post-dose (2)

3. DBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ADBP120_2	B1g3d. Diastolic BP (mmHg) 120 minutes post-dose (2)
ADBP240_2	[Added Version B] B1g3h. Diastolic BP (mmHg) 240 minutes post-dose (2)

4. MBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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AMBP120_2	B1g4d. Mean BP (mmHg) 120 minutes post-dose (2)
AMBP240_2	[Added Version B] B1g4h. Mean BP (mmHg) 240 minutes post-dose (2)

Form S104: Dose Adjustment/Uptitration Log

5. O ₂ Sat (%)								
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AOSAT120_2	B1g5d. O2 Sat (%) 120 minutes post-dose (2)
AOSAT240_2	[Added Version B] B1g5h. O2 Sat (%) 240 minutes post-dose (2)

h. **Lowest** SBP during post-dose monitoring ___ ___ ___ mmHg

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

1. Time lowest SBP taken ___ ___ : ___ ___

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

ALWSBP_2	B1h. Lowest SBP within 120 minutes post-dose (2)
ALWSBP_T_2	B1h1. Time lowest SBP taken, ___:___ (2)
ALWSBPTU_2	B1h2. Units of time lowest SBP taken (am/pm/24-hour) (2)
alwsbp24_2	<created var> Time lowest SBP taken, ___:___ (24-hour) (2)

B4. Dose Adjustment/Uptitration 4

a. Date of adjustment or uptitration

 / /
M M D D Y Y Y Y

Replaced by age at adjustment or uptitration

adjup_age_3 B1a <created var>Age at 4th adjustment/uptitration, days

b. Weight

 . kg

WT_ADJUP_3 B1b. Weight (kg) at adjustment/uptitration (3)

c. New dose prescribed

 . mg/kg/dose

ADOSERX_3 B1c. New dose prescribed (mg/kg/dose) (3)

d. Use table below to record vital signs **before** administration of study drug

Vital Signs	Before dose
1. Heart rate	<u> </u> <u> </u> <u> </u> bpm
2. Systolic BP	<u> </u> <u> </u> <u> </u> mmHg
3. Diastolic BP	<u> </u> <u> </u> <u> </u> mmHg
4. Mean BP	<u> </u> <u> </u> <u> </u> mmHg
5. O ₂ Saturation	<u> </u> <u> </u> <u> </u> %

AHRBEF_3 B1d1. Heart rate (bpm) before dose (3)

ASBPBEF_3 B1d2. Systolic BP (mmHg) before dose (3)

ADBPBEF_3 B1d3. Systolic BP (mmHg) before dose (3)

AMBPEF_3 B1d4. Mean BP (mmHg) before dose (3)

AOSATBEF_3 B1d5. O₂ Sat (%) before dose (3)

e. New dose administered

 . mg bid

ADOSEADM_3 B1e. New dose administered (mg bid) (3)

f. Time administered

___ : ___

1. Units

AM..... 1 PM2 24-HOUR.....3

ADOSE_T_3	B1f. Time new dose administered, __:__(3)
ADOSETU_3	B1f1. Units of time new dose administered (am/pm/24-hour) (3)
adose24_3	<created var> Time new dose administered, __:__(24-hour) (3)

g. Use table below to record vital signs after administration of study drug

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

AHR120_3	B1g1d. Heart rate (bpm) 120 minutes post-dose (3)
AHR240_3	[Added Version B] B1g1h. Heart rate (bpm) 240 minutes post-dose (3)

2. SBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ASBP120_3	B1g2d. Systolic BP (mmHg) 120 minutes post-dose (3)
ASBP240_3	[Added Version B] B1g2h. Systolic BP (mmHg) 240 minutes post-dose (3)

3. DBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ADBP120_3	B1g3d. Diastolic BP (mmHg) 120 minutes post-dose (3)
ADBP240_3	[Added Version B] B1g3h. Diastolic BP (mmHg) 240 minutes post-dose (3)

4. MBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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AMBP120_3	B1g4d. Mean BP (mmHg) 120 minutes post-dose (3)
AMBP240_3	[Added Version B] B1g4h. Mean BP (mmHg) 240 minutes post-dose (3)

Form S104: Dose Adjustment/Uptitration Log

5. O ₂ Sat (%)								
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AOSAT120_3	B1g5d. O2 Sat (%) 120 minutes post-dose (3)
AOSAT240_3	[Added Version B] B1g5h. O2 Sat (%) 240 minutes post-dose (3)

h. **Lowest** SBP during post-dose monitoring ___ ___ ___ mmHg

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

1. Time lowest SBP taken ___ : ___

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

ALWSBP_3	B1h. Lowest SBP within 120 minutes post-dose (3)
ALWSBP_T_3	B1h1. Time lowest SBP taken, __:__ (3)
ALWSBPTU_3	B1h2. Units of time lowest SBP taken (am/pm/24-hour) (3)
alwsbp24_3	<created var> Time lowest SBP taken, __:__ (24-hour) (3)

B5. Dose Adjustment/Uptitration 5

a. Date of adjustment or uptitration

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M M D D Y Y Y Y

adjup_age_4	B1a <created var>Age at 5th adjustment/uptitration, days
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b. Weight

 . kg

WT_ADJUP_4	B1b. Weight (kg) at adjustment/uptitration (4)
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c. New dose prescribed

 . mg/kg/dose

ADOSERX_4	B1c. New dose prescribed (mg/kg/dose) (4)
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d. Use table below to record vital signs **before** administration of study drug

Vital Signs	Before dose
1. Heart rate	<u> </u> <u> </u> <u> </u> bpm
2. Systolic BP	<u> </u> <u> </u> <u> </u> mmHg
3. Diastolic BP	<u> </u> <u> </u> <u> </u> mmHg
4. Mean BP	<u> </u> <u> </u> <u> </u> mmHg
5. O ₂ Saturation	<u> </u> <u> </u> <u> </u> %

AHRBEF_4	B1d1. Heart rate (bpm) before dose (4)
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ASBPBEF_4	B1d2. Systolic BP (mmHg) before dose (4)
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ADBPBEF_4	B1d3. Systolic BP (mmHg) before dose (4)
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AMBPBEF_4	B1d4. Mean BP (mmHg) before dose (4)
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AOSATBEF_4	B1d5. O ₂ Sat (%) before dose (4)
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e. New dose administered

 . mg bid

ADOSEADM_4	B1e. New dose administered (mg bid) (4)
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f. Time administered _____ : _____

1. Units

AM 1 PM 2 24-HOUR 3

ADOSE_T_4	B1f. Time new dose administered, __:__ (4)
ADOSETU_4	B1f1. Units of time new dose administered (am/pm/24-hour) (4)
adose24_4	<created var> Time new dose administered, __:__ (24-hour) (4)

g. Use table below to record vital signs after administration of study drug

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

AHR120_4	B1g1d. Heart rate (bpm) 120 minutes post-dose (4)
AHR240_4	[Added Version B] B1g1h. Heart rate (bpm) 240 minutes post-dose (4)

2. SBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ASBP120_4	B1g2d. Systolic BP (mmHg) 120 minutes post-dose (4)
ASBP240_4	[Added Version B] B1g2h. Systolic BP (mmHg) 240 minutes post-dose (4)

3. DBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ADBP120_4	B1g3d. Diastolic BP (mmHg) 120 minutes post-dose (4)
ADBP240_4	[Added Version B] B1g3h. Diastolic BP (mmHg) 240 minutes post-dose (4)

4. MBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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AMBP120_4	B1g4d. Mean BP (mmHg) 120 minutes post-dose (4)
AMBP240_4	[Added Version B] B1g4h. Mean BP (mmHg) 240 minutes post-dose (4)

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5. O ₂ Sat (%)								
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AOSAT120_4	B1g5d. O2 Sat (%) 120 minutes post-dose (4)
AOSAT240_4	[Added Version B] B1g5h. O2 Sat (%) 240 minutes post-dose (4)

h. **Lowest** SBP during post-dose monitoring ___ ___ ___ mmHg

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

1. Time lowest SBP taken ___ : ___

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

ALWSBP_4	B1h. Lowest SBP within 120 minutes post-dose (4)
ALWSBP_T_4	B1h1. Time lowest SBP taken, __:__ (4)
ALWSBPTU_4	B1h2. Units of time lowest SBP taken (am/pm/24-hour) (4)
alwsbp24_4	<created var> Time lowest SBP taken, __:__ (24-hour) (4)

B6. Dose Adjustment/Uptitration 6

a. Date of adjustment or uptitration $\frac{\text{M}}{\text{M}} / \frac{\text{D}}{\text{D}} / \frac{\text{Y}}{\text{Y}} \frac{\text{Y}}{\text{Y}}$

Replaced by age at adjustment or uptitration

adjup_age_5 B1a <created var>Age at 6th adjustment/uptitration, days

b. Weight _____ . _____ kg

WT_ADJUP_5 B1b. Weight (kg) at adjustment/uptitration (5)

c. New dose prescribed _____ . _____ mg/kg/dose

ADOSERX_5 B1c. New dose prescribed (mg/kg/dose) (5)

d. Use table below to record vital signs **before** administration of study drug

Vital Signs	Before dose
1. Heart rate	_____ bpm
2. Systolic BP	_____ mmHg
3. Diastolic BP	_____ mmHg
4. Mean BP	_____ mmHg
5. O ₂ Saturation	_____ %

AHRBEF_5	B1d1. Heart rate (bpm) before dose (5)
ASBPBEF_5	B1d2. Systolic BP (mmHg) before dose (5)
ADBPBEF_5	B1d3. Systolic BP (mmHg) before dose (5)
AMBPBEF_5	B1d4. Mean BP (mmHg) before dose (5)
AOSATBEF_5	B1d5. O ₂ Sat (%) before dose (5)

e. New dose administered _____ . _____ mg bid

ADOSEADM_5 B1e. New dose administered (mg bid) (5)

f. Time administered

___ : ___

1. Units

AM..... 1 PM2 24-HOUR.....3

ADOSE_T_5	B1f. Time new dose administered, __:__(5)
ADOSETU_5	B1f1. Units of time new dose administered (am/pm/24-hour) (5)
adose24_5	<created var> Time new dose administered, __:__(24-hour) (5)

g. Use table below to record vital signs after administration of study drug

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

AHR120_5	B1g1d. Heart rate (bpm) 120 minutes post-dose (5)
AHR240_5	[Added Version B] B1g1h. Heart rate (bpm) 240 minutes post-dose (5)

2. SBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ASBP120_5	B1g2d. Systolic BP (mmHg) 120 minutes post-dose (5)
ASBP240_5	[Added Version B] B1g2h. Systolic BP (mmHg) 240 minutes post-dose (5)

3. DBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ADBP120_5	B1g3d. Diastolic BP (mmHg) 120 minutes post-dose (5)
ADBP240_5	[Added Version B] B1g3h. Diastolic BP (mmHg) 240 minutes post-dose (5)

4. MBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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AMBP120_5	B1g4d. Mean BP (mmHg) 120 minutes post-dose (5)
AMBP240_5	[Added Version B] B1g4h. Mean BP (mmHg) 240 minutes post-dose (5)

Form S104: Dose Adjustment/Uptitration Log

5. O ₂ Sat (%)								
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AOSAT120_5	B1g5d. O2 Sat (%) 120 minutes post-dose (5)
AOSAT240_5	[Added Version B] B1g5h. O2 Sat (%) 240 minutes post-dose (5)

h. **Lowest** SBP during post-dose monitoring ___ ___ ___ mmHg

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

1. Time lowest SBP taken ___ ___ : ___ ___

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

ALWSBP_5	B1h. Lowest SBP within 120 minutes post-dose (5)
ALWSBP_T_5	B1h1. Time lowest SBP taken, ___:___ (5)
ALWSBPTU_5	B1h2. Units of time lowest SBP taken (am/pm/24-hour) (5)
alwsbp24_5	<created var> Time lowest SBP taken, ___:___ (24-hour) (5)

B7. Dose Adjustment/Uptitration 7

a. Date of adjustment or uptitration $\frac{\text{M}}{\text{M}} / \frac{\text{D}}{\text{D}} / \frac{\text{Y}}{\text{Y}} \frac{\text{Y}}{\text{Y}}$

Replaced by age at adjustment or uptitration

adjup_age_6 | B1a <created var>Age at 7th adjustment/uptitration, days

b. Weight _____ . _____ kg

WT_ADJUP_6 | B1b. Weight (kg) at adjustment/uptitration (6)

c. New dose prescribed _____ . _____ mg/kg/dose

ADOSERX_6 | B1c. New dose prescribed (mg/kg/dose) (6)

d. Use table below to record vital signs **before** administration of study drug

Vital Signs	Before dose
1. Heart rate	_____ bpm
2. Systolic BP	_____ mmHg
3. Diastolic BP	_____ mmHg
4. Mean BP	_____ mmHg
5. O ₂ Saturation	_____ %

AHRBEF_6 | B1d1. Heart rate (bpm) before dose (6)

ASBPBEF_6 | B1d2. Systolic BP (mmHg) before dose (6)

ADBPBEF_6 | B1d3. Systolic BP (mmHg) before dose (6)

AMBPBEF_6 | B1d4. Mean BP (mmHg) before dose (6)

AOSATBEF_6 | B1d5. O₂ Sat (%) before dose (6)

e. New dose administered _____ . _____ mg bid

ADOSEADM_6 | B1e. New dose administered (mg bid) (6)

f. Time administered _____ : _____

1. Units

AM..... 1 PM2 24-HOUR3

ADOSE_T_6	B1f. Time new dose administered, __:__(6)
ADOSETU_6	B1f1. Units of time new dose administered (am/pm/24-hour) (6)
adose24_6	<created var> Time new dose administered, __:__(24-hour) (6)

g. Use table below to record vital signs after administration of study drug

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

AHR120_6	B1g1d. Heart rate (bpm) 120 minutes post-dose (6)
AHR240_6	[Added Version B] B1g1h. Heart rate (bpm) 240 minutes post-dose (6)

2. SBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ASBP120_6	B1g2d. Systolic BP (mmHg) 120 minutes post-dose (6)
ASBP240_6	[Added Version B] B1g2h. Systolic BP (mmHg) 240 minutes post-dose (6)

3. DBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ADBP120_6	B1g3d. Diastolic BP (mmHg) 120 minutes post-dose (6)
ADBP240_6	[Added Version B] B1g3h. Diastolic BP (mmHg) 240 minutes post-dose (6)

4. MBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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AMBP120_6	B1g4d. Mean BP (mmHg) 120 minutes post-dose (6)
AMBP240_6	[Added Version B] B1g4h. Mean BP (mmHg) 240 minutes post-dose (6)

5. O ₂ Sat (%)	_____	_____	_____	_____	_____	_____	_____	_____
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Form S104: Dose Adjustment/Uptitration Log

AOSAT120_6	B1g5d. O2 Sat (%) 120 minutes post-dose (6)
AOSAT240_6	[Added Version B] B1g5h. O2 Sat (%) 240 minutes post-dose (6)

h. **Lowest** SBP during post-dose monitoring ___ ___ ___ mmHg

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

1. Time lowest SBP taken ___ ___ : ___ ___

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

ALWSBP_6	B1h. Lowest SBP within 120 minutes post-dose (6)
ALWSBP_T_6	B1h1. Time lowest SBP taken, ___:___ (6)
ALWSBPTU_6	B1h2. Units of time lowest SBP taken (am/pm/24-hour) (6)
alwsbp24_6	<created var> Time lowest SBP taken, ___:___ (24-hour) (6)

B8. Dose Adjustment/Uptitration 8

a. Date of adjustment or uptitration

__ __ / __ __ / __ __ __ __
M M D D Y Y Y Y

Replaced by age at adjustment or uptitration

adjup_age_7	B1a <created var>Age at 8th adjustment/uptitration, days
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b. Weight

__ __ . __ __ kg

WT_ADJUP_7	B1b. Weight (kg) at adjustment/uptitration (7)
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c. New dose prescribed

__ . __ __ __ mg/kg/dose

ADOSERX_7	B1c. New dose prescribed (mg/kg/dose) (7)
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d. Use table below to record vital signs **before** administration of study drug

Vital Signs	Before dose
1. Heart rate	__ __ __ bpm
2. Systolic BP	__ __ __ mmHg
3. Diastolic BP	__ __ __ mmHg
4. Mean BP	__ __ __ mmHg
5. O ₂ Saturation	__ __ __ %

AHRBEF_7	B1d1. Heart rate (bpm) before dose (7)
ASBPBEF_7	B1d2. Systolic BP (mmHg) before dose (7)
ADBPBEF_7	B1d3. Systolic BP (mmHg) before dose (7)
AMBPEF_7	B1d4. Mean BP (mmHg) before dose (7)
AOSATBEF_7	B1d5. O ₂ Sat (%) before dose (7)

e. New dose administered

__ . __ __ mg bid

ADOSEADM_7	B1e. New dose administered (mg bid) (7)
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f. Time administered

___ : ___

1. Units

AM..... 1 PM2 24-HOUR3

ADOSE_T_7	B1f. Time new dose administered, __:__(7)
ADOSETU_7	B1f1. Units of time new dose administered (am/pm/24-hour) (7)
adose24_7	<created var> Time new dose administered, __:__(24-hour) (7)

g. Use table below to record vital signs after administration of study drug

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

AHR120_7	B1g1d. Heart rate (bpm) 120 minutes post-dose (7)
AHR240_7	[Added Version B] B1g1h. Heart rate (bpm) 240 minutes post-dose (7)

2. SBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ASBP120_7	B1g2d. Systolic BP (mmHg) 120 minutes post-dose (7)
ASBP240_7	[Added Version B] B1g2h. Systolic BP (mmHg) 240 minutes post-dose (7)

3. DBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ADBP120_7	B1g3d. Diastolic BP (mmHg) 120 minutes post-dose (7)
ADBP240_7	[Added Version B] B1g3h. Diastolic BP (mmHg) 240 minutes post-dose (7)

4. MBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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AMBP120_7	B1g4d. Mean BP (mmHg) 120 minutes post-dose (7)
AMBP240_7	[Added Version B] B1g4h. Mean BP (mmHg) 240 minutes post-dose (7)

5. O ₂ Sat (%)	_____	_____	_____	_____	_____	_____	_____	_____
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Form S104: Dose Adjustment/Uptitration Log

AOSAT120_7	B1g5d. O2 Sat (%) 120 minutes post-dose (7)
AOSAT240_7	[Added Version B] B1g5h. O2 Sat (%) 240 minutes post-dose (7)

h. **Lowest** SBP during post-dose monitoring ___ ___ ___ mmHg

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

1. Time lowest SBP taken ___ ___ : ___ ___

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

ALWSBP_7	B1h. Lowest SBP within 120 minutes post-dose (7)
ALWSBP_T_7	B1h1. Time lowest SBP taken, ___:___ (7)
ALWSBPTU_7	B1h2. Units of time lowest SBP taken (am/pm/24-hour) (7)
alwsbp24_7	<created var> Time lowest SBP taken, ___:___ (24-hour) (7)

B9. Dose Adjustment/Uptitration 9

a. Date of adjustment or uptitration

___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age at adjustment or uptitration

adjup_age_8	B1a <created var>Age at 9th adjustment/uptitration, days
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b. Weight

___ ___ . ___ ___ kg

WT_ADJUP_8	B1b. Weight (kg) at adjustment/uptitration (8)
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c. New dose prescribed

___ . ___ ___ ___ mg/kg/dose

ADOSERX_8	B1c. New dose prescribed (mg/kg/dose) (8)
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d. Use table below to record vital signs **before** administration of study drug

Vital Signs	Before dose
1. Heart rate	___ ___ ___ bpm
2. Systolic BP	___ ___ ___ mmHg
3. Diastolic BP	___ ___ ___ mmHg
4. Mean BP	___ ___ ___ mmHg
5. O ₂ Saturation	___ ___ ___ %

AHRBEF_8	B1d1. Heart rate (bpm) before dose (8)
ASBPBEF_8	B1d2. Systolic BP (mmHg) before dose (8)
ADBPBEF_8	B1d3. Diastolic BP (mmHg) before dose (8)
AMBPBEF_8	B1d4. Mean BP (mmHg) before dose (8)
AOSATBEF_8	B1d5. O ₂ Sat (%) before dose (8)

e. New dose administered

___ . ___ ___ mg bid

ADOSEADM_8	B1e. New dose administered (mg bid) (8)
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f. Time administered _____ : _____

1. Units

AM..... 1 PM2 24-HOUR3

ADOSE_T_8	B1f. Time new dose administered, __:__ (8)
ADOSETU_8	B1f1. Units of time new dose administered (am/pm/24-hour) (8)
adose24_8	<created var> Time new dose administered, __:__ (24-hour) (8)

g. Use table below to record vital signs after administration of study drug

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

AHR120_8	B1g1d. Heart rate (bpm) 120 minutes post-dose (8)
AHR240_8	[Added Version B] B1g1h. Heart rate (bpm) 240 minutes post-dose (8)

2. SBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ASBP120_8	B1g2d. Systolic BP (mmHg) 120 minutes post-dose (8)
ASBP240_8	[Added Version B] B1g2h. Systolic BP (mmHg) 240 minutes post-dose (8)

3. DBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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ADBP120_8	B1g3d. Diastolic BP (mmHg) 120 minutes post-dose (8)
ADBP240_8	[Added Version B] B1g3h. Diastolic BP (mmHg) 240 minutes post-dose (8)

4. MBP (mmHg)	_____	_____	_____	_____	_____	_____	_____	_____
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AMBP120_8	B1g4d. Mean BP (mmHg) 120 minutes post-dose (8)
AMBP240_8	[Added Version B] B1g4h. Mean BP (mmHg) 240 minutes post-dose (8)

Form S104: Dose Adjustment/Uptitration Log

5. O ₂ Sat (%)								
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AOSAT120_8	B1g5d. O2 Sat (%) 120 minutes post-dose (8)
AOSAT240_8	[Added Version B] B1g5h. O2 Sat (%) 240 minutes post-dose (8)

h. **Lowest** SBP during post-dose monitoring ___ ___ ___ mmHg

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

1. Time lowest SBP taken ___ ___ : ___ ___

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

ALWSBP_8	B1h. Lowest SBP within 120 minutes post-dose (8)
ALWSBP_T_8	B1h1. Time lowest SBP taken, ___:___ (8)
ALWSBPTU_8	B1h2. Units of time lowest SBP taken (am/pm/24-hour) (8)
alwsbp24_8	<created var> Time lowest SBP taken, ___:___ (24-hour) (8)