

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 initial study drug administration / / / / / / /
M M D D Y Y Y Y

Replaced by age at initial study drug administration

idrug_age	A3. <created var>Age at administration of initial study drug, days
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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: GROWTH MEASUREMENTS AT BASELINE

INSTRUCTIONS: If Measures 1 and 2 for questions B1, B2 and B3 differ by more than the stated amount in the “Absolute Difference” column, a third measurement must be taken.

	a. <u>Measure 1</u>	b. <u>Measure 2</u>	Absolute Difference	c. <u>Measure 3</u>
B1. Weight (kg)	_____ . _____	_____ . _____	> 0.1 kg →	_____ . _____

WT1_INIT	B1a. Weight: Measure 1 (kg)
WT2_INIT	B1b. Weight: Measure 2 (kg)
WT3_INIT	B1c. Weight: Measure 3, if WT1_INIT-WT2_INIT >0.1 (kg)
meanblwt	<created var> Mean of all available baseline weights (kg)

Section C: STUDY DRUG AND ADMINISTRATION

C1. Initial dose of study drug prescribed ____ . ____ ____ mg/kg/dose (enter -3 if patient never started)

IDOSERX	C1. Initial dose of study drug prescribed (mg/kg/dose)
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a. Reason study drug never started _____

(END OF FORM)

NODRUG_S	[Added version B] Reason study drug never started
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C2. Use the table below to record the patient's vital signs **before** administration of study drug.

Vital Signs	Immediately before dose
a. Heart rate	____ ____ ____ bpm
b. Systolic BP	____ ____ ____ mmHg
c. Diastolic BP	____ ____ ____ mmHg
d. Mean BP	____ ____ ____ mmHg
e. Oxygen saturation	____ ____ ____ %

IHRBEF	C2a. Heart rate (before dose) (bpm)
ISBPBEF	C2b. Systolic BP (before dose) (mmHg)
IDBPBEF	C2c. Diastolic BP (before dose) (mmHg)
IMBPBEF	C2d. Mean BP (before dose) (mmHg)
IOSATBEF	C2e. Oxygen saturation (before dose) (%)

C3. Initial dose of study drug administered ____ . ____ ____ mg bid

IDOSEADM	C3. Initial dose of study drug administered (mg bid)
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C4. Time study drug administered ____ : ____

a. Units AM 1 PM 2 24-HOUR 3

IDOSE_T	C4. Time study drug administered: __ : __
IDOSETU	C4a. Time study drug administered -- Units (am/pm/24-hr)
idose24	<created var> Time study drug administered (24-hour time)

C5. Use the table below to record the patient's vital signs for **240 minutes** after administration of study drug.

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)	_____	_____	_____	_____	_____	_____	_____	_____

IHR30	[Added Version C] C5a1. Heart rate (30 minutes post-dose), bpm
IHR60	[Added Version C] C5b1. Heart rate (60 minutes post-dose), bpm
IHR90	[Added Version C] C5c1. Heart rate (90 minutes post-dose), bpm
IHR120	C5d1. Heart rate (120 minutes post-dose), bpm
IHR150	[Added Version C] C5e1. Heart rate (150 minutes post-dose), bpm
IHR180	[Added Version C] C5f1. Heart rate (180 minutes post-dose), bpm
IHR210	[Added Version C] C5g1. Heart rate (210 minutes post-dose), bpm
IHR240	[Added Version C] C5h1. Heart rate (240 minutes post-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)	_____	_____	_____	_____	_____	_____	_____	_____

ISBP30	[Added Version C] C5a2. Systolic BP (30 minutes post-dose), mmHg
ISBP60	[Added Version C] C5b2. Systolic BP (60 minutes post-dose), mmHg
ISBP90	[Added Version C] C5c2. Systolic BP (90 minutes post-dose), mmHg
ISBP120	C5d2. Systolic BP (120 minutes post-dose), mmHg
ISBP150	[Added Version C] C5e2. Systolic BP (150 minutes post-dose), mmHg
ISBP180	[Added Version C] C5f2. Systolic BP (180 minutes post-dose), mmHg
ISBP210	[Added Version C] C5g2. Systolic BP (210 minutes post-dose), mmHg
ISBP240	[Added Version C] C5h2. Systolic BP (240 minutes post-dose), mmHg

Form S103: Initial Study Drug Dose Form

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)	_____	_____	_____	_____	_____	_____	_____	_____

IDBP30	[Added Version C] C5a3. Diastolic BP (30 minutes post-dose), mmHg
IDBP60	[Added Version C] C5b3. Diastolic BP (60 minutes post-dose) , mmHg
IDBP90	[Added Version C] C5c3. Diastolic BP (90 minutes post-dose) , mmHg
IDBP120	C5d3. Diastolic BP (120 minutes post-dose) , mmHg
IDBP150	[Added Version C] C5e3. Diastolic BP (150 minutes post-dose) , mmHg
IDBP180	[Added Version C] C5f3. Diastolic BP (180 minutes post-dose) , mmHg
IDBP210	[Added Version C] C5g3. Diastolic BP (210 minutes post-dose) , mmHg
IDBP240	[Added Version C] C5h3. Diastolic BP (240 minutes post-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)	_____	_____	_____	_____	_____	_____	_____	_____

IMBP30	[Added Version C] C5a4. Mean BP (30 minutes post-dose) , mmHg
IMBP60	[Added Version C] C5b4. Mean BP (60 minutes post-dose) , mmHg
IMBP90	[Added Version C] C5c4. Mean BP (90 minutes post-dose) , mmHg
IMBP120	C5d4. Mean BP (120 minutes post-dose) , mmHg
IMBP150	[Added Version C] C5e4. Mean BP (150 minutes post-dose) , mmHg
IMBP180	[Added Version C] C5f4. Mean BP (180 minutes post-dose) , mmHg
IMBP210	[Added Version C] C5g4. Mean BP (210 minutes post-dose) , mmHg
IMBP240	[Added Version C] C5h4. Mean BP (240 minutes post-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 ₂ Sat (%)	_____	_____	_____	_____	_____	_____	_____	_____

↓
 Complete S200 (AE Form) if patient NOT stable after 120 minutes, e.g., sustained SBP <70 mmHg

IOSAT30	[Added Version C] C5a5. Oxygen saturation (30 minutes post-dose), %
IOSAT60	[Added Version C] C5b5. Oxygen saturation (60 minutes post-dose), %
IOSAT90	[Added Version C] C5c5. Oxygen saturation (90 minutes post-dose), %
IOSAT120	C5d5. Oxygen saturation (120 minutes post-dose), %
IOSAT150	[Added Version C] C5e5. Oxygen saturation (150 minutes post-dose), %
IOSAT180	[Added Version C] C5f5. Oxygen saturation (180 minutes post-dose), %
IOSAT210	[Added Version C] C5g5. Oxygen saturation (210 minutes post-dose), %
IOSAT240	[Added Version C] C5h5. Oxygen saturation (240 minutes post-dose), %

C6. **Lowest** systolic BP measured within **240** _____ mmHg
 minutes post-dose _____

ILWSBP	C6. Lowest systolic BP measured (mmHg)
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C7. Time lowest systolic BP measurement taken _____ : _____

a. Units AM1 PM.....2 24-HOUR.....3

ILWSBP_T	C7. Time lowest systolic BP measurement taken: __:__
ILWSBPTU	C7a. Time lowest systolic BP measurement taken -- Units (am/pm/24-hr)
ilwsbp24	<created var> Time lowest systolic BP measurement taken (24-hour time)

Section D: RESULT OF INITIAL DOSE

D1. Was initial dose of study drug tolerated? YES..... 1 NO.....2

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

IDOSETOL	D1. Was initial dose of study drug tolerated
INEWDOSE	D1a. Study drug dose prescribed (mg/kg/dose)