

## Source Documentation Worksheet

### SCREENING VISIT

Subject Initials \_\_\_\_\_ Subject Baseline #: \_\_\_\_\_

Subject Name: \_\_\_\_\_ Telephone: (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_

Address: \_\_\_\_\_

City/Province/Postal Code: \_\_\_\_\_ /ONTARIO/ \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Family Physician: \_\_\_\_\_

KGH/HDH CR #: \_\_\_\_\_

Visit Date (dd/mon/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_ Time (24-hour clock): \_\_\_\_:\_\_\_\_

#### Informed Consent:

Informed consent obtained? Y  N  Version of consent: \_\_\_\_\_

- The informed consent was signed by the subject prior to any study-related procedures performed.
- The subject had ample time to read over the informed consent and all questions/queries were addressed and answered to their satisfaction prior to signing the informed consent.
- The informed consent was understood by the subject.
- The informed consent was obtained in a quiet and private setting.
- The informed consent was obtained freely and voluntarily from the subject.
- A copy of the informed consent was given to subject.

Initials of Person Obtaining Consent \_\_\_\_\_ (dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_

#### Demographics:

Date of birth (dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_ Gender:  Male  Female

Race  White  Black  Asian  Hispanic  First Nations

Other: \_\_\_\_\_

Height: \_\_\_\_\_ cm Weight: \_\_\_\_\_ kg BMI: \_\_\_\_\_ (BMI = kg/m<sup>2</sup>)

(dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_ Signature of Person Performing Screening: \_\_\_\_\_

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Subject Initials \_\_\_\_\_

Subject Baseline #: \_\_\_\_\_

**Patient Recruitment:**

How was the subject recruited?

- Investigator Patient/Subject Database or Medical Records
- Physician Referral (Primary/Specialist/Family Doctor)
- Other Health Professionals
- Investigator's Local Recruitment Agency
- Central Recruitment (Company/Call Centre), if Yes \_\_\_\_\_

\_\_\_\_\_ Central Source Name  
 \_\_\_\_\_ Patient Referral Number

How did the subject learn about the study?

- TV
- Radio
- Internet (Web)
- Newspaper
- Magazine
- Study Site Personnel Contact
- Posted Bulletin, Brochure
- Direct Mail
- Community Outreach (i.e. support group, health screening)
- Other, specify: \_\_\_\_\_

**Smoking History:**

	Start date (dd/mmm/yy)	Stop date (dd/mmm/yy)	Average number of cigarettes per day
Never	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
Ex-smoker			
Currently smokes		NOT APPLICABLE	

Number of cigarette pack-years:

\_\_\_\_\_ Cigarettes per day / 20 cigarettes per pack X \_\_\_\_\_ years = \_\_\_\_\_ pack-years

**Other Forms of Tobacco:**

Cigar

Current  Ex-Smoker

Number of Units used: \_\_\_\_\_

Day  Week  Month  Year

Length of Use: \_\_\_\_\_

Quit? Yes  No  When \_\_\_\_\_

Chewing Tobacco

Current  Ex-Smoker

Number of Units used: \_\_\_\_\_

Day  Week  Month  Year

Length of Use: \_\_\_\_\_

Quit? Yes  No  When \_\_\_\_\_

(dd/mmm/yy): \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Signature of Person Performing Screening: \_\_\_\_\_

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### SCREENING VISIT

Subject Initials \_\_\_\_\_

Subject Baseline #: \_\_\_\_\_

Smokeless Tobacco

Current  Ex-Smoker

Number of Units used: \_\_\_\_\_

Day  Week  Month  Year

Length of Use: \_\_\_\_\_

Quit? Yes  No  When \_\_\_\_\_

Pipe Tobacco

Current  Ex-Smoker

Number of Units used: \_\_\_\_\_

Day  Week  Month  Year

Length of Use: \_\_\_\_\_

Quit? Yes  No  When \_\_\_\_\_

Cigarillo

Current  Ex-Smoker

Number of Units used: \_\_\_\_\_

Day  Week  Month  Year

Length of Use: \_\_\_\_\_

Quit? Yes  No  When \_\_\_\_\_

Other, specify: \_\_\_\_\_

Current  Ex-Smoker

Number of Units used: \_\_\_\_\_

Day  Week  Month  Year

Length of Use: \_\_\_\_\_

Quit? Yes  No  When \_\_\_\_\_

#### Alcohol History:

Non-drinker       Occasional drinker (<1/day)       Average drinker (1-3/day)

Excessive drinker (>3/day)

#### Child-Bearing Potential:

Is the subject of child-bearing potential?       Yes\*       No\*\*

If YES\*, what type of birth control method are they using? \_\_\_\_\_

Was a pregnancy test performed?       Yes       No, why? \_\_\_\_\_

Results:       Positive       Negative

If NO\*\*, why?       Hysterectomy       Tubal Ligation       >1 year post-menopausal

Male       Other: \_\_\_\_\_

(dd/mmm/yy): \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Signature of Person Performing Screening: \_\_\_\_\_

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### SCREENING VISIT

Subject Initials \_\_\_\_\_

Subject Baseline #: \_\_\_\_\_

#### Concomitant Therapy

Has the subject had any concomitant therapies for the past 3 months?  Yes  No

*\*If yes, record on Concomitant Medication Record within source documents.*

#### 12-Lead ECG:

Initials of Person Obtaining ECG \_\_\_\_\_ Date (dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_ Time (hh:mm): \_\_\_\_:\_\_\_\_

Was the 12-LEAD ECG performed?  Yes  No, if so why? \_\_\_\_\_

Are there any clinically relevant ECG findings?

Yes  Abnormal, but not clinically significant  Abnormal, but clinically significant  
 No

If yes, please comment:

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*\* Record clinically relevant findings on the Medical History page. Make a copy of the ECG. File both the original and copy with source documents. The Investigator must sign the original.*

#### Laboratory Assessment

Initials of Person Obtaining Samples \_\_\_\_\_ (dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_ Time (hh:mm): \_\_\_\_:\_\_\_\_

Are there any clinically relevant laboratory findings?

Yes  
 No

If yes, please comment:

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*\* Record clinically relevant findings on the Medical History page. The Investigator must sign the original laboratory reports.*

#### Diagnostic Testing:

Was a \_\_\_\_\_ performed in this visit?

Yes (dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_ Time (hh:mm): \_\_\_\_:\_\_\_\_  
 No, if so why? \_\_\_\_\_

Initials of Person Performing Test \_\_\_\_\_

*\* Record clinically relevant findings on the Medical History page. The Investigator must sign the original diagnostic reports.*

(dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_ Signature of Person Performing Screening: \_\_\_\_\_

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Subject Initials \_\_\_\_\_

Subject Baseline #: \_\_\_\_\_

**Relevant medical history/concomitant diagnoses (for the last 5 years)**

		Still present?		
		NO	YES	
Allergies	<input type="checkbox"/> None Please describe type of reaction.	1. _____	<input type="checkbox"/>	<input type="checkbox"/>
		2. _____	<input type="checkbox"/>	<input type="checkbox"/>
		3. _____	<input type="checkbox"/>	<input type="checkbox"/>
		4. _____	<input type="checkbox"/>	<input type="checkbox"/>
		5. _____	<input type="checkbox"/>	<input type="checkbox"/>
		6. _____	<input type="checkbox"/>	<input type="checkbox"/>
		7. _____	<input type="checkbox"/>	<input type="checkbox"/>
Cardio-vascular	<input type="checkbox"/> None	1. _____	<input type="checkbox"/>	<input type="checkbox"/>
		2. _____	<input type="checkbox"/>	<input type="checkbox"/>
		3. _____	<input type="checkbox"/>	<input type="checkbox"/>
		4. _____	<input type="checkbox"/>	<input type="checkbox"/>
		5. _____	<input type="checkbox"/>	<input type="checkbox"/>
		6. _____	<input type="checkbox"/>	<input type="checkbox"/>
		7. _____	<input type="checkbox"/>	<input type="checkbox"/>
Pulmonary	<input type="checkbox"/> None	1. _____	<input type="checkbox"/>	<input type="checkbox"/>
		2. _____	<input type="checkbox"/>	<input type="checkbox"/>
		3. _____	<input type="checkbox"/>	<input type="checkbox"/>
		4. _____	<input type="checkbox"/>	<input type="checkbox"/>
		5. _____	<input type="checkbox"/>	<input type="checkbox"/>
		6. _____	<input type="checkbox"/>	<input type="checkbox"/>
		7. _____	<input type="checkbox"/>	<input type="checkbox"/>
Gastrointestinal/ Hepatobiliary	<input type="checkbox"/> None	1. _____	<input type="checkbox"/>	<input type="checkbox"/>
		2. _____	<input type="checkbox"/>	<input type="checkbox"/>
		3. _____	<input type="checkbox"/>	<input type="checkbox"/>
		4. _____	<input type="checkbox"/>	<input type="checkbox"/>
		5. _____	<input type="checkbox"/>	<input type="checkbox"/>
		6. _____	<input type="checkbox"/>	<input type="checkbox"/>
		7. _____	<input type="checkbox"/>	<input type="checkbox"/>
Metabolic/ Endocrine	<input type="checkbox"/> None	1. _____	<input type="checkbox"/>	<input type="checkbox"/>
		2. _____	<input type="checkbox"/>	<input type="checkbox"/>
		3. _____	<input type="checkbox"/>	<input type="checkbox"/>
		4. _____	<input type="checkbox"/>	<input type="checkbox"/>
		5. _____	<input type="checkbox"/>	<input type="checkbox"/>
		6. _____	<input type="checkbox"/>	<input type="checkbox"/>
		7. _____	<input type="checkbox"/>	<input type="checkbox"/>

(dd/mmm/yy): \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Signature of Person Performing Screening: \_\_\_\_\_

# Source Documentation Worksheet

## SCREENING VISIT

Subject Initials \_\_\_\_\_

Subject Baseline #: \_\_\_\_\_

### Medical history (cont)

Still present?  
no      yes

Renal/ Urinary tract	<input type="checkbox"/> None	1. _____	<input type="checkbox"/>	<input type="checkbox"/>
		2. _____	<input type="checkbox"/>	<input type="checkbox"/>
		3. _____	<input type="checkbox"/>	<input type="checkbox"/>
		4. _____	<input type="checkbox"/>	<input type="checkbox"/>
		5. _____	<input type="checkbox"/>	<input type="checkbox"/>
		6. _____	<input type="checkbox"/>	<input type="checkbox"/>
		7. _____	<input type="checkbox"/>	<input type="checkbox"/>

Reproductive	<input type="checkbox"/> None	1. _____	<input type="checkbox"/>	<input type="checkbox"/>
		2. _____	<input type="checkbox"/>	<input type="checkbox"/>
		3. _____	<input type="checkbox"/>	<input type="checkbox"/>
		4. _____	<input type="checkbox"/>	<input type="checkbox"/>
		5. _____	<input type="checkbox"/>	<input type="checkbox"/>
		6. _____	<input type="checkbox"/>	<input type="checkbox"/>
		7. _____	<input type="checkbox"/>	<input type="checkbox"/>

Musculo skeletal/ Dermatological	<input type="checkbox"/> None	1. _____	<input type="checkbox"/>	<input type="checkbox"/>
		2. _____	<input type="checkbox"/>	<input type="checkbox"/>
		3. _____	<input type="checkbox"/>	<input type="checkbox"/>
		4. _____	<input type="checkbox"/>	<input type="checkbox"/>
		5. _____	<input type="checkbox"/>	<input type="checkbox"/>
		6. _____	<input type="checkbox"/>	<input type="checkbox"/>
		7. _____	<input type="checkbox"/>	<input type="checkbox"/>

Neurological	<input type="checkbox"/> None	1. _____	<input type="checkbox"/>	<input type="checkbox"/>
		2. _____	<input type="checkbox"/>	<input type="checkbox"/>
		3. _____	<input type="checkbox"/>	<input type="checkbox"/>
		4. _____	<input type="checkbox"/>	<input type="checkbox"/>
		5. _____	<input type="checkbox"/>	<input type="checkbox"/>
		6. _____	<input type="checkbox"/>	<input type="checkbox"/>
		7. _____	<input type="checkbox"/>	<input type="checkbox"/>

Psychiatric	<input type="checkbox"/> None	1. _____	<input type="checkbox"/>	<input type="checkbox"/>
		2. _____	<input type="checkbox"/>	<input type="checkbox"/>
		3. _____	<input type="checkbox"/>	<input type="checkbox"/>
		4. _____	<input type="checkbox"/>	<input type="checkbox"/>
		5. _____	<input type="checkbox"/>	<input type="checkbox"/>
		6. _____	<input type="checkbox"/>	<input type="checkbox"/>
		7. _____	<input type="checkbox"/>	<input type="checkbox"/>

(dd/mmm/yy): \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Signature of Person Performing Screening: \_\_\_\_\_

# Source Documentation Worksheet

## SCREENING VISIT

Subject Initials \_\_\_\_\_

Subject Baseline #: \_\_\_\_\_

### Medical history (cont)

Others

None

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_
6. \_\_\_\_\_
7. \_\_\_\_\_

Still present?  
no      yes

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

\* If medical condition requires subject to use concomitant therapy, please record details on Concomitant Medication Record Log.

### Oxygen Saturation Level:

Yes      (dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_      Time (hh:mm): \_\_\_\_:\_\_\_\_

Result: \_\_\_\_\_

No, if so why? \_\_\_\_\_

Initials of Person Performing Test \_\_\_\_\_

### Vitals Examination:

Initials of Person Obtaining BP/HR \_\_\_\_      Date (dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_      Time (hh:mm): \_\_\_\_:\_\_\_\_

Was the BP/HR performed?     Yes       No, if so why? \_\_\_\_\_

Blood Pressure (mmHg): \_\_\_\_/\_\_\_\_      Pulse (beats/min): \_\_\_\_\_      Respiration (breaths/min): \_\_\_\_\_

### Physical Examination:

General Appearance:    Normal     Abnormal     Not Done     Specify: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Clinically  
Significant?  
 Yes     No

(dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature of Person Performing Screening: \_\_\_\_\_

# Source Documentation Worksheet

## SCREENING VISIT

Subject Initials \_\_\_\_\_

Subject Baseline #: \_\_\_\_\_

*Physical Exam (cont)*

Head:                      Normal  Abnormal  Not Done  Specify: \_\_\_\_\_ Clinically Significant?  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Ears:                      Normal  Abnormal  Not Done  Specify: \_\_\_\_\_ Clinically Significant?  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Eyes:                      Normal  Abnormal  Not Done  Specify: \_\_\_\_\_ Clinically Significant?  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Ocular Fundi:            Normal  Abnormal  Not Done  Specify: \_\_\_\_\_ Clinically Significant?  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Nose:                      Normal  Abnormal  Not Done  Specify: \_\_\_\_\_ Clinically Significant?  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Mouth:                     Normal  Abnormal  Not Done  Specify: \_\_\_\_\_ Clinically Significant?  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

(dd/mmm/yy): \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Signature of Person Performing Screening: \_\_\_\_\_

# Source Documentation Worksheet

## SCREENING VISIT

Subject Initials \_\_\_\_\_

Subject Baseline #: \_\_\_\_\_

*Physical Exam (cont)*

Throat:                    Normal  Abnormal  Not Done  Specify: \_\_\_\_\_ Clinically Significant?  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Neck:                     Normal  Abnormal  Not Done  Specify: \_\_\_\_\_  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Thyroid:                 Normal  Abnormal  Not Done  Specify: \_\_\_\_\_  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Lungs:                   Normal  Abnormal  Not Done  Specify: \_\_\_\_\_  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Heart:                    Normal  Abnormal  Not Done  Specify: \_\_\_\_\_  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Abdomen:                Normal  Abnormal  Not Done  Specify: \_\_\_\_\_  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

(dd/mmm/yy): \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Signature of Person Performing Screening: \_\_\_\_\_

# Source Documentation Worksheet

## SCREENING VISIT

Subject Initials \_\_\_\_\_

Subject Baseline #: \_\_\_\_\_

*Physical Exam (cont)*

Musculoskeletal:    Normal     Abnormal     Not Done     Specify: \_\_\_\_\_    Clinically Significant?  Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Extremities            Normal     Abnormal     Not Done     Specify: \_\_\_\_\_     Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Skin                    Normal     Abnormal     Not Done     Specify: \_\_\_\_\_     Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Pulses                 Normal     Abnormal     Not Done     Specify: \_\_\_\_\_     Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Neurological         Normal     Abnormal     Not Done     Specify: \_\_\_\_\_     Yes  No

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

*\* Record clinically relevant findings on the Medical History page.*

Date (dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_

MD Signature: \_\_\_\_\_

(dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature of Person Performing Screening: \_\_\_\_\_

## Source Documentation Worksheet

### SCREENING VISIT

Subject Initials \_\_\_\_\_

Subject Baseline #: \_\_\_\_\_

#### Questionnaires:

Was the \_\_\_\_\_ questionnaire administered?

Yes (dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_

No, if so why? \_\_\_\_\_

Initials of Person Administering Questionnaire \_\_\_\_\_

#### Adverse Events:

Has the subject experienced any adverse events since signing the consent?  Yes  No

*\*If yes, record on Adverse Event(s) or Serious Adverse Event(s) page within source documents.*

#### Review inclusion/exclusion criteria:

Does the subject currently meets all criteria and is eligible for the trial:  Yes  No

If no, reason: \_\_\_\_\_

Additional comments:

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#### Investigator's Signature:

(dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_ \_\_\_\_\_

(dd/mmm/yy): \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature of Person Performing Screening: \_\_\_\_\_

## CONCOMITANT MEDICATIONS

Subject Initials \_\_\_\_\_

Subject Baseline # \_\_\_\_\_

Subject Medication #: \_\_\_\_\_

Concomitant Medications								
Medication (Trade name preferred)	Dose unit	Route	PT/DT/PoT	Date (dd/mmm/yy)		Indication	Medication given for NSAE/SAE	
				Start	End		Yes	NO
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>

\* Prior treatment = PT; during treatment = DT; post treatment = PoT.

Date (dd/mmm/yy) \_\_\_\_\_

Signature: \_\_\_\_\_

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## NON-SERIOUS ADVERSE EVENTS

Subject Initials \_\_\_\_\_

Subject Baseline # \_\_\_\_\_

Subject Medication # \_\_\_\_\_

Adverse Events								
Adverse Event	Date of Event		Intensity	Therapy Given?*	Action Taken?	Was event serious?	Causal relationship?	Outcome?
	Start Date (dd/mm/yy)	Stop Date (dd/mm/yy)						
			Mild <input type="checkbox"/>	YES <input type="checkbox"/>	Continued <input type="checkbox"/>	YES <input type="checkbox"/>	Definitely Not <input type="checkbox"/>	Recovered <input type="checkbox"/>
			Moderate <input type="checkbox"/>	_____	Reduced <input type="checkbox"/>	NO <input type="checkbox"/>	Probably Not <input type="checkbox"/>	Not recovered <input type="checkbox"/>
	Severe <input type="checkbox"/>	_____	Increased <input type="checkbox"/>	If yes: <input type="checkbox"/>	Possibly <input type="checkbox"/>	Sequelae <input type="checkbox"/>		
	Start Time (hh:mm:ss)	Stop Time (hh:mm:ss)		NO <input type="checkbox"/>	Discontinued <input type="checkbox"/>	Death <input type="checkbox"/>	Probably <input type="checkbox"/>	Fatal <input type="checkbox"/>
					Discontinued & Reintroduced <input type="checkbox"/>	Disability <input type="checkbox"/>	Definitely <input type="checkbox"/>	Unknown <input type="checkbox"/>
					Study Drug Already Done <input type="checkbox"/>	Hospitalization <input type="checkbox"/>		
					Not applicable as subject was never on study drug <input type="checkbox"/>	Life-Threatening <input type="checkbox"/>		
						Defect <input type="checkbox"/>		
						Other <input type="checkbox"/>		
						_____		

\* If yes, please indicate and record in concomitant medication sheet.

Date (dd/mmm/yy) \_\_\_\_\_

Signature: \_\_\_\_\_

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## SERIOUS ADVERSE EVENTS

Subject Initials \_\_\_\_\_

Subject Baseline # \_\_\_\_\_

Subject Medication # \_\_\_\_\_

Adverse Events								
Adverse Event	Date of Event		Intensity	Setting	Action Taken?	Was event serious?	Causal relationship?	Outcome?
	Start Date (dd/mm/yy)	Stop Date (dd/mm/yy)						
Initial <input type="checkbox"/>  Follow-Up <input type="checkbox"/>			Mild <input type="checkbox"/>  Moderate <input type="checkbox"/>  Severe <input type="checkbox"/>	Hospital <input type="checkbox"/>  Outpatient <input type="checkbox"/>  Home <input type="checkbox"/>  Nursing Home <input type="checkbox"/>  Not Reported <input type="checkbox"/>	Continued <input type="checkbox"/>  Reduced <input type="checkbox"/>  Increased <input type="checkbox"/>  Discontinued <input type="checkbox"/>  Discontinued & Reintroduced <input type="checkbox"/>  Study Drug Already Done <input type="checkbox"/>  Not Applicable as the Subject was Never on Study Drug <input type="checkbox"/>	YES <input type="checkbox"/>  NO <input type="checkbox"/>  If yes:  Death <input type="checkbox"/>  Disability <input type="checkbox"/>  Hospitalization <input type="checkbox"/>  Life-Threatening <input type="checkbox"/>  Defect <input type="checkbox"/>  Other <input type="checkbox"/>	Definitely Not <input type="checkbox"/>  Probably Not <input type="checkbox"/>  Possibly <input type="checkbox"/>  Probably <input type="checkbox"/>  Definitely <input type="checkbox"/>	Recovered <input type="checkbox"/>  Not recovered <input type="checkbox"/>  Sequelae <input type="checkbox"/>  Unknown <input type="checkbox"/>  Fatal <input type="checkbox"/>  If Fatal, was an autopsy done?  Yes <input type="checkbox"/>  No <input type="checkbox"/>  Cause of death: _____ _____

\* If yes, please indicate and record in concomitant medication sheet.

Date (dd/mmm/yy) \_\_\_\_\_

Signature: \_\_\_\_\_

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