

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 15:29:47

Report Parameters

Site: L0689282_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2012

Ending patient: R2012

Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	Abc 123

All time stamps displayed in this report are in the timezone of the database server.

The data contained in this report is current at the time of printing (time as shown above)

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

RDC CASE REPORT FORM

Information Correct Yes No

Protocol Number SM 08-01 Investigator Name:
Study Site:

A CONTROLLED STUDY OF THE ABILITY OF A TRADITIONAL SWEDISH SMOKELESS TOBACCO PRODUCT ("SNUS") TO INCREASE THE QUIT RATE AMONG CIGARETTE SMOKERS WHO WISH TO STOP SMOKING

Protocol No. SM 08-01
Covance Study No. 7694-105

for

SWEDISH MATCH AB
ROSENLUNDSGATAN 36
SE-118 85 STOCKHOLM
SWEDEN

by

Covance Clinical Research Unit Inc.
3402 Kinsman Blvd
Madison, Wisconsin 53704

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Page Version No. PAGE_01 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

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Inclusion Criteria

Subjects who meet the following criteria may be included in the study. Did the subject meet the following criteria requirements for inclusion? (check Yes or No)

- | | Yes/No* |
|---|------------------------------|
| <input type="checkbox"/> 01 The subject is male or female, between 25 and 65 years of age, inclusive. If female, the subject has a negative urine pregnancy test and is not lactating, or has not been of childbearing potential for at least 3 months prior to use of study product. To be considered to be not of childbearing potential, the subject must be postmenopausal for at least 2 years; have had a hysterectomy or bilateral tubal ligation, or be proven to be otherwise incapable of pregnancy. If of childbearing potential, the subject must have been practicing one of the following methods of contraception consistently for at least 1 month prior to study entry and agree to continue practicing it during the study: hormonal contraceptives, intrauterine device, spermicide and barrier, spouse/partner sterility; or is practicing abstinence and agrees to continue abstinence or to start an acceptable method of contraception from the above list if sexual activity commences. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 02 The subject smokes > 9 cigarettes per day (average daily consumption during past month). | <input type="checkbox"/> YES |
| <input type="checkbox"/> 03 The subject has smoked daily for >1 year. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 04 The subject is motivated to quit smoking with the help of a smokeless tobacco alternative. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 05 The subject is in good general health as evidenced by medical history, physical examination, routine blood chemistry (Hb, total WBC, transaminases, creatinine, electrolytes), and an ECG | <input type="checkbox"/> YES |
| <input type="checkbox"/> 06 The subject practices, by self-report, good oral hygiene (including brushing teeth at least twice per day and having regular dental check-ups). | <input type="checkbox"/> YES |
| <input type="checkbox"/> 07 The subject is able and willing to provide written informed consent. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 08 The subject agrees to comply with the requirements of the protocol and complete study measures. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 09 The subject has stable residence and telephone. | <input type="checkbox"/> YES |

* If No, document on Subject Eligibility Page.

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Page Version No. PAGE_02 (v1, 27-MAR-2009)

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Exclusion Criteria

The following will exclude potential subjects from the study. Does the subject have any of the following?
(Check Yes or No)

	Yes*/No
<input type="checkbox"/> 01 The subject is a current user of ST (defined as daily usage during more than 1 week within past 6 months) or is unable to refrain from NRT or any other non-protocol treatment during the study. Use of pipes, cigars, cigarillos, snuff, and chewing tobacco is also prohibited during the study.	<input type="checkbox"/> NO
<input type="checkbox"/> 02 The subject is a female who is pregnant or lactating.	<input type="checkbox"/> NO
<input type="checkbox"/> 03 The subject has oral conditions that could potentially be made worse by the use of study product, for instance, exposed dental services in the upper sulcus.	<input type="checkbox"/> NO
<input type="checkbox"/> 04 The subject has used any type of pharmaceutical (including some psychotropics, e.g., wellbutrin) or other products for smoking cessation within the past 3 months.	<input type="checkbox"/> NO
<input type="checkbox"/> 05 The subject has a history of clinically significant renal, hepatic, neurological, or chronic pulmonary disease that in the judgement of the investigator precludes participation.	<input type="checkbox"/> NO
<input type="checkbox"/> 06 The subject has a history of cardiovascular disease, including myocardial infarction within the last 3 months, significant cardiac arrhythmias, or poorly controlled hypertension (defined as a diastolic pressure of more than 90 mm Hg or a systolic pressure of more than 140 mm Hg) that in the judgment or the investigator precludes participation.	<input type="checkbox"/> NO
<input type="checkbox"/> 07 The subject has a history of alcohol or substance abuse or dependence other than cigarette smoking within the past year	<input type="checkbox"/> NO
<input type="checkbox"/> 08 Use of any illicit drug or smoked marijuana in the last 3 months	<input type="checkbox"/> NO
<input type="checkbox"/> 09 The subject is unwilling to be randomized into active or placebo conditions, or be available for follow-up assessments.	<input type="checkbox"/> NO
<input type="checkbox"/> 10 The subject resides in a household where another member is currently participating in the study.	<input type="checkbox"/> NO

* If Yes, document on Subject Eligibility Page.

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Information Session

Date of Information Session:
 Did the subject attend the Information Session?
 Yes
 No (explain, if No)
 Comments

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

Did the subject meet all of the inclusion/exclusion criteria? Yes No

If the subject did not meet all of the Inclusion/Exclusion criteria, provide criterion number and explanation below.

Inclusion/Category	Exclusion No.	Explanation	Exemption Granted?	If Yes, Date Granted?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Demographics

Date

Date of Birth

Gender Male Female

Ethnicity Hispanic or Latino Not Hispanic or latino

Race White Black or African American Asian

Native Hawaiian or Other Pacific Islander American Indian/Alaskan Native Other

Body Measurements

Were Body Measurements Collected? Yes No Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="063.0"/>

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

Were vital signs collected? Yes No Date Actual Time Was Subject seated for 5 minutes? Yes No

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	110
Diastolic Blood Pressure	MMHG	080
Heart Rate	BEATS/MINUTE	065
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.6
Weight	LB	129.6

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Safety Urine & Blood Tests; Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Were there any clinically significant labs? Yes (specify below) No

Requisition Number	Test Name	Test Code ID
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

Urine Pregnancy Test

Result

Positive Negative N/A, Male or Woman of Non-childbearing Potential

Urine Drug Screen

Drug Screen Result*

Positive Negative

*If result derived from test performed by a clinical laboratory, attach copy of signed laboratory report to the CRF.

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Links to Discrepancy and Audit Sections

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Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Least 5 Minutes?	<input type="text" value="15-APR-2009"/>	<input type="text" value="15:50"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
01	NASAL/SINUS CONGESTION EPISODIC/INTER	00-00-1989		<input checked="" type="checkbox"/> Ongoing
02	TENSION HEADACHES	00-00-2005		<input checked="" type="checkbox"/> Ongoing
03	SEASONAL ALLERGIES	00-00-1989		<input checked="" type="checkbox"/> Ongoing
04	GENERAL ACHES	00-00-1989		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

- * Skin
- * Ears, Eyes, Nose, Throat (EENT)
- * Breasts
- * Respiratory
- * Cardiovascular
- * Lymphatic/Hematologic
- * Gastrointestinal
- * Genitourinary
- * Musculoskeletal
- * Endocrine
- * Neurological
- * Immunological
- * Psychological
- * Allergies

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OverFlow Section For Document Number R243911913

1 NASAL/SINUS CONGESTION EPISODIC/INTERMITTENT

Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Smoking History

Was Smoking History collected?

Yes No

Date

Parameter	Result	Comments
Age subject began smoking daily	<input type="text" value="13"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="20"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="3"/>	NICOTINE PATCHES 2007 & 2008, NICOTINE GUM 2006
Has the subject attempted to quit with the use of Pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="1"/>	WELLBUTRIN 2003
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="3"/>	HYPNOTISM 2003, 2004, 2008
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="1"/>	COLD TURKEY 2003

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OverFlow Section For Document Number R243698213

1 NICOTINE PATCHES 2007 & 2008, NICOTINE GUM 2006

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
15-APR-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
15-APR-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
15-APR-2009	OTHER ORAL KERATOSIS	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>

* Indicate NE if system was not examined.

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Swedish Match AB

Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

Date	Parameter	Result	Comments
15-APR-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
15-APR-2009	WAS "CLEANING THE AIR" BOOKLET PROVIDED?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
27-APR-2009	08:20	16	3.1	

Behavioral Counseling

Date	Parameter	Result	Comments
27-APR-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires

Date

Questionnaire	Was Questionnaire Administered?
FTND	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
MNWS	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date Actual Time
Was Subject randomized? Yes No

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="8"/> logs
1.0 g of snus or matching placebo	<input type="text" value="4"/> logs

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="04-MAY-2009"/>	<input type="text" value="WEEK 1"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="42"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="11-MAY-2009"/>	<input type="text" value="WEEK 2"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="42"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="18-MAY-2009"/>	<input type="text" value="WEEK 3"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="40"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date Scheduled Timepoint

Parameter

Result

Comments

Was Subject contacted by telephone?

Yes No

Was Subject's smoking status reviewed?

Yes No

Was Subject's use of study product reviewed?

Yes No

Approximately how many cigarettes did the subject smoke that week?

Was Behavioral Counseling Given?

Yes No

Was Subject reminded about the complete switch from cigarettes no later than the first day of Week 5?

Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

Were vital signs collected? Yes No Date Actual Time Was Subject seated for 5 minutes? Yes No

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	119
Diastolic Blood Pressure	MMHG	070
Heart Rate	BEATS/MINUTE	079
Respiratory Rate	BREATHS/MINUTE	14
Body Temperature	C	36.7
Weight	LB	132.0

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Were there any clinically significant labs? Yes (specify below) No

Requisition Number	Test Name	Test Code ID
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
10-JUN-2009	13:37	32	5.7	

Behavioral Counseling

Date	Parameter	Result	Comments
10-JUN-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="1"/> logs
1.0 g of snus or matching placebo	<input type="text" value="0"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="10-JUN-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="84"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date	Did subject receive diary and usage instructions?
<input type="text" value="10-JUN-2009"/>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="22-JUN-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="20"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_21 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

Were vital signs collected? Yes No Date Actual Time Was Subject seated for 5 minutes? Yes No

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	108
Diastolic Blood Pressure	MMHG	083
Heart Rate	BEATS/MINUTE	080
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.7
Weight	LB	135.2

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
06-JUL-2009	08:26	17	3.3	

Behavioral Counseling

Date	Parameter	Result	Comments
06-JUL-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="2"/> logs
1.0 g of snus or matching placebo	<input type="text" value="0"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="06-JUL-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions? Yes No

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Links to Discrepancy and Audit Sections

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Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="27-JUL-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="42"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject instructed to cut down on product use during upcoming Weeks 14-16 to avoid a too abrupt ending of nicotine uptake?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_25 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

Were vital signs collected? Yes No Date Actual Time Was Subject seated for 5 minutes? Yes No

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	114
Diastolic Blood Pressure	MMHG	077
Heart Rate	BEATS/MINUTE	069
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.5
Weight	LB	133.4

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Page Version No. PAGE_26 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Were there any clinically significant labs? Yes (specify below) No

Requisition Number	Test Name	Test Code ID
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

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Page Version No. PAGE_27 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
18-AUG-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
18-AUG-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
18-AUG-2009	OTHER ORAL KERATOSIS	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	

* Indicate NE if system was not examined.

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Page Version No. PAGE_28 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
18-AUG-2009	09:32	10	2.2	

Behavioral Counseling

Date	Parameter	Result	Comments
18-AUG-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires

Date

Questionnaire	Was Questionnaire Administered?
FTND	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
MNWS	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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Page Version No. PAGE_30 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="18-AUG-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="21"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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Page Version No. PAGE_31 (v1, 12-MAY-2009)

Document Number

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="14"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

Page Version No. PAGE_32 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

Were vital signs collected? Yes No Date Actual Time Was Subject seated for 5 minutes? Yes No

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	119
Diastolic Blood Pressure	MMHG	087
Heart Rate	BEATS/MINUTE	063
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.6
Weight	LB	138.8

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Page Version No. PAGE_33 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Were there any clinically significant labs? Yes (specify below) No

Requisition Number	Test Name	Test Code ID
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

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Page Version No. PAGE_34 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
09-NOV-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
09-NOV-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
09-NOV-2009	OTHER ORAL KERATOSIS	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	

* Indicate NE if system was not examined.

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Page Version No. PAGE_35 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
09-NOV-2009	08:31	6	1.5	

Behavioral Counseling

Date	Parameter	Result	Comments
09-NOV-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires

Date

Questionnaire	Was Questionnaire Administered?
FTND	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
MNWS	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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Page Version No. PAGE_37 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="09-NOV-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="84"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_38 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

Has the subject taken any medications prior to the first dose and/or during the study as restricted by the protocol?

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

- grams
- micrograms
- milligrams
- milliliter
- tablet
- other, specify

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily

- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

1Start and Stop Date: If medication is given on a regular schedule, report start date only once. If dose regimen changes, report a new line of information. Report start and stop dates for each change in dose regimen.

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

Has the subject taken any medications prior to the first dose and/or during the study as restricted by the protocol?

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

- grams
- micrograms
- milligrams
- milliliter
- tablet
- other, specify

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily

- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

1Start and Stop Date: If medication is given on a regular schedule, report start date only once. If dose regimen changes, report a new line of information. Report start and stop dates for each change in dose regimen.

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Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

Has the subject taken any medications prior to the first dose and/or during the study as restricted by the protocol?

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

- grams
- micrograms
- milligrams
- milliliter
- tablet
- other, specify

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily

- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

1Start and Stop Date: If medication is given on a regular schedule, report start date only once. If dose regimen changes, report a new line of information. Report start and stop dates for each change in dose regimen.

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Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

Has the subject taken any medications prior to the first dose and/or during the study as restricted by the protocol?

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

- grams
- micrograms
- milligrams
- milliliter
- tablet
- other, specify

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily

- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

1Start and Stop Date: If medication is given on a regular schedule, report start date only once. If dose regimen changes, report a new line of information. Report start and stop dates for each change in dose regimen.

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Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

Has the subject taken any medications prior to the first dose and/or during the study as restricted by the protocol?

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

- grams
- micrograms
- milligrams
- milliliter
- tablet
- other, specify

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily

- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

1Start and Stop Date: If medication is given on a regular schedule, report start date only once. If dose regimen changes, report a new line of information. Report start and stop dates for each change in dose regimen.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

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Document Number

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[Click here to navigate to audit history for this CRF](#)

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified Approved Locked Frozen

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[Click here to navigate to discrepancy details for this CRF](#)

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

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[Click here to navigate to audit history for this CRF](#)

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

[Click here to navigate to audit history for this CRF](#)

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

[Click here to navigate to audit history for this CRF](#)

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

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- Continuing with Treatment
- Death

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Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

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- Continuing with Treatment
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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
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Outcome to Date Select only one

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Page Version No. PAGE_40 (v1, 27-MAR-2009)

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

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Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

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Document Number

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

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Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

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Document Number

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

Were any additional 12-lead ECGs collected? Yes, list below. No

Date	Actual Time	ECG Interpretation	Comments Regarding CS Findings:
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>

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Page Version No. PAGE_41 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Additional Assessments - Laboratory Evaluations

Were any additional laboratory evaluations collected? Yes, list below No

Date	Requisition Number	Clinically Significant?	Test Name CS Labs Only	Test Code ID CS Labs Only	Comments
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

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Page Version No. PAGE_42 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

Were any additional vital signs collected? Yes, list below. No

Date Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure		
<input type="checkbox"/> Supine	Diastolic Blood Pressure		
<input type="checkbox"/> Seated	Heart Rate		
<input type="checkbox"/> Other, specify	Respiratory Rate		
<input type="text"/>	Body Temperature		

Comments

Date Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure		
<input type="checkbox"/> Supine	Diastolic Blood Pressure		
<input type="checkbox"/> Seated	Heart Rate		
<input type="checkbox"/> Other, specify	Respiratory Rate		
<input type="text"/>	Body Temperature		

Comments

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>

* Indicate NE if system was not examined.

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

- NA, Completed Study
- Adverse Event, specify:
- Terminated by Sponsor
- Consent Withdrawn
- Lost to Follow-up
- Other, specify:

Investigator Comments (if none, leave blank):

By electronically approving this case report form, I have reviewed the data and found them to be complete and accurate.

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Page Version No. PAGE_46 (v1, 25-MAR-2009)

Document Number

Appendix: Audit and Discrepancy Information

Audit History Report

This section lists audited data that meets the parameters set when the report was run. It may not include all of the audited data in a particular CRF. Refer to the documentation for a complete description of the parameters that can affect this report.

Document #: R243697113

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Screening	Page_07 07

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
-----------------------------	--------------------------	-------------------------	----------------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-AUG-2009 13:53:22 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	12-AUG-2009 13:53:35 Amanda Lynn	Data Entry Error

Document #: R243697113

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Screening	Page_07 07

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	7	Screening

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Date 1	15-APR-2009		12-AUG-2009 13:53:35 Amanda Lynn	Row Inserted
No (Specify samples not done, reason)/Co 1			12-AUG-2009 13:53:35 Amanda Lynn	Row Inserted
Requisition Number 1: (1) 1	105-685-0003-0		12-AUG-2009 13:53:35 Amanda Lynn	Row Inserted
Requisition Number 2 (if applicable): (2) 1			12-AUG-2009 13:53:35 Amanda Lynn	Row Inserted
Requisition Number 3 (if applicable): (3) 1			12-AUG-2009 13:53:35 Amanda Lynn	Row Inserted
Were the scheduled laboratory samples ob 1	YES		12-AUG-2009 13:53:35 Amanda Lynn	Row Inserted
Were there any clinically significant la (1) 1	NO		12-AUG-2009 13:53:35 Amanda Lynn	Row Inserted

Document #: R243911913

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Screening	Page_09 09

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Mh	Page number	9	Screening

Group #	Group Name
1	DTE

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Date 1	10-APR-2009 15-APR-2009		29-APR-2009 16:19:26 Amanda Lynn	Data Entry Error

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Date of Onset 1	00-00-1989		11-JUN-2009 15:09:04 Amanda Lynn	Row Inserted
Date of Resolution 1			11-JUN-2009 15:09:04 Amanda Lynn	Row Inserted
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION		11-JUN-2009 15:09:04 Amanda Lynn	Row Inserted
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION NASAL/SINUS CONGESTION EPISODIC/INTERMITTENT		03-MAR-2010 12:01:03 Amanda Lynn	Data Entry Error
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION EPISODIC/INTERMITTENT NASAL/SINUS CONGESTION		03-MAR-2010 12:07:43 Amanda Lynn	Data Entry Error
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION NASAL/SINUS CONGESTION EPISODIC/INTERMITTENT		03-MAR-2010 12:15:53 Amanda Lynn	Data Entry Error
Does the subject have any relevant medication 1	NO YES		11-JUN-2009 15:09:04 Amanda Lynn	Data Entry Error
Ongoing 1	CHECKED		11-JUN-2009 15:09:04 Amanda Lynn	Row Inserted
Sequence Number 1	01		11-JUN-2009 15:09:04 Amanda Lynn	Row Inserted
Date of Onset 2	00-00-2005		11-JUN-2009 15:09:04 Amanda Lynn	Row Inserted

Document #: R243911913

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Screening	Page_09 09

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Mh	Page number	9	Screening

Group #	Group Name
2	MH1

Date of Resolution 2		11-JUN-2009 15:09:04	Row Inserted	Amanda Lynn
Diagnosis/Procedure 2	TENSION HEADACHES	11-JUN-2009 15:09:04	Row Inserted	Amanda Lynn
Ongoing 2	CHECKED	11-JUN-2009 15:09:04	Row Inserted	Amanda Lynn
Sequence Number 2	02	11-JUN-2009 15:09:04	Row Inserted	Amanda Lynn
Date of Onset 3	00-00-1989	11-JUN-2009 15:09:04	Row Inserted	Amanda Lynn
Date of Resolution 3		11-JUN-2009 15:09:04	Row Inserted	Amanda Lynn
Diagnosis/Procedure 3	SEASONAL ALLERGIES	11-JUN-2009 15:09:04	Row Inserted	Amanda Lynn
Ongoing 3	CHECKED	11-JUN-2009 15:09:04	Row Inserted	Amanda Lynn
Sequence Number 3	03	11-JUN-2009 15:09:04	Row Inserted	Amanda Lynn
Date of Onset 4	00-00-1985	14-APR-2010 16:40:07	Row Inserted	Amanda Lynn
Date of Onset 4	00-00-1985 00-00-1989	06-MAY-2010 13:34:34	Data Entry Error	Amanda Lynn
Date of Resolution 4		14-APR-2010 16:40:07	Row Inserted	Amanda Lynn
Diagnosis/Procedure 4	GENERAL ACHES	14-APR-2010 16:40:07	Row Inserted	Amanda Lynn
Ongoing 4	CHECKED	14-APR-2010 16:40:07	Row Inserted	Amanda Lynn
Sequence Number 4	04	14-APR-2010 16:40:07	Row Inserted	Amanda Lynn

Document #: R243699113

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Screening	Page_11 11

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Oral Health Exam	Page number	11	Screening

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Findings* 3	NE NO	11-JUN-2009 15:10:34 Amanda Lynn	Data Entry Error

Document #: R243700813

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Screening	Page_12 12

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	12	Screening

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does the subject have any abnormal findi 1	YES NO	12-AUG-2009 13:54:02 Amanda Lynn	Data Entry Error
Does the subject have any abnormal findi 1	NO YES	08-JAN-2010 14:45:27 Amanda Lynn	Data Entry Error
Findings 1	UPPER & LOWER DENTURES	12-AUG-2009 13:54:02 Amanda Lynn	Data Entry Error
Findings 1	<Row Deleted>	15-DEC-2009 12:21:25 Joanne Numrich	Investigator Correction
Findings 1	UPPER AND LOWER DENTURES	08-JAN-2010 14:45:27 Amanda Lynn	Row Inserted
Sequence Number 1	01	12-AUG-2009 13:54:02 Amanda Lynn	Data Entry Error
Sequence Number 1	<Row Deleted>	15-DEC-2009 12:21:25 Joanne Numrich	Investigator Correction
Sequence Number 1	01	08-JAN-2010 14:45:27 Amanda Lynn	Row Inserted

Document #: R263294213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ip, Week 10	Page_24 24

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	16-NOV-2009 09:37:02 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	16-NOV-2009 09:37:37 Amanda Lynn	Data Entry Error

Document #: R263294213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ip, Week 10	Page_24 24

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	24	Ip, Week 10

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Comments (HDYF) (8) 1			16-NOV-2009 09:37:37 Amanda Lynn	Row Inserted
Comments (compliant) (4) 1			16-NOV-2009 09:37:37 Amanda Lynn	Row Inserted
Comments (how many cigarettes) (5) 1			16-NOV-2009 09:37:37 Amanda Lynn	Row Inserted
Comments (smoking status reviewed) (2) 1			16-NOV-2009 09:37:37 Amanda Lynn	Row Inserted
Comments (study product reviewed) (3) 1			16-NOV-2009 09:37:37 Amanda Lynn	Row Inserted
Date 1	06-JUL-2009		16-NOV-2009 09:37:37 Amanda Lynn	Row Inserted
If Subject was not compliant, approximat (5) 1	60 70		23-OCT-2009 14:38:47 Amanda Lynn	Data Entry Error
If Subject was not compliant, approximat (5) 1	70		16-NOV-2009 09:37:37 Amanda Lynn	Row Inserted
Was Subject asked HDYF? (8) 1	YES		16-NOV-2009 09:37:37 Amanda Lynn	Row Inserted
Was Subject compliant (4) 1	NO		16-NOV-2009 09:37:37 Amanda Lynn	Row Inserted
Was Subject's smoking status reviewed (2) 1	YES		16-NOV-2009 09:37:37 Amanda Lynn	Row Inserted

Document #: R263294213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ip, Week 10	Page_24 24

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	24	Ip, Week 10

Group #	Group Name
1	CHKYN

Was Subject's
use of study
product review
(3)
1

YES

16-NOV-2009 09:37:37 Row Inserted
Amanda Lynn

Document #: R266251413

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ip, Week 16	Page_31 31

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	31	Ip, Week 16

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
If Subject was not compliant, approximat (5) 1	180 21	23-OCT-2009 14:39:55 Amanda Lynn	Data Entry Error

Document #: R243705713

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Pcm	Page_39 39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	C M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	C01 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CARDIAC THERAPY, C01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	C01E M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	OTHER CARDIAC PREPARATIONS, C01E ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STERIODS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	C01EB M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER CARDIAC PREPARATIONS, C01EB PROPIONIC ACID DERIVATIVES, M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change

Document #: R250006313

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Pcm.2	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.2

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	D R	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC1 Text 1	DERMATOLOGICALS, D RESPIRATORY SYSTEM, R	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC2 Code 1	D04 R06	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC2 Text 1	ANTIPRURITICS, INCL ANTI HIST, ANESTHET, ETC., D04 ANTI HISTAMINES FOR SYSTEMIC USE, R06	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC3 Code 1	D04A R06A	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC3 Text 1	ANTIPRURITICS, INCL ANTI HIST, ANESTHET, ETC., D04A ANTI HISTAMINES FOR SYSTEMIC USE, R06A	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC4 Code 1	D04AA R06AA	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC4 Text 1	ANTI HISTAMINES FOR TOPICAL USE, D04AA AMINOALKYL ETHERS, R06AA	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
Dose 1	800 4	27-APR-2010 12:24:54 Amanda Lynn	Data Entry Error
Unit 1	MILLIGRAMS OTHER	27-APR-2010 12:24:54 Amanda Lynn	Data Entry Error
other, specify (unit) 1	CAPSULES	27-APR-2010 12:24:54 Amanda Lynn	Data Entry Error

Document #: R246133313

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.1	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.1

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Adverse Event 1	HICCOUGHS INTERMITTENT HICCOUGHS		16-FEB-2010 14:52:14 Amanda Lynn	Data Entry Error
Relationship to Date 1	UNLIKELY POSSIBLY		13-AUG-2009 13:02:39 Amanda Lynn	Data Entry Error
Resolved Date 1	05-MAY-2009 24-JUL-2009		12-FEB-2010 14:10:26 Amanda Lynn	Data Entry Error
Resolved Time 1	0730 1002		12-FEB-2010 14:10:26 Amanda Lynn	Data Entry Error

Document #: R247729013

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.3	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.3

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Severity 1	SEVERE MODERATE	13-AUG-2009 13:03:16 Amanda Lynn	Data Entry Error

Document #: R247729213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.4	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.4

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Adverse Event 1	ESOPHAGEAL REFLUX INTERMITTENT ESOPHAGEAL REFLUX		16-FEB-2010 14:53:02 Amanda Lynn	Data Entry Error
Relationship to Date 1	UNLIKELY POSSIBLY		13-AUG-2009 13:03:44 Amanda Lynn	Data Entry Error
Resolved Date 1	15-MAY-2009 21-MAY-2009		16-FEB-2010 14:53:02 Amanda Lynn	Data Entry Error
Resolved Time 1	1832 1900		16-FEB-2010 14:53:02 Amanda Lynn	Data Entry Error

Document #: R247729913

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.5	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
DCI Blank Flag 1	N Y		12-FEB-2010 14:14:04 Amanda Lynn	CRA Correction
DCI Blank Flag 1	Y N		12-FEB-2010 14:18:00 Amanda Lynn	Data Entry Error

Document #: R247729913

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.5	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.5

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Action Specify 1			12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted
Action Taken 1	NONE		12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted
Adverse Event 1	DYSGUSIA		12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted
Adverse Event 1	DYSGUSIA DYSGEUSIA		12-FEB-2010 14:20:05 Amanda Lynn	Data Entry Error
Did the subject experience any adverse e 1	YES		12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted
Ongoing 1			12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted
Onset Date 1	06-MAY-2009		12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted
Onset Time 1	1330		12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED		12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted
Relationship to Date 1	UNLIKELY POSSIBLY		13-AUG-2009 13:04:14 Amanda Lynn	Data Entry Error
Relationship to Date 1	PROBABLY		12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted
Resolved Date 1	09-MAY-2009		12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted
Resolved Time 1	0700		12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted
Serious Event 1	NO		12-FEB-2010 14:18:00 Amanda Lynn	Row Inserted

Document #: R247729913

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.5	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.5

Group #	Group Name
1	AE1

Severity 1	MILD	12-FEB-2010 14:18:00	Row Inserted Amanda Lynn
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Document #: R247730213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.6	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:14:13 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	12-FEB-2010 14:18:59 Amanda Lynn	Data Entry Error

Document #: R247730213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.6	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.6

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Action Specify 1			12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted
Action Taken 1	NONE		12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted
Adverse Event 1	DYSGUSIA		12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted
Adverse Event 1	DYSGUSIA DYSGEUSIA		12-FEB-2010 14:20:18 Amanda Lynn	Data Entry Error
Did the subject experience any adverse e 1	YES		12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted
Ongoing 1			12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted
Onset Date 1	27-APR-2009		12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted
Onset Time 1	1330		12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED		12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted
Relationship to Date 1	UNLIKELY POSSIBLY		13-AUG-2009 13:04:34 Amanda Lynn	Data Entry Error
Relationship to Date 1	PROBABLY		12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted
Resolved Date 1	30-APR-2009		12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted
Resolved Time 1	1500		12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted
Serious Event 1	NO		12-FEB-2010 14:18:59 Amanda Lynn	Row Inserted

Document #: R247730213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.6	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.6

Group #	Group Name
1	AE1

Severity 1	MODERATE	12-FEB-2010 14:18:59	Row Inserted Amanda Lynn
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Document #: R247731213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.7	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:14:20 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	12-FEB-2010 14:20:44 Amanda Lynn	Data Entry Error

Document #: R247731213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.7	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.7

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Action Specify 1			12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Action Taken 1	NONE		12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Adverse Event 1	COUGH		12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Did the subject experience any adverse e 1	YES		12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Ongoing 1			12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Onset Date 1	06-MAY-2009		12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Onset Time 1	1330		12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED		12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Relationship to Date 1	UNLIKELY POSSIBLY		13-AUG-2009 13:04:53 Amanda Lynn	Data Entry Error
Relationship to Date 1	UNLIKELY		12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Resolved Date 1	09-MAY-2009		12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Resolved Time 1	0700		12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Serious Event 1	NO		12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted
Severity 1	MILD		12-FEB-2010 14:20:44 Amanda Lynn	Row Inserted

Document #: R247731613

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.8	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:14:27 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	12-FEB-2010 14:21:36 Amanda Lynn	Data Entry Error

Document #: R247731613

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.8	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.8

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Action Specify 1			12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Action Taken 1	NONE		12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Adverse Event 1	XEROSTOMIA		12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Did the subject experience any adverse e 1	YES		12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Ongoing 1			12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Onset Date 1	20-MAY-2009		12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Onset Time 1	0700		12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED		12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Relationship to Date 1	UNLIKELY POSSIBLY		13-AUG-2009 13:05:57 Amanda Lynn	Data Entry Error
Relationship to Date 1	UNLIKELY		12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Resolved Date 1	20-MAY-2009		12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Resolved Time 1	1500		12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Serious Event 1	NO		12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted
Severity 1	MILD		12-FEB-2010 14:21:36 Amanda Lynn	Row Inserted

Document #: R252099413

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.9	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-AUG-2009 14:07:40 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	12-AUG-2009 14:07:47 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	N Y	12-FEB-2010 14:18:38 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	12-FEB-2010 14:23:06 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	N Y	17-FEB-2010 11:42:11 Amanda Lynn	Data Entry Error

Document #: R252099413

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.9	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.9

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Specify 1		12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Action Specify 1		12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted
Action Taken 1	NONE	12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Action Taken 1	NONE	12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted
Adverse Event 1	DYSGUSIA	12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Adverse Event 1	GASTRO ESOPHAGEAL REFLUX DISEASE	12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted
Did the subject experience any adverse e 1	YES	12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Did the subject experience any adverse e 1	YES	12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted
Ongoing 1		12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Ongoing 1		12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted
Onset Date 1	06-MAY-2009	12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Onset Date 1	21-MAY-2009	12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted
Onset Time 1	1330	12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Onset Time 1	1830	12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted

Document #: R252099413

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.9	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.9

Group #	Group Name
1	AE1

Outcome to Date 1	RECOVERED	12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED	12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted
Relationship to Date 1	PROBABLY	12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Relationship to Date 1	POSSIBLY	12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted
Resolved Date 1	09-MAY-2009	12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Resolved Date 1	21-MAY-2009	12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted
Resolved Time 1	0700	12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Resolved Time 1	1900	12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted
Serious Event 1	NO	12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Serious Event 1	NO	12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted
Severity 1	MILD	12-AUG-2009 14:07:47 Amanda Lynn	Row Inserted
Severity 1	MILD	12-FEB-2010 14:23:06 Amanda Lynn	Row Inserted

Document #: R252099513

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.10	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:19:33 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	12-FEB-2010 14:24:04 Amanda Lynn	Data Entry Error

Document #: R252099513

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.10	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.10

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Specify 1		12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Action Taken 1	NONE	12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Adverse Event 1	AGITATION	12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Did the subject experience any adverse e 1	YES	12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Ongoing 1		12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Onset Date 1	28-MAY-2009	12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Onset Time 1	1930	12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED	12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Relationship to Date 1	UNLIKELY	12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Resolved Date 1	30-MAY-2009	12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Resolved Time 1	1500	12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Serious Event 1	NO	12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted
Severity 1	MODERATE	12-FEB-2010 14:24:04 Amanda Lynn	Row Inserted

Document #: R252099613

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.11	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
DCI Blank Flag 1	N Y		12-FEB-2010 14:21:15 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N		12-FEB-2010 14:24:55 Amanda Lynn	Data Entry Error

Document #: R252099613

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.11	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.11

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Specify 1		12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Action Taken 1	NONE	12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Adverse Event 1	ANXIETY	12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Did the subject experience any adverse e 1	YES	12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Ongoing 1		12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Onset Date 1	28-MAY-2009	12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Onset Time 1	1930	12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED	12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Relationship to Date 1	UNLIKELY	12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Resolved Date 1	30-MAY-2009	12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Resolved Time 1	1500	12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Serious Event 1	NO	12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted
Severity 1	MODERATE	12-FEB-2010 14:24:55 Amanda Lynn	Row Inserted

Document #: R252099813

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.12	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:22:18 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	12-FEB-2010 14:25:49 Amanda Lynn	Data Entry Error

Document #: R252099813

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.12	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.12

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Specify 1		12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Action Taken 1	NONE	12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Adverse Event 1	COUGH	12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Did the subject experience any adverse e 1	YES	12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Ongoing 1		12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Onset Date 1	12-MAY-2009	12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Onset Time 1	1500	12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED	12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Relationship to Date 1	UNLIKELY	12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Resolved Date 1	14-MAY-2009	12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Resolved Time 1	0700	12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Serious Event 1	NO	12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted
Severity 1	MILD	12-FEB-2010 14:25:49 Amanda Lynn	Row Inserted

Document #: R252099913

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.13	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:22:35 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	12-FEB-2010 14:39:56 Amanda Lynn	Data Entry Error

Document #: R252099913

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.13	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.13

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Action Specify 1			12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Action Taken 1	NONE		12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Adverse Event 1	RASH		12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Did the subject experience any adverse e 1	YES		12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Ongoing 1			12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Onset Date 1	02-JUL-2009		12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Onset Time 1	1500		12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED		12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Relationship to Date 1	UNLIKELY POSSIBLY		13-AUG-2009 13:07:55 Amanda Lynn	Data Entry Error
Relationship to Date 1	UNLIKELY		12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Resolved Date 1	03-JUL-2009		12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Resolved Time 1	0630		12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Serious Event 1	NO		12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted
Severity 1	MILD		12-FEB-2010 14:39:56 Amanda Lynn	Row Inserted

Document #: R252100013

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.14	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
DCI Blank Flag 1	N Y		12-FEB-2010 14:15:40 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N		12-FEB-2010 14:40:29 Amanda Lynn	Data Entry Error

Document #: R252100013

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.14	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.14

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Specify 1		12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Action Taken 1	NONE	12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Adverse Event 1	RASH	12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Did the subject experience any adverse e 1	YES	12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Ongoing 1		12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Onset Date 1	03-JUL-2009	12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Onset Time 1	0630	12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED	12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Relationship to Date 1	UNLIKELY POSSIBLY	13-AUG-2009 13:08:37 Amanda Lynn	Data Entry Error
Relationship to Date 1	UNLIKELY	12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Resolved Date 1	04-JUL-2009	12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Resolved Time 1	1700	12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Serious Event 1	NO	12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted
Severity 1	MODERATE	12-FEB-2010 14:40:29 Amanda Lynn	Row Inserted

Document #: R252100113

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.15	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:23:45 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	12-FEB-2010 14:40:55 Amanda Lynn	Data Entry Error

Document #: R252100113

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.15	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.15

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Action Specify 1			12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Action Taken 1	NONE		12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Adverse Event 1	RASH		12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Did the subject experience any adverse e 1	YES		12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Ongoing 1			12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Onset Date 1	04-JUL-2009		12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Onset Time 1	1700		12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED		12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Relationship to Date 1	UNLIKELY		12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Resolved Date 1	06-JUL-2009		12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Resolved Time 1	0632		12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Serious Event 1	NO		12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted
Severity 1	SEVERE MODERATE		13-AUG-2009 13:09:04 Amanda Lynn	Data Entry Error
Severity 1	SEVERE		12-FEB-2010 14:40:55 Amanda Lynn	Row Inserted

Document #: R252100213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.16	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:24:40 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	12-FEB-2010 14:41:42 Amanda Lynn	Data Entry Error

Document #: R252100213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.16	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.16

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Action Specify 1			12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Action Taken 1	NONE		12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Adverse Event 1	RASH		12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Did the subject experience any adverse e 1	YES		12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Ongoing 1			12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Onset Date 1	06-JUL-2009		12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Onset Time 1	0632		12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Outcome to Date 1	RECOVERED		12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Relationship to Date 1	UNLIKELY		12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Resolved Date 1	10-JUL-2009		12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Resolved Time 1	0630		12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Serious Event 1	NO		12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted
Severity 1	SEVERE MODERATE		13-AUG-2009 13:09:27 Amanda Lynn	Data Entry Error
Severity 1	MILD		12-FEB-2010 14:41:42 Amanda Lynn	Row Inserted

Document #: R263303913

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.17	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:25:31 Amanda Lynn	Data Entry Error

Document #: R263311013

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.18	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:16:15 Amanda Lynn	Data Entry Error

Document #: R263312213

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.19	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:16:23 Amanda Lynn	Data Entry Error

Document #: R263312713

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.20	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:16:29 Amanda Lynn	Data Entry Error

Document #: R263313713

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.21	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:16:36 Amanda Lynn	Data Entry Error

Document #: R263314513

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.22	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:16:43 Amanda Lynn	Data Entry Error

Document #: R263315113

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.23	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:16:50 Amanda Lynn	Data Entry Error

Document #: R263315813

Patient	Visit	CRF
Site	Visit Date	CRF Page
R2012	Ae.24	Page_40
L0689282_2		

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			

Group #	Group Name
0	CRF Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCI Blank Flag	N	12-FEB-2010	14:16:56	Data Entry Error
1	Y	Amanda Lynn		

Document #: R274944713

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.25	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:42:15 Amanda Lynn	Data Entry Error

Document #: R274944813

Patient Site	Visit Visit Date	CRF CRF Page
R2012	Ae.26	Page_40
L0689282_2		

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag	N	12-FEB-2010 14:42:26	Data Entry Error
1	Y	Amanda Lynn	

Document #: R274945313

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.27	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:42:31 Amanda Lynn	Data Entry Error

Document #: R274945413

Patient Site	Visit Visit Date	CRF CRF Page
R2012 L0689282_2	Ae.28	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	12-FEB-2010 14:42:37 Amanda Lynn	Data Entry Error

Discrepancy Detail Report

Document #: R243697113

Discrepancy ID: 1688692313

Site: L0689282_2

Patient: R2012

Visit: SCREENING

Visit Date:

CRF: PAGE_07

Section: UPREG

Qualifying Value: 7

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please complete uring preg and UDS modules

Internal Comment:

Resolution Type: Data value changed. Disc no longer applicable.

Resolution Text:

Document #: R243911913

Discrepancy ID: 116165511 **Site:** L0689282_2 **Patient:** R2012
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Date of Onset **Row:** 4
Value Text: 1989
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per monitor, please update onset date to 1985.
Internal Comment: changed to 1989 not 1985.
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 74090711 **Site:** L0689282_2 **Patient:** R2012
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 1
Value Text: NASAL/SINUS CONGESTION EPISODIC/INTERMITTENT
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update diagnosis/procedure term to clarify if this is an episodic/intermittent or an ongoing/chronic condition.
Internal Comment: updated
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R263294213

Discrepancy ID: 1790975613

Site: L0689282_2

Patient: R2012

Visit: IP, WEEK 10

Visit Date:

CRF: PAGE_24

Section: DIARY

Qualifying Value: 24

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please complete.

Internal Comment:

Resolution Type: Data value changed. Disc no longer applicable.

Resolution Text:

Document #: R250006313

Discrepancy ID: 112548711

Site: L0689282_2

Patient: R2012

Visit: PCM.2

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Dose

Row: 1

Value Text: 4

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify dose. Generally, benadryl is taken in 25 or 50 mg doses.

Internal Comment: changed to capsules since the dosage is incorrect.

Resolution Type: Confirmed

Resolution Text: Verified. JLM 27Apr2010

Document #: R246133313

Discrepancy ID: 66336511 **Site:** L0689282_2 **Patient:** R2012
Visit: AE.1 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Adverse Event **Row:** 1
Value Text: INTERMITTENT HICCOUGHS
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per source, the term 'intermittent' should be added.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 1688874013 **Site:** L0689282_2 **Patient:** R2012
Visit: AE.1 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Relationship to Date **Row:** 1
Value Text: POSSIBLY
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please have PI review relationship. Hiccups is a known side effect.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R247729013

Discrepancy ID: 1688696413

Site: L0689282_2

Patient: R2012

Visit: AE.3

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Severity

Row: 1

Value Text: MODERATE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please have PI review severity

Internal Comment:

Resolution Type: Data value changed. Disc no longer applicable.

Resolution Text:

Document #: R252099813

Discrepancy ID: 104303011

Site: L0689282_2

Patient: R2012

Visit: AE.12

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Resolved Date

Row: 1

Value Text: 20090514

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: There is another AE of cough with a Moderate severity with an onset date of 14May2009 at 11:30. Please verify these are two separate events. If not, and is a worsening of severity, please update resolved date/time and onset date/time to indicate this.

Internal Comment: this is a seperate AE leave as is.

Resolution Type: Confirmed

Resolution Text: Verified. JLM 23Apr2010

Deleted CRFs Report