

CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 16:35:43

Report Parameters

Site: CD_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R5023

Ending patient: R5023

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	Investigator Name:	<input type="text" value="DR. WILLIAM LEWIS"/>
SM 08-01	Study Site:	<input type="text" value="SITE 05"/>

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

Subject Number

Subject Initials

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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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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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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"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input 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

Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="14-JUL-2009"/>	<input type="text" value="(b) (6)"/>	<input type="checkbox"/> Male	<input type="checkbox"/> Hispanic or Latino
		<input checked="" type="checkbox"/> Female	<input checked="" type="checkbox"/> Not Hispanic or latino
Race			
<input checked="" type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Black or African American	<input type="checkbox"/> American Indian/Alaskan Native		
<input type="checkbox"/> Asian	<input type="checkbox"/> Other	<input type="text"/>	

Body Measurements

Were Body Measurements Collected? Yes No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="064.8"/>

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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	106
Diastolic Blood Pressure	MMHG	67
Heart Rate	BEATS/MINUTE	73
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.6
Weight	LB	133.2

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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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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at Least 5 Minutes?	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text" value="14-JUL-2009"/>	<input type="text" value="09:56"/>

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

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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

Medical History

Date

Does the subject have any (b) (6) medical history? Yes No

Sequence

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	DEGENERATIVE DISC C3-C5	00-00-2001		<input checked="" type="checkbox"/> Ongoing
2	PAIN FROM DEGENERATIVE DISC C3-C5	00-00-2001		<input checked="" type="checkbox"/> Ongoing
3	ADULT ATTENTION DEFICIT DISORDER	00-00-2005		<input checked="" type="checkbox"/> Ongoing
4	TUBAL LIGATION	00-00-1999	00-00-1999	<input type="checkbox"/> Ongoing
5	ACNE	00-00-2007		<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

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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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="24"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="12"/>	
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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
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
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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
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="2"/>	TRIED COLD TURKEY

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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

Oral Health Examination

Date	Procedure	Findings*	Findings
14-JUL-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
14-JUL-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
14-JUL-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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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

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

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
24-JUL-2009	12:04	8	1.9	

Behavioral Counseling

Date	Parameter	Result	Comments
24-JUL-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="ND"/>	<input type="text" value="WEEK 1"/>	Was Subject contacted by telephone?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text" value="SUBJECT NOT AT 1"/>
		Was Subject's smoking status reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="19-AUG-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="7"/>	<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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Document Number

OverFlow Section For Document Number R265106313

- 1 SUBJECT NOT AT TELEPHONE NUMBER GIVEN
- 2 SUBJECT'S TELEPHONE NUMBER DISCONNECTED

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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		
Diastolic Blood Pressure		
Heart Rate		
Respiratory Rate		
Body Temperature		
Weight		

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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: 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
<input type="text"/>				

Behavioral Counseling

Date	Parameter	Result	Comments
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS 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

Product Dispensation

Date

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

Status Review

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

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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	117
Diastolic Blood Pressure	MMHG	65
Heart Rate	BEATS/MINUTE	72
Respiratory Rate	BREATHS/MINUTE	22
Body Temperature	C	36.8
Weight	LB	134.4

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Page Version No. PAGE_22 (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

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
05-OCT-2009	17:34	1	0.7	

Behavioral Counseling

Date	Parameter	Result	Comments
05-OCT-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

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="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="05-OCT-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="14"/>	<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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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="26-OCT-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="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"/>
	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

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

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	109
Diastolic Blood Pressure	MMHG	62
Heart Rate	BEATS/MINUTE	63
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.8
Weight	LB	133.8

Verified Approved Locked Frozen

Page Version No. PAGE_26 (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

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.

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

[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

Oral Health Examination

Date	Procedure	Findings*	Findings
16-NOV-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
16-NOV-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
16-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.

Verified Approved Locked Frozen

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
16-NOV-2009	17:20	1	0.7	

Behavioral Counseling

Date	Parameter	Result	Comments
16-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_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="16-NOV-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="14"/>	<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

Verified Approved Locked Frozen

Page Version No. PAGE_31 (v1, 12-MAY-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 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="3"/>	<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	108
Diastolic Blood Pressure	MMHG	66
Heart Rate	BEATS/MINUTE	75
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	37.0
Weight	LB	136.6

Verified Approved Locked Frozen

Page Version No. PAGE_33 (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

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.

Verified Approved Locked Frozen

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
08-FEB-2010	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
08-FEB-2010	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
08-FEB-2010	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.

Verified Approved Locked Frozen

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
08-FEB-2010	15:49	3	1.1	

Behavioral Counseling

Date	Parameter	Result	Comments
08-FEB-2010	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

Verified Approved Locked Frozen

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="08-FEB-2010"/>	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="21"/>	<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_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.

Verified Approved Locked Frozen

Page Version No. PAGE_39 (v1, 25-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

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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Page Version No. PAGE_39 (v1, 25-MAR-2009)

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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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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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Page Version No. PAGE_39 (v1, 25-MAR-2009)

Document Number

OverFlow Section For Document Number R260796913

1 SERIES OF 3 SHOTS BEGINNING 22-JUL-09

Links to Discrepancy and Audit Sections

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

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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Page Version No. PAGE_39 (v1, 25-MAR-2009)

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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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Page Version No. PAGE_39 (v1, 25-MAR-2009)

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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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Page Version No. PAGE_39 (v1, 25-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

(b) (6) Select only one
to Date: Not (b) (6)
 Unlikely
 Possibly (b) (6)
 Probably (b) (6)
 Definitely (b) (6)

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

(b) (6) Select only one
to Date: Not (b) (6)
 Unlikely
 Possibly (b) (6)
 Probably (b) (6)
 Definitely (b) (6)

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

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

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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
28-SEP-2009	NA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
05-OCT-2009	B426997	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			

Note: Attach copy of signed laboratory report.

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

Document Number

Links to Discrepancy and Audit Sections

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

[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

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	MMHG	116
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	69
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS / MINUTE	63
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS / MINUTE	20
	Body Temperature	C	37.0

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 <input type="text"/>	Respiratory Rate		
	Body Temperature		

Comments

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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

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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Page Version No. PAGE_45 (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

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.

Verified Approved Locked Frozen

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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 #: R260784513

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Screening	Page_04 04

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Info_Session	Page number	4	Screening

Group #	Group Name
1	IC

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date of Information Session 1	24-JUL-2009 14-JUL-2009	30-JUL-2009 13:20:17 Sharon Ladenes	Data Entry Error

Document #: R260784513

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Screening	Page_04 04

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ifc	Page number	4	Screening

Group #	Group Name
1	IC

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date the Subject Signed the Informed Con 1	24-JUL-2009 14-JUL-2009	30-JUL-2009 13:20:17 Sharon Ladenes	Data Entry Error

Document #: R260784813

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Screening	Page_05 05

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Dm	Page number	5	Screening

Group #	Group Name
1	DM

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	24-JUL-2009 14-JUL-2009	30-JUL-2009 13:19:56 Sharon Ladenes	Data Entry Error

Document #: R260784813

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Screening	Page_05 05

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Bm	Page number	5	Screening

Group #	Group Name
1	BM

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	24-JUL-2009 14-JUL-2009	30-JUL-2009 13:19:56 Sharon Ladenes	Data Entry Error

Document #: R260785413

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Screening	Page_06 06

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	6	Screening

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	24-JUL-2009 14-JUL-2009	30-JUL-2009 13:19:37 Sharon Ladenes	Data Entry Error

Document #: R260786513

Patient Site	Visit Visit Date	CRF CRF Page
R5023	Screening	Page_07
CD_001		07

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	30-JUL-2009 13:11:21 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	30-JUL-2009 13:11:49 Sharon Ladenes	Data Entry Error

Document #: R260786513

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	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 On resequence By	Reason Comment
Date 1	24-JUL-2009	30-JUL-2009 13:11:49 Sharon Ladenes	Row Inserted
Date 1	24-JUL-2009 14-JUL-2009	30-JUL-2009 13:19:17 Sharon Ladenes	Data Entry Error
No (Specify samples not done, reason)/Co 1		30-JUL-2009 13:11:49 Sharon Ladenes	Row Inserted
Requisition Number 1: (1) 1	195-967-0004-0	30-JUL-2009 13:11:49 Sharon Ladenes	Row Inserted
Requisition Number 2 (if applicable): (2) 1		30-JUL-2009 13:11:49 Sharon Ladenes	Row Inserted
Requisition Number 3 (if applicable): (3) 1		30-JUL-2009 13:11:49 Sharon Ladenes	Row Inserted
Were the scheduled laboratory samples ob 1	YES	30-JUL-2009 13:11:49 Sharon Ladenes	Row Inserted
Were there any clinically significant la (1) 1	NO	30-JUL-2009 13:11:49 Sharon Ladenes	Row Inserted

Document #: R260787413

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Screening	Page_08 08

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eg	Page number	8	Screening

Group #	Group Name
1	EG

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	24-JUL-2009 14-JUL-2009	30-JUL-2009 13:19:04 Sharon Ladenes	Data Entry Error

Document #: R260787913

Patient Site	Visit	CRF
R5023	Visit Date	CRF Page
CD_001	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	24-JUL-2009 14-JUL-2009		30-JUL-2009 13:18:51 Sharon Ladenes	Data Entry Error

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Diagnosis/Procedure 1	DEGENERATIVE DISC DEGENERATIVE DISC C3-C5		13-JAN-2010 14:11:37 Sharon Ladenes	Data Entry Error
Diagnosis/Procedure 2	PAIN FROM DEGENERATIVE DISC PAIN FROM DEGENERATIVE DISC C3-C5		13-JAN-2010 14:11:37 Sharon Ladenes	Data Entry Error
Date of Onset 5	00-00-2007		08-DEC-2009 14:31:04 Sharon Ladenes	Row Inserted
Date of Resolution 5			08-DEC-2009 14:31:04 Sharon Ladenes	Row Inserted
Diagnosis/Procedure 5	ACNE		08-DEC-2009 14:31:04 Sharon Ladenes	Row Inserted
Ongoing 5	CHECKED		08-DEC-2009 14:31:04 Sharon Ladenes	Row Inserted
Sequence Number 5	5		08-DEC-2009 14:31:04 Sharon Ladenes	Row Inserted

Document #: R260789813

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Screening	Page_10 10

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Smoking History	Page number	10	Screening

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Comments (pharmaceuticals) (5) 1	WELLBUTRIM WELLBUTRIN		17-MAR-2010 17:28:11 Kryisia Magnuson	ODM/SEC Wellbutrim to Wellbutrin. KAY 17Mar2010.
Date 1	24-JUL-2009 14-JUL-2009		30-JUL-2009 13:18:31 Sharon Ladenes	Data Entry Error

Document #: R260793413

Patient Site	Visit Visit Date	CRF CRF Page	
R5023 CD_001	Baseline, Week 0	Page_14 14	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eco	Page number	14	Baseline, Week 0

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
%COHb	1.8		
1	1.9	22-OCT-2009 17:38:17 Sharon Ladenes	Data Entry Error

Document #: R260793713

Patient Site	Visit Visit Date	CRF CRF Page		
R5023 CD_001	Baseline, Week 0	Page_15 15		
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit	
Sc	Page number	15	Baseline, Week 0	
Group #	Group Name			
1	SC			
Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Actual Time 1	1252 1245		31-JUL-2009 17:22:32 Sharon Ladenes	Data Entry Error

Document #: R265106313

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Sptp, Weeks 1-4	Page_16 16

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	22-OCT-2009 18:40:16 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	22-OCT-2009 18:43:35 Sharon Ladenes	Data Entry Error

Document #: R265106313

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Sptp, Weeks 1-4	Page_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Approximately how many cigarettes did th (10) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (behavioral counseling) (6) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (contacted by phone) (1) 1	SUBJECT NOT AT TELEPHONE NUMBER GIVEN	22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (contacted by phone) (1) 1	SUBJECT NOT AT TELEPHONE NUMBER GIVEN	06-MAY-2010 13:03:26 Sharon Ladenes	Data Entry Error
Comments (contacted by phone) (1) 1	SUBJECT NOT AT TELEPHONE NUMBER GIVEN	06-MAY-2010 13:47:26 Sharon Ladenes	Data Entry Error
Comments (how many cigarettes) (5) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (smoking status reviewed) (2) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (study product reviewed) (3) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Date 1	03-AUG-2009	22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Date 1	03-AUG-2009 ND	06-MAY-2010 13:03:26 Sharon Ladenes	Data Entry Error

Document #: R265106313

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Sptp, Weeks 1-4	Page_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Scheduled Timepoint 1	WEEK 1	22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Behavioral Counseling Given (6) 1		22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Subject contacted by telephone (1) 1	NO	22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Subject's smoking status reviewed (2) 1		22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Subject's use of study product review (3) 1		22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Document #: R265106313

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Sptp, Weeks 1-4	Page_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16.1	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Approximately how many cigarettes did th (11) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (behavioral counseling) (6) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (contacted by phone) (1) 1	SUBJECT'S TELEPHONE NUMBER DISCONNECTED	22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (contacted by phone) (1) 1	SUBJECT'S TELEPHONE NUMBER DISCONNECTED	06-MAY-2010 13:03:26 Sharon Ladenes	Data Entry Error
Comments (contacted by phone) (1) 1	SUBJECT'S TELEPHONE NUMBER DISCONNECTED	06-MAY-2010 13:48:03 Sharon Ladenes	Data Entry Error
Comments (how many cigarettes) (5) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (smoking status reviewed) (2) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (study product reviewed) (3) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Date 1	10-AUG-2009	22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Date 1	10-AUG-2009 ND	06-MAY-2010 13:03:26 Sharon Ladenes	Data Entry Error

Document #: R265106313

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Sptp, Weeks 1-4	Page_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16.1	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Scheduled Timepoint 1	WEEK 2	22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Behavioral Counseling Given (6) 1		22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Subject contacted by telephone (1) 1	NO	22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Subject's smoking status reviewed (2) 1		22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Subject's use of study product review (3) 1		22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Document #: R265106313

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Sptp, Weeks 1-4	Page_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16A	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Approximately how many cigarettes did th (10) 1	7	22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (behavioral counseling) (6) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (contacted by phone) (1) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (how many cigarettes) (5) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (smoking status reviewed) (2) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Comments (study product reviewed) (3) 1	SUBJECT REPORTS THAT THEY DON'T FEEL PRODUCT IS EFFECTIVE. IT ALSO IRRITATES HER GUMS IF IN HER MOUTH FOR 15 MINUTES. THE SMELL OF THE PRODUCT ALSO MAKES HER REFRIGERATOR SMELL BAD	21-OCT-2009 11:16:18 Sharon Ladenes	Data Entry Error
Comments (study product reviewed) (3) 1		22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Date 1	19-AUG-2009	22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted
Scheduled Timepoint 1	WEEK 3	22-OCT-2009 18:43:35 Sharon Ladenes	Row Inserted

Document #: R265106313

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Sptp, Weeks 1-4	Page_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16A	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Was Behavioral Counseling Given (6) 1		22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Behavioral Counseling Given (6) 1	YES	18-MAR-2010 20:25:31	Data Entry Error Sharon Ladenes
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Was Subject contacted by telephone (1) 1	YES	22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Subject's smoking status reviewed (2) 1	YES	22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Subject's use of study product review (3) 1	NO	22-OCT-2009 18:43:35	Row Inserted Sharon Ladenes
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Was Subject's use of study product review (3) 1	NO YES	23-OCT-2009 10:49:42	Data Entry Error Sharon Ladenes
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Document #: R265106313

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Sptp, Weeks 1-4	Page_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16B	Sptp, Weeks 1-4

Group #	Group Name
0	Section Header

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
DCM Blank flag 1	N Y		07-OCT-2009 11:54:17 Diane Yann	Key Change

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Was Subject's use of study product review (3) 1	NO YES		23-OCT-2009 10:49:42 Sharon Ladenes	Data Entry Error
Was subject reminded about the complete (7) 1	YES		18-MAR-2010 11:21:05 Sharon Ladenes	Data Entry Error

Document #: R275390713

Patient Site	Visit Visit Date	CRF CRF Page
R5023	Ip, Week 6	Page_17
CD_001		17

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	09-MAR-2010 12:19:23	Data Entry Error
1	Y	Sharon Ladenes	

Document #: R275390813

Patient Site	Visit Visit Date	CRF CRF Page
R5023	Ip, Week 6	Page_18
CD_001		18

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	09-MAR-2010 12:20:55	Data Entry Error
1	Y	Sharon Ladenes	

Document #: R275390913

Patient Site	Visit Visit Date	CRF CRF Page
R5023	Ip, Week 6	Page_19
CD_001		19

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	09-MAR-2010 12:21:10	Data Entry Error
1	Y	Sharon Ladenes	

Document #: R275391013

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Ip, Week 6	Page_20 20

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	09-MAR-2010 12:21:22 Sharon Ladenes	Data Entry Error

Document #: R275391113

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Ip, Week 8	Page_21 21

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	21	Ip, Week 8

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	21-SEP-2009	01-MAR-2010 12:41:10 Sharon Ladenes	Data Entry Error

Document #: R282989013

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Ip, Week 16	Page_27 27

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	27	Ip, Week 16

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Were there any clinically significant la (1) 1	NO	09-MAR-2010 11:12:56 Sharon Ladenes	Data Entry Error

Document #: R260794813

Patient Site	Visit Visit Date	CRF CRF Page
R5023	Pcm	Page_39
CD_001		39

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	08-DEC-2009 14:33:02 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	08-DEC-2009 14:33:53 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	N Y	17-MAR-2010 12:17:30 Sharon Ladenes	Data Entry Error

Document #: R260794813

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	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
Dose 1	1000	03-SEP-2009 14:40:07 Sharon Ladenes	Data Entry Error
Dose 1		08-DEC-2009 14:33:53 Sharon Ladenes	Row Inserted
Dose 1	UNKNOWN	08-DEC-2009 14:35:11 Sharon Ladenes	Data Entry Error
Dose 1	UNKNOWN 1	04-JAN-2010 16:56:39 Sharon Ladenes	Data Entry Error
Dose 1	1 1000	11-MAR-2010 14:46:00 Stephanie Felton	Data Entry Error
Drug name 1	DOXYCYC DOXYCYCLINE HYCLATE	30-JUL-2009 13:34:59 Sharon Ladenes	Pass1
Drug name 1	DOXYCYCLINE HYCLATE	03-SEP-2009 14:40:07 Sharon Ladenes	Data Entry Error
Drug name 1		08-DEC-2009 14:33:53 Sharon Ladenes	Row Inserted
Frequency 1	EVERY DAY	03-SEP-2009 14:40:07 Sharon Ladenes	Data Entry Error
Frequency 1	EVERY DAY	08-DEC-2009 14:33:53 Sharon Ladenes	Row Inserted
Has the subject taken any medications pr 1	YES NO	03-SEP-2009 14:40:07 Sharon Ladenes	Data Entry Error
Has the subject taken any medications pr 1	YES	08-DEC-2009 14:33:53 Sharon Ladenes	Row Inserted
Indication 1	SKIN SKIN ACNE	30-JUL-2009 13:34:59 Sharon Ladenes	Pass1
Indication 1	SKIN ACNE	03-SEP-2009 14:40:07 Sharon Ladenes	Data Entry Error

Document #: R260794813

Patient Site	Visit Visit Date	CRF CRF Page
R5023	Pcm	Page_39
CD_001		39

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

Group #	Group Name
1	CM1

Indication		08-DEC-2009 14:33:53	Row Inserted
1	ACNE	Sharon Ladenes	
Ongoing		08-DEC-2009 14:33:53	Row Inserted
1	CHECKED	Sharon Ladenes	
Ongoing		04-JAN-2010 17:01:06	Data Entry Error
1	CHECKED	Sharon Ladenes	
Start Date	00-MAY-2009	03-SEP-2009 14:40:07	Data Entry Error
1		Sharon Ladenes	
Start Date		08-DEC-2009 14:33:53	Row Inserted
1	00-00-2007	Sharon Ladenes	
Start Date	00-00-2007	04-JAN-2010 16:56:39	Data Entry Error
1	00-00-2009	Sharon Ladenes	
Stop Date	15-JUN-2009	03-SEP-2009 14:40:07	Data Entry Error
1		Sharon Ladenes	
Stop Date		08-DEC-2009 14:33:53	Row Inserted
1		Sharon Ladenes	
Stop Date		04-JAN-2010 17:01:06	Data Entry Error
1	15-JUN-2009	Sharon Ladenes	
Unit	MILLIGRAMS	03-SEP-2009 14:40:07	Data Entry Error
1		Sharon Ladenes	
Unit		08-DEC-2009 14:33:53	Row Inserted
1	OTHER	Sharon Ladenes	
Unit	OTHER	04-JAN-2010 16:56:39	Data Entry Error
1	TABLET	Sharon Ladenes	
Unit	TABLET	11-MAR-2010 14:46:00	Data Entry Error
1	MILLIGRAMS	Stephanie Felton	
other, specify (frequency)		08-DEC-2009 14:33:53	Row Inserted
1		Sharon Ladenes	
other, specify (unit)		08-DEC-2009 14:33:53	Row Inserted
1	OINTMENT	Sharon Ladenes	
other, specify (unit)	OINTMENT	04-JAN-2010 16:56:39	Data Entry Error
1		Sharon Ladenes	

Document #: R260795713

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Pcm.1	Page_39

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	03-SEP-2009 14:42:13 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	04-JAN-2010 16:59:47 Sharon Ladenes	CRA Correction
DCI Blank Flag 1	N Y	27-APR-2010 12:29:18 Sharon Ladenes	Data Entry Error

Document #: R260795713

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Pcm.1	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.1

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A J	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A ANTIINFECTIVES FOR SYSTEMIC USE, J	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A01 J01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANTIBACTERIALS FOR SYSTEMIC USE, J01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A01A J01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A TETRACYCLINES, J01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A01AB J01AA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	ANTIINFECT. AND ANTISEPT. FOR LOCAL ORAL TREATMENT, A01AB TETRACYCLINES, J01AA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Dose 1	30	03-SEP-2009 14:41:26 Sharon Ladenes	Data Entry Error
Dose 1	1000	04-JAN-2010 16:59:47 Sharon Ladenes	Row Inserted
Drug name 1	ACCERALL XR	03-SEP-2009 14:41:26 Sharon Ladenes	Data Entry Error
Drug name 1	HYCLATE	04-JAN-2010 16:59:47 Sharon Ladenes	Row Inserted
Drug name 1	HYCLATE DOXYCYCLINE HYCLATE	15-MAR-2010 16:01:17 Stephanie Felton	Data Entry Error
Frequency 1	WHENEVER NECESSARY	03-SEP-2009 14:41:26 Sharon Ladenes	Data Entry Error

Document #: R260795713

Patient Site	Visit Visit Date	CRF CRF Page
R5023	Pcm.1	Page_39
CD_001		

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.1

Group #	Group Name
1	CM1

Frequency		04-JAN-2010 16:59:47	Row Inserted
1	EVERY DAY	Sharon Ladenes	
Has the subject taken any medications pr	YES	03-SEP-2009 14:39:47	Data Entry Error
1	NO	Sharon Ladenes	
Has the subject taken any medications pr		04-JAN-2010 16:59:47	Row Inserted
1	YES	Sharon Ladenes	
Indication	ADULT ATTENTION DEFICIT DISORDER	03-SEP-2009 14:41:26	Data Entry Error
1		Sharon Ladenes	
Indication		04-JAN-2010 16:59:47	Row Inserted
1	ACNE	Sharon Ladenes	
Ongoing	CHECKED	03-SEP-2009 14:41:26	Data Entry Error
1		Sharon Ladenes	
Ongoing		04-JAN-2010 16:59:47	Row Inserted
1		Sharon Ladenes	
Start Date	00-00-2005	03-SEP-2009 14:41:26	Data Entry Error
1		Sharon Ladenes	
Start Date		04-JAN-2010 16:59:47	Row Inserted
1	00-MAY-2009	Sharon Ladenes	
Stop Date		04-JAN-2010 16:59:47	Row Inserted
1	15-JUN-2009	Sharon Ladenes	
Unit	MILLIGRAMS	03-SEP-2009 14:41:26	Data Entry Error
1		Sharon Ladenes	
Unit		04-JAN-2010 16:59:47	Row Inserted
1	MILLIGRAMS	Sharon Ladenes	
other, specify (frequency)		04-JAN-2010 16:59:47	Row Inserted
1		Sharon Ladenes	
other, specify (unit)		04-JAN-2010 16:59:47	Row Inserted
1		Sharon Ladenes	

Document #: R260796213

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Pcm.2	Page_39

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	17-MAR-2010 12:15:21 Sharon Ladenes	Data Entry Error

Document #: R260796913

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Pcm.3	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.3

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	H	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC1 Text 1	SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Code 1	H02	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Text 1	CORTICOSTEROIDS FOR SYSTEMIC USE, H02	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Drug Modified Reported Term 1	CERVICAL EPIDURAL STERIOD CERVICAL EPIDURAL STERIOD	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	CERVICAL EPIDURAL STERIOD CERVICAL EPIDURAL STERIOD	09-APR-2010 16:13:24 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 09Apr2010
Ongoing 1	CHECKED	04-JAN-2010 17:01:40 Sharon Ladenes	Data Entry Error
Preferred Term 1	CORTICOSTEROID NOS	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Preferred Term Code 1	00768301001	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Stop Date 1	12-AUG-2009	04-JAN-2010 17:01:40 Sharon Ladenes	Data Entry Error
other, specify (unit) 1	UNKNOWN INJECTION	04-JAN-2010 17:01:40 Sharon Ladenes	Data Entry Error

Document #: R286409213

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Pcm.4	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.4

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A NERVOUS SYSTEM, N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A08 N06	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, A08 PSYCHOANALEPTICS, N06	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A08A N06B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, A08A PSYCHOSTIM., AGENTS USED FOR ADHD AND NOOTROPICS, N06B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A08AA N06BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CENTRALLY ACTING ANTI OBESITY PRODUCTS, A08AA CENTRALLY ACTING SYMPATHOMIMETICS, N06BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Frequency 1	WHENEVER NECESSARY	04-JAN-2010 17:05:00 Sharon Ladenes	Data Entry Error
Indication 1	ADULT DEFICIT DISORDER ATTENTION DEFICIT DISORDER	27-APR-2010 12:30:15 Sharon Ladenes	Data Entry Error

Document #: R286410313

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Pcm.6	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.6

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	G M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	GENITO URINARY SYSTEM AND SEX HORMONES, G MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	G02 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	OTHER GYNECOLOGICALS, G02 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	G02C M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	OTHER GYNECOLOGICALS, G02C ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STEROIDS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	G02CC M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	ANTIINFLAMMATORY PRODUCTS FOR VAGINAL ADMINISTRAT., G02CC PROPIONIC ACID DERIVATIVES, M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Dose 1	550 500	12-MAR-2010 17:40:33 Stephanie Felton	Data Entry Error

Document #: R267109113

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Ae	Page_40 40

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

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Adverse Event 1	DIFFICULTY SLEEPING INSOMNIA	05-OCT-2009 14:17:46 Sharon Ladenes	Pass1

Document #: R267109213

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	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 On resequence By	Reason Comment
Adverse Event 1	GUMS BURNING BURNING SENSATION TO GUMS	05-OCT-2009 14:19:07 Sharon Ladenes	Pass1
Ongoing 1	CHECKED	17-DEC-2009 15:45:21 Sharon Ladenes	Pass1

Document #: R293110713

Patient Site	Visit	CRF
R5023	Visit Date	CRF Page
CD_001	Additional Lab	Page_42
		42

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Lb	Page number	42	Additional Lab

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Clinically Significant (additional) (2) 1	NO	09-MAR-2010 12:21:50 Sharon Ladenes	Row Inserted
Comments 1		09-MAR-2010 12:21:50 Sharon Ladenes	Row Inserted
Date 1	28-SEP-2009	09-MAR-2010 12:21:50 Sharon Ladenes	Row Inserted
Requisition Number (additional labs) (4) 1	NA	09-MAR-2010 12:21:50 Sharon Ladenes	Row Inserted
Test Code ID CS Labs only 1		09-MAR-2010 12:21:50 Sharon Ladenes	Row Inserted
Test Name CS Labs only 1		09-MAR-2010 12:21:50 Sharon Ladenes	Row Inserted
Were any additional Laboratory evaluatio 1	NO YES	09-MAR-2010 12:21:50 Sharon Ladenes	Data Entry Error
Clinically Significant (additional) (2) 2		31-JAN-2012 16:10:23 Lindsey Falor	Row Inserted
Clinically Significant (additional) (2) 2	NO	07-FEB-2012 15:42:03 Sharon Ladenes	Data Entry Error
Comments 2		31-JAN-2012 16:10:23 Lindsey Falor	Row Inserted
Date 2		31-JAN-2012 16:10:23 Lindsey Falor	Row Inserted

Document #: R293110713

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Additional Lab	Page_42 42

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	42	Additional Lab

Group #	Group Name
1	LB

Date	07-FEB-2012 15:42:03	Data Entry Error
2	05-OCT-2009	Sharon Ladenes

Requisition Number (additional labs) (4)	31-JAN-2012 16:10:23	Row Inserted
2	Lindsey Falor	

Requisition Number (additional labs) (4)	07-FEB-2012 15:42:03	Data Entry Error
2	B426997 Sharon Ladenes	

Test Code ID CS Labs only	31-JAN-2012 16:10:23	Row Inserted
2	Lindsey Falor	

Test Name CS Labs only	31-JAN-2012 16:10:23	Row Inserted
2	Lindsey Falor	

Clinically Significant (additional) (2)	07-FEB-2012 15:43:04	Row Inserted
3	NO Sharon Ladenes	

Clinically Significant (additional) (2)	20-MAR-2012 13:16:08	Data Entry Error
3	NO Sharon Ladenes	

Clinically Significant (additional) (2)	20-MAR-2012 13:17:15	Data Entry Error
3	<Row Deleted> Sharon Ladenes	

Comments	07-FEB-2012 15:43:04	Row Inserted
3	Sharon Ladenes	

Comments	20-MAR-2012 13:17:15	Data Entry Error
3	<Row Deleted> Sharon Ladenes	

Date	07-FEB-2012 15:43:04	Row Inserted
3	08-FEB-2010 Sharon Ladenes	

Date	20-MAR-2012 13:16:08	Data Entry Error
3	08-FEB-2010 Sharon Ladenes	

Date	20-MAR-2012 13:17:15	Data Entry Error
3	<Row Deleted> Sharon Ladenes	

Document #: R293110713

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Additional Lab	Page_42 42

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	42	Additional Lab

Group #	Group Name
1	LB

Requisition Number (additional labs) (4) 3	S412493	07-FEB-2012 15:43:04 Sharon Ladenes	Row Inserted
Requisition Number (additional labs) (4) 3	S412493	20-MAR-2012 13:16:08 Sharon Ladenes	Data Entry Error
Requisition Number (additional labs) (4) 3	<Row Deleted>	20-MAR-2012 13:17:15 Sharon Ladenes	Data Entry Error
Test Code ID CS Labs only 3		07-FEB-2012 15:43:04 Sharon Ladenes	Row Inserted
Test Code ID CS Labs only 3	<Row Deleted>	20-MAR-2012 13:17:15 Sharon Ladenes	Data Entry Error
Test Name CS Labs only 3		07-FEB-2012 15:43:04 Sharon Ladenes	Row Inserted
Test Name CS Labs only 3	<Row Deleted>	20-MAR-2012 13:17:15 Sharon Ladenes	Data Entry Error

Document #: R293110813

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Additional Vs	Page_43 43

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	43	Additional Vs

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Actual Time 1	1715	09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Body Temperature 1	37.0	09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Body Temperature Unit 1	C	09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Comments (2) 1		09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Date 1	28-SEP-2009	09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Diastolic Blood Pressure 1	69	09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Diastolic Blood Pressure unit 1	MMHG	09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Heart Rate 1	63	09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Heart Rate Unit 1	BEATS/MINUTE	09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Other, specify (1) 1		09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Position (Unscheduled) (2) 1	SEATED	09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Respiratory Rate 1	20	09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted
Respiratory Rate Unit 1	BREATHS/MINUTE	09-MAR-2010 12:22:23 Sharon Ladenes	Row Inserted

Document #: R293110813

Patient Site	Visit Visit Date	CRF CRF Page
R5023 CD_001	Additional Vs	Page_43 43

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	43	Additional Vs

Group #	Group Name
1	VS

Systolic Blood Pressure 1	116	09-MAR-2010 12:22:23	Row Inserted Sharon Ladenes
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Systolic Blood Pressure unit 1	MMHG	09-MAR-2010 12:22:23	Row Inserted Sharon Ladenes
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Were Vital Signs Collected/Were any addi (1) 1	NO YES	09-MAR-2010 12:22:23	Data Entry Error Sharon Ladenes
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Discrepancy Detail Report

Document #: R260787913

Discrepancy ID: 1766230013

Site: CD_001

Patient: R5023

Visit: SCREENING

Visit Date:

CRF: PAGE_09

Section: MH

Qualifying Value: 9

Field: Diagnosis/Procedure

Row: 1

Value Text: DEGENERATIVE DISC C3-C5

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please add location to lines 1 and 2.

Internal Comment:

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

Resolution Text:

Document #: R260793413

Discrepancy ID: 1766230413 **Site:** CD_001 **Patient:** R5023
Visit: BASELINE, WEEK **Visit Date:**
CRF: PAGE_14 **Section:** ECO **Qualifying Value:** 14
Field: %COHb **Row:** 1
Value Text: 1.9
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per source 1.9 vs 1.8.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R265106313

Discrepancy ID: 115224911

Site: CD_001

Patient: R5023

Visit: SPTP, WEEKS 1-4 **Visit Date:**

CRF: PAGE_16

Section: STATUS REVIEW

Qualifying Value: 16.1

Field: Date

Row: 1

Value Text: ND

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please update date to 'ND' as assessment did not occur.

Internal Comment: DM Response: Please replace the comment that was previously present (SUBJECT'S TELEPHONE NUMBER DISCONNECTED).

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

Resolution Text:

Document #: R265106313

Discrepancy ID: 87082511 **Site:** CD_001 **Patient:** R5023
Visit: SPTP, WEEKS 1-4 **Visit Date:**
CRF: PAGE_16 **Section:** STATUS REVIEW **Qualifying Value:** 16A
Field: Was Behavioral Counseling Given **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please provide a response.

Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1766230713 **Site:** CD_001 **Patient:** R5023
Visit: SPTP, WEEKS 1-4 **Visit Date:**
CRF: PAGE_16 **Section:** STATUS REVIEW **Qualifying Value:** 16A
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please delete comments.

Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R265106313

Discrepancy ID: 86549211

Site: CD_001

Patient: R5023

Visit: SPTP, WEEKS 1-4 **Visit Date:**

CRF: PAGE_16

Section: STATUS REVIEW

Qualifying Value: 16B

Field: Was subject reminded about the complete

Row: 1

Value Text: YES

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please provide a response.

Internal Comment:

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

Resolution Text:

Document #: R275391113

Discrepancy ID: 74584211

Site: CD_001

Patient: R5023

Visit: IP, WEEK 8

Visit Date:

CRF: PAGE_21

Section: STATUS REVIEW

Qualifying Value: 21

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please provide a date.

Internal Comment:

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

Resolution Text:

Document #: R282989013

Discrepancy ID: 80570811

Site: CD_001

Patient: R5023

Visit: IP, WEEK 16

Visit Date:

CRF: PAGE_27

Section: LB

Qualifying Value: 27

Field: Were there any clinically significant la

Row: 1

Value Text: NO

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please answer question.

Internal Comment:

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

Resolution Text:

Document #: R260795713

Discrepancy ID: 104320311

Site: CD_001

Patient: R5023

Visit: PCM.1

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Previous query confirmed stop date. Please remove medication (mark page blank).

Internal Comment: done

Resolution Type: Confirmed

Resolution Text: Verified. JLM 27Apr2010

Document #: R286410013

Discrepancy ID: 80642511

Site: CD_001

Patient: R5023

Visit: PCM.5

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Stop Date

Row: 1

Value Text:

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review source progress note dated 11Jan10. Verify if this med is still being taken.

Internal Comment: Updated CRF, verified source.

Resolution Type: Confirmed

Resolution Text:

Document #: R286410313

Discrepancy ID: 80646611

Site: CD_001

Patient: R5023

Visit: PCM.6

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Dose

Row: 1

Value Text: 500

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please see source update for dose. Please revise CRF page.

Internal Comment: Updated CRF, verified source.

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

Resolution Text:

Document #: R293110713

Discrepancy ID: 476769911

Site: CD_001

Patient: R5023

Visit: ADDITIONAL LAB

Visit Date:

CRF: PAGE_42

Section: LB

Qualifying Value: 42

Field: Date

Row: 2

Value Text: 20091005

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Covance Clinical Laboratory Services has a requisition form for subject R5023, collection on 05-Oct-2009. As per previous correspondence with study manager, lab manager and sponsor approval please use corresponding requisition form as source to update the database accordingly.

Internal Comment: updated

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

Resolution Text: Updated, LCF 20Mar2012.

Deleted CRFs Report