

CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 15:08:56

Report Parameters

Site: CP_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R3031

Ending patient: R3031

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="text" value="NO"/>
<input type="checkbox"/> 02 The subject is a female who is pregnant or lactating.	<input type="text" value="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="text" value="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="text" value="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="text" value="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="text" value="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="text" value="NO"/>
<input type="checkbox"/> 08 Use of any illicit drug or smoked marijuana in the last 3 months	<input type="text" value="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="text" value="NO"/>
<input type="checkbox"/> 10 The subject resides in a household where another member is currently participating in the study.	<input type="text" value="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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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="06-MAY-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="66.0"/>

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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	125
Diastolic Blood Pressure	MMHG	079
Heart Rate	BEATS/MINUTE	055
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.5
Weight	LB	161.2

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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: 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

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

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

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Protocol Number: SM 08-01

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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="06-MAY-2009"/>	<input type="text" value="11:38"/>
	<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

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Visit Name

Subject Number

Subject Initials

Is Blank

Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

Sequence No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
				<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
				<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="15"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="15"/>	
Has subject used smokeless tobacco in the past?	<input checked="" type="checkbox"/> Yes <input 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="1"/>	NICOTINE PATCH FOR 3 WEEKS
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 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 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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	

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Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
06-MAY-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
06-MAY-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
06-MAY-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
06-MAY-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
06-MAY-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
19-MAY-2009	12:54	019	3.60	

Behavioral Counseling

Date	Parameter	Result	Comments
19-MAY-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="4"/> logs
1.0 g of snus or matching placebo	<input type="text" value="2"/> 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="26-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="49"/>	<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="02-JUN-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="49"/>	<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="10-JUN-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="28"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="16-JUN-2009"/>	<input type="text" value="WEEK 4"/>	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="21"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject reminded about the complete switch from cigarettes no later than the first day of Week 5?	<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		
Diastolic Blood Pressure		
Heart Rate		
Respiratory Rate		
Body Temperature		
Weight		

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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

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"/>
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Note: Attach copy of signed laboratory report.

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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

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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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

Status Review

Date	Parameter	Result	Comments
<input type="text"/>	Was Subject contacted by telephone?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	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"/>
	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 Behavioral Counseling Given?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_21 (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

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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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

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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Links to Discrepancy and Audit Sections

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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"/> 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's use of study product 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="18-AUG-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="7"/>	<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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text" value="SUBJECT HAD NOT BEEN USI"/>

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

Document Number

OverFlow Section For Document Number R266119113

1 SUBJECT HAD NOT BEEN USING PRODUCT FOR 14 DAYS AT VISIT

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

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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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.

Verified Approved Locked Frozen

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
<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_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
<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?
FTND	<input type="checkbox"/> Yes <input type="checkbox"/> No
MNWS	<input 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"/>	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"/>
	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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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="28"/>	<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="21"/>	<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_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	138
Diastolic Blood Pressure	MMHG	87
Heart Rate	BEATS/MINUTE	78
Respiratory Rate	BREATHS/MINUTE	14
Body Temperature	C	37.1
Weight	LB	164.2

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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.

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

[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
24-NOV-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
24-NOV-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
24-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
24-NOV-2009	10:36	14	2.8	

Behavioral Counseling

Date	Parameter	Result	Comments
24-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

Verified Approved Locked Frozen

Page Version No. PAGE_37 (v1, 31-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

Status Review

Date	Parameter	Result	Comments
<input type="text" value="24-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="21"/>	<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

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

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](#)

[Click here to navigate to discrepancy details 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.

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](#)

[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

Links to Discrepancy and Audit Sections

[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

Links to Discrepancy and Audit Sections

[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

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

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](#)

[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 - 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"/>

Verified Approved Locked Frozen

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
16-JUL-2009	NA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			WEEK 6 LABS DRAWN G
		<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			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

OverFlow Section For Document Number R281646513

1 WEEK 6 LABS DRAWN OUT OF WINDOW

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

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	134
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	089
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	067
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	16
	Body Temperature	C	36.9

Comments

Date Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	136
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	078
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	061
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	14
	Body Temperature	C	36.7

Comments

Verified Approved Locked Frozen

Page Version No. PAGE_43 (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

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

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

Document Number

Links to Discrepancy and Audit Sections

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

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 #: R250012813

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_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
Were there any clinically significant la (1) 1	NO	27-AUG-2009 20:31:22 Tricia Hunt	Data Entry Error

Document #: R266117413

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ip, Week 6	Page_17 17

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	18-MAR-2010 18:09:11 Tricia Hunt	Data Entry Error

Document #: R266117513

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ip, Week 6	Page_18 18

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	18-MAR-2010 18:10:09 Tricia Hunt	Data Entry Error

Document #: R266117513

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ip, Week 6	Page_18 18

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	18	Ip, Week 6

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	11-JUL-2009 16-JUL-2009	11-MAR-2010 13:29:31 Tricia Hunt	Data Entry Error

Document #: R266117613

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ip, Week 6	Page_19 19

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	18-MAR-2010 18:10:30 Tricia Hunt	Data Entry Error

Document #: R266117813

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ip, Week 6	Page_20 20

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	18-MAR-2010 18:10:57 Tricia Hunt	Data Entry Error

Document #: R266117913

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ip, Week 8	Page_21 21

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	18-MAR-2010 18:23:21 Tricia Hunt	Data Entry Error

Document #: R266118613

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ip, Week 10	Page_22 22

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	18-MAR-2010 18:40:16 Tricia Hunt	Data Entry Error

Document #: R266118813

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ip, Week 10	Page_23 23

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	18-MAR-2010 18:40:30 Tricia Hunt	Data Entry Error

Document #: R266119013

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ip, Week 10	Page_24 24

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	18-MAR-2010 18:40:39 Tricia Hunt	Data Entry Error

Document #: R266119113

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ip, Week 13	Page_25 25

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	25	Ip, Week 13

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments (contacted by phone) (1) 1	MISSED VISIT DUE TO VISIT WINDOW INFORMATION FROM WEEK 10 VISIT ENTERED.	18-MAR-2010 18:37:16 Tricia Hunt	Data Entry Error
Comments (contacted by phone) (1) 1	INFORMATION FROM WEEK 10 VISIT ENTERED.	20-MAR-2010 12:40:12 Tricia Hunt	Data Entry Error
Comments (cut down) (9) 1	SUBJECT HAD NOT BEEN USING PRODUCT FOR 14 DAYS AT VISIT	18-MAR-2010 18:37:16 Tricia Hunt	Data Entry Error
If Subject was not compliant, approximat (5) 1	7	18-MAR-2010 18:37:16 Tricia Hunt	Data Entry Error
Was Behavioral Counseling Given (6) 1	YES	18-MAR-2010 18:37:16 Tricia Hunt	Data Entry Error
Was Subject asked HDYF? (8) 1	YES	18-MAR-2010 18:37:16 Tricia Hunt	Data Entry Error
Was Subject compliant (4) 1	NO	18-MAR-2010 18:37:16 Tricia Hunt	Data Entry Error
Was Subject contacted by telephone (1) 1	NO YES	20-MAR-2010 12:40:12 Tricia Hunt	Data Entry Error
Was Subject's smoking status reviewed (2) 1	YES	18-MAR-2010 18:37:16 Tricia Hunt	Data Entry Error
Was Subject's use of study product review (3) 1	YES	18-MAR-2010 18:37:16 Tricia Hunt	Data Entry Error

Document #: R266119113

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ip, Week 13	Page_25 25

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	25	Ip, Week 13

Group #	Group Name
1	CHKYN

Was subject instructed to cut down on pr (9) 1	NO	18-MAR-2010 18:37:16 Tricia Hunt	Data Entry Error
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Document #: R281641413

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Fu, Week 28	Page_37 37

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eco	Page number	37	Fu, Week 28

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
%COHb 1	208 2.8	03-AUG-2010 12:47:15 Linda Jordan	Data Entry Error

Document #: R281641713

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Fu, Week 28	Page_38 38

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	38	Fu, Week 28

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	3 21	19-FEB-2010 10:02:23 Tricia Hunt	Data Entry Error

Document #: R266119313

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_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
Drug name 1	AMOXICILLAN AMOXICILLIN	19-FEB-2010 10:06:15 Tricia Hunt	Data Entry Error
Frequency 1	OTHER THREE TIMES DAILY	20-APR-2010 16:22:38 Tricia Hunt	Data Entry Error
Indication 1	DENTAL PAIN LOWER LEFT MOLAR PAIN	23-NOV-2009 13:11:18 Marilyn Mindolovich	Data Entry Error
Ongoing 1	CHECKED	24-NOV-2009 15:03:51 Marilyn Mindolovich	Investigator Correction
Stop Date 1	20-AUG-2009	24-NOV-2009 15:03:51 Marilyn Mindolovich	Investigator Correction
other, specify (frequency) 1	EVERY 8 HOURS	20-APR-2010 16:22:38 Tricia Hunt	Data Entry Error

Document #: R266119413

Patient Site	Visit Visit Date	CRF CRF Page
R3031	Pcm.1	Page_39
CP_001		

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	R	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC1 Text 1	RESPIRATORY SYSTEM, R	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Code 1	R05	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Text 1	COUGH AND COLD PREPARATIONS, R05	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Code 1	R05D	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Text 1	COUGH SUPPRESSANTS EXCL. COMB. WITH EXPECTORANTS, R05D	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Code 1	R05DA	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Text 1	OPIUM ALKALOIDS AND DERIVATIVES, R05DA	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Dose 1	5/500 1	24-APR-2010 10:29:59 Tricia Hunt	Data Entry Error
Indication 1	DENTAL PAIN LEFT LOWER MOLAR PAIN	23-NOV-2009 13:20:11 Marilyn Mindolovich	Investigator Correction
Preferred Term 1	PROCET /01554201/	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Preferred Term Code 1	01554201001	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name 1	HYDROCODONE W/APAP	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name Code 1	01554201003	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change

Document #: R266119413

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_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

Unit	MILLIGRAMS	24-APR-2010 10:29:59	Data Entry Error
1	TABLET	Tricia Hunt	

Document #: R253410913

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	Ae.2	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.2

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Ongoing 1	CHECKED	10-NOV-2009 16:05:02 Marilyn Mindolovich	Investigator Correction
Outcome to Date 1	CONT WITHOUT TREATMENT RECOVERED	11-FEB-2010 14:11:54 Tricia Hunt	Data Entry Error
Resolved Date 1	UNKSEP2009	10-NOV-2009 16:05:02 Marilyn Mindolovich	Investigator Correction
Resolved Date 1	UNKSEP2009 00-SEP-2009	11-FEB-2010 14:11:54 Tricia Hunt	Data Entry Error Time and Day resolved are UNK. Information is correct per source.
Resolved Time 1	UNK	10-NOV-2009 16:05:02 Marilyn Mindolovich	Investigator Correction

Document #: R303660413

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_001	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
High Level Group Term 1	DENTAL AND GINGIVAL CONDITIONS	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Group Term Code 1	10044018	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Term 1	DENTAL PAIN AND SENSATION DISORDERS	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Term Code 1	10044049	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Lower Level Term 1	TOOTH PAIN	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Lower Level Term Code 1	10059723	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Preferred Term 1	TOOTHACHE	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Preferred Term Code 1	10044055	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
System Organ Class 1	GASTROINTESTINAL DISORDERS	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
System Organ Class Code 1	10017947	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change

Document #: R281646513

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_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

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Clinically Significant (additional) (2) 1	NO		18-MAR-2010 18:08:07 Tricia Hunt	Row Inserted
Comments 1	WEEK 6 LABS DRAWN OUT OF WINDOW		18-MAR-2010 18:08:07 Tricia Hunt	Row Inserted
Date 1	16-JUL-2009		18-MAR-2010 18:08:07 Tricia Hunt	Row Inserted
Requisition Number (additional labs) (4) 1	NA		18-MAR-2010 18:08:07 Tricia Hunt	Row Inserted
Test Code ID CS Labs only 1			18-MAR-2010 18:08:07 Tricia Hunt	Row Inserted
Test Name CS Labs only 1			18-MAR-2010 18:08:07 Tricia Hunt	Row Inserted
Were any additional Laboratory evaluatio 1	NO YES		18-MAR-2010 18:08:07 Tricia Hunt	Data Entry Error

Document #: R281646713

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_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	1100	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Body Temperature 1	36.9	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Body Temperature Unit 1	C	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Comments (2) 1	WEEK 6 VITALS COMPLETED OUT OUT OF VISIT WINDOW.	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Date 1	16-JUL-2009	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Diastolic Blood Pressure 1	089	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Diastolic Blood Pressure unit 1	MMHG	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Heart Rate 1	067	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Heart Rate Unit 1	BEATS/MINUTE	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Other, specify (1) 1		18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Position (Unscheduled) (2) 1	SEATED	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Respiratory Rate 1	16	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Respiratory Rate Unit 1	BREATHS/MINUTE	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted

Document #: R281646713

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_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	134	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Systolic Blood Pressure unit 1	MMHG	18-MAR-2010 18:06:24 Tricia Hunt	Row Inserted
Were Vital Signs Collected/Were any addi (1) 1	NO YES	18-MAR-2010 18:06:24 Tricia Hunt	Data Entry Error
Actual Time 2	1325	18-MAR-2010 18:40:54 Tricia Hunt	Row Inserted
Body Temperature 2	36.7	18-MAR-2010 18:40:54 Tricia Hunt	Row Inserted
Body Temperature Unit 2	C	18-MAR-2010 18:40:54 Tricia Hunt	Row Inserted
Comments (2) 2	WEEK 10 VISIT COMPLETED OUT OF WINDOW	18-MAR-2010 18:40:54 Tricia Hunt	Row Inserted
Date 2	18-AUG-2009	18-MAR-2010 18:40:54 Tricia Hunt	Row Inserted
Diastolic Blood Pressure 2	078	18-MAR-2010 18:40:54 Tricia Hunt	Row Inserted
Diastolic Blood Pressure unit 2	MMHG	18-MAR-2010 18:40:54 Tricia Hunt	Row Inserted
Heart Rate 2	061	18-MAR-2010 18:40:54 Tricia Hunt	Row Inserted
Heart Rate Unit 2	BEATS/MINUTE	18-MAR-2010 18:40:54 Tricia Hunt	Row Inserted
Other, specify (1) 2		18-MAR-2010 18:40:54 Tricia Hunt	Row Inserted
Position (Unscheduled) (2) 2	SEATED	18-MAR-2010 18:40:54 Tricia Hunt	Row Inserted

Document #: R281646713

Patient Site	Visit Visit Date	CRF CRF Page
R3031 CP_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

Respiratory Rate 2	14	18-MAR-2010 18:40:54	Row Inserted Tricia Hunt
Respiratory Rate Unit 2	BREATHS/MINUTE	18-MAR-2010 18:40:54	Row Inserted Tricia Hunt
Systolic Blood Pressure 2	136	18-MAR-2010 18:40:54	Row Inserted Tricia Hunt
Systolic Blood Pressure unit 2	MMHG	18-MAR-2010 18:40:54	Row Inserted Tricia Hunt

Document #: R281647413

Patient Site	Visit Visit Date	CRF CRF Page	
R3031 CP_001	Study Competition	Page_46 46	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ds	Page number	46	Study Competition

Group #	Group Name
1	DS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Reason for withdrawal 1	NA	24-NOV-2009 15:11:12 Marilyn Mindolovich	Investigator Correction

Discrepancy Detail Report

Document #: R250012813

Discrepancy ID: 1683124413 Site: CP_001 Patient: R3031
Visit: SCREENING Visit Date:
CRF: PAGE_07 Section: LB Qualifying Value: 7
Field: Were there any clinically significant la Row: 1
Value Text: NO
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please answer this question.

Internal Comment:

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

Resolution Text:

Document #: R266119113

Discrepancy ID: 86037811 **Site:** CP_001 **Patient:** R3031
Visit: IP, WEEK 13 **Visit Date:**
CRF: PAGE_25 **Section:** STATUS REVIEW **Qualifying Value:** 25
Field: Comments (contacted by phone) **Row:** 1

Value Text:

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Date recorded (18-Aug-2009) is the date the visit was scheduled for, and the same date recorded for the Week 10 visit. Please remove existing data and transcribe status review data from Week 10 to here (Week 13).

Internal Comment: DM Response: These data are inconsistent. How were responses provided if subject was not contacted? Please remove comment in question 1 and update response to Yes. The date the assessment occurred corresponds to Week 13. It was recorded in Week 10 in error. The data in week 10 should have been transcribed exactly to week 13 as that is the timeframe in which the assessment occurred.
The subject completed the week 10 visit on this day rather than the phone contact. I will remove the comment, please advise if further steps are to be taken.
DM Response: If subject completed visit in person rather than via telephone, please check No for question 1 and add comment 'Assessment occurred in person'.

Resolution Type: No Action Required

Resolution Text:

Document #: R281640613

Discrepancy ID: 76429911

Site: CP_001

Patient: R3031

Visit: FU, WEEK 28

Visit Date:

CRF: PAGE_34

Section: LB

Qualifying Value: 34

Field: Were there any clinically significant la

Row: 1

Value Text:

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please provide a response.

Internal Comment: No labs were obtained. This entry would not be valid.

Resolution Type: No Action Required

Resolution Text:

Document #: R281641413

Discrepancy ID: 181060611 **Site:** CP_001 **Patient:** R3031
Visit: FU, WEEK 28 **Visit Date:**
CRF: PAGE_37 **Section:** ECO **Qualifying Value:** 37
Field: %COHb **Row:** 1
Value Text: 2.8
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify/update COHB% value.
Internal Comment: corrected
Resolution Type: Confirmed
Resolution Text: Verified. JLM 03Aug2010

Document #: R266119313

Discrepancy ID: 1796615113 **Site:** CP_001 **Patient:** R3031
Visit: PCM **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Drug name **Row:** 1
Value Text: AMOXICILLIN
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please correct spelling from amoxicillan to amoxicillin.

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

Discrepancy ID: 98544911 **Site:** CP_001 **Patient:** R3031
Visit: PCM **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Indication **Row:** 1
Value Text: LOWER LEFT MOLAR PAIN
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: There is not event of molar pain. Please verify and add adverse event 'molar pain.'

Internal Comment: AE was added, however, the subject had the tooth extracted sameday which ended the AE, the Con med contiued for 7 days. Please advise.
Resolution Type: Confirmed
Resolution Text: Verified. JLM 21Apr2010

Discrepancy ID: 98545011 **Site:** CP_001 **Patient:** R3031
Visit: PCM **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: other, specify (frequency) **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify if this would be best represented as 3 times daily.

Internal Comment: Updated
Resolution Type: Confirmed
Resolution Text: Verified. JLM 21Apr2010

Document #: R266119413

Discrepancy ID: 106996411 **Site:** CP_001 **Patient:** R3031
Visit: PCM.1 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Dose **Row:** 1
Value Text: 1
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Combination drugs should be entered as # of tablets taken. Please update dose and units.
Internal Comment: Updated.
Resolution Type: Confirmed
Resolution Text: Verfied. JLM 26Apr2010

Discrepancy ID: 1796614613 **Site:** CP_001 **Patient:** R3031
Visit: PCM.1 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Indication **Row:** 1
Value Text: LEFT LOWER MOLAR PAIN
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please change indication to match AE terminology. please change for amonxicillin too.
Internal Comment:
Resolution Type: No Action Required
Resolution Text:

Document #: R253410913

Discrepancy ID: 63686811 **Site:** CP_001 **Patient:** R3031
Visit: AE.2 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Resolved Date **Row:** 1
Value Text: 200909
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value of 00-SEP-2009 for Resolved Date is an incomplete date or time
Internal Comment: Time and Day resolved are UNK. Information is correct per source.
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 71442511 **Site:** CP_001 **Patient:** R3031
Visit: AE.2 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: **Row:**
Value Text:
Type: MULTIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Outcome to Date is equal to RECOVERED for PHARYNGITIS but Resolved Date and/or Time are missing. Please reconcile.
Internal Comment: Resolved date and time are complete per source.
Resolution Type: No Action Required
Resolution Text:

Discrepancy ID: 71438411 **Site:** CP_001 **Patient:** R3031
Visit: AE.2 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: **Row:**
Value Text:
Type: MULTIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Resolved Date and Time is missing and Ongoing is null for Adverse Event <PHARYNGITIS>. Please either provide resolved date and time OR check Ongoing.
Internal Comment: Resolved date and time are complete per source.
Resolution Type: No Action Required
Resolution Text:

Deleted CRFs Report