

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 16:02:52

Report Parameters

Site: L0689282_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2022

Ending patient: R2022

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

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

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

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

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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="18-JUN-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="067.3"/>

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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	110
Diastolic Blood Pressure	MMHG	073
Heart Rate	BEATS/MINUTE	083
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.7
Weight	LB	163.6

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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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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	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Least 5 Minutes?	<input type="text" value="18-JUN-2009"/>	<input type="text" value="11:01"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

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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

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
01	OCCASIONAL URINARY TRACT INFECTION	00-00-1978		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<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="43"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="20"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="1"/>	PATCH
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"/>	CHANTIX
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="1"/>	COLD TURKEY

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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

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Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

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

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
29-JUN-2009	12:22	17	3.3	

Behavioral Counseling

Date	Parameter	Result	Comments
29-JUN-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="10"/> logs
1.0 g of snus or matching placebo	<input type="text" value="6"/> 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

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="09-JUL-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="35"/>	<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="17-JUL-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="14"/>	<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="24-JUL-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="21"/>	<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="31-JUL-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="28"/>	<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	MMHG	139
Diastolic Blood Pressure	MMHG	093
Heart Rate	BEATS/MINUTE	087
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	36.6
Weight	LB	173.6

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
14-AUG-2009	10:39	10	2.2	

Behavioral Counseling

Date	Parameter	Result	Comments
14-AUG-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="3"/> 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="14-AUG-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="28"/>	<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
26-AUG-2009	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="14"/>	
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

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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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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'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"/>	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"/>
	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 type="checkbox"/> No	<input type="text"/>

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

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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

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

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

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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

Document Number

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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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

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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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

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 Scheduled Timepoint

Parameter	Result	Comments
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 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"/>

Date Scheduled Timepoint

Parameter	Result	Comments
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 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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[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

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	157
Diastolic Blood Pressure	MMHG	094
Heart Rate	BEATS/MINUTE	087
Respiratory Rate	BREATHS/MINUTE	14
Body Temperature	C	36.7
Weight	LB	179.4

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
11-FEB-2010	11:01	21	3.9	

Behavioral Counseling

Date	Parameter	Result	Comments
11-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

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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" value="11-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="63"/>	<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](#)

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

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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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

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

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

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

Action Taken: Select only one

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

Outcome to Date Select only one

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

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

Document Number

Links to Discrepancy and Audit Sections

[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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 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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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
20-NOV-2009	NA	<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			
		<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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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	139
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	088
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	ND
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	ND
	Body Temperature	C	ND

Comments

Date Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	146
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	088
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	085
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	20
	Body Temperature	C	36.7

Comments

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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 - 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	086
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	092
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	20
	Body Temperature	C	36.7

Comments

Date Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	157
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	094
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	087
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	14
	Body Temperature	C	36.7

Comments

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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
20-NOV-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
20-NOV-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
20-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_45 (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

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.

Verified Approved Locked Frozen

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

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

Investigator Comments (if none, leave blank):

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

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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 #: R264437813

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Date of Onset 1	00-00-1978		12-APR-2010 12:34:35 Amanda Lynn	Row Inserted
Date of Resolution 1			12-APR-2010 12:34:35 Amanda Lynn	Row Inserted
Diagnosis/Procedure 1	URINARY TRACT INFECTION		12-APR-2010 12:34:35 Amanda Lynn	Row Inserted
Diagnosis/Procedure 1	URINARY TRACT INFECTION OCCASIONAL URINARY TRACT INFECTION		20-APR-2010 13:24:29 Amanda Lynn	Data Entry Error
Does the subject have any relevant medication 1	NO YES		12-APR-2010 12:34:35 Amanda Lynn	Data Entry Error
Ongoing 1	CHECKED		12-APR-2010 12:34:35 Amanda Lynn	Row Inserted
Sequence Number 1	01		12-APR-2010 12:34:35 Amanda Lynn	Row Inserted

Document #: R264407213

Patient Site	Visit Visit Date	CRF CRF Page	
R2022 L0689282_2	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	6 3.3	17-AUG-2009 12:06:17 Amanda Lynn	Data Entry Error
Actual Time 1	1252 1222	17-AUG-2009 12:06:17 Amanda Lynn	Data Entry Error
ECO Level 1	10 17	17-AUG-2009 12:06:17 Amanda Lynn	Data Entry Error

Document #: R264408513

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 6	Page_20 20

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	20	Ip, Week 6

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	20 28	23-OCT-2009 15:06:18 Cindy Riojas Prakop	Data Entry Error

Document #: R271125113

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 10	Page_22 22

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	10-MAR-2010 10:14:56 Amanda Lynn	Data Entry Error

Document #: R271125713

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 10	Page_23 23

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	10-MAR-2010 10:15:07 Amanda Lynn	Data Entry Error

Document #: R271125913

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 10	Page_24 24

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

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	10-MAR-2010 10:15:19 Amanda Lynn	Data Entry Error

Document #: R271125913

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 10	Page_24 24

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
If Subject was not compliant, approximat (5) 1	56 42	14-DEC-2009 12:01:05 Amanda Lynn	Data Entry Error

Document #: R274800813

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 13	Page_25 25

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	10-MAR-2010 10:24:28 Amanda Lynn	Data Entry Error

Document #: R284400613

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 16	Page_26 26

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-FEB-2010 17:05:12 Amanda Lynn	Data Entry Error

Document #: R284400813

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 16	Page_27 27

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-FEB-2010 17:05:23 Amanda Lynn	Data Entry Error

Document #: R284400913

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 16	Page_28 28

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-FEB-2010 17:05:28 Amanda Lynn	Data Entry Error

Document #: R284401013

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 16	Page_29 29

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-FEB-2010 17:05:34 Amanda Lynn	Data Entry Error

Document #: R284401113

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 16	Page_30 30

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-FEB-2010 17:05:39 Amanda Lynn	Data Entry Error

Document #: R284401213

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Ip, Week 16	Page_31 31

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-FEB-2010 17:05:45 Amanda Lynn	Data Entry Error

Document #: R283610913

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 20 & 24	Page_32 32

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	10-MAR-2010 10:25:15 Amanda Lynn	Data Entry Error

Document #: R283610913

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 20 & 24	Page_32 32

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	32	Fu, Week 20 & 24

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments (contacted by phone) (1) 1	CALL WAS OUT OF WINDOW DUE TO SUBJECT SCHEDULE	19-FEB-2010 10:21:32 Amanda Lynn	Data Entry Error

Document #: R283610913

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 20 & 24	Page_32 32

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	32.1	Fu, Week 20 & 24

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments (contacted by phone) (1) 1	CALL WAS OUT OF WINDOW DUE TO SUBJECT SCHEDULE	19-FEB-2010 10:21:32 Amanda Lynn	Data Entry Error

Document #: R293518113

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_33 33

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-FEB-2010 17:05:58 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	10-MAR-2010 10:16:09 Amanda Lynn	Data Entry Error

Document #: R293518113

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_33 33

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	33	Fu, Week 28

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Actual Time 1	1049	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Body Temperature 1	36.7	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Body Temperature Unit 1	C	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Date 1	11-FEB-2010	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Diastolic Blood Pressure 1	094	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Diastolic Blood Pressure unit 1	MMHG	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Heart Rate 1	087	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Heart Rate Unit 1	BEATS/MINUTE	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Respiratory Rate 1	14	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Respiratory Rate Unit 1	BREATHS/MINUTE	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Systolic Blood Pressure 1	157	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Systolic Blood Pressure unit 1	MMHG	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted
Was subject seated for 5 Minutes? (2) 1	YES	10-MAR-2010 10:16:09 Amanda Lynn	Row Inserted

Document #: R293518113

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_33 33

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	33	Fu, Week 28

Group #	Group Name
1	VS

Weight	10-MAR-2010 10:16:09	Row Inserted
1	179.4	Amanda Lynn

Weight Unit	10-MAR-2010 10:16:09	Row Inserted
1	LB	Amanda Lynn

Were Vital Signs Collected/Were any addi (1)	10-MAR-2010 10:16:09	Row Inserted
1	YES	Amanda Lynn

Document #: R293518713

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_34 34

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-FEB-2010 17:06:31 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	10-MAR-2010 10:17:55 Amanda Lynn	Data Entry Error

Document #: R293518713

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_34 34

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	34	Fu, Week 28

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Date 1	11-FEB-2010		10-MAR-2010 10:17:55 Amanda Lynn	Row Inserted
No (Specify samples not done, reason)/Co 1			10-MAR-2010 10:17:55 Amanda Lynn	Row Inserted
Requisition Number 1: (1) 1	NA		10-MAR-2010 10:17:55 Amanda Lynn	Row Inserted
Requisition Number 2 (if applicable): (2) 1			10-MAR-2010 10:17:55 Amanda Lynn	Row Inserted
Requisition Number 3 (if applicable): (3) 1			10-MAR-2010 10:17:55 Amanda Lynn	Row Inserted
Were the scheduled laboratory samples ob 1	YES		10-MAR-2010 10:17:55 Amanda Lynn	Row Inserted
Were there any clinically significant la (1) 1	NO		10-MAR-2010 10:17:55 Amanda Lynn	Row Inserted

Document #: R293518813

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_35 35

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-FEB-2010 17:06:36 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	10-MAR-2010 10:18:23 Amanda Lynn	Data Entry Error

Document #: R293518813

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_35 35

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Oral Health Exam	Page number	35	Fu, Week 28

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Date 1	11-FEB-2010		10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted
Findings 1			10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted
Findings* 1	NO		10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted
Procedure 1	EVIDENCE OF LEUKOPLAKIA		10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted
Date 2	11-FEB-2010		10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted
Findings 2			10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted
Findings* 2	NO		10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted
Procedure 2	EXPOSED DENTAL CERVICES IN UPPER SULCUS?		10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted
Date 3	11-FEB-2010		10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted
Findings 3			10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted
Findings* 3	NO		10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted
Procedure 3	OTHER ORAL KERATOSIS		10-MAR-2010 10:18:23 Amanda Lynn	Row Inserted

Document #: R293519213

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_36 36

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-FEB-2010 17:06:42 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	10-MAR-2010 10:18:48 Amanda Lynn	Data Entry Error

Document #: R293519213

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_36 36

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	36	Fu, Week 28

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does the subject have any abnormal findi 1	NO	10-MAR-2010 10:18:48 Amanda Lynn	Row Inserted

Document #: R293519313

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_37 37

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-FEB-2010 17:06:47 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	10-MAR-2010 10:19:03 Amanda Lynn	Data Entry Error

Document #: R293519313

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	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 resequence	On By	Reason Comment
%COHb 1	3.9		10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted
Actual Time 1	1101		10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted
Comments 1			10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted
Date 1	11-FEB-2010		10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted
ECO Level 1	21		10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted
ECO unit 1	PPM		10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted

Document #: R293519313

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_37 37

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

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Comments 1			10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted
Date 1	11-FEB-2010		10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted
Parameter 1	WAS BEHAVIORAL COUNSELING GIVEN?		10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted
Result 1	YES		10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted

Document #: R293519313

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_37 37

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

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	11-FEB-2010	10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted
FTND 1	YES	10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted
MNWS 1	YES	10-MAR-2010 10:19:03 Amanda Lynn	Row Inserted

Document #: R293519513

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Fu, Week 28	Page_38 38

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-FEB-2010 17:06:54 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	10-MAR-2010 10:19:38 Amanda Lynn	Data Entry Error

Document #: R293519513

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	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 resequence	On By	Reason Comment
Comments (HDYF) (8) 1			10-MAR-2010 10:19:38 Amanda Lynn	Row Inserted
Comments (compliant) (4) 1			10-MAR-2010 10:19:38 Amanda Lynn	Row Inserted
Comments (how many cigarettes) (5) 1			10-MAR-2010 10:19:38 Amanda Lynn	Row Inserted
Comments (smoking status reviewed) (2) 1			10-MAR-2010 10:19:38 Amanda Lynn	Row Inserted
Date 1	11-FEB-2010		10-MAR-2010 10:19:38 Amanda Lynn	Row Inserted
If Subject was not compliant, approximat (5) 1	63		10-MAR-2010 10:19:38 Amanda Lynn	Row Inserted
Was Subject asked HDYF? (8) 1	YES		10-MAR-2010 10:19:38 Amanda Lynn	Row Inserted
Was Subject compliant (4) 1	NO		10-MAR-2010 10:19:38 Amanda Lynn	Row Inserted
Was Subject's smoking status reviewed (2) 1	YES		10-MAR-2010 10:19:38 Amanda Lynn	Row Inserted

Document #: R264409113

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	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	J	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC1 Text 1	ANTIINFECTIVES FOR SYSTEMIC USE, J	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Code 1	J01	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Text 1	ANTIBACTERIALS FOR SYSTEMIC USE, J01	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Code 1	J01X	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Text 1	OTHER ANTIBACTERIALS, J01X	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Code 1	J01XE	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Text 1	NITROFURAN DERIVATIVES, J01XE	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Preferred Term 1	NITROFURANTOIN	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Preferred Term Code 1	00024401001	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name 1	MACROBID /00024401/	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name Code 1	00024401041	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Unit 1	TABLET OTHER	02-SEP-2009 12:11:49 Amanda Lynn	Data Entry Error
other, specify (unit) 1	CAPSULE	02-SEP-2009 12:11:49 Amanda Lynn	Data Entry Error

Document #: R283611213

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Pcm.2	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	R	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC1 Text 1	RESPIRATORY SYSTEM, R	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Code 1	R05	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Text 1	COUGH AND COLD PREPARATIONS, R05	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Code 1	R05D	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Text 1	COUGH SUPPRESSANTS EXCL. COMB. WITH EXPECTORANTS, R05D	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Code 1	R05DB	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Text 1	OTHER COUGH SUPPRESSANTS, R05DB	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Drug Modified Reported Term 1	BENZONDATATE BENZONATATE	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	BENZONDATATE BENZONATATE	09-APR-2010 15:10:22 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 09Apr2010
Preferred Term 1	BENZONATATE	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Preferred Term Code 1	00097401001	20-APR-2010 11:39:56 Carol Kraucyk	Data Change

Document #: R283611813

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	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 J	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A ANTIINFECTIVES FOR SYSTEMIC USE, J	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	A01 J01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANTIBACTERIALS FOR SYSTEMIC USE, J01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	A01A J01X	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A OTHER ANTIBACTERIALS, J01X	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	A01AB J01XD	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Text 1	ANTIINFECT. AND ANTISEPT. FOR LOCAL ORAL TREATMENT, A01AB IMIDAZOLE DERIVATIVES, J01XD	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change

Document #: R293519813

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	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 On resequence By	Reason Comment
Clinically Significant (additional) (2) 1	NO	18-FEB-2010 10:51:03 Amanda Lynn	Row Inserted
Comments 1		18-FEB-2010 10:51:03 Amanda Lynn	Row Inserted
Date 1	20-NOV-2009	18-FEB-2010 10:51:03 Amanda Lynn	Row Inserted
Requisition Number (additional labs) (4) 1	NA	18-FEB-2010 10:51:03 Amanda Lynn	Row Inserted
Test Code ID CS Labs only 1		18-FEB-2010 10:51:03 Amanda Lynn	Row Inserted
Test Name CS Labs only 1		18-FEB-2010 10:51:03 Amanda Lynn	Row Inserted
Were any additional Laboratory evaluatio 1	NO YES	18-FEB-2010 10:50:21 Amanda Lynn	Data Entry Error
Clinically Significant (additional) (2) 2	NO	18-FEB-2010 10:51:03 Amanda Lynn	Row Inserted
Clinically Significant (additional) (2) 2	NO	10-MAR-2010 10:21:01 Amanda Lynn	Data Entry Error
Clinically Significant (additional) (2) 2	<Row Deleted>	24-MAR-2010 15:28:41 Krysia Magnuson	Data Entry Error
Comments 2		18-FEB-2010 10:51:03 Amanda Lynn	Row Inserted

Document #: R293519813

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	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

Comments		24-MAR-2010 15:28:41	Data Entry Error
2	<Row Deleted>	Kryisia Magnuson	
Date		18-FEB-2010 10:51:03	Row Inserted
2	11-FEB-2009	Amanda Lynn	
Date		10-MAR-2010 10:21:01	Data Entry Error
2	11-FEB-2009	Amanda Lynn	
Date		24-MAR-2010 15:28:41	Data Entry Error
2	<Row Deleted>	Kryisia Magnuson	
Requisition Number (additional labs) (4)		18-FEB-2010 10:51:03	Row Inserted
2	NA	Amanda Lynn	
Requisition Number (additional labs) (4)		10-MAR-2010 10:21:01	Data Entry Error
2	NA	Amanda Lynn	
Requisition Number (additional labs) (4)		24-MAR-2010 15:28:41	Data Entry Error
2	<Row Deleted>	Kryisia Magnuson	
Test Code ID CS Labs only		18-FEB-2010 10:51:03	Row Inserted
2		Amanda Lynn	
Test Code ID CS Labs only		24-MAR-2010 15:28:41	Data Entry Error
2	<Row Deleted>	Kryisia Magnuson	
Test Name CS Labs only		18-FEB-2010 10:51:03	Row Inserted
2		Amanda Lynn	
Test Name CS Labs only		24-MAR-2010 15:28:41	Data Entry Error
2	<Row Deleted>	Kryisia Magnuson	

Document #: R264408213

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	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 resequence	On By	Reason Comment
Body Temperature 1	NA ND		12-FEB-2010 12:27:34 Amanda Lynn	Pass1
Heart Rate 1	NA ND		12-FEB-2010 12:27:34 Amanda Lynn	Pass1
Respiratory Rate 1	NA ND		12-FEB-2010 12:27:34 Amanda Lynn	Pass1
Actual Time 2	1051 1141		10-MAR-2010 10:13:36 Amanda Lynn	Data Entry Error
Body Temperature 2	ND 36.7		10-MAR-2010 10:13:36 Amanda Lynn	Data Entry Error
Comments (2) 2			18-FEB-2010 10:51:40 Amanda Lynn	Data Entry Error
Comments (2) 2	BLOOD PRESSURE IS NCS		10-MAR-2010 10:13:36 Amanda Lynn	Data Entry Error
Date 2	11-FEB-2010 18-SEP-2009		10-MAR-2010 10:13:36 Amanda Lynn	Data Entry Error
Diastolic Blood Pressure 2	097 088		10-MAR-2010 10:13:36 Amanda Lynn	Data Entry Error
Heart Rate 2	086 085		10-MAR-2010 10:13:36 Amanda Lynn	Data Entry Error
Respiratory Rate 2	ND 20		10-MAR-2010 10:13:36 Amanda Lynn	Data Entry Error
Systolic Blood Pressure 2	161 146		10-MAR-2010 10:13:36 Amanda Lynn	Data Entry Error

Document #: R294295413

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Additional Vs.1	Page_43

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	43	Additional Vs.1

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Respiratory Rate 1	12 20	18-FEB-2010 10:52:41 Amanda Lynn	Data Entry Error

Document #: R293519913

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Additional Pe	Page_44 44

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	Y N	17-FEB-2010 17:01:29 Amanda Lynn	Data Entry Error

Document #: R294295713

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Additional Pe.1	Page_44

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	10-MAR-2010 10:22:14 Amanda Lynn	Data Entry Error

Document #: R293520013

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Oral Health Exam	Page_45 45

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	Y N	17-FEB-2010 17:04:09 Amanda Lynn	Data Entry Error

Document #: R294295813

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	Oral Health Exam.1	Page_45

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	10-MAR-2010 10:23:39 Amanda Lynn	Data Entry Error

Document #: R293520113

Patient Site	Visit Visit Date	CRF CRF Page
R2022 L0689282_2	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 resequence	On By	Reason Comment
Other specify (2) 1	SUBJECT COMPLETED, BUT WAS OUT OF WINDOW		10-MAR-2010 10:22:29 Amanda Lynn	Data Entry Error
Reason for withdrawal 1	NA OTHER		10-MAR-2010 10:22:29 Amanda Lynn	Data Entry Error

Discrepancy Detail Report

Document #: R264437813

Discrepancy ID: 104198811 Site: L0689282_2 Patient: R2022
Visit: SCREENING Visit Date:
CRF: PAGE_09 Section: MH Qualifying Value: 9
Field: Diagnosis/Procedure Row: 1
Value Text: OCCASIONAL URINARY TRACT INFECTION
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify start date and that the condition is still ongoing. Medication was only given from 11Jun2009 - 15Jun2009.
Internal Comment: this is occasional so I added it to the history but it is correct other than that.
Resolution Type: Confirmed
Resolution Text: Verified. JLM 23Apr2010

Document #: R283611813

Discrepancy ID: 18338411

Site: L0689282_2

Patient: R2022

Visit: PCM.4

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: Please provide stop date when available.

Internal Comment:

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

Resolution Text:

Document #: R293519813

Discrepancy ID: 68036811 **Site:** L0689282_2 **Patient:** R2022
Visit: ADDITIONAL LAB **Visit Date:**
CRF: PAGE_42 **Section:** LB **Qualifying Value:** 42
Field: Were any additional Laboratory evaluatio **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: You will need to add the biomarker labs obtained at week 16 and 28.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 80916411 **Site:** L0689282_2 **Patient:** R2022
Visit: ADDITIONAL LAB **Visit Date:**
CRF: PAGE_42 **Section:** LB **Qualifying Value:** 42
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please move all Additional Assessments occurring on 11-Feb-2010 to the corresponding Week 28 page.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R264408213

Discrepancy ID: 68185011 **Site:** L0689282_2 **Patient:** R2022
Visit: ADDITIONAL VS **Visit Date:**
CRF: PAGE_43 **Section:** VS **Qualifying Value:** 43
Field: Comments **Row:** 2
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please add comment by investigator, 'BP is NCS'
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 80916511 **Site:** L0689282_2 **Patient:** R2022
Visit: ADDITIONAL VS **Visit Date:**
CRF: PAGE_43 **Section:** VS **Qualifying Value:** 43
Field: Date **Row:** 2
Value Text: 20090918
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please move all Additional Assessments occurring on 11-Feb-2010 to the corresponding Week 28 page.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R294295413

Discrepancy ID: 68111411 **Site:** L0689282_2 **Patient:** R2022
Visit: ADDITIONAL VS.1 **Visit Date:**
CRF: PAGE_43 **Section:** VS **Qualifying Value:** 43
Field: Respiratory Rate **Row:** 1
Value Text: 20
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify respirations. Per source RR = 20. Please review and amend the CRF if applicable.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R293520113

Discrepancy ID: 80916711 **Site:** L0689282_2 **Patient:** R2022
Visit: STUDY COMPETITION **Visit Date:**
CRF: PAGE_46 **Section:** DS **Qualifying Value:** 46
Field: Reason for withdrawal **Row:** 1
Value Text: OTHER
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Week 28 assessments occurred outside of the +/- 7 day window. Please update Study Completion Status to `Other, specify:; with the specification `Subject completed but was out of window;.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Deleted CRFs Report