

CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 12:42:25

Report Parameters

Site: CDB_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1036

Ending patient: R1036

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

Is Blank

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"/> NO |
| <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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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

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?
I	6	SUBJECT DOES NOT HAVE REGULAR I	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	30-JUL-2009
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Page Version No. PAGE_04 (v1, 24-MAR-2009)

Document Number

OverFlow Section For Document Number R264237413

- 1 SUBJECT DOES NOT HAVE REGULAR DENTAL CHECK UPS (SUBJECT HAS UPPER AND LOWER DENTURES)

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

Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="28-JUL-2009"/>	<input type="text" value="(b) (6)"/>	<input type="checkbox"/> Male	<input type="checkbox"/> Hispanic or Latino
		<input checked="" type="checkbox"/> Female	<input checked="" type="checkbox"/> Not Hispanic or latino
Race			
<input checked="" type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Black or African American	<input type="checkbox"/> American Indian/Alaskan Native		
<input type="checkbox"/> Asian	<input type="checkbox"/> Other <input type="text"/>		

Body Measurements

Were Body Measurements Collected? Yes No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="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	126
Diastolic Blood Pressure	MMHG	080
Heart Rate	BEATS/MINUTE	077
Respiratory Rate	BREATHS/MINUTE	016
Body Temperature	C	036.7
Weight	LB	201.4

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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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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Least 5 Minutes?	<input type="text" value="28-JUL-2009"/>	<input type="text" value="11:23"/>
	<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

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

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	
1	HEARING LOSS	00-00-1970		<input checked="" type="checkbox"/> Ongoing
2	DENTURES	00-00-1992		<input checked="" type="checkbox"/> Ongoing
3	SHORTNESS OF BREATH UPON EXERTION	00-00-1989		<input checked="" type="checkbox"/> Ongoing
4	INCONTINENCE/BLADDER CONTROL PROBLEMS	00-00-1968		<input checked="" type="checkbox"/> Ongoing
5	TUBAL LIGATION	00-FEB-1998	00-FEB-1998	<input type="checkbox"/> Ongoing
6	HEADACHES (TENSION/STRESS)	00-00-2009		<input checked="" type="checkbox"/> Ongoing
7	RECURRENT JOINT PAIN (RIGHT SHOULDER)	00-00-2004		<input checked="" type="checkbox"/> Ongoing
8	DEPRESSION	00-00-1973		<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

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="17"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="40"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of Pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="2"/>	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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <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

Oral Health Examination

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

* Indicate NE if system was not examined.

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Swedish Match AB

Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

Date	Parameter	Result	Comments
28-JUL-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
28-JUL-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
30-JUL-2009	15:13	16	3.1	

Behavioral Counseling

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

Questionnaires

Date

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date Actual Time
Was Subject randomized? Yes No

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="5"/> logs
1.0 g of snus or matching placebo	<input type="text" value="3"/> logs

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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Document Number

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="06-AUG-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="105"/>	<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="13-AUG-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="70"/>	<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="20-AUG-2009"/>	<input type="text" value="WEEK 3"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="28"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date Scheduled Timepoint

Parameter

Result

Comments

Was Subject contacted by telephone?

Yes No

Was Subject's smoking status reviewed?

Yes No

Was Subject's use of study product reviewed?

Yes No

Approximately how many cigarettes did the subject smoke that week?

Was Behavioral Counseling Given?

Yes No

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

Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	108
Diastolic Blood Pressure	MMHG	073
Heart Rate	BEATS/MINUTE	069
Respiratory Rate	BREATHS/MINUTE	016
Body Temperature	C	036.7
Weight	LB	206.8

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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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
10-SEP-2009	08:41	6	1.5	

Behavioral Counseling

Date	Parameter	Result	Comments
10-SEP-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 logs

1.0 g of snus or matching placebo logs

Status Review

Date

Parameter

Result

Comments

Was Subject's smoking status reviewed? Yes No

Was Subject compliant? Yes No

If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?

Was Subject asked HDYF? question? Yes No

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="28-SEP-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="2"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	109
Diastolic Blood Pressure	MMHG	074
Heart Rate	BEATS/MINUTE	072
Respiratory Rate	BREATHS/MINUTE	014
Body Temperature	C	036.6
Weight	LB	209.6

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Page Version No. PAGE_22 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
08-OCT-2009	07:58	3	1.1	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="4"/> logs
1.0 g of snus or matching placebo	<input type="text" value="2"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="08-OCT-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="3"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions? Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="03-NOV-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="70"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject instructed to cut down on product use during upcoming Weeks 14-16 to avoid a too abrupt ending of nicotine uptake?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure		
Diastolic Blood Pressure		
Heart Rate		
Respiratory Rate		
Body Temperature		
Weight		

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

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

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

Verified Approved Locked Frozen

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input 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"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure		
Diastolic Blood Pressure		
Heart Rate		
Respiratory Rate		
Body Temperature		
Weight		

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
<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

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
<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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text"/>	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"/>

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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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 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

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](#)

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date Actual Time

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

Comments

Date Actual Time

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

Comments

Verified Approved Locked Frozen

Page Version No. PAGE_43 (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

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

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](#)

[Click here to navigate to discrepancy details 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 #: R264237113

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_001	Screening	Page_02 02

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ic	Page number	2	Screening

Group #	Group Name
1	IE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Inclusion Criteria Answer 6	YES NO	03-DEC-2009 13:11:44 Christina Breedlove	Investigator Correction Confirmed

Document #: R264237413

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_001	Screening	Page_04 04

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

Group #	Group Name
1	IE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Category 1	I	03-DEC-2009 13:14:46 Christina Breedlove	Row Inserted
Did the subject meet all of the inclusion 1	YES NO	03-DEC-2009 13:14:46 Christina Breedlove	Investigator Correction Per query. Exemption granted
Exemption Granted? 1	YES	03-DEC-2009 13:14:46 Christina Breedlove	Row Inserted
Explanation (1) 1	SUBJECT HAS UPPER AND LOWER DENTURES	03-DEC-2009 13:14:46 Christina Breedlove	Row Inserted
Explanation (1) 1	SUBJECT HAS UPPER AND LOWER DENTURES SUBJECT DOES NOT HAVE REGULAR DENTAL CHECK UPS (SUBJECT HAS UPPER AND LOWER DENTURES)	10-FEB-2010 16:03:47 Christina Breedlove	Validation Status changed
If Yes, Date Granted 1	30-JUL-2009	03-DEC-2009 13:14:46 Christina Breedlove	Row Inserted
Inclusion/Exclusion No. 1	6	03-DEC-2009 13:14:46 Christina Breedlove	Row Inserted

Document #: R264238513

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_001	Screening	Page_08 08

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

Group #	Group Name
1	EG

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Actual Time 1	1122 1123	03-DEC-2009 13:19:10 Christina Breedlove	Investigator Correction confirmed with source. Time captured of ECG was by atomic clock.

Document #: R264238613

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_001	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 On resequence By	Reason Comment
Date of Onset 1	00-OCT-1970 00-00-1970	10-FEB-2010 16:05:27 Christina Breedlove	Data Entry Error
Date of Onset 5	00-00-1998 00-FEB-1998	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Confirmed month to be FEB
Date of Resolution 5	00-FEB-1998	17-MAR-2010 09:18:54 Christina Breedlove	Investigator Correction per query
Ongoing 5	CHECKED	17-MAR-2010 09:18:54 Christina Breedlove	Investigator Correction per query
Date of Onset 6		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Date of Onset 6	00-00-2009	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions
Date of Resolution 6		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 6		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 6	HEADACHES (TENSION/STRESS)	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions
Ongoing 6		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Ongoing 6	CHECKED	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions
Sequence Number 6		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted

Document #: R264238613

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Sequence Number 6	6	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions
Date of Onset 7		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Date of Onset 7	00-00-2004	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions
Date of Resolution 7		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 7		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 7	RECURRENT JOINT PAIN (RIGHT SHOULDER)	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions
Ongoing 7		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Ongoing 7	CHECKED	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions
Sequence Number 7		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Sequence Number 7	7	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions
Date of Onset 8		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Date of Onset 8	00-00-1973	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions
Date of Resolution 8		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted

Document #: R264238613

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Diagnosis/Procedure 8		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 8	DEPRESSION	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions
Ongoing 8		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Ongoing 8	CHECKED	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions
Sequence Number 8		11-NOV-2009 14:22:10 Heather Kretschmer	Row Inserted
Sequence Number 8	8	03-DEC-2009 13:23:37 Christina Breedlove	Investigator Correction Added Medical History conditions

Document #: R264240213

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_001	Screening	Page_12 12

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does the subject have any abnormal findi 1	NO YES	10-FEB-2010 16:06:57 Christina Breedlove	Validation Status changed
Findings 1	UPPER AND LOWER DENTURES	10-FEB-2010 16:06:57 Christina Breedlove	Row Inserted
Sequence Number 1	1	10-FEB-2010 16:06:57 Christina Breedlove	Row Inserted

Document #: R264241513

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_001	Sptp, Weeks 1-4	Page_16 16

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

Group #	Group Name
0	Section Header

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
DCM Blank flag 1	N Y		09-NOV-2009 10:18:54 Rossana Matos	Key Change
DCM Blank flag 1	Y N		10-FEB-2010 16:08:24 Christina Breedlove	Validation Status changed

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Approximately how many cigarettes did th (10) 1	10		10-FEB-2010 16:14:50 Christina Breedlove	Data Entry Error
Approximately how many cigarettes did th (10) 1	10 42		12-FEB-2010 13:50:22 Christina Breedlove	Investigator Correction
Approximately how many cigarettes did th (10) 1	42 10		01-MAR-2010 11:39:00 Christina Breedlove	Data Entry Error confirmed with source for week 4 tc and diary. Subject reported that they smoked 1 1/2 cigarettes per day, during the week. Subject smoked 10 cigarettes for the week.
Comments (how many cigarettes) (5) 1	SUBJECT SMOKED 1 1/2 CIGARETTES PER DAY		10-FEB-2010 16:14:50 Christina Breedlove	Data Entry Error
Comments (how many cigarettes) (5) 1	SUBJECT SMOKED 1 1/2 CIGARETTES PER DAY		12-FEB-2010 13:50:22 Christina Breedlove	Data Entry Error

Document #: R273689813

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_001	Ip, Week 10	Page_24 24

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Did subject receive diary and usage inst 1	YES	09-OCT-2009 16:06:59 Sharon Daly	Data Entry Error

Document #: R264241613

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_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
Indication 1	PAIN RIGHT SHOULDER PAIN	10-FEB-2010 16:16:48 Christina Breedlove	Data Entry Error
Ongoing 1	CHECKED	28-AUG-2009 14:56:51 Christina Breedlove	Pass1

Document #: R264241713

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_001	Ae	Page_40 40

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

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Specify 1	PRODUCT REDUCED	10-FEB-2010 16:17:43 Christina Breedlove	Data Entry Error
Action Taken 1	OTHER TREATMENT NONE	10-FEB-2010 16:17:43 Christina Breedlove	Data Entry Error
Adverse Event 1	NUMBNESS (GUMS) NUMBNESS OF (GUMS)	10-FEB-2010 16:17:43 Christina Breedlove	Data Entry Error confirmed with source
Adverse Event 1	NUMBNESS OF (GUMS) NUMBNESS OF GUMS	12-FEB-2010 13:56:51 Christina Breedlove	Data Entry Error per query
Ongoing 1	CHECKED	09-NOV-2009 12:59:35 Rossana Matos	Data Entry Error
Outcome to Date 1	RECOVERED	14-AUG-2009 13:44:52 Rossana Matos	Data Entry Error
Outcome to Date 1	RECOVERED	14-AUG-2009 13:46:08 Rossana Matos	Data Entry Error
Outcome to Date 1	RECOVERED	09-NOV-2009 12:59:35 Rossana Matos	Data Entry Error
Relationship to Date 1	DEFINITELY	14-AUG-2009 13:46:08 Rossana Matos	Data Entry Error
Relationship to Date 1	DEFINITELY	14-AUG-2009 13:47:46 Rossana Matos	Data Entry Error
Relationship to Date 1	POSSIBLY	09-NOV-2009 12:59:35 Rossana Matos	Data Entry Error
Resolved Date 1	18-AUG-2009	09-NOV-2009 12:59:35 Rossana Matos	Data Entry Error
Resolved Time 1	NA	09-NOV-2009 12:59:35 Rossana Matos	Data Entry Error
Resolved Time 1	NA UNK	04-DEC-2009 11:37:26 Christina Breedlove	Data Entry Error

Document #: R264243213

Patient Site	Visit Visit Date	CRF CRF Page
R1036	Ae.1	Page_40
CDB_001		

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

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Adverse Event 1	RT SHOULDER PAIN RIGHT SHOULDER PAIN	12-FEB-2010 13:58:09 Christina Breedlove	Data Entry Error
High Level Group Term 1	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS NEC	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Group Term Code 1	10028393	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Term 1	MUSCULOSKELETAL AND CONNECTIVE TISSUE SIGNS AND SYMPTOMS NEC	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Term Code 1	10027688	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Lower Level Term 1	SHOULDER PAIN	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Lower Level Term Code 1	10040617	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Ongoing 1	CHECKED	09-NOV-2009 13:01:52 Rossana Matos	Pass1
Preferred Term 1	MUSCULOSKELETAL PAIN	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Preferred Term Code 1	10028391	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
System Organ Class 1	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
System Organ Class Code 1	10028395	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change

Document #: R278595413

Patient Site	Visit Visit Date	CRF CRF Page
R1036	Ae.2	Page_40
CDB_001		

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
Action Specify 1	STICHES STITCHES	19-APR-2010 14:23:43 Joanne Mccaigue	ODM/SEC Obvious spelling error. JLM 19Apr2010
Adverse Event 1	2 LACERATIONS TO RIGHT ARM LACERATIONS TO RIGHT ARM	12-FEB-2010 14:03:00 Christina Breedlove	Data Entry Error per query
High Level Group Term 1	INJURIES NEC	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Group Term Code 1	10022114	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Term 1	SKIN INJURIES NEC	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Term Code 1	10027699	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Lower Level Term 1	LACERATION OF ARM	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Lower Level Term Code 1	10023574	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Ongoing 1	CHECKED	07-JUN-2010 07:22:15 Christina Breedlove	Investigator Correction
Outcome to Date 1	CONT WITHOUT TREATMENT CONT WITH TREATMENT	01-MAR-2010 11:45:25 Christina Breedlove	Data Entry Error per PI and source
Outcome to Date 1	CONT WITH TREATMENT RECOVERED	07-JUN-2010 15:18:47 Christina Breedlove	Data Entry Error severity of moderate has been changed to recovered.
Preferred Term 1	SKIN LACERATION	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change

Document #: R278595413

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_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

Preferred Term Code 1	10058818	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Relationship to Date 1	NOT RELATED	12-FEB-2010 14:03:00 Christina Breedlove	Data Entry Error
Resolved Date 1	17-SEP-2009	07-JUN-2010 07:22:15 Christina Breedlove	Investigator Correction
Resolved Time 1	UNK	07-JUN-2010 07:22:15 Christina Breedlove	Investigator Correction
System Organ Class 1	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
System Organ Class Code 1	10022117	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change

Document #: R313756313

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_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	INJURIES NEC	07-JUN-2010 12:07:30 Joanne Mccaigue	Class. Change
High Level Group Term Code 1	10022114	07-JUN-2010 12:07:30 Joanne Mccaigue	Class. Change
High Level Term 1	SKIN INJURIES NEC	07-JUN-2010 12:07:30 Joanne Mccaigue	Class. Change
High Level Term Code 1	10027699	07-JUN-2010 12:07:30 Joanne Mccaigue	Class. Change
Lower Level Term 1	LACERATION OF ARM	07-JUN-2010 12:07:30 Joanne Mccaigue	Class. Change
Lower Level Term Code 1	10023574	07-JUN-2010 12:07:30 Joanne Mccaigue	Class. Change
Preferred Term 1	SKIN LACERATION	07-JUN-2010 12:07:30 Joanne Mccaigue	Class. Change
Preferred Term Code 1	10058818	07-JUN-2010 12:07:30 Joanne Mccaigue	Class. Change
System Organ Class 1	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	07-JUN-2010 12:07:30 Joanne Mccaigue	Class. Change
System Organ Class Code 1	10022117	07-JUN-2010 12:07:30 Joanne Mccaigue	Class. Change

Document #: R283178313

Patient Site	Visit Visit Date	CRF CRF Page
R1036 CDB_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
Date the subject completed OR withdrew f 1	04-DEC-2009 03NOV-2009	10-FEB-2010 17:32:23 Christina Breedlove	Investigator Correction

Discrepancy Detail Report

Document #: R264237113

Discrepancy ID: 1790204913 Site: CDB_001 Patient: R1036
Visit: SCREENING Visit Date:
CRF: PAGE_02 Section: IC Qualifying Value: 2
Field: Inclusion Criteria Answer Row: 6
Value Text: NO
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify should be no.
Internal Comment: Confirmed
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: Confirmed

Discrepancy ID: 20543811 Site: CDB_001 Patient: R1036
Visit: SCREENING Visit Date:
CRF: PAGE_02 Section: IC Qualifying Value: 2
Field: Row:
Value Text:
Type: MULTIVARIATE Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Response to Inclusion Criterion <06> is No. Please verify response and ensure subject eligibility page is completed as appropriate.
Internal Comment: subject has dentures and does not have dental check ups
Resolution Type: No Action Required
Resolution Text:

Document #: R264237413

Discrepancy ID: 1790205013 **Site:** CDB_001 **Patient:** R1036
Visit: SCREENING **Visit Date:**
CRF: PAGE_04 **Section:** ELIG **Qualifying Value:** 4
Field: Did the subject meet all of the inclusio **Row:** 1
Value Text: NO
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per source, see waiver.
Internal Comment: Per query. Exemption granted
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: Per query. Exemption granted

Discrepancy ID: 22666611 **Site:** CDB_001 **Patient:** R1036
Visit: SCREENING **Visit Date:**
CRF: PAGE_04 **Section:** ELIG **Qualifying Value:** 4
Field: Explanation **Row:** 1
Value Text: SUBJECT DOES NOT HAVE REGULAR DENTAL CHECK UPS (SUBJECT HAS UPPER AND LOWER DENTURES)
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please add to comment that she does not have regular check ups.
Internal Comment:
Resolution Type: Confirmed
Resolution Text: confirmed with source

Document #: R264238513

Discrepancy ID: 1790207313

Site: CDB_001

Patient: R1036

Visit: SCREENING

Visit Date:

CRF: PAGE_08

Section: EG

Qualifying Value: 8

Field: Actual Time

Row: 1

Value Text: 1123

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify time per source.

Internal Comment: confirmed with source. Time captured of ECG was by atomic clock.

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

Resolution Text: confirmed with source. Time captured of ECG was by atomic clock.

Document #: R264238613

Discrepancy ID: 59361811 **Site:** CDB_001 **Patient:** R1036
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Date of Onset **Row:** 1
Value Text: 1970
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per source month was not provided.

Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 1790237713 **Site:** CDB_001 **Patient:** R1036
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Date of Onset **Row:** 5
Value Text: 199802
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify month and year per source.

Internal Comment: Month confirmed to be FEB
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: Added Medical History conditions

Discrepancy ID: 86032611 **Site:** CDB_001 **Patient:** R1036
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Date of Resolution **Row:** 5
Value Text: 199802
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please add a date of resolution and uncheck Ongoing. Tubal ligation is a procedure rather than an ongoing condition and requires a stop date.

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

R264238613

Discrepancy ID: 1790237813 **Site:** CDB_001 **Patient:** R1036
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 6
Value Text: HEADACHES (TENSION/STRESS)
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify headaches should be entered.
Internal Comment: Added Medical History conditions
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: Added Medical History conditions

Discrepancy ID: 1790237913 **Site:** CDB_001 **Patient:** R1036
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 7
Value Text: RECURRENT JOINT PAIN (RIGHT SHOULDER)
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify ongoing back pain.
Internal Comment: Added Medical History conditions
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: Added Medical History conditions

Discrepancy ID: 1790238013 **Site:** CDB_001 **Patient:** R1036
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 8
Value Text: DEPRESSION
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify ongoing depression.
Internal Comment: Added Medical History conditions
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: Added Medical History conditions

Document #: R264241513

Discrepancy ID: 60987311

Site: CDB_001

Patient: R1036

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

CRF: PAGE_16

Section: STATUS REVIEW

Qualifying Value: 16

Field: Date

Row: 1

Value Text: 20090806

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please enter week 4 data.

Internal Comment: Scroll down to second page.

Resolution Type: Confirmed

Resolution Text:

Document #: R264241513

Discrepancy ID: 64059411 **Site:** CDB_001 **Patient:** R1036

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

CRF: PAGE_16 **Section:** STATUS REVIEW **Qualifying Value:** 16B

Field: Approximately how many cigarettes did th **Row:** 1

Value Text: 10

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: please verify per source.

Internal Comment: confirmed with source for week 4 tc and diary. Subject reported that they smoked 1 1/2 cigarettes per day, during the week. Subject smoked 10 cigarettes for the week.

Resolution Type: No Action Required

Resolution Text:

Discrepancy ID: 63261611 **Site:** CDB_001 **Patient:** R1036

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

CRF: PAGE_16 **Section:** STATUS REVIEW **Qualifying Value:** 16B

Field: Comments (how many cigarettes) **Row:** 1

Value Text:

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify per definition on subject diary 1-2 puffs = 1 cigarette. Please verify if source and CRF should be updated.

Internal Comment: per CRF guidelines "When diary and phone information do not reconcile, the data reported over the phone will override the data in the diary"

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

Resolution Text: per CRF guidelines "When diary and phone information do not reconcile, the data reported over the phone will override the data in the diary"

Discrepancy ID: 1790242613 **Site:** CDB_001 **Patient:** R1036

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

CRF: PAGE_16 **Section:** STATUS REVIEW **Qualifying Value:** 16B

Field: **Row:**

Value Text:

Type: MANUAL HEADER **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please complete entry.

Internal Comment: will complete

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

Resolution Text:

Document #: R264241613

Discrepancy ID: 60284311

Site: CDB_001

Patient: R1036

Visit: PCM

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: RIGHT SHOULDER PAIN

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please specify right shoulder pain.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R264241713

Discrepancy ID: 60360811 **Site:** CDB_001 **Patient:** R1036
Visit: AE **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Action Specify **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify action taken with respect to subject is "none".
Internal Comment: confirmed with source
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 63261711 **Site:** CDB_001 **Patient:** R1036
Visit: AE **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Adverse Event **Row:** 1
Value Text: NUMBNESS OF GUMS
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please remove parenthesis from gums.
Internal Comment: per query
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 60360711 **Site:** CDB_001 **Patient:** R1036
Visit: AE **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter medical term verbatim as diagnosed by MD.
Internal Comment: confirmed with source
Resolution Type: Confirmed
Resolution Text:

R264241713

Discrepancy ID: 71441111 **Site:** CDB_001 **Patient:** R1036
Visit: AE **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 NUMBNESS OF GUMS but Resolved Date and/or Time are missing. Please reconcile.
Internal Comment: Resolved date is "18/Aug/2009" and resolved time is "unknown"
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 71437211 **Site:** CDB_001 **Patient:** R1036
Visit: AE **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 <NUMBNESS OF GUMS>. Please either provide resolved date and time OR check Ongoing.
Internal Comment: Resolved date is "18/Aug/2009" and resolved time is "unknown"
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R278595413

Discrepancy ID: 143462011 **Site:** CDB_001 **Patient:** R1036
Visit: AE.2 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Adverse Event **Row:** 1
Value Text: LACERATIONS TO RIGHT ARM
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter as 2 separate AEs as the severity changed from moderate to mild.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 60662011 **Site:** CDB_001 **Patient:** R1036
Visit: AE.2 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Outcome to Date **Row:** 1
Value Text: RECOVERED
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per comment on page 2 of AE, is ongoing with treatment. Please updated source on page 1 of AE of match.
Internal Comment: per PI and source; AE of laceration to right arm is "continuing with treatment"
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 142818811 **Site:** CDB_001 **Patient:** R1036
Visit: AE.2 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Resolved Date **Row:** 1
Value Text: 20090917
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per source, severity changed from moderate to mild. Please enter two separate AEs.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R283178313

Discrepancy ID: 60664311 **Site:** CDB_001 **Patient:** R1036
Visit: STUDY COMPETITION **Visit Date:**
CRF: PAGE_46 **Section:** DS **Qualifying Value:** 46
Field: Date the subject completed OR withdrew f **Row:** 1
Value Text: 03NOV-2009
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per guidelines date of last visit should be entered. Please verify should be 03 NOV 2009.
Internal Comment: per CRF guidelines
Resolution Type: Confirmed
Resolution Text: per CRF guidelines

Discrepancy ID: 61975811 **Site:** CDB_001 **Patient:** R1036
Visit: STUDY COMPETITION **Visit Date:**
CRF: PAGE_46 **Section:** DS **Qualifying Value:** 46
Field: Date the subject completed OR withdrew f **Row:** 1
Value Text: 03NOV-2009
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value of 03NOV-2009 for Date the subject completed OR withdrew f is not a valid DATE
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Deleted CRFs Report