

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 16:58:58

Report Parameters

Site: CDB_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1003

Ending patient: R1003

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"/> YES |
| <input type="checkbox"/> 07 The subject is able and willing to provide written informed consent. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 08 The subject agrees to comply with the requirements of the protocol and complete study measures. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 09 The subject has stable residence and telephone. | <input type="checkbox"/> YES |

* If No, document on Subject Eligibility Page.

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

Document Number

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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Page Version No. PAGE_03 (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

Information Session

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

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

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

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

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

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Demographics

Date

Date of Birth

Gender Male Female

Ethnicity Hispanic or Latino Not Hispanic or latino

Race White Black or African American Asian

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

Body Measurements

Were Body Measurements Collected? Yes No Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="63.0"/>

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	111
Diastolic Blood Pressure	MMHG	062
Heart Rate	BEATS/MINUTE	062
Respiratory Rate	BREATHS/MINUTE	14
Body Temperature	C	36.4
Weight	LB	227.2

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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: Safety Urine & Blood Tests; Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Urine Pregnancy Test

Result

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

Urine Drug Screen

Drug Screen Result*

Positive Negative

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

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Links to Discrepancy and Audit Sections

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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="18-FEB-2009"/>	<input type="text" value="10:06"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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	INTERMITTENT NASAL/SINUS CONGESTION	00-00-1975		<input checked="" type="checkbox"/> Ongoing
2	HIGH BLOOD PRESSURE	00-00-1989		<input checked="" type="checkbox"/> Ongoing
3	RECURRENT BACK PAIN	00-00-2006		<input checked="" type="checkbox"/> Ongoing
4	SEASONAL ALLERGIES	00-00-1989		<input checked="" type="checkbox"/> Ongoing
5	INTERMITTENT EPISODES - NUMBNESS/TINGLI	00-00-2007		<input checked="" type="checkbox"/> Ongoing
6	HEMORRHOIDS	00-00-1998		<input checked="" type="checkbox"/> Ongoing
7	INTERMITTENT EPISODES - FOLLICULITIS/AB	00-00-1976		<input checked="" type="checkbox"/> Ongoing
8	POSTMENOPAUSAL	00-SEP-2007		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

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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Page Version No. PAGE_09 (v1, 24-MAR-2009)

Document Number

OverFlow Section For Document Number R243290213

- 1 INTERMITTENT EPISODES-NUMBNESS/TINGLING (EXTREMITIES)
- 2 INTERMITTENT EPISODES-FOLLICULITIS/ABSCESSSES OR BOILS (INNER THIGHS & PRIVATE AREA)

Links to Discrepancy and Audit Sections

[Click here to navigate to audit history for this 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

Smoking History

Was Smoking History collected?

Yes No

Date

Parameter	Result	Comments
Age subject began smoking daily	<input type="text" value="16"/>	
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"/>	PATCHES
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"/>	WELLBUTRIN USED ONCE IN 2005 & CHANTIX USED ONCE IN 2008
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="3"/>	QUIT SMART PROGRAM X2 & HYPNOSIS
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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Document Number

OverFlow Section For Document Number R243290313

1 WELLBUTRIN USED ONCE IN 2005 & CHANTIX USED ONCE IN 2008

Links to Discrepancy and Audit Sections

[Click here to navigate to audit history for this 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

Oral Health Examination

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

Behavioral Counseling

Date	Parameter	Result	Comments
18-FEB-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
18-FEB-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
03-MAR-2009	10:17	13	2.7	

Behavioral Counseling

Date	Parameter	Result	Comments
03-MAR-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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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date

Actual Time

Was Subject randomized? Yes No

Product Dispensation

Date

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

Diary Distribution

Date

Did subject receive diary and usage instructions? Yes No

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Page Version No. PAGE_15 (v1, 27-MAR-2009)

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Links to Discrepancy and Audit Sections

[Click here to navigate to audit history for this 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

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text"/>	<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"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text"/>	<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"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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

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Page Version No. PAGE_16 (v1, 14-APR-2009)

Document Number

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?	<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"/>
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 reminded about the complete switch from cigarettes no later than the first day of Week 5?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_16 (v1, 14-APR-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		

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Page Version No. PAGE_17 (v1, 30-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.

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Page Version No. PAGE_18 (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 MNWS Was Questionnaire Administered? Yes No

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Page Version No. PAGE_19 (v1, 31-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

Product Dispensation

Date

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

Status Review

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

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

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

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

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		

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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
<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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Page Version No. PAGE_24 (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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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)

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	095
Diastolic Blood Pressure	MMHG	052
Heart Rate	BEATS/MINUTE	072
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.9
Weight	LB	228.8

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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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
06-MAR-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
06-MAR-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
06-MAR-2009	OTHER ORAL KERATOSIS	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

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

Document Number

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

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
06-MAR-2009	10:18	13	2.7	

Behavioral Counseling

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

Questionnaires

Date

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

Verified Approved Locked Frozen

Page Version No. PAGE_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
06-MAR-2009	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="28"/>	
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

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"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

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

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Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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

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Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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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

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

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)

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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

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

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 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

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure		
<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 #: R243290013

Patient Site	Visit Visit Date	CRF CRF Page
R1003 CDB_001	Screening	Page_07 07

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

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Requisition Number 1: (1) 1	09888880-4 050-552-1501-0		18-MAY-2009 15:38:43 Sharon Daly	Data Entry Error
Were there any clinically significant la (1) 1	YES NO		18-MAY-2009 15:38:43 Sharon Daly	Data Entry Error

Document #: R243290213

Patient Site	Visit Visit Date	CRF CRF Page
R1003 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
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION NASAL/SINUS CONGESTION-NCS	19-AUG-2009 11:30:29 Christina Breedlove	Data Entry Mode Per PI -Relevant but NCS
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION-NCS NASAL/SINUS CONGESTION	13-NOV-2009 10:39:01 Christina Breedlove	Validation Status changed NCS was deleted per query
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION INTERMITTENT NASAL/SINUS CONGESTION	26-FEB-2010 12:41:49 Christina Breedlove	Data Entry Error
Diagnosis/Procedure 2	HIGH BLOOD PRESSURE HIGH BLOOD PRESSURE-NCS	19-AUG-2009 11:30:29 Christina Breedlove	Data Entry Mode correction to type-o
Diagnosis/Procedure 2	HIGH BLOOD PRESSURE-NCS HIGH BLOOD PRESSURE	13-NOV-2009 10:39:01 Christina Breedlove	Validation Status changed NCS was deleted per query
Sequence Number 2	2. 2	02-MAR-2010 11:12:10 Krysia Magnuson	ODM/SEC 2. to 2 (removed decimal). KAY 02Mar2010.
Date of Onset 3	00-00-1998	19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevant to study
Date of Onset 3	<Row Deleted>	6->3 03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Date of Resolution 3	<Row Deleted>	6->3 03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Diagnosis/Procedure 3	HEMORRHOIDS	19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevant to study
Diagnosis/Procedure 3	<Row Deleted>	6->3 03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Diagnosis/Procedure 3	RECURRENT BACK PAIN RECURRENT BACK PAIN-NCS	19-AUG-2009 11:30:29 Christina Breedlove	Data Entry Mode Per PI -Relevant but NCS

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Diagnosis/Procedure 3	RECURRENT BACK PAIN-NCS RECURRENT BACK PAIN	13-NOV-2009 10:39:01 Christina Breedlove	Validation Status changed NCS was deleted per query
Ongoing 3	CHECKED	19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study
Ongoing 3	<Row Deleted>	6->3 03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Sequence Number 3	3.	19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study
Sequence Number 3	<Row Deleted>	6->3 03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Sequence Number 3	6 3	19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error correction to sequence No. due to removal initial entries that are not relevent to study
Date of Onset 4	00-00-1985	19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study
Date of Onset 4	<Row Deleted>	6->3 03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Date of Onset 4		09-NOV-2009 15:14:42 Heather Kretschmer	Row Inserted
Date of Onset 4	<Row Deleted>	7->4 27-NOV-2009 03:48:22 Rossana Matos	Data Entry Error
Date of Onset 4	00-00-1989	13-NOV-2009 10:39:01 Christina Breedlove	Validation Status changed Seasonal allergies added to med hx as ongoing since 1989 per query
Date of Resolution 4	00-00-1985	19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study

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Date of Resolution 4	<Row Deleted>	6->3	03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Date of Resolution 4			09-NOV-2009 15:14:42 Heather Kretschmer	Row Inserted
Date of Resolution 4	<Row Deleted>	7->4	27-NOV-2009 03:48:22 Rossana Matos	Data Entry Error
Diagnosis/Procedure 4	OVARIAN CYST		19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevant to study
Diagnosis/Procedure 4	<Row Deleted>	6->3	03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Diagnosis/Procedure 4			09-NOV-2009 15:14:42 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 4	<Row Deleted>	7->4	27-NOV-2009 03:48:22 Rossana Matos	Data Entry Error
Diagnosis/Procedure 4	SEASONAL ALLERGIES		13-NOV-2009 10:39:01 Christina Breedlove	Validation Status changed Seasonal allergies added to med hx as ongoing since 1989 per query
Ongoing 4	<Row Deleted>	6->3	03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Ongoing 4			09-NOV-2009 15:14:42 Heather Kretschmer	Row Inserted
Ongoing 4	<Row Deleted>	7->4	27-NOV-2009 03:48:22 Rossana Matos	Data Entry Error
Ongoing 4	CHECKED		13-NOV-2009 10:39:01 Christina Breedlove	Validation Status changed Seasonal allergies added to med hx as ongoing since 1989 per query

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Sequence Number 4	4	19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study
Sequence Number 4	<Row Deleted>	6->3 03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Sequence Number 4		09-NOV-2009 15:14:42 Heather Kretschmer	Row Inserted
Sequence Number 4	<Row Deleted>	7->4 27-NOV-2009 03:48:22 Rossana Matos	Data Entry Error
Sequence Number 4	4	13-NOV-2009 10:39:01 Christina Breedlove	Validation Status changed Seasonal allergies added to med hx as ongoing since 1989 per query
Date of Onset 5	00-00-2007	19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study
Date of Onset 5	<Row Deleted>	6->3 03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Date of Onset 5		09-NOV-2009 15:14:42 Heather Kretschmer	Row Inserted
Date of Onset 5	<Row Deleted>	7->4 27-NOV-2009 03:48:22 Rossana Matos	Data Entry Error
Date of Onset 5	00-00-2007	27-NOV-2009 03:48:22 Rossana Matos	Row Inserted
Date of Resolution 5	<Row Deleted>	6->3 03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Date of Resolution 5		09-NOV-2009 15:14:42 Heather Kretschmer	Row Inserted
Date of Resolution 5	<Row Deleted>	7->4 27-NOV-2009 03:48:22 Rossana Matos	Data Entry Error
Date of Resolution 5		27-NOV-2009 03:48:22 Rossana Matos	Row Inserted

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Diagnosis/Procedure 5	NUMBNESS/TINLING		19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study
Diagnosis/Procedure 5	<Row Deleted>	6->3	03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Diagnosis/Procedure 5			09-NOV-2009 15:14:42 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 5	<Row Deleted>	7->4	27-NOV-2009 03:48:22 Rossana Matos	Data Entry Error
Diagnosis/Procedure 5	NUMBNESS/TINGLING (EXTRETIES)		27-NOV-2009 03:48:22 Rossana Matos	Row Inserted
Diagnosis/Procedure 5	NUMBNESS/TINGLING (EXTRETIES) NUMBNESS/TINGLING (EXTREMITIES)		03-DEC-2009 09:50:36 Christina Breedlove	Investigator Correction Corrected spelling of Extremities
Diagnosis/Procedure 5	NUMBNESS/TINGLING (EXTREMITIES) INTERMITTENT EPISODES- NUMBNESS/TINGLING (EXTREMITIES)		26-FEB-2010 12:41:49 Christina Breedlove	Data Entry Error
Ongoing 5	CHECKED		19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study
Ongoing 5	<Row Deleted>	6->3	03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Ongoing 5			09-NOV-2009 15:14:42 Heather Kretschmer	Row Inserted
Ongoing 5	<Row Deleted>	7->4	27-NOV-2009 03:48:22 Rossana Matos	Data Entry Error
Ongoing 5	CHECKED		27-NOV-2009 03:48:22 Rossana Matos	Row Inserted
Sequence Number 5	5		19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study
Sequence Number 5	<Row Deleted>	6->3	03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error

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Sequence Number 5			09-NOV-2009 15:14:42	Row Inserted Heather Kretschmer
Sequence Number 5		7->4	27-NOV-2009 03:48:22	Data Entry Error Rossana Matos
Sequence Number 5	<Row Deleted>			
Sequence Number 5	5		27-NOV-2009 03:48:22	Row Inserted Rossana Matos
Date of Onset 6			09-NOV-2009 15:27:17	Row Inserted Heather Kretschmer
Date of Onset 6		7->4	27-NOV-2009 03:48:22	Data Entry Error Rossana Matos
Date of Onset 6	<Row Deleted>			
Date of Onset 6			18-DEC-2009 12:34:32	Row Inserted Heather Kretschmer
Date of Onset 6	18-FEB-2009		07-JAN-2010 08:42:32	Data Entry Error Sharon Daly
Date of Onset 6	18-FEB-2009		20-JAN-2010 11:54:20	Data Entry Error Christina Breedlove
Date of Onset 6	00-00-1998		20-JAN-2010 13:58:15	Validation Status changed Christina Breedlove
Date of Resolution 6			09-NOV-2009 15:27:17	Row Inserted Heather Kretschmer
Date of Resolution 6		7->4	27-NOV-2009 03:48:22	Data Entry Error Rossana Matos
Date of Resolution 6	<Row Deleted>			
Date of Resolution 6			18-DEC-2009 12:34:32	Row Inserted Heather Kretschmer
Diagnosis/Proced ure 6			09-NOV-2009 15:27:17	Row Inserted Heather Kretschmer
Diagnosis/Proced ure 6		7->4	27-NOV-2009 03:48:22	Data Entry Error Rossana Matos
Diagnosis/Proced ure 6	<Row Deleted>			
Diagnosis/Proced ure 6			18-DEC-2009 12:34:32	Row Inserted Heather Kretschmer

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Diagnosis/Procedure 6	OBESE		07-JAN-2010 08:42:32 Sharon Daly	Data Entry Error
Diagnosis/Procedure 6	OBESE		20-JAN-2010 11:54:20 Christina Breedlove	Investigator Correction
Diagnosis/Procedure 6	HEMMORRHOIDS		20-JAN-2010 13:58:15 Christina Breedlove	Validation Status changed
Diagnosis/Procedure 6	HEMMORRHOIDS HEMORRHOIDS		23-FEB-2010 17:54:50 Krysia Magnuson	ODM/SEC Hemmorriods to Hemorrhoids.
Ongoing 6			09-NOV-2009 15:27:17 Heather Kretschmer	Row Inserted
Ongoing 6	<Row Deleted>	7->4	27-NOV-2009 03:48:22 Rossana Matos	Data Entry Error
Ongoing 6			18-DEC-2009 12:34:32 Heather Kretschmer	Row Inserted
Ongoing 6	CHECKED		07-JAN-2010 08:42:32 Sharon Daly	Data Entry Error
Ongoing 6	CHECKED		20-JAN-2010 11:57:05 Christina Breedlove	Data Entry Error
Ongoing 6	CHECKED		20-JAN-2010 13:58:15 Christina Breedlove	Validation Status changed
Sequence Number 6			09-NOV-2009 15:27:17 Heather Kretschmer	Row Inserted
Sequence Number 6	<Row Deleted>	7->4	27-NOV-2009 03:48:22 Rossana Matos	Data Entry Error
Sequence Number 6			18-DEC-2009 12:34:32 Heather Kretschmer	Row Inserted
Sequence Number 6	6		07-JAN-2010 08:42:32 Sharon Daly	Data Entry Error
Date of Onset 7	00-00-1976		19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study

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Date of Onset 7	<Row Deleted>	6->3	03-OCT-2009 11:15:18	Data Entry Error Rossana Matos
Date of Onset 7			09-NOV-2009 15:27:17	Row Inserted Heather Kretschmer
Date of Onset 7	18-FEB-2009		07-JAN-2010 08:42:32	Row Inserted Sharon Daly
Date of Onset 7	18-FEB-2009		20-JAN-2010 11:54:20	Data Entry Error Christina Breedlove
Date of Onset 7	00-00-1976		20-JAN-2010 14:17:59	Investigator Correction Christina Breedlove
Date of Resolution 7	<Row Deleted>	6->3	03-OCT-2009 11:15:18	Data Entry Error Rossana Matos
Date of Resolution 7			09-NOV-2009 15:27:17	Row Inserted Heather Kretschmer
Date of Resolution 7			07-JAN-2010 08:42:32	Row Inserted Sharon Daly
Diagnosis/Proced ure 7	CYSTS ON INNER THIGHS AND PRIVATE AREA		19-AUG-2009 11:14:33	Data Entry Error Christina Breedlove Per PI- Not relevent to study
Diagnosis/Proced ure 7	<Row Deleted>	6->3	03-OCT-2009 11:15:18	Data Entry Error Rossana Matos
Diagnosis/Proced ure 7			09-NOV-2009 15:27:17	Row Inserted Heather Kretschmer
Diagnosis/Proced ure 7	DERMATITIS		07-JAN-2010 08:42:32	Row Inserted Sharon Daly
Diagnosis/Proced ure 7	DERMATITIS		20-JAN-2010 11:54:20	Data Entry Error Christina Breedlove
Diagnosis/Proced ure 7	FOLLICULITIS/ABSCESSSES OR BOILS(INNER THIGHS & PRIVATE AREA)		20-JAN-2010 14:17:59	Investigator Correction Christina Breedlove

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Diagnosis/Procedure 7	FOLLICULITIS/ABSCESSSES OR BOILS(INNER THIGHS & PRIVATE AREA) FOLLICULITIS/ABSCESSSES OR BOILS (INNER THIGHS & PRIVATE AREA)	23-FEB-2010 17:56:50 Kryisia Magnuson	ODM/SEC Added a space between words.
Diagnosis/Procedure 7	FOLLICULITIS/ABSCESSSES OR BOILS (INNER THIGHS & PRIVATE AREA) INTERMITTENT EPISODES- FOLLICULITIS/ABSCESSSES OR BOILS (INNER THIGHS & PRIVATE AREA)	26-FEB-2010 12:41:49 Christina Breedlove	Data Entry Error
Ongoing 7	CHECKED	19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study
Ongoing 7	<Row Deleted>	6->3 03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Ongoing 7		09-NOV-2009 15:27:17 Heather Kretschmer	Row Inserted
Ongoing 7	CHECKED	07-JAN-2010 08:42:32 Sharon Daly	Row Inserted
Ongoing 7	CHECKED	20-JAN-2010 11:57:05 Christina Breedlove	Data Entry Error
Ongoing 7	CHECKED	20-JAN-2010 14:17:59 Christina Breedlove	Investigator Correction
Sequence Number 7	7	19-AUG-2009 11:14:33 Christina Breedlove	Data Entry Error Per PI- Not relevent to study
Sequence Number 7	<Row Deleted>	6->3 03-OCT-2009 11:15:18 Rossana Matos	Data Entry Error
Sequence Number 7		09-NOV-2009 15:27:17 Heather Kretschmer	Row Inserted
Sequence Number 7	7	07-JAN-2010 08:42:32 Sharon Daly	Row Inserted
Sequence Number 7	7	20-JAN-2010 13:58:15 Christina Breedlove	Validation Status changed

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Sequence Number		20-JAN-2010 14:17:59	Investigator Correction
7	7	Christina Breedlove	
Date of Onset		07-JAN-2010 08:42:32	Row Inserted
8	18-FEB-2009	Sharon Daly	
Date of Onset		20-JAN-2010 11:54:20	Data Entry Error
8	18-FEB-2009	Christina Breedlove	
Date of Onset		26-FEB-2010 12:41:49	Validation Status changed
8	00-SEP-2007	Christina Breedlove	
Date of Resolution		07-JAN-2010 08:42:32	Row Inserted
8		Sharon Daly	
Diagnosis/Procedure		07-JAN-2010 08:42:32	Row Inserted
8	BILATERAL CATARACTS	Sharon Daly	
Diagnosis/Procedure		20-JAN-2010 11:54:20	Data Entry Error
8	BILATERAL CATARACTS	Christina Breedlove	
Diagnosis/Procedure		26-FEB-2010 12:41:49	Validation Status changed
8	POSTMENOPAUSAL	Christina Breedlove	
Ongoing		07-JAN-2010 08:42:32	Row Inserted
8		Sharon Daly	
Ongoing		26-FEB-2010 12:41:49	Validation Status changed
8	CHECKED	Christina Breedlove	
Sequence Number		07-JAN-2010 08:42:32	Row Inserted
8	8	Sharon Daly	
Sequence Number		20-JAN-2010 13:58:15	Validation Status changed
8	8	Christina Breedlove	
Sequence Number		26-FEB-2010 12:41:49	Validation Status changed
8	8	Christina Breedlove	

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Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Attempted to quit (Nicotine Replacement) (2) 1	NO YES	17-DEC-2009 13:54:36 Christina Breedlove	Investigator Correction
Attempted to quit (Other attempts) (5) 1	YES NO	03-MAR-2010 15:06:20 Christina Breedlove	Data Entry Error
Attempted to quit (Other cessation aids) (4) 1	NO YES	17-DEC-2009 13:54:36 Christina Breedlove	Investigator Correction
Attempted to quit (Pharmaceuticals) (3) 1	NO YES	17-DEC-2009 13:54:36 Christina Breedlove	Investigator Correction
Comments (NRT) (4) 1	PATCHES	17-DEC-2009 13:54:36 Christina Breedlove	Investigator Correction
Comments (other attemps) (7) 1	COLD TURKEY	24-JUN-2009 10:35:58 Rossana Matos	Investigator Correction omited data
Comments (other attemps) (7) 1	COLD TURKEY HYPNOSIS / QUIT SMART PROGRAM / PATCHES	13-NOV-2009 11:16:15 Christina Breedlove	Data Entry Error Added; hypnosis/Quit Smart Program/patches, verified from progress note and answered per query
Comments (other attemps) (7) 1	HYPNOSIS / QUIT SMART PROGRAM / PATCHES HYPNOSIS	17-DEC-2009 13:54:36 Christina Breedlove	Investigator Correction
Comments (other attemps) (7) 1	HYPNOSIS	03-MAR-2010 15:06:20 Christina Breedlove	Data Entry Error

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Group #	Group Name
1	DRUGSCR

Comments (other cessation aids) (6) 1	QUIT SMART PROGRAM	17-DEC-2009 13:54:36 Christina Breedlove	Investigator Correction
Comments (other cessation aids) (6) 1	QUIT SMART PROGRAM QUIT SMART PROGRAM & HYPNOSIS	03-MAR-2010 15:06:20 Christina Breedlove	Data Entry Error
Comments (other cessation aids) (6) 1	QUIT SMART PROGRAM & HYPNOSIS QUIT SMART PROGRAM X2 & HYPNOSIS	03-JUN-2010 10:10:53 Christina Breedlove	Investigator Correction Subject used the "Quit Smart program" once in Sept 2005 & once in Oct 2008. Subject also tried hypnosis once.
Comments (pharmaceuticals) (5) 1	WELLBUTRIN USED ONCE IN 2005 & CHANTIX USED ONCE IN 2008	17-DEC-2009 13:54:36 Christina Breedlove	Investigator Correction
If Yes, how many (nicotine replacement) (3) 1	1	17-DEC-2009 13:54:36 Christina Breedlove	Investigator Correction
If Yes, how many (other cessation aids) (5) 1	1	17-DEC-2009 13:54:36 Christina Breedlove	Investigator Correction
If Yes, how many (other cessation aids) (5) 1	1 2	03-MAR-2010 15:06:20 Christina Breedlove	Data Entry Error
If Yes, how many (other cessation aids) (5) 1	2 3	03-JUN-2010 10:10:53 Christina Breedlove	Investigator Correction
If Yes, how many (pharmaceuticals) (4) 1	2	17-DEC-2009 13:54:36 Christina Breedlove	Investigator Correction

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Group #	Group Name
1	DRUGSCR

If yes, how many (other attempts to quit (6) 1	3 1	17-DEC-2009 13:54:36 Christina Breedlove	Data Entry Error confirmed with subject. Recorded in progress notes
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If yes, how many (other attempts to quit (6) 1	1	03-MAR-2010 15:06:20 Christina Breedlove	Data Entry Error
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Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does the subject have any abnormal findi 1	YES NO	10-NOV-2009 13:17:33 Rossana Matos	Data Entry Error
Does the subject have any abnormal findi 1	NO YES	31-DEC-2009 14:49:24 Sharon Daly	Data Entry Error
Findings 1	BILATERAL CATARACTS <Row Deleted>	24-JUN-2009 10:42:07 Rossana Matos	Pass1
Findings 1	DERMATITIS NECK <Row Deleted>	10-NOV-2009 13:17:33 Rossana Matos	Data Entry Error
Findings 1	OBESE	31-DEC-2009 14:51:02 Sharon Daly	Row Inserted
Sequence Number 1	1 <Row Deleted>	24-JUN-2009 10:42:07 Rossana Matos	Pass1
Sequence Number 1	1 <Row Deleted>	10-NOV-2009 13:17:33 Rossana Matos	Data Entry Error
Sequence Number 1	1	31-DEC-2009 14:51:02 Sharon Daly	Row Inserted
Findings 2	DERMATITIS NECK <Row Deleted>	24-JUN-2009 10:42:07 Rossana Matos	Pass1
Findings 2	DERMATITIS- NECK	31-DEC-2009 14:51:02 Sharon Daly	Row Inserted
Sequence Number 2	2. <Row Deleted>	24-JUN-2009 10:42:07 Rossana Matos	Pass1
Sequence Number 2	2	31-DEC-2009 14:51:02 Sharon Daly	Row Inserted
Findings 3	BILATERAL CATARACTS	31-DEC-2009 14:51:02 Sharon Daly	Row Inserted
Sequence Number 3	3	31-DEC-2009 14:51:02 Sharon Daly	Row Inserted

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1	SC

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Actual Time 1	1038 1044	16-JUN-2009 11:03:29 Rossana Matos	Data Entry Error

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Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	06-MAR-2009 09-MAR-2009	27-JAN-2012 16:11:40 Christina Breedlove	Investigator Correction

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Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Findings 1	ERYTHMATOSIS UPPER GUM ERYTHEMATOUS UPPER GUM	13-NOV-2009 11:23:49 Christina Breedlove	Validation Status changed Spelling correction of Erythematous, per query

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1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	C	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Code 1	C03	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Text 1	DIURETICS, C03	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Code 1	C03E	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Text 1	DIURETICS AND POTASSIUM- SPARING AGENTS IN COMB, C03E	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Code 1	C03EA	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Text 1	LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, C03EA	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Dose 1	37.5/25 1	20-APR-2010 11:33:28 Christina Breedlove	Investigator Correction Changed to 1 tab per query
Preferred Term 1	DYAZIDE	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Preferred Term Code 1	00081101001	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name 1	TRIAMTERENE/HCTZ	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name Code 1	00081101076	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change

Document #: R254128813

Patient Site	Visit Visit Date	CRF CRF Page
R1003 CDB_001	Pcm.2	Page_39

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

Group #	Group Name
1	CM1

Unit	MILLIGRAMS	20-APR-2010 11:33:28	Investigator
1	TABLET	Christina Breedlove	Correction Changed to 1 tab per query

Document #: R254131213

Patient Site	Visit Visit Date	CRF CRF Page
R1003 CDB_001	Pcm.6	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A BLOOD AND BLOOD FORMING ORGANS, B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A01 B01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANTITHROMBOTIC AGENTS, B01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A01A B01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A ANTITHROMBOTIC AGENTS, B01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A01AD B01AC	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, B01AC	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change

Document #: R254132213

Patient Site	Visit Visit Date	CRF CRF Page
R1003 CDB_001	Pcm.7	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.7

Group #	Group Name
1	CM1

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

Document #: R243302813

Patient Site	Visit Visit Date	CRF CRF Page
R1003 CDB_001	Additional Ecg	Page_41 41

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	16-OCT-2009 09:18:44 Sharon Daly	CRA Correction
DCI Blank Flag 1	N Y	13-NOV-2009 11:49:17 Christina Breedlove	Validation Status changed removed (No) and marked page blank per CRF guidelines
DCI Blank Flag 1	Y N	19-NOV-2009 13:26:55 Christina Breedlove	Data Entry Error Confirmed to be NO

Document #: R243302813

Patient Site	Visit Visit Date	CRF CRF Page
R1003 CDB_001	Additional Ecg	Page_41 41

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eg	Page number	41	Additional Ecg

Group #	Group Name
1	EG

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Was ECG Performed/Were any additional 12 1	NO	19-NOV-2009 13:26:55 Christina Breedlove	Row Inserted

Document #: R243302913

Patient Site	Visit	CRF
R1003	Visit Date	CRF Page
CDB_001	Additional Lab	Page_42
		42

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			

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	13-NOV-2009 11:52:28 Christina Breedlove	Validation Status changed removed (No) and marked page blank per CRF guidelines
DCI Blank Flag 1	Y N	19-NOV-2009 13:43:06 Christina Breedlove	Data Entry Error Confirmed to be NO

Document #: R243302913

Patient Site	Visit Visit Date	CRF CRF Page
R1003 CDB_001	Additional Lab	Page_42 42

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

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Were any additional Laboratory evaluatio 1	NO	19-NOV-2009 13:43:06 Christina Breedlove	Row Inserted

Document #: R243303513

Patient Site	Visit Visit Date	CRF CRF Page
R1003 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	09-MAR-2009 06-MAR-2009	08-MAR-2010 10:07:32 Christina Breedlove	Data Entry Mode per query
Date the subject completed OR withdrew f 1	06-MAR-2009 09-MAR-2009	03-JUN-2010 10:20:46 Christina Breedlove	Investigator Correction Subject had early term procedures on 06Mar2009 but returned on 09Mar2009 to have Investigator check subject's gums, have fasting labs, and return study product.

Discrepancy Detail Report

Document #: R243290013

Discrepancy ID: 1639742013 Site: CDB_001 Patient: R1003
Visit: SCREENING Visit Date:
CRF: PAGE_07 Section: LB Qualifying Value: 7
Field: Requisition Number 1: Row: 1
Value Text: 050-552-1501-0
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify that requisition number is the specimen number and should be 050-552-1501-0
Internal Comment: data is confirmed and corrected
Resolution Type: No Action Required
Resolution Text:

Discrepancy ID: 1639748513 Site: CDB_001 Patient: R1003
Visit: SCREENING Visit Date:
CRF: PAGE_07 Section: LB Qualifying Value: 7
Field: Were there any clinically significant la Row: 1
Value Text: NO
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify CS labs should be no.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R243290213

Discrepancy ID: 1788919913 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 1
Value Text: INTERMITTENT NASAL/SINUS CONGESTION
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify if nasal/sinus congestion is episodic. If so, please update diagnosis/procedure to reflect this (e.g. 'Intermittent nasal/sinus congestion'). If not episodic, please update to 'Chronic nasal/sinus congestion'.
Internal Comment: Intermittent episodes
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1788920013 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 2
Value Text: HIGH BLOOD PRESSURE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: please delete NCS from diagnosis, not required per guidelines.
Internal Comment: NCS was deleted per query
Resolution Type: Confirmed
Resolution Text: NCS was deleted per query

Discrepancy ID: 1788920713 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 3
Value Text: RECURRENT BACK PAIN
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: please verify NCS should not be entered.
Internal Comment: NCS was deleted per query
Resolution Type: Confirmed
Resolution Text: NCS was deleted per query

R243290213

Discrepancy ID: 1788920613 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 4
Value Text: SEASONAL ALLERGIES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: please verify seasonal allergy should be entered into CRF.
Internal Comment: Seasonal allergies added to med hx as ongoing since 1989 per query
Resolution Type: Confirmed
Resolution Text: Seasonal allergies added to med hx as ongoing since 1989 per query

Discrepancy ID: 73237111 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 5
Value Text: INTERMITTENT EPISODES-NUMBNESS/TINGLING (EXTREMITIES)
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update diagnosis/procedure term to clarify if this is an intermittent/episodic condition or a continuous chronic condition.
Internal Comment: Intermittent episodes
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 23092211 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 6
Value Text: HEMORRHOIDS
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please remove.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

R243290213

Discrepancy ID: 42964611 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 7
Value Text: INTERMITTENT EPISODES-FOLLICULITIS/ABSCESSSES OR BOILS (INNER THIGHS & PRIVATE AREA)
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update diagnosis/procedure term to clarify if this is an intermittent/episodic condition or a continuous chronic condition.
Internal Comment: Intermittent episodes
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 42964711 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 8
Value Text: POSTMENOPAUSAL
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify Gender (female) and Urine Pregnancy Test Result (N/A, Male or Woman of Non-childbearing potential). If gender and pregnancy result are correct, please update medical history as a corresponding medical history event must be recorded to show why the subject is of non-childbearing potential.
Internal Comment: Subject is postmenopausal since Sep 2007. Confimed UAP is NA.
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 45586711 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify hemorrhoids should be added.
Internal Comment: per query
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R243290313

Discrepancy ID: 21873611 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_10 **Section:** SMOKING HISTORY **Qualifying Value:** 10
Field: Attempted to quit (Other cessation aids) **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per 29 APR and 21 May progress report.
Internal Comment: confirmed with subject. Recorded in progress notes
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: confirmed with subject. Recorded in progress notes

Discrepancy ID: 21873511 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_10 **Section:** SMOKING HISTORY **Qualifying Value:** 10
Field: Attempted to quit (Pharmaceuticals) **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per progress note on 29 APR and 21 MAY 2009
Internal Comment: confirmed with subject. Recorded in progress notes
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: confirmed with subject. Recorded in progress notes

Discrepancy ID: 1788921013 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_10 **Section:** SMOKING HISTORY **Qualifying Value:** 10
Field: Comments (other attempts) **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Hypnosis is classified as an other smoking cessation aid. Please remove all data from other attempts to quit and add it to other smoking cessation aids data.
Internal Comment: per query
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R243290613

Discrepancy ID: 23092111 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_12 **Section:** PE **Qualifying Value:** 12
Field: Does the subject have any abnormal findi **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify obese, dermatosis neck, and bilateral caracts should be added to CRF.
Internal Comment: verified
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1678182013 **Site:** CDB_001 **Patient:** R1003
Visit: SCREENING **Visit Date:**
CRF: PAGE_12 **Section:** PE **Qualifying Value:** 12
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter only relevant findings, please have MD assign relevance.
Internal Comment: removed
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R243290913

Discrepancy ID: 1677914813 **Site:** CDB_001 **Patient:** R1003
Visit: BASELINE, WEEK **Visit Date:**
CRF: PAGE_15 **Section:** SC **Qualifying Value:** 15
Field: Actual Time **Row:** 1
Value Text: 1044
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update time per conventions.
Internal Comment: data correction
Resolution Type: No Action Required
Resolution Text: data correction

Document #: R243293813

Discrepancy ID: 473006311 **Site:** CDB_001 **Patient:** R1003
Visit: IP, WEEK 16 **Visit Date:**
CRF: PAGE_27 **Section:** LB **Qualifying Value:** 27
Field: Date **Row:** 1
Value Text: 20090309
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per correspondence with study coordinator on 16-Dec-2011, subject returned for an unscheduled visit on 06-Mar-2009 and was discontinued due to an adverse event. The visit 16/EOT procedures were then performed on 06-Mar-2009 however as the subject was not fasting the laboratory blood collection was not done until 09-Mar-2009. Please review date and amend as needed.

Internal Comment:

Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: Date updated to 09-Mar-2009, LF 30Jan2012.

Discrepancy ID: 1650002713 **Site:** CDB_001 **Patient:** R1003
Visit: IP, WEEK 16 **Visit Date:**
CRF: PAGE_27 **Section:** LB **Qualifying Value:** 27
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please provide source and verify date of lab sample collection.

Internal Comment:

Resolution Type: Confirmed
Resolution Text:

Document #: R243294313

Discrepancy ID: 1788921913 **Site:** CDB_001 **Patient:** R1003
Visit: IP, WEEK 16 **Visit Date:**
CRF: PAGE_29 **Section:** PE **Qualifying Value:** 29
Field: Findings **Row:** 1
Value Text: ERYTHEMATOUS UPPER GUM
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify spelling should be "erythematous".
Internal Comment: Spelling correction of Erythematous, per query
Resolution Type: Confirmed
Resolution Text: Spelling correction of Erythematous, per query

Discrepancy ID: 1650029613 **Site:** CDB_001 **Patient:** R1003
Visit: IP, WEEK 16 **Visit Date:**
CRF: PAGE_29 **Section:** PE **Qualifying Value:** 29
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify "erythmatosis" vs "erythematous" per source.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 1686342113 **Site:** CDB_001 **Patient:** R1003
Visit: IP, WEEK 16 **Visit Date:**
CRF: PAGE_29 **Section:** PE **Qualifying Value:** 29
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy:
Internal Comment: word misspelled was corrected
Resolution Type: Confirmed
Resolution Text:

R243294313

Discrepancy ID: 1718423513

Site: CDB_001

Patient: R1003

Visit: IP, WEEK 16

Visit Date:

CRF: PAGE_29

Section: PE

Qualifying Value: 29

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify relevant to study. Update as necessary.

Internal Comment: Per PI erythmatosis upper gum is Relevant to study as subject was discontinued from study.

Resolution Type: Confirmed

Resolution Text: Per PI erythmatosis upper gum is Relevant to study as subject was discontinued from study.

Document #: R254128813

Discrepancy ID: 102147411 **Site:** CDB_001 **Patient:** R1003
Visit: PCM.2 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Dose **Row:** 1
Value Text: 1
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Combination drug doses/units should be captured as # of tablets. Please verify updating dose to # of tablets (ex. 1) and units to tablet.
Internal Comment: Changed to 1 tab per query
Resolution Type: Confirmed
Resolution Text: Verified. JLM 23Apr2010

Discrepancy ID: 1718425713 **Site:** CDB_001 **Patient:** R1003
Visit: PCM.2 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Unit **Row:** 1
Value Text: TABLET
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per source, listed as CAP.
Internal Comment: Confirmed Units are (mg) and source has been corrected.
Resolution Type: Confirmed
Resolution Text: Confirmed Units are (mg) and source has been corrected.

Deleted CRFs Report