

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 09:45:29

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4033

Ending patient: R4033

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

Verified Approved Locked Frozen

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.

Verified Approved Locked Frozen

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.

Verified Approved Locked Frozen

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	

Verified Approved Locked Frozen

Page Version No. PAGE_04 (v1, 24-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

Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="15-APR-2009"/>	<input type="text" value="(b) (6)"/>	<input type="checkbox"/> Male	<input type="checkbox"/> Hispanic or Latino
		<input checked="" type="checkbox"/> Female	<input checked="" type="checkbox"/> Not Hispanic or latino
Race			
<input checked="" type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Black or African American	<input type="checkbox"/> American Indian/Alaskan Native		
<input type="checkbox"/> Asian	<input type="checkbox"/> Other		<input type="text"/>

Body Measurements

Were Body Measurements Collected? Yes No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="63.2"/>

Verified Approved Locked Frozen

Page Version No. PAGE_05 (v1, 24-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	116
Diastolic Blood Pressure	MMHG	80
Heart Rate	BEATS/MINUTE	82
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.8
Weight	LB	141.6

Verified Approved Locked Frozen

Page Version No. PAGE_06 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: 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.

Verified Approved Locked Frozen

Page Version No. PAGE_07 (v1, 24-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

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at Least 5 Minutes?	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text" value="15-APR-2009"/>	<input type="text" value="17:19"/>

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

Verified Approved Locked Frozen

Page Version No. PAGE_08 (v1, 24-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

Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

Sequence No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	CHRONIC CONSTIPATION	00-00-2007		<input checked="" type="checkbox"/> Ongoing
2	MIGRAINE HEADACHES	00-00-1981		<input checked="" type="checkbox"/> Ongoing
3	TENSION HEADACHES	00-00-2004		<input checked="" type="checkbox"/> Ongoing
4	ALLERGIC RHINITIS	00-00-1967		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

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

Verified Approved Locked Frozen

Page Version No. PAGE_09 (v1, 24-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

Smoking History

Was Smoking History collected?

Yes No

Date

Parameter	Result	Comments
Age subject began smoking daily	<input type="text" value="29"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="20"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="1"/>	PATCH-2004
Has the subject attempted to quit with the use of Pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	

Verified Approved Locked Frozen

Page Version No. PAGE_10 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
15-APR-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
15-APR-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
15-APR-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_11 (v1, 24-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

Behavioral Counseling

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

Verified Approved Locked Frozen

Page Version No. PAGE_13 (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
27-APR-2009	12:51	34	6.0	

Behavioral Counseling

Date	Parameter	Result	Comments
27-APR-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_14 (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

Randomization

Date Actual Time
Was Subject randomized? Yes No

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="10"/> logs
1.0 g of snus or matching placebo	<input type="text" value="6"/> logs

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_15 (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

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="04-MAY-2009"/>	<input type="text" value="WEEK 1"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="35"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text"/>	<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" value="18-MAY-2009"/>	<input type="text" value="WEEK 3"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="14"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

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?

Yes No

Was Subject's smoking status reviewed?

Yes No

Was Subject's use of study product reviewed?

Yes No

Approximately how many cigarettes did the subject smoke that week?

Was Behavioral Counseling Given?

Yes No

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

Yes No

Verified Approved Locked Frozen

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

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_17 (v1, 30-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

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_18 (v1, 25-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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

Verified Approved Locked Frozen

Page Version No. PAGE_19 (v1, 31-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

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

Verified Approved Locked Frozen

Page Version No. PAGE_20 (v1, 24-APR-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

Status Review

Date	Parameter	Result	Comments
<input type="text" value="23-JUN-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	105
Diastolic Blood Pressure	MMHG	67
Heart Rate	BEATS/MINUTE	79
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	36.9
Weight	LB	ND

Verified Approved Locked Frozen

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
07-JUL-2009	13:41	0	0.0	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_23 (v1, 31-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

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="6"/> logs
1.0 g of snus or matching placebo	<input type="text" value="0"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="07-JUL-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_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

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="27-JUL-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject instructed to cut down on product use during upcoming Weeks 14-16 to avoid a too abrupt ending of nicotine uptake?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	103
Diastolic Blood Pressure	MMHG	59
Heart Rate	BEATS/MINUTE	68
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.7
Weight	LB	138.6

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
20-AUG-2009	12:45	2	0.9	

Behavioral Counseling

Date	Parameter	Result	Comments
20-AUG-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
<input type="text" value="20-AUG-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	UNABLE TO CONTACT SUBJECT
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

OverFlow Section For Document Number R279314013

1 UNABLE TO CONTACT SUBJECT

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	106
Diastolic Blood Pressure	MMHG	71
Heart Rate	BEATS/MINUTE	83
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	36.6
Weight	LB	141.6

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_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
09-NOV-2009	13:27	2	0.9	

Behavioral Counseling

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

Questionnaires

Date

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="09-NOV-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

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.

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

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.

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

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number R4033

Covance Study Number: 7694-105

Subject Initials (b)

Visit Name PCM

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: METHYLPREDNISOLONE

Indication: CONTACT DERMATITIS

Dose: 3

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

09-JUN-2009

09-JUN-2009

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 R279320113

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number R4033

Covance Study Number: 7694-105

Subject Initials (b)

Visit Name PCM

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: TRIAMCINOLONE

Indication: CONTACT DERMATITIS

Dose: 1

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

APPLICATION

Start Date1

Stop Date1

06-JUN-2009

12-JUN-2009

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 R279321813

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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.

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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

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

Frequency Select only one

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily
- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

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

Document Number

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

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

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

Action Taken: Select only one

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

Outcome to Date Select only one

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

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

Document Number

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

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

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

Action Taken: Select only one

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

Outcome to Date Select only one

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

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

Action Taken: Select only one

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

Outcome to Date Select only one

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

Were any additional 12-lead ECGs collected? Yes, list below. No

Date	Actual Time	ECG Interpretation	Comments Regarding CS Findings:
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>

Verified Approved Locked Frozen

Page Version No. PAGE_41 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Laboratory Evaluations

Were any additional laboratory evaluations collected? Yes, list below No

Date	Requisition Number	Clinically Significant?	Test Name CS Labs Only	Test Code ID CS Labs Only	Comments
16-JUN-2009	NA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			

Note: Attach copy of signed laboratory report.

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	MMHG	116
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	59
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	81
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	16
	Body Temperature	C	37.1

Comments

Date Actual Time

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

Comments

Verified Approved Locked Frozen

Page Version No. PAGE_43 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>

* Indicate NE if system was not examined.

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

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 #: R279313313

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date of Onset 5	14-JUN-2009 <Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Date of Resolution 5	07-JUL-2009 <Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Diagnosis/Procedure 5	LACERATION TO LEFT LEG <Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Ongoing 5	<Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Sequence Number 5	5 <Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Date of Onset 6	06-JUN-2009 <Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Date of Resolution 6	12-JUN-2009 <Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Diagnosis/Procedure 6	CONTACT DERMATITIS <Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Ongoing 6	<Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Sequence Number 6	6 <Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Date of Onset 7	01-JUN-2009 <Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Date of Resolution 7	06-JUN-2009 <Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Diagnosis/Procedure 7	SEROUS OTITIS LEFT EAR <Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error
Ongoing 7	<Row Deleted>	03-MAR-2010 15:55:57 Kim Freschly	Data Entry Error

Document #: R279313313

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Sequence Number	7	03-MAR-2010 15:55:57	Data Entry Error
7	<Row Deleted>	Kim Freschly	

Document #: R251165213

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Screening	Page_10 10

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Date 1	27-APR-2009 15-APR-2009		18-MAR-2010 09:03:10 Lana Glaser	Data Entry Error
Date 1	15-APR-2009 27-APR-2009		23-APR-2010 10:57:39 Lana Glaser	Data Entry Error

Document #: R251168613

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Sptp, Weeks 1-4	Page_16 16

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

Group #	Group Name
0	Section Header

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
DCM Blank flag 1	N Y		19-MAR-2010 14:11:16 Lana Glaser	Data Entry Error

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Approximately how many cigarettes did th (11) 1	35		18-MAR-2010 17:00:24 Lana Glaser	Data Entry Error
Date 1	18-MAY-2009 ND		18-MAR-2010 17:00:24 Lana Glaser	Data Entry Error
Was Behavioral Counseling Given (6) 1	YES		18-MAR-2010 17:00:24 Lana Glaser	Data Entry Error
Was Subject contacted by telephone (1) 1	YES NO		18-MAR-2010 17:00:24 Lana Glaser	Data Entry Error
Was Subject's smoking status reviewed (2) 1	YES		18-MAR-2010 17:00:24 Lana Glaser	Data Entry Error
Was Subject's use of study product review (3) 1	YES		18-MAR-2010 17:00:24 Lana Glaser	Data Entry Error

Document #: R266269513

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Ip, Week 6	Page_17 17

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
-----------------------------	--------------------------	-------------------------	----------------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	18-MAR-2010 17:05:30 Lana Glaser	Data Entry Error

Document #: R266269813

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Ip, Week 6	Page_18 18

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
-----------------------------	--------------------------	-------------------------	----------------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	18-MAR-2010 17:06:14 Lana Glaser	Data Entry Error

Document #: R266269913

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Ip, Week 6	Page_19 19

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
-----------------------------	--------------------------	-------------------------	----------------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	18-MAR-2010 17:06:20 Lana Glaser	Data Entry Error

Document #: R266270213

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Ip, Week 6	Page_20 20

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
-----------------------------	--------------------------	-------------------------	----------------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	18-MAR-2010 17:06:27 Lana Glaser	Data Entry Error

Document #: R266273313

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Ip, Week 16	Page_27 27

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

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Were the scheduled laboratory samples ob 1	YES		31-AUG-2009 11:55:49 Lana Glaser	Data Entry Error

Document #: R266274213

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Ip, Week 16	Page_31 31

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	31	Ip, Week 16

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
If Subject was not compliant, approximat (5) 1	0	12-NOV-2009 16:07:56 Kim Freschly	Data Entry Error
Was Subject compliant (4) 1	YES	12-NOV-2009 16:07:14 Kim Freschly	Data Entry Error

Document #: R279314013

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Fu, Week 20 & 24	Page_32 32

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
-----------------------------	--------------------------	-------------------------	----------------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
DCI Blank Flag 1	N Y		07-JAN-2010 14:09:45 Lana Glaser	Data Entry Error
DCI Blank Flag 1	Y N		07-JAN-2010 14:12:41 Lana Glaser	Data Entry Error

Document #: R279314013

Patient Site	Visit Visit Date	CRF CRF Page	
R4033 P3880_0342	Fu, Week 20 & 24	Page_32 32	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	32	Fu, Week 20 & 24

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments (HDYF) (8) 1		07-JAN-2010 14:12:41 Lana Glaser	Row Inserted
Comments (behavioral counseling) (6) 1		07-JAN-2010 14:12:41 Lana Glaser	Row Inserted
Comments (compliant) (4) 1		07-JAN-2010 14:12:41 Lana Glaser	Row Inserted
Comments (contacted by phone) (1) 1		07-JAN-2010 14:12:41 Lana Glaser	Row Inserted
Comments (how many cigarettes) (5) 1		07-JAN-2010 14:12:41 Lana Glaser	Row Inserted
Comments (smoking status reviewed) (2) 1		07-JAN-2010 14:12:41 Lana Glaser	Row Inserted
Date 1	15-SEP-2009	07-JAN-2010 14:12:41 Lana Glaser	Row Inserted
If Subject was not compliant, approximat (5) 1		07-JAN-2010 14:12:41 Lana Glaser	Row Inserted
Scheduled Timepoint 1	WEEK 20	07-JAN-2010 14:12:41 Lana Glaser	Row Inserted
Was Behavioral Counseling Given (6) 1	YES	07-JAN-2010 14:12:41 Lana Glaser	Row Inserted
Was Subject asked HDYF? (8) 1	YES	07-JAN-2010 14:12:41 Lana Glaser	Row Inserted

Document #: R279314013

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Fu, Week 20 & 24	Page_32 32

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

Group #	Group Name
1	CHKYN

Was Subject compliant (4) 1	YES	07-JAN-2010 14:12:41	Row Inserted Lana Glaser
--------------------------------	-----	----------------------	-----------------------------

Was Subject contacted by telephone (1) 1	YES	07-JAN-2010 14:12:41	Row Inserted Lana Glaser
---	-----	----------------------	-----------------------------

Was Subject's smoking status reviewed (2) 1	YES	07-JAN-2010 14:12:41	Row Inserted Lana Glaser
--	-----	----------------------	-----------------------------

Document #: R279314013

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Fu, Week 20 & 24	Page_32 32

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

Group #	Group Name
0	Section Header

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
DCM Blank flag 1	N Y		05-JAN-2010 17:03:37 Katherine Bauer	Key Change

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Comments (contacted by phone) (1) 1	UNABLE TO CONTACT SUBJECT		18-MAR-2010 17:02:56 Lana Glaser	Data Entry Error
Was Subject contacted by telephone (1) 1	NO		07-JAN-2010 14:13:03 Lana Glaser	Data Entry Error

Document #: R279316313

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.2	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Indication 1	ALLERGIES ALLERGIC RHINITIS	12-JAN-2010 13:04:40 Kim Freschly	Data Entry Error

Document #: R279316613

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.3	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	N R	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	NERVOUS SYSTEM, N RESPIRATORY SYSTEM, R	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	N05 R06	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	PSYCHOLEPTICS, N05 ANTIHIISTAMINES FOR SYSTEMIC USE, R06	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	N05B R06A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	ANXIOLYTICS, N05B ANTIHIISTAMINES FOR SYSTEMIC USE, R06A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	N05BB R06AX	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	DIPHENYLMETHANE DERIVATIVES, N05BB OTHER ANTIHIISTAMINES FOR SYSTEMIC USE, R06AX	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Indication 1	ALLERGIES ALLERGIC RHINITIS	12-JAN-2010 13:05:30 Kim Freschly	Data Entry Error

Document #: R279318413

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	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	D H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	DERMATOLOGICALS, D SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	D07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, D07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	D07A H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	CORTICOSTEROIDS, PLAIN, D07A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	D07AA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS, WEAK (GROUP I), D07AA GLUCOCORTICIDS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Frequency 1	EVERY DAY ONCE	13-APR-2010 09:15:37 Lana Glaser	Data Entry Error
Stop Date 1	06-JUN-2009 12-JUN-2009	13-APR-2010 09:12:13 Lana Glaser	Data Entry Error
Stop Date 1	12-JUN-2009 06-JUN-2009	13-APR-2010 09:14:25 Lana Glaser	Data Entry Error

Document #: R279319913

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	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	D H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	DERMATOLOGICALS, D SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	D07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, D07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	D07A H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	CORTICOSTEROIDS, PLAIN, D07A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	D07AA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS, WEAK (GROUP I), D07AA GLUCOCORTICIDS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Frequency 1	EVERY DAY ONCE	13-APR-2010 09:15:09 Lana Glaser	Data Entry Error

Document #: R279320013

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.8	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.8

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	D H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	DERMATOLOGICALS, D SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	D07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, D07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	D07A H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	CORTICOSTEROIDS, PLAIN, D07A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	D07AA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS, WEAK (GROUP I), D07AA GLUCOCORTICIDS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Frequency 1	EVERY DAY ONCE	13-APR-2010 09:15:58 Lana Glaser	Data Entry Error

Document #: R279320113

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.9	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.9

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	D H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	DERMATOLOGICALS, D SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	D07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, D07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	D07A H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	CORTICOSTEROIDS, PLAIN, D07A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	D07AA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS, WEAK (GROUP I), D07AA GLUCOCORTICIDS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Frequency 1	EVERY DAY ONCE	13-APR-2010 09:16:22 Lana Glaser	Data Entry Error

Document #: R279320313

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.10	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.10

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	D H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	DERMATOLOGICALS, D SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	D07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, D07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	D07A H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	CORTICOSTEROIDS, PLAIN, D07A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	D07AA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS, WEAK (GROUP I), D07AA GLUCOCORTICIDS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Frequency 1	EVERY DAY ONCE	13-APR-2010 09:16:37 Lana Glaser	Data Entry Error

Document #: R279321113

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.11	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.11

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	D H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	DERMATOLOGICALS, D SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	D07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, D07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	D07A H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	CORTICOSTEROIDS, PLAIN, D07A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	D07AA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS, WEAK (GROUP I), D07AA GLUCOCORTICIDS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Frequency 1	EVERY DAY ONCE	13-APR-2010 09:16:52 Lana Glaser	Data Entry Error
Stop Date 1	11-JUN-2009 12-JUN-2009	07-JAN-2010 14:19:17 Lana Glaser	Data Entry Error
Stop Date 1	12-JUN-2009 11-JUN-2009	12-JAN-2010 13:06:48 Kim Freschly	Data Entry Error

Document #: R279321813

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.12	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.12

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A D	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A DERMATOLOGICALS, D	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A01 D07	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, D07	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A01A D07A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A CORTICOSTEROIDS, PLAIN, D07A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A01AC D07AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS FOR LOCAL ORAL TREATMENT, A01AC CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), D07AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change

Document #: R279324113

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.13	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.13

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	N R	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	NERVOUS SYSTEM, N RESPIRATORY SYSTEM, R	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	N05 R06	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	PSYCHOLEPTICS, N05 ANTIHIISTAMINES FOR SYSTEMIC USE, R06	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	N05B R06A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	ANXIOLYTICS, N05B ANTIHIISTAMINES FOR SYSTEMIC USE, R06A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	N05BB R06AX	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	DIPHENYLMETHANE DERIVATIVES, N05BB OTHER ANTIHIISTAMINES FOR SYSTEMIC USE, R06AX	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Indication 1	ALLERGIES ALLERGIC RHINITIS	12-JAN-2010 13:09:24 Kim Freschly	Data Entry Error
Stop Date 1	07-JUN-2009	12-JAN-2010 13:09:24 Kim Freschly	Data Entry Error

Document #: R279324713

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.14	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.14

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Dose 1	15	02-FEB-2010 14:50:23 Lana Glaser	Data Entry Mode

Document #: R279325313

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.15	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.15

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	C N	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C NERVOUS SYSTEM, N	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC2 Code 1	C05 N01	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC2 Text 1	VASOPROTECTIVES, C05 ANESTHETICS, N01	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC3 Code 1	C05A N01B	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC3 Text 1	AG.FOR TREATM.OF HEMORRH.AND ANAL FISS.FOR TOP.USE, C05A ANESTHETICS, LOCAL, N01B	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC4 Code 1	C05AD N01BA	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC4 Text 1	LOCAL ANESTHETICS, C05AD ESTERS OF AMINOBENZOIC ACID, N01BA	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
Drug name 1	NOVACAINE NOVACAINE	12-NOV-2009 16:42:07 Kim Freschly	Data Entry Error

Document #: R279326513

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.18	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.18

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	N	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC1 Text 1	NERVOUS SYSTEM, N	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC2 Code 1	N02	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC2 Text 1	ANALGESICS, N02	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC3 Code 1	N02A	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC3 Text 1	OPIOIDS, N02A	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC4 Code 1	N02AA	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC4 Text 1	NATURAL OPIUM ALKALOIDS, N02AA	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Drug Modified Reported Term 1	AVENZA AVINZA	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Drug name 1	AVENZA AVINZA	26-APR-2010 12:10:01 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 26Apr2010
Indication 1	LACERATION LEFT LEG LACERATION LEFT LEG PAIN	12-JAN-2010 13:12:06 Kim Freschly	Data Entry Error
Preferred Term 1	MORPHINE SULFATE	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Preferred Term Code 1	00036302001	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Trade Name 1	AVINZA	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change

Document #: R279326513

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.18	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.18

Group #	Group Name
1	CM1

Trade Name Code	26-APR-2010 12:25:24	Data Change
1	00036302049	Joanne Mccaigue

Document #: R279326613

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.19	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.19

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC1 Code 1	A G	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A GENITO URINARY SYSTEM AND SEX HORMONES, G	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	A01	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Code 1	A01 G01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS, G01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	A01A	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Code 1	A01A G01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS, G01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	A01AB	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change

Document #: R279326613

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.19	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.19

Group #	Group Name
1	CM1

ATC4 Code	A01AB	27-APR-2010 12:10:38	Data Change
1	G01AF	Joanne Mccaigue	
ATC4 Text		26-APR-2010 10:36:00	Class. Change
1	ANTIINFECT. AND ANTISEPT. FOR LOCAL ORAL TREATMENT, A01AB	Carol Kraucyk	
ATC4 Text		27-APR-2010 12:10:38	Data Change
1	ANTIINFECT. AND ANTISEPT. FOR LOCAL ORAL TREATMENT, A01AB IMIDAZOLE DERIVATIVES, G01AF	Joanne Mccaigue	
Indication	YEAST INFECTION	12-JAN-2010 13:13:00	Data Entry Error
1	VAGINAL CADIDIASIS	Kim Freschly	
Indication	VAGINAL CADIDIASIS	12-JAN-2010 13:22:36	Data Entry Error
1	VAGINAL CONDIDIASIS	Kim Freschly	
Indication	VAGINAL CONDIDIASIS	12-APR-2010 11:10:50	ODM/SEC
1	VAGINAL CANDIDIASIS	Joanne Mccaigue	Obvious spelling correction. JLM 12Apr2010
Preferred Term		26-APR-2010 10:36:00	Class. Change
1	MICONAZOLE NITRATE	Carol Kraucyk	
Preferred Term Code		26-APR-2010 10:36:00	Class. Change
1	00310802001	Carol Kraucyk	
Trade Name		26-APR-2010 10:36:00	Class. Change
1	MONISTAT-3	Carol Kraucyk	
Trade Name Code		26-APR-2010 10:36:00	Class. Change
1	00310802090	Carol Kraucyk	

Document #: R279326713

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.20	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.20

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Indication 1	INSOMNIA, LACERATION LEFT LEG INSOMNIA	12-JAN-2010 13:14:20 Kim Freschly	Data Entry Error

Document #: R279327013

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Pcm.21	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.21

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Drug name 1	AMITREX IMITREX	12-JAN-2010 13:14:54 Kim Freschly	Data Entry Error
Stop Date 1	17-JUN-2009	12-JAN-2010 13:14:54 Kim Freschly	Data Entry Error

Document #: R279327313

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Ae	Page_40 40

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

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Onset Time 1	1300 UNK	23-APR-2010 12:13:13 Lana Glaser	Data Entry Error per source, "subject noted symptoms with dosing", start time unknown.

Document #: R279327613

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Ae.1	Page_40

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

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Onset Time 1	1300 UNK	23-APR-2010 11:59:25 Lana Glaser	Investigator Correction

Document #: R279328513

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Ae.7	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.7

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Action Specify 1	STITCHES		04-MAR-2010 10:14:30 Kim Freschly	Data Entry Error
Action Taken 1	OTHER DRUG OTHER TREATMENT		04-MAR-2010 10:14:30 Kim Freschly	Data Entry Error
Serious Event 1	YES NO		07-JAN-2010 14:50:42 Lana Glaser	Data Entry Error
Severity 1	MILD MODERATE		07-JAN-2010 14:51:31 Lana Glaser	Data Entry Error
Severity 1	MODERATE MILD		03-MAR-2010 15:55:04 Kim Freschly	Data Entry Error

Document #: R279328713

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Ae.9	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.9

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Adverse Event 1	YEAST INFECTION VAGINAL CONDIDIASIS	07-JAN-2010 14:53:33 Lana Glaser	Data Entry Error
Adverse Event 1	VAGINAL CONDIDIASIS VAGINAL CANDIDIASIS	21-APR-2010 12:42:43 Joanne Mccaigue	ODM/SEC Obvious spelling error. JLM 21Apr2010
High Level Group Term 1	FUNGAL INFECTIOUS DISORDERS	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
High Level Group Term Code 1	10017528	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
High Level Term 1	CANDIDA INFECTIONS	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
High Level Term Code 1	10007134	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
Lower Level Term 1	VAGINAL CANDIDIASIS	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
Lower Level Term Code 1	10046898	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
Preferred Term 1	VULVOVAGINAL CANDIDIASIS	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
Preferred Term Code 1	10047784	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
System Organ Class 1	INFECTIONS AND INFESTATIONS	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
System Organ Class Code 1	10021881	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
Verbatim Term 1	VAGINAL CONDIDIASIS VAGINAL CANDIDIASIS	26-APR-2010 10:36:00 Carol Kraucyk	Data Change

Document #: R279328913

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Ae.10	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
----------------------	-------------------	------------------	---------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	23-APR-2010 14:33:58 Lana Glaser	Data Entry Error

Document #: R279330213

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Additional Lab	Page_42 42

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

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Clinically Significant (additional) (2) 1	NO	18-MAR-2010 17:06:39 Lana Glaser	Row Inserted
Comments 1		18-MAR-2010 17:06:39 Lana Glaser	Row Inserted
Date 1	16-JUN-2009	18-MAR-2010 17:06:39 Lana Glaser	Row Inserted
Requisition Number (additional labs) (4) 1	NA	18-MAR-2010 17:06:39 Lana Glaser	Row Inserted
Test Code ID CS Labs only 1		18-MAR-2010 17:06:39 Lana Glaser	Row Inserted
Test Name CS Labs only 1		18-MAR-2010 17:06:39 Lana Glaser	Row Inserted
Were any additional Laboratory evaluatio 1	NO YES	18-MAR-2010 17:06:39 Lana Glaser	Data Entry Error

Document #: R279330313

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Additional Vs	Page_43 43

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

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Actual Time 1	1233	18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Body Temperature 1	37.1	18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Body Temperature Unit 1	C	18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Comments (2) 1		18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Date 1	16-JUN-2009	18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Diastolic Blood Pressure 1	59	18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Diastolic Blood Pressure unit 1	MMHG	18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Heart Rate 1	81	18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Heart Rate Unit 1	BEATS/MINUTE	18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Other, specify (1) 1		18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Position (Unscheduled) (2) 1	SEATED	18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Respiratory Rate 1	16	18-MAR-2010 17:07:19 Lana Glaser	Row Inserted
Respiratory Rate Unit 1	BREATHS/MINUTE	18-MAR-2010 17:07:19 Lana Glaser	Row Inserted

Document #: R279330313

Patient Site	Visit Visit Date	CRF CRF Page
R4033 P3880_0342	Additional Vs	Page_43 43

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

Group #	Group Name
1	VS

Systolic Blood Pressure 1	116	18-MAR-2010 17:07:19	Row Inserted Lana Glaser
------------------------------	-----	----------------------	-----------------------------

Systolic Blood Pressure unit 1	MMHG	18-MAR-2010 17:07:19	Row Inserted Lana Glaser
-----------------------------------	------	----------------------	-----------------------------

Were Vital Signs Collected/Were any addi (1) 1	NO YES	18-MAR-2010 17:07:19	Data Entry Error Lana Glaser
---	-----------	----------------------	---------------------------------

Discrepancy Detail Report

Document #: R251165213

Discrepancy ID: 86556811 Site: P3880_0342 Patient: R4033

Visit: SCREENING

Visit Date:

CRF: PAGE_10

Section: SMOKING HISTORY Qualifying Value: 10

Field: Date

Row: 1

Value Text: 20090427

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per previous query date was updated, however source clearly indicated smoking history was captured (Medical History supplement questionnaire) on 27Apr09. Both the Study manager and subject dated the form 27Apr09

Internal Comment: Please route query to DM - Should this be updated to 27Apr2009?

Resolution Type: Confirmed

Resolution Text: Verified. JLM 26Apr2010

Document #: R266274213

Discrepancy ID: 1746295613 **Site:** P3880_0342 **Patient:** R4033
Visit: IP, WEEK 16 **Visit Date:**
CRF: PAGE_31 **Section:** STATUS REVIEW **Qualifying Value:** 31
Field: If Subject was not compliant, approximat **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please leave blank if subject was compliant
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 1746295513 **Site:** P3880_0342 **Patient:** R4033
Visit: IP, WEEK 16 **Visit Date:**
CRF: PAGE_31 **Section:** STATUS REVIEW **Qualifying Value:** 31
Field: Was Subject compliant **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please complete
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R279314013

Discrepancy ID: 86986711 **Site:** P3880_0342 **Patient:** R4033
Visit: FU, WEEK 20 & 2 **Visit Date:**
CRF: PAGE_32 **Section:** STATUS REVIEW **Qualifying Value:** 32.1
Field: Comments (contacted by phone) **Row:** 1
Value Text: UNABLE TO CONTACT SUBJECT
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please provide a comment for why subject was not contacted.
Internal Comment: comment added
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 34882711 **Site:** P3880_0342 **Patient:** R4033
Visit: FU, WEEK 20 & 2 **Visit Date:**
CRF: PAGE_32 **Section:** STATUS REVIEW **Qualifying Value:** 32.1
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Since call was not completed, should date be ND?
Internal Comment: corrected to ND
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R279316313

Discrepancy ID: 34884111

Site: P3880_0342

Patient: R4033

Visit: PCM.2

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: ALLERGIC RHINITIS

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This appears to be related to an AE, but there is no corresponding listing for an episode of allergy.

Internal Comment: Please consult the Con Med source document and document the absence of an AE of allergy on this date.

Resolution Type: Confirmed

Resolution Text: allergic rhinitis on Med Hx

Document #: R279316613

Discrepancy ID: 34884211

Site: P3880_0342

Patient: R4033

Visit: PCM.3

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Drug name

Row: 1

Value Text: HYDROXYZINE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This appears to be related to an AE, but there is no corresponding listing for an episode of allergy.

Internal Comment: Please consult source; confirm and document that the AE was not captured.

Resolution Type: Confirmed

Resolution Text: allergic rhinitis on Med Hx

Document #: R279318413

Discrepancy ID: 99032511

Site: P3880_0342

Patient: R4033

Visit: PCM.6

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Frequency

Row: 1

Value Text: ONCE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This medication/dose was only taken one day. Please verify updating frequency to 'one time.'

Internal Comment: these were taken in descending dose so number of tablets are different.

Resolution Type: Confirmed

Resolution Text: Verified. JLM 21Apr2010

Document #: R279319913

Discrepancy ID: 99032611

Site: P3880_0342

Patient: R4033

Visit: PCM.7

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Frequency

Row: 1

Value Text: ONCE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This medication/dose was only taken one day. Please verify updating frequency to 'one time.'

Internal Comment:

Resolution Type: Confirmed

Resolution Text: Verified. JLM 21Apr2010

Document #: R279320013

Discrepancy ID: 99032711

Site: P3880_0342

Patient: R4033

Visit: PCM.8

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Frequency

Row: 1

Value Text: ONCE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This medication/dose was only taken one day. Please verify updating frequency to 'one time.'

Internal Comment:

Resolution Type: Confirmed

Resolution Text: Verified. JLM 21Apr2010

Document #: R279320113

Discrepancy ID: 99032811

Site: P3880_0342

Patient: R4033

Visit: PCM.9

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Frequency

Row: 1

Value Text: ONCE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This medication/dose was only taken one day. Please verify updating frequency to 'one time.'

Internal Comment:

Resolution Type: Confirmed

Resolution Text: Verified. JLM 21Apr2010

Document #: R279320313

Discrepancy ID: 99032911

Site: P3880_0342

Patient: R4033

Visit: PCM.10

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Frequency

Row: 1

Value Text: ONCE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This medication/dose was only taken one day. Please verify updating frequency to 'one time.'

Internal Comment:

Resolution Type: Confirmed

Resolution Text: Verified. JLM 21Apr2010

Document #: R279321813

Discrepancy ID: 34879611

Site: P3880_0342

Patient: R4033

Visit: PCM.12

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Stop Date

Row: 1

Value Text: 20090612

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per source, last use of con med was Day 6. This was calculated using Day 1 as 6Jun.
Please confirm date of stop of con med.

Internal Comment: Source doc needs review and possible revision.

Resolution Type: No Action Required

Resolution Text: Monitor error.

Document #: R279324713

Discrepancy ID: 34881911

Site: P3880_0342

Patient: R4033

Visit: PCM.14

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per source, the calculation of dose is not provided and unit is not clear. Consider entry of UNK.

Internal Comment: Please review source and clarify if possible or provide data for entry of dose/unit.

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

Resolution Text:

Document #: R279326513

Discrepancy ID: 34882111

Site: P3880_0342

Patient: R4033

Visit: PCM.18

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: LACERATION LEFT LEG PAIN

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per source, this con med is related to pain. Please confirm and adjust accordingly.

Internal Comment:

Resolution Type: Confirmed

Resolution Text: pain added to indication

Document #: R279326613

Discrepancy ID: 34882311

Site: P3880_0342

Patient: R4033

Visit: PCM.19

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: VAGINAL CANDIDIASIS

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per AE, the diagnosis is vaginal candidiasis. Con Med page does not match AE form.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R279326713

Discrepancy ID: 34883211

Site: P3880_0342

Patient: R4033

Visit: PCM.20

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: INSOMNIA

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per source, this con med is for insomnia only. Please confirm.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R279327013

Discrepancy ID: 34883411

Site: P3880_0342

Patient: R4033

Visit: PCM.21

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per source, there is an end date. Please complete.

Internal Comment:

Resolution Type: Confirmed

Resolution Text: corrected per source

Document #: R279327113

Discrepancy ID: 34883611

Site: P3880_0342

Patient: R4033

Visit: PCM.22

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Drug name

Row: 1

Value Text: CEPHALEXIN

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per source, there is an UNK con med that has not been entered. Please create a CRF and enter this con med.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R287551613

Discrepancy ID: 78100511

Site: P3880_0342

Patient: R4033

Visit: PCM.23

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Stop Date is missing and 'Ongoing' field was not completed for <UNKNOWN>. Please provide Stop Date or enter 'checked' in the 'Ongoing' field.

Internal Comment: stop date unknown

Resolution Type: Confirmed

Resolution Text:

Document #: R279327313

Discrepancy ID: 110445311

Site: P3880_0342

Patient: R4033

Visit: AE

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Onset Time

Row: 1

Value Text: UNK

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This event has an onset date/time prior to randomization. Please verify date/time. If correct, please remove as AE and move to MH page.

Internal Comment: per source, "subject noted symptoms with dosing", start time unknown.

Resolution Type: Confirmed

Resolution Text: Verified. JLM 26Apr2010

Document #: R279327613

Discrepancy ID: 110445511

Site: P3880_0342

Patient: R4033

Visit: AE.1

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Onset Date

Row: 1

Value Text: 20090427

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This event has an onset date/time prior to randomization. Please verify date/time. If correct, please remove as AE and move to MH page.

Internal Comment: per source, "subject noted symptoms with dosing", start time unknown.

Resolution Type: Confirmed

Resolution Text: Verified. JLM 26Apr2010

Document #: R279328013

Discrepancy ID: 111373311

Site: P3880_0342

Patient: R4033

Visit: AE.4

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Adverse Event

Row: 1

Value Text: CONSTIPATION

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Constipation is present as medical history. Please verify this is a worsening of condition. If not, please remove event.

Internal Comment: constipation due to antibiotics

Resolution Type: Confirmed

Resolution Text: Verified. JLM 26Apr2010

Document #: R279328713

Discrepancy ID: 34885911

Site: P3880_0342

Patient: R4033

Visit: AE.9

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Adverse Event

Row: 1

Value Text: VAGINAL CANDIDIASIS

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per source, the AE diagnosis is vaginal candidiasis. Please confirm and change if you agree.

Internal Comment: confirmed and corrected

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

Resolution Text:

Document #: R279329313

Discrepancy ID: 35326011 **Site:** P3880_0342 **Patient:** R4033
Visit: AE.11 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Action Taken **Row:** 1
Value Text:
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for Action Taken has not been supplied
Internal Comment:
Resolution Type: No Action Required
Resolution Text: action taken not documented on source

Discrepancy ID: 35326111 **Site:** P3880_0342 **Patient:** R4033
Visit: AE.11 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Outcome to Date **Row:** 1
Value Text:
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for Outcome to Date has not been supplied
Internal Comment:
Resolution Type: No Action Required
Resolution Text: outcome not documented on source

Discrepancy ID: 35325911 **Site:** P3880_0342 **Patient:** R4033
Visit: AE.11 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Severity **Row:** 1
Value Text:
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for Severity has not been supplied
Internal Comment:
Resolution Type: Confirmed
Resolution Text: severity not documented

Discrepancy ID: 35325811 **Site:** P3880_0342 **Patient:** R4033
Visit: AE.11 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: No data in source.
Internal Comment: Can any additional information be provided on any missing data?
Resolution Type: Confirmed
Resolution Text:

Deleted CRFs Report