

CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 13:24:37

Report Parameters

Site: CP_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R3006

Ending patient: R3006

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

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

RDC CASE REPORT FORM

Information Correct Yes No

Protocol Number SM 08-01 Investigator Name:
Study Site:

A CONTROLLED STUDY OF THE ABILITY OF A TRADITIONAL SWEDISH SMOKELESS TOBACCO PRODUCT ("SNUS") TO INCREASE THE QUIT RATE AMONG CIGARETTE SMOKERS WHO WISH TO STOP SMOKING

Protocol No. SM 08-01
Covance Study No. 7694-105

for

SWEDISH MATCH AB
ROSENLUNDSGATAN 36
SE-118 85 STOCKHOLM
SWEDEN

by

Covance Clinical Research Unit Inc.
3402 Kinsman Blvd
Madison, Wisconsin 53704

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Page Version No. PAGE_01 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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Inclusion Criteria

Subjects who meet the following criteria may be included in the study. Did the subject meet the following criteria requirements for inclusion? (check Yes or No)

- | | Yes/No* |
|---|------------------------------|
| <input type="checkbox"/> 01 The subject is male or female, between 25 and 65 years of age, inclusive. If female, the subject has a negative urine pregnancy test and is not lactating, or has not been of childbearing potential for at least 3 months prior to use of study product. To be considered to be not of childbearing potential, the subject must be postmenopausal for at least 2 years; have had a hysterectomy or bilateral tubal ligation, or be proven to be otherwise incapable of pregnancy. If of childbearing potential, the subject must have been practicing one of the following methods of contraception consistently for at least 1 month prior to study entry and agree to continue practicing it during the study: hormonal contraceptives, intrauterine device, spermicide and barrier, spouse/partner sterility; or is practicing abstinence and agrees to continue abstinence or to start an acceptable method of contraception from the above list if sexual activity commences. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 02 The subject smokes > 9 cigarettes per day (average daily consumption during past month). | <input type="checkbox"/> YES |
| <input type="checkbox"/> 03 The subject has smoked daily for >1 year. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 04 The subject is motivated to quit smoking with the help of a smokeless tobacco alternative. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 05 The subject is in good general health as evidenced by medical history, physical examination, routine blood chemistry (Hb, total WBC, transaminases, creatinine, electrolytes), and an ECG | <input type="checkbox"/> YES |
| <input type="checkbox"/> 06 The subject practices, by self-report, good oral hygiene (including brushing teeth at least twice per day and having regular dental check-ups). | <input type="checkbox"/> YES |
| <input type="checkbox"/> 07 The subject is able and willing to provide written informed consent. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 08 The subject agrees to comply with the requirements of the protocol and complete study measures. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 09 The subject has stable residence and telephone. | <input type="checkbox"/> YES |

* If No, document on Subject Eligibility Page.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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Exclusion Criteria

The following will exclude potential subjects from the study. Does the subject have any of the following?
(Check Yes or No)

	Yes*/No
<input type="checkbox"/> 01 The subject is a current user of ST (defined as daily usage during more than 1 week within past 6 months) or is unable to refrain from NRT or any other non-protocol treatment during the study. Use of pipes, cigars, cigarillos, snuff, and chewing tobacco is also prohibited during the study.	<input type="checkbox"/> NO
<input type="checkbox"/> 02 The subject is a female who is pregnant or lactating.	<input type="checkbox"/> NO
<input type="checkbox"/> 03 The subject has oral conditions that could potentially be made worse by the use of study product, for instance, exposed dental services in the upper sulcus.	<input type="checkbox"/> NO
<input type="checkbox"/> 04 The subject has used any type of pharmaceutical (including some psychotropics, e.g., wellbutrin) or other products for smoking cessation within the past 3 months.	<input type="checkbox"/> NO
<input type="checkbox"/> 05 The subject has a history of clinically significant renal, hepatic, neurological, or chronic pulmonary disease that in the judgement of the investigator precludes participation.	<input type="checkbox"/> NO
<input type="checkbox"/> 06 The subject has a history of cardiovascular disease, including myocardial infarction within the last 3 months, significant cardiac arrhythmias, or poorly controlled hypertension (defined as a diastolic pressure of more than 90 mm Hg or a systolic pressure of more than 140 mm Hg) that in the judgment or the investigator precludes participation.	<input type="checkbox"/> NO
<input type="checkbox"/> 07 The subject has a history of alcohol or substance abuse or dependence other than cigarette smoking within the past year	<input type="checkbox"/> NO
<input type="checkbox"/> 08 Use of any illicit drug or smoked marijuana in the last 3 months	<input type="checkbox"/> NO
<input type="checkbox"/> 09 The subject is unwilling to be randomized into active or placebo conditions, or be available for follow-up assessments.	<input type="checkbox"/> NO
<input type="checkbox"/> 10 The subject resides in a household where another member is currently participating in the study.	<input type="checkbox"/> NO

* If Yes, document on Subject Eligibility Page.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Information Session

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

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

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

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

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

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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="25-FEB-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="65.5"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	124
Diastolic Blood Pressure	MMHG	69
Heart Rate	BEATS/MINUTE	101
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.7
Weight	LB	170.2

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Safety Urine & Blood Tests; Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Urine Pregnancy Test

Result

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

Urine Drug Screen

Drug Screen Result*

Positive Negative

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Least 5 Minutes?	<input type="text" value="25-FEB-2009"/>	<input type="text" value="14:04"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	NASAL/SINUS CONGESTION DUE TO ALLERGI	00-00-1958		<input checked="" type="checkbox"/> Ongoing
2	HIGH BLOOD PRESSURE	00-00-2000		<input checked="" type="checkbox"/> Ongoing
3	HIGH CHOLESTEROL	00-00-2000		<input checked="" type="checkbox"/> Ongoing
4	HEART MURMUR	00-00-2000		<input checked="" type="checkbox"/> Ongoing
5	CHRONIC CONSTIPATION	00-00-1975		<input checked="" type="checkbox"/> Ongoing
6	INSOMNIA	00-00-2008		<input checked="" type="checkbox"/> Ongoing
7	HEADACHES-EYESTRAIN	00-00-1962		<input checked="" type="checkbox"/> Ongoing
8	HEADACHES-HEAD INJURY	00-00-2007		<input checked="" type="checkbox"/> Ongoing
9	OCCASIONAL DIZZINESS/LIGHTHEADEDNESS	00-00-2000		<input checked="" type="checkbox"/> Ongoing
10	ACHES BILATERAL SHOULDERS	00-00-1962		<input checked="" type="checkbox"/> Ongoing
11	DEPRESSION-SEASONAL	00-00-1984		<input checked="" type="checkbox"/> Ongoing
12	ALLERGY-DUST	00-JAN-2009		<input checked="" type="checkbox"/> Ongoing
13	ALLERGY-SEASONAL/POLLEN	00-00-1958		<input checked="" type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

- * Skin
- * Ears, Eyes, Nose, Throat (EENT)
- * Breasts
- * Respiratory
- * Cardiovascular
- * Lymphatic/Hematologic
- * Gastrointestinal
- * Genitourinary
- * Musculoskeletal
- * Endocrine
- * Neurological
- * Immunological
- * Psychological
- * Allergies

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OverFlow Section For Document Number R240263013

1 NASAL/SINUS CONGESTION DUE TO ALLERGIES

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Smoking History

Was Smoking History collected?

Yes No

Date

Parameter	Result	Comments
Age subject began smoking daily	<input type="text" value="19"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="10"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of Pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	

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

* Indicate NE if system was not examined.

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Swedish Match AB

Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
14	COLD SORES, HERPES SIMPLEX	00-00-1982		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

- * Skin
- * Ears, Eyes, Nose, Throat (EENT)
- * Breasts
- * Respiratory
- * Cardiovascular
- * Lymphatic/Hematologic
- * Gastrointestinal
- * Genitourinary
- * Musculoskeletal
- * Endocrine
- * Neurological
- * Immunological
- * Psychological
- * Allergies

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
03-MAR-2009	10:04	008	01.9	

Behavioral Counseling

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

Questionnaires

Date

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date Actual Time

Was Subject randomized? Yes No

Product Dispensation

Date

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

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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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="10-MAR-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="70"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="17-MAR-2009"/>	<input type="text" value="WEEK 2"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="42"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="24-MAR-2009"/>	<input type="text" value="WEEK 3"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="28"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="31-MAR-2009"/>	<input type="text" value="WEEK 4"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="32"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject reminded about the complete switch from cigarettes no later than the first day of Week 5?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	119
Diastolic Blood Pressure	MMHG	077
Heart Rate	BEATS/MINUTE	083
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.1
Weight	LB	165.0

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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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
13-APR-2009	09:12	006	01.5	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product

Amount Dispensed

0.5 g of snus or matching placebo logs

1.0 g of snus or matching placebo logs

Status Review

Date

Parameter

Result

Comments

Was Subject's smoking status reviewed? Yes No

Was Subject compliant? Yes No

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

Was Subject asked HDYF? question? Yes No

Diary Distribution

Date

Did subject receive diary and usage instructions?

Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="28-APR-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="4"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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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	120
Diastolic Blood Pressure	MMHG	078
Heart Rate	BEATS/MINUTE	083
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.9
Weight	LB	155.6

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
11-MAY-2009	09:40	006	01.5	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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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="1"/> logs
1.0 g of snus or matching placebo	<input type="text" value="1"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="11-MAY-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="6"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions? Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="02-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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="3"/>	<input type="text"/>
	Was 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"/>

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	124
Diastolic Blood Pressure	MMHG	082
Heart Rate	BEATS/MINUTE	088
Respiratory Rate	BREATHS/MINUTE	12
Body Temperature	C	36.5
Weight	LB	153.0

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
23-JUN-2009	EVIDENCE OF LEUKOPLAKIA	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NE	INSIDE RIGHT UPPER CHEEK WITH H
23-JUN-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
23-JUN-2009	OTHER ORAL KERATOSIS	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	

* Indicate NE if system was not examined.

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Document Number

Overflow Section For Document Number R266302413

1 INSIDE RIGHT UPPER CHEEK WITH HEALING LEUKOPLAKIA 1X3CM

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
23-JUN-2009	10:18	4	01.2	

Behavioral Counseling

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

Questionnaires

Date

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

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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="23-JUN-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="1"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="7"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="1"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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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	123
Diastolic Blood Pressure	MMHG	83
Heart Rate	BEATS/MINUTE	91
Respiratory Rate	BREATHS/MINUTE	14
Body Temperature	C	36.7
Weight	LB	167.8

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
16-SEP-2009	10:15	5	1.4	

Behavioral Counseling

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

Questionnaires

Date

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

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="16-SEP-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="2"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

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.

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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

Document Number

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

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

Action Taken: Select only one

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

Outcome to Date Select only one

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

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

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

 Discontinuation from Study
 Discontinuation of Drug Therapy

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

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

Action Taken: Select only one

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

Outcome to Date Select only one

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

Verified Approved Locked Frozen

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

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Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

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

Action Taken: Select only one

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

Outcome to Date Select only one

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

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

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Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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

Additional Assessments - 12-Lead Electrocardiogram Report

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

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Laboratory Evaluations

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

Date	Requisition Number	Clinically Significant?	Test Name CS Labs Only	Test Code ID CS Labs Only	Comments
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 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	122
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	078
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	098
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	14
	Body Temperature	C	36.7

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

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

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Page Version No. PAGE_45 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

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

Investigator Comments (if none, leave blank):

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

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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 #: R240262313

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Screening	Page_07 07

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

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Requisition Number 1: (1) 1	NA	02-JUN-2009 15:57:44 Tricia Hunt	Data Entry Error

Document #: R240262313

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Screening	Page_07 07

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Result 1	NEGATIVE POSITIVE	14-MAY-2009 11:12:01 Tricia Hunt	Data Entry Error

Document #: R240263013

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Diagnosis/Procedure 10	ACHES BILAT SHOULDERS ACHES BILATERAL SHOULDERS	11-MAR-2010 12:30:44 Tricia Hunt	Data Entry Error

Document #: R240303213

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	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 On resequence By	Reason Comment
Attempted to quit (Other cessation aids) (4) 1	NO	14-MAY-2009 12:29:40 Tricia Hunt	Data Entry Error

Document #: R240304513

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Screening	Page_11 11

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Oral Health Exam	Page number	11	Screening

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	25-FEB-2009	02-APR-2009 15:56:36 Tricia Hunt	Data Entry Error
Date 2	25-FEB-2009	02-APR-2009 15:56:36 Tricia Hunt	Data Entry Error
Date 3	25-FEB-2009	02-APR-2009 15:56:36 Tricia Hunt	Data Entry Error

Document #: R240304813

Patient Site	Visit Visit Date	CRF CRF Page	
R3006 CP_001	Baseline, Week 0	Page_14 14	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eco	Page number	14	Baseline, Week 0

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
%COHb 1	1.9 01.9	01-MAY-2009 13:31:55 Kyle Freadman	Investigator Correction PER QUERY
ECO Level 1	8 008	01-MAY-2009 13:31:55 Kyle Freadman	Investigator Correction PER QUERY

Document #: R240305013

Patient Site	Visit Visit Date	CRF CRF Page	
R3006 CP_001	Baseline, Week 0	Page_15 15	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Sc	Page number	15	Baseline, Week 0

Group #	Group Name
1	SC

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Actual Time 1	1035 1038	17-JUN-2009 16:44:31 Tricia Hunt	Data Entry Error

Document #: R244420413

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Sptp, Weeks 1-4	Page_16 16

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Approximately how many cigarettes did th (10) 1	60-70 70	17-JUN-2009 17:46:17 Tricia Hunt	Data Entry Error New information

Document #: R243751713

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Ip, Week 8	Page_21 21

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	21	Ip, Week 8

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments (HDYF) (8) 1	AE'S REVIEWED	17-JUN-2009 17:47:18 Tricia Hunt	Data Entry Error

Document #: R246515413

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Ip, Week 10	Page_24 24

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Comments (how many cigarettes) (5) 1	SENSE WEEK 8 CALL		18-MAR-2010 18:24:33 Tricia Hunt	Data Entry Error
If Subject was not compliant, approximat (5) 1	10-11 11		17-JUN-2009 17:48:02 Tricia Hunt	Data Entry Error New information
If Subject was not compliant, approximat (5) 1	11 6		18-MAR-2010 18:24:33 Tricia Hunt	Data Entry Error

Document #: R266302713

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Ip, Week 16	Page_31 31

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Did subject receive diary and usage inst 1	YES	31-AUG-2009 16:30:57 Tricia Hunt	Data Entry Error

Document #: R274825213

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Fu, Week 28	Page_34 34

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

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Requisition Number 1: (1) 1	NA	09-NOV-2009 14:14:19 Marilyn Mindolovich	Investigator Correction
Were there any clinically significant la (1) 1	NO	09-NOV-2009 14:14:19 Marilyn Mindolovich	Investigator Correction

Document #: R240316313

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Pcm.1	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.1

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	C	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Code 1	C08	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Text 1	CALCIUM CHANNEL BLOCKERS, C08	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Code 1	C08C	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Text 1	SELECTIVE CALC.CHANNEL BLOCK. W/MAINLY VASC. EFF., C08C	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Code 1	C08CA	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Text 1	DIHYDROPYRIDINE DERIVATIVES, C08CA	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Drug Modified Reported Term 1	AMLODIPINE BESYL AMLODIPINE BESYLATE	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	AMLODIPINE BESYL AMLODIPINE BESYLATE	09-APR-2010 15:27:50 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 09Apr2010
Indication 1	HTN HYPERTENSION	20-APR-2010 15:03:45 Tricia Hunt	Data Entry Error
Ongoing 1	CHECKED	17-JUN-2009 17:48:49 Tricia Hunt	Data Entry Error
Preferred Term 1	AMLODIPINE BESILATE	20-APR-2010 11:39:56 Carol Kraucyk	Data Change

Document #: R240316313

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Pcm.1	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.1

Group #	Group Name
1	CM1

Preferred Term Code 1	00972402001	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Stop Date 1	09-APR-2009	17-JUN-2009 17:48:49 Tricia Hunt	Data Entry Error
Trade Name 1	AMLODIPINE BESYLATE	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Trade Name Code 1	00972402020	20-APR-2010 11:39:56 Carol Kraucyk	Data Change

Document #: R240316513

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	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
Ongoing 1	CHECKED	17-JUN-2009 17:49:51 Tricia Hunt	Data Entry Error
Stop Date 1	09-APR-2009	17-JUN-2009 17:49:51 Tricia Hunt	Data Entry Error

Document #: R240316713

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Pcm.4	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.4

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Indication 1	HTN HYPERTENSION		20-APR-2010 15:04:28 Tricia Hunt	Data Entry Error
Ongoing 1	CHECKED		14-MAY-2009 16:41:41 Tricia Hunt	Validation Status changed
Start Date 1	23-FEB-2009 00-JAN-2009		14-MAY-2009 16:41:41 Tricia Hunt	Data Entry Error
Stop Date 1	09-APR-2009		14-MAY-2009 16:41:41 Tricia Hunt	Validation Status changed
Stop Date 1	09-APR-2009 21-FEB-2009		17-JUN-2009 17:50:31 Tricia Hunt	Data Entry Error

Document #: R240316913

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Pcm.5	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.5

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A NERVOUS SYSTEM, N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A01 N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANALGESICS, N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A01A N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A OTHER ANALGESICS AND ANTIPYRETICS, N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A01AD N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD SALICYLIC ACID AND DERIVATIVES, N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change

Document #: R240317013

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Pcm.6	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	N	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC1 Text 1	NERVOUS SYSTEM, N	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Code 1	N02	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Text 1	ANALGESICS, N02	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Code 1	N02B	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Text 1	OTHER ANALGESICS AND ANTIPYRETICS, N02B	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Dose 1	500/25 1	14-MAY-2009 17:13:20 Tricia Hunt	CRA Correction
Preferred Term 1	TYLENOL PM /01088101/	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Preferred Term Code 1	01088101001	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name 1	DIPHENHYDRAMINE W/PARACETAMOL	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name Code 1	01088101004	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Unit 1	MILLIGRAMS	02-APR-2009 18:00:38 Tricia Hunt	Data Entry Error
Unit 1	MILLIGRAMS TABLET	14-MAY-2009 17:13:20 Tricia Hunt	CRA Correction

Document #: R240317113

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Pcm.7	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Dose 1	1 2000		14-MAY-2009 16:45:40 Tricia Hunt	Data Entry Error
Unit 1	TABLET OTHER		14-MAY-2009 16:45:40 Tricia Hunt	Data Entry Error
other, specify (unit) 1	IU		14-MAY-2009 16:45:40 Tricia Hunt	Data Entry Error

Document #: R240317213

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	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
Dose 1	1 1000	14-MAY-2009 16:46:41 Tricia Hunt	Data Entry Error
Unit 1	TABLET MILLIGRAMS	14-MAY-2009 16:46:41 Tricia Hunt	Data Entry Error

Document #: R240317313

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	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
Dose 1	1 500	14-MAY-2009 16:47:21 Tricia Hunt	Data Entry Error
Unit 1	TABLET MILLIGRAMS	14-MAY-2009 16:47:21 Tricia Hunt	Data Entry Error

Document #: R240317413

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	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 resequence	On By	Reason Comment
Dose 1	1 200		14-MAY-2009 16:48:09 Tricia Hunt	Data Entry Error
other, specify (unit) 1	CAP IU		14-MAY-2009 16:48:09 Tricia Hunt	Data Entry Error

Document #: R246513413

Patient Site	Visit Visit Date	CRF CRF Page
R3006 CP_001	Ae.2	Page_40

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

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Ongoing 1	CHECKED	19-OCT-2009 17:46:34 Marilyn Mindolovich	Investigator Correction
Outcome to Date 1	CONT WITHOUT TREATMENT	14-MAY-2009 12:03:10 Tricia Hunt	Data Entry Error
Outcome to Date 1	CONT WITHOUT TREATMENT RECOVERED	19-OCT-2009 17:46:34 Marilyn Mindolovich	Investigator Correction
Resolved Date 1	23-JUN-2009	19-OCT-2009 17:46:34 Marilyn Mindolovich	Investigator Correction
Resolved Time 1	UNK	19-OCT-2009 17:46:34 Marilyn Mindolovich	Investigator Correction

Discrepancy Detail Report

Document #: R240257713

Discrepancy ID: 1626128013 Site: CP_001 Patient: R3006
Visit: SCREENING Visit Date:
CRF: PAGE_04 Section: ELIG Qualifying Value: 4
Field: Did the subject meet all of the inclusio Row: 1
Value Text: YES
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please change yes to no and enter explanation information regarding this subject's +UDS
at screening.
Internal Comment:
Resolution Type: No Action Required
Resolution Text: Per Dr. Dixon because the subject has a valid prescription this is not an exclusion

Document #: R240259813

Discrepancy ID: 1626128213

Site: CP_001

Patient: R3006

Visit: SCREENING

Visit Date:

CRF: PAGE_06

Section: VS

Qualifying Value: 6

Field: Heart Rate

Row: 1

Value Text: 101

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please enter repeat vitals on additiona VS page.

Internal Comment:

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

Resolution Text: Added repeat vitals

Document #: R240262313

Discrepancy ID: 1648801113

Site: CP_001

Patient: R3006

Visit: SCREENING

Visit Date:

CRF: PAGE_07

Section: LB

Qualifying Value: 7

Field: Requisition Number 1:

Row: 1

Value Text: NA

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please enter NA for requisition #

Internal Comment:

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

Resolution Text:

Document #: R240262313

Discrepancy ID: 1626128113 **Site:** CP_001 **Patient:** R3006
Visit: SCREENING **Visit Date:**
CRF: PAGE_07 **Section:** DRGSCR **Qualifying Value:** 7
Field: Result **Row:** 1
Value Text: POSITIVE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please change no to yes, since this subject had a + UDS at screening.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1660191913 **Site:** CP_001 **Patient:** R3006
Visit: SCREENING **Visit Date:**
CRF: PAGE_07 **Section:** DRGSCR **Qualifying Value:** 7
Field: **Row:**
Value Text:
Type: MULTIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Urine drug screen result is Positive. Please verify result and subject eligibility.
Internal Comment: A waiver was grated. Also a clarification that sense the subject had a valid Rx for the positive test it was not an exclusion because the exclusion states "illicit drug use"
Resolution Type: No Action Required
Resolution Text: Subject qualified for study based due to having a valid Rx for the positive drug test. Only illicit drugs are an exclusion.

Document #: R240262713

Discrepancy ID: 1626128913 **Site:** CP_001 **Patient:** R3006
Visit: SCREENING **Visit Date:**
CRF: PAGE_08 **Section:** EG **Qualifying Value:** 8
Field: ECG Interpretation **Row:** 1
Value Text: NORM
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify entry, ECG has sinus tachcardia listed. Should entry be Abnormal NCS?
Internal Comment: Dr. Yuen selected WNL. I will have him reassess and will update if necessary.
Resolution Type: Confirmed
Resolution Text:

Document #: R240305013

Discrepancy ID: 1667686213

Site: CP_001

Patient: R3006

Visit: BASELINE, WEEK

Visit Date:

CRF: PAGE_15

Section: SC

Qualifying Value: 15

Field: Actual Time

Row: 1

Value Text: 1038

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please enter 1038 as the time.

Internal Comment:

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

Resolution Text:

Document #: R244420413

Discrepancy ID: 1667686313 **Site:** CP_001 **Patient:** R3006

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

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

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

Value Text: 70

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please use the upper limit of the range as the CRF entry.

Internal Comment:

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

Resolution Text:

Document #: R243751713

Discrepancy ID: 1667688613

Site: CP_001

Patient: R3006

Visit: IP, WEEK 8

Visit Date:

CRF: PAGE_21

Section: STATUS REVIEW

Qualifying Value: 21

Field: Comments (HDYF)

Row: 1

Value Text:

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify that this comment needs to be here. If not please delete comment.

Internal Comment:

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

Resolution Text:

Document #: R274825213

Discrepancy ID: 1779453113 **Site:** CP_001 **Patient:** R3006
Visit: FU, WEEK 28 **Visit Date:**
CRF: PAGE_34 **Section:** LB **Qualifying Value:** 34
Field: Requisition Number 1: **Row:** 1
Value Text: NA
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter NA and answer CS questions with a NO.
Internal Comment: done
Resolution Type: Confirmed
Resolution Text:

Document #: R240316513

Discrepancy ID: 1683163413 **Site:** CP_001 **Patient:** R3006
Visit: PCM.3 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Drug name **Row:** 1
Value Text: SIMVASTATIN
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per progress note, this was restarted on 13Apr09. Please verify and enter.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1648802113 **Site:** CP_001 **Patient:** R3006
Visit: PCM.3 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Stop Date **Row:** 1
Value Text: 20090409
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Subject ran out of this med. on 09Apr09 and restarted on 13Apr09, please enter stop date on this page and enter the med with new start date on a separate con .med page.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R240316913

Discrepancy ID: 98542811

Site: CP_001

Patient: R3006

Visit: PCM.5

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Start Date

Row: 1

Value Text: 1955

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Medical history has headaches with start dates of 1962 and 2007. Please reconcile start dates of MH and medication.

Internal Comment: The dates are correct on both the medical hx and the con med sheet. Please advise.

Resolution Type: Confirmed

Resolution Text: Will have to leave as is. Verified. JLM 21Apr2010

Document #: R240317013

Discrepancy ID: 1637954013 **Site:** CP_001 **Patient:** R3006
Visit: PCM.6 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Dose **Row:** 1
Value Text: 1
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify if combination drugs should be listed as 1, tab. Also could you please enter the frequency, see source.
Internal Comment: Source for frequency states as needed at bedtime. Please clarify if it needs to be changed to a different frequency.
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 98543011 **Site:** CP_001 **Patient:** R3006
Visit: PCM.6 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Start Date **Row:** 1
Value Text: 2004
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: MH of insomnia does not begin until 2008. Please reconcile dates of medication/MH.
Internal Comment: MH states Diagnosed 2008. Lifetime problem. Start date is listed as date of DX.
Resolution Type: Confirmed
Resolution Text: Verified. JLM 21Apr2010

Document #: R240317113

Discrepancy ID: 1637954213

Site: CP_001

Patient: R3006

Visit: PCM.7

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Dose

Row: 1

Value Text: 2000

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please enter dose amount, 2000 IU. Enter IU in "Other"

Internal Comment:

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

Resolution Text:

Document #: R240317213

Discrepancy ID: 1637954413

Site: CP_001

Patient: R3006

Visit: PCM.8

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Dose

Row: 1

Value Text: 1000

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please enter mg dose amount, see source.

Internal Comment:

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

Resolution Text:

Document #: R240317313

Discrepancy ID: 1637954513

Site: CP_001

Patient: R3006

Visit: PCM.9

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Dose

Row: 1

Value Text: 500

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please enter mg dose amount, see source.

Internal Comment:

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

Resolution Text:

Document #: R240317413

Discrepancy ID: 1637954613

Site: CP_001

Patient: R3006

Visit: PCM.10

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Dose

Row: 1

Value Text: 200

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please enter IU dose amount, see source. Enter IU in "Other"

Internal Comment:

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

Resolution Text:

Document #: R266303513

Discrepancy ID: 98543911 **Site:** CP_001 **Patient:** R3006
Visit: PCM.15 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Indication **Row:** 1
Value Text: COLD SORES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: There is not a currently entry of cold sores on MH or AE. Please provide.
Internal Comment:
Resolution Type: No Action Required
Resolution Text:

Discrepancy ID: 112436311 **Site:** CP_001 **Patient:** R3006
Visit: PCM.15 **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: There is not a currently entry of cold sores on MH or AE. Please provide.
Internal Comment: There are no additional lines to add to the medical hx. Please advise.
Resolution Type: Confirmed
Resolution Text: Verified. JLM 27Apr2010

Document #: R246513413

Discrepancy ID: 1763811113 **Site:** CP_001 **Patient:** R3006
Visit: AE.2 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Resolved Date **Row:** 1
Value Text: 20090623
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please add resolve date per source.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 20537911 **Site:** CP_001 **Patient:** R3006
Visit: AE.2 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: **Row:**
Value Text:
Type: MULTIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Outcome to Date is equal to RECOVERED for GINGIVITIS but Resolved Date and/or Time are missing. Please reconcile.
Internal Comment: The time resolved is UNK. This information is complete per source.
Resolution Type: No Action Required
Resolution Text: The time resolved is UNK. This information is complete per source.

Discrepancy ID: 20527511 **Site:** CP_001 **Patient:** R3006
Visit: AE.2 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: **Row:**
Value Text:
Type: MULTIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Resolved Date and Time is missing and Ongoing is null for Adverse Event <GINGIVITIS>. Please either provide resolved date and time OR check Ongoing.
Internal Comment: The time resolved is UNK. This information is complete per source.
Resolution Type: No Action Required
Resolution Text: The time resolved is UNK. This information is complete per source.

Document #: R253426013

Discrepancy ID: 1763811213

Site: CP_001

Patient: R3006

Visit: AE.3

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Resolved Date

Row: 1

Value Text:

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please follow-up with subject for resolution.

Internal Comment:

Resolution Type: Confirmed

Resolution Text: neck pain continues

Deleted CRFs Report