

# CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 16:35:52

## Report Parameters

Site: CD\_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R5025

Ending patient: R5025

## Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	<b>Abc 123</b>

All time stamps displayed in this report are in the timezone of the database server.

The data contained in this report is current at the time of printing (time as shown above)



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

RDC CASE REPORT FORM

Information Correct  Yes  No

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

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

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

for

SWEDISH MATCH AB  
ROSENLUNDSGATAN 36  
SE-118 85 STOCKHOLM  
SWEDEN

by

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

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Page Version No. PAGE\_01 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

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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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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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Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="21-JUL-2009"/>	<input type="text" value="(b) (6)"/>	<input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	<input checked="" type="checkbox"/> Hispanic or Latino <input 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"/>		

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Body Measurements

Were Body Measurements Collected?  Yes  No      Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="070.6"/>

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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	121
Diastolic Blood Pressure	MMHG	87
Heart Rate	BEATS/MINUTE	69
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.6
Weight	LB	168.0

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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: 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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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="21-JUL-2009"/>	<input type="text" value="10:39"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal  Abnormal, NCS  Abnormal, CS

Comments Regarding CS Findings:

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Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Medical History

Date

Does the subject have any relevant medical history?  Yes  No

Sequence

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	00-MAY-2009		<input checked="" type="checkbox"/> Ongoing
2	SHORTNESS OF BREATH UPON EXERTION	00-00-2008		<input checked="" type="checkbox"/> Ongoing
3	TEMPOROMANDIBULAR JOINT DISORDER	00-00-1982		<input checked="" type="checkbox"/> Ongoing
4	HYPOTHYROIDISM	00-00-2004		<input checked="" type="checkbox"/> Ongoing
5	BLOCKED SINUSES	00-00-2004		<input checked="" type="checkbox"/> Ongoing
6	FLATULENCE DUE TO INGESTION OF MILK	00-APR-2009		<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

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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## **Links to Discrepancy and Audit Sections**

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

Swedish Match AB

Protocol Number: SM 08-01

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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="21"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="40"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of Pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the COMMENTS section.	<input 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="2"/>	ON THEIR OWN - NO AIDS

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## **Links to Discrepancy and Audit Sections**

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Swedish Match AB

Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

\* Indicate NE if system was not examined.

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Subject Number

Subject Initials

Is Blank

### Behavioral Counseling

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

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Swedish Match AB

Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

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Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
28-JUL-2009	11:17	29	5.2	

Behavioral Counseling

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

Questionnaires

Date

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

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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

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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
ND	WEEK 1	Was Subject contacted by telephone?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	SUBJECT NOT CON
		Was Subject's smoking status reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
		Was Subject's use of study product reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
		Approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	
		Was Behavioral Counseling Given?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Date	Scheduled Timepoint	Parameter	Result	Comments
10-AUG-2009	WEEK 2	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
		Approximately how many cigarettes did the subject smoke that week?	105	
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Date	Scheduled Timepoint	Parameter	Result	Comments
17-AUG-2009	WEEK 3	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
		Approximately how many cigarettes did the subject smoke that week?	35	
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

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Visit Name

Subject Number

Subject Initials

Is Blank

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="24-AUG-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="70"/>	<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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Document Number

## OverFlow Section For Document Number R265930313

1 SUBJECT NOT CONTACTED IN ERROR

## **Links to Discrepancy and Audit Sections**

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[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	118
Diastolic Blood Pressure	MMHG	72
Heart Rate	BEATS/MINUTE	91
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	36.9
Weight	LB	167.2

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: 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
09-SEP-2009	13:19	32	5.7	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="3"/> logs
1.0 g of snus or matching placebo	<input type="text" value="0"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="09-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="91"/>	<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?
<input type="text" value="09-SEP-2009"/>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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Protocol Number: SM 08-01

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Subject Number

Subject Initials

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Status Review

Date	Parameter	Result	Comments
<input type="text" value="21-SEP-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="49"/>	<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	123
Diastolic Blood Pressure	MMHG	87
Heart Rate	BEATS/MINUTE	73
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.5
Weight	LB	165.0

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
05-OCT-2009	10:54	19	3.6	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

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Swedish Match AB

Protocol Number: SM 08-01

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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="2"/> 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="05-OCT-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="91"/>	<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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Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="27-OCT-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="56"/>	<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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Page Version No. PAGE\_25 (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

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	112
Diastolic Blood Pressure	MMHG	73
Heart Rate	BEATS/MINUTE	83
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.4
Weight	LB	167.2

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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](#)

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

\* Indicate NE if system was not examined.

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Page Version No. PAGE\_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
18-NOV-2009	12:45	27	4.9	

Behavioral Counseling

Date	Parameter	Result	Comments
18-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

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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
18-NOV-2009	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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Page Version No. PAGE\_31 (v1, 12-MAY-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date  Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input 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="70"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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="49"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE\_32 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	116
Diastolic Blood Pressure	MMHG	81
Heart Rate	BEATS/MINUTE	90
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.4
Weight	LB	170.6

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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.

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

\* Indicate NE if system was not examined.

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Page Version No. PAGE\_35 (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
08-FEB-2010	11:14	20	3.8	

Behavioral Counseling

Date	Parameter	Result	Comments
08-FEB-2010	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires

Date

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

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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="08-FEB-2010"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="91"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE\_38 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Page Version No. PAGE\_39 (v1, 25-MAR-2009)

Document Number

## **Links to Discrepancy and Audit Sections**

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Page Version No. PAGE\_39 (v1, 25-MAR-2009)

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## **Links to Discrepancy and Audit Sections**

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Page Version No. PAGE\_39 (v1, 25-MAR-2009)

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## **Links to Discrepancy and Audit Sections**

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Page Version No. PAGE\_39 (v1, 25-MAR-2009)

Document Number

## **Links to Discrepancy and Audit Sections**

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Page Version No. PAGE\_39 (v1, 25-MAR-2009)

Document Number

## **Links to Discrepancy and Audit Sections**

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Page Version No. PAGE\_39 (v1, 25-MAR-2009)

Document Number

## **Links to Discrepancy and Audit Sections**

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events?  Yes  No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time   Ongoing

Serious Event: Select only one  
 Yes  
 No

Severity: Select only one  
 Mild  
 Moderate  
 Severe

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

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

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

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Page Version No. PAGE\_40 (v1, 27-MAR-2009)

Document Number

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to 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)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

### Additional Assessments - 12-Lead Electrocardiogram Report

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

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

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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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Page Version No. PAGE\_42 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date  Actual Time

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

Comments

Date  Actual Time

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

Comments

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Page Version No. PAGE\_43 (v1, 27-MAR-2009)

Document Number



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

\* Indicate NE if system was not examined.

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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 #:** R260818013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025	Screening	Page_09
CD_001		09

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Mh	Page number	9	Screening

<b>Group #</b>	<b>Group Name</b>
2	MH1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Diagnosis/Procedure 1	CHRONIC OGSTRUCTIVE PULMONARY DISEASE CHRONIC OBSTRUCTIVE PULMONARY DISEASE		12-JAN-2010 17:28:13 Sharon Ladenes Data Entry Error
Date of Onset 3	00-00-1997 <Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes Data Entry Error
Date of Onset 3			22-OCT-2009 19:41:24 Sharon Ladenes Row Inserted
Date of Onset 3	UNK		17-DEC-2009 19:35:45 Sharon Ladenes Data Entry Error
Date of Onset 3	UNK 00-00-1982		09-MAR-2010 16:50:17 Sharon Ladenes Data Entry Error
Date of Resolution 3	<Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes Data Entry Error
Date of Resolution 3			22-OCT-2009 19:41:24 Sharon Ladenes Row Inserted
Diagnosis/Procedure 3	OCCASIONAL HEADACHES <Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes Data Entry Error
Diagnosis/Procedure 3	TEMPOROMANDIBULAR JOINT DISORDER		22-OCT-2009 19:41:24 Sharon Ladenes Row Inserted
Ongoing 3	CHECKED <Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes Data Entry Error
Ongoing 3	CHECKED		22-OCT-2009 19:41:24 Sharon Ladenes Row Inserted
Sequence Number 3	3 <Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes Data Entry Error
Sequence Number 3	3		22-OCT-2009 19:41:24 Sharon Ladenes Row Inserted
Date of Onset 4	00-00-1997 <Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes Data Entry Error

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Group #	Group Name
2	MH1

Date of Onset 4	00-00-2004		22-OCT-2009 19:41:24	Row Inserted Sharon Ladenes
Date of Resolution 4	<Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Date of Resolution 4			22-OCT-2009 19:41:24	Row Inserted Sharon Ladenes
Diagnosis/Procedure 4	DIZZINESS LIGHHEADEDNESS <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Diagnosis/Procedure 4	HYPOTHYROIDISM		22-OCT-2009 19:41:24	Row Inserted Sharon Ladenes
Ongoing 4	CHECKED <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Ongoing 4	CHECKED		22-OCT-2009 19:41:24	Row Inserted Sharon Ladenes
Sequence Number 4	4 <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Sequence Number 4	4		22-OCT-2009 19:41:24	Row Inserted Sharon Ladenes
Date of Onset 5	00-00-1997 <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Date of Onset 5	UNK <Row Deleted>		17-DEC-2009 19:35:45	Data Entry Error Sharon Ladenes
Date of Onset 5	00-00-2004		12-JAN-2010 17:28:13	Row Inserted Sharon Ladenes
Date of Resolution 5	<Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Date of Resolution 5	<Row Deleted>		17-DEC-2009 19:35:45	Data Entry Error Sharon Ladenes
Date of Resolution 5			12-JAN-2010 17:28:13	Row Inserted Sharon Ladenes

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<b>Group #</b>	<b>Group Name</b>
2	MH1

Diagnosis/Procedure 5	RECURRENT JOINT PAIN <Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes	Data Entry Error
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Diagnosis/Procedure 5	TEMPOROMANDIBULAR JOINT DISORDER <Row Deleted>		17-DEC-2009 19:35:45 Sharon Ladenes	Data Entry Error
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Diagnosis/Procedure 5	BLOCKED SINUSES		12-JAN-2010 17:28:13 Sharon Ladenes	Row Inserted
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Ongoing 5	CHECKED <Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes	Data Entry Error
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Ongoing 5	CHECKED <Row Deleted>		17-DEC-2009 19:35:45 Sharon Ladenes	Data Entry Error
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Ongoing 5	CHECKED		12-JAN-2010 17:28:13 Sharon Ladenes	Row Inserted
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Sequence Number 5	5 <Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes	Data Entry Error
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Sequence Number 5	5		04-DEC-2009 13:47:57 Sharon Ladenes	Data Entry Error
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Sequence Number 5	5 <Row Deleted>		17-DEC-2009 19:35:45 Sharon Ladenes	Data Entry Error
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Sequence Number 5	5		12-JAN-2010 17:28:13 Sharon Ladenes	Row Inserted
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Date of Onset 6	00-00-2004 <Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes	Data Entry Error
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Date of Onset 6	00-APR-2009		12-JAN-2010 17:30:27 Sharon Ladenes	Row Inserted
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Date of Resolution 6	00-00-2004 <Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes	Data Entry Error
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Date of Resolution 6			12-JAN-2010 17:30:27 Sharon Ladenes	Row Inserted
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Diagnosis/Procedure 6	RHINOPLASTY <Row Deleted>	8->5	22-OCT-2009 19:41:24 Sharon Ladenes	Data Entry Error
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<b>Group #</b>	<b>Group Name</b>
2	MH1

Diagnosis/Procedure 6	FLATULENCE		12-JAN-2010 17:30:27	Sharon Ladenes	Row Inserted
Diagnosis/Procedure 6	FLATULENCE FLATULENCE DUE TO INGESTION OF MILK		11-MAR-2010 15:25:03	Stephanie Felton	Data Entry Error
Ongoing 6	<Row Deleted>	8->5	22-OCT-2009 19:41:24	Sharon Ladenes	Data Entry Error
Ongoing 6	CHECKED		12-JAN-2010 17:30:27	Sharon Ladenes	Row Inserted
Sequence Number 6	6 <Row Deleted>	8->5	22-OCT-2009 19:41:24	Sharon Ladenes	Data Entry Error
Sequence Number 6	6		12-JAN-2010 17:30:27	Sharon Ladenes	Row Inserted
Date of Onset 7	00-APR-2004		30-JUL-2009 15:29:11	Sharon Ladenes	Row Inserted
Date of Onset 7	00-APR-2004 <Row Deleted>	8->5	22-OCT-2009 19:41:24	Sharon Ladenes	Data Entry Error
Date of Resolution 7			30-JUL-2009 15:29:11	Sharon Ladenes	Row Inserted
Date of Resolution 7	<Row Deleted>	8->5	22-OCT-2009 19:41:24	Sharon Ladenes	Data Entry Error
Diagnosis/Procedure 7	SINUS CONGESTION		30-JUL-2009 15:29:11	Sharon Ladenes	Row Inserted
Diagnosis/Procedure 7	SINUS CONGESTION <Row Deleted>	8->5	22-OCT-2009 19:41:24	Sharon Ladenes	Data Entry Error
Ongoing 7	CHECKED		30-JUL-2009 15:29:11	Sharon Ladenes	Row Inserted
Ongoing 7	CHECKED <Row Deleted>	8->5	22-OCT-2009 19:41:24	Sharon Ladenes	Data Entry Error
Sequence Number 7	7		30-JUL-2009 15:29:11	Sharon Ladenes	Row Inserted

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Group #	Group Name
2	MH1

Sequence Number 7	7 <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Date of Onset 8	UNK		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Date of Resolution 8			02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Diagnosis/Procedure 8	TEMPOROMANDIBULAR JOINT DISORDER		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Ongoing 8	CHECKED		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Sequence Number 8	8		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Sequence Number 8	8		22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Date of Onset 9	00-00-2000		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Date of Onset 9	00-00-2000 <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Date of Resolution 9	00-00-2000		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Date of Resolution 9	00-00-2000 <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Diagnosis/Procedure 9	TRANSURETHRAL INCISION OF THE PROSTATE		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Diagnosis/Procedure 9	TRANSURETHRAL INCISION OF THE PROSTATE <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Ongoing 9			02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Ongoing 9	<Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes

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Group #	Group Name
2	MH1

Sequence Number 9	9		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Sequence Number 9	9 <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Date of Onset 10	00-00-2002		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Date of Onset 10	00-00-2002 <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Date of Resolution 10	00-00-2002		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Date of Resolution 10	00-00-2002 <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Diagnosis/Procedure 10	TRANSURETHRAL RESECTION OF THE PROSTATE		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Diagnosis/Procedure 10	TRANSURETHRAL RESECTION OF THE PROSTATE <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Ongoing 10			02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Ongoing 10	<Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes
Sequence Number 10	10		02-SEP-2009 19:10:07	Row Inserted Sharon Ladenes
Sequence Number 10	10 <Row Deleted>	8->5	22-OCT-2009 19:41:24	Data Entry Error Sharon Ladenes

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Patient Site	Visit Visit Date	CRF CRF Page
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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
Comments (other attempts) (7) 1	ON THEIR OWN ON THEIR OWN - NO AIDS	22-OCT-2009 19:45:23 Sharon Ladenes	Data Entry Error

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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Sptp, Weeks 1-4	Page_16 16

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	22-OCT-2009 19:46:08 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	22-OCT-2009 19:47:14 Sharon Ladenes	Data Entry Error

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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Sptp, Weeks 1-4	Page_16 16

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

<b>Group #</b>	<b>Group Name</b>
1	CHKYN

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Approximately how many cigarettes did th (10) 1	140 70	02-SEP-2009 19:20:45 Sharon Ladenes	Pass1
Approximately how many cigarettes did th (10) 1	70	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Approximately how many cigarettes did th (10) 1	70	09-MAR-2010 16:51:52 Sharon Ladenes	Data Entry Error
Comments (behavioral counseling) (6) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (contacted by phone) (1) 1	REPORTED DURING SUBJECT'S WEEK 2 TELEPHONE CALL	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (contacted by phone) (1) 1	REPORTED DURING SUBJECT'S WEEK 2 TELEPHONE CALL SEE ENOTE; SUBJECT NOT CONTACTED IN ERROR	09-MAR-2010 16:51:52 Sharon Ladenes	Data Entry Error
Comments (contacted by phone) (1) 1	SEE ENOTE; SUBJECT NOT CONTACTED IN ERROR SUBJECT NOT CONTACTED IN ERROR	18-MAR-2010 11:21:36 Sharon Ladenes	Data Entry Error
Comments (contacted by phone) (1) 1	SUBJECT NOT CONTACTED IN ERROR	06-MAY-2010 13:05:58 Sharon Ladenes	Data Entry Error
Comments (contacted by phone) (1) 1	SUBJECT NOT CONTACTED IN ERROR	06-MAY-2010 13:58:12 Sharon Ladenes	Data Entry Error

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Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit	
Status Review	Page number	16	Sptp, Weeks 1-4	
Group #	Group Name			
1	CHKYN			
Comments (how many cigarettes) (5) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted	
Comments (smoking status reviewed) (2) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted	
Comments (study product reviewed) (3) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted	
Date 1	10-AUG-2009	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted	
Date 1	10-AUG-2009 03-AUG-2009	09-MAR-2010 16:51:52 Sharon Ladenes	Data Entry Error	
Date 1	03-AUG-2009 ND	06-MAY-2010 13:05:58 Sharon Ladenes	Data Entry Error	
Scheduled Timepoint 1	WEEK 1	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted	
Was Behavioral Counseling Given (6) 1	YES	02-SEP-2009 19:20:45 Sharon Ladenes	Pass1	
Was Behavioral Counseling Given (6) 1	YES	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted	
Was Behavioral Counseling Given (6) 1	YES	09-MAR-2010 16:51:52 Sharon Ladenes	Data Entry Error	
Was Subject contacted by telephone (1) 1	YES NO	02-SEP-2009 19:20:45 Sharon Ladenes	Pass1	
Was Subject contacted by telephone (1) 1	YES	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted	

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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
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<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	16	Sptp, Weeks 1-4

<b>Group #</b>	<b>Group Name</b>
1	CHKYN

Was Subject contacted by telephone (1) 1	YES NO	09-MAR-2010 16:51:52 Sharon Ladenes	Data Entry Error
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Was Subject's smoking status reviewed (2) 1	YES	02-SEP-2009 19:20:45 Sharon Ladenes	Pass1
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Was Subject's smoking status reviewed (2) 1	YES	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
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Was Subject's smoking status reviewed (2) 1	YES	09-MAR-2010 16:51:52 Sharon Ladenes	Data Entry Error
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Was Subject's use of study product review (3) 1	YES	02-SEP-2009 19:20:45 Sharon Ladenes	Pass1
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Was Subject's use of study product review (3) 1	YES	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
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Was Subject's use of study product review (3) 1	YES	09-MAR-2010 16:51:52 Sharon Ladenes	Data Entry Error
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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
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<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	16.1	Sptp, Weeks 1-4

<b>Group #</b>	<b>Group Name</b>
1	CHKYN

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Approximately how many cigarettes did th (11) 1	105	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (behavioral counseling) (6) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (contacted by phone) (1) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (how many cigarettes) (5) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (smoking status reviewed) (2) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (study product reviewed) (3) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Date 1	10-AUG-2009	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Scheduled Timepoint 1	WEEK 2	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Was Behavioral Counseling Given (6) 1	YES	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Was Subject contacted by telephone (1) 1	YES	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted

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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Sptp, Weeks 1-4	Page_16 16

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

<b>Group #</b>	<b>Group Name</b>
1	CHKYN

Was Subject's smoking status reviewed (2) 1	YES	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
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Was Subject's use of study product review (3) 1	NO	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
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Was Subject's use of study product review (3) 1	NO YES	23-OCT-2009 10:48:36 Sharon Ladenes	Data Entry Error
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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Sptp, Weeks 1-4	Page_16 16

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	16A	Sptp, Weeks 1-4

<b>Group #</b>	<b>Group Name</b>
1	CHKYN

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Approximately how many cigarettes did th (10) 1	35	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (behavioral counseling) (6) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (contacted by phone) (1) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (how many cigarettes) (5) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (smoking status reviewed) (2) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Comments (study product reviewed) (3) 1		22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Date 1	17-AUG-2009	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Scheduled Timepoint 1	WEEK 3	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Was Behavioral Counseling Given (6) 1	YES	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted
Was Subject contacted by telephone (1) 1	YES	22-OCT-2009 19:47:14 Sharon Ladenes	Row Inserted

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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
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<b>Group #</b>	<b>Group Name</b>
1	CHKYN

Was Subject's smoking status reviewed (2) 1	YES	22-OCT-2009 19:47:14	Row Inserted Sharon Ladenes
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Was Subject's use of study product review (3) 1		22-OCT-2009 19:47:14	Row Inserted Sharon Ladenes
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Was Subject's use of study product review (3) 1	YES	23-OCT-2009 10:48:36	Data Entry Error Sharon Ladenes
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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
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0	Section Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
DCM Blank flag 1	N Y		07-OCT-2009 13:53:42 Diane Yann	Key Change

<b>Group #</b>	<b>Group Name</b>
1	CHKYN

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
Was Subject's use of study product review (3) 1	NO YES		23-OCT-2009 10:48:36 Sharon Ladenes	Data Entry Error

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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025	Ip, Week 13	Page_25
CD_001		25

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag	Y	11-MAR-2010 14:12:01	Data Entry Error
1	N	Stephanie Felton	

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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
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<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Lb	Page number	27	Ip, Week 16

<b>Group #</b>	<b>Group Name</b>
1	LB

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Were there any clinically significant la (1) 1	NO	09-MAR-2010 16:55:47 Sharon Ladenes	Data Entry Error

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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
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<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pe	Page number	36	Fu, Week 28

<b>Group #</b>	<b>Group Name</b>
2	MH1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Does the subject have any abnormal findi 1	YES NO	10-FEB-2010 15:40:10 Sharon Ladenes	Data Entry Error

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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025	Pcm	Page_39
CD_001		39

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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	03-SEP-2009 14:43:29 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	03-SEP-2009 14:43:47 Sharon Ladenes	Data Entry Error

Document #: R260825813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Pcm	Page_39 39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm

<b>Group #</b>	<b>Group Name</b>
1	CM1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Dose 1	0.15	04-JAN-2010 17:13:41 Sharon Ladenes	Row Inserted
Drug name 1	SYNTHROID	04-JAN-2010 17:13:41 Sharon Ladenes	Row Inserted
Frequency 1	EVERY DAY	04-JAN-2010 17:13:41 Sharon Ladenes	Row Inserted
Has the subject taken any medications pr 1	NO	03-SEP-2009 14:43:47 Sharon Ladenes	Row Inserted
Has the subject taken any medications pr 1	NO YES	04-JAN-2010 17:13:41 Sharon Ladenes	Data Entry Error
Indication 1	HYPOTHYROIDISM	04-JAN-2010 17:13:41 Sharon Ladenes	Row Inserted
Ongoing 1	CHECKED	04-JAN-2010 17:13:41 Sharon Ladenes	Row Inserted
Start Date 1	00-00-2004	04-JAN-2010 17:13:41 Sharon Ladenes	Row Inserted
Start Date 1	00-00-2004 00-SEP-2004	11-MAR-2010 14:25:52 Stephanie Felton	Data Entry Error
Stop Date 1		04-JAN-2010 17:13:41 Sharon Ladenes	Row Inserted
Unit 1	MILLIGRAMS	04-JAN-2010 17:13:41 Sharon Ladenes	Row Inserted
other, specify (frequency) 1		04-JAN-2010 17:13:41 Sharon Ladenes	Row Inserted
other, specify (unit) 1		04-JAN-2010 17:13:41 Sharon Ladenes	Row Inserted

**Document #:** R260826413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Pcm.1	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	03-SEP-2009 14:43:15 Sharon Ladenes	Key Change
DCI Blank Flag 1	Y N	04-JAN-2010 17:15:21 Sharon Ladenes	Data Entry Error

**Document #:** R260826913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Pcm.2	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	30-JUL-2009 16:36:28 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	04-JAN-2010 17:16:41 Sharon Ladenes	Data Entry Error

Document #: R260826913

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Pcm.2	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Dose 1	1200	04-JAN-2010 17:16:41 Sharon Ladenes	Row Inserted
Drug name 1	MEGA-3 FISH OIL	04-JAN-2010 17:16:41 Sharon Ladenes	Row Inserted
Frequency 1	EVERY DAY	04-JAN-2010 17:16:41 Sharon Ladenes	Row Inserted
Has the subject taken any medications pr 1	YES	04-JAN-2010 17:16:41 Sharon Ladenes	Row Inserted
Indication 1	SUPPLEMENT	04-JAN-2010 17:16:41 Sharon Ladenes	Row Inserted
Ongoing 1	CHECKED	04-JAN-2010 17:16:41 Sharon Ladenes	Row Inserted
Start Date 1	00-00-2006	04-JAN-2010 17:16:41 Sharon Ladenes	Row Inserted
Stop Date 1		04-JAN-2010 17:16:41 Sharon Ladenes	Row Inserted
Unit 1	MILLIGRAMS	04-JAN-2010 17:16:41 Sharon Ladenes	Row Inserted
other, specify (frequency) 1		04-JAN-2010 17:16:41 Sharon Ladenes	Row Inserted
other, specify (unit) 1		04-JAN-2010 17:16:41 Sharon Ladenes	Row Inserted

**Document #:** R260827213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Pcm.3	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	30-JUL-2009 16:36:20 Sharon Ladenes	Key Change
DCI Blank Flag 1	Y N	04-JAN-2010 17:17:42 Sharon Ladenes	Data Entry Error

**Document #:** R260827213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Pcm.3	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm.3

<b>Group #</b>	<b>Group Name</b>
1	CM1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Drug name 1	VITAMIN E CENTRUM COMPLETE	11-MAR-2010 14:28:05 Stephanie Felton	Data Entry Error

**Document #:** R260827813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Pcm.4	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	30-JUL-2009 16:36:01 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	04-JAN-2010 17:18:57 Sharon Ladenes	Data Entry Error

Document #: R260827813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Pcm.4	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm.4

<b>Group #</b>	<b>Group Name</b>
1	CM1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Dose 1	10	04-JAN-2010 17:18:57 Sharon Ladenes	Row Inserted
Drug name 1	XCID ANTACID	04-JAN-2010 17:18:57 Sharon Ladenes	Row Inserted
Drug name 1	XCID ANTACID PEPCID AC	11-MAR-2010 14:29:15 Stephanie Felton	Data Entry Error
Frequency 1	ONCE	04-JAN-2010 17:18:57 Sharon Ladenes	Row Inserted
Has the subject taken any medications pr 1	YES	04-JAN-2010 17:18:57 Sharon Ladenes	Row Inserted
Indication 1		04-JAN-2010 17:18:57 Sharon Ladenes	Row Inserted
Indication 1	ANTACID	04-JAN-2010 17:21:31 Sharon Ladenes	Data Entry Error
Indication 1	ANTACID FLATULENCE	13-APR-2010 11:32:05 Sharon Ladenes	Data Entry Error
Ongoing 1		04-JAN-2010 17:18:57 Sharon Ladenes	Row Inserted
Start Date 1	20-JUL-2009	04-JAN-2010 17:18:57 Sharon Ladenes	Row Inserted
Stop Date 1	22-JUL-2009	04-JAN-2010 17:18:57 Sharon Ladenes	Row Inserted
Unit 1	GRAM	04-JAN-2010 17:18:57 Sharon Ladenes	Row Inserted
other, specify (frequency) 1		04-JAN-2010 17:18:57 Sharon Ladenes	Row Inserted
other, specify (unit) 1		04-JAN-2010 17:18:57 Sharon Ladenes	Row Inserted

Document #: R260828513

Patient Site	Visit Visit Date	CRF CRF Page
R5025	Pcm.5	Page_39
CD_001		

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

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	30-JUL-2009 16:35:30 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	04-JAN-2010 17:21:52 Sharon Ladenes	Data Entry Error

Document #: R260828513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5025 CD_001	Pcm.5	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm.5

<b>Group #</b>	<b>Group Name</b>
1	CM1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Dose 1	200	04-JAN-2010 17:21:52 Sharon Ladenes	Row Inserted
Drug name 1	SUDAFED	04-JAN-2010 17:21:52 Sharon Ladenes	Row Inserted
Frequency 1	WHENEVER NECESSARY	04-JAN-2010 17:21:52 Sharon Ladenes	Row Inserted
Has the subject taken any medications pr 1	YES	04-JAN-2010 17:21:52 Sharon Ladenes	Row Inserted
Indication 1	BLOCKED SINUSES	04-JAN-2010 17:21:52 Sharon Ladenes	Row Inserted
Ongoing 1		04-JAN-2010 17:21:52 Sharon Ladenes	Row Inserted
Start Date 1	00-SEP-2004	04-JAN-2010 17:21:52 Sharon Ladenes	Row Inserted
Stop Date 1	10-JUL-2009	04-JAN-2010 17:21:52 Sharon Ladenes	Row Inserted
Unit 1	MILLIGRAMS	04-JAN-2010 17:21:52 Sharon Ladenes	Row Inserted
other, specify (frequency) 1		04-JAN-2010 17:21:52 Sharon Ladenes	Row Inserted
other, specify (unit) 1		04-JAN-2010 17:21:52 Sharon Ladenes	Row Inserted

Document #: R267109313

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Ae	Page_40 40

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

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Onset Time 1	1030 1230	21-APR-2010 11:35:07 Sharon Ladenes	Data Entry Error
Onset Time 1	1230 UNK	21-APR-2010 11:56:20 Sharon Ladenes	Data Entry Error

# Discrepancy Detail Report

Document #: R260818013

Discrepancy ID: 1766245713 Site: CD\_001 Patient: R5025

Visit: SCREENING

Visit Date:

CRF: PAGE\_09

Section: MH

Qualifying Value: 9

Field: Date

Row: 1

Value Text: 20090721

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please delete 3,4, 5,6,7,9,and 10. 3, 4, 5 are covered under TMJ per subject. Please add hypothyroidism with start date of 2004. Also takes meds for this.

Internal Comment:

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

Resolution Text:

Discrepancy ID: 80887611 Site: CD\_001 Patient: R5025

Visit: SCREENING

Visit Date:

CRF: PAGE\_09

Section: MH

Qualifying Value: 9

Field: Date of Onset

Row: 3

Value Text: 1982

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per source TMJ started in 1982. Please review and revise CRF page if applicable.

Internal Comment:

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

Resolution Text:

Discrepancy ID: 80915611 Site: CD\_001 Patient: R5025

Visit: SCREENING

Visit Date:

CRF: PAGE\_09

Section: MH

Qualifying Value: 9

Field: Diagnosis/Procedure

Row: 6

Value Text: FLATULENCE DUE TO INGESTION OF MILK

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: The previous query was asking you to review source and revise CRF page to reflect flatulence due to milk ingestion. Please review source and revise CRF page.

Internal Comment: Updated CRF, verified source

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

Resolution Text:

**Document #: R260823813**

**Discrepancy ID:** 1766245913                      **Site:** CD\_001                      **Patient:** R5025  
**Visit:** SCREENING                      **Visit Date:**  
**CRF:** PAGE\_10                      **Section:** SMOKING HISTORY                      **Qualifying Value:** 10  
**Field:** Comments (other attempts)                      **Row:** 1  
**Value Text:** ON THEIR OWN - NO AIDS  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please add 'no aids'  
**Internal Comment:**  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Document #: R265930313**

**Discrepancy ID:** 86550811                      **Site:** CD\_001                      **Patient:** R5025  
**Visit:** SPTP, WEEKS 1-4    **Visit Date:**  
**CRF:** PAGE\_16                      **Section:** STATUS REVIEW                      **Qualifying Value:** 16  
**Field:** Comments (contacted by phone)                      **Row:** 1  
**Value Text:** SUBJECT NOT CONTACTED IN ERROR  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please amend comment to 'Subject not contacted in error'.

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

**Discrepancy ID:** 115225611                      **Site:** CD\_001                      **Patient:** R5025  
**Visit:** SPTP, WEEKS 1-4    **Visit Date:**  
**CRF:** PAGE\_16                      **Section:** STATUS REVIEW                      **Qualifying Value:** 16  
**Field:** Date                      **Row:** 1  
**Value Text:** ND  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please update date to 'ND' as assessment did not occur.

**Internal Comment:** DM Response: Please replace the comment that was previously present (SUBJECT NOT CONTACTED IN ERROR).  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Discrepancy ID:** 80891811                      **Site:** CD\_001                      **Patient:** R5025  
**Visit:** SPTP, WEEKS 1-4    **Visit Date:**  
**CRF:** PAGE\_16                      **Section:** STATUS REVIEW                      **Qualifying Value:** 16  
**Field:** Was Subject contacted by telephone                      **Row:** 1  
**Value Text:** NO  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** For consistency, please check No, add comment regarding eNote and delete the other entries for this phone call. Add date of scheduled week 1 phone call (03Aug2009).

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



**Document #: R287566813**

**Discrepancy ID:** 80915211

**Site:** CD\_001

**Patient:** R5025

**Visit:** IP, WEEK 13

**Visit Date:**

**CRF:** PAGE\_25

**Section:** STATUS REVIEW

**Qualifying Value:** 25

**Field:**

**Row:**

**Value Text:**

**Type:** MANUAL HEADER

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** If contact was attempted, please enter scheduled date, answer first question 'No' and add comment. see source data correction form for instructions for staff to generate eNote for deviation if the phone visit was not attempted.

**Internal Comment:** Updated CRF, verified source

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

**Resolution Text:**

**Document #: R282980613**

**Discrepancy ID:** 80915911

**Site:** CD\_001

**Patient:** R5025

**Visit:** IP, WEEK 16

**Visit Date:**

**CRF:** PAGE\_27

**Section:** LB

**Qualifying Value:** 27

**Field:** Were there any clinically significant la

**Row:** 1

**Value Text:** NO

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please answer quetion.

**Internal Comment:**

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

**Resolution Text:**

**Document #: R260825813**

**Discrepancy ID:** 82833611

**Site:** CD\_001

**Patient:** R5025

**Visit:** PCM

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:** Start Date

**Row:** 1

**Value Text:** 200409

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Per source update please add Sep. to start date.

**Internal Comment:** Updated CRF, verified source

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

**Resolution Text:**

**Document #: R260827213**

**Discrepancy ID:** 80921011

**Site:** CD\_001

**Patient:** R5025

**Visit:** PCM.3

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:** Drug name

**Row:** 1

**Value Text:** CENTRUM COMPLETE

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify which vitamin is taken, source is not clear.

**Internal Comment:** Updated CRF, verified source

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

**Resolution Text:**



**Document #: R267109313**

**Discrepancy ID:** 104386011

**Site:** CD\_001

**Patient:** R5025

**Visit:** AE

**Visit Date:**

**CRF:** PAGE\_40

**Section:** AE

**Qualifying Value:** 40

**Field:** Onset Date

**Row:** 1

**Value Text:** 20090728

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Onset date/time is prior to randomization. Please verify date/time. If correct, please remove AE and add to MH.

**Internal Comment:** exact time unknown, subject stated following use of product

**Resolution Type:** Confirmed

**Resolution Text:** Verfied. JLM 23Apr2010

# Deleted CRFs Report