

# CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 11:01:46

## Report Parameters

Site: P3880\_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4063

Ending patient: R4063

## 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

Visit Name

Subject Number

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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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Page Version No. PAGE\_02 (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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Exclusion Criteria

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

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

\* If Yes, document on Subject Eligibility Page.

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Page Version No. PAGE\_03 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Information Session

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

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

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

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

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

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Page Version No. PAGE\_04 (v1, 24-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="10-JUN-2009"/>	<input type="text" value="(b) (6)"/>	<input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	<input type="checkbox"/> Hispanic or Latino <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"/>		

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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="70.5"/>

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Page Version No. PAGE\_05 (v1, 24-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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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	117
Diastolic Blood Pressure	MMHG	84
Heart Rate	BEATS/MINUTE	90
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.6
Weight	LB	199.6

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Page Version No. PAGE\_06 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Safety Urine & Blood Tests; Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Urine Pregnancy Test

Result

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

Urine Drug Screen

Drug Screen Result\*

Positive  Negative

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

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Page Version No. PAGE\_07 (v1, 24-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at Least 5 Minutes?	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text" value="10-JUN-2009"/>	<input type="text" value="09:32"/>

ECG Interpretation

Normal  Abnormal, NCS  Abnormal, CS

Comments Regarding CS Findings:

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Page Version No. PAGE\_08 (v1, 24-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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Medical History

Date

Does the subject have any relevant medical history?  Yes  No

Sequence

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	HYPERTENSION	00-00-2007		<input checked="" type="checkbox"/> Ongoing
2	HYPERCHOLESTEROLEMIA	00-00-2009		<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
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

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

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Page Version No. PAGE\_09 (v1, 24-MAR-2009)

Document Number

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="20"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="15"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="1"/>	NICORETTE GUM
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="6"/>	COLD TURKEY

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Page Version No. PAGE\_10 (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
10-JUN-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
10-JUN-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
10-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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Page Version No. PAGE\_11 (v1, 24-MAR-2009)

Document Number



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

### Behavioral Counseling

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

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Page Version No. PAGE\_13 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
18-JUN-2009	14:21	13	2.7	

Behavioral Counseling

Date	Parameter	Result	Comments
18-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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Page Version No. PAGE\_14 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date  Actual Time   
Was Subject randomized?  Yes  No

---

Product Dispensation

Date

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

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Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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Page Version No. PAGE\_15 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="25-JUN-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="63"/>	<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="06-JUL-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="13-JUL-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="42"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE\_16 (v1, 14-APR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date  Scheduled Timepoint

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

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Page Version No. PAGE\_16 (v1, 14-APR-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

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

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Page Version No. PAGE\_17 (v1, 30-MAR-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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Page Version No. PAGE\_18 (v1, 25-MAR-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
<input type="text"/>				

Behavioral Counseling

Date	Parameter	Result	Comments
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Questionnaires

Date

Questionnaire MNWS Was Questionnaire Administered?  Yes  No

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Page Version No. PAGE\_19 (v1, 31-MAR-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

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

Status Review

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

Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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Page Version No. PAGE\_20 (v1, 24-APR-2009)

Document Number

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="13-AUG-2009"/>	Was Subject contacted by telephone?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<u>ASSESSMENT OCCURED IN PEH</u>
	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="21"/>	
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

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Page Version No. PAGE\_21 (v1, 25-MAR-2009)

Document Number

## OverFlow Section For Document Number R274288513

1 ASSESSMENT OCCURED IN PERSON

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

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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	79
Heart Rate	BEATS/MINUTE	82
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	36.6
Weight	LB	194.4

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Page Version No. PAGE\_22 (v1, 27-MAR-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
27-AUG-2009	08:47	4	1.2	

Behavioral Counseling

Date	Parameter	Result	Comments
27-AUG-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="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="27-AUG-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input 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="14"/>	<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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Page Version No. PAGE\_24 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="17-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="21"/>	<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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	109
Diastolic Blood Pressure	MMHG	67
Heart Rate	BEATS/MINUTE	81
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.7
Weight	LB	198.4

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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.

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Page Version No. PAGE\_27 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
08-OCT-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
08-OCT-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
08-OCT-2009	OTHER ORAL KERATOSIS	<input type="checkbox"/> Yes <input checked="" 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\_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
08-OCT-2009	09:08	3	1.1	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire	Was Questionnaire Administered?
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
<input type="text" value="08-OCT-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="14"/>	
	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="21"/>	<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="14"/>	<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	112
Diastolic Blood Pressure	MMHG	72
Heart Rate	BEATS/MINUTE	98
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.7
Weight	LB	209.8

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Page Version No. PAGE\_33 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_34 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
<input type="text" value="30-DEC-2009"/>	<input type="text" value="EVIDENCE OF LEUKOPLAKIA"/>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text" value="30-DEC-2009"/>	<input type="text" value="EXPOSED DENTAL CERVICES IN UPPER SULCUS?"/>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text" value="30-DEC-2009"/>	<input type="text" value="OTHER ORAL KERATOSIS"/>	<input type="checkbox"/> Yes <input checked="" 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\_35 (v1, 25-MAR-2009)

Document Number



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
30-DEC-2009	08:50	3	1.1	

Behavioral Counseling

Date	Parameter	Result	Comments
30-DEC-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\_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="30-DEC-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="28"/>	<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.

Verified  Approved  Locked  Frozen

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

Document Number

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified  Approved  Locked  Frozen

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

Document Number

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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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

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

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
13-AUG-2009	NA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			

Note: Attach copy of signed laboratory report.

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

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date  Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	122
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	79
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	77
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	16
	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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Page Version No. PAGE\_43 (v1, 27-MAR-2009)

Document Number

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

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



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

\* Indicate NE if system was not examined.

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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.

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_46 (v1, 25-MAR-2009)

Document Number

# Appendix: Audit and Discrepancy Information



# Audit History Report

This section lists audited data that meets the parameters set when the report was run. It may not include all of the audited data in a particular CRF. Refer to the documentation for a complete description of the parameters that can affect this report.

**Document #:** R260787613

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	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	16B	Sptp, Weeks 1-4

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCM Blank flag 1	N Y	23-MAR-2010 10:11:09 Kim Freschly	Data Entry Error

**Document #:** R274287213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Ip, Week 6	Page_17 17

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
-----------------------------	--------------------------	-------------------------	----------------------

<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	10-MAR-2010 14:11:39 Kim Freschly	Data Entry Error

**Document #:** R274287713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Ip, Week 6	Page_18 18

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
-----------------------------	--------------------------	-------------------------	----------------------

<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	10-MAR-2010 14:13:29 Kim Freschly	Data Entry Error

Document #: R274288013

Patient Site	Visit Visit Date	CRF CRF Page
R4063 P3880_0342	Ip, Week 6	Page_19 19

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

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	10-MAR-2010 14:13:50 Kim Freschly	Data Entry Error

**Document #:** R274288113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Ip, Week 6	Page_20 20

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
-----------------------------	--------------------------	-------------------------	----------------------

<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	10-MAR-2010 14:14:01 Kim Freschly	Data Entry Error
DCI Blank Flag 1	Y N	11-MAR-2010 15:10:08 Kim Freschly	Data Entry Error
DCI Blank Flag 1	N Y	23-MAR-2010 10:11:39 Kim Freschly	Data Entry Error

Document #: R274288113

Patient Site	Visit Visit Date	CRF CRF Page
R4063 P3880_0342	Ip, Week 6	Page_20 20

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ex	Page number	20	Ip, Week 6

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
0.5 g of snus or placebo logs dispensed 1	ND	11-MAR-2010 15:12:37 Kim Freschly	Data Entry Error
1.0 g of snus or placebo logs dispensed 1	ND	11-MAR-2010 15:12:37 Kim Freschly	Data Entry Error

Document #: R274288113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Ip, Week 6	Page_20 20

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	20	Ip, Week 6

<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>
Comments (HDYF) (8) 1		11-MAR-2010 15:10:08 Kim Freschly	Row Inserted
Comments (HDYF) (8) 1	PER DIARY	11-MAR-2010 15:15:17 Kim Freschly	Data Entry Error
Comments (compliant) (4) 1		11-MAR-2010 15:10:08 Kim Freschly	Row Inserted
Comments (compliant) (4) 1	PER DIARY	11-MAR-2010 15:15:17 Kim Freschly	Data Entry Error
Comments (how many cigarettes) (5) 1		11-MAR-2010 15:10:08 Kim Freschly	Row Inserted
Comments (how many cigarettes) (5) 1	PER DIARY	11-MAR-2010 15:15:17 Kim Freschly	Data Entry Error
Comments (smoking status reviewed) (2) 1	PER DIARY	11-MAR-2010 15:10:08 Kim Freschly	Row Inserted
Date 1	30-JUL-2009	11-MAR-2010 15:10:08 Kim Freschly	Row Inserted
If Subject was not compliant, approximat (5) 1	35	11-MAR-2010 15:10:08 Kim Freschly	Row Inserted
Was Subject asked HDYF? (8) 1	YES	11-MAR-2010 15:10:08 Kim Freschly	Row Inserted
Was Subject compliant (4) 1	NO	11-MAR-2010 15:10:08 Kim Freschly	Row Inserted

**Document #:** R274288113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Ip, Week 6	Page_20 20

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	20	Ip, Week 6

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

Was Subject's smoking status reviewed (2) 1	YES	11-MAR-2010 15:10:08 Row Inserted Kim Freschly
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**Document #:** R274288113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Ip, Week 6	Page_20 20

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Diary	Page number	20	Ip, Week 6

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Did subject receive diary and usage inst 1	NO	11-MAR-2010 15:11:39 Kim Freschly	Data Entry Error

**Document #:** R274288513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Ip, Week 8	Page_21 21

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	21	Ip, Week 8

<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>
Comments (contacted by phone) (1) 1	TOOK PLACE IN PERSON AT WEEK 6 VISIT ASSESSMENT OCCURED IN PERSON	23-MAR-2010 10:12:25 Kim Freschly	Data Entry Error

**Document #:** R274288713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Ip, Week 10	Page_22 22

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Vs	Page number	22	Ip, Week 10

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Was subject seated for 5 Minutes? (2) 1	YES	14-OCT-2009 10:10:49 Kim Freschly	Data Entry Error

**Document #:** R260789113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	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>
Start Date 1	00-00-2006 00-00-2007	13-APR-2010 13:12:05 Lana Glaser	Data Entry Error
Start Date 1	00-00-2007 00-00-2006	02-JUN-2010 17:01:50 Lana Glaser	Data Entry Error

Document #: R260789713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Pcm.1	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm.1

<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>
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	C10	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Text 1	LIPID MODIFYING AGENTS, C10	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Code 1	C10A	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Text 1	LIPID MODIFYING AGENTS, PLAIN, C10A	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Code 1	C10AA	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Text 1	HMG COA REDUCTASE INHIBITORS, C10AA	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Dose 1	160 40	15-JAN-2010 11:39:01 Kim Freschly	Data Entry Error
Drug Modified Reported Term 1	SIMIVASTIN SIMVASTATIN	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	SIMIVASTIN SIMVASTATIN	12-APR-2010 11:54:55 Joanne Mccaigue	ODM/SEC Obvious spelling update. JLM 12Apr2010
Indication 1	CHOLESTEROL HYPERCHOLESTEROLEMIA	11-MAR-2010 15:17:56 Kim Freschly	Data Entry Error
Preferred Term 1	SIMVASTATIN	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Preferred Term Code 1	00848101001	20-APR-2010 11:39:56 Carol Kraucyk	Data Change

Document #: R260792313

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Pcm.2	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm.2

<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>
ATC1 Code 1	A B	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A BLOOD AND BLOOD FORMING ORGANS, B	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	A01 B01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANTITHROMBOTIC AGENTS, B01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	A01A B01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A ANTITHROMBOTIC AGENTS, B01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	A01AD B01AC	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, B01AC	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
Drug Modified Reported Term 1	ASA ASPIRIN	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	ASA ASPIRIN	13-APR-2010 10:07:36 Lana Glaser	Data Entry Error
Trade Name 1	ASA ASPIRIN	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Trade Name Code 1	00002701003 00002701004	20-APR-2010 11:39:56 Carol Kraucyk	Data Change

Document #: R288295013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	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>
ATC1 Code 1	J	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC1 Text 1	ANTIINFECTIVES FOR SYSTEMIC USE, J	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Code 1	J07	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Text 1	VACCINES, J07	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Code 1	J07B	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Text 1	VIRAL VACCINES, J07B	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Code 1	J07BB	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Text 1	INFLUENZA VACCINES, J07BB	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Indication 1	PROPHALAXIS PROPHYLAXIS	12-APR-2010 11:55:21 Joanne Mccaigue	ODM/SEC Obvious spelling update. JLM 12Apr2010
Preferred Term 1	INFLUENZA VACCINE	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Preferred Term Code 1	01389801001	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change

**Document #:** R288296313

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Additional Lab	Page_42 42

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Lb	Page number	42	Additional Lab

<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>
Clinically Significant (additional) (2) 1	NO	10-MAR-2010 14:15:31 Kim Freschly	Row Inserted
Comments 1		10-MAR-2010 14:15:31 Kim Freschly	Row Inserted
Date 1	13-AUG-2009	10-MAR-2010 14:15:31 Kim Freschly	Row Inserted
Requisition Number (additional labs) (4) 1	NA	10-MAR-2010 14:15:31 Kim Freschly	Row Inserted
Test Code ID CS Labs only 1		10-MAR-2010 14:15:31 Kim Freschly	Row Inserted
Test Name CS Labs only 1		10-MAR-2010 14:15:31 Kim Freschly	Row Inserted
Were any additional Laboratory evaluatio 1	NO YES	10-MAR-2010 14:15:31 Kim Freschly	Data Entry Error

**Document #:** R288296413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Additional Vs	Page_43 43

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Vs	Page number	43	Additional Vs

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Actual Time 1	1013	10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Body Temperature 1	36.7	10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Body Temperature Unit 1	C	10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Comments (2) 1		10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Date 1	13-AUG-2009	10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Diastolic Blood Pressure 1	79	10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Diastolic Blood Pressure unit 1	MMHG	10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Heart Rate 1	77	10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Heart Rate Unit 1	BEATS/MINUTE	10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Other, specify (1) 1		10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Position (Unscheduled) (2) 1	SEATED	10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Respiratory Rate 1	16	10-MAR-2010 14:16:12 Kim Freschly	Row Inserted
Respiratory Rate Unit 1	BREATHS/MINUTE	10-MAR-2010 14:16:12 Kim Freschly	Row Inserted

**Document #:** R288296413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4063 P3880_0342	Additional Vs	Page_43 43

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Vs	Page number	43	Additional Vs

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

Systolic Blood Pressure 1	122	10-MAR-2010 14:16:12	Row Inserted Kim Freschly
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Systolic Blood Pressure unit 1	MMHG	10-MAR-2010 14:16:12	Row Inserted Kim Freschly
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Were Vital Signs Collected/Were any addi (1) 1	NO YES	10-MAR-2010 14:16:12	Data Entry Error Kim Freschly
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# Discrepancy Detail Report

Document #: R274288113

Discrepancy ID: 82847911

Site: P3880\_0342

Patient: R4063

Visit: IP, WEEK 6

Visit Date:

CRF: PAGE\_20

Section: STATUS REVIEW

Qualifying Value: 20

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please add info from week 6 diary regarding #smoked - see NTF

Internal Comment: done

Resolution Type: Confirmed

Resolution Text:

**Document #: R274288513**

**Discrepancy ID:** 88232711

**Site:** P3880\_0342

**Patient:** R4063

**Visit:** IP, WEEK 8

**Visit Date:**

**CRF:** PAGE\_21

**Section:** STATUS REVIEW

**Qualifying Value:** 21

**Field:** Comments (contacted by phone)

**Row:** 1

**Value Text:** ASSESSMENT OCCURED IN PERSON

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please clarify what happened here. Week 6 assessments were not done. If the Week 8 assessment occurred on 13-AUG-2009 (as shown), then it occurred at Week 8.

If Week 8 assessment occurred on 13-Aug, and the assessment occurred in person, please amend the comment to 'Assessment occurred in person'.

**Internal Comment:** COMMENT CHANGED

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

**Resolution Text:**

**Document #: R260789113**

**Discrepancy ID:** 99108811

**Site:** P3880\_0342

**Patient:** R4063

**Visit:** PCM

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:** Start Date

**Row:** 1

**Value Text:** 2006

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please review source ConMed source for start date

**Internal Comment:** Please confirm if start date is not equal to start date of related Medical history.

Confirmed--Start date is not equal to start date of related medical history

**Resolution Type:** Confirmed

**Resolution Text:** Verified. JLM 02Jun2010

**Document #: R260789713**

**Discrepancy ID:** 1789640313                      **Site:** P3880\_0342                      **Patient:** R4063  
**Visit:** PCM.1                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:** Dose    **Row:** 1  
**Value Text:** 40  
**Type:** MANUAL    **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please review dose; perhaps 40 mg?  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Discrepancy ID:** 82858911                      **Site:** P3880\_0342                      **Patient:** R4063  
**Visit:** PCM.1                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:** Indication    **Row:** 1  
**Value Text:** HYPERCHOLESTEROLEMIA  
**Type:** MANUAL    **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please match Med Hx terminology  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R260792313**

**Discrepancy ID:** 99106711

**Site:** P3880\_0342

**Patient:** R4063

**Visit:** PCM.2

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:** Drug name

**Row:** 1

**Value Text:** ASPIRIN

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify updating to 'aspirin' for clarity.

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:** Verified. JLM 21Apr2010

# Deleted CRFs Report