

# CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 15:55:29

## Report Parameters

Site: CD\_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R5007

Ending patient: R5007

## 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

Subject Initials

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### Inclusion Criteria

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

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

\* If No, document on Subject Eligibility Page.

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## **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

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="22-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="071.0"/>

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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	129
Diastolic Blood Pressure	MMHG	86
Heart Rate	BEATS/MINUTE	83
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	36.7
Weight	LB	302.2

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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

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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Protocol Number: SM 08-01

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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="22-JUN-2009"/>	<input type="text" value="10:45"/>
	<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

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Visit Name

Subject Number

Subject Initials

Is Blank

Medical History

Date

Does the subject have any relevant medical history?  Yes  No

Sequence

Sequence No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Smoking History

Was Smoking History collected?

Yes  No

Date

Parameter	Result	Comments
Age subject began smoking daily	<input type="text" value="26"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="20"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input 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="1"/>	JUST TRIED TO STOP ON OWN

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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
22-JUN-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
22-JUN-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
22-JUN-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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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

### Behavioral Counseling

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

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
06-JUL-2009	12:03	18	3.5	

Behavioral Counseling

Date	Parameter	Result	Comments
06-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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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date  Actual Time   
Was Subject randomized?  Yes  No

---

Product Dispensation

Date

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

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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
<input type="text"/>	<input type="text"/>	Was Subject contacted by telephone?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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

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

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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date	Scheduled Timepoint	Parameter	Result	Comments
		Was Subject contacted by telephone?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
		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	
		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	

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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		
Diastolic Blood Pressure		
Heart Rate		
Respiratory Rate		
Body Temperature		
Weight		

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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

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
<input type="text"/>				

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

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

Status Review

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

Diary Distribution

Date	Did subject receive diary and usage instructions?
<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

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

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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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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

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

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

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Swedish Match AB

Protocol Number: SM 08-01

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

Status Review

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

Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text"/>	Was Subject contacted by telephone?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject instructed to cut down on product use during upcoming Weeks 14-16 to avoid a too abrupt ending of nicotine uptake?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE\_25 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

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

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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

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\_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
<input type="text"/>				

Behavioral Counseling

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

Questionnaires

Date

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

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

Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date  Scheduled Timepoint

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

Date  Scheduled Timepoint

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

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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		
Diastolic Blood Pressure		
Heart Rate		
Respiratory Rate		
Body Temperature		
Weight		

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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.

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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
<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\_35 (v1, 25-MAR-2009)

Document Number



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

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

Behavioral Counseling

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

Questionnaires

Date

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

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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"/>	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"/>

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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

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date  Actual Time

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

Comments

Date  Actual Time

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

Comments

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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.

Verified  Approved  Locked  Frozen

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

Document Number

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

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

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

## Appendix: Audit and Discrepancy Information



# Audit History Report

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

Document #: **R258640513**

Patient Site	Visit Visit Date	CRF CRF Page	
R5007 CD_001	Screening	Page_02 02	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ic	Page number	2	Screening

Group #	Group Name
1	IE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Inclusion Criteria Answer 6	YES NO	17-JUL-2009 12:25:32 Sharon Ladenes	Data Entry Error
Inclusion Criteria Answer 6	NO YES	21-OCT-2009 11:34:48 Sharon Ladenes	Data Entry Error

Document #: **R258580513**

Patient Site	Visit Visit Date	CRF CRF Page	
R5007 CD_001	Screening	Page_03 03	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ec	Page number	3	Screening

Group #	Group Name
1	IE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Exclusion Criteria Answer 2	NO NAM	17-JUL-2009 12:00:05 Sharon Ladenes	Data Entry Error
Exclusion Criteria Answer 2	NAM NO	23-JUL-2009 12:16:47 Sharon Ladenes	Data Entry Error

Document #: **R258641213**

Patient Site	Visit Visit Date	CRF CRF Page
R5007 CD_001	Screening	Page_04 04

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Elig	Page number	4	Screening

Group #	Group Name
1	IE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Did the subject meet all of the inclusio 1	YES NO	17-JUL-2009 12:26:52 Sharon Ladenes	Data Entry Error
Did the subject meet all of the inclusio 1	NO YES	29-JUL-2009 18:19:02 Sharon Ladenes	Data Entry Error

Document #: **R258641913**

Patient Site	Visit Visit Date	CRF CRF Page
R5007 CD_001	Screening	Page_07 07

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

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Requisition Number 2 (if applicable): (2) 1	187-967-0007-0	31-MAR-2010 12:10:11 Sharon Ladenes	Data Entry Error
Requisition Number 2 (if applicable): (2) 1	187-967-0007-0	26-APR-2010 11:21:14 Sharon Ladenes	Investigator Correction

Document #: **R258643213**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5007 CD_001	Screening	Page_09 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>
Date of Onset 1	00-MAR-2009 <Row Deleted>	09-OCT-2009 16:05:34 Sharon Ladenes	Data Entry Error
Date of Resolution 1	00-MAR-2009 <Row Deleted>	09-OCT-2009 16:05:34 Sharon Ladenes	Data Entry Error
Diagnosis/Procedure 1	NOSE FRACTURE <Row Deleted>	09-OCT-2009 16:05:34 Sharon Ladenes	Data Entry Error
Does the subject have any relevant medication 1	YES NO	09-OCT-2009 16:05:34 Sharon Ladenes	Data Entry Error
Ongoing 1	<Row Deleted>	09-OCT-2009 16:05:34 Sharon Ladenes	Data Entry Error
Sequence Number 1	1 <Row Deleted>	09-OCT-2009 16:05:34 Sharon Ladenes	Data Entry Error
Date of Onset 2	00-00-2002 <Row Deleted>	09-OCT-2009 16:05:34 Sharon Ladenes	Data Entry Error
Date of Resolution 2	00-00-2002 <Row Deleted>	09-OCT-2009 16:05:34 Sharon Ladenes	Data Entry Error
Diagnosis/Procedure 2	APPENDECTOMY <Row Deleted>	09-OCT-2009 16:05:34 Sharon Ladenes	Data Entry Error
Ongoing 2	<Row Deleted>	09-OCT-2009 16:05:34 Sharon Ladenes	Data Entry Error
Sequence Number 2	2 <Row Deleted>	09-OCT-2009 16:05:34 Sharon Ladenes	Data Entry Error

Document #: R258604913

<b>Patient Site</b>	<b>Visit</b>	<b>CRF</b>
R5007	Screening	Page_12
CD_001		12

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pe	Page number	12	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>
Does the subject have any abnormal findi 1	YES NO	09-OCT-2009 16:06:46 Sharon Ladenes	Data Entry Error
Findings 1	SKIN - APPENDECTOMY SCAR <Row Deleted>	09-OCT-2009 16:06:46 Sharon Ladenes	Data Entry Error
Sequence Number 1	1 <Row Deleted>	09-OCT-2009 16:06:46 Sharon Ladenes	Data Entry Error
Findings 2	SKIN - SCAR ON BACK OF RIGHT HAND <Row Deleted>	09-OCT-2009 16:06:46 Sharon Ladenes	Data Entry Error
Sequence Number 2	2 <Row Deleted>	09-OCT-2009 16:06:46 Sharon Ladenes	Data Entry Error
Findings 3	SKIN - SCAR IB LEFT THUMB SKIN - SCAR ON LEFT THUMB	16-JUL-2009 17:28:47 Sharon Ladenes	Pass1
Findings 3	SKIN - SCAR ON LEFT THUMB <Row Deleted>	09-OCT-2009 16:06:46 Sharon Ladenes	Data Entry Error
Sequence Number 3	3 <Row Deleted>	09-OCT-2009 16:06:46 Sharon Ladenes	Data Entry Error

Document #: **R258604713**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5007	Pcm	Page_39
CD_001		39

<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	20-JUL-2009 19:28:26 Sharon Ladenes	Key Change
DCI Blank Flag 1	Y N	03-SEP-2009 14:35:23 Sharon Ladenes	Data Entry Error

Document #: R258604713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5007 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>
ATC1 Code 1	H	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC1 Text 1	SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC2 Code 1	H03	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC2 Text 1	THYROID THERAPY, H03	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC3 Code 1	H03A	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC3 Text 1	THYROID PREPARATIONS, H03A	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC4 Code 1	H03AA	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC4 Text 1	THYROID HORMONES, H03AA	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
Dose 1	100	17-DEC-2009 15:20:31 Sharon Ladenes	Row Inserted
Drug Modified Reported Term 1	THYROID MEDICATION - NAME UNKNOWN THYROID MEDICATION - NAME UNKNOWN	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Drug name 1	THYROID MEDICATION - NAME UNKNOWN	17-DEC-2009 15:20:31 Sharon Ladenes	Row Inserted
Drug name 1	THYROID MEDICATION - NAME UNKNOWN THYROID MEDICATION - NAME UNKNOWN	26-APR-2010 12:21:51 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 26Apr2010
Frequency 1		17-DEC-2009 15:20:31 Sharon Ladenes	Row Inserted

Document #: **R258604713**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5007 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

Frequency		17-DEC-2009 15:24:32	Data Entry Error
1	EVERY DAY	Sharon Ladenes	

Has the subject taken any medications pr	NO	17-DEC-2009 15:20:31	Data Entry Error
1	YES	Sharon Ladenes	

Indication		17-DEC-2009 15:20:31	Row Inserted
1	THYROID	Sharon Ladenes	

Indication	THYROID	21-JAN-2010 11:32:11	Data Entry Error
1	UNKNOWN	Sharon Ladenes	

Ongoing		17-DEC-2009 15:20:31	Row Inserted
1		Sharon Ladenes	

Preferred Term		26-APR-2010 14:24:56	Data Change
1	THYROID	Joanne Mccaigue	

Preferred Term Code		26-APR-2010 14:24:56	Data Change
1	00053701001	Joanne Mccaigue	

Start Date		17-DEC-2009 15:20:31	Row Inserted
1	00-00-2005	Sharon Ladenes	

Stop Date		17-DEC-2009 15:20:31	Row Inserted
1	20-JUN-2009	Sharon Ladenes	

Unit		17-DEC-2009 15:20:31	Row Inserted
1	MILLIGRAMS	Sharon Ladenes	

Unit	MILLIGRAMS	19-JAN-2010 12:33:47	Data Entry Error
1	MICROGRAMS	Sharon Ladenes	

other, specify (frequency)		17-DEC-2009 15:20:31	Row Inserted
1		Sharon Ladenes	

other, specify (unit)		17-DEC-2009 15:20:31	Row Inserted
1		Sharon Ladenes	

Document #: **R260481613**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5007	Additional Lab	Page_42
CD_001		42

<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	29-JUL-2009 18:27:06 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	29-JUL-2009 18:27:35 Sharon Ladenes	Data Entry Error

Document #: **R260481613**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5007 CD_001	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>
Were any additional Laboratory evaluation 1	NO	21-OCT-2009 11:38:14 Sharon Ladenes	Row Inserted
Clinically Significant (additional) (2) 2	NO	29-JUL-2009 18:21:18 Sharon Ladenes	Row Inserted
Comments 2		29-JUL-2009 18:21:18 Sharon Ladenes	Row Inserted
Date 2	29-JUN-2009	29-JUL-2009 18:21:18 Sharon Ladenes	Row Inserted
Requisition Number (additional labs) (4) 2	181-967-0052-0	29-JUL-2009 18:21:18 Sharon Ladenes	Row Inserted
Test Code ID CS Labs only 2		29-JUL-2009 18:21:18 Sharon Ladenes	Row Inserted
Test Name CS Labs only 2		29-JUL-2009 18:21:18 Sharon Ladenes	Row Inserted

Document #: **R275171213**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R5007 CD_001	Study Competition	Page_46 46

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Ds	Page number	46	Study Competition

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Date the subject completed OR withdrew f 1	17-JUL-2009 06-JUL-2009	17-DEC-2009 17:51:13 Sharon Ladenes	Data Entry Error
Other specify (2) 1	SUBJECT NEVER RETURNED WEEK 1 TELEPHONE CALL SUBJECT LOST TO FOLLOW- UP	10-NOV-2009 17:42:10 Sharon Ladenes	Data Entry Error
Other specify (2) 1	SUBJECT LOST TO FOLLOW- UP	17-DEC-2009 15:18:22 Sharon Ladenes	Data Entry Error
Reason for withdrawal 1	OTHER LOST	17-DEC-2009 15:18:22 Sharon Ladenes	Data Entry Error

# Discrepancy Detail Report

Document #: **R258604913**

Discrepancy ID: 1765647413

Site: CD\_001

Patient: R5007

Visit: SCREENING

Visit Date:

CRF: PAGE\_12

Section: PE

Qualifying Value: 12

Field: Does the subject have any abnormal findi

Row: 1

Value Text: NO

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please check No and delete lines 1-3.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

**Document #: R258640513**

**Discrepancy ID:** 1765647213

**Site:** CD\_001

**Patient:** R5007

**Visit:** SCREENING

**Visit Date:**

**CRF:** PAGE\_02

**Section:** IC

**Qualifying Value:** 2

**Field:** Inclusion Criteria Answer

**Row:** 6

**Value Text:** YES

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Per source, this should be yes.

**Internal Comment:**

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

**Resolution Text:**

**Document #: R258641913**

**Discrepancy ID:** 93271611

**Site:** CD\_001

**Patient:** R5007

**Visit:** SCREENING

**Visit Date:**

**CRF:** PAGE\_07

**Section:** LB

**Qualifying Value:** 7

**Field:** Requisition Number 2 (if applicable):

**Row:** 1

**Value Text:**

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Per PM, please remove serology req # 187-967-0007-0

**Internal Comment:**

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

**Resolution Text:**

**Document #: R258643213**

**Discrepancy ID:** 1790107713

**Site:** CD\_001

**Patient:** R5007

**Visit:** SCREENING

**Visit Date:**

**CRF:** PAGE\_09

**Section:** MH

**Qualifying Value:** 9

**Field:** Does the subject have any relevant medic

**Row:** 1

**Value Text:** NO

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** In reviewing the con meds today, I see that the subject was taking a thyroid medication, however there is not a medical condition listed on source other than the con-med page. Please clarify.

**Internal Comment:**

**Resolution Type:** Due Diligence

**Resolution Text:** Subject lost to followup - no contact

**Document #: R258604713**

**Discrepancy ID:** 1790105713                      **Site:** CD\_001                      **Patient:** R5007  
**Visit:** PCM                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:** Has the subject taken any medications pr                      **Row:** 1  
**Value Text:** YES  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please provide source, med. hx states OTC for heartburn.  
**Internal Comment:** Source found, please enter thyroid med listed on conmed source.  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Discrepancy ID:** 46034611                      **Site:** CD\_001                      **Patient:** R5007  
**Visit:** PCM                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:** Indication                      **Row:** 1  
**Value Text:** UNKNOWN  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Since the source does not specify the specific thyroid indication, please enter unk for indication. Please add resolution comment regarding subject lost to follow-up.

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

**Discrepancy ID:** 35441211                      **Site:** CD\_001                      **Patient:** R5007  
**Visit:** PCM                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:** Unit                      **Row:** 1  
**Value Text:** MICROGRAMS  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please review source for units. This medication is usually in micrograms. Have the staff clarify source entry and amend the CRF page if applicable.

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

## R258604713

**Discrepancy ID:** 98556311

**Site:** CD\_001

**Patient:** R5007

**Visit:** PCM

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:**

**Row:**

**Value Text:**

**Type:** MANUAL HEADER

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify subject did not have any medical history of 'hypothyroidism.'

**Internal Comment:** unable to contact subject - 3 attempts made. Lost to followup

**Resolution Type:** Confirmed

**Resolution Text:** Verified. JLM 20Apr2010

**Document #:** R275171213

**Discrepancy ID:** 1789619813                      **Site:** CD\_001                      **Patient:** R5007  
**Visit:** STUDY COMPETITION    **Visit Date:**  
**CRF:** PAGE\_46                      **Section:** DS                      **Qualifying Value:** 46  
**Field:** Reason for withdrawal                      **Row:** 1  
**Value Text:** LOST  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** You can actually check box for Lost to follow and delete other and comment.  
**Internal Comment:**  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

# Deleted CRFs Report