

# CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 13:07:55

## Report Parameters

Site: CDB\_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1017

Ending patient: R1017

### 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

## **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

Inclusion Criteria

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

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

\* If No, document on Subject Eligibility Page.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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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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="08-MAY-2009"/>	<input type="text" value="(b) (6)"/>	<input type="checkbox"/> Male	<input type="checkbox"/> Hispanic or Latino
		<input checked="" type="checkbox"/> Female	<input checked="" type="checkbox"/> Not Hispanic or latino
Race			
<input checked="" type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Black or African American	<input type="checkbox"/> American Indian/Alaskan Native		
<input type="checkbox"/> Asian	<input type="checkbox"/> Other	<input type="text"/>	

---

Body Measurements

Were Body Measurements Collected?  Yes  No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="062.0"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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	126
Diastolic Blood Pressure	MMHG	088
Heart Rate	BEATS/MINUTE	078
Respiratory Rate	BREATHS/MINUTE	016
Body Temperature	C	036.8
Weight	LB	115.8

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Safety Urine & Blood Tests; Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Urine Pregnancy Test

Result

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

Urine Drug Screen

Drug Screen Result\*

Positive  Negative

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Least 5 Minutes?	<input type="text" value="08-MAY-2009"/>	<input type="text" value="11:10"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal  Abnormal, NCS  Abnormal, CS

Comments Regarding CS Findings:

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Medical History

Date

Does the subject have any relevant medical history?  Yes  No

Sequence

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

\* Indicate NE if system was not examined.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

### Behavioral Counseling

Date	Parameter	Result	Comments
08-MAY-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
08-MAY-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
15-MAY-2009	09:56	30	5.4	

Behavioral Counseling

Date	Parameter	Result	Comments
15-MAY-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  logs  
1.0 g of snus or matching placebo  logs

---

Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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

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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

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="23-MAY-2009"/>	<input type="text" value="WEEK 1"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="29-MAY-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="56"/>	<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="05-JUN-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="35"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date Scheduled Timepoint

Parameter

Result

Comments

Was Subject contacted by telephone?

Yes  No

Was Subject's smoking status reviewed?

Yes  No

Was Subject's use of study product reviewed?

Yes  No

Approximately how many cigarettes did the subject smoke that week?

Was Behavioral Counseling Given?

Yes  No

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

Yes  No

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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	149
Diastolic Blood Pressure	MMHG	100
Heart Rate	BEATS/MINUTE	072
Respiratory Rate	BREATHS/MINUTE	018
Body Temperature	C	036.8
Weight	LB	117.0

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
26-JUN-2009	10:17	7	1.7	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<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="26-JUN-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="42"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date	Did subject receive diary and usage instructions?
<input type="text" value="26-JUN-2009"/>	<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

Status Review

Date	Parameter	Result	Comments
<input type="text" value="10-JUL-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input 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="35"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	119
Diastolic Blood Pressure	MMHG	082
Heart Rate	BEATS/MINUTE	071
Respiratory Rate	BREATHS/MINUTE	016
Body Temperature	C	036.7
Weight	LB	116.0

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
24-JUL-2009	10:14	10	2.2	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="1"/> 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="24-JUL-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input 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="35"/>	<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

## **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="14-AUG-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="28"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject instructed to cut down on product use during upcoming Weeks 14-16 to avoid a too abrupt ending of nicotine uptake?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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

Document Number

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	142
Diastolic Blood Pressure	MMHG	093
Heart Rate	BEATS/MINUTE	068
Respiratory Rate	BREATHS/MINUTE	14
Body Temperature	C	036.8
Weight	LB	119.0

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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
04-SEP-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
04-SEP-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
04-SEP-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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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
04-SEP-2009	10:17	8	1.9	

Behavioral Counseling

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

Questionnaires

Date

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

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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
04-SEP-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="28"/>	
	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="35"/>	<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="35"/>	<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	132
Diastolic Blood Pressure	MMHG	093
Heart Rate	BEATS/MINUTE	069
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	36.7
Weight	LB	115.2

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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

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

\* Indicate NE if system was not examined.

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Page Version No. PAGE\_35 (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

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
20-NOV-2009	16:04	15	3.0	

Behavioral Counseling

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

Questionnaires

Date

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

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Page Version No. PAGE\_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="20-NOV-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="35"/>	<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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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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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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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Laboratory Evaluations

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

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

Note: Attach copy of signed laboratory report.

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date  Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	159
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	102
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	ND
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	ND
	Body Temperature	C	ND

Comments

Date  Actual Time

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

Comments

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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	139
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	092
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	ND
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	ND
	Body Temperature	C	ND

Comments

Date  Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	139
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	093
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	ND
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	ND
	Body Temperature	C	ND

Comments

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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.

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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 #: **R247229413**

Patient Site	Visit Visit Date	CRF CRF Page	
R1017 CDB_001	Screening	Page_01 01	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Header	Page number	1	Screening

Group #	Group Name
1	DM

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Check Box 1	YES NO	09-JUN-2009 11:40:19 Sharon Daly	Pass1
Check Box 1	NO YES	09-JUN-2009 11:40:34 Sharon Daly	Pass1

Document #: **R247230613**

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Screening	Page_04 04

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

Group #	Group Name
1	IC

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Did the subject attend the information s 1	YES NO		09-JUN-2009 11:41:20 Sharon Daly	Pass1
Did the subject attend the information s 1	NO YES		09-JUN-2009 11:41:37 Sharon Daly	Pass1

Document #: **R247231013**

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Screening	Page_05 05

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Bm	Page number	5	Screening

Group #	Group Name
1	BM

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Were Body Measurements Collected 1	YES NO	09-JUN-2009 11:41:56 Sharon Daly	Pass1
Were Body Measurements Collected 1	NO YES	09-JUN-2009 11:42:14 Sharon Daly	Pass1

Document #: **R247231913**

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Screening	Page_06 06

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	6	Screening

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Was subject seated for 5 Minutes? (2) 1	YES NO	09-JUN-2009 11:42:25 Sharon Daly	Pass1
Was subject seated for 5 Minutes? (2) 1	NO YES	09-JUN-2009 11:42:41 Sharon Daly	Pass1

Document #: **R247232713**

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_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 resequence	On By	Reason Comment
Were the scheduled laboratory samples ob 1	YES NO		09-JUN-2009 11:43:05 Sharon Daly	Pass1
Were the scheduled laboratory samples ob 1	NO YES		09-JUN-2009 11:43:20 Sharon Daly	Pass1

Document #: **R247233513**

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Screening	Page_08 08

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eg	Page number	8	Screening

Group #	Group Name
1	EG

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Was subject Supine at least 5 minutes 1	YES NO		09-JUN-2009 11:43:30 Sharon Daly	Pass1
Was subject Supine at least 5 minutes 1	NO YES		09-JUN-2009 11:43:43 Sharon Daly	Pass1

Document #: **R247233913**

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Does the subject have any relevant medic 1	NO YES		09-JUN-2009 11:43:52 Sharon Daly	Pass1
Does the subject have any relevant medic 1	YES NO		09-JUN-2009 11:44:07 Sharon Daly	Pass1

Document #: **R247234613**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
R1017 CDB_001	Screening	Page_10 10	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Smoking History	Page number	10	Screening

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
Was Smoking History collected? 1	YES NO		09-JUN-2009 11:44:20 Sharon Daly	Pass1
Was Smoking History collected? 1	NO YES		09-JUN-2009 11:44:34 Sharon Daly	Pass1

Document #: **R247235913**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1017 CDB_001	Screening	Page_11 11

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Oral Health Exam	Page number	11	Screening

<b>Group #</b>	<b>Group Name</b>
1	EX1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
Findings* 1	NO YES		09-JUN-2009 11:44:45 Sharon Daly	Pass1
Findings* 1	YES NO		09-JUN-2009 11:45:03 Sharon Daly	Pass1
Date 3			09-JUN-2009 11:45:10 Sharon Daly	Data Entry Error
Findings* 3	NE NO		17-JUN-2009 16:05:52 Christina Breedlove	Data Entry Error

Document #: **R247236313**

Patient Site	Visit Visit Date	CRF CRF Page	
R1017 CDB_001	Screening	Page_12 12	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	12	Screening

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does the subject have any abnormal findi 1	NO YES	09-JUN-2009 11:46:11 Sharon Daly	Pass1
Does the subject have any abnormal findi 1	YES NO	09-JUN-2009 11:46:23 Sharon Daly	Pass1

Document #: **R247236613**

Patient Site	Visit Visit Date	CRF CRF Page		
R1017 CDB_001	Screening	Page_13 13		
Section Section Date	Qualifying Prompt	Qualifying Value		Section Visit
Behavioral Coun	Page number	13		Screening

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Result 1	YES NO	09-JUN-2009 11:46:35 Sharon Daly	Pass1
Result 1	NO YES	09-JUN-2009 11:46:49 Sharon Daly	Pass1

Document #: **R247236913**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
R1017 CDB_001	Baseline, Week 0	Page_14 14	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Questionnaires	Page number	14	Baseline, Week 0

<b>Group #</b>	<b>Group Name</b>
1	EX1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
FTND 1	YES NO	09-JUN-2009 11:39:27 Sharon Daly	Pass1
FTND 1	NO YES	09-JUN-2009 11:39:40 Sharon Daly	Pass1

Document #: **R247237313**

<b>Patient Site</b>	<b>Visit</b>	<b>CRF</b>	
R1017	<b>Visit Date</b>	<b>CRF Page</b>	
CDB_001	Baseline, Week 0	Page_15	
		15	
<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			
Sc	Page number	15	Baseline, Week 0

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

<b>Field</b>	<b>Changed From</b>	<b>Impact on</b>	<b>On</b>	<b>Reason</b>
<b>Row</b>	<b>Changed To</b>	<b>resequence</b>	<b>By</b>	<b>Comment</b>
Was Subject randomized?	YES		09-JUN-2009 11:39:49	Pass1
1	NO		Sharon Daly	
Was Subject randomized?	NO		09-JUN-2009 11:40:02	Pass1
1	YES		Sharon Daly	

Document #: **R255338813**

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Ip, Week 6	Page_20 20

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
If Subject was not compliant, approximat (5) 1	35 42	15-OCT-2009 14:54:31 Sharon Daly	Data Entry Error

Document #: **R265930413**

Patient Site	Visit Visit Date	CRF CRF Page	
R1017 CDB_001	Ip, Week 10	Page_22 22	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	22	Ip, Week 10

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Weight 1	116 116.0	25-MAR-2010 10:32:17 Christina Breedlove	Data Entry Error Decimal added Per Query

Document #: **R265930613**

Patient Site	Visit Visit Date	CRF CRF Page	
R1017 CDB_001	Ip, Week 10	Page_24 24	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Diary	Page number	24	Ip, Week 10

Group #	Group Name
0	Section Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCM Blank flag 1	Y N	17-DEC-2009 10:16:07 Christina Breedlove	Data Entry Error open to add data

Document #: **R265930713**

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Ip, Week 13	Page_25 25

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	25	Ip, Week 13

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
If Subject was not compliant, approximat (5) 1	21-28 28	02-DEC-2009 13:18:55 Christina Breedlove	Data Entry Error Corrected per query

Document #: **R282803313**

Patient Site	Visit Visit Date	CRF CRF Page	
R1017 CDB_001	Fu, Week 28	Page_34 34	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	34	Fu, Week 28

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Requisition Number 1: (1) 1	NA	03-MAR-2010 16:28:40 Christina Breedlove	Data Entry Error

Document #: **R282803413**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1017 CDB_001	Fu, Week 28	Page_35 35

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Oral Health Exam	Page number	35	Fu, Week 28

<b>Group #</b>	<b>Group Name</b>
1	EX1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
Findings* 1	NE NO		07-JAN-2010 09:46:34 Sharon Daly	Data Entry Error
Findings* 2	NE NO		07-JAN-2010 09:46:34 Sharon Daly	Data Entry Error
Findings* 3	NE NO		07-JAN-2010 09:46:34 Sharon Daly	Data Entry Error

Document #: **R255339213**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1017 CDB_001	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>
Body Temperature 1	ND NA	07-JAN-2010 09:51:53 Sharon Daly	Data Entry Error
Body Temperature 1	NA ND	25-FEB-2010 13:24:17 Christina Breedlove	Data Entry Error
Heart Rate 1	ND NA	07-JAN-2010 09:51:53 Sharon Daly	Data Entry Error
Heart Rate 1	NA ND	25-FEB-2010 13:24:17 Christina Breedlove	Data Entry Error
Respiratory Rate 1	ND NA	07-JAN-2010 09:51:53 Sharon Daly	Data Entry Error
Respiratory Rate 1	NA ND	25-FEB-2010 13:24:17 Christina Breedlove	Data Entry Error
Actual Time 2	1010	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
Actual Time 2	1010	24-MAY-2010 10:25:07 Christina Breedlove	Investigator Correction Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.
Body Temperature 2	ND	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
Body Temperature 2	ND NA	20-JAN-2010 11:00:50 Christina Breedlove	Validation Status changed
Body Temperature 2	NA ND	25-FEB-2010 13:24:17 Christina Breedlove	Data Entry Error

Document #: R255339213

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Additional Vs	Page_43 43

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

Group #	Group Name
1	VS

Body Temperature 2	ND	24-MAY-2010 10:25:07 Christina Breedlove	Investigator Correction Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.
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Body Temperature Unit 2	C	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
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Comments (2) 2		02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
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Date 2	04-SEP-2009	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
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Date 2	04-SEP-2009	24-MAY-2010 10:25:07 Christina Breedlove	Investigator Correction Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.
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Diastolic Blood Pressure 2	092	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
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Document #: R255339213

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Additional Vs	Page_43 43

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

Group #	Group Name
1	VS

Diastolic Blood Pressure 2	092	24-MAY-2010 10:25:07 Christina Breedlove	Investigator Correction Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.
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Diastolic Blood Pressure unit 2	MMHG	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
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Heart Rate 2	ND	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
-----------------	----	---	--------------

Heart Rate 2	ND NA	20-JAN-2010 11:00:50 Christina Breedlove	Validation Status changed
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Heart Rate 2	NA ND	25-FEB-2010 13:24:17 Christina Breedlove	Data Entry Error
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Heart Rate 2	ND	24-MAY-2010 10:25:07 Christina Breedlove	Investigator Correction Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.
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Heart Rate Unit 2	BEATS/MINUTE	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
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Other, specify (1) 2		02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
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Document #: R255339213

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Additional Vs	Page_43 43

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

Group #	Group Name
1	VS

Position (Unscheduled) (2) 2	SEATED	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
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Position (Unscheduled) (2) 2	SEATED	24-MAY-2010 10:25:07 Christina Breedlove	Investigator Correction Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.
---------------------------------	--------	---	--

Respiratory Rate 2	ND	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
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Respiratory Rate 2	ND NA	20-JAN-2010 11:00:50 Christina Breedlove	Validation Status changed
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Respiratory Rate 2	NA ND	25-FEB-2010 13:24:17 Christina Breedlove	Data Entry Error
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Respiratory Rate 2	ND	24-MAY-2010 10:25:07 Christina Breedlove	Investigator Correction Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.
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Respiratory Rate Unit 2	BREATHS/MINUTE	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
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Systolic Blood Pressure 2	139	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted
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Document #: **R255339213**

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Additional Vs	Page_43 43

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

Group #	Group Name
1	VS

Systolic Blood Pressure 2	139	24-MAY-2010 10:25:07 Christina Breedlove	Investigator Correction Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.
Systolic Blood Pressure unit 2	MMHG	02-DEC-2009 13:33:45 Christina Breedlove	Row Inserted

Document #: R267261813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1017 CDB_001	Additional Vs.1	Page_43

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Vs	Page number	43	Additional Vs.1

<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>
Body Temperature 1	NA ND	25-FEB-2010 13:37:01 Christina Breedlove	Data Entry Error
Heart Rate 1	NA ND	25-FEB-2010 13:37:01 Christina Breedlove	Data Entry Error
Respiratory Rate 1	NA ND	25-FEB-2010 13:37:01 Christina Breedlove	Data Entry Error
Actual Time 2	1529	02-DEC-2009 13:36:20 Christina Breedlove	Row Inserted
Body Temperature 2	ND	02-DEC-2009 13:36:20 Christina Breedlove	Row Inserted
Body Temperature Unit 2	C	02-DEC-2009 13:36:20 Christina Breedlove	Row Inserted
Comments (2) 2		02-DEC-2009 13:36:20 Christina Breedlove	Row Inserted
Date 2	20-NOV-2009	02-DEC-2009 13:36:20 Christina Breedlove	Row Inserted
Diastolic Blood Pressure 2	093	02-DEC-2009 13:36:20 Christina Breedlove	Row Inserted
Diastolic Blood Pressure unit 2	MMHG	02-DEC-2009 13:36:20 Christina Breedlove	Row Inserted
Heart Rate 2	ND	02-DEC-2009 13:36:20 Christina Breedlove	Row Inserted
Heart Rate Unit 2	BEATS/MINUTE	02-DEC-2009 13:36:20 Christina Breedlove	Row Inserted
Other, specify (1) 2		02-DEC-2009 13:36:20 Christina Breedlove	Row Inserted
Position (Unscheduled) (2) 2	SEATED	02-DEC-2009 13:36:20 Christina Breedlove	Row Inserted

Document #: **R267261813**

Patient Site	Visit Visit Date	CRF CRF Page
R1017 CDB_001	Additional Vs.1	Page_43

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	43	Additional Vs.1

Group #	Group Name
1	VS

Respiratory Rate	02-DEC-2009 13:36:20	Row Inserted
2	ND	Christina Breedlove

Respiratory Rate	02-DEC-2009 13:36:20	Row Inserted
Unit	BREATHS/MINUTE	Christina Breedlove
2		

Systolic Blood	02-DEC-2009 13:36:20	Row Inserted
Pressure	139	Christina Breedlove
2		

Systolic Blood	02-DEC-2009 13:36:20	Row Inserted
Pressure unit	MMHG	Christina Breedlove
2		

# Discrepancy Detail Report

Document #: **R247231013**

Discrepancy ID: 93291411                      Site: CDB\_001                      Patient: R1017  
Visit: SCREENING                      Visit Date:  
CRF: PAGE\_05                      Section: DM                      Qualifying Value: 5  
Field: Date of Birth                      Row: 1  
Value Text: 19620423  
Type: MANUAL                      Status: CURRENT  
Review Status: Resolved-Response Edited  
Discrepancy: Please verify date of birth (23-Apr-1962) as it is 23-Apr-1961 in the electronic lab file. Please amend here or send an updated lab file with the correct date.  
Internal Comment: Confirmed that date of birth is 23/Apr/1962  
Resolution Type: Confirmed  
Resolution Text:

**Document #: R247235913**

**Discrepancy ID:** 1679216913

**Site:** CDB\_001

**Patient:** R1017

**Visit:** SCREENING

**Visit Date:**

**CRF:** PAGE\_11

**Section:** ORAL HEALTH EXA **Qualifying Value:** 11

**Field:** Findings\*

**Row:** 3

**Value Text:** NO

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify per CRF conventions should be 'no'

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R255338813**

**Discrepancy ID:** 1718898313

**Site:** CDB\_001

**Patient:** R1017

**Visit:** IP, WEEK 6

**Visit Date:**

**CRF:** PAGE\_20

**Section:** STATUS REVIEW

**Qualifying Value:** 20

**Field:** If Subject was not compliant, approximat

**Row:** 1

**Value Text:** 42

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify per subject diary per CRF guidelines.

**Internal Comment:** 42

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

**Resolution Text:**



**Document #:** R265930613

**Discrepancy ID:** 1789584413

**Site:** CDB\_001

**Patient:** R1017

**Visit:** IP, WEEK 10

**Visit Date:**

**CRF:** PAGE\_24

**Section:** DIARY

**Qualifying Value:** 24

**Field:**

**Row:**

**Value Text:**

**Type:** MANUAL HEADER

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify per source diary was dispensed.

**Internal Comment:** Subject diaries were dispensed on 24Jul2009 however eCRF page won't allow data to be entered.

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

**Resolution Text:**

**Document #: R265930713**

**Discrepancy ID:** 1789584613                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** IP, WEEK 13                      **Visit Date:**  
**CRF:** PAGE\_25                      **Section:** STATUS REVIEW                      **Qualifying Value:** 25  
**Field:** If Subject was not compliant, approximat                      **Row:** 1  
**Value Text:** 28  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify per guidelines, ranges should not be entered. Please verify 28 should be entered.  
**Internal Comment:** Corrected per query  
**Resolution Type:** Confirmed  
**Resolution Text:** Corrected per query

**Document #: R282803313**

**Discrepancy ID:** 76396311                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** FU, WEEK 28                      **Visit Date:**  
**CRF:** PAGE\_34                      **Section:** LB                      **Qualifying Value:** 34  
**Field:** Requisition Number 1:                      **Row:** 1  
**Value Text:** NA  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please provide requisition number or enter NA.  
**Internal Comment:** per query  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**



**Document #: R255339213**

**Discrepancy ID:** 129411611                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS                      **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Actual Time                      **Row:** 2

**Value Text:**

**Type:** UNIVARIATE                      **Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Value for Actual Time has not been supplied

**Internal Comment:** Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.

**Resolution Type:** No Action Required

**Resolution Text:**

**Discrepancy ID:** 22372411                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS                      **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Body Temperature                      **Row:** 1

**Value Text:** ND

**Type:** MANUAL                      **Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify should be NA

**Internal Comment:** will change

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

**Resolution Text:**

**Discrepancy ID:** 22372711                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS                      **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Body Temperature                      **Row:** 2

**Value Text:**

**Type:** MANUAL                      **Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify should be NA

**Internal Comment:**

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

**Resolution Text:**

## R255339213

**Discrepancy ID:** 129412111                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS                      **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Body Temperature                      **Row:** 2  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Body Temperature has not been supplied  
**Internal Comment:** Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.  
**Resolution Type:** No Action Required  
**Resolution Text:**

**Discrepancy ID:** 128978211                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS                      **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Date                      **Row:** 2  
**Value Text:**  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Two additional vitals assessments are recorded for 04-Sep-2009 at 10:10 with all data the same. Please remove the duplicate assessment or verify that two assessments were performed at this time.  
**Internal Comment:** Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Discrepancy ID:** 129411511                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS                      **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Date                      **Row:** 2  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Date has not been supplied  
**Internal Comment:** Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.  
**Resolution Type:** No Action Required  
**Resolution Text:**

**R255339213**

**Discrepancy ID:** 1689810313                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS                      **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Diastolic Blood Pressure                      **Row:** 1  
**Value Text:** 102  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value of 102 for Diastolic Blood Pressure above expected maximum of 100  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Discrepancy ID:** 129411811                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS                      **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Diastolic Blood Pressure                      **Row:** 2  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Diastolic Blood Pressure has not been supplied  
**Internal Comment:** Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.  
**Resolution Type:** No Action Required  
**Resolution Text:**

**Discrepancy ID:** 22372211                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS                      **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Heart Rate                      **Row:** 1  
**Value Text:** ND  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** please verify should be NA  
**Internal Comment:** will change  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

## R255339213

**Discrepancy ID:** 22372511                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS              **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Heart Rate                      **Row:** 2  
**Value Text:**  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify should be NA  
**Internal Comment:**  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Discrepancy ID:** 129411911                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS              **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Heart Rate                      **Row:** 2  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Heart Rate has not been supplied  
**Internal Comment:** Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.  
**Resolution Type:** No Action Required  
**Resolution Text:**

**Discrepancy ID:** 129412211                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS              **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Position (Unscheduled)                      **Row:** 2  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Position (Unscheduled) has not been supplied  
**Internal Comment:** All Data has been removed. System will not allow me to mark this section "Blank".  
**Resolution Type:** No Action Required  
**Resolution Text:**

**R255339213**

**Discrepancy ID:** 22372311                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS              **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Respiratory Rate                      **Row:** 1  
**Value Text:** ND  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify should be NA  
**Internal Comment:** will change  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Discrepancy ID:** 22372611                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS              **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Respiratory Rate                      **Row:** 2  
**Value Text:**  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify should be NA  
**Internal Comment:**  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Discrepancy ID:** 129412011                      **Site:** CDB\_001                      **Patient:** R1017  
**Visit:** ADDITIONAL VS              **Visit Date:**  
**CRF:** PAGE\_43                      **Section:** VS                      **Qualifying Value:** 43  
**Field:** Respiratory Rate                      **Row:** 2  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Respiratory Rate has not been supplied  
**Internal Comment:** Repeat vitals dated 04/Sep/2009 were entered twice, in error. The data for the repeated vitals is on the second unplanned vitals page. This section of this page will be marked blank.  
**Resolution Type:** No Action Required  
**Resolution Text:**



# Deleted CRFs Report