

# CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 16:58:54

## Report Parameters

Site: CDB\_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1002

Ending patient: R1002

## 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

(b) (6)

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

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

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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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  Male  Female

Ethnicity  Hispanic or Latino  Not Hispanic or latino

Race  White  Black or African American  Asian

Native Hawaiian or Other Pacific Islander  American Indian/Alaskan Native  Other

Body Measurements

Were Body Measurements Collected?  Yes  No Date

Parameter Unit Result  
Height

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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	134
Diastolic Blood Pressure	MMHG	081
Heart Rate	BEATS/MINUTE	062
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.3
Weight	LB	164.4

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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 Least 5 Minutes?	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text" value="18-FEB-2009"/>	<input type="text" value="12:37"/>

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

Sequence No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	OSTEOARTHRITIS (C-SPINE, KNEES)	00-00-2005		<input checked="" type="checkbox"/> Ongoing
2	HYPERTENSION	00-00-2007		<input checked="" type="checkbox"/> Ongoing
3	HOT FLASHES	00-00-2004		<input checked="" type="checkbox"/> Ongoing
4	POLLEN ALLERGIES	00-00-2002		<input checked="" type="checkbox"/> Ongoing
5	POSTMENOPAUSAL	00-OCT-2006		<input checked="" type="checkbox"/> Ongoing
6	CATARACTS	18-FEB-2009		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

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

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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="18"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="15"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of Pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="2"/>	NO SMOKING CESSATION AIDES WERE USED

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## OverFlow Section For Document Number R242828313

1 NO SMOKING CESSATION AIDES WERE USED

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

\* Indicate NE if system was not examined.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
02-MAR-2009	15:36	14	2.8	

Behavioral Counseling

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

Questionnaires

Date

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date  Actual Time   
Was Subject randomized?  Yes  No

---

Product Dispensation

Date

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

---

Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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## **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="09-MAR-2009"/>	<input type="text" value="WEEK 1"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="28"/>	<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="16-MAR-2009"/>	<input type="text" value="WEEK 2"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="14"/>	<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="23-MAR-2009"/>	<input type="text" value="WEEK 3"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="14"/>	<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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## **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

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	122
Diastolic Blood Pressure	MMHG	070
Heart Rate	BEATS/MINUTE	055
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.5
Weight	LB	165.6

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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
13-APR-2009	11:31	5	1.4	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<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="13-APR-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="4"/> logs	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="28-APR-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="10"/>	<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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## **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

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	148
Diastolic Blood Pressure	MMHG	081
Heart Rate	BEATS/MINUTE	060
Respiratory Rate	BREATHS/MINUTE	020
Body Temperature	C	036.6
Weight	LB	ND

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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
08-MAY-2009	12:47	6	1.5	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

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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  logs

1.0 g of snus or matching placebo  logs

Status Review

Date

Parameter

Result

Comments

Was Subject's smoking status reviewed?

Yes  No

Was Subject's use of study product reviewed?

Yes  No

Was Subject compliant?

Yes  No

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

Was Subject asked HDYF? question?

Yes  No

Diary Distribution

Date

Did subject receive diary and usage instructions?

Yes  No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="02-JUN-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="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"/>
	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](#)

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	130
Diastolic Blood Pressure	MMHG	083
Heart Rate	BEATS/MINUTE	063
Respiratory Rate	BREATHS/MINUTE	016
Body Temperature	C	036.7
Weight	LB	170.0

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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
<input type="text" value="24-JUN-2009"/>	<input type="text" value="EVIDENCE OF LEUKOPLAKIA"/>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text" value="24-JUN-2009"/>	<input type="text" value="EXPOSED DENTAL SERVICES IN UPPER SULCUS?"/>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text" value="24-JUN-2009"/>	<input type="text" value="OTHER ORAL KERATOSIS"/>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>

\* Indicate NE if system was not examined.

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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
24-JUN-2009	08:54	22	4.1	

Behavioral Counseling

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

Questionnaires

Date

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

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## **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

Status Review

Date	Parameter	Result	Comments
<input type="text" value="24-JUN-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<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\_31 (v1, 12-MAY-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  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="42"/>	<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

## **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	100
Diastolic Blood Pressure	MMHG	069
Heart Rate	BEATS/MINUTE	061
Respiratory Rate	BREATHS/MINUTE	015
Body Temperature	C	36.6
Weight	LB	160.6

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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

\* Indicate NE if system was not examined.

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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
16-SEP-2009	08:33	6	1.5	

Behavioral Counseling

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

Questionnaires

Date

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

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="16-SEP-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="15"/>	<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)

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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

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

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

Frequency Select only one

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily
- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

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

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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## **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

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events?  Yes  No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time   Ongoing

Serious Event: Select only one  
 Yes  
 No

Severity: Select only one  
 Mild  
 Moderate  
 Severe

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

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

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

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

Document Number

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events?  Yes  No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time   Ongoing

Serious Event: Select only one  
 Yes  
 No

Severity: Select only one  
 Mild  
 Moderate  
 Severe

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

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

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

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

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

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

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

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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 - Laboratory Evaluations

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

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

Note: Attach copy of signed laboratory report.

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Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date  Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	131
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	077
<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		
<input type="checkbox"/> Supine	Diastolic Blood Pressure		
<input type="checkbox"/> Seated	Heart Rate		
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate		
	Body Temperature		

Comments

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## **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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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

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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 #:** R242827413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Screening	Page_01 01

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Header	Page number	1	Screening

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Check Box 1	YES NO	19-MAY-2009 14:47:38 Christina Breedlove	Pass1
Check Box 1	NO YES	19-MAY-2009 14:47:52 Christina Breedlove	Pass1

**Document #:** R242827613

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Screening	Page_03 03

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Ec	Page number	3	Screening

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
Exclusion Criteria Answer 1	NO YES		19-MAY-2009 14:48:01 Christina Breedlove	Pass1
Exclusion Criteria Answer 1	YES NO		19-MAY-2009 14:48:25 Christina Breedlove	Pass1

**Document #:** R242827813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Screening	Page_05 05

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Dm	Page number	5	Screening

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Gender 1	FEMALE MALE	19-MAY-2009 14:48:47 Christina Breedlove	Pass1
Gender 1	MALE FEMALE	19-MAY-2009 14:49:05 Christina Breedlove	Pass1

**Document #:** R242827813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Screening	Page_05 05

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Bm	Page number	5	Screening

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Date 1	18-FEB-2009 08-MAY-2009	18-JUN-2009 10:30:24 Christina Breedlove	Data Entry Error
Height 1	65.0	19-MAY-2009 15:05:19 Christina Breedlove	Data Entry Error

**Document #:** R242828013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Screening	Page_07 07

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Lb	Page number	7	Screening

<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>
Requisition Number 1: (1) 1	09888880-4 050-552-1503-0	16-JUN-2009 10:47:26 Rossana Matos	Data Entry Error
Were there any clinically significant la (1) 1	NO	16-JUN-2009 10:47:26 Rossana Matos	Data Entry Error

**Document #:** R242828113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Screening	Page_08 08

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Eg	Page number	8	Screening

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Was ECG Performed/Were any additional 12 1	YES NO	19-MAY-2009 14:51:15 Christina Breedlove	Pass1
Was ECG Performed/Were any additional 12 1	NO YES	19-MAY-2009 14:51:48 Christina Breedlove	Pass1

**Document #:** R242828213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_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 2	00-00-2007	11-AUG-2009 13:07:19 Christina Breedlove	Row Inserted
Date of Resolution 2		11-AUG-2009 13:07:19 Christina Breedlove	Row Inserted
Diagnosis/Procedure 2	HYPERTENSION	11-AUG-2009 13:07:19 Christina Breedlove	Row Inserted
Ongoing 2	CHECKED	11-AUG-2009 13:07:19 Christina Breedlove	Row Inserted
Sequence Number 2	2	11-AUG-2009 13:07:19 Christina Breedlove	Row Inserted
Date of Onset 3		09-NOV-2009 15:02:33 Heather Kretschmer	Row Inserted
Date of Onset 3	00-00-2004	13-NOV-2009 09:48:48 Christina Breedlove	Data Entry Error Hot flashes will be added to med hx as ongoing since 2004
Date of Resolution 3		09-NOV-2009 15:02:33 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 3		09-NOV-2009 15:02:33 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 3	HOT FLASHES	13-NOV-2009 09:48:48 Christina Breedlove	Data Entry Error Hot flashes will be added to med hx as ongoing since 2004
Ongoing 3		09-NOV-2009 15:02:33 Heather Kretschmer	Row Inserted
Ongoing 3	CHECKED	13-NOV-2009 09:48:48 Christina Breedlove	Data Entry Error Hot flashes will be added to med hx as ongoing since 2004

Document #: R242828213

Patient Site	Visit Visit Date	CRF CRF Page
R1002 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

Sequence Number 3		09-NOV-2009 15:02:33 Heather Kretschmer	Row Inserted
Sequence Number 3	3	13-NOV-2009 09:48:48 Christina Breedlove	Data Entry Error Hot flashes will be added to med hx as ongoing since 2004
Date of Onset 4		09-NOV-2009 15:02:33 Heather Kretschmer	Row Inserted
Date of Onset 4	00-00-2002	13-NOV-2009 09:56:26 Christina Breedlove	Data Entry Error confirmed Pollen Allergy will be added to med hx as ongoing since 2002
Date of Resolution 4		09-NOV-2009 15:02:33 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 4		09-NOV-2009 15:02:33 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 4	POLLEN ALLERGIES	13-NOV-2009 09:56:26 Christina Breedlove	Data Entry Error confirmed Pollen Allergy will be added to med hx as ongoing since 2002
Ongoing 4		09-NOV-2009 15:02:33 Heather Kretschmer	Row Inserted
Ongoing 4	CHECKED	13-NOV-2009 09:56:26 Christina Breedlove	Data Entry Error confirmed Pollen Allergy will be added to med hx as ongoing since 2002
Sequence Number 4		09-NOV-2009 15:02:33 Heather Kretschmer	Row Inserted
Sequence Number 4	4	13-NOV-2009 09:56:26 Christina Breedlove	Data Entry Error confirmed Pollen Allergy will be added to med hx as ongoing since 2002
Date of Onset 5		17-DEC-2009 11:50:35 Heather Kretschmer	Row Inserted

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<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_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

Date of Onset 5	00-OCT-2006	17-DEC-2009 13:01:52 Christina Breedlove	Data Entry Error
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Date of Resolution 5		17-DEC-2009 11:50:35 Heather Kretschmer	Row Inserted
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Diagnosis/Procedure 5		17-DEC-2009 11:50:35 Heather Kretschmer	Row Inserted
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Diagnosis/Procedure 5	POSTMENOPAUSAL	17-DEC-2009 13:01:52 Christina Breedlove	Investigator Correction
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Ongoing 5		17-DEC-2009 11:50:35 Heather Kretschmer	Row Inserted
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Ongoing 5	CHECKED	17-DEC-2009 13:01:52 Christina Breedlove	Data Entry Error
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Sequence Number 5		17-DEC-2009 11:50:35 Heather Kretschmer	Row Inserted
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Sequence Number 5	5	17-DEC-2009 13:01:52 Christina Breedlove	Investigator Correction
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Date of Onset 6		17-DEC-2009 11:54:00 Heather Kretschmer	Row Inserted
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Date of Onset 6	18-FEB-2009	17-DEC-2009 13:28:55 Christina Breedlove	Investigator Correction
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Date of Resolution 6		17-DEC-2009 11:54:00 Heather Kretschmer	Row Inserted
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Diagnosis/Procedure 6		17-DEC-2009 11:54:00 Heather Kretschmer	Row Inserted
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Diagnosis/Procedure 6	CATARACTS	17-DEC-2009 13:28:55 Christina Breedlove	Investigator Correction
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Ongoing 6		17-DEC-2009 11:54:00 Heather Kretschmer	Row Inserted
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**Document #:** R242828213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_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

Ongoing		17-DEC-2009 13:28:55	Investigator
6	CHECKED	Christina Breedlove	Correction

Sequence Number		17-DEC-2009 11:54:00	Row Inserted
6		Heather Kretschmer	

Sequence Number		17-DEC-2009 13:28:55	Investigator
6	6	Christina Breedlove	Correction

**Document #:** R242828313

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 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 On resequence By</b>	<b>Reason Comment</b>
Average number of cigarettes smoked per (2) 1	10-15 15	03-MAR-2010 15:04:57 Christina Breedlove	Data Entry Error

Document #: R242828513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Screening	Page_12 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	18-JUN-2009 10:35:24 Christina Breedlove	Data Entry Error
Does the subject have any abnormal findi 1	NO YES	23-JUL-2009 14:53:33 Sharon Daly	Data Entry Error
Does the subject have any abnormal findi 1	YES NO	10-NOV-2009 13:17:13 Rossana Matos	Data Entry Error
Does the subject have any abnormal findi 1	NO YES	31-DEC-2009 14:45:25 Sharon Daly	Data Entry Error
Findings 1	CATARACTS <Row Deleted>	10-NOV-2009 13:17:13 Rossana Matos	Data Entry Error
Findings 1	CATARACTS	31-DEC-2009 14:46:49 Sharon Daly	Row Inserted
Sequence Number 1	1 <Row Deleted>	10-NOV-2009 13:17:13 Rossana Matos	Data Entry Error
Sequence Number 1	1	31-DEC-2009 14:46:49 Sharon Daly	Row Inserted

**Document #:** R243304413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Screening	Page_13 13

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Behavioral Coun	Page number	13	Screening

<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>
Date 1	02-MAR-2009 18-FEB-2009	01-MAR-2010 09:25:45 Christina Breedlove	Data Entry Error
Date 2	02-MAR-2009 18-FEB-2009	01-MAR-2010 09:25:45 Christina Breedlove	Data Entry Error

**Document #:** R243304613

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
R1002 CDB_001	Baseline, Week 0	Page_15 15	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Sc	Page number	15	Baseline, Week 0

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Date 1	20-MAR-2009 02-MAR-2009	23-MAY-2009 16:36:55 Rossana Matos	Pass1
Was Subject randomized? 1	YES NO	19-MAY-2009 15:04:29 Christina Breedlove	Pass1
Was Subject randomized? 1	NO YES	19-MAY-2009 15:04:51 Christina Breedlove	Pass1
Was Subject randomized? 1	YES NO	19-MAY-2009 15:06:34 Christina Breedlove	Pass1
Was Subject randomized? 1	NO YES	19-MAY-2009 15:06:51 Christina Breedlove	Pass1

**Document #:** R243304813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Sptp, Weeks 1-4	Page_16 16

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

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Was Behavioral Counseling Given (6) 1	YES NO	23-MAY-2009 16:39:46 Rossana Matos	Pass1
Was Behavioral Counseling Given (6) 1	NO YES	23-MAY-2009 16:40:40 Rossana Matos	Pass1

**Document #:** R248876113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Ip, Week 10	Page_24 24

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	24	Ip, Week 10

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
If Subject was not compliant, approximat (5) 1	14-21 21	24-JUN-2009 11:25:00 Rossana Matos	Investigator Correction

**Document #:** R252829613

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Ip, Week 13	Page_25 25

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	25	Ip, Week 13

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Was Subject contacted by telephone (1) 1	YES	15-JUN-2009 18:01:26 Christina Breedlove	Data Entry Error

**Document #:** R254575513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Ip, Week 16	Page_30 30

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Behavioral Coun	Page number	30	Ip, Week 16

<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>
Result 1	YES	24-JUN-2009 09:54:22 Rossana Matos	Data Entry Error

**Document #:** R254575913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Ip, Week 16	Page_31 31

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	31	Ip, Week 16

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
If Subject was not compliant, approximat (5) 1	42 35	11-AUG-2009 10:39:15 Christina Breedlove	Data Entry Error Subject reported to have smoked 2-10 cigarettes per day during wk 16. Average was calculated by $10/2=5$ and $5 \times 7 \text{days}$ per wk.
If Subject was not compliant, approximat (5) 1	35 42	03-OCT-2009 11:22:10 Rossana Matos	Data Entry Error
If Subject was not compliant, approximat (5) 1	42 70	15-OCT-2009 15:14:12 Sharon Daly	Data Entry Error

**Document #:** R258780213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Fu, Week 20 & 24	Page_32 32

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	32.1	Fu, Week 20 & 24

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
If Subject was not compliant, approximat (5) 1	5 35	03-OCT-2009 11:24:49 Rossana Matos	Data Entry Error

**Document #:** R272689213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Fu, Week 28	Page_38 38

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	38	Fu, Week 28

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
If Subject was not compliant, approximat (5) 1	35 70	15-OCT-2009 15:18:37 Sharon Daly	Data Entry Error
If Subject was not compliant, approximat (5) 1	70 15	18-DEC-2009 10:55:00 Christina Breedlove	Data Entry Error

Document #: R254121213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Pcm.1	Page_39

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

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
ATC1 Code 1	C	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Code 1	C03	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Text 1	DIURETICS, C03	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Code 1	C03E	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Text 1	DIURETICS AND POTASSIUM- SPARING AGENTS IN COMB, C03E	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Code 1	C03EA	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Text 1	LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, C03EA	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Dose 1	37.5/25 1	20-APR-2010 11:30:50 Christina Breedlove	Investigator Correction Changed to 1 tab per query
Drug name 1	HYDROCHLOROTHIAZIDE TRIAM/HYDROCHLOROTHIAZID E	17-DEC-2009 17:19:25 Christina Breedlove	Data Entry Error
Preferred Term 1	DYAZIDE	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Preferred Term Code 1	00081101001	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name 1	TRIAMTERENE/HCTZ	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change

**Document #:** R254121213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Pcm.1	Page_39

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

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

Trade Name Code		26-APR-2010 10:36:00	Class. Change
1	00081101076	Carol Kraucyk	
Unit	MILLIGRAMS	20-APR-2010 11:30:50	Investigator
1	TABLET	Christina Breedlove	Correction Changed to 1 tab per query

**Document #:** R254124713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Pcm.2	Page_39

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

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Frequency 1	EVERY DAY	22-JUN-2009 10:44:29 Christina Breedlove	Data Entry Error

**Document #:** R254125313

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Pcm.3	Page_39

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

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Unit 1	MICROGRAMS MILLIGRAMS	17-DEC-2009 17:20:30 Christina Breedlove	Data Entry Error

Document #: R254577513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Pcm.5	Page_39

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

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
ATC1 Code 1	C M	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	C01 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	CARDIAC THERAPY, C01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	C01E M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	OTHER CARDIAC PREPARATIONS, C01E ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STERIODS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	C01EB M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Text 1	OTHER CARDIAC PREPARATIONS, C01EB PROPIONIC ACID DERIVATIVES, M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change

**Document #:** R279447513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002	Ae	Page_40
CDB_001		40

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag	Y	19-NOV-2009 13:33:35	Data Entry Error
1	N	Christina Breedlove	Confirmed to be NO

Document #: R279447513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 CDB_001	Ae	Page_40 40

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Ae	Page number	40	Ae

<b>Group #</b>	<b>Group Name</b>
1	AE1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Action Specify 1		17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted
Action Taken 1	NONE	17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted
Adverse Event 1	IRRITABILITY	17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted
Did the subject experience any adverse e 1	NO YES	17-DEC-2009 13:17:49 Christina Breedlove	Investigator Correction
Ongoing 1		17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted
Onset Date 1	22-MAR-2009	17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted
Onset Time 1	UNK	17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted
Outcome to Date 1	RECOVERED	17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted
Relationship to Date 1	PROBABLY	17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted
Resolved Date 1	27-MAR-2009	17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted
Resolved Time 1	UNK	17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted
Serious Event 1	NO	17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted
Severity 1	MILD	17-DEC-2009 13:17:49 Christina Breedlove	Row Inserted

**Document #:** R279447613

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002	Additional Ecg	Page_41
CDB_001		41

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag	Y	19-NOV-2009 13:29:14	Data Entry Error
1	N	Christina Breedlove	Confirmed to be NO

**Document #:** R279447713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002	Additional Lab	Page_42
CDB_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	Y	19-NOV-2009 13:30:50	Data Entry Error
1	N	Christina Breedlove	Confirmed to be NO

**Document #:** R279449213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R1002 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	NA ND	25-FEB-2010 13:04:37 Christina Breedlove	Data Entry Error
Heart Rate 1	NA ND	25-FEB-2010 13:04:37 Christina Breedlove	Data Entry Error
Respiratory Rate 1	NA ND	25-FEB-2010 13:04:37 Christina Breedlove	Data Entry Error

# Discrepancy Detail Report

Document #: R242827813

Discrepancy ID: 1650758213                      Site: CDB\_001                      Patient: R1002  
Visit: SCREENING                      Visit Date:  
CRF: PAGE\_05                      Section: BM                      Qualifying Value: 5  
Field: Date                      Row: 1  
Value Text: 20090508  
Type: MANUAL                      Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify date of body measurements (08-May-2009) as it is not consistent with all other Screening assessments (18-Feb-2009). If correct, please provide an in-query comment to explain the discrepancy.

Internal Comment: When entering height into eCRF it was discovered that the subject's height was recorded incorrectly on the source. The subject is taller than (53.0 ins). Height was retaken on 08May2009 when the subject returned for week 10 clinic visit & the subject is 65 inches.

Resolution Type: No Action Required

Resolution Text:

**Document #: R242828013**

**Discrepancy ID:** 1650758313                      **Site:** CDB\_001                      **Patient:** R1002  
**Visit:** SCREENING                      **Visit Date:**  
**CRF:** PAGE\_07                      **Section:** LB                      **Qualifying Value:** 7  
**Field:** Requisition Number 1:                      **Row:** 1  
**Value Text:** 050-552-1503-0  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify per source.  
**Internal Comment:** Data entry correction  
**Resolution Type:** Confirmed  
**Resolution Text:** Data entry correction

**Discrepancy ID:** 1650758413                      **Site:** CDB\_001                      **Patient:** R1002  
**Visit:** SCREENING                      **Visit Date:**  
**CRF:** PAGE\_07                      **Section:** LB                      **Qualifying Value:** 7  
**Field:** Were there any clinically significant la                      **Row:** 1  
**Value Text:** NO  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please complete entry.  
**Internal Comment:** Data entry correction  
**Resolution Type:** Confirmed  
**Resolution Text:** Data entry correction

**Document #: R242828213**

**Discrepancy ID:** 1788919313                      **Site:** CDB\_001                      **Patient:** R1002  
**Visit:** SCREENING                      **Visit Date:**  
**CRF:** PAGE\_09                      **Section:** MH                      **Qualifying Value:** 9  
**Field:** Diagnosis/Procedure                      **Row:** 3  
**Value Text:** HOT FLASHES  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify per source and enote 455584 that med hx of "hot flashes" was ongoing at time of study start and should therefore be entered into the medical history CRF page.  
**Internal Comment:** Hot flashes will be added to med hx as ongoing since 2004  
**Resolution Type:** Confirmed  
**Resolution Text:** Hot flashes will be added to med hx as ongoing since 2004

**Discrepancy ID:** 1788919413                      **Site:** CDB\_001                      **Patient:** R1002  
**Visit:** SCREENING                      **Visit Date:**  
**CRF:** PAGE\_09                      **Section:** MH                      **Qualifying Value:** 9  
**Field:** Diagnosis/Procedure                      **Row:** 4  
**Value Text:** POLLEN ALLERGIES  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify per source and enote 455584 med hx of pollen allergy should be added to the CRF.  
**Internal Comment:** confirmed Pollen Allergy will be added to med hx as ongoing since 2002  
**Resolution Type:** Confirmed  
**Resolution Text:** confirmed Pollen Allergy will be added to med hx as ongoing since 2002

**Discrepancy ID:** 22075811                      **Site:** CDB\_001                      **Patient:** R1002  
**Visit:** SCREENING                      **Visit Date:**  
**CRF:** PAGE\_09                      **Section:** MH                      **Qualifying Value:** 9  
**Field:** Diagnosis/Procedure                      **Row:** 5  
**Value Text:** POSTMENOPAUSAL  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify postmenopausal should be entered.  
**Internal Comment:** postmenopausal added  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**





**Document #: R242828513**

**Discrepancy ID:** 23092311                      **Site:** CDB\_001                      **Patient:** R1002  
**Visit:** SCREENING                      **Visit Date:**  
**CRF:** PAGE\_12                      **Section:** PE                      **Qualifying Value:** 12  
**Field:** Does the subject have any abnormal findi                      **Row:** 1  
**Value Text:** YES  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify cataracts should be added to crf from PE.  
**Internal Comment:** verified  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**



**Document #: R243304813**

**Discrepancy ID:** 1678174013                      **Site:** CDB\_001                      **Patient:** R1002

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

**CRF:** PAGE\_16                      **Section:** STATUS REVIEW                      **Qualifying Value:** 16A

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

**Value Text:** 14

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

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify average, per source subject smoked 10 in one day.

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R248876513**

**Discrepancy ID:** 1678174813                      **Site:** CDB\_001                      **Patient:** R1002  
**Visit:** IP, WEEK 8                      **Visit Date:**  
**CRF:** PAGE\_21                      **Section:** STATUS REVIEW                      **Qualifying Value:** 21  
**Field:** If Subject was not compliant, approximat                      **Row:** 1  
**Value Text:** 10  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** please verify the total number of cigarettes smoked per source.  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R248876113**

**Discrepancy ID:** 1678178813                      **Site:** CDB\_001                      **Patient:** R1002  
**Visit:** IP, WEEK 10                      **Visit Date:**  
**CRF:** PAGE\_24                      **Section:** STATUS REVIEW                      **Qualifying Value:** 24  
**Field:** If Subject was not compliant, approximat                      **Row:** 1  
**Value Text:** 21  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Pease enter one number only, highest if range is given.  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R254575913**

**Discrepancy ID:** 1718422213

**Site:** CDB\_001

**Patient:** R1002

**Visit:** IP, WEEK 16

**Visit Date:**

**CRF:** PAGE\_31

**Section:** STATUS REVIEW

**Qualifying Value:** 31

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

**Row:** 1

**Value Text:** 70

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify per guidelines, diary entry should be used for this visit, please enter the average based on the highest number of the range given.

**Internal Comment:**

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

**Resolution Text:**

**Document #: R258780213**

**Discrepancy ID:** 1743201913                      **Site:** CDB\_001                      **Patient:** R1002  
**Visit:** FU, WEEK 20 & 2    **Visit Date:**  
**CRF:** PAGE\_32                      **Section:** STATUS REVIEW                      **Qualifying Value:** 32.1  
**Field:** If Subject was not compliant, approximat                      **Row:** 1  
**Value Text:** 35  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify subject smoked 35 over the weekend (5 per day)  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R272689213**

**Discrepancy ID:** 1765633613                      **Site:** CDB\_001                      **Patient:** R1002

**Visit:** FU, WEEK 28                      **Visit Date:**

**CRF:** PAGE\_38                      **Section:** STATUS REVIEW                      **Qualifying Value:** 38

**Field:** If Subject was not compliant, approximat                      **Row:** 1

**Value Text:** 15

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

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify per source.

**Internal Comment:** Value was determined from 06/Sep - 10/Sep. Subject noted that they did not smoke any cigarettes on the 11th 12th of Sep.

**Resolution Type:** Due Diligence

**Resolution Text:** Value was determined from 06/Sep - 10/Sep. Subject noted that they did not smoke any cigarettes on the 11th 12th of Sep.

**Document #: R254121213**

**Discrepancy ID:** 102147311                      **Site:** CDB\_001                      **Patient:** R1002  
**Visit:** PCM.1                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:** Dose    **Row:** 1  
**Value Text:** 1  
**Type:** MANUAL                                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Combination drug doses/units should be captured as # of tablets. Please verify updating dose to # of tablets (ex. 1) and units to tablet.  
**Internal Comment:** Changed to 1 tab per query  
**Resolution Type:** Confirmed  
**Resolution Text:** Verified. JLM 23Apr2010

**Discrepancy ID:** 1765634513                      **Site:** CDB\_001                      **Patient:** R1002  
**Visit:** PCM.1                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:** Drug name    **Row:** 1  
**Value Text:** TRIAM/HYDROCHLOROTHIAZIDE  
**Type:** MANUAL                                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify per source subject is taking Triam/Hydrochlorothiazide  
**Internal Comment:** per query  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Document #: R254125313**

**Discrepancy ID:** 1765634713

**Site:** CDB\_001

**Patient:** R1002

**Visit:** PCM.3

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:** Unit

**Row:** 1

**Value Text:** MILLIGRAMS

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify per source.

**Internal Comment:** changed to mg per source

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

**Resolution Text:** changed to mg per source





# Deleted CRFs Report

Document #: R263001813

Patient	Visit	CRF
Site	Visit Date	CRF Page #
R1002	Pcm	Page_45
CDB_001		

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Oral Health Exam	Page number	45	Pcm

Group #	Group Name
0	CRF

Field	Changed From	On	Reason
Row	Changed To	By	Comment
1		11-NOV-2009 14:47:59	Key Changes
		Jennifer Curtis	