

# CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 08:32:04

## Report Parameters

Site: P3880\_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4002

Ending patient: R4002

## 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 | Investigator Name: | <input type="text" value="DR. RANDALL STOLTZ"/> |
| SM 08-01        | Study Site:        | <input type="text" value="SITE 04"/>            |

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

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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.

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_02 (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

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.

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Information Session

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

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

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

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

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

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Demographics

|  |  |  |  |
|--|--|--|--|
| Date   | Date of Birth  | Gender                                     | Ethnicity  |
| <input type="text" value="20-FEB-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="67.0"/> |

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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           | 111    |
| Diastolic Blood Pressure | MMHG           | 65     |
| Heart Rate               | BEATS/MINUTE   | 80     |
| Respiratory Rate         | BREATHS/MINUTE | 18     |
| Body Temperature         | C              | 36.2   |
| Weight                   | LB             | 146.0  |

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_06 (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: 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.

Verified  Approved  Locked  Frozen

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

12-Lead Electrocardiogram Report

| Was ECG Performed?  | Was Subject Supine at<br>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="20-FEB-2009"/> | <input type="text" value="11:18"/> |

ECG Interpretation

Normal  Abnormal, NCS  Abnormal, CS

Comments Regarding CS Findings:

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Medical History

Date

Does the subject have any relevant medical history?  Yes  No

Sequence

| No. | Diagnosis/Procedure | Date of Onset | Date of Resolution |   |
|-----|---------------------|---------------|--------------------|---|
| 1   | POST-MENOPAUSAL     | 00-00-1994    |                    | <input checked="" type="checkbox"/> Ongoing |
|     |                     |               |                    | <input type="checkbox"/> Ongoing            |
|     |                     |               |                    | <input type="checkbox"/> Ongoing            |
|     |                     |               |                    | <input type="checkbox"/> Ongoing            |
|     |                     |               |                    | <input type="checkbox"/> Ongoing            |
|     |                     |               |                    | <input type="checkbox"/> Ongoing            |
|     |                     |               |                    | <input type="checkbox"/> Ongoing            |
|     |                     |               |                    | <input type="checkbox"/> Ongoing            |
|     |                     |               |                    | <input type="checkbox"/> Ongoing            |
|     |                     |               |                    | <input type="checkbox"/> Ongoing            |
|     |                     |               |                    | <input type="checkbox"/> Ongoing            |
|     |                     |               |                    | <input type="checkbox"/> Ongoing            |
|     |                     |               |                    | <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

Verified  Approved  Locked  Frozen

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

Smoking History

Was Smoking History collected?

Yes  No

Date

| Parameter  | Result   | Comments                |
|--|--|-------------------------|
| Age subject began smoking daily  | <input type="text" value="17"/>  |                         |
| Average number of cigarettes smoked per day over the past year   | <input type="text" value="20"/>  |                         |
| Has subject used smokeless tobacco in the past?  | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  |                         |
| Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.               | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>If yes, how many times?<br><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<br>If yes, how many times?<br><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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No<br>If yes, how many times?<br><input type="text" value="2"/> | SMOKING CESSATION CLASS |
| 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<br>If yes, how many times?<br><input type="text" value="2"/> | COLD TURKEY             |

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_10 (v1, 27-MAR-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_11 (v1, 24-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](#)



## **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

### Behavioral Counseling

| Date        | Parameter                                | Result  | Comments |
|-------------|--|---|----------|
| 20-FEB-2009 | WAS BEHAVIORAL COUNSELING GIVEN?         | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |
| 20-FEB-2009 | WAS "CLEANING THE AIR" BOOKLET PROVIDED? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

| Date        | Actual Time | ECO Level<br>ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 02-MAR-2009 | 09:31       | 22               | 4.1   |          |

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 |

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_14 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date  Actual Time   
Was Subject randomized?  Yes  No

---

Product Dispensation

Date

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

---

Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

| Date                                     | 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="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="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="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="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="70"/>                                     | <input type="text"/> |
|  |                                     | Was Behavioral Counseling Given?                                   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date Scheduled Timepoint

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

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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           | 110    |
| Diastolic Blood Pressure | MMHG           | 58     |
| Heart Rate               | BEATS/MINUTE   | 67     |
| Respiratory Rate         | BREATHS/MINUTE | 12     |
| Body Temperature         | C              | 36.5   |
| Weight                   | LB             | 147.8  |

Verified  Approved  Locked  Frozen

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

Document Number

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

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

[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

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified  Approved  Locked  Frozen

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

Expired Carbon Monoxide

| Date        | Actual Time | ECO Level<br>ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 13-APR-2009 | 10:01       | 0                | 0.0   |          |

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

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_19 (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

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="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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
|  | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text"/>  | <input type="text"/> |
|  | Was Subject asked HDYF? question?  | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

Diary Distribution

Date  Did subject receive diary and usage instructions?  Yes  No

Verified  Approved  Locked  Frozen

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

Document Number

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

| Date                                     | Parameter  | Result  | Comments             |
|--|--|---|----------------------|
| <input type="text" value="27-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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
|  | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text"/>  | <input type="text"/> |
|  | Was Behavioral Counseling Given?   | <input 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"/> |

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_21 (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

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           | 111    |
| Diastolic Blood Pressure | MMHG           | 68     |
| Heart Rate               | BEATS/MINUTE   | 74     |
| Respiratory Rate         | BREATHS/MINUTE | 16     |
| Body Temperature         | C              | 37.0   |
| Weight                   | LB             | 145.4  |

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_22 (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

Expired Carbon Monoxide

| Date        | Actual Time | ECO Level<br>ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 11-MAY-2009 | 07:51       | 2                | 0.9   |          |

Behavioral Counseling

| Date        | Parameter                        | Result  | Comments |
|-------------|----------------------------------|---|----------|
| 11-MAY-2009 | WAS BEHAVIORAL COUNSELING GIVEN? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_23 (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

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="11-MAY-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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
|  | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text"/>  | <input type="text"/> |
|  | Was Subject asked HDYF? question?  | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

Diary Distribution

Date  Did subject receive diary and usage instructions?  Yes  No

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_24 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

| Date                                     | Parameter  | Result  | Comments             |
|--|--|---|----------------------|
| <input type="text" value="01-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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
|  | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?                               | <input type="text"/>  | <input type="text"/> |
|  | Was Behavioral Counseling Given?   | <input 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"/> |

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

| Parameter                | Unit           | Result |
|--------------------------|----------------|--------|
| Systolic Blood Pressure  | MMHG           | 118    |
| Diastolic Blood Pressure | MMHG           | 57     |
| Heart Rate               | BEATS/MINUTE   | 76     |
| Respiratory Rate         | BREATHS/MINUTE | 16     |
| Body Temperature         | C              | 36.3   |
| Weight                   | LB             | 153.8  |

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_26 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

| Date        | Procedure                                | Findings*   | Findings |
|-------------|--|---|----------|
| 22-JUN-2009 | EVIDENCE OF LEUKOPLAKIA                  | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE |          |
| 22-JUN-2009 | EXPOSED DENTAL CERVICES IN UPPER SULCUS? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE |          |
| 22-JUN-2009 | OTHER ORAL KERATOSIS                     | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE |          |

\* Indicate NE if system was not examined.

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_28 (v1, 25-MAR-2009)

Document Number



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

| Date        | Actual Time | ECO Level<br>ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 22-JUN-2009 | 08:26       | 1                | 0.7   |          |

Behavioral Counseling

| Date        | Parameter                        | Result  | Comments |
|-------------|----------------------------------|---|----------|
| 22-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 |

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_30 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

| Date                                     | Parameter  | Result  | Comments             |
|--|--|---|----------------------|
| <input type="text" value="22-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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
|  | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text"/>  | <input type="text"/> |
|  | Was Subject asked HDYF? question?  | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

Verified  Approved  Locked  Frozen

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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text"/>  | <input type="text"/> |
| Was Behavioral Counseling Given?   | <input 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text"/>  | <input type="text"/> |
| Was Behavioral Counseling Given?   | <input 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"/> |

Verified  Approved  Locked  Frozen

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           | 101    |
| Diastolic Blood Pressure | MMHG           | 58     |
| Heart Rate               | BEATS/MINUTE   | 60     |
| Respiratory Rate         | BREATHS/MINUTE | 16     |
| Body Temperature         | C              | 36.6   |
| Weight                   | LB             | 145.8  |

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

| Date        | Procedure                                | Findings*   | Findings |
|-------------|--|---|----------|
| 14-SEP-2009 | EVIDENCE OF LEUKOPLAKIA                  | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE |          |
| 14-SEP-2009 | EXPOSED DENTAL CERVICES IN UPPER SULCUS? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE |          |
| 14-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.

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_35 (v1, 25-MAR-2009)

Document Number



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

| Date        | Actual Time | ECO Level<br>ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 14-SEP-2009 | 08:54       | 0                | 0.0   |          |

Behavioral Counseling

| Date        | Parameter                        | Result  | Comments |
|-------------|----------------------------------|---|----------|
| 14-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 |

Verified  Approved  Locked  Frozen

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="14-SEP-2009"/> | Was Subject's smoking status reviewed?   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
|  | Was Subject compliant?   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
|  | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text"/>  | <input type="text"/> |
|  | Was Subject asked HDYF? question?  | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_38 (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

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified  Approved  Locked  Frozen

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

Document Number

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

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.

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_39 (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

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

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events?  Yes  No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time   Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
  - Unlikely
  - Possibly Related
  - Probably Related
  - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events?  Yes  No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time   Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
  - Unlikely
  - Possibly Related
  - Probably Related
  - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events?  Yes  No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time   Ongoing

Serious Event: Select only one  
 Yes  
 No

Severity: Select only one  
 Mild  
 Moderate  
 Severe

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

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

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

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events?  Yes  No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time   Ongoing

Serious Event: Select only one  
 Yes  
 No

Severity: Select only one  
 Mild  
 Moderate  
 Severe

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

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

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

Verified  Approved  Locked  Frozen

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](#)

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

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events?  Yes  No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time   Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
  - Unlikely
  - Possibly Related
  - Probably Related
  - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified  Approved  Locked  Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

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

| Date                                     | Actual Time                        | ECG Interpretation  | Comments Regarding CS Findings: |
|--|------------------------------------|---|---------------------------------|
| <input type="text" value="20-FEB-2009"/> | <input type="text" value="11:21"/> | <input checked="" 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"/>            |

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_41 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Laboratory Evaluations

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

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

Note: Attach copy of signed laboratory report.

Verified  Approved  Locked  Frozen

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           | 119    |
| <input type="checkbox"/> Supine                              | Diastolic Blood Pressure | MMHG           | 64     |
| <input checked="" type="checkbox"/> Seated                   | Heart Rate               | BEATS/MINUTE   | 68     |
| <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

Verified  Approved  Locked  Frozen

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

Document Number

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

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



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

\* Indicate NE if system was not examined.

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_45 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

- NA, Completed Study
- Adverse Event, specify:
- Terminated by Sponsor
- Consent Withdrawn
- Lost to Follow-up
- Other, specify:

Investigator Comments (if none, leave blank):

By electronically approving this case report form, I have reviewed the data and found them to be complete and accurate.

Verified  Approved  Locked  Frozen

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

Document Number

## Appendix: Audit and Discrepancy Information



# Audit History Report

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

**Document #:** R240049913

|                     |                         |                     |
|---------------------|-------------------------|---------------------|
| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
| R4002<br>P3880_0342 | Screening               | Page_09<br>09       |

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

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

| <b>Field Row</b>    | <b>Changed From Changed To</b> | <b>Impact on On resequence By</b>   | <b>Reason Comment</b> |
|---------------------|--------------------------------|-------------------------------------|-----------------------|
| DCI Blank Flag<br>1 | N<br>Y                         | 20-OCT-2009 14:27:33<br>Lana Glaser | Key Change            |
| DCI Blank Flag<br>1 | Y<br>N                         | 20-OCT-2009 14:27:53<br>Lana Glaser | Data Entry Error      |

**Document #:** R240049913

|                     |                         |                     |
|---------------------|-------------------------|---------------------|
| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
| R4002<br>P3880_0342 | Screening               | Page_09<br>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<br>1                                 | 00-00-1994                     | 03-MAR-2010 10:43:34<br>Kim Freschly | Row Inserted          |
| Date of Resolution<br>1                            |                                | 03-MAR-2010 10:43:34<br>Kim Freschly | Row Inserted          |
| Diagnosis/Procedure<br>1                           | POST-MENOPAUSAL                | 03-MAR-2010 10:43:34<br>Kim Freschly | Row Inserted          |
| Does the subject have any relevant medication<br>1 | NO<br>YES                      | 03-MAR-2010 10:43:34<br>Kim Freschly | Data Entry Error      |
| Ongoing<br>1                                       | CHECKED                        | 03-MAR-2010 10:43:34<br>Kim Freschly | Row Inserted          |
| Sequence Number<br>1                               | 1                              | 03-MAR-2010 10:43:34<br>Kim Freschly | Row Inserted          |

**Document #:** R240051113

| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
|---------------------|-------------------------|---------------------|
| R4002<br>P3880_0342 | Screening               | Page_10<br>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> |
|---|--------------------------------|--------------------------------------|-----------------------|
| Attempted to quit (Other cessation aids) (4)<br>1 | NO<br>YES                      | 10-JUN-2009 09:12:10<br>Kim Freschly | Data Entry Error      |
| Comments (other attemps) (7)<br>1                 | COLD TURKEY                    | 10-JUN-2009 09:10:53<br>Kim Freschly | Data Entry Error      |
| Comments (other cessation aids) (6)<br>1          | SMOKING CESSATION CLASS        | 10-JUN-2009 09:12:10<br>Kim Freschly | Data Entry Error      |
| If Yes, how many (other cessation aids) (5)<br>1  | 2                              | 10-JUN-2009 09:12:10<br>Kim Freschly | Data Entry Error      |

**Document #:** R240051913

| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
|---------------------|-------------------------|---------------------|
| R4002<br>P3880_0342 | Screening               | Page_11<br>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 On resequence By</b>    | <b>Reason Comment</b> |
|------------------|--------------------------------|--------------------------------------|-----------------------|
| Findings*<br>3   | NO<br>NE                       | 13-MAY-2009 11:26:58<br>Kim Freschly | Data Entry Error      |
| Findings*<br>3   | NE<br>NO                       | 10-JUN-2009 09:13:02<br>Kim Freschly | Data Entry Error      |

**Document #:** R240052313

| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
|---------------------|-------------------------|---------------------|
| R4002<br>P3880_0342 | Screening               | Page_12<br>12       |

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

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

| <b>Field Row</b>    | <b>Changed From Changed To</b> | <b>Impact on On resequence By</b>   | <b>Reason Comment</b> |
|---------------------|--------------------------------|-------------------------------------|-----------------------|
| DCI Blank Flag<br>1 | N<br>Y                         | 20-OCT-2009 14:48:34<br>Lana Glaser | Data Entry Error      |
| DCI Blank Flag<br>1 | Y<br>N                         | 20-OCT-2009 14:48:41<br>Lana Glaser | Data Entry Error      |

Document #: R240052313

| Patient Site        | Visit Visit Date | CRF CRF Page  |
|---------------------|------------------|---------------|
| R4002<br>P3880_0342 | Screening        | Page_12<br>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<br>1 | YES<br>NO                    | 20-OCT-2009 14:28:36<br>Lana Glaser  | Pass1            |
| Does the subject have any abnormal findi<br>1 | NO                           | 20-OCT-2009 14:48:41<br>Lana Glaser  | Row Inserted     |
| Does the subject have any abnormal findi<br>1 | NO<br>YES                    | 08-JAN-2010 09:27:19<br>Kim Freschly | Data Entry Error |
| Findings<br>1                                 | ABSENT TONSILS               | 08-JAN-2010 09:27:19<br>Kim Freschly | Row Inserted     |
| Sequence Number<br>1                          | 1                            | 08-JAN-2010 09:27:19<br>Kim Freschly | Row Inserted     |
| Findings<br>2                                 | RIGHT LOWER MOLAR<br>CRACKED | 08-JAN-2010 09:27:19<br>Kim Freschly | Row Inserted     |
| Sequence Number<br>2                          | 2                            | 08-JAN-2010 09:27:19<br>Kim Freschly | Row Inserted     |

**Document #:** R242653813

| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
|---------------------|-------------------------|---------------------|
| R4002<br>P3880_0342 | Ip, Week 6              | Page_17<br>17       |

| <b>Section Section Date</b> | <b>Qualifying Prompt</b> | <b>Qualifying Value</b> | <b>Section Visit</b> |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Vs                          | Page number              | 17                      | Ip, Week 6           |

| <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> |
|------------------|--------------------------------|--------------------------------------|-----------------------|
| Date<br>1        | 13-MAR-2009<br>13-APR-2009     | 10-JUN-2009 09:13:30<br>Kim Freschly | Data Entry Error      |

**Document #:** R251813313

| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
|---------------------|-------------------------|---------------------|
| R4002<br>P3880_0342 | Ip, Week 6              | Page_20<br>20       |

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

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

| <b>Field Row</b>                                  | <b>Changed From Changed To</b> | <b>Impact on On resequence By</b>    | <b>Reason Comment</b> |
|---|--------------------------------|--------------------------------------|-----------------------|
| If Subject was not compliant, approximat (5)<br>1 | 0                              | 07-JUL-2009 14:00:12<br>Kim Freschly | Data Entry Error      |

Document #: R240078413

|                     |                         |                     |
|---------------------|-------------------------|---------------------|
| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
| R4002<br>P3880_0342 | Pcm                     | Page_39<br>39       |

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

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

| <b>Field Row</b>                 | <b>Changed From Changed To</b>           | <b>Impact on On resequence By</b>       | <b>Reason Comment</b>                                    |
|----------------------------------|--|---|--|
| ATC1 Code<br>1                   | A  | 26-APR-2010 10:36:00<br>Carol Kraucyk   | Data Change  |
| ATC1 Text<br>1                   | ALIMENTARY TRACT AND METABOLISM, A       | 26-APR-2010 10:36:00<br>Carol Kraucyk   | Data Change  |
| ATC2 Code<br>1                   | A11                                      | 26-APR-2010 10:36:00<br>Carol Kraucyk   | Data Change  |
| ATC2 Text<br>1                   | VITAMINS, A11                            | 26-APR-2010 10:36:00<br>Carol Kraucyk   | Data Change  |
| ATC3 Code<br>1                   | A11A                                     | 26-APR-2010 10:36:00<br>Carol Kraucyk   | Data Change  |
| ATC3 Text<br>1                   | MULTIVITAMINS, COMBINATIONS, A11A        | 26-APR-2010 10:36:00<br>Carol Kraucyk   | Data Change  |
| ATC4 Code<br>1                   | A11AB                                    | 26-APR-2010 10:36:00<br>Carol Kraucyk   | Data Change  |
| ATC4 Text<br>1                   | MULTIVITAMINS, OTHER COMBINATIONS, A11AB | 26-APR-2010 10:36:00<br>Carol Kraucyk   | Data Change  |
| Drug Modified Reported Term<br>1 | MULTI VITAMIN<br>MULTIVITAMIN            | 20-APR-2010 11:29:16<br>Carol Kraucyk   | Data Change  |
| Drug name<br>1                   | MULTI VITAMIN<br>MULTIVITAMIN            | 12-APR-2010 10:01:26<br>Joanne Mccaigue | ODM/SEC<br>Obvious spelling correction. JLM<br>12Apr2010 |
| Preferred Term<br>1              | MULTIVITAMINS                            | 26-APR-2010 10:36:00<br>Carol Kraucyk   | Data Change  |
| Preferred Term Code<br>1         | 00116001001                              | 26-APR-2010 10:36:00<br>Carol Kraucyk   | Data Change  |
| Start Date<br>1                  | 00-00-2004<br>00-JAN-2004                | 07-JUL-2009 14:00:42<br>Kim Freschly    | Data Entry Error   |

**Document #:** R251822813

| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
|---------------------|-------------------------|---------------------|
| R4002<br>P3880_0342 | Ae.4                    | Page_40             |

| <b>Section Section Date</b> | <b>Qualifying Prompt</b> | <b>Qualifying Value</b> | <b>Section Visit</b> |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Ae                          | Page number              | 40                      | Ae.4                 |

| <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> |
|--------------------|---------------------------------------|-------------------------------------|-----------------------|
| Adverse Event<br>1 | INCREASED SALIVATION<br>HYPERMOTILITY | 20-OCT-2009 14:57:12<br>Lana Glaser | Data Entry Error      |

Document #: R251814213

|                     |                         |                     |
|---------------------|-------------------------|---------------------|
| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
| R4002<br>P3880_0342 | Additional Vs           | Page_43<br>43       |

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

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

| <b>Field Row</b>                 | <b>Changed From Changed To</b> | <b>Impact on On resequence By</b>       | <b>Reason Comment</b> |
|----------------------------------|--------------------------------|---|-----------------------|
| Actual Time<br>2                 |                                | 27-OCT-2009 13:15:50<br>Laurie Rydstrom | Row Inserted          |
| Actual Time<br>2                 | <Row Deleted>                  | 24-MAR-2010 15:35:46<br>Krysia Magnuson | Data Entry Error      |
| Body Temperature<br>2            |                                | 27-OCT-2009 13:15:50<br>Laurie Rydstrom | Row Inserted          |
| Body Temperature<br>2            | <Row Deleted>                  | 24-MAR-2010 15:35:46<br>Krysia Magnuson | Data Entry Error      |
| Body Temperature<br>Unit<br>2    | C                              | 27-OCT-2009 13:15:50<br>Laurie Rydstrom | Row Inserted          |
| Body Temperature<br>Unit<br>2    | C<br><Row Deleted>             | 24-MAR-2010 15:35:46<br>Krysia Magnuson | Data Entry Error      |
| Comments (2)<br>2                |                                | 27-OCT-2009 13:15:50<br>Laurie Rydstrom | Row Inserted          |
| Comments (2)<br>2                | <Row Deleted>                  | 24-MAR-2010 15:35:46<br>Krysia Magnuson | Data Entry Error      |
| Date<br>2                        |                                | 27-OCT-2009 13:15:50<br>Laurie Rydstrom | Row Inserted          |
| Date<br>2                        | ND                             | 04-JAN-2010 09:31:53<br>Kim Freschly    | Data Entry Error      |
| Date<br>2                        | ND                             | 25-FEB-2010 10:29:30<br>Kim Freschly    | Data Entry Error      |
| Date<br>2                        | <Row Deleted>                  | 24-MAR-2010 15:35:46<br>Krysia Magnuson | Data Entry Error      |
| Diastolic Blood<br>Pressure<br>2 |                                | 27-OCT-2009 13:15:50<br>Laurie Rydstrom | Row Inserted          |
| Diastolic Blood<br>Pressure<br>2 | <Row Deleted>                  | 24-MAR-2010 15:35:46<br>Krysia Magnuson | Data Entry Error      |

Document #: R251814213

| Patient Site        | Visit Visit Date | CRF CRF Page  |
|---------------------|------------------|---------------|
| R4002<br>P3880_0342 | Additional Vs    | Page_43<br>43 |

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

| Group # | Group Name |
|---------|------------|
| 1       | VS         |

|                                       |                                 |  |                  |
|---------------------------------------|---------------------------------|--|------------------|
| Diastolic Blood Pressure unit<br>2    | MMHG                            | 27-OCT-2009 13:15:50<br>Laurie Rydstrom  | Row Inserted     |
| Diastolic Blood Pressure unit<br>2    | MMHG<br><Row Deleted>           | 24-MAR-2010 15:35:46<br>Kryisia Magnuson | Data Entry Error |
| Heart Rate<br>2                       |                                 | 27-OCT-2009 13:15:50<br>Laurie Rydstrom  | Row Inserted     |
| Heart Rate<br>2                       | <Row Deleted>                   | 24-MAR-2010 15:35:46<br>Kryisia Magnuson | Data Entry Error |
| Heart Rate Unit<br>2                  | BEATS/MINUTE                    | 27-OCT-2009 13:15:50<br>Laurie Rydstrom  | Row Inserted     |
| Heart Rate Unit<br>2                  | BEATS/MINUTE<br><Row Deleted>   | 24-MAR-2010 15:35:46<br>Kryisia Magnuson | Data Entry Error |
| Other, specify<br>(1)<br>2            |                                 | 27-OCT-2009 13:15:50<br>Laurie Rydstrom  | Row Inserted     |
| Other, specify<br>(1)<br>2            | <Row Deleted>                   | 24-MAR-2010 15:35:46<br>Kryisia Magnuson | Data Entry Error |
| Position<br>(Unscheduled)<br>(2)<br>2 |                                 | 27-OCT-2009 13:15:50<br>Laurie Rydstrom  | Row Inserted     |
| Position<br>(Unscheduled)<br>(2)<br>2 | <Row Deleted>                   | 24-MAR-2010 15:35:46<br>Kryisia Magnuson | Data Entry Error |
| Respiratory Rate<br>2                 |                                 | 27-OCT-2009 13:15:50<br>Laurie Rydstrom  | Row Inserted     |
| Respiratory Rate<br>2                 | <Row Deleted>                   | 24-MAR-2010 15:35:46<br>Kryisia Magnuson | Data Entry Error |
| Respiratory Rate Unit<br>2            | BREATHS/MINUTE                  | 27-OCT-2009 13:15:50<br>Laurie Rydstrom  | Row Inserted     |
| Respiratory Rate Unit<br>2            | BREATHS/MINUTE<br><Row Deleted> | 24-MAR-2010 15:35:46<br>Kryisia Magnuson | Data Entry Error |

**Document #:** R251814213

| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
|---------------------|-------------------------|---------------------|
| R4002<br>P3880_0342 | Additional Vs           | Page_43<br>43       |

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

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

|                                   |                       |   |                  |
|-----------------------------------|-----------------------|---|------------------|
| Systolic Blood Pressure<br>2      |                       | 27-OCT-2009 13:15:50<br>Laurie Rydstrom | Row Inserted     |
| Systolic Blood Pressure<br>2      | <Row Deleted>         | 24-MAR-2010 15:35:46<br>Krysia Magnuson | Data Entry Error |
| Systolic Blood Pressure unit<br>2 | MMHG                  | 27-OCT-2009 13:15:50<br>Laurie Rydstrom | Row Inserted     |
| Systolic Blood Pressure unit<br>2 | MMHG<br><Row Deleted> | 24-MAR-2010 15:35:46<br>Krysia Magnuson | Data Entry Error |





**Document #: R240052313**

**Discrepancy ID:** 36096511

**Site:** P3880\_0342

**Patient:** R4002

**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 add absent tonsils and cracked molar - per PE source

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R242653813**

**Discrepancy ID:** 1637950513

**Site:** P3880\_0342

**Patient:** R4002

**Visit:** IP, WEEK 6

**Visit Date:**

**CRF:** PAGE\_17

**Section:** VS

**Qualifying Value:** 17

**Field:** Date

**Row:** 1

**Value Text:** 20090413

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please review date (month)

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R251813013**

**Discrepancy ID:** 53426711

**Site:** P3880\_0342

**Patient:** R4002

**Visit:** IP, WEEK 6

**Visit Date:**

**CRF:** PAGE\_18

**Section:** LB

**Qualifying Value:** 18

**Field:** Date

**Row:** 1

**Value Text:** 20090414

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify date of Week 6 labs (14Apr2009) as it is inconsistent with all other Week 6 assessments (13Apr2009). If correct, please provide an explanation via query resolution comment.

**Internal Comment:** subject was nonfasting on April 13 so returned Apr 14 for fasting labs, date correct as entered

**Resolution Type:** No Action Required

**Resolution Text:** See query comment. KAY 24Feb2010.

**Document #: R251813313**

**Discrepancy ID:** 1690539413

**Site:** P3880\_0342

**Patient:** R4002

**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:**

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Subject was compliant - please leave blank.

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R240078413**

**Discrepancy ID:** 1690539713

**Site:** P3880\_0342

**Patient:** R4002

**Visit:** PCM

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:** Start Date

**Row:** 1

**Value Text:** 200401

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Per source, subject started in Jan 2004

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

# Deleted CRFs Report