

# CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 15:09:44

## Report Parameters

Site: CP\_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R3014

Ending patient: R3014

### Legend: How different values appear in the report

|                             |                |
|-----------------------------|----------------|
| Prompt                      | Abc 123        |
| Data value                  | Abc 123        |
| Data value with discrepancy | <b>Abc 123</b> |

All time stamps displayed in this report are in the timezone of the database server.

The data contained in this report is current at the time of printing (time as shown above)



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

RDC CASE REPORT FORM

Information Correct  Yes  No

Protocol Number SM 08-01 Investigator Name:   
Study Site:

A CONTROLLED STUDY OF THE ABILITY OF A TRADITIONAL SWEDISH SMOKELESS TOBACCO PRODUCT ("SNUS") TO INCREASE THE QUIT RATE AMONG CIGARETTE SMOKERS WHO WISH TO STOP SMOKING

Protocol No. SM 08-01  
Covance Study No. 7694-105

for

SWEDISH MATCH AB  
ROSENLUNDSGATAN 36  
SE-118 85 STOCKHOLM  
SWEDEN

by

Covance Clinical Research Unit Inc.  
3402 Kinsman Blvd  
Madison, Wisconsin 53704

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

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Swedish Match AB

Protocol Number: SM 08-01

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Inclusion Criteria

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

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

\* If No, document on Subject Eligibility Page.

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

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Exclusion Criteria

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

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

\* If Yes, document on Subject Eligibility Page.

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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                                     | Ethnicity  |
| <input type="text" value="26-MAR-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="66.0"/> |

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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](#)

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Protocol Number: SM 08-01

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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           | 69     |
| Heart Rate               | BEATS/MINUTE   | 64     |
| Respiratory Rate         | BREATHS/MINUTE | 12     |
| Body Temperature         | C              | 36.9   |
| Weight                   | LB             | 147.1  |

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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

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Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

|   |   |  |                                    |
|---|---|--|------------------------------------|
| Was ECG Performed?  | Was Subject Supine at   | Date                                     | Actual Time                        |
| <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Least 5 Minutes?  | <input type="text" value="26-MAR-2009"/> | <input type="text" value="13:34"/> |
|   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |  |                                    |

ECG Interpretation

Normal  Abnormal, NCS  Abnormal, CS

Comments Regarding CS Findings:

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Protocol Number: SM 08-01

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 |   |
|-----|---------------------|---------------|--------------------|---|
| 01  | TUBAL LIGATION      | 00-00-1985    | 00-00-1985         | <input type="checkbox"/> Ongoing            |
| 02  | SCOLIOSIS           | 00-00-1975    |                    | <input checked="" type="checkbox"/> Ongoing |
| 03  | ROSACEA             | 00-00-1995    |                    | <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            |

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="16"/>  |          |
| 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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>If yes, how many times?<br><input type="text"/> |          |
| Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section.                                      | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>If yes, how many times?<br><input type="text"/> |          |

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Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

| Date        | Procedure                                | Findings*   | Findings             |
|-------------|--|---|----------------------|
| 26-MAR-2009 | EVIDENCE OF LEUKOPLAKIA                  | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE | <input type="text"/> |
| 26-MAR-2009 | EXPOSED DENTAL CERVICES IN UPPER SULCUS? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE | <input type="text"/> |
| 26-MAR-2009 | OTHER ORAL KERATOSIS                     | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE | <input type="text"/> |

\* Indicate NE if system was not examined.

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

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Visit Name

Subject Number

Subject Initials

Is Blank

### Behavioral Counseling

| Date        | Parameter                                | Result  | Comments |
|-------------|--|---|----------|
| 26-MAR-2009 | WAS BEHAVIORAL COUNSELING GIVEN?         | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |
| 26-MAR-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<br>ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 07-APR-2009 | 09:08       | 059              | 10.0  |          |

Behavioral Counseling

| Date        | Parameter                        | Result  | Comments |
|-------------|----------------------------------|---|----------|
| 07-APR-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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Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date  Actual Time   
Was Subject randomized?  Yes  No

---

Product Dispensation

Date

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

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Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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Swedish Match AB

Protocol Number: SM 08-01

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="14-APR-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="40"/>                                     | <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="21-APR-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="30"/>                                     | <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="28-APR-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="100"/>                                    | <input type="text"/> |
|  |                                     | Was Behavioral Counseling Given?                                   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

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Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

| Date                                     | Scheduled Timepoint                 | Parameter   | Result  | Comments             |
|--|-------------------------------------|---|---|----------------------|
| <input type="text" value="07-MAY-2009"/> | <input type="text" value="WEEK 4"/> | 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="30"/>                                     | <input type="text"/> |
|  |                                     | Was Behavioral Counseling Given?  | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
|  |                                     | Was Subject reminded about the complete switch from cigarettes no later than the first day of Week 5? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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           | 120    |
| Diastolic Blood Pressure | MMHG           | 073    |
| Heart Rate               | BEATS/MINUTE   | 076    |
| Respiratory Rate         | BREATHS/MINUTE | 16     |
| Body Temperature         | C              | 36.9   |
| Weight                   | LB             | 148.6  |

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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<br>ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 21-MAY-2009 | 10:55       | 039              | 06.8  |          |

Behavioral Counseling

| Date        | Parameter                        | Result  | Comments |
|-------------|----------------------------------|---|----------|
| 21-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

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  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 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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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

| Date        | Parameter  | Result  | Comments |
|-------------|--|---|----------|
| 04-JUN-2009 | Was Subject contacted by telephone?  | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |
|             | Was Subject's smoking status reviewed?   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |
|             | Was Subject's use of study product reviewed?   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |
|             | Was Subject compliant?   | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |          |
|             | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text" value="70"/>                                     |          |
|             | Was Behavioral Counseling Given?   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |
|             | Was Subject asked HDYF? question?  | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |

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Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

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

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Page Version No. PAGE\_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             |
|----------------------|----------------------|----------------------|----------------------|----------------------|
| <input type="text"/> |

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

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Page Version No. PAGE\_23 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Product Dispensation

Date

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

Status Review

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

Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

| Parameter                | Unit           | Result |
|--------------------------|----------------|--------|
| Systolic Blood Pressure  | MMHG           | 095    |
| Diastolic Blood Pressure | MMHG           | 058    |
| Heart Rate               | BEATS/MINUTE   | 077    |
| Respiratory Rate         | BREATHS/MINUTE | 12     |
| Body Temperature         | C              | 36.8   |
| Weight                   | LB             | 150.0  |

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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 |
|-------------|--|---|----------|
| 17-JUL-2009 | EVIDENCE OF LEUKOPLAKIA                  | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE |          |
| 17-JUL-2009 | EXPOSED DENTAL CERVICES IN UPPER SULCUS? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE |          |
| 17-JUL-2009 | OTHER ORAL KERATOSIS                     | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE |          |

\* Indicate NE if system was not examined.

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Page Version No. PAGE\_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 |
|-------------|-------------|------------------|-------|----------|
| 17-JUL-2009 | 12:50       | 45               | 07.8  |          |

Behavioral Counseling

| Date        | Parameter                        | Result  | Comments |
|-------------|----------------------------------|---|----------|
| 17-JUL-2009 | WAS BEHAVIORAL COUNSELING GIVEN? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |

Questionnaires

Date

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

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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="17-JUL-2009"/> | Was Subject's smoking status reviewed?   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |
|  | Was Subject's use of study product reviewed?   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |
|  | Was Subject compliant?   | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |          |
|  | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text" value="105"/>                                    |          |
|  | Was Subject asked HDYF? question?  | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |          |

Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date  Scheduled Timepoint

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

Date  Scheduled Timepoint

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

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Page Version No. PAGE\_32 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

\* Indicate NE if system was not examined.

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

Document Number



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

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

Behavioral Counseling

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

Questionnaires

Date

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

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Page Version No. PAGE\_37 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

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

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Page Version No. PAGE\_38 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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

Document Number

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)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events?  Yes  No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time   Ongoing

Serious Event: Select only one  
 Yes  
 No

Severity: Select only one  
 Mild  
 Moderate  
 Severe

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

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

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

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

Document Number

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

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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.

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

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date  Actual Time

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

Comments

Date  Actual Time

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

Comments

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

Document Number

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

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



Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

\* Indicate NE if system was not examined.

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

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

Investigator Comments (if none, leave blank):

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

Verified  Approved  Locked  Frozen

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

Document Number

## Appendix: Audit and Discrepancy Information



# Audit History Report

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

Document #: **R243403613**

| Patient Site    | Visit Visit Date | CRF CRF Page  |
|-----------------|------------------|---------------|
| R3014<br>CP_001 | Screening        | Page_05<br>05 |

| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
|----------------------|-------------------|------------------|---------------|
| Dm                   | Page number       | 5                | Screening     |

| Group # | Group Name |
|---------|------------|
| 1       | DM         |

| Field Row   | Changed From Changed To | Impact on resequence | On By                               | Reason Comment   |
|-------------|-------------------------|----------------------|-------------------------------------|------------------|
| Gender<br>1 | MALE<br>FEMALE          |                      | 16-JUN-2009 12:54:01<br>Tricia Hunt | Data Entry Error |

Document #: **R243403813**

|                     |                         |                     |
|---------------------|-------------------------|---------------------|
| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
| R3014<br>CP_001     | Screening               | Page_07<br>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>                  |
|--|------------------------------------|-------------------------------------|--|
| No (Specify samples not done, reason)/Co 1     | FSH NOT PROCESSED DUE TO LAB ERROR | 16-JUN-2009 13:06:16<br>Tricia Hunt | CRA Correction                         |
| No (Specify samples not done, reason)/Co 1     | FSH NOT PROCESSED DUE TO LAB ERROR | 13-AUG-2009 17:17:22<br>Tricia Hunt | Data Entry Error<br>Deleted per query  |
| Were the scheduled laboratory samples ob 1     | YES<br>NO                          | 16-JUN-2009 13:06:16<br>Tricia Hunt | CRA Correction                         |
| Were the scheduled laboratory samples ob 1     | NO<br>YES                          | 13-AUG-2009 17:17:22<br>Tricia Hunt | Data Entry Error<br>Changed per query. |
| Were there any clinically significant la (1) 1 | NO                                 | 16-JUN-2009 13:06:16<br>Tricia Hunt | CRA Correction                         |

Document #: **R243412013**

|                     |                         |                     |
|---------------------|-------------------------|---------------------|
| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
| R3014<br>CP_001     | Screening               | Page_12<br>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 resequence</b> | <b>On By</b>                        | <b>Reason Comment</b> |
|--|---|-----------------------------|-------------------------------------|-----------------------|
| Does the subject have any abnormal findings<br>1 | YES<br>NO   |                             | 16-JUN-2009 13:08:03<br>Tricia Hunt | CRA Correction        |
| Findings<br>1                                    | THORAX/LUNGS: INCREASED BREATHING SOUNDS DIFFUSE<br><Row Deleted> |                             | 16-JUN-2009 13:08:03<br>Tricia Hunt | CRA Correction        |
| Sequence Number<br>1                             | 01<br><Row Deleted>   |                             | 16-JUN-2009 13:08:03<br>Tricia Hunt | CRA Correction        |
| Findings<br>2                                    | SKIN: MIDLINE SCAR ON BACK<br><Row Deleted>                       |                             | 16-JUN-2009 13:08:03<br>Tricia Hunt | CRA Correction        |
| Sequence Number<br>2                             | 02<br><Row Deleted>   |                             | 16-JUN-2009 13:08:03<br>Tricia Hunt | CRA Correction        |

Document #: **R266313713**

| Patient Site    | Visit Visit Date | CRF CRF Page  |
|-----------------|------------------|---------------|
| R3014<br>CP_001 | Additional Ecg   | Page_41<br>41 |

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

| Group # | Group Name |
|---------|------------|
| 0       | CRF Header |

| Field Row           | Changed From Changed To | Impact on On resequence By                  | Reason Comment |
|---------------------|-------------------------|---|----------------|
| DCI Blank Flag<br>1 | Y<br>N                  | 20-OCT-2009 18:07:01<br>Marilyn Mindolovich | CRA Correction |

Document #: **R266313613**

| Patient Site | Visit Visit Date | CRF CRF Page |
|--------------|------------------|--------------|
| R3014        | Additional Lab   | Page_42      |
| CP_001       |                  | 42           |

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

| Group # | Group Name |
|---------|------------|
| 0       | CRF Header |

| Field Row      | Changed From Changed To | Impact on On resequence By | Reason Comment |
|----------------|-------------------------|----------------------------|----------------|
| DCI Blank Flag | Y                       | 20-OCT-2009 18:07:23       | CRA Correction |
| 1              | N                       | Marilyn Mindolovich        |                |

Document #: **R266313513**

| Patient Site    | Visit Visit Date | CRF CRF Page  |
|-----------------|------------------|---------------|
| R3014<br>CP_001 | Additional Vs    | Page_43<br>43 |

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

| Group # | Group Name |
|---------|------------|
| 0       | CRF Header |

| Field Row           | Changed From Changed To | Impact on On resequence By                  | Reason Comment |
|---------------------|-------------------------|---|----------------|
| DCI Blank Flag<br>1 | Y<br>N                  | 20-OCT-2009 18:07:39<br>Marilyn Mindolovich | CRA Correction |

# Discrepancy Detail Report

Document #: **R243403613**

Discrepancy ID: 1668720313                      Site: CP\_001                      Patient: R3014  
Visit: SCREENING                      Visit Date:  
CRF: PAGE\_05                      Section: DM                      Qualifying Value: 5  
Field: Gender                      Row: 1  
Value Text: FEMALE  
Type: MANUAL                      Status: CURRENT  
Review Status: Resolved-Response Edited  
Discrepancy: Please change response to female.  
Internal Comment:  
Resolution Type: Data value changed. Disc no longer applicable.  
Resolution Text:

**Document #: R243403813**

**Discrepancy ID:** 1718422313                      **Site:** CP\_001                      **Patient:** R3014  
**Visit:** SCREENING                      **Visit Date:**  
**CRF:** PAGE\_07                      **Section:** LB                      **Qualifying Value:** 7  
**Field:** No (Specify samples not done, reason)/Co                      **Row:** 1  
**Value Text:**  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please change the no to yes and delete comment regarding FSH. Subject is not postmenopausal.

**Internal Comment:**

**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:** Updated per query.

**Discrepancy ID:** 1668738713                      **Site:** CP\_001                      **Patient:** R3014  
**Visit:** SCREENING                      **Visit Date:**  
**CRF:** PAGE\_07                      **Section:** LB                      **Qualifying Value:** 7  
**Field:** Were the scheduled laboratory samples ob                      **Row:** 1  
**Value Text:** YES  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify that the answer should be NO and a comment regarding lab error in not processing FSH sample. Please enter the repeat FSH drawn on 30Mar09 in the additional lab CRF pages.

**Internal Comment:**

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

**Document #: R243403813**

**Discrepancy ID:** 74034411

**Site:** CP\_001

**Patient:** R3014

**Visit:** SCREENING

**Visit Date:**

**CRF:** PAGE\_07

**Section:** UPREG

**Qualifying Value:** 7

**Field:** Result

**Row:** 1

**Value Text:** NEGATIVE

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify updating urine pregnancy test result to N/A as subject has a medical history diagnosis/procedure indicating she is of non-childbearing potential.

**Internal Comment:** A pregnancy test was completed on all female subjects even if thier medical history stated "non-childbearing potential". Please see note to file.

**Resolution Type:** Confirmed

**Resolution Text:**



# Deleted CRFs Report