

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 12:33:24

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4062

Ending patient: R4062

Legend: How different values appear in the report

| | |
|-----------------------------|----------------|
| Prompt | Abc 123 |
| Data value | Abc 123 |
| Data value with discrepancy | Abc 123 |

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

RDC CASE REPORT FORM

Information Correct Yes No

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

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

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

for

SWEDISH MATCH AB
ROSENLUNDSGATAN 36
SE-118 85 STOCKHOLM
SWEDEN

by

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

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Page Version No. PAGE_01 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Inclusion Criteria

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

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

* If No, document on Subject Eligibility Page.

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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.

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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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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="10-JUN-2009"/> | <input type="text" value="(b) (6)"/> | <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female | <input type="checkbox"/> Hispanic or Latino <input checked="" type="checkbox"/> Not Hispanic or latino |
| Race | | | |
| <input type="checkbox"/> White | <input type="checkbox"/> Native Hawaiian or Other Pacific Islander | | |
| <input checked="" 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="69.8"/> |

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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 | 111 |
| Diastolic Blood Pressure | MMHG | 69 |
| Heart Rate | BEATS/MINUTE | 64 |
| Respiratory Rate | BREATHS/MINUTE | 12 |
| Body Temperature | C | 36.5 |
| Weight | LB | 228.6 |

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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.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

| | | | |
|---|---|--|------------------------------------|
| Was ECG Performed? | Was Subject Supine at | Date | Actual Time |
| <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Least 5 Minutes? | <input type="text" value="10-JUN-2009"/> | <input type="text" value="11:22"/> |
| | <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

| Sequence No. | Diagnosis/Procedure | Date of Onset | Date of Resolution | |
|--------------|---------------------|---------------|--------------------|----------------------------------|
| | | | | <input type="checkbox"/> Ongoing |
| | | | | <input type="checkbox"/> Ongoing |
| | | | | <input type="checkbox"/> Ongoing |
| | | | | <input type="checkbox"/> Ongoing |
| | | | | <input type="checkbox"/> Ongoing |
| | | | | <input type="checkbox"/> Ongoing |
| | | | | <input type="checkbox"/> Ongoing |
| | | | | <input type="checkbox"/> Ongoing |
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| | | | | <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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Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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 If yes, how many times? <input type="text"/> | |
| Has the subject attempted to quit with the use of Pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the COMMENTS section. | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/> | |
| Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section. | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/> | |
| Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section. | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="2"/> | COLD TURKEY |

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

| Date | Procedure | Findings* | Findings |
|-------------|--|---|----------------------|
| 10-JUN-2009 | EVIDENCE OF LEUKOPLAKIA | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE | <input type="text"/> |
| 10-JUN-2009 | EXPOSED DENTAL CERVICES IN UPPER SULCUS? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE | <input type="text"/> |
| 10-JUN-2009 | OTHER ORAL KERATOSIS | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE | <input type="text"/> |

* Indicate NE if system was not examined.

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Page Version No. PAGE_11 (v1, 24-MAR-2009)

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

| Date | Parameter | Result | Comments |
|-------------|--|---|----------|
| 10-JUN-2009 | WAS BEHAVIORAL COUNSELING GIVEN? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 10-JUN-2009 | WAS "CLEANING THE AIR" BOOKLET PROVIDED? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

| Date | Actual Time | ECO Level ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 18-JUN-2009 | 10:12 | 12 | 2.5 | |

Behavioral Counseling

| Date | Parameter | Result | Comments |
|-------------|----------------------------------|---|----------|
| 18-JUN-2009 | WAS BEHAVIORAL COUNSELING GIVEN? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |

Questionnaires

Date

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

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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="4"/> logs |
| 1.0 g of snus or matching placebo | <input type="text" value="2"/> logs |

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

| Date | Scheduled Timepoint | Parameter | Result | Comments |
|--|-------------------------------------|--|---|----------------------|
| <input type="text" value="25-JUN-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="105"/> | <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="06-JUL-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="98"/> | <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="09-JUL-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="98"/> | <input type="text"/> |
| | | Was Behavioral Counseling Given? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

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Page Version No. PAGE_16 (v1, 14-APR-2009)

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date Scheduled Timepoint

Parameter

Result

Comments

Was Subject contacted by telephone?

Yes No

Was Subject's smoking status reviewed?

Yes No

Was Subject's use of study product reviewed?

Yes No

Approximately how many cigarettes did the subject smoke that week?

Was Behavioral Counseling Given?

Yes No

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

Yes No

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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 | 114 |
| Diastolic Blood Pressure | MMHG | 67 |
| Heart Rate | BEATS/MINUTE | 60 |
| Respiratory Rate | BREATHS/MINUTE | 16 |
| Body Temperature | C | 36.4 |
| Weight | LB | 230.4 |

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Page Version No. PAGE_17 (v1, 30-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_18 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

| Date | Actual Time | ECO Level ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 30-JUL-2009 | 10:20 | 9 | 2.0 | |

Behavioral Counseling

| Date | Parameter | Result | Comments |
|-------------|----------------------------------|---|----------|
| 30-JUL-2009 | WAS BEHAVIORAL COUNSELING GIVEN? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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Page Version No. PAGE_19 (v1, 31-MAR-2009)

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Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

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="0"/> logs |
| 1.0 g of snus or matching placebo | <input type="text" value="2"/> logs |

Status Review

| Date | Parameter | Result | Comments |
|--|--|---|----------------------|
| <input type="text" value="30-JUL-2009"/> | Was Subject's smoking status reviewed? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject compliant? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | <input type="text"/> |
| | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text" value="84"/> | <input type="text"/> |
| | Was Subject asked HDYF? question? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

Diary Distribution

Date Did subject receive diary and usage instructions? Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

| Date | Parameter | Result | Comments |
|--|--|---|----------------------|
| <input type="text" value="13-AUG-2009"/> | Was Subject contacted by telephone? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject's smoking status reviewed? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject's use of study product reviewed? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject compliant? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | <input type="text"/> |
| | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text" value="70"/> | <input type="text"/> |
| | Was Behavioral Counseling Given? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject asked HDYF? question? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

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Page Version No. PAGE_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 | 130 |
| Diastolic Blood Pressure | MMHG | 82 |
| Heart Rate | BEATS/MINUTE | ND |
| Respiratory Rate | BREATHS/MINUTE | ND |
| Body Temperature | C | 36.7 |
| Weight | LB | 231.0 |

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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 ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 27-AUG-2009 | 14:36 | 6 | 1.5 | |

Behavioral Counseling

| Date | Parameter | Result | Comments |
|-------------|----------------------------------|---|----------|
| 27-AUG-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)

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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's use of study product reviewed?

Yes No

Was Subject compliant?

Yes No

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

Was Subject asked HDYF? question?

Yes No

Diary Distribution

Date

Did subject receive diary and usage instructions?

Yes No

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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-SEP-2009"/> | Was Subject contacted by telephone? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject's smoking status reviewed? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject's use of study product reviewed? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject compliant? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | <input type="text"/> |
| | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text" value="56"/> | <input type="text"/> |
| | Was Behavioral Counseling Given? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject asked HDYF? question? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject instructed to cut down on product use during upcoming Weeks 14-16 to avoid a too abrupt ending of nicotine uptake? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

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Page Version No. PAGE_25 (v1, 27-MAR-2009)

Document Number

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 | 123 |
| Diastolic Blood Pressure | MMHG | 81 |
| Heart Rate | BEATS/MINUTE | 60 |
| Respiratory Rate | BREATHS/MINUTE | 20 |
| Body Temperature | C | 36.8 |
| Weight | LB | 232.0 |

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Page Version No. PAGE_26 (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_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 |
|-------------|--|---|----------------------|
| 08-OCT-2009 | EVIDENCE OF LEUKOPLAKIA | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE | <input type="text"/> |
| 08-OCT-2009 | EXPOSED DENTAL CERVICES IN UPPER SULCUS? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE | <input type="text"/> |
| 08-OCT-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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Page Version No. PAGE_28 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

| Date | Actual Time | ECO Level ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 08-OCT-2009 | 08:40 | 12 | 2.5 | |

Behavioral Counseling

| Date | Parameter | Result | Comments |
|-------------|----------------------------------|---|----------|
| 08-OCT-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="08-OCT-2009"/> | Was Subject's smoking status reviewed? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject's use of study product reviewed? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject compliant? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | <input type="text"/> |
| | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text" value="70"/> | <input type="text"/> |
| | Was Subject asked HDYF? question? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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Page Version No. PAGE_31 (v1, 12-MAY-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date Scheduled Timepoint

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

Date Scheduled Timepoint

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

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Page Version No. PAGE_32 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

| Parameter | Unit | Result |
|--------------------------|----------------|--------|
| Systolic Blood Pressure | MMHG | 135 |
| Diastolic Blood Pressure | MMHG | 99 |
| Heart Rate | BEATS/MINUTE | 65 |
| Respiratory Rate | BREATHS/MINUTE | 16 |
| Body Temperature | C | 36.6 |
| Weight | LB | 228.6 |

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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.

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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 |
|-------------|--|---|----------|
| 30-DEC-2009 | EVIDENCE OF LEUKOPLAKIA | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE | |
| 30-DEC-2009 | EXPOSED DENTAL CERVICES IN UPPER SULCUS? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE | |
| 30-DEC-2009 | OTHER ORAL KERATOSIS | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE | |

* Indicate NE if system was not examined.

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Page Version No. PAGE_35 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

| Date | Actual Time | ECO Level ppm | %COHb | Comments |
|-------------|-------------|------------------|-------|----------|
| 30-DEC-2009 | 08:51 | 10 | 2.2 | |

Behavioral Counseling

| Date | Parameter | Result | Comments |
|-------------|----------------------------------|---|----------|
| 30-DEC-2009 | WAS BEHAVIORAL COUNSELING GIVEN? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |

Questionnaires

Date

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

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Page Version No. PAGE_37 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

| Date | Parameter | Result | Comments |
|--|--|---|----------------------|
| <input type="text" value="30-DEC-2009"/> | Was Subject's smoking status reviewed? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |
| | Was Subject compliant? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | <input type="text"/> |
| | If Subject was not compliant, approximately how many cigarettes did the subject smoke that week? | <input type="text" value="84"/> | <input type="text"/> |
| | Was Subject asked HDYF? question? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="text"/> |

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Page Version No. PAGE_38 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

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

Frequency Select only one

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

Start Date1

Stop Date1

Ongoing

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

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Page Version No. PAGE_39 (v1, 25-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number R4062

Covance Study Number: 7694-105

Subject Initials (b)

Visit Name PCM

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: PRILOSEC

Indication: DYSPEPSIA

Dose: 1

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

03-SEP-2009

18-SEP-2009

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 R288288713

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

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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

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

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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

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"/> | <input type="text"/> | <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS | <input type="text"/> |

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Page Version No. PAGE_41 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Laboratory Evaluations

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

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

Note: Attach copy of signed laboratory report.

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 | 145 |
| <input type="checkbox"/> Supine | Diastolic Blood Pressure | MMHG | 97 |
| <input checked="" type="checkbox"/> Seated | Heart Rate | BEATS/MINUTE | ND |
| <input type="checkbox"/> Other, specify <input type="text"/> | Respiratory Rate | BREATHS/MINUTE | ND |
| | Body Temperature | C | ND |

Comments

Date Actual Time

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

Comments

Verified Approved Locked Frozen

Page Version No. PAGE_43 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

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 #: R296077513

| | | |
|---------------------|-------------------------|---------------------|
| Patient Site | Visit Visit Date | CRF CRF Page |
| R4062 P3880_0342 | Screening | Page_09 09 |

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

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|----------------|-------------------|
| Group # | Group Name |
| 2 | MH1 |

| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
|--|---|--------------------------------------|-----------------------|
| Date of Onset 1 | 30-JUN-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Date of Resolution 1 | 09-OCT-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Diagnosis/Procedure 1 | NEURALIGIA RIGHT LOWER EXTREMITY <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Does the subject have any relevant medication 1 | YES NO | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Ongoing 1 | <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Sequence Number 1 | 1 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Date of Onset 2 | 30-JUN-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Date of Resolution 2 | 03-SEP-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Diagnosis/Procedure 2 | MUSCLE SPASM <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Ongoing 2 | <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Sequence Number 2 | 2 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Date of Onset 3 | 21-JUN-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Date of Resolution 3 | 10-NOV-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |

Document #: R296077513

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|------------------|---------------|
| R4062 P3880_0342 | Screening | Page_09 09 |

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

| Group # | Group Name |
|---------|------------|
| 2 | MH1 |

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|--------------------------|------------------------------|--------------------------------------|------------------|
| Diagnosis/Procedure 3 | ANXIETY <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Ongoing 3 | <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Sequence Number 3 | 3 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Date of Onset 4 | 13-JUL-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Date of Resolution 4 | 01-OCT-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Diagnosis/Procedure 4 | BACK PAIN <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Ongoing 4 | <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Sequence Number 4 | 4 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Date of Onset 5 | 03-SEP-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Date of Resolution 5 | 11-OCT-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Diagnosis/Procedure 5 | DYSPEPSIA <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Ongoing 5 | <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Sequence Number 5 | 5 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Date of Onset 6 | 23-JUL-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Date of Resolution 6 | 23-JUL-2009 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |

Document #: R296077513

| Patient Site | Visit Visit Date | CRF CRF Page |
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| R4062 P3880_0342 | Screening | Page_09 09 |

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

| Group # | Group Name |
|----------------|-------------------|
| 2 | MH1 |

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|--------------------------|-----------------------------------|--------------------------------------|------------------|
| Diagnosis/Procedure 6 | MOOD DISTURBANCE <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Ongoing 6 | <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |
| Sequence Number 6 | 6 <Row Deleted> | 10-MAR-2010 14:08:21 Kim Freschly | Data Entry Error |

Document #: R260796713

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|-------------------------|---------------------|
| R4062 P3880_0342 | Screening | Page_10 10 |

| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Smoking History | Page number | 10 | Screening |

| Group # | Group Name |
|----------------|-------------------|
| 1 | DRUGSCR |

| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
|---|--------------------------------|--------------------------------------|-----------------------|
| If yes, how many (other attempts to quit (6) 1 | 2 | 14-OCT-2009 09:42:12 Kim Freschly | Data Entry Error |

Document #: R260800913

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|-------------------------|---------------------|
| R4062 P3880_0342 | Ip, Week 6 | Page_19 19 |

| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Eco | Page number | 19 | Ip, Week 6 |

| Group # | Group Name |
|----------------|-------------------|
| 0 | Section Header |

| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
|---------------------|--------------------------------|--------------------------------------|-----------------------|
| DCM Blank flag 1 | Y N | 15-JAN-2010 11:18:33 Kim Freschly | Data Entry Error |

Document #: R288288313

| | | |
|---------------------|-------------------------|---------------------|
| Patient Site | Visit Visit Date | CRF CRF Page |
| R4062 P3880_0342 | Pcm | Page_39 39 |

| | | | |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
| Pcm | Page number | 39 | Pcm |

| | |
|----------------|-------------------|
| Group # | Group Name |
| 1 | CM1 |

| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
|------------------|---|---|-----------------------|
| ATC1 Code 1 | G M | 27-APR-2010 12:10:38 Joanne Mccaigue | Class. Change |
| ATC1 Text 1 | GENITO URINARY SYSTEM AND SEX HORMONES, G MUSCULO-SKELETAL SYSTEM, M | 27-APR-2010 12:10:38 Joanne Mccaigue | Class. Change |
| ATC2 Code 1 | G02 M01 | 27-APR-2010 12:10:38 Joanne Mccaigue | Class. Change |
| ATC2 Text 1 | OTHER GYNECOLOGICALS, G02 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01 | 27-APR-2010 12:10:38 Joanne Mccaigue | Class. Change |
| ATC3 Code 1 | G02C M01A | 27-APR-2010 12:10:38 Joanne Mccaigue | Class. Change |
| ATC3 Text 1 | OTHER GYNECOLOGICALS, G02C ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STEROIDS, M01A | 27-APR-2010 12:10:38 Joanne Mccaigue | Class. Change |
| ATC4 Code 1 | G02CC M01AE | 27-APR-2010 12:10:38 Joanne Mccaigue | Class. Change |
| ATC4 Text 1 | ANTIINFLAMMATORY PRODUCTS FOR VAGINAL ADMINISTRAT., G02CC PROPIONIC ACID DERIVATIVES, M01AE | 27-APR-2010 12:10:38 Joanne Mccaigue | Class. Change |
| Indication 1 | LEG PAIN NEURALGIA RIGHT LEG | 23-APR-2010 12:51:35 Lana Glaser | Data Entry Error |

Document #: R288289013

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|-------------------------|---------------------|
| R4062 P3880_0342 | Ae | Page_40 40 |

| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Ae | Page number | 40 | Ae |

| Group # | Group Name |
|----------------|-------------------|
| 1 | AE1 |

| Field Row | Changed From Changed To | Impact on resequence | On By | Reason Comment |
|--------------------|--------------------------------|-----------------------------|--------------------------------------|-----------------------|
| Resolved Date 1 | 09-OCT-2009 20-NOV-2009 | | 10-MAR-2010 14:10:07 Kim Freschly | Data Entry Error |
| Resolved Time 1 | 2200 UNK | | 10-MAR-2010 14:11:03 Kim Freschly | Data Entry Error |
| Resolved Time 1 | UNK 2200 | | 17-MAR-2010 09:19:40 Lana Glaser | Data Entry Error |

Document #: R288290513

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|-------------------------|---------------------|
| R4062 P3880_0342 | Ae.6 | Page_40 |

| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Ae | Page number | 40 | Ae.6 |

| Group # | Group Name |
|----------------|-------------------|
| 1 | AE1 |

| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
|--------------------|--------------------------------|-------------------------------------|-----------------------|
| Resolved Time 1 | 0200 1200 | 01-MAR-2010 11:59:58 Lana Glaser | Data Entry Error |

Discrepancy Detail Report

Document #: R260800913

Discrepancy ID: 1789620213

Site: P3880_0342

Patient: R4062

Visit: IP, WEEK 6

Visit Date:

CRF: PAGE_19

Section: ECO

Qualifying Value: 19

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please add data

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R288289013

Discrepancy ID: 78077611

Site: P3880_0342

Patient: R4062

Visit: AE

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Resolved Date

Row: 1

Value Text: 20091120

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per conmed page, subject used aleve for leg pain until 20Nov09, however AE ended 09Oct09.
Pls review.

Internal Comment: Source correction needed

Resolution Type: Confirmed

Resolution Text:

Deleted CRFs Report