

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 08:32:40

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4008

Ending patient: R4008

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

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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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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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Page Version No. PAGE_03 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Information Session

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

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

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

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

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

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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="26-FEB-2009"/>	<input type="text" value="(b) (6)"/>	<input type="checkbox"/> Male	<input type="checkbox"/> Hispanic or Latino
		<input checked="" type="checkbox"/> Female	<input checked="" type="checkbox"/> Not Hispanic or latino
Race			
<input checked="" type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Black or African American	<input type="checkbox"/> American Indian/Alaskan Native		
<input type="checkbox"/> Asian	<input type="checkbox"/> Other		<input type="text"/>

Body Measurements

Were Body Measurements Collected? Yes No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="64.5"/>

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Page Version No. PAGE_05 (v1, 24-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	128
Diastolic Blood Pressure	MMHG	87
Heart Rate	BEATS/MINUTE	68
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.7
Weight	LB	177.2

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Page Version No. PAGE_06 (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: 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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Page Version No. PAGE_07 (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

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-FEB-2009"/>	<input type="text" value="09:35"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

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Page Version No. PAGE_08 (v1, 24-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	RECURRENT JOINT PAIN	00-00-1979		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

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

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Page Version No. PAGE_09 (v1, 24-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

[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

Smoking History

Was Smoking History collected?

Yes No

Date

Parameter	Result	Comments
Age subject began smoking daily	<input type="text" value="8"/>	
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="2"/>	NICORETTE GUM
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="1"/>	WELLBUTRIN
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="6"/>	HYPNOSIS, MINERAL/VITAMIN COMBINATION, LAVENDER SUBSTANCE BEHIND EARS, ACUPUNCTURE
Has the subject made any other attempts to quit smoking? List details of other quit attemps in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	

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Page Version No. PAGE_10 (v1, 27-MAR-2009)

Document Number

OverFlow Section For Document Number R240090613

- 1 HYPNOSIS, MINERAL/VITAMIN COMBINATION, LAVENDER SUBSTANCE BEHIND EARS, ACUPUNCTURE

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

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

Document Number

Links to Discrepancy and Audit Sections

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

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

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

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Page Version No. PAGE_13 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
11-MAR-2009	08:35	43	7.5	

Behavioral Counseling

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

Questionnaires

Date

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

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Page Version No. PAGE_14 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date Actual Time

Was Subject randomized? Yes No

Product Dispensation

Date

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

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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Page Version No. PAGE_15 (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

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="19-MAR-2009"/>	<input type="text" value="WEEK 1"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="25-MAR-2009"/>	<input type="text" value="WEEK 2"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="01-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="70"/>	<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)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date Scheduled Timepoint

Parameter

Result

Comments

Was Subject contacted by telephone?

Yes No

Was Subject's smoking status reviewed?

Yes No

Was Subject's use of study product reviewed?

Yes No

Approximately how many cigarettes did the subject smoke that week?

Was Behavioral Counseling Given?

Yes No

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

Yes No

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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	127
Diastolic Blood Pressure	MMHG	88
Heart Rate	BEATS/MINUTE	65
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.9
Weight	LB	177.4

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Page Version No. PAGE_17 (v1, 30-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_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
22-APR-2009	08:31	0	0	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="0"/> logs
1.0 g of snus or matching placebo	<input type="text" value="3"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="22-APR-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="9"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date	Did subject receive diary and usage instructions?
<input type="text" value="22-APR-2009"/>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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Page Version No. PAGE_20 (v1, 24-APR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
06-MAY-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="42"/>	
	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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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	125
Diastolic Blood Pressure	MMHG	88
Heart Rate	BEATS/MINUTE	85
Respiratory Rate	BREATHS/MINUTE	12
Body Temperature	C	37.1
Weight	LB	177.2

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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
20-MAY-2009	07:41	43	7.5	

Behavioral Counseling

Date	Parameter	Result	Comments
20-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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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" value="3"/> logs
1.0 g of snus or matching placebo	<input type="text" value="0"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="20-MAY-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input 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="105"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions? Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_24 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="10-JUN-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="140"/>	<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	127
Diastolic Blood Pressure	MMHG	86
Heart Rate	BEATS/MINUTE	70
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.7
Weight	LB	175.0

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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
02-JUL-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
02-JUL-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
02-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 ppm	%COHb	Comments
02-JUL-2009	07:25	28	5.1	

Behavioral Counseling

Date	Parameter	Result	Comments
02-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
02-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="35"/>	
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="84"/>	<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="105"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	127
Diastolic Blood Pressure	MMHG	87
Heart Rate	BEATS/MINUTE	81
Respiratory Rate	BREATHS/MINUTE	12
Body Temperature	C	37.1
Weight	LB	176.6

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Page Version No. PAGE_33 (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

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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Page Version No. PAGE_34 (v1, 25-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

* Indicate NE if system was not examined.

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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
23-SEP-2009	08:25	36	6.3	

Behavioral Counseling

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

Questionnaires

Date

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="23-SEP-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="126"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

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

Frequency Select only one

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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.

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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.

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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.

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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

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](#)

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

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

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

 Discontinuation from Study
 Discontinuation of Drug Therapy

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

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](#)

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

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

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

 Discontinuation from Study
 Discontinuation of Drug Therapy

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

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](#)

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

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

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

 Discontinuation from Study
 Discontinuation of Drug Therapy

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

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](#)

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

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

Action Taken: Select only one

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

Outcome to Date Select only one

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

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Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

[Click here to navigate to 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

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

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

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

 Discontinuation from Study
 Discontinuation of Drug Therapy

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

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		
<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

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.

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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 #: R275308113

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date of Onset 1	00-00-1979	05-JAN-2010 15:00:40 Kim Freschly	Row Inserted
Date of Resolution 1		05-JAN-2010 15:00:40 Kim Freschly	Row Inserted
Diagnosis/Procedure 1	RECURRENT JOINT PAIN	05-JAN-2010 15:00:40 Kim Freschly	Row Inserted
Does the subject have any relevant medication 1	NO YES	05-JAN-2010 15:00:40 Kim Freschly	Data Entry Error
Ongoing 1	CHECKED	05-JAN-2010 15:00:40 Kim Freschly	Row Inserted
Sequence Number 1	1	05-JAN-2010 15:00:40 Kim Freschly	Row Inserted

Document #: R240090613

Patient Site	Visit Visit Date	CRF CRF Page
R4008 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
Attempted to quit (Other attempts) (5) 1	YES NO	03-FEB-2010 14:56:07 Kim Freschly	Data Entry Error
Attempted to quit (Other cessation aids) (4) 1	NO YES	03-FEB-2010 14:56:07 Kim Freschly	Data Entry Error
Comments (other attemps) (7) 1	HYPNOSIS, MINERAL/VITAMIN COMBINATION, LAVENDER SUBSTANCE BEHIND EARS, ACCUPUNCTURE	10-JUN-2009 10:49:40 Kim Freschly	Data Entry Error
Comments (other attemps) (7) 1	HYPNOSIS, MINERAL/VITAMIN COMBINATION, LAVENDER SUBSTANCE BEHIND EARS, ACCUPUNCTURE	03-FEB-2010 14:56:07 Kim Freschly	Data Entry Error
Comments (other cessation aids) (6) 1	HYPNOSIS, MINERAL/VITAMIN COMBINATION, LAVENDER SUBSTANCE BEHIND EARS, ACCUPUNCTURE	03-FEB-2010 14:56:07 Kim Freschly	Data Entry Error
Comments (other cessation aids) (6) 1	HYPNOSIS, MINERAL/VITAMIN COMBINATION, LAVENDER SUBSTANCE BEHIND EARS, ACCUPUNCTURE HYPNOSIS, MINERAL/VITAMIN COMBINATION, LAVENDER SUBSTANCE BEHIND EARS, ACUPUNCTURE	24-MAR-2010 15:22:10 Kryisia Magnuson	ODM/SEC accupuncture to acupuncture. KAY 24Mar2010.
If Yes, how many (nicotine replacement) (3) 1	1 2	10-JUN-2009 10:48:11 Kim Freschly	Data Entry Error

Document #: R240090613

Patient Site	Visit Visit Date	CRF CRF Page
R4008 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

If Yes, how many (nicotine replacement) (3) 1	2 1	22-OCT-2009 10:52:19 Kim Freschly	Data Entry Error
--	--------	--------------------------------------	------------------

If Yes, how many (nicotine replacement) (3) 1	1 2	04-JAN-2010 09:45:57 Kim Freschly	Data Entry Error
--	--------	--------------------------------------	------------------

If Yes, how many (other cessation aids) (5) 1	6	03-FEB-2010 14:56:07 Kim Freschly	Data Entry Error
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If yes, how many (other attempts to quit) (6) 1	6	03-FEB-2010 14:56:07 Kim Freschly	Data Entry Error
--	---	--------------------------------------	------------------

Document #: R240092013

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Screening	Page_11 11

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Oral Health Exam	Page number	11	Screening

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Findings* 3	NO NE	13-MAY-2009 11:28:50 Kim Freschly	Data Entry Error
Findings* 3	NE NO	10-JUN-2009 10:53:05 Kim Freschly	Data Entry Error

Document #: R243263513

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Sptp, Weeks 1-4	Page_16 16

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	04-JAN-2009 01-APR-2009	10-JUN-2009 10:53:34 Kim Freschly	Data Entry Error

Document #: R251851413

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Ip, Week 6	Page_20 20

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
If Subject was not compliant, approximat (5) 1	9 8	22-OCT-2009 10:53:28 Kim Freschly	Data Entry Error
If Subject was not compliant, approximat (5) 1	8 9	04-JAN-2010 09:48:27 Kim Freschly	Data Entry Error

Document #: R251853013

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Ip, Week 10	Page_24 24

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	24	Ip, Week 10

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
If Subject was not compliant, approximat (5) 1	84 105	11-SEP-2009 13:34:43 Kim Freschly	Data Entry Error

Document #: R275311213

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Fu, Week 28	Page_33 33

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	33	Fu, Week 28

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	26-AUG-2009 23-SEP-2009	22-OCT-2009 11:00:53 Kim Freschly	Data Entry Error

Document #: R275311613

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Fu, Week 28	Page_34 34

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	34	Fu, Week 28

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	26-AUG-2009 23-SEP-2009	22-OCT-2009 11:01:05 Kim Freschly	Data Entry Error

Document #: R240097213

Patient Site	Visit Visit Date	CRF CRF Page
R4008 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	A N	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A NERVOUS SYSTEM, N	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	A01 N02	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANALGESICS, N02	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	A01A N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A OTHER ANALGESICS AND ANTIPYRETICS, N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	A01AD N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD SALICYLIC ACID AND DERIVATIVES, N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
Drug Modified Reported Term 1	ASA ASPIRIN	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	ASA ASPIRIN	13-APR-2010 08:27:11 Lana Glaser	Data Entry Error
Frequency 1	EVERY DAY ONCE	10-JUN-2009 11:47:38 Kim Freschly	Data Entry Error
Trade Name 1	ASA ASPIRIN	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Trade Name Code 1	00002701003 00002701004	20-APR-2010 11:39:56 Carol Kraucyk	Data Change

Document #: R240098713

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Pcm.2	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.2

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A NERVOUS SYSTEM, N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A01 N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANALGESICS, N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A01A N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A OTHER ANALGESICS AND ANTIPYRETICS, N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A01AD N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD SALICYLIC ACID AND DERIVATIVES, N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change

Document #: R275313413

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Pcm.3	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.3

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A NERVOUS SYSTEM, N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A01 N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANALGESICS, N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A01A N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A OTHER ANALGESICS AND ANTIPYRETICS, N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A01AD N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD SALICYLIC ACID AND DERIVATIVES, N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change

Document #: R275313813

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Pcm.4	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.4

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A NERVOUS SYSTEM, N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A01 N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANALGESICS, N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A01A N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A OTHER ANALGESICS AND ANTIPYRETICS, N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A01AD N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD SALICYLIC ACID AND DERIVATIVES, N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change

Document #: R304604713

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Pcm.5	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.5

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC1 Code 1	A N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A NERVOUS SYSTEM, N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A01	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC2 Code 1	A01 N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANALGESICS, N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A01A	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC3 Code 1	A01A N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A OTHER ANALGESICS AND ANTIPYRETICS, N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A01AD	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC4 Code 1	A01AD N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change

Document #: R304604713

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Pcm.5	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.5

Group #	Group Name
1	CM1

ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD SALICYLIC ACID AND DERIVATIVES, N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Preferred Term 1	ACETYLSALICYLIC ACID	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
Preferred Term Code 1	00002701001	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
Trade Name 1	ASPIRIN	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
Trade Name Code 1	00002701004	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change

Document #: R243265013

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Ae.1	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.1

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Onset Date 1	16-MAR-2009 11-MAR-2009	23-APR-2010 14:36:17 Lana Glaser	Data Entry Error
Onset Time 1	1000 UNK	23-APR-2010 14:36:17 Lana Glaser	Data Entry Error
Resolved Date 1	03-APR-2009 30-APR-2009	23-APR-2010 14:36:17 Lana Glaser	Data Entry Error

Document #: R275314613

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Ae.3	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.3

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
High Level Group Term 1	RESPIRATORY DISORDERS NEC	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Group Term Code 1	10038716	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Term 1	UPPER RESPIRATORY TRACT SIGNS AND SYMPTOMS	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Term Code 1	10046313	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Lower Level Term 1	PAIN PHARYNX	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Lower Level Term Code 1	10033481	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Onset Time 1	0800 UNK	23-APR-2010 12:15:25 Lana Glaser	Data Entry Error
Preferred Term 1	OROPHARYNGEAL PAIN	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Preferred Term Code 1	10068319	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
System Organ Class 1	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
System Organ Class Code 1	10038738	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change

Document #: R275315013

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Ae.4	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.4

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
High Level Group Term 1	BONE DISORDERS (EXCL CONGENITAL AND FRACTURES)	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Group Term Code 1	10005959	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Term 1	BONE RELATED SIGNS AND SYMPTOMS	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
High Level Term Code 1	10006006	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Lower Level Term 1	JAW PAIN	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Lower Level Term Code 1	10023157	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Onset Time 1	0800 UNK	23-APR-2010 12:17:44 Lana Glaser	Data Entry Error
Preferred Term 1	PAIN IN JAW	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
Preferred Term Code 1	10033433	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
System Organ Class 1	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change
System Organ Class Code 1	10028395	26-APR-2010 16:50:41 Joanne Mccaigue	Class. Change

Document #: R275315413

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Ae.5	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.5

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Action Taken 1	NONE OTHER DRUG		04-JAN-2010 09:53:33 Kim Freschly	Data Entry Error
Resolved Date 1	20-APR-2009 30-APR-2009		08-JAN-2010 09:59:22 Kim Freschly	Data Entry Error
Resolved Time 1	0800 0500		08-JAN-2010 09:59:22 Kim Freschly	Data Entry Error

Document #: R275317013

Patient Site	Visit Visit Date	CRF CRF Page
R4008	Ae.7	Page_40
P3880_0342		

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag	N	23-APR-2010 15:26:02	Data Entry Error
1	Y	Lana Glaser	

Document #: R275317513

Patient Site	Visit Visit Date	CRF CRF Page
R4008 P3880_0342	Ae.8	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.8

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Onset Time 1	0800 UNK	23-APR-2010 12:20:04 Lana Glaser	Data Entry Error

Discrepancy Detail Report

Document #: R240090613

Discrepancy ID: 52871611 Site: P3880_0342 Patient: R4008
Visit: SCREENING Visit Date:
CRF: PAGE_10 Section: SMOKING HISTORY Qualifying Value: 10
Field: Age subject began smoking Row: 1
Value Text: 8
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify age subject began smoking daily as 8 years old. Please amend if incorrect.
Internal Comment:
Resolution Type: Confirmed
Resolution Text: correct as entered

Discrepancy ID: 53436711 Site: P3880_0342 Patient: R4008
Visit: SCREENING Visit Date:
CRF: PAGE_10 Section: SMOKING HISTORY Qualifying Value: 10
Field: Comments (other attempts) Row: 1
Value Text:
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify data. All aids listed fall under the category of 'other smoking cessation aids' rather than 'other attempts to quit'. If data is correct, please amend all responses to the parameteres 'other smoking cessation aids' and 'other attempts to quit' accordingly.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: Verified. KAY 24Feb2010.

Discrepancy ID: 1645391913 Site: P3880_0342 Patient: R4008
Visit: SCREENING Visit Date:
CRF: PAGE_10 Section: SMOKING HISTORY Qualifying Value: 10
Field: If Yes, how many (nicotine replacement) Row: 1
Value Text: 2
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per Progress note on 4/8/09 subject tried gum 2x
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

R240090613

Discrepancy ID: 1645392013 **Site:** P3880_0342 **Patient:** R4008
Visit: SCREENING **Visit Date:**
CRF: PAGE_10 **Section:** SMOKING HISTORY **Qualifying Value:** 10
Field: If yes, how many (other attempts to quit **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review if 4 is correct per progress note on 4/8/09.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 1781021713 **Site:** P3880_0342 **Patient:** R4008
Visit: SCREENING **Visit Date:**
CRF: PAGE_10 **Section:** SMOKING HISTORY **Qualifying Value:** 10
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Progress note still indicates 2 separate times for nicorette gum. Please review.
Internal Comment:
Resolution Type: Confirmed
Resolution Text: corrected per source

Document #: R240092013

Discrepancy ID: 1645392113

Site: P3880_0342

Patient: R4008

Visit: SCREENING

Visit Date:

CRF: PAGE_11

Section: ORAL HEALTH EXA

Qualifying Value: 11

Field: Findings*

Row: 3

Value Text: NO

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please update to 'No' per CRF guidelines

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R275308113

Discrepancy ID: 1781116713

Site: P3880_0342

Patient: R4008

Visit: SCREENING

Visit Date:

CRF: PAGE_09

Section: MH

Qualifying Value: 9

Field: Does the subject have any relevant medic

Row: 1

Value Text: YES

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review Med Hx for relevance. Conmeds are present for ASA and Lexapro, taken prestudy for joint pain and stress.

Internal Comment: Please have PI update Relevant med HX source.

Resolution Type: Confirmed

Resolution Text: PI added recurrent joint pain

Document #: R251851413

Discrepancy ID: 1690547713

Site: P3880_0342

Patient: R4008

Visit: IP, WEEK 6

Visit Date:

CRF: PAGE_20

Section: STATUS REVIEW

Qualifying Value: 20

Field: If Subject was not compliant, approximat

Row: 1

Value Text: 9

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Week 6 source (page 4 of 4) indicates subject smokes an average of 9/day (63/week). Please review.

Internal Comment:

Resolution Type: Confirmed

Resolution Text: source indicates 9/week

Document #: R251853013

Discrepancy ID: 1690568113

Site: P3880_0342

Patient: R4008

Visit: IP, WEEK 10

Visit Date:

CRF: PAGE_24

Section: STATUS REVIEW

Qualifying Value: 24

Field: If Subject was not compliant, approximat

Row: 1

Value Text: 105

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please use value from week 10 diary

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R240097513

Discrepancy ID: 98968511

Site: P3880_0342

Patient: R4008

Visit: PCM.1

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: STRESS

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: There is not any medical history of 'Stress' recorded. Please verify adding.

Internal Comment: per Dr. Stoltz subject's history of stress isnot relevant to study

Resolution Type: Confirmed

Resolution Text: Verified. JLM 21Apr2010

Document #: R304604713

Discrepancy ID: 111986811

Site: P3880_0342

Patient: R4008

Visit: PCM.5

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Stop Date is missing and 'Ongoing' field was not completed for <ASPIRIN>. Please provide Stop Date or enter 'checked' in the 'Ongoing' field.

Internal Comment: stop date unknown

Resolution Type: Confirmed

Resolution Text: Verified. JLM 26Apr2010

Document #: R243265013

Discrepancy ID: 111320111

Site: P3880_0342

Patient: R4008

Visit: AE.1

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Onset Date

Row: 1

Value Text: 20090311

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This event of nasea overlaps (is within) another event of nausea that occurs from 11Mar2009 to 30Apr2009. If same event, please remove or reconcile.

Internal Comment: AE's combined

Resolution Type: Confirmed

Resolution Text: Verified. JLM 26Apr2010

Document #: R275314613

Discrepancy ID: 110345811

Site: P3880_0342

Patient: R4008

Visit: AE.3

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Onset Date

Row: 1

Value Text: 20090311

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This event has an onset date/time prior to randomization. Please verify date/time. If correct, please remove as AE and move to MH page.

Internal Comment: per source, "per subject this happens when she uses the snus", start time unknown.

Resolution Type: Confirmed

Resolution Text: Verified. JLM 26Apr2010

Document #: R275315013

Discrepancy ID: 1781135713 **Site:** P3880_0342 **Patient:** R4008
Visit: AE.4 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Action Taken **Row:** 1
Value Text: OTHER DRUG
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Source indicates a ConMed taken, however there is no conmed with this AE term.
Internal Comment: SM to reconcile source documnts
Resolution Type: Confirmed
Resolution Text: source corrected

Discrepancy ID: 110521011 **Site:** P3880_0342 **Patient:** R4008
Visit: AE.4 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: There is not currently a medication recorded for this event. Please add medication or update Action taken.
Internal Comment: per source, "per subject this happens when she uses the snus", start time unknown. - THIS DOES NOT ANSWER QUERY
Aspirin added to ConMed page, start and stop dates and times unknown
Resolution Type: Confirmed
Resolution Text: Verified. JLM 26Apr2010

Document #: R275315413

Discrepancy ID: 1781138413 **Site:** P3880_0342 **Patient:** R4008
Visit: AE.5 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Action Taken **Row:** 1
Value Text: OTHER DRUG
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please also check box for non drug therapy as a cold compress was given for swelling on face (combined with additional AEs to Contusions from fall)

Internal Comment:
Resolution Type: Confirmed
Resolution Text: can only choose one box

Discrepancy ID: 1781138213 **Site:** P3880_0342 **Patient:** R4008
Visit: AE.5 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Resolved Date **Row:** 1
Value Text: 20090430
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review date and time of resolution - severity for AE#4 (pain from fall) was moderate from 19apr09 thru 30Apr09.

Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 1781138313 **Site:** P3880_0342 **Patient:** R4008
Visit: AE.5 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Resolved Time **Row:** 1
Value Text: 0500
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review date and time.

Internal Comment:
Resolution Type: Confirmed
Resolution Text: correct as entered, due to severity change

Document #: R275317513

Discrepancy ID: 110346211

Site: P3880_0342

Patient: R4008

Visit: AE.8

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Onset Date

Row: 1

Value Text: 20090311

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This event has an onset date/time prior to randomization. Please verify date/time. If correct, please remove as AE and move to MH page.

Internal Comment: per source, "per subject due to swallowing the product's juice", start time unknown.

Resolution Type: Confirmed

Resolution Text: Verified. JLM 26Apr2010

Deleted CRFs Report

Document #: R275316813

Patient Site	Visit Visit Date	CRF CRF Page #
R4008 P3880_0342	Ae.6	Page_40

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

Group #	Group Name
0	CRF

Field Row	Changed From Changed To	On By	Reason Comment
1		08-JAN-2010 10:01:58 Kim Freschly	Data Entry Error