

CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 12:06:30

Report Parameters

Site: CDB_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1020

Ending patient: R1020

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

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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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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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Exclusion Criteria

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

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

* If Yes, document on Subject Eligibility Page.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Information Session

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

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

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

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

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

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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="29-MAY-2009"/>	<input type="text" value=""/>	<input checked="" type="checkbox"/> Male	<input type="checkbox"/> Hispanic or Latino
		<input 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" value=""/>

Body Measurements

Were Body Measurements Collected? Yes No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="66.0"/>

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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	117
Diastolic Blood Pressure	MMHG	070
Heart Rate	BEATS/MINUTE	056
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	36.5
Weight	LB	239.8

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Protocol Number: SM 08-01

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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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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="29-MAY-2009"/>	<input type="text" value="12:09"/>
	<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

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

Sequence No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	PERIODICALLY NASAL/SINUS CONGESTION	00-00-2000		<input checked="" type="checkbox"/> Ongoing
2	SHORTNESS OF BREATH UPON EXERTION	00-00-2002		<input checked="" type="checkbox"/> Ongoing
3	RECURRENT JOINT PAIN (BILATERAL KNEES)	00-00-2002		<input checked="" type="checkbox"/> Ongoing
4	RECURRENT BACK PAIN	00-00-2002		<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

Consider the following systems when performing the assessment:

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Smoking History

Was Smoking History collected?

Yes No

Date

Parameter	Result	Comments
Age subject began smoking daily	<input type="text" value="15"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="28"/>	
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="10"/>	COLD TURKEY

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Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
<input type="text" value="29-MAY-2009"/>	<input type="text" value="EVIDENCE OF LEUKOPLAKIA"/>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text" value="29-MAY-2009"/>	<input type="text" value="EXPOSED DENTAL CERVICES IN UPPER SULCUS?"/>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text" value="29-MAY-2009"/>	<input type="text" value="OTHER ORAL KERATOSIS"/>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>

* Indicate NE if system was not examined.

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Swedish Match AB

Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

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

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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
04-JUN-2009	11:27	13	2.7	

Behavioral Counseling

Date	Parameter	Result	Comments
04-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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Swedish Match AB

Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date Actual Time
Was Subject randomized? Yes No

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="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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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="12-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="100"/>	<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="18-JUN-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="25-JUN-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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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
<input type="text" value="02-JUL-2009"/>	<input type="text" value="WEEK 4"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject reminded about the complete switch from cigarettes no later than the first day of Week 5?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	122
Diastolic Blood Pressure	MMHG	074
Heart Rate	BEATS/MINUTE	065
Respiratory Rate	BREATHS/MINUTE	016
Body Temperature	C	036.7
Weight	LB	242.0

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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

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"/>
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Note: Attach copy of signed laboratory report.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
16-JUL-2009	09:53	2	0.9	

Behavioral Counseling

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

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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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="03-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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	128
Diastolic Blood Pressure	MMHG	072
Heart Rate	BEATS/MINUTE	054
Respiratory Rate	BREATHS/MINUTE	020
Body Temperature	C	036.5
Weight	LB	245.0

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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
13-AUG-2009	09:50	2	0.9	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="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="13-AUG-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions? Yes No

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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="04-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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject instructed to cut down on product use during upcoming Weeks 14-16 to avoid a too abrupt ending of nicotine uptake?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	122
Diastolic Blood Pressure	MMHG	070
Heart Rate	BEATS/MINUTE	061
Respiratory Rate	BREATHS/MINUTE	020
Body Temperature	C	036.5
Weight	LB	240.2

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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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
25-SEP-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
25-SEP-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
25-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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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
25-SEP-2009	09:46	3	1.1	

Behavioral Counseling

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

Questionnaires

Date

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

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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="25-SEP-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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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
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="7"/>	<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="1"/>	<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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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	075
Heart Rate	BEATS/MINUTE	054
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	36.6
Weight	LB	248.4

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
23-NOV-2009	08:10	4	1.2	

Behavioral Counseling

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

Questionnaires

Date

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

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

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

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Document Number

OverFlow Section For Document Number R282810313

1 SUBJECT EARLY TERMED AT WEEK 26 AND WEEK 28 PROCEDURES WERE PERFORMED

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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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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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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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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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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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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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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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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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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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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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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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

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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

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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

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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

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.

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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

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.

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Document Number

Appendix: Audit and Discrepancy Information

Audit History Report

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

Document #: R253664113

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date of Onset 1	00-00-2000	15-OCT-2009 13:25:43 Rossana Matos	Row Inserted
Date of Resolution 1		15-OCT-2009 13:25:43 Rossana Matos	Row Inserted
Diagnosis/Procedure 1	NASAL/SINUS INFECTION	15-OCT-2009 13:25:43 Rossana Matos	Row Inserted
Diagnosis/Procedure 1	NASAL/SINUS INFECTION NASAL/SINUS CONGESTION	19-NOV-2009 17:20:28 Christina Breedlove	Data Entry Error per Query
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION PERIODICALLY NASAL/SINUS CONGESTION	01-MAR-2010 10:56:14 Christina Breedlove	Investigator Correction Subject reported periodically Nasal/Sinus congestion
Does the subject have any relevant medic 1	NO YES	15-OCT-2009 13:23:12 Rossana Matos	Data Entry Error
Ongoing 1	CHECKED	15-OCT-2009 13:25:43 Rossana Matos	Row Inserted
Sequence Number 1	1	15-OCT-2009 13:25:43 Rossana Matos	Row Inserted
Date of Onset 2	00-00-2002	15-OCT-2009 13:25:43 Rossana Matos	Row Inserted
Date of Resolution 2		15-OCT-2009 13:25:43 Rossana Matos	Row Inserted
Diagnosis/Procedure 2	SHORTNESS OF BREATH UPON EXERTION	15-OCT-2009 13:25:43 Rossana Matos	Row Inserted
Ongoing 2	CHECKED	15-OCT-2009 13:25:43 Rossana Matos	Row Inserted
Sequence Number 2	2	15-OCT-2009 13:25:43 Rossana Matos	Row Inserted

Document #: R253664113

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Date of Onset		15-OCT-2009 13:25:43	Row Inserted
3	00-00-2002	Rossana Matos	
Date of Resolution		15-OCT-2009 13:25:43	Row Inserted
3		Rossana Matos	
Diagnosis/Procedure		15-OCT-2009 13:25:43	Row Inserted
3	RECURRENT JOINT AND BACK PAIN	Rossana Matos	
Diagnosis/Procedure	RECURRENT JOINT AND BACK PAIN	19-NOV-2009 17:20:28	Data Entry Error
3	RECURRENT JOINT PAIN (BILATERAL KNEES)	Christina Breedlove	per Query
Ongoing		15-OCT-2009 13:25:43	Row Inserted
3	CHECKED	Rossana Matos	
Sequence Number		15-OCT-2009 13:25:43	Row Inserted
3	3	Rossana Matos	
Date of Onset		19-NOV-2009 17:20:28	Row Inserted
4	00-00-2002	Christina Breedlove	
Date of Resolution		19-NOV-2009 17:20:28	Row Inserted
4		Christina Breedlove	
Diagnosis/Procedure		19-NOV-2009 17:20:28	Row Inserted
4	RECURRENT BACK PAIN	Christina Breedlove	
Ongoing		19-NOV-2009 17:20:28	Row Inserted
4	CHECKED	Christina Breedlove	
Sequence Number		19-NOV-2009 17:20:28	Row Inserted
4	4	Christina Breedlove	

Document #: R253664913

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	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* 1	YES NO	18-JUN-2009 13:35:03 Rossana Matos	Data Entry Error
Findings* 2	YES NO	18-JUN-2009 13:35:03 Rossana Matos	Data Entry Error
Findings* 3	YES NO	18-JUN-2009 13:35:03 Rossana Matos	Data Entry Error

Document #: R253665013

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Screening	Page_12 12

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	12	Screening

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does the subject have any abnormal findi 1	NO YES	10-FEB-2010 17:55:57 Christina Breedlove	Validation Status changed
Findings 1	RIGHT MYRINGOTOMY TUBE	10-FEB-2010 17:57:25 Christina Breedlove	Row Inserted
Sequence Number 1	1	10-FEB-2010 17:57:25 Christina Breedlove	Row Inserted
Findings 2	RIGHT ELBOW JOINT DEFORMITY	10-FEB-2010 17:57:25 Christina Breedlove	Row Inserted
Sequence Number 2	2	10-FEB-2010 17:57:25 Christina Breedlove	Row Inserted

Document #: R253665813

Patient Site	Visit Visit Date	CRF CRF Page	
R1020 CDB_001	Baseline, Week 0	Page_15 15	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Sc	Page number	15	Baseline, Week 0

Group #	Group Name
1	SC

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	04-MAY-2009 04-JUN-2009	05-MAR-2010 15:06:20 Christina Breedlove	Data Entry Error

Document #: R253665813

Patient Site	Visit Visit Date	CRF CRF Page	
R1020 CDB_001	Baseline, Week 0	Page_15 15	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ex	Page number	15	Baseline, Week 0

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	04-MAY-2009 04-JUN-2009	05-MAR-2010 15:06:20 Christina Breedlove	Data Entry Error per query

Document #: R253665813

Patient Site	Visit Visit Date	CRF CRF Page	
R1020 CDB_001	Baseline, Week 0	Page_15 15	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Diary	Page number	15	Baseline, Week 0

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	04-MAY-2009 04-JUN-2009	05-MAR-2010 15:06:20 Christina Breedlove	Data Entry Error per query

Document #: R253666013

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Sptp, Weeks 1-4	Page_16 16

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Was Subject's use of study product review (3) 1	NO YES	15-OCT-2009 13:58:57 Sharon Daly	Data Entry Error

Document #: R253666013

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Sptp, Weeks 1-4	Page_16 16

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

Group #	Group Name
0	Section Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCM Blank flag 1	N Y	25-JUN-2009 09:34:34 Sharon Daly	Key Change
DCM Blank flag 1	Y N	06-JUL-2009 11:08:40 Rossana Matos	Data Entry Error

Document #: R258581013

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Ip, Week 6	Page_17 17

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	17	Ip, Week 6

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Was subject seated for 5 Minutes? (2) 1	YES NO	19-NOV-2009 17:29:39 Christina Breedlove	Data Entry Error Can not confirm subject was seated for 5 mins.

Document #: R258581213

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Ip, Week 6	Page_19 19

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Behavioral Coun	Page number	19	Ip, Week 6

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Result 1	YES	16-JUL-2009 14:19:34 Rossana Matos	Investigator Correction

Document #: R258581413

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	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	105	15-OCT-2009 15:06:15 Sharon Daly	Data Entry Error
Was Subject compliant (4) 1	NO YES	15-OCT-2009 15:06:15 Sharon Daly	Data Entry Error

Document #: R265732013

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Ip, Week 8	Page_21 21

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	21	Ip, Week 8

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	0	07-JAN-2010 09:26:57 Sharon Daly	Data Entry Error

Document #: R265733213

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	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	0	07-JAN-2010 09:29:43 Sharon Daly	Data Entry Error

Document #: R265733213

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Ip, Week 10	Page_24 24

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	13-AUG-2009 14-AUG-2009	26-AUG-2009 11:53:21 Rossana Matos	Data Entry Error

Document #: R267262813

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Ip, Week 13	Page_25 25

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	25	Ip, Week 13

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	0	07-JAN-2010 09:30:54 Sharon Daly	Data Entry Error

Document #: R272502913

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Ip, Week 16	Page_29 29

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	29	Ip, Week 16

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does the subject have any abnormal findi 1	YES NO	10-FEB-2010 17:58:51 Christina Breedlove	Data Entry Error per query
Findings 1	RIGHT MYRINGOTOMY TUBE	10-FEB-2010 17:58:51 Christina Breedlove	Data Entry Error
Findings 1	<Row Deleted>	24-MAR-2010 11:40:13 Kryisia Magnuson	Data Entry Error
Sequence Number 1	1	10-FEB-2010 17:58:51 Christina Breedlove	Data Entry Error
Sequence Number 1	<Row Deleted>	24-MAR-2010 11:40:13 Kryisia Magnuson	Data Entry Error
Findings 2	RIGHT ELBOW JOINT DEFORMITY	10-FEB-2010 17:58:51 Christina Breedlove	Data Entry Error
Findings 2	<Row Deleted>	24-MAR-2010 11:40:13 Kryisia Magnuson	Data Entry Error
Sequence Number 2	2	10-FEB-2010 17:58:51 Christina Breedlove	Data Entry Error
Sequence Number 2	<Row Deleted>	24-MAR-2010 11:40:13 Kryisia Magnuson	Data Entry Error
Findings 3	TATTOO RIGHT LOWER EXTREMITY, LEFT LOWER EXTREMITY POSTERIOR THORAX AREA	03-DEC-2009 09:07:09 Christina Breedlove	Investigator Correction
Findings 3	<Row Deleted>	24-MAR-2010 11:40:13 Kryisia Magnuson	Data Entry Error
Sequence Number 3	3	03-DEC-2009 09:07:09 Christina Breedlove	Investigator Correction
Sequence Number 3	<Row Deleted>	24-MAR-2010 11:40:13 Kryisia Magnuson	Data Entry Error

Document #: R275327713

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Fu, Week 20 & 24	Page_32 32

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	32	Fu, Week 20 & 24

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	0 7	07-JAN-2010 09:41:54 Sharon Daly	Data Entry Error
Was Subject compliant (4) 1	YES NO	07-JAN-2010 09:41:54 Sharon Daly	Data Entry Error

Document #: R282809413

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	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	23-NOV-2009	02-DEC-2009 13:52:09 Christina Breedlove	Data Entry Error
Requisition Number 1: (1) 1	NA	10-FEB-2010 18:01:45 Christina Breedlove	Data Entry Error per CRF guidelines

Document #: R282809613

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Fu, Week 28	Page_35 35

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 1	Y N	02-DEC-2009 13:52:59 Christina Breedlove	Data Entry Error

Document #: R282810313

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Fu, Week 28	Page_38 38

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	38	Fu, Week 28

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments (compliant) (4) 1	SUBJECT WAS AN EARLY TERM AND CAME IN AT WEEK 26 AND ALL WEEK 28 PROCEDURES WERE PERFORMED.	04-MAR-2010 12:19:15 Christina Breedlove	Validation Status changed per query
Comments (smoking status reviewed) (2) 1	SUBJECT EARLY TERMED AT WEEK 26 AND WEEK 28 PROCEDURES WERE PERFORMED	04-MAR-2010 12:19:15 Christina Breedlove	Validation Status changed per query

Document #: R254179313

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	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	C M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	C01 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CARDIAC THERAPY, C01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	C01E M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	OTHER CARDIAC PREPARATIONS, C01E ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STERIODS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	C01EB M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER CARDIAC PREPARATIONS, C01EB PROPIONIC ACID DERIVATIVES, M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Indication 1	KNEE/BACK ACHE KNEE/BACK PAIN	22-JUN-2009 14:31:09 Rossana Matos	Data Entry Error

Document #: R254179713

Patient Site	Visit Visit Date	CRF CRF Page
R1020	Pcm.1	Page_39
CDB_001		

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.1

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	N	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC1 Text 1	NERVOUS SYSTEM, N	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Code 1	N02	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Text 1	ANALGESICS, N02	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Code 1	N02B	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Text 1	OTHER ANALGESICS AND ANTIPYRETICS, N02B	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Code 1	N02BE	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Text 1	ANILIDES, N02BE	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Dose 1	2 650 ACETAMINOPHEN/1000 ASPIRIN	13-APR-2010 12:17:37 Christina Breedlove	Data Entry Error total mg for 2 packets of GoodY's Powder.
Dose 1	650 ACETAMINOPHEN/1000 ASPIRIN 2	20-APR-2010 16:14:15 Christina Breedlove	Investigator Correction per query; Dose updated to 2 and units updated to other, packets
Drug Modified Reported Term 1	GOODIES GOODYS	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	GOODIES GOODYS	09-APR-2010 11:53:16 Joanne Mccaigue	ODM/SEC Obvious spelling error. JLM 09Apr2010
Preferred Term 1	THOMAPYRIN N	20-APR-2010 11:39:56 Carol Kraucyk	Data Change

Document #: R254179713

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Pcm.1	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.1

Group #	Group Name
1	CM1

Preferred Term Code	20-APR-2010 11:39:56	Data Change
1	00391201001 Carol Kraucyk	
Start Date	11-FEB-2010 15:07:14	Data Entry Error
1	00-FEB-2009 Christina Breedlove	per query
Trade Name	20-APR-2010 11:39:56	Data Change
1	GOODYS Carol Kraucyk	
Trade Name Code	20-APR-2010 11:39:56	Data Change
1	00391201014 Carol Kraucyk	
Unit	13-APR-2010 12:17:37	Data Entry Error
1	OTHER MILLIGRAMS Christina Breedlove	
Unit	20-APR-2010 16:14:15	Investigator
1	MILLIGRAMS OTHER Christina Breedlove	Correction per query; Dose updated to 2 and units updated to other, packets
other, specify (unit)	13-APR-2010 12:17:37	Data Entry Error
1	PKTS Christina Breedlove	
other, specify (unit)	20-APR-2010 16:14:15	Investigator
1	PACKETS Christina Breedlove	Correction per query; Dose updated to 2 and units updated to other, packets

Document #: R254181013

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	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
Ongoing 1	CHECKED	22-JUN-2009 14:35:19 Rossana Matos	Data Entry Error
Stop Date 1	23-MAY-2009	22-JUN-2009 14:35:19 Rossana Matos	Data Entry Error

Document #: R282811913

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	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 resequence	On By	Reason Comment
Dose 1	IM 1		13-APR-2010 13:30:36 Christina Breedlove	Investigator Correction per query
Drug name 1	TORADAL TORADOL		11-FEB-2010 15:08:25 Christina Breedlove	Data Entry Error confirmed
Frequency 1	AT BEDTIME ONCE		11-FEB-2010 15:08:25 Christina Breedlove	Data Entry Error confirmed
other, specify (unit) 1	ONE INJECTION INJECTION		13-APR-2010 13:30:36 Christina Breedlove	Investigator Correction per query

Document #: R282814113

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	Pcm.9	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.9

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	D R	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC1 Text 1	DERMATOLOGICALS, D RESPIRATORY SYSTEM, R	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC2 Code 1	D04 R06	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC2 Text 1	ANTIPRURITICS, INCL ANTI HIST, ANESTHET, ETC., D04 ANTI HISTAMINES FOR SYSTEMIC USE, R06	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC3 Code 1	D04A R06A	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC3 Text 1	ANTIPRURITICS, INCL ANTI HIST, ANESTHET, ETC., D04A ANTI HISTAMINES FOR SYSTEMIC USE, R06A	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC4 Code 1	D04AA R06AA	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change
ATC4 Text 1	ANTI HISTAMINES FOR TOPICAL USE, D04AA AMINOALKYL ETHERS, R06AA	26-APR-2010 14:24:56 Joanne Mccaigue	Data Change

Document #: R282815413

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	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
High Level Group Term 1	RESPIRATORY DISORDERS NEC	27-APR-2010 09:36:45 Joanne Mccaigue	Class. Change
High Level Group Term Code 1	10038716	27-APR-2010 09:36:45 Joanne Mccaigue	Class. Change
High Level Term 1	RESPIRATORY TRACT DISORDERS NEC	27-APR-2010 09:36:45 Joanne Mccaigue	Class. Change
High Level Term Code 1	10057184	27-APR-2010 09:36:45 Joanne Mccaigue	Class. Change
Lower Level Term 1	RESPIRATORY TRACT CONGESTION	27-APR-2010 09:36:45 Joanne Mccaigue	Class. Change
Lower Level Term Code 1	10052251	27-APR-2010 09:36:45 Joanne Mccaigue	Class. Change
Preferred Term 1	RESPIRATORY TRACT CONGESTION	27-APR-2010 09:36:45 Joanne Mccaigue	Class. Change
Preferred Term Code 1	10052251	27-APR-2010 09:36:45 Joanne Mccaigue	Class. Change
System Organ Class 1	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	27-APR-2010 09:36:45 Joanne Mccaigue	Class. Change
System Organ Class Code 1	10038738	27-APR-2010 09:36:45 Joanne Mccaigue	Class. Change

Document #: R282817413

Patient Site	Visit Visit Date	CRF CRF Page
R1020	Ae.2	Page_40
CDB_001		

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.2

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Adverse Event 1	BACK PAIN BACK STRAIN	01-MAR-2010 14:02:41 Christina Breedlove	Data Entry Error medical terminology is back strain
Adverse Event 1	BACK STRAIN BACK PAIN	01-MAR-2010 14:27:43 Christina Breedlove	Data Entry Error confirmed medical terminology is "back pain"
Ongoing 1	CHECKED	01-MAR-2010 14:27:43 Christina Breedlove	Data Entry Error confirmed AE "back pain" is ongoing with treatment
Ongoing 1	CHECKED	07-JUN-2010 13:00:17 Christina Breedlove	Data Entry Error Removed ongoing
Outcome to Date 1	CONT WITH TREATMENT RECOVERED	07-JUN-2010 16:11:28 Christina Breedlove	Investigator Correction moderate severity has resolved
Resolved Date 1	23-NOV-2009 02-NOV-2009	11-FEB-2010 15:52:20 Christina Breedlove	Data Entry Error
Resolved Date 1	02-NOV-2009 17-AUG-2009	01-MAR-2010 14:02:41 Christina Breedlove	Data Entry Error Per source, Resolved date of back strain is 17/Aug/2009 resolved time is 12:00
Resolved Date 1	17-AUG-2009 23-NOV-2009	01-MAR-2010 14:27:43 Christina Breedlove	Data Entry Error confirmed Resolved date is 23Nov2009
Resolved Date 1	23-NOV-2009	04-MAR-2010 12:30:18 Christina Breedlove	Data Entry Error AE continuing with treatment
Resolved Date 1	31-AUG-2009	03-JUN-2010 10:35:25 Christina Breedlove	Investigator Correction Entered resolved time due to change in severity

Document #: R282817413

Patient Site	Visit Visit Date	CRF CRF Page
R1020	Ae.2	Page_40
CDB_001		

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.2

Group #	Group Name
1	AE1

Resolved Date	31-AUG-2009	03-JUN-2010 15:52:48	Data Entry Error
1	02-NOV-2009	Sharon Daly	
Resolved Time	0830	11-FEB-2010 15:52:20	Data Entry Error
1	UNK	Christina Breedlove	
Resolved Time	UNK	01-MAR-2010 14:02:41	Data Entry Error
1	1200	Christina Breedlove	Per source, Resolved date of back strain is 17/Aug/2009 resolved time is 12:00
Resolved Time	1200	01-MAR-2010 14:27:43	Data Entry Error
1		Christina Breedlove	confirmed AE "back pain" is ongoing with treatment
Resolved Time		03-JUN-2010 10:35:25	Investigator
1	UNK	Christina Breedlove	Correction Entered resolved time due to change in severity
Serious Event		02-DEC-2009 14:38:25	Data Entry Error
1	NO	Christina Breedlove	
Severity	MILD	11-FEB-2010 15:09:48	Data Entry Error
1	MODERATE	Christina Breedlove	
Severity	MODERATE	11-FEB-2010 15:48:34	Data Entry Error
1	MILD	Christina Breedlove	
Severity	MILD	11-FEB-2010 15:52:20	Data Entry Error
1	MODERATE	Christina Breedlove	

Document #: R293321013

Patient Site	Visit Visit Date	CRF CRF Page
R1020 CDB_001	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 On resequence By	Reason Comment
Ongoing 1	CHECKED	20-APR-2010 16:23:31 Christina Breedlove	Investigator Correction
Outcome to Date 1	CONT WITH TREATMENT CONT WITHOUT TREATMENT	08-JUN-2010 13:40:20 Christina Breedlove	Data Entry Error Corrected to; continuing without treatment
Resolved Date 1	23-NOV-2009	20-APR-2010 16:23:31 Christina Breedlove	Investigator Correction confirmed as "ngoing" when subject completed the study.
Resolved Date 1	23-NOV-2009	03-JUN-2010 10:37:25 Christina Breedlove	Investigator Correction
Resolved Date 1	23-NOV-2009	07-JUN-2010 13:27:16 Christina Breedlove	Data Entry Error
Resolved Time 1	0830	20-APR-2010 16:23:31 Christina Breedlove	Investigator Correction
Resolved Time 1	UNK	03-JUN-2010 10:37:25 Christina Breedlove	Investigator Correction
Resolved Time 1	UNK 0830	03-JUN-2010 15:54:22 Sharon Daly	Data Entry Error
Resolved Time 1	0830	07-JUN-2010 13:27:16 Christina Breedlove	Data Entry Error

Discrepancy Detail Report

Document #: R253664113

Discrepancy ID: 1789604713 Site: CDB_001 Patient: R1020
Visit: SCREENING Visit Date:
CRF: PAGE_09 Section: MH Qualifying Value: 9
Field: Diagnosis/Procedure Row: 1
Value Text: PERIODICALLY NASAL/SINUS CONGESTION
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update diagnosis/procedure term to clarify if this is an intermittent/episodic condition or a continuous chronic condition.
Internal Comment: Subject reported periodically Nasal/Sinus congestion
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1789604813 Site: CDB_001 Patient: R1020
Visit: SCREENING Visit Date:
CRF: PAGE_09 Section: MH Qualifying Value: 9
Field: Diagnosis/Procedure Row: 3
Value Text: RECURRENT JOINT PAIN (BILATERAL KNEES)
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please separate joint and back pain into 2 med hx items.
Internal Comment: per Query
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: per Query

Discrepancy ID: 1716045413 Site: CDB_001 Patient: R1020
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:
Internal Comment: medical history not entered in error
Resolution Type: Confirmed
Resolution Text:

Document #: R253665413

Discrepancy ID: 78500011

Site: CDB_001

Patient: R1020

Visit: BASELINE, WEEK

Visit Date:

CRF: PAGE_14

Section: ECO

Qualifying Value: 14

Field: Date

Row: 1

Value Text: 20090604

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify all Baseline, Week 0 assessments as they are not consistent. (04-Jun-2009 and 04-May-2009). Please update.

Internal Comment: DM Comment: Please verify updating all (randomization, product dispensation, diary distribution) to 04-Jun-2009 as 04-May-2009 would be prior to Screening date.

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

Resolution Text:

Document #: R253666013

Discrepancy ID: 1717616813 **Site:** CDB_001 **Patient:** R1020
Visit: SPTP, WEEKS 1-4 **Visit Date:**
CRF: PAGE_16 **Section:** STATUS REVIEW **Qualifying Value:** 16
Field: Was Subject's use of study product revie **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per source
Internal Comment: reviewed
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R258581013

Discrepancy ID: 1717618113 **Site:** CDB_001 **Patient:** R1020
Visit: IP, WEEK 6 **Visit Date:**
CRF: PAGE_17 **Section:** VS **Qualifying Value:** 17
Field: Was subject seated for 5 Minutes? **Row:** 1
Value Text: NO
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify subject was not seated for 5 minutes. Answer should be "no".
Internal Comment: Can not confirm subject was seated for 5 mins.
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text: Can not confirm subject was seated for 5 mins.

Document #: R258581413

Discrepancy ID: 1717618813 **Site:** CDB_001 **Patient:** R1020
Visit: IP, WEEK 6 **Visit Date:**
CRF: PAGE_20 **Section:** STATUS REVIEW **Qualifying Value:** 20
Field: If Subject was not compliant, approximat **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per source. This data should come from subject diary, however is not present.
Internal Comment: week 6 subject did not smoke/diary
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1772623313 **Site:** CDB_001 **Patient:** R1020
Visit: IP, WEEK 6 **Visit Date:**
CRF: PAGE_20 **Section:** STATUS REVIEW **Qualifying Value:** 20
Field: Was Subject compliant **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy:
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R258625413

Discrepancy ID: 76420811

Site: CDB_001

Patient: R1020

Visit: IP, WEEK 6

Visit Date:

CRF: PAGE_18

Section: LB

Qualifying Value: 18

Field: Date

Row: 1

Value Text: 20090717

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify date of Week 6 lab (17-Jul-2009) as it is inconsistent with all other Week 6 assessments (16-Jul-2009). If incorrect, please update. If correct, please provide an in-query comment to explain the discrepancy.

Internal Comment: Date confirmed to be 17/Jul/2009. Subject wasn't fasting for wk 6 visit, on 16/Jul/2009. Subject returned on 17/Jul/2009 for fasting blood draw.

Resolution Type: Confirmed

Resolution Text:

Document #: R265733213

Discrepancy ID: 78545011

Site: CDB_001

Patient: R1020

Visit: IP, WEEK 10

Visit Date:

CRF: PAGE_24

Section: DIARY

Qualifying Value: 24

Field: Date

Row: 1

Value Text: 20090814

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify date of week 10 diary distribution (14-Aug-2010) as it is inconsistent with all other week 10 assessments (13-Aug-2010). If correct, please provide an in-query text to explain the deviation.

Internal Comment: During the baseline visit subjects were given a folder with all diaries, (28 weeks). On each return clinic visit the diaries were returned and the applicable diaries were removed from the subject's folder. The folder containing the remaining diaries were dispensed back to the subject. The subject forgot to bring in diary folder for week 10 clinic visit on 13Aug2009. The subject returned diary folder to the clinic on 14Aug2009. At this time the diaries were reviewed with the subject and the remaining diaries were dispensed back to the subject.

Resolution Type: Confirmed

Resolution Text:

Document #: R267262813

Discrepancy ID: 36037211 **Site:** CDB_001 **Patient:** R1020
Visit: IP, WEEK 13 **Visit Date:**
CRF: PAGE_25 **Section:** STATUS REVIEW **Qualifying Value:** 25
Field: If Subject was not compliant, approximat **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy:
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R272502913

Discrepancy ID: 1789614913 **Site:** CDB_001 **Patient:** R1020
Visit: IP, WEEK 16 **Visit Date:**
CRF: PAGE_29 **Section:** PE **Qualifying Value:** 29
Field: Does the subject have any abnormal findi **Row:** 1
Value Text: NO
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please delete, per source these items will not change and therefore should only be entered on the screening PE page.

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

Document #: R282810313

Discrepancy ID: 77961011

Site: CDB_001

Patient: R1020

Visit: FU, WEEK 28

Visit Date:

CRF: PAGE_38

Section: STATUS REVIEW

Qualifying Value: 38

Field: Comments (compliant)

Row: 1

Value Text:

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy:

Internal Comment: Please verify moving comment to the field associated with 'Was subject's smoking status reviewed?' as it seems to correspond more to that question.

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

Resolution Text:

Document #: R254179713

Discrepancy ID: 58646111 **Site:** CDB_001 **Patient:** R1020
Visit: PCM.1 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Start Date **Row:** 1
Value Text: 200902
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify start month is FEB.

Internal Comment:
Resolution Type: Confirmed
Resolution Text: per query

Discrepancy ID: 98503911 **Site:** CDB_001 **Patient:** R1020
Visit: PCM.1 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: other, specify (unit) **Row:** 1
Value Text: PACKETS
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: PKTS is not an acceptable abbreviation. Please provide full unit.

Internal Comment: total mg for 2 packets of GoodY's Powder.
Resolution Type: Confirmed
Resolution Text: Verified. JLM 19Apr2010

Discrepancy ID: 102144011 **Site:** CDB_001 **Patient:** R1020
Visit: PCM.1 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Dose can only contain a number. Combination drugs should be updated to reflect # of items. Please verify updating Dose to 2 and unit to Packets.

Internal Comment: per query; Dose updated to 2 and units updated to other, packets
Resolution Type: Confirmed
Resolution Text: Verified. JLM 23Apr2010

Document #: R282811913

Discrepancy ID: 98504111 **Site:** CDB_001 **Patient:** R1020
Visit: PCM.5 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Dose **Row:** 1
Value Text: 1
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify and update dose to '1' and units to 'injection'
Internal Comment: per query
Resolution Type: Confirmed
Resolution Text: Verified. JLM 19Apr2010

Discrepancy ID: 58646711 **Site:** CDB_001 **Patient:** R1020
Visit: PCM.5 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Drug name **Row:** 1
Value Text: TORADOL
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify spelling of "toradol".
Internal Comment: per query
Resolution Type: Confirmed
Resolution Text: per query

Discrepancy ID: 58646811 **Site:** CDB_001 **Patient:** R1020
Visit: PCM.5 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Frequency **Row:** 1
Value Text: ONCE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per source, should be one time.
Internal Comment: per query
Resolution Type: Confirmed
Resolution Text:

Document #: R282815413

Discrepancy ID: 102316611 **Site:** CDB_001 **Patient:** R1020
Visit: AE.1 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Adverse Event **Row:** 1
Value Text: CHEST/NASAL CONGESTION
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: There is currently a MH of Periodic nasal/sinus congestion. Please verify this is a worsening of condition. If not, please verify removing AE.
Internal Comment: Confirmed "chest/nasal congestion" was a worsening condition and subject took con meds
Resolution Type: Confirmed
Resolution Text: Verified. JLM 23Apr2010

Document #: R293321013

Discrepancy ID: 102327611 **Site:** CDB_001 **Patient:** R1020
Visit: AE.5 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Adverse Event **Row:** 1
Value Text: BACK PAIN
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: There is currently a MH of Recurrent Back Pain. Please verify this is a worsening of condition. If not, please verify removing AE.
Internal Comment: confirmed AE 'back pain" is a worsening condition,
Resolution Type: Confirmed
Resolution Text: Verified. JLM 23Apr2010

Discrepancy ID: 102247611 **Site:** CDB_001 **Patient:** R1020
Visit: AE.5 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Outcome to Date **Row:** 1
Value Text: CONT WITHOUT TREATMENT
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review source data. Source data indicates "continuing without treatment." Please address this inconsistency.
Internal Comment: Corrected to; continuing without treatment
Resolution Type: Confirmed
Resolution Text: Corrected to; continuing without treatment

Discrepancy ID: 142215411 **Site:** CDB_001 **Patient:** R1020
Visit: AE.5 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Resolved Date **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please complete resolved date and time.
Internal Comment: 23Nov2009 AE resolved with treatment
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

R293321013

Discrepancy ID: 142909311 **Site:** CDB_001 **Patient:** R1020
Visit: AE.5 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Resolved Time **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify resolved time. Per source, AE resolved at 0830.
Internal Comment: verified at 08:30
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Deleted CRFs Report