

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 10:15:17

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4053

Ending patient: R4053

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

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

RDC CASE REPORT FORM

Information Correct Yes No

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

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

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

for

SWEDISH MATCH AB
ROSENLUNDSGATAN 36
SE-118 85 STOCKHOLM
SWEDEN

by

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Inclusion Criteria

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

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

* If No, document on Subject Eligibility Page.

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Page Version No. PAGE_02 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Exclusion Criteria

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

	Yes*/No
<input type="checkbox"/> 01 The subject is a current user of ST (defined as daily usage during more than 1 week within past 6 months) or is unable to refrain from NRT or any other non-protocol treatment during the study. Use of pipes, cigars, cigarillos, snuff, and chewing tobacco is also prohibited during the study.	<input type="text" value="NO"/>
<input type="checkbox"/> 02 The subject is a female who is pregnant or lactating.	<input type="text" value="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="text" value="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="text" value="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="text" value="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="text" value="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="text" value="NO"/>
<input type="checkbox"/> 08 Use of any illicit drug or smoked marijuana in the last 3 months	<input type="text" value="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="text" value="NO"/>
<input type="checkbox"/> 10 The subject resides in a household where another member is currently participating in the study.	<input type="text" value="NO"/>

* If Yes, document on Subject Eligibility Page.

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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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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

Demographics

Date

Date of Birth

Gender Male Female

Ethnicity Hispanic or Latino Not Hispanic or latino

Race White Black or African American Asian

Native Hawaiian or Other Pacific Islander American Indian/Alaskan Native Other

Body Measurements

Were Body Measurements Collected? Yes No Date

Parameter Unit Result
Height

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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	144
Diastolic Blood Pressure	MMHG	95
Heart Rate	BEATS/MINUTE	90
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.5
Weight	LB	186.9

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Safety Urine & Blood Tests; Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Urine Pregnancy Test

Result

Positive Negative N/A, Male or Woman of Non-childbearing Potential

Urine Drug Screen

Drug Screen Result*

Positive Negative

*If result derived from test performed by a clinical laboratory, attach copy of signed laboratory report to the CRF.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Least 5 Minutes?	<input type="text" value="02-JUN-2009"/>	<input type="text" value="09:43"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

Sequence No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<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="17"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="20"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="1"/>	PATCHES
Has the subject attempted to quit with the use of Pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="2"/>	CHANTIX, WELLBUTRIN
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input 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
02-JUN-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
02-JUN-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
02-JUN-2009	OTHER ORAL KERATOSIS	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	

* Indicate NE if system was not examined.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

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

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
02-JUN-2009	12:35	26	4.7	

Behavioral Counseling

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

Questionnaires

Date

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

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date Actual Time

Was Subject randomized? Yes No

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="4"/> logs
1.0 g of snus or matching placebo	<input type="text" value="2"/> logs

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="10-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="210"/>	<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="17-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="105"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="23-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="105"/>	<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

Was Subject contacted by telephone?

Yes No

Was Subject's smoking status reviewed?

Yes No

Was Subject's use of study product reviewed?

Yes No

Approximately how many cigarettes did the subject smoke that week?

Was Behavioral Counseling Given?

Yes No

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

Yes No

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Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

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

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Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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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Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

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

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

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

Status Review

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

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="28-JUL-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_21 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

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

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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
<input type="text"/>				

Behavioral Counseling

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

Questionnaires

Date

Questionnaire MNWS Was Questionnaire Administered? Yes No

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Page Version No. PAGE_23 (v1, 31-MAR-2009)

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

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

Status Review

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

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

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

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Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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	136
Diastolic Blood Pressure	MMHG	85
Heart Rate	BEATS/MINUTE	93
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	37.0
Weight	LB	189.2

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Page Version No. PAGE_26 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

Page Version No. PAGE_27 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_28 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
31-AUG-2009	09:25	11	2.3	

Behavioral Counseling

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

Questionnaires

Date

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

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Page Version No. PAGE_30 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="31-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 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="UNK"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date Scheduled Timepoint

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

Date Scheduled Timepoint

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

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

Document Number

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

Vital Signs

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

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

Verified Approved Locked Frozen

Page Version No. PAGE_33 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

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

Behavioral Counseling

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

Questionnaires

Date

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

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

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

 Discontinuation from Study
 Discontinuation of Drug Therapy

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

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

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

Date	Actual Time	ECG Interpretation	Comments Regarding CS Findings:
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>

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

Document Number

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
30-JUL-2009	NA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			BLUE TOP TUBE NOT I
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

Page Version No. PAGE_42 (v1, 27-MAR-2009)

Document Number

OverFlow Section For Document Number R286860813

- 1 BLUE TOP TUBE NOT DRAWN, NOT IN BLOOD DRAW PACKET

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	140
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	86
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	ND
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	ND
	Body Temperature	C	ND

Comments

Date Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	132
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	85
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	ND
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	ND
	Body Temperature	C	ND

Comments

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	139
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	100
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	82
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	20
	Body Temperature	C	37.0

Comments

Date Actual Time

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

Comments

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_45 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

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

Investigator Comments (if none, leave blank):

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

Verified Approved Locked Frozen

Page Version No. PAGE_46 (v1, 25-MAR-2009)

Document Number

Appendix: Audit and Discrepancy Information

Audit History Report

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

Document #: R260445713

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	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	Y N	29-JUL-2009 15:35:34 Kim Freschly	Data Entry Error

Document #: R273333213

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Ip, Week 6	Page_17 17

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	N Y	23-MAR-2010 09:31:07 Kim Freschly	Data Entry Error

Document #: R273333613

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Ip, Week 6	Page_18 18

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	N Y	23-MAR-2010 09:32:30 Kim Freschly	Data Entry Error

Document #: R273333613

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Ip, Week 6	Page_18 18

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	18	Ip, Week 6

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
No (Specify samples not done, reason)/Co 1	BLUE TOP TUBE NOT DRAWN	07-OCT-2009 14:42:14 Lana Glaser	Data Entry Error
No (Specify samples not done, reason)/Co 1	BLUE TOP TUBE NOT DRAWN BLUE TOP TUBE NOT DRAWN, NOT IN BLOOD DRAW PACKET	07-JAN-2010 10:21:13 Kim Freschly	Data Entry Error
Were the scheduled laboratory samples ob 1	YES NO	07-JAN-2010 10:21:13 Kim Freschly	Data Entry Error

Document #: R273338113

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Ip, Week 6	Page_19 19

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	N Y	23-MAR-2010 09:32:37 Kim Freschly	Data Entry Error

Document #: R273338513

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Ip, Week 6	Page_20 20

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	N Y	23-MAR-2010 09:32:45 Kim Freschly	Data Entry Error

Document #: R286857213

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Pcm	Page_39 39

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	N Y	13-APR-2010 16:03:54 Lana Glaser	Data Entry Error
DCI Blank Flag 1	Y N	23-APR-2010 15:39:24 Lana Glaser	Data Entry Error
DCI Blank Flag 1	N Y	26-APR-2010 13:28:02 Kim Freschly	Data Entry Error
DCI Blank Flag 1	Y N	26-APR-2010 13:28:09 Kim Freschly	Data Entry Error
DCI Blank Flag 1	N Y	02-JUN-2010 14:57:35 Lana Glaser	Data Entry Error
DCI Blank Flag 1	Y N	02-JUN-2010 15:40:40 Lana Glaser	Data Entry Error

Document #: R286857213

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Pcm	Page_39 39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	J	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC1 Code 1	N	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change
ATC1 Text 1	ANTIINFECTIVES FOR SYSTEMIC USE, J	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC1 Text 1	NERVOUS SYSTEM, N	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change
ATC2 Code 1	J01	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC2 Code 1	N02	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change
ATC2 Text 1	ANTIBACTERIALS FOR SYSTEMIC USE, J01	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC2 Text 1	ANALGESICS, N02	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change
ATC3 Code 1	J01C	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC3 Code 1	N02B	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change
ATC3 Text 1	BETA-LACTAM ANTIBACTERIALS, PENICILLINS, J01C	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC3 Text 1	OTHER ANALGESICS AND ANTIPYRETICS, N02B	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change
ATC4 Code 1	J01CA	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC4 Code 1	N02BE	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change

Document #: R286857213

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Pcm	Page_39 39

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

Group #	Group Name
1	CM1

ATC4 Text 1	PENICILLINS WITH EXTENDED SPECTRUM, J01CA	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC4 Text 1	ANILIDES, N02BE	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change
Dose 1	1	23-APR-2010 15:39:24 Lana Glaser	Row Inserted
Dose 1	1	02-JUN-2010 14:50:13 Lana Glaser	Row Inserted
Dose 1	1	02-JUN-2010 15:40:40 Lana Glaser	Row Inserted
Drug name 1	AMOXICILLIN	23-APR-2010 15:39:24 Lana Glaser	Row Inserted
Drug name 1	AMOXICILLIN	02-JUN-2010 14:50:13 Lana Glaser	Row Inserted
Drug name 1	MIDRIN	02-JUN-2010 15:40:40 Lana Glaser	Row Inserted
Frequency 1	THREE TIMES DAILY	23-APR-2010 15:39:24 Lana Glaser	Row Inserted
Frequency 1	THREE TIMES DAILY	02-JUN-2010 14:50:13 Lana Glaser	Row Inserted
Frequency 1	WHENEVER NECESSARY	02-JUN-2010 15:40:40 Lana Glaser	Row Inserted
Has the subject taken any medications pr 1	YES	23-APR-2010 15:39:24 Lana Glaser	Row Inserted
Has the subject taken any medications pr 1	YES NO	26-APR-2010 13:24:26 Kim Freschly	Data Entry Error
Has the subject taken any medications pr 1	NO	26-APR-2010 13:28:09 Kim Freschly	Row Inserted

Document #: R286857213

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Pcm	Page_39 39

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

Group #	Group Name
1	CM1

Has the subject taken any medications pr 1	NO YES	02-JUN-2010 14:50:13 Lana Glaser	Data Entry Error
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Has the subject taken any medications pr 1	YES	02-JUN-2010 15:40:40 Lana Glaser	Row Inserted
--	-----	-------------------------------------	--------------

Indication 1	SINUSITIS	23-APR-2010 15:39:24 Lana Glaser	Row Inserted
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Indication 1	SINUSITIS	02-JUN-2010 14:50:13 Lana Glaser	Row Inserted
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Indication 1	MIGRAINE HEADACHE	02-JUN-2010 15:40:40 Lana Glaser	Row Inserted
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Ongoing 1		23-APR-2010 15:39:24 Lana Glaser	Row Inserted
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Ongoing 1		02-JUN-2010 14:50:13 Lana Glaser	Row Inserted
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Ongoing 1		02-JUN-2010 15:40:40 Lana Glaser	Row Inserted
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Preferred Term 1	AMOXICILLIN	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
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Preferred Term 1	MIDRID /00450801/	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change
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Preferred Term Code 1	00249601001	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
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Preferred Term Code 1	00450801001	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change
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Start Date 1	20-APR-2009	23-APR-2010 15:39:24 Lana Glaser	Row Inserted
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Start Date 1	20-APR-2010	02-JUN-2010 14:50:13 Lana Glaser	Row Inserted
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Start Date 1	03-AUG-2009	02-JUN-2010 15:40:40 Lana Glaser	Row Inserted
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Document #: R286857213

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Pcm	Page_39 39

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

Group #	Group Name
1	CM1

Stop Date 1	30-APR-2009	23-APR-2010 15:39:24 Lana Glaser	Row Inserted
Stop Date 1	30-APR-2009	02-JUN-2010 14:50:13 Lana Glaser	Row Inserted
Stop Date 1	04-AUG-2009	02-JUN-2010 15:40:40 Lana Glaser	Row Inserted
Trade Name 1	MIDRIN /00450801/	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change
Trade Name Code 1	00450801002	07-JUN-2010 12:22:09 Joanne Mccaigue	Class. Change
Unit 1	OTHER	23-APR-2010 15:39:24 Lana Glaser	Row Inserted
Unit 1	OTHER	02-JUN-2010 14:50:13 Lana Glaser	Row Inserted
Unit 1	OTHER	02-JUN-2010 15:40:40 Lana Glaser	Row Inserted
other, specify (frequency) 1		23-APR-2010 15:39:24 Lana Glaser	Row Inserted
other, specify (frequency) 1		02-JUN-2010 14:50:13 Lana Glaser	Row Inserted
other, specify (frequency) 1		02-JUN-2010 15:40:40 Lana Glaser	Row Inserted
other, specify (unit) 1	CAPSULE	23-APR-2010 15:39:24 Lana Glaser	Row Inserted
other, specify (unit) 1	CAPSULE	02-JUN-2010 14:50:13 Lana Glaser	Row Inserted
other, specify (unit) 1	CAP	02-JUN-2010 15:40:40 Lana Glaser	Row Inserted

Document #: R313268813

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Pcm.1	Page_39

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	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change
ATC1 Text 1	NERVOUS SYSTEM, N	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change
ATC2 Code 1	N07	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change
ATC2 Text 1	OTHER NERVOUS SYSTEM DRUGS, N07	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change
ATC3 Code 1	N07B	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change
ATC3 Text 1	DRUGS USED IN ADDICTIVE DISORDERS, N07B	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change
ATC4 Code 1	N07BA	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change
ATC4 Text 1	DRUGS USED IN NICOTINE DEPENDENCE, N07BA	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change
Ongoing 1	CHECKED	02-JUN-2010 17:02:29 Lana Glaser	Data Entry Error
Preferred Term 1	VARENICLINE TARTRATE	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change
Preferred Term Code 1	05703002001	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change
Start Date 1	UNK 24-AUG-2009	02-JUN-2010 17:02:29 Lana Glaser	Data Entry Error
Stop Date 1	UNK	03-JUN-2010 09:43:23 Kim Freschly	Data Entry Error
Trade Name 1	CHANTIX /05703002/	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change
Trade Name Code 1	05703002003	03-JUN-2010 10:21:16 Joanne Mccaigue	Class. Change

Document #: R286860813

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Additional Lab	Page_42 42

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	42	Additional Lab

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Clinically Significant (additional) (2) 1	NO		23-MAR-2010 09:33:43 Kim Freschly	Row Inserted
Comments 1			23-MAR-2010 09:33:43 Kim Freschly	Row Inserted
Comments 1	BLUE TOP TUBE NOT DRAWN, NOT IN BLOOD DRAW PACKET		23-MAR-2010 10:22:48 Kim Freschly	Data Entry Error
Date 1	30-JUL-2009		23-MAR-2010 09:33:43 Kim Freschly	Row Inserted
Requisition Number (additional labs) (4) 1	NA		23-MAR-2010 09:33:43 Kim Freschly	Row Inserted
Test Code ID CS Labs only 1			23-MAR-2010 09:33:43 Kim Freschly	Row Inserted
Test Name CS Labs only 1			23-MAR-2010 09:33:43 Kim Freschly	Row Inserted
Were any additional Laboratory evaluatio 1	NO YES		23-MAR-2010 09:33:43 Kim Freschly	Data Entry Error

Document #: R260440913

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Additional Vs	Page_43 43

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

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Actual Time 2	0928	07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Body Temperature 2	ND	07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Body Temperature Unit 2	C	07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Comments (2) 2		07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Date 2	30-JUL-2009	07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Diastolic Blood Pressure 2	85	07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Diastolic Blood Pressure unit 2	MMHG	07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Heart Rate 2	ND	07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Heart Rate Unit 2	BEATS/MINUTE	07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Other, specify (1) 2		07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Position (Unscheduled) (2) 2	SEATED	07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Respiratory Rate 2	ND	07-OCT-2009 14:32:30 Lana Glaser	Row Inserted
Respiratory Rate Unit 2	BREATHS/MINUTE	07-OCT-2009 14:32:30 Lana Glaser	Row Inserted

Document #: R260440913

Patient Site	Visit Visit Date	CRF CRF Page
R4053 P3880_0342	Additional Vs	Page_43 43

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

Group #	Group Name
1	VS

Systolic Blood Pressure 2	132	07-OCT-2009 14:32:30	Row Inserted Lana Glaser
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Systolic Blood Pressure unit 2	MMHG	07-OCT-2009 14:32:30	Row Inserted Lana Glaser
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Discrepancy Detail Report

Document #: R260439313

Discrepancy ID: 1782415113 Site: P3880_0342 Patient: R4053

Visit: SCREENING

Visit Date:

CRF: PAGE_04

Section: INFO_SESSION

Qualifying Value: 4

Field: Did the subject attend the information s

Row: 1

Value Text: YES

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Source correction/clarification

Internal Comment: Pls footnote page 1 screening source - time of information session is missing

Resolution Type: Confirmed

Resolution Text: comment added to source

Document #: R286853013

Discrepancy ID: 77690911

Site: P3880_0342

Patient: R4053

Visit: IP, WEEK 10

Visit Date:

CRF: PAGE_22

Section: VS

Qualifying Value: 22

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Cannot verify against source; no pages for Week 10. No correction to data required.

Internal Comment: visit 10 not performed, early visit

Resolution Type: No Action Required

Resolution Text:

Document #: R286853313

Discrepancy ID: 77691111

Site: P3880_0342

Patient: R4053

Visit: IP, WEEK 10

Visit Date:

CRF: PAGE_23

Section: ECO

Qualifying Value: 23

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Cannot verify against source; no pages for Week 10. No correction to data required.

Internal Comment: Please provide source.

NO SOURCE TO PROVIDE, EARLY TERM.

Resolution Type: No Action Required

Resolution Text:

Document #: R286853413

Discrepancy ID: 77691011

Site: P3880_0342

Patient: R4053

Visit: IP, WEEK 10

Visit Date:

CRF: PAGE_24

Section: EX

Qualifying Value: 24

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Cannot verify against source; no pages for Week 10. No correction to data required.

Internal Comment: Please provide blank pages as source.
NO SOURCE, EARLY TERM

Resolution Type: No Action Required

Resolution Text:

Document #: R286853713

Discrepancy ID: 77691311

Site: P3880_0342

Patient: R4053

Visit: IP, WEEK 13

Visit Date:

CRF: PAGE_25

Section: STATUS REVIEW

Qualifying Value: 25

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Cannot verify against source; no pages for Week 13. No correction to data required.

Internal Comment: Please provide source; source cannot be the absence of data in this case.
NO SOURCE, EARLY TERM

Resolution Type: No Action Required

Resolution Text:

Document #: R28685513

Discrepancy ID: 77692211

Site: P3880_0342

Patient: R4053

Visit: FU, WEEK 20 & 2 **Visit Date:**

CRF: PAGE_32

Section: STATUS REVIEW

Qualifying Value: 32

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Cannot verify against source; no pages for Week 20. No correction to data required.

Internal Comment: Please provide Week 20 completed as appropriate.
NO SOURCE, EARLY TERM

Resolution Type: No Action Required

Resolution Text:

Document #: R286857213

Discrepancy ID: 142079811

Site: P3880_0342

Patient: R4053

Visit: PCM

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: Please add 2 ConMeds (Chantix and Midrin) listed in source. Midrin was taken for a not relevant to study Med Hx of Migraine headaches and Chantix was taken as a smoking cessation aid.

Internal Comment: Chantix was taken prior to the subject discontinuing for study, however not reported to staff until date of discontinuation. As this is a protocol deviation and eNote will need to be issued to document this issue.

Resolution Type: Confirmed

Resolution Text: Verified. JLM 02Jun2010

Document #: R313268813

Discrepancy ID: 142199011 **Site:** P3880_0342 **Patient:** R4053
Visit: PCM.1 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Start Date **Row:** 1
Value Text: 20090824
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review start date - per source start date is 24Aug09
Internal Comment: corrected date
Resolution Type: Confirmed
Resolution Text: Verified. JLM 02Jun2010

Discrepancy ID: 142199111 **Site:** P3880_0342 **Patient:** R4053
Visit: PCM.1 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Stop Date **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review - per source use of chantix is ongoing
Internal Comment: please remove stop date - ongoing is checked
Resolution Type: Confirmed
Resolution Text: Verified. JLM 03Jun2010

Document #: R286857713

Discrepancy ID: 110586911 **Site:** P3880_0342 **Patient:** R4053
Visit: AE **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Action Taken **Row:** 1
Value Text: OTHER DRUG
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review; there are no relevant conmeds listed for this event
Internal Comment: Please verify AE source indicates a conmed was given and conmed source does not list a conmed for AE of sinusitis on 11-21Aug09. THERE IS NO MED FOR SINUSITIS.

per source a conmed was given; however, no additional information was provided.
Resolution Type: Confirmed
Resolution Text: Verified. JLM 02Jun2010

Discrepancy ID: 110587211 **Site:** P3880_0342 **Patient:** R4053
Visit: AE **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: There is no medications entered for this subject. Please add medication or update action taken.
Internal Comment: medication added to con meds
Resolution Type: Confirmed
Resolution Text: Verified. JLM 26Apr2010

Deleted CRFs Report