

CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 12:27:15

Report Parameters

Site: CDB_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1024

Ending patient: R1024

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

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Inclusion Criteria

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

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

* If No, document on Subject Eligibility Page.

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

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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

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="16-JUN-2009"/>	<input type="text" value="(b) (6)"/>	<input type="checkbox"/> Male	<input type="checkbox"/> Hispanic or Latino
		<input checked="" type="checkbox"/> Female	<input checked="" type="checkbox"/> Not Hispanic or latino
Race			
<input checked="" type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Black or African American	<input type="checkbox"/> American Indian/Alaskan Native		
<input type="checkbox"/> Asian	<input type="checkbox"/> Other		<input type="text"/>

Body Measurements

Were Body Measurements Collected? Yes No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="063.5"/>

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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	088
Heart Rate	BEATS/MINUTE	058
Respiratory Rate	BREATHS/MINUTE	016
Body Temperature	C	036.8
Weight	LB	157.2

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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: 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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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="16-JUN-2009"/>	<input type="text" value="11:05"/>
	<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	
1	CHRONIC BRONCHITIS	00-00-1998		<input checked="" type="checkbox"/> Ongoing
2	DENTURES FULL SET	00-00-2007		<input checked="" type="checkbox"/> Ongoing
3	CHRONIC COUGH	00-00-2001		<input checked="" type="checkbox"/> Ongoing
4	ACNE	00-00-1999		<input checked="" type="checkbox"/> Ongoing
5	TINEO CORPORIS	22-JUN-2009	22-AUG-2009	<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="20"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="25"/>	
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="1"/>	COLD TURKEY

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Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
16-JUN-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
16-JUN-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
16-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
16-JUN-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
16-JUN-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
23-JUN-2009	09:11	18	3.5	

Behavioral Counseling

Date	Parameter	Result	Comments
23-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

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="10"/> logs
1.0 g of snus or matching placebo	<input type="text" value="6"/> 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="30-JUN-2009"/>	<input type="text" value="WEEK 1"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="105"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="07-JUL-2009"/>	<input type="text" value="WEEK 2"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="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="14-JUL-2009"/>	<input type="text" value="WEEK 3"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="84"/>	<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?	<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	125
Diastolic Blood Pressure	MMHG	092
Heart Rate	BEATS/MINUTE	069
Respiratory Rate	BREATHS/MINUTE	020
Body Temperature	C	036.5
Weight	LB	148.6

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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

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
04-AUG-2009	09:07	20	3.8	

Behavioral Counseling

Date	Parameter	Result	Comments
04-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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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="2"/> 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="04-AUG-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="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

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

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

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Page Version No. PAGE_21 (v1, 25-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

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	078
Heart Rate	BEATS/MINUTE	075
Respiratory Rate	BREATHS/MINUTE	020
Body Temperature	C	037.1
Weight	LB	147.0

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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
31-AUG-2009	09:22	19	3.6	

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?
MNWS 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

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="2"/> logs
1.0 g of snus or matching placebo	<input type="text" value="1"/> logs

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="70"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions? Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="23-SEP-2009"/>	Was Subject 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"/>
	Was Subject instructed to cut down on product use during upcoming Weeks 14-16 to avoid a too abrupt ending of nicotine uptake?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

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	080
Heart Rate	BEATS/MINUTE	061
Respiratory Rate	BREATHS/MINUTE	016
Body Temperature	C	036.8
Weight	LB	143.8

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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

* Indicate NE if system was not examined.

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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
15-OCT-2009	09:39	21	3.9	

Behavioral Counseling

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

Questionnaires

Date

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="15-OCT-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="105"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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

Date Scheduled Timepoint

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

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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	089
Heart Rate	BEATS/MINUTE	064
Respiratory Rate	BREATHS/MINUTE	016
Body Temperature	C	036.5
Weight	LB	141.6

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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"/>

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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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
06-JAN-2010	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
06-JAN-2010	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
06-JAN-2010	OTHER ORAL KERATOSIS	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>

* Indicate NE if system was not examined.

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Page Version No. PAGE_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
06-JAN-2010	09:44	19	3.6	

Behavioral Counseling

Date	Parameter	Result	Comments
06-JAN-2010	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="06-JAN-2010"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="105"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<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

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

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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?

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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

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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

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

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

Frequency Select only one

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

Start Date1

Stop Date1

Ongoing

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

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

Document Number

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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

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

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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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Laboratory Evaluations

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

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	122
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	089
<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	131
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	088
<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](#)

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

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

Investigator Comments (if none, leave blank):

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

Verified Approved Locked Frozen

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

Document Number

Appendix: Audit and Discrepancy Information

Audit History Report

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

Document #: **R254399913**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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 Resolution 2	00-00-2007	01-MAR-2010 11:02:45 Christina Breedlove	Data Entry Error Confirmed to be ongoing
Ongoing 2	CHECKED	01-MAR-2010 11:02:45 Christina Breedlove	Data Entry Error
Date of Onset 3		18-DEC-2009 10:34:06 Heather Kretschmer	Row Inserted
Date of Onset 3	00-00-2001	07-JAN-2010 09:21:32 Sharon Daly	Data Entry Error
Date of Resolution 3		18-DEC-2009 10:34:06 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 3		18-DEC-2009 10:34:06 Heather Kretschmer	Row Inserted
Diagnosis/Procedure 3	CHRONIC COUGH	07-JAN-2010 09:21:32 Sharon Daly	Data Entry Error
Ongoing 3		18-DEC-2009 10:34:06 Heather Kretschmer	Row Inserted
Ongoing 3	CHECKED	07-JAN-2010 09:21:32 Sharon Daly	Data Entry Error
Sequence Number 3		18-DEC-2009 10:34:06 Heather Kretschmer	Row Inserted
Sequence Number 3	3	07-JAN-2010 09:21:32 Sharon Daly	Data Entry Error
Date of Onset 4	00-00-1999	07-JAN-2010 09:21:32 Sharon Daly	Row Inserted
Date of Resolution 4		07-JAN-2010 09:21:32 Sharon Daly	Row Inserted
Diagnosis/Procedure 4	ACNE	07-JAN-2010 09:21:32 Sharon Daly	Row Inserted

Document #: **R254399913**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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

Ongoing		07-JAN-2010 09:21:32	Row Inserted
4	CHECKED	Sharon Daly	
Sequence Number		07-JAN-2010 09:21:32	Row Inserted
4	4	Sharon Daly	
Date of Onset		20-APR-2010 14:01:44	Row Inserted
5	22-JUN-2009	Christina Breedlove	
Date of Resolution		20-APR-2010 14:01:44	Row Inserted
5	22-AUG-2009	Christina Breedlove	
Diagnosis/Procedure		20-APR-2010 14:01:44	Row Inserted
5	TINEO CORPORA	Christina Breedlove	
Diagnosis/Procedure		20-APR-2010 14:13:33	Investigator Correction
5	TINEO CORPORIS	Christina Breedlove	
Ongoing		20-APR-2010 14:01:44	Row Inserted
5		Christina Breedlove	
Sequence Number		20-APR-2010 14:01:44	Row Inserted
5	5	Christina Breedlove	

Document #: **R255966513**

Patient Site	Visit Visit Date	CRF CRF Page	
R1024 CDB_001	Sptp, Weeks 1-4	Page_16 16	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16A	Sptp, Weeks 1-4

Group #	Group Name
0	Section Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCM Blank flag 1	N Y	07-JUL-2009 09:33:01 Sharon Daly	Key Change
DCM Blank flag 1	Y N	14-JUL-2009 14:39:02 Rossana Matos	CRA Correction

Document #: **R255966513**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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 resequence	On By	Reason Comment
DCM Blank flag 1	N Y		07-JUL-2009 09:33:01 Sharon Daly	Key Change
DCM Blank flag 1	Y N		23-JUL-2009 13:03:42 Sharon Daly	Data Entry Error

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Approximately how many cigarettes did th (10) 1	56-70 70		15-OCT-2009 14:08:32 Sharon Daly	Data Entry Error

Document #: **R266284413**

Patient Site	Visit Visit Date	CRF CRF Page	
R1024 CDB_001	Ip, Week 10	Page_22 22	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	22	Ip, Week 10

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Weight 1	147 147.0	25-MAR-2010 10:31:09 Christina Breedlove	Data Entry Error Decimal added Per Query

Document #: **R274518713**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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
Findings 1	WHEEZING RIGHT LOWER LOBE WHEEZING RIGHT LOWER LOBE (BRONCHITIS)	15-OCT-2009 14:07:47 Rossana Matos	Data Entry Error

Document #: **R274519113**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Ip, Week 16	Page_31 31

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	31	Ip, Week 16

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	15 105	10-FEB-2010 18:05:13 Christina Breedlove	Data Entry Error per query

Document #: **R278828713**

Patient Site	Visit Visit Date	CRF CRF Page	
R1024 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
Was Subject contacted by telephone (1) 1	NO YES	07-JAN-2010 09:44:23 Sharon Daly	Data Entry Error
Was Subject's smoking status reviewed (2) 1	NO YES	07-JAN-2010 09:44:23 Sharon Daly	Data Entry Error

Document #: **R286931513**

Patient Site	Visit Visit Date	CRF CRF Page	
R1024 CDB_001	Fu, Week 28	Page_33 33	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	33	Fu, Week 28

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	06-JAN-2009 06-JAN-2010	03-MAR-2010 16:30:28 Christina Breedlove	Data Entry Error

Document #: **R286931613**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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
Were there any clinically significant la (1) 1	NO	10-FEB-2010 18:06:49 Christina Breedlove	Data Entry Error

Document #: R266135313

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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	A G	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A GENITO URINARY SYSTEM AND SEX HORMONES, G	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A01 G01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS, G01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A01A G01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS, G01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A01AB G01AF	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	ANTIINFECT. AND ANTISEPT. FOR LOCAL ORAL TREATMENT, A01AB IMIDAZOLE DERIVATIVES, G01AF	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Drug name 1	MICONAZOLE MICONAZOLE NITRATE	10-FEB-2010 18:07:55 Christina Breedlove	Data Entry Error
Frequency 1	EVERY DAY AT BEDTIME	11-NOV-2009 14:44:09 Rossana Matos	Pass1
Frequency 1	AT BEDTIME EVERY DAY	11-NOV-2009 14:44:43 Rossana Matos	Pass1
Unit 1	OTHER	28-AUG-2009 14:30:02 Christina Breedlove	Pass1

Document #: **R266135313**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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

other, specify (unit) 1	CREAM	10-FEB-2010 18:07:55 Christina Breedlove	Data Entry Error
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Document #: R266136413

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	D	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC1 Text 1	DERMATOLOGICALS, D	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Code 1	D01	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Text 1	ANTIFUNGALS FOR DERMATOLOGICAL USE, D01	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC3 Code 1	D01A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC3 Text 1	ANTIFUNGALS FOR TOPICAL USE, D01A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC4 Code 1	D01AC	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC4 Text 1	IMIDAZOLE AND TRIAZOLE DERIVATIVES, D01AC	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Drug Modified Reported Term 1	KETOCONAZOLE CREAM KETOCONAZOLE CREAM	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	KETOCONAZOLE CREAM KETOCONAZOLE CREAM	09-APR-2010 12:00:19 Joanne Mccaigue	ODM/SEC Obvious spelling error. JLM 09Apr2010
Frequency 1	EVERY DAY TWICE DAILY	11-NOV-2009 14:45:06 Rossana Matos	Pass1
Frequency 1	TWICE DAILY EVERY DAY	11-NOV-2009 14:45:24 Rossana Matos	Pass1
Indication 1	FUNGUS TINEO CORPORA	11-FEB-2010 16:19:01 Christina Breedlove	Data Entry Error

Document #: **R266136413**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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

Indication 1	TINEO CORPORA TINEO CORPORIS	09-APR-2010 12:00:19 Joanne Mccaigue	ODM/SEC Obvious spelling error. JLM 09Apr2010
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Indication 1	TINEO CORPORIS TINEO CORPORA	03-JUN-2010 10:52:57 Christina Breedlove	Data Entry Error spelling correction
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Preferred Term 1	KETOCONAZOLE	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
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Preferred Term Code 1	00532501001	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
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other, specify (unit) 1	CREAM	11-FEB-2010 15:29:31 Christina Breedlove	Data Entry Error
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Document #: **R279074613**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Pcm.2	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A J	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A ANTIINFECTIVES FOR SYSTEMIC USE, J	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	A01 J01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANTIBACTERIALS FOR SYSTEMIC USE, J01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	A01A J01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A TETRACYCLINES, J01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	A01AB J01AA	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Text 1	ANTIINFECT. AND ANTISEPT. FOR LOCAL ORAL TREATMENT, A01AB TETRACYCLINES, J01AA	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change

Document #: **R279075413**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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
ATC1 Code 1	D H	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	DERMATOLOGICALS, D SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	D07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, D07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	D07A H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	CORTICOSTEROIDS, PLAIN, D07A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	D07AA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Text 1	CORTICOSTEROIDS, WEAK (GROUP I), D07AA GLUCOCORTICIODS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change

Document #: **R279075813**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Pcm.4	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Drug name 1	PROVANTIL PROVENTIL	03-DEC-2009 08:44:08 Sharon Daly	Data Entry Error

Document #: **R279076613**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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 On resequence By	Reason Comment
Frequency 1	FOUR TIMES DAILY EVERY DAY	11-FEB-2010 15:30:23 Christina Breedlove	Data Entry Error
Start Date 1	18-OCT-2009 08-OCT-2009	11-NOV-2009 14:52:33 Rossana Matos	Pass1
Stop Date 1	12OCT2009 12-OCT-2009	11-NOV-2009 14:52:33 Rossana Matos	Pass1

Document #: **R279077013**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Pcm.6	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.6

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	ANTIIDIARR., INTEST. ANTIINFL./ANTIINFECT. AGENTS, A07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A07E H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	INTESTINAL ANTIINFLAMMATORY AGENTS, A07E CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A07EA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS ACTING LOCALLY, A07EA GLUCOCORTICIODS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Frequency 1	OTHER THREE TIMES DAILY	13-APR-2010 13:16:04 Christina Breedlove	Investigator Correction Separated decending doses
Frequency 1	THREE TIMES DAILY	03-JUN-2010 15:50:19 Sharon Daly	Data Entry Error
Frequency 1	OTHER	03-JUN-2010 15:51:20 Sharon Daly	Data Entry Error
Stop Date 1	17-OCT-2009 11-OCT-2009	13-APR-2010 13:16:04 Christina Breedlove	Investigator Correction Separated decending doses

Document #: **R279077013**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Pcm.6	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.6

Group #	Group Name
1	CM1

Stop Date	11-OCT-2009	13-APR-2010 13:22:54	Data Entry Error
1	10-OCT-2009	Christina Breedlove	
Stop Date	10-OCT-2009	03-JUN-2010 15:15:03	Data Entry Error
1	17-OCT-2009	Christina Breedlove	Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009.
other, specify (frequency)	TID 3 DAYS, BID 3 DAYS, QD 3 DAYS	13-APR-2010 13:16:04	Investigator Correction Separated decending doses
1		Christina Breedlove	
other, specify (frequency)	UNK	03-JUN-2010 15:50:19	Data Entry Error
1		Sharon Daly	

Document #: **R282869713**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Pcm.7	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.7

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Frequency 1	EVERY MORNING EVERY DAY	11-FEB-2010 15:31:24 Christina Breedlove	Data Entry Error
Ongoing 1	CHECKED	11-FEB-2010 15:32:34 Christina Breedlove	Data Entry Error
Stop Date 1	17-OCT-2009	11-FEB-2010 15:32:34 Christina Breedlove	Data Entry Error confirmed

Document #: **R302474613**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Pcm.8	Page_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	03-JUN-2010 15:22:45 Christina Breedlove	Key Change

Document #: R302474613

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Pcm.8	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.8

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC1 Code 1	A H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A07	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC2 Code 1	A07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	ANTIDIARR., INTEST. ANTIINFL./ANTIINFECT. AGENTS, A07	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC2 Text 1	ANTIDIARR., INTEST. ANTIINFL./ANTIINFECT. AGENTS, A07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A07E	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC3 Code 1	A07E H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	INTESTINAL ANTIINFLAMMATORY AGENTS, A07E	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change

Document #: R302474613

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Pcm.8	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.8

Group #	Group Name
1	CM1

ATC3 Text 1	INTESTINAL ANTIINFLAMMATORY AGENTS, A07E CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A07EA	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC4 Code 1	A07EA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS ACTING LOCALLY, A07EA	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS ACTING LOCALLY, A07EA GLUCOCORTICIODS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Dose 1	20	03-JUN-2010 15:19:50 Christina Breedlove	Data Entry Error Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.
Drug name 1	PREDNISONE	03-JUN-2010 15:19:50 Christina Breedlove	Data Entry Error Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.

Document #: R302474613

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Pcm.8	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.8

Group #	Group Name
1	CM1

Frequency	TWICE DAILY	03-JUN-2010 15:19:50	Data Entry Error
1		Christina Breedlove	Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.

Has the subject taken any medications pr	YES	03-JUN-2010 15:19:50	Data Entry Error
1		Christina Breedlove	Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.

Indication	BRONCHITIS	03-JUN-2010 15:19:50	Data Entry Error
1		Christina Breedlove	Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.

Preferred Term		26-APR-2010 12:04:29	Class. Change
1	PREDNISONE	Joanne Mccaigue	

Preferred Term Code		26-APR-2010 12:04:29	Class. Change
1	00044701001	Joanne Mccaigue	

Start Date	11-OCT-2009	03-JUN-2010 15:19:50	Data Entry Error
1		Christina Breedlove	

Stop Date	14-OCT-2009	13-APR-2010 13:22:27	Data Entry Error
1	13-OCT-2009	Christina Breedlove	

Document #: **R302474613**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Pcm.8	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.8

Group #	Group Name
1	CM1

Stop Date	13-OCT-2009	03-JUN-2010 15:19:50 Christina Breedlove	Data Entry Error Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.
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Unit	MILLIGRAMS	03-JUN-2010 15:19:50 Christina Breedlove	Data Entry Error Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.
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Document #: **R302475113**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Pcm.9	Page_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	03-JUN-2010 15:24:56 Christina Breedlove	Key Change

Document #: R302475113

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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	A	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC1 Code 1	A H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A07	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC2 Code 1	A07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	ANTIDIARR., INTEST. ANTIINFL./ANTIINFECT. AGENTS, A07	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC2 Text 1	ANTIDIARR., INTEST. ANTIINFL./ANTIINFECT. AGENTS, A07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A07E	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC3 Code 1	A07E H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	INTESTINAL ANTIINFLAMMATORY AGENTS, A07E	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change

Document #: **R302475113**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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

ATC3 Text 1	INTESTINAL ANTIINFLAMMATORY AGENTS, A07E CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A07EA	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC4 Code 1	A07EA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS ACTING LOCALLY, A07EA	26-APR-2010 12:04:29 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS ACTING LOCALLY, A07EA GLUCOCORTICIODS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Dose 1	20	03-JUN-2010 15:23:17 Christina Breedlove	Data Entry Error Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.
Drug name 1	PREDNISONE	03-JUN-2010 15:23:17 Christina Breedlove	Data Entry Error Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.

Document #: **R302475113**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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

Frequency	EVERY DAY	03-JUN-2010 15:23:17	Data Entry Error
1		Christina Breedlove	Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.

Has the subject taken any medications pr	YES	03-JUN-2010 15:23:17	Data Entry Error
1		Christina Breedlove	Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.

Indication	BRONCHITIS	03-JUN-2010 15:23:17	Data Entry Error
1		Christina Breedlove	Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.

Preferred Term		26-APR-2010 12:04:29	Class. Change
1	PREDNISONE	Joanne Mccaigue	

Preferred Term Code		26-APR-2010 12:04:29	Class. Change
1	00044701001	Joanne Mccaigue	

Document #: **R302475113**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 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

Start Date	14-OCT-2009	03-JUN-2010 15:23:17	Data Entry Error
1		Christina Breedlove	Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.

Stop Date	17-OCT-2009	03-JUN-2010 15:23:17	Data Entry Error
1		Christina Breedlove	Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.

Unit	MILLIGRAMS	03-JUN-2010 15:23:17	Data Entry Error
1		Christina Breedlove	Subject went to ER on 08-Oct-2009 and was given prednisone 20 mg to take 3xday & stopped medication on 17-Oct-2009. Prednisone con med has been updated on Pcm.6 pg39.

Document #: **R266283413**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Ae	Page_40 40

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	20-APR-2010 16:09:05 Christina Breedlove	Data Entry Error

Document #: **R266283413**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Ae	Page_40 40

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

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Taken 1	OTHER DRUG	20-APR-2010 16:03:33 Christina Breedlove	Investigator Correction Confirmed with source, onset date of "Tinea Corporis" was added to med hx and CRF AE page will be removed. Subject's source has been updated.
Adverse Event 1	TINEA CORPORA TINEA CORPORIS	19-APR-2010 14:08:46 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 19Apr2010
High Level Group Term 1	FUNGAL INFECTIOUS DISORDERS	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
High Level Group Term Code 1	10017528	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
High Level Term 1	TINEA INFECTIONS	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
High Level Term Code 1	10043870	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Lower Level Term 1	TINEA CORPORIS	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Lower Level Term Code 1	10043867	20-APR-2010 11:39:56 Carol Kraucyk	Data Change

Document #: **R266283413**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Ae	Page_40 40

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

Group #	Group Name
1	AE1

Onset Date	22-JUN-2009	20-APR-2010 16:03:33	Investigator Correction Confirmed with source, onset date of "Tinea Corporis" was added to med hx and CRF AE page will be removed. Subject's source has been updated.
1		Christina Breedlove	

Onset Time	UNK	20-APR-2010 16:03:33	Investigator Correction Confirmed with source, onset date of "Tinea Corporis" was added to med hx and CRF AE page will be removed. Subject's source has been updated.
1		Christina Breedlove	

Outcome to Date	RECOVERED	20-APR-2010 16:03:33	Investigator Correction Confirmed with source, onset date of "Tinea Corporis" was added to med hx and CRF AE page will be removed. Subject's source has been updated.
1		Christina Breedlove	

Preferred Term		20-APR-2010 11:39:56	Data Change
1	BODY TINEA	Carol Kraucyk	

Preferred Term Code	10005913	20-APR-2010 11:39:56	Data Change
1		Carol Kraucyk	

Document #: R266283413

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Ae	Page_40 40

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

Group #	Group Name
1	AE1

Relationship to Date 1	NOT RELATED	20-APR-2010 16:03:33 Christina Breedlove	Investigator Correction Confirmed with source, onset date of "Tinea Corporis" was added to med hx and CRF AE page will be removed. Subject's source has been updated.
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Resolved Date 1	22-AUG-2009	20-APR-2010 16:03:33 Christina Breedlove	Investigator Correction Confirmed with source, onset date of "Tinea Corporis" was added to med hx and CRF AE page will be removed. Subject's source has been updated.
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Resolved Time 1	0800	20-APR-2010 16:03:33 Christina Breedlove	Investigator Correction Confirmed with source, onset date of "Tinea Corporis" was added to med hx and CRF AE page will be removed. Subject's source has been updated.
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Serious Event 1	NO	20-APR-2010 16:03:33 Christina Breedlove	Investigator Correction Confirmed with source, onset date of "Tinea Corporis" was added to med hx and CRF AE page will be removed. Subject's source has been updated.
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Document #: **R266283413**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Ae	Page_40 40

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

Group #	Group Name
1	AE1

Severity 1	MILD	20-APR-2010 16:03:33 Christina Breedlove	Investigator Correction Confirmed with source, onset date of "Tinea Corporis" was added to med hx and CRF AE page will be removed. Subject's source has been updated.
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System Organ Class 1	INFECTIONS AND INFESTATIONS	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
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System Organ Class Code 1	10021881	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
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Verbatim Term 1	TINEA CORPORA TINEA CORPORIS	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
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Document #: **R279072013**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Ae.2	Page_40

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
Action Taken 1	OTHER TREATMENT OTHER DRUG	31-DEC-2009 11:58:58 Sharon Daly	Data Entry Error

Document #: **R286939513**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Additional Ecg	Page_41 41

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	07-JAN-2010 15:49:03 Sharon Daly	Data Entry Error

Document #: **R286939613**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Additional Lab	Page_42 42

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	07-JAN-2010 15:48:16 Sharon Daly	Data Entry Error

Document #: **R286939813**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Additional Vs	Page_43 43

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	07-JAN-2010 15:47:47 Sharon Daly	Data Entry Error

Document #: R286939813

Patient Site	Visit Visit Date	CRF CRF Page
R1024	Additional Vs	Page_43
CDB_001		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 1	0902	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Body Temperature 1	NA	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Body Temperature 1	NA ND	25-FEB-2010 13:38:10 Christina Breedlove	Data Entry Error
Body Temperature Unit 1	C	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Comments (2) 1	0902	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Comments (2) 1	0902	11-FEB-2010 15:21:01 Christina Breedlove	Data Entry Error
Date 1	04-AUG-2009	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Diastolic Blood Pressure 1	089	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Diastolic Blood Pressure unit 1	MMHG	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Heart Rate 1	NA	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Heart Rate 1	NA ND	25-FEB-2010 13:38:10 Christina Breedlove	Data Entry Error
Heart Rate Unit 1	BEATS/MINUTE	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Other, specify (1) 1		10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Position (Unscheduled) (2) 1	SEATED	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted

Document #: **R286939813**

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	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

Respiratory Rate 1	NA	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Respiratory Rate 1	NA ND	25-FEB-2010 13:38:10 Christina Breedlove	Data Entry Error
Respiratory Rate Unit 1	BREATHS/MINUTE	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Systolic Blood Pressure 1	122	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Systolic Blood Pressure unit 1	MMHG	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Were Vital Signs Collected/Were any addi (1) 1	NO YES	10-FEB-2010 18:09:54 Christina Breedlove	Data Entry Error
Actual Time 2	0927	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Body Temperature 2	NA	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Body Temperature 2	NA ND	25-FEB-2010 13:38:10 Christina Breedlove	Data Entry Error
Body Temperature Unit 2	C	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Comments (2) 2		10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Date 2	15-OCT-2009	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Diastolic Blood Pressure 2	088	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Diastolic Blood Pressure unit 2	MMHG	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted
Heart Rate 2	NA	10-FEB-2010 18:12:20 Christina Breedlove	Row Inserted

Document #: R286939813

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	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		
Heart Rate	NA	25-FEB-2010 13:38:10	Data Entry Error
2	ND	Christina Breedlove	
Heart Rate Unit		10-FEB-2010 18:12:20	Row Inserted
2	BEATS/MINUTE	Christina Breedlove	
Other, specify		10-FEB-2010 18:12:20	Row Inserted
(1)		Christina Breedlove	
2			
Position		10-FEB-2010 18:12:20	Row Inserted
(Unscheduled)	SEATED	Christina Breedlove	
(2)			
2			
Respiratory Rate		10-FEB-2010 18:12:20	Row Inserted
2	NA	Christina Breedlove	
Respiratory Rate	NA	25-FEB-2010 13:38:10	Data Entry Error
2	ND	Christina Breedlove	
Respiratory Rate		10-FEB-2010 18:12:20	Row Inserted
Unit	BREATHS/MINUTE	Christina Breedlove	
2			
Systolic Blood		10-FEB-2010 18:12:20	Row Inserted
Pressure	131	Christina Breedlove	
2			
Systolic Blood		10-FEB-2010 18:12:20	Row Inserted
Pressure unit	MMHG	Christina Breedlove	
2			

Discrepancy Detail Report

Document #: **R254399913**

Discrepancy ID: 36034311 Site: CDB_001 Patient: R1024
Visit: SCREENING Visit Date:
CRF: PAGE_09 Section: MH Qualifying Value: 9
Field: Date of Onset Row: 3
Value Text: 2001
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy:
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 73237811 Site: CDB_001 Patient: R1024
Visit: SCREENING Visit Date:
CRF: PAGE_09 Section: MH Qualifying Value: 9
Field: Date of Resolution Row: 2
Value Text:
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: **Please verify if date of resolution should be present. If subject continues to require a full set of dentures, please remove resolution date and check 'Ongoing'.**
Internal Comment: Confirmed to be ongoing
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 23055811 Site: CDB_001 Patient: R1024
Visit: SCREENING Visit Date:
CRF: PAGE_09 Section: MH Qualifying Value: 9
Field: Diagnosis/Procedure Row: 3
Value Text: CHRONIC COUGH
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: **please verify that chronic cough and acne.**
Internal Comment: will add
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

R254399913

Discrepancy ID: 1717721613 **Site:** CDB_001 **Patient:** R1024
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Does the subject have any relevant medic **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please have MD assign relevance. Update CRF as necessary.
Internal Comment: investigator find relevance, but NCS.
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 36034211 **Site:** CDB_001 **Patient:** R1024
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Sequence Number **Row:** 3
Value Text: 3
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy:
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R255966513

Discrepancy ID: 1717721713 **Site:** CDB_001 **Patient:** R1024

Visit: SPTP, WEEKS 1-4 **Visit Date:**

CRF: PAGE_16 **Section:** STATUS REVIEW **Qualifying Value:** 16B

Field: Approximately how many cigarettes did th **Row:** 1

Value Text: 70

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please enter highest number when range is given.

Internal Comment:

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

Resolution Text:

Document #: R265766013

Discrepancy ID: 36034511 **Site:** CDB_001 **Patient:** R1024
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: UNK
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy:
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 23063911 **Site:** CDB_001 **Patient:** R1024
Visit: IP, WEEK 6 **Visit Date:**
CRF: PAGE_20 **Section:** STATUS REVIEW **Qualifying Value:** 20
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify should be UNK since week 6 diary is not present.
Internal Comment: verified, will change to UNK
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R266284413

Discrepancy ID: 90338311

Site: CDB_001

Patient: R1024

Visit: IP, WEEK 10

Visit Date:

CRF: PAGE_22

Section: VS

Qualifying Value: 22

Field: Weight

Row: 1

Value Text: 147.0

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please report weight with one decimal.

Internal Comment: Decimal added Per Query

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

Resolution Text:

Document #: R274519113

Discrepancy ID: 58657811 **Site:** CDB_001 **Patient:** R1024
Visit: IP, WEEK 16 **Visit Date:**
CRF: PAGE_31 **Section:** STATUS REVIEW **Qualifying Value:** 31
Field: If Subject was not compliant, approximat **Row:** 1
Value Text: 105
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify should be 105 as it was 15 per day.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R278828713

Discrepancy ID: 23070711 **Site:** CDB_001 **Patient:** R1024
Visit: FU, WEEK 20 & 2 **Visit Date:**
CRF: PAGE_32 **Section:** STATUS REVIEW **Qualifying Value:** 32
Field: Was Subject contacted by telephone **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify should be yes
Internal Comment: should be yes
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 23070811 **Site:** CDB_001 **Patient:** R1024
Visit: FU, WEEK 20 & 2 **Visit Date:**
CRF: PAGE_32 **Section:** STATUS REVIEW **Qualifying Value:** 32
Field: Was Subject's smoking status reviewed **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify should be yes.
Internal Comment: verified
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R286931513

Discrepancy ID: 76421211

Site: CDB_001

Patient: R1024

Visit: FU, WEEK 28

Visit Date:

CRF: PAGE_33

Section: VS

Qualifying Value: 33

Field: Date

Row: 1

Value Text: 20100106

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify updating date to 06-Jan-2010.

Internal Comment:

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

Resolution Text:

Document #: R286931613

Discrepancy ID: 59184011

Site: CDB_001

Patient: R1024

Visit: FU, WEEK 28

Visit Date:

CRF: PAGE_34

Section: LB

Qualifying Value: 34

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify per guidelines "no" should be checked.

Internal Comment: per CRF guidelines

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

Resolution Text:

Document #: R279076613

Discrepancy ID: 59188111

Site: CDB_001

Patient: R1024

Visit: PCM.5

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Frequency

Row: 1

Value Text: EVERY DAY

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify per source.

Internal Comment: confirmed

Resolution Type: Confirmed

Resolution Text:

Document #: R279077013

Discrepancy ID: 142912711 **Site:** CDB_001 **Patient:** R1024
Visit: PCM.6 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Frequency **Row:** 1
Value Text: OTHER
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify if three times daily should be changed to unknown. Per source, it is not clear.
Internal Comment: unk
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Discrepancy ID: 98505911 **Site:** CDB_001 **Patient:** R1024
Visit: PCM.6 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: other, specify (frequency) **Row:** 1
Value Text: UNK
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: This medication needs to be split into 3 separate medications - 1 for each frequency. Please add separate medication forms for the TID, BID and QD frequencies.
Internal Comment: Separated decending doses
Resolution Type: Confirmed
Resolution Text: Verified. JLM 19Apr2010

Document #: R286939813

Discrepancy ID: 63190611 **Site:** CDB_001 **Patient:** R1024
Visit: ADDITIONAL VS **Visit Date:**
CRF: PAGE_43 **Section:** VS **Qualifying Value:** 43
Field: Comments **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify comment is not needed and delete.
Internal Comment: per query
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 59230311 **Site:** CDB_001 **Patient:** R1024
Visit: ADDITIONAL VS **Visit Date:**
CRF: PAGE_43 **Section:** VS **Qualifying Value:** 43
Field: Were Vital Signs Collected/Were any addi **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify there was a repeat at week 6 and 16 visit.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Deleted CRFs Report