### 16.1.2 Sample Case Report Form

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

#### RDC CASE REPORT FORM

# 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

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### **INCLUSION CRITERIA**

_	who meet the following criteria may be included in the study. Did the subject following criteria requirements for inclusion? (✓ Yes or No)	Yes 1	<b>No*</b> 2
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.		
02	The subject smokes > 9 cigarettes per day (average daily consumption during past month).		
03	The subject has smoked daily for > 1 year.		
04	The subject is motivated to quit smoking with the help of a smokeless tobacco alternative.		
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		
06	The subject practices, by self-report, good oral hygiene (including brushing teeth at least twice per day and having regular dental check-ups).		
07	The subject is able and willing to provide written informed consent.		
08	The subject agrees to comply with the requirements of the protocol and complete study measures.		
09	The subject has stable residence and telephone.		

<sup>\*</sup>If No, document on Subject Eligibility Page.

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SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### **EXCLUSION CRITERIA**

	ollowing will exclude potential subjects from the study. Does the subject have any e following? (✓ Yes or No)	Yes*	<b>No</b> 2
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.		
02	The subject is a female who is pregnant or lactating.		
03	The subject has oral conditions that could potentially be made worse by use of study product, for instance, exposed dental cervices in the upper sulcus.		
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.		
05	The subject has a history of clinically significant renal, hepatic, neurological, or chronic pulmonary disease that in the judgment of the investigator precludes participation.		
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 of the investigator precludes participation.		
07	The subject has a history of alcohol or substance abuse or dependence other than cigarette smoking within the past year		
08	Use of any illicit drug or smoked marijuana in the last 3 months.		
09	The subject is unwilling to be randomized into active or placebo conditions, or be available for follow-up assessments.		_
10	The subject resides in a household where another member is currently participating in the study.		

<sup>\*</sup>If Yes, document on Subject Eligibility Page.

SWEDISH MATCH AB			S	ubject Number:	
Protocol Number: SM 08-01 Investigator:  Covance Study Number: 7694-105 Site:				ubject Initials:	
			INFORMATION SESSION		
Date of Inf	ormation Ses	sion	Did the subject attend the Information Session?	Commer	nts
/_ DD/MMM/	/ YYYY		1 Yes 2 No (explain, if No)		
	SUBJECT ELIGIBILITY				
Date the S	Date the Subject Signed the Informed Consent Form:/ DD/MMM/YYYY				
Did the su	bject meet all	of the	inclusion/exclusion criteria? 1 🔲 Y	es <sub>2</sub> No	
If the subject explanation		et all c	of the Inclusion/Exclusion criteria, pro	ovide criterio	on number and
Category	Inclusion/ Exclusion No.	Expla	nation	Exemption Granted?	If Yes, Date Granted DD/MMM/YYYY
1 ☐ Inclusion 2 ☐ Exclusion				1☐ Yes 2☐ No	
1 ☐ Inclusion 2 ☐ Exclusion				1 Yes 2 No	
1 Inclusion				₁☐ Yes	

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:
<u> </u>		

### **DEMOGRAPHICS**

Date DD/MMM/YYYY	Date of Birth DD/MMM/YYYY	Gender	Ethnicity
		$_{1}$ $\square$ Male $_{2}$ $\square$ Female	<ul><li>Hispanic or Latino</li><li>Not Hispanic or Latino</li></ul>
Race			
1	· =	waiian or Other Pacific Isla Indian/Alaskan Native	ander

### **BODY MEASUREMENTS**

Were Body Measurements Collected?		Date DD/MMM/YYYY
1  Yes 2 No		
Parameter	Unit	Result
Height	in	·

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### **VITAL SIGNS**

Were vital signs collected?	Date DD/MMM/YYYY	Actual Time 24-hour clock	Was Subject seated for 5 minutes?
1 Yes 2 No		::	1 Yes 2 No
Parameter	Unit	Result	
Systolic Blood Pressure	mmHg		
Diastolic Blood Pressure	mmHg		
Heart Rate	beats/minute		
Respiratory Rate	breaths/minute		
Body Temperature	°C	·	
Weight	lb	·	

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01	Investigator:	Subject Initials:
Covance Study Number: 7694-105	Site:	

#### LABORATORY EVALUATIONS

Were the scheduled laboratory samples obtained?			Date DD/MMM/YYYY	
1 Yes 2 No (Specify samples not done, r	eason):			
Evaluation: Safety Urine & Blood Tes	sts; Biomarker Bloo	d Tests		
Requisition Number 1:				
Requisition Number 2 (if applicable	e):			
Requisition Number 3 (if applicable	e):			
Were there any clinically significan	t labs? 1 Tyes (s	specify below) 2	No	
Requisition Number	Test Name Test Code		Test Code II	D
Note: Attach copy of signed laboratory report.				
URINE PREGNANCY TEST				
Result				
1 Positive 2 Negative	sitive 2 Negative 9 N/A, Male or Woman of Non-childbearing Potential		otential	
URINE DRUG SCREEN				
Drug Screen Result*				_
<sub>1</sub> Positive <sub>2</sub> Negative				

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

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01	Investigator:	Subject Initials:
Covance Study Number: 7694-105	Site:	

### 12-LEAD ELECTROCARDIOGRAM REPORT

Was ECG performed?	Was Subject Supine at Least 5 Minutes?	Date DD/MMM/YYYY	Actual Time 24-hour clock
1 Yes 2 No	1 Yes 2 No		:
ECG Interpretation: 1 Normal 2 Abnormal, NCS 3 Abnormal, CS			
Comments Regarding CS Findings:			

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### **MEDICAL HISTORY**

Does the subject have any relevant medical history?	Date DD/MMM/YYYY		
1 Yes 2 No			
Diagnosis/Procedure	Date of Onset	Date of Resolution	1
1.			9 ONGOING
2.			9 ☐ ONGOING
3.			9 ☐ ONGOING
4.			9 ☐ ONGOING
5.			9 ☐ ONGOING
6.			9 ☐ ONGOING
7.			9 ONGOING
8.			9 ☐ ONGOING
9.			9 ☐ ONGOING
10.			9 ☐ ONGOING
11.			9 ☐ ONGOING
12.			9 ONGOING
13.			9 ☐ ONGOING
14.			9 ONGOING
15.			9 ☐ ONGOING
Consider the following systems when performing the a	assessment:		
<ul> <li>Skin</li> <li>Ears, Eyes, Nose, Throat (EENT)</li> <li>Breasts</li> <li>Respiratory</li> <li>Cardiovascular</li> <li>Lymphatic/Hemato</li> <li>Gastrointestinal</li> <li>Genitourinary</li> <li>Musculoskeletal</li> <li>Endocrine</li> </ul>	logic	<ul><li>Neurological</li><li>Immunological</li><li>Psychological</li><li>Allergies</li></ul>	

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### **SMOKING HISTORY**

Was Smoking History collected?	Date DD/MMM/YYYY	
1 Yes 2 No		
Parameter	Result	Comments
Age subject began smoking daily		
Average number of cigarettes smoked per day over the past year		
Has subject used smokeless tobacco in the past?	₁ ☐ Yes ₂ ☐ No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in <b>Comments</b> section.	1 Yes 2 No  If yes, how many times?	
Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the <b>Comments</b> section.	1 Yes 2 No  If yes, how many times?	
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.	1 Yes 2 No  If yes, how many times?	
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the <b>Comments</b> section.	1 Yes 2 No  If yes, how many times?	

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01	Investigator:	Subject Initials:
Covance Study Number: 7694-105	Site:	
<b>,</b>		··

### **ORAL HEALTH EXAMINATION**

Date DD/MMM/YYYY	Procedure	Findings*	Findings
	Evidence of Leukoplakia	1 Yes 2 No 9 NE	
	Exposed dental cervices in upper sulcus?	1 Wes 2 No 9 NE	
	Other Oral Keratosis	1 Wes 2 No 9 NE	

<sup>\*</sup>Indicate NE if system was not examined.

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### PHYSICAL EXAMINATIONS

Does the subject have any abnormal findings?	Date DD/MMM/YYYY
1 Yes 2 No	
Findings	
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	
Consider the following systems when performing the a	issessment:
Oral Cavity     Neck (including)	g thyroid) • Extremities
• General Appearance • Lungs	<ul> <li>Neurologic/Nervous System</li> </ul>
• Skin • Heart	<ul><li>Lymph Nodes</li></ul>
● HEENT • Abdomen	

SWEDISH MATCH AB		Subject Number:
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### BEHAVIORAL COUNSELING

Date DD/MMM/YYYY	Parameter	Result	Comments
	Was Behavioral Counseling Given?	1 Yes 2 No	
	Was "Cleaning the Air" booklet provided?	1 Yes 2 No	

SWEDISH MATCH AB						Subject Number:		
Protocol Number: SM 08-01 Covance Study Number: 7694-105				ito:			Subject Initials:	
BASELINE, WEEK 0								
		EXPIRE	D CARE	ON MONO	XIDE			
Date DD/MMM/YYYY		Actual Time 24-hour clock	ECO	O Level	%COI	Hb	Comments	
/		::				·		
		BEHAV	/IORAL	COUNSEL	ING			
Date DD/MMM/YYYY	Param	neter		Result		Com	Comments	
	Was E Given	sehavioral Counselin ?	g	1  Yes 2 No				
		Q	UESTIO	NNAIRES				
Date DD/MMM/YYYY								
Questionnaire	aire Was Questionnaire Administered?							
FTND		1 ☐ Yes 2 ☐ No						
MNWS		1  Yes 2 No						

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SWEDISH MATCH AB			Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	5	Investigator:	•
BASELINE, WEEK 0			
	R <i>A</i>	ANDOMIZATION	
Date DD/MMM/YYYY	Actual Tin 24-hour clock	me	
	:_	_	
Was Subject randomized?	1 Yes 2	₂ ☐ No	
	PRODU	JCT DISPENSATION	
Date DD/MMM/YYYY			
Product		Amount Dispensed	
0.5 g of snus or matching placebo		logs	
1.0 g of snus or matching placebo		logs	
	DIAF	RY DISTRIBUTION	
Date DD/MMM/YYYY			
Did subject receive diary and usage instructions?	₁ ☐ Yes ₂	2 No	

SWEDISH MATCH AB		Subject Number:
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# STUDY PRODUCT TEST PERIOD WEEKS 1 THROUGH 4

#### **STATUS REVIEW**

Date DD/MMM/YYYY	Scheduled Timepoint	Parameter	Result	Comments
	Week 1	Was Subject contacted by telephone?	1 Yes 2 No	
		Was Subject's smoking status reviewed?	1 Yes 2 No	
		Was Subject's use of study product reviewed?	1 Yes 2 No	
		Approximately how many cigarettes did the subject smoke that week?		
		Was Behavioral Counseling Given?	1 Yes 2 No	
	Week 2	Was Subject contacted by telephone?	1 Yes 2 No	
		Was Subject's smoking status reviewed?	1 Yes 2 No	
		Was Subject's use of study product reviewed?	1 Yes 2 No	
		Approximately how many cigarettes did the subject smoke that week?		
		Was Behavioral Counseling Given?	1 Yes 2 No	
	Week 3	Was Subject contacted by telephone?	1 Yes 2 No	
		Was Subject's smoking status reviewed?	1 Yes 2 No	
		Was Subject's use of study product reviewed?	1 Yes 2 No	
		Approximately how many cigarettes did the subject smoke that week?		
		Was Behavioral Counseling Given?	1 Yes 2 No	
	Week 4	Was Subject contacted by telephone?	1 Yes 2 No	
		Was Subject's smoking status reviewed?	1 Yes 2 No	
		Was Subject's use of study product reviewed?	1 Yes 2 No	
		Approximately how many cigarettes did the subject smoke that week?		
		Was Behavioral Counseling Given?	1 Yes 2 No	
		Was Subject reminded about the complete switch from cigarettes no later than the first day of Week 5?	1 Yes 2 No	

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SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### **STATUS REVIEW**

Date DD/MMM/YYYY	Parameter	Result	Comments
	Was Subject asked HDYF? question during Week 5?	1 Yes 2 No	

### **VITAL SIGNS**

Were vital signs collected?	Date DD/MMM/YYYY	Actual Time 24-hour clock	Was Subject seated for 5 minutes?
1 Yes 2 No		::	1 Yes 2 No
Parameter	Unit	Result	
Systolic Blood Pressure	mmHg		
Diastolic Blood Pressure	mmHg		
Heart Rate	beats/minute		
Respiratory Rate	breaths/minute		
Body Temperature	°C	·	
Weight	lb	·	

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### LABORATORY EVALUATIONS

Were the scheduled laboratory san	Date DD/MMM/YYYY					
1 Yes 2 No (Specify samples not done, r						
Evaluation: Biomarker Blood Tests						
Requisition Number 1:						
Requisition Number 2 (if applicable Requisition Number 3 (if applicable	Requisition Number 2 (if applicable):					
Were there any clinically significan	nt labs? 1 Yes (specify below) 2	] No				
Requisition Number	Test Code ID					

Note: Attach copy of signed laboratory report.

SWEDISH N	SWEDISH MATCH AB					Subject Number:		
Protocol Number: SM 08-01 Covance Study Number: 7694-105						•	Subject Initials:	
INTERVENTIO WEEK 6	N PI	HASE					<del></del>	
		EXPIRE	D CARE	BON MONC	XIDE			
Date DD/MMM/YYYY				D Level	%COHb		Comments	
		::		·		·		
		BEHAV	/IORAL	COUNSEL	ING			
Date DD/MMM/YYYY	Para	ameter		Result		Comments		
	Was Give	s Behavioral Counselin en?	ıg	₁ ☐ Yes ₂ [	☐ No			
	QUESTIONNAIRES							
Date DD/MMM/YYYY								
Questionnaire Was Questionnaire Administered?								
MNWS 1 Tyes 2 TNo								

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OMEDIC	LINANTOLL AD		Subject N	Number:	
SWEDISI	H MATCH AB				
	ımber: SM 08-01 udy Number: 7694-105	Investigator:	_		
INTERVEN WEEK 6	TION PHASE				
	PRODI	JCT DISPENSATION	I		
Date DD/MMM/YYYY					
	<del></del>	<u> </u>			
Product		Amount Dispensed			
0.5 g of snus of	or matching placebo	logs			
1.0 g of snus of	or matching placebo	logs			
	S	TATUS REVIEW			
Date DD/MMM/YYYY	Parameter		Result	Comments	
	Was Subject's smoking status r	eviewed?	1 Yes 2 No		
	Was Subject compliant?		1 Yes 2 No		
	If Subject was not compliant, ap	pproximately how many e that week?			
Was Subject asked HDYF? question?			₁ ☐ Yes ₂ ☐ No		
	DIAI	RY DISTRIBUTION			
Date DD/MMM/YYYY					

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1 Yes 2 No

Did subject receive diary and usage instructions?

SWEDISH MATCH AB		Subject Number:
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Covance Study Number: 7694-105	Site:	

### **STATUS REVIEW**

Date DD/MMM/YYYY	Parameter	Result	Comments
	Was Subject contacted by telephone?	1  Yes 2 No	
	Was Subject's smoking status reviewed?	1 Yes 2 No	
	Was Subject's use of study product reviewed?	1  Yes 2  No	
	Was Subject compliant?	1 Yes 2 No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?		
	Was Behavioral Counseling Given?	1 Yes 2 No	
	Was Subject asked HDYF? question?	1 Yes 2 No	

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### **VITAL SIGNS**

Were vital signs collected?	Date DD/MMM/YYYY	Actual Time 24-hour clock	Was Subject seated for 5 minutes?
1 Wes 2 No		::	1 Yes 2 No
Parameter	Unit	Result	
Systolic Blood Pressure	mmHg		
Diastolic Blood Pressure	mmHg		
Heart Rate	beats/minute		
Respiratory Rate	breaths/minute		
Body Temperature	°C	·	
Weight	lb		

SWEDISH N	1ATC	CH AB				Subject	Number:
				Investigator:		Subject Initials:	
Covarice Study	INGITIC		Jitc			<u></u>	··
INTERVENTIO WEEK 10	N PI	HASE					
		EXPIRE	D CARE	SON MONO	XIDE		
Date DD/MMM/YYYY		Actual Time 24-hour clock		D Level	%COF	łb	Comments
		::				·	
		BEHAV	/IORAL	COUNSEL	ING		
Date DD/MMM/YYYY	Para	ameter		Result		Com	ments
	// Was Behavioral Counseling Given?		₁ ☐ Yes ₂ [	□No			
		Q	UESTIO	NNAIRES			
Date DD/MMM/YYYY							
Questionnaire	Questionnaire Was Questionnaire Administered?						
MNWS	MNWS 1 Yes 2 No						

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SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:
INTERVENTION PHASE WEEK 10		
PF	RODUCT DISPENSATION	

Date DD/MMM/YYYY		
Product	Amount Dispensed	
0.5 g of snus or matching placebo	logs	
1.0 g of snus or matching placebo	logs	

### **STATUS REVIEW**

Date DD/MMM/YYYY	Parameter	Result	Comments
	Was Subject's smoking status reviewed?	1  Yes 2 No	
	Was Subject's use of study product reviewed?	1  Yes 2 No	
	Was Subject compliant?	1 Yes 2 No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?		
	Was Subject asked HDYF? question?	1 Yes 2 No	

### **DIARY DISTRIBUTION**

Date DD/MMM/YYYY	
Did subject receive diary and usage instructions?	1 ☐ Yes 2 ☐ No

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### **STATUS REVIEW**

Date DD/MMM/YYYY	Parameter	Result	Comments
	Was Subject contacted by telephone?	1 Yes 2 No	
	Was Subject's smoking status reviewed?	1 Yes 2 No	
	Was Subject's use of study product reviewed?	1 Yes 2 No	
	Was Subject compliant?	1 Yes 2 No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?		
	Was Behavioral Counseling Given?	1 Yes 2 No	
	Was Subject asked HDYF? question?	1 Yes 2 No	
	Was Subject instructed to cut down on product use during upcoming Weeks 14 – 16 to avoid a too abrupt ending of nicotine uptake?	1 Yes 2 No	

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### **VITAL SIGNS**

Were vital signs collected?	Date DD/MMM/YYYY	Actual Time 24-hour clock	Was Subject seated for 5 minutes?
1 Yes 2 No		::	1 Yes 2 No
Parameter	Unit	Result	
Systolic Blood Pressure	mmHg		
Diastolic Blood Pressure	mmHg		
Heart Rate	beats/minute		
Respiratory Rate	breaths/minute		
Body Temperature	°C	·	
Weight	lb	·	

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### LABORATORY EVALUATIONS

Were the scheduled laboratory samples obtained?			Date DD/MMM/YYYY
1 Yes 2 No (Specify samples not done, r			
<b>Evaluation</b> : Biomarker Blood Tests			
Requisition Number 1:			
Requisition Number 2 (if applicable):  Requisition Number 3 (if applicable):			
Were there any clinically significant labs? 1  Yes (specify below) 2  No			
Requisition Number Test Name Test Code II			D

Note: Attach copy of signed laboratory report.

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01	Investigator:	Subject Initials:
Covance Study Number: 7694-105	Site:	

### **ORAL HEALTH EXAMINATION**

Date DD/MMM/YYYY	Procedure	Findings*	Findings
	Evidence of Leukoplakia	1 Yes 2 No 9 NE	
	Exposed dental cervices in upper sulcus?	1 Yes 2 No 9 NE	
	Other Oral Keratosis	1 Wes 2 No 9 NE	

<sup>\*</sup>Indicate NE if system was not examined.

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### PHYSICAL EXAMINATIONS

Does the subject have any abnormal findings?	Date DD/MMM/YYYY
1 Yes 2 No	
Findings	
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	
Consider the following systems when performing the as	sessment:
<ul> <li>Oral Cavity</li> <li>General Appearance</li> <li>Skin</li> <li>HEENT</li> <li>Neck (including</li> <li>Lungs</li> <li>Heart</li> <li>Abdomen</li> </ul>	

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SWEDISH MATCH AB			S		Subject	Number:	
Protocol Number: SM 08-01		Investigator:			Subject	Initials:	
Covance Study I	Number	: 7694-105					·
INTERVENTIO WEEK 16	N PH <i>A</i>		D CARE	SON MONC			
Date DD/MMM/YYYY		Actual Time ECO Level %COHb Comm				Comments	
		::					
		BEHAV	/IORAL	COUNSEL	ING		
Date DD/MMM/YYYY	Param	neter		Result		Com	ments
	Was B Given?		ehavioral Counseling 1  Yes 2 No		No		
		Q	UESTIO	NNAIRES			
Date DD/MMM/YYYY							
Questionnaire		Was Questionnaire Administered?					
FTND		1 ☐ Yes 2 ☐ No					
MNWS		1 Yes 2 No					

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SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01	Investigator:	Subject Initials:
Covance Study Number: 7694-105	Site:	

### **STATUS REVIEW**

Date DD/MMM/YYYY	Parameter	Result	Comments
	Was Subject's smoking status reviewed?	1 Yes 2 No	
	Was Subject's use of study product reviewed?	1  Yes 2 No	
	Was Subject compliant?	1 Yes 2 No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?		
	Was Subject asked HDYF? question?	1 Yes 2 No	

### **DIARY DISTRIBUTION**

Date DD/MMM/YYYY	
Did subject receive diary and usage instructions?	1 ☐ Yes 2 ☐ No

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### FOLLOW-UP PHASE WEEKS 20 AND 24

### **STATUS REVIEW**

Date DD/MMM/YYYY	Scheduled Timepoint	Parameter	Result	Comments
	Week 20	Was Subject contacted by telephone?	1 Yes 2 No	
		Was Subject's smoking status reviewed?	1 Yes 2 No	
		Was Subject compliant?	1 Yes 2 No	
		If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?		
		Was Behavioral Counseling Given?	1  Yes 2 No	
		Was Subject asked HDYF? question?	1 Yes 2 No	
	Week 24	Was Subject contacted by telephone?	1 Yes 2 No	
		Was Subject's smoking status reviewed?	1 Yes 2 No	
		Was Subject compliant?	1 Yes 2 No	
		If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?		
		Was Behavioral Counseling Given?	1  Yes 2 No	
		Was Subject asked HDYF? question?	1 Yes 2 No	

SWEDISH MATCH AB		Subject Number:
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# FOLLOW-UP PHASE WEEK 28

### **VITAL SIGNS**

Were vital signs collected?	Date DD/MMM/YYYY	Actual Time 24-hour clock	Was Subject seated for 5 minutes?
1 Yes 2 No		:	1 Yes 2 No
Parameter	Unit	Result	
Systolic Blood Pressure	mmHg		
Diastolic Blood Pressure	mmHg		
Heart Rate	beats/minute		
Respiratory Rate	breaths/minute		
Body Temperature	°C	·	
Weight	lb	·	

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

### FOLLOW-UP PHASE WEEK 28

### LABORATORY EVALUATIONS

Were the scheduled laboratory san	nples obtained?		Date DD/MMM/YYYY
1 Yes 2 No (Specify samples not done, r	reason):		
<b>Evaluation</b> : Biomarker Blood Tests			
Requisition Number 1:			
Requisition Number 2 (if applicable):			
Requisition Number 3 (if applicable):			
Were there any clinically significant labs? 1 Tes (specify below) 2 No			
Requisition Number	Test Name	Test Code II	D

Note: Attach copy of signed laboratory report.

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01	Investigator:	Subject Initials:
Covance Study Number: 7694-105	Site:	

# FOLLOW-UP PHASE WEEK 28

### **ORAL HEALTH EXAMINATION**

Date DD/MMM/YYYY	Procedure	Findings*	Findings
	Evidence of Leukoplakia	1 Yes 2 No 9 NE	
	Exposed dental cervices in upper sulcus?	1 Wes 2 No 9 NE	
	Other Oral Keratosis	1 Wes 2 No 9 NE	

<sup>\*</sup>Indicate NE if system was not examined.

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

# FOLLOW-UP PHASE WEEK 28

### PHYSICAL EXAMINATIONS

Does the subject have any abnormal findings?	Date DD/MMM/YYYY
1 Yes 2 No	
Findings	
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	
Consider the following systems when performing the as	sessment:
<ul> <li>Oral Cavity</li> <li>General Appearance</li> <li>Skin</li> <li>HEENT</li> <li>Neck (including</li> <li>Lungs</li> <li>Heart</li> <li>Abdomen</li> </ul>	

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SWEDISH MATCH AB						Subject	Subject Number:	
Protocol Number: SM 08-01 Covance Study Number: 7694-105		Investigator:		_	Subject Initials:			
FOLLOW-UP P WEEK 28	PHASE							
		EXPIRE	D CARE	ON MONO	XIDE			
Date DD/MMM/YYYY		Actual Time 24-hour clock			%COF	łb	Comments	
		:				·		
		BEHA	/IORAL	COUNSEL	ING			
Date DD/MMM/YYYY	Param	eter		Result		Com	ments	
	Was Behavioral Counseling Given?		g	₁ ☐ Yes ₂ ☐ No				
		Q	UESTIO	NNAIRES				
Date DD/MMM/YYYY								
Questionnaire		Was Questionnaire Administered?						
FTND		1 Yes 2 No						
MNWS		1 Yes 2 No	1 Yes 2 No					

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SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

# FOLLOW-UP PHASE WEEK 28

#### **STATUS REVIEW**

Date DD/MMM/YYYY	Parameter	Result	Comments
	Was Subject's smoking status reviewed?	1  Yes 2 No	
	Was Subject compliant?	1 Wes 2 No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?		
	Was Subject asked HDYF? question?	1 Yes 2 No	

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01	Investigator:	Subject Initials:
Covance Study Number: 7694-105	Site:	··

## PREVIOUS AND CONCOMITANT MEDICATIONS

Has the subject taken any medion $\frac{1}{1}$ Yes, list below. $\frac{1}{2}$ No	cations prior to t	ne first dose and/or during the st	udy as restricted by the protocol?
Drug Name:			
Indication:			
Dose:			
Unit:  Select only one  grams  micrograms  milligrams  milliliter  milliliter  tablet  other	Frequency:	Select only one  one time whenever necessary every morning at bedtime every day with twice daily	three times daily four times daily every four hours every other day every week other, specify
Start Date <sup>1</sup> DD/MMM/YYYY	Stop Date <sup>1</sup>		
		9  ONGOING	
Drug Name:			
Indication:			
Dose:			
Unit: Select only one  1  grams 2  micrograms 3  milligrams 4  milliliter 5  tablet	Frequency:	Select only one  1  one time 2  whenever necessary 3  every morning 4  at bedtime 5  every day 6  twice daily	three times daily four times daily every four hours every other day every week other, specify
Start Date <sup>1</sup> DD/MMM/YYYY	Stop Date <sup>1</sup>		
		9 ONGOING	
<sup>1</sup> START AND STOP DATE: If medic as a new line of information. Report s			once. If dose regimen changes, report

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SWEDISH	MATCH AB		Subject Number:
Protocol Numb	oer: SM 08-01	Investigator:	Subject Initials:
Covance Study	y Number: 7694-105	Site:	
ADVERSE EVE	NTS perience any adverse events?	1 ☐ Yes, list below. 2 ☐ No	
Adverse Event:			
Onset Date	Onset Time 24-hour clock	Resolved Date	Resolved Time 24-hour clock
	::	// <sub>9</sub>	:
Serious Event:	Select only one  1 Yes 2 No	Select only one  1	•
Action Taken:	Select only one  1 None  2 Other Drug Therapy, Sp  3 Other Treatment or Pro  4 Discontinuation of Drug  5 Discontinuation from St	cedure, Specify: Therapy	O Select only one

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SWEDISH N	Subject Number:			
Protocol Number: SM 08-01 Investigator:  Covance Study Number: 7694-105 Site:		Subject Initials:		
ADDITIONAL ASSESSMENTS - 12-LEAD ELECTROCARDIOGRAM REPORT  Were any additional 12-lead ECGs collected? 1  Yes, list below. 2  No				
Date DD/MMM/YYYY	Actual Time 24-hour clock	ECG Interpretation:	Comments Regarding CS Findings	
	:	1 Normal 2 Abnormal, NCS 3 Abnormal, CS		
	:	1 Normal 2 Abnormal, NCS 3 Abnormal, CS		
	:	1 Normal 2 Abnormal, NCS 3 Abnormal, CS		

 $_1$  Normal  $_2$  Abnormal, NCS  $_3$  Abnormal, CS

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

## ADDITIONAL ASSESSMENTS - LABORATORY EVALUATIONS

Were any additional	laboratory evalu	uations collected	? 1 Yes, list k	pelow. 2	No
Date DD/MMM/YYYY	Requisition Number	Clinically Significant?	Test Name CS Labs Only	Test Code ID CS Labs Only	Comments
		1 Yes 2 No			
		1 Yes 2 No			
		1 Yes 2 No			
		1 Yes 2 No			
		1 Yes 2 No			
		1 Yes 2 No			
//		1 Yes 2 No			
		1 Yes 2 No			
		1 Yes 2 No			
		1 Yes 2 No			
		1 Yes 2 No			
		1 Yes 2 No			
		1 Yes 2 No			
		1 Yes 2 No			

Note: Attach copy of signed laboratory report.

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01	Investigator:	Subject Initials:
Covance Study Number: 7694-105	Site:	
•		

## ADDITIONAL ASSESSMENTS - VITAL SIGNS

Were any additiona	l vital signs col	llected? 1 Y	es, list below. 2	No	
Date DD/MMM/YYYY	Actual Time 24-hour clock	Position	Parameter	Unit	Result
	:	1 Standing 2 Supine	Systolic Blood Pressure	mmHg	
		3 Seated 4 Other,	Diastolic Blood Pressure	mmHg	
		Specify:	Heart Rate	beats/minute	
			Respiratory Rate	breaths/minute	
			Body Temperature	°C	
			Comments:		
	:	1 Standing	Systolic Blood Pressure	mmHg	
		4 Other, Specify:	Diastolic Blood Pressure	mmHg	
			Heart Rate	beats/minute	
			Respiratory Rate	breaths/minute	
			Body Temperature	°C	
			Comments:		
	:	1 Standing 2 Supine	Systolic Blood Pressure	mmHg	
		3 Seated 4 Other,	Diastolic Blood Pressure	mmHg	
		Specify:	Heart Rate	beats/minute	
			Respiratory Rate	breaths/minute	
			Body Temperature	°C	
			Comments:		

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator:	Subject Initials:

## ADDITIONAL ASSESSMENTS - PHYSICAL EXAMINATIONS

Does the subject have any abnormal findings?	Date DD/MMM/YYYY
1 Yes 2 No	
Findings	
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	
Consider the following systems when performing the as	sessment:
<ul> <li>Oral Cavity</li> <li>General Appearance</li> <li>Skin</li> <li>HEENT</li> <li>Neck (including</li> <li>Lungs</li> <li>Heart</li> <li>Abdomen</li> </ul>	

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01	Investigator:	Subject Initials:
Covance Study Number: 7694-105	Site:	
<b>,</b>		··

## **ORAL HEALTH EXAMINATION**

Date DD/MMM/YYYY	Procedure	Findings*	Findings
	Evidence of Leukoplakia	1 Yes 2 No 9 NE	
	Exposed dental cervices in upper sulcus?	1 Wes 2 No 9 NE	
	Other Oral Keratosis	1 Yes 2 No 9 NE	
	Evidence of Leukoplakia	1 Wes 2 No 9 NE	
	Exposed dental cervices in upper sulcus?	1 Yes 2 No 9 NE	
	Other Oral Keratosis	1 Wes 2 No 9 NE	
	Evidence of Leukoplakia	1 Yes 2 No 9 NE	
	Exposed dental cervices in upper sulcus?	1 Yes 2 No 9 NE	
	Other Oral Keratosis	1 Wes 2 No 9 NE	

<sup>\*</sup>Indicate NE if system was not examined.

SWEDISH MATCH AB		Subject Number:
Protocol Number: SM 08-01 Covance Study Number: 7694-105	Investigator: Site:	
	STUDY COMPLETION	N
Date the subject completed OR with	drew from the study:	/ DD/MMM/YYYY
Reason for Withdrawal (chec	k one):	
<sub>99</sub> NA, Completed Study		
<sub>1</sub> Adverse Event, specify:		_
<sub>2</sub> Terminated by Sponsor		
3 Consent Withdrawn		
4 Lost to Follow–up		
9 Other, specify:		
Investigator Comments (if none, leave blank):		
	•	nem to be complete and accurate. d participation in the study.)
Principal Investigator		Date DD/MMM/YYYY

Blank Case Report Form for Study: E7694105D

Book: CRF

Initials:		5	Subject #:
	STUDY PRODUCT USE		Blank
During the past week:	Dat	te of completion:	
1. I have not smoked any cigarett  Correct Incorrect	es at all during the past week (	1 or 2 puffs = 1 cigarett	e)
2. I have smoked on average	cigarettes per d	lay	
3. I have smoked tobacco product No Yes-please specify:	s other than cigarettes:		
4. Did you use smokeless tobacco cessation products this week?  ☐Yes ☐ No	products, nicotine-containing	g products (e.g., gum or	patch), or other smoking
If yes, what type (smokeless toba nicotine products [e.g., lozenges]		eplacement products [gu	um / patch / other], other
5. I have consumed on average th	e following number of snus sa	chets ner dav	
Sachet Size: Large (1g) Small (0.5g)	e following figure of shas sa	eneus per day.	
6. I have experienced the following	ng Adverse Events:		
7. I think the Adverse Event is red Correct Incorrect Don't Know I have not experienced an Adv			
Verified Approved L	ocked  Frozen	Page Version No. Document Number	WEEK_1 (v1, 25-MAR-2009)

Initials:		s	subject #:	
[		ls E	Blank	
	STUDY PRODUCT USE	EDIARY		
During the past week:	Da	ate of completion:		
1. I have not smoked any ciga Correct Incorrect	rettes at all during the past week	(1 or 2 puffs = 1 cigarette	e)	
2. I have smoked on average [	cigarettes per	day		
3. I have smoked tobacco production of the second of the s				
4. Did you use smokeless toba cessation products this week?  ☐ Yes ☐ No	acco products, nicotine-containin	g products (e.g., gum or p	oatch), or other smo	king
	obacco, pharmaceutical nicotine (es])?	replacement products [gu	m / patch / other], o	other
5. I have consumed on average	e the following number of snus s	achets per day:		
Sachet Size: Large (1g) Small (0.5g)				
6. I have experienced the follo	owing Adverse Events:			
7. I think the Adverse Event is  Correct Incorrect Don't Know I have not experienced an A				
Verified Approved	Locked Frozen	Page Version No. Document Number	WEEK_2 (v1, 25-N	ИAR-2009)

Initials:		5	Subject #:
	STUDY PRODUCT US		Blank
During the past week:	Ω	Date of completion:	
1. I have not smoked any cigare  Correct Incorrect	ettes at all during the past week	k (1 or 2 puffs = 1 cigarette	e)
2. I have smoked on average	cigarettes per	r day	
3. I have smoked tobacco produ No Yes-please specify:			
4. Did you use smokeless tobac cessation products this week?  ☐Yes ☐ No	co products, nicotine-containi	ng products (e.g., gum or p	patch), or other smoking
If yes, what type (smokeless tol nicotine products [e.g., lozenge		e replacement products [gu	ım / patch / other], other
5. I have consumed on average	the following number of snus	sachets per day:	
Sachet Size: Large (1g) Small (0.5g)	]	· · · · · · · · · · · · · · · · · · ·	
6. I have experienced the follow	ving Adverse Events:		
7. I think the Adverse Event is a Correct Incorrect Don't Know I have not experienced an A			
Verified Approved	Locked Frozen	Page Version No. Document Number	WEEK_3 (v1, 25-MAR-2009)

Initials:		s	ubject #:	
[		Is E	Blank	
	STUDY PRODUCT USE	E DIARY		
During the past week:	Da	ate of completion:		
1. I have not smoked any ciga Correct Incorrect	rettes at all during the past week	(1 or 2 puffs = 1 cigarette	2)	
2. I have smoked on average [	cigarettes per	day		
3. I have smoked tobacco production No Yes-please specify				
4. Did you use smokeless tobacessation products this week?  ☐ Yes ☐ No	acco products, nicotine-containin	g products (e.g., gum or p	oatch), or other smoking	ğ.
If yes, what type (smokeless to nicotine products [e.g., lozeng	obacco, pharmaceutical nicotine (es])?	replacement products [gu	m / patch / other], other	r
5. I have consumed on average	e the following number of snus s	achets per day:		
Sachet Size: Large (1g) Small (0.5g)				
6. I have experienced the follo	owing Adverse Events:			
7. I think the Adverse Event is  Correct Incorrect Don't Know I have not experienced an A	-			
Verified Approved	Locked Frozen	Page Version No. Document Number	WEEK_4 (v1, 25-MAR	:-2009)

Initials:		5	Subject #:
	STUDY PRODUCT USE I		Blank
During the past week:	Date	e of completion:	
1. I have not smoked any cigarette Correct Incorrect	es at all during the past week (	1 or 2 puffs = 1 cigarett	e)
2. I have smoked on average	cigarettes per da	ay	
3. I have smoked tobacco product  No Yes-please specify:	s other than cigarettes:		
4. Did you use smokeless tobacco cessation products this week?  Yes No	products, nicotine-containing	products (e.g., gum or	patch), or other smoking
If yes, what type (smokeless tobac nicotine products [e.g., lozenges])		eplacement products [gu	um / patch / other], other
5. I have consumed on average th	e following number of snus sag	chets per day:	
Sachet Size: Large (1g) Small (0.5g)	Ü		
6. I have experienced the following	ng Adverse Events:		
7. I think the Adverse Event is rel Correct Incorrect Don't Know I have not experienced an Adv			
Verified Approved Lo	ocked Frozen	Page Version No. Document Number	WEEK_5 (v1, 25-MAR-2009

Initials:		5	Subject #:
	STUDY PRODUCT US		Blank
During the past week:	D	Date of completion:	
1. I have not smoked any cigare Correct Incorrect	ttes at all during the past week	x (1 or 2 puffs = 1 cigarett	e)
2. I have smoked on average	cigarettes per	r day	
3. I have smoked tobacco produ No Yes-please specify:	cts other than cigarettes:		
4. Did you use smokeless tobaccessation products this week?  ☐Yes ☐ No	co products, nicotine-containi	ng products (e.g., gum or	patch), or other smoking
If yes, what type (smokeless tob nicotine products [e.g., lozenges		e replacement products [gu	um / patch / other], other
5. I have consumed on average	the following number of snus	sachets per day:	
Sachet Size: Large (1g) Small (0.5g)		···· ··· ··· ··· ··· ··· ··· ··· ··· ·	
6. I have experienced the follow	ring Adverse Events:		
7. I think the Adverse Event is r Correct Incorrect Don't Know I have not experienced an Adverse Event is r			
Verified Approved	Locked Frozen	Page Version No. Document Number	WEEK_6 (v1, 25-MAR-2009)

Initials:		:	Subject #:
	STUDY PRODUCT US		Blank
During the past week:	D	Date of completion:	
1. I have not smoked any cigare Correct Incorrect	ttes at all during the past week	x (1 or 2 puffs = 1 cigarett	e)
2. I have smoked on average	cigarettes per	r day	
3. I have smoked tobacco produ No Yes-please specify:	cts other than cigarettes:		
4. Did you use smokeless tobaccessation products this week?  ☐Yes ☐ No	co products, nicotine-containing	ng products (e.g., gum or	patch), or other smoking
If yes, what type (smokeless tobnicotine products [e.g., lozenges		e replacement products [gr	um / patch / other], other
5. I have consumed on average	the following number of snus	sachets per day:	
Sachet Size: Large (1g) Small (0.5g)	10110 m.mg 1101110 22 01 01101	sacrotto per day.	
6. I have experienced the follow	ring Adverse Events:		
7. I think the Adverse Event is r Correct Incorrect Don't Know I have not experienced an Adverse Event is r			
Verified Approved	Locked Frozen	Page Version No. Document Number	WEEK_7 (v1, 25-MAR-2009)

Initials:		5	Subject #:
[	STUDY PRODUCT U		Blank
During the past week:		Date of completion:	
1. I have not smoked any cigar  Correct Incorrect			e)
2. I have smoked on average [	cigarettes pe	er day	
3. I have smoked tobacco production in the smoked tobacco producti			
4. Did you use smokeless toba cessation products this week?  ☐ Yes ☐ No	cco products, nicotine-contain	ing products (e.g., gum or	patch), or other smoking
If yes, what type (smokeless to nicotine products [e.g., lozeng		ne replacement products [gu	um / patch / other], other
5. I have consumed on average	e the following number of snus	s sachets per day:	
Sachet Size: Large (1g) Small (0.5g)			
6. I have experienced the follo	wing Adverse Events:		
7. I think the Adverse Event is  Correct Incorrect Don't Know I have not experienced an A			
Verified Approved	Locked Frozen	Page Version No. Document Number	WEEK_8 (v1, 25-MAR-2009)

Initials:		5	Subject #:
	STUDY PRODUCT US		Blank
During the past week:	D	Date of completion:	
1. I have not smoked any cigare Correct Incorrect	ettes at all during the past week	x (1 or 2 puffs = 1 cigarett	e)
2. I have smoked on average	cigarettes per	r day	
3. I have smoked tobacco produ No Yes-please specify:			
4. Did you use smokeless tobac cessation products this week?  ☐Yes ☐ No	co products, nicotine-containin	ng products (e.g., gum or	patch), or other smoking
If yes, what type (smokeless tol nicotine products [e.g., lozenge		e replacement products [gu	um / patch / other], other
5. I have consumed on average	the following number of snus	sachets per day:	
Sachet Size: Large (1g) Small (0.5g)	]		
6. I have experienced the follow	ving Adverse Events:		
7. I think the Adverse Event is a Correct Incorrect Don't Know I have not experienced an A			
Verified Approved	Locked Frozen	Page Version No. Document Number	WEEK_9 (v1, 25-MAR-2009)

Initials:		<u>:</u>	Subject #:	
Γ		ls	Blank	
L	STUDY PRODUCT USE I			
During the past week:	Date	of completion:		
1. I have not smoked any cigar  Correct Incorrect	rettes at all during the past week (1	or 2 puffs = 1 cigaret	te)	
2. I have smoked on average [	cigarettes per da	у		
3. I have smoked tobacco production in the smoked tobacco producti				
4. Did you use smokeless toba cessation products this week?	cco products, nicotine-containing	products (e.g., gum or	patch), or other smo	oking
☐Yes ☐ No	de constante de la tradicione	.1	/	-41
nicotine products [e.g., lozeng	obacco, pharmaceutical nicotine reges])?	pracement products [g	um / patcn / otnerj,	otner
5. I have consumed on average Sachet Size:	e the following number of snus sac	hets per day:		
Large (1g) Small (0.5g)	]			
6. I have experienced the follo	wing Adverse Events:			
7. I think the Adverse Event is  Correct Incorrect Don't Know I have not experienced an A	-			
Verified Approved	Locked Frozen	Page Version No.	WEEK_10 (v1, 25	-MAR-2009)

Initials:			Subject #:
		ı	s Blank
		IADV	
	STUDY PRODUCT USE D	IARY	
During the past week:	Date	of completion:	
1. I have not smoked any cigarettes  Correct Incorrect	s at all during the past week (1	or 2 puffs = 1 cigare	ette)
2. I have smoked on average	cigarettes per day	į.	
3. I have smoked tobacco products  No Yes-please specify:	other than cigarettes:		
4. Did you use smokeless tobacco cessation products this week?  ☐Yes ☐ No	products, nicotine-containing p	roducts (e.g., gum o	r patch), or other smoking
If yes, what type (smokeless tobaconicotine products [e.g., lozenges])?	=	lacement products [	gum / patch / other], other
5. I have consumed on average the	following number of snus sach	nets per day:	
Sachet Size: Large (1g) Small (0.5g)			
6. I have experienced the following	g Adverse Events:		
7. I think the Adverse Event is related Correct Incorrect Don't Know I have not experienced an Adverse			
Verified Approved Loc	cked Frozen	Page Version No	

Initials:	Subject #:
	Is Blank
STUDY PRODU	CT USE DIARY
During the past week:	Date of completion:
1. I have not smoked any cigarettes at all during the pa ☐ Correct ☐ Incorrect	st week (1 or 2 puffs = 1 cigarette)
2. I have smoked on averagecigare	ttes per day
3. I have smoked tobacco products other than cigarette	s:
□No □ Yes-please specify: □	
4. Did you use smokeless tobacco products, nicotine-co cessation products this week?	ontaining products (e.g., gum or patch), or other smoking
☐Yes ☐ No	
	nicotine replacement products [gum / patch / other], other
nicotine products [e.g., lozenges])?	
5. I have consumed on average the following number of	of snus sachets per day:
Sachet Size:	
Large (1g)	
Small (0.5g)	
6. I have experienced the following Adverse Events:	
7. I think the Adverse Event is related to the snus production.  Correct  Incorrect  Don't Know  I have not experienced an Adverse Event	ıct:
Verified Approved Locked Frozen	Page Version No. WEEK_12 (v1, 25-MAR-2009)  Document Number

Initials:	Subject #:
	Is Blank
STUDY PRODUCT US	SE DIARY
During the past week:	Date of completion:
1. I have not smoked any cigarettes at all during the past wee	k (1 or 2 puffs = 1 cigarette)
2. I have smoked on averagecigarettes pe	er day
3. I have smoked tobacco products other than cigarettes:	
No ☐ Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-contains cessation products this week?	ing products (e.g., gum or patch), or other smoking
Yes No	
If yes, what type (smokeless tobacco, pharmaceutical nicotin nicotine products [e.g., lozenges])?	e replacement products [gum / patch / other], other
5. I have consumed on average the following number of snus	sachets per day:
Sachet Size:	
Large (1g)	
Small (0.5g)	
6. I have experienced the following Adverse Events:	
7. I think the Adverse Event is related to the snus product:  Correct  Incorrect  Don't Know  I have not experienced an Adverse Event	
Verified Approved Locked Frozen	Page Version No. WEEK_13 (v1, 25-MAR-2009)  Document Number

Initials:		<u>:</u>	Subject #:	
Γ		ls	Blank	
L	STUDY PRODUCT USE D			
During the past week:	Date	of completion:		
1. I have not smoked any cigar  Correct Incorrect	rettes at all during the past week (1	or 2 puffs = 1 cigaret	te)	
2. I have smoked on average [	cigarettes per da	y		
3. I have smoked tobacco production in the smoked tobacco producti				
4. Did you use smokeless toba cessation products this week?	cco products, nicotine-containing p	products (e.g., gum or	patch), or other smok	cing
☐Yes ☐ No		1	/ .1 / .1 .1	.1
nicotine products [e.g., lozeng	obacco, pharmaceutical nicotine rejes])?	placement products [g	um / patch / other], o	ther
	e the following number of snus sac	hets per day:		
Sachet Size: Large (1g) Small (0.5g)	]			
6. I have experienced the follo	wing Adverse Events:			
7. I think the Adverse Event is  Correct Incorrect Don't Know I have not experienced an A				
Verified Approved	Locked Frozen	Page Version No.	WEEK_14 (v1, 25-	MAR-2009)

Initials:	Subject #:
	Is Blank
<u> </u>	
STUDY PRODUCT USI	3 DIARY
During the past week:	ate of completion:
1. I have not smoked any cigarettes at all during the past week  Correct Incorrect	(1 or 2 puffs = 1 cigarette)
2. I have smoked on averagecigarettes per	day
3. I have smoked tobacco products other than cigarettes:	
No ☐ Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-containing cessation products this week?	g products (e.g., gum or patch), or other smoking
☐Yes ☐ No	
If yes, what type (smokeless tobacco, pharmaceutical nicotine nicotine products [e.g., lozenges])?	replacement products [gum / patch / other], other
5. I have consumed on average the following number of snus s	sachets per day:
Sachet Size:	
Large (1g)	
Small (0.5g)	
6. I have experienced the following Adverse Events:	
7. I think the Adverse Event is related to the snus product:  Correct  Incorrect  Don't Know  I have not experienced an Adverse Event	
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	Document Number

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l	STUDY PRODUCT USE D			
During the past week:	Date	of completion:		
1. I have not smoked any ciga Correct Incorrect	rettes at all during the past week (1	or 2 puffs = 1 cigarett	te)	
2. I have smoked on average	cigarettes per da	у		
3. I have smoked tobacco procuring No Yes-please specify				
cessation products this week?	acco products, nicotine-containing	products (e.g., gum or	patch), or other smokir	ıg
☐Yes ☐ No		.1	/	
nicotine products [e.g., lozeng	obacco, pharmaceutical nicotine reges])?	pracement products [g	um / patch / other], oth	er ——
5. I have consumed on average Sachet Size:	e the following number of snus sac	hets per day:		
Large (1g) Small (0.5g)				
6. I have experienced the following	owing Adverse Events:			
7. I think the Adverse Event is  Correct Incorrect Don't Know I have not experienced an A				
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Initials:	Subject #:
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STUDY PRODUCT U	SE DIARY
	Date of completion:
1. I have not smoked any cigarettes at all during the past we Correct Incorrect	ek (1 or 2 puffs = 1 cigarette)
2. I have smoked on averagecigarettes p	per day
3. I have smoked tobacco products other than cigarettes:	
No Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-contain cessation products this week?	ning products (e.g., gum or patch), or other smoking
□Yes □ No	
If yes, what type (smokeless tobacco, pharmaceutical nicotin nicotine products [e.g., lozenges])?	ne replacement products [gum / patch / other], other
Verified D	Page Version No WEEK_17 (v1, 25-MAR-2009)
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Initials:	Subject #:
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STUDY PRODUCT US	SE DIARY
	Date of completion:
1. I have not smoked any cigarettes at all during the past wee	k (1 or 2 puffs = 1 cigarette)
2. I have smoked on average cigarettes pe	r day
3. I have smoked tobacco products other than cigarettes:	
No Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-containi cessation products this week?	ng products (e.g., gum or patch), or other smoking
☐Yes ☐ No	
If yes, what type (smokeless tobacco, pharmaceutical nicotine nicotine products [e.g., lozenges])?	e replacement products [gum / patch / other], other
	Page Version No WEEK_18 (v1, 25-MAR-2009)
Verified Approved Locked Frozen	Page Version No. WEEK_18 (v1, 25-MAR-2009)  Document Number

Initials:	Subject #:
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STUDY PRODUC	CT USE DIARY
During the past week:	Date of completion:
1. I have not smoked any cigarettes at all during the past Correct Incorrect	st week (1 or 2 puffs = 1 cigarette)
2. I have smoked on averagecigaret	ttes per day
3. I have smoked tobacco products other than cigarettee	3:
No Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-co cessation products this week?	ontaining products (e.g., gum or patch), or other smoking
☐Yes ☐ No	
If yes, what type (smokeless tobacco, pharmaceutical n nicotine products [e.g., lozenges])?	icotine replacement products [gum / patch / other], other
Verified Approved Locked Frozen	Page Version No. WEEK_19 (v1, 25-MAR-2009)
	Document Number

Initials:	Subject #:
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STUDY PRODUCT	USE DIARY
During the past week:	Date of completion:
1. I have not smoked any cigarettes at all during the past w  Correct Incorrect	eek (1 or 2 puffs = 1 cigarette)
2. I have smoked on averagecigarettes	per day
3. I have smoked tobacco products other than cigarettes:	
No Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-conta cessation products this week?	ining products (e.g., gum or patch), or other smoking
☐Yes ☐ No	
If yes, what type (smokeless tobacco, pharmaceutical nicot nicotine products [e.g., lozenges])?	ine replacement products [gum / patch / other], other
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Verified Approved Locked Frozen	Document Number

Initials:	Subject #:
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STUDY PRODUCT U	SE DIARY
	Date of completion:
1. I have not smoked any cigarettes at all during the past wee	ek (1 or 2 puffs = 1 cigarette)
2. I have smoked on averagecigarettes pe	er day
3. I have smoked tobacco products other than cigarettes:	
No Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-contain cessation products this week?	ing products (e.g., gum or patch), or other smoking
□Yes □No	
If yes, what type (smokeless tobacco, pharmaceutical nicotin nicotine products [e.g., lozenges])?	ne replacement products [gum / patch / other], other
Verifical Co	Page Version No. WEEK_21 (v1, 25-MAR-2009)
Verified Approved Locked Frozen	Page Version No. WEEK_21 (v1, 25-MAR-2009)  Document Number

Initials:	Subject #:
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STUDY PRODUCT U	SE DIARY
	Date of completion:
1. I have not smoked any cigarettes at all during the past wee	ek (1 or 2 puffs = 1 cigarette)
2. I have smoked on averagecigarettes pe	er day
3. I have smoked tobacco products other than cigarettes:	
No Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-contain cessation products this week?	ing products (e.g., gum or patch), or other smoking
□Yes □No	
If yes, what type (smokeless tobacco, pharmaceutical nicotin nicotine products [e.g., lozenges])?	ne replacement products [gum / patch / other], other
	Page Version No. WEEK_22 (v1, 25-MAR-2009)
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Initials:	Subject #:
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STUDY PRODUCT U	SE DIARY
	Date of completion:
1. I have not smoked any cigarettes at all during the past wer Correct Incorrect	ek (1 or 2 puffs = 1 cigarette)
2. I have smoked on averagecigarettes p	er day
3. I have smoked tobacco products other than cigarettes:	
No Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-contain cessation products this week?	ning products (e.g., gum or patch), or other smoking
□Yes □No	
If yes, what type (smokeless tobacco, pharmaceutical nicotin nicotine products [e.g., lozenges])?	ne replacement products [gum / patch / other], other
Verificat D	Page Version No WEEK_23 (v1, 25-MAR-2009)
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Initials:	Subject #:
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STUDY PRODUCT US	SE DIARY
	Date of completion:
1. I have not smoked any cigarettes at all during the past wee Correct Incorrect	k (1 or 2 puffs = 1 cigarette)
2. I have smoked on average cigarettes pe	er day
3. I have smoked tobacco products other than cigarettes:	
No Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-contains cessation products this week?	ing products (e.g., gum or patch), or other smoking
☐Yes ☐ No	
If yes, what type (smokeless tobacco, pharmaceutical nicotin nicotine products [e.g., lozenges])?	e replacement products [gum / patch / other], other
Verified Approved Locked Frozen	Page Version No. WEEK_24 (v1, 25-MAR-2009)
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Initials:	Subject #:
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STUDY PRODUCT U	JSE DIARY
During the past week:	Date of completion:
1. I have not smoked any cigarettes at all during the past we Correct \sum Incorrect	eek (1 or 2 puffs = 1 cigarette)
2. I have smoked on averagecigarettes	per day
3. I have smoked tobacco products other than cigarettes:	
No Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-contain cessation products this week?	ning products (e.g., gum or patch), or other smoking
☐Yes ☐ No	
If yes, what type (smokeless tobacco, pharmaceutical nicot nicotine products [e.g., lozenges])?	ine replacement products [gum / patch / other], other
Verified D	Page Version No WEEK_25 (v1, 25-MAR-2009)
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During the past week:  Date of completion:  1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)  Correct   Incorrect  2. I have smoked on average   cigarettes per day  3. I have smoked tobacco products other than cigarettes:  No   Yes-please specify:    4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?    Yes   No  If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?
During the past week:  Date of completion:  1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)  Correct Incorrect  2. I have smoked on average cigarettes per day  3. I have smoked tobacco products other than cigarettes:  No Yes-please specify:  4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?  Yes No  If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other
During the past week:  Date of completion:  1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)  Correct Incorrect  2. I have smoked on average cigarettes per day  3. I have smoked tobacco products other than cigarettes:  No Yes-please specify:  4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?  Yes No  If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other
During the past week:  Date of completion:  1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)  Correct
1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)  Correct Incorrect  2. I have smoked on average cigarettes per day  3. I have smoked tobacco products other than cigarettes:  No Yes-please specify:  4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?  Yes No  If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other
Correct
3. I have smoked tobacco products other than cigarettes:  No Yes-please specify:  4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?  Yes No  If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other
No Yes-please specify:  4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?  Yes No  If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other
4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?  Yes No  If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other
cessation products this week?  Yes No  If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other
Yes No  If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other
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Initials:		Subject #:
		Is Blank
	STUDY PRODUCT USE DIA	ARY
	STODITHODOOT CSZ DI	
During the past week:	Date o	f completion:
1. I have not smoked any ciga Correct Incorrect	arettes at all during the past week (1 o	r 2 puffs = 1 cigarette)
2. I have smoked on average	cigarettes per day	
3. I have smoked tobacco pro-	ducts other than cigarettes:	
☐ No ☐ Yes-please specify	71	
4. Did you use smokeless tobacessation products this week?		oducts (e.g., gum or patch), or other smoking
☐Yes ☐ No		
		acement products [gum / patch / other], other
nicotine products [e.g., lozeng	ges])?	
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Initials:	Subject #:
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STUDY PRODUCT US	SE DIARY
	Date of completion:
1. I have not smoked any cigarettes at all during the past wee Correct Incorrect	k (1 or 2 puffs = 1 cigarette)
2. I have smoked on average cigarettes pe	er day
3. I have smoked tobacco products other than cigarettes:	
No Yes-please specify:	
4. Did you use smokeless tobacco products, nicotine-contains cessation products this week?	ing products (e.g., gum or patch), or other smoking
☐Yes ☐ No	
If yes, what type (smokeless tobacco, pharmaceutical nicotin nicotine products [e.g., lozenges])?	e replacement products [gum / patch / other], other
Verified Approved Locked Frozen	Page Version No. WEEK_28 (v1, 25-MAR-2009)
	Document Number