

16.1.2 Sample Case Report Form

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

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	Investigator: _____	Subject Initials: _____. _____. ____.
Covance Study Number: 7694-105	Site: _____	

INCLUSION CRITERIA

Subjects who meet the following criteria may be included in the study. Did the subject meet the following criteria requirements for inclusion? (✓ Yes or No)		Yes 1	No* 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.		

*If No, document on Subject Eligibility Page.

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EXCLUSION CRITERIA

The following will exclude potential subjects from the study. Does the subject have any of the following? (✓ Yes or No)		Yes* 1	No 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 services 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.		

*If Yes, document on Subject Eligibility Page.