



**Swedish Match AB  
Clinical Study Protocol  
SM 07-01  
Case Report Form**

**To assess the efficacy of a traditional Swedish  
smokeless tobacco product (“snus”) to reduce  
smoking among adult smokers in Serbia**

**Subject/ Serial Number**

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**Subject Initials**

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**Confidential**

This document is a confidential communication. It is agreed that no unpublished information contained herein will be published or disclosed without prior approval from the sponsor. However, this document can be disclosed to an appropriate Institutional Review Board/Ethics Committee (IRB/EC) or authorized representatives of national regulatory authorities under the condition that they respect its confidential nature.

# INSTRUCTIONS FOR COMPLETION OF CASE REPORT FORMS

1. Complete all forms legibly in black permanent ballpoint pen.
2. Please use the guardboard (protection board) provided to prevent data being copied through the CRF.
3. The subject's initials and subject number must be written on all pages.
4. All boxes/data entry fields must be completed e.g. a double figure diastolic blood pressure should be recorded as:

1 | 2 | 0 | / | 0 | 8 | 0

5. Where data are missing, unknown or not done, record as "NK" in the CRF.
6. Data entered incorrectly should be crossed out with a single horizontal line. Write correct data next to it. All corrections or revisions to the CRF must be initialled and dated by authorised staff., e.g.:

Weight: 

			3	.	5
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 kg **3.8 KLM**  
**08/08/2000**

7. If no assessments on a CRF page have been completed, strike through the page with a single diagonal line, initial and date the page as above.
8. DO NOT USE CORRECTION FLUID OR OBLITERATE THE ORIGINAL DATA ENTRY.
9. The CRF data must be reviewed and signed by the Investigator who should sign the Investigator's Certification statement at the end of the CRF. Either the PI or other authorised investigator to whom this responsibility has been delegated may sign the certification.

<b>Subject Number</b> [ ][ ][ ][ ][ ]	<b>Subject Initials</b> [ ][ ][ ]	<b>Site Number</b> [ ][ ]	<b>Date of Visit</b> [ ][ ][ ][ ][ ][ ][ ][ ][ ] D D M M M Y Y Y Y
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**Inclusion Criteria**

Subjects meeting all of the following inclusion criteria at Screening should be considered for admission to the study.

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	1. Is the subject able to understand the requirements of the study and provide written informed consent to participate?
<input type="checkbox"/>	<input type="checkbox"/>	2. Is the subject male or female between the ages of 20 and 65 years, inclusive?
<input type="checkbox"/>	<input type="checkbox"/>	3. The subject smokes 10 or more cigarettes per day (average during the past month).
<input type="checkbox"/>	<input type="checkbox"/>	4. The subject smokes daily and has done so for more than 1 year.
<input type="checkbox"/>	<input type="checkbox"/>	5. The subject is motivated to substantially reduce or quit smoking.
<input type="checkbox"/>	<input type="checkbox"/>	6. The subject is in good general health.
<input type="checkbox"/>	<input type="checkbox"/>	7. The subject accepts not to take NRT or any other non-protocol treatment to facilitate smoking cessation, and accepts not to use any other form of tobacco products other than cigarettes during the study period.

**Exclusion Criteria**

Subjects meeting any of the following exclusion criteria at Screening will not be enrolled in the study.

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	1. Does the subject have uncontrolled hypertension( systolic> 140 mg Hg, diastolic> 90 mg Hg)?
<input type="checkbox"/>	<input type="checkbox"/>	2. Does the subject have a history of coronary heart disease or other significant heart condition?
<input type="checkbox"/>	<input type="checkbox"/>	3. Does the subject have a history of another significant medical condition which may interfere with study procedures?
<input type="checkbox"/>	<input type="checkbox"/>	4. Is the subject a pregnant or nursing mother?
<input type="checkbox"/>	<input type="checkbox"/>	5. Does the subject currently abuse alcohol or drugs?
<input type="checkbox"/>	<input type="checkbox"/>	6. Does the subject currently have active oral disease that may interfere with use of snus?
<input type="checkbox"/>	<input type="checkbox"/>	7. Does the subject have significant psychiatric or psychosocial problems that may interfere with study procedures?
<input type="checkbox"/>	<input type="checkbox"/>	8. Has the subject used any type of pharmaceutical or other products for smoking reduction or cessation within the past 3 months?



<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
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**Medical History**

1. The subject has had a previous medical condition?

- Yes      *If Yes, please specify:* \_\_\_\_\_
- No

2. The subject has a current significant medical condition (*based on investigator's medical opinion, medical condition excluding child birth that required hospitalisation or medical check ups during > 3 months, or medical treatment with prescription drugs during > 3 months*)?

- Yes      *If Yes, please specify:* \_\_\_\_\_
- No

3. The subject is currently taking prescription drugs on a regular basis?

- Yes      *If Yes, please complete Prior and Concomitant medications page*
- No

**CO In Exhaled Air**

CO in exhaled air: □ □ □ ppm (<1 to be recorded as 0)

**Lung Function Tests**

FVC (litres) □ . □ □

FEV<sub>1</sub> (litres) □ . □ □

FEV<sub>%</sub> □ □ □

**Vital Signs**

Supine recordings will be made after the subject has been recumbent for 3 minutes.

Blood Pressure: □ □ □ mmHg  
Systolic

□ □ □ mmHg  
Diastolic

Weight (without shoes): □ □ □ kgs

Height: □ □ □ cms

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
<b>Hematology</b>			
<b>Test Name</b>	<b>Value</b>	<b>Units</b>	
1. Total S-WBC			

<b>Chemistry</b>		
<b>Test Name</b>	<b>Value</b>	<b>Units</b>
1. S-CRP		
2. Total S-cholesterol		
3. S-HDL		
4. S-LDL		
5. S-Fibrinogen		
6. S- Cotinine		

<b>Subject Number</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Subject Initials</b> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Site Number</b> <input type="text"/> <input type="text"/>	
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**Fagerstrom Test**

Please tick (✓) one box for each question to determine your level of dependence on nicotine.

1. How soon after you wake up do you smoke your first cigarette?

- 0 = After 60 minutes
- 1 = 31-60 minutes
- 2 = 6-30 minutes
- 3 = Within 5 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden?

- 0 = No
- 1 = Yes

3. Which cigarette would you hate most to give up?

- 1 = The first in the morning
- 0 = Any other

4. How many cigarettes per day do you smoke?

- 0 = 10 or less
- 1 = 11-20
- 2 = 21-30
- 3 = 31 or more

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?

- 0 = No
- 1 = Yes

6. Do you smoke even if you are so ill that you are in bed most of the day?

- 0 = No
- 1 = Yes

Total Score( Sum of scores for individual questions) :

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
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**Self Reported Smoking Status**

During the past year:

1. The subject has smoked on average □ □ □ cigarettes per day.

2. The subject has smoked tobacco products other than cigarettes:

- Yes *If Yes, please specify:* \_\_\_\_\_
- No

Please record the unique number from tear-off portion of label in the boxes provided here.

□	□	□	□
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Please attach the starter pack tear-off label in the space provided below

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	<b>Date of Visit</b> <table border="1" style="width: 100%; text-align: center;"> <tr> <td>□</td><td>□</td><td>□</td><td>□</td><td>□</td><td>2</td><td>0</td><td>0</td><td>□</td> </tr> <tr> <td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	□	□	□	□	□	2	0	0	□	D	D	M	M	M	Y	Y	Y	Y
□	□	□	□	□	2	0	0	□													
D	D	M	M	M	Y	Y	Y	Y													

**Telephone Contact**

1. Flavour of snus packets preferred by the subject:

- Eucalyptus
- Liquorice

2. Size of snus packets preferred by the subject:

- 0.5g (Small)
- 1g (Large)

**Compliance**

1. Has the subject tried the study products as instructed at least once every day (i.e. has the subject tried the product instead of immediately lighting up a cigarette when he/she felt an urge to smoke) ?

- Yes
- No

2. Has subject used any source of nicotine other than cigarettes or snus e.g. cigars, NRT or other pharmaceutical smoking cessation aid?

- Yes *If Yes, please specify:* \_\_\_\_\_
- No

**Adverse Events**

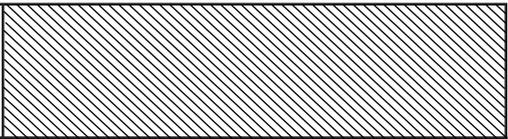
Review Adverse Events and enter on the Adverse Events page

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	<b>Date of Visit</b> □ □ □ □ <b>2 0 0</b> □ D D M M M Y Y Y Y
<b>CO In Exhaled Air</b>			
CO in exhaled air: □ □ □ ppm (<1 to be recorded as 0)			

<b>Compliance</b>
<p>1. Has the subject tried the study products as instructed at least once every day (i.e. has the subject tried the product instead of immediately lighting up a cigarette when he/she felt an urge to smoke) ?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>2. Has subject used any source of nicotine other than cigarettes or snus e.g. cigars, NRT or other pharmaceutical smoking cessation aid?</p> <p><input type="checkbox"/> Yes <i>If Yes, please specify:</i> _____</p> <p><input type="checkbox"/> No</p>

<b>Adverse Events</b>
Review Adverse Events and enter on the Adverse Events page

<b>Log Labels</b>
<p>1. Have additional logs been administered to the subject ?</p> <p><input type="checkbox"/> Yes (if yes then please complete the question below)</p> <p><input type="checkbox"/> No</p> <p>2. How many logs were administered to the subject? □ □</p>

<b>Subject Number</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Subject Initials</b> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Site Number</b> <input type="text"/> <input type="text"/>	
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Please attach the log tear-off label in the space provided below

<b>Subject Number</b> [ ][ ][ ][ ]	<b>Subject Initials</b> [ ][ ][ ]	<b>Site Number</b> [ ][ ]	<b>Date of Visit</b> [ ][ ][ ][ ][ ][ ][ ][ ][ ] D D M M M Y Y Y Y Y 2 0 0
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**CO In Exhaled Air**

CO in exhaled air: [ ][ ][ ] ppm (<1 to be recorded as 0)

**Vital Signs**

Supine recordings will be made after the subject has been recumbent for 3 minutes.

Blood Pressure: [ ][ ][ ] mmHg  NCS\* [ ][ ][ ] mmHg  NCS\*  
Systolic Diastolic

Weight (without shoes): [ ][ ][ ] kgs

\*NCS- Not Clinically Significant

**Self Reported Smoking Status**

Please transcribe from the subject's diary.

1. The subject has smoked on average the following number of cigarettes per day.

(0 means NO CIGARETTES FOR THE ENTIRE DAY. Even one puff on one occasion should be recorded as one cigarette).

Week 1	Week 2	Week 3
[ ][ ][ ]	[ ][ ][ ]	[ ][ ][ ]
Week 4	Week 5	Week 6
[ ][ ][ ]	[ ][ ][ ]	[ ][ ][ ]

2. The subject has consumed the following number of snus packets per day.

Week 1:	Large (1g)	[ ][ ][ ]	Small (0.5g)	[ ][ ][ ]
Week 2:	Large (1g)	[ ][ ][ ]	Small (0.5g)	[ ][ ][ ]
Week 3:	Large (1g)	[ ][ ][ ]	Small (0.5g)	[ ][ ][ ]
Week 4:	Large (1g)	[ ][ ][ ]	Small (0.5g)	[ ][ ][ ]
Week 5:	Large (1g)	[ ][ ][ ]	Small (0.5g)	[ ][ ][ ]
Week 6:	Large (1g)	[ ][ ][ ]	Small (0.5g)	[ ][ ][ ]

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
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**Compliance**

1. Has the subject tried the study products as instructed at least once every day (i.e. has the subject tried the product instead of immediately lighting up a cigarette when he/she felt an urge to smoke) ?

- Yes
- No

2. Has subject used any source of nicotine other than cigarettes or snus e.g. cigars, NRT or other pharmaceutical smoking cessation aid?

- Yes *If Yes, please specify:* \_\_\_\_\_
- No

**Adverse Events**

Review Adverse Events and enter on the Adverse Events page

**Log Labels**

1. Have additional logs been administered to the subject ?

- Yes (if yes then please complete the question below)
- No

2. How many logs were administered to the subject? □ □

Please attach the log tear-off label in the space provided below

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	<b>Date of Visit</b> <table border="1"> <tr> <td>□</td><td>□</td><td>□</td><td>□</td><td>□</td><td>2</td><td>0</td><td>0</td><td>□</td> </tr> <tr> <td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	□	□	□	□	□	2	0	0	□	D	D	M	M	M	Y	Y	Y	Y
□	□	□	□	□	2	0	0	□													
D	D	M	M	M	Y	Y	Y	Y													
<b>Telephone Contact</b>																					

**Self Reported Smoking Status**

Please transcribe from the subject's diary.

1. The subject has smoked on average the following number of cigarettes per day.  
(0 means NO CIGARETTES FOR THE ENTIRE DAY. Even one puff on one occasion should be recorded as one cigarette).

Week 7	Week 8	Week 9
□ □ □	□ □ □	□ □ □

2. The subject has consumed the following number of snus packets per day.

Week 7:	Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 8:	Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 9:	Large (1g)	□ □ □	Small (0.5g)	□ □ □

**Compliance**

1. Has the subject tried the study products as instructed at least once every day (i.e. has the subject tried the product instead of immediately lighting up a cigarette when he/she felt an urge to smoke) ?

Yes  
 No

2. Has subject used any source of nicotine other than cigarettes or snus e.g. cigars, NRT or other pharmaceutical smoking cessation aid?

Yes *If Yes, please specify:* \_\_\_\_\_  
 No

**Adverse Events**

Review Adverse Events and enter on the Adverse Events page

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	<b>Date of Visit</b> □ □ □ □ □ □ <b>2 0 0</b> □ D D M M M Y Y Y Y
<b>CO In Exhaled Air</b>			
CO in exhaled air: □ □ □ ppm (<1 to be recorded as 0)			

<b>Lung Function Tests</b>			
<b>FVC (litres)</b>	□ . □ □		
<b>FEV<sub>1.0</sub> (litres)</b>	□ . □ □		
<b>FEV<sub>%</sub></b>	□ □ □		

<b>Vital Signs</b>			
Supine recordings will be made after the subject has been recumbent for 3 minutes.			
Blood Pressure:	□ □ □ mmHg	<input type="checkbox"/> NCS*	□ □ □ mmHg <input type="checkbox"/> NCS*
	Systolic		Diastolic
Weight (without shoes):	□ □ □ kgs		
<i>*NCS- Not Clinically Significant</i>			

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
<b>Hematology</b>			
<b>Test Name</b>	<b>Value</b>	<b>Units</b>	
1. Total S-WBC			

<b>Chemistry</b>		
<b>Test Name</b>	<b>Value</b>	<b>Units</b>
1. S-CRP		
2. Total S-cholesterol		
3. S-HDL		
4. S-LDL		
5. S-Fibrinogen		
6. S- Cotinine		

<b>Self Reported Smoking Status</b>		
<u>Please transcribe from the subject's diary.</u>		
1. The subject has smoked on average the following number of cigarettes per day. (0 means NO CIGARETTES FOR THE ENTIRE DAY. Even one puff on one occasion should be recorded as one cigarette).		
Week 10 □ □ □	Week 11 □ □ □	Week 12 □ □ □
2. The subject has consumed the following number of snus packets per day.		
Week 10: Large (1g) □ □ □	Small (0.5g) □ □ □	
Week 11: Large (1g) □ □ □	Small (0.5g) □ □ □	
Week 12: Large (1g) □ □ □	Small (0.5g) □ □ □	

<b>Subject Number</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Subject Initials</b> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Site Number</b> <input type="text"/> <input type="text"/>	
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**Efficacy Assessments**

1. Has the subject reduced smoking (*smoking reduction defined as self reported reduction of  $\geq 50\%$  compared to baseline in the average number of smoked cigarettes per day during the preceding 4 week period i.e. week 9-12 verified by a reduced concentration of carbon monoxide (CO) in exhaled air of at least 1 ppm*)?

- Yes
- No

2. Has the subject been able to stop smoking completely (*smoking cessation defined as self reported total abstinence from cigarettes during the preceding 1 and 4 week period, verified by a CO- concentration in exhaled air of  $< 10$  ppm at this visit*)?

1 week period

- Yes
- No

4 week period (weeks 9-12)

- Yes
- No

**Compliance**

1. Has the subject tried the study products as instructed at least once every day (i.e. has the subject tried the product instead of immediately lighting up a cigarette when he/she felt an urge to smoke) ?

- Yes
- No

2. Has subject used any source of nicotine other than cigarettes or snus e.g. cigars, NRT or other pharmaceutical smoking cessation aid?

- Yes *If Yes, please specify:* \_\_\_\_\_
- No

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
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**Adverse Events**

Review Adverse Events and enter on the Adverse Events page

**Log Labels**

- Have the additional logs been administered to the subject ?
  - Yes (if yes then please complete the question below)
  - No
- How many logs were administered to the subject? □ □

Please attach the log tear-off label in the space provided below

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	<b>Date of Visit</b> □ □ □ □ □ □ <b>2 0 0</b> □ D D M M M Y Y Y Y
<b>CO In Exhaled Air</b>			
CO in exhaled air: □ □ □ ppm (<1 to be recorded as 0)			

<b>Self Reported Smoking Status</b>			
<u>Please transcribe from the subject's diary.</u>			
1. The subject has smoked on average the following number of cigarettes per day. (0 means NO CIGARETTES FOR THE ENTIRE DAY. Even one puff on one occasion should be recorded as one cigarette).			
Week 13	Week 14	Week 15	
□ □ □	□ □ □	□ □ □	
Week 16	Week 17	Week 18	
□ □ □	□ □ □	□ □ □	
2. The subject has consumed the following number of snus packets per day.			
Week 13: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 14: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 15: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 16: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 17: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 18: Large (1g)	□ □ □	Small (0.5g)	□ □ □

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
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**Compliance**

1. Has the subject tried the study products as instructed at least once every day (i.e. has the subject tried the product instead of immediately lighting up a cigarette when he/she felt an urge to smoke) ?

- Yes
- No

2. Has subject used any source of nicotine other than cigarettes or snus e.g. cigars, NRT or other pharmaceutical smoking cessation aid?

- Yes *If Yes, please specify:* \_\_\_\_\_
- No

**Adverse Events**

Review Adverse Events and enter on the Adverse Events page

**Log Labels**

1. Have the additional logs been administered to the subject ?

- Yes (if yes then please complete the question below)
- No

2. How many logs were administered to the subject? □ □

Please attach the log tear-off label in the space provided below

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □ □	<b>Site Number</b> □ □	<b>Date of Visit</b> □ □ □ □ □ □ <b>2 0 0</b> □ □ □ □ D D M M M Y Y Y Y
<b>CO In Exhaled Air</b>			
CO in exhaled air: □ □ □ ppm (<1 to be recorded as 0)			

<b>Lung Function Tests</b>			
<b>FVC (litres)</b>	□ . □ □		
<b>FEV<sub>1.0</sub> (litres)</b>	□ . □ □		
<b>FEV<sub>%</sub></b>	□ □ □		

<b>Vital Signs</b>			
Supine recordings will be made after the subject has been recumbent for 3 minutes.			
Blood Pressure:	□ □ □ mmHg	<input type="checkbox"/> NCS*	□ □ □ mmHg <input type="checkbox"/> NCS*
	Systolic		Diastolic
Weight (without shoes):	□ □ □ kgs		
<i>*NCS- Not Clinically Significant</i>			

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
<b>Hematology</b>			
<b>Test Name</b>	<b>Value</b>	<b>Units</b>	
1. Total S-WBC			

<b>Chemistry</b>		
<b>Test Name</b>	<b>Value</b>	<b>Units</b>
1. S-CRP		
2. Total S-cholesterol		
3. S-HDL		
4. S-LDL		
5. S-Fibrinogen		
6. S- Cotinine		

<b>Subject Number</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Subject Initials</b> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Site Number</b> <input type="text"/> <input type="text"/>	
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**Self Reported Smoking Status**

Please transcribe from the subject's diary.

1. The subject has smoked on average the following number of cigarettes per day.

(0 means NO CIGARETTES FOR THE ENTIRE DAY. Even one puff on one occasion should be recorded as one cigarette).

Week 19	Week 20	Week 21
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Week 22	Week 23	Week 24
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>

2. The subject has consumed the following number of snus packets per day.

Week 19: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 20: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 21: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 22: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 23: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 24: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>

<b>Subject Number</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Subject Initials</b> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Site Number</b> <input type="text"/> <input type="text"/>	
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**Efficacy Assessments**

1. Has the subject reduced smoking (*smoking reduction defined as self reported reduction of  $\geq 50$  % compared to baseline in the average number of smoked cigarettes per day during the preceding 4 week period ,before this visit verified by a reduced concentration of carbon monoxide (CO) in exhaled air of at least 1ppm at this visit*)?

- Yes
- No

2. Has the subject fulfilled the above criteria ?

- Yes *The subject continues the study*
- No *The subject discontinues the study\**

\*Complete the final status page if the subject has been discontinued from the study

3. Has the subject been able to stop smoking completely (*smoking cessation defined as self reported total abstention from cigarettes during the preceding 1 or 4 week period, verified by a CO- concentration in exhaled air of  $< 10$  ppm at this visit*)?

1 week period

- Yes
- No

4 week period

- Yes
- No

<b>Subject Number</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Subject Initials</b> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Site Number</b> <input type="text"/> <input type="text"/>	
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**Fagerstrom Test**

Has participant stopped smoking during past week?

- = No *If no, Fagerstrom does not need to be performed.*
- = Yes *If yes, please fill in the Fagerstrom test.*

Please tick (✓) one box for each question to determine your level of dependence on nicotine.

1. How soon after you wake up do you smoke your first cigarette?

- 0 = After 60 minutes
- 1 = 31-60 minutes
- 2 = 6-30 minutes
- 3 = Within 5 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden?

- 0 = No
- 1 = Yes

3. Which cigarette would you hate most to give up?

- 1 = The first in the morning
- 0 = Any other

4. How many cigarettes per day do you smoke?

- 0 = 10 or less
- 1 = 11-20
- 2 = 21-30
- 3 = 31 or more

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?

- 0 = No
- 1 = Yes

6. Do you smoke even if you are so ill that you are in bed most of the day?

- 0 = No
- 1 = Yes

Total Score( Sum of scores for individual questions) :

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
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**Compliance**

1. Has the subject tried the study products as instructed at least once every day (i.e. has the subject tried the product instead of immediately lighting up a cigarette when he/she felt an urge to smoke) ?

- Yes
- No

2. Has subject used any source of nicotine other than cigarettes or snus e.g. cigars, NRT or other pharmaceutical smoking cessation aid?

- Yes *If Yes, please specify:* \_\_\_\_\_
- No

**Adverse Events**

Review Adverse Events and enter on the Adverse Events page

**Log Labels**

1. Have the additional logs been administered to the subject ?

- Yes (if yes then please complete the question below)
- No

2. How many logs were administered to the subject? □ □

Please attach the log tear-off label in the space provided below

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	<b>Date of Visit</b> □ □ □ □ □ <b>2 0 0</b> □ D D M M M Y Y Y Y
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**CO In Exhaled Air**

CO in exhaled air: □ □ □ ppm (<1 to be recorded as 0)

**Self Reported Smoking Status**

Please transcribe from the subject's diary.

1. The subject has smoked on average the following number of cigarettes per day.

(0 means NO CIGARETTES FOR THE ENTIRE DAY. Even one puff on one occasion should be recorded as one cigarette).

Week 25 □ □ □	Week 26 □ □ □	Week 27 □ □ □
Week 28 □ □ □	Week 29 □ □ □	Week 30 □ □ □

2. The subject has consumed the following number of snus packets per day.

Week 25: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 26: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 27: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 28: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 29: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 30: Large (1g)	□ □ □	Small (0.5g)	□ □ □

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
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**Compliance**

1. Has the subject tried the study products as instructed at least once every day (i.e. has the subject tried the product instead of immediately lighting up a cigarette when he/she felt an urge to smoke) ?

Yes

No

2. Has subject used any source of nicotine other than cigarettes or snus e.g. cigars, NRT or other pharmaceutical smoking cessation aid?

Yes *If Yes, please specify:* \_\_\_\_\_

No

**Adverse Events**

Review Adverse Events and enter on the Adverse Events page

**Log Labels**

1. Have the additional logs been administered to the subject ?

Yes (if yes then please complete the question below)

No

2. How many logs were administered to the subject? □ □

Please attach the log tear-off label in the space provided below

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	<b>Date of Visit</b> □ □ □ □ □ □ <b>2 0 0</b> □ D D M M M Y Y Y Y
<b>CO In Exhaled Air</b>			
CO in exhaled air: □ □ □ ppm (<1 to be recorded as 0)			

<b>Lung Function Tests</b>
FVC (litres) □ . □ □
FEV <sub>1.0</sub> (litres) □ . □ □
FEV <sub>%</sub> □ □ □

<b>Vital Signs</b>
Supine recordings will be made after the subject has been recumbent for 3 minutes.
Blood Pressure: □ □ □ mmHg □ NCS* □ □ □ mmHg □ NCS* Systolic Diastolic
Weight (without shoes): □ □ □ kgs
<i>*NCS- Not Clinically Significant</i>

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
<b>Hematology</b>			
<b>Test Name</b>	<b>Value</b>	<b>Units</b>	
1. Total S-WBC			

<b>Chemistry</b>		
<b>Test Name</b>	<b>Value</b>	<b>Units</b>
1. S-CRP		
2. Total S-cholesterol		
3. S-HDL		
4. S-LDL		
5. S-Fibrinogen		
6. S- Cotinine		

<b>Subject Number</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Subject Initials</b> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Site Number</b> <input type="text"/> <input type="text"/>	
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**Self Reported Smoking Status**

Please transcribe from the subject's diary.

1. The subject has smoked on average the following number of cigarettes per day.

(0 means NO CIGARETTES FOR THE ENTIRE DAY. Even one puff on one occasion should be recorded as one cigarette).

Week 31	Week 32	Week 33
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Week 34	Week 35	Week 36
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>

2. The subject has consumed the following number of snus packets per day.

Week 31: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 32: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 33: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 34: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 35: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 36: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
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**Efficacy Assessments**

1. Has the subject been able to stop smoking completely (*smoking cessation defined as self reported total abstinence from cigarettes during the preceding 1,4, 12, or 24 week period, verified by a CO- concentration in exhaled air of <10 ppm at all measurements during the specified time period*)?

1 week period (based on self report and CO value at week 36)

Yes

No

4 week period (weeks 33- 36) based on self report and CO value at week 36

Yes

No

12 week period (weeks 25-36) based on self report and CO value at week 30 and week 36

Yes

No

24 week period (weeks 13-36) based on self report and CO value at weeks 18, 24, 30 and 36

Yes

No

**Compliance**

1. Has the subject tried the study products as instructed at least once every day (i.e. has the subject tried the product instead of immediately lighting up a cigarette when he/she felt an urge to smoke) ?

Yes

No

2. Has subject used any source of nicotine other than cigarettes or snus e.g. cigars, NRT or other pharmaceutical smoking cessation aid?

Yes *If Yes, please specify:* \_\_\_\_\_

No

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
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**Adverse Events**

Review Adverse Events and enter on the Adverse Events page

**Log Labels**

- Have the additional logs been administered to the subject ?  
 Yes (if yes then please complete the question below)  
 No
- How many logs were administered to the subject? □ □

Please attach the log tear-off label in the space provided below

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	<b>Date of Visit</b> □ □ □ □ □ □ <b>2 0 0</b> □ □ □ □ D D M M M Y Y Y Y
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**CO In Exhaled Air**

CO in exhaled air: □ □ □ ppm (<1 to be recorded as 0)

**Self Reported Smoking Status**

Please transcribe from the subject's diary.

1. The subject has smoked on average the following number of cigarettes per day.

(0 means NO CIGARETTES FOR THE ENTIRE DAY. Even one puff on one occasion should be recorded as one cigarette).

Week 37 □ □ □	Week 38 □ □ □	Week 39 □ □ □
Week 40 □ □ □	Week 41 □ □ □	Week 42 □ □ □

2. The subject has consumed the following number of snus packets per day.

Week 37: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 38: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 39: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 40: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 41: Large (1g)	□ □ □	Small (0.5g)	□ □ □
Week 42: Large (1g)	□ □ □	Small (0.5g)	□ □ □

**Adverse Events**

Review Adverse Events and enter on the Adverse Events page

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	<b>Date of Visit</b> □ □ □ □ □ □ <b>2 0 0</b> □ D D M M M Y Y Y Y
<b>CO In Exhaled Air</b>			
CO in exhaled air: □ □ □ ppm (<1 to be recorded as 0)			

<b>Lung Function Tests</b>			
<b>FVC (litres)</b>	□ . □ □		
<b>FEV<sub>1.0</sub> (litres)</b>	□ . □ □		
<b>FEV<sub>%</sub></b>	□ □ □		

<b>Vital Signs</b>			
Supine recordings will be made after the subject has been recumbent for 3 minutes.			
Blood Pressure:	□ □ □ mmHg	<input type="checkbox"/> NCS*	□ □ □ mmHg <input type="checkbox"/> NCS*
	Systolic		Diastolic
Weight (without shoes):	□ □ □ kgs		
*NCS- Not Clinically Significant			

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
<b>Hematology</b>			
<b>Test Name</b>	<b>Value</b>	<b>Units</b>	
1. Total S-WBC			

<b>Chemistry</b>		
<b>Test Name</b>	<b>Value</b>	<b>Units</b>
1. S-CRP		
2. Total S-cholesterol		
3. S-HDL		
4. S-LDL		
5. S-Fibrinogen		
6. S- Cotinine		

<b>Subject Number</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Subject Initials</b> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Site Number</b> <input type="text"/> <input type="text"/>	
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**Self Reported Smoking Status**

Please transcribe from the subject's diary.

1. The subject has smoked on average the following number of cigarettes per day.

(0 means NO CIGARETTES FOR THE ENTIRE DAY. Even one puff on one occasion should be recorded as one cigarette).

Week 43	Week 44	Week 45
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Week 46	Week 47	Week 48
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>

2. The subject has consumed the following number of snus packets per day.

Week 43: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 44: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 45: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 46: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 47: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>
Week 48: Large (1g)	<input type="text"/> <input type="text"/> <input type="text"/>	Small (0.5g)	<input type="text"/> <input type="text"/> <input type="text"/>

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
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**Efficacy Assessments**

1. Has the subject been able to stop smoking completely (*smoking cessation defined as self reported total abstinence from cigarettes during the preceding 1,4, 12, or 24 week period, verified by a CO- concentration in exhaled air of <10 ppm at all measurements during the specified time period*)?

1 week period (based on CO value at week 48)

Yes

No

4 week period (weeks 45- 48) based on CO value at week 48

Yes

No

12 week period (weeks 37-48) based on CO value at week 42 and week 48

Yes

No

24 week period (weeks 24-48) based on CO value at weeks 30, 42 and 48

Yes

No

<b>Subject Number</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Subject Initials</b> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Site Number</b> <input type="text"/> <input type="text"/>	
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**Fagerstrom Test**

Has participant stopped smoking during past week?

- = No *If no, Fagerstrom does not need to be performed.*
- = Yes *If yes, please fill in the Fagerstrom test.*

Please tick (✓) one box for each question to determine your level of dependence on nicotine.

1. How soon after you wake up do you smoke your first cigarette?

- 0 = After 60 minutes
- 1 = 31-60 minutes
- 2 = 6-30 minutes
- 3 = Within 5 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden?

- 0 = No
- 1 = Yes

3. Which cigarette would you hate most to give up?

- 1 = The first in the morning
- 0 = Any other

4. How many cigarettes per day do you smoke?

- 0 = 10 or less
- 1 = 11-20
- 2 = 21-30
- 3 = 31 or more

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?

- 0 = No
- 1 = Yes

6. Do you smoke even if you are so ill that you are in bed most of the day?

- 0 = No
- 1 = Yes

Total Score( Sum of scores for individual questions) :

<b>Subject Number</b> □ □ □ □	<b>Subject Initials</b> □ □ □	<b>Site Number</b> □ □	
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**Compliance**

1. Has the subject tried the study products as instructed at least once every day (i.e. has the subject tried the product instead of immediately lighting up a cigarette when he/she felt an urge to smoke) ?

Yes

No

2. Has subject used any source of nicotine other than cigarettes or snus e.g. cigars, NRT or other pharmaceutical smoking cessation aid?

Yes *If Yes, please specify:* \_\_\_\_\_

No

**Adverse Events**

Review Adverse Events and enter on the Adverse Events page

**Log Labels**

1. Have the additional logs been administered to the subject ?

Yes (if yes then please complete the question below)

No

2. How many logs were administered to the subject? □ □

Please attach the log tear-off label in the space provided below

<b>Subject Number</b> □ □ □ □ □	<b>Subject Initials</b> □ □ □ □ □	<b>Site Number</b> □ □ □ □ □	
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**Termination Case Report**

Has the subject completed the study?  Yes  No

Date completed or withdrawn: □ □ □ □ □ **2 0 0** □ □ □ □ □  
D D M M M Y Y Y Y

If withdrawn choose one:

- Failure to achieve "smoking reduction" at 24 weeks (>50% reduction of self reported number of smoked cigarettes during week 20-24, and CO in exhaled air <1ppm, compared to baseline)
- Protocol violation
- Lost to follow up
- Withdrawal of consent
- Adverse Event (Adverse Reaction)
- Death
- Other: \_\_\_\_\_

*Specify*

Was the treatment unblinded?  Yes  No

If Yes, date of unblinding. □ □ □ □ □ **2 0 0** □ □ □ □ □  
D D M M M Y Y Y Y

Reason: \_\_\_\_\_

**PI Signature**

I have reviewed the case report form pages for the above subject and certify that they are accurate and complete

Signature: \_\_\_\_\_ Date: □ □ □ □ □ **2 0 0** □ □ □ □ □  
D D M M M Y Y Y Y

Name printed: \_\_\_\_\_

<b>Subject Number</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Subject Initials</b> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Site Number</b> <input type="text"/> <input type="text"/>	<b>Date of Visit</b> <input type="text"/> <input type="text"/> D D M M M Y Y Y Y
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**Visit Week**

Please mention the reason for visit \_\_\_\_\_

Please attach the log tear-off label in the space provided below



# Swedish Match - SM 07-01

Subject Number		Subject Initials		Site Number		Tick here if this is the last page <input type="checkbox"/>																															
Adverse Events		Adverse Events		Adverse Events		Adverse Events		Adverse Events		Adverse Events																											
Description of Adverse Events		Description of Adverse Events		Description of Adverse Events		Description of Adverse Events		Description of Adverse Events		Description of Adverse Events																											
Start and Stop Dates		Start and Stop Dates		Start and Stop Dates		Start and Stop Dates		Start and Stop Dates		Start and Stop Dates																											
Description of AE Start <table border="1" style="display: inline-table; vertical-align: middle;"> <tr><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>D</td><td>D</td><td>M</td><td>M</td><td>Y</td><td>Y</td></tr> </table> Stop <table border="1" style="display: inline-table; vertical-align: middle;"> <tr><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>D</td><td>D</td><td>M</td><td>M</td><td>Y</td><td>Y</td></tr> </table> 2 0 0 <input type="checkbox"/> OR Ongoing								D	D	M	M	Y	Y							D	D	M	M	Y	Y	Severity 1 Mild 2 Moderate 3 Severe 4 Not Applicable		Action taken regarding study drug 1 None 2 Dose interrupted 3 Discontinued		Concomitant therapy started due to AE 1 Yes 2 No		Relationship to study drug 1 Unrelated 2 Unlikely 3 Possibly 4 Probably 5 Definitely		Subject Outcome 1 Resolved with no sequelae 2 Resolved with sequelae 3 Death 4 Unknown 5 Lost to Follow Up		Serious 1 No 2 Yes, If Yes please complete serious adverse event form	
D	D	M	M	Y	Y																																
D	D	M	M	Y	Y																																
Description of AE Start <table border="1" style="display: inline-table; vertical-align: middle;"> <tr><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>D</td><td>D</td><td>M</td><td>M</td><td>Y</td><td>Y</td></tr> </table> Stop <table border="1" style="display: inline-table; vertical-align: middle;"> <tr><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>D</td><td>D</td><td>M</td><td>M</td><td>Y</td><td>Y</td></tr> </table> 2 0 0 <input type="checkbox"/> OR Ongoing								D	D	M	M	Y	Y							D	D	M	M	Y	Y	Severity <input type="checkbox"/>		Action taken regarding study drug <input type="checkbox"/>		Concomitant therapy started due to AE <input type="checkbox"/>		Relationship to study drug <input type="checkbox"/>		Subject Outcome <input type="checkbox"/>		Serious <input type="checkbox"/>	
D	D	M	M	Y	Y																																
D	D	M	M	Y	Y																																
Description of AE Start <table border="1" style="display: inline-table; vertical-align: middle;"> <tr><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>D</td><td>D</td><td>M</td><td>M</td><td>Y</td><td>Y</td></tr> </table> Stop <table border="1" style="display: inline-table; vertical-align: middle;"> <tr><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>D</td><td>D</td><td>M</td><td>M</td><td>Y</td><td>Y</td></tr> </table> 2 0 0 <input type="checkbox"/> OR Ongoing								D	D	M	M	Y	Y							D	D	M	M	Y	Y	Severity <input type="checkbox"/>		Action taken regarding study drug <input type="checkbox"/>		Concomitant therapy started due to AE <input type="checkbox"/>		Relationship to study drug <input type="checkbox"/>		Subject Outcome <input type="checkbox"/>		Serious <input type="checkbox"/>	
D	D	M	M	Y	Y																																
D	D	M	M	Y	Y																																

# SWEDISH MATCH - SM 07-01

<b>Subject Number</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Subject Initials</b> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Site Number</b> <input type="text"/> <input type="text"/>	
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## Comments Page

Tick here if this is the last page

Date of Comment	CRF Page Number	Comments
D D M M M Y Y Y Y		
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <b>2 0 0</b> <input type="text"/>		
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <b>2 0 0</b> <input type="text"/>		
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# SWEDISH MATCH - SM 07-01

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## Comments Page - Continued

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# Swedish Match - SM 07-01

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<b>Serious Adverse Event Report</b>			
Type of Report: <input type="checkbox"/> Initial <input type="checkbox"/> Follow Up			
<b>Subject Details:</b> Date of Birth: <input style="width: 20px; height: 20px;" type="text"/> Height <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> cms <small style="display: flex; justify-content: space-around; width: 100%;"> <span>D D M M M Y Y Y Y</span> </small>			
Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female                    Body Weight <input style="width: 20px; height: 20px;" type="text"/> Kgs			
Date of onset: <input style="width: 20px; height: 20px;" type="text"/> Date of Resolution: <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; width: 100%;"> <span>D D M M M Y Y Y Y</span> <span>D D M M M Y Y Y Y</span> </small>			
Name of Serious Adverse Event <hr/>			
Nature of Serious Adverse Event <hr/> <hr/> <hr/> <hr/> <hr/>			
<b>Likely Relationship of the Adverse Event</b> <input type="checkbox"/> Unrelated <input type="checkbox"/> Unlikely <input type="checkbox"/> Possibly <input type="checkbox"/> Probably <input type="checkbox"/> Definitely			
Duration and treatment received <hr/> <hr/> <hr/>			
<b>Outcome</b> <input type="checkbox"/> Resolved no sequelae <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Death <input type="checkbox"/> Ongoing <input type="checkbox"/> Unknown <input type="checkbox"/> Lost to Follow-up			
<b>Type of Serious Adverse Event</b> <input type="checkbox"/> Results in Death <input type="checkbox"/> Is life threatening <input type="checkbox"/> Results in permanent disability or incapacity <input type="checkbox"/> Is a congenital anomaly or birth defect <input type="checkbox"/> Requires unplanned hospitalisation or prolongation of existing hospitalisation. Date of Hospitalisation <input type="checkbox"/> Requires medical intervention of any kind in order to prevent any of the aforementioned outcomes <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; width: 100%;"> <span>D D M M M Y Y Y Y</span> </small>			

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