CRF Report for Study E7694105S

Report run by Brian Saari at 04-MAR-2013 14:58:42

Report Parameters

Site:	**P3880_0342**
Discrepancy status choice:	**All statuses**
Approval status choice:	**All statuses**
Verification status choice:	**All statuses**
Starting patient:	**R4044**
Ending patient:	**R4044**

Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	**Abc 123**

All time stamps displayed in this report are in the timezone of the database server.

The data contained in this report is current at the time of printing (time as shown above)

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R4044

BASELINE

Is Blank ☐

MINNESOTA NICOTINE WITHDRAWAL SCALE

Minnesota Nicotine Withdrawal Scale (check answers)

Time Taken: 14:13 (24-hr clock)

Please rate yourself for the period of the last 24 hours.
0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = severe

1. Angry, irritable, frustrated	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
2. Anxious, nervous	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
3. Depressed mood, sad	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
4. Desire or craving to smoke	☐ 0	☐ 1	☐ 2	☑ 3	☐ 4
5. Difficulty concentrating	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
6. Increased appetite, hungry, weight gain	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
7. Insomnia, sleep problems, awakening at night	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
8. Restless	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
9. Impatient	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4

Date: 05-MAY-2009

Total Score: 3

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4044

BASELINE

Is Blank ☐

FAGERSTROM TEST FOR NICOTINE DEPENDENCE

Fagerstrom Test for Nicotine Dependence (check answers)

Time Taken: 14:14 (24-hr clock)

1. How soon after waking do you smoke your first cigarette?
   - ☐ Less than five minutes
   - ☑ 5-30 minutes
   - ☐ 31-60 minutes
   - ☐ More than an hour
2. Do you find it difficult to refrain from smoking in places where it is forbidden?
   - ☐ Yes
   - ☑ No
3. Which cigarette would you hate to give up?
   - ☑ First one in the morning?
   - ☐ Any other
4. How many cigarettes do you smoke per day?
   - ☐ More than 30 per day
   - ☑ 21-30 per day
   - ☐ 11-20 per day
   - ☐ 10 or less per day
5. Do you smoke mare frequently during the first hours after waking than during the rest of the day?
   - ☐ Yes
   - ☑ No
6. Do you smoke if you are so ill that you are in bed most of the day?
   - ☑ Yes
   - ☐ No

Date: 05-MAY-2009

Total Score: 6

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Click here to navigate to discrepancy details for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4044

WEEK 6

Is Blank ☐

MINNESOTA NICOTINE WITHDRAWAL SCALE

Minnesota Nicotine Withdrawal Scale (check answers)

Time Taken: 13:40 (24-hr clock)

Please rate yourself for the period of the last 24 hours.
0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = severe

1. Angry, irritable, frustrated	☐ 0	☐ 1	☑ 2	☐ 3	☐ 4
2. Anxious, nervous	☐ 0	☑ 1	☐ 2	☐ 3	☐ 4
3. Depressed mood, sad	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
4. Desire or craving to smoke	☐ 0	☐ 1	☑ 2	☐ 3	☐ 4
5. Difficulty concentrating	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
6. Increased appetite, hungry, weight gain	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
7. Insomnia, sleep problems, awakening at night	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
8. Restless	☐ 0	☑ 1	☐ 2	☐ 3	☐ 4
9. Impatient	☐ 0	☑ 1	☐ 2	☐ 3	☐ 4

Date: 19-JUN-2009

Total Score: 7

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Click here to navigate to discrepancy details for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4044

WEEK 10

Is Blank ☑

MINNESOTA NICOTINE WITHDRAWAL SCALE

Minnesota Nicotine Withdrawal Scale (check answers)

Time Taken: _____ (24-hr clock)

Please rate yourself for the period of the last 24 hours.
0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = severe

1. Angry, irritable, frustrated	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2. Anxious, nervous	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
3. Depressed mood, sad	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
4. Desire or craving to smoke	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
5. Difficulty concentrating	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
6. Increased appetite, hungry, weight gain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
7. Insomnia, sleep problems, awakening at night	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
8. Restless	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
9. Impatient	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

Date: _____

Total Score: _____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4044

WEEK 16

Is Blank ☐

MINNESOTA NICOTINE WITHDRAWAL SCALE

Minnesota Nicotine Withdrawal Scale (check answers)

Time Taken: 11:13 (24-hr clock)

Please rate yourself for the period of the last 24 hours.
0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = severe

1. Angry, irritable, frustrated	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
2. Anxious, nervous	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
3. Depressed mood, sad	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
4. Desire or craving to smoke	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
5. Difficulty concentrating	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
6. Increased appetite, hungry, weight gain	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
7. Insomnia, sleep problems, awakening at night	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
8. Restless	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4
9. Impatient	☑ 0	☐ 1	☐ 2	☐ 3	☐ 4

Date: 15-JUL-2009

Total Score: 0

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4044

WEEK 16

Is Blank ☐

Did subject smoke at least 1 cigarette per day during the past week? ☑ Yes ☐ No

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4044

WEEK 16

Is Blank ☐

FAGERSTROM TEST FOR NICOTINE DEPENDENCE

Fagerstrom Test for Nicotine Dependence (check answers)

Time Taken: 11:14 (24-hr clock)

1. How soon after waking do you smoke your first cigarette?
   - ☐ Less than five minutes
   - ☑ 5-30 minutes
   - ☐ 31-60 minutes
   - ☐ More than an hour
2. Do you find it difficult to refrain from smoking in places where it is forbidden?
   - ☐ Yes
   - ☑ No
3. Which cigarette would you hate to give up?
   - ☑ First one in the morning?
   - ☐ Any other
4. How many cigarettes do you smoke per day?
   - ☐ More than 30 per day
   - ☐ 21-30 per day
   - ☐ 11-20 per day
   - ☑ 10 or less per day
5. Do you smoke mare frequently during the first hours after waking than during the rest of the day?
   - ☐ Yes
   - ☑ No
6. Do you smoke if you are so ill that you are in bed most of the day?
   - ☐ Yes
   - ☑ No

Date: 15-JUL-2009

Total Score: 3

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4044

WEEK 28

Is Blank ☑

MINNESOTA NICOTINE WITHDRAWAL SCALE

Minnesota Nicotine Withdrawal Scale (check answers)

Time Taken: _____ (24-hr clock)

Please rate yourself for the period of the last 24 hours.
0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = severe

1. Angry, irritable, frustrated	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2. Anxious, nervous	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
3. Depressed mood, sad	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
4. Desire or craving to smoke	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
5. Difficulty concentrating	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
6. Increased appetite, hungry, weight gain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
7. Insomnia, sleep problems, awakening at night	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
8. Restless	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
9. Impatient	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

Date: _____

Total Score: _____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4044

WEEK 28

Is Blank ☑

Did subject smoke at least 1 cigarette per day during the past week? ☐ Yes ☐ No

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4044

WEEK 28

Is Blank ☑

FAGERSTROM TEST FOR NICOTINE DEPENDENCE

Fagerstrom Test for Nicotine Dependence (check answers)

Time Taken: _____ (24-hr clock)

1. How soon after waking do you smoke your first cigarette?
   - ☐ Less than five minutes
   - ☐ 5-30 minutes
   - ☐ 31-60 minutes
   - ☐ More than an hour
2. Do you find it difficult to refrain from smoking in places where it is forbidden?
   - ☐ Yes
   - ☐ No
3. Which cigarette would you hate to give up?
   - ☐ First one in the morning?
   - ☐ Any other
4. How many cigarettes do you smoke per day?
   - ☐ More than 30 per day
   - ☐ 21-30 per day
   - ☐ 11-20 per day
   - ☐ 10 or less per day
5. Do you smoke mare frequently during the first hours after waking than during the rest of the day?
   - ☐ Yes
   - ☐ No
6. Do you smoke if you are so ill that you are in bed most of the day?
   - ☐ Yes
   - ☐ No

Date: _____

Total Score: _____

Appendix: Audit and Discrepancy Information

Audit History Report

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

Document #: **R268087013**

Patient Site	Visit Visit Date	CRF CRF Page
R4044 P3880_0342	Baseline	Fagerstrom 02

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Fagerstrom	Page number	1	Baseline

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Total Score (7) 1	5 6		12-JAN-2010 13:46:33 Lana Glaser	Data Entry Error

Document #: **R268090513**

Patient Site	Visit Visit Date	CRF CRF Page
R4044 P3880_0342	Week 6	Withdrawal Scale 03

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Withdrawl Scale	Page number	2	Week 6

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Date	09-JUN-2009		30-MAR-2010 13:22:21	Data Entry Error
1	19-JUN-2009		Kim Freschly	

Discrepancy Detail Report

Document #: R268087013

Discrepancy ID: 35433511 **Site:** P3880_0342 **Patient:** R4044
Visit: BASELINE **Visit Date:**
CRF: FAGERSTROM **Section:** FAGERSTROM **Qualifying Value:** 1
Field: Total Score **Row:** 1
Value Text: 6
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: **Please verify score calculation and update source and CRF appropriately.**
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R268090513

Discrepancy ID: 90896711 **Site:** P3880_0342 **Patient:** R4044
Visit: WEEK 6 **Visit Date:**
CRF: WITHDRAWAL SCAL **Section:** WITHDRAWL SCALE **Qualifying Value:** 2
Field: Date **Row:** 1
Value Text: 20090619
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: **Please verify updating date to 19-Jun-2009 as this is the date of all other Week 6 assessments. If 09-Jun-2009 is correct, please provide an in-query comment to explain the discrepancy.**
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Deleted CRFs Report