

# CRF Report for Study E7694105S

Report run by Tressa Brown at 13-FEB-2013 11:11:51

## Report Parameters

Site: L0689282\_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2006

Ending patient: R2006

### Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	<b>Abc 123</b>

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)



Initials:

(b)

Subject #:

R2006

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                 | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 2. Anxious, nervous                             | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |
| 3. Depressed mood, sad                          | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 4. Desire or craving to smoke                   | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input checked="" type="checkbox"/> 4 |
| 5. Difficulty concentrating                     | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 6. Increased appetite, hungry, weight gain      | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 7. Insomnia, sleep problems, awakening at night | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 8. Restless                                     | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 9. Impatient                                    | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |

Date:

Total Score:

Verified  Approved  Locked  Frozen

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

Document Number

## **Links to Discrepancy and Audit Sections**

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

Initials:

(b)

Subject #:

R2006

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 more 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:

Verified  Approved  Locked  Frozen

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

Document Number

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

Initials:

Subject #:

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                 | <input type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 2. Anxious, nervous                             | <input type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |
| 3. Depressed mood, sad                          | <input type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |
| 4. Desire or craving to smoke                   | <input type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input checked="" type="checkbox"/> 4 |
| 5. Difficulty concentrating                     | <input type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input checked="" type="checkbox"/> 4 |
| 6. Increased appetite, hungry, weight gain      | <input type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |
| 7. Insomnia, sleep problems, awakening at night | <input type="checkbox"/> 0 | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 8. Restless                                     | <input type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 9. Impatient                                    | <input type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |

Date:

Total Score:

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

Document Number

Initials:

(b)

Subject #:

R2006

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                 | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 2. Anxious, nervous                             | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |
| 3. Depressed mood, sad                          | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 4. Desire or craving to smoke                   | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 5. Difficulty concentrating                     | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4            |
| 6. Increased appetite, hungry, weight gain      | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 7. Insomnia, sleep problems, awakening at night | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |
| 8. Restless                                     | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input checked="" type="checkbox"/> 4 |
| 9. Impatient                                    | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4            |

Date:

Total Score:

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

Document Number

Initials:

(b)

Subject #:

R2006

WEEK 16

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                 | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 2. Anxious, nervous                             | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| 3. Depressed mood, sad                          | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| 4. Desire or craving to smoke                   | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| 5. Difficulty concentrating                     | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| 6. Increased appetite, hungry, weight gain      | <input type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 7. Insomnia, sleep problems, awakening at night | <input checked="" type="checkbox"/> 0 | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 8. Restless                                     | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 9. Impatient                                    | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |

Date:

Total Score:

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

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Initials:

(b)

Subject #:

R2006

WEEK 16

Is Blank

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

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Page Version No. FAG-INDICA (v1, 30-DEC-2009)

Document Number R286650413

Initials:

(b)

Subject #:

R2006

WEEK 16

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 more 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:

Verified  Approved  Locked  Frozen

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

Document Number

Initials:

(b)

Subject #:

R2006

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                 | <input type="checkbox"/> | 0 | <input type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 2. Anxious, nervous                             | <input type="checkbox"/> | 0 | <input type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 3. Depressed mood, sad                          | <input type="checkbox"/> | 0 | <input type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 4. Desire or craving to smoke                   | <input type="checkbox"/> | 0 | <input type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 5. Difficulty concentrating                     | <input type="checkbox"/> | 0 | <input type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 6. Increased appetite, hungry, weight gain      | <input type="checkbox"/> | 0 | <input type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 7. Insomnia, sleep problems, awakening at night | <input type="checkbox"/> | 0 | <input type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 8. Restless                                     | <input type="checkbox"/> | 0 | <input type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |
| 9. Impatient                                    | <input type="checkbox"/> | 0 | <input type="checkbox"/> | 1 | <input type="checkbox"/> | 2 | <input type="checkbox"/> | 3 | <input type="checkbox"/> | 4 |

Date:

Total Score:

Verified  Approved  Locked  Frozen

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

Document Number R266108113

Initials:

(b)

Subject #:

R2006

WEEK 28

Is Blank

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

Verified  Approved  Locked  Frozen

Page Version No. FAG-INDICA (v1, 30-DEC-2009)

Document Number R286650513

Initials:

(b)

Subject #:

R2006

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 more 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:

Verified  Approved  Locked  Frozen

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

Document Number R266108313

## 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 #:** R239907013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2006 L0689282_2	Baseline	Fagerstrom 02

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Fagerstrom	Page number	1	Baseline

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Date 1	29-MAR-2009 26-MAR-2009	11-MAY-2010 14:52:59 Amanda Lynn	Data Entry Error



# Deleted CRFs Report