

# CRF Report for Study E7694105S

Report run by Tressa Brown at 11-FEB-2013 12:00:28

## Report Parameters

Site: CP\_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R3013

Ending patient: R3013

### 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 #:

R3013

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

Date:

Total Score:

Verified  Approved  Locked  Frozen

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

Document Number

Initials:

(b)

Subject #:

R3013

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:

(b)

Subject #:

R3013

WEEK 6

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

Date:

Total Score:

Verified  Approved  Locked  Frozen

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

Document Number

Initials:

(b)

Subject #:

R3013

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

Date:

Total Score:

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

Document Number

Initials:

(b)

Subject #:

R3013

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

Date:

Total Score:

Verified  Approved  Locked  Frozen

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

Document Number

Initials:

(b)

Subject #:

R3013

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 R290798513

Initials:

(b)

Subject #:

R3013

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 #:

R3013

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

Date:

Total Score:

Verified  Approved  Locked  Frozen

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

Document Number

Initials:

(b)

Subject #:

R3013

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 R290802213

## **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](#)

Initials:

(b)

Subject #:

R3013

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

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

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

# 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 #:** R244424413

| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
|---------------------|-------------------------|---------------------|
| R3013<br>CP_001     | Baseline                | Fagerstrom<br>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> |
|------------------|--------------------------------|-------------------------------------|-----------------------|
| Time Taken<br>1  | 0939                           | 01-MAY-2009 16:05:58<br>Tricia Hunt | Data Entry Error      |

**Document #:** R290802213

| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b>          |
|---------------------|-------------------------|------------------------------|
| R3013<br>CP_001     | Week 28                 | Fagerstrom Indicator<br>07.1 |

| <b>Section Section Date</b> | <b>Qualifying Prompt</b> | <b>Qualifying Value</b> | <b>Section Visit</b> |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Fagerstrom Indic            | Page number              | 3                       | Week 28              |

| <b>Group #</b> | <b>Group Name</b> |
|----------------|-------------------|
| 1              | CHKBOX            |

| <b>Field Row</b>                              | <b>Changed From Changed To</b> | <b>Impact on On resequence By</b>   | <b>Reason Comment</b> |
|---|--------------------------------|-------------------------------------|-----------------------|
| Did subject smoke at least 1 cigarette p<br>1 | NO<br>YES                      | 30-MAR-2010 12:26:02<br>Tricia Hunt | Data Entry Error      |

Document #: R275087813

|                     |                         |                     |
|---------------------|-------------------------|---------------------|
| <b>Patient Site</b> | <b>Visit Visit Date</b> | <b>CRF CRF Page</b> |
| R3013<br>CP_001     | Week 28                 | Fagerstrom<br>08    |

|                             |                          |                         |                      |
|-----------------------------|--------------------------|-------------------------|----------------------|
| <b>Section Section Date</b> | <b>Qualifying Prompt</b> | <b>Qualifying Value</b> | <b>Section Visit</b> |
| Fagerstrom                  | Page number              | 1                       | Week 28              |

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

|                      |                                |                             |   |  |
|----------------------|--------------------------------|-----------------------------|---|--|
| <b>Field Row</b>     | <b>Changed From Changed To</b> | <b>Impact on resequence</b> | <b>On By</b>                            | <b>Reason Comment</b>  |
| Total Score (7)<br>1 | 0<br>8                         |                             | 23-JUN-2010 13:24:57<br>Joanne Mccaigue | ODM/SEC<br>Obvious correction. JLM<br>23Jun2010 Missing values are converted to the worst score. |

# Discrepancy Detail Report

Document #: R290802213

Discrepancy ID: 90897611 Site: CP\_001 Patient: R3013

Visit: WEEK 28

Visit Date:

CRF: FAGERSTROM INDIC Section: FAGERSTROM INDI Qualifying Value: 3

Field: Did subject smoke at least 1 cigarette p Row: 1

Value Text: YES

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Indicator question for FTND survey=No, but data is present in FTND survey. Please update response to Yes or delete Week 28 FTND data. \*\*If week 28 FTND data is to be retained, please fully complete the survey- currently questions 1, 3, 4, 5 are blank.

Internal Comment: DM Response: Please see query text. Several FTND responses are blank. Please provide responses if data is retained.  
The subject had not smoked for several weeks, but per source the subject stated he had smoked a pack of cigarettes over the weekend before his visit. When the subject completed the questionnaire he answered NA to most of the questions because he had not been smoking for the several weeks. The data is complete per the source for the survey.

Resolution Type: Confirmed

Resolution Text:

# Deleted CRFs Report