

# CRF Report for Study E7694105S

Report run by Tressa Brown at 13-FEB-2013 11:14:48

## Report Parameters

Site: L0689282\_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2016

Ending patient: R2016

## 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 #:

R2016

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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

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 audit history for this CRF](#)

[Click here to navigate to discrepancy details 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 type="checkbox"/>            | 2 | <input checked="" 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 checked="" 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 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 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 type="checkbox"/> | 1 | <input type="checkbox"/>            | 2 | <input checked="" 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:

Verified  Approved  Locked  Frozen

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

Document Number

Initials:

(b)

Subject #:

R2016

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 checked="" type="checkbox"/> 2 | <input 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 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 type="checkbox"/> 0            | <input type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input type="checkbox"/> 3 | <input checked="" 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 checked="" 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

Initials:

(b)

Subject #:

R2016

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 checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input type="checkbox"/> 3            | <input type="checkbox"/> 4 |
| 2. Anxious, nervous                             | <input type="checkbox"/> 0            | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 2            | <input 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 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 checked="" 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 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 checked="" 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 checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4 |

Date:

Total Score:

Verified  Approved  Locked  Frozen

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

Document Number

Initials:

(b)

Subject #:

R2016

WEEK 16

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 R286658313

Initials:

(b)

Subject #:

R2016

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 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 type="checkbox"/> 1            | <input type="checkbox"/> 2            | <input checked="" type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| 5. Difficulty concentrating                     | <input type="checkbox"/> 0            | <input checked="" 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 checked="" 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 checked="" 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:

Verified  Approved  Locked  Frozen

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

Document Number

Initials:

(b)

Subject #:

R2016

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 R286658513

# 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 #:** R246063713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2016 L0689282_2	Baseline	Withdrawal Scale 01

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Withdrawal Scale	Page number	2	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	08-MAY-2009 07-MAY-2009	14-DEC-2009 13:22:08 Cindy Riojas Prakop	Data Entry Error
Date 1	07-MAY-2009 08-MAY-2009	11-MAY-2010 14:37:55 Amanda Lynn	Data Entry Error

**Document #:** R246065013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2016 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	07-MAY-2009 08-MAY-2009	11-MAY-2010 14:39:27 Amanda Lynn	Data Entry Error





# Deleted CRFs Report