

CRF Report for Study E7694105S

Report run by Tressa Brown at 13-FEB-2013 11:14:44

Report Parameters

Site: L0689282_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2011

Ending patient: R2011

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)

Initials:

(b)

Subject #:

R2011

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"/> |
| 2. Anxious, nervous | <input checked="" 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"/> |
| 4. Desire or craving to smoke | <input type="checkbox"/> | <input type="checkbox"/> | <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"/> |
| 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"/> |
| 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"/> |
| 8. Restless | <input checked="" 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"/> |

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](#)

Initials:

(b)

Subject #:

R2011

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 #:

R2011

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"/> |
| 2. Anxious, nervous | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" 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"/> |
| 4. Desire or craving to smoke | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" 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"/> |
| 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"/> |
| 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"/> |
| 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"/> |
| 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"/> |

Date:

Total Score:

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

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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 checked="" type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 |
| 3. Depressed mood, sad | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input checked="" 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 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 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 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 #:

R2011

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"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Anxious, nervous | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" 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"/> |
| 4. Desire or craving to smoke | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 5. Difficulty concentrating | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Increased appetite, hungry, weight gain | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" 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 checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Restless | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" 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"/> | <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 #:

R2011

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 R286654113

Initials:

(b)

Subject #:

R2011

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 #:

R2011

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 #:

R2011

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 R286654213

Initials:

(b)

Subject #:

R2011

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](#)

[Click here to navigate to discrepancy details 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 #: R244110213

Patient Site	Visit Visit Date	CRF CRF Page
R2011 L0689282_2	Baseline	Withdrawal Scale 01

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Withdrawl Scale	Page number	2	Baseline

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	24-APR-2009 23-APR-2009	30-APR-2009 14:15:29 Amanda Lynn	Data Entry Error

Document #: R279071613

Patient Site	Visit Visit Date	CRF CRF Page
R2011 L0689282_2	Week 28	Fagerstrom 08

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Fagerstrom	Page number	1	Week 28

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Time Taken 1	0511 0834	14-DEC-2009 13:26:15 Cindy Riojas Prakop	Data Entry Error

Discrepancy Detail Report

Document #: R279071613

Discrepancy ID: 19329911

Site: L0689282_2

Patient: R2011

Visit: WEEK 28

Visit Date:

CRF: FAGERSTROM

Section: FAGERSTROM

Qualifying Value: 1

Field: Time Taken

Row: 1

Value Text: 0834

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify time.

Internal Comment: time corrected

Resolution Type: No Action Required

Resolution Text:

Deleted CRFs Report