

CRF Report for Study E7694105S

Report run by Brian Saari at 26-FEB-2013 10:36:15

Report Parameters

Site: CDB_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1030

Ending patient: R1030

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 #:

R1030

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 type="checkbox"/> | <input checked="" 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 checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Difficulty concentrating | <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 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"/> |
| 8. Restless | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Impatient | <input type="checkbox"/> | <input checked="" 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 #:

R1030

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 #:

R1030

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 type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 4. Desire or craving to smoke | <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"/> | <input type="checkbox"/> |
| 5. Difficulty concentrating | <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"/> | <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"/> | <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 type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" 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"/> | <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 #:

R1030

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 type="checkbox"/> 2 | <input checked="" 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 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 type="checkbox"/> 2 | <input checked="" 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 checked="" 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 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

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 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 checked="" 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 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 type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input checked="" 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 #:

R1030

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 R289428313

Initials:

(b)

Subject #:

R1030

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 #:

R1030

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

R1030

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 R293436413

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R1030

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 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 #: R265934213

Patient Site	Visit Visit Date	CRF CRF Page
R1030 CDB_001	Week 6	Withdrawal Scale 03

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Total Score (10) 1	10	09-SEP-2009 14:58:01 Rossana Matos	Data Entry Error

Discrepancy Detail Report

Document #: R293436413

Discrepancy ID: 64031411 Site: CDB_001 Patient: R1030
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: Please verify per source subject reported less than 1.
Internal Comment: Diary states "1 or 2 puffs=1cigarette
Resolution Type: Due Diligence
Resolution Text:

Deleted CRFs Report