

CRF Report for Study E7694105S

Report run by Brian Saari at 04-MAR-2013 14:33:42

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4029

Ending patient: R4029

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 #:

R4029

BASELINE

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 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 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 #:

R4029

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:

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

Document Number

Initials:

(b)

Subject #:

R4029

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

Initials:

(b)

Subject #:

R4029

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

(b)

Subject #:

R4029

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

Document Number

Initials:

(b)

Subject #:

R4029

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 R286939113

Initials:

(b)

Subject #:

R4029

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 R268072513

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R4029

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

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 #:

R4029

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 R286940913

Initials:

(b)

Subject #:

R4029

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 R281640113

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 #: **R268072513**

Patient Site	Visit Visit Date	CRF CRF Page
R4029 P3880_0342	Week 16	Fagerstrom 06

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	07-JAN-2010 15:36:56 Lana Glaser	Data Entry Error

Document #: **R281640013**

Patient Site	Visit Visit Date	CRF CRF Page
R4029 P3880_0342	Week 28	Withdrawal Scale 07

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Withdrawal Scale	Page number	2	Week 28

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Time Taken 1	ND UNK		07-JAN-2010 15:37:04 Lana Glaser	Data Entry Error

Document #: **R281640113**

Patient Site	Visit Visit Date	CRF CRF Page
R4029 P3880_0342	Week 28	Fagerstrom 08

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
-----------------------------	--------------------------	-------------------------	----------------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	07-JAN-2010 15:48:36 Lana Glaser	Data Entry Error

Discrepancy Detail Report

Document #: **R281640013**

Discrepancy ID: 35350811

Site: P3880_0342

Patient: R4029

Visit: WEEK 28

Visit Date:

CRF: WITHDRAWAL SCAL

Section: WITHDRAWAL SCALE

Qualifying Value: 2

Field: Time Taken

Row: 1

Value Text: UNK

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify should be UNK, ND as survey was performed.

Internal Comment:

Resolution Type: Data value changed. Disc no longer applicable.

Resolution Text: corrected

Deleted CRFs Report