

CRF Report for Study E7694105D

Report run by Brian Saari at 25-FEB-2013 15:48:49

Report Parameters

Site: CD_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R5025

Ending patient: R5025

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 #:

R5025

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 03-AUG-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 10

6. I have experienced the following Adverse Events:

STOMACH ACHE AND NAUSEA

7. I think the Adverse Event is related to the snus product:

Correct
 Incorrect
 Don't Know
 I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_1 (v1, 25-MAR-2009)

Document Number R275085813

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 #:

R5025

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 10-AUG-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 10

6. I have experienced the following Adverse Events:

NAUSEA

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_2 (v1, 25-MAR-2009)

Document Number R275086013

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 #:

R5025

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 17-AUG-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 10

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_3 (v1, 25-MAR-2009)

Document Number R275086313

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 #:

R5025

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 24-AUG-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 10

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_4 (v1, 25-MAR-2009)

Document Number R275086613

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 #:

R5025

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 31-AUG-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 10

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_5 (v1, 25-MAR-2009)

Document Number R275086713

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 #:

R5025

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 07-SEP-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 10

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_6 (v1, 25-MAR-2009)

Document Number R275086813

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 #:

R5025

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-SEP-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 10 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 10

6. I have experienced the following Adverse Events:

NONE

7. I think the Adverse Event is related to the snus product:

Correct
 Incorrect
 Don't Know
 I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_7 (v1, 25-MAR-2009)

Document Number R275086913

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R5025

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-SEP-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 10 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 10

6. I have experienced the following Adverse Events:

NONE

7. I think the Adverse Event is related to the snus product:

Correct
 Incorrect
 Don't Know
 I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_8 (v1, 25-MAR-2009)

Document Number R275087013

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R5025

WEEK 9

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 04-OCT-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 10 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 10

6. I have experienced the following Adverse Events:

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_9 (v1, 25-MAR-2009)

Document Number R275087113

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 #:

R5025

WEEK 10

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 11-OCT-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 17 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 6

6. I have experienced the following Adverse Events:

NONE

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_10 (v1, 25-MAR-2009)

Document Number R283217913

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 #:

R5025

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 18-OCT-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 10 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 6

6. I have experienced the following Adverse Events:

NONE

7. I think the Adverse Event is related to the snus product:

Correct
 Incorrect
 Don't Know
 I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_11 (v1, 25-MAR-2009)

Document Number R283218213

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R5025

WEEK 12

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 25-OCT-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 10 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 6

6. I have experienced the following Adverse Events:

NONE

7. I think the Adverse Event is related to the snus product:

Correct
 Incorrect
 Don't Know
 I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_12 (v1, 25-MAR-2009)

Document Number R283218613

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R5025

WEEK 13

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-NOV-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 10 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 6

6. I have experienced the following Adverse Events:

NONE

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_13 (v1, 25-MAR-2009)

Document Number R283218913

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R5025

WEEK 14

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-NOV-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 10 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 6

6. I have experienced the following Adverse Events:

NONE

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_14 (v1, 25-MAR-2009)

Document Number R283219213

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R5025

WEEK 15

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 15-NOV-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 10 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 6

6. I have experienced the following Adverse Events:

NONE

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_15 (v1, 25-MAR-2009)

Document Number R283219613

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R5025

WEEK 16

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 18-NOV-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 10 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

5. I have consumed on average the following number of snus sachets per day:

Sachet Size:

Large (1g) 0

Small (0.5g) 6

6. I have experienced the following Adverse Events:

NONE

7. I think the Adverse Event is related to the snus product:

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

Page Version No. WEEK_16 (v1, 25-MAR-2009)

Document Number R283220013

Links to Discrepancy and Audit Sections

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

Initials:

(b) _____

Subject #:

R5025

FOLLOW-UP WK 17

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 00-00-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 13 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_17 (v1, 25-MAR-2009)

Document Number R293112513

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 #:

R5025

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 00-00-2009

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 13 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_18 (v1, 25-MAR-2009)

Document Number R293112613

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 #:

R5025

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: _____

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average _____ cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_19 (v1, 25-MAR-2009)

Document Number R293112713

Initials:

(b) _____

Subject #:

R5025

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: _____

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average _____ cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_20 (v1, 25-MAR-2009)

Document Number R293112813

Initials:

(b) _____

Subject #:

R5025

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: _____

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average _____ cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_21 (v1, 25-MAR-2009)

Document Number R293112913

Initials:

(b) _____

Subject #:

R5025

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: _____

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average _____ cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_22 (v1, 25-MAR-2009)

Document Number R293113013

Initials:

(b) _____

Subject #:

R5025

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: _____

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average _____ cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_23 (v1, 25-MAR-2009)

Document Number R293113113

Initials:

(b) _____

Subject #:

R5025

FOLLOW-UP WK 24

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: _____

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average _____ cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_24 (v1, 25-MAR-2009)

Document Number R293113213

Initials:

(b) _____

Subject #:

R5025

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: _____

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average _____ cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_25 (v1, 25-MAR-2009)

Document Number R293113313

Initials:

(b) _____

Subject #:

R5025

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: _____

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average _____ cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_26 (v1, 25-MAR-2009)

Document Number R293113413

Initials:

(b) _____

Subject #:

R5025

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: _____

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average _____ cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_27 (v1, 25-MAR-2009)

Document Number R293113513

Initials:

(b) _____

Subject #:

R5025

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-FEB-2010

1. I have not smoked any cigarettes at all during the past week (1 or 2 puffs = 1 cigarette)

Correct Incorrect

2. I have smoked on average 13 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: _____

4. Did you use smokeless tobacco products, nicotine-containing products (e.g., gum or patch), or other smoking cessation products this week?

Yes No

If yes, what type (smokeless tobacco, pharmaceutical nicotine replacement products [gum / patch / other], other nicotine products [e.g., lozenges])?

Verified Approved Locked Frozen

Page Version No. WEEK_28 (v1, 25-MAR-2009)

Document Number R296088613

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 #: R275085813

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 1	Week_1 01

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	1	Week 1

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	15 10-15	11-MAR-2010 10:07:00 Stephanie Felton	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10-15 15	31-MAR-2010 16:47:23 Krysia Magnuson	ODM/SEC 10-15 to 15.

Document #: R275086013

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 2	Week_2 02

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	2	Week 2

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	15 10-15	11-MAR-2010 10:08:59 Stephanie Felton	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10-15 15	31-MAR-2010 16:47:42 Krysia Magnuson	ODM/SEC 10-15 to 15.

Document #: R275086313

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 3	Week_3 03

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	3	Week 3

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	15 10-15	11-MAR-2010 10:09:30 Stephanie Felton	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10-15 15	31-MAR-2010 16:47:51 Kryisia Magnuson	ODM/SEC 10-15 to 15.

Document #: R275086613

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 4	Week_4 04

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	4	Week 4

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	15 10-15	11-MAR-2010 10:10:00 Stephanie Felton	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10-15 15	31-MAR-2010 16:48:02 Krysia Magnuson	ODM/SEC 10-15 to 15.

Document #: R275086713

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 5	Week_5 05

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	5	Week 5

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	15 10-15	11-MAR-2010 10:10:31 Stephanie Felton	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10-15 15	31-MAR-2010 16:48:11 Krysia Magnuson	ODM/SEC 10-15 to 15.

Document #: R275086813

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 6	Week_6 06

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	6	Week 6

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	15 10-15	11-MAR-2010 10:11:05 Stephanie Felton	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10-15 15	31-MAR-2010 16:48:20 Kryisia Magnuson	ODM/SEC 10-15 to 15.

Document #: R275086913

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 7	Week_7 07

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	7	Week 7

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. (3) 1	I have experienced the following AEs NONE	20-JAN-2010 12:42:25 Sharon Ladenes	Data Entry Error

Document #: R275087013

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 8	Week_8 08

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	8	Week 8

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE	20-JAN-2010 12:42:46 Sharon Ladenes	Data Entry Error

Document #: R275087113

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 9	Week_9 09

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	9	Week 9

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	10 7-10	11-MAR-2010 10:11:43 Stephanie Felton	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	7-10 10	31-MAR-2010 16:48:48 Krysia Magnuson	ODM/SEC 7-10 to 10.

Document #: R283217913

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 10	Week_10 10

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	10	Week 10

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	17 10-17	11-MAR-2010 10:12:16 Stephanie Felton	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10-17 17	31-MAR-2010 16:49:07 Krysia Magnuson	ODM/SEC 10-17 to 17.
6. I have experienced the following AEs (3) 1	NONE	20-JAN-2010 12:43:09 Sharon Ladenes	Data Entry Error

Document #: R283218213

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 11	Week_11 11

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	11	Week 11

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE	20-JAN-2010 12:43:25 Sharon Ladenes	Data Entry Error

Document #: R283218613

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 12	Week_12 12

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	12	Week 12

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. (3) 1	I have experienced the following AEs NONE	20-JAN-2010 12:43:34 Sharon Ladenes	Data Entry Error

Document #: R283218913

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 13	Week_13 13

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	13	Week 13

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. (3) 1	I have experienced the following AEs NONE	20-JAN-2010 12:43:45 Sharon Ladenes	Data Entry Error

Document #: R283219213

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 14	Week_14 14

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	14	Week 14

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. (3) 1	I have experienced the following AEs NONE	20-JAN-2010 12:43:54 Sharon Ladenes	Data Entry Error

Document #: R283219613

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 15	Week_15 15

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	15	Week 15

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. (3) 1	I have experienced the following AEs NONE	20-JAN-2010 12:44:06 Sharon Ladenes	Data Entry Error

Document #: R283220013

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Week 16	Week_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	16	Week 16

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. (3) 1	I have experienced the following AEs NONE	20-JAN-2010 12:44:24 Sharon Ladenes	Data Entry Error

Document #: R293112513

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Follow-Up Wk 17	Week_17 17

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	Y N	11-MAR-2010 10:13:01 Stephanie Felton	Data Entry Error

Document #: R293112513

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Follow-Up Wk 17	Week_17 17

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	17	Follow-Up Wk 17

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	10-13 13		31-MAR-2010 16:49:38 Kryisia Magnuson	ODM/SEC 10-13 to 13.

Document #: R293112613

Patient Site	Visit Visit Date	CRF CRF Page
R5025 CD_001	Follow-Up Wk 18	Week_18 18

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	Y N	11-MAR-2010 14:08:33 Stephanie Felton	Data Entry Error

Document #: R293112613

Patient Site	Visit Visit Date	CRF CRF Page	
R5025 CD_001	Follow-Up Wk 18	Week_18 18	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	18	Follow-Up Wk 18

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	10-13 13	31-MAR-2010 16:49:59 Kryisia Magnuson	ODM/SEC 10-13 to 13.

Discrepancy Detail Report

Document #: R275085813

Discrepancy ID: 81493111

Site: CD_001

Patient: R5025

Visit: WEEK 1

Visit Date:

CRF: WEEK_1

Section: STUDY DIARY

Qualifying Value: 1

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 15

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per verbatim, please enter 10-15.

Internal Comment: Updated CRF, verified source

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

Resolution Text:

Document #: R275086013

Discrepancy ID: 81493311

Site: CD_001

Patient: R5025

Visit: WEEK 2

Visit Date:

CRF: WEEK_2

Section: STUDY DIARY

Qualifying Value: 2

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 15

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per verbatim, please enter 10-15

Internal Comment: Updated CRF, verified source

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

Resolution Text:

Document #: R275086313

Discrepancy ID: 81493711

Site: CD_001

Patient: R5025

Visit: WEEK 3

Visit Date:

CRF: WEEK_3

Section: STUDY DIARY

Qualifying Value: 3

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 15

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per verbatim, 10-15.

Internal Comment: Updated CRF, verified source

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

Resolution Text:

Document #: R275086613

Discrepancy ID: 81493811

Site: CD_001

Patient: R5025

Visit: WEEK 4

Visit Date:

CRF: WEEK_4

Section: STUDY DIARY

Qualifying Value: 4

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 15

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per verbatim, 10-15.

Internal Comment: Updated CRF, verified source

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

Resolution Text:

Document #: R275086713

Discrepancy ID: 81493911

Site: CD_001

Patient: R5025

Visit: WEEK 5

Visit Date:

CRF: WEEK_5

Section: STUDY DIARY

Qualifying Value: 5

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 15

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per verbatim, 10-15.

Internal Comment: Updated CRF, verified source

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

Resolution Text:

Document #: R275086813

Discrepancy ID: 81494111

Site: CD_001

Patient: R5025

Visit: WEEK 6

Visit Date:

CRF: WEEK_6

Section: STUDY DIARY

Qualifying Value: 6

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 15

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per verbatim, 10-15

Internal Comment: Updated CRF, verified source

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

Resolution Text:

Document #: R275087113

Discrepancy ID: 81494411

Site: CD_001

Patient: R5025

Visit: WEEK 9

Visit Date:

CRF: WEEK_9

Section: STUDY DIARY

Qualifying Value: 9

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 10

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per verbatim, 7-10

Internal Comment: Updated CRF, verified source

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

Resolution Text:

Document #: R283217913

Discrepancy ID: 81494611

Site: CD_001

Patient: R5025

Visit: WEEK 10

Visit Date:

CRF: WEEK_10

Section: STUDY DIARY

Qualifying Value: 10

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 17

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per verbatim, 10-17

Internal Comment: Updated CRF, verified source

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

Resolution Text:

Deleted CRFs Report