

CRF Report for Study E7694105D

Report run by Brian Saari at 25-FEB-2013 11:56:58

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4084

Ending patient: R4084

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 #:

R4084

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-JUL-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) 6

Small (0.5g) 0

6. I have experienced the following Adverse Events:

NA

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

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

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

Document Number R288762113

Initials:

(b)

Subject #:

R4084

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 15-JUL-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 18 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) 5

Small (0.5g) 0

6. I have experienced the following Adverse Events:

NA

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R288762313

Initials:

(b)

Subject #:

R4084

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-JUL-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) 6

Small (0.5g) 0

6. I have experienced the following Adverse Events:

NA

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

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

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

Document Number R288762413

Initials:

(b)

Subject #:

R4084

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-JUL-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) 11

Small (0.5g) 0

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

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

Document Number R288762513

Initials:

(b)

Subject #:

R4084

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 07-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 12 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) 16

Small (0.5g) 0

6. I have experienced the following Adverse Events:

NA

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

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

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

Document Number R288762613

Initials:

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Subject #:

R4084

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 21-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 14 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) 10

Small (0.5g) 0

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

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

Document Number R288762713

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 #:

R4084

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-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 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) 1 CONTAINER

Small (0.5g) 0

6. I have experienced the following Adverse Events:

-N-

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

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

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

Document Number R288763013

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R4084

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-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 5 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) -N-

Small (0.5g) 0

6. I have experienced the following Adverse Events:

-N-

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R288763613

Initials:

(b)

Subject #:

R4084

WEEK 9

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) 1/2 CONTAINI

Small (0.5g) 0

6. I have experienced the following Adverse Events:

-N-

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

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

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Document Number R288763713

OverFlow Section For Document Number R288763713

1 1/2 CONTAINER

Initials:

(b) _____

Subject #:

R4084

WEEK 10

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])?

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

Sachet Size:

Large (1g) _____

Small (0.5g) _____

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

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

Document Number R288763813

Initials:

(b) _____

Subject #:

R4084

WEEK 11

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])?

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

Sachet Size:

Large (1g) _____

Small (0.5g) _____

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

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

Document Number R288764313

Initials:

(b) _____

Subject #:

R4084

WEEK 12

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])?

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

Sachet Size:

Large (1g) _____

Small (0.5g) _____

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

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

Document Number R288764513

Initials:

(b) _____

Subject #:

R4084

WEEK 13

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])?

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

Sachet Size:

Large (1g) _____

Small (0.5g) _____

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_13 (v1, 25-MAR-2009)

Document Number R288764713

Initials:

(b) _____

Subject #:

R4084

WEEK 14

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])?

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

Sachet Size:

Large (1g) _____

Small (0.5g) _____

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

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

Document Number R288764813

Initials:

(b) _____

Subject #:

R4084

WEEK 15

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])?

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

Sachet Size:

Large (1g) _____

Small (0.5g) _____

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_15 (v1, 25-MAR-2009)

Document Number R288764913

Initials:

(b) _____

Subject #:

R4084

WEEK 16

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])?

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

Sachet Size:

Large (1g) _____

Small (0.5g) _____

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

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

Document Number R288765013

Initials:

(b) _____

Subject #:

R4084

FOLLOW-UP WK 17

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])?

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

Document Number R288765113

Initials:

(b) _____

Subject #:

R4084

FOLLOW-UP WK 18

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])?

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Document Number R288765313

Initials:

(b) _____

Subject #:

R4084

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])?

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

Document Number R288765413

Initials:

(b) _____

Subject #:

R4084

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])?

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

Document Number R288765513

Initials:

(b) _____

Subject #:

R4084

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])?

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

Document Number R288765713

Initials:

(b) _____

Subject #:

R4084

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])?

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

Document Number R288765813

Initials:

(b) _____

Subject #:

R4084

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])?

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

Document Number R288765913

Initials:

(b) _____

Subject #:

R4084

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])?

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

Document Number R288766013

Initials:

(b) _____

Subject #:

R4084

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])?

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

Document Number R288766113

Initials:

(b) _____

Subject #:

R4084

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])?

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Document Number R288766313

Initials:

(b) _____

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R4084

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])?

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Initials:

(b) _____

Subject #:

R4084

FOLLOW-UP WK 28

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])?

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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 #: R288762713

Patient Site	Visit Visit Date	CRF CRF Page
R4084 P3880_0342	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
Date 1	UNK 21-AUG-2009	03-MAR-2010 16:05:51 Lana Glaser	Data Entry Error

Document #: R288763013

Patient Site	Visit Visit Date	CRF CRF Page
R4084 P3880_0342	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 resequence	On By	Reason Comment
5. Small (0.5g) (3) 1	0		19-JAN-2010 14:35:24 Lana Glaser	Data Entry Error
6. I have experienced the following AEs (3) 1	NA -N-		19-JAN-2010 14:36:29 Lana Glaser	Data Entry Error

Deleted CRFs Report