

# CRF Report for Study E7694105D

Report run by Brian Saari at 22-FEB-2013 11:08:52

## Report Parameters

Site: CP\_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R3029

Ending patient: R3029

## Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	<b>Abc 123</b>

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 #:

R3029

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 26-MAY-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])?

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

Sachet Size:

Large (1g) 0

Small (0.5g) 82

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\_1 (v1, 25-MAR-2009)

Document Number R266298313

## **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 #:

R3029

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 02-JUN-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) 0

Small (0.5g) 77

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\_2 (v1, 25-MAR-2009)

Document Number R266298413

## **Links to Discrepancy and Audit Sections**

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

Initials:

(b)

Subject #:

R3029

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 09-JUN-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  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:

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\_3 (v1, 25-MAR-2009)

Document Number

## **Links to Discrepancy and Audit Sections**

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

Initials:

(b)

Subject #:

R3029

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 16-JUN-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 11 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) 68

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 R266298613

## **Links to Discrepancy and Audit Sections**

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

Initials:

(b)

Subject #:

R3029

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 23-JUN-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  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:

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\_5 (v1, 25-MAR-2009)

Document Number R266298713

## **Links to Discrepancy and Audit Sections**

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

Initials:

(b)

Subject #:

R3029

WEEK 6

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\_6 (v1, 25-MAR-2009)

Document Number R275377713

Initials:

(b)

Subject #:

R3029

WEEK 7

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\_7 (v1, 25-MAR-2009)

Document Number R275377813

Initials:

(b)

Subject #:

R3029

WEEK 8

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\_8 (v1, 25-MAR-2009)

Document Number R275377913

Initials:

(b)

Subject #:

R3029

WEEK 9

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\_9 (v1, 25-MAR-2009)

Document Number R275378013

Initials:

(b)

Subject #:

R3029

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 R275378113

Initials:

(b)

Subject #:

R3029

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

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_11 (v1, 25-MAR-2009)

Document Number R275378213

Initials:

(b)

Subject #:

R3029

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

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_12 (v1, 25-MAR-2009)

Document Number R275378313

Initials:

(b)

Subject #:

R3029

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 R275378413

Initials:

(b)

Subject #:

R3029

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

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_14 (v1, 25-MAR-2009)

Document Number R275378513

Initials:

(b)

Subject #:

R3029

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 R275378613

Initials:

(b)

Subject #:

R3029

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

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_16 (v1, 25-MAR-2009)

Document Number R275378713

Initials:

(b)

Subject #:

R3029

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 R275378813

Initials:

(b)

Subject #:

R3029

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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Page Version No. WEEK\_18 (v1, 25-MAR-2009)

Document Number R275378913

Initials:

(b)

Subject #:

R3029

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 R275379013

Initials:

(b)

Subject #:

R3029

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 R275379113

Initials:

(b)

Subject #:

R3029

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 R275379313

Initials:

(b)

Subject #:

R3029

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

Initials:

(b)

Subject #:

R3029

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 R275379613

Initials:

(b)

Subject #:

R3029

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 R275379713

Initials:

(b)

Subject #:

R3029

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 R275379813

Initials:

(b)

Subject #:

R3029

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 R275379913

Initials:

(b)

Subject #:

R3029

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 R275380013

Initials:

(b)

Subject #:

R3029

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])?

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_28 (v1, 25-MAR-2009)

Document Number R275380113

# 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 #:** R266298313

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R3029 CP_001	Week 1	Week_1 01

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	1	Week 1

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
6. (3) 1	I have experienced the following AEs NONE	19-FEB-2010 09:34:49 Tricia Hunt	Data Entry Error

**Document #:** R266298413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R3029 CP_001	Week 2	Week_2 02

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	2	Week 2

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
6. (3) 1	I have experienced the following AEs NONE	19-FEB-2010 09:36:03 Tricia Hunt	Data Entry Error

**Document #:** R266298513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R3029 CP_001	Week 3	Week_3 03

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	3	Week 3

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
2. I have smoked on average_cigarettes p (1) 1	84 12		31-AUG-2009 15:59:52 Tricia Hunt	Data Entry Error
6. I have experienced the following AEs (3) 1	NONE		19-FEB-2010 09:36:21 Tricia Hunt	Data Entry Error

**Document #:** R266298613

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R3029 CP_001	Week 4	Week_4 04

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	4	Week 4

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
6. (3) 1	I have experienced the following AEs NONE	19-FEB-2010 09:36:46 Tricia Hunt	Data Entry Error

**Document #:** R266298713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R3029 CP_001	Week 5	Week_5 05

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	5	Week 5

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
6. I have experienced the following AEs (3) 1	NONE	19-FEB-2010 09:37:11 Tricia Hunt	Data Entry Error



# Deleted CRFs Report