

# CRF Report for Study E7694105D

Report run by Brian Saari at 25-FEB-2013 15:23:46

## Report Parameters

Site: P3880\_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4108

Ending patient: R4108

### 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 #:

R4108

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-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 7 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) 12

6. I have experienced the following Adverse Events:

OVER USE OF SNUS PRODUCTS PACKETS MAKE ME FEEL QUEASY ON STOMACH

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 R289238713

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

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

Initials:

(b)

Subject #:

R4108

WEEK 2

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 7 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:

STILL MAKES STOMACH FEEL SOUR

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 R289239013

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

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

Initials:

(b)

Subject #:

R4108

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 14-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) 0

Small (0.5g) 7

6. I have experienced the following Adverse Events:

STOMACH NOT BOTHER ME AS MUCH, HAVEN'T BEEN USING PRODUCT AS MUCH

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 R289239113

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

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Initials:

(b)

Subject #:

R4108

WEEK 4

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 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) 4

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 R289239213

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

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

Initials:

(b)

Subject #:

R4108

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-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) 0

Small (0.5g) 5

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\_5 (v1, 25-MAR-2009)

Document Number R289239413

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

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

Initials:

(b)

Subject #:

R4108

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

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Page Version No. WEEK\_6 (v1, 25-MAR-2009)

Document Number

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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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Document Number R289239713

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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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Document Number R289239813

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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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Document Number R289239913

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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 R289240013

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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 R289240113

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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 R289240213

Initials:

(b)

Subject #:

R4108

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

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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 R289240513

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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 R289240613

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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 R289240713

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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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Document Number R289240813

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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 R289240913

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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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Document Number R289241013

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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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Document Number R289241113

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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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Document Number R289241213

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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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Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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 R289241413

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

FOLLOW-UP WK 24

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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 R289241513

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

FOLLOW-UP WK 25

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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 R289241613

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

FOLLOW-UP WK 26

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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\_26 (v1, 25-MAR-2009)

Document Number R289241713

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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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Page Version No. WEEK\_27 (v1, 25-MAR-2009)

Document Number R289241813

Initials:

(b) \_\_\_\_\_

Subject #:

R4108

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

Document Number R289241913

## 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 #: **R289238713**

Patient Site	Visit Visit Date	CRF CRF Page
R4108 P3880_0342	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	5-7 7	01-APR-2010 09:38:17 Kryisia Magnuson	ODM/SEC 5-7 to 7.
5. Small (0.5g) (3) 1	10-12 12	01-APR-2010 09:38:17 Kryisia Magnuson	ODM/SEC 10-12 to 12.

Document #: **R289239013**

Patient Site	Visit Visit Date	CRF CRF Page
R4108 P3880_0342	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	5-7 7	01-APR-2010 12:53:08 Krysia Magnuson	ODM/SEC 5-7 to 7.
5. Small (0.5g) (3) 1	8-10 10	01-APR-2010 12:53:08 Krysia Magnuson	ODM/SEC 8-10 to 10.

Document #: R289239113

Patient Site	Visit Visit Date	CRF CRF Page
R4108 P3880_0342	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	10-12 12	01-APR-2010 09:41:23 Kryisia Magnuson	ODM/SEC 10-12 to 12.
5. Small (0.5g) (3) 1	5-7 7	01-APR-2010 09:41:23 Kryisia Magnuson	ODM/SEC 5-7 to 7.

Document #: **R289239213**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4108 P3880_0342	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>
2. I have smoked on average_cigarettes p (1) 1	13-15 15	01-APR-2010 12:52:03 Kryisia Magnuson	ODM/SEC 13-15 to 15
5. Small (0.5g) (3) 1	3-4 DAY 4	01-APR-2010 12:52:03 Kryisia Magnuson	ODM/SEC 3-4 DAY to 4

Document #: **R289239413**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4108 P3880_0342	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>
2. I have smoked on average_cigarettes p (1) 1	10-12 12	01-APR-2010 09:37:38 Kryisia Magnuson	ODM/SEC 10-12 to 12.
5. Small (0.5g) (3) 1	4-5 5	01-APR-2010 09:37:38 Kryisia Magnuson	ODM/SEC 4-5 to 5.

# Discrepancy Detail Report

# Deleted CRFs Report