

# CRF Report for Study E7694105D

Report run by Brian Saari at 25-FEB-2013 11:32:29

## Report Parameters

Site: P3880\_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4061

Ending patient: R4061

### 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 #:

R4061

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 25-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 20 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:

NAUSEATED, SINUSES POUNDING, HEADACHES, DRY HEAVES

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 R287058013

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

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

Initials:

(b)

Subject #:

R4061

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-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 20 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:

NAUSEA, HEADACHE, SINUS PRESSURE

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 R287058113

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

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

Initials:

(b)

Subject #:

R4061

WEEK 3

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) 2

Small (0.5g) 7

6. I have experienced the following Adverse Events:

VOMITED (STATES "DRY HEAVES" WHEN USING SNUS NOT VOMITTING PER SM) , NAUSEA, H<sub>1</sub>

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 R287058213

## OverFlow Section For Document Number R287058213

- 1 VOMITED (STATES "DRY HEAVES" WHEN USING SNUS NOT VOMITTING PER SM), NAUSEA, HEADACHES, SINUS PRESSURE

## **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 #:

R4061

WEEK 4

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 20 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) 0

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_4 (v1, 25-MAR-2009)

Document Number R287058713

Initials:

(b)

Subject #:

R4061

WEEK 5

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 20 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) 0

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_5 (v1, 25-MAR-2009)

Document Number R287058813

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

[Click here to navigate to discrepancy details for this CRF](#)

Initials:

(b)

Subject #:

R4061

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 R287059013

Initials:

(b)

Subject #:

R4061

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

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_7 (v1, 25-MAR-2009)

Document Number R287059113

Initials:

(b)

Subject #:

R4061

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

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_8 (v1, 25-MAR-2009)

Document Number R287059213

Initials:

(b)

Subject #:

R4061

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

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_9 (v1, 25-MAR-2009)

Document Number R287059313

Initials:

(b)

Subject #:

R4061

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

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_10 (v1, 25-MAR-2009)

Document Number R287059413

Initials:

(b)

Subject #:

R4061

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 R287059513

Initials:

(b)

Subject #:

R4061

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 R287059613

Initials:

(b)

Subject #:

R4061

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 R287059713

Initials:

(b)

Subject #:

R4061

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 R287059813

Initials:

(b)

Subject #:

R4061

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 R287060013

Initials:

(b)

Subject #:

R4061

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 R287060113

Initials:

(b)

Subject #:

R4061

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 R287060213

Initials:

(b)

Subject #:

R4061

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])?

Verified  Approved  Locked  Frozen

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

Document Number R287060313

Initials:

(b)

Subject #:

R4061

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 R287060513

Initials:

(b)

Subject #:

R4061

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 R287060613

Initials:

(b)

Subject #:

R4061

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 R287060713

Initials:

(b)

Subject #:

R4061

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct  Incorrect

2. I have smoked on average  cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No  Yes-please specify:

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

Yes  No

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

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_22 (v1, 25-MAR-2009)

Document Number R287060813

Initials:

(b)

Subject #:

R4061

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct  Incorrect

2. I have smoked on average  cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No  Yes-please specify:

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

Yes  No

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

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_23 (v1, 25-MAR-2009)

Document Number R287060913

Initials:

(b)

Subject #:

R4061

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 R287061013

Initials:

(b)

Subject #:

R4061

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

Initials:

(b)

Subject #:

R4061

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 R287061213

Initials:

(b)

Subject #:

R4061

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 R287061313

Initials:

(b)

Subject #:

R4061

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 R287061413

## 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 #: R287058013

Patient Site	Visit Visit Date	CRF CRF Page	
R4061 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	20+ 20	05-APR-2010 12:38:56 Kryisia Magnuson	ODM/SEC 20+ to 20.

**Document #:** R287058113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4061 P3880_0342	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>
5. Small (0.5g) (3) 1	7	08-JAN-2010 14:27:00 Lana Glaser	Data Entry Error

**Document #:** R287058213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4061 P3880_0342	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 On resequence By</b>	<b>Reason Comment</b>
6. (3) 1	I have experienced the following AEs VOMITED (STATES "DRY HEAVES" WHEN USING SNUS NOT VOMITTING PER SM, NAUSEA, HEADACHES, SINUS PRESSURE VOMITED (STATES "DRY HEAVES" WHEN USING SNUS NOT VOMITTING PER SM), NAUSEA, HEADACHES, SINUS PRESSURE	03-MAR-2010 14:45:53 Lana Glaser	Data Entry Error



**Document #: R287058813**

**Discrepancy ID:** 36570711                      **Site:** P3880\_0342                      **Patient:** R4061  
**Visit:** WEEK 5                      **Visit Date:**  
**CRF:** WEEK\_5                      **Section:** STUDY DIARY                      **Qualifying Value:** 5  
**Field:** 7. I think the AE is related to the snus                      **Row:** 1  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for 7. I think the AE is related to the snus has not been supplied  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:** not documented on patient diary

# Deleted CRFs Report