

# CRF Report for Study E7694105D

Report run by Brian Saari at 25-FEB-2013 11:22:00

## Report Parameters

Site: P3880\_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4060

Ending patient: R4060

## 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 #:

R4060

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 19-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:

MINOR SORE THROAT

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 R286913413

Initials:

(b)

Subject #:

R4060

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 26-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:

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

Initials:

(b)

Subject #:

R4060

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 03-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  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\_3 (v1, 25-MAR-2009)

Document Number R286913813

Initials:

(b)

Subject #:

R4060

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 10-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) 1

Small (0.5g) 3

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\_4 (v1, 25-MAR-2009)

Document Number R286914013

Initials:

(b) [ ]

Subject #:

R4060

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 17-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) 3

Small (0.5g) 5

6. I have experienced the following Adverse Events:

1 ALEVE, 10 CEPHALEXIN 500MG DUE TO TOOTH, TOOTH PROBLEM STARTED 7-11-09 ENDE<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\_5 (v1, 25-MAR-2009)

Document Number R286914213

## OverFlow Section For Document Number R286914213

1 1 ALEVE, 10 CEPHALEXIN 500MG DUE TO TOOTH, TOOTH PROBLEM STARTED 7-11-09 ENDED 7-14-09

Initials:

(b)

Subject #:

R4060

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 24-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) 3

Small (0.5g) 5

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 R286914913

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

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

Initials:

(b)

Subject #:

R4060

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 31-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) 6

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 R286915213

Initials:

(b)

Subject #:

R4060

WEEK 8

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 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) 6

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 R286915513

Initials:

(b)

Subject #:

R4060

WEEK 9

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 16 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:

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 R286915813

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

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

Initials:

(b)

Subject #:

R4060

WEEK 10

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 18 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No  Yes-please specify:

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

Yes  No

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

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

Sachet Size:

Large (1g) 0

Small (0.5g) 5

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 R286916213

Initials:

(b)

Subject #:

R4060

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 28-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  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 R286916313

Initials:

(b)

Subject #:

R4060

WEEK 12

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 04-SEP-2009

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

Correct  Incorrect

2. I have smoked on average  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 R286916613

Initials:

(b)

Subject #:

R4060

WEEK 13

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 11-SEP-2009

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

Correct  Incorrect

2. I have smoked on average 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:

COLD & SORE THROAT; TOOK DINATAB STARTING 9-5-09 2 TIMES PER DAY STOPPED 9-8-1

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 R286916813

## OverFlow Section For Document Number R286916813

1 COLD & SORE THROAT; TOOK DINATAB STARTING 9-5-09 2 TIMES PER DAY STOPPED 9-8-09

## **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 #:

R4060

WEEK 14

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 18-SEP-2009

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

Correct  Incorrect

2. I have smoked on average  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

Initials:

(b)

Subject #:

R4060

WEEK 15

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 25-SEP-2009

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

Correct  Incorrect

2. I have smoked on average  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 R286917213

Initials:

(b)

Subject #:

R4060

WEEK 16

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-OCT-2009

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

Correct  Incorrect

2. I have smoked on average 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) 4

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

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Document Number R286917413

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 17

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 09-OCT-2009

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

Correct  Incorrect

2. I have smoked on average 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])?

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Document Number R286917713

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 16-OCT-2009

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

Correct  Incorrect

2. I have smoked on average 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])?

Verified  Approved  Locked  Frozen

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Document Number R286917813

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 23-OCT-2009

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

Correct  Incorrect

2. I have smoked on average 19 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 R286917913

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-OCT-2009

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

Correct  Incorrect

2. I have smoked on average 19 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 R286918113

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 06-NOV-2009

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

Correct  Incorrect

2. I have smoked on average 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])?

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Document Number R286918313

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-NOV-2009

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

Correct  Incorrect

2. I have smoked on average 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])?

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Document Number R286918413

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-NOV-2009

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

Correct  Incorrect

2. I have smoked on average 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])?

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Document Number R286918613

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 24

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-NOV-2009

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

Correct  Incorrect

2. I have smoked on average 18 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No  Yes-please specify:

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

Yes  No

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

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Document Number R286918713

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 04-DEC-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])?

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_25 (v1, 25-MAR-2009)

Document Number R286918813

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 11-DEC-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])?

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_26 (v1, 25-MAR-2009)

Document Number R286918913

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 18-DEC-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])?

Verified  Approved  Locked  Frozen

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

Document Number R286919013

Initials:

(b)

Subject #:

R4060

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 23-DEC-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])?

Verified  Approved  Locked  Frozen

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

Document Number R286919213

## 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 #:** R286914913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4060 P3880_0342	Week 6	Week_6 06

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	6	Week 6

<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>
1. I have not smoked any cigarettes at a (1) 1	INCORRECT	07-JAN-2010 11:29:13 Kim Freschly	Data Entry Error

**Document #:** R286916813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4060 P3880_0342	Week 13	Week_13 13

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	13	Week 13

<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	COLD & SORE THROAT; TOOK DIMETAPP STARTING 9-5-09 2 TIMES PER DAY STOPPED 9-8-09 COLD & SORE THROAT; TOOK DINATAB STARTING 9-5-09 2 TIMES PER DAY STOPPED 9-8-09	03-MAR-2010 14:48:48 Lana Glaser	Data Entry Error

# Discrepancy Detail Report

Document #: R286915813

Discrepancy ID: 36133011                      Site: P3880\_0342                      Patient: R4060  
Visit: WEEK 9                      Visit Date:  
CRF: WEEK\_9                      Section: STUDY DIARY                      Qualifying Value: 9  
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: No Action Required  
Resolution Text: unknown, not answered on subject diary

**Document #: R286916813**

**Discrepancy ID:** 76548311

**Site:** P3880\_0342

**Patient:** R4060

**Visit:** WEEK 13

**Visit Date:**

**CRF:** WEEK\_13

**Section:** STUDY DIARY

**Qualifying Value:** 13

**Field:** 6. I have experienced the following AEs

**Row:** 1

**Value Text:** COLD & SORE THROAT; TOOK DINATAB STARTING 9-5-09 2 TIMES PER DAY STOPPED 9-8-09

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify spelling of "dimetapp" should be "dimatab" per source.

**Internal Comment:**

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

**Resolution Text:**

# Deleted CRFs Report