

# CRF Report for Study E7694105D

Report run by Brian Saari at 25-FEB-2013 15:23:41

## Report Parameters

Site: P3880\_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4096

Ending patient: R4096

## 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 #:

R4096

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 14-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

Verified  Approved  Locked  Frozen

Page Version No. WEEK\_1 (v1, 25-MAR-2009)

Document Number R289853213

Initials:

(b)

Subject #:

R4096

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 21-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:

TURNED ANKLE - TOOK ALIEVE

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 R289853313

Initials:

(b)

Subject #:

R4096

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 28-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:

HEAD & CHEST COLD; BEGAN 7-26-09 @ 9 AM. HAVE TAKEN ALKA SELTZER & NYQUIL CO<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 R289853513

## OverFlow Section For Document Number R289853513

- 1 HEAD & CHEST COLD; BEGAN 7-26-09 @ 9 AM. HAVE TAKEN ALKA SELTZER & NYQUIL COLD MEIDCINE & ZICAM

Initials:

(b)

Subject #:

R4096

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 04-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:

HEAD COLD W/COUGHING, SINUS CONGESTIONS, SNEEZING, TOOK DAY & NYQUIL TO RELIEVE

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 R289853613

## OverFlow Section For Document Number R289853613

- 1 HEAD COLD W/COUGHING, SINUS CONGESTIONS, SNEEZING, TOOK DAY & NYQUIL TO RELIEVE SYMPTOMS. END ON 8/3/09 @ 9 AM

Initials:

(b)

Subject #:

R4096

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 11-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\_5 (v1, 25-MAR-2009)

Document Number R289854113

Initials:

(b)

Subject #:

R4096

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 18-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:

SEVERE PAIN & NUMBNESS IN RIGHT ARM. DICLOFENAC SODIUM 50 MG & GABAPENTIN 30,

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 R289854413

## OverFlow Section For Document Number R289854413

1 SEVERE PAIN & NUMBNESS IN RIGHT ARM. DICLOFENAC SODIUM 50 MG & GABAPENTIN 300 MG

## **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 #:

R4096

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 25-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:

SEVERE PAIN IN RIGHT ARM STOPPED ON 9-2-09 9 AM

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 R289854513

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

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

Initials:

(b)

Subject #:

R4096

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-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

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

Document Number

Initials:

(b)

Subject #:

R4096

WEEK 9

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-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

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

Document Number R289854713

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

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

Initials:

(b)

Subject #:

R4096

WEEK 10

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 15-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

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

Document Number R289854813

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

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

Initials:

(b)

Subject #:

R4096

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-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\_11 (v1, 25-MAR-2009)

Document Number R289854913

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

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

Initials:

(b)

Subject #:

R4096

WEEK 12

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-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 R289855113

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

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

Initials:

(b)

Subject #:

R4096

WEEK 13

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 06-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  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 R289855213

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

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

Initials:

(b)

Subject #:

R4096

WEEK 14

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-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  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 R289855313

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

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

Initials:

(b)

Subject #:

R4096

WEEK 15

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-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  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 R289855413

Initials:

(b)

Subject #:

R4096

WEEK 16

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-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  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 R289855613

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

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

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 17

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 03-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  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\_17 (v1, 25-MAR-2009)

Document Number R295764513

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 10-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 9  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 R295765013

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 17-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 9  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 R295765113

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 17-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 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])?

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Page Version No. WEEK\_20 (v1, 25-MAR-2009)

Document Number R295765313

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 24-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  cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No  Yes-please specify:

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

Yes  No

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

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Page Version No. WEEK\_21 (v1, 25-MAR-2009)

Document Number R295765713

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-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 8  cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No  Yes-please specify:

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

Yes  No

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

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

Document Number R295766013

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-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  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 R295768613

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 24

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 15-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 9  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 R295769013

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-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 9  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 R295769313

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-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 10 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No  Yes-please specify:

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

Yes  No

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

Verified  Approved  Locked  Frozen

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

Document Number R295769413

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 05-JAN-2010

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 R295769613

Initials:

(b)

Subject #:

R4096

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 12-JAN-2010

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 9  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 R295769913

# 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 #:** R289854413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4096 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>
5. Large (1g) (2) 1	5-6 6	01-APR-2010 13:51:58 Krysia Magnuson	ODM/SEC 5-6 to 6.
6. I have experienced the following AEs (3) 1	SEVERE PAIN & NUMBNESS IN RIGHT ARM. DICLOENAC SODIUM 50 MG & GABAPENTIN 300 MG SEVERE PAIN & NUMBNESS IN RIGHT ARM. DICLOFENAC SODIUM 50 MG & GABAPENTIN 300 MG	11-MAR-2010 14:15:48 Lana Glaser	Data Entry Error

**Document #:** R289854513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4096 P3880_0342	Week 7	Week_7 07

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	7	Week 7

<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. Large (1g) (2) 1	6-7 7	01-APR-2010 13:55:34 Kryisia Magnuson	ODM/SEC 6-7 to 7.

**Document #:** R289854713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4096 P3880_0342	Week 9	Week_9 09

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	9	Week 9

<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	02-FEB-2010 15:47:33 Lana Glaser	Data Entry Error
5. Large (1g) (2) 1	6-7 7	01-APR-2010 13:55:57 Kryisia Magnuson	ODM/SEC 6-7 to 7.

**Document #:** R289854813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
R4096 P3880_0342	Week 10	Week_10 10	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	10	Week 10

<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	7-8 8	01-APR-2010 09:32:32 Kryisia Magnuson	ODM/SEC 7-8 to 8.
5. Large (1g) (2) 1	6-7 7	01-APR-2010 09:32:32 Kryisia Magnuson	ODM/SEC 6-7 to 7.

**Document #:** R289854913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4096 P3880_0342	Week 11	Week_11 11

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	11	Week 11

<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	9-10 10	01-APR-2010 12:55:00 Kryisia Magnuson	ODM/SEC 9-10 to 10.
5. Large (1g) (2) 1	3-5 5	01-APR-2010 12:55:00 Kryisia Magnuson	ODM/SEC 3-5 to 5.

**Document #:** R289855113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4096 P3880_0342	Week 12	Week_12 12

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	12	Week 12

<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. Large (1g) (2) 1	2-3 3	01-APR-2010 13:56:32 Kryisia Magnuson	ODM/SEC 2-3 to 3.

**Document #:** R289855213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4096 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 resequence</b>	<b>On By</b>	<b>Reason Comment</b>
2. I have smoked on average_cigarettes p (1) 1	9-10 10		01-APR-2010 12:54:31 Krysia Magnuson	ODM/SEC 9-10 to 10.
5. Large (1g) (2) 1	2-3 3		01-APR-2010 12:54:31 Krysia Magnuson	ODM/SEC 2-3 to 3.
5. Small (0.5g) (3) 1	0		25-JAN-2010 16:15:40 Lana Glaser	Data Entry Error

Document #: R289855313

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Week 14	Week_14 14

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	14	Week 14

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	10-11 11	01-APR-2010 12:53:51 Kryisia Magnuson	ODM/SEC 10-11 to 11.
5. Large (1g) (2) 1	3-4 4	01-APR-2010 12:53:51 Kryisia Magnuson	ODM/SEC 3-4 to 4.

**Document #:** R289855613

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4096 P3880_0342	Week 16	Week_16 16

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Study Diary	Page number	16	Week 16

<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. Large (1g) (2) 1	3-4 4	01-APR-2010 13:57:06 Kryisia Magnuson	ODM/SEC 3-4 to 4.

# Discrepancy Detail Report

Document #: R289854413

Discrepancy ID: 82742711                      Site: P3880\_0342                      Patient: R4096  
Visit: WEEK 6                      Visit Date:  
CRF: WEEK\_6                      Section: STUDY DIARY                      Qualifying Value: 6  
Field: 6. I have experienced the following AEs                      Row: 1  
Value Text: SEVERE PAIN & NUMBNESS IN RIGHT ARM. DICLOFENAC SODIUM 50 MG & GABAPENTIN 300 MG  
Type: MANUAL                      Status: CURRENT  
Review Status: Resolved-Response Edited  
Discrepancy: Please verify spelling of "diclotenac".  
Internal Comment:  
Resolution Type: Data value changed. Disc no longer applicable.  
Resolution Text:

# Deleted CRFs Report