

CRF Report for Study E7694105D

Report run by Brian Saari at 21-FEB-2013 09:36:29

Report Parameters

Site: CDB_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1008

Ending patient: R1008

Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	Abc 123

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 #:

R1008

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-MAR-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:

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

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Page Version No. WEEK_1 (v1, 25-MAR-2009)

Document Number R264893413

Initials:

(b)

Subject #:

R1008

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-MAR-2009

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

Correct Incorrect

2. I have smoked on average 14 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 0

Small (0.5g) 18

6. I have experienced the following Adverse Events:

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

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Page Version No. WEEK_2 (v1, 25-MAR-2009)

Document Number R264893613

Initials:

(b)

Subject #:

R1008

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 05-APR-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:

LEFT SHOULDER PAIN

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

Initials:

(b)

Subject #:

R1008

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 12-APR-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:

LEFT SHOULDER PAIN

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 R264894313

Initials:

(b)

Subject #:

R1008

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 19-APR-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 4 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) 13

Small (0.5g) 24

6. I have experienced the following Adverse Events:

SORE PALATE AND THROAT (CORRECT) LEFT SHOULDER PAIN SAW DOCTOR ON 15/APR/09 (INC)

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 R264894913

OverFlow Section For Document Number R264894913

- 1 SORE PALATE AND THROAT(CORRECT)LEFT SHOULDER PAIN SAW DOCTOR ON
15/APR/09(INCORRECT)

Links to Discrepancy and Audit Sections

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

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Initials:

(b)

Subject #:

R1008

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 26-APR-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:

SORE THROAT AND PALATE (CORRECT)/LEFT SHOULDER PAIN (INCORRECT)

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 R264896113

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R1008

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 03-MAY-2009

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

Correct Incorrect

2. I have smoked on average 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:

SORE PALATE AND 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

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Page Version No. WEEK_7 (v1, 25-MAR-2009)

Document Number R264896313

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R1008

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 10-MAY-2009

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

Correct Incorrect

2. I have smoked on average 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:

SORE THROAT/PALATE

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 R264896413

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R1008

WEEK 9

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 17-MAY-2009

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

Correct Incorrect

2. I have smoked on average 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 0

Small (0.5g) 0

6. I have experienced the following Adverse Events:

NONE

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_9 (v1, 25-MAR-2009)

Document Number R264896513

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R1008

WEEK 10

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_10 (v1, 25-MAR-2009)

Document Number R264896613

Initials:

(b)

Subject #:

R1008

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Document Number R264896713

Initials:

(b)

Subject #:

R1008

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

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Page Version No. WEEK_12 (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R1008

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

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Page Version No. WEEK_13 (v1, 25-MAR-2009)

Document Number R264896913

Initials:

(b)

Subject #:

R1008

WEEK 14

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_14 (v1, 25-MAR-2009)

Document Number R264897013

Initials:

(b)

Subject #:

R1008

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

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Page Version No. WEEK_15 (v1, 25-MAR-2009)

Document Number R264897113

Initials:

(b)

Subject #:

R1008

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

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Page Version No. WEEK_16 (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R1008

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 R264897313

Initials:

(b)

Subject #:

R1008

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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Page Version No. WEEK_18 (v1, 25-MAR-2009)

Document Number R264897413

Initials:

(b)

Subject #:

R1008

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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Page Version No. WEEK_19 (v1, 25-MAR-2009)

Document Number R264897513

Initials:

(b)

Subject #:

R1008

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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Page Version No. WEEK_20 (v1, 25-MAR-2009)

Document Number R264897613

Initials:

(b)

Subject #:

R1008

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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Page Version No. WEEK_21 (v1, 25-MAR-2009)

Document Number R264897713

Initials:

(b)

Subject #:

R1008

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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Page Version No. WEEK_22 (v1, 25-MAR-2009)

Document Number R264897813

Initials:

(b)

Subject #:

R1008

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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Page Version No. WEEK_23 (v1, 25-MAR-2009)

Document Number R264897913

Initials:

(b)

Subject #:

R1008

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])?

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Page Version No. WEEK_24 (v1, 25-MAR-2009)

Document Number R264898013

Initials:

(b)

Subject #:

R1008

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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Page Version No. WEEK_25 (v1, 25-MAR-2009)

Document Number R264898113

Initials:

(b)

Subject #:

R1008

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

Initials:

(b)

Subject #:

R1008

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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Page Version No. WEEK_27 (v1, 25-MAR-2009)

Document Number R264898313

Initials:

(b)

Subject #:

R1008

FOLLOW-UP WK 28

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STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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Page Version No. WEEK_28 (v1, 25-MAR-2009)

Document Number R264898413

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 #: R264894913

Patient Site	Visit Visit Date	CRF CRF Page
R1008 CDB_001	Week 5	Week_5 05

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	5	Week 5

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	SORE PALATE AND THROAT/ LEFT SHOULDER PAIN SAW DOCTOR ON 15/APR/09 SORE PALATE AND THROAT/ LEFT SHOULDER PAIN SAW DOCTOR ON 15/APR/09(NOT RELATED TO SNUS)	10-NOV-2009 08:20:13 Rossana Matos	Data Entry Error
6. I have experienced the following AEs (3) 1	SORE PALATE AND THROAT/ LEFT SHOULDER PAIN SAW DOCTOR ON 15/APR/09(NOT RELATED TO SNUS) SORE PALATE AND THROAT(CORRECT)LEFT SHOULDER PAIN SAW DOCTOR ON 15/APR/09(INCORRECT)	19-JAN-2010 14:06:41 Christina Breedlove	Data Entry Error Entered per subject diary

Document #: R264896113

Patient Site	Visit Visit Date	CRF CRF Page
R1008 CDB_001	Week 6	Week_6 06

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	6	Week 6

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	SORE THROAT AND PALATE AND LEFT SHOULDER PAIN (SORE THROAT AND PALATE (LEFT SHOULDER PAIN(NOT RELATED TO SNUS))	10-NOV-2009 08:22:07 Rossana Matos	Pass1
6. I have experienced the following AEs (3) 1	SORE THROAT AND PALATE (LEFT SHOULDER PAIN(NOT RELATED TO SNUS)) SORE THROAT AND PALATE (CORRECT/LEFT SHOULDER PAIN(INCORRECT)	19-JAN-2010 14:16:21 Christina Breedlove	Data Entry Error confirmed per subject diary

Document #: R264896313

Patient Site	Visit Visit Date	CRF CRF Page
R1008 CDB_001	Week 7	Week_7 07

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	7	Week 7

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
5. Small (0.5g) (3) 1	23 3	07-OCT-2009 16:08:08 Sharon Daly	Data Entry Error
5. Small (0.5g) (3) 1	3 23 PER WK	19-JAN-2010 12:36:12 Christina Breedlove	Validation Status changed Per V1.4 updated CRF guidelines
5. Small (0.5g) (3) 1	23 PER WK 23 PER WEEK	19-JAN-2010 14:18:29 Christina Breedlove	Investigator Correction per query
5. Small (0.5g) (3) 1	23 PER WEEK 3	05-APR-2010 15:13:23 Krysia Magnuson	ODM/SEC 23 PER WEEK to 3 (converted weekly value to daily).
6. I have experienced the following AEs (3) 1	SORE THROAT AND PALATE SORE THROAT AND PALATE/ LEFT SHOULDER PAIN	19-AUG-2009 14:50:42 Christina Breedlove	Data Entry Error confirmed with subject
6. I have experienced the following AEs (3) 1	SORE THROAT AND PALATE/ LEFT SHOULDER PAIN SORE PALATE AND THROAT	07-OCT-2009 16:08:08 Sharon Daly	Data Entry Error

Document #: R264896413

Patient Site	Visit Visit Date	CRF CRF Page
R1008 CDB_001	Week 8	Week_8 08

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	8	Week 8

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
5. Small (0.5g) (3) 1	16 2	07-OCT-2009 16:11:07 Sharon Daly	Data Entry Error
5. Small (0.5g) (3) 1	2 16 PER WK	19-JAN-2010 12:37:45 Christina Breedlove	Validation Status changed Per V1.4 updated CRF guidelines
5. Small (0.5g) (3) 1	16 PER WK 16 PER WEEK	19-JAN-2010 14:19:49 Christina Breedlove	Data Entry Error per query
5. Small (0.5g) (3) 1	16 PER WEEK 2	05-APR-2010 15:11:54 Krysia Magnuson	ODM/SEC 16 PER WEEK to 2. (converted weekly to daily).
6. I have experienced the following AEs (3) 1	SORE THROAT AND PALATE SORE THROAT AND PALATE/ LEFT SHOULDER PAIN	19-AUG-2009 14:51:26 Christina Breedlove	Data Entry Error confirmed with subject
6. I have experienced the following AEs (3) 1	SORE THROAT AND PALATE/ LEFT SHOULDER PAIN SORE THTOAT/PALATE	07-OCT-2009 16:11:07 Sharon Daly	Data Entry Error
6. I have experienced the following AEs (3) 1	SORE THTOAT/PALATE SORE THROAT/PALATE	19-JAN-2010 16:00:56 Christina Breedlove	Data Entry Error spelling correction

Document #: R264896513

Patient Site	Visit Visit Date	CRF CRF Page
R1008 CDB_001	Week 9	Week_9 09

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	9	Week 9

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE LEFT SHOULDER PAIN	19-AUG-2009 14:51:54 Christina Breedlove	Data Entry Error confirmed with subject
6. I have experienced the following AEs (3) 1	LEFT SHOULDER PAIN NONE	07-OCT-2009 16:13:15 Sharon Daly	Data Entry Error

Discrepancy Detail Report

Document #: R264894913

Discrepancy ID: 43213811 Site: CDB_001 Patient: R1008
Visit: WEEK 5 Visit Date:
CRF: WEEK_5 Section: STUDY DIARY Qualifying Value: 5
Field: 6. I have experienced the following AEs Row: 1
Value Text: SORE PALATE AND THROAT(CORRECT)LEFT SHOULDER PAIN SAW DOCTOR ON 15/APR/09(INCORRECT)
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please indicate in text "sore palate and throat" related to snus product.
Internal Comment: confirmed per subject diary
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 1766071813 Site: CDB_001 Patient: R1008
Visit: WEEK 5 Visit Date:
CRF: WEEK_5 Section: STUDY DIARY Qualifying Value: 5
Field: Row:
Value Text:
Type: MANUAL HEADER Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: I think it is ok that "correct was entered", I think we would want to capture that they believe the AE is related to the snus.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 1766071913 Site: CDB_001 Patient: R1008
Visit: WEEK 5 Visit Date:
CRF: WEEK_5 Section: STUDY DIARY Qualifying Value: 5
Field: Row:
Value Text:
Type: MANUAL HEADER Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: I would comment next to the left should pain that the subject indicated they did no believe it was related to the snus.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

R264894913

Discrepancy ID: 1789217713

Site: CDB_001

Patient: R1008

Visit: WEEK 5

Visit Date:

CRF: WEEK_5

Section: STUDY DIARY

Qualifying Value: 5

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy:

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R264896113

Discrepancy ID: 43213911 **Site:** CDB_001 **Patient:** R1008

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: SORE THROAT AND PALATE(CORRECT/LEFT SHOULDER PAIN(INCORRECT))

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please indicate for "sore palate and throat" subject felt it was related to snus product.

Internal Comment: confirmed per subject diary

Resolution Type: Confirmed

Resolution Text: confirmed per subject diary

Discrepancy ID: 1766072213 **Site:** CDB_001 **Patient:** R1008

Visit: WEEK 6

Visit Date:

CRF: WEEK_6

Section: STUDY DIARY

Qualifying Value: 6

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please mark correct as was done on previous page.

Internal Comment: After confirming with subject correct was mark for sore palate and throat

Resolution Type: Confirmed

Resolution Text:

Discrepancy ID: 1766074813 **Site:** CDB_001 **Patient:** R1008

Visit: WEEK 6

Visit Date:

CRF: WEEK_6

Section: STUDY DIARY

Qualifying Value: 6

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please comment regarding left shoulder pain that the subject indicated they did not believe it was related to the snus product.

Internal Comment: shoulder pain not related to snus

Resolution Type: Confirmed

Resolution Text:

Document #: R264896313

Discrepancy ID: 1766081013 **Site:** CDB_001 **Patient:** R1008
Visit: WEEK 7 **Visit Date:**
CRF: WEEK_7 **Section:** STUDY DIARY **Qualifying Value:** 7
Field: 5. Small (0.5g) **Row:** 1
Value Text: 3
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please spell out "week".
Internal Comment: per query
Resolution Type: Due Diligence
Resolution Text: per query

Discrepancy ID: 1766081113 **Site:** CDB_001 **Patient:** R1008
Visit: WEEK 7 **Visit Date:**
CRF: WEEK_7 **Section:** STUDY DIARY **Qualifying Value:** 7
Field: 6. I have experienced the following AEs **Row:** 1
Value Text: SORE PALATE AND THROAT
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please delete Left shoulder pain, the subject did not indicate this on their diary.
Internal Comment: will delete
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R264896413

Discrepancy ID: 1766082413 **Site:** CDB_001 **Patient:** R1008
Visit: WEEK 8 **Visit Date:**
CRF: WEEK_8 **Section:** STUDY DIARY **Qualifying Value:** 8
Field: 5. Small (0.5g) **Row:** 1
Value Text: 2
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please spell out "week".
Internal Comment: per query
Resolution Type: Due Diligence
Resolution Text:

Discrepancy ID: 1766082513 **Site:** CDB_001 **Patient:** R1008
Visit: WEEK 8 **Visit Date:**
CRF: WEEK_8 **Section:** STUDY DIARY **Qualifying Value:** 8
Field: 6. I have experienced the following AEs **Row:** 1
Value Text: SORE THROAT/PALATE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify spelling of "throat".
Internal Comment: Corrected per Query
Resolution Type: Due Diligence
Resolution Text:

Document #: R264896513

Discrepancy ID: 1766083413

Site: CDB_001

Patient: R1008

Visit: WEEK 9

Visit Date:

CRF: WEEK_9

Section: STUDY DIARY

Qualifying Value: 9

Field: 6. I have experienced the following AEs

Row: 1

Value Text: NONE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please delete left shoulder pain, the subject did no indicate this on their diary.

Internal Comment: will delete

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

Resolution Text:

Deleted CRFs Report