

CRF Report for Study E7694105D

Report run by Brian Saari at 22-FEB-2013 16:20:32

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4002

Ending patient: R4002

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 #:

R4002

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 09-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:

HICCUPS, SALIVATING MORE THAN USUAL & BURNING SENSATION IN THROAT WHEN USING

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

OverFlow Section For Document Number R242654513

- 1 HICCUPS, SALIVATING MORE THAN USUAL & BURNING SENSATION IN THROAT WHEN USING THE LARGE SACHETS; UPSET STOMACH IF PACKET LEFT IN MOUTH MORE THAN 20 MINUTES

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 #:

R4002

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 16-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:

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_2 (v1, 25-MAR-2009)

Document Number R242654713

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R4002

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 23-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:

BURNING IN 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_3 (v1, 25-MAR-2009)

Document Number R242654813

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Initials:

(b)

Subject #:

R4002

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-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:

BURNING IN MY 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_4 (v1, 25-MAR-2009)

Document Number R242654913

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Initials:

(b)

Subject #:

R4002

WEEK 5

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:

SOME BURNING IN MY 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_5 (v1, 25-MAR-2009)

Document Number R242655013

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Initials:

(b)

Subject #:

R4002

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-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:

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 R257359813

Initials:

(b)

Subject #:

R4002

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-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:

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 R257360013

Initials:

(b)

Subject #:

R4002

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-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:

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 R257360113

Initials:

(b)

Subject #:

R4002

WEEK 9

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 04-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:

BURNING GUMS, MOUTH 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_9 (v1, 25-MAR-2009)

Document Number R257360313

Initials:

(b)

Subject #:

R4002

WEEK 10

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 18-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:

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 R257360513

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Initials:

(b)

Subject #:

R4002

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 25-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:

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 R257360813

Initials:

(b)

Subject #:

R4002

WEEK 12

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-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_12 (v1, 25-MAR-2009)

Document Number R257361013

Initials:

(b)

Subject #:

R4002

WEEK 13

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-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_13 (v1, 25-MAR-2009)

Document Number R257361213

Initials:

(b)

Subject #:

R4002

WEEK 14

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 15-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_14 (v1, 25-MAR-2009)

Document Number R257361313

Initials:

(b)

Subject #:

R4002

WEEK 15

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-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_15 (v1, 25-MAR-2009)

Document Number R257365013

Initials:

(b)

Subject #:

R4002

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 R286324513

Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 17

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-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])?

SNUS CAMEL

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Page Version No. WEEK_17 (v1, 25-MAR-2009)

Document Number R275031613

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Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 06-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])?

SNUS CAMEL

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

Document Number R275032313

Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-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])?

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

Document Number R275032713

Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-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])?

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

Document Number R275033013

Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-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])?

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

Document Number R275033213

Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 03-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])?

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

Document Number R275033313

Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 10-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])?

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Document Number R275033513

Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 24

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 17-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])?

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Document Number R275033613

Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 24-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])?

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

Document Number R275033813

Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 31-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])?

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Page Version No. WEEK_26 (v1, 25-MAR-2009)

Document Number R275033913

Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 27

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STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 07-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])?

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

Document Number R275034013

Initials:

(b)

Subject #:

R4002

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 14-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])?

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

Document Number R275034113

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 #: R242654513

Patient Site	Visit Visit Date	CRF CRF Page
R4002 P3880_0342	Week 1	Week_1 01

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	1	Week 1

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
5. Small (0.5g) (3) 1	23 3	20-OCT-2009 15:13:41 Lana Glaser	Data Entry Error
5. Small (0.5g) (3) 1	3 23	04-JAN-2010 10:45:57 Lana Glaser	Data Entry Error
6. I have experienced the following AEs (3) 1	HICCUPS, SALIVATING MORE THAN USUAL, BURNING SENSATION IN THROAT, UPSET STOMACH	17-APR-2009 15:49:54 Kim Freschly	Data Entry Error
6. I have experienced the following AEs (3) 1	HICCUPS, SALIVATING MORE THAN USUAL, BURNING SENSATION IN THROAT, UPSET STOMACH	05-JAN-2010 11:54:32 Lana Glaser	Data Entry Error
6. I have experienced the following AEs (3) 1	HICCUPS, SALIVATING MORE THAN USUAL & BURNING SENSATION IN THROAT WHEN USING THE LARGE SACHETS; UPSET STOMACH IF PACKET LEFT IN MOUTH MORE THAN 20 MINUTES	08-JAN-2010 09:28:50 Kim Freschly	Data Entry Error
7. I think the AE is related to the snus (4) 1	CORRECT	17-APR-2009 15:49:54 Kim Freschly	Data Entry Error
7. I think the AE is related to the snus (4) 1	CORRECT AE	05-JAN-2010 11:54:32 Lana Glaser	Data Entry Error
7. I think the AE is related to the snus (4) 1	AE CORRECT	08-JAN-2010 09:33:33 Kim Freschly	Data Entry Error
Date 1	13-MAR-2009 09-MAR-2009	17-APR-2009 15:44:10 Kim Freschly	Pass1

Document #: R242654713

Patient Site	Visit Visit Date	CRF CRF Page
R4002 P3880_0342	Week 2	Week_2 02

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	2	Week 2

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
5. Small (0.5g) (3) 1	21 3	20-OCT-2009 15:14:16 Lana Glaser	Data Entry Error
6. I have experienced the following AEs (3) 1	HICCUPS, SALIVATING MORE THAN USUAL, BURNING SENSATION IN THROAT, UPSET STOMACH IF PACKET LEFT IN MOUTH MORE THAN 20 MINUTES,	05-JAN-2010 11:56:29 Lana Glaser	Data Entry Error
6. I have experienced the following AEs (3) 1	HICCUPS, SALIVATING MORE THAN USUAL, BURNING SENSATION IN THROAT, UPSET STOMACH IF PACKET LEFT IN MOUTH MORE THAN 20 MINUTES, NONE	08-JAN-2010 09:32:50 Kim Freschly	Data Entry Error
7. I think the AE is related to the snus (4) 1	AE CORRECT	05-JAN-2010 11:56:29 Lana Glaser	Data Entry Error
7. I think the AE is related to the snus (4) 1	CORRECT AE	08-JAN-2010 09:32:50 Kim Freschly	Data Entry Error

Document #: R242654813

Patient Site	Visit Visit Date	CRF CRF Page
R4002 P3880_0342	Week 3	Week_3 03

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	3	Week 3

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
1. I have not smoked any cigarettes at a (1) 1	INCORRECT CORRECT		04-JAN-2010 10:58:40 Lana Glaser	Data Entry Error
1. I have not smoked any cigarettes at a (1) 1	CORRECT INCORRECT		05-JAN-2010 12:10:47 Lana Glaser	Data Entry Error
5. Small (0.5g) (3) 1	24 3		20-OCT-2009 15:14:48 Lana Glaser	Data Entry Error

Document #: R242654913

Patient Site	Visit Visit Date	CRF CRF Page
R4002 P3880_0342	Week 4	Week_4 04

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	4	Week 4

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	30-MAR-2009 23-MAR-2009	04-JAN-2010 11:01:27 Lana Glaser	Data Entry Error
Date 1	23-MAR-2009 30-MAR-2009	08-JAN-2010 09:34:49 Kim Freschly	Data Entry Error

Document #: R242655013

Patient Site	Visit Visit Date	CRF CRF Page
R4002 P3880_0342	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
Date 1	06-APR-2009 05-APR-2009	08-JAN-2010 09:36:36 Kim Freschly	Data Entry Error

Document #: R275031613

Patient Site	Visit Visit Date	CRF CRF Page
R4002 P3880_0342	Follow-Up Wk 17	Week_17 17

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	17	Follow-Up Wk 17

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	26-JUN-2009 29-JUN-2009	04-JAN-2010 11:11:42 Lana Glaser	Data Entry Error

Discrepancy Detail Report

Document #: R242654513

Discrepancy ID: 1720047513 Site: P3880_0342 Patient: R4002

Visit: WEEK 1

Visit Date:

CRF: WEEK_1

Section: STUDY DIARY

Qualifying Value: 1

Field: 5. Small (0.5g)

Row: 1

Value Text: 23

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review - source updated

Internal Comment: corrected

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

Resolution Text:

Discrepancy ID: 1780388813 Site: P3880_0342 Patient: R4002

Visit: WEEK 1

Visit Date:

CRF: WEEK_1

Section: STUDY DIARY

Qualifying Value: 1

Field: 6. I have experienced the following AEs

Row: 1

Value Text: HICCUPS, SALIVATING MORE THAN USUAL & BURNING SENSATION IN THROAT WHEN USING THE LARGE SACHETS; UPSET STOMACH IF PACKET LEFT IN MOUTH MORE THAN 20 MINUTES

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per Original Diary (daily) source, subject 4002 experienced AE's Hiccups, salivating and burning sensation. These have also been captured as source AE's. Please update weekly Diary source.

Internal Comment: Please review daily diaries (weekly diary was a transcription, however subject did not transcribe AE data). Please see me if further clarification is needed.

Resolution Type: Confirmed

Resolution Text:

Discrepancy ID: 35448411 Site: P3880_0342 Patient: R4002

Visit: WEEK 1

Visit Date:

CRF: WEEK_1

Section: STUDY DIARY

Qualifying Value: 1

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: This subject completed a daily diary for the first 6 weeks, then transferred the information onto the weekly diary. The subject indicated multiple AE's on the daily diary. These should be documented in the CRF and a note indicating the change from Daily to Weekly Diaries should be noted.

Internal Comment: Study Manager to document on NTF the process for subject who received a daily diary.

Resolution Type: Confirmed

Resolution Text: added comments from daily diary

Document #: R242654713

Discrepancy ID: 1720077313 **Site:** P3880_0342 **Patient:** R4002
Visit: WEEK 2 **Visit Date:**
CRF: WEEK_2 **Section:** STUDY DIARY **Qualifying Value:** 2
Field: 5. Small (0.5g) **Row:** 1
Value Text: 3
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review (per source 3/day)
Internal Comment: corrected
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 36153911 **Site:** P3880_0342 **Patient:** R4002
Visit: WEEK 2 **Visit Date:**
CRF: WEEK_2 **Section:** STUDY DIARY **Qualifying Value:** 2
Field: 6. I have experienced the following AEs **Row:** 1
Value Text: NONE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per daily diary source and week 2 weekly diary, these comments were not documented. Please delete.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 1780389613 **Site:** P3880_0342 **Patient:** R4002
Visit: WEEK 2 **Visit Date:**
CRF: WEEK_2 **Section:** STUDY DIARY **Qualifying Value:** 2
Field: 7. I think the AE is related to the snus **Row:** 1
Value Text: AE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per subject Diary (daily) subject did not experience any AEs. Per soubject Diary (weekly) subject did not indicate any AE's, however did indicate CORRECT for related to Snus. Please clarify weekly diary source.
Internal Comment: corrected
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R242654813

Discrepancy ID: 1780404913 **Site:** P3880_0342 **Patient:** R4002

Visit: WEEK 3

Visit Date:

CRF: WEEK_3

Section: STUDY DIARY

Qualifying Value: 3

Field: 1. I have not smoked any cigarettes at a

Row: 1

Value Text: INCORRECT

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per subject diary (daily) response to #1 is incorrect, however on subject diary (weekly) response is correct. Please clarify. Also review response to #6 on weekly diary, subject indicates an AE on daily diary.

Internal Comment: Please comment/document in source if subject noted AE of burning sensation on 3/23/09 and 3/24/09 was review for an AE.

Resolution Type: Confirmed

Resolution Text:

Discrepancy ID: 1720077413 **Site:** P3880_0342 **Patient:** R4002

Visit: WEEK 3

Visit Date:

CRF: WEEK_3

Section: STUDY DIARY

Qualifying Value: 3

Field: 5. Small (0.5g)

Row: 1

Value Text: 3

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review - source updated 3/day

Internal Comment: corrected

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

Resolution Text:

Document #: R242654913

Discrepancy ID: 1780407413

Site: P3880_0342

Patient: R4002

Visit: WEEK 4

Visit Date:

CRF: WEEK_4

Section: STUDY DIARY

Qualifying Value: 4

Field: Date

Row: 1

Value Text: 20090330

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please use correct date from daily diary source 3/24/09- 3/30/09

Internal Comment: Please verify per the daily diary data was collected from 3/24/09-3/30/09, therefore the completion date for this week is 3/30/2009. Please verify this date should be entered.

Resolution Type: Confirmed

Resolution Text:

Document #: R242655013

Discrepancy ID: 1780408813

Site: P3880_0342

Patient: R4002

Visit: WEEK 5

Visit Date:

CRF: WEEK_5

Section: STUDY DIARY

Qualifying Value: 5

Field: Date

Row: 1

Value Text: 20090405

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per daily diary source date of week 5 is 05Apr09 - Please review.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R257360513

Discrepancy ID: 1780426513

Site: P3880_0342

Patient: R4002

Visit: WEEK 10

Visit Date:

CRF: WEEK_10

Section: STUDY DIARY

Qualifying Value: 10

Field: 4. Yes specify:

Row: 1

Value Text:

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Data is missing from subject Diary. Week 28 source indicates use of camel snus but not for this time period - please clarify.

Internal Comment: product used was not documented

Resolution Type: Confirmed

Resolution Text:

Document #: R275031613

Discrepancy ID: 1780487213

Site: P3880_0342

Patient: R4002

Visit: FOLLOW-UP WK 17 **Visit Date:**

CRF: WEEK_17

Section: STUDY DIARY

Qualifying Value: 17

Field: Date

Row: 1

Value Text: 20090629

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review date to subject Diary

Internal Comment:

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

Resolution Text:

Deleted CRFs Report