

CRF Report for Study E7694105D

Report run by Brian Saari at 25-FEB-2013 11:47:25

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4074

Ending patient: R4074

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 #:

R4074

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: UNK

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_1 (v1, 25-MAR-2009)

Document Number R288660313

Links to Discrepancy and Audit Sections

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

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Initials:

(b)

Subject #:

R4074

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: UNK

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 g 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) g

Small (0.5g) g

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R288661513

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R4074

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: UNK

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_3 (v1, 25-MAR-2009)

Document Number R288661713

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R4074

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: UNK

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 3 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) 5

Small (0.5g) 0

6. I have experienced the following Adverse Events:

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

- Correct
 Incorrect
 Don't Know
 I have not experienced an Adverse Event

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Page Version No. WEEK_4 (v1, 25-MAR-2009)

Document Number R288661913

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R4074

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: UNK

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 R288662113

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R4074

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_6 (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R4074

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R288663713

Initials:

(b)

Subject #:

R4074

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_8 (v1, 25-MAR-2009)

Document Number R288663813

Initials:

(b)

Subject #:

R4074

WEEK 9

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R288664013

Initials:

(b)

Subject #:

R4074

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 R288664313

Initials:

(b)

Subject #:

R4074

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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Page Version No. WEEK_11 (v1, 25-MAR-2009)

Document Number R288664513

Initials:

(b)

Subject #:

R4074

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 R288664713

Initials:

(b)

Subject #:

R4074

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 R288664913

Initials:

(b)

Subject #:

R4074

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 R288665113

Initials:

(b)

Subject #:

R4074

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 R288665213

Initials:

(b)

Subject #:

R4074

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 R288665413

Initials:

(b)

Subject #:

R4074

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 R288665513

Initials:

(b)

Subject #:

R4074

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 R288665713

Initials:

(b)

Subject #:

R4074

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 R288665813

Initials:

(b)

Subject #:

R4074

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 R288665913

Initials:

(b)

Subject #:

R4074

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 R288666113

Initials:

(b)

Subject #:

R4074

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 R288668713

Initials:

(b)

Subject #:

R4074

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 R288668913

Initials:

(b)

Subject #:

R4074

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 R288669013

Initials:

(b)

Subject #:

R4074

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 R288669113

Initials:

(b)

Subject #:

R4074

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

Verified Approved Locked Frozen

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

Document Number R288669213

Initials:

(b)

Subject #:

R4074

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 R288669313

Initials:

(b)

Subject #:

R4074

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

Verified Approved Locked Frozen

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

Document Number R288669413

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 #: R288660313

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|-------------------------|---------------------|
| R4074 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 |
|------------------|--------------------------------|-------------------------------------|-----------------------|
| Date 1 | 03-APR-2009 UNK | 05-MAR-2010 11:27:33 Lana Glaser | Data Entry Error |

Document #: R288661513

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|-------------------------|---------------------|
| R4074 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 |
|------------------|--------------------------------|-------------------------------------|-----------------------|
| Date 1 | 10-APR-2009 UNK | 05-MAR-2010 11:29:17 Lana Glaser | Data Entry Error |

Document #: R288661713

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|-------------------------|---------------------|
| R4074 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 On resequence By | Reason Comment |
|------------------|--------------------------------|-------------------------------------|-----------------------|
| Date 1 | 17-APR-2009 UNK | 05-MAR-2010 11:30:03 Lana Glaser | Data Entry Error |

Document #: R288661913

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|-------------------------|---------------------|
| R4074 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 | 24-APR-2009 UNK | 05-MAR-2010 11:30:22 Lana Glaser | Data Entry Error |

Discrepancy Detail Report

Document #: R288660313

Discrepancy ID: 43030511 Site: P3880_0342 Patient: R4074
Visit: WEEK 1 Visit Date:
CRF: WEEK_1 Section: STUDY DIARY Qualifying Value: 1
Field: 7. I think the AE is related to the snus Row: 1
Value Text:
Type: UNIVARIATE Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied
Internal Comment: not documented on subject's diary
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 76590611 Site: P3880_0342 Patient: R4074
Visit: WEEK 1 Visit Date:
CRF: WEEK_1 Section: STUDY DIARY Qualifying Value: 1
Field: Date Row: 1
Value Text: UNK
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter UNK for date, as subject was not enrolled in study until 22 JUN 2009.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R288661513

Discrepancy ID: 43030811 **Site:** P3880_0342 **Patient:** R4074
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:
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied
Internal Comment: not documented on subject's diary
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 76590711 **Site:** P3880_0342 **Patient:** R4074
Visit: WEEK 2 **Visit Date:**
CRF: WEEK_2 **Section:** STUDY DIARY **Qualifying Value:** 2
Field: Date **Row:** 1
Value Text: UNK
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter UNK for date, as subject was not enrolled in study until 22 JUN 2009.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R288661713

Discrepancy ID: 43031611 **Site:** P3880_0342 **Patient:** R4074
Visit: WEEK 3 **Visit Date:**
CRF: WEEK_3 **Section:** STUDY DIARY **Qualifying Value:** 3
Field: 7. I think the AE is related to the snus **Row:** 1
Value Text:
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied
Internal Comment: not documented on subject's diary
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 76590811 **Site:** P3880_0342 **Patient:** R4074
Visit: WEEK 3 **Visit Date:**
CRF: WEEK_3 **Section:** STUDY DIARY **Qualifying Value:** 3
Field: Date **Row:** 1
Value Text: UNK
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter UNK for date, as subject was not enrolled in study until 22 JUN 2009.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R288661913

Discrepancy ID: 43031911 **Site:** P3880_0342 **Patient:** R4074
Visit: WEEK 4 **Visit Date:**
CRF: WEEK_4 **Section:** STUDY DIARY **Qualifying Value:** 4
Field: 7. I think the AE is related to the snus **Row:** 1
Value Text:
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied
Internal Comment: not documented on subject's diary
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 76591011 **Site:** P3880_0342 **Patient:** R4074
Visit: WEEK 4 **Visit Date:**
CRF: WEEK_4 **Section:** STUDY DIARY **Qualifying Value:** 4
Field: Date **Row:** 1
Value Text: UNK
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter UNK for date, as subject was not enrolled in study until 22 JUN 2009.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R288662113

Discrepancy ID: 43033411 **Site:** P3880_0342 **Patient:** R4074
Visit: WEEK 5 **Visit Date:**
CRF: WEEK_5 **Section:** STUDY DIARY **Qualifying Value:** 5
Field: 7. I think the AE is related to the snus **Row:** 1
Value Text:
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied
Internal Comment: not documented on subject's diary
Resolution Type: Confirmed
Resolution Text:

Deleted CRFs Report