

CRF Report for Study E7694105D

Report run by Brian Saari at 25-FEB-2013 10:41:43

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4037

Ending patient: R4037

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 #:

R4037

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 12-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 5 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) 23

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_1 (v1, 25-MAR-2009)

Document Number R281656813

Initials:

(b)

Subject #:

R4037

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 19-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_2 (v1, 25-MAR-2009)

Document Number R281657113

Initials:

(b)

Subject #:

R4037

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 26-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_3 (v1, 25-MAR-2009)

Document Number R281657213

Initials:

(b)

Subject #:

R4037

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 31-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_4 (v1, 25-MAR-2009)

Document Number R281657313

Initials:

(b)

Subject #:

R4037

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 07-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_5 (v1, 25-MAR-2009)

Document Number R281657513

Initials:

(b)

Subject #:

R4037

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 16-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 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) 0

Small (0.5g) 6

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R281657613

Initials:

(b)

Subject #:

R4037

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 23-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_7 (v1, 25-MAR-2009)

Document Number R281658013

Initials:

(b)

Subject #:

R4037

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-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_8 (v1, 25-MAR-2009)

Document Number R281658113

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R4037

WEEK 9

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 07-JUL-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R281658213

Initials:

(b)

Subject #:

R4037

WEEK 10

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 14-JUL-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R281659013

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R4037

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 21-JUL-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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 R281659213

Initials:

(b)

Subject #:

R4037

WEEK 12

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 28-JUL-2009

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

Correct Incorrect

2. I have smoked on average 5 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 0

Small (0.5g) 4

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R281659413

Initials:

(b)

Subject #:

R4037

WEEK 13

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 04-AUG-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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 R281659613

Initials:

(b)

Subject #:

R4037

WEEK 14

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 11-AUG-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

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

Document Number R281659813

Initials:

(b)

Subject #:

R4037

WEEK 15

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 18-AUG-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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 R281660113

Initials:

(b)

Subject #:

R4037

WEEK 16

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 25-AUG-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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 R281660213

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 17

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 02-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 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])?

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

Document Number R281660413

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 09-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 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])?

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

Document Number R281660613

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 16-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 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])?

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

Document Number R281660913

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 23-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 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])?

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

Document Number R281661013

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-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 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])?

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

Document Number R281661113

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 07-OCT-2009

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

Correct Incorrect

2. I have smoked on average 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])?

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

Document Number R281661513

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 14-OCT-2009

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

Correct Incorrect

2. I have smoked on average 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])?

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

Document Number R281661713

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 24

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 21-OCT-2009

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

Correct Incorrect

2. I have smoked on average 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])?

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

Document Number R281661813

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 28-OCT-2009

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

Correct Incorrect

2. I have smoked on average 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])?

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

Document Number R281661913

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 04-NOV-2009

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

Correct Incorrect

2. I have smoked on average 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])?

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

Document Number R281662113

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 11-NOV-2009

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

Correct Incorrect

2. I have smoked on average 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])?

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

Document Number R281662313

Initials:

(b)

Subject #:

R4037

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 17-NOV-2009

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

Correct Incorrect

2. I have smoked on average 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])?

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Document Number R281662413

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 #: R281658113

Patient Site	Visit Visit Date	CRF CRF Page
R4037 P3880_0342	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
3. 1	I have smoked tobacco products other (2) NO	24-NOV-2009 15:34:09 Lana Glaser	CRA Correction

Document #: R281659013

Patient Site	Visit Visit Date	CRF CRF Page
R4037 P3880_0342	Week 10	Week_10 10

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	10	Week 10

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
5. Small (0.5g) (3) 1	4 5	14-JAN-2010 09:14:36 Lana Glaser	Data Entry Error

Discrepancy Detail Report

Document #: R281659013

Discrepancy ID: 35383611

Site: P3880_0342

Patient: R4037

Visit: WEEK 10

Visit Date:

CRF: WEEK_10

Section: STUDY DIARY

Qualifying Value: 10

Field: 5. Small (0.5g)

Row: 1

Value Text: 5

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review value

Internal Comment:

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

Resolution Text:

Deleted CRFs Report