

CRF Report for Study E7694105D

Report run by Brian Saari at 22-FEB-2013 10:49:13

Report Parameters

Site: CP_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R3018

Ending patient: R3018

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 #:

R3018

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 21-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 20 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) 2

Small (0.5g) 3

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

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

Document Number R253882413

Initials:

(b)

Subject #:

R3018

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-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 20 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) 2

Small (0.5g) 3

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_2 (v1, 25-MAR-2009)

Document Number R253882613

Initials:

(b)

Subject #:

R3018

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 06-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

Verified Approved Locked Frozen

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

Document Number

Initials:

(b)

Subject #:

R3018

WEEK 4

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 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_4 (v1, 25-MAR-2009)

Document Number R253883013

Initials:

(b)

Subject #:

R3018

WEEK 5

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

Verified Approved Locked Frozen

Page Version No. WEEK_5 (v1, 25-MAR-2009)

Document Number R253883113

Initials:

(b)

Subject #:

R3018

WEEK 6

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:

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

Verified Approved Locked Frozen

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

Document Number R265941813

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 #:

R3018

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 00-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:

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

Verified Approved Locked Frozen

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

Document Number R265941913

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 #:

R3018

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 09-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

Verified Approved Locked Frozen

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

Document Number R265942013

Initials:

(b)

Subject #:

R3018

WEEK 9

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 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_9 (v1, 25-MAR-2009)

Document Number R265942113

Initials:

(b)

Subject #:

R3018

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

Verified Approved Locked Frozen

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

Document Number R265942213

Initials:

(b)

Subject #:

R3018

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-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:

NO

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

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

Document Number R265942313

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 #:

R3018

WEEK 12

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:

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

Verified Approved Locked Frozen

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

Document Number R265942413

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R3018

WEEK 13

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:

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

Verified Approved Locked Frozen

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

Document Number R265942513

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R3018

WEEK 14

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:

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

Verified Approved Locked Frozen

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

Document Number R265942613

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R3018

WEEK 15

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 28-JUL-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Verified Approved Locked Frozen

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

Document Number R265942713

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R3018

WEEK 16

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:

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

Verified Approved Locked Frozen

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

Document Number R265942813

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R3018

FOLLOW-UP WK 17

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])?

SUBJECT STILL HAD PRODUCT DUE TO BEING OUT OF WINDOW AND WAS USING ABOUT 4 A.

Verified Approved Locked Frozen

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

Document Number R265942913

OverFlow Section For Document Number R265942913

- 1 SUBJECT STILL HAD PRODUCT DUE TO BEING OUT OF WINDOW AND WAS USING ABOUT 4 A DAY

Initials:

(b)

Subject #:

R3018

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_18 (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R3018

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_19 (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R3018

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_20 (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R3018

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])?

Verified Approved Locked Frozen

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

Document Number R280392813

Initials:

(b)

Subject #:

R3018

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])?

Verified Approved Locked Frozen

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

Document Number R280392913

Initials:

(b)

Subject #:

R3018

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_23 (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R3018

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_24 (v1, 25-MAR-2009)

Document Number

Initials:

(b)

Subject #:

R3018

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])?

Verified Approved Locked Frozen

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

Document Number R280393213

Initials:

(b)

Subject #:

R3018

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

Verified Approved Locked Frozen

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

Document Number

Initials:

(b)

Subject #:

R3018

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])?

Verified Approved Locked Frozen

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

Document Number R280393513

Initials:

(b)

Subject #:

R3018

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 R280393613

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 #: R265941813

Patient Site	Visit Visit Date	CRF CRF Page
R3018 CP_001	Week 6	Week_6 06

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE	11-FEB-2010 11:40:44 Tricia Hunt	Data Entry Error
Date 1	01-JUN-2009 26-MAY-2009	18-NOV-2009 15:26:13 Heather Aiona	Investigator Correction

Document #: R265941913

Patient Site	Visit Visit Date	CRF CRF Page
R3018 CP_001	Week 7	Week_7 07

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE	19-FEB-2010 09:01:34 Tricia Hunt	Data Entry Error
Date 1	07-JUN-2009 00-JUN-2009	18-NOV-2009 15:28:36 Heather Aiona	Investigator Correction

Document #: R265942313

Patient Site	Visit Visit Date	CRF CRF Page
R3018 CP_001	Week 11	Week_11 11

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	11	Week 11

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NO	19-FEB-2010 09:02:25 Tricia Hunt	Data Entry Error

Document #: R265942413

Patient Site	Visit Visit Date	CRF CRF Page
R3018 CP_001	Week 12	Week_12 12

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	12	Week 12

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. (3) 1	I have experienced the following AEs NONE	19-FEB-2010 09:03:44 Tricia Hunt	Data Entry Error

Document #: R265942513

Patient Site	Visit Visit Date	CRF CRF Page
R3018 CP_001	Week 13	Week_13 13

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	13	Week 13

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. (3) 1	I have experienced the following AEs NONE	19-FEB-2010 09:04:10 Tricia Hunt	Data Entry Error

Document #: R265942613

Patient Site	Visit Visit Date	CRF CRF Page
R3018 CP_001	Week 14	Week_14 14

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE	19-FEB-2010 09:04:31 Tricia Hunt	Data Entry Error

Document #: R265942713

Patient Site	Visit Visit Date	CRF CRF Page
R3018 CP_001	Week 15	Week_15 15

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	15	Week 15

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE	19-FEB-2010 09:04:49 Tricia Hunt	Data Entry Error

Document #: R265942813

Patient Site	Visit Visit Date	CRF CRF Page
R3018 CP_001	Week 16	Week_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	16	Week 16

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE	19-FEB-2010 09:05:09 Tricia Hunt	Data Entry Error

Document #: R265941913

Discrepancy ID: 69063011 **Site:** CP_001 **Patient:** R3018
Visit: WEEK 7 **Visit Date:**
CRF: WEEK_7 **Section:** STUDY DIARY **Qualifying Value:** 7
Field: 6. I have experienced the following AEs **Row:** 1
Value Text: NONE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter 'None'

Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1796461213 **Site:** CP_001 **Patient:** R3018
Visit: WEEK 7 **Visit Date:**
CRF: WEEK_7 **Section:** STUDY DIARY **Qualifying Value:** 7
Field: Date **Row:** 1
Value Text: 200906
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited

Discrepancy: Please review date of completion. Source date is incomplete. Please also verify the dates for week 6. Week 5 diary completed on 19May09, week 6 visit was on 01Jun09. There is a notation on week 6 diary date 'for 26th' Is this May 26? The original date on week 7 diary was 02Jun09, but the day is crossed out. It appears the subject came in for week 6 visit on week 7. Is this possible. Weeks 8 and 9 appear to be correct. Please review diaries for weeks 6 and 7.

Internal Comment: I believe it was 02JUN2009, but day is crossed out, there is no way to determine exact date completed.
Resolution Type: No Action Required
Resolution Text:

Discrepancy ID: 1796475113 **Site:** CP_001 **Patient:** R3018
Visit: WEEK 7 **Visit Date:**
CRF: WEEK_7 **Section:** STUDY DIARY **Qualifying Value:** 7
Field: Date **Row:** 1
Value Text: 200906
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited

Discrepancy: Value of 00-JUN-2009 for Date is an incomplete date or time

Internal Comment: exact date is unknown
Resolution Type: No Action Required
Resolution Text:

Document #: R265942313

Discrepancy ID: 69064511

Site: CP_001

Patient: R3018

Visit: WEEK 11

Visit Date:

CRF: WEEK_11

Section: STUDY DIARY

Qualifying Value: 11

Field: 6. I have experienced the following AEs

Row: 1

Value Text: NO

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per verbatim instructions, please enter 'None' on wks 12-17 diary pages

Internal Comment:

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

Resolution Text:

Deleted CRFs Report