

CRF Report for Study E7694105D

Report run by Brian Saari at 21-FEB-2013 10:31:13

Report Parameters

Site: CDB_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1015

Ending patient: R1015

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 #:

R1015

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 05-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

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

Document Number R265512913

Initials:

(b)

Subject #:

R1015

WEEK 2

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 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) 4

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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Initials:

(b)

Subject #:

R1015

WEEK 3

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:

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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Document Number R265513113

Initials:

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Subject #:

R1015

WEEK 4

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

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Initials:

(b)

Subject #:

R1015

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 02-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

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Initials:

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Subject #:

R1015

WEEK 6

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:

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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Initials:

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Subject #:

R1015

WEEK 7

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 0.4 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:

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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Subject #:

R1015

WEEK 8

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 0.4 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) 8

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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Initials:

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Subject #:

R1015

WEEK 9

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 0.4 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) 8

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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Subject #:

R1015

WEEK 10

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 2.1 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:

ANXIETY, TALKED TO MY SON AFTER NINE YEARS VERY OVERWHELMING

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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Initials:

(b)

Subject #:

R1015

WEEK 11

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 0.4 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) 8

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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Initials:

(b)

Subject #:

R1015

WEEK 12

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 0.4 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) 8

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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Initials:

(b)

Subject #:

R1015

WEEK 13

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 0.4 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) 8

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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Initials:

(b)

Subject #:

R1015

WEEK 14

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 0.4 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) 8

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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Initials:

(b)

Subject #:

R1015

WEEK 15

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 0.4 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) 8

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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Initials:

(b)

Subject #:

R1015

WEEK 16

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 0.4 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) 8

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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Initials:

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Subject #:

R1015

FOLLOW-UP WK 17

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 0.4 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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Initials:

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Subject #:

R1015

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-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 0.3 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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Initials:

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Subject #:

R1015

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-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 0.3 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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Initials:

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Subject #:

R1015

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 15-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 0.3 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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Initials:

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Subject #:

R1015

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-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 0.3 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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Initials:

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Subject #:

R1015

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-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 0.3 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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Initials:

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R1015

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 06-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 0.3 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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R1015

FOLLOW-UP WK 24

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-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 0.3 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 R278843913

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 #:

R1015

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-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 0.3 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])?

Verified Approved Locked Frozen

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

Document Number R278844113

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 #:

R1015

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-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 0.3 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])?

Verified Approved Locked Frozen

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

Document Number R278844913

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 #:

R1015

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 03-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 1.4 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])?

Verified Approved Locked Frozen

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

Document Number R278845313

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 #:

R1015

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 10-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 0.7 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 R278846013

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](#)

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 #: R265513613

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Week 7	Week_7 07

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	3 1	07-OCT-2009 16:49:02 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 3 PER WK	19-JAN-2010 11:15:03 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WK 3 PER WEEK	19-JAN-2010 14:22:29 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WEEK 0.43	05-APR-2010 12:27:10 Krysia Magnuson	ODM/SEC 3 PER WEEK to 0.43 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.43 0.4	03-JUN-2010 09:08:57 Sharon Daly	Data Entry Error

Document #: R265513813

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Week 8	Week_8 08

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	3 1	07-OCT-2009 16:50:13 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 3 PER WK	19-JAN-2010 11:16:20 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WK 3 PER WEEK	19-JAN-2010 14:22:47 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WEEK 0.43	05-APR-2010 12:27:53 Krysia Magnuson	ODM/SEC 3 PER WEEK to 0.43 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.43 0.40	03-JUN-2010 09:14:58 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	0.40 0.4	03-JUN-2010 16:09:55 Sharon Daly	Data Entry Error

Document #: R265513913

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Week 9	Week_9 09

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	3 1	07-OCT-2009 16:51:02 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 3 PER WK	19-JAN-2010 11:17:06 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WK 3 PER WEEK	19-JAN-2010 14:23:03 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WEEK 0.43	05-APR-2010 12:28:05 Krysia Magnuson	ODM/SEC 3 PER WEEK to 0.43 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.43 0.4	03-JUN-2010 09:16:39 Sharon Daly	Data Entry Error
5. Large (1g) (2) 1	0	25-AUG-2009 10:25:32 Sharon Daly	Data Entry Error
5. Small (0.5g) (3) 1	8	25-AUG-2009 10:25:32 Sharon Daly	Data Entry Error

Document #: R265514213

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	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
2. I have smoked on average_cigarettes p (1) 1	15 2	07-OCT-2009 16:51:48 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 15 PER WK	19-JAN-2010 11:17:51 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	15 PER WK 15 PER WEEK	19-JAN-2010 14:23:18 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	15 PER WEEK 2.14	05-APR-2010 12:25:19 Krysia Magnuson	ODM/SEC 15 PER WEEK to 2.14 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	2.14 2.1	03-JUN-2010 09:17:28 Sharon Daly	Data Entry Error

Document #: R265514613

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_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
2. I have smoked on average_cigarettes p (1) 1	3 1	25-AUG-2009 10:30:23 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 3 PER WK	19-JAN-2010 11:18:38 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WK 3 PER WEEK	19-JAN-2010 14:23:30 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WEEK 0.43	05-APR-2010 12:28:23 Krysia Magnuson	ODM/SEC 3 PER WEEK to 0.43 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.43 0.4	03-JUN-2010 09:19:26 Sharon Daly	Data Entry Error

Document #: R265518413

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_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
2. I have smoked on average_cigarettes p (1) 1	1 3 PER WK	19-JAN-2010 11:19:36 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WK 3 PER WEEK	19-JAN-2010 14:23:41 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WEEK 0.43	05-APR-2010 12:28:47 Krysia Magnuson	ODM/SEC 3 PER WEEK to 0.43 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.43 0.4	03-JUN-2010 16:10:38 Sharon Daly	Data Entry Error

Document #: R265522413

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_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
2. I have smoked on average_cigarettes p (1) 1	1 3 PER WK	19-JAN-2010 11:20:20 Christina Breedlove	Investigator Correction
2. I have smoked on average_cigarettes p (1) 1	3 PER WK 3 PER WEEK	19-JAN-2010 14:23:50 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WEEK 0.43	05-APR-2010 12:28:58 Kryisia Magnuson	ODM/SEC 3 PER WEEK to 0.43 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.43 0.4	03-JUN-2010 09:20:45 Sharon Daly	Data Entry Error

Document #: R265524513

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_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
2. I have smoked on average_cigarettes p (1) 1	1 3 PER WK	19-JAN-2010 11:21:02 Christina Breedlove	Investigator Correction
2. I have smoked on average_cigarettes p (1) 1	3 PER WK 3 PER WEEK	19-JAN-2010 14:23:58 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WEEK 0.43	05-APR-2010 12:29:07 Kryisia Magnuson	ODM/SEC 3 PER WEEK to 0.43 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.43 0.4	03-JUN-2010 09:21:28 Sharon Daly	Data Entry Error

Document #: R265528413

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_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
2. I have smoked on average_cigarettes p (1) 1	1 3 PER WK	19-JAN-2010 11:21:48 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WK 3 PER WEEK	19-JAN-2010 14:24:11 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WEEK 0.43	05-APR-2010 12:29:18 Kryisia Magnuson	ODM/SEC 3 PER WEEK to 0.43 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.43 0.4	03-JUN-2010 09:22:07 Sharon Daly	Data Entry Error

Document #: R265531313

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_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
2. I have smoked on average_cigarettes p (1) 1	1 3 PER WK	19-JAN-2010 11:22:27 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WK 3 PER WEEK	19-JAN-2010 14:24:21 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WEEK 0.43	05-APR-2010 12:29:30 Kryisia Magnuson	ODM/SEC 3 PER WEEK to 0.43 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.43 0.4	03-JUN-2010 09:22:49 Sharon Daly	Data Entry Error

Document #: R278840613

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Follow-Up Wk 17	Week_17 17

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	3-WEEK 1	31-DEC-2009 13:33:05 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 3 PER WK	19-JAN-2010 11:23:47 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WK 3 PER WEEK	19-JAN-2010 14:24:31 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	3 PER WEEK 0.43	05-APR-2010 12:29:41 Krysia Magnuson	ODM/SEC 3 PER WEEK to 0.43 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.43 0.4	03-JUN-2010 09:23:29 Sharon Daly	Data Entry Error

Document #: R278841113

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Follow-Up Wk 18	Week_18 18

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	18	Follow-Up Wk 18

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-WEEK 1	31-DEC-2009 13:34:36 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 10	31-DEC-2009 13:40:22 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10 1	31-DEC-2009 13:43:44 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 2 PER WK	19-JAN-2010 11:24:25 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WK 2 PER WEEK	19-JAN-2010 14:24:41 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WEEK 0.29	05-APR-2010 12:20:54 Krysia Magnuson	ODM/SEC 2 PER WEEK to 0.29 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.29 0.3	03-JUN-2010 09:24:04 Sharon Daly	Data Entry Error

Document #: R278841513

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Follow-Up Wk 19	Week_19 19

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	19	Follow-Up Wk 19

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-WEEK 1	31-DEC-2009 13:36:55 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 10	31-DEC-2009 13:39:46 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10 1	31-DEC-2009 13:44:14 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 2 PER WK	19-JAN-2010 11:25:07 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WK 2 PER WEEK	19-JAN-2010 14:24:50 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WEEK 0.29	05-APR-2010 12:21:13 Krysia Magnuson	ODM/SEC 2 PER WEEK to 0.29 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.29 0.3	03-JUN-2010 09:25:28 Sharon Daly	Data Entry Error
4. Did you use smokeless tobacco product (3) 1	NO	10-NOV-2009 14:12:46 Rossana Matos	Data Entry Error

Document #: R278842013

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Follow-Up Wk 20	Week_20 20

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	20	Follow-Up Wk 20

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-WEEK 11	31-DEC-2009 13:37:42 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	11 1	31-DEC-2009 13:44:36 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 2 PER WK	19-JAN-2010 11:25:52 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WK 2 PER WEEK	19-JAN-2010 14:25:03 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WEEK 0.29	05-APR-2010 12:21:24 Krysia Magnuson	ODM/SEC 2 PER WEEK to 0.29 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.29 0.3	03-JUN-2010 09:26:06 Sharon Daly	Data Entry Error

Document #: R278843213

Patient Site	Visit Visit Date	CRF CRF Page	
R1015 CDB_001	Follow-Up Wk 21	Week_21 21	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	21	Follow-Up Wk 21

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-WEEK 1	31-DEC-2009 13:45:01 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 2 PER WK	19-JAN-2010 11:29:40 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WK 2 PER WEEK	19-JAN-2010 14:25:14 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WEEK 0.29	05-APR-2010 12:21:34 Krysia Magnuson	ODM/SEC 2 PER WEEK to 0.29 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.29 0.3	03-JUN-2010 09:26:49 Sharon Daly	Data Entry Error

Document #: R278843513

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Follow-Up Wk 22	Week_22 22

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	22	Follow-Up Wk 22

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2WEEK 1	31-DEC-2009 13:46:15 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 2 PER WK	19-JAN-2010 11:34:42 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WK 2 PER WEEK	19-JAN-2010 14:25:26 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WEEK 0.29	05-APR-2010 12:21:45 Krysia Magnuson	ODM/SEC 2 PER WEEK to 0.29 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.29 0.3	03-JUN-2010 09:30:26 Sharon Daly	Data Entry Error

Document #: R278843713

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Follow-Up Wk 23	Week_23 23

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	23	Follow-Up Wk 23

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-WEEK 1	31-DEC-2009 13:46:57 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 2 PER WK	19-JAN-2010 11:35:37 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WK 2 PER WEEK	19-JAN-2010 14:25:35 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WEEK 0.29	05-APR-2010 12:21:56 Krysia Magnuson	ODM/SEC 2 PER WEEK to 0.29 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.29 0.3	03-JUN-2010 09:31:07 Sharon Daly	Data Entry Error

Document #: R278843913

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Follow-Up Wk 24	Week_24 24

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	24	Follow-Up Wk 24

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-WEEK 1	31-DEC-2009 13:47:37 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 2 PER WK	19-JAN-2010 11:36:21 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WK 2 PER WEEK	19-JAN-2010 14:25:42 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WEEK 0.29	05-APR-2010 12:22:07 Krysia Magnuson	ODM/SEC 2 PER WEEK to 0.29 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.29 0.3	03-JUN-2010 09:31:45 Sharon Daly	Data Entry Error

Document #: R278844113

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Follow-Up Wk 25	Week_25 25

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	25	Follow-Up Wk 25

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-WEEK 1	31-DEC-2009 13:48:17 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 2 PER WK	19-JAN-2010 11:37:05 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WK 2 PER WEEK	19-JAN-2010 14:25:50 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WEEK 0.29	05-APR-2010 12:22:17 Krysia Magnuson	ODM/SEC 2 PER WEEK to 0.29 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.29 0.3	03-JUN-2010 09:32:17 Sharon Daly	Data Entry Error

Document #: R278844913

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Follow-Up Wk 26	Week_26 26

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	26	Follow-Up Wk 26

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-WEEK 1	31-DEC-2009 13:49:02 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 2 PER WK	19-JAN-2010 11:37:46 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WK 2 PER WEEK	19-JAN-2010 14:25:59 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 PER WEEK 0.29	05-APR-2010 12:22:37 Krysia Magnuson	ODM/SEC 2 PER WEEK to 0.29 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.29 0.3	03-JUN-2010 09:32:50 Sharon Daly	Data Entry Error

Document #: R278845313

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Follow-Up Wk 27	Week_27 27

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	27	Follow-Up Wk 27

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	10-WEEK 2	31-DEC-2009 13:49:45 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 10 PER WK	19-JAN-2010 11:38:28 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10 PER WK 10 PER WEEK	19-JAN-2010 14:26:07 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10 PER WEEK 1.43	05-APR-2010 12:24:37 Krysia Magnuson	ODM/SEC 10 PER WEEK to 1.43 (Weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	1.43 1.4	03-JUN-2010 09:33:23 Sharon Daly	Data Entry Error

Document #: R278846013

Patient Site	Visit Visit Date	CRF CRF Page
R1015 CDB_001	Follow-Up Wk 28	Week_28 28

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	28	Follow-Up Wk 28

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	5-WEEK 1	31-DEC-2009 13:50:36 Sharon Daly	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1 5 PER WK	19-JAN-2010 11:39:12 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	5 PER WK 5 PER WEEK	19-JAN-2010 14:26:15 Christina Breedlove	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	5 PER WEEK 0.71	05-APR-2010 12:30:04 Krysia Magnuson	ODM/SEC 5 PER WEEK to 0.71 (weekly value converted to daily).
2. I have smoked on average_cigarettes p (1) 1	0.71 0.7	03-JUN-2010 09:33:58 Sharon Daly	Data Entry Error

Discrepancy Detail Report

Document #: R265513613

Discrepancy ID: 1766239313 Site: CDB_001 Patient: R1015
Visit: WEEK 7 Visit Date:
CRF: WEEK_7 Section: STUDY DIARY Qualifying Value: 7
Field: 2. I have smoked on average_cigarettes p Row: 1
Value Text: 0.4
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (0.43 vs. 0.4). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 0.4
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Document #: R265513813

Discrepancy ID: 1766239413

Site: CDB_001

Patient: R1015

Visit: WEEK 8

Visit Date:

CRF: WEEK_8

Section: STUDY DIARY

Qualifying Value: 8

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 0.4

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please clarify (0.40 vs. 0.4).

Internal Comment: 0.4

Resolution Type: Confirmed

Resolution Text:

Document #: R265513913

Discrepancy ID: 1766239513

Site: CDB_001

Patient: R1015

Visit: WEEK 9

Visit Date:

CRF: WEEK_9

Section: STUDY DIARY

Qualifying Value: 9

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 0.4

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify no. of cigarettes smoked per day (0.43 vs. 0.4). Per NTF, no. of cigarettes should be entered to one decimal place.

Internal Comment: 0.4

Resolution Type: Confirmed

Resolution Text: Confirmed data was corrected.

Document #: R265514213

Discrepancy ID: 1766239613

Site: CDB_001

Patient: R1015

Visit: WEEK 10

Visit Date:

CRF: WEEK_10

Section: STUDY DIARY

Qualifying Value: 10

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 2.1

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify no. of cigarettes smoked per day (2.14 vs. 2.1). Per NTF, no. of cigarettes should be entered to one decimal place.

Internal Comment: 2.1

Resolution Type: Confirmed

Resolution Text: Confirmed data was corrected.

Document #: R265514613

Discrepancy ID: 42881211

Site: CDB_001

Patient: R1015

Visit: WEEK 11

Visit Date:

CRF: WEEK_11

Section: STUDY DIARY

Qualifying Value: 11

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 0.4

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify no. of cigarettes smoked per day (0.43 vs. 0.4). Per NTF, no. of cigarettes should be entered to one decimal place.

Internal Comment: 0.4

Resolution Type: Confirmed

Resolution Text: Confirmed data was corrected.

Document #: R265518413

Discrepancy ID: 42881411

Site: CDB_001

Patient: R1015

Visit: WEEK 12

Visit Date:

CRF: WEEK_12

Section: STUDY DIARY

Qualifying Value: 12

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 0.4

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify (0.43 vs. 0.4).

Internal Comment: 0.4

Resolution Type: Confirmed

Resolution Text:

Document #: R265522413

Discrepancy ID: 42881511

Site: CDB_001

Patient: R1015

Visit: WEEK 13

Visit Date:

CRF: WEEK_13

Section: STUDY DIARY

Qualifying Value: 13

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 0.4

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify no. of cigarettes smoked per day (0.43 vs. 0.4). Per NTF, no. of cigarettes should be entered to one decimal place.

Internal Comment: 0.4

Resolution Type: Confirmed

Resolution Text: Confirmed data was corrected.

Document #: R265524513

Discrepancy ID: 42881611

Site: CDB_001

Patient: R1015

Visit: WEEK 14

Visit Date:

CRF: WEEK_14

Section: STUDY DIARY

Qualifying Value: 14

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 0.4

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify no. of cigarettes smoked per day (0.43 vs. 0.4). Per NTF, no. of cigarettes should be entered to one decimal place.

Internal Comment: 0.4

Resolution Type: Confirmed

Resolution Text: Confirmed data was corrected.

Document #: R265528413

Discrepancy ID: 42881711

Site: CDB_001

Patient: R1015

Visit: WEEK 15

Visit Date:

CRF: WEEK_15

Section: STUDY DIARY

Qualifying Value: 15

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 0.4

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify no. of cigarettes smoked per day (0.43 vs. 0.4). Per NTF, no. of cigarettes should be entered to one decimal place.

Internal Comment: 0.4

Resolution Type: Confirmed

Resolution Text: Confirmed data was corrected.

Document #: R265531313

Discrepancy ID: 42881811

Site: CDB_001

Patient: R1015

Visit: WEEK 16

Visit Date:

CRF: WEEK_16

Section: STUDY DIARY

Qualifying Value: 16

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 0.4

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify no. of cigarettes smoked per day (0.43 vs. 0.4). Per NTF, no. of cigarettes should be entered to one decimal place.

Internal Comment: 0.4

Resolution Type: Confirmed

Resolution Text: Confirmed data was corrected.

Document #: R278840613

Discrepancy ID: 20929211 **Site:** CDB_001 **Patient:** R1015
Visit: FOLLOW-UP WK 17 **Visit Date:**
CRF: WEEK_17 **Section:** STUDY DIARY **Qualifying Value:** 17
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 0.4
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (0.43 vs. 0.4). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 0.4
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Document #: R278841113

Discrepancy ID: 20929311 **Site:** CDB_001 **Patient:** R1015
Visit: FOLLOW-UP WK 18 **Visit Date:**
CRF: WEEK_18 **Section:** STUDY DIARY **Qualifying Value:** 18
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 0.3
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (0.29 vs. 0.3). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 0.3
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Document #: R278841513

Discrepancy ID: 20929511 **Site:** CDB_001 **Patient:** R1015
Visit: FOLLOW-UP WK 19 **Visit Date:**
CRF: WEEK_19 **Section:** STUDY DIARY **Qualifying Value:** 19
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 0.3
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (0.29 vs. 0.3). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 0.3
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Document #: R278842013

Discrepancy ID: 20929611 **Site:** CDB_001 **Patient:** R1015
Visit: FOLLOW-UP WK 20 **Visit Date:**
CRF: WEEK_20 **Section:** STUDY DIARY **Qualifying Value:** 20
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 0.3
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (0.29 vs. 0.3). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 0.3
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Document #: R278843213

Discrepancy ID: 20929711 **Site:** CDB_001 **Patient:** R1015
Visit: FOLLOW-UP WK 21 **Visit Date:**
CRF: WEEK_21 **Section:** STUDY DIARY **Qualifying Value:** 21
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 0.3
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (0.29 vs. 0.3). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 0.3
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Document #: R278843513

Discrepancy ID: 20929811 **Site:** CDB_001 **Patient:** R1015
Visit: FOLLOW-UP WK 22 **Visit Date:**
CRF: WEEK_22 **Section:** STUDY DIARY **Qualifying Value:** 22
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 0.3
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (0.29 vs. 0.3). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 0.3
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Document #: R278843713

Discrepancy ID: 20929911 **Site:** CDB_001 **Patient:** R1015
Visit: FOLLOW-UP WK 23 **Visit Date:**
CRF: WEEK_23 **Section:** STUDY DIARY **Qualifying Value:** 23
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 0.3
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (0.29 vs. 0.3). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 0.3
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Document #: R278843913

Discrepancy ID: 20930011

Site: CDB_001

Patient: R1015

Visit: FOLLOW-UP WK 24 **Visit Date:**

CRF: WEEK_24

Section: STUDY DIARY

Qualifying Value: 24

Field: 2. I have smoked on average_cigarettes p

Row: 1

Value Text: 0.3

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify no. of cigarettes smoked per day (0.29 vs. 0.3). Per NTF, no. of cigarettes should be entered to one decimal place.

Internal Comment: 0.3

Resolution Type: Confirmed

Resolution Text: Confirmed data was corrected.

Document #: R278844113

Discrepancy ID: 20930111 **Site:** CDB_001 **Patient:** R1015
Visit: FOLLOW-UP WK 25 **Visit Date:**
CRF: WEEK_25 **Section:** STUDY DIARY **Qualifying Value:** 25
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 0.3
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (0.29 vs. 0.3). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 0.3
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Document #: R278844913

Discrepancy ID: 20930211 **Site:** CDB_001 **Patient:** R1015
Visit: FOLLOW-UP WK 26 **Visit Date:**
CRF: WEEK_26 **Section:** STUDY DIARY **Qualifying Value:** 26
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 0.3
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (0.29 vs. 0.3). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 0.3
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Document #: R278845313

Discrepancy ID: 20930311 **Site:** CDB_001 **Patient:** R1015
Visit: FOLLOW-UP WK 27 **Visit Date:**
CRF: WEEK_27 **Section:** STUDY DIARY **Qualifying Value:** 27
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 1.4
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (1.43 vs. 1.4). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 1.4
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Document #: R278846013

Discrepancy ID: 20930411 **Site:** CDB_001 **Patient:** R1015
Visit: FOLLOW-UP WK 28 **Visit Date:**
CRF: WEEK_28 **Section:** STUDY DIARY **Qualifying Value:** 28
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 0.7
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify no. of cigarettes smoked per day (0.71 vs. 0.7). Per NTF, no. of cigarettes should be entered to one decimal place.
Internal Comment: 0.7
Resolution Type: Confirmed
Resolution Text: Confirmed data was corrected.

Deleted CRFs Report