

CRF Report for Study E7694105D

Report run by Brian Saari at 21-FEB-2013 15:37:14

Report Parameters

Site: CD_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R5006

Ending patient: R5006

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 #:

R5006

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-JUL-2009

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

Correct Incorrect

2. I have smoked on average 18 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) UNK

Small (0.5g) UNK

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 R267050413

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R5006

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-JUL-2009

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

Correct Incorrect

2. I have smoked on average 18 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) 7

Small (0.5g) 2

6. I have experienced the following Adverse Events:

NONE

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

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

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

Document Number R267050813

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Initials:

(b)

Subject #:

R5006

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-JUL-2009

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

Correct Incorrect

2. I have smoked on average 18 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 5

Small (0.5g) 0

6. I have experienced the following Adverse Events:

N/A

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R267051113

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Initials:

(b)

Subject #:

R5006

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 03-AUG-2009

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

Correct Incorrect

2. I have smoked on average 18 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) 6

Small (0.5g) 0

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

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

Document Number R267051313

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Initials:

(b)

Subject #:

R5006

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 10-AUG-2009

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

Correct Incorrect

2. I have smoked on average 18 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 5

Small (0.5g) 0

6. I have experienced the following Adverse Events:

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_5 (v1, 25-MAR-2009)

Document Number R267051713

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Initials:

(b)

Subject #:

R5006

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 17-AUG-2009

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

Correct Incorrect

2. I have smoked on average 18 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) 6

Small (0.5g) 0

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_6 (v1, 25-MAR-2009)

Document Number R275018013

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Initials:

(b)

Subject #:

R5006

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 24-AUG-2009

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

Correct Incorrect

2. I have smoked on average 10 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) 9

Small (0.5g) 0

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_7 (v1, 25-MAR-2009)

Document Number R275018113

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Initials:

(b)

Subject #:

R5006

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 31-AUG-2009

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

Correct Incorrect

2. I have smoked on average 12 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) 7

Small (0.5g) 0

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_8 (v1, 25-MAR-2009)

Document Number R275018213

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Initials:

(b)

Subject #:

R5006

WEEK 9

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 07-SEP-2009

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

Correct Incorrect

2. I have smoked on average 6 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) 8

Small (0.5g) 0

6. I have experienced the following Adverse Events:

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

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

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

Document Number R275018313

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Initials:

(b)

Subject #:

R5006

WEEK 10

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 14-SEP-2009

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

Correct Incorrect

2. I have smoked on average 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])?

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

Sachet Size:

Large (1g) 10

Small (0.5g) 0

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_10 (v1, 25-MAR-2009)

Document Number R275018613

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Initials:

(b)

Subject #:

R5006

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 21-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 10 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) 10

Small (0.5g) 0

6. I have experienced the following Adverse Events:

N/A

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 R276775913

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Initials:

(b)

Subject #:

R5006

WEEK 12

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 28-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 15 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) 10

Small (0.5g) 0

6. I have experienced the following Adverse Events:

N/A

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R276776213

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R5006

WEEK 13

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 05-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 15 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) 7

Small (0.5g) 0

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_13 (v1, 25-MAR-2009)

Document Number R276776413

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Initials:

(b)

Subject #:

R5006

WEEK 14

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 12-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 5 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 15

Small (0.5g) 0

6. I have experienced the following Adverse Events:

N/A

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R276776713

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Initials:

(b)

Subject #:

R5006

WEEK 15

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 19-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 5 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 15

Small (0.5g) 0

6. I have experienced the following Adverse Events:

N/A

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R276777113

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Initials:

(b)

Subject #:

R5006

WEEK 16

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 26-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 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) 8

Small (0.5g) 0

6. I have experienced the following Adverse Events:

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

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

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

Document Number R276777413

Initials:

(b) _____

Subject #:

R5006

FOLLOW-UP WK 17

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-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 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])?

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

Document Number R288744413

Initials:

(b) _____

Subject #:

R5006

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 09-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 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])?

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

Document Number R288745113

Initials:

(b) _____

Subject #:

R5006

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 16-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 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])?

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Document Number R288745213

Initials:

(b) _____

Subject #:

R5006

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 23-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 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])?

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Document Number R288745413

Initials:

(b) _____

Subject #:

R5006

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-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 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])?

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

Document Number R288745513

Initials:

(b)

Subject #:

R5006

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 07-DEC-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])?

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

Document Number R288745613

Initials:

(b)

Subject #:

R5006

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 14-DEC-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])?

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

Document Number R288745713

Initials:

(b)

Subject #:

R5006

FOLLOW-UP WK 24

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 21-DEC-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])?

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Document Number R288745813

Initials:

(b) _____

Subject #:

R5006

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 28-DEC-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])?

Verified Approved Locked Frozen

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

Document Number R288746113

Initials:

(b)

Subject #:

R5006

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 04-JAN-2010

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])?

Verified Approved Locked Frozen

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

Document Number R288746213

Initials:

(b) _____

Subject #:

R5006

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 11-JAN-2010

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])?

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

Document Number R288746413

Initials:

(b)

Subject #:

R5006

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 18-JAN-2010

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])?

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

Document Number R288746513

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 #: R267050413

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_001	Week 1	Week_1 01

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
5. Large (1g) (2) 1	UNKNOWN		20-JAN-2010 16:43:16 Sharon Ladenes	Data Entry Error
5. Large (1g) (2) 1	UNKNOWN UNK		31-MAR-2010 16:51:51 Krysia Magnuson	Investigator Correction UNKNOWN to UNK
5. Small (0.5g) (3) 1	UNKNOWN		20-JAN-2010 16:43:16 Sharon Ladenes	Data Entry Error
5. Small (0.5g) (3) 1	UNKNOWN UNK		31-MAR-2010 16:51:51 Krysia Magnuson	Investigator Correction UNKNOWN to UNK
6. I have experienced the following AEs (3) 1	NONE		19-JAN-2010 18:50:40 Sharon Ladenes	Data Entry Error

Document #: R267050813

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_001	Week 2	Week_2 02

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. (3) 1	I have experienced the following AEs NONE	19-JAN-2010 18:51:07 Sharon Ladenes	Data Entry Error

Document #: R267051113

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_001	Week 3	Week_3 03

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. (3) 1	I have experienced the following AEs N/A	19-JAN-2010 18:51:17 Sharon Ladenes	Data Entry Error

Document #: R267051313

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_001	Week 4	Week_4 04

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NO	19-JAN-2010 18:51:30 Sharon Ladenes	Data Entry Error

Document #: R267051713

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_001	Week 5	Week_5 05

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	5	Week 5

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE	19-JAN-2010 18:51:39 Sharon Ladenes	Data Entry Error
Date 1	10-AUG-2009	03-SEP-2009 13:11:18 Sharon Ladenes	Data Entry Error

Document #: R275018013

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_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
4. Did you use smokeless tobacco product (3) 1	NO	20-OCT-2009 14:45:09 Sharon Ladenes	Data Entry Error
6. I have experienced the following AEs (3) 1	NONE	19-JAN-2010 18:51:51 Sharon Ladenes	Data Entry Error

Document #: R275018113

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_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. (3) 1	I have experienced the following AEs NONE	19-JAN-2010 18:52:02 Sharon Ladenes	Data Entry Error

Document #: R275018213

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_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
6. (3) 1	I have experienced the following AEs NONE	19-JAN-2010 18:52:20 Sharon Ladenes	Data Entry Error

Document #: R275018313

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_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
3. I have smoked tobacco products other (2) 1	YES NO	10-NOV-2009 17:50:02 Sharon Ladenes	Data Entry Error
6. I have experienced the following AEs (3) 1	NONE	19-JAN-2010 18:52:29 Sharon Ladenes	Data Entry Error
6. I have experienced the following AEs (3) 1	NONE	19-JAN-2010 18:52:47 Sharon Ladenes	Data Entry Error

Document #: R275018613

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_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
6. (3) 1	I have experienced the following AEs NONE	19-JAN-2010 18:53:03 Sharon Ladenes	Data Entry Error

Document #: R276775913

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_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	N/A	19-JAN-2010 18:53:14 Sharon Ladenes	Data Entry Error

Document #: R276776213

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_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. I have experienced the following AEs (3) 1	N/A	19-JAN-2010 18:53:26 Sharon Ladenes	Data Entry Error

Document #: R276776413

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_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-JAN-2010 18:53:38 Sharon Ladenes	Data Entry Error

Document #: R276776713

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_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. (3) 1	I have experienced the following AEs N/A	19-JAN-2010 18:53:46 Sharon Ladenes	Data Entry Error

Document #: R276777113

Patient Site	Visit Visit Date	CRF CRF Page
R5006 CD_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. (3) 1	I have experienced the following AEs N/A	19-JAN-2010 18:53:59 Sharon Ladenes	Data Entry Error

Discrepancy Detail Report

Document #: R267050413

Discrepancy ID: 45540811

Site: CD_001

Patient: R5006

Visit: WEEK 1

Visit Date:

CRF: WEEK_1

Section: STUDY DIARY

Qualifying Value: 1

Field: 5. Large (1g)

Row: 1

Value Text: UNK

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Can you enter UNK?

Internal Comment:

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

Resolution Text: it appears so

Document #: R267051313

Discrepancy ID: 1738765013

Site: CD_001

Patient: R5006

Visit: WEEK 4

Visit Date:

CRF: WEEK_4

Section: STUDY DIARY

Qualifying Value: 4

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

Row: 1

Value Text:

Type: UNIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Value for 1. I have not smoked any cigarettes at a has not been supplied

Internal Comment:

Resolution Type: Due Diligence

Resolution Text: not recorded by subject

Deleted CRFs Report