

CRF Report for Study E7694105D

Report run by Brian Saari at 21-FEB-2013 16:01:00

Report Parameters

Site: CD_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R5022

Ending patient: R5022

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 #:

R5022

WEEK 1

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 UNK cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 0

Small (0.5g) 23

6. I have experienced the following Adverse Events:

SINUS ISSUES

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 R275083313

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Initials:

(b)

Subject #:

R5022

WEEK 2

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 13 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) 14

6. I have experienced the following Adverse Events:

SINUS HEADACHES

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 R275083513

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Initials:

(b)

Subject #:

R5022

WEEK 3

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 13 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) 14

6. I have experienced the following Adverse Events:

HEADACHES ; SINUS PROBLEMS

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 R275083613

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Initials:

(b)

Subject #:

R5022

WEEK 4

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 11.5 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 0

Small (0.5g) 11

6. I have experienced the following Adverse Events:

SINUS ISSUES AND HEADACHES

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 #:

R5022

WEEK 5

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 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) 0

Small (0.5g) 14

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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Initials:

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Subject #:

R5022

WEEK 6

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 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) 11

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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Initials:

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Subject #:

R5022

WEEK 7

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 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) 20

6. I have experienced the following Adverse Events:

SINUS DRAINAGE

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 #:

R5022

WEEK 8

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 2 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) 26

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 #:

R5022

WEEK 9

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 2 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) 11

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 #:

R5022

WEEK 10

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 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) 9

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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Initials:

(b)

Subject #:

R5022

WEEK 11

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 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) 12

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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Initials:

(b)

Subject #:

R5022

WEEK 12

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 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) 9

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 R283211513

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Initials:

(b)

Subject #:

R5022

WEEK 13

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 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) 8

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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Initials:

(b)

Subject #:

R5022

WEEK 14

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 02-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 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:

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 R283211813

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Initials:

(b)

Subject #:

R5022

WEEK 15

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 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:

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 R283211913

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Initials:

(b)

Subject #:

R5022

WEEK 16

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 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) 5

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 R283212013

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Initials:

(b)

Subject #:

R5022

FOLLOW-UP WK 17

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 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])?

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Document Number R293095813

Initials:

(b)

Subject #:

R5022

FOLLOW-UP WK 18

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 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])?

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Initials:

(b)

Subject #:

R5022

FOLLOW-UP WK 19

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 2 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 R293096213

Initials:

(b)

Subject #:

R5022

FOLLOW-UP WK 20

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 2 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 R293096313

Initials:

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Subject #:

R5022

FOLLOW-UP WK 21

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 2 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 #:

R5022

FOLLOW-UP WK 22

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 2 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 R293098713

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Subject #:

R5022

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-APR-2009

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

Correct Incorrect

2. I have smoked on average 2 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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Subject #:

R5022

FOLLOW-UP WK 24

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 2 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 R293099113

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R5022

FOLLOW-UP WK 25

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 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_25 (v1, 25-MAR-2009)

Document Number R293099513

Initials:

(b)

Subject #:

R5022

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 25-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 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])?

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

Document Number R293099713

Initials:

(b)

Subject #:

R5022

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-FEB-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 8 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 R293099813

Initials:

(b)

Subject #:

R5022

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-FEB-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 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])?

Verified Approved Locked Frozen

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

Document Number R293100013

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 #: R275083313

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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
2. I have smoked on average_cigarettes p (1) 1	UNK		21-DEC-2009 17:03:55 Sharon Ladenes	Data Entry Error
5. Large (1g) (2) 1	0		20-OCT-2009 17:12:16 Sharon Ladenes	Data Entry Error
5. Small (0.5g) (3) 1	160 23		21-DEC-2009 17:04:31 Sharon Ladenes	Data Entry Error

Document #: R275083513

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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
5. Small (0.5g) (3) 1	100 14	21-DEC-2009 17:05:23 Sharon Ladenes	Data Entry Error

Document #: R275083613

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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
5. Small (0.5g) (3) 1	100 14	21-DEC-2009 17:05:43 Sharon Ladenes	Data Entry Error

Document #: R275083713

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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
5. Small (0.5g) (3) 1	80 11	21-DEC-2009 17:06:09 Sharon Ladenes	Data Entry Error

Document #: R275083813

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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
5. Small (0.5g) (3) 1	100 14	21-DEC-2009 17:06:35 Sharon Ladenes	Data Entry Error

Document #: R275083913

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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
5. Small (0.5g) (3) 1	80 11	21-DEC-2009 17:06:52 Sharon Ladenes	Data Entry Error

Document #: R275084013

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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
5. Small (0.5g) (3) 1	140 20	21-DEC-2009 17:07:10 Sharon Ladenes	Data Entry Error

Document #: R275084113

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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
5. Small (0.5g) (3) 1	180 11	21-DEC-2009 17:08:11 Sharon Ladenes	Data Entry Error
5. Small (0.5g) (3) 1	11 26	20-JAN-2010 12:25:59 Sharon Ladenes	Data Entry Error
6. I have experienced the following AEs (3) 1	NONE	20-JAN-2010 12:25:59 Sharon Ladenes	Data Entry Error
7. I think the AE is related to the snus (4) 1	AE	11-MAR-2010 12:14:39 Stephanie Felton	Data Entry Error

Document #: R275084213

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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 resequence	On By	Reason Comment
5. Small (0.5g) (3) 1	80 11		21-DEC-2009 17:08:55 Sharon Ladenes	Data Entry Error
6. I have experienced the following AEs (3) 1	NONE		20-JAN-2010 12:26:45 Sharon Ladenes	Data Entry Error
7. I think the AE is related to the snus (4) 1	AE		11-MAR-2010 12:20:02 Stephanie Felton	Data Entry Error

Document #: R275084313

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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
5. Large (1g) (2) 1	60 9	21-DEC-2009 17:09:18 Sharon Ladenes	Data Entry Error

Document #: R283211213

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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. (3) 1	I have experienced the following AEs N/A	20-JAN-2010 12:27:20 Sharon Ladenes	Data Entry Error

Document #: R283211513

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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. (3) 1	I have experienced the following AEs N/A	20-JAN-2010 12:27:33 Sharon Ladenes	Data Entry Error

Document #: R283211613

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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 N/A	20-JAN-2010 12:27:54 Sharon Ladenes	Data Entry Error

Document #: R283211813

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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	20-JAN-2010 12:28:12 Sharon Ladenes	Data Entry Error

Document #: R283211913

Patient Site	Visit Visit Date	CRF CRF Page
R5022 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. I have experienced the following AEs (3) 1	N/A	20-JAN-2010 12:28:26 Sharon Ladenes	Data Entry Error

Document #: R283212013

Patient Site	Visit Visit Date	CRF CRF Page
R5022 CD_001	Week 16	Week_16 16

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. (3) 1	I have experienced the following AEs N/A	20-JAN-2010 12:28:42 Sharon Ladenes	Data Entry Error

Document #: R293099013

Patient Site	Visit Visit Date	CRF CRF Page	
R5022 CD_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
Date 1	01-APR-2010 01-APR-2009	11-MAR-2010 12:21:49 Stephanie Felton	Data Entry Error

Document #: R293099113

Patient Site	Visit Visit Date	CRF CRF Page	
R5022 CD_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
Date 1	11-JAN-2010	10-FEB-2010 13:35:01 Sharon Ladenes	Data Entry Error

Discrepancy Detail Report

Document #: R275083313

Discrepancy ID: 1775759313 Site: CD_001 Patient: R5022
Visit: WEEK 1 Visit Date:
CRF: WEEK_1 Section: STUDY DIARY Qualifying Value: 1
Field: 7. I think the AE is related to the snus Row: 1
Value Text:
Type: UNIVARIATE Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied
Internal Comment:
Resolution Type: Confirmed
Resolution Text: subject did not respond

Document #: R275083513

Discrepancy ID: 1775759413 **Site:** CD_001 **Patient:** R5022
Visit: WEEK 2 **Visit Date:**
CRF: WEEK_2 **Section:** STUDY DIARY **Qualifying Value:** 2
Field: 7. I think the AE is related to the snus **Row:** 1
Value Text:
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied
Internal Comment:
Resolution Type: Confirmed
Resolution Text: subject did not respond

Document #: R275083613

Discrepancy ID: 1775759513 **Site:** CD_001 **Patient:** R5022
Visit: WEEK 3 **Visit Date:**
CRF: WEEK_3 **Section:** STUDY DIARY **Qualifying Value:** 3
Field: 7. I think the AE is related to the snus **Row:** 1
Value Text:
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied
Internal Comment:
Resolution Type: Confirmed
Resolution Text: subject did not respond

Document #: R275083713

Discrepancy ID: 1775759613

Site: CD_001

Patient: R5022

Visit: WEEK 4

Visit Date:

CRF: WEEK_4

Section: STUDY DIARY

Qualifying Value: 4

Field: 7. I think the AE is related to the snus

Row: 1

Value Text:

Type: UNIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied

Internal Comment:

Resolution Type: Confirmed

Resolution Text: subject did not respond

Document #: R275084013

Discrepancy ID: 1775759713 **Site:** CD_001 **Patient:** R5022
Visit: WEEK 7 **Visit Date:**
CRF: WEEK_7 **Section:** STUDY DIARY **Qualifying Value:** 7
Field: 7. I think the AE is related to the snus **Row:** 1
Value Text:
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied
Internal Comment:
Resolution Type: Confirmed
Resolution Text: subject did not respond

Document #: R275084213

Discrepancy ID: 81474211 **Site:** CD_001 **Patient:** R5022
Visit: WEEK 9 **Visit Date:**
CRF: WEEK_9 **Section:** STUDY DIARY **Qualifying Value:** 9
Field: 7. I think the AE is related to the snus **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: This is not checked on diary.
Internal Comment: Updated CRF, verified source
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 82815711 **Site:** CD_001 **Patient:** R5022
Visit: WEEK 9 **Visit Date:**
CRF: WEEK_9 **Section:** STUDY DIARY **Qualifying Value:** 9
Field: 7. I think the AE is related to the snus **Row:** 1
Value Text:
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied
Internal Comment: SUBJECT DID NOT DOCUMENT ANY AE'S
Resolution Type: Confirmed
Resolution Text:

Document #: R275084313

Discrepancy ID: 1775759813

Site: CD_001

Patient: R5022

Visit: WEEK 10

Visit Date:

CRF: WEEK_10

Section: STUDY DIARY

Qualifying Value: 10

Field: 7. I think the AE is related to the snus

Row: 1

Value Text:

Type: UNIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Value for 7. I think the AE is related to the snus has not been supplied

Internal Comment:

Resolution Type: Confirmed

Resolution Text: subject did not respond.

Document #: R293099013

Discrepancy ID: 81476211

Site: CD_001

Patient: R5022

Visit: FOLLOW-UP WK 23 **Visit Date:**

CRF: WEEK_23

Section: STUDY DIARY

Qualifying Value: 23

Field: Date

Row: 1

Value Text: 20090401

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify date.

Internal Comment: Updated CRF, verified source

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

Resolution Text:

Deleted CRFs Report