

CRF Report for Study E7694105D

Report run by Brian Saari at 22-FEB-2013 15:33:55

Report Parameters

Site: L0689282_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2021

Ending patient: R2021

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 #:

R2021

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 12-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 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) UNK

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R264402913

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2021

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 19-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 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) UNK

6. I have experienced the following Adverse Events:

INCREASE IN SALIVIA, SLIGHT STINGING SENSATION

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 R264403013

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Initials:

(b)

Subject #:

R2021

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 26-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:

INCREASE IN SALIVIA, SLIGHT STINGING FEELING WHEN I USE SNUS (LASTS FOR THE E₁)

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

OverFlow Section For Document Number R264403113

- 1 INCREASE IN SALIVIA, SLIGHT STINGING FEELING WHEN I USE SNUS (LASTS FOR THE ENTIRE DURATION)

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R2021

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 03-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 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) UNK

6. I have experienced the following Adverse Events:

SLIGHT STINGING SENSATION WHEN I USE THE SNUS

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 #:

R2021

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 10-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 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) UNK

6. I have experienced the following Adverse Events:

NO, JUST SLIGHT STINGING SENSATION

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 #:

R2021

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 17-JUL-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Document Number

Initials:

(b)

Subject #:

R2021

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 24-JUL-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

SENSITIVITY ON FRONT TOOTH, NOTICED TO THIS MORNING WHEN BRUSHING MY TEETH.

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 #:

R2021

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 31-JUL-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

SENSITIVITY FRONT TOOTH

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 #:

R2021

WEEK 9

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 07-AUG-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

SENSITIVITY ON FRONT TOOTH

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 #:

R2021

WEEK 10

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 14-AUG-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

NONE

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Initials:

(b)

Subject #:

R2021

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 21-AUG-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

NONE, NO LONGER HAD PAIN ON GUM WHERE SNUS WAS PLACED.

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 R274804313

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Initials:

(b)

Subject #:

R2021

WEEK 12

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 28-AUG-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

NONE

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R274804413

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2021

WEEK 13

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 04-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 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 R274804613

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Initials:

(b)

Subject #:

R2021

WEEK 14

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 11-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 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_14 (v1, 25-MAR-2009)

Document Number R274804713

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2021

WEEK 15

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 18-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 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 R274804813

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2021

WEEK 16

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 25-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 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_16 (v1, 25-MAR-2009)

Document Number R274805013

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2021

FOLLOW-UP WK 17

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-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 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 R286299413

Initials:

(b)

Subject #:

R2021

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-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 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 R286299613

Initials:

(b)

Subject #:

R2021

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 15-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 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 #:

R2021

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-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 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 R286299813

Initials:

(b)

Subject #:

R2021

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-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 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 R286300013

Initials:

(b)

Subject #:

R2021

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 06-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 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 R286300113

Initials:

(b)

Subject #:

R2021

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-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 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 R286300313

Initials:

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Subject #:

R2021

FOLLOW-UP WK 24

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-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 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 R286300613

Initials:

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R2021

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 26-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 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])?

Verified Approved Locked Frozen

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

Document Number R286300713

Initials:

(b)

Subject #:

R2021

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 04-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 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])?

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

Document Number R286300813

Initials:

(b)

Subject #:

R2021

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 11-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 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_27 (v1, 25-MAR-2009)

Document Number R286301013

Initials:

(b)

Subject #:

R2021

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Document Number R286301213

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 #: R264402913

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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. Small (0.5g) (3) 1	70 10		17-AUG-2009 11:18:55 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	10 70		14-JAN-2010 11:57:37 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	70 UNK		27-JAN-2010 11:46:08 Cindy Riojas Prakop	Data Entry Error

Document #: R264403013

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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 resequence	On By	Reason Comment
5. Small (0.5g) (3) 1	70 10		17-AUG-2009 11:19:19 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	10 70		14-JAN-2010 11:56:01 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	70 UNK		27-JAN-2010 11:46:51 Cindy Riojas Prakop	Data Entry Error

Document #: R264403113

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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	70 10	17-AUG-2009 11:19:30 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	10 7	14-JAN-2010 11:55:37 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	7 UNK	27-JAN-2010 11:47:05 Cindy Riojas Prakop	Data Entry Error
6. I have experienced the following AEs (3) 1	INCREASE IN SALIVIA, SLIGHT STINGING FEELING INCREASE IN SALIVIA, SLIGHT STINGING FEELING WHEN I USE SNUS (LASTS FOR THE ENTIRE DURATION)	08-JAN-2010 11:05:01 Amanda Lynn	Data Entry Error

Document #: R264403213

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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
2. I have smoked on average_cigarettes p (1) 1	70	17-AUG-2009 11:21:52 Amanda Lynn	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10	15-DEC-2009 10:45:10 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	80 11	17-AUG-2009 11:19:46 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	11 0	14-JAN-2010 11:54:30 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	0 UNK	27-JAN-2010 11:47:19 Cindy Riojas Prakop	Data Entry Error
6. I have experienced the following AEs (3) 1	SLIGHT STINGING SENSATION SLIGHT STINGING SENSATION WHEN I USE THE SNUS	08-JAN-2010 11:05:43 Amanda Lynn	Data Entry Error

Document #: R264403513

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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
2. I have smoked on average_cigarettes p (1) 1	10	15-DEC-2009 10:45:41 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	11 0	14-JAN-2010 11:53:40 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	0 UNK	27-JAN-2010 11:47:37 Cindy Riojas Prakop	Data Entry Error
6. I have experienced the following AEs (3) 1	SLIGHT STINGING SENSATION NO, JUST SLIGHT STINGING SENSATION	08-JAN-2010 11:06:05 Amanda Lynn	Data Entry Error

Document #: R264403913

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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 resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	0		17-AUG-2009 11:25:29 Amanda Lynn	Data Entry Error
5. Large (1g) (2) 1	10 0		14-JAN-2010 12:00:26 Amanda Lynn	Data Entry Error
5. Large (1g) (2) 1	0 10		14-JAN-2010 12:00:41 Amanda Lynn	Data Entry Error
5. Large (1g) (2) 1	10 UNK		27-JAN-2010 11:48:28 Cindy Riojas Prakop	Data Entry Error
5. Small (0.5g) (3) 1	0		17-AUG-2009 11:25:29 Amanda Lynn	Data Entry Error
6. I have experienced the following AEs (3) 1	SENSITIVITY ON FRONT TOOTH SENSITIVITY ON FRONT TOOTH,NOTICED TO THIS MORNING WHEN BRUSHING MY TEETH.		08-JAN-2010 11:07:14 Amanda Lynn	Data Entry Error

Document #: R264404013

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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 resequence	On By	Reason Comment
4. Did you use smokeless tobacco product (3) 1	NO		17-AUG-2009 11:26:26 Amanda Lynn	Data Entry Error
5. Large (1g) (2) 1	10 UNK		27-JAN-2010 11:48:44 Cindy Riojas Prakop	Data Entry Error
6. I have experienced the following AEs (3) 1	SENSITIVITY TO TOOTH SENSITIVITY FRONT TOOTH		16-FEB-2010 14:09:50 Amanda Lynn	Data Entry Error

Document #: R274803913

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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
1. I have not smoked any cigarettes at a (1) 1	CORRECT	19-OCT-2009 15:35:42 Amanda Lynn	Data Entry Error
5. Large (1g) (2) 1	0 UNK	27-JAN-2010 11:49:02 Cindy Riojas Prakop	Data Entry Error

Document #: R274804213

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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. I have experienced the following AEs (3) 1	NONE	08-JAN-2010 11:08:08 Amanda Lynn	Data Entry Error

Document #: R274804313

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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 NONE, NO LONGER HAD PAIN ON GUM WHERE SNUS WAS PLACED.	08-JAN-2010 11:08:45 Amanda Lynn	Data Entry Error

Document #: R274804413

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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	NONE	08-JAN-2010 11:09:14 Amanda Lynn	Data Entry Error

Document #: R274804613

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	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. I have experienced the following AEs (3) 1	NONE	08-JAN-2010 11:10:39 Amanda Lynn	Data Entry Error

Document #: R274804713

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	Week 14	Week_14 14

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE	08-JAN-2010 11:10:55 Amanda Lynn	Data Entry Error

Document #: R274804813

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	Week 15	Week_15 15

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE	08-JAN-2010 11:11:09 Amanda Lynn	Data Entry Error

Document #: R274805013

Patient Site	Visit Visit Date	CRF CRF Page
R2021 L0689282_2	Week 16	Week_16 16

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	NONE	08-JAN-2010 11:11:22 Amanda Lynn	Data Entry Error

Discrepancy Detail Report

Document #: R264404013

Discrepancy ID: 66100111

Site: L0689282_2

Patient: R2021

Visit: WEEK 8

Visit Date:

CRF: WEEK_8

Section: STUDY DIARY

Qualifying Value: 8

Field: 6. I have experienced the following AEs

Row: 1

Value Text: SENSITIVITY FRONT TOOTH

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please enter verbatim. Sensitivity front tooth.

Internal Comment:

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

Resolution Text:

Deleted CRFs Report