

CRF Report for Study E7694105D

Report run by Brian Saari at 22-FEB-2013 12:00:59

Report Parameters

Site: L0689282_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2002

Ending patient: R2002

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 #:

R2002

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 25-MAR-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

NONE

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R244960413

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2002

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-MAR-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:

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_2 (v1, 25-MAR-2009)

Document Number R244960513

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2002

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 07-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 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:

GUM IRRITATION

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 R244960613

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2002

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 14-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 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:

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_4 (v1, 25-MAR-2009)

Document Number R244960713

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2002

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-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 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:

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_5 (v1, 25-MAR-2009)

Document Number R244960813

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R2002

WEEK 6

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 28-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 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:

SORE THROAT, GUM IRRITATION ALSO MY FACE HAS BROKEN OUT WORSE SINCE USING PRO₁

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 R249629213

OverFlow Section For Document Number R249629213

- 1 SORE THROAT, GUM IRRITATION ALSO MY FACE HAS BROKEN OUT WORSE SINCE USING PRODUCT (FRIEND POINTED OUT)

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R2002

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 05-MAY-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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_7 (v1, 25-MAR-2009)

Document Number R249629413

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2002

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 12-MAY-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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_8 (v1, 25-MAR-2009)

Document Number R249629713

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2002

WEEK 9

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 19-MAY-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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_9 (v1, 25-MAR-2009)

Document Number R260393413

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2002

WEEK 10

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion:

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R260393613

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2002

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 02-JUN-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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_11 (v1, 25-MAR-2009)

Document Number R260394013

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Initials:

(b)

Subject #:

R2002

WEEK 12

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 09-JUN-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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 R260394113

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2002

WEEK 13

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 16-JUN-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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_13 (v1, 25-MAR-2009)

Document Number R260394213

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2002

WEEK 14

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 23-JUN-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

NONE

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

Verified Approved Locked Frozen

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

Document Number R260394313

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R2002

WEEK 15

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-JUN-2009

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

Correct Incorrect

2. I have smoked on average 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:

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 R260394413

Links to Discrepancy and Audit Sections

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

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Initials:

(b)

Subject #:

R2002

WEEK 16

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 07-JUL-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g)

Small (0.5g)

6. I have experienced the following Adverse Events:

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

Verified Approved Locked Frozen

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

Document Number R260401913

Links to Discrepancy and Audit Sections

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

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Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 17

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 14-JUL-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

SNUS

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

Document Number R274978313

Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 21-JUL-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Document Number R274978413

Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 28-JUL-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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Page Version No. WEEK_19 (v1, 25-MAR-2009)

Document Number R274978613

Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 04-AUG-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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Page Version No. WEEK_20 (v1, 25-MAR-2009)

Document Number R274978713

Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 11-AUG-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Document Number R274978813

Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 18-AUG-2009

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

Correct Incorrect

2. I have smoked on average 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 R274979013

Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 25-AUG-2009

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

Correct Incorrect

2. I have smoked on average 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 R274979113

Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 24

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-SEP-2009

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

Correct Incorrect

2. I have smoked on average cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

Verified Approved Locked Frozen

Page Version No. WEEK_24 (v1, 25-MAR-2009)

Document Number R274979213

Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-SEP-2009

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

Correct Incorrect

2. I have smoked on average 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 R274979413

Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 15-SEP-2009

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

Correct Incorrect

2. I have smoked on average 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 R274979613

Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-SEP-2009

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

Correct Incorrect

2. I have smoked on average 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 R274979713

Initials:

(b)

Subject #:

R2002

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-SEP-2009

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

Correct Incorrect

2. I have smoked on average 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 R274979813

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 #: R244960413

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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 On resequence By	Reason Comment
5. Large (1g) (2) 1	3-5 5	14-JAN-2010 10:04:17 Amanda Lynn	Data Entry Error
6. I have experienced the following AEs (3) 1	NONE	27-JAN-2010 13:53:54 Amanda Lynn	Data Entry Error

Document #: R244960513

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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 On resequence By	Reason Comment
3. Yes specify: (1) 1	N/A	27-JAN-2010 13:54:27 Amanda Lynn	Data Entry Error
3. Yes specify: (1) 1	N/A	05-APR-2010 12:57:04 Kryisia Magnuson	ODM/SEC N/A to blank
4. Yes specify: (2) 1	N/A	27-JAN-2010 13:54:27 Amanda Lynn	Data Entry Error
4. Yes specify: (2) 1	N/A	05-APR-2010 13:41:54 Kryisia Magnuson	ODM/SEC N/A to blank.
6. I have experienced the following AEs (3) 1	N/A	27-JAN-2010 13:54:27 Amanda Lynn	Data Entry Error

Document #: R244960613

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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. Large (1g) (2) 1	6-10 10	14-JAN-2010 10:04:45 Amanda Lynn	Data Entry Error
6. I have experienced the following AEs (3) 1	GINGIVAL DISCOMFORT GUM IRRITATION	27-JAN-2010 13:55:31 Amanda Lynn	Data Entry Error

Document #: R244960713

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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
4. Yes specify: (2) 1	N/A	27-JAN-2010 13:56:44 Amanda Lynn	Data Entry Error
4. Yes specify: (2) 1	N/A	05-APR-2010 13:43:22 Krysia Magnuson	ODM/SEC N/A to blank.
5. Large (lg) (2) 1	6-10 10	14-JAN-2010 10:05:00 Amanda Lynn	Data Entry Error
6. I have experienced the following AEs (3) 1	N/A	27-JAN-2010 13:56:44 Amanda Lynn	Data Entry Error

Document #: R244960813

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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 resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	0		06-MAY-2009 11:21:23 Amanda Lynn	Data Entry Error
5. Large (1g) (2) 1	6-10 10		14-JAN-2010 10:05:23 Amanda Lynn	Data Entry Error
6. I have experienced the following AEs (3) 1	N/A		27-JAN-2010 13:56:08 Amanda Lynn	Data Entry Error

Document #: R249629213

Patient Site	Visit Visit Date	CRF CRF Page
R2002 L0689282_2	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. Yes specify: (2) 1	N/A	27-JAN-2010 13:57:10 Amanda Lynn	Data Entry Error
4. Yes specify: (2) 1	N/A	05-APR-2010 13:43:35 Kryisia Magnuson	ODM/SEC N/A to blank.
5. Large (lg) (2) 1	6-10 10	14-JAN-2010 10:03:37 Amanda Lynn	Data Entry Error
6. I have experienced the following AEs (3) 1	SORE THROAT AND GUM IRRITATION; ALSO MY FACE HAS BROKEN OUT WORSE SINCE USING PRODUCT SORE THROAT, GUM IRRITATION ALSO MY FACE HAS BROKEN OUT WORSE SINCE USING PRODUCT (FRIEND POINTED OUT)	14-JAN-2010 09:48:35 Amanda Lynn	Data Entry Error
Date 1	23-APR-2009 28-APR-2009	29-JUL-2009 14:02:41 Amanda Lynn	Data Entry Error

Document #: R249629413

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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 On resequence By	Reason Comment
4. Yes specify: (2) 1	N/A	27-JAN-2010 13:57:28 Amanda Lynn	Data Entry Error
4. Yes specify: (2) 1	N/A	05-APR-2010 13:43:45 Krysia Magnuson	ODM/SEC N/A to blank.
5. Large (1g) (2) 1	4-6 6	14-JAN-2010 10:05:44 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	3-5 5	14-JAN-2010 10:05:44 Amanda Lynn	Data Entry Error
6. I have experienced the following AEs (3) 1	N/A	27-JAN-2010 13:57:28 Amanda Lynn	Data Entry Error

Document #: R249629713

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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 On resequence By	Reason Comment
4. Yes specify: (2) 1	N/A	27-JAN-2010 13:57:45 Amanda Lynn	Data Entry Error
4. Yes specify: (2) 1	N/A	05-APR-2010 13:43:55 Krysia Magnuson	ODM/SEC N/A to blank.
5. Large (1g) (2) 1	1-2 2	14-JAN-2010 10:06:04 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	8-10 10	14-JAN-2010 10:06:04 Amanda Lynn	Data Entry Error
6. I have experienced the following AEs (3) 1	N/A	27-JAN-2010 13:57:45 Amanda Lynn	Data Entry Error

Document #: R260393413

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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
4. Yes specify: (2) 1	N/A	27-JAN-2010 13:58:00 Amanda Lynn	Data Entry Error
4. Yes specify: (2) 1	N/A	05-APR-2010 13:44:09 Krysia Magnuson	ODM/SEC N/A to blank.
5. Small (0.5g) (3) 1	6-10 10	14-JAN-2010 10:06:21 Amanda Lynn	Data Entry Error
6. I have experienced the following AEs (3) 1	N/A	27-JAN-2010 13:58:00 Amanda Lynn	Data Entry Error

Document #: R260393613

Patient Site	Visit Visit Date	CRF CRF Page
R2002 L0689282_2	Week 10	Week_10 10

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
DCI Blank Flag 1	N Y		29-JUL-2009 14:04:01 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N		22-SEP-2009 10:53:22 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	N Y		11-NOV-2009 11:31:39 Amanda Lynn	Data Entry Error

Document #: R260393613

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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
5. Small (0.5g) (3) 1	6-10 10	29-JUL-2009 13:28:01 Amanda Lynn	Data Entry Error

Document #: R260394013

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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
3. Yes specify: (1) 1	N/A	27-JAN-2010 13:58:33 Amanda Lynn	Data Entry Error
3. Yes specify: (1) 1	N/A	05-APR-2010 12:58:08 Krysia Magnuson	ODM/SEC N/A to blank.
5. Small (0.5g) (3) 1	5-7 10	29-JUL-2009 13:33:43 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	10 5-7	22-SEP-2009 10:55:23 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	5-7 6-10	11-NOV-2009 11:32:38 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	6-10 10	14-JAN-2010 10:06:50 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	10 6-10	17-FEB-2010 16:17:54 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	6-10 10	31-MAR-2010 17:17:50 Krysia Magnuson	ODM/SEC 6-10 to 10.
6. I have experienced the following AEs (3) 1	N/A	27-JAN-2010 13:58:33 Amanda Lynn	Data Entry Error
Date 1	09-JUN-2009 02-JUN-2009	11-NOV-2009 11:32:38 Amanda Lynn	Investigator Correction

Document #: R260394113

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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 resequence	On By	Reason Comment
3. Yes specify: (1) 1	N/A		27-JAN-2010 13:58:51 Amanda Lynn	Data Entry Error
3. Yes specify: (1) 1	N/A		05-APR-2010 12:58:28 Krysia Magnuson	ODM/SEC N/A to blank.
5. Small (0.5g) (3) 1	5-7 7		29-JUL-2009 14:05:08 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	7 5-7		22-SEP-2009 10:54:31 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	5-7 7		14-JAN-2010 10:07:11 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	7 5-7		17-FEB-2010 16:18:24 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	5-7 7		31-MAR-2010 17:18:10 Krysia Magnuson	ODM/SEC 5-7 to 7.
6. I have experienced the following AEs (3) 1	N/A		27-JAN-2010 13:58:51 Amanda Lynn	Data Entry Error
Date 1	16-JUN-2009 09-JUN-2009		29-JUL-2009 14:05:08 Amanda Lynn	Data Entry Error
Date 1	09-JUN-2009 16-JUN-2009		22-SEP-2009 10:54:31 Amanda Lynn	Data Entry Error
Date 1	16-JUN-2009 09-JUN-2009		11-NOV-2009 11:33:05 Amanda Lynn	Data Entry Error

Document #: R260394213

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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
3. Yes specify: (1) 1	N/A	27-JAN-2010 13:59:09 Amanda Lynn	Data Entry Error
3. Yes specify: (1) 1	N/A	05-APR-2010 12:58:38 Krysia Magnuson	ODM/SEC N/A to blank.
5. Small (0.5g) (3) 1	3-5 7	29-JUL-2009 14:05:39 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	7 3-5	22-SEP-2009 10:55:43 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	3-5 5-7	11-NOV-2009 11:33:24 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	5-7 7	14-JAN-2010 10:07:22 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	7 5-7	17-FEB-2010 16:18:52 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	5-7 7	31-MAR-2010 17:18:25 Krysia Magnuson	ODM/SEC 5-7 to 7.
6. I have experienced the following AEs (3) 1	N/A	27-JAN-2010 13:59:09 Amanda Lynn	Data Entry Error
Date 1	23-JUN-2009 16-JUN-2009	29-JUL-2009 14:05:39 Amanda Lynn	Data Entry Error
Date 1	16-JUN-2009 23-JUN-2009	22-SEP-2009 10:55:43 Amanda Lynn	Data Entry Error
Date 1	23-JUN-2009 16-JUN-2009	11-NOV-2009 11:33:24 Amanda Lynn	Data Entry Error

Document #: R260394313

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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
5. Small (0.5g) (3) 1	5 3-5	22-SEP-2009 10:56:13 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	3-5 5	14-JAN-2010 10:07:46 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	5 3-5	17-FEB-2010 16:19:21 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	3-5 5	31-MAR-2010 17:18:43 Kryisia Magnuson	ODM/SEC 3-5 to 5.
6. I have experienced the following AEs (3) 1	NONE	27-JAN-2010 13:59:28 Amanda Lynn	Data Entry Error
Date 1	30-JUN-2009 23-JUN-2009	29-JUL-2009 14:06:09 Amanda Lynn	Data Entry Error
Date 1	23-JUN-2009 30-JUN-2009	22-SEP-2009 10:56:13 Amanda Lynn	Data Entry Error
Date 1	30-JUN-2009 23-JUN-2009	11-NOV-2009 11:33:49 Amanda Lynn	Data Entry Error

Document #: R260394413

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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
1. I have not smoked any cigarettes at a (1) 1	INCORRECT CORRECT	11-NOV-2009 11:34:06 Amanda Lynn	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1-2 0	29-JUL-2009 14:06:26 Amanda Lynn	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	0 1-2	22-SEP-2009 10:56:49 Amanda Lynn	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1-2 0	11-NOV-2009 11:34:06 Amanda Lynn	Data Entry Error
3. Yes specify: (1) 1	N/A	27-JAN-2010 13:59:39 Amanda Lynn	Data Entry Error
3. Yes specify: (1) 1	N/A	05-APR-2010 12:58:54 Kryisia Magnuson	ODM/SEC N/A to blank.
5. Small (0.5g) (3) 1	2 5	29-JUL-2009 14:06:26 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	5 1-2	22-SEP-2009 10:56:49 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	1-2 3-5	11-NOV-2009 11:34:06 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	3-5 5	14-JAN-2010 10:08:02 Amanda Lynn	Data Entry Error

Document #: R260394413

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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

5. Small (0.5g) (3) 1	5 3-5	17-FEB-2010 16:19:46 Amanda Lynn	Data Entry Error
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5. Small (0.5g) (3) 1	3-5 5	31-MAR-2010 17:18:59 Krysia Magnuson	ODM/SEC 3-5 to 5.
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6. I have experienced the following AEs (3) 1	N/A	27-JAN-2010 13:59:39 Amanda Lynn	Data Entry Error
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Date 1	07-JUL-2009 30-JUN-2009	29-JUL-2009 14:06:26 Amanda Lynn	Data Entry Error
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Date 1	30-JUN-2009 07-JUL-2009	22-SEP-2009 10:56:49 Amanda Lynn	Data Entry Error
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Date 1	07-JUL-2009 30-JUN-2009	11-NOV-2009 11:34:06 Amanda Lynn	Data Entry Error
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Document #: R260401913

Patient Site	Visit Visit Date	CRF CRF Page
R2002 L0689282_2	Week 16	Week_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	22-SEP-2009 10:57:34 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	11-NOV-2009 11:35:15 Amanda Lynn	Data Entry Error

Document #: R260401913

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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
2. I have smoked on average_cigarettes p (1) 1	1-2 2	14-JAN-2010 10:08:24 Amanda Lynn	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	2 1-2	17-FEB-2010 16:20:09 Amanda Lynn	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	1-2 2	31-MAR-2010 16:55:02 Kryisia Magnuson	ODM/SEC 1-2 to 2.
3. Yes specify: (1) 1	N/A	27-JAN-2010 13:59:54 Amanda Lynn	Data Entry Error
3. Yes specify: (1) 1	N/A	05-APR-2010 12:59:06 Kryisia Magnuson	ODM/SEC N/A to blank.
4. Yes specify: (2) 1	N/A	27-JAN-2010 13:59:54 Amanda Lynn	Data Entry Error
4. Yes specify: (2) 1	N/A	05-APR-2010 13:44:25 Kryisia Magnuson	ODM/SEC N/A to blank.
5. Small (0.5g) (3) 1	1-2 2	14-JAN-2010 10:08:24 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	2 1-2	17-FEB-2010 16:20:33 Amanda Lynn	Data Entry Error
5. Small (0.5g) (3) 1	1-2 2	31-MAR-2010 16:55:02 Kryisia Magnuson	ODM/SEC 1-2 to 2.

Document #: R260401913

Patient Site	Visit Visit Date	CRF CRF Page
R2002 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

6. I have experienced the following AEs (3) 1	N/A	27-JAN-2010 13:59:54 Amanda Lynn	Data Entry Error
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Discrepancy Detail Report

Document #: R244960413

Discrepancy ID: 49537511 Site: L0689282_2 Patient: R2002
Visit: WEEK 1 Visit Date:
CRF: WEEK_1 Section: STUDY DIARY Qualifying Value: 1
Field: 6. I have experienced the following AEs Row: 1
Value Text: NONE
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review diaries and enter 'None' or 'N/A' or the AE verbatim per guidelines for all weeks.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R244960613

Discrepancy ID: 49537611 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 3 **Visit Date:**
CRF: WEEK_3 **Section:** STUDY DIARY **Qualifying Value:** 3
Field: 6. I have experienced the following AEs **Row:** 1
Value Text: GUM IRRITATION
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: diary states " gum irritation", please review for verbatim per guidelines.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R260393613

Discrepancy ID: 1737356513

Site: L0689282_2

Patient: R2002

Visit: WEEK 10

Visit Date:

CRF: WEEK_10

Section: STUDY DIARY

Qualifying Value: 10

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please complete week 10

Internal Comment:

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

Resolution Text:

Document #: R260394013

Discrepancy ID: 1737356813

Site: L0689282_2

Patient: R2002

Visit: WEEK 11

Visit Date:

CRF: WEEK_11

Section: STUDY DIARY

Qualifying Value: 11

Field: 5. Small (0.5g)

Row: 1

Value Text: 10

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please enter verbatim, 6-10.

Internal Comment:

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

Resolution Text:

Document #: R260394113

Discrepancy ID: 1737357013 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 12 **Visit Date:**
CRF: WEEK_12 **Section:** STUDY DIARY **Qualifying Value:** 12
Field: 5. Small (0.5g) **Row:** 1
Value Text: 7
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter verbatim from diary, 5-7.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1737356913 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 12 **Visit Date:**
CRF: WEEK_12 **Section:** STUDY DIARY **Qualifying Value:** 12
Field: Date **Row:** 1
Value Text: 20090609
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review date
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R260394213

Discrepancy ID: 1737358813 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 13 **Visit Date:**
CRF: WEEK_13 **Section:** STUDY DIARY **Qualifying Value:** 13
Field: 5. Small (0.5g) **Row:** 1
Value Text: 7
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter verbatim, 5-7.

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

Discrepancy ID: 1737358713 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 13 **Visit Date:**
CRF: WEEK_13 **Section:** STUDY DIARY **Qualifying Value:** 13
Field: Date **Row:** 1
Value Text: 20090616
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review date

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

Document #: R260394313

Discrepancy ID: 1737359013 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 14 **Visit Date:**
CRF: WEEK_14 **Section:** STUDY DIARY **Qualifying Value:** 14
Field: 5. Small (0.5g) **Row:** 1
Value Text: 5
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per previous query, please enter verbatim, 3-5.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1737358913 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 14 **Visit Date:**
CRF: WEEK_14 **Section:** STUDY DIARY **Qualifying Value:** 14
Field: Date **Row:** 1
Value Text: 20090623
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R260394413

Discrepancy ID: 1737359313 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 15 **Visit Date:**
CRF: WEEK_15 **Section:** STUDY DIARY **Qualifying Value:** 15
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 0
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 67349111 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 15 **Visit Date:**
CRF: WEEK_15 **Section:** STUDY DIARY **Qualifying Value:** 15
Field: 5. Small (0.5g) **Row:** 1
Value Text: 5
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter verbatim, 3-5.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1737359213 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 15 **Visit Date:**
CRF: WEEK_15 **Section:** STUDY DIARY **Qualifying Value:** 15
Field: Date **Row:** 1
Value Text: 20090630
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R260401913

Discrepancy ID: 67349611 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 16 **Visit Date:**
CRF: WEEK_16 **Section:** STUDY DIARY **Qualifying Value:** 16
Field: 2. I have smoked on average_cigarettes p **Row:** 1
Value Text: 2
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter verbatim, 1-2.

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

Discrepancy ID: 67349711 **Site:** L0689282_2 **Patient:** R2002
Visit: WEEK 16 **Visit Date:**
CRF: WEEK_16 **Section:** STUDY DIARY **Qualifying Value:** 16
Field: 5. Small (0.5g) **Row:** 1
Value Text: 2
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter verbatim, 1-2.

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

Deleted CRFs Report