CRF Report for Study E7694105D

Report run by Brian Saari at 25-FEB-2013 09:59:09

Report Parameters

Site:	**P3880_0342**
Discrepancy status choice:	**All statuses**
Approval status choice:	**All statuses**
Verification status choice:	**All statuses**
Starting patient:	**R4014**
Ending patient:	**R4014**

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)

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

WEEK 1

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 18-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 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) 12

Small (0.5g) 5

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

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

Document Number R243279713

Links to Discrepancy and Audit Sections

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Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

WEEK 2

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 5 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

☑ No ☐ Yes-please specify:

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

☐ Yes ☑ No

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

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

Sachet Size:

Large (1g) 15

Small (0.5g) 5

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

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

Document Number R243279913

Links to Discrepancy and Audit Sections

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Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

WEEK 3

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 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) 20

Small (0.5g) 5

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

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

Document Number R243280113

Links to Discrepancy and Audit Sections

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Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R4014

WEEK 4

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-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])?

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

Sachet Size:

Large (1g) 25

Small (0.5g) 8

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

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

Document Number R243280313

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R4014

WEEK 5

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 15-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])?

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

Sachet Size:

Large (1g) 25

Small (0.5g) 5

6. I have experienced the following Adverse Events:

HEAD COLD

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_5 (v1, 25-MAR-2009)

Document Number R243280513

Links to Discrepancy and Audit Sections

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Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

WEEK 6

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 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) 20

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

Page Version No. WEEK_6 (v1, 25-MAR-2009)

Document Number R277661613

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

WEEK 7

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-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 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) 20

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

Page Version No. WEEK_7 (v1, 25-MAR-2009)

Document Number R277663113

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

WEEK 8

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 06-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 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) 20

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

Page Version No. WEEK_8 (v1, 25-MAR-2009)

Document Number R277663213

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R4014

WEEK 9

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-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 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) 20

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

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

Document Number R277663413

Links to Discrepancy and Audit Sections

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Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R4014

WEEK 10

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-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 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) 20

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

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

Document Number R277663713

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

WEEK 11

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-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 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) 20

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

Page Version No. WEEK_11 (v1, 25-MAR-2009)

Document Number R277663813

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

WEEK 12

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 05-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 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) 20

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

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

Document Number R277664113

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

WEEK 13

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 13-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 3 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

☑ No ☐ Yes-please specify:

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

☐ Yes ☑ No

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

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

Sachet Size:

Large (1g) 25

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

Page Version No. WEEK_13 (v1, 25-MAR-2009)

Document Number R277664513

Links to Discrepancy and Audit Sections

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Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

WEEK 14

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-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 3 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

☑ No ☐ Yes-please specify:

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

☐ Yes ☑ No

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

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

Sachet Size:

Large (1g) 30

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

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

Document Number R277664813

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

WEEK 15

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-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 3 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

☑ No ☐ Yes-please specify:

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

☐ Yes ☑ No

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

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

Sachet Size:

Large (1g) 30

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

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

Document Number R277665213

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b)

Subject #: R4014

WEEK 16

Is Blank ☐

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 02-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 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) 30

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

Verified ☑ Approved ☐ Locked ☑ Frozen ☑

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

Document Number R277665513

Links to Discrepancy and Audit Sections

Click here to navigate to audit history for this CRF

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

FOLLOW-UP WK 17

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])?

_____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

FOLLOW-UP WK 18

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])?

_____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

FOLLOW-UP WK 19

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])?

_____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

FOLLOW-UP WK 20

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])?

_____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

FOLLOW-UP WK 21

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])?

_____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

FOLLOW-UP WK 22

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])?

_____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

FOLLOW-UP WK 23

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])?

_____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

FOLLOW-UP WK 24

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])?

_____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

FOLLOW-UP WK 25

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])?

_____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

FOLLOW-UP WK 26

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])?

_____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

FOLLOW-UP WK 27

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])?

_____

Study # 7694-105 / Protocol # SM 08-01

Initials: (b) _____

Subject #: R4014

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])?

_____

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 #: **R243279713**

Patient Site	Visit Visit Date	CRF CRF Page
R4014	Week 1	Week_1
P3880_0342		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	3-5 5		31-MAR-2010 17:29:07 Krysia Magnuson	ODM/SEC 3-5 to 5.
5. Large (1g) (2) 1	10-12 12		01-APR-2010 09:40:13 Krysia Magnuson	ODM/SEC 10-12 to 12.
5. Small (0.5g) (3) 1	1-5 5		01-APR-2010 09:40:13 Krysia Magnuson	ODM/SEC 1-5 to 5.

Document #: **R243279913**

Patient Site	Visit Visit Date	CRF CRF Page
R4014	Week 2	Week_2
P3880_0342		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
2. I have smoked on average_cigarettes p (1) 1	3-5 5		31-MAR-2010 17:29:20 Krysia Magnuson	ODM/SEC 3-5 to 5.
5. Large (1g) (2) 1	13-15 15		01-APR-2010 13:09:50 Krysia Magnuson	Investigator Correction 13-15 to 15.
5. Small (0.5g) (3) 1	1-5 5		01-APR-2010 13:09:50 Krysia Magnuson	Investigator Correction 1-5 to 5.

Document #: **R243280113**

Patient Site	Visit Visit Date	CRF CRF Page
R4014 P3880_0342	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 resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	3-5 5		31-MAR-2010 17:29:31 Krysia Magnuson	ODM/SEC 3-5 to 5.
5. Large (1g) (2) 1	18-20 20		01-APR-2010 13:10:35 Krysia Magnuson	ODM/SEC 18-20 to 20.
5. Small (0.5g) (3) 1	1-5 5		01-APR-2010 13:10:35 Krysia Magnuson	ODM/SEC 1-5 to 5

Document #: **R243280313**

Patient Site	Visit Visit Date	CRF CRF Page
R4014	Week 4	Week_4
P3880_0342		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 resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	1-2 2		01-APR-2010 09:59:54 Krysia Magnuson	ODM/SEC 1-2 to 2.
5. Large (1g) (2) 1	20-25 25		01-APR-2010 09:59:54 Krysia Magnuson	ODM/SEC 20-25 to 25.
5. Small (0.5g) (3) 1	5-8 8		01-APR-2010 09:59:54 Krysia Magnuson	ODM/SEC 5-8 to 8.

Document #: **R243280513**

Patient Site	Visit Visit Date	CRF CRF Page
R4014 P3880_0342	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	1-2 2		01-APR-2010 10:00:35 Krysia Magnuson	ODM/SEC 1-2 to 2.
5. Large (1g) (2) 1	20-25 25		01-APR-2010 10:00:35 Krysia Magnuson	ODM/SEC 20-25 to 25.

Document #: **R277661613**

Patient Site	Visit Visit Date	CRF CRF Page
R4014 P3880_0342	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 resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	3-5 5		31-MAR-2010 17:29:55 Krysia Magnuson	ODM/SEC 3-5 to 5.
5. Large (1g) (2) 1	15-20 20		01-APR-2010 12:47:42 Krysia Magnuson	ODM/SEC 15-20 to 20.

Document #: **R277663113**

Patient Site	Visit Visit Date	CRF CRF Page
R4014	Week 7	Week_7
P3880_0342		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	3-5 5		31-MAR-2010 17:30:07 Krysia Magnuson	ODM/SEC 3-5 to 5.
5. Large (1g) (2) 1	15-20 20		01-APR-2010 12:47:31 Krysia Magnuson	ODM/SEC 15-20 to 20.

Document #: **R277663213**

Patient Site	Visit Visit Date	CRF CRF Page
R4014	Week 8	Week_8
P3880_0342		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
2. I have smoked on average_cigarettes p (1) 1	3-5 5		31-MAR-2010 17:30:15 Krysia Magnuson	ODM/SEC 3-5 to 5.
5. Large (1g) (2) 1	15-20 20		01-APR-2010 12:47:08 Krysia Magnuson	ODM/SEC 15-20 to 20.

Document #: **R277663413**

Patient Site	Visit Visit Date	CRF CRF Page
R4014 P3880_0342	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
2. I have smoked on average_cigarettes p (1) 1	3-5 5		31-MAR-2010 17:30:25 Krysia Magnuson	ODM/SEC 3-5 to 5.
5. Large (1g) (2) 1	15-20 20		01-APR-2010 12:48:02 Krysia Magnuson	ODM/SEC 15-20 to 20.

Document #: **R277663713**

Patient Site	Visit Visit Date	CRF CRF Page
R4014 P3880_0342	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 resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	3-5 5		31-MAR-2010 17:30:33 Krysia Magnuson	ODM/SEC 3-5 to 5.
5. Large (1g) (2) 1	15-20 20		01-APR-2010 12:48:19 Krysia Magnuson	ODM/SEC 15-20 to 20.

Document #: **R277663813**

Patient Site	Visit Visit Date	CRF CRF Page
R4014	Week 11	Week_11
P3880_0342		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 resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	3-5 5		31-MAR-2010 17:30:46 Krysia Magnuson	ODM/SEC 3-5 to 5.
5. Large (1g) (2) 1	15-20 20		01-APR-2010 12:48:29 Krysia Magnuson	ODM/SEC 15-20 to 20.

Document #: **R277664113**

Patient Site	Visit Visit Date	CRF CRF Page
R4014 P3880_0342	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
2. I have smoked on average_cigarettes p (1) 1	3-5 5		31-MAR-2010 17:30:55 Krysia Magnuson	ODM/SEC 3-5 to 5.
5. Large (1g) (2) 1	15-20 20		31-MAR-2010 17:30:55 Krysia Magnuson	ODM/SEC 15-20 to 20.

Document #: **R277664513**

Patient Site	Visit Visit Date	CRF CRF Page
R4014	Week 13	Week_13
P3880_0342		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 resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-3 3		01-APR-2010 13:11:18 Krysia Magnuson	ODM/SEC 2-3 to 3.
5. Large (1g) (2) 1	20-25 25		01-APR-2010 13:11:18 Krysia Magnuson	ODM/SEC 20-25 to 25.

Document #: **R277664813**

Patient Site	Visit Visit Date	CRF CRF Page
R4014	Week 14	Week_14
P3880_0342		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 resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-3 3		01-APR-2010 13:11:57 Krysia Magnuson	ODM/SEC 2-3 to 3
5. Large (1g) (2) 1	25-30 30		01-APR-2010 13:11:57 Krysia Magnuson	ODM/SEC 25-30 to 30.
5. Small (0.5g) (3) 1	0		04-NOV-2009 16:15:28 Lana Glaser	Data Entry Error

Document #: **R277665213**

Patient Site	Visit Visit Date	CRF CRF Page
R4014	Week 15	Week_15
P3880_0342		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 resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-3 3		01-APR-2010 13:12:38 Krysia Magnuson	ODM/SEC 2-3 to 3
5. Large (1g) (2) 1	25-30 30		01-APR-2010 13:12:38 Krysia Magnuson	ODM/SEC 25-30 to 30

Document #: **R277665513**

Patient Site	Visit Visit Date	CRF CRF Page
R4014	Week 16	Week_16
P3880_0342		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 resequence	On By	Reason Comment
2. I have smoked on average_cigarettes p (1) 1	2-5 5		31-MAR-2010 17:31:33 Krysia Magnuson	ODM/SEC 2-5 to 5.
5. Large (1g) (2) 1	30+ 30		05-APR-2010 14:10:23 Krysia Magnuson	ODM/SEC 30+ to 30.

Discrepancy Detail Report

Deleted CRFs Report