

CRF Report for Study E7694105D

Report run by Brian Saari at 21-FEB-2013 11:32:51

Report Parameters

Site: CDB_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1024

Ending patient: R1024

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 #:

R1024

WEEK 1

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-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 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 10

Small (0.5g) 15

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 R265762413

Initials:

(b)

Subject #:

R1024

WEEK 2

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 06-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 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 10

Small (0.5g) 15

6. I have experienced the following Adverse Events:

NONE

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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

Document Number R265763013

Initials:

(b)

Subject #:

R1024

WEEK 3

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 12-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 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 10

Small (0.5g) 15

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_3 (v1, 25-MAR-2009)

Document Number R265763613

Initials:

(b)

Subject #:

R1024

WEEK 4

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-JUL-2009

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

Correct Incorrect

2. I have smoked on average 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_4 (v1, 25-MAR-2009)

Document Number R265764513

Initials:

(b)

Subject #:

R1024

WEEK 5

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-JUL-2009

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

Correct Incorrect

2. I have smoked on average 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 0

Small (0.5g) 7

6. I have experienced the following Adverse Events:

NONE

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

Correct

Incorrect

Don't Know

I have not experienced an Adverse Event

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Page Version No. WEEK_5 (v1, 25-MAR-2009)

Document Number R265764713

Initials:

(b)

Subject #:

R1024

WEEK 6

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_6 (v1, 25-MAR-2009)

Document Number R274520113

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R1024

WEEK 7

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 10-AUG-2009

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

Correct Incorrect

2. I have smoked on average 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_7 (v1, 25-MAR-2009)

Document Number R273673213

Initials:

(b)

Subject #:

R1024

WEEK 8

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 17-AUG-2009

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

Correct Incorrect

2. I have smoked on average 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_8 (v1, 25-MAR-2009)

Document Number R273673313

Initials:

(b)

Subject #:

R1024

WEEK 9

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])?

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_9 (v1, 25-MAR-2009)

Document Number R272693713

Initials:

(b)

Subject #:

R1024

WEEK 10

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 30-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_10 (v1, 25-MAR-2009)

Document Number R272693813

Initials:

(b)

Subject #:

R1024

WEEK 11

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: UNK

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_11 (v1, 25-MAR-2009)

Document Number R274521313

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R1024

WEEK 12

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: UNK

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) 3

Small (0.5g) 5

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 R274521513

Links to Discrepancy and Audit Sections

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Initials:

(b) []

Subject #:

R1024

WEEK 13

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: UNK

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

Correct Incorrect

2. I have smoked on average 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify: []

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

Yes No

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

[]

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

Sachet Size:

Large (1g) 2

Small (0.5g) 5

6. I have experienced the following Adverse Events:

BRONCHITIS PROVENTIL INHALER, DOXYCYCLINE HYCLATE 100 MG TABS 1 TAB BID X 7 D₁

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 R274521713

OverFlow Section For Document Number R274521713

- 1 BRONCHITIS PROVENTIL INHALER, DOXYCYCLINE HYCLATE 100 MG TABS 1 TAB BID X 7 DAYS.
METHYLPREDNISOLONE 4MG DOSEPACK

Links to Discrepancy and Audit Sections

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Initials:

(b)

Subject #:

R1024

WEEK 14

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:

I AM STILL COUGHING AND HAVE BRONCHITIS

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

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Initials:

(b)

Subject #:

R1024

WEEK 15

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:

BRONCHITIS, PHARYNGITIS

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

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Initials:

(b)

Subject #:

R1024

WEEK 16

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: UNK

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

Correct Incorrect

2. I have smoked on average 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Sachet Size:

Large (1g) 0

Small (0.5g) 0

6. I have experienced the following Adverse Events:

BRONCHITIS-AZITHROMYCIN 500 MG TABLETS; 1 PO QD. PREDNNISONE 20MG TABLETS, TI₁

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 R274522413

OverFlow Section For Document Number R274522413

- 1 BRONCHITIS-AZITHROMYCIN 500 MG TABLETS; 1 PO QD. PREDNNISONE 20MG TABLETS, TID X 3 DAYS, BID X 3, 1/DAY X 3

Links to Discrepancy and Audit Sections

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

[Click here to navigate to discrepancy details for this CRF](#)

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 17

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 20-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 12 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Document Number R286932713

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 18

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 27-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 12 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Document Number R286932813

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 19

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 03-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 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Document Number R286932913

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 20

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 10-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 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Document Number R286933013

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 21

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 17-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 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Document Number R286933213

Links to Discrepancy and Audit Sections

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

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 22

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 24-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 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Document Number R286933313

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 23

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 01-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 12 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

Verified Approved Locked Frozen

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

Document Number R286933413

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 24

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 08-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 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Document Number R286933513

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 25

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 15-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 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

Verified Approved Locked Frozen

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

Document Number R286933613

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 26

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 22-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 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

Verified Approved Locked Frozen

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

Document Number R286933713

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 27

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 29-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 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

Verified Approved Locked Frozen

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

Document Number R286933813

Initials:

(b)

Subject #:

R1024

FOLLOW-UP WK 28

Is Blank

STUDY PRODUCT USE DIARY

During the past week:

Date of completion: 05-JAN-2010

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

Correct Incorrect

2. I have smoked on average 15 cigarettes per day

3. I have smoked tobacco products other than cigarettes:

No Yes-please specify:

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

Yes No

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

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

Document Number R286933913

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 #: R274520113

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Week 6	Week_6 06

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
-----------------------------	--------------------------	-------------------------	----------------------

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	15-OCT-2009 14:22:20 Rossana Matos	Key Change

Document #: R274520113

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Week 6	Week_6 06

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	6	Week 6

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
1. I have not smoked any cigarettes at a (1) 1	INCORRECT	15-OCT-2009 14:19:46 Rossana Matos	Data Entry Error
2. I have smoked on average_cigarettes p (1) 1	10	15-OCT-2009 14:19:46 Rossana Matos	Data Entry Error
3. I have smoked tobacco products other (2) 1	NO	15-OCT-2009 14:19:46 Rossana Matos	Data Entry Error
4. Did you use smokeless tobacco product (3) 1	NO	15-OCT-2009 14:19:46 Rossana Matos	Data Entry Error
5. Large (1g) (2) 1	3	15-OCT-2009 14:19:46 Rossana Matos	Data Entry Error
5. Small (0.5g) (3) 1	7	15-OCT-2009 14:19:46 Rossana Matos	Data Entry Error
6. I have experienced the following AEs (3) 1	NONE	15-OCT-2009 14:19:46 Rossana Matos	Data Entry Error
7. I think the AE is related to the snus (4) 1	AE	15-OCT-2009 14:19:46 Rossana Matos	Data Entry Error
Date 1	10-AUG-2009	15-OCT-2009 14:19:46 Rossana Matos	Data Entry Error

Document #: R274521313

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Week 11	Week_11 11

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	11	Week 11

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	01-SEP-2009 UNK	11-FEB-2010 15:34:34 Christina Breedlove	Data Entry Error will write a NTF

Document #: R274521513

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Week 12	Week_12 12

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	12	Week 12

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	09-SEP-2009 UNK	11-FEB-2010 15:35:34 Christina Breedlove	Data Entry Error WILL WRITE A NTF

Document #: R274521713

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Week 13	Week_13 13

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	13	Week 13

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	BRONCHITIS BRONCHITIS PROVENTIL INHALER, DOXYCYCLINE HYCLATE 100 MG TABS 1 TAB BID X 7 DAYS. METHYLPREDNISOLONE 4MG DOSEPACK	11-FEB-2010 15:38:42 Christina Breedlove	Investigator Correction
Date 1	16-SEP-2009 UNK	11-FEB-2010 15:36:26 Christina Breedlove	Data Entry Error WILL WRITE A NTF

Document #: R274521913

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Week 14	Week_14 14

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	BRONCHITIS I AM STILL COUGHING AND HAVE BRONCHITIS	11-FEB-2010 15:40:56 Christina Breedlove	Investigator Correction
Date 1	23-SEP-2009 UNK	11-FEB-2010 15:36:57 Christina Breedlove	Data Entry Error WILL WRITE A NTF

Document #: R274522013

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Week 15	Week_15 15

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	BRONCHITIS BRONCHITIS, PHARYNGITIS	11-FEB-2010 15:41:39 Christina Breedlove	Data Entry Error
Date 1	30-SEP-2009 UNK	11-FEB-2010 15:37:24 Christina Breedlove	Data Entry Error WILL WRITE A NTF

Document #: R274522413

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Week 16	Week_16 16

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
6. I have experienced the following AEs (3) 1	BRONCHITIS BRONCHITIS-AZITHROMYCIN 500 MG TABLETS; 1 PO QD. PREDNNISONE 20MG TABLETS, TID X 3 DAYS, BID X 3, 1/DAY X 3	11-FEB-2010 15:42:17 Christina Breedlove	Data Entry Error
Date 1	08-OCT-2009 UNK	11-FEB-2010 15:37:50 Christina Breedlove	Data Entry Error WILL WRITE A NTF

Document #: R286933213

Patient Site	Visit Visit Date	CRF CRF Page
R1024 CDB_001	Follow-Up Wk 21	Week_21 21

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Study Diary	Page number	21	Follow-Up Wk 21

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
4. Did you use smokeless tobacco product (3) 1	NO	07-JAN-2010 13:54:01 Sharon Daly	Data Entry Error

Discrepancy Detail Report

Document #: R274521313

Discrepancy ID: 63634111

Site: CDB_001

Patient: R1024

Visit: WEEK 11

Visit Date:

CRF: WEEK_11

Section: STUDY DIARY

Qualifying Value: 11

Field: Date

Row: 1

Value Text: UNK

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per our discussion, please enter UNK.

Internal Comment:

Resolution Type: Due Diligence

Resolution Text:

Document #: R274521513

Discrepancy ID: 63634211

Site: CDB_001

Patient: R1024

Visit: WEEK 12

Visit Date:

CRF: WEEK_12

Section: STUDY DIARY

Qualifying Value: 12

Field: Date

Row: 1

Value Text: UNK

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per our discussion, please enter UNK.

Internal Comment: WILL WRITE A NTF

Resolution Type: Due Diligence

Resolution Text:

Document #: R274521713

Discrepancy ID: 63634411 **Site:** CDB_001 **Patient:** R1024
Visit: WEEK 13 **Visit Date:**
CRF: WEEK_13 **Section:** STUDY DIARY **Qualifying Value:** 13
Field: 6. I have experienced the following AEs **Row:** 1
Value Text: BRONCHITIS PROVENTIL INHALER, DOXYCYCLINE HYCLATE 100 MG TABS 1 TAB BID X 7 DAYS.
METHYLPREDNISOLONE 4MG DOSEPACK
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter comments verbatim.
Internal Comment: PER QUERY
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 63634311 **Site:** CDB_001 **Patient:** R1024
Visit: WEEK 13 **Visit Date:**
CRF: WEEK_13 **Section:** STUDY DIARY **Qualifying Value:** 13
Field: Date **Row:** 1
Value Text: UNK
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per our discussion, please enter UNK.
Internal Comment: WILL WRITE A NTF
Resolution Type: Due Diligence
Resolution Text:

Document #: R274521913

Discrepancy ID: 63637311 **Site:** CDB_001 **Patient:** R1024
Visit: WEEK 14 **Visit Date:**
CRF: WEEK_14 **Section:** STUDY DIARY **Qualifying Value:** 14
Field: 6. I have experienced the following AEs **Row:** 1
Value Text: I AM STILL COUGHING AND HAVE BRONCHITIS
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter comments verbatim.
Internal Comment: PER QUERY
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 63637211 **Site:** CDB_001 **Patient:** R1024
Visit: WEEK 14 **Visit Date:**
CRF: WEEK_14 **Section:** STUDY DIARY **Qualifying Value:** 14
Field: Date **Row:** 1
Value Text: UNK
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per our discussion, please enter UNK.
Internal Comment: WILL WRITE A NTF
Resolution Type: Due Diligence
Resolution Text:

Document #: R274522013

Discrepancy ID: 63638311 **Site:** CDB_001 **Patient:** R1024
Visit: WEEK 15 **Visit Date:**
CRF: WEEK_15 **Section:** STUDY DIARY **Qualifying Value:** 15
Field: 6. I have experienced the following AEs **Row:** 1
Value Text: BRONCHITIS, PHARYNGITIS
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter comments verbatim.
Internal Comment: PER QUERY
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 63638211 **Site:** CDB_001 **Patient:** R1024
Visit: WEEK 15 **Visit Date:**
CRF: WEEK_15 **Section:** STUDY DIARY **Qualifying Value:** 15
Field: Date **Row:** 1
Value Text: UNK
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per our discussion, please enter UNK.
Internal Comment: WILL WRITE A NTF
Resolution Type: Due Diligence
Resolution Text:

Deleted CRFs Report