

Subject : 5098

Study Name	RJRT CSD1010
Archive Date	31-Oct-2013
Site Name	Meta Clin (5)

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Demographics
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

DEMOGRAPHICS

Informed Consent Date:

06-APR-2011

DD-MMM-YYYY

Informed Consent Time:

Date of Birth:

(b) (6)

DD-MMM-YYYY

Age

Gender:

Male
Female

Ethnicity:

Hispanic or Latino
Not Hispanic or Latino

Race (please check all that apply):

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific Islander

White

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Demographics
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

What was the last grade of school you completed?

- Grade School (grades 1-8)
- High school (grades 9-11)
- High school graduate (grade 12)
- Technical school
- Some college
- College graduate
- Graduate school

What is approximate yearly household income group?

- Less than \$20,000
- \$20,000 to \$39,999
- \$40,000 to \$59,999
- \$60,000 to \$79,999
- \$80,000 to \$99,999
- \$100,000 to \$119,999
- \$120,000 or more

Reason for Screen Failure:

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Brief Med. History
Casebook Signature	: dpampe	Form Status	: DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery	Year	Status
---------------------	------	--------

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Comprehensive PE
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

COMPREHENSIVE PHYSICAL EXAM

Date Physical Exam Completed: DD-MMM-YYYY

System	Finding	*Specify Any Abnormal Finding
General Appearance		<input type="text"/>
Head and Neck (including Thyroid)		<input type="text"/>
Oral (mouth cavity)		<input type="text"/>
Eyes, Nose		<input type="text"/>
Chest and Lungs		<input type="text"/>
Heart		<input type="text"/>
Abdomen		<input type="text"/>
Back		<input type="text"/>
Lymph Nodes		<input type="text"/>
Neurological		<input type="text"/>
Musculoskeletal		<input type="text"/>

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Comprehensive PE
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

Extremities

Skin

Other

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

VITAL SIGNS

Date/Time Completed: DD-MMM-YYYY (24:00 hr clock)

Height (cm)

Weight (kg)

Calculated BMI (kg/m2)

Systolic/Diastolic Blood Pressure	Pulse Rate	Respiration Rate	Temperature
<input type="text"/> / <input type="text"/> (mmHg)	<input type="text"/> (bpm)	<input type="text"/> (brpm)	<input type="text"/> (°C)

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: ECG
Casebook Signature	: dpampe	Form Status	: DM Reviewed

ECG

Date/Time Completed: DD-MMM-YYYY (24:00 hr clock)

Overall Assessment: Normal Abnormal NCS Abnormal CS

Specify Findings:

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: dpampe	Form Status	: DM Reviewed

SCREENING LABS

Blood Sample Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Urine Sample Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Breathalyzer Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Results:

Urine Drug Screen:	Negative	Positive	
Urine Pregnancy Screen:	Negative	Positive	N/A (Male)
Alcohol Breathalyzer Screen:	Negative	Positive	

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Results:

ECO (ppm)

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: UB Descriptors
Casebook Signature	: dpampe	Form Status	: DM Reviewed

UB DESCRIPTORS AND SELF-REPORTED CPD

Date completed:

06-APR-2011

 DD-MMM-YYYY

Average Cigarettes Smoked Per Day:

Duration of Smoking (in years)?

Did subject use smokeless tobacco product or nicotine replacement therapy within the past 30 days?

Yes

No

Is the Subject willing to quit smoking with the aid of Camel SNUS or Nicorette nicotine lozenge?

Yes

No

Brand:

Sub-brand:

Length:

72 mm

85 mm

100 mm

120 mm

Other (mm)

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: UB Descriptors
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Packaging:

Soft-pack box

Hard-pack box

Menthol/non-menthol:

Menthol

Non-menthol

Filter type:

Filter

Non-filter

Charcoal

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Inc/Exc
Casebook Signature	: dpampe	Form Status	: DM Reviewed

INCLUSION/EXCLUSION CRITERIA

Did the subject meet all eligibility criteria for enrollment

Yes

No

If no, which criteria were not met (Check all that apply)?

Inclusion:

- | | | | | |
|------|------|------|------|------|
| IN01 | IN02 | IN03 | IN04 | IN05 |
| IN06 | IN07 | IN08 | | |

Exclusion:

- | | | | | |
|------|------|------|------|------|
| EX01 | EX02 | EX03 | EX04 | EX05 |
| EX06 | EX07 | EX08 | EX09 | EX10 |
| EX11 | EX12 | EX13 | EX14 | EX15 |
| EX16 | EX17 | EX18 | EX19 | EX20 |
| EX21 | | | | |

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5098	Event Date	: 06-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Test Product Allot
Casebook Signature	: dpampe	Form Status	: DM Reviewed

TEST PRODUCT ALLOTMENT

Preferred Flavor of SNUS:

Frost
Mellow

Preferred Flavor of Lozenge:

Original
Mint

Study Name	: RJRT CSD1010	Course Name	: Visit 1
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 1
Casebook Name	: 5098	Event Date	: 14-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

VITAL SIGNS

Date/Time Completed: DD-MMM-YYYY (24:00 hr clock)

Systolic/Diastolic Blood Pressure

/ (mmHg)

Pulse Rate

(bpm)

Respiration Rate

(brpm)

Temperature

(°C)

Study Name	: RJRT CSD1010	Course Name	: Visit 1
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 1
Casebook Name	: 5098	Event Date	: 14-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Visit 1 Labs

Urine Sample Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Results:

Urine Pregnancy Screen: Negative Positive N/A (Male)

Study Name	: RJRT CSD1010	Course Name	: Visit 1
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 1
Casebook Name	: 5098	Event Date	: 14-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Results:

ECO (ppm)

Study Name : RJRT CSD1010

Site Name : 005 - MetaClin Research, Inc.

Casebook Name : 5098

Casebook Status : Casebook Frozen And Locked

Casebook Signature : dpampe

Course Name : Visit 1

Event Name : Visit 1

Event Date : 14-APR-2011

Form Name : Test Product Allot

Form Status : DM Reviewed

TEST PRODUCT ALLOTMENT

Preferred Flavor of SNUS:

Frost

Mellow

N/A

Preferred Flavor of Lozenge:

Original

Mint

N/A

Number of Units Returned:

Number of Units Dispensed:

Study Name	: RJRT CSD1010	Course Name	: Visit 2
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 2
Casebook Name	: 5098	Event Date	: 29-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

VITAL SIGNS

Date/Time Completed: DD-MMM-YYYY (24:00 hr clock)

Systolic/Diastolic Blood Pressure	Pulse Rate	Respiration Rate	Temperature
<input type="text"/> / <input type="text"/> (mmHg)	<input type="text"/> (bpm)	<input type="text"/> (brpm)	<input type="text"/> (°C)

Study Name	: RJRT CSD1010	Course Name	: Visit 2
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 2
Casebook Name	: 5098	Event Date	: 29-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Visit 1 Labs

Urine Sample Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Results:

Urine Pregnancy Screen: Negative Positive N/A (Male)

Study Name	: RJRT CSD1010	Course Name	: Visit 2
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 2
Casebook Name	: 5098	Event Date	: 29-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

Was ECO Test Performed?

Yes

N/A

Date/Time Obtained:

DD-MMM-YYYY

(24:00 hr clock)

Results:

ECO

(ppm)

Study Name : RJRT CSD1010

Site Name : 005 - MetaClin Research, Inc.

Casebook Name : 5098

Casebook Status : Casebook Frozen And Locked

Casebook Signature : dpampe

Course Name : Visit 2

Event Name : Visit 2

Event Date : 29-APR-2011

Form Name : Test Product Allot

Form Status : DM Reviewed

TEST PRODUCT ALLOTMENT

Preferred Flavor of SNUS:

Frost

Mellow

N/A

Preferred Flavor of Lozenge:

Original

Mint

N/A

Number of Units Returned:

Number of Units Dispensed:

Study Name	: RJRT CSD1010	Course Name	: Visit 3
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 3
Casebook Name	: 5098	Event Date	: 01-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

VITAL SIGNS

Date/Time Completed: DD-MMM-YYYY (24:00 hr clock)

Systolic/Diastolic Blood Pressure	Pulse Rate	Respiration Rate	Temperature
<input type="text"/> / <input type="text"/> (mmHg)	<input type="text"/> (bpm)	<input type="text"/> (brpm)	<input type="text"/> (°C)

Study Name	: RJRT CSD1010	Course Name	: Visit 3
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 3
Casebook Name	: 5098	Event Date	: 01-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Visit 1 Labs

Urine Sample Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Results:

Urine Pregnancy Screen: Negative Positive N/A (Male)

Study Name	: RJRT CSD1010	Course Name	: Visit 3
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 3
Casebook Name	: 5098	Event Date	: 01-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

Was ECO Test Performed?

Yes

N/A

Date/Time Obtained:

DD-MMM-YYYY

(24:00 hr clock)

Results:

ECO

(ppm)

Study Name	: RJRT CSD1010	Course Name	: Visit 3
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 3
Casebook Name	: 5098	Event Date	: 01-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Test Product Allot
Casebook Signature	: dpampe	Form Status	: DM Reviewed

TEST PRODUCT ALLOTMENT

Preferred Flavor of SNUS:	Frost
	Mellow
	N/A
Preferred Flavor of Lozenge:	Original
	Mint
	N/A

Number of Units Returned:	<input type="text"/>
Number of Units Dispensed:	<input type="text"/>

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 1
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Tel Contact 1
Casebook Name	: 5098	Event Date	: 01-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: dpampe	Form Status	: DM Reviewed

SMOKING STATUS, CIGARETTE, AND TEST PRODUCT USAGE QUESTIONNAIRE

1. Have you smoked any cigarettes or tobacco products since your last visit or phone contact?

Yes

No

If Yes, first date of use

DD-MMM-YYYY

2. If you did smoke, did you smoke on any two consecutive weeks since the week prior to your last visit or phone contact?

Yes

No

3. Have you smoked at all, even one puff, in the last week?

Yes

No

4. Which of the following other tobacco products, if any, did you use in the last two weeks?

(Check all that apply)

Cigarettes

Moist snuff or dip in a round can

Chewing tobacco

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 1
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Tel Contact 1
Casebook Name	: 5098	Event Date	: 01-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: dpampe	Form Status	: DM Reviewed

SNUS

Pipe tobacco

Cigars

Little cigars

Tobacco tablets

Other (Specify)

For each "used" answer...

5. How many days in the last two weeks did you use the following products?

Cigarettes (# of days) 1-14

Moist snuff or dip in a round can (# of days) 1-14

Chewing tobacco (# of days) 1-14

SNUS (# of days) 1-14

Pipe tobacco (# of days) 1-14

Cigars (# of days) 1-14

Little cigars (# of days) 1-14

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 1
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Tel Contact 1
Casebook Name	: 5098	Event Date	: 01-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Tobacco tablets (# of days) 1-14

Other (# of days) 1-14

6. On each day that you used the following products, how much did you use?

Cigarettes (# used daily)

Moist snuff or dip in a round can (# used daily)

Chewing tobacco (pouches) (# used daily)

SNUS (portions) (# used daily)

Pipe tobacco (pipe-fulls) (# used daily)

Cigars (# used daily)

Little cigars (# used daily)

Tobacco tablets (# used daily)

Other (# used daily)

7. Which of the following nicotine containing products, if any, did you use in the last two weeks?

Nicotine patch

Nicotine gum

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 1
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Tel Contact 1
Casebook Name	: 5098	Event Date	: 01-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Nicotine lozenges

Nicotine nasal spray

Nicotine inhaler

Other

Specify

e-cigarette

For each "used" answer,

8. How many days in the last two weeks did you use the following products?

Nicotine patch (# of days)

1-14

Nicotine gum (# of days)

1-14

Nicotine lozenges (# of days)

1-14

Nicotine nasal spray (# of days)

1-14

Nicotine inhaler (# of days)

1-14

Other (# of days)

1-14

e-cigarette (# of days)

1-14

9. On each day that you used the following products, how much did you use?

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 1
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Tel Contact 1
Casebook Name	: 5098	Event Date	: 01-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Nicotine patch -mg (# used daily)	<input type="text"/>
Nicotine gum -pieces (# used daily)	<input type="text"/>
Nicotine lozenges-pieces (# used daily)	<input type="text"/>
Nicotine nasal spray-puffs (# used daily)	<input type="text"/>
Nicotine inhaler-draws or inhaled breaths (# used daily)	<input type="text"/>
Other (# used daily)	<input type="text"/>
e-cigarette-puffs (# used daily)	<input type="text"/>

Study Name	: RJRT CSD1010	Course Name	: Visit 4
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 4
Casebook Name	: 5098	Event Date	: 08-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

VITAL SIGNS

Date/Time Completed: DD-MMM-YYYY (24:00 hr clock)

Height (cm)

Weight (kg)

Calculated BMI (kg/m2)

Systolic/Diastolic Blood Pressure	Pulse Rate	Respiration Rate	Temperature
<input type="text"/> / <input type="text"/> (mmHg)	<input type="text"/> (bpm)	<input type="text"/> (brpm)	<input type="text"/> (°C)

Study Name	: RJRT CSD1010	Course Name	: Visit 4
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 4
Casebook Name	: 5098	Event Date	: 08-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

Was ECO Test Performed?

Yes

N/A

Date/Time Obtained:

08-JUL-2011

DD-MMM-YYYY

(24:00 hr clock)

Results:

ECO

(ppm)

Study Name	: RJRT CSD1010	Course Name	: Visit 4
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 4
Casebook Name	: 5098	Event Date	: 08-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Visit 4 Labs

Blood Sample N/A

Blood Sample Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Urine Sample Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Results:

Urine Pregnancy Screen: Negative Positive N/A (Male)

Study Name	: RJRT CSD1010	Course Name	: Visit 4
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 4
Casebook Name	: 5098	Event Date	: 08-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Oral Assessment
Casebook Signature	: dpampe	Form Status	: DM Reviewed

ORAL ASSESSMENT

System	Finding			*Specify Any Abnormal Finding
Oral (mouth cavity)	Normal	Abnormal	Not Done	<div>1</div>

*1) small irritated red area inner molar gumline (upper) on right. Some increased injection overall (between first and second molar) - NCS

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 2
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Tel Contact 2
Casebook Name	: 5098	Event Date	: 05-OCT-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: dpampe	Form Status	: DM Reviewed

SMOKING STATUS, CIGARETTE, AND TEST PRODUCT USAGE QUESTIONNAIRE

1. Have you smoked any cigarettes or tobacco products since your last visit or phone contact?

Yes

No

If Yes, first date of use

DD-MMM-YYYY

2. If you did smoke, did you smoke on any two consecutive weeks since the week prior to your last visit or phone contact?

Yes

No

3. Have you smoked at all, even one puff, in the last week?

Yes

No

4. Which of the following other tobacco products, if any, did you use in the last two weeks?

(Check all that apply)

Cigarettes

Moist snuff or dip in a round can

Chewing tobacco

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 2
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Tel Contact 2
Casebook Name	: 5098	Event Date	: 05-OCT-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: dpampe	Form Status	: DM Reviewed

SNUS

Pipe tobacco

Cigars

Little cigars

Tobacco tablets

Other (Specify)

For each "used" answer...

5. How many days in the last two weeks did you use the following products?

Cigarettes (# of days) 1-14

Moist snuff or dip in a round can (# of days) 1-14

Chewing tobacco (# of days) 1-14

SNUS (# of days) 1-14

Pipe tobacco (# of days) 1-14

Cigars (# of days) 1-14

Little cigars (# of days) 1-14

Study Name : RJRT CSD1010

Course Name : Tel Contact 2

Site Name : 005 - MetaClin Research, Inc.

Event Name : Tel Contact 2

Casebook Name : 5098

Event Date : 05-OCT-2011

Casebook Status : Casebook Frozen And Locked

Form Name : Product Usage Q

Casebook Signature : dpampe

Form Status : DM Reviewed

Tobacco tablets (# of days)

 1-14

Other (# of days)

 1-14

6. On each day that you used the following products, how much did you use?

Cigarettes (# used daily)

Moist snuff or dip in a round can (# used daily)

Chewing tobacco (pouches) (# used daily)

SNUS (portions) (# used daily)

Pipe tobacco (pipe-fulls) (# used daily)

Cigars (# used daily)

Little cigars (# used daily)

Tobacco tablets (# used daily)

Other (# used daily)

7. Which of the following nicotine containing products, if any, did you use in the last two weeks?

Nicotine patch

Nicotine gum

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 2
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Tel Contact 2
Casebook Name	: 5098	Event Date	: 05-OCT-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Nicotine lozenges

Nicotine nasal spray

Nicotine inhaler

Other

Specify

e-cigarette

For each "used" answer,

8. How many days in the last two weeks did you use the following products?

Nicotine patch (# of days)

1-14

Nicotine gum (# of days)

1-14

Nicotine lozenges (# of days)

1-14

Nicotine nasal spray (# of days)

1-14

Nicotine inhaler (# of days)

1-14

Other (# of days)

1-14

e-cigarette (# of days)

1-14

9. On each day that you used the following products, how much did you use?

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 2
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Tel Contact 2
Casebook Name	: 5098	Event Date	: 05-OCT-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Nicotine patch -mg (# used daily)	<input type="text"/>
Nicotine gum -pieces (# used daily)	<input type="text"/>
Nicotine lozenges-pieces (# used daily)	<input type="text"/>
Nicotine nasal spray-puffs (# used daily)	<input type="text"/>
Nicotine inhaler-draws or inhaled breaths (# used daily)	<input type="text"/>
Other (# used daily)	<input type="text"/>
e-cigarette-puffs (# used daily)	<input type="text"/>

Study Name	: RJRT CSD1010	Course Name	: Visit 5
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 5
Casebook Name	: 5098	Event Date	: 14-OCT-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

VITAL SIGNS

Date/Time Completed: DD-MMM-YYYY (24:00 hr clock)

Systolic/Diastolic Blood Pressure	Pulse Rate	Respiration Rate	Temperature
<input type="text"/> / <input type="text"/> (mmHg)	<input type="text"/> (bpm)	<input type="text"/> (brpm)	<input type="text"/> (°C)

Study Name	: RJRT CSD1010	Course Name	: Visit 5
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 5
Casebook Name	: 5098	Event Date	: 14-OCT-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

Was ECO Test Performed?

Yes

N/A

Date/Time Obtained:

14-OCT-2011

DD-MMM-YYYY

(24:00 hr clock)

Results:

ECO

(ppm)

Study Name	: RJRT CSD1010	Course Name	: Visit 5
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 5
Casebook Name	: 5098	Event Date	: 14-OCT-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Visit 4 Labs

Blood Sample N/A

Blood Sample Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Urine Sample Date/Time Obtained: DD-MMM-YYYY (24:00 hr clock)

Results:

Urine Pregnancy Screen: Negative Positive N/A (Male)

Study Name	: RJRT CSD1010	Course Name	: Adverse Events
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Small irritated red area inner molar gumline (upper) Right. Some increased injection
Casebook Name	: 5098	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Adverse Events
Casebook Signature	: dpampe	Form Status	: DM Reviewed

ADVERSE EVENTS

AE Term:

1

Start Date/Time: Stop Date/Time: Outcome:

DD-MMM-YYYY

DD-MMM-YYYY

(24:00 hr clock)

(24:00 hr clock)

Severity:

Action Taken toward product:

Concomitant Therapy for AE: Yes No

Relationship:

SAE: Yes No

SAE, Criteria:

*1) Small irritated red area inner molar gumline (upper) Right. Some increased injection overall (between 1st and 2nd molar) - NCS

Study Name	: RJRT CSD1010	Course Name	: Adverse Events
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Small irritated red area inner molar gumline (upper) Right. Some increased injection
Casebook Name	: 5098	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: AE Code
Casebook Signature	: dpampe	Form Status	: Data Entry In Progress

ADVERSE EVENT MedDRA CODING

This form is for the central coder. The site should not enter into it.

Original AE Description:

1

Code Term Search:

1	<div></div>	<div></div>
2	<div></div>	<div></div>
3	<div></div>	<div></div>
4	<div></div>	<div></div>

Not on list

Coding Completed?

*1) Small irritated red area inner molar gumline (upper) Right. Some increased injection overall (between 1st and 2nd molar) - NCS

Study Name	: RJRT CSD1010	Course Name	: Con Meds
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Con Meds
Casebook Name	: 5098	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds
Casebook Signature	: dpampe	Form Status	: Blank DM Reviewed

CONCOMITANT MEDICATIONS

Medication	<input type="text"/>		
Dose	<input type="text"/>		
Units			
Route			
Start Date/Time	<input type="text"/>	DD-MMM-YYYY	<input type="text"/> (24:00 hr clock)
Stop Date/Time	<input type="text"/>	DD-MMM-YYYY	<input type="text"/> (24:00 hr clock)
Indication	<input type="text"/>		

Ongoing

CONCOMITANT MEDICATION WHO Drug CODING

This section is for the central coder. The site should not enter into it.

Drug Name	<input type="text"/>
Drug Term Search:	<input type="text"/>

Study Name	: RJRT CSD1010	Course Name	: Con Meds
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Con Meds
Casebook Name	: 5098	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds
Casebook Signature	: dpampe	Form Status	: Blank DM Reviewed

1

2

3

4

Not on list

Coding Completed?

Study Name	: RJRT CSD1010	Course Name	: Prtcl Deviations
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Prtcl Deviations
Casebook Name	: 5098	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Prtcl Deviations (1)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

DEVIATIONS

Date of Deviation	Deviation Category	Deviation Description
<div>08-JUL-2011</div> <div>DD-MMM-YYYY</div>		<div></div> <div>1</div>

*1) AE from visit 4 oral assessment (small irritated red area inner molar gumline (upper on right). Some increased injection overall (between 1st and 2nd molar) - was not followed to resolution in error

Study Name	: RJRT CSD1010	Course Name	: Prtcl Deviations
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Prtcl Deviations
Casebook Name	: 5098	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Prtcl Deviations (2)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

DEVIATIONS

Date of Deviation	Deviation Category	Deviation Description
<div>14-OCT-2011</div> <div>DD-MMM-YYYY</div>		<div></div> <div>1</div>

*1) Study sponsor was not notified within two days of subject's discontinuation from study as per section 4.6 of the protocol.

Study Name	: RJRT CSD1010	Course Name	: Randomization
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Randomization
Casebook Name	: 5098	Event Date	: 14-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Randomization
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

RANDOMIZATION

Randomization Number:

Please select Cohort:

Study Name	: RJRT CSD1010	Course Name	: Study Conc.
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Study Conclusion
Casebook Name	: 5098	Event Date	: 14-OCT-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Study Conclusion
Casebook Signature	: dpampe	Form Status	: DM Reviewed

END OF STUDY / EARLY TERMINATION FORM

Did the Subject complete the study as planned?

Completed the study

Discontinued prior to completion of the study

Date of Study Completion or Discontinuation:

14-OCT-2011

DD-MMM-YYYY

Reason for Early Withdrawal

Specify:

*1) Subject states abstinent from smoking, but with >8 ECO at visit 5

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
64107	4/7/2011 9:27:50	4-7-2011 8:25:44:493	4909	rcajigas	Rafael Cajigas	TD_CASE-BOOK	2086	0:0					Casebook Created
64116	4/7/2011 9:28:25	4-7-2011 8:26:19:852	4909	rcajigas	Rafael Cajigas	TD_CASE-BOOK	2086	0:0				a8c1a40a2749510b01c0786a9a423be9	LUID Created
64133	4/7/2011 9:32:48	4-7-2011 8:30:43:446	4909	rcajigas	Rafael Cajigas	TD_EVENT	9296	0:0				4-6-2011	Event Created
64134	4/7/2011 9:34:0	4-7-2011 8:31:55:477	4909	rcajigas	Rafael Cajigas	TD_FORM	25922	25922:0	Demographics		0	1	Form Status set to 1
64135	4/7/2011 9:34:0	4-7-2011 8:31:55:477	4909	rcajigas	Rafael Cajigas	TD_DATA	48379	25922:754976	Demographics	DM.DMICDT		4-6-2011	Data Added
64136	4/7/2011 9:34:0	4-7-2011 8:31:55:477	4909	rcajigas	Rafael Cajigas	TD_DATA	48380	25922:754978	Demographics	DM.DMICTM		12:08	Data Added
64137	4/7/2011 9:34:0	4-7-2011 8:31:55:477	4909	rcajigas	Rafael Cajigas	TD_DATA	48381	25922:754980	Demographics	DM.DMDOBDT		(b) (6)	Data Added
64138	4/7/2011 9:34:0	4-7-2011 8:31:55:477	4909	rcajigas	Rafael Cajigas	TD_DATA	48382	25922:754984	Demographics	DM.DMSEX		Male	Data Added
64139	4/7/2011 9:34:0	4-7-2011 8:31:55:477	4909	rcajigas	Rafael Cajigas	TD_DATA	48383	25922:754986	Demographics	DM.DMETH		Not Hispanic or Latino	Data Added
64140	4/7/2011 9:34:0	4-7-2011 8:31:55:477	4909	rcajigas	Rafael Cajigas	TD_DATA	48384	25922:754992	Demographics	DM.DMRACE5		true	Data Added
64141	4/7/2011 9:34:0	4-7-2011 8:31:55:477	4909	rcajigas	Rafael Cajigas	TD_DATA	48385	25922:754994	Demographics	DM.DMGRADE		Some college	Data Added
64142	4/7/2011 9:34:1		4909	rcajigas	Rafael Cajigas	TD_DATA	48386	25922:754982	Demographics	DM.DMAGE		21	computed value
108421	5/1/2011 1:7:40:12	5-1-2011 1:6:37:35:953	461	swampler	Sarah Wampler	TD_EVENT	9297	0:0			04-07-2011	4-14-2011	Event Created
108422	5/1/2011 1:7:40:31	5-1-2011 1:6:37:54:906	461	swampler	Sarah Wampler	TD_FORM	25935	25935:0	Test Product Allot		0	1	Form Status set to 1
108423	5/1/2011 1:7:40:31	5-1-2011 1:6:37:54:906	461	swampler	Sarah Wampler	TD_DATA	78500	25935:755225	Test Product Allot	PU.PUSNUS2		Frost	Data Added
108424	5/1/2011 1:7:40:31	5-1-2011 1:6:37:54:906	461	swampler	Sarah Wampler	TD_DATA	78501	25935:755227	Test Product Allot	PU.PULOZG2		N/A	Data Added
108425	5/1/2011 1:7:40:31	5-1-2011 1:6:37:54:906	461	swampler	Sarah Wampler	TD_DATA	78502	25935:755231	Test Product Allot	PU.PUDIS2		11	Data Added
108426	5/1/2011 1:7:40:53	5-1-2011 1:6:38:17:375	461	swampler	Sarah Wampler	TD_EVENT	9311	0:0			04-07-2011	4-14-2011	Event Created
108427	5/1/2011 1:7:41:11	5-1-2011 1:6:38:35:484	461	swampler	Sarah Wampler	TD_FORM	25963	25963:0	Randomization		0	1	Form Status set to 1
108428	5/1/2011 1:7:41:11	5-1-2011 1:6:38:35:484	461	swampler	Sarah Wampler	TD_DATA	78503	25963:756105	Randomization	RAND.RAND		510027	Data Added
108429	5/1/2011 1:7:41:11	5-1-2011 1:6:38:35:484	461	swampler	Sarah Wampler	TD_DATA	78504	25963:756107	Randomization	RAND.COHORT		Cohort 1	Data Added
124711	5/5/2011 1:7:5:43	5-5-2011 1:6:03:24:296	461	swampler	Sarah Wampler	TD_FORM	25922	25922:0	Demographics		1	2	Form Status set to 2
124720	5/5/2011 1:7:6:9	5-5-2011 1:6:03:50:687	461	swampler	Sarah Wampler	TD_FORM	25923	25923:0	Brief Med. History		0	2	Form Status set to 2
124721	5/5/2011 1:7:6:9	5-5-2011 1:6:03:50:687	461	swampler	Sarah Wampler	TD_DATA	89750	25923:755004	Brief Med. History	MH.MHCOND		seasonal allergies	Data Added
124722	5/5/2011 1:7:6:9	5-5-2011 1:6:03:50:687	461	swampler	Sarah Wampler	TD_DATA	89751	25923:755005	Brief Med. History	MH.MHSTYYYY		2009	Data Added
124723	5/5/2011 1:7:6:9	5-5-2011 1:6:03:50:687	461	swampler	Sarah Wampler	TD_DATA	89752	25923:755006	Brief Med. History	MH.MHENRF		Ongoing	Data Added
124725	5/5/2011 1:7:6:46	5-5-2011 1:6:04:27:671	461	swampler	Sarah Wampler	TD_FORM	25924	25924:0	Comprehensive PE		0	2	Form Status set to 2
124726	5/5/2011 1:7:6:46	5-5-2011 1:6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89753	25924:755009	Comprehensive PE	PE.PEDT		4-6-2011	Data Added
124727	5/5/2011 1:7:6:46	5-5-2011 1:6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89754	25924:755014	Comprehensive PE	PE.PEGNAP		Normal	Data Added

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
124728	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89755	25924:755017	Comprehensive PE	PE.PEHEAD		Normal	Data Added
124729	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89756	25924:755020	Comprehensive PE	PE.PEORAL		Normal	Data Added
124730	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89757	25924:755023	Comprehensive PE	PE.PEEN		Normal	Data Added
124731	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89758	25924:755026	Comprehensive PE	PE.PECHST		Normal	Data Added
124732	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89759	25924:755029	Comprehensive PE	PE.PEHRT		Normal	Data Added
124733	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89760	25924:755032	Comprehensive PE	PE.PEAB		Normal	Data Added
124734	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89761	25924:755035	Comprehensive PE	PE.PEBACK		Normal	Data Added
124735	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89762	25924:755038	Comprehensive PE	PE.PELYP		Normal	Data Added
124736	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89763	25924:755041	Comprehensive PE	PE.PENEUR		Normal	Data Added
124737	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89764	25924:755044	Comprehensive PE	PE.PEMUSC		Normal	Data Added
124738	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89765	25924:755047	Comprehensive PE	PE.PEEXT		Normal	Data Added
124739	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89766	25924:755050	Comprehensive PE	PE.PESKIN		Normal	Data Added
124740	5/5/2011 1-7:6:46	5-5-2011 1-6:04:27:671	461	swampler	Sarah Wampler	TD_DATA	89767	25924:755053	Comprehensive PE	PE.PEOTH		Not Done	Data Added
124747	5/5/2011 1-7:7:36	5-5-2011 1-6:05:16:796	461	swampler	Sarah Wampler	TD_FORM	25925	25925:0	Vital Signs		0	2	Form Status set to 2
124748	5/5/2011 1-7:7:36	5-5-2011 1-6:05:16:796	461	swampler	Sarah Wampler	TD_DATA	89768	25925:755058	Vital Signs	VS.VSDT		4-6-2011	Data Added
124749	5/5/2011 1-7:7:36	5-5-2011 1-6:05:16:796	461	swampler	Sarah Wampler	TD_DATA	89769	25925:755059	Vital Signs	VS.VSTM		12:15	Data Added
124750	5/5/2011 1-7:7:36	5-5-2011 1-6:05:16:796	461	swampler	Sarah Wampler	TD_DATA	89770	25925:755063	Vital Signs	VS.VSHT		192	Data Added
124751	5/5/2011 1-7:7:36	5-5-2011 1-6:05:16:796	461	swampler	Sarah Wampler	TD_DATA	89771	25925:755066	Vital Signs	VS.VSWT		92.4	Data Added
124752	5/5/2011 1-7:7:36	5-5-2011 1-6:05:16:796	461	swampler	Sarah Wampler	TD_DATA	89772	25925:755075	Vital Signs	VS.VSSYS		113	Data Added
124753	5/5/2011 1-7:7:36	5-5-2011 1-6:05:16:796	461	swampler	Sarah Wampler	TD_DATA	89773	25925:755077	Vital Signs	VS.VSDIA		59	Data Added
124754	5/5/2011 1-7:7:36	5-5-2011 1-6:05:16:796	461	swampler	Sarah Wampler	TD_DATA	89774	25925:755079	Vital Signs	VS.VSHR		59	Data Added
124755	5/5/2011 1-7:7:36	5-5-2011 1-6:05:16:796	461	swampler	Sarah Wampler	TD_DATA	89775	25925:755081	Vital Signs	VS.VSRR		14	Data Added
124756	5/5/2011 1-7:7:36	5-5-2011 1-6:05:16:796	461	swampler	Sarah Wampler	TD_DATA	89776	25925:755083	Vital Signs	VS.VSTEMP		36.7	Data Added
124757	5/5/2011 1-7:7:36		461	swampler	Sarah Wampler	TD_DATA	89777	25955:755911	Vital Signs	VS.VSHT		192	computed value
124758	5/5/2011 1-7:7:36		461	swampler	Sarah Wampler	TD_DATA	89778	25945:755452	Vital Signs	VS.VSHT		192	computed value
124759	5/5/2011 1-7:7:36		461	swampler	Sarah Wampler	TD_DATA	89779	25925:755069	Vital Signs	VS.VSBMI		25.1	computed value
124763	5/5/2011 1-7:7:54	5-5-2011 1-6:05:35:750	461	swampler	Sarah Wampler	TD_FORM	25926	25926:0	ECG		0	2	Form Status set to 2
124764	5/5/2011 1-7:7:54	5-5-2011 1-6:05:35:750	461	swampler	Sarah Wampler	TD_DATA	89783	25926:755086	ECG	EG.EGDT		4-6-2011	Data Added
124765	5/5/2011 1-7:7:54	5-5-2011 1-6:05:35:750	461	swampler	Sarah Wampler	TD_DATA	89784	25926:755087	ECG	EG.EGTM		12:42	Data Added

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
124766	5/5/2011 1-7:7:54	5-5-2011 1-6:05:35:750	461	swampler	Sarah Wampler	TD_DATA	89785	25926:755090	ECG	EG.EGASMT		Normal	Data Added
124767	5/5/2011 1-7:8:24	5-5-2011 1-6:06:05:187	461	swampler	Sarah Wampler	TD_FORM	25927	25927:0	Labs		0	2	Form Status set to 2
124768	5/5/2011 1-7:8:24	5-5-2011 1-6:06:05:187	461	swampler	Sarah Wampler	TD_DATA	89786	25927:755095	Labs	LB.LBBLDT		4-6-2011	Data Added
124769	5/5/2011 1-7:8:24	5-5-2011 1-6:06:05:187	461	swampler	Sarah Wampler	TD_DATA	89787	25927:755096	Labs	LB.LBBLTM		13:04	Data Added
124770	5/5/2011 1-7:8:24	5-5-2011 1-6:06:05:187	461	swampler	Sarah Wampler	TD_DATA	89788	25927:755099	Labs	LB.LBURDT		4-6-2011	Data Added
124771	5/5/2011 1-7:8:24	5-5-2011 1-6:06:05:187	461	swampler	Sarah Wampler	TD_DATA	89789	25927:755100	Labs	LB.LBURTM		13:08	Data Added
124772	5/5/2011 1-7:8:24	5-5-2011 1-6:06:05:187	461	swampler	Sarah Wampler	TD_DATA	89790	25927:755103	Labs	LB.LBBRDT		4-6-2011	Data Added
124773	5/5/2011 1-7:8:24	5-5-2011 1-6:06:05:187	461	swampler	Sarah Wampler	TD_DATA	89791	25927:755104	Labs	LB.LBBRTM		12:26	Data Added
124774	5/5/2011 1-7:8:24	5-5-2011 1-6:06:05:187	461	swampler	Sarah Wampler	TD_DATA	89792	25927:755108	Labs	LB.LBUDS		Negative	Data Added
124775	5/5/2011 1-7:8:24	5-5-2011 1-6:06:05:187	461	swampler	Sarah Wampler	TD_DATA	89793	25927:755110	Labs	LB.LBUCS		N/A (Male)	Data Added
124776	5/5/2011 1-7:8:24	5-5-2011 1-6:06:05:187	461	swampler	Sarah Wampler	TD_DATA	89794	25927:755112	Labs	LB.LBABS		Negative	Data Added
124782	5/5/2011 1-7:8:41	5-5-2011 1-6:06:22:203	461	swampler	Sarah Wampler	TD_FORM	25928	25928:0	Exhaled CO		0	2	Form Status set to 2
124783	5/5/2011 1-7:8:41	5-5-2011 1-6:06:22:203	461	swampler	Sarah Wampler	TD_DATA	89799	25928:755115	Exhaled CO	EC.ECDT		4-6-2011	Data Added
124784	5/5/2011 1-7:8:41	5-5-2011 1-6:06:22:203	461	swampler	Sarah Wampler	TD_DATA	89800	25928:755116	Exhaled CO	EC.ECTM		12:26	Data Added
124785	5/5/2011 1-7:8:41	5-5-2011 1-6:06:22:203	461	swampler	Sarah Wampler	TD_DATA	89801	25928:755120	Exhaled CO	EC.ECRES1		11	Data Added
124788	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_FORM	25929	25929:0	UB Descriptors		0	2	Form Status set to 2
124789	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_DATA	89803	25929:755124	UB Descriptors	UB.UBDT		4-6-2011	Data Added
124790	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_DATA	89804	25929:755126	UB Descriptors	UB.UBCPD		10	Data Added
124791	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_DATA	89805	25929:755128	UB Descriptors	UB.UBYEAR		4	Data Added
124792	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_DATA	89806	25929:755130	UB Descriptors	UB.UBSMKLS		No	Data Added
124793	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_DATA	89807	25929:755132	UB Descriptors	UB.UBQUIT		Yes	Data Added
124794	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_DATA	89808	25929:755134	UB Descriptors	UB.UBBRND		American Spirit	Data Added
124795	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_DATA	89809	25929:755136	UB Descriptors	UB.UBSBRND		Natural Blues	Data Added
124796	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_DATA	89810	25929:755138	UB Descriptors	UB.UBLTH		85 mm	Data Added
124797	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_DATA	89811	25929:755141	UB Descriptors	UB.UBPACK		Hard-pack box	Data Added
124798	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_DATA	89812	25929:755143	UB Descriptors	UB.UBMENTH		Non-menthol	Data Added
124799	5/5/2011 1-7:9:14	5-5-2011 1-6:06:54:312	461	swampler	Sarah Wampler	TD_DATA	89813	25929:755145	UB Descriptors	UB.UBFILT		Filter	Data Added
124800	5/5/2011 1-7:10:0	5-5-2011 1-6:07:42:15	461	swampler	Sarah Wampler	TD_FORM	25930	25930:0	Inc/Exc		0	2	Form Status set to 2
124801	5/5/2011 1-7:10:0	5-5-2011 1-6:07:42:15	461	swampler	Sarah Wampler	TD_DATA	89814	25930:755149	Inc/Exc	IE.IECRITYN		Yes	Data Added

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
124802	5/5/2011 1-7:10:7	5-5-2011 1-6:07:48:875	461	swampler	Sarah Wampler	TD_FORM	25931	25931:0	Test Product Allot		0	2	Form Status set to 2
124803	5/5/2011 1-7:10:7	5-5-2011 1-6:07:48:875	461	swampler	Sarah Wampler	TD_DATA	89815	25931:755184	Test Product Allot	PU.PUSNUS1		Frost	Data Added
124804	5/5/2011 1-7:10:7	5-5-2011 1-6:07:48:875	461	swampler	Sarah Wampler	TD_DATA	89816	25931:755186	Test Product Allot	PU.PULOZG1		Mint	Data Added
124805	5/5/2011 1-7:10:36	5-5-2011 1-6:08:17:125	461	swampler	Sarah Wampler	TD_FORM	25932	25932:0	Vital Signs		0	2	Form Status set to 2
124806	5/5/2011 1-7:10:36	5-5-2011 1-6:08:17:125	461	swampler	Sarah Wampler	TD_DATA	89817	25932:755188	Vital Signs	VS.VSDT		4-14-2011	Data Added
124807	5/5/2011 1-7:10:36	5-5-2011 1-6:08:17:125	461	swampler	Sarah Wampler	TD_DATA	89818	25932:755189	Vital Signs	VS.VSTM		15:37	Data Added
124808	5/5/2011 1-7:10:36	5-5-2011 1-6:08:17:125	461	swampler	Sarah Wampler	TD_DATA	89819	25932:755196	Vital Signs	VS.VSSYS		135	Data Added
124809	5/5/2011 1-7:10:36	5-5-2011 1-6:08:17:125	461	swampler	Sarah Wampler	TD_DATA	89820	25932:755198	Vital Signs	VS.VSDIA		79	Data Added
124810	5/5/2011 1-7:10:36	5-5-2011 1-6:08:17:125	461	swampler	Sarah Wampler	TD_DATA	89821	25932:755200	Vital Signs	VS.VSHR		86	Data Added
124811	5/5/2011 1-7:10:36	5-5-2011 1-6:08:17:125	461	swampler	Sarah Wampler	TD_DATA	89822	25932:755202	Vital Signs	VS.VSRR		14	Data Added
124812	5/5/2011 1-7:10:36	5-5-2011 1-6:08:17:125	461	swampler	Sarah Wampler	TD_DATA	89823	25932:755204	Vital Signs	VS.VSTEMP		36.7	Data Added
124813	5/5/2011 1-7:10:55	5-5-2011 1-6:08:36:140	461	swampler	Sarah Wampler	TD_FORM	25933	25933:0	Labs		0	2	Form Status set to 2
124814	5/5/2011 1-7:10:55	5-5-2011 1-6:08:36:140	461	swampler	Sarah Wampler	TD_DATA	89824	25933:755213	Labs	LB.LBUCS		N/A (Male)	Data Added
124817	5/5/2011 1-7:11:24	5-5-2011 1-6:09:05:546	461	swampler	Sarah Wampler	TD_FORM	25934	25934:0	Exhaled CO		0	2	Form Status set to 2
124818	5/5/2011 1-7:11:24	5-5-2011 1-6:09:05:546	461	swampler	Sarah Wampler	TD_DATA	89826	25934:755216	Exhaled CO	EC.ECDT		4-14-2011	Data Added
124819	5/5/2011 1-7:11:24	5-5-2011 1-6:09:05:546	461	swampler	Sarah Wampler	TD_DATA	89827	25934:755217	Exhaled CO	EC.ECTM		15:54	Data Added
124820	5/5/2011 1-7:11:24	5-5-2011 1-6:09:05:546	461	swampler	Sarah Wampler	TD_DATA	89828	25934:755221	Exhaled CO	EC.ECRES1		14	Data Added
124839	5/5/2011 1-7:11:43	5-5-2011 1-6:09:24:531	461	swampler	Sarah Wampler	TD_FORM	25935	25935:0	Test Product Allot		1	2	Form Status set to 2
124840	5/5/2011 1-7:11:56	5-5-2011 1-6:09:38:31	461	swampler	Sarah Wampler	TD_FORM	25963	25963:0	Randomization		1	2	Form Status set to 2
124841	5/5/2011 1-7:12:9	5-5-2011 1-6:09:50:625	461	swampler	Sarah Wampler	TD_EVENT	9308	0:0					Shared Event Added
124842	5/5/2011 1-7:12:18	5-5-2011 1-6:09:59:890	461	swampler	Sarah Wampler	TD_FORM	25960	25960:0	Con Meds		0	2	Form Status set to 2
124843	5/5/2011 1-7:12:18	5-5-2011 1-6:09:59:890	461	swampler	Sarah Wampler	TD_FORM	25960	25960:0	Con Meds		0	1	Form Checked Intentionally Left Blank
126514	5/6/2011 1-1:22:36	5-6-2011 1-0:20:17:953	461	swampler	Sarah Wampler	TD_EVENT	9298	0:0				4-29-2011	Event Created
126515	5/6/2011 1-1:23:10	5-6-2011 1-0:20:51:656	461	swampler	Sarah Wampler	TD_FORM	25936	25936:0	Vital Signs		0	2	Form Status set to 2
126516	5/6/2011 1-1:23:10	5-6-2011 1-0:20:51:656	461	swampler	Sarah Wampler	TD_DATA	90985	25936:755233	Vital Signs	VS.VSDT		4-29-2011	Data Added
126517	5/6/2011 1-1:23:10	5-6-2011 1-0:20:51:656	461	swampler	Sarah Wampler	TD_DATA	90986	25936:755234	Vital Signs	VS.VSTM		14:59	Data Added
126518	5/6/2011 1-1:23:10	5-6-2011 1-0:20:51:656	461	swampler	Sarah Wampler	TD_DATA	90987	25936:755241	Vital Signs	VS.VSSYS		129	Data Added
126519	5/6/2011 1-1:23:10	5-6-2011 1-0:20:51:656	461	swampler	Sarah Wampler	TD_DATA	90988	25936:755243	Vital Signs	VS.VSDIA		65	Data Added
126520	5/6/2011 1-1:23:10	5-6-2011 1-0:20:51:656	461	swampler	Sarah Wampler	TD_DATA	90989	25936:755245	Vital Signs	VS.VSHR		60	Data Added

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
126521	5/6/2011 1-1:23:10	5-6-2011 1-0:20:51:656	461	swampler	Sarah Wampler	TD_DATA	90990	25936:755247	Vital Signs	VS.VSRR		20	Data Added
126522	5/6/2011 1-1:23:10	5-6-2011 1-0:20:51:656	461	swampler	Sarah Wampler	TD_DATA	90991	25936:755249	Vital Signs	VS.VSTEMP		36.8	Data Added
126523	5/6/2011 1-1:23:27	5-6-2011 1-0:21:08:500	461	swampler	Sarah Wampler	TD_FORM	25937	25937:0	Labs		0	2	Form Status set to 2
126524	5/6/2011 1-1:23:27	5-6-2011 1-0:21:08:500	461	swampler	Sarah Wampler	TD_DATA	90992	25937:755258	Labs	LB.LBUCS		N/A (Male)	Data Added
126525	5/6/2011 1-1:23:55	5-6-2011 1-0:21:36:875	461	swampler	Sarah Wampler	TD_FORM	25938	25938:0	Exhaled CO		0	2	Form Status set to 2
126526	5/6/2011 1-1:23:55	5-6-2011 1-0:21:36:875	461	swampler	Sarah Wampler	TD_DATA	90993	25938:755261	Exhaled CO	EC.ECYN		N/A	Data Added
126527	5/6/2011 1-1:24:37	5-6-2011 1-0:22:18:578	461	swampler	Sarah Wampler	TD_FORM	25939	25939:0	Test Product Allot		0	2	Form Status set to 2
126528	5/6/2011 1-1:24:37	5-6-2011 1-0:22:18:578	461	swampler	Sarah Wampler	TD_DATA	90994	25939:755272	Test Product Allot	PU.PUSNUS2		Frost	Data Added
126529	5/6/2011 1-1:24:37	5-6-2011 1-0:22:18:578	461	swampler	Sarah Wampler	TD_DATA	90995	25939:755274	Test Product Allot	PU.PULOZG2		N/A	Data Added
126530	5/6/2011 1-1:24:37	5-6-2011 1-0:22:18:578	461	swampler	Sarah Wampler	TD_DATA	90996	25939:755276	Test Product Allot	PU.PURET		11	Data Added
126531	5/6/2011 1-1:24:37	5-6-2011 1-0:22:18:578	461	swampler	Sarah Wampler	TD_DATA	90997	25939:755278	Test Product Allot	PU.PUDIS2		4	Data Added
178111	6/2/2011 8-:27:3	6-2-2011 7-:24:22:328	4909	rcajigas	Rafael Cajigas	TD_EVENT	9299	0:0				6-1-2011	Event Created
178115	6/2/2011 8-:27:23	6-2-2011 7-:24:42:31	4909	rcajigas	Rafael Cajigas	TD_FORM	25940	25940:0	Vital Signs		0	1	Form Status set to 1
178116	6/2/2011 8-:27:23	6-2-2011 7-:24:42:31	4909	rcajigas	Rafael Cajigas	TD_DATA	129081	25940:755280	Vital Signs	VS.VSDT		6-1-2011	Data Added
178117	6/2/2011 8-:27:23	6-2-2011 7-:24:42:31	4909	rcajigas	Rafael Cajigas	TD_DATA	129082	25940:755281	Vital Signs	VS.VSTM		15:00	Data Added
178118	6/2/2011 8-:27:23	6-2-2011 7-:24:42:31	4909	rcajigas	Rafael Cajigas	TD_DATA	129083	25940:755288	Vital Signs	VS.VSSYS		147	Data Added
178119	6/2/2011 8-:27:23	6-2-2011 7-:24:42:31	4909	rcajigas	Rafael Cajigas	TD_DATA	129084	25940:755290	Vital Signs	VS.VSDIA		66	Data Added
178120	6/2/2011 8-:27:23	6-2-2011 7-:24:42:31	4909	rcajigas	Rafael Cajigas	TD_DATA	129085	25940:755292	Vital Signs	VS.VSHR		93	Data Added
178121	6/2/2011 8-:27:23	6-2-2011 7-:24:42:31	4909	rcajigas	Rafael Cajigas	TD_DATA	129086	25940:755294	Vital Signs	VS.VSRR		16	Data Added
178122	6/2/2011 8-:27:23	6-2-2011 7-:24:42:31	4909	rcajigas	Rafael Cajigas	TD_DATA	129087	25940:755296	Vital Signs	VS.VSTEMP		36.7	Data Added
178123	6/2/2011 8-:27:30	6-2-2011 7-:24:49:875	4909	rcajigas	Rafael Cajigas	TD_FORM	25941	25941:0	Labs		0	1	Form Status set to 1
178124	6/2/2011 8-:27:30	6-2-2011 7-:24:49:875	4909	rcajigas	Rafael Cajigas	TD_DATA	129088	25941:755305	Labs	LB.LBUCS		N/A (Male)	Data Added
178126	6/2/2011 8-:28:0	6-2-2011 7-:25:19:968	4909	rcajigas	Rafael Cajigas	TD_FORM	25942	25942:0	Exhaled CO		0	1	Form Status set to 1
178127	6/2/2011 8-:28:0	6-2-2011 7-:25:19:968	4909	rcajigas	Rafael Cajigas	TD_DATA	129089	25942:755308	Exhaled CO	EC.ECYN		N/A	Data Added
178128	6/2/2011 8-:29:35	6-2-2011 7-:26:54:875	4909	rcajigas	Rafael Cajigas	TD_FORM	25943	25943:0	Test Product Allot		0	1	Form Status set to 1
178129	6/2/2011 8-:29:35	6-2-2011 7-:26:54:875	4909	rcajigas	Rafael Cajigas	TD_DATA	129090	25943:755319	Test Product Allot	PU.PUSNUS2		Frost	Data Added
178130	6/2/2011 8-:29:35	6-2-2011 7-:26:54:875	4909	rcajigas	Rafael Cajigas	TD_DATA	129091	25943:755321	Test Product Allot	PU.PULOZG2		N/A	Data Added
178131	6/2/2011 8-:29:35	6-2-2011 7-:26:54:875	4909	rcajigas	Rafael Cajigas	TD_DATA	129092	25943:755323	Test Product Allot	PU.PURET		0	Data Added
178132	6/2/2011 8-:29:35	6-2-2011 7-:26:54:875	4909	rcajigas	Rafael Cajigas	TD_DATA	129093	25943:755325	Test Product Allot	PU.PUDIS2		18	Data Added

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
181846	6/3/2011 1-2:7:21	6-3-2011 1-2:04:57:674	624	jbaskowski	Janet Baskowski	TD_FORM	25922	25922:0	Demographics		2	3	Form Status set to 3
181847	6/3/2011 1-2:7:53	6-3-2011 1-2:05:29:754	624	jbaskowski	Janet Baskowski	TD_FORM	25925	25925:0	Vital Signs		2	3	Form Status set to 3
181848	6/3/2011 1-2:8:30	6-3-2011 1-2:06:07:101	624	jbaskowski	Janet Baskowski	TD_FORM	25928	25928:0	Exhaled CO		2	3	Form Status set to 3
181849	6/3/2011 1-2:8:51	6-3-2011 1-2:06:28:363	624	jbaskowski	Janet Baskowski	TD_FORM	25927	25927:0	Labs		2	3	Form Status set to 3
181850	6/3/2011 1-2:9:31	6-3-2011 1-2:07:08:619	624	jbaskowski	Janet Baskowski	TD_FORM	25924	25924:0	Comprehensive PE		2	3	Form Status set to 3
181851	6/3/2011 1-2:10:47	6-3-2011 1-2:08:24:313	624	jbaskowski	Janet Baskowski	TD_FORM	25932	25932:0	Vital Signs		2	3	Form Status set to 3
181852	6/3/2011 1-2:11:4	6-3-2011 1-2:08:40:978	624	jbaskowski	Janet Baskowski	TD_FORM	25934	25934:0	Exhaled CO		2	3	Form Status set to 3
181853	6/3/2011 1-2:11:29	6-3-2011 1-2:09:05:996	624	jbaskowski	Janet Baskowski	TD_FORM	25933	25933:0	Labs		2	3	Form Status set to 3
181854	6/3/2011 1-2:12:4	6-3-2011 1-2:09:40:718	624	jbaskowski	Janet Baskowski	TD_FORM	25963	25963:0	Randomization		2	3	Form Status set to 3
181855	6/3/2011 1-2:13:1	6-3-2011 1-2:10:38:183	624	jbaskowski	Janet Baskowski	TD_FORM	25936	25936:0	Vital Signs		2	3	Form Status set to 3
181856	6/3/2011 1-2:13:8	6-3-2011 1-2:10:45:648	624	jbaskowski	Janet Baskowski	TD_FORM	25937	25937:0	Labs		2	3	Form Status set to 3
181857	6/3/2011 1-2:13:17	6-3-2011 1-2:10:54:120	624	jbaskowski	Janet Baskowski	TD_FORM	25938	25938:0	Exhaled CO		2	3	Form Status set to 3
185364	6/6/2011 1-2:22:13	6-6-2011 1-1:18:46:203	461	swampler	Sarah Wampler	TD_FORM	25940	25940:0	Vital Signs		1	2	Form Status set to 2
185365	6/6/2011 1-2:22:15	6-6-2011 1-1:18:48:453	461	swampler	Sarah Wampler	TD_FORM	25941	25941:0	Labs		1	2	Form Status set to 2
185366	6/6/2011 1-2:22:18	6-6-2011 1-1:18:50:546	461	swampler	Sarah Wampler	TD_FORM	25942	25942:0	Exhaled CO		1	2	Form Status set to 2
185367	6/6/2011 1-2:22:20	6-6-2011 1-1:18:52:968	461	swampler	Sarah Wampler	TD_FORM	25943	25943:0	Test Product Allot		1	2	Form Status set to 2
200272	6/10/2011 17:42:13	6-10-2011 17:38:57:757	624	jbaskowski	Janet Baskowski	TD_FORM	25940	25940:0	Vital Signs		2	3	Form Status set to 3
200273	6/10/2011 17:43:25	6-10-2011 17:40:09:570	624	jbaskowski	Janet Baskowski	TD_FORM	25941	25941:0	Labs		2	3	Form Status set to 3
200274	6/10/2011 17:44:46	6-10-2011 17:41:30:636	624	jbaskowski	Janet Baskowski	TD_FORM	25942	25942:0	Exhaled CO		2	3	Form Status set to 3
203673	6/13/2011 14:47:13	6-13-2011 14:44:04:748	6603	yovalle57	Yuliana Ovalle	TD_FORM	25922	25922:0	Demographics		3	4	Form Status set to 4
203675	6/13/2011 14:47:18	6-13-2011 14:44:10:445	6603	yovalle57	Yuliana Ovalle	TD_FORM	25924	25924:0	Comprehensive PE		3	4	Form Status set to 4
203676	6/13/2011 14:47:23	6-13-2011 14:44:14:982	6603	yovalle57	Yuliana Ovalle	TD_FORM	25925	25925:0	Vital Signs		3	4	Form Status set to 4
203677	6/13/2011 14:47:26	6-13-2011 14:44:18:310	6603	yovalle57	Yuliana Ovalle	TD_FORM	25927	25927:0	Labs		3	4	Form Status set to 4
203678	6/13/2011 14:47:30	6-13-2011 14:44:22:310	6603	yovalle57	Yuliana Ovalle	TD_FORM	25928	25928:0	Exhaled CO		3	4	Form Status set to 4
203686	6/13/2011 14:48:19	6-13-2011 14:45:10:688	6603	yovalle57	Yuliana Ovalle	TD_FORM	25963	25963:0	Randomization		3	4	Form Status set to 4
207349	6/14/2011 13:42:37	6-14-2011 13:39:33:58	6603	yovalle57	Yuliana Ovalle	TD_FORM	25934	25934:0	Exhaled CO		3	4	Form Status set to 4
207350	6/14/2011 13:42:40	6-14-2011 13:39:36:74	6603	yovalle57	Yuliana Ovalle	TD_FORM	25933	25933:0	Labs		3	4	Form Status set to 4
207351	6/14/2011 13:42:44	6-14-2011 13:39:39:949	6603	yovalle57	Yuliana Ovalle	TD_FORM	25932	25932:0	Vital Signs		3	4	Form Status set to 4
207419	6/14/2011 13:50:29	6-14-2011 13:47:24:168	6603	yovalle57	Yuliana Ovalle	TD_FORM	25938	25938:0	Exhaled CO		3	4	Form Status set to 4

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
207420	6/14/2011 13:50:31	6-14-2011 13:47:26:933	6603	yovalle57	Yuliana Ov- alle	TD_FORM	25936	25936:0	Vital Signs		3	4	Form Status set to 4
207421	6/14/2011 13:50:39	6-14-2011 13:47:35:74	6603	yovalle57	Yuliana Ov- alle	TD_FORM	25937	25937:0	Labs		3	4	Form Status set to 4
207422	6/14/2011 13:50:52	6-14-2011 13:47:47:840	6603	yovalle57	Yuliana Ov- alle	TD_FORM	25942	25942:0	Exhaled CO		3	4	Form Status set to 4
207423	6/14/2011 13:50:55	6-14-2011 13:47:51:74	6603	yovalle57	Yuliana Ov- alle	TD_FORM	25941	25941:0	Labs		3	4	Form Status set to 4
207424	6/14/2011 13:50:58	6-14-2011 13:47:54:121	6603	yovalle57	Yuliana Ov- alle	TD_FORM	25940	25940:0	Vital Signs		3	4	Form Status set to 4
254829	7/1/2011 1-6:40:36	7-1-2011 1-5:37:32:187	461	swampler	Sarah Wa- mpler	TD_EVENT	9300	0:0			05-31-2011	7-1-2011	Event Created
254830	7/1/2011 1-6:41:18	7-1-2011 1-5:38:13:671	461	swampler	Sarah Wa- mpler	TD_FORM	25944	25944:0	Product Usage Q		0	1	Form Status set to 1
254831	7/1/2011 1-6:41:18	7-1-2011 1-5:38:13:671	461	swampler	Sarah Wa- mpler	TD_DATA	184972	25944:755328	Product Usage Q	SC.SCQ1		No	Data Added
254832	7/1/2011 1-6:41:18	7-1-2011 1-5:38:13:671	461	swampler	Sarah Wa- mpler	TD_DATA	184973	25944:755332	Product Usage Q	SC.SCQ2		No	Data Added
254833	7/1/2011 1-6:41:18	7-1-2011 1-5:38:13:671	461	swampler	Sarah Wa- mpler	TD_DATA	184974	25944:755334	Product Usage Q	SC.SCQ3		No	Data Added
254834	7/1/2011 1-6:41:18	7-1-2011 1-5:38:13:671	461	swampler	Sarah Wa- mpler	TD_DATA	184975	25944:755340	Product Usage Q	SC.SCQ4D		true	Data Added
254835	7/1/2011 1-6:41:18	7-1-2011 1-5:38:13:671	461	swampler	Sarah Wa- mpler	TD_DATA	184976	25944:755360	Product Usage Q	SC.SCQ5D		14	Data Added
254836	7/1/2011 1-6:41:18	7-1-2011 1-5:38:13:671	461	swampler	Sarah Wa- mpler	TD_DATA	184977	25944:755385	Product Usage Q	SC.SCQ6D		7	Data Added
269506	7/8/2011 1-5:39:54	7-8-2011 1-4:36:12:81	4907	ssmithhart	Sara Smith- hart	TD_EVENT	9301	0:0			07-05-2011	7-8-2011	Event Created
269507	7/8/2011 1-5:40:39	7-8-2011 1-4:36:57:3	4907	ssmithhart	Sara Smith- hart	TD_FORM	25945	25945:0	Vital Signs		0	1	Form Status set to 1
269508	7/8/2011 1-5:40:39	7-8-2011 1-4:36:57:3	4907	ssmithhart	Sara Smith- hart	TD_DATA	195571	25945:755447	Vital Signs	VS.VSDT		7-8-2011	Data Added
269509	7/8/2011 1-5:40:39	7-8-2011 1-4:36:57:3	4907	ssmithhart	Sara Smith- hart	TD_DATA	195572	25945:755448	Vital Signs	VS.VSTM		13:08	Data Added
269510	7/8/2011 1-5:40:39	7-8-2011 1-4:36:57:3	4907	ssmithhart	Sara Smith- hart	TD_DATA	195573	25945:755455	Vital Signs	VS.VSWT		93.6	Data Added
269511	7/8/2011 1-5:40:39	7-8-2011 1-4:36:57:3	4907	ssmithhart	Sara Smith- hart	TD_DATA	195574	25945:755464	Vital Signs	VS.VSSYS		119	Data Added
269512	7/8/2011 1-5:40:39	7-8-2011 1-4:36:57:3	4907	ssmithhart	Sara Smith- hart	TD_DATA	195575	25945:755466	Vital Signs	VS.VSDIA		59	Data Added
269513	7/8/2011 1-5:40:39	7-8-2011 1-4:36:57:3	4907	ssmithhart	Sara Smith- hart	TD_DATA	195576	25945:755468	Vital Signs	VS.VSHR		61	Data Added
269514	7/8/2011 1-5:40:39	7-8-2011 1-4:36:57:3	4907	ssmithhart	Sara Smith- hart	TD_DATA	195577	25945:755470	Vital Signs	VS.VSRR		18	Data Added
269515	7/8/2011 1-5:40:39	7-8-2011 1-4:36:57:3	4907	ssmithhart	Sara Smith- hart	TD_DATA	195578	25945:755472	Vital Signs	VS.VSTEMP		36.2	Data Added
269516	7/8/2011 1-5:40:39		4907	ssmithhart	Sara Smith- hart	TD_DATA	195579	25945:755458	Vital Signs	VS.VSBMI		25.4	computed value
269536	7/8/2011 1-5:44:21	7-8-2011 1-4:40:39:628	4907	ssmithhart	Sara Smith- hart	TD_FORM	25946	25946:0	Exhaled CO		0	1	Form Status set to 1
269537	7/8/2011 1-5:44:21	7-8-2011 1-4:40:39:628	4907	ssmithhart	Sara Smith- hart	TD_DATA	195580	25946:755475	Exhaled CO	EC.ECYN		Yes	Data Added
269538	7/8/2011 1-5:44:21	7-8-2011 1-4:40:39:628	4907	ssmithhart	Sara Smith- hart	TD_DATA	195581	25946:755477	Exhaled CO	EC.ECDT		7-8-2011	Data Added
269539	7/8/2011 1-5:44:21	7-8-2011 1-4:40:39:628	4907	ssmithhart	Sara Smith- hart	TD_DATA	195582	25946:755478	Exhaled CO	EC.ECTM		13:02	Data Added
269540	7/8/2011 1-5:44:21	7-8-2011 1-4:40:39:628	4907	ssmithhart	Sara Smith- hart	TD_DATA	195583	25946:755482	Exhaled CO	EC.ECRES1		3	Data Added

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
269542	7/8/2011 1-5:44:38	7-8-2011 1-4:40:56.674	4907	ssmithhart	Sara Smith-hart	TD_FORM	25947	25947:0	Labs		0	1	Form Status set to 1
269543	7/8/2011 1-5:44:38	7-8-2011 1-4:40:56.674	4907	ssmithhart	Sara Smith-hart	TD_DATA	195584	25947:755487	Labs	LB.LBBLDT		7-8-2011	Data Added
269544	7/8/2011 1-5:44:38	7-8-2011 1-4:40:56.674	4907	ssmithhart	Sara Smith-hart	TD_DATA	195585	25947:755488	Labs	LB.LBBLTM		13:18	Data Added
269545	7/8/2011 1-5:44:38	7-8-2011 1-4:40:56.674	4907	ssmithhart	Sara Smith-hart	TD_DATA	195586	25947:755496	Labs	LB.LBUCS		N/A (Male)	Data Added
269556	7/8/2011 1-5:48:33	7-8-2011 1-4:44:51:596	4907	ssmithhart	Sara Smith-hart	TD_FORM	25948	25948:0	Oral Assessment		0	1	Form Status set to 1
269557	7/8/2011 1-5:48:33	7-8-2011 1-4:44:51:596	4907	ssmithhart	Sara Smith-hart	TD_DATA	195587	25948:755502	Oral Assessment	PE.PEORAL		Abnormal	Data Added
269558	7/8/2011 1-5:48:33	7-8-2011 1-4:44:51:596	4907	ssmithhart	Sara Smith-hart	TD_DATA	195588	25948:755503	Oral Assessment	PE.PEORALSP		small irritated red area inner molar gumline (upper) on right. Some increased injection overall (between first and second molar)	Data Added
281669	7/18/2011 15:48:17	7-18-2011 14:44:13.234	4909	rcajigas	Rafael Cajigas	TD_FORM	25945	25945:0	Vital Signs		1	2	Form Status set to 2
281670	7/18/2011 15:48:19	7-18-2011 14:44:15.875	4909	rcajigas	Rafael Cajigas	TD_FORM	25946	25946:0	Exhaled CO		1	2	Form Status set to 2
281671	7/18/2011 15:48:22	7-18-2011 14:44:18.406	4909	rcajigas	Rafael Cajigas	TD_FORM	25947	25947:0	Labs		1	2	Form Status set to 2
281672	7/18/2011 15:48:25	7-18-2011 14:44:22.15	4909	rcajigas	Rafael Cajigas	TD_FORM	25948	25948:0	Oral Assessment		1	2	Form Status set to 2
281694	7/18/2011 15:51:8	7-18-2011 14:47:04.296	4909	rcajigas	Rafael Cajigas	TD_FORM	25944	25944:0	Product Usage Q		1	2	Form Status set to 2
295713	8/3/2011 7:52:10	8-3-2011 7:48:03.94	624	jbaskowski	Janet Baskowski	TD_FORM	25944	25944:0	Product Usage Q		2	3	Form Status set to 3
295714	8/3/2011 7:52:40	8-3-2011 7:48:32.896	624	jbaskowski	Janet Baskowski	TD_FORM	25945	25945:0	Vital Signs		2	3	Form Status set to 3
295715	8/3/2011 7:52:55	8-3-2011 7:48:48.58	624	jbaskowski	Janet Baskowski	TD_FORM	25946	25946:0	Exhaled CO		2	3	Form Status set to 3
295716	8/3/2011 7:53:29	8-3-2011 7:49:21.789	624	jbaskowski	Janet Baskowski	TD_FORM	25947	25947:0	Labs		2	3	Form Status set to 3
312472	8/24/2011 12:47:5	8-24-2011 12:43:00.273	6603	yovalle57	Yuliana Ovalle	TD_FORM	25945	25945:0	Vital Signs		3	4	Form Status set to 4
312473	8/24/2011 12:47:9	8-24-2011 12:43:03.867	6603	yovalle57	Yuliana Ovalle	TD_FORM	25946	25946:0	Exhaled CO		3	4	Form Status set to 4
312474	8/24/2011 12:47:11	8-24-2011 12:43:06.180	6603	yovalle57	Yuliana Ovalle	TD_FORM	25947	25947:0	Labs		3	4	Form Status set to 4
337844	9/7/2011 1-5:56:22	9-7-2011 1-5:52:04:276	6603	yovalle57	Yuliana Ovalle	TD_FORM	25944	25944:0	Product Usage Q		3	4	Form Status set to 4
356156	9/23/2011 10:19:4	9-23-2011 10:14:41.797	624	jbaskowski	Janet Baskowski	TD_FORM	25931	25931:0	Test Product Allot		2	3	Form Status set to 3
367395	10/5/2011 14:12:33	10-5-2011 13:07:54:171	4909	rcajigas	Rafael Cajigas	TD_EVENT	9302	0:0				10-5-2011	Event Created
367396	10/5/2011 14:12:50	10-5-2011 13:08:11:875	4909	rcajigas	Rafael Cajigas	TD_FORM	25949	25949:0	Product Usage Q		0	1	Form Status set to 1
367397	10/5/2011 14:12:50	10-5-2011 13:08:11:875	4909	rcajigas	Rafael Cajigas	TD_DATA	241121	25949:755506	Product Usage Q	SC.SCQ1		No	Data Added
367398	10/5/2011 14:12:50	10-5-2011 13:08:11:875	4909	rcajigas	Rafael Cajigas	TD_DATA	241122	25949:755510	Product Usage Q	SC.SCQ2		No	Data Added
367399	10/5/2011 14:12:50	10-5-2011 13:08:11:875	4909	rcajigas	Rafael Cajigas	TD_DATA	241123	25949:755512	Product Usage Q	SC.SCQ3		No	Data Added
367400	10/5/2011 14:13:39	10-5-2011 13:09:00:750	4909	rcajigas	Rafael Cajigas	TD_FORM	25949	25949:0	Product Usage Q		1	2	Form Status set to 2
369166	10/7/2011 9:44:49	10-7-2011 9:40:11:327	6603	yovalle57	Yuliana Ovalle	TD_FORM	25931	25931:0	Test Product Allot		3	4	Form Status set to 4
377945	10/17/2011 10:55:39	10-17-2011 9:50:38:703	4909	rcajigas	Rafael Cajigas	TD_EVENT	9303	0:0				10-14-2011	Event Created

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
377946	10/17/2011 10:56:0	10-17-2011 9:51:00:390	4909	rcajigas	Rafael Cajigas	TD_FORM	25950	25950:0	Vital Signs		0	1	Form Status set to 1
377947	10/17/2011 10:56:1	10-17-2011 9:51:00:390	4909	rcajigas	Rafael Cajigas	TD_DATA	243544	25950:755624	Vital Signs	VS.VSDT		10-14-2011	Data Added
377948	10/17/2011 10:56:1	10-17-2011 9:51:00:390	4909	rcajigas	Rafael Cajigas	TD_DATA	243545	25950:755625	Vital Signs	VS.VSTM		14:38	Data Added
377949	10/17/2011 10:56:1	10-17-2011 9:51:00:390	4909	rcajigas	Rafael Cajigas	TD_DATA	243546	25950:755632	Vital Signs	VS.VSSYS		135	Data Added
377950	10/17/2011 10:56:1	10-17-2011 9:51:00:390	4909	rcajigas	Rafael Cajigas	TD_DATA	243547	25950:755634	Vital Signs	VS.VSDIA		79	Data Added
377951	10/17/2011 10:56:1	10-17-2011 9:51:00:390	4909	rcajigas	Rafael Cajigas	TD_DATA	243548	25950:755636	Vital Signs	VS.VSHR		70	Data Added
377952	10/17/2011 10:56:1	10-17-2011 9:51:00:390	4909	rcajigas	Rafael Cajigas	TD_DATA	243549	25950:755638	Vital Signs	VS.VSRR		19	Data Added
377953	10/17/2011 10:56:1	10-17-2011 9:51:00:390	4909	rcajigas	Rafael Cajigas	TD_DATA	243550	25950:755640	Vital Signs	VS.VSTEMP		36.3	Data Added
377954	10/17/2011 10:56:23	10-17-2011 9:51:22:765	4909	rcajigas	Rafael Cajigas	TD_FORM	25951	25951:0	Exhaled CO		0	1	Form Status set to 1
377955	10/17/2011 10:56:23	10-17-2011 9:51:22:765	4909	rcajigas	Rafael Cajigas	TD_DATA	243551	25951:755644	Exhaled CO	EC.ECYN		Yes	Data Added
377956	10/17/2011 10:56:23	10-17-2011 9:51:22:765	4909	rcajigas	Rafael Cajigas	TD_DATA	243552	25951:755646	Exhaled CO	EC.ECDT		10-14-2011	Data Added
377957	10/17/2011 10:56:23	10-17-2011 9:51:22:765	4909	rcajigas	Rafael Cajigas	TD_DATA	243553	25951:755647	Exhaled CO	EC.ECTM		14:42	Data Added
377958	10/17/2011 10:56:23	10-17-2011 9:51:22:765	4909	rcajigas	Rafael Cajigas	TD_DATA	243554	25951:755651	Exhaled CO	EC.ECRES1		13	Data Added
377959	10/17/2011 10:56:28	10-17-2011 9:51:27:750	4909	rcajigas	Rafael Cajigas	TD_FORM	25952	25952:0	Labs		0	1	Form Status set to 1
377960	10/17/2011 10:56:28	10-17-2011 9:51:27:750	4909	rcajigas	Rafael Cajigas	TD_DATA	243555	25952:755654	Labs	LB.LBBSAMP		true	Data Added
377961	10/17/2011 10:56:28	10-17-2011 9:51:27:750	4909	rcajigas	Rafael Cajigas	TD_DATA	243556	25952:755665	Labs	LB.LBUCS		N/A (Male)	Data Added
377981	10/17/2011 11:4:56	10-17-2011 9:59:56:328	4909	rcajigas	Rafael Cajigas	TD_EVENT	9307	0:0					Shared Event Added
377982	10/17/2011 11:5:4	10-17-2011 10:00:03:765	4909	rcajigas	Rafael Cajigas	TD_FORM	25958	25958:0	Adverse Events		0	2	Form Status set to 2
377983	10/17/2011 11:5:4	10-17-2011 10:00:03:765	4909	rcajigas	Rafael Cajigas	TD_FORM	25958	25958:0	Adverse Events		0	1	Form Checked Intentionally Left Blank
377984	10/17/2011 11:5:9	10-17-2011 10:00:09:218	4909	rcajigas	Rafael Cajigas	TD_EVENT	9309	0:0					Shared Event Added
377985	10/17/2011 11:5:30	10-17-2011 10:00:30:218	4909	rcajigas	Rafael Cajigas	TD_FORM	25961	25961:0	Prtcl Deviations		0	1	Form Status set to 1
377986	10/17/2011 11:5:30	10-17-2011 10:00:30:218	4909	rcajigas	Rafael Cajigas	TD_DATA	243561	25961:756040	Prtcl Deviations	PV.PVDT		10-14-2011	Data Added
377987	10/17/2011 11:5:30	10-17-2011 10:00:30:218	4909	rcajigas	Rafael Cajigas	TD_DATA	243562	25961:756041	Prtcl Deviations	PV.PVCAT		Study Procedures	Data Added
377988	10/17/2011 11:5:30	10-17-2011 10:00:30:218	4909	rcajigas	Rafael Cajigas	TD_DATA	243563	25961:756042	Prtcl Deviations	PV.PVSPEC		Subject blew a 13 on his ECO test at V5	Data Added
377989	10/17/2011 11:5:44	10-17-2011 10:00:44:265	4909	rcajigas	Rafael Cajigas	TD_EVENT	9312	0:0				10-14-2011	Event Created
377990	10/17/2011 11:5:56	10-17-2011 10:00:55:921	4909	rcajigas	Rafael Cajigas	TD_FORM	25964	25964:0	Study Conclusion		0	1	Form Status set to 1
377991	10/17/2011 11:5:56	10-17-2011 10:00:55:921	4909	rcajigas	Rafael Cajigas	TD_DATA	243564	25964:756110	Study Conclusion	DS.DSETSC		Discontinued prior to completion of the study	Data Added
377992	10/17/2011 11:5:56	10-17-2011 10:00:55:921	4909	rcajigas	Rafael Cajigas	TD_DATA	243565	25964:756112	Study Conclusion	DS.DSETSCDT		10-14-2011	Data Added
377993	10/17/2011 11:5:56	10-17-2011 10:00:55:921	4909	rcajigas	Rafael Cajigas	TD_DATA	243566	25964:756114	Study Conclusion	DS.DSETREAS		Protocol Violation	Data Added

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
378018	10/17/2011 13:23:25	10-17-2011 12:18:25:781	4909	rcajigas	Rafael Cajigas	TD_FORM	25950	25950:0	Vital Signs		1	2	Form Status set to 2
378022	10/17/2011 13:23:28	10-17-2011 12:18:28:93	4909	rcajigas	Rafael Cajigas	TD_FORM	25951	25951:0	Exhaled CO		1	2	Form Status set to 2
378023	10/17/2011 13:23:30	10-17-2011 12:18:30:718	4909	rcajigas	Rafael Cajigas	TD_FORM	25952	25952:0	Labs		1	2	Form Status set to 2
378024	10/17/2011 13:23:45	10-17-2011 12:18:45:640	4909	rcajigas	Rafael Cajigas	TD_FORM	25961	25961:0	Prtcl Deviations		1	2	Form Status set to 2
378025	10/17/2011 13:24:2	10-17-2011 12:19:02:765	4909	rcajigas	Rafael Cajigas	TD_FORM	25964	25964:0	Study Conclusion		1	2	Form Status set to 2
384413	10/27/2011 13:14:37	10-27-2011 13:09:10:540	624	jbaskowski	Janet Baskowski	TD_FORM	25949	25949:0	Product Usage Q		2	3	Form Status set to 3
384415	10/27/2011 13:15:20	10-27-2011 13:09:52:628	624	jbaskowski	Janet Baskowski	TD_FORM	25950	25950:0	Vital Signs		2	3	Form Status set to 3
384417	10/27/2011 13:15:37	10-27-2011 13:10:10:250	624	jbaskowski	Janet Baskowski	TD_FORM	25951	25951:0	Exhaled CO		2	3	Form Status set to 3
384419	10/27/2011 13:15:58	10-27-2011 13:10:31:501	624	jbaskowski	Janet Baskowski	TD_FORM	25952	25952:0	Labs		2	3	Form Status set to 3
384421	10/27/2011 13:16:43	10-27-2011 13:11:15:759	624	jbaskowski	Janet Baskowski	TD_FORM	25964	25964:0	Study Conclusion		2	3	Form Status set to 3
385481	10/28/2011 15:28:33	10-28-2011 15:23:06:952	6604	rtillman26	Roscoe Tillman	TD_FORM	25949	25949:0	Product Usage Q		3	4	Form Status set to 4
385498	10/28/2011 15:34:27	10-28-2011 15:29:01:640	6604	rtillman26	Roscoe Tillman	TD_FORM	25952	25952:0	Labs		3	4	Form Status set to 4
385499	10/28/2011 15:34:58	10-28-2011 15:29:32:233	6604	rtillman26	Roscoe Tillman	TD_FORM	25951	25951:0	Exhaled CO		3	4	Form Status set to 4
385500	10/28/2011 15:35:3	10-28-2011 15:29:36:952	6604	rtillman26	Roscoe Tillman	TD_FORM	25950	25950:0	Vital Signs		3	4	Form Status set to 4
385721	10/31/2011 12:49:36	10-31-2011 12:44:19:762	6604	rtillman26	Roscoe Tillman	TD_FORM	25964	25964:0	Study Conclusion		3	4	Form Status set to 4
400323	11/17/2011 21:37:9	11-17-2011 21:32:59:416	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25923	25923:0	Brief Med. History		2	3	Form Status set to 3
400324	11/17/2011 21:37:38	11-17-2011 21:33:27:604	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25922	25922:0	Demographics		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400325	11/17/2011 21:37:48	11-17-2011 21:33:37:746	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25925	25925:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400326	11/17/2011 21:37:50	11-17-2011 21:33:40:187	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25926	25926:0	ECG		2	3	Form Status set to 3
400327	11/17/2011 21:38:0	11-17-2011 21:33:49:429	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25928	25928:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400328	11/17/2011 21:38:57	11-17-2011 21:34:46:620	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25929	25929:0	UB Descriptors		2	3	Form Status set to 3
400329	11/17/2011 21:39:0	11-17-2011 21:34:49:881	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25929	25929:0	UB Descriptors		3	2	Form Status demoted to 2
400330	11/17/2011 21:39:3	11-17-2011 21:34:53:2	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25929	25929:0	UB Descriptors		2	3	Form Status set to 3
400331	11/17/2011 21:39:15	11-17-2011 21:35:04:955	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25924	25924:0	Comprehensive PE		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400332	11/17/2011 21:39:21	11-17-2011 21:35:10:577	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25930	25930:0	Inc/Exc		2	3	Form Status set to 3
400333	11/17/2011 21:39:59	11-17-2011 21:35:48:344	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25932	25932:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400334	11/17/2011 21:40:6	11-17-2011 21:35:55:977	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25934	25934:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400335	11/17/2011 21:40:22	11-17-2011 21:36:11:893	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25935	25935:0	Test Product Allot		2	3	Form Status set to 3
400336	11/17/2011 21:40:44	11-17-2011 21:36:33:910	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25963	25963:0	Randomization		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
400337	11/17/2011 21:41:23	11-17-2011 21:37:12:871	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25936	25936:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400338	11/17/2011 21:41:31	11-17-2011 21:37:20:954	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25938	25938:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400339	11/17/2011 21:43:51	11-17-2011 21:39:41:173	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25940	25940:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400340	11/17/2011 21:43:59	11-17-2011 21:39:48:407	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25942	25942:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400341	11/17/2011 21:45:13	11-17-2011 21:41:02:946	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25943	25943:0	Test Product Allot		2	3	Form Status set to 3
400342	11/17/2011 21:45:55	11-17-2011 21:41:44:728	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25945	25945:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400343	11/17/2011 21:46:2	11-17-2011 21:41:51:905	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25946	25946:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400344	11/17/2011 22:16:46	11-17-2011 22:12:35:455	0	elise_ho_jung-@msn.com		TD_FORM	25950	25950:0	Vital Signs				Form Sign attempt unsuccessful. That password is not recognized. Please try again.
400345	11/17/2011 22:17:14	11-17-2011 22:13:03:922	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25950	25950:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400346	11/17/2011 22:17:23	11-17-2011 22:13:12:444	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25951	25951:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
400347	11/17/2011 22:17:57	11-17-2011 22:13:46:292	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25960	25960:0	Con Meds		2	3	Form Status set to 3
401043	11/18/2011 13:22:26	11-18-2011 13:18:10:686	6603	yovalle57	Yuliana Ov-alle	TD_FORM	25923	25923:0	Brief Med. History		3	4	Form Status set to 4
401044	11/18/2011 13:22:28	11-18-2011 13:18:13:311	6603	yovalle57	Yuliana Ov-alle	TD_FORM	25926	25926:0	ECG		3	4	Form Status set to 4
401045	11/18/2011 13:22:32	11-18-2011 13:18:17:264	6603	yovalle57	Yuliana Ov-alle	TD_FORM	25930	25930:0	Inc/Exc		3	4	Form Status set to 4
401064	11/18/2011 13:25:15	11-18-2011 13:21:00:809	6603	yovalle57	Yuliana Ov-alle	TD_FORM	25943	25943:0	Test Product Allot		3	4	Form Status set to 4
401066	11/18/2011 13:25:31	11-18-2011 13:21:16:325	6603	yovalle57	Yuliana Ov-alle	TD_FORM	25935	25935:0	Test Product Allot		3	4	Form Status set to 4
403222	11/21/2011 11:48:23	11-21-2011 10:43:17:816	4909	rcajigas	Rafael Cajigas	TD_FORM	25939	25939:0	Test Product Allot		2	1	Form Status demoted to 1
403223	11/21/2011 11:48:23	11-21-2011 10:43:17:816	4909	rcajigas	Rafael Cajigas	TD_DATA	90996	25939:755276	Test Product Allot	PU.PURET	11	6	Incorrect data
403224	11/21/2011 11:48:25	11-21-2011 10:43:20:191	4909	rcajigas	Rafael Cajigas	TD_FORM	25939	25939:0	Test Product Allot		1	2	Form Status set to 2
421855	1/13/2012 12:15:45	1-13-2012 11:11:36:187	4909	rcajigas	Rafael Cajigas	TD_FORM	25958	25958:0	Adverse Events		2	1	Form Status set to 1
421856	1/13/2012 12:15:45	1-13-2012 11:11:36:187	4909	rcajigas	Rafael Cajigas	TD_FORM	25958	25958:0	Adverse Events		1	0	Form Unchecked Intentionally Left Blank
421857	1/13/2012 12:15:45	1-13-2012 11:11:36:187	4909	rcajigas	Rafael Cajigas	TD_DATA	252868	25958:755958	Adverse Events	AE.AETERM			Small irritated red area inner molar gumline (upper) Right. Some increased injection overall (between 1st and 2nd molar) - NCS
421858	1/13/2012 12:15:45	1-13-2012 11:11:36:187	4909	rcajigas	Rafael Cajigas	TD_DATA	252869	25958:755962	Adverse Events	AE.AESTDT		7-8-2011	Data Added
421859	1/13/2012 12:15:45	1-13-2012 11:11:36:187	4909	rcajigas	Rafael Cajigas	TD_DATA	252870	25958:755965	Adverse Events	AE.AESTTM		13:15	Data Added
421860	1/13/2012 12:15:45	1-13-2012 11:11:36:187	4909	rcajigas	Rafael Cajigas	TD_DATA	252871	25958:755970	Adverse Events	AE.AESEV		Mild	Data Added
421861	1/13/2012 12:15:45	1-13-2012 11:11:36:187	4909	rcajigas	Rafael Cajigas	TD_DATA	252872	25958:755972	Adverse Events	AE.AEACT		None	Data Added
421862	1/13/2012	1-13-2012	4909	rcajigas	Rafael Cajigas	TD_DATA	252873	25958:755974	Adverse Events	AE.AETRT		No	Data Added

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
421865	1/13/2012 12:15:49		4909	rcajigas	Rafael Cajigas	TD_DATA	252876	25959:755986	AE Code	AE.TERM		Small irritated red area inner molar gumline (upper) Right. Some increased injection overall (between 1st and 2nd molar) - NCS	computed value
421866	1/13/2012 12:15:49		4909	rcajigas	Rafael Cajigas	TD_DATA	252877	25959:755984	AE Code	AE.AEDESC		Small irritated red area inner molar gumline (upper) Right. Some increased injection overall (between 1st and 2nd molar) - NCS	computed value
421867	1/13/2012 12:15:50		4909	rcajigas	Rafael Cajigas	TD_DATA	252878	25959:755988	AE Code	AE.RSLT1		Sorry, no results were found.	computed value
421868	1/13/2012 12:15:50		4909	rcajigas	Rafael Cajigas	TD_DATA	252879	25959:755990	AE Code	AE.RSLT2			computed value
421869	1/13/2012 12:15:50		4909	rcajigas	Rafael Cajigas	TD_DATA	252880	25959:755992	AE Code	AE.RSLT3			computed value
421870	1/13/2012 12:15:50		4909	rcajigas	Rafael Cajigas	TD_DATA	252881	25959:755994	AE Code	AE.RSLT4			computed value
421871	1/13/2012 12:15:50		4909	rcajigas	Rafael Cajigas	TD_DATA	252882	25959:755989	AE Code	AE.CODE1			computed value
421872	1/13/2012 12:15:50		4909	rcajigas	Rafael Cajigas	TD_DATA	252883	25959:755991	AE Code	AE.CODE2			computed value
421873	1/13/2012 12:15:50		4909	rcajigas	Rafael Cajigas	TD_DATA	252884	25959:755993	AE Code	AE.CODE3			computed value
421874	1/13/2012 12:15:50		4909	rcajigas	Rafael Cajigas	TD_DATA	252885	25959:755995	AE Code	AE.CODE4			computed value
421875	1/13/2012 12:17:40	1-13-2012 11:13:31:812	4909	rcajigas	Rafael Cajigas	TD_FORM	25961	25961:0	Prtcl Deviations		2	1	Form Status demoted to 1
421876	1/13/2012 12:17:40	1-13-2012 11:13:31:812	4909	rcajigas	Rafael Cajigas	TD_DATA	243561	25961:756040	Prtcl Deviations	PV.PVDT	10-14-2011	--	Corrected as per query
421877	1/13/2012 12:17:40	1-13-2012 11:13:31:812	4909	rcajigas	Rafael Cajigas	TD_DATA	243562	25961:756041	Prtcl Deviations	PV.PVCAT	Study Procedures		Corrected as per query
421878	1/13/2012 12:17:40	1-13-2012 11:13:31:812	4909	rcajigas	Rafael Cajigas	TD_DATA	243563	25961:756042	Prtcl Deviations	PV.PVSPEC	Subject blew a 13 on his ECO test at V5		Corrected as per query
421879	1/13/2012 12:17:48	1-13-2012 11:13:39:687	4909	rcajigas	Rafael Cajigas	TD_FORM	25961	25961:0	Prtcl Deviations		1	0	Form Status demoted to 0 Reason : Corrected as per query
421880	1/13/2012 12:17:48	1-13-2012 11:13:39:687	4909	rcajigas	Rafael Cajigas	TD_DATA	243561	25961:756040	Prtcl Deviations	PV.PVDT	--		Corrected as per query
421881	1/13/2012 12:17:48	1-13-2012 11:13:39:687	4909	rcajigas	Rafael Cajigas	TD_DATA	243562	25961:756041	Prtcl Deviations	PV.PVCAT			Corrected as per query
421882	1/13/2012 12:17:48	1-13-2012 11:13:39:687	4909	rcajigas	Rafael Cajigas	TD_DATA	243563	25961:756042	Prtcl Deviations	PV.PVSPEC			Corrected as per query
421883	1/13/2012 12:17:54	1-13-2012 11:13:46:140	4909	rcajigas	Rafael Cajigas	TD_FORM	25961	25961:0	Prtcl Deviations		0	2	Form Status set to 2
421884	1/13/2012 12:17:54	1-13-2012 11:13:46:140	4909	rcajigas	Rafael Cajigas	TD_FORM	25961	25961:0	Prtcl Deviations		0	1	Form Checked Intentionally Left Blank
421885	1/13/2012 12:21:41	1-13-2012 11:17:32:828	4909	rcajigas	Rafael Cajigas	TD_FORM	25964	25964:0	Study Conclusion		4	2	Form Status demoted to 2
421886	1/13/2012 12:21:41	1-13-2012 11:17:32:828	4909	rcajigas	Rafael Cajigas	TD_DATA	243566	25964:756114	Study Conclusion	DS.DSETREAS	Protocol Violation	Other	Corrected as per query
421887	1/13/2012 12:21:41	1-13-2012 11:17:32:828	4909	rcajigas	Rafael Cajigas	TD_DATA	252886	25964:756116	Study Conclusion	DS.DSETSP		Subject states abstinent from smoking, but with >.8 ECO at visit 5	Data Added
436445	2/27/2012 12:36:50	2-27-2012 12:31:17:240	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25939	25939:0	Test Product Allot		2	3	Form Status set to 3
436451	2/27/2012 12:39:30	2-27-2012 12:33:57:464	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25964	25964:0	Study Conclusion				Form Sign attempt unsuccessful. That password is not recognized. Please try again.
436452	2/27/2012 12:39:49	2-27-2012 12:34:16:458	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	25964	25964:0	Study Conclusion		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
440072	3/15/2012 13:50:14	3-15-2012 13:45:41:468	6603	yovalle57	Yuliana Ov-alle	TD_FORM	25960	25960:0	Con Meds		3	4	Form Status set to 4
440083	3/15/2012 13:54:9	3-15-2012 13:49:36:762	6603	yovalle57	Yuliana Ov-alle	TD_FORM	25939	25939:0	Test Product Allot		3	4	Form Status set to 4
447913	4/23/2012 13:18:0	4-23-2012 13:12:43:902	7302	jgottliebco	Joanne Gottlieb	TD_FORM	25959	25959:0	AE Code		0	1	Form Status set to 1

AUDIT TRAIL													
ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
447914	4/23/2012 13:18:0	4-23-2012 13:12:43:902	7302	jgottliebco	Joanne Gottlieb	TD_DATA	252876	25959:755986	AE Code	AE.TERM	Small irritated red area inner molar gumline (upper) Right. Some increased injection overall (between 1st and 2nd molar) - NCS	irritated gumline	Requires update
447915	4/23/2012 13:18:1		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252878	25959:755988	AE Code	AE.RSLT1	Sorry, no results were found.	Feeling irritated Irritability 10022998 Behaviour and socialisation disturbances Personality disorders and disturbances in behaviour Psychiatric disorders 13.1	computed value
447916	4/23/2012 13:18:1		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252879	25959:755990	AE Code	AE.RSLT2		Feeling irritated Irritability 10022998 General signs and symptoms NEC General system disorders NEC General disorders and administration site conditions 13.1	computed value
447917	4/23/2012 13:18:1		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252880	25959:755992	AE Code	AE.RSLT3		Pain irritated Pain 10033371 Pain and discomfort NEC General system disorders NEC General disorders and administration site conditions 13.1	computed value
447918	4/23/2012 13:18:1		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252881	25959:755994	AE Code	AE.RSLT4		Pharynx irritated sensation of Throat irritation 10043521 Oral soft tissue pain and paraesthesia Oral soft tissue conditions Gastrointestinal disorders 13.1	computed value
447919	4/23/2012 13:18:1		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252882	25959:755989	AE Code	AE.CODE1		10016337	computed value
447920	4/23/2012 13:18:1		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252883	25959:755991	AE Code	AE.CODE2		10016337	computed value
447921	4/23/2012 13:18:1		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252884	25959:755993	AE Code	AE.CODE3		10033454	computed value
447922	4/23/2012 13:18:1		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252885	25959:755995	AE Code	AE.CODE4		10034855	computed value
447923	4/23/2012 13:19:17	4-23-2012 13:13:57:521	7302	jgottliebco	Joanne Gottlieb	TD_DATA	252876	25959:755986	AE Code	AE.TERM	irritated gumline	red irritated gumline	Requires update
447924	4/23/2012 13:19:17		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252878	25959:755988	AE Code	AE.RSLT1	Feeling irritated Irritability 10022998 Behaviour and socialisation disturbances Personality disorders and disturbances in behaviour Psychiatric disorders 13.1	Abnormality of red blood cells Red blood cell abnormality 10061548 Red blood cell abnormal findings NEC Red blood cell disorders Blood and lymphatic system disorders 13.1	computed value
447925	4/23/2012 13:19:17		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252879	25959:755990	AE Code	AE.RSLT2	Feeling irritated Irritability 10022998 General signs and symptoms NEC General system disorders NEC General disorders and administration site conditions 13.1	Nucleated red cells Nucleated red cells 10029825 Red blood cell abnormal findings NEC Red blood cell disorders Blood and lymphatic system disorders 13.1	computed value
447926	4/23/2012 13:19:17		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252880	25959:755992	AE Code	AE.RSLT3	Pain irritated Pain 10033371 Pain and discomfort NEC General system disorders NEC General disorders and administration site conditions 13.1	Red blood cell abnormalities (excl anaemia) Red blood cell abnormality 10061548 Red blood cell abnormal findings NEC Red blood cell disorders Blood and lymphatic system disorders 13.1	computed value
447927	4/23/2012 13:19:17		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252881	25959:755994	AE Code	AE.RSLT4	Pharynx irritated sensation of Throat irritation 10043521 Oral soft tissue pain and paraesthesia Oral soft tissue conditions Gastrointestinal disorders 13.1	Red blood cell abnormality NOS Red blood cell abnormality 10061548 Red blood cell abnormal findings NEC Red blood cell disorders Blood and lymphatic system disorders 13.1	computed value
447928	4/23/2012 13:19:17		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252882	25959:755989	AE Code	AE.CODE1	10016337	10000202	computed value
447929	4/23/2012 13:19:17		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252883	25959:755991	AE Code	AE.CODE2	10016337	10029825	computed value
447930	4/23/2012 13:19:17		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252884	25959:755993	AE Code	AE.CODE3	10033454	10038145	computed value
447931	4/23/2012 13:19:17		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252885	25959:755995	AE Code	AE.CODE4	10034855	10038146	computed value
448329	4/23/2012 14:41:52	4-23-2012 14:36:35:762	7302	jgottliebco	Joanne Gottlieb	TD_DATA	252876	25959:755986	AE Code	AE.TERM	red irritated gumline	red irritated inner molar gumline	Requires update
448330	4/23/2012 14:41:52		7302	jgottliebco	Joanne Gottlieb	TD_DATA	252878	25959:755988	AE Code	AE.RSLT1	Abnormality of red blood cells Red blood cell abnormality 10061548 Red blood cell abnormal findings NEC Red blood cell disorders Blood and lymphatic system disorders 13.1	Acute inflammation of the inner ear Inner ear inflammation 10066966 Inner ear infections and inflammations Inner ear and VIIIth cranial nerve disorders Ear and labyrinth disorders 13.1	computed value

AUDIT TRAIL													
ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
448391	4/23/2012 14:47:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	252879	25959:755990	AE Code	AE.RSLT2	Inflammation of the inner ear(s) Inner ear inflammation 10066966 Inner ear infections and inflammations Inner ear and VIIIth cranial nerve disorders Ear and labyrinth disorders 13.1	Application site irritation Application site irritation 10003046 Application and instillation site reactions Administration site reactions General disorders and administration site conditions 13.1	computed value
448392	4/23/2012 14:47:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	252880	25959:755992	AE Code	AE.RSLT3	Inner ear disorder NOS Inner ear disorders NEC Inner ear and VIIIth cranial nerve disorders Ear and labyrinth disorders 13.1	Application site irritation Application site irritation 10003046 Application and instillation site reactions Administration site reactions Injury, poisoning and procedural complications 13.1	computed value
448393	4/23/2012 14:47:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	252881	25959:755994	AE Code	AE.RSLT4	Inner ear disorder Inner ear disorder 10061524 Inner ear disorders NEC Inner ear and VIIIth cranial nerve disorders Ear and labyrinth disorders 13.1	Bladder irritation Bladder irritation 10005052 Bladder and urethral symptoms Urinary tract signs and symptoms Renal and urinary disorders 13.1	computed value
448394	4/23/2012 14:47:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	252882	25959:755989	AE Code	AE.CODE1		10000816	computed value
448395	4/23/2012 14:47:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	252883	25959:755991	AE Code	AE.CODE2		10021964	computed value
448396	4/23/2012 14:47:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	252884	25959:755993	AE Code	AE.CODE3		10049276	computed value
448397	4/23/2012 14:47:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	252885	25959:755995	AE Code	AE.CODE4		10061524	computed value
448398	4/23/2012 14:48:9	4-23-2012 14:42:53:180	7302	igottliebco	Joanne Gottlieb	TD_DATA	260505	25959:755987	AE Code	AE.CHOICE		1	Data Added
448399	4/23/2012 14:48:9	4-23-2012 14:42:53:180	7302	igottliebco	Joanne Gottlieb	TD_DATA	252875	25959:755997	AE Code	AE.CODECPLT		true	Requires update
448400	4/23/2012 14:48:10		7302	igottliebco	Joanne Gottlieb	TD_DATA	252878	25959:755988	AE Code	AE.RSLT1	Irritation gum Gingival pain 10018286 Gingival pains Dental and gingival conditions Gastrointestinal disorders 13.1	** Irritation gum Gingival pain 10018286 Gingival pains Dental and gingival conditions Gastrointestinal disorders 13.1	computed value
459090	6/20/2012 16:5:5	6-20-2012 15:59:11:471	551	yovalle	Yulina Ovalle	TD_FORM	25929	25929:0	UB Descriptors		3	4	Form Status set to 4
469167	8/7/2012 1-5:2:23	8-7-2012 1-3:56:17:975	4909	rcajigas	Rafael Cajigas	TD_DATA	267944	25961:756040	Prtcl Deviations	PV.PVDT		7-8-2011	Data Added
469168	8/7/2012 1-5:2:23	8-7-2012 1-3:56:17:975	4909	rcajigas	Rafael Cajigas	TD_DATA	267945	25961:756041	Prtcl Deviations	PV.PVCAT		Other	Data Added
469169	8/7/2012 1-5:2:23	8-7-2012 1-3:56:17:975	4909	rcajigas	Rafael Cajigas	TD_DATA	267946	25961:756042	Prtcl Deviations	PV.PVSPEC		AE from visit 4 oral assessment (small irritated red area inner molar gumline (upper on right). Some increased injection overall (between 1st and 2nd molar) - was not followed to resolution in error	Data Added
476221	9/2/2012 2-3:22:25	9-2-2012 2-3:15:48:710	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	25961	25961:0	Prtcl Deviations		2	3	Form Status set to 3
476316	9/3/2012 1-5:57:48	9-3-2012 1-5:52:03:656	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	25948	25948:0	Oral Assessment		2	3	Form Status set to 3
476317	9/3/2012 1-5:58:13	9-3-2012 1-5:52:28:562	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	25948	25948:0	Oral Assessment		3	2	Form Status demoted to 2
477239	9/5/2012 1-6:20:17	9-5-2012 1-6:13:50:869	6603	yovalle57	Yuliana Ovalle	TD_FORM	25961	25961:0	Prtcl Deviations		3	4	Form Status set to 4
478284	9/11/2012 10:22:42	9-11-2012 9:15:40:265	4909	rcajigas	Rafael Cajigas	TD_FORM	25961	25961:0	Prtcl Deviations		4	1	Form Status set to 1
478285	9/11/2012 10:22:42	9-11-2012 9:15:40:265	4909	rcajigas	Rafael Cajigas	TD_FORM	25961	25961:0	Prtcl Deviations		1	0	Form Unchecked Intentionally Left Blank
478286	9/11/2012 10:22:42	9-11-2012 9:15:40:578	4909	rcajigas	Rafael Cajigas	TD_FORM	77904	77904:0	Prtcl Deviations				Repeating Form Created
478287	9/11/2012 10:22:56	9-11-2012 9:15:54:531	4909	rcajigas	Rafael Cajigas	TD_FORM	77904	77904:0	Prtcl Deviations		0	2	Form Status set to 2
478288	9/11/2012 10:22:56	9-11-2012 9:15:54:531	4909	rcajigas	Rafael Cajigas	TD_DATA	269497	77904:2127026	Prtcl Deviations	PV.PVDT		10-14-2011	Data Added
478289	9/11/2012 10:22:56	9-11-2012 9:15:54:531	4909	rcajigas	Rafael Cajigas	TD_DATA	269498	77904:					

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
479363	9/11/2012 21:5:22	9-11-2012 20:58:14:545	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	77904	77904:0	Prtcl Deviations		2	3	Form Status set to 3
479364	9/11/2012 21:5:47	9-11-2012 20:58:40:21	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	25961	25961:0	Prtcl Deviations		2	3	Form Status set to 3
479395	9/11/2012 21:55:13	9-11-2012 21:48:04:732	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	25948	25948:0	Oral Assessment		2	3	Form Status set to 3
479500	9/12/2012 10:15:18	9-12-2012 9:08:15:437	4909	rcajigas	Rafael Cajigas	TD_DATA	269665	25958:755964	Adverse Events	AE.AEOUT		Ongoing	Data Added
479501	9/12/2012 10:15:18	9-12-2012 9:08:15:437	4909	rcajigas	Rafael Cajigas	TD_DATA	269666	25958:755976	Adverse Events	AE.AEREL		Not Related	Data Added
479502	9/12/2012 10:15:45	9-12-2012 9:08:43:109	4909	rcajigas	Rafael Cajigas	TD_FORM	25958	25958:0	Adverse Events		1	2	Form Status set to 2
479930	9/12/2012 20:56:3	9-12-2012 20:49:26:768	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	25958	25958:0	Adverse Events		2	3	Form Status set to 3
480445	9/13/2012 10:52:26	9-13-2012 10:45:29:659	551	yovalle	Yulina Ovalle	TD_FORM	25948	25948:0	Oral Assessment		3	4	Form Status set to 4
480446	9/13/2012 10:52:32	9-13-2012 10:45:35:300	551	yovalle	Yulina Ovalle	TD_FORM	25958	25958:0	Adverse Events		3	4	Form Status set to 4
480447	9/13/2012 10:52:44	9-13-2012 10:45:47:643	551	yovalle	Yulina Ovalle	TD_FORM	77904	77904:0	Prtcl Deviations		3	4	Form Status set to 4
480448	9/13/2012 10:52:46	9-13-2012 10:45:49:690	551	yovalle	Yulina Ovalle	TD_FORM	25961	25961:0	Prtcl Deviations		3	4	Form Status set to 4
483554	9/21/2012 13:20:45	9-21-2012 13:14:09:955	782	kcorey	Kris Corey	TD_FORM	25964	25964:0	Study Conclusion		2	3	Form Status set to 3
483601	9/21/2012 13:40:53	9-21-2012 13:34:22:105	6603	yovalle57	Yuliana Ovalle	TD_FORM	25964	25964:0	Study Conclusion		3	4	Form Status set to 4
485111	9/26/2012 12:6:57	9-26-2012 10:59:42:718	3200	dpampe	David Pampe	TD_CASE-BOOK	2086	0:0			0	1	I CERTIFY THAT THE DATA RECORDED ON THIS CASEBOOK IS ACCURATE.
485426	9/26/2012 16:6:26	9-26-2012 15:59:12:267	7641	yovallemon	Yuliana Ovalle	TD_CASE-BOOK	2086	0:0			0	1	Casebook Frozen

DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
Demographics	What is approximate yearly household income group?	DM.DMINC		APPROVED	Data is missing. Please provide.		04-07-2011	SYSTEM	
				RESOLVED		Patient declined to answer	2011-04-07 09:34:14.0	rcajigas	Rafael Cajigas
				APPROVED		Confirmed Data, no action	2011-04-15 13:03:55.0	yovalle	Yulina Ovalle
Inc/Exc	Did the subject meet all eligibility criteria for enrollment	IE.IECRITYN 1		APPROVED	Email		05-05-2011	SYSTEM	
Labs	Urine Date Obtained	LB.LBURDT		APPROVED	Data is missing. Please provide.		05-05-2011	SYSTEM	
				RESOLVED		N/A	2011-05-05 17:11:06.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 10:29:21.0	yovalle57	Yuliana Ovalle
Labs	Urine Time Obtained	LB.LBURTM		APPROVED	Data is missing. Please provide.		05-05-2011	SYSTEM	
				RESOLVED		N/A	2011-05-05 17:11:10.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 10:30:56.0	yovalle57	Yuliana Ovalle
Labs	Urine Date Obtained	LB.LBURDT		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		na - male	2011-05-06 11:23:43.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 10:31:33.0	yovalle57	Yuliana Ovalle
Labs	Urine Time Obtained	LB.LBURTM		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		na - male	2011-05-06 11:23:47.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 10:31:29.0	yovalle57	Yuliana Ovalle
Exhaled CO	Date ECO Obtained	EC.ECDT		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		N/A	2011-05-06 11:24:04.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 09:45:48.0	yovalle57	Yuliana Ovalle
Exhaled CO	Time ECO Obtained	EC.ECTM		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		N/A	2011-05-06 11:24:10.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 09:45:53.0	yovalle57	Yuliana Ovalle
Exhaled CO	ECO	EC.ECRES1		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		N/A	2011-05-06 11:24:13.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 09:45:58.0	yovalle57	Yuliana Ovalle
Labs	Urine Date Obtained	LB.LBURDT		APPROVED	Data is missing. Please provide.		06-02-2011	SYSTEM	
				RESOLVED		Patient is male	2011-06-02 08:27:40.0	rcajigas	Rafael Cajigas
				APPROVED		Patient is male. Test N/A. Data matches	2011-06-10 17:42:53.0	jbaskowski	Janet Baskowski
Labs	Urine Time Obtained	LB.LBURTM		APPROVED	Data is missing. Please provide.		06-02-2011	SYSTEM	
				RESOLVED		Patient is male	2011-06-02 08:27:48.0	rcajigas	Rafael Cajigas
				APPROVED		Patient is male. Test N/A. Data matches.	2011-06-10 17:43:18.0	jbaskowski	Janet Baskowski
Exhaled CO	Date ECO Obtained	EC.ECDT		APPROVED	Data is missing. Please provide.		06-02-2011	SYSTEM	
				RESOLVED		Patient smoked at least one cigarette since the last visit	2011-06-02 08:29:07.0	rcajigas	Rafael Cajigas

DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
				APPROVED		Test N/A. Data matches.	2011-06-10 17:44:02.0	jbaskowski	Janet Baskowski
Exhaled CO	Time ECO Obtained	EC.ECTM		APPROVED	Data is missing. Please provide.		06-02-2011	SYSTEM	
				RESOLVED		Patient smoked at least one cigarette since the last visit	2011-06-02 08:29:12.0	rcajigas	Rafael Cajigas
				APPROVED		Test N/A. Data matches	2011-06-10 17:44:17.0	jbaskowski	Janet Baskowski
Exhaled CO	ECO	EC.ECRES1		APPROVED	Data is missing. Please provide.		06-02-2011	SYSTEM	
				RESOLVED		Patient smoked at least one cigarette since the last visit	2011-06-02 08:29:16.0	rcajigas	Rafael Cajigas
				APPROVED		Test N/A. Data matches.	2011-06-10 17:44:39.0	jbaskowski	Janet Baskowski
Labs	Urine Date Obtained	LB.LBURDT		APPROVED	Data is missing. Please provide.		07-08-2011	SYSTEM	
				RESOLVED		subject is male	2011-07-08 15:44:56.0	ssmithhart	Sara Smithhart
				APPROVED		Confirmed Data, no action	2011-07-12 14:14:26.0	yovalle57	Yuliana Ovalle
Labs	Urine Time Obtained	LB.LBURTM		APPROVED	Data is missing. Please provide.		07-08-2011	SYSTEM	
				RESOLVED		subject is male	2011-07-08 15:45:03.0	ssmithhart	Sara Smithhart
				APPROVED		Confirmed Data, no action	2011-07-12 14:14:30.0	yovalle57	Yuliana Ovalle
Labs	Urine Date Obtained	LB.LBURDT		APPROVED	Data is missing. Please provide.		10-17-2011	SYSTEM	
				RESOLVED		N/A. Patient is male.	2011-10-17 10:57:43.0	rcajigas	Rafael Cajigas
				APPROVED		Confirmed Data, no action subject is male.	2011-10-18 14:04:10.0	rtillman26	Roscoe Tillman
Labs	Urine Time Obtained	LB.LBURTM		APPROVED	Data is missing. Please provide.		10-17-2011	SYSTEM	
				RESOLVED		N/A. Patient is male.	2011-10-17 10:58:00.0	rcajigas	Rafael Cajigas
				APPROVED		Confirmed Data, no action subject is male.	2011-10-18 14:04:19.0	rtillman26	Roscoe Tillman
Test Product Allot	Number of Units Returned	PU.PURET	6	APPROVED	Pls correct to 6 unused tins returned.		11-17-2011	ajungstreisand	Ashley Jung-Streisand
			11	RESOLVED		COMPLETED	2011-11-21 11:48:09.0	rcajigas	Rafael Cajigas
			6	APPROVED		thanks	2012-02-27 12:36:44.0	ajungstreisand	Ashley Jung-Streisand
Oral Assessment	Specify Any Abnormal Finding	PE.PEORALSP	small irritated red area inner molar gumline (upper) on right. Some increased injection overall (between first and second molar) - NCS	APPROVED	Pls clarify with MD the word after increased _____. Injection does not fit with the description.		11-17-2011	ajungstreisand	Ashley Jung-Streisand
			small irritated red area inner molar gumline (upper) on right. Some increased injection overall (between first and second molar)	RESOLVED		Injection appears to be the correct word.	2012-01-13 12:07:53.0	rcajigas	Rafael Cajigas
			small irritated red area inner molar gumline (upper) on right. Some increased injection overall (between first and second molar)	APPROVED		thanks	2012-02-27 12:37:52.0	ajungstreisand	Ashley Jung-Streisand
Oral Assessment	Specify Any Abnormal Finding	PE.PEORALSP	small irritated red area inner molar gumline (upper) on right. Some increased injection overall (between first and second molar) - NCS	APPROVED	Pls add this abnormal Oral Assessment as an AE since it is new since the start of the study. thanks		11-17-2011	ajungstreisand	Ashley Jung-Streisand
			small irritated red area inner molar gumline (upper) on right. Some increased injection overall (between first and second molar)	RESOLVED		Corrected as per query	2012-01-13 12:10:12.0	rcajigas	Rafael Cajigas
			small irritated red area inner molar gumline (upper) on right. Some increased injection overall (between first and second molar)	APPROVED		thanks	2012-02-27 12:38:09.0	ajungstreisand	Ashley Jung-Streisand
Con Meds	FORM LEVEL	-form-.-form-		APPROVED	Pls generate AE for AbnL Oral Assessment at Visit 4.		11-17-2011	ajungstreisand	Ashley Jung-Streisand
				APPROVED		sorry, wrong section.	2011-11-17 22:19:17.0	ajungstreisand	Ashley Jung-Streisand
Adverse Events	FORM LEVEL	-form-.-form-		APPROVED	Pls generate AE for AbnL Oral Assessment finding at Visit 4. thanks		11-17-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Corrected as per query	2012-01-13 12:16:06.0	rcajigas	Rafael Cajigas

DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
				APPROVED		thanks	2012-02-27 12:38:49.0	ajungstreisand	Ashley Jung-Streisand
Prtcl Deviations	Deviation Description	PV.PVSPEC	AE from visit 4 oral assessment (small irritated red area inner molar gumline (upper on right). Some increased injection overall (between 1st and 2nd molar) - was not followed to resolution in error	RESOLVED	Pls delete this Protocol Deviation. I don't think this is considered PD. Thanks		11-17-2011	ajungstreisand	Ashley Jung-Streisand
			Subject blew a 13 on his ECO test at V5	RESOLVED		Corrected as per query	2012-01-13 12:17:14.0	rcajigas	Rafael Cajigas
Study Conclusion	Reason for Withdrawal	DS.DSETREAS	99	APPROVED	Pls correct to "OTHER" and specify "Subject states abstinent from smoking but with >8 on ECO at Visit 5". Thanks		11-17-2011	ajungstreisand	Ashley Jung-Streisand
			3	RESOLVED		Corrected as per query	2012-01-13 12:21:05.0	rcajigas	Rafael Cajigas
			99	APPROVED		thanks	2012-02-27 12:39:23.0	ajungstreisand	Ashley Jung-Streisand
Adverse Events	Outcome	AE.AEOUT	1	APPROVED	Data is missing. Please provide.		01-13-2012	SYSTEM	
				RESOLVED		Pending PI's assessment	2012-01-13 12:16:17.0	rcajigas	Rafael Cajigas
				APPROVED		requeried	2012-09-11 16:58:50.0	lgottliebdm	Joanne Gottlieb
Adverse Events	Relationship	AE.AEREL	1	APPROVED	Data is missing. Please provide.		01-13-2012	SYSTEM	
				RESOLVED		Pending PI's assessment	2012-01-13 12:16:41.0	rcajigas	Rafael Cajigas
				APPROVED		requeried	2012-09-11 16:59:02.0	lgottliebdm	Joanne Gottlieb
AE Code	Coding Completed?	AE.CODECPLT	true	APPROVED	Please verify that coding has been completed or recode due to the change in AE Description.		01-13-2012	SYSTEM	
Prtcl Deviations	Date of Deviation	PV.PVDT	7-8-2011	RESOLVED	Data is missing. Please provide.		01-13-2012	SYSTEM	
			--	RESOLVED		Corrected as per query	2012-01-13 12:17:48.0	SYSTEM	
Prtcl Deviations	Deviation Category	PV.PVCAT	99	RESOLVED	Data is missing. Please provide.		01-13-2012	SYSTEM	
			null	RESOLVED		Corrected as per query	2012-01-13 12:17:48.0	SYSTEM	
Prtcl Deviations	Deviation Description	PV.PVSPEC	AE from visit 4 oral assessment (small irritated red area inner molar gumline (upper on right). Some increased injection overall (between 1st and 2nd molar) - was not followed to resolution in error	RESOLVED	Data is missing. Please provide.		01-13-2012	SYSTEM	
			-null-	RESOLVED		Corrected as per query	2012-01-13 12:17:48.0	SYSTEM	
Oral Assessment	Specify Any Abnormal Finding	PE.PEORALSP	small irritated red area inner molar gumline (upper) on right. Some increased injection overall (between first and second molar) - NCS	APPROVED	Per source "NCS". Please add to CRF finding description.		9-3-2012	mcaballero	Maria Isabel Caballero Valiente
			small irritated red area inner molar gumline (upper) on right. Some increased injection overall (between first and second molar) - NCS	RESOLVED		NCS added.	2012-09-11 14:04:59.0	rcajigas	Rafael Cajigas
			small irritated red area inner molar gumline (upper) on right. Some increased injection overall (between first and second molar) - NCS	APPROVED		Updated CRF, no source change	2012-09-11 21:54:52.0	mcaballero	Maria Isabel Caballero Valiente
Adverse Events	Outcome	AE.AEOUT	1	APPROVED	Please fill in the blank		9-11-2012	lgottliebdm	Joanne Gottlieb
			1	RESOLVED		Information entered.	2012-09-12 10:15:36.0	rcajigas	Rafael Cajigas
			1	APPROVED		Confirmed Data, no action	2012-09-12 16:46:16.0	yovalle57	Yuliana Ovalle
Adverse Events	Relationship	AE.AEREL	1	APPROVED	Please fill in the blank		9-11-2012	lgottliebdm	Joanne Gottlieb
			1	RESOLVED		Information entered.	2012-09-12 10:15:40.0	rcajigas	Rafael Cajigas
			1	APPROVED		Confirmed Data, no action	2012-09-12 16:46:22.0	yovalle57	Yuliana Ovalle