

Subject : 5071

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	: 5071	Event Date	: 23-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Demographics
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

DEMOGRAPHICS

Informed Consent Date:

23-MAR-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	: 5071	Event Date	: 23-MAR-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	: 5071	Event Date	: 23-MAR-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
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<input type="text"/>	<input type="text"/>	
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Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5071	Event Date	: 23-MAR-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:

23-MAR-2011

 DD-MMM-YYYY

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

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
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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	: 5071	Event Date	: 23-MAR-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	: 5071	Event Date	: 23-MAR-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	: 5071	Event Date	: 23-MAR-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	: 5071	Event Date	: 23-MAR-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	: 5071	Event Date	: 23-MAR-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:

23-MAR-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
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Casebook Name	: 5071	Event Date	: 23-MAR-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	: 5071	Event Date	: 23-MAR-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	: 5071	Event Date	: 23-MAR-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	: 5071	Event Date	: 15-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 1
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 1
Casebook Name	: 5071	Event Date	: 15-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	: 5071	Event Date	: 15-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 : 5071

Casebook Status : Casebook Frozen And Locked

Casebook Signature : dpampe

Course Name : Visit 1

Event Name : Visit 1

Event Date : 15-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	: 5071	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	: 5071	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

Site Name : 005 - MetaClin Research, Inc.

Casebook Name : 5071

Casebook Status : Casebook Frozen And Locked

Casebook Signature : dpampe

Course Name : Visit 2

Event Name : Visit 2

Event Date : 29-APR-2011

Form Name : Exhaled CO

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 : 5071

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	: 5071	Event Date	: 06-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	: 5071	Event Date	: 06-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	: 5071	Event Date	: 06-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	: 5071	Event Date	: 06-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	: 5071	Event Date	: 30-JUN-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

09-JUN-2011

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	: 5071	Event Date	: 30-JUN-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	: 5071	Event Date	: 30-JUN-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	: 5071	Event Date	: 30-JUN-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	: 5071	Event Date	: 30-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Nicotine patch -mg (# used daily)

Nicotine gum -pieces (# used daily)

Nicotine lozenges-pieces (# used daily)

Nicotine nasal spray-puffs (# used daily)

Nicotine inhaler-draws or inhaled
breaths (# used daily)

Other (# used daily)

e-cigarette-puffs (# used daily)

Study Name	: RJRT CSD1010	Course Name	: Visit 4
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 4
Casebook Name	: 5071	Event Date	: 07-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	: 5071	Event Date	: 07-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:

07-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	: 5071	Event Date	: 07-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	: 5071	Event Date	: 07-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) injected pharynx leukoplakia posterior to last molar lower gumline bilaterally - CS

Study Name	: RJRT CSD1010	Course Name	: Adverse Events
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Leukoplakia at lower gumline
Casebook Name	: 5071	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Adverse Events
Casebook Signature	: dpampe	Form Status	: DM Reviewed

ADVERSE EVENTS

AE Term:

Start Date/Time:

DD-MMM-YYYY

(24:00 hr clock)

Stop Date/Time:

DD-MMM-YYYY

(24:00 hr clock)

Outcome:

Severity:

Action Taken toward product:

Concomitant Therapy for AE: Yes No

Relationship:

SAE: Yes No

SAE, Criteria:

Study Name	: RJRT CSD1010	Course Name	: Adverse Events
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Leukoplakia at lower gumline
Casebook Name	: 5071	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:

Code Term Search:

1	<input type="text"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>
3	<input type="text"/>	<input type="text"/>
4	<input type="text"/>	<input type="text"/>

Not on list

Coding Completed?

Study Name	: RJRT CSD1010	Course Name	: Adverse Events
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Injected Pharynx
Casebook Name	: 5071	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Adverse Events
Casebook Signature	: dpampe	Form Status	: DM Reviewed

ADVERSE EVENTS

AE Term:

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:

Study Name	: RJRT CSD1010	Course Name	: Adverse Events
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Injected Pharynx
Casebook Name	: 5071	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:

Code Term Search:

1	<input type="text"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>
3	<input type="text"/>	<input type="text"/>
4	<input type="text"/>	<input type="text"/>

Not on list

Coding Completed?

Study Name	: RJRT CSD1010	Course Name	: Con Meds
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Con Meds
Casebook Name	: 5071	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	: 5071	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	: 5071	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>15-APR-2011</div> DD-MMM-YYYY		

Study Name	: RJRT CSD1010	Course Name	: Prtcl Deviations
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Prtcl Deviations
Casebook Name	: 5071	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>15-APR-2011</div> <div>DD-MMM-YYYY</div>		<div></div> <div>1</div>

*1) Dispensed study product not rounded to nearest whole number

Study Name	: RJRT CSD1010	Course Name	: Prtcl Deviations
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Prtcl Deviations
Casebook Name	: 5071	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Prtcl Deviations (3)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

DEVIATIONS

Date of Deviation	Deviation Category	Deviation Description
<div>07-JUL-2011</div> <div>DD-MMM-YYYY</div>		<div></div> <div>1</div>

*1) AE that resulted from the visit 4 oral assessment (leukoplakia at lower gumline and injected pharynx) were 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	: 5071	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Prtcl Deviations (4)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

DEVIATIONS

Date of Deviation	Deviation Category	Deviation Description
<div>07-JUL-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	: 5071	Event Date	: 15-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	: 5071	Event Date	: 07-JUL-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:

07-JUL-2011

DD-MMM-YYYY

Reason for Early Withdrawal

Specify:

*1) Subject states abstinent from smoking but with >8 on ECO

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
36125	3/24/2011 9:50:12	3-24-2011 8:48:17:529	4909	rcajigas	Rafael Cajigas	TD_CASE-BOOK	1495	0:0					Casebook Created
36126	3/24/2011 9:50:51	3-24-2011 8:48:56:623	4909	rcajigas	Rafael Cajigas	TD_CASE-BOOK	1495	0:0				cf08ba5e20a229adce9dca28c8325bc	LUID Created
36127	3/24/2011 9:50:56	3-24-2011 8:49:01:795	4909	rcajigas	Rafael Cajigas	TD_EVENT	6569	0:0				3-23-2011	Event Created
36130	3/24/2011 9:51:30	3-24-2011 8:49:36:92	4909	rcajigas	Rafael Cajigas	TD_FORM	18238	18238:0	Demographics		0	1	Form Status set to 1
36131	3/24/2011 9:51:30	3-24-2011 8:49:36:92	4909	rcajigas	Rafael Cajigas	TD_DATA	27476	18238:534810	Demographics	DM.DMICDT		3-23-2011	Data Added
36132	3/24/2011 9:51:30	3-24-2011 8:49:36:92	4909	rcajigas	Rafael Cajigas	TD_DATA	27477	18238:534812	Demographics	DM.DMICTM		12:55	Data Added
36133	3/24/2011 9:51:30	3-24-2011 8:49:36:92	4909	rcajigas	Rafael Cajigas	TD_DATA	27478	18238:534814	Demographics	DM.DMDOBDT		(b) (6)	Data Added
36134	3/24/2011 9:51:30	3-24-2011 8:49:36:92	4909	rcajigas	Rafael Cajigas	TD_DATA	27479	18238:534818	Demographics	DM.DMSEX		Male	Data Added
36135	3/24/2011 9:51:30	3-24-2011 8:49:36:92	4909	rcajigas	Rafael Cajigas	TD_DATA	27480	18238:534820	Demographics	DM.DMETH		Not Hispanic or Latino	Data Added
36136	3/24/2011 9:51:30	3-24-2011 8:49:36:92	4909	rcajigas	Rafael Cajigas	TD_DATA	27481	18238:534824	Demographics	DM.DMRACE3		true	Data Added
36137	3/24/2011 9:51:30	3-24-2011 8:49:36:92	4909	rcajigas	Rafael Cajigas	TD_DATA	27482	18238:534828	Demographics	DM.DMGRADE		Some college	Data Added
36138	3/24/2011 9:51:30	3-24-2011 8:49:36:92	4909	rcajigas	Rafael Cajigas	TD_DATA	27483	18238:534830	Demographics	DM.DMINC		Less than \$20,000	Data Added
36140	3/24/2011 9:51:39		4909	rcajigas	Rafael Cajigas	TD_DATA	27484	18238:534816	Demographics	DM.DMAGE		24	computed value
127202	5/6/2011 1-3:25:56	5-6-2011 1-2:23:39:46	461	swampler	Sarah Wampler	TD_FORM	18238	18238:0	Demographics		1	2	Form Status set to 2
127203	5/6/2011 1-3:26:18	5-6-2011 1-2:24:00:890	461	swampler	Sarah Wampler	TD_FORM	18239	18239:0	Brief Med. History		0	2	Form Status set to 2
127204	5/6/2011 1-3:26:18	5-6-2011 1-2:24:00:890	461	swampler	Sarah Wampler	TD_DATA	91395	18239:534838	Brief Med. History	MH.MHCOND		left tibia fracture	Data Added
127205	5/6/2011 1-3:26:18	5-6-2011 1-2:24:00:890	461	swampler	Sarah Wampler	TD_DATA	91396	18239:534839	Brief Med. History	MH.MHSTYYYY		1991	Data Added
127206	5/6/2011 1-3:26:18	5-6-2011 1-2:24:00:890	461	swampler	Sarah Wampler	TD_DATA	91397	18239:534840	Brief Med. History	MH.MHENRF		Prior	Data Added
127207	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_FORM	18240	18240:0	Comprehensive PE		0	2	Form Status set to 2
127208	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91398	18240:534843	Comprehensive PE	PE.PEDT		3-23-2011	Data Added
127209	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91399	18240:534848	Comprehensive PE	PE.PEGNAP		Normal	Data Added
127210	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91400	18240:534851	Comprehensive PE	PE.PEHEAD		Normal	Data Added
127211	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91401	18240:534854	Comprehensive PE	PE.PEORAL		Normal	Data Added
127212	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91402	18240:534857	Comprehensive PE	PE.PEEN		Normal	Data Added
127213	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91403	18240:534860	Comprehensive PE	PE.PECHST		Normal	Data Added
127214	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91404	18240:534863	Comprehensive PE	PE.PEVRT		Normal	Data Added
127215	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91405	18240:534866	Comprehensive PE	PE.PEAB		Normal	Data Added
127216	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91406	18240:534869	Comprehensive PE	PE.PEBACK		Normal	Data Added
127217	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91407	18240:534872	Comprehensive PE	PE.PELYP		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
127218	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91408	18240:534875	Comprehensive PE	PE.PENEUR		Normal	Data Added
127219	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91409	18240:534878	Comprehensive PE	PE.PEMUSC		Normal	Data Added
127220	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91410	18240:534881	Comprehensive PE	PE.PEEXT		Normal	Data Added
127221	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91411	18240:534884	Comprehensive PE	PE.PESKIN		Normal	Data Added
127222	5/6/2011 1-3:26:42	5-6-2011 1-2:24:25:312	461	swampler	Sarah Wampler	TD_DATA	91412	18240:534887	Comprehensive PE	PE.PEOTH		Not Done	Data Added
127223	5/6/2011 1-3:27:23	5-6-2011 1-2:25:06:234	461	swampler	Sarah Wampler	TD_FORM	18241	18241:0	Vital Signs		0	2	Form Status set to 2
127224	5/6/2011 1-3:27:23	5-6-2011 1-2:25:06:234	461	swampler	Sarah Wampler	TD_DATA	91413	18241:534892	Vital Signs	VS.VSDT		3-23-2011	Data Added
127225	5/6/2011 1-3:27:23	5-6-2011 1-2:25:06:234	461	swampler	Sarah Wampler	TD_DATA	91414	18241:534893	Vital Signs	VS.VSTM		13:05	Data Added
127226	5/6/2011 1-3:27:23	5-6-2011 1-2:25:06:234	461	swampler	Sarah Wampler	TD_DATA	91415	18241:534897	Vital Signs	VS.VSHT		187	Data Added
127227	5/6/2011 1-3:27:23	5-6-2011 1-2:25:06:234	461	swampler	Sarah Wampler	TD_DATA	91416	18241:534900	Vital Signs	VS.VSWT		94.2	Data Added
127228	5/6/2011 1-3:27:23	5-6-2011 1-2:25:06:234	461	swampler	Sarah Wampler	TD_DATA	91417	18241:534909	Vital Signs	VS.VSSYS		125	Data Added
127229	5/6/2011 1-3:27:23	5-6-2011 1-2:25:06:234	461	swampler	Sarah Wampler	TD_DATA	91418	18241:534911	Vital Signs	VS.VSDIA		86	Data Added
127230	5/6/2011 1-3:27:23	5-6-2011 1-2:25:06:234	461	swampler	Sarah Wampler	TD_DATA	91419	18241:534913	Vital Signs	VS.VSHR		80	Data Added
127231	5/6/2011 1-3:27:23	5-6-2011 1-2:25:06:234	461	swampler	Sarah Wampler	TD_DATA	91420	18241:534915	Vital Signs	VS.VSRR		16	Data Added
127232	5/6/2011 1-3:27:23	5-6-2011 1-2:25:06:234	461	swampler	Sarah Wampler	TD_DATA	91421	18241:534917	Vital Signs	VS.VSTEMP		36.9	Data Added
127233	5/6/2011 1-3:27:23		461	swampler	Sarah Wampler	TD_DATA	91422	18271:535745	Vital Signs	VS.VSHT		187	computed value
127234	5/6/2011 1-3:27:23		461	swampler	Sarah Wampler	TD_DATA	91423	18261:535286	Vital Signs	VS.VSHT		187	computed value
127235	5/6/2011 1-3:27:23		461	swampler	Sarah Wampler	TD_DATA	91424	18241:534903	Vital Signs	VS.VSBMI		26.9	computed value
127236	5/6/2011 1-3:27:49	5-6-2011 1-2:25:31:984	461	swampler	Sarah Wampler	TD_FORM	18242	18242:0	ECG		0	2	Form Status set to 2
127237	5/6/2011 1-3:27:49	5-6-2011 1-2:25:31:984	461	swampler	Sarah Wampler	TD_DATA	91425	18242:534920	ECG	EG.EGDT		3-23-2011	Data Added
127238	5/6/2011 1-3:27:49	5-6-2011 1-2:25:31:984	461	swampler	Sarah Wampler	TD_DATA	91426	18242:534921	ECG	EG.EGTM		13:37	Data Added
127239	5/6/2011 1-3:27:49	5-6-2011 1-2:25:31:984	461	swampler	Sarah Wampler	TD_DATA	91427	18242:534924	ECG	EG.EGASMT		Normal	Data Added
127258	5/6/2011 1-3:28:37	5-6-2011 1-2:26:20:281	461	swampler	Sarah Wampler	TD_FORM	18243	18243:0	Labs		0	2	Form Status set to 2
127259	5/6/2011 1-3:28:37	5-6-2011 1-2:26:20:281	461	swampler	Sarah Wampler	TD_DATA	91445	18243:534929	Labs	LB.LBBLDT		3-23-2011	Data Added
127260	5/6/2011 1-3:28:37	5-6-2011 1-2:26:20:281	461	swampler	Sarah Wampler	TD_DATA	91446	18243:534930	Labs	LB.LBBLTM		13:48	Data Added
127261	5/6/2011 1-3:28:37	5-6-2011 1-2:26:20:281	461	swampler	Sarah Wampler	TD_DATA	91447	18243:534933	Labs	LB.LBURDT		3-23-2011	Data Added
127262	5/6/2011 1-3:28:37	5-6-2011 1-2:26:20:281	461	swampler	Sarah Wampler	TD_DATA	91448	18243:534934	Labs	LB.LBURTM		13:46	Data Added
127263	5/6/2011 1-3:28:37	5-6-2011 1-2:26:20:281	461	swampler	Sarah Wampler	TD_DATA	91449	18243:534937	Labs	LB.LBBRDT		3-23-2011	Data Added
127264	5/6/2011 1-3:28:37	5-6-2011 1-2:26:20:281	461	swampler	Sarah Wampler	TD_DATA	91450	18243:534938	Labs	LB.LBBRTM		13:21	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
127265	5/6/2011 1-3:28:37	5-6-2011 1-2:26:20:281	461	swampler	Sarah Wampler	TD_DATA	91451	18243:534942	Labs	LB.LBUDS		Negative	Data Added
127266	5/6/2011 1-3:28:37	5-6-2011 1-2:26:20:281	461	swampler	Sarah Wampler	TD_DATA	91452	18243:534944	Labs	LB.LBUCS		N/A (Male)	Data Added
127267	5/6/2011 1-3:28:37	5-6-2011 1-2:26:20:281	461	swampler	Sarah Wampler	TD_DATA	91453	18243:534946	Labs	LB.LBABS		Negative	Data Added
127268	5/6/2011 1-3:28:51	5-6-2011 1-2:26:33:953	461	swampler	Sarah Wampler	TD_FORM	18244	18244:0	Exhaled CO		0	2	Form Status set to 2
127269	5/6/2011 1-3:28:51	5-6-2011 1-2:26:33:953	461	swampler	Sarah Wampler	TD_DATA	91454	18244:534949	Exhaled CO	EC.ECDT		3-23-2011	Data Added
127270	5/6/2011 1-3:28:51	5-6-2011 1-2:26:33:953	461	swampler	Sarah Wampler	TD_DATA	91455	18244:534950	Exhaled CO	EC.ECTM		13:23	Data Added
127271	5/6/2011 1-3:28:51	5-6-2011 1-2:26:33:953	461	swampler	Sarah Wampler	TD_DATA	91456	18244:534954	Exhaled CO	EC.ECRES1		16	Data Added
127272	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_FORM	18245	18245:0	UB Descriptors		0	2	Form Status set to 2
127273	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_DATA	91457	18245:534958	UB Descriptors	UB.UBDT		3-23-2011	Data Added
127274	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_DATA	91458	18245:534960	UB Descriptors	UB.UBCPD		12	Data Added
127275	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_DATA	91459	18245:534962	UB Descriptors	UB.UBYEAR		24	Data Added
127276	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_DATA	91460	18245:534964	UB Descriptors	UB.UBSMKLS		No	Data Added
127277	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_DATA	91461	18245:534966	UB Descriptors	UB.UBQUIT		Yes	Data Added
127278	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_DATA	91462	18245:534968	UB Descriptors	UB.UBBRND		Newport	Data Added
127279	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_DATA	91463	18245:534970	UB Descriptors	UB.UBSBRND		Menthol	Data Added
127280	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_DATA	91464	18245:534972	UB Descriptors	UB.UBLTH		85 mm	Data Added
127281	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_DATA	91465	18245:534975	UB Descriptors	UB.UBPACK		Hard-pack box	Data Added
127282	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_DATA	91466	18245:534977	UB Descriptors	UB.UBMENTH		Menthol	Data Added
127283	5/6/2011 1-3:29:23	5-6-2011 1-2:27:05:984	461	swampler	Sarah Wampler	TD_DATA	91467	18245:534979	UB Descriptors	UB.UBFILT		Filter	Data Added
127284	5/6/2011 1-3:29:28	5-6-2011 1-2:27:11:203	461	swampler	Sarah Wampler	TD_FORM	18246	18246:0	Inc/Exc		0	2	Form Status set to 2
127285	5/6/2011 1-3:29:28	5-6-2011 1-2:27:11:203	461	swampler	Sarah Wampler	TD_DATA	91468	18246:534983	Inc/Exc	IE.IECRITYN		Yes	Data Added
127286	5/6/2011 1-3:29:38	5-6-2011 1-2:27:21:390	461	swampler	Sarah Wampler	TD_FORM	18247	18247:0	Test Product Allot		0	2	Form Status set to 2
127287	5/6/2011 1-3:29:38	5-6-2011 1-2:27:21:390	461	swampler	Sarah Wampler	TD_DATA	91469	18247:535018	Test Product Allot	PU.PUSNUS1		Frost	Data Added
127288	5/6/2011 1-3:29:38	5-6-2011 1-2:27:21:390	461	swampler	Sarah Wampler	TD_DATA	91470	18247:535020	Test Product Allot	PU.PULOZG1		Mint	Data Added
127289	5/6/2011 1-3:29:57	5-6-2011 1-2:27:39:859	461	swampler	Sarah Wampler	TD_EVENT	6570	0:0				4-15-2011	Event Created
127290	5/6/2011 1-3:30:17	5-6-2011 1-2:27:59:890	461	swampler	Sarah Wampler	TD_FORM	18248	18248:0	Vital Signs		0	2	Form Status set to 2
127291	5/6/2011 1-3:30:17	5-6-2011 1-2:27:59:890	461	swampler	Sarah Wampler	TD_DATA	91471	18248:535022	Vital Signs	VS.VSDT		4-15-2011	Data Added
127292	5/6/2011 1-3:30:17	5-6-2011 1-2:27:59:890	461	swampler	Sarah Wampler	TD_DATA	91472	18248:535023	Vital Signs	VS.VSTM		12:53	Data Added
127293	5/6/2011 1-3:30:17	5-6-2011 1-2:27:59:890	461	swampler	Sarah Wampler	TD_DATA	91473	18248:535030	Vital Signs	VS.VSSYS		135	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
127294	5/6/2011 1-3:30:17	5-6-2011 1-2:27:59.890	461	swampler	Sarah Wampler	TD_DATA	91474	18248:535032	Vital Signs	VS.VSDIA		77	Data Added
127295	5/6/2011 1-3:30:17	5-6-2011 1-2:27:59.890	461	swampler	Sarah Wampler	TD_DATA	91475	18248:535034	Vital Signs	VS.VSHR		85	Data Added
127296	5/6/2011 1-3:30:17	5-6-2011 1-2:27:59.890	461	swampler	Sarah Wampler	TD_DATA	91476	18248:535036	Vital Signs	VS.VSRR		16	Data Added
127297	5/6/2011 1-3:30:17	5-6-2011 1-2:27:59.890	461	swampler	Sarah Wampler	TD_DATA	91477	18248:535038	Vital Signs	VS.VSTEMP		36.9	Data Added
127298	5/6/2011 1-3:30:23	5-6-2011 1-2:28:06.437	461	swampler	Sarah Wampler	TD_FORM	18249	18249:0	Labs		0	2	Form Status set to 2
127299	5/6/2011 1-3:30:23	5-6-2011 1-2:28:06.437	461	swampler	Sarah Wampler	TD_DATA	91478	18249:535047	Labs	LB.LBUCS		N/A (Male)	Data Added
127300	5/6/2011 1-3:30:57	5-6-2011 1-2:28:40:359	461	swampler	Sarah Wampler	TD_FORM	18250	18250:0	Exhaled CO		0	2	Form Status set to 2
127301	5/6/2011 1-3:30:57	5-6-2011 1-2:28:40:359	461	swampler	Sarah Wampler	TD_DATA	91479	18250:535050	Exhaled CO	EC.ECDT		4-15-2011	Data Added
127302	5/6/2011 1-3:30:57	5-6-2011 1-2:28:40:359	461	swampler	Sarah Wampler	TD_DATA	91480	18250:535051	Exhaled CO	EC.ECTM		13:01	Data Added
127303	5/6/2011 1-3:30:57	5-6-2011 1-2:28:40:359	461	swampler	Sarah Wampler	TD_DATA	91481	18250:535055	Exhaled CO	EC.ECRES1		13	Data Added
127304	5/6/2011 1-3:31:14	5-6-2011 1-2:28:57:343	461	swampler	Sarah Wampler	TD_FORM	18251	18251:0	Test Product Allot		0	2	Form Status set to 2
127305	5/6/2011 1-3:31:14	5-6-2011 1-2:28:57:343	461	swampler	Sarah Wampler	TD_DATA	91482	18251:535059	Test Product Allot	PU.PUSNUS2		Frost	Data Added
127306	5/6/2011 1-3:31:14	5-6-2011 1-2:28:57:343	461	swampler	Sarah Wampler	TD_DATA	91483	18251:535061	Test Product Allot	PU.PULOZG2		N/A	Data Added
127307	5/6/2011 1-3:31:14	5-6-2011 1-2:28:57:343	461	swampler	Sarah Wampler	TD_DATA	91484	18251:535065	Test Product Allot	PU.PUDIS2		12	Data Added
127308	5/6/2011 1-3:31:26	5-6-2011 1-2:29:09:312	461	swampler	Sarah Wampler	TD_EVENT	6571	0:0				4-29-2011	Event Created
127309	5/6/2011 1-3:32:15	5-6-2011 1-2:29:57:812	461	swampler	Sarah Wampler	TD_FORM	18252	18252:0	Vital Signs		0	2	Form Status set to 2
127310	5/6/2011 1-3:32:15	5-6-2011 1-2:29:57:812	461	swampler	Sarah Wampler	TD_DATA	91485	18252:535067	Vital Signs	VS.VSDT		4-29-2011	Data Added
127311	5/6/2011 1-3:32:15	5-6-2011 1-2:29:57:812	461	swampler	Sarah Wampler	TD_DATA	91486	18252:535068	Vital Signs	VS.VSTM		13:14	Data Added
127312	5/6/2011 1-3:32:15	5-6-2011 1-2:29:57:812	461	swampler	Sarah Wampler	TD_DATA	91487	18252:535075	Vital Signs	VS.VSSYS		134	Data Added
127313	5/6/2011 1-3:32:15	5-6-2011 1-2:29:57:812	461	swampler	Sarah Wampler	TD_DATA	91488	18252:535077	Vital Signs	VS.VSDIA		77	Data Added
127314	5/6/2011 1-3:32:15	5-6-2011 1-2:29:57:812	461	swampler	Sarah Wampler	TD_DATA	91489	18252:535079	Vital Signs	VS.VSHR		66	Data Added
127315	5/6/2011 1-3:32:15	5-6-2011 1-2:29:57:812	461	swampler	Sarah Wampler	TD_DATA	91490	18252:535081	Vital Signs	VS.VSRR		18	Data Added
127316	5/6/2011 1-3:32:15	5-6-2011 1-2:29:57:812	461	swampler	Sarah Wampler	TD_DATA	91491	18252:535083	Vital Signs	VS.VSTEMP		36.9	Data Added
127317	5/6/2011 1-3:32:27	5-6-2011 1-2:30:10:578	461	swampler	Sarah Wampler	TD_FORM	18253	18253:0	Labs		0	1	Form Status set to 1
127318	5/6/2011 1-3:32:27	5-6-2011 1-2:30:10:578	461	swampler	Sarah Wampler	TD_DATA	91492	18253:535092	Labs	LB.LBUCS		N/A (Male)	Data Added
127321	5/6/2011 1-3:32:46	5-6-2011 1-2:30:28:859	461	swampler	Sarah Wampler	TD_FORM	18254	18254:0	Exhaled CO		0	2	Form Status set to 2
127322	5/6/2011 1-3:32:46	5-6-2011 1-2:30:28:859	461	swampler	Sarah Wampler	TD_DATA	91493	18254:535095	Exhaled CO	EC.ECYN		N/A	Data Added
127327	5/6/2011 1-3:33:5	5-6-2011 1-2:30:47:921	461	swampler	Sarah Wampler	TD_FORM	18253	18253:0	Labs		1	2	Form Status set to 2
127331	5/6/2011 1-3:33:17	5-6-2011 1-2:31:00:437	461	swampler	Sarah Wampler	TD_FORM	18255	18255:0	Test Product Allot		0	2	Form Status set to 2

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
127332	5/6/2011 1-3:33:17	5-6-2011 1-2:31:00:437	461	swampler	Sarah Wampler	TD_DATA	91494	18255:535106	Test Product Allot	PU.PUSNUS2		Frost	Data Added
127333	5/6/2011 1-3:33:17	5-6-2011 1-2:31:00:437	461	swampler	Sarah Wampler	TD_DATA	91495	18255:535108	Test Product Allot	PU.PULOZG2		N/A	Data Added
127334	5/6/2011 1-3:33:17	5-6-2011 1-2:31:00:437	461	swampler	Sarah Wampler	TD_DATA	91496	18255:535110	Test Product Allot	PU.PURET		12	Data Added
127335	5/6/2011 1-3:33:17	5-6-2011 1-2:31:00:437	461	swampler	Sarah Wampler	TD_DATA	91497	18255:535112	Test Product Allot	PU.PUDIS2		14	Data Added
127336	5/6/2011 1-3:33:32	5-6-2011 1-2:31:15:453	461	swampler	Sarah Wampler	TD_EVENT	6584	0:0				4-15-2011	Event Created
127337	5/6/2011 1-3:33:46	5-6-2011 1-2:31:29:375	461	swampler	Sarah Wampler	TD_FORM	18279	18279:0	Randomization		0	2	Form Status set to 2
127338	5/6/2011 1-3:33:46	5-6-2011 1-2:31:29:375	461	swampler	Sarah Wampler	TD_DATA	91498	18279:535939	Randomization	RAND.RAND		510029	Data Added
127339	5/6/2011 1-3:33:46	5-6-2011 1-2:31:29:375	461	swampler	Sarah Wampler	TD_DATA	91499	18279:535941	Randomization	RAND.COHORT		Cohort 1	Data Added
127340	5/6/2011 1-3:33:50	5-6-2011 1-2:31:33:609	461	swampler	Sarah Wampler	TD_EVENT	6581	0:0					Shared Event Added
127341	5/6/2011 1-3:33:59	5-6-2011 1-2:31:42:515	461	swampler	Sarah Wampler	TD_FORM	18276	18276:0	Con Meds		0	2	Form Status set to 2
127342	5/6/2011 1-3:33:59	5-6-2011 1-2:31:42:515	461	swampler	Sarah Wampler	TD_FORM	18276	18276:0	Con Meds		0	1	Form Checked Intentionally Left Blank
179585	6/2/2011 1-3:25:31	6-2-2011 1-3:23:03:989	624	jbaskowski	Janet Baskowski	TD_FORM	18238	18238:0	Demographics		2	3	Form Status set to 3
179586	6/2/2011 1-3:25:58	6-2-2011 1-3:23:31:420	624	jbaskowski	Janet Baskowski	TD_FORM	18241	18241:0	Vital Signs		2	3	Form Status set to 3
179596	6/2/2011 1-3:26:23	6-2-2011 1-3:23:56:560	624	jbaskowski	Janet Baskowski	TD_FORM	18244	18244:0	Exhaled CO		2	3	Form Status set to 3
179598	6/2/2011 1-3:27:2	6-2-2011 1-3:24:35:50	624	jbaskowski	Janet Baskowski	TD_FORM	18243	18243:0	Labs		2	3	Form Status set to 3
179632	6/2/2011 1-3:27:38	6-2-2011 1-3:25:11:521	624	jbaskowski	Janet Baskowski	TD_FORM	18240	18240:0	Comprehensive PE		2	3	Form Status set to 3
179688	6/2/2011 1-3:29:27	6-2-2011 1-3:26:59:861	624	jbaskowski	Janet Baskowski	TD_FORM	18248	18248:0	Vital Signs		2	3	Form Status set to 3
179691	6/2/2011 1-3:29:46	6-2-2011 1-3:27:19:613	624	jbaskowski	Janet Baskowski	TD_FORM	18250	18250:0	Exhaled CO		2	3	Form Status set to 3
179692	6/2/2011 1-3:30:5	6-2-2011 1-3:27:38:12	624	jbaskowski	Janet Baskowski	TD_FORM	18249	18249:0	Labs		2	3	Form Status set to 3
179698	6/2/2011 1-3:30:38	6-2-2011 1-3:28:11:83	624	jbaskowski	Janet Baskowski	TD_FORM	18279	18279:0	Randomization		2	3	Form Status set to 3
179706	6/2/2011 1-3:32:32	6-2-2011 1-3:30:05:18	624	jbaskowski	Janet Baskowski	TD_FORM	18252	18252:0	Vital Signs		2	3	Form Status set to 3
179721	6/2/2011 1-3:32:55	6-2-2011 1-3:30:28:87	624	jbaskowski	Janet Baskowski	TD_FORM	18253	18253:0	Labs		2	3	Form Status set to 3
179722	6/2/2011 1-3:33:13	6-2-2011 1-3:30:46:89	624	jbaskowski	Janet Baskowski	TD_FORM	18254	18254:0	Exhaled CO		2	3	Form Status set to 3
188485	6/7/2011 1-0:21:0	6-7-2011 9-:17:34:796	4909	rcajigas	Rafael Cajigas	TD_EVENT	6572	0:0				6-6-2011	Event Created
188490	6/7/2011 1-0:21:24	6-7-2011 9-:17:58:921	4909	rcajigas	Rafael Cajigas	TD_FORM	18256	18256:0	Vital Signs		0	1	Form Status set to 1
188491	6/7/2011 1-0:21:24	6-7-2011 9-:17:58:921	4909	rcajigas	Rafael Cajigas	TD_DATA	136033	18256:535114	Vital Signs	VS.VSDT		6-6-2011	Data Added
188492	6/7/2011 1-0:21:24	6-7-2011 9-:17:58:921	4909	rcajigas	Rafael Cajigas	TD_DATA	136034	18256:535115	Vital Signs	VS.VSTM		13:07	Data Added
188493	6/7/2011 1-0:21:24	6-7-2011 9-:17:58:921	4909	rcajigas	Rafael Cajigas	TD_DATA	136035	18256:535122	Vital Signs	VS.VSSYS		126	Data Added
188494	6/7/2011 1-0:21:24	6-7-2011 9-:17:58:921	4909	rcajigas	Rafael Cajigas	TD_DATA	136036	18256:535124	Vital Signs	VS.VSDIA		73	Data Added

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
188495	6/7/2011 1-0:21:24	6-7-2011 9-:17:58:921	4909	rcajigas	Rafael Cajigas	TD_DATA	136037	18256:535126	Vital Signs	VS.VSHR		89	Data Added
188496	6/7/2011 1-0:21:24	6-7-2011 9-:17:58:921	4909	rcajigas	Rafael Cajigas	TD_DATA	136038	18256:535128	Vital Signs	VS.VSRR		15	Data Added
188497	6/7/2011 1-0:21:24	6-7-2011 9-:17:58:921	4909	rcajigas	Rafael Cajigas	TD_DATA	136039	18256:535130	Vital Signs	VS.VSTEMP		37.0	Data Added
188499	6/7/2011 1-0:21:43	6-7-2011 9-:18:17:859	4909	rcajigas	Rafael Cajigas	TD_FORM	18257	18257:0	Labs		0	1	Form Status set to 1
188500	6/7/2011 1-0:21:43	6-7-2011 9-:18:17:859	4909	rcajigas	Rafael Cajigas	TD_DATA	136040	18257:535139	Labs	LB.LBUCS		N/A (Male)	Data Added
188503	6/7/2011 1-0:22:11	6-7-2011 9-:18:46:312	4909	rcajigas	Rafael Cajigas	TD_FORM	18258	18258:0	Exhaled CO		0	1	Form Status set to 1
188504	6/7/2011 1-0:22:11	6-7-2011 9-:18:46:312	4909	rcajigas	Rafael Cajigas	TD_DATA	136041	18258:535142	Exhaled CO	EC.ECYN		N/A	Data Added
188518	6/7/2011 1-0:25:45	6-7-2011 9-:22:19:640	4909	rcajigas	Rafael Cajigas	TD_FORM	18259	18259:0	Test Product Allot		0	1	Form Status set to 1
188519	6/7/2011 1-0:25:45	6-7-2011 9-:22:19:640	4909	rcajigas	Rafael Cajigas	TD_DATA	136049	18259:535157	Test Product Allot	PU.PURET		12	Data Added
188520	6/7/2011 1-0:25:45	6-7-2011 9-:22:19:640	4909	rcajigas	Rafael Cajigas	TD_DATA	136050	18259:535159	Test Product Allot	PU.PUDIS2		4	Data Added
188535	6/7/2011 1-0:26:52	6-7-2011 9-:23:27:468	4909	rcajigas	Rafael Cajigas	TD_DATA	136064	18259:535153	Test Product Allot	PU.PUSNUS2		Frost	Data Added
188536	6/7/2011 1-0:26:52	6-7-2011 9-:23:27:468	4909	rcajigas	Rafael Cajigas	TD_DATA	136065	18259:535155	Test Product Allot	PU.PULOZG2		N/A	Data Added
191044	6/7/2011 1-6:33:33	6-7-2011 1-6:30:04:553	6603	yovalle57	Yuliana Ovalle	TD_FORM	18254	18254:0	Exhaled CO		3	4	Form Status set to 4
191045	6/7/2011 1-6:33:36	6-7-2011 1-6:30:07:397	6603	yovalle57	Yuliana Ovalle	TD_FORM	18253	18253:0	Labs		3	4	Form Status set to 4
191046	6/7/2011 1-6:33:39	6-7-2011 1-6:30:10:444	6603	yovalle57	Yuliana Ovalle	TD_FORM	18252	18252:0	Vital Signs		3	4	Form Status set to 4
199249	6/10/2011 11:1:37	6-10-2011 9:58:22:671	461	swampler	Sarah Wampler	TD_FORM	18256	18256:0	Vital Signs		1	2	Form Status set to 2
199250	6/10/2011 11:1:39	6-10-2011 9:58:25:250	461	swampler	Sarah Wampler	TD_FORM	18257	18257:0	Labs		1	2	Form Status set to 2
199251	6/10/2011 11:1:41	6-10-2011 9:58:27:265	461	swampler	Sarah Wampler	TD_FORM	18258	18258:0	Exhaled CO		1	2	Form Status set to 2
199252	6/10/2011 11:1:44	6-10-2011 9:58:29:671	461	swampler	Sarah Wampler	TD_FORM	18259	18259:0	Test Product Allot		1	2	Form Status set to 2
199689	6/10/2011 13:40:17	6-10-2011 13:37:01:337	624	jbaskowski	Janet Baskowski	TD_FORM	18256	18256:0	Vital Signs		2	3	Form Status set to 3
199712	6/10/2011 13:41:31	6-10-2011 13:38:15:340	624	jbaskowski	Janet Baskowski	TD_FORM	18257	18257:0	Labs		2	3	Form Status set to 3
199727	6/10/2011 13:43:1	6-10-2011 13:39:45:46	624	jbaskowski	Janet Baskowski	TD_FORM	18258	18258:0	Exhaled CO		2	3	Form Status set to 3
201908	6/13/2011 11:1:58	6-13-2011 10:58:49:250	6603	yovalle57	Yuliana Ovalle	TD_FORM	18258	18258:0	Exhaled CO		3	4	Form Status set to 4
201909	6/13/2011 11:2:2	6-13-2011 10:58:53:297	6603	yovalle57	Yuliana Ovalle	TD_FORM	18257	18257:0	Labs		3	4	Form Status set to 4
201912	6/13/2011 11:2:7	6-13-2011 10:58:57:984	6603	yovalle57	Yuliana Ovalle	TD_FORM	18256	18256:0	Vital Signs		3	4	Form Status set to 4
202044	6/13/2011 11:16:41	6-13-2011 11:13:32:873	6603	yovalle57	Yuliana Ovalle	TD_FORM	18250	18250:0	Exhaled CO		3	4	Form Status set to 4
202071	6/13/2011 11:18:3	6-13-2011 11:14:54:435	6603	yovalle57	Yuliana Ovalle	TD_FORM	18249	18249:0	Labs		3	4	Form Status set to 4
202072	6/13/2011 11:18:8	6-13-2011 11:14:59:701	6603	yovalle57	Yuliana Ovalle	TD_FORM	18248	18248:0	Vital Signs		3	4	Form Status set to 4
202073	6/13/2011 11:18:46	6-13-2011 11:15:37:420	6603	yovalle57	Yuliana Ovalle	TD_FORM	18279	18279:0	Randomization		3	4	Form Status set to 4

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
202075	6/13/2011 11:20:28	6-13-2011 11:17:19:670	6603	yovalle57	Yuliana Ov- alle	TD_FORM	18241	18241:0	Vital Signs		3	4	Form Status set to 4
202076	6/13/2011 11:20:36	6-13-2011 11:17:27:545	6603	yovalle57	Yuliana Ov- alle	TD_FORM	18243	18243:0	Labs		3	4	Form Status set to 4
202077	6/13/2011 11:20:41	6-13-2011 11:17:32:482	6603	yovalle57	Yuliana Ov- alle	TD_FORM	18244	18244:0	Exhaled CO		3	4	Form Status set to 4
202078	6/13/2011 11:20:48	6-13-2011 11:17:39:232	6603	yovalle57	Yuliana Ov- alle	TD_FORM	18240	18240:0	Comprehensive PE		3	4	Form Status set to 4
202079	6/13/2011 11:21:2	6-13-2011 11:17:53:592	6603	yovalle57	Yuliana Ov- alle	TD_FORM	18238	18238:0	Demographics		3	4	Form Status set to 4
251326	6/30/2011 12:56:49	6-30-2011 11:53:40:938	4907	ssmithhart	Sara Smith- hart	TD_EVENT	6573	0:0			06-08-2011	6-30-2011	Event Created
251327	6/30/2011 12:57:42	6-30-2011 11:54:33:767	4907	ssmithhart	Sara Smith- hart	TD_FORM	18260	18260:0	Product Usage Q		0	1	Form Status set to 1
251328	6/30/2011 12:57:42	6-30-2011 11:54:33:767	4907	ssmithhart	Sara Smith- hart	TD_DATA	182242	18260:535162	Product Usage Q	SC.SCQ1		Yes	Data Added
251329	6/30/2011 12:57:42	6-30-2011 11:54:33:767	4907	ssmithhart	Sara Smith- hart	TD_DATA	182243	18260:535164	Product Usage Q	SC.SCQ1DT		6-9-2011	Data Added
251330	6/30/2011 12:57:42	6-30-2011 11:54:33:767	4907	ssmithhart	Sara Smith- hart	TD_DATA	182244	18260:535166	Product Usage Q	SC.SCQ2		No	Data Added
251331	6/30/2011 12:57:42	6-30-2011 11:54:33:767	4907	ssmithhart	Sara Smith- hart	TD_DATA	182245	18260:535168	Product Usage Q	SC.SCQ3		No	Data Added
251332	6/30/2011 12:57:42	6-30-2011 11:54:33:767	4907	ssmithhart	Sara Smith- hart	TD_DATA	182246	18260:535171	Product Usage Q	SC.SCQ4A		true	Data Added
251333	6/30/2011 12:57:42	6-30-2011 11:54:33:767	4907	ssmithhart	Sara Smith- hart	TD_DATA	182247	18260:535174	Product Usage Q	SC.SCQ4D		true	Data Added
251334	6/30/2011 12:57:42	6-30-2011 11:54:33:767	4907	ssmithhart	Sara Smith- hart	TD_DATA	182248	18260:535185	Product Usage Q	SC.SCQ5A		4	Data Added
251335	6/30/2011 12:57:42	6-30-2011 11:54:33:767	4907	ssmithhart	Sara Smith- hart	TD_DATA	182249	18260:535194	Product Usage Q	SC.SCQ5D		1	Data Added
251336	6/30/2011 12:57:42	6-30-2011 11:54:33:767	4907	ssmithhart	Sara Smith- hart	TD_DATA	182250	18260:535213	Product Usage Q	SC.SCQ6A		2	Data Added
251337	6/30/2011 12:57:42	6-30-2011 11:54:33:767	4907	ssmithhart	Sara Smith- hart	TD_DATA	182251	18260:535219	Product Usage Q	SC.SCQ6D		1	Data Added
268635	7/8/2011 1-2:18:50	7-8-2011 1-1:15:08:34	4907	ssmithhart	Sara Smith- hart	TD_EVENT	6574	0:0			07-05-2011	7-7-2011	Event Created
268643	7/8/2011 1-2:20:27	7-8-2011 1-1:16:44:924	4907	ssmithhart	Sara Smith- hart	TD_FORM	18261	18261:0	Vital Signs		0	1	Form Status set to 1
268644	7/8/2011 1-2:20:27	7-8-2011 1-1:16:44:924	4907	ssmithhart	Sara Smith- hart	TD_DATA	195093	18261:535281	Vital Signs	VS.VSDT		7-7-2011	Data Added
268645	7/8/2011 1-2:20:27	7-8-2011 1-1:16:44:924	4907	ssmithhart	Sara Smith- hart	TD_DATA	195094	18261:535282	Vital Signs	VS.VSTM		13:25	Data Added
268646	7/8/2011 1-2:20:27	7-8-2011 1-1:16:44:924	4907	ssmithhart	Sara Smith- hart	TD_DATA	195095	18261:535289	Vital Signs	VS.VSWT		94.7	Data Added
268647	7/8/2011 1-2:20:27	7-8-2011 1-1:16:44:924	4907	ssmithhart	Sara Smith- hart	TD_DATA	195096	18261:535298	Vital Signs	VS.VSSYS		140	Data Added
268648	7/8/2011 1-2:20:27	7-8-2011 1-1:16:44:924	4907	ssmithhart	Sara Smith- hart	TD_DATA	195097	18261:535300	Vital Signs	VS.VSDIA		71	Data Added
268649	7/8/2011 1-2:20:27	7-8-2011 1-1:16:44:924	4907	ssmithhart	Sara Smith- hart	TD_DATA	195098	18261:535302	Vital Signs	VS.VSHR		63	Data Added
268650	7/8/2011 1-2:20:27	7-8-2011 1-1:16:44:924	4907	ssmithhart	Sara Smith- hart	TD_DATA	195099	18261:535304	Vital Signs	VS.VSRR		18	Data Added
268651	7/8/2011 1-2:20:27	7-8-2011 1-1:16:44:924	4907	ssmithhart	Sara Smith- hart	TD_DATA	195100	18261:535306	Vital Signs	VS.VSTEMP		36.7	Data Added
268652	7/8/2011 1-2:20:27		4907	ssmithhart	Sara Smith- hart	TD_DATA	195101	18261:535292	Vital Signs	VS.VSBMI		27.1	computed value
268657	7/8/2011 1-2:20:44	7-8-2011 1-1:17:02:284	4907	ssmithhart	Sara Smith- hart	TD_FORM	18262	18262:0	Exhaled CO		0	1	Form Status set to 1

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
268658	7/8/2011 1-2:20:44	7-8-2011 1-1:17:02:284	4907	ssmithhart	Sara Smith-hart	TD_DATA	195102	18262:535309	Exhaled CO	EC.ECYN		Yes	Data Added
268659	7/8/2011 1-2:20:44	7-8-2011 1-1:17:02:284	4907	ssmithhart	Sara Smith-hart	TD_DATA	195103	18262:535311	Exhaled CO	EC.ECDT		7-7-2011	Data Added
268660	7/8/2011 1-2:20:44	7-8-2011 1-1:17:02:284	4907	ssmithhart	Sara Smith-hart	TD_DATA	195104	18262:535312	Exhaled CO	EC.ECTM		13:26	Data Added
268661	7/8/2011 1-2:20:44	7-8-2011 1-1:17:02:284	4907	ssmithhart	Sara Smith-hart	TD_DATA	195105	18262:535316	Exhaled CO	EC.ECRES1		14	Data Added
268662	7/8/2011 1-2:20:56	7-8-2011 1-1:17:14:549	4907	ssmithhart	Sara Smith-hart	TD_FORM	18263	18263:0	Labs		0	1	Form Status set to 1
268663	7/8/2011 1-2:20:56	7-8-2011 1-1:17:14:549	4907	ssmithhart	Sara Smith-hart	TD_DATA	195106	18263:535319	Labs	LB.LBBSAMP		true	Data Added
268664	7/8/2011 1-2:20:56	7-8-2011 1-1:17:14:549	4907	ssmithhart	Sara Smith-hart	TD_DATA	195107	18263:535330	Labs	LB.LBUCS		N/A (Male)	Data Added
268669	7/8/2011 1-2:24:7	7-8-2011 1-1:20:25:628	4907	ssmithhart	Sara Smith-hart	TD_FORM	18264	18264:0	Oral Assessment		0	1	Form Status set to 1
268670	7/8/2011 1-2:24:7	7-8-2011 1-1:20:25:628	4907	ssmithhart	Sara Smith-hart	TD_DATA	195108	18264:535336	Oral Assessment	PE.PEORAL		Abnormal	Data Added
268671	7/8/2011 1-2:24:7	7-8-2011 1-1:20:25:628	4907	ssmithhart	Sara Smith-hart	TD_DATA	195109	18264:535337	Oral Assessment	PE.PEORALSP		injected pharynx leukoplakia postier to last molar lower gumline bilaterally	Data Added
281806	7/18/2011 16:8:30	7-18-2011 15:04:27:171	4909	rcajigas	Rafael Cajigas	TD_FORM	18260	18260:0	Product Usage Q		1	2	Form Status set to 2
281808	7/18/2011 16:8:36	7-18-2011 15:04:32:937	4909	rcajigas	Rafael Cajigas	TD_FORM	18261	18261:0	Vital Signs		1	2	Form Status set to 2
281809	7/18/2011 16:8:38	7-18-2011 15:04:35:281	4909	rcajigas	Rafael Cajigas	TD_FORM	18262	18262:0	Exhaled CO		1	2	Form Status set to 2
281810	7/18/2011 16:8:40	7-18-2011 15:04:37:312	4909	rcajigas	Rafael Cajigas	TD_FORM	18263	18263:0	Labs		1	2	Form Status set to 2
281812	7/18/2011 16:8:42	7-18-2011 15:04:39:375	4909	rcajigas	Rafael Cajigas	TD_FORM	18264	18264:0	Oral Assessment		1	2	Form Status set to 2
281813	7/18/2011 16:8:56	7-18-2011 15:04:52:593	4909	rcajigas	Rafael Cajigas	TD_EVENT	6582	0:0					Shared Event Added
281819	7/18/2011 16:9:36	7-18-2011 15:05:32:406	4909	rcajigas	Rafael Cajigas	TD_FORM	18277	18277:0	Prtcl Deviations		0	1	Form Status set to 1
281820	7/18/2011 16:9:36	7-18-2011 15:05:32:406	4909	rcajigas	Rafael Cajigas	TD_DATA	203678	18277:535874	Prtcl Deviations	PV.PVDT		7-7-2011	Data Added
281821	7/18/2011 16:9:36	7-18-2011 15:05:32:406	4909	rcajigas	Rafael Cajigas	TD_DATA	203679	18277:535875	Prtcl Deviations	PV.PVCAT		Study Procedures	Data Added
281822	7/18/2011 16:9:36	7-18-2011 15:05:32:406	4909	rcajigas	Rafael Cajigas	TD_DATA	203680	18277:535876	Prtcl Deviations	PV.PVSPEC		Subject's ECO was 14 at V4	Data Added
281823	7/18/2011 16:9:38	7-18-2011 15:05:35:218	4909	rcajigas	Rafael Cajigas	TD_FORM	18277	18277:0	Prtcl Deviations		1	2	Form Status set to 2
281826	7/18/2011 16:9:55	7-18-2011 15:05:52:31	4909	rcajigas	Rafael Cajigas	TD_EVENT	6580	0:0					Shared Event Added
281828	7/18/2011 16:10:2	7-18-2011 15:05:58:531	4909	rcajigas	Rafael Cajigas	TD_FORM	18274	18274:0	Adverse Events		0	2	Form Status set to 2
281829	7/18/2011 16:10:2	7-18-2011 15:05:58:531	4909	rcajigas	Rafael Cajigas	TD_FORM	18274	18274:0	Adverse Events		0	1	Form Checked Intentionally Left Blank
281830	7/18/2011 16:10:18	7-18-2011 15:06:14:953	4909	rcajigas	Rafael Cajigas	TD_EVENT	6585	0:0				7-7-2011	Event Created
281831	7/18/2011 16:10:33	7-18-2011 15:06:29:828	4909	rcajigas	Rafael Cajigas	TD_FORM	18280	18280:0	Study Conclusion		0	1	Form Status set to 1
281832	7/18/2011 16:10:33	7-18-2011 15:06:29:828	4909	rcajigas	Rafael Cajigas	TD_DATA	203681	18280:535944	Study Conclusion	DS.DSETSC		Discontinued prior to completion of the study	Data Added
281833	7/18/2011 16:10:33	7-18-2011 15:06:29:828	4909	rcajigas	Rafael Cajigas	TD_DATA	203682	18280:535946	Study Conclusion	DS.DSETSCDT		7-7-2011	Data Added
281834	7/18/2011 16:10:33	7-18-2011 15:06:29:828	4909	rcajigas	Rafael Cajigas	TD_DATA	203683	18280:535948	Study Conclusion	DS.DSETREAS		Protocol Violation	Data Added

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
281836	7/18/2011 16:10:36	7-18-2011 15:06:32:531	4909	rcajigas	Rafael Cajigas	TD_FORM	18280	18280:0	Study Conclusion		1	2	Form Status set to 2
295006	8/2/2011 1-0:57:19	8-2-2011 1-0:53:08:364	624	jbaskowski	Janet Baskowski	TD_FORM	18261	18261:0	Vital Signs		2	3	Form Status set to 3
295007	8/2/2011 1-0:57:39	8-2-2011 1-0:53:28:386	624	jbaskowski	Janet Baskowski	TD_FORM	18262	18262:0	Exhaled CO		2	3	Form Status set to 3
295008	8/2/2011 1-0:57:56	8-2-2011 1-0:53:45:178	624	jbaskowski	Janet Baskowski	TD_FORM	18263	18263:0	Labs		2	3	Form Status set to 3
295009	8/2/2011 1-0:59:5	8-2-2011 1-0:54:54:312	624	jbaskowski	Janet Baskowski	TD_FORM	18280	18280:0	Study Conclusion		2	3	Form Status set to 3
302958	8/15/2011 10:16:43	8-15-2011 10:12:09:441	3263	avillalbacdr	Artemisa Villalba	TD_FORM	18275	18275:0	AE Code		0	1	Form Status set to 1
302959	8/15/2011 10:16:43	8-15-2011 10:12:09:441	3263	avillalbacdr	Artemisa Villalba	TD_DATA	217304	18275:535831	AE Code	AE.CODECPLT		true	Data Added
302960	8/15/2011 10:16:43		3263	avillalbacdr	Artemisa Villalba	TD_DATA	217305	18275:535820	AE Code	AE.TERM			computed value
302961	8/15/2011 10:16:43		3263	avillalbacdr	Artemisa Villalba	TD_DATA	217306	18275:535818	AE Code	AE.AEDESC			computed value
312428	8/24/2011 12:40:15	8-24-2011 12:36:09:854	6603	yovalle57	Yuliana Ovalle	TD_FORM	18263	18263:0	Labs		3	4	Form Status set to 4
312429	8/24/2011 12:40:18	8-24-2011 12:36:12:370	6603	yovalle57	Yuliana Ovalle	TD_FORM	18262	18262:0	Exhaled CO		3	4	Form Status set to 4
312430	8/24/2011 12:40:20	8-24-2011 12:36:15:57	6603	yovalle57	Yuliana Ovalle	TD_FORM	18261	18261:0	Vital Signs		3	4	Form Status set to 4
312431	8/24/2011 12:40:30	8-24-2011 12:36:24:495	6603	yovalle57	Yuliana Ovalle	TD_FORM	18280	18280:0	Study Conclusion		3	4	Form Status set to 4
350905	9/20/2011 11:55:35	9-20-2011 11:50:59:415	624	jbaskowski	Janet Baskowski	TD_FORM	18247	18247:0	Test Product Allot		2	3	Form Status set to 3
350906	9/20/2011 11:55:37	9-20-2011 11:51:00:825	624	jbaskowski	Janet Baskowski	TD_FORM	18247	18247:0	Test Product Allot		3	2	Form Status demoted to 2
351261	9/20/2011 16:37:52	9-20-2011 16:33:17:484	624	jbaskowski	Janet Baskowski	TD_FORM	18247	18247:0	Test Product Allot		2	3	Form Status set to 3
351281	9/20/2011 16:39:49	9-20-2011 16:35:14:442	624	jbaskowski	Janet Baskowski	TD_FORM	18260	18260:0	Product Usage Q		2	3	Form Status set to 3
351878	9/21/2011 11:14:43	9-21-2011 11:10:11:621	6603	yovalle57	Yuliana Ovalle	TD_FORM	18247	18247:0	Test Product Allot		3	4	Form Status set to 4
351932	9/21/2011 11:17:40	9-21-2011 11:13:08:559	6603	yovalle57	Yuliana Ovalle	TD_FORM	18260	18260:0	Product Usage Q		3	4	Form Status set to 4
397419	11/15/2011 11:27:13	11-15-2011 10:22:49:125	4909	rcajigas	Rafael Cajigas	TD_FORM	18255	18255:0	Test Product Allot		2	1	Form Status demoted to 1
397420	11/15/2011 11:27:13	11-15-2011 10:22:49:125	4909	rcajigas	Rafael Cajigas	TD_DATA	91496	18255:535110	Test Product Allot	PU.PURET	12	9	Incorrect data
397421	11/15/2011 11:27:15	11-15-2011 10:22:51:140	4909	rcajigas	Rafael Cajigas	TD_FORM	18255	18255:0	Test Product Allot		1	2	Form Status set to 2
397422	11/15/2011 11:27:31	11-15-2011 10:23:06:562	4909	rcajigas	Rafael Cajigas	TD_FORM	18259	18259:0	Test Product Allot		2	1	Form Status demoted to 1
397423	11/15/2011 11:27:31	11-15-2011 10:23:06:562	4909	rcajigas	Rafael Cajigas	TD_DATA	136049	18259:535157	Test Product Allot	PU.PURET	12	9	Incorrect data
397424	11/15/2011 11:27:32	11-15-2011 10:23:08:15	4909	rcajigas	Rafael Cajigas	TD_FORM	18259	18259:0	Test Product Allot		1	2	Form Status set to 2
401739	11/18/2011 16:57:40	11-18-2011 16:53:33:565	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18242	18242:0	ECG		2	3	Form Status set to 3
401760	11/18/2011 17:0:9	11-18-2011 16:56:01:988	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18239	18239:0	Brief Med. History		2	3	Form Status set to 3
401761	11/18/2011 17:0:35	11-18-2011 16:56:28:384	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18244	18244:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
401762	11/18/2011 17:0:53	11-18-2011 16:56:46:66	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18241	18241:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
401763	11/18/2011 17:1:4	11-18-2011 16:56:56.719	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18238	18238:0	Demographics		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
401764	11/18/2011 17:1:27	11-18-2011 16:57:20.634	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18240	18240:0	Comprehensive PE		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
401765	11/18/2011 17:1:43	11-18-2011 16:57:36.197	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18245	18245:0	UB Descriptors		2	3	Form Status set to 3
401766	11/18/2011 17:5:11	11-18-2011 17:01:04.293	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18246	18246:0	Inc/Exc		2	3	Form Status set to 3
401767	11/18/2011 17:7:9	11-18-2011 17:03:01.744	0		Pls generate a protocol deviation-per protocol, study procedures must occur AFTER 1PM.	TD_FORM	18248	18248:0	Vital Signs				Form Sign attempt unsuccessful. That password is not recognized. Please try again.
401768	11/18/2011 17:7:37	11-18-2011 17:03:30.631	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18248	18248:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
401769	11/18/2011 17:7:46	11-18-2011 17:03:39.93	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18250	18250:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
401770	11/18/2011 17:8:6	11-18-2011 17:03:59.306	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18251	18251:0	Test Product Allot		2	3	Form Status set to 3
401771	11/18/2011 17:8:23	11-18-2011 17:04:15.869	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18279	18279:0	Randomization		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
401772	11/18/2011 17:12:6	11-18-2011 17:07:59.553	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18255	18255:0	Test Product Allot		2	3	Form Status set to 3
401773	11/18/2011 17:12:40	11-18-2011 17:08:33.401	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18254	18254:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
401774	11/18/2011 17:12:47	11-18-2011 17:08:40.563	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18252	18252:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
401775	11/18/2011 17:14:3	11-18-2011 17:09:56.117	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18256	18256:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
401776	11/18/2011 17:14:10	11-18-2011 17:10:03.569	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18258	18258:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
401777	11/18/2011 17:15:4	11-18-2011 17:10:57.548	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18259	18259:0	Test Product Allot		2	3	Form Status set to 3
401778	11/18/2011 17:16:9	11-18-2011 17:12:02.168	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18261	18261:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
401779	11/18/2011 17:16:17	11-18-2011 17:12:10.169	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18262	18262:0	Exhaled CO				Form Sign attempt unsuccessful. That password is not recognized. Please try again.
401780	11/18/2011 17:17:59	11-18-2011 17:13:51.745	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	18262	18262:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
405068	11/22/2011 14:27:37	11-22-2011 14:22:35.909	6603	yovalle57	Yuliana Ov-alle	TD_FORM	18251	18251:0	Test Product Allot		3	4	Form Status set to 4
407851	12/1/2011 12:56:3	12-1-2011 12:51:32.313	6603	yovalle57	Yuliana Ov-alle	TD_FORM	18242	18242:0	ECG		3	4	Form Status set to 4
407852	12/1/2011 12:56:6	12-1-2011 12:51:34.938	6603	yovalle57	Yuliana Ov-alle	TD_FORM	18239	18239:0	Brief Med. History		3	4	Form Status set to 4
407853	12/1/2011 12:56:11	12-1-2011 12:51:39.860	6603	yovalle57	Yuliana Ov-alle	TD_FORM	18246	18246:0	Inc/Exc		3	4	Form Status set to 4
410552	12/9/2011 15:29:34	12-9-2011 15:24:24.471	6603	yovalle57	Yuliana Ov-alle	TD_FORM	18255	18255:0	Test Product Allot		3	4	Form Status set to 4
410553	12/9/2011	12-9-2011	6603	yovalle57	Yuliana Ov-	TD_FORM	18259	18259:0	Test Product Allot		3	4	Form Status set to 4

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
418721	1/6/2012 1-1:45:32	1-6-2012 1-0:41:00:578	4909	rcajigas	Rafael Cajigas	TD_DATA	252238	75955:2119503	Prtcl Deviations	PV.PVDT		4-15-2011	Data Added
418722	1/6/2012 1-1:45:32	1-6-2012 1-0:41:00:578	4909	rcajigas	Rafael Cajigas	TD_DATA	252239	75955:2119504	Prtcl Deviations	PV.PVCAT		Study Procedures	Data Added
418723	1/6/2012 1-1:45:32	1-6-2012 1-0:41:00:578	4909	rcajigas	Rafael Cajigas	TD_DATA	252240	75955:2119505	Prtcl Deviations	PV.PVSPEC		Dispensed study product not rounded to nearest whole number	Data Added
418724	1/6/2012 1-1:48:47	1-6-2012 1-0:44:15:703	4909	rcajigas	Rafael Cajigas	TD_FORM	18277	18277:0	Prtcl Deviations		2	1	Form Status demoted to 1
418725	1/6/2012 1-1:48:54	1-6-2012 1-0:44:22:765	4909	rcajigas	Rafael Cajigas	TD_FORM	18277	18277:0	Prtcl Deviations		1	0	Form Status demoted to 0 Reason : Corrected as per query
418726	1/6/2012 1-1:48:54	1-6-2012 1-0:44:22:765	4909	rcajigas	Rafael Cajigas	TD_DATA	203678	18277:535874	Prtcl Deviations	PV.PVDT	7-7-2011		Corrected as per query
418727	1/6/2012 1-1:48:54	1-6-2012 1-0:44:22:765	4909	rcajigas	Rafael Cajigas	TD_DATA	203679	18277:535875	Prtcl Deviations	PV.PVCAT	Study Procedures		Corrected as per query
418728	1/6/2012 1-1:48:54	1-6-2012 1-0:44:22:765	4909	rcajigas	Rafael Cajigas	TD_DATA	203680	18277:535876	Prtcl Deviations	PV.PVSPEC	Subject's ECO was 14 at V4		Corrected as per query
418729	1/6/2012 1-1:49:16	1-6-2012 1-0:44:44:765	4909	rcajigas	Rafael Cajigas	TD_FORM	18277	18277:0	Prtcl Deviations		0	2	Form Status set to 2
418730	1/6/2012 1-1:49:16	1-6-2012 1-0:44:44:765	4909	rcajigas	Rafael Cajigas	TD_DATA	252241	18277:535874	Prtcl Deviations	PV.PVDT		4-15-2011	Data Added
418731	1/6/2012 1-1:49:16	1-6-2012 1-0:44:44:765	4909	rcajigas	Rafael Cajigas	TD_DATA	252242	18277:535875	Prtcl Deviations	PV.PVCAT		Study Procedures	Data Added
418732	1/6/2012 1-1:49:16	1-6-2012 1-0:44:44:765	4909	rcajigas	Rafael Cajigas	TD_DATA	252243	18277:535876	Prtcl Deviations	PV.PVSPEC		Study procedure done prior to 1300 at visit 1	Data Added
418733	1/6/2012 1-1:51:52	1-6-2012 1-0:47:20:875	4909	rcajigas	Rafael Cajigas	TD_FORM	18280	18280:0	Study Conclusion		4	2	Form Status demoted to 2
418734	1/6/2012 1-1:51:52	1-6-2012 1-0:47:20:875	4909	rcajigas	Rafael Cajigas	TD_DATA	203683	18280:535948	Study Conclusion	DS.DSETREAS	Protocol Violation	Other	Corrected as per query
418735	1/6/2012 1-1:51:52	1-6-2012 1-0:47:20:875	4909	rcajigas	Rafael Cajigas	TD_DATA	252244	18280:535950	Study Conclusion	DS.DSETSP		Subject states abstinent from smoking but with >.8 on ECO	Data Added
420759	1/11/2012 15:57:2	1-11-2012 14:52:50:656	4909	rcajigas	Rafael Cajigas	TD_FORM	18274	18274:0	Adverse Events		2	1	Form Status set to 1
420760	1/11/2012 15:57:2	1-11-2012 14:52:50:656	4909	rcajigas	Rafael Cajigas	TD_FORM	18274	18274:0	Adverse Events		1	0	Form Unchecked Intentionally Left Blank
420761	1/11/2012 15:57:2	1-11-2012 14:52:50:656	4909	rcajigas	Rafael Cajigas	TD_DATA	252742	18274:535792	Adverse Events	AE.AETERM		Leukoplakia at lower gumline	Data Added
420762	1/11/2012 15:57:2	1-11-2012 14:52:50:656	4909	rcajigas	Rafael Cajigas	TD_DATA	252743	18274:535796	Adverse Events	AE.AESTDT		7-7-2011	Data Added
420763	1/11/2012 15:57:2	1-11-2012 14:52:50:656	4909	rcajigas	Rafael Cajigas	TD_DATA	252744	18274:535799	Adverse Events	AE.AESTTM		13:47	Data Added
420764	1/11/2012 15:57:2	1-11-2012 14:52:50:656	4909	rcajigas	Rafael Cajigas	TD_DATA	252745	18274:535804	Adverse Events	AE.AESEV		Mild	Data Added
420765	1/11/2012 15:57:2	1-11-2012 14:52:50:656	4909	rcajigas	Rafael Cajigas	TD_DATA	252746	18274:535806	Adverse Events	AE.AEACT		None	Data Added
420766	1/11/2012 15:57:2	1-11-2012 14:52:50:656	4909	rcajigas	Rafael Cajigas	TD_DATA	252747	18274:535808	Adverse Events	AE.AETRT		No	Data Added
420767	1/11/2012 15:57:2	1-11-2012 14:52:50:656	4909	rcajigas	Rafael Cajigas	TD_DATA	252748	18274:535810	Adverse Events	AE.AEREL		Possible	Data Added
420768	1/11/2012 15:57:2	1-11-2012 14:52:50:656	4909	rcajigas	Rafael Cajigas	TD_DATA	252749	18274:535812	Adverse Events	AE.AESAE		No	Data Added
420769	1/11/2012 15:57:2		4909	rcajigas	Rafael Cajigas	TD_DATA	217305	18275:535820	AE Code	AE.TERM		Leukoplakia at lower gumline	computed value
420770	1/11/2012 15:57:2		4909	rcajigas	Rafael Cajigas	TD_DATA	217306	18275:535818	AE Code	AE.AEDESC		Leukoplakia at lower gumline	computed value
420771	1/11/2012 15:57:2		4909	rcajigas	Rafael Cajigas	TD_DATA	252750	18275:535822	AE Code	AE.RSLT1		Lower respiratory tract inflammation Lower respiratory tract inflammation 10057260 Lower respiratory tract inflammatory and immunologic conditions Lower respiratory tract disorders (excl obstruction and infection) Respiratory, thoracic and mediastinal disorders 13.1	computed value
420772	1/11/2012 15:57:2		4909	rcajigas	Rafael Cajigas	TD_DATA	252751	18275:535824	AE Code	AE.RSLT2		Anal leukoplakia Anal leukoplakia 10002161 Anal and rectal disorders NEC Anal and rectal conditions NEC Gastrointestinal 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
420773	1/11/2012 15:57:2		4909	rcajigas	Rafael Cajigas	TD_DATA	252752	18275:535826	AE Code	AE.RSLT3		Cervical leukoplakia Cervical leukoplakia 10008282 Cervix disorders NEC Cervix disorders (excl infections and inflammations) Reproductive system and breast disorders 13.1	computed value
420774	1/11/2012 15:57:2		4909	rcajigas	Rafael Cajigas	TD_DATA	252753	18275:535828	AE Code	AE.RSLT4		Esophageal leukoplakia Leukoplakia oesophageal 10024389 Oesophageal disorders NEC Gastrointestinal conditions NEC Gastrointestinal disorders 13.1	computed value
420775	1/11/2012 15:57:2		4909	rcajigas	Rafael Cajigas	TD_DATA	252754	18275:535823	AE Code	AE.CODE1		10057260	computed value
420776	1/11/2012 15:57:2		4909	rcajigas	Rafael Cajigas	TD_DATA	252755	18275:535825	AE Code	AE.CODE2		10002161	computed value
420777	1/11/2012 15:57:2		4909	rcajigas	Rafael Cajigas	TD_DATA	252756	18275:535827	AE Code	AE.CODE3		10008282	computed value
420778	1/11/2012 15:57:2		4909	rcajigas	Rafael Cajigas	TD_DATA	252757	18275:535829	AE Code	AE.CODE4		10015385	computed value
420779	1/11/2012 15:58:43	1-11-2012 14:54:32:156	4909	rcajigas	Rafael Cajigas	TD_FORM	18274	18274:0	Adverse Events		1	2	Form Status set to 2
420784	1/11/2012 16:2:29	1-11-2012 14:58:18:31	4909	rcajigas	Rafael Cajigas	TD_EVENT	26861	0:0					Shared Event Added
420786	1/11/2012 16:3:8	1-11-2012 14:58:57:546	4909	rcajigas	Rafael Cajigas	TD_FORM	76061	76061:0	Adverse Events		0	1	Form Status set to 1
420787	1/11/2012 16:3:8	1-11-2012 14:58:57:546	4909	rcajigas	Rafael Cajigas	TD_DATA	252758	76061:2119723	Adverse Events	AE.AETERM		Injected Pharynx	Data Added
420788	1/11/2012 16:3:8	1-11-2012 14:58:57:546	4909	rcajigas	Rafael Cajigas	TD_DATA	252759	76061:2119727	Adverse Events	AE.AESTDT		7-7-2011	Data Added
420789	1/11/2012 16:3:8	1-11-2012 14:58:57:546	4909	rcajigas	Rafael Cajigas	TD_DATA	252760	76061:2119730	Adverse Events	AE.AESTTM		13:47	Data Added
420790	1/11/2012 16:3:8	1-11-2012 14:58:57:546	4909	rcajigas	Rafael Cajigas	TD_DATA	252761	76061:2119735	Adverse Events	AE.AESEV		Mild	Data Added
420791	1/11/2012 16:3:8	1-11-2012 14:58:57:546	4909	rcajigas	Rafael Cajigas	TD_DATA	252762	76061:2119737	Adverse Events	AE.AEACT		None	Data Added
420792	1/11/2012 16:3:8	1-11-2012 14:58:57:546	4909	rcajigas	Rafael Cajigas	TD_DATA	252763	76061:2119739	Adverse Events	AE.AETRT		No	Data Added
420793	1/11/2012 16:3:8	1-11-2012 14:58:57:546	4909	rcajigas	Rafael Cajigas	TD_DATA	252764	76061:2119741	Adverse Events	AE.AEREL		Possible	Data Added
420794	1/11/2012 16:3:8	1-11-2012 14:58:57:546	4909	rcajigas	Rafael Cajigas	TD_DATA	252765	76061:2119743	Adverse Events	AE.AESAE		No	Data Added
420795	1/11/2012 16:3:9		4909	rcajigas	Rafael Cajigas	TD_DATA	252766	76062:2119762	AE Code	AE.CODECPLT			computed value
420796	1/11/2012 16:3:9		4909	rcajigas	Rafael Cajigas	TD_DATA	252767	76062:2119751	AE Code	AE.TERM		Injected Pharynx	computed value
420797	1/11/2012 16:3:9		4909	rcajigas	Rafael Cajigas	TD_DATA	252768	76062:2119749	AE Code	AE.AEDESC		Injected Pharynx	computed value
420798	1/11/2012 16:3:9		4909	rcajigas	Rafael Cajigas	TD_DATA	252769	76062:2119753	AE Code	AE.RSLT1		Injected limb mobility decreased Injected limb mobility decreased 10057664 Injection site reactions Administration site reactions General disorders and administration site conditions 13.1	computed value
420799	1/11/2012 16:3:9		4909	rcajigas	Rafael Cajigas	TD_DATA	252770	76062:2119755	AE Code	AE.RSLT2		Injected limb mobility decreased Injected limb mobility decreased 10057664 Injection site reactions Administration site reactions Injury, poisoning and procedural complications 13.1	computed value
420800	1/11/2012 16:3:9		4909	rcajigas	Rafael Cajigas	TD_DATA	252771	76062:2119757	AE Code	AE.RSLT3		Biopsy pharynx Biopsy pharynx 10004851 Respiratory tract and thoracic histopathology procedures Respiratory and pulmonary investigations (excl blood gases) Investigations 13.1	computed value
420801	1/11/2012 16:3:9		4909	rcajigas	Rafael Cajigas	TD_DATA	252772	76062:2119759	AE Code	AE.RSLT4		Biopsy pharynx abnormal Biopsy pharynx abnormal 10004852 Respiratory tract and thoracic histopathology procedures Respiratory and pulmonary investigations (excl blood gases) Investigations 13.1	computed value
420802	1/11/2012		4909	rcajigas	Rafael Cajigas	TD_DATA	252773	76062:2119754	AE Code	AE.CODE1		10057664	computed value

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
448137	4/23/2012 14:16:5		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252756	18275:535827	AE Code	AE.CODE3	10015385	10019057	computed value
448138	4/23/2012 14:16:5		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252757	18275:535829	AE Code	AE.CODE4	10018158	10019057	computed value
448139	4/23/2012 14:16:29	4-23-2012 14:11:13:97	7302	igottliebco	Joanne Go-ttleb	TD_DATA	217305	18275:535820	AE Code	AE.TERM	leukoplakia exc anal	leukoplakia	Requires update
448140	4/23/2012 14:16:29		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252751	18275:535824	AE Code	AE.RSLT2	Leukoplakia of anus Anal leukoplakia 10002161 Anal and rectal disorders NEC Anal and rectal conditions NEC Gastrointestinal disorders 13.1	Cervical leukoplakia Cervical leukoplakia 10008282 Cervix disorders NEC Cervix disorders (excl infections and inflammations) Reproductive system and breast disorders 13.1	computed value
448141	4/23/2012 14:16:29		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252752	18275:535826	AE Code	AE.RSLT3	Hairy leukoplakia (exc oral) Leukoplakia 10062037 Mucosal findings abnormal General system disorders NEC General disorders and administration site conditions 13.1	Esophageal leukoplakia Leukoplakia oesophageal 10024389 Oesophageal disorders NEC Gastrointestinal conditions NEC Gastrointestinal disorders 13.1	computed value
448142	4/23/2012 14:16:29		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252753	18275:535828	AE Code	AE.RSLT4	Hairy leukoplakia (exc oral) Leukoplakia 10062037 Skin preneoplastic conditions NEC Cornification and dystrophic skin disorders Skin and subcutaneous tissue disorders 13.1	Genital leukoplakia Genital leukoplakia 10018158 Reproductive tract disorders NEC (excl neoplasms) Reproductive tract disorders NEC Reproductive system and breast disorders 13.1	computed value
448143	4/23/2012 14:16:30		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252755	18275:535825	AE Code	AE.CODE2	10024390	10008282	computed value
448144	4/23/2012 14:16:30		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252756	18275:535827	AE Code	AE.CODE3	10019057	10015385	computed value
448145	4/23/2012 14:16:30		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252757	18275:535829	AE Code	AE.CODE4	10019057	10018158	computed value
448147	4/23/2012 14:17:31	4-23-2012 14:12:15:207	7302	igottliebco	Joanne Go-ttleb	TD_DATA	217305	18275:535820	AE Code	AE.TERM	leukoplakia	leukoplakia NOS	Requires update
448148	4/23/2012 14:17:32		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252750	18275:535822	AE Code	AE.RSLT1	Anal leukoplakia Anal leukoplakia 10002161 Anal and rectal disorders NEC Anal and rectal conditions NEC Gastrointestinal disorders 13.1	Leukoplakia NOS Leukoplakia 10062037 Mucosal findings abnormal General system disorders NEC General disorders and administration site conditions 13.1	computed value
448149	4/23/2012 14:17:32		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252751	18275:535824	AE Code	AE.RSLT2	Cervical leukoplakia Cervical leukoplakia 10008282 Cervix disorders NEC Cervix disorders (excl infections and inflammations) Reproductive system and breast disorders 13.1	Leukoplakia NOS Leukoplakia 10062037 Skin preneoplastic conditions NEC Cornification and dystrophic skin disorders Skin and subcutaneous tissue disorders 13.1	computed value
448150	4/23/2012 14:17:32		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252752	18275:535826	AE Code	AE.RSLT3	Esophageal leukoplakia Leukoplakia oesophageal 10024389 Oesophageal disorders NEC Gastrointestinal conditions NEC Gastrointestinal disorders 13.1	Leukoplakia oral NOS Leukoplakia oral 10024396 Oral soft tissue disorders NEC Oral soft tissue conditions Gastrointestinal disorders 13.1	computed value
448151	4/23/2012 14:17:32		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252753	18275:535828	AE Code	AE.RSLT4	Genital leukoplakia Genital leukoplakia 10018158 Reproductive tract disorders NEC (excl neoplasms) Reproductive tract disorders NEC Reproductive system and breast disorders 13.1	Oral leukoplakia NOS Leukoplakia oral 10024396 Oral soft tissue disorders NEC Oral soft tissue conditions Gastrointestinal disorders 13.1	computed value
448152	4/23/2012 14:17:32		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252754	18275:535823	AE Code	AE.CODE1	10002161	10024388	computed value
448153	4/23/2012 14:17:32		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252755	18275:535825	AE Code	AE.CODE2	10008282	10024388	computed value
448154	4/23/2012 14:17:32		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252756	18275:535827	AE Code	AE.CODE3	10015385	10024398	computed value
448155	4/23/2012 14:17:32		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252757	18275:535829	AE Code	AE.CODE4	10018158	10030982	computed value
448157	4/23/2012 14:18:6	4-23-2012 14:12:50:8	7302	igottliebco	Joanne Go-ttleb	TD_DATA	260425	18275:535821	AE Code	AE.CHOICE		3	Data Added
448158	4/23/2012 14:18:6	4-23-2012 14:12:50:8	7302	igottliebco	Joanne Go-ttleb	TD_DATA	217304	18275:535831	AE Code	AE.CODECPLT	false	true	Requires update
448159	4/23/2012 14:18:6		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252750	18275:535822	AE Code	AE.RSLT1	Leukoplakia NOS Leukoplakia 10062037 Mucosal findings abnormal General system disorders NEC General disorders and administration site conditions 13.1	** Leukoplakia oral NOS Leukoplakia oral 10024396 Oral soft tissue disorders NEC Oral soft tissue conditions Gastrointestinal disorders 13.1	computed value
448160	4/23/2012 14:18:6		7302	igottliebco	Joanne Go-ttleb	TD_DATA	252751	18275:535824	AE Code	AE.RSLT2	Leukoplakia NOS Leukoplakia 10062037 Skin preneoplastic conditions NEC Cornification and dystrophic skin disorders Skin and	Leukoplakia NOS Leukoplakia 10062037 Mucosal findings abnormal General system disorders NEC General disorders and	computed value

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
469021	8/7/2012 1-1:58:45	8-7-2012 1-0:52:36:569	4909	rcajigas	Rafael Cajigas	TD_FORM	77445	77445:0	Prtcl Deviations				Repeating Form Created
469026	8/7/2012 1-2:0:4	8-7-2012 1-0:53:55:194	4909	rcajigas	Rafael Cajigas	TD_FORM	77445	77445:0	Prtcl Deviations		0	2	Form Status set to 2
469027	8/7/2012 1-2:0:4	8-7-2012 1-0:53:55:194	4909	rcajigas	Rafael Cajigas	TD_DATA	267871	77445:2125113	Prtcl Deviations	PV.PVDT		7-7-2011	Data Added
469028	8/7/2012 1-2:0:4	8-7-2012 1-0:53:55:194	4909	rcajigas	Rafael Cajigas	TD_DATA	267872	77445:2125114	Prtcl Deviations	PV.PVCAT		Other	Data Added
469029	8/7/2012 1-2:0:4	8-7-2012 1-0:53:55:194	4909	rcajigas	Rafael Cajigas	TD_DATA	267873	77445:2125115	Prtcl Deviations	PV.PVSPEC		AE that resulted from the visit 4 oral assessment (leukoplakia at lower gumline and injected pharynx) were not followed to resolution in error	Data Added
476251	9/3/2012 1-43:58	9-3-2012 1-37:20:379	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	77445	77445:0	Prtcl Deviations		2	3	Form Status set to 3
476252	9/3/2012 1-46:55	9-3-2012 1-40:18:77	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	18277	18277:0	Prtcl Deviations		2	3	Form Status set to 3
477082	9/5/2012 1-5:59:54	9-5-2012 1-4:53:31:468	4909	rcajigas	Rafael Cajigas	TD_FORM	77862	77862:0	Prtcl Deviations				Repeating Form Created
477084	9/5/2012 1-6:1:13	9-5-2012 1-4:54:51:171	4909	rcajigas	Rafael Cajigas	TD_FORM	77862	77862:0	Prtcl Deviations		0	1	Form Status set to 1
477085	9/5/2012 1-6:1:14	9-5-2012 1-4:54:51:171	4909	rcajigas	Rafael Cajigas	TD_DATA	269420	77862:2126912	Prtcl Deviations	PV.PVDT		7-7-2011	Data Added
477086	9/5/2012 1-6:1:14	9-5-2012 1-4:54:51:171	4909	rcajigas	Rafael Cajigas	TD_DATA	269421	77862:2126913	Prtcl Deviations	PV.PVCAT		Other	Data Added
477087	9/5/2012 1-6:1:14	9-5-2012 1-4:54:51:171	4909	rcajigas	Rafael Cajigas	TD_DATA	269422	77862:2126914	Prtcl Deviations	PV.PVSPEC		Study sponsor was not notified within two days of subject's discontinuation from study as per section 4.6 of the protocol.	Data Added
477088	9/5/2012 1-6:1:15	9-5-2012 1-4:54:52:968	4909	rcajigas	Rafael Cajigas	TD_FORM	77862	77862:0	Prtcl Deviations		1	2	Form Status set to 2
477194	9/5/2012 1-6:18:3	9-5-2012 1-6:11:36:931	6603	yovalle57	Yuliana Ovalle	TD_FORM	77445	77445:0	Prtcl Deviations		3	4	Form Status set to 4
477196	9/5/2012 1-6:18:5	9-5-2012 1-6:11:39:72	6603	yovalle57	Yuliana Ovalle	TD_FORM	18277	18277:0	Prtcl Deviations		3	4	Form Status set to 4
477522	9/8/2012 1-5:25:46	9-8-2012 1-5:19:25:564	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	77862	77862:0	Prtcl Deviations		2	3	Form Status set to 3
477649	9/9/2012 1-2:3:49	9-9-2012 1-1:57:31:674	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	18274	18274:0	Adverse Events		2	3	Form Status set to 3
477650	9/9/2012 1-2:4:55	9-9-2012 1-1:58:41:865	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	18276	18276:0	Con Meds		2	3	Form Status set to 3
477651	9/9/2012 1-2:7:52	9-9-2012 1-2:01:39:254	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	76061	76061:0	Adverse Events		2	3	Form Status set to 3
478714	9/11/2012 12:27:20	9-11-2012 11:20:13:568	4909	rcajigas	Rafael Cajigas	TD_FORM	18264	18264:0	Oral Assessment		1	0	Form Unsigned
478715	9/11/2012 12:27:30	9-11-2012 11:20:23:756	4909	rcajigas	Rafael Cajigas	TD_FORM	18264	18264:0	Oral Assessment		2	1	Form Status demoted to 1
478716	9/11/2012 12:27:30	9-11-2012 11:20:23:756	4909	rcajigas	Rafael Cajigas	TD_DATA	195109	18264:535337	Oral Assessment	PE.PEORALSP	injected pharynx leukoplakia posterior to last molar lower gumline bilaterally	injected pharynx leukoplakia posterior to last molar lower gumline bilaterally - CS	Requires update
478717	9/11/2012 12:27:47	9-11-2012 11:20:40:365	4909	rcajigas	Rafael Cajigas	TD_FORM	18264	18264:0	Oral Assessment		1	2	Form Status set to 2
479124	9/11/2012 17:0:49	9-11-2012 16:53:49:861	6603	yovalle57	Yuliana Ovalle	TD_FORM	18274	18274:0	Adverse Events		3	4	Form Status set to 4
479125	9/11/2012 17:1:10	9-11-2012 16:54:10:361	6603	yovalle57	Yuliana Ovalle	TD_FORM	76061	76061:0	Adverse Events		3	4	Form Status set to 4
479134	9/11/2012 17:3:14	9-11-2012 16:56:14:876	6603	yovalle57	Yuliana Ovalle	TD_FORM	18276	18276:0	Con Meds		3	4	Form Status set to 4
479137	9/11/2012 17:4:4	9-11-2012 16:57:04:267	6603	yovalle57	Yuliana Ovalle	TD_FORM	77862	77862:0	Prtcl Deviations		3	4	Form Status set to 4
479327	9/11/2012 19:54:39	9-11-2012 19:47:34:27	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	75955	75955:0	Prtcl Deviations		2	3	Form Status set to 3
479396	9/11/2012 21:55:49	9-11-2012 21:48:40:899	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	18264	18264:0	Oral Assessment		2	3	Form Status set to 3

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
480419	9/13/2012 10:50:8	9-13-2012 10:43:11:427	551	yovalle	Yulina Ovalle	TD_FORM	18264	18264:0	Oral Assessment		3	4	Form Status set to 4
480424	9/13/2012 10:50:31	9-13-2012 10:43:34:661	551	yovalle	Yulina Ovalle	TD_FORM	75955	75955:0	Prtcl Deviations		3	4	Form Status set to 4
483547	9/21/2012 13:8:38	9-21-2012 13:02:02:455	782	kcorey	Kris Corey	TD_FORM	18280	18280:0	Study Conclusion		2	3	Form Status set to 3
483582	9/21/2012 13:37:29	9-21-2012 13:30:58:751	6603	yovalle57	Yuliana Ov-alle	TD_FORM	18280	18280:0	Study Conclusion		3	4	Form Status set to 4
485082	9/26/2012 12:1:26	9-26-2012 10:54:11:953	3200	dpampe	David Pampe	TD_CASE-BOOK	1495	0:0			0	1	I CERTIFY THAT THE DATA RECORDED ON THIS CASEBOOK IS ACCURATE.
485717	9/27/2012 10:46:57	9-27-2012 10:39:45:726	7641	yovallemon	Yuliana Ov-alle	TD_CASE-BOOK	1495	0:0			0	1	Casebook Frozen
488122	10/15/2012 12:3:32	10-15-2012 11:56:22:909	7303	jgottliebmon	Joanne Go-ttleb	TD_CASE-BOOK	1495	0:0			1	0	Casebook Thawed
488138	10/15/2012 12:26:53	10-15-2012 12:19:34:379	7302	jgottliebco	Joanne Go-ttleb	TD_DATA	252767	76062:2119751	AE Code	AE.TERM	Injected Pharynx	Pharyngitis	Requires update
488139	10/15/2012 12:26:53	10-15-2012 12:19:34:379	7302	jgottliebco	Joanne Go-ttleb	TD_CASE-BOOK	1495	0:0			1	0	Unsigning Casebook 1495
488140	10/15/2012 12:26:53		7302	jgottliebco	Joanne Go-ttleb	TD_DATA	252769	76062:2119753	AE Code	AE.RSLT1	** Injected limb mobility decreased Injected limb mobility decreased 10057664 Injection site reactions Administration site reactions Injury, poisoning and procedural complications 13.1	** Acute pharyngitis Pharyngitis 10034835 Upper respiratory tract infections Infections - pathogen unspecified Infections and infestations 13.1	computed value
488141	10/15/2012 12:26:53		7302	jgottliebco	Joanne Go-ttleb	TD_DATA	252770	76062:2119755	AE Code	AE.RSLT2	Biopsy pharynx Biopsy pharynx 10004851 Respiratory tract and thoracic histopathology procedures Respiratory and pulmonary investigations (excl blood gases) Investigations 13.1	Chronic pharyngitis Pharyngitis 10034835 Oral soft tissue infections Oral soft tissue conditions Gastrointestinal disorders 13.1	computed value
488142	10/15/2012 12:26:53		7302	jgottliebco	Joanne Go-ttleb	TD_DATA	252771	76062:2119757	AE Code	AE.RSLT3	Biopsy pharynx abnormal Biopsy pharynx abnormal 10004852 Respiratory tract and thoracic histopathology procedures Respiratory and pulmonary investigations (excl blood gases) Investigations 13.1	Chronic pharyngitis Pharyngitis 10034835 Upper respiratory tract infections NEC Respiratory tract infections Respiratory, thoracic and mediastinal disorders 13.1	computed value
488143	10/15/2012 12:26:53		7302	jgottliebco	Joanne Go-ttleb	TD_DATA	252772	76062:2119759	AE Code	AE.RSLT4	Biopsy pharynx normal Biopsy pharynx normal 10004853 Respiratory tract and thoracic histopathology procedures Respiratory and pulmonary investigations (excl blood gases) Investigations 13.1	Chronic pharyngitis Pharyngitis 10034835 Upper respiratory tract infections Infections - pathogen unspecified Infections and infestations 13.1	computed value
488144	10/15/2012 12:26:53		7302	jgottliebco	Joanne Go-ttleb	TD_DATA	252773	76062:2119754	AE Code	AE.CODE1	10057664	10001002	computed value
488145	10/15/2012 12:26:53		7302	jgottliebco	Joanne Go-ttleb	TD_DATA	252774	76062:2119756	AE Code	AE.CODE2	10004851	10009105	computed value
488146	10/15/2012 12:26:53		7302	jgottliebco	Joanne Go-ttleb	TD_DATA	252775	76062:2119758	AE Code	AE.CODE3	10004852	10009105	computed value
488147	10/15/2012 12:26:53		7302	jgottliebco	Joanne Go-ttleb	TD_DATA	252776	76062:2119760	AE Code	AE.CODE4	10004853	10009105	computed value
488301	10/16/2012 10:8:0	10-16-2012 10:00:53:811	7303	jgottliebmon	Joanne Go-ttleb	TD_CASE-BOOK	1495	0:0			0	1	Casebook Frozen
488483	10/17/2012 10:38:5	10-17-2012 9:31:11:890	3200	dpampe	David Pampe	TD_CASE-BOOK	1495	0:0			0	1	I CERTIFY THAT THE DATA RECORDED ON THIS CASEBOOK IS ACCURATE.

DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
Inc/Exc	Did the subject meet all eligibility criteria for enrollment	IE.IECRITYN 1		APPROVED	Email		05-06-2011	SYSTEM	
Labs	Urine Date Obtained	LB.LBURDT		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		NA	2011-05-06 13:30:35.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 10:50:40.0	yovalle57	Yuliana Ovalle
Labs	Urine Time Obtained	LB.LBURTM		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		NA	2011-05-06 13:30:39.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 10:50:44.0	yovalle57	Yuliana Ovalle
Labs	Urine Date Obtained	LB.LBURDT		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		NA	2011-05-06 13:32:37.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 10:51:17.0	yovalle57	Yuliana Ovalle
Labs	Urine Time Obtained	LB.LBURTM		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		NA	2011-05-06 13:32:40.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 10:51:21.0	yovalle57	Yuliana Ovalle
Exhaled CO	Date ECO Obtained	EC.ECDT		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		NA	2011-05-06 13:32:53.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 10:04:26.0	yovalle57	Yuliana Ovalle
Exhaled CO	Time ECO Obtained	EC.ECTM		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		NA	2011-05-06 13:32:57.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 10:04:30.0	yovalle57	Yuliana Ovalle
Exhaled CO	ECO	EC.ECRES1		APPROVED	Data is missing. Please provide.		05-06-2011	SYSTEM	
				RESOLVED		NA	2011-05-06 13:33:01.0	swampler	Sarah Wampler
				APPROVED		Confirmed Data, no action	2011-05-17 10:04:33.0	yovalle57	Yuliana Ovalle
Labs	Urine Date Obtained	LB.LBURDT		APPROVED	Data is missing. Please provide.		06-07-2011	SYSTEM	
				RESOLVED		Patient is male	2011-06-07 10:21:52.0	rcajigas	Rafael Cajigas
				APPROVED		Patient is male. Test N/A. Data matches	2011-06-10 13:40:57.0	jbaskowski	Janet Baskowski
Labs	Urine Time Obtained	LB.LBURTM		APPROVED	Data is missing. Please provide.		06-07-2011	SYSTEM	
				RESOLVED		Patient is male	2011-06-07 10:21:58.0	rcajigas	Rafael Cajigas
				APPROVED		Patient is male. Test N/A. Data matches.	2011-06-10 13:41:27.0	jbaskowski	Janet Baskowski
Exhaled CO	Date ECO Obtained	EC.ECDT		APPROVED	Data is missing. Please provide.		06-07-2011	SYSTEM	
				RESOLVED		Patient continues to smoke thus the ECO test is not required at this time	2011-06-07 10:22:18.0	rcajigas	Rafael Cajigas
				APPROVED		Test N/A. Data matches	2011-06-10 13:42:16.0	jbaskowski	Janet Baskowski
Exhaled CO	Time ECO Obtained	EC.ECTM		APPROVED	Data is missing. Please provide.		06-07-2011	SYSTEM	
				RESOLVED		Patient continues to smoke thus the ECO test is not required at this time	2011-06-07 10:22:22.0	rcajigas	Rafael Cajigas
				APPROVED		Test N/A . Data matches.	2011-06-10	jbaskowski	Janet Baskowski

DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
Exhaled CO	ECO	EC.ECRES1		APPROVED	Data is missing. Please provide.		06-07-2011	SYSTEM	
				RESOLVED		Patient continues to smoke thus the ECO test is not required at this time	2011-06-07 10:22:27.0	rcajigas	Rafael Cajigas
				APPROVED		Test N/A. Data matches.	2011-06-10 13:42:56.0	jbaskowski	Janet Baskowski
Test Product Allot	Preferred Flavor of SNUS	PU.PUSNUS2	1	APPROVED	Data is missing. Please provide.		06-07-2011	SYSTEM	
Test Product Allot	Preferred Flavor of Lozenge	PU.PULOZG2	3	APPROVED	Data is missing. Please provide.		06-07-2011	SYSTEM	
Product Usage Q	Cigarettes (# used daily)	SC.SCQ6A	2	APPROVED	It has been recorded that the number of cigarettes used daily is 1 or 2. Please review and confirm that this is the correct number of cigarettes and not packs of cigarettes.		06-30-2011	SYSTEM	
			2	RESOLVED		patient smoked 2 cigarettes	2011-06-30 12:58:11.0	ssmithhart	Sara Smithhart
			2	APPROVED		Confirmed Data, no action	2011-07-12 15:02:06.0	yovalle57	Yuliana Ovalle
Labs	Urine Date Obtained	LB.LBURDT		APPROVED	Data is missing. Please provide.		07-08-2011	SYSTEM	
				RESOLVED		patient is male	2011-07-08 12:22:47.0	ssmithhart	Sara Smithhart
				APPROVED		Confirmed Data, no action	2011-07-08 13:12:10.0	yovalle57	Yuliana Ovalle
Labs	Urine Time Obtained	LB.LBURTM		APPROVED	Data is missing. Please provide.		07-08-2011	SYSTEM	
				RESOLVED		patient is male	2011-07-08 12:22:55.0	ssmithhart	Sara Smithhart
				APPROVED		Confirmed Data, no action	2011-07-08 13:12:13.0	yovalle57	Yuliana Ovalle
Prtcl Deviations	FORM LEVEL	-form--form-		RESOLVED	Pls generate PD for NOT dispensing study product per protocol at Visit 1 (did not round up to nearest whole number for SNUS).		11-18-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Corrected as per query	2012-01-06 11:43:30.0	rcajigas	Rafael Cajigas
Prtcl Deviations	FORM LEVEL	-form--form-		RESOLVED	Pls generate a protocol deviation for Visit 1 Vitals- per protocol, study procedures must occur AFTER 1PM.		11-18-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Corrected as per query	2012-01-06 11:48:41.0	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". Thanks		11-18-2011	ajungstreisand	Ashley Jung-Streisand
			3	RESOLVED		Corrected as per query	2012-01-06 11:51:21.0	rcajigas	Rafael Cajigas
			99	APPROVED		thanks	2012-02-22 15:18:23.0	ajungstreisand	Ashley Jung-Streisand
Prtcl Deviations	Deviation Description	PV.PVSPEC	Study procedure done prior to 1300 at visit 1	RESOLVED	Pls delete this Protocol Deviation. I don't think this is considered PD. Thanks		11-18-2011	ajungstreisand	Ashley Jung-Streisand
			Subject's ECO was 14 at V4	RESOLVED		Corrected as per query	2012-01-06 11:36:39.0	rcajigas	Rafael Cajigas
Oral Assessment	Specify Any Abnormal Finding	PE.PEORALSP	injected pharynx leukoplakia posterior to last molar lower gumline bilaterally - CS	APPROVED	Pls clarify "injected". Would ERYTHEMATOUS be a good substitute? Pls correct as prm. Pls correct spelling of POSTERIOR.		11-18-2011	ajungstreisand	Ashley Jung-Streisand
			injected pharynx leukoplakia posterior to last molar lower gumline bilaterally	RESOLVED		Injected is correct.	2012-01-06 11:26:54.0	rcajigas	Rafael Cajigas
			injected pharynx leukoplakia posterior to last molar lower gumline bilaterally	APPROVED		thanks	2012-02-22 15:19:42.0	ajungstreisand	Ashley Jung-Streisand
Adverse Events	FORM LEVEL	-form--form-		APPROVED	Pls generate 2 AEs for findings during Visit 4 Oral Assessment of ERYTHEMATOUS PHARYNX and LEUKOPLAKIA AT LOWER GUMLINE.		11-18-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Completed as per query	2012-01-11 15:54:56.0	rcajigas	Rafael Cajigas
				APPROVED		thanks	2012-02-22 15:20:37.0	ajungstreisand	Ashley Jung-Streisand
Adverse Events	Outcome	AE.AEOUT	1	APPROVED	Data is missing. Please provide.		01-11-2012	SYSTEM	
				RESOLVED		Patient was terminated at visit 4. The AE resolution is unknown.	2012-01-11 15:58:12.0	rcajigas	Rafael Cajigas
				OPEN		You may enter as "LOST TO FOLLOW UP".	2012-02-22 15:22:55.0	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Ongoing at V4	2012-04-27	rcajigas	Rafael Cajigas

DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
			1	APPROVED		AE entered as Ongoing	2012-06-20 17:15:51.0	yovalle	Yulina Ovalle
Adverse Events	Outcome	AE.AEOUT	1	APPROVED	Data is missing. Please provide.		01-11-2012	SYSTEM	
				RESOLVED		Resolution of AE is unknown. Subject was terminated at visit 4	2012-01-11 16:03:30.0	rcajigas	Rafael Cajigas
				OPEN		see comment above (forgot to unclick the RESOLVE button to requery.	2012-02-22 15:23:54.0	ajungstreisand	Ashley Jung-Streisand
				OPEN		You may enter as "LOST TO FOLLOW UP"	2012-02-22 15:32:17.6	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Completed.	2012-04-27 13:47:26.0	rcajigas	Rafael Cajigas
			1	APPROVED		Outcome was recorded as ONGOING	2012-06-20 17:19:20.0	yovalle	Yulina Ovalle
AE Code	Coding Completed?	AE.CODECPLT	true	APPROVED	Please verify that coding has been completed or recode due to the change in AE Description.		01-11-2012	SYSTEM	
Adverse Events	FORM LEVEL	-form-.-form-		APPROVED	Pls generate an AE for Oral Exam finding of "INJECTED PHARYNX". thanks		2-22-2012	ajungstreisand	Ashley Jung-Streisand
				APPROVED		Pls disregard, did not see the entry.	2012-02-22 15:31:16.0	ajungstreisand	Ashley Jung-Streisand
AE Code	Coding Completed?	AE.CODECPLT	true	APPROVED	Please verify that coding has been completed or recode due to the change in AE Description.		04-23-2012	SYSTEM	
Prtcl Deviations	Deviation Description	PV,PVSPEC	Dispensed study product not rounded to nearest whole number	APPROVED	Unable to verify, source not found. Please upload.		9-3-2012	mcaballero	Maria Isabel Caballero Valiente
			Dispensed study product not rounded to nearest whole number	RESOLVED		Source is uploaded. Look under query resolution.	2012-09-11 12:53:09.0	rcajigas	Rafael Cajigas
			Dispensed study product not rounded to nearest whole number	APPROVED		Confirmed Data, no action	2012-09-11 19:54:35.0	mcaballero	Maria Isabel Caballero Valiente
Oral Assessment	Specify Any Abnormal Finding	PE.PEORALSP	injected pharynx leukoplakia posterior to last molar lower gumline bilaterally - CS	APPROVED	Per source CS. Please add to CRF finding description.		9-3-2012	mcaballero	Maria Isabel Caballero Valiente
			injected pharynx leukoplakia posterior to last molar lower gumline bilaterally - CS	RESOLVED		CS added to description.	2012-09-11 12:27:42.0	rcajigas	Rafael Cajigas
			injected pharynx leukoplakia posterior to last molar lower gumline bilaterally - CS	APPROVED		Updated CRF, no source change	2012-09-11 21:55:45.0	mcaballero	Maria Isabel Caballero Valiente