

Subject : 2067

Study Name RJRT CSD1010

Archive Date 31-Oct-2013

Site Name Central Kentucky Research Associates (2)

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Screening
Casebook Name	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Demographics
Casebook Signature	: jborders	Form Status	: DM Reviewed Signed

DEMOGRAPHICS

Informed Consent Date:

19-MAY-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	: 002 - Central Kentucky Research Associates	Event Name	: Screening
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Casebook Status	: Casebook Frozen And Locked	Form Name	: Demographics
Casebook Signature	: jrborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Screening
Casebook Name	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Brief Med. History (1)
Casebook Signature	: jborders	Form Status	: DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery	Year	Status
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Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Screening
Casebook Name	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Brief Med. History (2)
Casebook Signature	: jborders	Form Status	: DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery	Year	Status
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Study Name : RJRT CSD1010

Site Name : 002 - Central Kentucky Research Associates

Casebook Name : 2067

Casebook Status : Casebook Frozen And Locked

Casebook Signature : jbborders

Course Name : Screening

Event Name : Screening

Event Date : 19-MAY-2011

Form Name : Brief Med. History (3)

Form Status : DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery

Year

Status

Study Name : RJRT CSD1010

Site Name : 002 - Central Kentucky Research Associates

Casebook Name : 2067

Casebook Status : Casebook Frozen And Locked

Casebook Signature : jbborders

Course Name : Screening

Event Name : Screening

Event Date : 19-MAY-2011

Form Name : Brief Med. History (4)

Form Status : DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery

Year

Status

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Screening
Casebook Name	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Comprehensive PE
Casebook Signature	: jborders	Form Status	: DM Reviewed Signed

COMPREHENSIVE PHYSICAL EXAM

Date Physical Exam Completed: 19-MAY-2011 DD-MMM-YYYY

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

Study Name : RJRT CSD1010

Site Name : 002 - Central Kentucky Research Associates

Casebook Name : 2067

Casebook Status : Casebook Frozen And Locked

Casebook Signature : jborders

Course Name : Screening

Event Name : Screening

Event Date : 19-MAY-2011

Form Name : Comprehensive PE

Form Status : DM Reviewed Signed

Extremities

Skin

Other

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Screening
Casebook Name	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Screening
Casebook Name	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: ECG
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Screening
Casebook Name	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: jborders	Form Status	: DM Reviewed

SCREENING LABS

Blood Sample Date/Time Obtained: 19-MAY-2011 DD-MMM-YYYY (24:00 hr clock)

Urine Sample Date/Time Obtained: 19-MAY-2011 DD-MMM-YYYY (24:00 hr clock)

Breathalyzer Date/Time Obtained: 19-MAY-2011 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	: 002 - Central Kentucky Research Associates	Event Name	: Screening
Casebook Name	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: jborders	Form Status	: DM Reviewed

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	: 002 - Central Kentucky Research Associates	Event Name	: Screening
Casebook Name	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: UB Descriptors
Casebook Signature	: jborders	Form Status	: DM Reviewed

UB DESCRIPTORS AND SELF-REPORTED CPD

Date completed: 19-MAY-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	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: UB Descriptors
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Screening
Casebook Name	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Inc/Exc
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Screening
Casebook Name	: 2067	Event Date	: 19-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Test Product Allot
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Visit 1
Casebook Name	: 2067	Event Date	: 06-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: jrborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Visit 1
Casebook Name	: 2067	Event Date	: 06-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Visit 1
Casebook Name	: 2067	Event Date	: 06-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: jborders	Form Status	: DM Reviewed

EXPIRED CARBON MONOXIDE

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

Results:

ECO (ppm)

Study Name	: RJRT CSD1010	Course Name	: Visit 1
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Visit 1
Casebook Name	: 2067	Event Date	: 06-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Test Product Allot
Casebook Signature	: jborders	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	: Visit 2
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Visit 2
Casebook Name	: 2067	Event Date	: 22-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Visit 2
Casebook Name	: 2067	Event Date	: 22-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: jborders	Form Status	: DM Reviewed

Visit 1 Labs

Urine Sample Date/Time Obtained:

22-JUN-2011

 DD-MMM-YYYY (24:00 hr clock)

Results:

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

Study Name	: RJRT CSD1010	Course Name	: Visit 2
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Visit 2
Casebook Name	: 2067	Event Date	: 22-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: jborders	Form Status	: DM Reviewed

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 2
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Visit 2
Casebook Name	: 2067	Event Date	: 22-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Test Product Allot
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Visit 3
Casebook Name	: 2067	Event Date	: 25-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: jrborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Visit 3
Casebook Name	: 2067	Event Date	: 25-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: jborders	Form Status	: DM Reviewed

Visit 1 Labs

Urine Sample Date/Time Obtained:

25-JUL-2011

 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	: 002 - Central Kentucky Research Associates	Event Name	: Visit 3
Casebook Name	: 2067	Event Date	: 25-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: jborders	Form Status	: DM Reviewed

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	: 002 - Central Kentucky Research Associates	Event Name	: Visit 3
Casebook Name	: 2067	Event Date	: 25-JUL-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Test Product Allot
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 1
Casebook Name	: 2067	Event Date	: 22-AUG-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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

26-JUL-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	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 1
Casebook Name	: 2067	Event Date	: 22-AUG-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 1
Casebook Name	: 2067	Event Date	: 22-AUG-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 1
Casebook Name	: 2067	Event Date	: 22-AUG-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 1
Casebook Name	: 2067	Event Date	: 22-AUG-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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	: Tel Contact 2
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 2
Casebook Name	: 2067	Event Date	: 22-NOV-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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

22-AUG-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 2
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 2
Casebook Name	: 2067	Event Date	: 22-NOV-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	Form Status	: DM Reviewed

SNUS

Pipe tobacco

Cigars

Little cigars

Tobacco tablets

Other (Specify)

For each "used" answer...

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

Cigarettes (# of days) 1-14

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

Chewing tobacco (# of days) 1-14

SNUS (# of days) 1-14

Pipe tobacco (# of days) 1-14

Cigars (# of days) 1-14

Little cigars (# of days) 1-14

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 2
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 2
Casebook Name	: 2067	Event Date	: 22-NOV-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	Form Status	: DM Reviewed

Tobacco tablets (# of days) 1-14

Other (# of days) 1-14

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

Cigarettes (# used daily)

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

Chewing tobacco (pouches) (# used daily)

SNUS (portions) (# used daily)

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

Cigars (# used daily)

Little cigars (# used daily)

Tobacco tablets (# used daily)

Other (# used daily)

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

Nicotine patch

Nicotine gum

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 2
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 2
Casebook Name	: 2067	Event Date	: 22-NOV-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	Form Status	: DM Reviewed

Nicotine lozenges

Nicotine nasal spray

Nicotine inhaler

Other

Specify

e-cigarette

For each "used" answer,

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

Nicotine patch (# of days)

1-14

Nicotine gum (# of days)

1-14

Nicotine lozenges (# of days)

1-14

Nicotine nasal spray (# of days)

1-14

Nicotine inhaler (# of days)

1-14

Other (# of days)

1-14

e-cigarette (# of days)

1-14

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

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 2
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 2
Casebook Name	: 2067	Event Date	: 22-NOV-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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	: Tel Contact 3
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 3
Casebook Name	: 2067	Event Date	: 08-MAR-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	Form Status	: DM Reviewed

SMOKING STATUS, CIGARETTE, AND TEST PRODUCT USAGE QUESTIONNAIRE

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

Yes

No

If Yes, first date of use

DD-MMM-YYYY

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

Yes

No

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

Yes

No

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

(Check all that apply)

Cigarettes

Moist snuff or dip in a round can

Chewing tobacco

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 3
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 3
Casebook Name	: 2067	Event Date	: 08-MAR-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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 3
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 3
Casebook Name	: 2067	Event Date	: 08-MAR-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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 3
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 3
Casebook Name	: 2067	Event Date	: 08-MAR-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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 3
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 3
Casebook Name	: 2067	Event Date	: 08-MAR-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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	: Tel Contact 4
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 4
Casebook Name	: 2067	Event Date	: 29-MAY-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	Form Status	: DM Reviewed

SMOKING STATUS, CIGARETTE, AND TEST PRODUCT USAGE QUESTIONNAIRE

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

Yes

No

If Yes, first date of use

DD-MMM-YYYY

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

Yes

No

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

Yes

No

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

(Check all that apply)

Cigarettes

Moist snuff or dip in a round can

Chewing tobacco

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 4
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 4
Casebook Name	: 2067	Event Date	: 29-MAY-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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 4
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 4
Casebook Name	: 2067	Event Date	: 29-MAY-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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 4
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 4
Casebook Name	: 2067	Event Date	: 29-MAY-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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 4
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Tel Contact 4
Casebook Name	: 2067	Event Date	: 29-MAY-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: jborders	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 6
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Visit 6
Casebook Name	: 2067	Event Date	: 07-JUN-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: jborders	Form Status	: Blank DM Reviewed

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 6
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Visit 6
Casebook Name	: 2067	Event Date	: 07-JUN-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: jborders	Form Status	: Blank DM Reviewed

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 6
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Visit 6
Casebook Name	: 2067	Event Date	: 07-JUN-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: jborders	Form Status	: Blank DM Reviewed

Visit 4 Labs

Blood Sample N/A

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

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

Results:

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

Study Name	: RJRT CSD1010	Course Name	: Adverse Events
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Adverse Events
Casebook Name	: 2067	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Adverse Events
Casebook Signature	: jborders	Form Status	: Blank DM Reviewed

ADVERSE EVENTS

AE Term:

Start Date/Time:

DD-MMM-YYYY

Stop Date/Time:

DD-MMM-YYYY

Outcome:

(24:00 hr clock)

(24:00 hr clock)

Severity:

Action Taken toward product:

Concomitant Therapy for AE:	Yes	No
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Relationship:

SAE:	Yes	No
------	-----	----

SAE, Criteria:

Study Name	: RJRT CSD1010	Course Name	: Adverse Events
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Adverse Events
Casebook Name	: 2067	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: AE Code
Casebook Signature	: jborders	Form Status	:

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	: 002 - Central Kentucky Research Associates	Event Name	: Con Meds
Casebook Name	: 2067	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds
Casebook Signature	: jborders	Form Status	: DM Reviewed

CONCOMITANT MEDICATIONS

Medication	<input type="text"/>			
Dose	<input type="text"/>			
Units				
Route				
Start Date/Time	<input type="text" value="UNK-UNK-2010"/>	DD-MMM-YYYY	<input type="text"/>	(24:00 hr clock)
Stop Date/Time	<input type="text" value="UNK-JAN-2012"/>	DD-MMM-YYYY	<input type="text"/>	(24:00 hr clock)
	Ongoing			
Indication	<input type="text"/>			

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	: 002 - Central Kentucky Research Associates	Event Name	: Con Meds
Casebook Name	: 2067	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds
Casebook Signature	: jborders	Form Status	: DM Reviewed

1

2

3

4

Not on list

Coding Completed?

Study Name	: RJRT CSD1010	Course Name	: Prtcl Deviations
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Prtcl Deviations
Casebook Name	: 2067	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Prtcl Deviations (1)
Casebook Signature	: jborders	Form Status	: DM Reviewed

DEVIATIONS

Date of Deviation	Deviation Category	Deviation Description
<div>07-JUN-2012</div> <div>DD-MMM-YYYY</div>		<div></div> <div>1</div>

*1) visit 6 done in error to confirm pregnancy. subject was a treatment success but ammended to failure per medical monitor due to pregnancy.

Study Name	: RJRT CSD1010	Course Name	: Prtcl Deviations
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Prtcl Deviations
Casebook Name	: 2067	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Prtcl Deviations (2)
Casebook Signature	: jborders	Form Status	: DM Reviewed

DEVIATIONS

Date of Deviation	Deviation Category	Deviation Description
<div>22-JUN-2011</div> <div>DD-MMM-YYYY</div>		<div></div> <div>1</div>

*1) visit 2 week 2 visit conducted outside of protocol visit window, sponsor not notified.

Study Name	: RJRT CSD1010	Course Name	: Randomization
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Randomization
Casebook Name	: 2067	Event Date	: 06-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Randomization
Casebook Signature	: jborders	Form Status	: DM Reviewed

RANDOMIZATION

Randomization Number:

Please select Cohort:

Study Name	: RJRT CSD1010	Course Name	: Study Conc.
Site Name	: 002 - Central Kentucky Research Associates	Event Name	: Study Conclusion
Casebook Name	: 2067	Event Date	: 29-MAY-2012
Casebook Status	: Casebook Frozen And Locked	Form Name	: Study Conclusion
Casebook Signature	: jborders	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:

29-MAY-2012

DD-MMM-YYYY

Reason for Early Withdrawal

Specify:

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
155795	5/20/2011 11:5:51	5-20-2011 11:03:15:677	4921	rbennett	Renita Bennett	TD_CASE-BOOK	3902	0:0					Casebook Created
155796	5/20/2011 11:6:54	5-20-2011 11:04:22:937	4921	rbennett	Renita Bennett	TD_CASE-BOOK	3902	0:0				2c87b4784df0aa5551b8fd5939c5e04e	LUID Created
155797	5/20/2011 11:7:6	5-20-2011 11:04:35:311	4921	rbennett	Renita Bennett	TD_EVENT	16628	0:0				5-19-2011	Event Created
155801	5/20/2011 11:7:54	5-20-2011 11:05:22:385	4921	rbennett	Renita Bennett	TD_FORM	46567	46567:0	Demographics		0	1	Form Status set to 1
155802	5/20/2011 11:7:54	5-20-2011 11:05:22:385	4921	rbennett	Renita Bennett	TD_DATA	112501	46567:1334290	Demographics	DM.DMICDT		5-19-2011	Data Added
155803	5/20/2011 11:7:54	5-20-2011 11:05:22:385	4921	rbennett	Renita Bennett	TD_DATA	112502	46567:1334292	Demographics	DM.DMICTM		09:50	Data Added
155804	5/20/2011 11:7:54	5-20-2011 11:05:22:385	4921	rbennett	Renita Bennett	TD_DATA	112503	46567:1334294	Demographics	DM.DMDOBDT		(b) (6)	Data Added
155805	5/20/2011 11:7:54	5-20-2011 11:05:22:385	4921	rbennett	Renita Bennett	TD_DATA	112504	46567:1334298	Demographics	DM.DMSEX		Female	Data Added
155806	5/20/2011 11:7:54	5-20-2011 11:05:22:385	4921	rbennett	Renita Bennett	TD_DATA	112505	46567:1334300	Demographics	DM.DMETH		Not Hispanic or Latino	Data Added
155807	5/20/2011 11:7:54	5-20-2011 11:05:22:385	4921	rbennett	Renita Bennett	TD_DATA	112506	46567:1334306	Demographics	DM.DMRACE5		true	Data Added
155808	5/20/2011 11:7:54	5-20-2011 11:05:22:385	4921	rbennett	Renita Bennett	TD_DATA	112507	46567:1334308	Demographics	DM.DMGRADE		High school graduate (grade 12)	Data Added
155809	5/20/2011 11:7:54	5-20-2011 11:05:22:385	4921	rbennett	Renita Bennett	TD_DATA	112508	46567:1334310	Demographics	DM.DMINC		Less than \$20,000	Data Added
155810	5/20/2011 11:7:55		4921	rbennett	Renita Bennett	TD_DATA	112509	46567:1334296	Demographics	DM.DMAGE		22	computed value
155811	5/20/2011 11:7:57	5-20-2011 11:05:27:291	4921	rbennett	Renita Bennett	TD_FORM	46567	46567:0	Demographics		1	2	Form Status set to 2
189279	6/7/2011 1-3:46:36	6-7-2011 1-3:43:05:159	4921	rbennett	Renita Bennett	TD_FORM	46568	46568:0	Brief Med. History		0	1	Form Status set to 1
189280	6/7/2011 1-3:46:36	6-7-2011 1-3:43:05:159	4921	rbennett	Renita Bennett	TD_DATA	136557	46568:1334318	Brief Med. History	MH.MHCOND		Seasonal allergies	Data Added
189281	6/7/2011 1-3:46:36	6-7-2011 1-3:43:05:159	4921	rbennett	Renita Bennett	TD_DATA	136558	46568:1334319	Brief Med. History	MH.MHSTYYYY		1998	Data Added
189282	6/7/2011 1-3:46:36	6-7-2011 1-3:43:05:159	4921	rbennett	Renita Bennett	TD_DATA	136559	46568:1334320	Brief Med. History	MH.MHENRF		Ongoing	Data Added
189283	6/7/2011 1-3:46:37	6-7-2011 1-3:43:06:237	4921	rbennett	Renita Bennett	TD_FORM	46568	46568:0	Brief Med. History		1	2	Form Status set to 2
189284	6/7/2011 1-3:46:40	6-7-2011 1-3:43:09:736	4921	rbennett	Renita Bennett	TD_FORM	55774	55774:0	Brief Med. History				Repeating Form Created
189285	6/7/2011 1-3:47:3	6-7-2011 1-3:43:32:274	4921	rbennett	Renita Bennett	TD_FORM	55774	55774:0	Brief Med. History		0	1	Form Status set to 1
189286	6/7/2011 1-3:47:3	6-7-2011 1-3:43:32:274	4921	rbennett	Renita Bennett	TD_DATA	136560	55774:1601712	Brief Med. History	MH.MHCOND		Hysterectomy	Data Added
189287	6/7/2011 1-3:47:3	6-7-2011 1-3:43:32:274	4921	rbennett	Renita Bennett	TD_DATA	136561	55774:1601713	Brief Med. History	MH.MHSTYYYY		2004	Data Added
189288	6/7/2011 1-3:47:3	6-7-2011 1-3:43:32:274	4921	rbennett	Renita Bennett	TD_DATA	136562	55774:1601714	Brief Med. History	MH.MHENRF		Prior	Data Added
189289	6/7/2011 1-3:47:4	6-7-2011 1-3:43:33:868	4921	rbennett	Renita Bennett	TD_FORM	55774	55774:0	Brief Med. History		1	2	Form Status set to 2
189290	6/7/2011 1-3:47:7	6-7-2011 1-3:43:36:898	4921	rbennett	Renita Bennett	TD_FORM	55775	55775:0	Brief Med. History				Repeating Form Created
189329	6/7/2011 1-3:49:8	6-7-2011 1-3:45:37:573	4921	rbennett	Renita Bennett	TD_FORM	55775	55775:0	Brief Med. History		0	1	Form Status set to 1
189330	6/7/2011 1-3:49:8	6-7-2011 1-3:45:37:573	4921	rbennett	Renita Bennett	TD_DATA	136595	55775:1601719	Brief Med. History	MH.MHCOND		Menorrhagia (abnormal vaginal bleeding)	Data Added
189331	6/7/2011 1-3:49:8	6-7-2011 1-3:45:37:573	4921	rbennett	Renita Bennett	TD_DATA	136596	55775:1601720	Brief Med. History	MH.MHSTYYYY		2004	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
189332	6/7/2011 1-3:49:8	6-7-2011 1-3:45:37:573	4921	rbennett	Renita Ben- nett	TD_DATA	136597	55775:1601721	Brief Med. History	MH.MHENRF		Prior	Data Added
189333	6/7/2011 1-3:49:10	6-7-2011 1-3:45:39:151	4921	rbennett	Renita Ben- nett	TD_FORM	55775	55775:0	Brief Med. History		1	2	Form Status set to 2
189334	6/7/2011 1-3:49:12	6-7-2011 1-3:45:41:134	4921	rbennett	Renita Ben- nett	TD_FORM	55776	55776:0	Brief Med. History				Repeating Form Created
189336	6/7/2011 1-3:49:33	6-7-2011 1-3:46:02:127	4921	rbennett	Renita Ben- nett	TD_FORM	55776	55776:0	Brief Med. History		0	1	Form Status set to 1
189337	6/7/2011 1-3:49:33	6-7-2011 1-3:46:02:127	4921	rbennett	Renita Ben- nett	TD_DATA	136598	55776:1601726	Brief Med. History	MH.MHCOND		Urinary tract infection	Data Added
189338	6/7/2011 1-3:49:33	6-7-2011 1-3:46:02:127	4921	rbennett	Renita Ben- nett	TD_DATA	136599	55776:1601727	Brief Med. History	MH.MHSTYYYY		2008	Data Added
189339	6/7/2011 1-3:49:33	6-7-2011 1-3:46:02:127	4921	rbennett	Renita Ben- nett	TD_DATA	136600	55776:1601728	Brief Med. History	MH.MHENRF		Prior	Data Added
189340	6/7/2011 1-3:49:34	6-7-2011 1-3:46:03:392	4921	rbennett	Renita Ben- nett	TD_FORM	55776	55776:0	Brief Med. History		1	2	Form Status set to 2
189361	6/7/2011 1-3:50:9	6-7-2011 1-3:46:38:270	4921	rbennett	Renita Ben- nett	TD_FORM	55776	55776:0	Brief Med. History		2	1	Form Status demoted to 1
189362	6/7/2011 1-3:50:12	6-7-2011 1-3:46:41:144	4921	rbennett	Renita Ben- nett	TD_FORM	55776	55776:0	Brief Med. History		1	2	Form Status set to 2
189381	6/7/2011 1-3:50:54	6-7-2011 1-3:47:23:723	4921	rbennett	Renita Ben- nett	TD_FORM	46570	46570:0	Vital Signs		0	1	Form Status set to 1
189382	6/7/2011 1-3:50:54	6-7-2011 1-3:47:23:723	4921	rbennett	Renita Ben- nett	TD_DATA	136635	46570:1334372	Vital Signs	VS.VSDT		5-19-2011	Data Added
189383	6/7/2011 1-3:50:54	6-7-2011 1-3:47:23:723	4921	rbennett	Renita Ben- nett	TD_DATA	136636	46570:1334373	Vital Signs	VS.VSTM		10:05	Data Added
189384	6/7/2011 1-3:50:54	6-7-2011 1-3:47:23:723	4921	rbennett	Renita Ben- nett	TD_DATA	136637	46570:1334377	Vital Signs	VS.VSHT		157	Data Added
189385	6/7/2011 1-3:50:54	6-7-2011 1-3:47:23:723	4921	rbennett	Renita Ben- nett	TD_DATA	136638	46570:1334380	Vital Signs	VS.VSWT		057.1	Data Added
189386	6/7/2011 1-3:50:54	6-7-2011 1-3:47:23:723	4921	rbennett	Renita Ben- nett	TD_DATA	136639	46570:1334389	Vital Signs	VS.VSSYS		115	Data Added
189387	6/7/2011 1-3:50:54	6-7-2011 1-3:47:23:723	4921	rbennett	Renita Ben- nett	TD_DATA	136640	46570:1334391	Vital Signs	VS.VSDIA		079	Data Added
189388	6/7/2011 1-3:50:54	6-7-2011 1-3:47:23:723	4921	rbennett	Renita Ben- nett	TD_DATA	136641	46570:1334393	Vital Signs	VS.VSHR		091	Data Added
189389	6/7/2011 1-3:50:54	6-7-2011 1-3:47:23:723	4921	rbennett	Renita Ben- nett	TD_DATA	136642	46570:1334395	Vital Signs	VS.VSRR		014	Data Added
189390	6/7/2011 1-3:50:54	6-7-2011 1-3:47:23:723	4921	rbennett	Renita Ben- nett	TD_DATA	136643	46570:1334397	Vital Signs	VS.VSTEMP		37.0	Data Added
189391	6/7/2011 1-3:50:55		4921	rbennett	Renita Ben- nett	TD_DATA	136644	46600:1335225	Vital Signs	VS.VSHT		157	computed value
189392	6/7/2011 1-3:50:55		4921	rbennett	Renita Ben- nett	TD_DATA	136645	46590:1334766	Vital Signs	VS.VSHT		157	computed value
189393	6/7/2011 1-3:50:55		4921	rbennett	Renita Ben- nett	TD_DATA	136646	46570:1334383	Vital Signs	VS.VSBMI		23.2	computed value
189394	6/7/2011 1-3:50:56	6-7-2011 1-3:47:25:394	4921	rbennett	Renita Ben- nett	TD_FORM	46570	46570:0	Vital Signs		1	2	Form Status set to 2
189395	6/7/2011 1-3:51:27	6-7-2011 1-3:47:56:211	4921	rbennett	Renita Ben- nett	TD_FORM	46571	46571:0	ECG		0	1	Form Status set to 1
189396	6/7/2011 1-3:51:27	6-7-2011 1-3:47:56:211	4921	rbennett	Renita Ben- nett	TD_DATA	136647	46571:1334400	ECG	EG.EGDT		5-19-2011	Data Added
189397	6/7/2011 1-3:51:27	6-7-2011 1-3:47:56:211	4921	rbennett	Renita Ben- nett	TD_DATA	136648	46571:1334401	ECG	EG.EGTM		10:31	Data Added
189398	6/7/2011 1-3:51:27	6-7-2011 1-3:47:56:211	4921	rbennett	Renita Ben- nett	TD_DATA	136649	46571:1334404	ECG	EG.EGASMT		Normal	Data Added
189399	6/7/2011 1-3:51:28	6-7-2011 1-3:47:57:648	4921	rbennett	Renita Ben- nett	TD_FORM	46571	46571:0	ECG		1	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
189403	6/7/2011 1-3:51:55	6-7-2011 1-3:48:23:920	4921	rbennett	Renita Ben- nett	TD_FORM	46573	46573:0	Exhaled CO		0	1	Form Status set to 1
189404	6/7/2011 1-3:51:55	6-7-2011 1-3:48:23:920	4921	rbennett	Renita Ben- nett	TD_DATA	136650	46573:1334429	Exhaled CO	EC.ECDT		5-19-2011	Data Added
189405	6/7/2011 1-3:51:55	6-7-2011 1-3:48:23:920	4921	rbennett	Renita Ben- nett	TD_DATA	136651	46573:1334430	Exhaled CO	EC.ECTM		10:20	Data Added
189406	6/7/2011 1-3:51:55	6-7-2011 1-3:48:23:920	4921	rbennett	Renita Ben- nett	TD_DATA	136652	46573:1334434	Exhaled CO	EC.ECRES1		13	Data Added
189407	6/7/2011 1-3:51:56	6-7-2011 1-3:48:25:372	4921	rbennett	Renita Ben- nett	TD_FORM	46573	46573:0	Exhaled CO		1	2	Form Status set to 2
189409	6/7/2011 1-3:52:36	6-7-2011 1-3:49:05:655	4921	rbennett	Renita Ben- nett	TD_FORM	46572	46572:0	Labs		0	1	Form Status set to 1
189410	6/7/2011 1-3:52:36	6-7-2011 1-3:49:05:655	4921	rbennett	Renita Ben- nett	TD_DATA	136653	46572:1334409	Labs	LB.LBBLDT		5-19-2011	Data Added
189411	6/7/2011 1-3:52:36	6-7-2011 1-3:49:05:655	4921	rbennett	Renita Ben- nett	TD_DATA	136654	46572:1334410	Labs	LB.LBBLTM		10:52	Data Added
189412	6/7/2011 1-3:52:36	6-7-2011 1-3:49:05:655	4921	rbennett	Renita Ben- nett	TD_DATA	136655	46572:1334413	Labs	LB.LBURDT		5-19-2011	Data Added
189413	6/7/2011 1-3:52:36	6-7-2011 1-3:49:05:655	4921	rbennett	Renita Ben- nett	TD_DATA	136656	46572:1334414	Labs	LB.LBURTM		09:55	Data Added
189414	6/7/2011 1-3:52:36	6-7-2011 1-3:49:05:655	4921	rbennett	Renita Ben- nett	TD_DATA	136657	46572:1334417	Labs	LB.LBBRDT		5-19-2011	Data Added
189415	6/7/2011 1-3:52:36	6-7-2011 1-3:49:05:655	4921	rbennett	Renita Ben- nett	TD_DATA	136658	46572:1334418	Labs	LB.LBBRTM		10:07	Data Added
189416	6/7/2011 1-3:52:36	6-7-2011 1-3:49:05:655	4921	rbennett	Renita Ben- nett	TD_DATA	136659	46572:1334422	Labs	LB.LBUDS		Negative	Data Added
189417	6/7/2011 1-3:52:36	6-7-2011 1-3:49:05:655	4921	rbennett	Renita Ben- nett	TD_DATA	136660	46572:1334424	Labs	LB.LBUCS		Negative	Data Added
189418	6/7/2011 1-3:52:36	6-7-2011 1-3:49:05:655	4921	rbennett	Renita Ben- nett	TD_DATA	136661	46572:1334426	Labs	LB.LBABS		Negative	Data Added
189419	6/7/2011 1-3:52:38	6-7-2011 1-3:49:07:139	4921	rbennett	Renita Ben- nett	TD_FORM	46572	46572:0	Labs		1	2	Form Status set to 2
189426	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_FORM	46569	46569:0	Comprehensive PE		0	1	Form Status set to 1
189427	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136664	46569:1334323	Comprehensive PE	PE.PEDT		5-19-2011	Data Added
189428	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136665	46569:1334328	Comprehensive PE	PE.PEGNAP		Normal	Data Added
189429	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136666	46569:1334331	Comprehensive PE	PE.PEHEAD		Normal	Data Added
189430	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136667	46569:1334334	Comprehensive PE	PE.PEORAL		Normal	Data Added
189431	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136668	46569:1334337	Comprehensive PE	PE.PEEN		Normal	Data Added
189432	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136669	46569:1334340	Comprehensive PE	PE.PECHST		Normal	Data Added
189433	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136670	46569:1334343	Comprehensive PE	PE.PEHR		Normal	Data Added
189434	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136671	46569:1334346	Comprehensive PE	PE.PEAB		Normal	Data Added
189435	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136672	46569:1334349	Comprehensive PE	PE.PEBACK		Normal	Data Added
189436	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136673	46569:1334352	Comprehensive PE	PE.PELYP		Normal	Data Added
189437	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136674	46569:1334355	Comprehensive PE	PE.PENEUR		Normal	Data Added
189438	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136675	46569:1334358	Comprehensive PE	PE.PEMUSC		Normal	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
189439	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136676	46569:1334361	Comprehensive PE	PE.PEEXT		Normal	Data Added
189440	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136677	46569:1334364	Comprehensive PE	PE.PESKIN		Normal	Data Added
189441	6/7/2011 1-3:53:0	6-7-2011 1-3:49:29:677	4921	rbennett	Renita Ben- nett	TD_DATA	136678	46569:1334367	Comprehensive PE	PE.PEOTH		Normal	Data Added
189442	6/7/2011 1-3:53:17	6-7-2011 1-3:49:46:765	4921	rbennett	Renita Ben- nett	TD_FORM	46569	46569:0	Comprehensive PE		1	2	Form Status set to 2
189454	6/7/2011 1-3:55:21	6-7-2011 1-3:51:50:174	4921	rbennett	Renita Ben- nett	TD_FORM	46569	46569:0	Comprehensive PE		2	1	Form Status demoted to 1
189455	6/7/2011 1-3:55:21	6-7-2011 1-3:51:50:174	4921	rbennett	Renita Ben- nett	TD_DATA	136678	46569:1334367	Comprehensive PE	PE.PEOTH	Normal	Not Done	Typographical error
189456	6/7/2011 1-3:55:24	6-7-2011 1-3:51:53:470	4921	rbennett	Renita Ben- nett	TD_FORM	46569	46569:0	Comprehensive PE		1	2	Form Status set to 2
189468	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_FORM	46574	46574:0	UB Descriptors		0	1	Form Status set to 1
189469	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_DATA	136693	46574:1334438	UB Descriptors	UB.UBDT		5-19-2011	Data Added
189470	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_DATA	136694	46574:1334440	UB Descriptors	UB.UBCPD		20	Data Added
189471	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_DATA	136695	46574:1334442	UB Descriptors	UB.UBYEAR		07	Data Added
189472	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_DATA	136696	46574:1334444	UB Descriptors	UB.UBSMKLS		No	Data Added
189473	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_DATA	136697	46574:1334446	UB Descriptors	UB.UBQUIT		Yes	Data Added
189474	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_DATA	136698	46574:1334448	UB Descriptors	UB.UBBRND		Marlboro	Data Added
189475	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_DATA	136699	46574:1334450	UB Descriptors	UB.UBSBRND		Seventy-twos	Data Added
189476	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_DATA	136700	46574:1334452	UB Descriptors	UB.UBLTH		72 mm	Data Added
189477	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_DATA	136701	46574:1334455	UB Descriptors	UB.UBPACK		Hard-pack box	Data Added
189478	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_DATA	136702	46574:1334457	UB Descriptors	UB.UBMENTH		Non-menthol	Data Added
189479	6/7/2011 1-3:56:51	6-7-2011 1-3:53:20:423	4921	rbennett	Renita Ben- nett	TD_DATA	136703	46574:1334459	UB Descriptors	UB.UBFILT		Filter	Data Added
189480	6/7/2011 1-3:56:54	6-7-2011 1-3:53:23:141	4921	rbennett	Renita Ben- nett	TD_FORM	46574	46574:0	UB Descriptors		1	2	Form Status set to 2
189495	6/7/2011 1-3:57:47	6-7-2011 1-3:54:16:512	4921	rbennett	Renita Ben- nett	TD_FORM	46575	46575:0	Inc/Exc		0	1	Form Status set to 1
189496	6/7/2011 1-3:57:47	6-7-2011 1-3:54:16:512	4921	rbennett	Renita Ben- nett	TD_DATA	136717	46575:1334463	Inc/Exc	IE.IECRITYN		Yes	Data Added
189505	6/7/2011 1-3:58:6	6-7-2011 1-3:54:34:974	4921	rbennett	Renita Ben- nett	TD_FORM	46575	46575:0	Inc/Exc		1	2	Form Status set to 2
189506	6/7/2011 1-3:58:28	6-7-2011 1-3:54:56:826	4921	rbennett	Renita Ben- nett	TD_FORM	46576	46576:0	Test Product Allot		0	1	Form Status set to 1
189507	6/7/2011 1-3:58:28	6-7-2011 1-3:54:56:826	4921	rbennett	Renita Ben- nett	TD_DATA	136725	46576:1334498	Test Product Allot	PU.PUSNUS1		Frost	Data Added
189508	6/7/2011 1-3:58:28	6-7-2011 1-3:54:56:826	4921	rbennett	Renita Ben- nett	TD_DATA	136726	46576:1334500	Test Product Allot	PU.PULOZG1		Mint	Data Added
189509	6/7/2011 1-3:58:30	6-7-2011 1-3:54:59:44	4921	rbennett	Renita Ben- nett	TD_FORM	46576	46576:0	Test Product Allot		1	2	Form Status set to 2
189522	6/7/2011 1-3:59:52	6-7-2011 1-3:56:21:405	4921	rbennett	Renita Ben- nett	TD_EVENT	16629	0:0				6-6-2011	Event Created
189524	6/7/2011 1-4:0:42	6-7-2011 1-3:57:10:981	4921	rbennett	Renita Ben- nett	TD_FORM	46577	46577:0	Vital Signs		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
189525	6/7/2011 1-4:0:42	6-7-2011 1-3:57:10:981	4921	rbennett	Renita Ben- nett	TD_DATA	136737	46577:1334502	Vital Signs	VS.VSDT		6-6-2011	Data Added
189526	6/7/2011 1-4:0:42	6-7-2011 1-3:57:10:981	4921	rbennett	Renita Ben- nett	TD_DATA	136738	46577:1334503	Vital Signs	VS.VSTM		13:14	Data Added
189527	6/7/2011 1-4:0:42	6-7-2011 1-3:57:10:981	4921	rbennett	Renita Ben- nett	TD_DATA	136739	46577:1334510	Vital Signs	VS.VSSYS		108	Data Added
189528	6/7/2011 1-4:0:42	6-7-2011 1-3:57:10:981	4921	rbennett	Renita Ben- nett	TD_DATA	136740	46577:1334512	Vital Signs	VS.VSDIA		047	Data Added
189529	6/7/2011 1-4:0:42	6-7-2011 1-3:57:10:981	4921	rbennett	Renita Ben- nett	TD_DATA	136741	46577:1334514	Vital Signs	VS.VSHR		111	Data Added
189530	6/7/2011 1-4:0:42	6-7-2011 1-3:57:10:981	4921	rbennett	Renita Ben- nett	TD_DATA	136742	46577:1334516	Vital Signs	VS.VSRR		014	Data Added
189531	6/7/2011 1-4:0:42	6-7-2011 1-3:57:10:981	4921	rbennett	Renita Ben- nett	TD_DATA	136743	46577:1334518	Vital Signs	VS.VSTEMP		37.1	Data Added
189532	6/7/2011 1-4:0:43	6-7-2011 1-3:57:12:324	4921	rbennett	Renita Ben- nett	TD_FORM	46577	46577:0	Vital Signs		1	2	Form Status set to 2
189534	6/7/2011 1-4:1:0	6-7-2011 1-3:57:29:459	4921	rbennett	Renita Ben- nett	TD_FORM	46578	46578:0	Labs		0	1	Form Status set to 1
189535	6/7/2011 1-4:1:0	6-7-2011 1-3:57:29:459	4921	rbennett	Renita Ben- nett	TD_DATA	136744	46578:1334522	Labs	LB.LBURDT		6-6-2011	Data Added
189536	6/7/2011 1-4:1:0	6-7-2011 1-3:57:29:459	4921	rbennett	Renita Ben- nett	TD_DATA	136745	46578:1334523	Labs	LB.LBURTM		13:10	Data Added
189537	6/7/2011 1-4:1:0	6-7-2011 1-3:57:29:459	4921	rbennett	Renita Ben- nett	TD_DATA	136746	46578:1334527	Labs	LB.LBUCS		Negative	Data Added
189538	6/7/2011 1-4:1:2	6-7-2011 1-3:57:30:864	4921	rbennett	Renita Ben- nett	TD_FORM	46578	46578:0	Labs		1	2	Form Status set to 2
189540	6/7/2011 1-4:1:15	6-7-2011 1-3:57:44:547	4921	rbennett	Renita Ben- nett	TD_FORM	46579	46579:0	Exhaled CO		0	1	Form Status set to 1
189541	6/7/2011 1-4:1:15	6-7-2011 1-3:57:44:547	4921	rbennett	Renita Ben- nett	TD_DATA	136747	46579:1334530	Exhaled CO	EC.ECDT		6-6-2011	Data Added
189542	6/7/2011 1-4:1:15	6-7-2011 1-3:57:44:547	4921	rbennett	Renita Ben- nett	TD_DATA	136748	46579:1334531	Exhaled CO	EC.ECTM		13:15	Data Added
189543	6/7/2011 1-4:1:15	6-7-2011 1-3:57:44:547	4921	rbennett	Renita Ben- nett	TD_DATA	136749	46579:1334535	Exhaled CO	EC.ECRES1		21	Data Added
189544	6/7/2011 1-4:1:16	6-7-2011 1-3:57:45:593	4921	rbennett	Renita Ben- nett	TD_FORM	46579	46579:0	Exhaled CO		1	2	Form Status set to 2
189545	6/7/2011 1-4:1:38	6-7-2011 1-3:58:06:930	4921	rbennett	Renita Ben- nett	TD_FORM	46580	46580:0	Test Product Allot		0	1	Form Status set to 1
189546	6/7/2011 1-4:1:38	6-7-2011 1-3:58:06:930	4921	rbennett	Renita Ben- nett	TD_DATA	136750	46580:1334539	Test Product Allot	PU.PUSNUS2		N/A	Data Added
189547	6/7/2011 1-4:1:38	6-7-2011 1-3:58:06:930	4921	rbennett	Renita Ben- nett	TD_DATA	136751	46580:1334541	Test Product Allot	PU.PULOZG2		Mint	Data Added
189548	6/7/2011 1-4:1:38	6-7-2011 1-3:58:06:930	4921	rbennett	Renita Ben- nett	TD_DATA	136752	46580:1334545	Test Product Allot	PU.PUDIS2		312	Data Added
189549	6/7/2011 1-4:1:39	6-7-2011 1-3:58:08:320	4921	rbennett	Renita Ben- nett	TD_FORM	46580	46580:0	Test Product Allot		1	2	Form Status set to 2
189550	6/7/2011 1-4:1:57	6-7-2011 1-3:58:26:219	4921	rbennett	Renita Ben- nett	TD_EVENT	16643	0:0				6-6-2011	Event Created
189551	6/7/2011 1-4:2:14	6-7-2011 1-3:58:42:823	4921	rbennett	Renita Ben- nett	TD_FORM	46608	46608:0	Randomization		0	1	Form Status set to 1
189552	6/7/2011 1-4:2:14	6-7-2011 1-3:58:42:823	4921	rbennett	Renita Ben- nett	TD_DATA	136753	46608:1335419	Randomization	RAND.RAND		220020	Data Added
189553	6/7/2011 1-4:2:14	6-7-2011 1-3:58:42:823	4921	rbennett	Renita Ben- nett	TD_DATA	136754	46608:1335421	Randomization	RAND.COHORT		Cohort 3	Data Added
189554	6/7/2011 1-4:2:15	6-7-2011 1-3:58:44:541	4921	rbennett	Renita Ben- nett	TD_FORM	46608	46608:0	Randomization		1	2	Form Status set to 2
195930	6/9/2011 1-1:43:18	6-9-2011 1-1:39:48:773	4321	rzabielski	Rita Zabielski	TD_FORM	46567	46567:0	Demographics		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
203085	6/13/2011 14:1:25	6-13-2011 13:58:17.349	6604	rtillman26	Roscoe Tillman	TD_FORM	46567	46567:0	Demographics		3	4	Form Status set to 4
232277	6/23/2011 10:45:56	6-23-2011 10:42:23.840	4921	rbennett	Renita Bennett	TD_EVENT	16630	0:0				6-22-2011	Event Created
232278	6/23/2011 10:46:16	6-23-2011 10:42:44:699	4921	rbennett	Renita Bennett	TD_FORM	46581	46581:0	Vital Signs		0	1	Form Status set to 1
232279	6/23/2011 10:46:16	6-23-2011 10:42:44:699	4921	rbennett	Renita Bennett	TD_DATA	167598	46581:1334547	Vital Signs	VS.VSDT		6-22-2011	Data Added
232280	6/23/2011 10:46:16	6-23-2011 10:42:44:699	4921	rbennett	Renita Bennett	TD_DATA	167599	46581:1334548	Vital Signs	VS.VSTM		13:59	Data Added
232281	6/23/2011 10:46:16	6-23-2011 10:42:44:699	4921	rbennett	Renita Bennett	TD_DATA	167600	46581:1334555	Vital Signs	VS.VSSYS		119	Data Added
232282	6/23/2011 10:46:16	6-23-2011 10:42:44:699	4921	rbennett	Renita Bennett	TD_DATA	167601	46581:1334557	Vital Signs	VS.VSDIA		081	Data Added
232283	6/23/2011 10:46:16	6-23-2011 10:42:44:699	4921	rbennett	Renita Bennett	TD_DATA	167602	46581:1334559	Vital Signs	VS.VSHR		098	Data Added
232284	6/23/2011 10:46:16	6-23-2011 10:42:44:699	4921	rbennett	Renita Bennett	TD_DATA	167603	46581:1334561	Vital Signs	VS.VSRR		014	Data Added
232285	6/23/2011 10:46:16	6-23-2011 10:42:44:699	4921	rbennett	Renita Bennett	TD_DATA	167604	46581:1334563	Vital Signs	VS.VSTEMP		36.8	Data Added
232286	6/23/2011 10:46:18	6-23-2011 10:42:46:90	4921	rbennett	Renita Bennett	TD_FORM	46581	46581:0	Vital Signs		1	2	Form Status set to 2
232287	6/23/2011 10:46:33	6-23-2011 10:43:01:262	4921	rbennett	Renita Bennett	TD_FORM	46582	46582:0	Labs		0	1	Form Status set to 1
232288	6/23/2011 10:46:33	6-23-2011 10:43:01:262	4921	rbennett	Renita Bennett	TD_DATA	167605	46582:1334567	Labs	LB.LBURDT		6-22-2011	Data Added
232289	6/23/2011 10:46:33	6-23-2011 10:43:01:262	4921	rbennett	Renita Bennett	TD_DATA	167606	46582:1334568	Labs	LB.LBURTM		13:52	Data Added
232290	6/23/2011 10:46:33	6-23-2011 10:43:01:262	4921	rbennett	Renita Bennett	TD_DATA	167607	46582:1334572	Labs	LB.LBUCS		Negative	Data Added
232291	6/23/2011 10:46:34	6-23-2011 10:43:02:527	4921	rbennett	Renita Bennett	TD_FORM	46582	46582:0	Labs		1	2	Form Status set to 2
232292	6/23/2011 10:46:39	6-23-2011 10:43:06:902	4921	rbennett	Renita Bennett	TD_FORM	46583	46583:0	Exhaled CO		0	1	Form Status set to 1
232293	6/23/2011 10:46:39	6-23-2011 10:43:06:902	4921	rbennett	Renita Bennett	TD_DATA	167608	46583:1334575	Exhaled CO	EC.ECYN		N/A	Data Added
232294	6/23/2011 10:47:5	6-23-2011 10:43:32:933	4921	rbennett	Renita Bennett	TD_FORM	46583	46583:0	Exhaled CO		1	2	Form Status set to 2
232295	6/23/2011 10:47:19	6-23-2011 10:43:47:729	4921	rbennett	Renita Bennett	TD_FORM	46584	46584:0	Test Product Allot		0	1	Form Status set to 1
232296	6/23/2011 10:47:19	6-23-2011 10:43:47:729	4921	rbennett	Renita Bennett	TD_DATA	167609	46584:1334586	Test Product Allot	PU.PUSNUS2		N/A	Data Added
232297	6/23/2011 10:47:19	6-23-2011 10:43:47:729	4921	rbennett	Renita Bennett	TD_DATA	167610	46584:1334588	Test Product Allot	PU.PULOZG2		Mint	Data Added
232298	6/23/2011 10:47:19	6-23-2011 10:43:47:729	4921	rbennett	Renita Bennett	TD_DATA	167611	46584:1334590	Test Product Allot	PU.PURET		297	Data Added
232299	6/23/2011 10:47:19	6-23-2011 10:43:47:729	4921	rbennett	Renita Bennett	TD_DATA	167612	46584:1334592	Test Product Allot	PU.PUDIS2		648	Data Added
232300	6/23/2011 10:47:22	6-23-2011 10:43:50:245	4921	rbennett	Renita Bennett	TD_FORM	46584	46584:0	Test Product Allot		1	2	Form Status set to 2
274478	7/12/2011 13:9:39	7-12-2011 13:06:04:584	4321	rzabielski	Rita Zabielski	TD_FORM	46570	46570:0	Vital Signs		2	3	Form Status set to 3
274479	7/12/2011 13:9:57	7-12-2011 13:06:21:751	4321	rzabielski	Rita Zabielski	TD_FORM	46573	46573:0	Exhaled CO		2	3	Form Status set to 3
274480	7/12/2011 13:10:20	7-12-2011 13:06:44:654	4321	rzabielski	Rita Zabielski	TD_FORM	46572	46572:0	Labs		2	3	Form Status set to 3
274481	7/12/2011 13:10:38	7-12-2011 13:07:03:473	4321	rzabielski	Rita Zabielski	TD_FORM	46569	46569:0	Comprehensive PE		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
274482	7/12/2011 13:11:52	7-12-2011 13:08:16.744	4321	rzabielski	Rita Zabielski	TD_FORM	46577	46577:0	Vital Signs		2	3	Form Status set to 3
274483	7/12/2011 13:12:1	7-12-2011 13:08:26.283	4321	rzabielski	Rita Zabielski	TD_FORM	46579	46579:0	Exhaled CO		2	3	Form Status set to 3
274484	7/12/2011 13:12:13	7-12-2011 13:08:38.294	4321	rzabielski	Rita Zabielski	TD_FORM	46578	46578:0	Labs		2	3	Form Status set to 3
274485	7/12/2011 13:13:0	7-12-2011 13:09:25.532	4321	rzabielski	Rita Zabielski	TD_FORM	46581	46581:0	Vital Signs		2	3	Form Status set to 3
274487	7/12/2011 13:13:14	7-12-2011 13:09:39.252	4321	rzabielski	Rita Zabielski	TD_FORM	46582	46582:0	Labs		2	3	Form Status set to 3
274488	7/12/2011 13:13:25	7-12-2011 13:09:50.203	4321	rzabielski	Rita Zabielski	TD_FORM	46583	46583:0	Exhaled CO		2	3	Form Status set to 3
274501	7/12/2011 13:13:58	7-12-2011 13:10:22.757	4321	rzabielski	Rita Zabielski	TD_FORM	46608	46608:0	Randomization		2	3	Form Status set to 3
281307	7/18/2011 14:3:8	7-18-2011 13:59:00.448	6604	rtillman26	Roscoe Tillman	TD_FORM	46569	46569:0	Comprehensive PE		3	4	Form Status set to 4
281308	7/18/2011 14:3:16	7-18-2011 13:59:08.448	6604	rtillman26	Roscoe Tillman	TD_FORM	46570	46570:0	Vital Signs		3	4	Form Status set to 4
281309	7/18/2011 14:3:21	7-18-2011 13:59:13.511	6604	rtillman26	Roscoe Tillman	TD_FORM	46572	46572:0	Labs		3	4	Form Status set to 4
281310	7/18/2011 14:3:25	7-18-2011 13:59:16.933	6604	rtillman26	Roscoe Tillman	TD_FORM	46573	46573:0	Exhaled CO		3	4	Form Status set to 4
281311	7/18/2011 14:3:34	7-18-2011 13:59:26.683	6604	rtillman26	Roscoe Tillman	TD_FORM	46577	46577:0	Vital Signs		3	4	Form Status set to 4
281312	7/18/2011 14:3:40	7-18-2011 13:59:32.89	6604	rtillman26	Roscoe Tillman	TD_FORM	46578	46578:0	Labs		3	4	Form Status set to 4
281313	7/18/2011 14:3:44	7-18-2011 13:59:36.58	6604	rtillman26	Roscoe Tillman	TD_FORM	46579	46579:0	Exhaled CO		3	4	Form Status set to 4
281314	7/18/2011 14:3:50	7-18-2011 13:59:42.589	6604	rtillman26	Roscoe Tillman	TD_FORM	46581	46581:0	Vital Signs		3	4	Form Status set to 4
281315	7/18/2011 14:3:55	7-18-2011 13:59:47.418	6604	rtillman26	Roscoe Tillman	TD_FORM	46582	46582:0	Labs		3	4	Form Status set to 4
281316	7/18/2011 14:3:59	7-18-2011 13:59:51.339	6604	rtillman26	Roscoe Tillman	TD_FORM	46583	46583:0	Exhaled CO		3	4	Form Status set to 4
281317	7/18/2011 14:4:2	7-18-2011 13:59:54.839	6604	rtillman26	Roscoe Tillman	TD_FORM	46608	46608:0	Randomization		3	4	Form Status set to 4
291088	7/26/2011 11:45:53	7-26-2011 11:42:10.550	342	jsoper	Joy Soper	TD_EVENT	16631	0:0				7-25-2011	Event Created
291089	7/26/2011 11:46:11	7-26-2011 11:42:28:9	342	jsoper	Joy Soper	TD_FORM	46585	46585:0	Vital Signs		0	2	Form Status set to 2
291090	7/26/2011 11:46:11	7-26-2011 11:42:28:9	342	jsoper	Joy Soper	TD_DATA	209921	46585:1334594	Vital Signs	VS.VSDT		7-25-2011	Data Added
291091	7/26/2011 11:46:11	7-26-2011 11:42:28:9	342	jsoper	Joy Soper	TD_DATA	209922	46585:1334595	Vital Signs	VS.VSTM		15:35	Data Added
291092	7/26/2011 11:46:11	7-26-2011 11:42:28:9	342	jsoper	Joy Soper	TD_DATA	209923	46585:1334602	Vital Signs	VS.VSSYS		105	Data Added
291093	7/26/2011 11:46:11	7-26-2011 11:42:28:9	342	jsoper	Joy Soper	TD_DATA	209924	46585:1334604	Vital Signs	VS.VSDIA		75	Data Added
291094	7/26/2011 11:46:11	7-26-2011 11:42:28:9	342	jsoper	Joy Soper	TD_DATA	209925	46585:1334606	Vital Signs	VS.VSHR		110	Data Added
291095	7/26/2011 11:46:11	7-26-2011 11:42:28:9	342	jsoper	Joy Soper	TD_DATA	209926	46585:1334608	Vital Signs	VS.VSRR		16	Data Added
291096	7/26/2011 11:46:11	7-26-2011 11:42:28:9	342	jsoper	Joy Soper	TD_DATA	209927	46585:1334610	Vital Signs	VS.VSTEMP		36.8	Data Added
291097	7/26/2011 11:46:24	7-26-2011 11:42:41:325	342	jsoper	Joy Soper	TD_FORM	46586	46586:0	Labs		0	2	Form Status set to 2
291098	7/26/2011 11:46:24	7-26-2011 11:42:41:325	342	jsoper	Joy Soper	TD_DATA	209928	46586:1334614	Labs	LB.LBURDT		7-25-2011	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
291099	7/26/2011 11:46:24	7-26-2011 11:42:41:325	342	jsoper	Joy Soper	TD_DATA	209929	46586:1334615	Labs	LB.LBURTM		15:29	Data Added
291100	7/26/2011 11:46:24	7-26-2011 11:42:41:325	342	jsoper	Joy Soper	TD_DATA	209930	46586:1334619	Labs	LB.LBUCS		Negative	Data Added
291101	7/26/2011 11:46:33	7-26-2011 11:42:50:688	342	jsoper	Joy Soper	TD_FORM	46587	46587:0	Exhaled CO		0	1	Form Status set to 1
291102	7/26/2011 11:46:33	7-26-2011 11:42:50:688	342	jsoper	Joy Soper	TD_DATA	209931	46587:1334622	Exhaled CO	EC.ECYN		N/A	Data Added
291103	7/26/2011 11:47:1	7-26-2011 11:43:18:71	342	jsoper	Joy Soper	TD_FORM	46587	46587:0	Exhaled CO		1	2	Form Status set to 2
291104	7/26/2011 11:47:14	7-26-2011 11:43:31:420	342	jsoper	Joy Soper	TD_FORM	46588	46588:0	Test Product Allot		0	2	Form Status set to 2
291105	7/26/2011 11:47:14	7-26-2011 11:43:31:420	342	jsoper	Joy Soper	TD_DATA	209932	46588:1334633	Test Product Allot	PU.PUSNUS2		N/A	Data Added
291106	7/26/2011 11:47:14	7-26-2011 11:43:31:420	342	jsoper	Joy Soper	TD_DATA	209933	46588:1334635	Test Product Allot	PU.PULOZG2		Mint	Data Added
291107	7/26/2011 11:47:14	7-26-2011 11:43:31:420	342	jsoper	Joy Soper	TD_DATA	209934	46588:1334637	Test Product Allot	PU.PURET		551	Data Added
291108	7/26/2011 11:47:14	7-26-2011 11:43:31:420	342	jsoper	Joy Soper	TD_DATA	209935	46588:1334639	Test Product Allot	PU.PUDIS2		0	Data Added
313455	8/24/2011 21:39:20	8-24-2011 21:35:10:42	342	jsoper	Joy Soper	TD_EVENT	16632	0:0				8-22-2011	Event Created
313456	8/24/2011 21:41:18	8-24-2011 21:37:07:260	342	jsoper	Joy Soper	TD_FORM	46589	46589:0	Product Usage Q		0	2	Form Status set to 2
313457	8/24/2011 21:41:18	8-24-2011 21:37:07:260	342	jsoper	Joy Soper	TD_DATA	222853	46589:1334642	Product Usage Q	SC.SCQ1		Yes	Data Added
313458	8/24/2011 21:41:18	8-24-2011 21:37:07:260	342	jsoper	Joy Soper	TD_DATA	222854	46589:1334644	Product Usage Q	SC.SCQ1DT		7-26-2011	Data Added
313459	8/24/2011 21:41:18	8-24-2011 21:37:07:260	342	jsoper	Joy Soper	TD_DATA	222855	46589:1334646	Product Usage Q	SC.SCQ2		Yes	Data Added
313460	8/24/2011 21:41:18	8-24-2011 21:37:07:260	342	jsoper	Joy Soper	TD_DATA	222856	46589:1334648	Product Usage Q	SC.SCQ3		Yes	Data Added
313461	8/24/2011 21:41:18	8-24-2011 21:37:07:260	342	jsoper	Joy Soper	TD_DATA	222857	46589:1334651	Product Usage Q	SC.SCQ4A		true	Data Added
313462	8/24/2011 21:41:18	8-24-2011 21:37:07:260	342	jsoper	Joy Soper	TD_DATA	222858	46589:1334665	Product Usage Q	SC.SCQ5A		14	Data Added
313463	8/24/2011 21:41:18	8-24-2011 21:37:07:260	342	jsoper	Joy Soper	TD_DATA	222859	46589:1334693	Product Usage Q	SC.SCQ6A		10	Data Added
320561	8/25/2011 16:6:21	8-25-2011 16:01:36:208	4321	rzabielski	Rita Zabielski	TD_FORM	46576	46576:0	Test Product Allot		2	3	Form Status set to 3
320581	8/25/2011 16:8:39	8-25-2011 16:03:54:387	4321	rzabielski	Rita Zabielski	TD_FORM	46589	46589:0	Product Usage Q		2	3	Form Status set to 3
326265	8/30/2011 12:37:4	8-30-2011 12:32:18:337	6604	rtillman26	Roscoe Tillman	TD_FORM	46576	46576:0	Test Product Allot		3	4	Form Status set to 4
326367	8/30/2011 12:42:19	8-30-2011 12:37:33:560	6604	rtillman26	Roscoe Tillman	TD_FORM	46589	46589:0	Product Usage Q		3	4	Form Status set to 4
383023	10/26/2011 15:27:20	10-26-2011 15:21:36:633	4321	rzabielski	Rita Zabielski	TD_FORM	46585	46585:0	Vital Signs		2	3	Form Status set to 3
383024	10/26/2011 15:27:37	10-26-2011 15:21:53:137	4321	rzabielski	Rita Zabielski	TD_FORM	46586	46586:0	Labs		2	3	Form Status set to 3
383026	10/26/2011 15:27:49	10-26-2011 15:22:05:581	4321	rzabielski	Rita Zabielski	TD_FORM	46587	46587:0	Exhaled CO		2	3	Form Status set to 3
383199	10/26/2011 17:25:27	10-26-2011 17:19:54:650	6604	rtillman26	Roscoe Tillman	TD_FORM	46586	46586:0	Labs		3	4	Form Status set to 4
383200	10/26/2011 17:25:40	10-26-2011 17:20:07:776	6604	rtillman26	Roscoe Tillman	TD_FORM	46587	46587:0	Exhaled CO		3	4	Form Status set to 4
383202	10/26/2011 17:29:3	10-26-2011 17:23:30:432	6604	rtillman26	Roscoe Tillman	TD_FORM	46585	46585:0	Vital Signs		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
386796	11/2/2011 13:51:45	11-2-2011 13:47:24:322	103	cbaker	Cynthia Baker	TD_FORM	46580	46580:0	Test Product Allot		2	3	Form Status set to 3
386797	11/2/2011 13:52:7	11-2-2011 13:47:46:16	103	cbaker	Cynthia Baker	TD_FORM	46584	46584:0	Test Product Allot		2	3	Form Status set to 3
386798	11/2/2011 13:52:53	11-2-2011 13:48:32:404	103	cbaker	Cynthia Baker	TD_FORM	46588	46588:0	Test Product Allot		2	3	Form Status set to 3
388844	11/4/2011 15:43:54	11-4-2011 15:38:50:688	103	cbaker	Cynthia Baker	TD_FORM	46571	46571:0	ECG		2	3	Form Status set to 3
393593	11/11/2011 15:58:48	11-11-2011 15:54:09:287	6602	gpreciado34	Gina Preci- ado	TD_FORM	46580	46580:0	Test Product Allot		3	4	Form Status set to 4
393594	11/11/2011 15:58:58	11-11-2011 15:54:19:37	6602	gpreciado34	Gina Preci- ado	TD_FORM	46584	46584:0	Test Product Allot		3	4	Form Status set to 4
393595	11/11/2011 15:59:10	11-11-2011 15:54:30:380	6602	gpreciado34	Gina Preci- ado	TD_FORM	46588	46588:0	Test Product Allot		3	4	Form Status set to 4
393623	11/11/2011 16:4:20	11-11-2011 15:59:40:742	6602	gpreciado34	Gina Preci- ado	TD_FORM	46571	46571:0	ECG		3	4	Form Status set to 4
395702	11/14/2011 14:9:23	11-14-2011 14:06:04:108	103	cbaker	Cynthia Baker	TD_FORM	46568	46568:0	Brief Med. History		2	3	Form Status set to 3
395703	11/14/2011 14:9:33	11-14-2011 14:06:15:525	103	cbaker	Cynthia Baker	TD_FORM	55774	55774:0	Brief Med. History		2	3	Form Status set to 3
395704	11/14/2011 14:9:49	11-14-2011 14:06:30:184	103	cbaker	Cynthia Baker	TD_FORM	55775	55775:0	Brief Med. History		2	3	Form Status set to 3
395705	11/14/2011 14:10:0	11-14-2011 14:06:42:554	103	cbaker	Cynthia Baker	TD_FORM	55776	55776:0	Brief Med. History		2	3	Form Status set to 3
395706	11/14/2011 14:10:37	11-14-2011 14:07:19:943	103	cbaker	Cynthia Baker	TD_FORM	46567	46567:0	Demographics		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
395707	11/14/2011 14:10:54	11-14-2011 14:07:36:691	103	cbaker	Cynthia Baker	TD_FORM	46569	46569:0	Comprehensive PE		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
395708	11/14/2011 14:11:10	11-14-2011 14:07:52:859	103	cbaker	Cynthia Baker	TD_FORM	46570	46570:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
395718	11/14/2011 14:12:37	11-14-2011 14:09:20:54	103	cbaker	Cynthia Baker	TD_FORM	46575	46575:0	Inc/Exc		2	3	Form Status set to 3
395721	11/14/2011 14:12:59	11-14-2011 14:09:41:560	103	cbaker	Cynthia Baker	TD_FORM	46577	46577:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
395722	11/14/2011 14:13:18	11-14-2011 14:10:00:393	103	cbaker	Cynthia Baker	TD_FORM	46581	46581:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
395723	11/14/2011 14:13:30	11-14-2011 14:10:12:794	103	cbaker	Cynthia Baker	TD_FORM	46585	46585:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
399434	11/17/2011 14:1:58	11-17-2011 13:57:39:723	6602	gpreciado34	Gina Preci- ado	TD_FORM	55776	55776:0	Brief Med. History		3	4	Form Status set to 4
399435	11/17/2011 14:2:5	11-17-2011 13:57:46:332	6602	gpreciado34	Gina Preci- ado	TD_FORM	55775	55775:0	Brief Med. History		3	4	Form Status set to 4
399436	11/17/2011 14:2:9	11-17-2011 13:57:50:223	6602	gpreciado34	Gina Preci- ado	TD_FORM	55774	55774:0	Brief Med. History		3	4	Form Status set to 4
399437	11/17/2011 14:2:12	11-17-2011 13:57:53:629	6602	gpreciado34	Gina Preci- ado	TD_FORM	46568	46568:0	Brief Med. History		3	4	Form Status set to 4
399438	11/17/2011 14:2:17	11-17-2011 13:57:58:207	6602	gpreciado34	Gina Preci- ado	TD_FORM	46575	46575:0	Inc/Exc		3	4	Form Status set to 4
405643	11/23/2011 11:42:11	11-23-2011 11:36:29:999	4921	rbennett	Renita Ben- nett	TD_EVENT	16633	0:0			0	1	No Event Flag set to 1
405644	11/23/2011 11:42:23	11-23-2011 11:36:37:795	4921	rbennett	Renita Ben- nett	TD_EVENT	16634	0:0				11-22-2011	Event Created
405645	11/23/2011 11:43:12	11-23-2011 11:37:30:991	4921	rbennett	Renita Ben- nett	TD_FORM	46594	46594:0	Product Usage Q		0	2	Form Status set to 2
405646	11/23/2011 11:43:12	11-23-2011 11:37:30:991	4921	rbennett	Renita Ben- nett	TD_DATA	247641	46594:1334820	Product Usage Q	SC.SQ1		Yes	Data Added
405647	11/23/2011 11:43:12	11-23-2011 11:37:30:991	4921	rbennett	Renita Ben- nett	TD_DATA	247642	46594:1334822	Product Usage Q	SC.SQ1DT		8-22-2011	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
405648	11/23/2011 11:43:12	11-23-2011 11:37:30:991	4921	rbennett	Renita Ben- nett	TD_DATA	247643	46594:1334824	Product Usage Q	SC.SCQ2		Yes	Data Added
405649	11/23/2011 11:43:12	11-23-2011 11:37:30:991	4921	rbennett	Renita Ben- nett	TD_DATA	247644	46594:1334826	Product Usage Q	SC.SCQ3		Yes	Data Added
405650	11/23/2011 11:43:12	11-23-2011 11:37:30:991	4921	rbennett	Renita Ben- nett	TD_DATA	247645	46594:1334829	Product Usage Q	SC.SCQ4A		true	Data Added
405651	11/23/2011 11:43:12	11-23-2011 11:37:30:991	4921	rbennett	Renita Ben- nett	TD_DATA	247646	46594:1334843	Product Usage Q	SC.SCQ5A		14	Data Added
405652	11/23/2011 11:43:12	11-23-2011 11:37:30:991	4921	rbennett	Renita Ben- nett	TD_DATA	247647	46594:1334871	Product Usage Q	SC.SCQ6A		15	Data Added
405653	11/23/2011 11:53:3	11-23-2011 11:47:22:408	4921	rbennett	Renita Ben- nett	TD_FORM	46574	46574:0	UB Descriptors		2	1	Form Status demoted to 1
405654	11/23/2011 11:53:3	11-23-2011 11:47:22:408	4921	rbennett	Renita Ben- nett	TD_DATA	136699	46574:1334450	UB Descriptors	UB.UBSBRND	Seventy-twos	Red	Updated Source and CRF
405655	11/23/2011 11:53:11	11-23-2011 11:47:29:610	4921	rbennett	Renita Ben- nett	TD_FORM	46574	46574:0	UB Descriptors		1	2	Form Status set to 2
418180	1/5/2012 1-2:30:22	1-5-2012 1-2:25:39:491	4321	rzabielski	Rita Zabielski	TD_FORM	46594	46594:0	Product Usage Q		2	3	Form Status set to 3
420519	1/11/2012 15:4:58	1-11-2012 15:00:41:840	6602	gpreciado34	Gina Preci- ado	TD_FORM	46594	46594:0	Product Usage Q		3	4	Form Status set to 4
430943	1/31/2012 17:16:14	1-31-2012 17:11:05:796	103	cbaker	Cynthia Baker	TD_FORM	46574	46574:0	UB Descriptors		2	3	Form Status set to 3
430945	1/31/2012 17:17:54	1-31-2012 17:12:48:768	6602	gpreciado34	Gina Preci- ado	TD_FORM	46574	46574:0	UB Descriptors		3	4	Form Status set to 4
438921	3/8/2012 1-4:32:27	3-8-2012 1-4:27:30:446	4921	rbennett	Renita Ben- nett	TD_EVENT	16635	0:0			0	1	No Event Flag set to 1
438922	3/8/2012 1-4:32:37	3-8-2012 1-4:27:40:114	4921	rbennett	Renita Ben- nett	TD_EVENT	16636	0:0				3-8-2012	Event Created
438923	3/8/2012 1-4:32:46	3-8-2012 1-4:27:49:658	4921	rbennett	Renita Ben- nett	TD_FORM	46598	46598:0	Product Usage Q		0	2	Form Status set to 2
438924	3/8/2012 1-4:32:46	3-8-2012 1-4:27:49:658	4921	rbennett	Renita Ben- nett	TD_DATA	256218	46598:1334982	Product Usage Q	SC.SCQ1		No	Data Added
438925	3/8/2012 1-4:32:46	3-8-2012 1-4:27:49:658	4921	rbennett	Renita Ben- nett	TD_DATA	256219	46598:1334986	Product Usage Q	SC.SCQ2		No	Data Added
438926	3/8/2012 1-4:32:46	3-8-2012 1-4:27:49:658	4921	rbennett	Renita Ben- nett	TD_DATA	256220	46598:1334988	Product Usage Q	SC.SCQ3		No	Data Added
441850	3/22/2012 13:59:19	3-22-2012 13:54:58:833	4321	rzabielski	Rita Zabielski	TD_FORM	46598	46598:0	Product Usage Q		2	3	Form Status set to 3
446973	4/19/2012 16:35:3	4-19-2012 16:30:33:91	6602	gpreciado34	Gina Preci- ado	TD_FORM	46598	46598:0	Product Usage Q		3	4	Form Status set to 4
455015	5/29/2012 15:3:44	5-29-2012 14:58:30:170	4921	rbennett	Renita Ben- nett	TD_EVENT	16637	0:0				5-29-2012	Event Created
455016	5/29/2012 15:3:59	5-29-2012 14:58:49:608	4921	rbennett	Renita Ben- nett	TD_FORM	46599	46599:0	Product Usage Q		0	2	Form Status set to 2
455017	5/29/2012 15:3:59	5-29-2012 14:58:49:608	4921	rbennett	Renita Ben- nett	TD_DATA	263574	46599:1335101	Product Usage Q	SC.SCQ1		No	Data Added
455018	5/29/2012 15:3:59	5-29-2012 14:58:49:608	4921	rbennett	Renita Ben- nett	TD_DATA	263575	46599:1335105	Product Usage Q	SC.SCQ2		No	Data Added
455019	5/29/2012 15:3:59	5-29-2012 14:58:49:608	4921	rbennett	Renita Ben- nett	TD_DATA	263576	46599:1335107	Product Usage Q	SC.SCQ3		No	Data Added
455059	5/30/2012 11:38:17	5-30-2012 11:33:14:925	342	jsoper	Joy Soper	TD_EVENT	16644	0:0				5-29-2012	Event Created
455060	5/30/2012 11:38:33	5-30-2012 11:33:33:972	342	jsoper	Joy Soper	TD_FORM	46609	46609:0	Study Conclusion		0	1	Form Status set to 1
455061	5/30/2012 11:38:33	5-30-2012 11:33:33:972	342	jsoper	Joy Soper	TD_DATA	263610	46609:1335424	Study Conclusion	DS.DSETSC		Discontinued prior to completion of the study	Data Added
455062	5/30/2012 11:38:33	5-30-2012 11:33:33:972	342	jsoper	Joy Soper	TD_DATA	263611	46609:1335428	Study Conclusion	DS.DSETREAS		Other	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
455080	5/31/2012 7:46:17	5-31-2012 7:41:13.215	4921	rbennett	Renita Ben- nett	TD_FORM	46609	46609:0	Study Conclusion		1	0	Form Status demoted to 0 Reason : Entered in error.
455081	5/31/2012 7:46:17	5-31-2012 7:41:13.215	4921	rbennett	Renita Ben- nett	TD_DATA	263610	46609:1335424	Study Conclusion	DS.DSETSC	Discontinued prior to completion of the study		Entered in error.
455082	5/31/2012 7:46:17	5-31-2012 7:41:13.215	4921	rbennett	Renita Ben- nett	TD_DATA	263611	46609:1335428	Study Conclusion	DS.DSETREAS	Other		Entered in error.
456120	6/8/2012 1-0:28:6	6-8-2012 1-0:22:26.982	4921	rbennett	Renita Ben- nett	TD_EVENT	16639	0:0			0	1	No Event Flag set to 1
456121	6/8/2012 1-0:32:6	6-8-2012 1-0:26:23.355	4921	rbennett	Renita Ben- nett	TD_EVENT	16640	0:0					Shared Event Added
456122	6/8/2012 1-0:33:13	6-8-2012 1-0:27:38.81	4921	rbennett	Renita Ben- nett	TD_FORM	46605	46605:0	Con Meds		0	2	Form Status set to 2
456123	6/8/2012 1-0:33:14	6-8-2012 1-0:27:38.81	4921	rbennett	Renita Ben- nett	TD_DATA	264245	46605:1335314	Con Meds	CM.CMTRT		Orthotricycline	Data Added
456124	6/8/2012 1-0:33:14	6-8-2012 1-0:27:38.81	4921	rbennett	Renita Ben- nett	TD_DATA	264246	46605:1335316	Con Meds	CM.CMDOSE		1	Data Added
456125	6/8/2012 1-0:33:14	6-8-2012 1-0:27:38.81	4921	rbennett	Renita Ben- nett	TD_DATA	264247	46605:1335318	Con Meds	CM.CMDOSU		Tablet	Data Added
456126	6/8/2012 1-0:33:14	6-8-2012 1-0:27:38.81	4921	rbennett	Renita Ben- nett	TD_DATA	264248	46605:1335320	Con Meds	CM.CMROUT		Oral	Data Added
456127	6/8/2012 1-0:33:14	6-8-2012 1-0:27:38.81	4921	rbennett	Renita Ben- nett	TD_DATA	264249	46605:1335322	Con Meds	CM.CMSTDT		UNK-UNK-2010	Data Added
456128	6/8/2012 1-0:33:14	6-8-2012 1-0:27:38.81	4921	rbennett	Renita Ben- nett	TD_DATA	264250	46605:1335329	Con Meds	CM.CMONGO		true	Data Added
456129	6/8/2012 1-0:33:14	6-8-2012 1-0:27:38.81	4921	rbennett	Renita Ben- nett	TD_DATA	264251	46605:1335331	Con Meds	CM.CMINDC		Birth control	Data Added
456130	6/8/2012 1-0:33:18		4921	rbennett	Renita Ben- nett	TD_DATA	264252	46605:1335348	Con Meds	CM.CODECPLT			computed value
456131	6/8/2012 1-0:33:18		4921	rbennett	Renita Ben- nett	TD_DATA	264253	46605:1335337	Con Meds	CM.TERM		Orthotricycline	computed value
456132	6/8/2012 1-0:33:18		4921	rbennett	Renita Ben- nett	TD_DATA	264254	46605:1335335	Con Meds	CM.ORIGNAME		Orthotricycline	computed value
456133	6/8/2012 1-0:33:19		4921	rbennett	Renita Ben- nett	TD_DATA	264255	46605:1335339	Con Meds	CM.RSLT1		Sorry, no results were found.	computed value
456134	6/8/2012 1-0:33:19		4921	rbennett	Renita Ben- nett	TD_DATA	264256	46605:1335341	Con Meds	CM.RSLT2			computed value
456135	6/8/2012 1-0:33:19		4921	rbennett	Renita Ben- nett	TD_DATA	264257	46605:1335343	Con Meds	CM.RSLT3			computed value
456136	6/8/2012 1-0:33:19		4921	rbennett	Renita Ben- nett	TD_DATA	264258	46605:1335345	Con Meds	CM.RSLT4			computed value
456137	6/8/2012 1-0:33:19		4921	rbennett	Renita Ben- nett	TD_DATA	264259	46605:1335340	Con Meds	CM.CODE1			computed value
456138	6/8/2012 1-0:33:19		4921	rbennett	Renita Ben- nett	TD_DATA	264260	46605:1335342	Con Meds	CM.CODE2			computed value
456139	6/8/2012 1-0:33:19		4921	rbennett	Renita Ben- nett	TD_DATA	264261	46605:1335344	Con Meds	CM.CODE3			computed value
456140	6/8/2012 1-0:33:19		4921	rbennett	Renita Ben- nett	TD_DATA	264262	46605:1335346	Con Meds	CM.CODE4			computed value
456141	6/8/2012 1-0:37:56	6-8-2012 1-0:32:18.445	4921	rbennett	Renita Ben- nett	TD_EVENT	16638	0:0				6-7-2012	Event Created
456142	6/8/2012 1-0:38:35	6-8-2012 1-0:32:59.301	4921	rbennett	Renita Ben- nett	TD_FORM	46600	46600:0	Vital Signs		0	2	Form Status set to 2
456143	6/8/2012 1-0:38:35	6-8-2012 1-0:32:59.301	4921	rbennett	Renita Ben- nett	TD_DATA	264263	46600:1335220	Vital Signs	VS.VSDT		6-7-2012	Data Added
456144	6/8/2012 1-0:38:35	6-8-2012 1-0:32:59.301	4921	rbennett	Renita Ben- nett	TD_DATA	264264	46600:1335221	Vital Signs	VS.VSTM		15:30	Data Added
456145	6/8/2012 1-0:38:35	6-8-2012 1-0:32:59.301	4921	rbennett	Renita Ben- nett	TD_DATA	264265	46600:1335228	Vital Signs	VS.VSWT		69.7	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
456146	6/8/2012 1-0:38:35	6-8-2012 1-0:32:59:301	4921	rbennett	Renita Ben- nett	TD_DATA	264266	46600:1335237	Vital Signs	VS.VSSYS		105	Data Added
456147	6/8/2012 1-0:38:35	6-8-2012 1-0:32:59:301	4921	rbennett	Renita Ben- nett	TD_DATA	264267	46600:1335239	Vital Signs	VS.VSDIA		071	Data Added
456148	6/8/2012 1-0:38:35	6-8-2012 1-0:32:59:301	4921	rbennett	Renita Ben- nett	TD_DATA	264268	46600:1335241	Vital Signs	VS.VSHR		97	Data Added
456149	6/8/2012 1-0:38:35	6-8-2012 1-0:32:59:301	4921	rbennett	Renita Ben- nett	TD_DATA	264269	46600:1335243	Vital Signs	VS.VSRR		16	Data Added
456150	6/8/2012 1-0:38:35	6-8-2012 1-0:32:59:301	4921	rbennett	Renita Ben- nett	TD_DATA	264270	46600:1335245	Vital Signs	VS.VSTEMP		37.1	Data Added
456151	6/8/2012 1-0:38:35		4921	rbennett	Renita Ben- nett	TD_DATA	264271	46600:1335231	Vital Signs	VS.VSBMI		28.3	computed value
456152	6/8/2012 1-0:38:51	6-8-2012 1-0:33:15:831	4921	rbennett	Renita Ben- nett	TD_FORM	46601	46601:0	Exhaled CO		0	2	Form Status set to 2
456153	6/8/2012 1-0:38:51	6-8-2012 1-0:33:15:831	4921	rbennett	Renita Ben- nett	TD_DATA	264272	46601:1335248	Exhaled CO	EC.ECYN		Yes	Data Added
456154	6/8/2012 1-0:38:51	6-8-2012 1-0:33:15:831	4921	rbennett	Renita Ben- nett	TD_DATA	264273	46601:1335250	Exhaled CO	EC.ECDT		6-7-2012	Data Added
456155	6/8/2012 1-0:38:51	6-8-2012 1-0:33:15:831	4921	rbennett	Renita Ben- nett	TD_DATA	264274	46601:1335251	Exhaled CO	EC.ECTM		15:32	Data Added
456156	6/8/2012 1-0:38:51	6-8-2012 1-0:33:15:831	4921	rbennett	Renita Ben- nett	TD_DATA	264275	46601:1335255	Exhaled CO	EC.ECRES1		00	Data Added
456157	6/8/2012 1-0:40:38	6-8-2012 1-0:35:02:703	4921	rbennett	Renita Ben- nett	TD_FORM	46602	46602:0	Labs		0	2	Form Status set to 2
456158	6/8/2012 1-0:40:38	6-8-2012 1-0:35:02:703	4921	rbennett	Renita Ben- nett	TD_DATA	264276	46602:1335260	Labs	LB.LBBLDT		6-7-2012	Data Added
456159	6/8/2012 1-0:40:38	6-8-2012 1-0:35:02:703	4921	rbennett	Renita Ben- nett	TD_DATA	264277	46602:1335261	Labs	LB.LBBLTM		15:40	Data Added
456160	6/8/2012 1-0:40:38	6-8-2012 1-0:35:02:703	4921	rbennett	Renita Ben- nett	TD_DATA	264278	46602:1335264	Labs	LB.LBURDT		6-7-2012	Data Added
456161	6/8/2012 1-0:40:38	6-8-2012 1-0:35:02:703	4921	rbennett	Renita Ben- nett	TD_DATA	264279	46602:1335265	Labs	LB.LBURTM		15:35	Data Added
456162	6/8/2012 1-0:40:38	6-8-2012 1-0:35:02:703	4921	rbennett	Renita Ben- nett	TD_DATA	264280	46602:1335269	Labs	LB.LBUCS		Positive	Data Added
456163	6/8/2012 1-0:47:2	6-8-2012 1-0:41:25:532	4921	rbennett	Renita Ben- nett	TD_EVENT	16641	0:0			0	1	No Event Flag set to 1
456164	6/8/2012 1-0:47:14	6-8-2012 1-0:41:38:595	4921	rbennett	Renita Ben- nett	TD_FORM	46609	46609:0	Study Conclusion		0	2	Form Status set to 2
456165	6/8/2012 1-0:47:14	6-8-2012 1-0:41:38:595	4921	rbennett	Renita Ben- nett	TD_DATA	264281	46609:1335424	Study Conclusion	DS.DSETSC		Completed the study	Data Added
456166	6/8/2012 1-0:47:14	6-8-2012 1-0:41:38:595	4921	rbennett	Renita Ben- nett	TD_DATA	264282	46609:1335426	Study Conclusion	DS.DSETSCDT		6-7-2012	Data Added
456167	6/8/2012 1-0:53:17	6-8-2012 1-0:47:41:804	4921	rbennett	Renita Ben- nett	TD_FORM	46609	46609:0	Study Conclusion		2	1	Form Status demoted to 1
456168	6/8/2012 1-0:53:33	6-8-2012 1-0:47:57:163	4921	rbennett	Renita Ben- nett	TD_FORM	46609	46609:0	Study Conclusion		1	0	Form Status demoted to 0 Reason : Entred completion date in error.
456169	6/8/2012 1-0:53:33	6-8-2012 1-0:47:57:163	4921	rbennett	Renita Ben- nett	TD_DATA	264281	46609:1335424	Study Conclusion	DS.DSETSC	Completed the study		Entred completion date in error.
456170	6/8/2012 1-0:53:33	6-8-2012 1-0:47:57:163	4921	rbennett	Renita Ben- nett	TD_DATA	264282	46609:1335426	Study Conclusion	DS.DSETSCDT	6-7-2012		Entred completion date in error.
457235	6/15/2012 9:44:41	6-15-2012 9:39:30:111	4921	rbennett	Renita Ben- nett	TD_FORM	46605	46605:0	Con Meds		2	1	Form Status demoted to 1
457236	6/15/2012 9:44:41	6-15-2012 9:39:30:111	4921	rbennett	Renita Ben- nett	TD_DATA	264774	46605:1335326	Con Meds	CM.CMENDDT		1-UNK-2012	Data Added
457237	6/15/2012 9:44:41	6-15-2012 9:39:30:111	4921	rbennett	Renita Ben- nett	TD_DATA	264250	46605:1335329	Con Meds	CM.CMONGO	true	false	Requires update
457238	6/15/2012 9:51:5	6-15-2012 9:45:53:594	4921	rbennett	Renita Ben- nett	TD_FORM	46605	46605:0	Con Meds		1	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
457475	6/17/2012 14:37:53	6-17-2012 14:32:56:327	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	46605	46605:0	Con Meds		2	3	Form Status set to 3
458628	6/20/2012 13:15:42	6-20-2012 13:09:35:660	7302	igottliebco	Joanne Gottlieb	TD_DATA	264253	46605:1335337	Con Meds	CM.TERM	Orthotricycline	orthotricycline	Requires update
458629	6/20/2012 13:18:49	6-20-2012 13:12:56:90	7302	igottliebco	Joanne Gottlieb	TD_DATA	264253	46605:1335337	Con Meds	CM.TERM	orthotricycline	Ortho Tri-Cyclen	Requires update
458630	6/20/2012 13:18:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	264255	46605:1335339	Con Meds	CM.RSLT1	Sorry, no results were found.	Ortho tri-cyclen Cilest GENITO URINARY SYSTEM AND SEX HORMONES SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE Progestogens and estrogens, fixed combinations	computed value
458631	6/20/2012 13:18:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	264256	46605:1335341	Con Meds	CM.RSLT2		Ortho tri-cyclen lo Cilest GENITO URINARY SYSTEM AND SEX HORMONES SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE Progestogens and estrogens, fixed combinations	computed value
458632	6/20/2012 13:18:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	264257	46605:1335343	Con Meds	CM.RSLT3		Ortho-tri-cyclen 28 Cilest GENITO URINARY SYSTEM AND SEX HORMONES SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE Progestogens and estrogens, fixed combinations	computed value
458633	6/20/2012 13:18:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	264258	46605:1335345	Con Meds	CM.RSLT4		Ortho-tri-cyclen 21 Cilest GENITO URINARY SYSTEM AND SEX HORMONES SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE Progestogens and estrogens, fixed combinations	computed value
458634	6/20/2012 13:18:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	264259	46605:1335340	Con Meds	CM.CODE1		00918101005G03AA	computed value
458635	6/20/2012 13:18:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	264260	46605:1335342	Con Meds	CM.CODE2		00918101011G03AA	computed value
458636	6/20/2012 13:18:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	264261	46605:1335344	Con Meds	CM.CODE3		00918101020G03AA	computed value
458637	6/20/2012 13:18:50		7302	igottliebco	Joanne Gottlieb	TD_DATA	264262	46605:1335346	Con Meds	CM.CODE4		00918101021G03AA	computed value
458638	6/20/2012 13:19:25	6-20-2012 13:13:31:400	7302	igottliebco	Joanne Gottlieb	TD_DATA	265455	46605:1335338	Con Meds	CM.CHOICE		1	Data Added
458639	6/20/2012 13:19:25	6-20-2012 13:13:31:400	7302	igottliebco	Joanne Gottlieb	TD_DATA	264252	46605:1335348	Con Meds	CM.CODECPLT		true	Requires update
458640	6/20/2012 13:19:25		7302	igottliebco	Joanne Gottlieb	TD_DATA	264255	46605:1335339	Con Meds	CM.RSLT1	Ortho tri-cyclen Cilest GENITO URINARY SYSTEM AND SEX HORMONES SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE Progestogens and estrogens, fixed combinations	** Ortho tri-cyclen Cilest GENITO URINARY SYSTEM AND SEX HORMONES SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE Progestogens and estrogens, fixed combinations	computed value
459468	6/20/2012 16:55:40	6-20-2012 16:49:44:596	6602	gpreciado34	Gina Preciado	TD_FORM	46605	46605:0	Con Meds		3	4	Form Status set to 4
460404	6/25/2012 9:42:28	6-25-2012 9:36:51:917	4921	rbennett	Renita Bennett	TD_FORM	46600	46600:0	Vital Signs		2	1	Form Status demoted to 1
460405	6/25/2012 9:43:19	6-25-2012 9:37:37:382	4921	rbennett	Renita Bennett	TD_FORM	46600	46600:0	Vital Signs		1	0	Form Status demoted to 0 Reason : Data entered in error.
460406	6/25/2012 9:43:19	6-25-2012 9:37:37:382	4921	rbennett	Renita Bennett	TD_DATA	264263	46600:1335220	Vital Signs	VS.VSDT	6-7-2012		Data entered in error.
460407	6/25/2012 9:43:19	6-25-2012 9:37:37:382	4921	rbennett	Renita Bennett	TD_DATA	264264	46600:1335221	Vital Signs	VS.VSTM	15:30		Data entered in error.
460408	6/25/2012 9:43:19	6-25-2012 9:37:37:382	4921	rbennett	Renita Bennett	TD_DATA	136644	46600:1335225	Vital Signs	VS.VSHT	157		Data entered in error.
460409	6/25/2012 9:43:19	6-25-2012 9:37:37:382	4921	rbennett	Renita Bennett	TD_DATA	264265	46600:1335228	Vital Signs	VS.VSWT	69.7		Data entered in error.
460410	6/25/2012 9:43:19	6-25-2012 9:37:37:382	4921	rbennett	Renita Bennett	TD_DATA	264271	46600:1335231	Vital Signs	VS.VSBMI	28.3		Data entered in error.

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
460418	6/25/2012 9:43:25	6-25-2012 9:37:48:302	4921	rbennett	Renita Ben- nett	TD_FORM	46601	46601:0	Exhaled CO		2	1	Form Status demoted to 1
460419	6/25/2012 9:43:40	6-25-2012 9:38:03:410	4921	rbennett	Renita Ben- nett	TD_FORM	46601	46601:0	Exhaled CO		1	0	Form Status demoted to 0 Reason : data entered in error
460420	6/25/2012 9:43:40	6-25-2012 9:38:03:410	4921	rbennett	Renita Ben- nett	TD_DATA	264272	46601:1335248	Exhaled CO	EC.ECYN	Yes		data entered in error
460421	6/25/2012 9:43:40	6-25-2012 9:38:03:410	4921	rbennett	Renita Ben- nett	TD_DATA	264273	46601:1335250	Exhaled CO	EC.ECDT	6-7-2012		data entered in error
460422	6/25/2012 9:43:40	6-25-2012 9:38:03:410	4921	rbennett	Renita Ben- nett	TD_DATA	264274	46601:1335251	Exhaled CO	EC.ECTM	15:32		data entered in error
460423	6/25/2012 9:43:40	6-25-2012 9:38:03:410	4921	rbennett	Renita Ben- nett	TD_DATA	264275	46601:1335255	Exhaled CO	EC.ECRES1	00		data entered in error
460424	6/25/2012 9:43:43	6-25-2012 9:38:06:613	4921	rbennett	Renita Ben- nett	TD_FORM	46601	46601:0	Exhaled CO		0	2	Form Status set to 2
460425	6/25/2012 9:43:43	6-25-2012 9:38:06:613	4921	rbennett	Renita Ben- nett	TD_FORM	46601	46601:0	Exhaled CO		0	1	Form Checked Intentionally Left Blank
460426	6/25/2012 9:43:45	6-25-2012 9:38:08:285	4921	rbennett	Renita Ben- nett	TD_FORM	46602	46602:0	Labs		2	1	Form Status demoted to 1
460427	6/25/2012 9:43:49	6-25-2012 9:38:12:753	4921	rbennett	Renita Ben- nett	TD_FORM	46602	46602:0	Labs		1	0	Form Status demoted to 0 Reason : data entered in error
460428	6/25/2012 9:43:49	6-25-2012 9:38:12:753	4921	rbennett	Renita Ben- nett	TD_DATA	264276	46602:1335260	Labs	LB.LBBLDT	6-7-2012		data entered in error
460429	6/25/2012 9:43:49	6-25-2012 9:38:12:753	4921	rbennett	Renita Ben- nett	TD_DATA	264277	46602:1335261	Labs	LB.LBBLTM	15:40		data entered in error
460430	6/25/2012 9:43:49	6-25-2012 9:38:12:753	4921	rbennett	Renita Ben- nett	TD_DATA	264278	46602:1335264	Labs	LB.LBURDT	6-7-2012		data entered in error
460431	6/25/2012 9:43:49	6-25-2012 9:38:12:753	4921	rbennett	Renita Ben- nett	TD_DATA	264279	46602:1335265	Labs	LB.LBURTM	15:35		data entered in error
460432	6/25/2012 9:43:49	6-25-2012 9:38:12:753	4921	rbennett	Renita Ben- nett	TD_DATA	264280	46602:1335269	Labs	LB.LBUCS	Positive		data entered in error
460433	6/25/2012 9:43:55	6-25-2012 9:38:18:237	4921	rbennett	Renita Ben- nett	TD_FORM	46602	46602:0	Labs		0	2	Form Status set to 2
460434	6/25/2012 9:43:55	6-25-2012 9:38:18:237	4921	rbennett	Renita Ben- nett	TD_FORM	46602	46602:0	Labs		0	1	Form Checked Intentionally Left Blank
460435	6/25/2012 9:44:45	6-25-2012 9:39:07:998	4921	rbennett	Renita Ben- nett	TD_FORM	46609	46609:0	Study Conclusion		0	1	Form Status set to 1
460436	6/25/2012 9:44:45	6-25-2012 9:39:07:998	4921	rbennett	Renita Ben- nett	TD_DATA	265878	46609:1335424	Study Conclusion	DS.DSETSC		Discontinued prior to completion of the study	Data Added
460437	6/25/2012 9:44:45	6-25-2012 9:39:07:998	4921	rbennett	Renita Ben- nett	TD_DATA	265879	46609:1335426	Study Conclusion	DS.DSETSCDT		6-7-2012	Data Added
460438	6/25/2012 9:44:45	6-25-2012 9:39:07:998	4921	rbennett	Renita Ben- nett	TD_DATA	265880	46609:1335428	Study Conclusion	DS.DSETREAS		Other	Data Added
460439	6/25/2012 9:44:45	6-25-2012 9:39:07:998	4921	rbennett	Renita Ben- nett	TD_DATA	265881	46609:1335430	Study Conclusion	DS.DSETSP		Pregnancy	Data Added
460440	6/25/2012 9:45:10	6-25-2012 9:39:33:621	4921	rbennett	Renita Ben- nett	TD_FORM	46609	46609:0	Study Conclusion		1	2	Form Status set to 2
460441	6/25/2012 9:46:0	6-25-2012 9:40:17:148	4921	rbennett	Renita Ben- nett	TD_EVENT	16641	0:0			1	0	No Event Flag set to 0
460442	6/25/2012 9:46:7	6-25-2012 9:40:25:476	4921	rbennett	Renita Ben- nett	TD_EVENT	16641	0:0					Shared Event Added
460443	6/25/2012 9:47:50	6-25-2012 9:42:10:964	4921	rbennett	Renita Ben- nett	TD_FORM	46606	46606:0	Prtcl Deviations		0	2	Form Status set to 2
460444	6/25/2012 9:47:50	6-25-2012 9:42:10:964	4921	rbennett	Renita Ben- nett	TD_DATA	265882	46606:1335354	Prtcl Deviations	PV.PVDT		6-7-2012	Data Added
460445	6/25/2012 9:47:50	6-25-2012 9:42:10:964	4921	rbennett	Renita Ben- nett	TD_DATA	265883	46606:1335355	Prtcl Deviations	PV.PVCAT		Laboratory Assessments/Procedures	Data Added
460446	6/25/2012 9:47:50	6-25-2012 9:42:10:964	4921	rbennett	Renita Ben- nett	TD_DATA	265884	46606:1335356	Prtcl Deviations	PV.PVSPEC		Due to scheduling conflicts, patient came in for visit 6 to confirm pregnancy. Patient was a treatment success, therefore site completed all visit 6 procedures.	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
463335	7/10/2012 13:35:27	7-10-2012 13:29:34:310	342	jsoper	Joy Soper	TD_FORM	55774	55774:0	Brief Med. History		4	2	Form Status demoted to 2
463336	7/10/2012 13:35:27	7-10-2012 13:29:34:310	342	jsoper	Joy Soper	TD_DATA	136560	55774:1601712	Brief Med. History	MH.MHCOND	Hysterectomy	Hysteroscopy	Requires update
463800	7/15/2012 9:36:11	7-15-2012 9:31:12:343	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	55774	55774:0	Brief Med. History		2	3	Form Status set to 3
464200	7/17/2012 7:46:23	7-17-2012 7:40:00:760	4921	rbennett	Renita Bennett	TD_EVENT	16639	0:0			1	0	No Event Flag set to 0
464201	7/17/2012 7:46:30	7-17-2012 7:40:08:367	4921	rbennett	Renita Bennett	TD_EVENT	16639	0:0					Shared Event Added
464202	7/17/2012 7:46:47	7-17-2012 7:40:25:173	4921	rbennett	Renita Bennett	TD_FORM	46603	46603:0	Adverse Events		0	2	Form Status set to 2
464203	7/17/2012 7:46:47	7-17-2012 7:40:25:173	4921	rbennett	Renita Bennett	TD_FORM	46603	46603:0	Adverse Events		0	1	Form Checked Intentionally Left Blank
464476	7/19/2012 21:5:55	7-19-2012 21:00:16:687	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	46603	46603:0	Adverse Events		2	3	Form Status set to 3
464540	7/20/2012 10:33:9	7-20-2012 10:26:58:517	7302	jgottliebco	Joanne Gottlieb	TD_FORM	46604	46604:0	AE Code		0	7	Form Status set to 7
464541	7/20/2012 10:33:10	7-20-2012 10:26:58:517	7302	jgottliebco	Joanne Gottlieb	TD_FORM	46604	46604:0	AE Code		0	1	Form Checked Intentionally Left Blank
464960	7/23/2012 9:18:21	7-23-2012 9:12:15:305	4921	rbennett	Renita Bennett	TD_FORM	46606	46606:0	Prtcl Deviations		2	1	Form Status demoted to 1
464961	7/23/2012 9:18:21	7-23-2012 9:12:15:305	4921	rbennett	Renita Bennett	TD_DATA	265884	46606:1335356	Prtcl Deviations	PV.PVSPEC	Due to scheduling conflicts, patient came in for visit 6 to confirm pregnancy. Patient was a treatment success, therefore site completed all visit 6 procedures.	Due to scheduling conflicts, patient came in for visit 6 to confirm pregnancy. Patient was a treatment success, therefore site completed all visit 6 procedures.	Requires update
465160	7/25/2012 10:12:33	7-25-2012 10:06:39:338	4921	rbennett	Renita Bennett	TD_DATA	265884	46606:1335356	Prtcl Deviations	PV.PVSPEC	Due to scheduling conflicts, patient came in for visit 6 to confirm pregnancy. Patient was a treatment success, therefore site completed all visit 6 procedures.	visit 6 done in error to confirm pregnancy. subject was a treatment success but ammended to failure per medical monitor due to pregnancy.	Requires update
465161	7/25/2012 10:19:3	7-25-2012 10:13:09:595	4921	rbennett	Renita Bennett	TD_FORM	46606	46606:0	Prtcl Deviations		1	2	Form Status set to 2
465261	7/25/2012 18:49:57	7-25-2012 18:44:46:921	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	46606	46606:0	Prtcl Deviations		2	3	Form Status set to 3
465561	7/27/2012 10:46:46	7-27-2012 10:40:59:485	551	yovalle	Yulina Ovalle	TD_FORM	46606	46606:0	Prtcl Deviations		3	4	Form Status set to 4
465578	7/27/2012 10:48:22	7-27-2012 10:42:35:611	551	yovalle	Yulina Ovalle	TD_FORM	46603	46603:0	Adverse Events		3	4	Form Status set to 4
465585	7/27/2012 10:50:29	7-27-2012 10:44:42:784	551	yovalle	Yulina Ovalle	TD_FORM	55774	55774:0	Brief Med. History		3	4	Form Status set to 4
467226	8/2/2012 1-6:7:42	8-2-2012 1-6:01:16:580	782	kcorey	Kris Corey	TD_FORM	46599	46599:0	Product Usage Q		2	3	Form Status set to 3
467227	8/2/2012 1-6:8:2	8-2-2012 1-6:01:37:300	782	kcorey	Kris Corey	TD_FORM	46600	46600:0	Vital Signs		2	3	Form Status set to 3
467228	8/2/2012 1-6:8:5	8-2-2012 1-6:01:39:710	782	kcorey	Kris Corey	TD_FORM	46601	46601:0	Exhaled CO		2	3	Form Status set to 3
467229	8/2/2012 1-6:8:7	8-2-2012 1-6:01:41:780	782	kcorey	Kris Corey	TD_FORM	46602	46602:0	Labs		2	3	Form Status set to 3
467230	8/2/2012 1-6:8:45	8-2-2012 1-6:02:20:370	782	kcorey	Kris Corey	TD_FORM	46609	46609:0	Study Conclusion		2	3	Form Status set to 3
469157	8/7/2012 1-4:55:39	8-7-2012 1-4:49:31:0	4921	rbennett	Renita Bennett	TD_FORM	77462	77462:0	Prtcl Deviations				Repeating Form Created
469158	8/7/2012 1-4:57:42	8-7-2012 1-4:51:34:131	4921	rbennett	Renita Bennett	TD_FORM	77462	77462:0	Prtcl Deviations		0	2	Form Status set to 2
469159	8/7/2012 1-4:57:42	8-7-2012 1-4:51:34:131	4921	rbennett	Renita Bennett	TD_DATA	267938	77462:2125152	Prtcl Deviations	PV.PVDT		6-22-2011	Data Added
469160	8/7/2012 1-4:57:42	8-7-2012 1-4:51:34:131	4921	rbennett	Renita Bennett	TD_DATA	267939	77462:2125153	Prtcl Deviations	PV.PVCAT		Visit Schedule/Interval	Data Added
469161	8/7/2012 1-4:57:42	8-7-2012 1-4:51:34:131	4921	rbennett	Renita Bennett	TD_DATA	267940	77462:2125154	Prtcl Deviations	PV.PVSPEC		visit 2 week 2 visit conducted outside of protocol visit window, sponsor not notified.	Data Added
470380	8/12/2012 18:55:32	8-12-2012 18:48:40:477	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	77462	77462:0	Prtcl Deviations		2	3	Form Status set to 3

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
472063	8/16/2012 11:19:19	8-16-2012 11:12:40:381	4921	rbennett	Renita Ben- nett	TD_FORM	46609	46609:0	Study Conclusion		3	1	Form Status demoted to 1
472064	8/16/2012 11:19:19	8-16-2012 11:12:40:381	4921	rbennett	Renita Ben- nett	TD_DATA	265879	46609:1335426	Study Conclusion	DS.DSETSCDT	6-7-2012	5-29-2012	Requires update
472065	8/16/2012 11:19:21	8-16-2012 11:12:44:224	4921	rbennett	Renita Ben- nett	TD_FORM	46609	46609:0	Study Conclusion		1	2	Form Status set to 2
472077	8/16/2012 11:21:23	8-16-2012 11:14:36:802	6602	gpreciado34	Gina Preci- ado	TD_FORM	46599	46599:0	Product Usage Q		3	4	Form Status set to 4
472079	8/16/2012 11:22:6	8-16-2012 11:15:19:448	6602	gpreciado34	Gina Preci- ado	TD_FORM	46600	46600:0	Vital Signs		3	4	Form Status set to 4
472081	8/16/2012 11:22:17	8-16-2012 11:15:30:671	6602	gpreciado34	Gina Preci- ado	TD_FORM	46601	46601:0	Exhaled CO		3	4	Form Status set to 4
472082	8/16/2012 11:22:24	8-16-2012 11:15:36:859	6602	gpreciado34	Gina Preci- ado	TD_FORM	46602	46602:0	Labs		3	4	Form Status set to 4
472145	8/16/2012 11:33:1	8-16-2012 11:26:12:142	6602	gpreciado34	Gina Preci- ado	TD_FORM	77462	77462:0	Prtcl Deviations		3	4	Form Status set to 4
473421	8/21/2012 19:13:48	8-21-2012 19:07:32:171	782	kcorey	Kris Corey	TD_FORM	46609	46609:0	Study Conclusion		2	3	Form Status set to 3
474631	8/28/2012 17:33:59	8-28-2012 17:27:05:586	6602	gpreciado34	Gina Preci- ado	TD_FORM	46609	46609:0	Study Conclusion		3	4	Form Status set to 4
484017	9/24/2012 13:49:14	9-24-2012 13:41:51:647	7681	dchampagne234	Daphne C- hamapagne	TD_CASE- BOOK	3902	0:0			0	1	Casebook Frozen
485883	9/27/2012 13:21:21	9-27-2012 13:14:09:309	2964	jborders	James Bor- ders	TD_CASE- BOOK	3902	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		06-07-2011	SYSTEM	
Exhaled CO	Date ECO Obtained	EC.ECDT		APPROVED	Data is missing. Please provide.		06-23-2011	SYSTEM	
				RESOLVED		Confirmed Data, no action	2011-06-23 10:46:47.0	rbennett	Renita Bennett
				APPROVED		Confirmed Data, no action	2011-06-29 10:55:29.0	rtillman26	Roscoe Tillman
Exhaled CO	Time ECO Obtained	EC.ECTM		APPROVED	Data is missing. Please provide.		06-23-2011	SYSTEM	
				RESOLVED		Confirmed Data, no action	2011-06-23 10:46:52.0	rbennett	Renita Bennett
				APPROVED		Confirmed Data, no action	2011-06-29 10:55:51.0	rtillman26	Roscoe Tillman
Exhaled CO	ECO	EC.ECRES1		APPROVED	Data is missing. Please provide.		06-23-2011	SYSTEM	
				RESOLVED		Confirmed Data, no action	2011-06-23 10:46:57.0	rbennett	Renita Bennett
				APPROVED		Confirmed Data, no action	2011-06-29 10:55:56.0	rtillman26	Roscoe Tillman
Exhaled CO	Date ECO Obtained	EC.ECDT		APPROVED	Data is missing. Please provide.		07-26-2011	SYSTEM	
				RESOLVED		Confirmed Data, no action	2011-07-26 11:46:46.0	jsoper	Joy Soper
				APPROVED		Confirmed Data, no action	2011-07-27 16:12:24.0	rtillman26	Roscoe Tillman
Exhaled CO	Time ECO Obtained	EC.ECTM		APPROVED	Data is missing. Please provide.		07-26-2011	SYSTEM	
				RESOLVED		Confirmed Data, no action	2011-07-26 11:46:51.0	jsoper	Joy Soper
				APPROVED		Confirmed Data, no action	2011-07-27 16:12:32.0	rtillman26	Roscoe Tillman
Exhaled CO	ECO	EC.ECRES1		APPROVED	Data is missing. Please provide.		07-26-2011	SYSTEM	
				RESOLVED		Confirmed Data, no action	2011-07-26 11:46:56.0	jsoper	Joy Soper
				APPROVED		Confirmed Data, no action	2011-07-27 16:12:40.0	rtillman26	Roscoe Tillman
Vital Signs	FORM LEVEL	-form--form-		APPROVED	Please electronically sign source document.		8-25-2011	rzabielski	Rita Zabielski
				RESOLVED		Updated source document, no CRF change	2011-08-25 16:22:36.0	jsoper	Joy Soper
				APPROVED		Thank you.	2012-09-11 13:20:47.0	kcory	Kris Corey
UB Descriptors	Sub-brand:	UB.UBSBRND	Red	APPROVED	72's refers to length & is not a sub-brand. If no sub-brand, enter color of packaging.		11-14-2011	cbaker	Cynthia Baker
			Red	RESOLVED		Updated Source and CRF	2011-11-23 11:53:01.0	rbennett	Renita Bennett
			Red	APPROVED		ok	2012-01-31 17:16:06.0	cbaker	Cynthia Baker
Study Conclusion	Date of Completion	DS.DSETSCDT	5-29-2012	RESOLVED	Data is missing. Please provide.		05-30-2012	SYSTEM	
			-null-	RESOLVED		Entered in error.	2012-05-31 07:46:17.0	SYSTEM	
Study Conclusion	Other Specify	DS.DSETSP	Pregnancy	RESOLVED	Data is missing. Please provide.		05-30-2012	SYSTEM	
			-null-	RESOLVED		Entered in error.	2012-05-31 07:46:17.0	SYSTEM	
Labs	Urine Pregnancy Screen	LB.LBUCS		RESOLVED	Result for urine pregnancy screen is positive. Subject should be discontinued. Please correct or clarify.		06-08-2012	SYSTEM	
			2	RESOLVED		Confirmed Data, no action	2012-06-08 10:40:50.0	rbennett	Renita Bennett
			2	APPROVED		Confirmed Data, no action	2012-06-21 17:38:24.0	gpreciado34	Gina Preciado
Con Meds	FORM LEVEL	-form--form-		APPROVED	Per Source, subject learned of pregnancy in February 2012. Please verify end date and update source and eCRF as appropriate.		6-14-2012	mcaballero	Maria Isabel Caballero V-aliente
				RESOLVED		Updated Source and CRF	2012-06-15 09:44:57.0	rbennett	Renita Bennett

DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
				APPROVED		Updated Source and CRF	2012-06-19 12:27:01.0	mcaballero	Maria Isabel Caballero V-aliente
Study Conclusion	FORM LEVEL	-form--form-		APPROVED	Subject had a positive pregnancy test on Visit 6 and it should have been discontinued from the study, however, study conclusion hasnt been completed. Please complete		6-21-2012	gpreciado34	Gina Preciado
				RESOLVED		Updated Source and CRF	2012-06-25 09:45:05.0	rbennett	Renita Bennett
				APPROVED		Confirmed Data, no action	2012-07-30 14:33:55.0	gpreciado34	Gina Preciado
Prtcl Deviations	Deviation Description	PV.PVSPEC	visit 6 done in error to confirm pregnancy. subject was a treatment success but ammended to failure per medical monitor due to pregnancy.	APPROVED	Subject had a hysterectomy on the medical history and she came at visit 6 to complete all study procedures but all the forms are blank on visit 6, please complete all forms and if they were not done please add a protocol deviation.		7-10-2012	gpreciado34	Gina Preciado
			Due to scheduling conflicts, patient came in for visit 6 to confirm pregnancy. Patient was a treatment success, therfore site completed all visit 6 procedures.	RESOLVED		Confirmed Data, no action	2012-07-10 13:49:46.0	jsoper	Joy Soper
			Due to scheduling conflicts, patient came in for visit 6 to confirm pregnancy. Patient was a treatment success, therfore site completed all visit 6 procedures.	OPEN		forms were uploaded into I-VAULT, waiting for the site to complete the form in the database	2012-07-13 10:13:09.0	gpreciado34	Gina Preciado
			Due to scheduling conflicts, patient came in for visit 6 to confirm pregnancy. Patient was a treatment success, therfore site completed all visit 6 procedures.	RESOLVED		Updated CRF, no source change	2012-07-17 07:56:31.0	rbennett	Renita Bennett
			visit 6 done in error to confirm pregnancy. subject was a treatment success but ammended to failure per medical monitor due to pregnancy.	APPROVED		Entry error, updated CRF	2012-07-25 18:49:46.0	mcaballero	Maria Isabel Caballero V-aliente
Prtcl Deviations	Deviation Description	PV.PVSPEC	visit 6 done in error to confirm pregnancy. subject was a treatment success but ammended to failure per medical monitor due to pregnancy.	APPROVED	If subject ended being pregnant an AE follow with an SAE and Visit 6 forms must be completed and present. Please address asap.		7-10-2012	gpreciado34	Gina Preciado
			Due to scheduling conflicts, patient came in for visit 6 to confirm pregnancy. Patient was a treatment success, therfore site completed all visit 6 procedures.	RESOLVED		Confirmed Data, no action. Data has been removed from visit 6 as site was instructed to do.	2012-07-10 13:49:30.0	jsoper	Joy Soper
			Due to scheduling conflicts, patient came in for visit 6 to confirm pregnancy. Patient was a treatment success, therfore site completed all visit 6 procedures.	APPROVED		To requery. Per protocol (and MM's guidance), subject was not a Tx success as subject had to be discontinued due to PG.	2012-07-19 21:25:00.0	mcaballero	Maria Isabel Caballero V-aliente
Prtcl Deviations	FORM LEVEL	-form--form-		APPROVED	Per source, Subject reports pregnancy on TC4. Visit scheduled to confirm pregnancy. Per protocol, subject should have been discontinued upon confirmation of pregnancy. V6 procedures should not have been conducted. Modify PD text as appropriate.		7-15-2012	mcaballero	Maria Isabel Caballero V-aliente
				RESOLVED		Confirmed Data, no action	2012-07-17 07:52:17.0	rbennett	Renita Bennett
				APPROVED		Entry error, updated CRF	2012-07-25 18:48:56.0	mcaballero	Maria Isabel Caballero V-aliente
Vital Signs	FORM LEVEL	-form--form-		APPROVED	Per DEG, if no AE, create/add AE Form and mark it ILB. Please proceed accordingly.		7-15-2012	mcaballero	Maria Isabel Caballero V-aliente
				RESOLVED		Updated CRF, no source change	2012-07-17 07:47:08.0	rbennett	Renita Bennett
				APPROVED		Updated CRF, no source change	2012-09-12 19:25:25.0	mcaballero	Maria Isabel Caballero V-aliente
Prtcl Deviations	Deviation Description	PV.PVSPEC	visit 6 done in error to confirm pregnancy. subject was a treatment success but ammended to failure per medical monitor due to pregnancy.	APPROVED	Per protocol (and MM's guidance), subject was not a Tx success as subject had to be discontinued due to PG. PD text must reconcile w/source. Please review and update as appropriate.		7-19-2012	mcaballero	Maria Isabel Caballero V-aliente
			visit 6 done in error to confirm pregnancy. subject was a treatment success but ammended to failure per medical monitor due to pregnancy.	RESOLVED		Updated Source and CRF. Source description does not exactly match EDC description due to lack of character space in EDC.	2012-07-25 10:18:42.0	rbennett	Renita Bennett
			visit 6 done in error to confirm pregnancy. subject was a treatment success but ammended to failure per medical monitor due to pregnancy.	APPROVED		Updated CRF, no source change	2012-07-25 18:48:27.0	mcaballero	Maria Isabel Caballero V-aliente
Study Conclusion	FORM LEVEL	-form--form-		APPROVED	schedule date is not the same as end of study date, Please amend		7-30-2012	gpreciado34	Gina Preciado
				RESOLVED		Confirmed Data, no action.	2012-07-31 08:32:43.0	rbennett	Renita Bennett
				OPEN		If subject ET because of pregnancy, the study conclusion date and and schedule of events must be the same. PLease correct date	2012-08-16 10:40:21.0	gpreciado34	Gina Preciado
				RESOLVED		Updated Source and CRF	2012-08-16	rbennett	Renita Bennett

DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
				APPROVED		Confirmed Data, no action	2012-08-16 14:24:32.0	gpreciado34	Gina Preciado
Vital Signs	FORM LEVEL	-form-.form-		APPROVED	Please upload ILB form for this visit for rSDV. Thank you		8-2-2012	kcorey	Kris Corey
				RESOLVED		please see protocol deviation number 1.	2012-08-08 16:25:54.0	rbennett	Renita Bennett
				APPROVED		Thank you.	2012-09-10 09:11:17.0	kcorey	Kris Corey
Exhaled CO	FORM LEVEL	-form-.form-		APPROVED	Please upload ILB form for this visit for rSDV. Thank you		8-2-2012	kcorey	Kris Corey
				OPEN		Confirmed Data, no action, please see protocol deviation number 1.	2012-08-08 16:25:14.0	rbennett	Renita Bennett
				RESOLVED		please see protocol deviation number 1.	2012-08-08 16:25:24.0	rbennett	Renita Bennett
				APPROVED		Thank you.	2012-09-10 09:11:35.0	kcorey	Kris Corey
Labs	FORM LEVEL	-form-.form-		APPROVED	Please upload ILB form for this visit for rSDV. Thank you		8-2-2012	kcorey	Kris Corey
				RESOLVED		Confirmed Data, no action, please see protocol deviation number 1.	2012-08-08 16:24:58.0	rbennett	Renita Bennett
				APPROVED		Thank you.	2012-09-10 09:11:48.0	kcorey	Kris Corey