

Subject : 4025

Study Name RJRT CSD1010

Archive Date 31-Oct-2013

Site Name Orlando Clinical Research Center (4)

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Demographics
Casebook Signature	: tmarbury	Form Status	: DM Reviewed Signed

DEMOGRAPHICS

Informed Consent Date:

22-MAR-2011

DD-MMM-YYYY

Informed Consent Time:

Date of Birth:

(b) (6)

DD-MMM-YYYY

Age

Gender:

Male

Female

Ethnicity:

Hispanic or Latino

Not Hispanic or Latino

Race (please check all that apply):

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific Islander

White

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Demographics
Casebook Signature	: tmarbury	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	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Brief Med. History (1)
Casebook Signature	: tmarbury	Form Status	: DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery	Year	Status
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Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Brief Med. History (2)
Casebook Signature	: tmarbury	Form Status	: DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery	Year	Status
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Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Comprehensive PE
Casebook Signature	: tmarbury	Form Status	: DM Reviewed Signed

COMPREHENSIVE PHYSICAL EXAM

Date Physical Exam Completed: DD-MMM-YYYY

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

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Comprehensive PE
Casebook Signature	: tmarbury	Form Status	: DM Reviewed Signed

Extremities

Skin

Other

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: tmarbury	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	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: ECG
Casebook Signature	: tmarbury	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	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: tmarbury	Form Status	: DM Reviewed

SCREENING LABS

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

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

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

Results:

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

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: tmarbury	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

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

Results:

ECO (ppm)

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: UB Descriptors
Casebook Signature	: tmarbury	Form Status	: DM Reviewed

UB DESCRIPTORS AND SELF-REPORTED CPD

Date completed:

22-MAR-2011

 DD-MMM-YYYY

Average Cigarettes Smoked Per Day:

Duration of Smoking (in years)?

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

Yes

No

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

Yes

No

Brand:

Sub-brand:

Length:

72 mm

85 mm

100 mm

120 mm

Other (mm)

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: UB Descriptors
Casebook Signature	: tmarbury	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	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Inc/Exc
Casebook Signature	: tmarbury	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	: 004 - Orlando Clinical Research Center	Event Name	: Screening
Casebook Name	: 4025	Event Date	: 22-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Test Product Allot
Casebook Signature	: tmarbury	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	: 004 - Orlando Clinical Research Center	Event Name	: Visit 1
Casebook Name	: 4025	Event Date	: 31-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: tmarbury	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	: 004 - Orlando Clinical Research Center	Event Name	: Visit 1
Casebook Name	: 4025	Event Date	: 31-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: tmarbury	Form Status	: DM Reviewed

Visit 1 Labs

Urine Sample Date/Time Obtained:

31-MAR-2011

 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	: 004 - Orlando Clinical Research Center	Event Name	: Visit 1
Casebook Name	: 4025	Event Date	: 31-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: tmarbury	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

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

Results:

ECO (ppm)

Study Name : RJRT CSD1010

Site Name : 004 - Orlando Clinical Research Center

Casebook Name : 4025

Casebook Status : Casebook Frozen And Locked

Casebook Signature : tmarbury

Course Name : Visit 1

Event Name : Visit 1

Event Date : 31-MAR-2011

Form Name : Test Product Allot

Form Status : DM Reviewed

TEST PRODUCT ALLOTMENT

Preferred Flavor of SNUS:

Frost

Mellow

N/A

Preferred Flavor of Lozenge:

Original

Mint

N/A

Number of Units Returned:

Number of Units Dispensed:

Study Name	: RJRT CSD1010	Course Name	: Visit 2
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Visit 2
Casebook Name	: 4025	Event Date	: 15-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: tmarbury	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	: 004 - Orlando Clinical Research Center	Event Name	: Visit 2
Casebook Name	: 4025	Event Date	: 15-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: tmarbury	Form Status	: DM Reviewed

Visit 1 Labs

Urine Sample Date/Time Obtained:

15-APR-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	: 004 - Orlando Clinical Research Center	Event Name	: Visit 2
Casebook Name	: 4025	Event Date	: 15-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: tmarbury	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

Was ECO Test Performed?

Yes

N/A

Date/Time Obtained:

15-APR-2011

DD-MMM-YYYY

(24:00 hr clock)

Results:

ECO

(ppm)

Study Name : RJRT CSD1010

Site Name : 004 - Orlando Clinical Research Center

Casebook Name : 4025

Casebook Status : Casebook Frozen And Locked

Casebook Signature : tmarbury

Course Name : Visit 2

Event Name : Visit 2

Event Date : 15-APR-2011

Form Name : Test Product Allot

Form Status : DM Reviewed

TEST PRODUCT ALLOTMENT

Preferred Flavor of SNUS:

Frost

Mellow

N/A

Preferred Flavor of Lozenge:

Original

Mint

N/A

Number of Units Returned:

Number of Units Dispensed:

Study Name	: RJRT CSD1010	Course Name	: Visit 3
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Visit 3
Casebook Name	: 4025	Event Date	: 23-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: tmarbury	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	: 004 - Orlando Clinical Research Center	Event Name	: Visit 3
Casebook Name	: 4025	Event Date	: 23-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: tmarbury	Form Status	: DM Reviewed

Visit 1 Labs

Urine Sample Date/Time Obtained:

23-MAY-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	: 004 - Orlando Clinical Research Center	Event Name	: Visit 3
Casebook Name	: 4025	Event Date	: 23-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: tmarbury	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

Was ECO Test Performed?

Yes

N/A

Date/Time Obtained:

23-MAY-2011

DD-MMM-YYYY

(24:00 hr clock)

Results:

ECO

(ppm)

Study Name	: RJRT CSD1010	Course Name	: Visit 3
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Visit 3
Casebook Name	: 4025	Event Date	: 23-MAY-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Test Product Allot
Casebook Signature	: tmarbury	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	: 004 - Orlando Clinical Research Center	Event Name	: Tel Contact 1
Casebook Name	: 4025	Event Date	: 16-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: tmarbury	Form Status	: No Data

SMOKING STATUS, CIGARETTE, AND TEST PRODUCT USAGE QUESTIONNAIRE

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

Yes

No

If Yes, first date of use

DD-MMM-YYYY

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

Yes

No

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

Yes

No

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

(Check all that apply)

Cigarettes

Moist snuff or dip in a round can

Chewing tobacco

Study Name	: RJRT CSD1010	Course Name	: Tel Contact 1
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Tel Contact 1
Casebook Name	: 4025	Event Date	: 16-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: tmarbury	Form Status	: No Data

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	: 004 - Orlando Clinical Research Center	Event Name	: Tel Contact 1
Casebook Name	: 4025	Event Date	: 16-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: tmarbury	Form Status	: No Data

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	: 004 - Orlando Clinical Research Center	Event Name	: Tel Contact 1
Casebook Name	: 4025	Event Date	: 16-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: tmarbury	Form Status	: No Data

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	: 004 - Orlando Clinical Research Center	Event Name	: Tel Contact 1
Casebook Name	: 4025	Event Date	: 16-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Product Usage Q
Casebook Signature	: tmarbury	Form Status	: No Data

Nicotine patch -mg (# used daily)

Nicotine gum -pieces (# used daily)

Nicotine lozenges-pieces (# used daily)

Nicotine nasal spray-puffs (# used daily)

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

Other (# used daily)

e-cigarette-puffs (# used daily)

Study Name	: RJRT CSD1010	Course Name	: Visit 4
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Visit 4
Casebook Name	: 4025	Event Date	: 22-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: tmarbury	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 4
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Visit 4
Casebook Name	: 4025	Event Date	: 22-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: tmarbury	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 4
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Visit 4
Casebook Name	: 4025	Event Date	: 22-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: tmarbury	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	: Visit 4
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Visit 4
Casebook Name	: 4025	Event Date	: 22-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Oral Assessment
Casebook Signature	: tmarbury	Form Status	: Blank DM Reviewed

ORAL ASSESSMENT

System	Finding			*Specify Any Abnormal Finding
Oral (mouth cavity)	Normal	Abnormal	Not Done	

Study Name	: RJRT CSD1010	Course Name	: Prtcl Deviations
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Prtcl Deviations
Casebook Name	: 4025	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Prtcl Deviations (1)
Casebook Signature	: tmarbury	Form Status	: DM Reviewed

DEVIATIONS

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

Study Name	: RJRT CSD1010	Course Name	: Prtcl Deviations
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Prtcl Deviations
Casebook Name	: 4025	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Prtcl Deviations (2)
Casebook Signature	: tmarbury	Form Status	: DM Reviewed

DEVIATIONS

Date of Deviation	Deviation Category	Deviation Description
<div>23-MAY-2011</div> <div>DD-MMM-YYYY</div>		<div></div> <div>1</div>

*1) subject was under dispensed study product per protocol at visit 3 (did not round up to nearest whole number for SNUS)

Study Name	: RJRT CSD1010	Course Name	: Prtcl Deviations
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Prtcl Deviations
Casebook Name	: 4025	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Prtcl Deviations (3)
Casebook Signature	: tmarbury	Form Status	: DM Reviewed

DEVIATIONS

Date of Deviation	Deviation Category	Deviation Description
<div>16-JUN-2011</div> <div>DD-MMM-YYYY</div>		<div></div> <div>1</div>

*1) inadvertently did telephone call 1 per protocol since subject should have been discontinued at visit 3 for ECO > 8

Study Name	: RJRT CSD1010	Course Name	: Prtcl Deviations
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Prtcl Deviations
Casebook Name	: 4025	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Prtcl Deviations (4)
Casebook Signature	: tmarbury	Form Status	: DM Reviewed

DEVIATIONS

Date of Deviation	Deviation Category	Deviation Description
<div>15-APR-2011</div> <div>DD-MMM-YYYY</div>		

Study Name	: RJRT CSD1010	Course Name	: Randomization
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Randomization
Casebook Name	: 4025	Event Date	: 31-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Randomization
Casebook Signature	: tmarbury	Form Status	: DM Reviewed Signed

RANDOMIZATION

Randomization Number:

Please select Cohort:

Study Name	: RJRT CSD1010	Course Name	: Study Conc.
Site Name	: 004 - Orlando Clinical Research Center	Event Name	: Study Conclusion
Casebook Name	: 4025	Event Date	: 22-JUN-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Study Conclusion
Casebook Signature	: tmarbury	Form Status	: DM Reviewed Signed

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:

23-MAY-2011

DD-MMM-YYYY

Reason for Early Withdrawal

Specify:

*1) Subject states abstinent from smoking; but with ECO > 8 at Visit 3.

AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
29776	3/22/2011 12:31:22	3-22-2011 12:29:19:443	4905	croush	Conni Roush	TD_CASE-BOOK	1326	0:0					Casebook Created
29777	3/22/2011 12:31:57	3-22-2011 12:29:54:693	4905	croush	Conni Roush	TD_CASE-BOOK	1326	0:0				b63bda8e4736e70551517a8e885dc678	LUID Created
29778	3/22/2011 12:32:7	3-22-2011 12:30:05:818	4905	croush	Conni Roush	TD_EVENT	5706	0:0			03-07-2011	3-22-2011	Event Created
29779	3/22/2011 12:33:9	3-22-2011 12:31:05:474	4905	croush	Conni Roush	TD_FORM	15849	15849:0	Demographics		0	1	Form Status set to 1
29780	3/22/2011 12:33:9	3-22-2011 12:31:05:474	4905	croush	Conni Roush	TD_DATA	22948	15849:463304	Demographics	DM.DMICDT		3-22-2011	Data Added
29781	3/22/2011 12:33:9	3-22-2011 12:31:05:474	4905	croush	Conni Roush	TD_DATA	22949	15849:463306	Demographics	DM.DMICTM		11:18	Data Added
29782	3/22/2011 12:33:9	3-22-2011 12:31:05:474	4905	croush	Conni Roush	TD_DATA	22950	15849:463308	Demographics	DM.DMDOBDT		(b) (6)	Data Added
29783	3/22/2011 12:33:9	3-22-2011 12:31:05:474	4905	croush	Conni Roush	TD_DATA	22951	15849:463312	Demographics	DM.DMSEX		Female	Data Added
29784	3/22/2011 12:33:9	3-22-2011 12:31:05:474	4905	croush	Conni Roush	TD_DATA	22952	15849:463314	Demographics	DM.DMETH		Not Hispanic or Latino	Data Added
29785	3/22/2011 12:33:9	3-22-2011 12:31:05:474	4905	croush	Conni Roush	TD_DATA	22953	15849:463320	Demographics	DM.DMRACE5		true	Data Added
29786	3/22/2011 12:33:9	3-22-2011 12:31:05:474	4905	croush	Conni Roush	TD_DATA	22954	15849:463322	Demographics	DM.DMGRADE		High school graduate (grade 12)	Data Added
29787	3/22/2011 12:33:9	3-22-2011 12:31:05:474	4905	croush	Conni Roush	TD_DATA	22955	15849:463324	Demographics	DM.DMINC		\$20,000 to \$39,999	Data Added
29788	3/22/2011 12:33:9		4905	croush	Conni Roush	TD_DATA	22956	15849:463310	Demographics	DM.DMAGE		25	computed value
55413	4/4/2011 1-1:51:23	4-3-2011 1-1:48:09:456	4902	kwhite	Karen White	TD_FORM	15849	15849:0	Demographics		1	2	Form Status set to 2
55414	4/4/2011 1-1:53:59	4-3-2011 1-1:50:45:676	4902	kwhite	Karen White	TD_FORM	15850	15850:0	Brief Med. History		0	2	Form Status set to 2
55415	4/4/2011 1-1:53:59	4-3-2011 1-1:50:45:676	4902	kwhite	Karen White	TD_FORM	15850	15850:0	Brief Med. History		0	1	Form Checked Intentionally Left Blank
55416	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_FORM	15851	15851:0	Comprehensive PE		0	1	Form Status set to 1
55417	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42083	15851:463337	Comprehensive PE	PE.PEDT		3-22-2011	Data Added
55418	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42084	15851:463342	Comprehensive PE	PE.PEGNAP		Normal	Data Added
55419	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42085	15851:463345	Comprehensive PE	PE.PEHEAD		Normal	Data Added
55420	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42086	15851:463348	Comprehensive PE	PE.PEORAL		Normal	Data Added
55421	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42087	15851:463351	Comprehensive PE	PE.PEEN		Normal	Data Added
55422	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42088	15851:463354	Comprehensive PE	PE.PECHST		Normal	Data Added
55423	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42089	15851:463357	Comprehensive PE	PE.PEVRT		Normal	Data Added
55424	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42090	15851:463360	Comprehensive PE	PE.PEAB		Normal	Data Added
55425	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42091	15851:463363	Comprehensive PE	PE.PEBACK		Normal	Data Added
55426	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42092	15851:463366	Comprehensive PE	PE.PELIMP		Normal	Data Added
55427	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42093	15851:463369	Comprehensive PE	PE.PENEUR		Normal	Data Added
55428	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16:867	4902	kwhite	Karen White	TD_DATA	42094	15851:463372	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
55429	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16.867	4902	kwhite	Karen White	TD_DATA	42095	15851:463375	Comprehensive PE	PE.PEEXT		Normal	Data Added
55430	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16.867	4902	kwhite	Karen White	TD_DATA	42096	15851:463378	Comprehensive PE	PE.PESKIN		Normal	Data Added
55431	4/4/2011 1-1:56:30	4-3-2011 1-1:53:16.867	4902	kwhite	Karen White	TD_DATA	42097	15851:463381	Comprehensive PE	PE.PEOTH		Not Done	Data Added
55432	4/4/2011 1-1:56:32	4-3-2011 1-1:53:19.377	4902	kwhite	Karen White	TD_FORM	15851	15851:0	Comprehensive PE		1	2	Form Status set to 2
55433	4/4/2011 1-1:56:56	4-3-2011 1-1:53:43.267	4902	kwhite	Karen White	TD_FORM	15852	15852:0	Vital Signs		0	1	Form Status set to 1
55434	4/4/2011 1-1:56:56	4-3-2011 1-1:53:43.267	4902	kwhite	Karen White	TD_DATA	42098	15852:463386	Vital Signs	VS.VSDT		3-22-2011	Data Added
55435	4/4/2011 1-1:56:56	4-3-2011 1-1:53:43.267	4902	kwhite	Karen White	TD_DATA	42099	15852:463387	Vital Signs	VS.VSTM		11:40	Data Added
55436	4/4/2011 1-1:56:56	4-3-2011 1-1:53:43.267	4902	kwhite	Karen White	TD_DATA	42100	15852:463391	Vital Signs	VS.VSHT		159	Data Added
55437	4/4/2011 1-1:56:56	4-3-2011 1-1:53:43.267	4902	kwhite	Karen White	TD_DATA	42101	15852:463394	Vital Signs	VS.VSWT		76.8	Data Added
55438	4/4/2011 1-1:56:56	4-3-2011 1-1:53:43.267	4902	kwhite	Karen White	TD_DATA	42102	15852:463403	Vital Signs	VS.VSSYS		128	Data Added
55439	4/4/2011 1-1:56:56	4-3-2011 1-1:53:43.267	4902	kwhite	Karen White	TD_DATA	42103	15852:463405	Vital Signs	VS.VSDIA		90	Data Added
55440	4/4/2011 1-1:56:56	4-3-2011 1-1:53:43.267	4902	kwhite	Karen White	TD_DATA	42104	15852:463407	Vital Signs	VS.VSHR		74	Data Added
55441	4/4/2011 1-1:56:56	4-3-2011 1-1:53:43.267	4902	kwhite	Karen White	TD_DATA	42105	15852:463409	Vital Signs	VS.VSRR		16	Data Added
55442	4/4/2011 1-1:56:56	4-3-2011 1-1:53:43.267	4902	kwhite	Karen White	TD_DATA	42106	15852:463411	Vital Signs	VS.VSTEMP		36.0	Data Added
55443	4/4/2011 1-1:56:57		4902	kwhite	Karen White	TD_DATA	42107	15882:464239	Vital Signs	VS.VSHT		159	computed value
55444	4/4/2011 1-1:56:57		4902	kwhite	Karen White	TD_DATA	42108	15872:463780	Vital Signs	VS.VSHT		159	computed value
55445	4/4/2011 1-1:56:57		4902	kwhite	Karen White	TD_DATA	42109	15852:463397	Vital Signs	VS.VSBMI		30.4	computed value
55446	4/4/2011 1-1:56:58	4-3-2011 1-1:53:44.897	4902	kwhite	Karen White	TD_FORM	15852	15852:0	Vital Signs		1	2	Form Status set to 2
55447	4/4/2011 1-1:57:26	4-3-2011 1-1:54:12.767	4902	kwhite	Karen White	TD_FORM	15853	15853:0	ECG		0	1	Form Status set to 1
55448	4/4/2011 1-1:57:26	4-3-2011 1-1:54:12.767	4902	kwhite	Karen White	TD_DATA	42110	15853:463414	ECG	EG.EGDT		3-22-2011	Data Added
55449	4/4/2011 1-1:57:26	4-3-2011 1-1:54:12.767	4902	kwhite	Karen White	TD_DATA	42111	15853:463415	ECG	EG.EGTM		10:50	Data Added
55450	4/4/2011 1-1:57:26	4-3-2011 1-1:54:12.767	4902	kwhite	Karen White	TD_DATA	42112	15853:463418	ECG	EG.EGASMT		Normal	Data Added
55451	4/4/2011 1-1:57:27	4-3-2011 1-1:54:13.927	4902	kwhite	Karen White	TD_FORM	15853	15853:0	ECG		1	2	Form Status set to 2
55452	4/4/2011 1-1:58:16	4-3-2011 1-1:55:03.337	4902	kwhite	Karen White	TD_FORM	15854	15854:0	Labs		0	1	Form Status set to 1
55453	4/4/2011 1-1:58:16	4-3-2011 1-1:55:03.337	4902	kwhite	Karen White	TD_DATA	42113	15854:463423	Labs	LB.LBBLDT		3-22-2011	Data Added
55454	4/4/2011 1-1:58:16	4-3-2011 1-1:55:03.337	4902	kwhite	Karen White	TD_DATA	42114	15854:463424	Labs	LB.LBBLTM		13:00	Data Added
55455	4/4/2011 1-1:58:16	4-3-2011 1-1:55:03.337	4902	kwhite	Karen White	TD_DATA	42115	15854:463427	Labs	LB.LBURDT		3-22-2011	Data Added
55456	4/4/2011 1-1:58:16	4-3-2011 1-1:55:03.337	4902	kwhite	Karen White	TD_DATA	42116	15854:463428	Labs	LB.LBURTM		12:05	Data Added
55457	4/4/2011 1-1:58:16	4-3-2011 1-1:55:03.337	4902	kwhite	Karen White	TD_DATA	42117	15854:463431	Labs	LB.LBRDT		3-22-2011	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
55458	4/4/2011 1-1:58:16	4-3-2011 1-1:55:03:337	4902	kwhite	Karen White	TD_DATA	42118	15854:463432	Labs	LB.LBBRTM		12:14	Data Added
55459	4/4/2011 1-1:58:16	4-3-2011 1-1:55:03:337	4902	kwhite	Karen White	TD_DATA	42119	15854:463436	Labs	LB.LBUDS		Negative	Data Added
55460	4/4/2011 1-1:58:17	4-3-2011 1-1:55:03:337	4902	kwhite	Karen White	TD_DATA	42120	15854:463438	Labs	LB.LBUCS		Negative	Data Added
55461	4/4/2011 1-1:58:17	4-3-2011 1-1:55:03:337	4902	kwhite	Karen White	TD_DATA	42121	15854:463440	Labs	LB.LBABS		Negative	Data Added
55462	4/4/2011 1-1:58:18	4-3-2011 1-1:55:04:997	4902	kwhite	Karen White	TD_FORM	15854	15854:0	Labs		1	2	Form Status set to 2
55463	4/4/2011 1-1:58:45	4-3-2011 1-1:55:32:257	4902	kwhite	Karen White	TD_FORM	15855	15855:0	Exhaled CO		0	1	Form Status set to 1
55464	4/4/2011 1-1:58:45	4-3-2011 1-1:55:32:257	4902	kwhite	Karen White	TD_DATA	42122	15855:463443	Exhaled CO	EC.ECDT		3-22-2011	Data Added
55465	4/4/2011 1-1:58:45	4-3-2011 1-1:55:32:257	4902	kwhite	Karen White	TD_DATA	42123	15855:463444	Exhaled CO	EC.ECTM		11:43	Data Added
55466	4/4/2011 1-1:58:45	4-3-2011 1-1:55:32:257	4902	kwhite	Karen White	TD_DATA	42124	15855:463448	Exhaled CO	EC.ECRES1		20	Data Added
55467	4/4/2011 1-1:58:48	4-3-2011 1-1:55:34:767	4902	kwhite	Karen White	TD_FORM	15855	15855:0	Exhaled CO		1	2	Form Status set to 2
55468	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_FORM	15856	15856:0	UB Descriptors		0	1	Form Status set to 1
55469	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_DATA	42125	15856:463452	UB Descriptors	UB.UBDT		3-22-2011	Data Added
55470	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_DATA	42126	15856:463456	UB Descriptors	UB.UBYEAR		10	Data Added
55471	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_DATA	42127	15856:463458	UB Descriptors	UB.UBSMKLS		No	Data Added
55472	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_DATA	42128	15856:463460	UB Descriptors	UB.UBQUIT		Yes	Data Added
55473	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_DATA	42129	15856:463462	UB Descriptors	UB.UBBRND		Marlboro	Data Added
55474	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_DATA	42130	15856:463464	UB Descriptors	UB.UBSBRND		Ultra Light/Silver Pack	Data Added
55475	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_DATA	42131	15856:463466	UB Descriptors	UB.UBLTH		Other (mm)	Data Added
55476	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_DATA	42132	15856:463467	UB Descriptors	UB.UBLTOT		Kinds	Data Added
55477	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_DATA	42133	15856:463469	UB Descriptors	UB.UBPACK		Hard-pack box	Data Added
55478	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_DATA	42134	15856:463471	UB Descriptors	UB.UBMENTH		Non-menthol	Data Added
55479	4/4/2011 1-2:0:2	4-3-2011 1-1:56:49:207	4902	kwhite	Karen White	TD_DATA	42135	15856:463473	UB Descriptors	UB.UBFILT		Filter	Data Added
55480	4/4/2011 1-2:0:9	4-3-2011 1-1:56:56:147	4902	kwhite	Karen White	TD_FORM	15857	15857:0	Inc/Exc		0	2	Form Status set to 2
55481	4/4/2011 1-2:0:9	4-3-2011 1-1:56:56:147	4902	kwhite	Karen White	TD_DATA	42136	15857:463477	Inc/Exc	IE.IECRITYN		Yes	Data Added
55482	4/4/2011 1-2:1:33	4-3-2011 1-1:58:20:27	4902	kwhite	Karen White	TD_FORM	15858	15858:0	Test Product Allot		0	2	Form Status set to 2
55483	4/4/2011 1-2:1:33	4-3-2011 1-1:58:20:27	4902	kwhite	Karen White	TD_DATA	42137	15858:463512	Test Product Allot	PU.PUSNUS1		Frost	Data Added
55484	4/4/2011 1-2:1:33	4-3-2011 1-1:58:20:27	4902	kwhite	Karen White	TD_DATA	42138	15858:463514	Test Product Allot	PU.PULOZG1		Mint	Data Added
55485	4/4/2011 1-2:2:26	4-3-2011 1-1:59:13:407	4902	kwhite	Karen White	TD_EVENT	5707	0:0				3-31-2011	Event Created
55486	4/4/2011 1-2:2:52	4-3-2011 1-1:59:38:537	4902	kwhite	Karen White	TD_FORM	15859	15859:0	Vital Signs		0	2	Form Status set to 2

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
55487	4/4/2011 1-2:2:52	4-3-2011 1-1:59:38:537	4902	kwhite	Karen White	TD_DATA	42139	15859:463516	Vital Signs	VS.VSDT		3-31-2011	Data Added
55488	4/4/2011 1-2:2:52	4-3-2011 1-1:59:38:537	4902	kwhite	Karen White	TD_DATA	42140	15859:463517	Vital Signs	VS.VSTM		13:55	Data Added
55489	4/4/2011 1-2:2:52	4-3-2011 1-1:59:38:537	4902	kwhite	Karen White	TD_DATA	42141	15859:463524	Vital Signs	VS.VSSYS		133	Data Added
55490	4/4/2011 1-2:2:52	4-3-2011 1-1:59:38:537	4902	kwhite	Karen White	TD_DATA	42142	15859:463526	Vital Signs	VS.VSDIA		90	Data Added
55491	4/4/2011 1-2:2:52	4-3-2011 1-1:59:38:537	4902	kwhite	Karen White	TD_DATA	42143	15859:463528	Vital Signs	VS.VSHR		84	Data Added
55492	4/4/2011 1-2:2:52	4-3-2011 1-1:59:38:537	4902	kwhite	Karen White	TD_DATA	42144	15859:463530	Vital Signs	VS.VSRR		16	Data Added
55493	4/4/2011 1-2:2:52	4-3-2011 1-1:59:38:537	4902	kwhite	Karen White	TD_DATA	42145	15859:463532	Vital Signs	VS.VSTEMP		36.9	Data Added
55494	4/4/2011 1-2:3:17	4-3-2011 1-2:00:03:607	4902	kwhite	Karen White	TD_FORM	15860	15860:0	Labs		0	2	Form Status set to 2
55495	4/4/2011 1-2:3:17	4-3-2011 1-2:00:03:607	4902	kwhite	Karen White	TD_DATA	42146	15860:463536	Labs	LB.LBURDT		3-31-2011	Data Added
55496	4/4/2011 1-2:3:17	4-3-2011 1-2:00:03:607	4902	kwhite	Karen White	TD_DATA	42147	15860:463537	Labs	LB.LBURTM		13:49	Data Added
55497	4/4/2011 1-2:3:17	4-3-2011 1-2:00:03:607	4902	kwhite	Karen White	TD_DATA	42148	15860:463541	Labs	LB.LBUCS		Negative	Data Added
55498	4/4/2011 1-2:3:36	4-3-2011 1-2:00:22:567	4902	kwhite	Karen White	TD_FORM	15861	15861:0	Exhaled CO		0	2	Form Status set to 2
55499	4/4/2011 1-2:3:36	4-3-2011 1-2:00:22:567	4902	kwhite	Karen White	TD_DATA	42149	15861:463544	Exhaled CO	EC.ECDT		3-31-2011	Data Added
55500	4/4/2011 1-2:3:36	4-3-2011 1-2:00:22:567	4902	kwhite	Karen White	TD_DATA	42150	15861:463545	Exhaled CO	EC.ECTM		13:58	Data Added
55501	4/4/2011 1-2:3:36	4-3-2011 1-2:00:22:567	4902	kwhite	Karen White	TD_DATA	42151	15861:463549	Exhaled CO	EC.ECRES1		13	Data Added
55502	4/4/2011 1-2:3:53	4-3-2011 1-2:00:40:247	4902	kwhite	Karen White	TD_FORM	15862	15862:0	Test Product Allot		0	2	Form Status set to 2
55503	4/4/2011 1-2:3:53	4-3-2011 1-2:00:40:247	4902	kwhite	Karen White	TD_DATA	42152	15862:463553	Test Product Allot	PU.PUSNUS2		Frost	Data Added
55504	4/4/2011 1-2:3:53	4-3-2011 1-2:00:40:247	4902	kwhite	Karen White	TD_DATA	42153	15862:463555	Test Product Allot	PU.PULOZG2		Mint	Data Added
55505	4/4/2011 1-2:3:53	4-3-2011 1-2:00:40:247	4902	kwhite	Karen White	TD_DATA	42154	15862:463559	Test Product Allot	PU.PUDIS2		26	Data Added
60869	4/6/2011 1-1:30:11	4-6-2011 1-1:27:58:890	4905	croush	Conni Roush	TD_DATA	46087	15856:463454	UB Descriptors	UB.UBCPD		30	Data Added
60870	4/6/2011 1-1:30:15	4-6-2011 1-1:28:02:406	4905	croush	Conni Roush	TD_FORM	15856	15856:0	UB Descriptors		1	2	Form Status set to 2
61017	4/6/2011 1-2:18:42	4-5-2011 1-2:15:32:907	4902	kwhite	Karen White	TD_EVENT	5721	0:0				3-31-2011	Event Created
61018	4/6/2011 1-2:19:4	4-5-2011 1-2:15:54:727	4902	kwhite	Karen White	TD_FORM	15890	15890:0	Randomization		0	1	Form Status set to 1
61019	4/6/2011 1-2:19:4	4-5-2011 1-2:15:54:727	4902	kwhite	Karen White	TD_DATA	46190	15890:464433	Randomization	RAND.RAND		420005	Data Added
61020	4/6/2011 1-2:19:4	4-5-2011 1-2:15:54:727	4902	kwhite	Karen White	TD_DATA	46191	15890:464435	Randomization	RAND.COHORT		Cohort 3	Data Added
61021	4/6/2011 1-2:19:6	4-5-2011 1-2:15:56:567	4902	kwhite	Karen White	TD_FORM	15890	15890:0	Randomization		1	2	Form Status set to 2
61022	4/6/2011 1-2:20:13	4-5-2011 1-2:17:03:807	4902	kwhite	Karen White	TD_FORM	15890	15890:0	Randomization		2	1	Form Status demoted to 1
61023	4/6/2011 1-2:20:13	4-5-2011 1-2:17:03:807	4902	kwhite	Karen White	TD_DATA	46191	15890:464435	Randomization	RAND.COHORT	Cohort 3	Cohort 1	Typographical error
61042	4/6/2011 1-2:25:8	4-5-2011 1-2:21:58:527	4902	kwhite	Karen White	TD_FORM	15862	15862:0	Test Product Allot		2	1	Form Status demoted 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
61043	4/6/2011 1-2:25:8	4-5-2011 1-2:21:58:527	4902	kwhite	Karen White	TD_DATA	42153	15862:463555	Test Product Allot	PU.PULOZG2	Mint	N/A	Entry error, updated CRF
61070	4/6/2011 1-2:31:3	4-5-2011 1-2:27:53:548	4902	kwhite	Karen White	TD_FORM	15890	15890:0	Randomization		1	2	Form Status set to 2
62720	4/6/2011 1-5:42:41	4-5-2011 1-5:39:32:186	4902	kwhite	Karen White	TD_DATA	42154	15862:463559	Test Product Allot	PU.PUDIS2	26	381	Typographical error
62721	4/6/2011 1-5:42:43	4-5-2011 1-5:39:34:596	4902	kwhite	Karen White	TD_FORM	15862	15862:0	Test Product Allot		1	2	Form Status set to 2
82118	4/18/2011 15:4:37	4-17-2011 15:00:59:36	4902	kwhite	Karen White	TD_EVENT	5708	0:0			03-02-2011	4-15-2011	Event Created
82133	4/18/2011 15:5:1	4-17-2011 15:01:22:466	4902	kwhite	Karen White	TD_FORM	15863	15863:0	Vital Signs		0	1	Form Status set to 1
82134	4/18/2011 15:5:1	4-17-2011 15:01:22:466	4902	kwhite	Karen White	TD_DATA	61490	15863:463561	Vital Signs	VS.VSDT		4-15-2011	Data Added
82135	4/18/2011 15:5:1	4-17-2011 15:01:22:466	4902	kwhite	Karen White	TD_DATA	61491	15863:463562	Vital Signs	VS.VSTM		13:58	Data Added
82136	4/18/2011 15:5:1	4-17-2011 15:01:22:466	4902	kwhite	Karen White	TD_DATA	61492	15863:463569	Vital Signs	VS.VSSYS		134	Data Added
82137	4/18/2011 15:5:1	4-17-2011 15:01:22:466	4902	kwhite	Karen White	TD_DATA	61493	15863:463571	Vital Signs	VS.VSDIA		90	Data Added
82138	4/18/2011 15:5:1	4-17-2011 15:01:22:466	4902	kwhite	Karen White	TD_DATA	61494	15863:463573	Vital Signs	VS.VSHR		76	Data Added
82139	4/18/2011 15:5:1	4-17-2011 15:01:22:466	4902	kwhite	Karen White	TD_DATA	61495	15863:463575	Vital Signs	VS.VSRR		18	Data Added
82140	4/18/2011 15:5:1	4-17-2011 15:01:22:466	4902	kwhite	Karen White	TD_DATA	61496	15863:463577	Vital Signs	VS.VSTEMP		36.2	Data Added
82141	4/18/2011 15:5:2	4-17-2011 15:01:24:56	4902	kwhite	Karen White	TD_FORM	15863	15863:0	Vital Signs		1	2	Form Status set to 2
82142	4/18/2011 15:5:22	4-17-2011 15:01:43:386	4902	kwhite	Karen White	TD_FORM	15864	15864:0	Labs		0	1	Form Status set to 1
82143	4/18/2011 15:5:22	4-17-2011 15:01:43:386	4902	kwhite	Karen White	TD_DATA	61497	15864:463581	Labs	LB.LBURDT		4-15-2011	Data Added
82144	4/18/2011 15:5:22	4-17-2011 15:01:43:386	4902	kwhite	Karen White	TD_DATA	61498	15864:463582	Labs	LB.LBURTM		14:13	Data Added
82145	4/18/2011 15:5:22	4-17-2011 15:01:43:386	4902	kwhite	Karen White	TD_DATA	61499	15864:463586	Labs	LB.LBUCS		Negative	Data Added
82146	4/18/2011 15:5:23	4-17-2011 15:01:44:916	4902	kwhite	Karen White	TD_FORM	15864	15864:0	Labs		1	2	Form Status set to 2
82147	4/18/2011 15:5:39	4-17-2011 15:02:00:366	4902	kwhite	Karen White	TD_FORM	15865	15865:0	Exhaled CO		0	1	Form Status set to 1
82148	4/18/2011 15:5:39	4-17-2011 15:02:00:366	4902	kwhite	Karen White	TD_DATA	61500	15865:463589	Exhaled CO	EC.ECYN		Yes	Data Added
82149	4/18/2011 15:5:39	4-17-2011 15:02:00:366	4902	kwhite	Karen White	TD_DATA	61501	15865:463591	Exhaled CO	EC.ECDT		4-15-2011	Data Added
82150	4/18/2011 15:5:39	4-17-2011 15:02:00:366	4902	kwhite	Karen White	TD_DATA	61502	15865:463592	Exhaled CO	EC.ECTM		14:03	Data Added
82151	4/18/2011 15:5:39	4-17-2011 15:02:00:366	4902	kwhite	Karen White	TD_DATA	61503	15865:463596	Exhaled CO	EC.ECRES1		03	Data Added
82152	4/18/2011 15:5:40	4-17-2011 15:02:01:816	4902	kwhite	Karen White	TD_FORM	15865	15865:0	Exhaled CO		1	2	Form Status set to 2
82153	4/18/2011 15:6:5	4-17-2011 15:02:26:296	4902	kwhite	Karen White	TD_FORM	15866	15866:0	Test Product Allot		0	1	Form Status set to 1
82154	4/18/2011 15:6:5	4-17-2011 15:02:26:296	4902	kwhite	Karen White	TD_DATA	61504	15866:463600	Test Product Allot	PU.PUSNUS2		Frost	Data Added
82155	4/18/2011 15:6:5	4-17-2011 15:02:26:296	4902	kwhite	Karen White	TD_DATA	61505	15866:463602	Test Product Allot	PU.PULOZG2		N/A	Data Added
82156	4/18/2011 15:6:5	4-17-2011 15:02:26:296	4902	kwhite	Karen White	TD_DATA	61506	15866:463604	Test Product Allot	PU.PURET		9	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
82157	4/18/2011 15:6:5	4-17-2011 15:02:26:296	4902	kwhite	Karen White	TD_DATA	61507	15866:463606	Test Product Allot	PU.PUDIS2		284	Data Added
82158	4/18/2011 15:6:6	4-17-2011 15:02:27:806	4902	kwhite	Karen White	TD_FORM	15866	15866:0	Test Product Allot		1	2	Form Status set to 2
99161	4/26/2011 23:6:24	4-26-2011 23:03:38:690	781	mhunt	Michelle Hunt	TD_FORM	15849	15849:0	Demographics		2	3	Form Status set to 3
99162	4/26/2011 23:7:24	4-26-2011 23:04:38:708	781	mhunt	Michelle Hunt	TD_FORM	15852	15852:0	Vital Signs		2	3	Form Status set to 3
99163	4/26/2011 23:7:57	4-26-2011 23:05:11:258	781	mhunt	Michelle Hunt	TD_FORM	15855	15855:0	Exhaled CO		2	3	Form Status set to 3
99164	4/26/2011 23:8:23	4-26-2011 23:05:37:291	781	mhunt	Michelle Hunt	TD_FORM	15854	15854:0	Labs		2	3	Form Status set to 3
99165	4/26/2011 23:14:26	4-26-2011 23:11:39:704	781	mhunt	Michelle Hunt	TD_FORM	15859	15859:0	Vital Signs		2	3	Form Status set to 3
99166	4/26/2011 23:15:17	4-26-2011 23:12:30:714	781	mhunt	Michelle Hunt	TD_FORM	15861	15861:0	Exhaled CO		2	3	Form Status set to 3
99167	4/26/2011 23:16:8	4-26-2011 23:13:21:980	781	mhunt	Michelle Hunt	TD_FORM	15860	15860:0	Labs		2	3	Form Status set to 3
99168	4/26/2011 23:16:55	4-26-2011 23:14:09:195	781	mhunt	Michelle Hunt	TD_FORM	15890	15890:0	Randomization		2	3	Form Status set to 3
99169	4/26/2011 23:17:31	4-26-2011 23:14:45:195	781	mhunt	Michelle Hunt	TD_FORM	15863	15863:0	Vital Signs		2	3	Form Status set to 3
99170	4/26/2011 23:18:3	4-26-2011 23:15:16:974	781	mhunt	Michelle Hunt	TD_FORM	15864	15864:0	Labs		2	3	Form Status set to 3
99171	4/26/2011 23:18:30	4-26-2011 23:15:43:851	781	mhunt	Michelle Hunt	TD_FORM	15865	15865:0	Exhaled CO		2	3	Form Status set to 3
102016	4/27/2011 15:41:5	4-27-2011 15:38:12:125	4903	emedina	Elsie Medina	TD_FORM	15851	15851:0	Comprehensive PE		2	1	Form Status demoted to 1
102017	4/27/2011 15:41:5	4-27-2011 15:38:12:125	4903	emedina	Elsie Medina	TD_DATA	42097	15851:463381	Comprehensive PE	PE.PEOTH	Not Done		Requires update
102018	4/27/2011 15:41:48	4-27-2011 15:38:54:562	4903	emedina	Elsie Medina	TD_FORM	15851	15851:0	Comprehensive PE		1	2	Form Status set to 2
102259	4/27/2011 16:10:20	4-27-2011 16:07:31:244	550	gpreciado	Gina Preci- ado	TD_FORM	15852	15852:0	Vital Signs		3	4	Form Status set to 4
102260	4/27/2011 16:10:30	4-27-2011 16:07:41:338	550	gpreciado	Gina Preci- ado	TD_FORM	15849	15849:0	Demographics		3	4	Form Status set to 4
102290	4/27/2011 16:11:49	4-27-2011 16:09:00:42	550	gpreciado	Gina Preci- ado	TD_FORM	15854	15854:0	Labs		3	4	Form Status set to 4
102296	4/27/2011 16:11:59	4-27-2011 16:09:09:979	550	gpreciado	Gina Preci- ado	TD_FORM	15859	15859:0	Vital Signs		3	4	Form Status set to 4
102298	4/27/2011 16:12:30	4-27-2011 16:09:41:120	550	gpreciado	Gina Preci- ado	TD_FORM	15860	15860:0	Labs		3	4	Form Status set to 4
102317	4/27/2011 16:13:58	4-27-2011 16:11:09:58	550	gpreciado	Gina Preci- ado	TD_FORM	15861	15861:0	Exhaled CO		3	4	Form Status set to 4
102330	4/27/2011 16:14:41	4-27-2011 16:11:52:637	550	gpreciado	Gina Preci- ado	TD_FORM	15863	15863:0	Vital Signs		3	4	Form Status set to 4
102331	4/27/2011 16:14:46	4-27-2011 16:11:57:105	550	gpreciado	Gina Preci- ado	TD_FORM	15864	15864:0	Labs		3	4	Form Status set to 4
102336	4/27/2011 16:14:55	4-27-2011 16:12:06:746	550	gpreciado	Gina Preci- ado	TD_FORM	15865	15865:0	Exhaled CO		3	4	Form Status set to 4
102350	4/27/2011 16:15:37	4-27-2011 16:12:48:481	550	gpreciado	Gina Preci- ado	TD_FORM	15855	15855:0	Exhaled CO		3	4	Form Status set to 4
102352	4/27/2011 16:15:55	4-27-2011 16:13:06:137	550	gpreciado	Gina Preci- ado	TD_FORM	15890	15890:0	Randomization		3	4	Form Status set to 4
158865	5/24/2011 10:14:57	5-24-2011 10:11:39:734	4902	kwhite	Karen White	TD_EVENT	5709	0:0				5-23-2011	Event Created
158871	5/24/2011 10:15:20	5-24-2011 10:12:02:671	4902	kwhite	Karen White	TD_FORM	15867	15867:0	Vital Signs		0	2	Form Status set to 2

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
158872	5/24/2011 10:15:20	5-24-2011 10:12:02:671	4902	kwhite	Karen White	TD_DATA	114781	15867:463608	Vital Signs	VS.VSDT		5-23-2011	Data Added
158873	5/24/2011 10:15:20	5-24-2011 10:12:02:671	4902	kwhite	Karen White	TD_DATA	114782	15867:463609	Vital Signs	VS.VSTM		13:11	Data Added
158874	5/24/2011 10:15:20	5-24-2011 10:12:02:671	4902	kwhite	Karen White	TD_DATA	114783	15867:463616	Vital Signs	VS.VSSYS		142	Data Added
158875	5/24/2011 10:15:20	5-24-2011 10:12:02:671	4902	kwhite	Karen White	TD_DATA	114784	15867:463618	Vital Signs	VS.VSDIA		95	Data Added
158876	5/24/2011 10:15:20	5-24-2011 10:12:02:671	4902	kwhite	Karen White	TD_DATA	114785	15867:463620	Vital Signs	VS.VSHR		77	Data Added
158877	5/24/2011 10:15:20	5-24-2011 10:12:02:671	4902	kwhite	Karen White	TD_DATA	114786	15867:463622	Vital Signs	VS.VSRR		16	Data Added
158878	5/24/2011 10:15:20	5-24-2011 10:12:02:671	4902	kwhite	Karen White	TD_DATA	114787	15867:463624	Vital Signs	VS.VSTEMP		36.5	Data Added
158879	5/24/2011 10:15:34	5-24-2011 10:12:16:984	4902	kwhite	Karen White	TD_FORM	15868	15868:0	Labs		0	2	Form Status set to 2
158880	5/24/2011 10:15:34	5-24-2011 10:12:16:984	4902	kwhite	Karen White	TD_DATA	114788	15868:463628	Labs	LB.LBURDT		5-23-2011	Data Added
158881	5/24/2011 10:15:34	5-24-2011 10:12:16:984	4902	kwhite	Karen White	TD_DATA	114789	15868:463629	Labs	LB.LBURTM		13:05	Data Added
158882	5/24/2011 10:15:34	5-24-2011 10:12:16:984	4902	kwhite	Karen White	TD_DATA	114790	15868:463633	Labs	LB.LBUCS		Negative	Data Added
158887	5/24/2011 10:15:50	5-24-2011 10:12:32:890	4902	kwhite	Karen White	TD_FORM	15869	15869:0	Exhaled CO		0	2	Form Status set to 2
158888	5/24/2011 10:15:50	5-24-2011 10:12:32:890	4902	kwhite	Karen White	TD_DATA	114794	15869:463636	Exhaled CO	EC.ECYN		Yes	Data Added
158889	5/24/2011 10:15:50	5-24-2011 10:12:32:890	4902	kwhite	Karen White	TD_DATA	114795	15869:463638	Exhaled CO	EC.ECDT		5-23-2011	Data Added
158890	5/24/2011 10:15:50	5-24-2011 10:12:32:890	4902	kwhite	Karen White	TD_DATA	114796	15869:463639	Exhaled CO	EC.ECTM		13:12	Data Added
158891	5/24/2011 10:15:50	5-24-2011 10:12:32:890	4902	kwhite	Karen White	TD_DATA	114797	15869:463643	Exhaled CO	EC.ECRES1		9	Data Added
158892	5/24/2011 10:16:2	5-24-2011 10:12:44:656	4902	kwhite	Karen White	TD_FORM	15870	15870:0	Test Product Allot		0	2	Form Status set to 2
158893	5/24/2011 10:16:2	5-24-2011 10:12:44:656	4902	kwhite	Karen White	TD_DATA	114798	15870:463647	Test Product Allot	PU.PUSNUS2		Frost	Data Added
158894	5/24/2011 10:16:2	5-24-2011 10:12:44:656	4902	kwhite	Karen White	TD_DATA	114799	15870:463649	Test Product Allot	PU.PULOZG2		N/A	Data Added
158895	5/24/2011 10:16:2	5-24-2011 10:12:44:656	4902	kwhite	Karen White	TD_DATA	114800	15870:463651	Test Product Allot	PU.PURET		0	Data Added
158896	5/24/2011 10:16:2	5-24-2011 10:12:44:656	4902	kwhite	Karen White	TD_DATA	114801	15870:463653	Test Product Allot	PU.PUDIS2		13	Data Added
220234	6/17/2011 14:32:24	6-17-2011 14:29:29:515	4902	kwhite	Karen White	TD_EVENT	5710	0:0				6-16-2011	Event Created
220235	6/17/2011 14:33:0	6-17-2011 14:30:05:921	4902	kwhite	Karen White	TD_FORM	15871	15871:0	Product Usage Q		0	2	Form Status set to 2
220236	6/17/2011 14:33:0	6-17-2011 14:30:05:921	4902	kwhite	Karen White	TD_DATA	158502	15871:463656	Product Usage Q	SC.SCQ1		No	Data Added
220237	6/17/2011 14:33:0	6-17-2011 14:30:05:921	4902	kwhite	Karen White	TD_DATA	158503	15871:463660	Product Usage Q	SC.SCQ2		No	Data Added
220238	6/17/2011 14:33:0	6-17-2011 14:30:05:921	4902	kwhite	Karen White	TD_DATA	158504	15871:463662	Product Usage Q	SC.SCQ3		No	Data Added
220239	6/17/2011 14:33:0	6-17-2011 14:30:05:921	4902	kwhite	Karen White	TD_DATA	158505	15871:463668	Product Usage Q	SC.SCQ4D		true	Data Added
220240	6/17/2011 14:33:0	6-17-2011 14:30:05:921	4902	kwhite	Karen White	TD_DATA	158506	15871:463688	Product Usage Q	SC.SCQ5D		14	Data Added
220241	6/17/2011 14:33:0	6-17-2011 14:30:05:921	4902	kwhite	Karen White	TD_DATA	158507	15871:463713	Product Usage Q	SC.SCQ6D		6	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
221141	6/18/2011 22:23:17	6-18-2011 22:19:30:537	781	mhunt	Michelle Hunt	TD_FORM	15851	15851:0	Comprehensive PE		2	3	Form Status set to 3
221142	6/18/2011 22:26:2	6-18-2011 22:22:15:660	781	mhunt	Michelle Hunt	TD_FORM	15867	15867:0	Vital Signs		2	3	Form Status set to 3
221143	6/18/2011 22:27:2	6-18-2011 22:23:15:880	781	mhunt	Michelle Hunt	TD_FORM	15868	15868:0	Labs		2	3	Form Status set to 3
221144	6/18/2011 22:27:46	6-18-2011 22:23:59:892	781	mhunt	Michelle Hunt	TD_FORM	15869	15869:0	Exhaled CO		2	3	Form Status set to 3
221145	6/18/2011 22:30:13	6-18-2011 22:26:25:122	781	mhunt	Michelle Hunt	TD_FORM	15871	15871:0	Product Usage Q		2	3	Form Status set to 3
232736	6/23/2011 11:49:53	6-23-2011 11:46:25:892	4902	kwhite	Karen White	TD_EVENT	5711	0:0				6-22-2011	Event Created
232759	6/23/2011 11:51:6	6-23-2011 11:47:39:283	4902	kwhite	Karen White	TD_FORM	15874	15874:0	Labs		0	2	Form Status set to 2
232760	6/23/2011 11:51:7	6-23-2011 11:47:39:283	4902	kwhite	Karen White	TD_DATA	167971	15874:463813	Labs	LB.LBBSAMP		true	Data Added
232761	6/23/2011 11:51:7	6-23-2011 11:47:39:283	4902	kwhite	Karen White	TD_DATA	167972	15874:463819	Labs	LB.LBURDT		6-22-2011	Data Added
232762	6/23/2011 11:51:7	6-23-2011 11:47:39:283	4902	kwhite	Karen White	TD_DATA	167973	15874:463820	Labs	LB.LBURTM		13:04	Data Added
232763	6/23/2011 11:51:7	6-23-2011 11:47:39:283	4902	kwhite	Karen White	TD_DATA	167974	15874:463824	Labs	LB.LBUCS		Positive	Data Added
232768	6/23/2011 11:51:25	6-23-2011 11:47:58:236	4902	kwhite	Karen White	TD_FORM	15875	15875:0	Oral Assessment		0	2	Form Status set to 2
232769	6/23/2011 11:51:25	6-23-2011 11:47:58:236	4902	kwhite	Karen White	TD_DATA	167978	15875:463830	Oral Assessment	PE.PEORAL		Normal	Data Added
232774	6/23/2011 11:52:33	6-23-2011 11:49:06:95	4902	kwhite	Karen White	TD_EVENT	5722	0:0				6-22-2011	Event Created
232778	6/23/2011 11:52:56	6-23-2011 11:49:29:33	4902	kwhite	Karen White	TD_FORM	15891	15891:0	Study Conclusion		0	2	Form Status set to 2
232779	6/23/2011 11:52:56	6-23-2011 11:49:29:33	4902	kwhite	Karen White	TD_DATA	167982	15891:464438	Study Conclusion	DS.DSETSC		Discontinued prior to completion of the study	Data Added
232780	6/23/2011 11:52:56	6-23-2011 11:49:29:33	4902	kwhite	Karen White	TD_DATA	167983	15891:464440	Study Conclusion	DS.DSETSCDT		6-22-2011	Data Added
232781	6/23/2011 11:52:56	6-23-2011 11:49:29:33	4902	kwhite	Karen White	TD_DATA	167984	15891:464442	Study Conclusion	DS.DSETREAS		Other	Data Added
232782	6/23/2011 11:52:56	6-23-2011 11:49:29:33	4902	kwhite	Karen White	TD_DATA	167985	15891:464444	Study Conclusion	DS.DSETSP		Pregnancy and ECO >.8.	Data Added
232794	6/23/2011 11:54:36	6-23-2011 11:51:08:642	4902	kwhite	Karen White	TD_FORM	15872	15872:0	Vital Signs		0	2	Form Status set to 2
232795	6/23/2011 11:54:36	6-23-2011 11:51:08:642	4902	kwhite	Karen White	TD_DATA	167992	15872:463775	Vital Signs	VS.VSDT		6-22-2011	Data Added
232796	6/23/2011 11:54:36	6-23-2011 11:51:08:642	4902	kwhite	Karen White	TD_DATA	167993	15872:463776	Vital Signs	VS.VSTM		13:10	Data Added
232797	6/23/2011 11:54:36	6-23-2011 11:51:08:642	4902	kwhite	Karen White	TD_DATA	167994	15872:463783	Vital Signs	VS.VSWT		77.8	Data Added
232798	6/23/2011 11:54:36	6-23-2011 11:51:08:642	4902	kwhite	Karen White	TD_DATA	167995	15872:463792	Vital Signs	VS.VSSYS		119	Data Added
232799	6/23/2011 11:54:36	6-23-2011 11:51:08:642	4902	kwhite	Karen White	TD_DATA	167996	15872:463794	Vital Signs	VS.VSDIA		82	Data Added
232800	6/23/2011 11:54:36	6-23-2011 11:51:08:642	4902	kwhite	Karen White	TD_DATA	167997	15872:463796	Vital Signs	VS.VSHR		82	Data Added
232801	6/23/2011 11:54:36	6-23-2011 11:51:08:642	4902	kwhite	Karen White	TD_DATA	167998	15872:463798	Vital Signs	VS.VSRR		16	Data Added
232802	6/23/2011 11:54:36	6-23-2011 11:51:08:642	4902	kwhite	Karen White	TD_DATA	167999	15872:463800	Vital Signs	VS.VSTEMP		36.2	Data Added
232803	6/23/2011 11:54:36		4902	kwhite	Karen White	TD_DATA	168000	15872:463786	Vital Signs	VS.VSBMI		30.8	computed value

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
232819	6/23/2011 11:54:53	6-23-2011 11:51:26:377	4902	kwhite	Karen White	TD_FORM	15873	15873:0	Exhaled CO		0	2	Form Status set to 2
232820	6/23/2011 11:54:53	6-23-2011 11:51:26:377	4902	kwhite	Karen White	TD_DATA	168013	15873:463803	Exhaled CO	EC.ECYN		Yes	Data Added
232821	6/23/2011 11:54:53	6-23-2011 11:51:26:377	4902	kwhite	Karen White	TD_DATA	168014	15873:463805	Exhaled CO	EC.ECDT		6-22-2011	Data Added
232822	6/23/2011 11:54:53	6-23-2011 11:51:26:377	4902	kwhite	Karen White	TD_DATA	168015	15873:463806	Exhaled CO	EC.ECTM		13:12	Data Added
232823	6/23/2011 11:54:53	6-23-2011 11:51:26:377	4902	kwhite	Karen White	TD_DATA	168016	15873:463810	Exhaled CO	EC.ECRES1		15	Data Added
270124	7/8/2011 1-7:43:12	7-8-2011 1-7:39:36:205	6602	gpreciado34	Gina Preciado	TD_FORM	15851	15851:0	Comprehensive PE		3	4	Form Status set to 4
270125	7/8/2011 1-7:43:39	7-8-2011 1-7:40:03:225	6602	gpreciado34	Gina Preciado	TD_FORM	15867	15867:0	Vital Signs		3	4	Form Status set to 4
270126	7/8/2011 1-7:43:41	7-8-2011 1-7:40:05:549	6602	gpreciado34	Gina Preciado	TD_FORM	15868	15868:0	Labs		3	4	Form Status set to 4
270127	7/8/2011 1-7:43:43	7-8-2011 1-7:40:07:889	6602	gpreciado34	Gina Preciado	TD_FORM	15869	15869:0	Exhaled CO		3	4	Form Status set to 4
270128	7/8/2011 1-7:43:48	7-8-2011 1-7:40:12:616	6602	gpreciado34	Gina Preciado	TD_FORM	15871	15871:0	Product Usage Q		3	4	Form Status set to 4
271922	7/11/2011 11:36:49	7-11-2011 11:33:15:406	4902	kwhite	Karen White	TD_FORM	15851	15851:0	Comprehensive PE		4	1	Form Status demoted to 1
271923	7/11/2011 11:36:49	7-11-2011 11:33:15:406	4902	kwhite	Karen White	TD_DATA	42097	15851:463381	Comprehensive PE	PE.PEOTH		Not Done	Typographical error
271925	7/11/2011 11:36:53	7-11-2011 11:33:18:984	4902	kwhite	Karen White	TD_FORM	15851	15851:0	Comprehensive PE		1	2	Form Status set to 2
278463	7/14/2011 0:21:20	7-14-2011 0:17:55:632	781	mhunt	Michelle Hunt	TD_FORM	15872	15872:0	Vital Signs		2	3	Form Status set to 3
278464	7/14/2011 0:22:8	7-14-2011 0:18:44:490	781	mhunt	Michelle Hunt	TD_FORM	15873	15873:0	Exhaled CO		2	3	Form Status set to 3
278465	7/14/2011 0:22:37	7-14-2011 0:19:13:696	781	mhunt	Michelle Hunt	TD_FORM	15874	15874:0	Labs		2	3	Form Status set to 3
279441	7/15/2011 9:10:1	7-15-2011 9:06:44:432	6602	gpreciado34	Gina Preciado	TD_FORM	15872	15872:0	Vital Signs		3	4	Form Status set to 4
279442	7/15/2011 9:10:16	7-15-2011 9:06:58:659	6602	gpreciado34	Gina Preciado	TD_FORM	15873	15873:0	Exhaled CO		3	4	Form Status set to 4
279443	7/15/2011 9:10:18	7-15-2011 9:07:01:343	6602	gpreciado34	Gina Preciado	TD_FORM	15874	15874:0	Labs		3	4	Form Status set to 4
281186	7/18/2011 10:19:26	7-18-2011 10:15:13:46	4902	kwhite	Karen White	TD_FORM	15862	15862:0	Test Product Allot		2	1	Form Status demoted to 1
281187	7/18/2011 10:19:26	7-18-2011 10:15:13:46	4902	kwhite	Karen White	TD_DATA	42154	15862:463559	Test Product Allot	PU.PUDIS2	381	26	Updated Source and CRF
281188	7/18/2011 10:19:33	7-18-2011 10:15:19:750	4902	kwhite	Karen White	TD_FORM	15862	15862:0	Test Product Allot		1	2	Form Status set to 2
281189	7/18/2011 10:20:1	7-18-2011 10:15:48:515	4902	kwhite	Karen White	TD_FORM	15866	15866:0	Test Product Allot		2	1	Form Status demoted to 1
281190	7/18/2011 10:20:1	7-18-2011 10:15:48:515	4902	kwhite	Karen White	TD_DATA	61507	15866:463606	Test Product Allot	PU.PUDIS2	284	19	Updated Source and CRF
281191	7/18/2011 10:20:13	7-18-2011 10:16:00:78	4902	kwhite	Karen White	TD_FORM	15866	15866:0	Test Product Allot		1	2	Form Status set to 2
281192	7/18/2011 10:20:13	7-18-2011 10:16:00:78	4902	kwhite	Karen White	TD_DATA	61506	15866:463604	Test Product Allot	PU.PURET	9	17	Requires update
336281	9/7/2011 9:59:27	9-7-2011 9:54:54:734	4905	crouch	Conni Roush	TD_FORM	15856	15856:0	UB Descriptors		2	1	Form Status demoted to 1
336282	9/7/2011 9:59:27	9-7-2011 9:54:54:734	4905	crouch	Conni Roush	TD_DATA	42131	15856:463466	UB Descriptors	UB.UBLTH	Other (mm)	85 mm	Incorrect data
336283	9/7/2011 9:59:27	9-7-2011 9:54:54:734	4905	crouch	Conni Roush	TD_DATA	42132	15856:463467	UB Descriptors	UB.UBLTOT	Kinds		Incorrect data

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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
336301	9/7/2011 1-0:13:17	9-7-2011 1-0:08:40:171	4905	croush	Conni Roush	TD_DATA	42132	15856:463467	UB Descriptors	UB.UBLTOT		85	Updated Source and CRF
386538	11/2/2011 10:53:21	11-2-2011 10:48:08:824	781	mhunt	Michelle Hunt	TD_FORM	15858	15858:0	Test Product Allot		2	3	Form Status set to 3
386543	11/2/2011 10:55:29	11-2-2011 10:50:18:762	781	mhunt	Michelle Hunt	TD_FORM	15891	15891:0	Study Conclusion		2	3	Form Status set to 3
387960	11/3/2011 16:49:32	11-3-2011 16:44:26:940	6602	gpreciado34	Gina Preciado	TD_FORM	15858	15858:0	Test Product Allot		3	4	Form Status set to 4
387961	11/3/2011 16:49:51	11-3-2011 16:44:45:112	6602	gpreciado34	Gina Preciado	TD_FORM	15891	15891:0	Study Conclusion		3	4	Form Status set to 4
395602	11/14/2011 13:30:31	11-14-2011 13:25:59:156	4905	croush	Conni Roush	TD_FORM	15866	15866:0	Test Product Allot		2	1	Form Status demoted to 1
395603	11/14/2011 13:30:31	11-14-2011 13:25:59:156	4905	croush	Conni Roush	TD_DATA	61506	15866:463604	Test Product Allot	PU.PURET	17	8	Requires update
395608	11/14/2011 13:31:5	11-14-2011 13:26:33:31	4905	croush	Conni Roush	TD_FORM	15866	15866:0	Test Product Allot		1	2	Form Status set to 2
397347	11/15/2011 7:20:6	11-15-2011 7:15:36:156	4905	croush	Conni Roush	TD_FORM	15856	15856:0	UB Descriptors		1	2	Form Status set to 2
397348	11/15/2011 7:20:6	11-15-2011 7:15:36:156	4905	croush	Conni Roush	TD_DATA	42132	15856:463467	UB Descriptors	UB.UBLTOT	85		Requires update
405260	11/22/2011 18:55:18	11-22-2011 18:50:20:447	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15855	15855:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
405261	11/22/2011 18:55:35	11-22-2011 18:50:37:560	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15851	15851:0	Comprehensive PE		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
405262	11/22/2011 18:57:43	11-22-2011 18:52:45:740	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15852	15852:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
405263	11/22/2011 18:59:3	11-22-2011 18:54:05:179	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15849	15849:0	Demographics		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
405264	11/22/2011 18:59:18	11-22-2011 18:54:20:982	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15856	15856:0	UB Descriptors		2	3	Form Status set to 3
405265	11/22/2011 18:59:22	11-22-2011 18:54:24:683	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15857	15857:0	Inc/Exc		2	3	Form Status set to 3
405266	11/22/2011 20:6:32	11-22-2011 20:01:34:607	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15862	15862:0	Test Product Allot		2	3	Form Status set to 3
405267	11/22/2011 20:7:5	11-22-2011 20:02:07:914	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15890	15890:0	Randomization		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
405268	11/22/2011 20:7:41	11-22-2011 20:02:43:448	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15859	15859:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
405269	11/22/2011 20:7:49	11-22-2011 20:02:51:360	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15861	15861:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
405270	11/22/2011 20:9:17	11-22-2011 20:04:19:764	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15863	15863:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
405271	11/22/2011 20:9:29	11-22-2011 20:04:31:856	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15865	15865:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
405272	11/22/2011 20:10:0	11-22-2011 20:05:03:171	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15866	15866:0	Test Product Allot		2	3	Form Status set to 3
405273	11/22/2011 20:13:51	11-22-2011 20:08:53:358	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15869	15869:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
405274	11/22/2011 20												

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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
407887	12/1/2011 15:45:31	12-1-2011 15:40:57:640	4901	lmarks	Larry Marks	TD_DATA	158503	15871:463660	Product Usage Q	SC.SCQ2	No	Yes	Typographical error
407888	12/1/2011 15:45:41	12-1-2011 15:41:08:296	4901	lmarks	Larry Marks	TD_FORM	15871	15871:0	Product Usage Q		1	0	Form Status demoted to 0 Reason : page entered in error
407889	12/1/2011 15:45:41	12-1-2011 15:41:08:296	4901	lmarks	Larry Marks	TD_DATA	158502	15871:463656	Product Usage Q	SC.SCQ1	No		page entered in error
407890	12/1/2011 15:45:41	12-1-2011 15:41:08:296	4901	lmarks	Larry Marks	TD_DATA	158503	15871:463660	Product Usage Q	SC.SCQ2	Yes		page entered in error
407891	12/1/2011 15:45:41	12-1-2011 15:41:08:296	4901	lmarks	Larry Marks	TD_DATA	158504	15871:463662	Product Usage Q	SC.SCQ3	No		page entered in error
407892	12/1/2011 15:45:41	12-1-2011 15:41:08:296	4901	lmarks	Larry Marks	TD_DATA	158505	15871:463668	Product Usage Q	SC.SCQ4D	true		page entered in error
407893	12/1/2011 15:45:41	12-1-2011 15:41:08:296	4901	lmarks	Larry Marks	TD_DATA	158506	15871:463688	Product Usage Q	SC.SCQ5D	14		page entered in error
407894	12/1/2011 15:45:41	12-1-2011 15:41:08:296	4901	lmarks	Larry Marks	TD_DATA	158507	15871:463713	Product Usage Q	SC.SCQ6D	6		page entered in error
407899	12/1/2011 15:47:39	12-1-2011 15:43:05:671	4901	lmarks	Larry Marks	TD_FORM	15872	15872:0	Vital Signs		4	1	Form Status demoted to 1
407900	12/1/2011 15:47:39	12-1-2011 15:43:05:671	4901	lmarks	Larry Marks	TD_DATA	167997	15872:463796	Vital Signs	VS.VSHR	82	8	Typographical error
407901	12/1/2011 15:47:47	12-1-2011 15:43:14:156	4901	lmarks	Larry Marks	TD_FORM	15872	15872:0	Vital Signs		1	0	Form Status demoted to 0 Reason : page entered in error
407902	12/1/2011 15:47:47	12-1-2011 15:43:14:156	4901	lmarks	Larry Marks	TD_DATA	167992	15872:463775	Vital Signs	VS.VSDT	6-22-2011		page entered in error
407903	12/1/2011 15:47:47	12-1-2011 15:43:14:156	4901	lmarks	Larry Marks	TD_DATA	167993	15872:463776	Vital Signs	VS.VSTM	13:10		page entered in error
407904	12/1/2011 15:47:47	12-1-2011 15:43:14:156	4901	lmarks	Larry Marks	TD_DATA	42108	15872:463780	Vital Signs	VS.VSHT	159		page entered in error
407905	12/1/2011 15:47:47	12-1-2011 15:43:14:156	4901	lmarks	Larry Marks	TD_DATA	167994	15872:463783	Vital Signs	VS.VSWT	77.8		page entered in error
407906	12/1/2011 15:47:47	12-1-2011 15:43:14:156	4901	lmarks	Larry Marks	TD_DATA	168000	15872:463786	Vital Signs	VS.VSBMI	30.8		page entered in error
407907	12/1/2011 15:47:47	12-1-2011 15:43:14:156	4901	lmarks	Larry Marks	TD_DATA	167995	15872:463792	Vital Signs	VS.VSSYS	119		page entered in error
407908	12/1/2011 15:47:47	12-1-2011 15:43:14:156	4901	lmarks	Larry Marks	TD_DATA	167996	15872:463794	Vital Signs	VS.VSDIA	82		page entered in error
407909	12/1/2011 15:47:47	12-1-2011 15:43:14:156	4901	lmarks	Larry Marks	TD_DATA	167997	15872:463796	Vital Signs	VS.VSHR	8		page entered in error
407910	12/1/2011 15:47:47	12-1-2011 15:43:14:156	4901	lmarks	Larry Marks	TD_DATA	167998	15872:463798	Vital Signs	VS.VSRR	16		page entered in error
407911	12/1/2011 15:47:47	12-1-2011 15:43:14:156	4901	lmarks	Larry Marks	TD_DATA	167999	15872:463800	Vital Signs	VS.VSTEMP	36.2		page entered in error
407912	12/1/2011 15:47:56	12-1-2011 15:43:22:796	4901	lmarks	Larry Marks	TD_FORM	15872	15872:0	Vital Signs		0	2	Form Status set to 2
407913	12/1/2011 15:47:56	12-1-2011 15:43:22:796	4901	lmarks	Larry Marks	TD_FORM	15872	15872:0	Vital Signs		0	1	Form Checked Intentionally Left Blank
407914	12/1/2011 15:48:15	12-1-2011 15:43:41:687	4901	lmarks	Larry Marks	TD_EVENT	5719	0:0					Shared Event Added
407915	12/1/2011 15:48:39	12-1-2011 15:44:06:0	4901	lmarks	Larry Marks	TD_FORM	15888	15888:0	Prtcl Deviations		0	1	Form Status set to 1
407916	12/1/2011 15:48:39	12-1-2011 15:44:06:0	4901	lmarks	Larry Marks	TD_DATA	247993	15888:464368	Prtcl Deviations	PV.PVDT		6-22-2011	Data Added
407917	12/1/2011 15:48:39	12-1-2011 15:44:06:0	4901	lmarks	Larry Marks	TD_DATA	247994	15888:464369	Prtcl Deviations	PV.PVCAT		Visit Schedule/Interval	Data Added
407918	12/1/2011 15:48:39	12-1-2011 15:44:06:0	4901	lmarks	Larry Marks	TD_DATA	247995	15888:464370	Prtcl Deviations	PV.PVSPEC		inadvertently seen at visit 4 per protocol	Data Added
407919	12/1/2011 15:48:41	12-1-2011 15:44:07:593	4901	lmarks	Larry Marks	TD_FORM	15888	15888:0	Prtcl Deviations		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
407920	12/1/2011 15:48:52	12-1-2011 15:44:19:265	4901	lmarks	Larry Marks	TD_FORM	75502	75502:0	Prtcl Deviations				Repeating Form Created
407921	12/1/2011 15:49:20	12-1-2011 15:44:46:640	4901	lmarks	Larry Marks	TD_FORM	75502	75502:0	Prtcl Deviations		0	1	Form Status set to 1
407922	12/1/2011 15:49:20	12-1-2011 15:44:46:640	4901	lmarks	Larry Marks	TD_DATA	247996	75502:2117125	Prtcl Deviations	PV.PVDT		5-23-2011	Data Added
407923	12/1/2011 15:49:20	12-1-2011 15:44:46:640	4901	lmarks	Larry Marks	TD_DATA	247997	75502:2117126	Prtcl Deviations	PV.PVCAT		Other	Data Added
407924	12/1/2011 15:49:20	12-1-2011 15:44:46:640	4901	lmarks	Larry Marks	TD_DATA	247998	75502:2117127	Prtcl Deviations	PV.PVSPEC		subject was under dispensed study product per protocol at visit 3	Data Added
407925	12/1/2011 15:49:21	12-1-2011 15:44:47:812	4901	lmarks	Larry Marks	TD_FORM	75502	75502:0	Prtcl Deviations		1	2	Form Status set to 2
407926	12/1/2011 15:49:38	12-1-2011 15:45:04:875	4901	lmarks	Larry Marks	TD_FORM	75503	75503:0	Prtcl Deviations				Repeating Form Created
407927	12/1/2011 15:50:41	12-1-2011 15:46:07:562	4901	lmarks	Larry Marks	TD_FORM	75503	75503:0	Prtcl Deviations		0	1	Form Status set to 1
407928	12/1/2011 15:50:41	12-1-2011 15:46:07:562	4901	lmarks	Larry Marks	TD_DATA	247999	75503:2117132	Prtcl Deviations	PV.PVDT		6-16-2011	Data Added
407929	12/1/2011 15:50:41	12-1-2011 15:46:07:562	4901	lmarks	Larry Marks	TD_DATA	248000	75503:2117133	Prtcl Deviations	PV.PVCAT		Visit Schedule/Interval	Data Added
407930	12/1/2011 15:50:41	12-1-2011 15:46:07:562	4901	lmarks	Larry Marks	TD_DATA	248001	75503:2117134	Prtcl Deviations	PV.PVSPEC		inadvertently did telephone call 1 per protocol since subject should have been discontinued at visit 3 for ECO >., 8	Data Added
407931	12/1/2011 15:50:43	12-1-2011 15:46:10:156	4901	lmarks	Larry Marks	TD_FORM	75503	75503:0	Prtcl Deviations		1	2	Form Status set to 2
407932	12/1/2011 15:52:44	12-1-2011 15:48:11:250	4901	lmarks	Larry Marks	TD_FORM	15850	15850:0	Brief Med. History		2	1	Form Status set to 1
407933	12/1/2011 15:52:44	12-1-2011 15:48:11:250	4901	lmarks	Larry Marks	TD_FORM	15850	15850:0	Brief Med. History		1	0	Form Unchecked Intentionally Left Blank
407934	12/1/2011 15:52:44	12-1-2011 15:48:11:250	4901	lmarks	Larry Marks	TD_DATA	248002	15850:463332	Brief Med. History	MH.MHCOND		hyperopia	Data Added
407935	12/1/2011 15:52:44	12-1-2011 15:48:11:250	4901	lmarks	Larry Marks	TD_DATA	248003	15850:463333	Brief Med. History	MH.MHSTYYYY		2004	Data Added
407936	12/1/2011 15:52:44	12-1-2011 15:48:11:250	4901	lmarks	Larry Marks	TD_DATA	248004	15850:463334	Brief Med. History	MH.MHENRF		Ongoing	Data Added
407937	12/1/2011 15:52:49	12-1-2011 15:48:15:671	4901	lmarks	Larry Marks	TD_FORM	75504	75504:0	Brief Med. History				Repeating Form Created
407938	12/1/2011 15:53:0	12-1-2011 15:48:27:390	4901	lmarks	Larry Marks	TD_FORM	75504	75504:0	Brief Med. History		0	1	Form Status set to 1
407939	12/1/2011 15:53:0	12-1-2011 15:48:27:390	4901	lmarks	Larry Marks	TD_DATA	248005	75504:2117139	Brief Med. History	MH.MHCOND		myopia	Data Added
407940	12/1/2011 15:53:0	12-1-2011 15:48:27:390	4901	lmarks	Larry Marks	TD_DATA	248006	75504:2117140	Brief Med. History	MH.MHSTYYYY		2004	Data Added
407941	12/1/2011 15:53:0	12-1-2011 15:48:27:390	4901	lmarks	Larry Marks	TD_DATA	248007	75504:2117141	Brief Med. History	MH.MHENRF		Ongoing	Data Added
407942	12/1/2011 15:53:1	12-1-2011 15:48:28:265	4901	lmarks	Larry Marks	TD_FORM	75504	75504:0	Brief Med. History		1	2	Form Status set to 2
407943	12/1/2011 15:53:11	12-1-2011 15:48:38:46	4901	lmarks	Larry Marks	TD_FORM	15850	15850:0	Brief Med. History		1	2	Form Status set to 2
408466	12/2/2011 11:30:15	12-2-2011 11:25:47:205	6602	gpreciado34	Gina Preciado	TD_FORM	15857	15857:0	Inc/Exc		3	4	Form Status set to 4
408467	12/2/2011 11:30:29	12-2-2011 11:26:01:252	6602	gpreciado34	Gina Preciado	TD_FORM	15862	15862:0	Test Product Allot		3	4	Form Status set to 4
408563	12/2/2011 15:11:46	12-2-2011 15:07:18:610	6602	gpreciado34	Gina Preciado	TD_FORM	15849	15849:0	Demographics		4	3	Form Status demoted to 3
408564	12/2/2011 15:12:0	12-2-2011 15:07:32:532	6602	gpreciado34	Gina Preciado	TD_FORM	15852	15852:0	Vital Signs		4	3	Form Status demoted to 3
408565	12/2/2011 15:12:4	12-2-2011 15:07:36:797	6602	gpreciado34	Gina Preciado	TD_FORM	15854	15854:0	Labs		4	3	Form Status demoted 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
408566	12/2/2011 15:12:8	12-2-2011 15:07:40:360	6602	gpreciado34	Gina Preciado	TD_FORM	15855	15855:0	Exhaled CO		4	3	Form Status demoted to 3
408567	12/2/2011 15:12:13	12-2-2011 15:07:45:313	6602	gpreciado34	Gina Preciado	TD_FORM	15857	15857:0	Inc/Exc		4	3	Form Status demoted to 3
408568	12/2/2011 15:12:19	12-2-2011 15:07:51:922	6602	gpreciado34	Gina Preciado	TD_FORM	15858	15858:0	Test Product Allot		4	3	Form Status demoted to 3
408716	12/2/2011 16:21:8	12-2-2011 16:16:40:343	4901	lmarks	Larry Marks	TD_FORM	15891	15891:0	Study Conclusion		4	1	Form Status demoted to 1
408717	12/2/2011 16:21:8	12-2-2011 16:16:40:343	4901	lmarks	Larry Marks	TD_DATA	167985	15891:464444	Study Conclusion	DS.DSETSP	Pregnancy and ECO >.8.	Subject states abstinent from smoking., but with ECO >.8 at Visit 3.	Typographical error
408720	12/2/2011 16:21:24	12-2-2011 16:16:56:203	4901	lmarks	Larry Marks	TD_FORM	15891	15891:0	Study Conclusion		1	2	Form Status set to 2
409448	12/6/2011 16:49:51	12-6-2011 16:44:39:109	4901	lmarks	Larry Marks	TD_FORM	75502	75502:0	Prtcl Deviations		2	1	Form Status demoted to 1
409449	12/6/2011 16:49:51	12-6-2011 16:44:39:109	4901	lmarks	Larry Marks	TD_DATA	247998	75502:2117127	Prtcl Deviations	PV.PVSPEC	subject was under dispensed study product per protocol at visit 3	subject was under dispensed study product per protocol at visit 3 (did not round up to nearest whole number for SNUS)	Typographical error
409450	12/6/2011 16:49:52	12-6-2011 16:44:40:187	4901	lmarks	Larry Marks	TD_FORM	75502	75502:0	Prtcl Deviations		1	2	Form Status set to 2
411384	12/14/2011 11:14:1	12-14-2011 11:09:07:449	6602	gpreciado34	Gina Preciado	TD_FORM	15866	15866:0	Test Product Allot		3	4	Form Status set to 4
413320	12/21/2011 15:56:17	12-21-2011 15:50:49:56	6602	gpreciado34	Gina Preciado	TD_FORM	15852	15852:0	Vital Signs		3	4	Form Status set to 4
413321	12/21/2011 15:56:23	12-21-2011 15:50:55:10	6602	gpreciado34	Gina Preciado	TD_FORM	15849	15849:0	Demographics		3	4	Form Status set to 4
413322	12/21/2011 15:56:34	12-21-2011 15:51:05:479	6602	gpreciado34	Gina Preciado	TD_FORM	15854	15854:0	Labs		3	4	Form Status set to 4
413323	12/21/2011 15:56:39	12-21-2011 15:51:10:947	6602	gpreciado34	Gina Preciado	TD_FORM	15855	15855:0	Exhaled CO		3	4	Form Status set to 4
413324	12/21/2011 15:56:46	12-21-2011 15:51:18:57	6602	gpreciado34	Gina Preciado	TD_FORM	15857	15857:0	Inc/Exc		3	4	Form Status set to 4
413325	12/21/2011 15:56:57	12-21-2011 15:51:28:542	6602	gpreciado34	Gina Preciado	TD_FORM	15858	15858:0	Test Product Allot		3	4	Form Status set to 4
413981	12/26/2011 22:46:26	12-26-2011 22:41:22:101	781	mhunt	Michelle Hunt	TD_FORM	15851	15851:0	Comprehensive PE		2	3	Form Status set to 3
413982	12/26/2011 22:47:55	12-26-2011 22:42:51:185	781	mhunt	Michelle Hunt	TD_FORM	15872	15872:0	Vital Signs		2	3	Form Status set to 3
414015	12/27/2011 8:26:59	12-27-2011 8:21:45:265	4905	croush	Conni Roush	TD_DATA	167983	15891:464440	Study Conclusion	DS.DSETSCDT	6-22-2011	5-23-2011	Requires update
414916	12/28/2011 11:7:33	12-28-2011 11:02:28:704	6602	gpreciado34	Gina Preciado	TD_FORM	15851	15851:0	Comprehensive PE		3	4	Form Status set to 4
414917	12/28/2011 11:9:53	12-28-2011 11:04:45:222	6602	gpreciado34	Gina Preciado	TD_FORM	15872	15872:0	Vital Signs		3	4	Form Status set to 4
416841	1/1/2012 2-2:20:6	1-1-2012 2-2:15:17:214	781	mhunt	Michelle Hunt	TD_FORM	15891	15891:0	Study Conclusion		2	3	Form Status set to 3
427551	1/23/2012 10:38:52	1-23-2012 10:34:17:50	6602	gpreciado34	Gina Preciado	TD_FORM	15891	15891:0	Study Conclusion		3	4	Form Status set to 4
436891	2/28/2012 15:31:21	2-28-2012 15:25:53:93	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15850	15850:0	Brief Med. History		2	3	Form Status set to 3
436892	2/28/2012 15:31:24	2-28-2012 15:25:56:685	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	75504	75504:0	Brief Med. History		2	3	Form Status set to 3
436893	2/28/2012 15:31:49	2-28-2012 15:26:21:450	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15849	15849:0	Demographics		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
436894	2/28/2012 15:32:19	2-28-2012 15:26:51:656	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15851	15851:0	Comprehensive PE		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
436895	2/28/2012 15:32:38	2-28-2012 15:27:11:17	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15852	15852:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
436896	2/28/2012 15:34:25	2-28-2012 15:28:57:518	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15855	15855:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
436897	2/28/2012 15:35:8	2-28-2012 15:29:39:788	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15856	15856:0	UB Descriptors		2	3	Form Status set to 3
436898	2/28/2012 15:36:57	2-28-2012 15:31:30:76	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15891	15891:0	Study Conclusion		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
436899	2/28/2012 15:37:30	2-28-2012 15:32:02:425	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	75502	75502:0	Prtcl Deviations		2	3	Form Status set to 3
436900	2/28/2012 15:38:16	2-28-2012 15:32:48:598	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	15870	15870:0	Test Product Allot		2	3	Form Status set to 3
436942	2/29/2012 12:15:0	2-29-2012 12:09:33:855	4905	croush	Conni Roush	TD_FORM	15853	15853:0	ECG		2	1	Form Status demoted to 1
436943	2/29/2012 12:15:0	2-29-2012 12:09:33:855	4905	croush	Conni Roush	TD_DATA	42111	15853:463415	ECG	EG.EGTM	10:50	11:50	Typographical error
436944	2/29/2012 12:41:24	2-29-2012 12:35:53:152	4905	croush	Conni Roush	TD_FORM	15853	15853:0	ECG		1	2	Form Status set to 2
436945	2/29/2012 12:44:5	2-29-2012 12:38:38:137	4905	croush	Conni Roush	TD_FORM	15866	15866:0	Test Product Allot		4	1	Form Status demoted to 1
436946	2/29/2012 12:44:5	2-29-2012 12:38:38:137	4905	croush	Conni Roush	TD_DATA	61506	15866:463604	Test Product Allot	PU.PURET	8	17	Typographical error
437044	2/29/2012 16:49:24	2-29-2012 16:43:59:451	6602	gpreciado34	Gina Preciado	TD_FORM	15856	15856:0	UB Descriptors		3	4	Form Status set to 4
437045	2/29/2012 16:49:31	2-29-2012 16:44:06:842	6602	gpreciado34	Gina Preciado	TD_FORM	75504	75504:0	Brief Med. History		3	4	Form Status set to 4
437046	2/29/2012 16:49:35	2-29-2012 16:44:10:217	6602	gpreciado34	Gina Preciado	TD_FORM	15850	15850:0	Brief Med. History		3	4	Form Status set to 4
437048	2/29/2012 16:50:26	2-29-2012 16:45:02:30	6602	gpreciado34	Gina Preciado	TD_FORM	75502	75502:0	Prtcl Deviations		3	4	Form Status set to 4
437049	2/29/2012 16:50:51	2-29-2012 16:45:26:561	6602	gpreciado34	Gina Preciado	TD_FORM	15870	15870:0	Test Product Allot		3	4	Form Status set to 4
441872	3/22/2012 15:56:26	3-22-2012 15:52:18:218	4901	lmarks	Larry Marks	TD_FORM	15866	15866:0	Test Product Allot		1	2	Form Status set to 2
441873	3/22/2012 15:56:26	3-22-2012 15:52:18:218	4901	lmarks	Larry Marks	TD_DATA	61506	15866:463604	Test Product Allot	PU.PURET	17	9	Typographical error
465860	7/29/2012 21:56:5	7-29-2012 21:49:28:453	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	15888	15888:0	Prtcl Deviations		2	3	Form Status set to 3
465861	7/29/2012 21:57:4	7-29-2012 21:50:26:750	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	75503	75503:0	Prtcl Deviations		2	3	Form Status set to 3
466383	7/30/2012 11:27:34	7-30-2012 11:21:01:682	6602	gpreciado34	Gina Preciado	TD_FORM	15888	15888:0	Prtcl Deviations		3	4	Form Status set to 4
466385	7/30/2012 11:27:38	7-30-2012 11:21:05:875	6602	gpreciado34	Gina Preciado	TD_FORM	75503	75503:0	Prtcl Deviations		3	4	Form Status set to 4
467074	7/31/2012 14:40:24	7-31-2012 14:33:46:890	4905	croush	Conni Roush	TD_FORM	15875	15875:0	Oral Assessment		2	1	Form Status demoted to 1
467075	7/31/2012 14:40:24	7-31-2012 14:33:46:890	4905	croush	Conni Roush	TD_DATA	167978	15875:463830	Oral Assessment	PE.PEORAL	Normal	Not Done	Requires update
467076	7/31/2012 14:40:27	7-31-2012 14:33:49:953	4905	croush	Conni Roush	TD_FORM	15875	15875:0	Oral Assessment		1	2	Form Status set to 2
468396	8/5/2012 1-7:22	8-5-2012 1-7:01:03:147	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	15853	15853:0	ECG		2	3	Form Status set to 3
470990	8/14/2012 13:36:8	8-14-2012 13:29:24:875	4901	lmarks	Larry Marks	TD_FORM	15874	15874:0	Labs		4	1	Form Status demoted to 1
470991	8/14/2012 13:36:26	8-14-2012 13:29:42:828	4901	lmarks	Larry Marks	TD_DATA	167972	15874:463819	Labs	LB.LBURDT	6-22-2011	--	Requires update
470992	8/14/2012 13:36:26	8-14-2012 13:29:42:828	4901	lmarks	Larry Marks	TD_DATA	167973	15874:463820	Labs	LB.LBURTM	13:04		Requires update
470993	8/14/2012 13:37:5	8-14-2012 13:30:21:921	4901	lmarks	Larry Marks	TD_FORM	15874	15874:0	Labs		1	2	Form Status set to 2
470994	8/14/2012 13:37:13	8-14-2012 13:30:29:156	4901	lmarks	Larry Marks	TD_FORM	15874	15874:0	Labs		2	1	Form Status demoted 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
470995	8/14/2012 13:37:30	8-14-2012 13:30:46:843	4901	lmarks	Larry Marks	TD_FORM	15874	15874:0	Labs		1	0	Form Status demoted to 0 Reason : requires update
470996	8/14/2012 13:37:30	8-14-2012 13:30:46:843	4901	lmarks	Larry Marks	TD_DATA	167971	15874:463813	Labs	LB.LBBSAMP	true		requires update
470997	8/14/2012 13:37:30	8-14-2012 13:30:46:843	4901	lmarks	Larry Marks	TD_DATA	167972	15874:463819	Labs	LB.LBURDT	--		requires update
470998	8/14/2012 13:37:30	8-14-2012 13:30:46:843	4901	lmarks	Larry Marks	TD_DATA	167973	15874:463820	Labs	LB.LBURTM			requires update
470999	8/14/2012 13:37:30	8-14-2012 13:30:46:843	4901	lmarks	Larry Marks	TD_DATA	167974	15874:463824	Labs	LB.LBUCS	Positive		requires update
471000	8/14/2012 13:37:36	8-14-2012 13:30:52:187	4901	lmarks	Larry Marks	TD_FORM	15874	15874:0	Labs		0	2	Form Status set to 2
471001	8/14/2012 13:37:36	8-14-2012 13:30:52:187	4901	lmarks	Larry Marks	TD_FORM	15874	15874:0	Labs		0	1	Form Checked Intentionally Left Blank
471002	8/14/2012 13:37:39	8-14-2012 13:30:55:781	4901	lmarks	Larry Marks	TD_FORM	15875	15875:0	Oral Assessment		2	1	Form Status demoted to 1
471003	8/14/2012 13:37:49	8-14-2012 13:31:05:843	4901	lmarks	Larry Marks	TD_FORM	15875	15875:0	Oral Assessment		1	0	Form Status demoted to 0 Reason : requires update
471004	8/14/2012 13:37:49	8-14-2012 13:31:05:843	4901	lmarks	Larry Marks	TD_DATA	167978	15875:463830	Oral Assessment	PE.PEORAL	Not Done		requires update
471005	8/14/2012 13:38:4	8-14-2012 13:31:20:812	4901	lmarks	Larry Marks	TD_FORM	15875	15875:0	Oral Assessment		0	2	Form Status set to 2
471006	8/14/2012 13:38:4	8-14-2012 13:31:20:812	4901	lmarks	Larry Marks	TD_FORM	15875	15875:0	Oral Assessment		0	1	Form Checked Intentionally Left Blank
472515	8/16/2012 14:2:9	8-16-2012 13:55:09:162	6602	gpreciado34	Gina Preciado	TD_FORM	15853	15853:0	ECG		3	4	Form Status set to 4
472757	8/17/2012 7:16:59	8-17-2012 7:10:26:203	4905	croush	Conni Roush	TD_FORM	77665	77665:0	Prtcl Deviations				Repeating Form Created
472758	8/17/2012 7:17:27	8-17-2012 7:10:53:266	4905	croush	Conni Roush	TD_FORM	77665	77665:0	Prtcl Deviations		0	2	Form Status set to 2
472759	8/17/2012 7:17:27	8-17-2012 7:10:53:266	4905	croush	Conni Roush	TD_DATA	268614	77665:2125973	Prtcl Deviations	PV.PVDT		4-25-2011	Data Added
472760	8/17/2012 7:17:27	8-17-2012 7:10:53:266	4905	croush	Conni Roush	TD_DATA	268615	77665:2125974	Prtcl Deviations	PV.PVCAT		Visit Schedule/Interval	Data Added
472761	8/17/2012 7:17:27	8-17-2012 7:10:53:266	4905	croush	Conni Roush	TD_DATA	268616	77665:2125975	Prtcl Deviations	PV.PVSPEC		visit 2 was out of window in error	Data Added
473500	8/22/2012 1:44:32	8-22-2012 1:38:18:120	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	15875	15875:0	Oral Assessment		2	3	Form Status set to 3
473946	8/27/2012 10:37:30	8-27-2012 10:30:28:921	4905	croush	Conni Roush	TD_FORM	77665	77665:0	Prtcl Deviations		2	1	Form Status demoted to 1
473947	8/27/2012 10:37:30	8-27-2012 10:30:28:921	4905	croush	Conni Roush	TD_DATA	268614	77665:2125973	Prtcl Deviations	PV.PVDT	4-25-2011	4-15-2011	Typographical error
473948	8/27/2012 10:38:42	8-27-2012 10:31:41:375	4905	croush	Conni Roush	TD_FORM	77665	77665:0	Prtcl Deviations		1	2	Form Status set to 2
474486	8/27/2012 14:47:54	8-27-2012 14:41:36:703	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	77665	77665:0	Prtcl Deviations		2	3	Form Status set to 3
474650	8/28/2012 17:37:58	8-28-2012 17:31:03:834	6602	gpreciado34	Gina Preciado	TD_FORM	15875	15875:0	Oral Assessment		3	4	Form Status set to 4
474651	8/28/2012 17:38:8	8-28-2012 17:31:13:825	6602	gpreciado34	Gina Preciado	TD_FORM	77665	77665:0	Prtcl Deviations		3	4	Form Status set to 4
483523	9/21/2012 12:20:2	9-21-2012 12:13:27:243	782	kcorey	Kris Corey	TD_FORM	15874	15874:0	Labs		2	3	Form Status set to 3
483661	9/21/2012 15:25:57	9-21-2012 15:19:21:254	782	kcorey	Kris Corey	TD_FORM	15866	15866:0	Test Product Allot		2	3	Form Status set to 3
483710	9/21/2012 16:13:16	9-21-2012 16:06:45:78	6602	gpreciado34	Gina Preciado	TD_FORM	15866	15866:0	Test Product Allot		3	4	Form Status set to 4
483712	9/21/2012 16:13:42	9-21-2012 16:07:10:723	6602	gpreciado34	Gina Preciado	TD_FORM	15874	15874:0	Labs		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
484605	9/25/2012 14:27:15	9-25-2012 14:19:55:918	7681	dchampagne234	Daphne C-hamapagne	TD_CASE-BOOK	1326	0:0			0	1	Casebook Frozen
485841	9/27/2012 12:1:44	9-27-2012 11:54:33:261	7303	ygottliebmon	Joanne G-ottlieb	TD_CASE-BOOK	1326	0:0			1	0	Casebook Thawed
488057	10/10/2012 13:47:46	10-10-2012 13:40:19:151	6821	yovalle2346	Yuliana Ov-alle	TD_FORM	15873	15873:0	Exhaled CO		4	3	Form Status demoted to 3
488080	10/11/2012 14:6:52	10-11-2012 13:59:26:640	4905	croush	Conni Roush	TD_FORM	15873	15873:0	Exhaled CO		3	0	Form Status demoted to 0 Reason : data entry error
488081	10/11/2012 14:6:52	10-11-2012 13:59:26:640	4905	croush	Conni Roush	TD_DATA	168013	15873:463803	Exhaled CO	EC.ECYN	Yes		data entry error
488082	10/11/2012 14:6:52	10-11-2012 13:59:26:640	4905	croush	Conni Roush	TD_DATA	168014	15873:463805	Exhaled CO	EC.ECDT	6-22-2011		data entry error
488083	10/11/2012 14:6:52	10-11-2012 13:59:26:640	4905	croush	Conni Roush	TD_DATA	168015	15873:463806	Exhaled CO	EC.ECTM	13:12		data entry error
488084	10/11/2012 14:6:52	10-11-2012 13:59:26:640	4905	croush	Conni Roush	TD_DATA	168016	15873:463810	Exhaled CO	EC.ECRES1	15		data entry error
488085	10/11/2012 14:7:29	10-11-2012 14:00:04:281	4905	croush	Conni Roush	TD_FORM	15873	15873:0	Exhaled CO		0	2	Form Status set to 2
488086	10/11/2012 14:7:29	10-11-2012 14:00:04:281	4905	croush	Conni Roush	TD_FORM	15873	15873:0	Exhaled CO		0	1	Form Checked Intentionally Left Blank
488087	10/11/2012 14:31:29	10-11-2012 14:24:05:406	782	kcurey	Kris Corey	TD_FORM	15873	15873:0	Exhaled CO		2	3	Form Status set to 3
488088	10/11/2012 15:8:39	10-11-2012 15:01:16:517	7301	ygottliebdm	Joanne G-ottlieb	TD_FORM	15873	15873:0	Exhaled CO		3	4	Form Status set to 4
488089	10/11/2012 15:10:11	10-11-2012 15:02:47:828	7303	ygottliebmon	Joanne G-ottlieb	TD_CASE-BOOK	1326	0:0			0	1	Casebook Frozen
491748	11/15/2012 13:23:4	11-15-2012 13:23:09:269	5003	tmarbury	Thomas M-arbury	TD_CASE-BOOK	1326	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
UB Descriptors	Average Cigarettes Smoked Per Day	UB.UBCPD	30	APPROVED	Data is missing. Please provide.		04-04-2011	SYSTEM	
Inc/Exc	Did the subject meet all eligibility criteria for enrollment	IE.IECRITYN	1	APPROVED	Email		04-04-2011	SYSTEM	
Test Product Allot	Preferred Flavor of SNUS	PU.PUSNUS2	1	APPROVED	SNUS has been checked, however Cohort 3 has been selected Please review and reconcile.		04-06-2011	SYSTEM	
Test Product Allot	Preferred Flavor of Lozenge	PU.PULOZG2	3	APPROVED	Lozenge has been checked, however Cohort 1 or 2 has been selected Please review and reconcile.		04-06-2011	SYSTEM	
			2	OPEN		Entry error, updated CRF	2011-04-06 12:20:47.0	kwhite	Karen White
			3	OPEN		Entry error, updated CRF	2011-04-06 12:25:00.0	kwhite	Karen White
Test Product Allot	Number of Units Returned	PU.PURET		APPROVED	Number of Units returned cannot be blank. If units were returned a value of (0) must be present		4-26-2011	gpreciado	Gina Preciado
				APPROVED		invalid	2011-04-27 12:27:51.0	gpreciado	Gina Preciado
Comprehensive PE	Other	PE.PEOTH	3	APPROVED	EDC says "Not Done" and SW is blank. Please update SW and upload into IVault.		4-26-2011	mhunt	Michelle Hunt
			null	RESOLVED		Data has been verified and updated.	2011-04-27 15:41:27.0	emedina	Elsie Medina
			null	APPROVED		eCRF has been updated.	2011-06-18 22:23:10.0	mhunt	Michelle Hunt
Comprehensive PE	Other	PE.PEOTH	3	APPROVED	Data is missing. Please provide.		04-27-2011	SYSTEM	
			null	RESOLVED		Data is confirmed as correct.	2011-04-27 15:41:39.0	emedina	Elsie Medina
			null	OPEN		Please provide finding other	2011-07-08 17:43:29.0	gpreciado34	Gina Preciado
Labs	Urine Pregnancy Screen	LB.LBUCS		RESOLVED	Result for urine pregnancy screen is positive. Subject should be discontinued. Please correct or clarify.		06-23-2011	SYSTEM	
			2	RESOLVED		Confirmed Data, no action	2011-06-23 11:51:17.0	kwhite	Karen White
			2	APPROVED		Confirmed Data, no action	2011-07-15 09:10:32.0	gpreciado34	Gina Preciado
Demographics	FORM LEVEL	-form--form-		APPROVED	Pls delete the current ICF "folder" uploaded in IVault (08-MAR-2011 version and 21-MAR-2011 version uploaded back-to-back). 08-MAR-2011 version is missing pages 1 and 2 from the folder. Pls upload as TWO SEPARATE folders. thanks		6-30-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Done per Coordinator.	2011-07-14 11:19:00.0	kwhite	Karen White
				APPROVED		done	2011-11-22 18:48:05.0	ajungstreisand	Ashley Jung-Streisand
Study Conclusion	FORM LEVEL	-form--form-		APPROVED	Please upload Study Conclusion SW into IVault.		7-14-2011	mhunt	Michelle Hunt
				RESOLVED		Study Conclusion SW was uploaded/signed by 23-JUN-2011.	2011-07-14 11:24:05.0	kwhite	Karen White
				APPROVED		SW has been uploaded into IVault.	2011-11-02 10:55:22.0	mhunt	Michelle Hunt
Test Product Allot	Number of Units Dispensed	PU.PUDIS2	26	APPROVED	Please confirm or correct product allotment		7-15-2011	gpreciado34	Gina Preciado
			26	RESOLVED		Updated Source and CRF	2011-07-18 10:19:22.0	kwhite	Karen White
			26	APPROVED		Confirmed Data, no action	2011-07-19 10:30:36.0	yovalle2346	Yuliana Ovalle
Test Product Allot	Number of Units Dispensed	PU.PUDIS2	19	APPROVED	Please confirm or correct product allotment		7-15-2011	gpreciado34	Gina Preciado
			19	RESOLVED		Updated Source and CRF	2011-07-18 10:19:58.0	kwhite	Karen White
			19	APPROVED		Confirmed Data, no action	2011-07-19 10:31:17.0	yovalle2346	Yuliana Ovalle
UB Descriptors	Length Specify	UB.UBLTOT		APPROVED	Is it Kings? If so, please correct spelling		9-6-2011	gpreciado34	Gina Preciado
			85	RESOLVED		Updated Source and CRF	2011-09-07 09:59:54.0	croush	Conni Roush
			85	APPROVED		Confirmed Data, no action	2011-09-07 14:23:47.0	gpreciado34	Gina Preciado

DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
Comprehensive PE	Other	PE.PEOTH	3	APPROVED	EDC says Not Done and SW is blank. Please update eCRF or upload a new SW into IVault. eCRF and SW should mirror one another.		11-2-2011	mhunt	Michelle Hunt
				RESOLVED		Updated source document, no CRF change	2011-11-15 07:20:39.0	croush	Conni Roush
			3	OPEN		Please upload updated SW into IVault.	2011-11-24 00:55:49.0	mhunt	Michelle Hunt
				RESOLVED		Updated Source and CRF	2011-12-07 13:41:50.0	croush	Conni Roush
			3	APPROVED		SW has been updated to match eCRF.	2011-12-26 22:46:22.0	mhunt	Michelle Hunt
Test Product Allot	Number of Units Returned	PU.PURET	9	APPROVED	Pls correct to "8" tins of unused products.		11-11-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Updated Source and CRF	2011-11-14 13:30:53.0	croush	Conni Roush
			8	APPROVED		thanks	2011-11-22 20:09:48.0	ajungstreisand	Ashley Jung-Streisand
ECG	Time Completed	EG.EGTM	11:50	APPROVED	Pls correct time to 11.:50 per ECG report.		11-22-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		source says supine time	2011-12-01 14:41:32.0	croush	Conni Roush
			10:50	OPEN		EDC requts Time of ECG completion on the ECG report. Pls correct to 11:50. thanks	2012-02-28 15:34:00.0	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Entry error, updated CRF	2012-02-29 12:14:45.0	croush	Conni Roush
			11:50	APPROVED		Entry error, updated CRF	2012-08-05 17:07:14.0	mcaballero	Maria Isabel Caballero V-aliente
Brief Med. History	FORM LEVEL	-form-.-form-		APPROVED	Pls add 2 separate entries of: MYOPIA 2004 ONGOING HYPEROPIA 2004 ONGOING, per SDW.		11-22-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		data added	2011-12-01 15:53:09.0	lmarks	Larry Marks
				APPROVED		thanks	2012-02-28 15:31:09.0	ajungstreisand	Ashley Jung-Streisand
UB Descriptors	Sub-brand:	UB.UBSBRND	Silver Pack	APPROVED	Pls delete ULTRA LIGHT, per SDW.		11-22-2011	ajungstreisand	Ashley Jung-Streisand
			Silver Pack	RESOLVED		Entry error, updated CRF	2011-12-01 15:44:18.0	lmarks	Larry Marks
			Silver Pack	APPROVED		thanks	2012-02-28 15:35:02.0	ajungstreisand	Ashley Jung-Streisand
Test Product Allot	FORM LEVEL	-form-.-form-		APPROVED	Pls upload the corrected SDW in IVault.		11-22-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Updated Source and CRF	2011-12-12 12:10:32.0	croush	Conni Roush
				OPEN		Sorry. I do not see the updated SDW with corrected 8 tins returned in IVault. thanks	2012-02-28 15:29:15.0	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Entry error, updated CRF	2012-02-29 12:44:20.0	croush	Conni Roush
				APPROVED		to beSDV by PV	2012-09-11 16:08:06.0	lgottlieb	Joanne Gottlieb
Test Product Allot	Number of Units Dispensed	PU.PUDIS2	13	APPROVED	Pls generate PD for NOT dispensing study product per protocol at Visit 3 (did not round up to nearest whole number for SNUS).		11-22-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Updated Source and CRF	2011-12-07 13:42:15.0	croush	Conni Roush
			13	APPROVED		thanks	2012-02-28 15:37:51.0	ajungstreisand	Ashley Jung-Streisand
Vital Signs	FORM LEVEL	-form-.-form-		RESOLVED	Pls generate a protocol deviation for inadvertent Visit 4 since subject should have been Discontinued at Visit 3 since ECO >8 at Visit 3.		11-22-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		page entered in error	2011-12-01 15:47:47.0	ajungstreisand	Ashley Jung-Streisand
Product Usage Q	FORM LEVEL	-form-.-form-		RESOLVED	Pls generate a protocol deviation for inadvertent Visit 4 since subject should have been Discontinued at Visit 3 since ECO >8 at Visit 3.		11-22-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		page entered in error	2011-12-01 15:45:41.0	ajungstreisand	Ashley Jung-Streisand
Product Usage Q	FORM LEVEL	-form-.-form-		RESOLVED	Pls line thru the visit source and re-upload in I-Vault for inadvertent visit. Delete the data from the EDC,		11-22-2011	ajungstreisand	Ashley Jung-Streisand

DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
				RESOLVED		page entered in error	2011-12-01 15:45:41.0	ajungstreisand	Ashley Jung-Streisand
Vital Signs	FORM LEVEL	-form--form-		RESOLVED	Pls line thru the visit source and re-upload in I-Vault for inadvertent visit. Delete the data from the EDC, marking the form as No Event.		11-22-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		page entered in error	2011-12-01 15:47:47.0	ajungstreisand	Ashley Jung-Streisand
Study Conclusion	Reason for Withdrawal	DS.DSETREAS	99	APPROVED	Pls correct D/C to state "Subject states abstinent from smoking but with >8 on ECO at Visit 3". Date of D/C should be 23-MAY-2011 (Visit 3 Date).		11-22-2011	ajungstreisand	Ashley Jung-Streisand
			99	RESOLVED		Updated Source and CRF	2011-12-02 16:21:22.0	lmarks	Larry Marks
			99	APPROVED		thanks	2012-02-28 15:36:03.0	ajungstreisand	Ashley Jung-Streisand
Vital Signs	Pulse Rate	VS.VSHR		RESOLVED	The value for Pulse Rate is outside of the acceptable range. Please correct or provide clinical significance in query response.		12-01-2011	SYSTEM	
			8	RESOLVED		page entered in error	2011-12-01 15:47:47.0	SYSTEM	
Study Conclusion	Date of Completion	DS.DSETSCDT	5-23-2011	APPROVED	EDC says 22-JUN-2011 and SW says 23-MAY-2011. Please update eCRF or upload a new SW into IVault. eCRF and SW should mirror one another.		12-26-2011	mhunt	Michelle Hunt
				RESOLVED		Entry error, updated CRF	2011-12-27 08:25:54.0	croush	Conni Roush
			5-23-2011	APPROVED		Data now matches. Thank you.	2012-09-11 13:47:53.0	kcorey	Kris Corey
Test Product Allot	Number of Units Dispensed	PU.PUDIS2	13	APPROVED	It seems the containers/boxes are being recorded and not the units. Please confirm or correct value		5-24-2012	gpreciado34	Gina Preciado
				RESOLVED		the subject had SNUS which was calculated by the tins not the packets	2012-05-29 07:44:11.0	croush	Conni Roush
			13	APPROVED		Confirmed Data, no action	2012-06-21 17:25:40.0	gpreciado34	Gina Preciado
Oral Assessment	Specify Any Abnormal Finding	PE.PEORALSP		RESOLVED	Per source, V4 data lined through. Procedure conducted in error as subject was deemed Tx Failure at V3. Please remove data, complete Protocol Deviation form and upload.		7-29-2012	mcaballero	Maria Isabel Caballero V-aliente
				RESOLVED		Updated Source and CRF	2012-07-31 14:40:04.0	croush	Conni Roush
				APPROVED		To requery.	2012-08-05 15:10:13.0	mcaballero	Maria Isabel Caballero V-aliente
Oral Assessment	FORM LEVEL	-form--form-		RESOLVED	Please remove "Not Done" check. Please submit/promote ILB form. All data must be removed due to procedures conducted in error (PD 6/22/2011).		8-5-2012	mcaballero	Maria Isabel Caballero V-aliente
				RESOLVED		it won't let me remove it	2012-08-14 13:34:58.0	lmarks	Larry Marks
Labs	Urine Date Obtained	LB.LBURDT		RESOLVED	Data is missing. Please provide.		08-14-2012	SYSTEM	
				RESOLVED		Entry error, updated CRF	2012-08-14 13:36:45.0	lmarks	Larry Marks
Labs	Urine Time Obtained	LB.LBURTM		RESOLVED	Data is missing. Please provide.		08-14-2012	SYSTEM	
				RESOLVED		Updated CRF, no source change	2012-08-14 13:36:56.0	lmarks	Larry Marks
Prtcl Deviations	Date of Deviation	PV.PVDT	4-15-2011	APPROVED	Visit 2 conducted on "15" April 2011. Please verify "Date of Deviation" in both the source and the CRF. Please update source and CRF as appropriate.		8-25-2012	mcaballero	Maria Isabel Caballero V-aliente
				RESOLVED		Updated Source and CRF	2012-08-27 10:38:28.0	croush	Conni Roush
			4-15-2011	APPROVED		Updated Source and CRF	2012-08-27 14:47:09.0	mcaballero	Maria Isabel Caballero V-aliente