

Subject : 5018

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

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Demographics
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

DEMOGRAPHICS

Informed Consent Date:

02-MAR-2011

DD-MMM-YYYY

Informed Consent Time:

Date of Birth:

(b) (6)

DD-MMM-YYYY

Age

Gender:

Male

Female

Ethnicity:

Hispanic or Latino

Not Hispanic or Latino

Race (please check all that apply):

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific Islander

White

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Demographics
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

What was the last grade of school you completed?

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

What is approximate yearly household income group?

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

Reason for Screen Failure:

Study Name : RJRT CSD1010

Site Name : 005 - MetaClin Research, Inc.

Casebook Name : 5018

Casebook Status : Casebook Frozen And Locked

Casebook Signature : dpampe

Course Name : Screening

Event Name : Screening

Event Date : 02-MAR-2011

Form Name : Brief Med. History (1)

Form Status : DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery

Year

Status

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Brief Med. History (2)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery	Year	Status
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Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Brief Med. History (3)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery	Year	Status
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Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Brief Med. History (4)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery	Year	Status
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Study Name : RJRT CSD1010

Site Name : 005 - MetaClin Research, Inc.

Casebook Name : 5018

Casebook Status : Casebook Frozen And Locked

Casebook Signature : dpampe

Course Name : Screening

Event Name : Screening

Event Date : 02-MAR-2011

Form Name : Brief Med. History (5)

Form Status : DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery

Year

Status



Study Name : RJRT CSD1010

Site Name : 005 - MetaClin Research, Inc.

Casebook Name : 5018

Casebook Status : Casebook Frozen And Locked

Casebook Signature : dpampe

Course Name : Screening

Event Name : Screening

Event Date : 02-MAR-2011

Form Name : Brief Med. History (6)

Form Status : DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery

Year

Status

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Brief Med. History (7)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

BRIEF MEDICAL HISTORY

Diagnosis / Surgery	Year	Status
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<input type="text"/>	<input type="text"/>	
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Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Comprehensive PE
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

COMPREHENSIVE PHYSICAL EXAM

Date Physical Exam Completed: 

02-MAR-2011

 DD-MMM-YYYY

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

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Comprehensive PE
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

Extremities

Skin

Other

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

VITAL SIGNS

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

Height  (cm)

Weight  (kg)

Calculated BMI  (kg/m2)

Systolic/Diastolic Blood Pressure

/  (mmHg)

Pulse Rate

(bpm)

Respiration Rate

(brpm)

Temperature

(°C)

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: ECG
Casebook Signature	: dpampe	Form Status	: DM Reviewed

ECG

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

Overall Assessment:      Normal                      Abnormal NCS                      Abnormal CS

Specify Findings:

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: dpampe	Form Status	: DM Reviewed

SCREENING LABS

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

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

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

Results:

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

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

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

Results:

ECO  (ppm)



Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: UB Descriptors
Casebook Signature	: dpampe	Form Status	: DM Reviewed

UB DESCRIPTORS AND SELF-REPORTED CPD

Date completed: 

02-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	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: UB Descriptors
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Packaging:

Soft-pack box

Hard-pack box

Menthol/non-menthol:

Menthol

Non-menthol

Filter type:

Filter

Non-filter

Charcoal

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Inc/Exc
Casebook Signature	: dpampe	Form Status	: DM Reviewed

INCLUSION/EXCLUSION CRITERIA

Did the subject meet all eligibility criteria for enrollment

Yes

No

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

Inclusion:

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

Exclusion:

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

Study Name	: RJRT CSD1010	Course Name	: Screening
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Screening
Casebook Name	: 5018	Event Date	: 02-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Test Product Allot
Casebook Signature	: dpampe	Form Status	: DM Reviewed

TEST PRODUCT ALLOTMENT

Preferred Flavor of SNUS:

Frost  
Mellow

Preferred Flavor of Lozenge:

Original  
Mint

Study Name	: RJRT CSD1010	Course Name	: Visit 1
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 1
Casebook Name	: 5018	Event Date	: 10-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

VITAL SIGNS

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

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

Study Name	: RJRT CSD1010	Course Name	: Visit 1
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 1
Casebook Name	: 5018	Event Date	: 10-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Visit 1 Labs

Urine Sample Date/Time Obtained: 

10-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	: 005 - MetaClin Research, Inc.	Event Name	: Visit 1
Casebook Name	: 5018	Event Date	: 10-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Exhaled CO
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

EXPIRED CARBON MONOXIDE

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

Results:

ECO  (ppm)

Study Name : RJRT CSD1010

Site Name : 005 - MetaClin Research, Inc.

Casebook Name : 5018

Casebook Status : Casebook Frozen And Locked

Casebook Signature : dpampe

Course Name : Visit 1

Event Name : Visit 1

Event Date : 10-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	: 005 - MetaClin Research, Inc.	Event Name	: Visit 2
Casebook Name	: 5018	Event Date	: 25-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Vital Signs
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

VITAL SIGNS

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

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

Study Name	: RJRT CSD1010	Course Name	: Visit 2
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Visit 2
Casebook Name	: 5018	Event Date	: 25-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Labs
Casebook Signature	: dpampe	Form Status	: DM Reviewed

Visit 1 Labs

Urine Sample Date/Time Obtained: 

25-MAR-2011

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

Results:

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

Study Name : RJRT CSD1010

Site Name : 005 - MetaClin Research, Inc.

Casebook Name : 5018

Casebook Status : Casebook Frozen And Locked

Casebook Signature : dpampe

Course Name : Visit 2

Event Name : Visit 2

Event Date : 25-MAR-2011

Form Name : Exhaled CO

Form Status : DM Reviewed Signed

EXPIRED CARBON MONOXIDE

Was ECO Test Performed?

Yes

N/A

Date/Time Obtained:

DD-MMM-YYYY

(24:00 hr clock)

Results:

ECO

(ppm)

Study Name : RJRT CSD1010

Site Name : 005 - MetaClin Research, Inc.

Casebook Name : 5018

Casebook Status : Casebook Frozen And Locked

Casebook Signature : dpampe

Course Name : Visit 2

Event Name : Visit 2

Event Date : 25-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	: Adverse Events
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: new onset ulcer, peptic N.O.S
Casebook Name	: 5018	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Adverse Events
Casebook Signature	: dpampe	Form Status	: DM Reviewed

ADVERSE EVENTS

AE Term:

Start Date/Time:

DD-MMM-YYYY

(24:00 hr clock)

Stop Date/Time:

DD-MMM-YYYY

(24:00 hr clock)

Outcome:

Severity:

Action Taken toward product:

Concomitant Therapy for AE:                      Yes                      No

Relationship:

SAE:    Yes                      No

SAE, Criteria:

Study Name	: RJRT CSD1010	Course Name	: Adverse Events
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: new onset ulcer, peptic N.O.S
Casebook Name	: 5018	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: AE Code
Casebook Signature	: dpampe	Form Status	: Data Entry In Progress

ADVERSE EVENT MedDRA CODING

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

Original AE Description:

Code Term Search:

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

Not on list

Coding Completed?

\*1) Acute peptic ulcer of unspecified site with haemorrhage and perforation | Peptic ulcer perforation | 10034354 | Peptic ulcers and perforation | Gastrointestinal ulceration and perforation | Gastrointestinal disorders | 13.1

Study Name	: RJRT CSD1010	Course Name	: Con Meds
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Con Meds
Casebook Name	: 5018	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds (1)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

CONCOMITANT MEDICATIONS

Medication	<input type="text"/>		
Dose	<input type="text"/>		
Units			
Route			
Start Date/Time	<input type="text" value="24-FEB-2011"/> DD-MMM-YYYY	<input type="text"/> (24:00 hr clock)	
Stop Date/Time	<input type="text"/> DD-MMM-YYYY	<input type="text"/> (24:00 hr clock)	Ongoing
Indication	<input type="text"/>		

CONCOMITANT MEDICATION WHO Drug CODING

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

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



Study Name	: RJRT CSD1010	Course Name	: Con Meds
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Con Meds
Casebook Name	: 5018	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds (1)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

1

2

3

4

Not on list

Coding Completed?

Study Name	: RJRT CSD1010	Course Name	: Con Meds
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Con Meds
Casebook Name	: 5018	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds (2)
Casebook Signature	: dpampe	Form Status	: Blank DM Reviewed

CONCOMITANT MEDICATIONS

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

CONCOMITANT MEDICATION WHO Drug CODING

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

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

Study Name	: RJRT CSD1010	Course Name	: Con Meds
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Con Meds
Casebook Name	: 5018	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds (2)
Casebook Signature	: dpampe	Form Status	: Blank DM Reviewed

1

2

3

4

Not on list

Coding Completed?

Study Name	: RJRT CSD1010	Course Name	: Con Meds
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Con Meds
Casebook Name	: 5018	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds (3)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

CONCOMITANT MEDICATIONS

Medication	<input type="text"/>			
Dose	<input type="text"/>			
Units				
Route				
Start Date/Time	<input type="text" value="24-MAR-2011"/>	DD-MMM-YYYY	<input type="text"/>	(24:00 hr clock)
Stop Date/Time	<input type="text"/>	DD-MMM-YYYY	<input type="text"/>	(24:00 hr clock)
	Ongoing			
Indication	<input type="text"/>			

CONCOMITANT MEDICATION WHO Drug CODING

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

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

Study Name	: RJRT CSD1010	Course Name	: Con Meds
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Con Meds
Casebook Name	: 5018	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds (3)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

1

2

3

4

Not on list

Coding Completed?

Study Name	: RJRT CSD1010	Course Name	: Con Meds
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Con Meds
Casebook Name	: 5018	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds (4)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

CONCOMITANT MEDICATIONS

Medication	<input type="text"/>			
Dose	<input type="text"/>			
Units				
Route				
Start Date/Time	<input type="text" value="21-APR-2011"/>	DD-MMM-YYYY	<input type="text"/>	(24:00 hr clock)
Stop Date/Time	<input type="text"/>	DD-MMM-YYYY	<input type="text"/>	(24:00 hr clock)
	Ongoing			
Indication	<input type="text"/>			

CONCOMITANT MEDICATION WHO Drug CODING

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

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

Study Name	: RJRT CSD1010	Course Name	: Con Meds
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Con Meds
Casebook Name	: 5018	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Con Meds (4)
Casebook Signature	: dpampe	Form Status	: DM Reviewed

1

2

3

4

Not on list

Coding Completed?

Study Name	: RJRT CSD1010	Course Name	: Prtcl Deviations
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Prtcl Deviations
Casebook Name	: 5018	Event Date	:
Casebook Status	: Casebook Frozen And Locked	Form Name	: Prtcl Deviations
Casebook Signature	: dpampe	Form Status	: DM Reviewed

DEVIATIONS

Date of Deviation

Deviation Category

Deviation Description

28-APR-2011

DD-MMM-YYYY



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

Study Name	: RJRT CSD1010	Course Name	: Randomization
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Randomization
Casebook Name	: 5018	Event Date	: 10-MAR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Randomization
Casebook Signature	: dpampe	Form Status	: DM Reviewed Signed

RANDOMIZATION

Randomization Number:

Please select Cohort:

Study Name	: RJRT CSD1010	Course Name	: Study Conc.
Site Name	: 005 - MetaClin Research, Inc.	Event Name	: Study Conclusion
Casebook Name	: 5018	Event Date	: 28-APR-2011
Casebook Status	: Casebook Frozen And Locked	Form Name	: Study Conclusion
Casebook Signature	: dpampe	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:

28-APR-2011

DD-MMM-YYYY

Reason for Early Withdrawal

Specify:

# AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
7448	3/2/2011 1-5:33:33	3-2-2011 1-4:30:22:828	461	swampler	Sarah Wampler	TD_CASE-BOOK	443	0:0					Casebook Created
7454	3/2/2011 1-5:34:2	3-2-2011 1-4:30:51:640	461	swampler	Sarah Wampler	TD_CASE-BOOK	443	0:0				b0d3402f3d2875f0e6aac5fd852f0044	LUID Created
7455	3/2/2011 1-5:34:27	3-2-2011 1-4:31:17:546	461	swampler	Sarah Wampler	TD_EVENT	1615	0:0				3-2-2011	Event Created
8297	3/2/2011 1-7:52:25	3-2-2011 1-6:49:12:437	4909	rcajigas	Rafael Cajigas	TD_FORM	4623	4623:0	Demographics		0	1	Form Status set to 1
8298	3/2/2011 1-7:52:25	3-2-2011 1-6:49:12:437	4909	rcajigas	Rafael Cajigas	TD_DATA	6680	4623:132861	Demographics	DM.DMICDT		3-2-2011	Data Added
8299	3/2/2011 1-7:52:25	3-2-2011 1-6:49:12:437	4909	rcajigas	Rafael Cajigas	TD_DATA	6681	4623:132863	Demographics	DM.DMICTM		14:25	Data Added
8300	3/2/2011 1-7:52:25	3-2-2011 1-6:49:12:437	4909	rcajigas	Rafael Cajigas	TD_DATA	6682	4623:132865	Demographics	DM.DMDOBDT		(b) (6)	Data Added
8301	3/2/2011 1-7:52:25	3-2-2011 1-6:49:12:437	4909	rcajigas	Rafael Cajigas	TD_DATA	6683	4623:132869	Demographics	DM.DMSEX		Female	Data Added
8302	3/2/2011 1-7:52:25	3-2-2011 1-6:49:12:437	4909	rcajigas	Rafael Cajigas	TD_DATA	6684	4623:132871	Demographics	DM.DMETH		Hispanic or Latino	Data Added
8303	3/2/2011 1-7:52:25	3-2-2011 1-6:49:12:437	4909	rcajigas	Rafael Cajigas	TD_DATA	6685	4623:132877	Demographics	DM.DMRACE5		true	Data Added
8304	3/2/2011 1-7:52:25	3-2-2011 1-6:49:12:437	4909	rcajigas	Rafael Cajigas	TD_DATA	6686	4623:132879	Demographics	DM.DMGRADE		College graduate	Data Added
8305	3/2/2011 1-7:52:25		4909	rcajigas	Rafael Cajigas	TD_DATA	6687	4623:132867	Demographics	DM.DMAGE		30	computed value
17986	3/14/2011 8:34:39	3-14-2011 7:32:12:78	4909	rcajigas	Rafael Cajigas	TD_FORM	4623	4623:0	Demographics		1	2	Form Status set to 2
17987	3/14/2011 8:35:32	3-14-2011 7:33:06:125	4909	rcajigas	Rafael Cajigas	TD_FORM	4624	4624:0	Brief Med. History		0	1	Form Status set to 1
17988	3/14/2011 8:35:32	3-14-2011 7:33:06:125	4909	rcajigas	Rafael Cajigas	TD_DATA	14144	4624:132889	Brief Med. History	MH.MHCOND		Broken foot / foot surgery	Data Added
17989	3/14/2011 8:35:32	3-14-2011 7:33:06:125	4909	rcajigas	Rafael Cajigas	TD_DATA	14145	4624:132890	Brief Med. History	MH.MHSTYYYY		2011	Data Added
17990	3/14/2011 8:35:32	3-14-2011 7:33:06:125	4909	rcajigas	Rafael Cajigas	TD_DATA	14146	4624:132891	Brief Med. History	MH.MHENRF		Prior	Data Added
17991	3/14/2011 8:35:33	3-14-2011 7:33:06:687	4909	rcajigas	Rafael Cajigas	TD_FORM	11162	11162:0	Brief Med. History				Repeating Form Created
17992	3/14/2011 8:36:0	3-14-2011 7:33:33:656	4909	rcajigas	Rafael Cajigas	TD_FORM	11162	11162:0	Brief Med. History		0	1	Form Status set to 1
17993	3/14/2011 8:36:0	3-14-2011 7:33:33:656	4909	rcajigas	Rafael Cajigas	TD_DATA	14147	11162:325552	Brief Med. History	MH.MHCOND		Bilateral tubal ligation	Data Added
17994	3/14/2011 8:36:0	3-14-2011 7:33:33:656	4909	rcajigas	Rafael Cajigas	TD_DATA	14148	11162:325553	Brief Med. History	MH.MHSTYYYY		2003	Data Added
17995	3/14/2011 8:36:0	3-14-2011 7:33:33:656	4909	rcajigas	Rafael Cajigas	TD_DATA	14149	11162:325554	Brief Med. History	MH.MHENRF		Prior	Data Added
17996	3/14/2011 8:36:0	3-14-2011 7:33:34:218	4909	rcajigas	Rafael Cajigas	TD_FORM	11163	11163:0	Brief Med. History				Repeating Form Created
17997	3/14/2011 8:36:30	3-14-2011 7:34:03:390	4909	rcajigas	Rafael Cajigas	TD_FORM	11163	11163:0	Brief Med. History		0	1	Form Status set to 1
17998	3/14/2011 8:36:30	3-14-2011 7:34:03:390	4909	rcajigas	Rafael Cajigas	TD_DATA	14150	11163:325559	Brief Med. History	MH.MHCOND		Allergic to Steroid ear drops	Data Added
17999	3/14/2011 8:36:30	3-14-2011 7:34:03:390	4909	rcajigas	Rafael Cajigas	TD_DATA	14151	11163:325560	Brief Med. History	MH.MHSTYYYY		1985	Data Added
18000	3/14/2011 8:36:30	3-14-2011 7:34:03:390	4909	rcajigas	Rafael Cajigas	TD_DATA	14152	11163:325561	Brief Med. History	MH.MHENRF		Ongoing	Data Added
18001	3/14/2011 8:36:36	3-14-2011 7:34:09:859	4909	rcajigas	Rafael Cajigas	TD_FORM	11163	11163:0	Brief Med. History		1	2	Form Status set to 2
18002	3/14/2011 8:36:39	3-14-2011 7:34:12:671	4909	rcajigas	Rafael Cajigas	TD_FORM	11162	11162:0	Brief Med. History		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
18003	3/14/2011 8:36:41	3-14-2011 7:34:14:812	4909	rcajigas	Rafael Cajigas	TD_FORM	4624	4624:0	Brief Med. History		1	2	Form Status set to 2
18007	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_FORM	4625	4625:0	Comprehensive PE		0	1	Form Status set to 1
18008	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14155	4625:132894	Comprehensive PE	PE.PEDT		3-2-2011	Data Added
18009	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14156	4625:132899	Comprehensive PE	PE.PEGNAP		Normal	Data Added
18010	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14157	4625:132902	Comprehensive PE	PE.PEHEAD		Normal	Data Added
18011	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14158	4625:132905	Comprehensive PE	PE.PEORAL		Normal	Data Added
18012	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14159	4625:132908	Comprehensive PE	PE.PEEN		Abnormal	Data Added
18013	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14160	4625:132909	Comprehensive PE	PE.PEENSP		Tonsillar hyperplasia / Left tympanic membrane obscured	Data Added
18014	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14161	4625:132911	Comprehensive PE	PE.PECHST		Normal	Data Added
18015	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14162	4625:132914	Comprehensive PE	PE.PEHRT		Normal	Data Added
18016	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14163	4625:132917	Comprehensive PE	PE.PEAB		Normal	Data Added
18017	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14164	4625:132920	Comprehensive PE	PE.PEBACK		Normal	Data Added
18018	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14165	4625:132923	Comprehensive PE	PE.PELYP		Normal	Data Added
18019	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14166	4625:132926	Comprehensive PE	PE.PENEUR		Normal	Data Added
18020	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14167	4625:132929	Comprehensive PE	PE.PEMUSC		Normal	Data Added
18021	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14168	4625:132932	Comprehensive PE	PE.PEEXT		Normal	Data Added
18022	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14169	4625:132935	Comprehensive PE	PE.PESKIN		Normal	Data Added
18023	3/14/2011 8:39:22	3-14-2011 7:36:55:609	4909	rcajigas	Rafael Cajigas	TD_DATA	14170	4625:132938	Comprehensive PE	PE.PEOTH		Not Done	Data Added
18024	3/14/2011 8:39:25	3-14-2011 7:36:59:281	4909	rcajigas	Rafael Cajigas	TD_FORM	4625	4625:0	Comprehensive PE		1	2	Form Status set to 2
18037	3/14/2011 8:40:12	3-14-2011 7:37:45:703	4909	rcajigas	Rafael Cajigas	TD_FORM	4626	4626:0	Vital Signs		0	1	Form Status set to 1
18038	3/14/2011 8:40:12	3-14-2011 7:37:45:703	4909	rcajigas	Rafael Cajigas	TD_DATA	14181	4626:132943	Vital Signs	VS.VSDT		3-2-2011	Data Added
18039	3/14/2011 8:40:12	3-14-2011 7:37:45:703	4909	rcajigas	Rafael Cajigas	TD_DATA	14182	4626:132944	Vital Signs	VS.VSTM		14:31	Data Added
18040	3/14/2011 8:40:12	3-14-2011 7:37:45:703	4909	rcajigas	Rafael Cajigas	TD_DATA	14183	4626:132948	Vital Signs	VS.VSHT		153	Data Added
18041	3/14/2011 8:40:12	3-14-2011 7:37:45:703	4909	rcajigas	Rafael Cajigas	TD_DATA	14184	4626:132951	Vital Signs	VS.VSWT		85.1	Data Added
18042	3/14/2011 8:40:12	3-14-2011 7:37:45:703	4909	rcajigas	Rafael Cajigas	TD_DATA	14185	4626:132960	Vital Signs	VS.VSSYS		118	Data Added
18043	3/14/2011 8:40:12	3-14-2011 7:37:45:703	4909	rcajigas	Rafael Cajigas	TD_DATA	14186	4626:132962	Vital Signs	VS.VSDIA		72	Data Added
18044	3/14/2011 8:40:12	3-14-2011 7:37:45:703	4909	rcajigas	Rafael Cajigas	TD_DATA	14187	4626:132964	Vital Signs	VS.VSHR		80	Data Added
18045	3/14/2011 8:40:12	3-14-2011 7:37:45:703	4909	rcajigas	Rafael Cajigas	TD_DATA	14188	4626:132966	Vital Signs	VS.VSRR		16	Data Added
18046	3/14/2011 8:40:12	3-14-2011 7:37:45:703	4909	rcajigas	Rafael Cajigas	TD_DATA	14189	4626:132968	Vital Signs	VS.VSTEMP		37.3	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
18047	3/14/2011 8:40:12		4909	rcajigas	Rafael Cajigas	TD_DATA	14190	4656:133796	Vital Signs	VS.VSHT		153	computed value
18048	3/14/2011 8:40:12		4909	rcajigas	Rafael Cajigas	TD_DATA	14191	4646:133337	Vital Signs	VS.VSHT		153	computed value
18049	3/14/2011 8:40:12		4909	rcajigas	Rafael Cajigas	TD_DATA	14192	4626:132954	Vital Signs	VS.VSBMI		36.4	computed value
18050	3/14/2011 8:40:14	3-14-2011 7:37:48:78	4909	rcajigas	Rafael Cajigas	TD_FORM	4626	4626:0	Vital Signs		1	2	Form Status set to 2
18051	3/14/2011 8:40:32	3-14-2011 7:38:06:296	4909	rcajigas	Rafael Cajigas	TD_FORM	4627	4627:0	ECG		0	1	Form Status set to 1
18052	3/14/2011 8:40:32	3-14-2011 7:38:06:296	4909	rcajigas	Rafael Cajigas	TD_DATA	14193	4627:132971	ECG	EG.EGDT		3-2-2011	Data Added
18053	3/14/2011 8:40:32	3-14-2011 7:38:06:296	4909	rcajigas	Rafael Cajigas	TD_DATA	14194	4627:132972	ECG	EG.EGTM		14:39	Data Added
18054	3/14/2011 8:40:32	3-14-2011 7:38:06:296	4909	rcajigas	Rafael Cajigas	TD_DATA	14195	4627:132975	ECG	EG.EGASMT		Normal	Data Added
18055	3/14/2011 8:40:34	3-14-2011 7:38:08:46	4909	rcajigas	Rafael Cajigas	TD_FORM	4627	4627:0	ECG		1	2	Form Status set to 2
18056	3/14/2011 8:41:21	3-14-2011 7:38:55:187	4909	rcajigas	Rafael Cajigas	TD_FORM	4628	4628:0	Labs		0	1	Form Status set to 1
18057	3/14/2011 8:41:21	3-14-2011 7:38:55:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14196	4628:132980	Labs	LB.LBBLDT		3-2-2011	Data Added
18058	3/14/2011 8:41:21	3-14-2011 7:38:55:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14197	4628:132981	Labs	LB.LBBLTM		15:16	Data Added
18059	3/14/2011 8:41:21	3-14-2011 7:38:55:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14198	4628:132984	Labs	LB.LBURDT		3-2-2011	Data Added
18060	3/14/2011 8:41:21	3-14-2011 7:38:55:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14199	4628:132985	Labs	LB.LBURTM		15:21	Data Added
18061	3/14/2011 8:41:21	3-14-2011 7:38:55:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14200	4628:132988	Labs	LB.LBBRDT		3-2-2011	Data Added
18062	3/14/2011 8:41:21	3-14-2011 7:38:55:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14201	4628:132989	Labs	LB.LBBRTM		15:30	Data Added
18063	3/14/2011 8:41:21	3-14-2011 7:38:55:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14202	4628:132993	Labs	LB.LBUDS		Positive	Data Added
18064	3/14/2011 8:41:21	3-14-2011 7:38:55:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14203	4628:132995	Labs	LB.LBUCS		Negative	Data Added
18065	3/14/2011 8:41:21	3-14-2011 7:38:55:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14204	4628:132997	Labs	LB.LBABS		Negative	Data Added
18066	3/14/2011 8:41:25	3-14-2011 7:38:59:93	4909	rcajigas	Rafael Cajigas	TD_FORM	4628	4628:0	Labs		1	2	Form Status set to 2
18067	3/14/2011 8:41:47	3-14-2011 7:39:21:156	4909	rcajigas	Rafael Cajigas	TD_FORM	4629	4629:0	Exhaled CO		0	1	Form Status set to 1
18068	3/14/2011 8:41:47	3-14-2011 7:39:21:156	4909	rcajigas	Rafael Cajigas	TD_DATA	14205	4629:133000	Exhaled CO	EC.ECDT		3-2-2011	Data Added
18069	3/14/2011 8:41:47	3-14-2011 7:39:21:156	4909	rcajigas	Rafael Cajigas	TD_DATA	14206	4629:133001	Exhaled CO	EC.ECTM		15:30	Data Added
18070	3/14/2011 8:41:47	3-14-2011 7:39:21:156	4909	rcajigas	Rafael Cajigas	TD_DATA	14207	4629:133005	Exhaled CO	EC.ECRES1		08	Data Added
18071	3/14/2011 8:41:49	3-14-2011 7:39:23:390	4909	rcajigas	Rafael Cajigas	TD_FORM	4629	4629:0	Exhaled CO		1	2	Form Status set to 2
18072	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_FORM	4630	4630:0	UB Descriptors		0	1	Form Status set to 1
18073	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_DATA	14208	4630:133009	UB Descriptors	UB.UBDT		3-2-2011	Data Added
18074	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_DATA	14209	4630:133011	UB Descriptors	UB.UBCPD		19	Data Added
18075	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_DATA	14210	4630:133013	UB Descriptors	UB.UBYEAR		18	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
18076	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_DATA	14211	4630:133015	UB Descriptors	UB.UBSMKLS		No	Data Added
18077	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_DATA	14212	4630:133017	UB Descriptors	UB.UBQUIT		Yes	Data Added
18078	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_DATA	14213	4630:133019	UB Descriptors	UB.UBBRND		Camel	Data Added
18079	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_DATA	14214	4630:133021	UB Descriptors	UB.UBSBRND		99's	Data Added
18080	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_DATA	14215	4630:133023	UB Descriptors	UB.UBLTH		100 mm	Data Added
18081	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_DATA	14216	4630:133026	UB Descriptors	UB.UBPACK		Hard-pack box	Data Added
18082	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_DATA	14217	4630:133028	UB Descriptors	UB.UBMENTH		Non-menthol	Data Added
18083	3/14/2011 8:43:57	3-14-2011 7:41:30:640	4909	rcajigas	Rafael Cajigas	TD_DATA	14218	4630:133030	UB Descriptors	UB.UBFILT		Filter	Data Added
18084	3/14/2011 8:43:59	3-14-2011 7:41:33:109	4909	rcajigas	Rafael Cajigas	TD_FORM	4630	4630:0	UB Descriptors		1	2	Form Status set to 2
18085	3/14/2011 8:44:6	3-14-2011 7:41:40:578	4909	rcajigas	Rafael Cajigas	TD_FORM	4631	4631:0	Inc/Exc		0	1	Form Status set to 1
18086	3/14/2011 8:44:6	3-14-2011 7:41:40:578	4909	rcajigas	Rafael Cajigas	TD_DATA	14219	4631:133034	Inc/Exc	IE.IECRITYN		Yes	Data Added
18087	3/14/2011 8:44:9	3-14-2011 7:41:43:46	4909	rcajigas	Rafael Cajigas	TD_FORM	4631	4631:0	Inc/Exc		1	2	Form Status set to 2
18088	3/14/2011 8:45:36	3-14-2011 7:43:09:750	4909	rcajigas	Rafael Cajigas	TD_FORM	4632	4632:0	Test Product Allot		0	1	Form Status set to 1
18089	3/14/2011 8:45:36	3-14-2011 7:43:09:750	4909	rcajigas	Rafael Cajigas	TD_DATA	14220	4632:133069	Test Product Allot	PU.PUSNUS1		Mellow	Data Added
18090	3/14/2011 8:45:36	3-14-2011 7:43:09:750	4909	rcajigas	Rafael Cajigas	TD_DATA	14221	4632:133071	Test Product Allot	PU.PULOZG1		Original	Data Added
18091	3/14/2011 8:45:37	3-14-2011 7:43:10:875	4909	rcajigas	Rafael Cajigas	TD_FORM	4632	4632:0	Test Product Allot		1	2	Form Status set to 2
18092	3/14/2011 8:46:14	3-14-2011 7:43:48:0	4909	rcajigas	Rafael Cajigas	TD_EVENT	1616	0:0				3-10-2011	Event Created
18093	3/14/2011 8:46:56	3-14-2011 7:44:30:187	4909	rcajigas	Rafael Cajigas	TD_FORM	4633	4633:0	Vital Signs		0	1	Form Status set to 1
18094	3/14/2011 8:46:56	3-14-2011 7:44:30:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14222	4633:133073	Vital Signs	VS.VSDT		3-10-2011	Data Added
18095	3/14/2011 8:46:56	3-14-2011 7:44:30:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14223	4633:133074	Vital Signs	VS.VSTM		14:11	Data Added
18096	3/14/2011 8:46:56	3-14-2011 7:44:30:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14224	4633:133081	Vital Signs	VS.VSSYS		118	Data Added
18097	3/14/2011 8:46:56	3-14-2011 7:44:30:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14225	4633:133083	Vital Signs	VS.VSDIA		79	Data Added
18098	3/14/2011 8:46:56	3-14-2011 7:44:30:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14226	4633:133085	Vital Signs	VS.VSHR		91	Data Added
18099	3/14/2011 8:46:56	3-14-2011 7:44:30:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14227	4633:133087	Vital Signs	VS.VSRR		20	Data Added
18100	3/14/2011 8:46:56	3-14-2011 7:44:30:187	4909	rcajigas	Rafael Cajigas	TD_DATA	14228	4633:133089	Vital Signs	VS.VSTEMP		36.8	Data Added
18101	3/14/2011 8:46:58	3-14-2011 7:44:32:15	4909	rcajigas	Rafael Cajigas	TD_FORM	4633	4633:0	Vital Signs		1	2	Form Status set to 2
18102	3/14/2011 8:47:19	3-14-2011 7:44:53:93	4909	rcajigas	Rafael Cajigas	TD_FORM	4634	4634:0	Labs		0	1	Form Status set to 1
18103	3/14/2011 8:47:19	3-14-2011 7:44:53:93	4909	rcajigas	Rafael Cajigas	TD_DATA	14229	4634:133093	Labs	LB.LBURDT		3-10-2011	Data Added
18104	3/14/2011 8:47:19	3-14-2011 7:44:53:93	4909	rcajigas	Rafael Cajigas	TD_DATA	14230	4634:133094	Labs	LB.LBURTM		14:03	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
18105	3/14/2011 8:47:19	3-14-2011 7:44:53:93	4909	rcajigas	Rafael Cajigas	TD_DATA	14231	4634:133098	Labs	LB.LBUCS		Negative	Data Added
18106	3/14/2011 8:47:21	3-14-2011 7:44:54:843	4909	rcajigas	Rafael Cajigas	TD_FORM	4634	4634:0	Labs		1	2	Form Status set to 2
18107	3/14/2011 8:47:35	3-14-2011 7:45:09:31	4909	rcajigas	Rafael Cajigas	TD_FORM	4635	4635:0	Exhaled CO		0	1	Form Status set to 1
18108	3/14/2011 8:47:35	3-14-2011 7:45:09:31	4909	rcajigas	Rafael Cajigas	TD_DATA	14232	4635:133101	Exhaled CO	EC.ECDT		3-10-2011	Data Added
18109	3/14/2011 8:47:35	3-14-2011 7:45:09:31	4909	rcajigas	Rafael Cajigas	TD_DATA	14233	4635:133102	Exhaled CO	EC.ECTM		14:08	Data Added
18110	3/14/2011 8:47:35	3-14-2011 7:45:09:31	4909	rcajigas	Rafael Cajigas	TD_DATA	14234	4635:133106	Exhaled CO	EC.ECRES1		17	Data Added
18111	3/14/2011 8:47:36	3-14-2011 7:45:10:125	4909	rcajigas	Rafael Cajigas	TD_FORM	4635	4635:0	Exhaled CO		1	2	Form Status set to 2
18112	3/14/2011 8:47:55	3-14-2011 7:45:29:31	4909	rcajigas	Rafael Cajigas	TD_FORM	4636	4636:0	Test Product Allot		0	1	Form Status set to 1
18113	3/14/2011 8:47:55	3-14-2011 7:45:29:31	4909	rcajigas	Rafael Cajigas	TD_DATA	14235	4636:133110	Test Product Allot	PU.PUSNUS2		Mellow	Data Added
18114	3/14/2011 8:47:55	3-14-2011 7:45:29:31	4909	rcajigas	Rafael Cajigas	TD_DATA	14236	4636:133112	Test Product Allot	PU.PULOZG2		N/A	Data Added
18115	3/14/2011 8:47:55	3-14-2011 7:45:29:31	4909	rcajigas	Rafael Cajigas	TD_DATA	14237	4636:133116	Test Product Allot	PU.PUDIS2		20	Data Added
18116	3/14/2011 8:47:56	3-14-2011 7:45:30:609	4909	rcajigas	Rafael Cajigas	TD_FORM	4636	4636:0	Test Product Allot		1	2	Form Status set to 2
21447	3/15/2011 23:21:31	3-15-2011 22:16:27:775	4909	rcajigas	Rafael Cajigas	TD_FORM	4623	4623:0	Demographics		2	1	Form Status demoted to 1
21448	3/15/2011 23:21:35	3-15-2011 22:16:30:995	4909	rcajigas	Rafael Cajigas	TD_FORM	11163	11163:0	Brief Med. History		2	1	Form Status demoted to 1
21449	3/15/2011 23:21:37	3-15-2011 22:16:33:225	4909	rcajigas	Rafael Cajigas	TD_FORM	11162	11162:0	Brief Med. History		2	1	Form Status demoted to 1
21450	3/15/2011 23:21:39	3-15-2011 22:16:35:295	4909	rcajigas	Rafael Cajigas	TD_FORM	4624	4624:0	Brief Med. History		2	1	Form Status demoted to 1
21451	3/15/2011 23:21:42	3-15-2011 22:16:38:565	4909	rcajigas	Rafael Cajigas	TD_FORM	4625	4625:0	Comprehensive PE		2	1	Form Status demoted to 1
21452	3/15/2011 23:21:47	3-15-2011 22:16:43:555	4909	rcajigas	Rafael Cajigas	TD_FORM	4626	4626:0	Vital Signs		2	1	Form Status demoted to 1
21453	3/15/2011 23:21:50	3-15-2011 22:16:46:295	4909	rcajigas	Rafael Cajigas	TD_FORM	4627	4627:0	ECG		2	1	Form Status demoted to 1
21454	3/15/2011 23:21:52	3-15-2011 22:16:48:725	4909	rcajigas	Rafael Cajigas	TD_FORM	4628	4628:0	Labs		2	1	Form Status demoted to 1
21455	3/15/2011 23:21:55	3-15-2011 22:16:51:105	4909	rcajigas	Rafael Cajigas	TD_FORM	4629	4629:0	Exhaled CO		2	1	Form Status demoted to 1
21456	3/15/2011 23:21:57	3-15-2011 22:16:53:845	4909	rcajigas	Rafael Cajigas	TD_FORM	4630	4630:0	UB Descriptors		2	1	Form Status demoted to 1
21457	3/15/2011 23:22:2	3-15-2011 22:16:58:405	4909	rcajigas	Rafael Cajigas	TD_FORM	4631	4631:0	Inc/Exc		2	1	Form Status demoted to 1
21458	3/15/2011 23:22:6	3-15-2011 22:17:02:75	4909	rcajigas	Rafael Cajigas	TD_FORM	4632	4632:0	Test Product Allot		2	1	Form Status demoted to 1
21459	3/15/2011 23:22:11	3-15-2011 22:17:06:965	4909	rcajigas	Rafael Cajigas	TD_FORM	4633	4633:0	Vital Signs		2	1	Form Status demoted to 1
21460	3/15/2011 23:22:13	3-15-2011 22:17:09:635	4909	rcajigas	Rafael Cajigas	TD_FORM	4634	4634:0	Labs		2	1	Form Status demoted to 1
21461	3/15/2011 23:22:15	3-15-2011 22:17:11:805	4909	rcajigas	Rafael Cajigas	TD_FORM	4635	4635:0	Exhaled CO		2	1	Form Status demoted to 1
21462	3/15/2011 23:22:18	3-15-2011 22:17:14:355	4909	rcajigas	Rafael Cajigas	TD_FORM	4636	4636:0	Test Product Allot		2	1	Form Status demoted to 1
26152	3/18/2011 14:17:24	3-18-2011 13:15:14:718	461	swampler	Sarah Wampler	TD_FORM	4623	4623:0	Demographics		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
26153	3/18/2011 14:17:29	3-18-2011 13:15:20:31	461	swampler	Sarah Wampler	TD_FORM	11163	11163:0	Brief Med. History		1	2	Form Status set to 2
26154	3/18/2011 14:17:32	3-18-2011 13:15:22:812	461	swampler	Sarah Wampler	TD_FORM	11162	11162:0	Brief Med. History		1	2	Form Status set to 2
26155	3/18/2011 14:17:34	3-18-2011 13:15:24:968	461	swampler	Sarah Wampler	TD_FORM	4624	4624:0	Brief Med. History		1	2	Form Status set to 2
26156	3/18/2011 14:17:38	3-18-2011 13:15:28:562	461	swampler	Sarah Wampler	TD_FORM	4625	4625:0	Comprehensive PE		1	2	Form Status set to 2
26157	3/18/2011 14:17:42	3-18-2011 13:15:33:31	461	swampler	Sarah Wampler	TD_FORM	4626	4626:0	Vital Signs		1	2	Form Status set to 2
26158	3/18/2011 14:17:46	3-18-2011 13:15:36:609	461	swampler	Sarah Wampler	TD_FORM	4627	4627:0	ECG		1	2	Form Status set to 2
26159	3/18/2011 14:17:48	3-18-2011 13:15:39:156	461	swampler	Sarah Wampler	TD_FORM	4628	4628:0	Labs		1	2	Form Status set to 2
26160	3/18/2011 14:17:51	3-18-2011 13:15:41:968	461	swampler	Sarah Wampler	TD_FORM	4629	4629:0	Exhaled CO		1	2	Form Status set to 2
26161	3/18/2011 14:17:54	3-18-2011 13:15:45:15	461	swampler	Sarah Wampler	TD_FORM	4630	4630:0	UB Descriptors		1	2	Form Status set to 2
26162	3/18/2011 14:18:1	3-18-2011 13:15:52:312	461	swampler	Sarah Wampler	TD_FORM	4632	4632:0	Test Product Allot		1	2	Form Status set to 2
26165	3/18/2011 14:18:8	3-18-2011 13:15:58:921	461	swampler	Sarah Wampler	TD_FORM	4631	4631:0	Inc/Exc		1	2	Form Status set to 2
26166	3/18/2011 14:18:13	3-18-2011 13:16:03:875	461	swampler	Sarah Wampler	TD_FORM	4633	4633:0	Vital Signs		1	2	Form Status set to 2
26167	3/18/2011 14:18:16	3-18-2011 13:16:06:578	461	swampler	Sarah Wampler	TD_FORM	4634	4634:0	Labs		1	2	Form Status set to 2
26169	3/18/2011 14:18:18	3-18-2011 13:16:08:828	461	swampler	Sarah Wampler	TD_FORM	4635	4635:0	Exhaled CO		1	2	Form Status set to 2
26170	3/18/2011 14:18:20	3-18-2011 13:16:11:281	461	swampler	Sarah Wampler	TD_FORM	4636	4636:0	Test Product Allot		1	2	Form Status set to 2
32740	3/23/2011 8:12:10	3-23-2011 8:10:21:8	624	jbaskowski	Janet Baskowski	TD_FORM	4623	4623:0	Demographics		2	3	Form Status set to 3
32741	3/23/2011 8:13:45	3-23-2011 8:11:55:778	624	jbaskowski	Janet Baskowski	TD_FORM	4626	4626:0	Vital Signs		2	3	Form Status set to 3
32742	3/23/2011 8:14:14	3-23-2011 8:12:24:716	624	jbaskowski	Janet Baskowski	TD_FORM	4629	4629:0	Exhaled CO		2	3	Form Status set to 3
32743	3/23/2011 8:15:1	3-23-2011 8:13:11:854	624	jbaskowski	Janet Baskowski	TD_FORM	4628	4628:0	Labs		2	3	Form Status set to 3
32744	3/23/2011 8:15:55	3-23-2011 8:14:05:540	624	jbaskowski	Janet Baskowski	TD_FORM	4625	4625:0	Comprehensive PE		2	3	Form Status set to 3
32745	3/23/2011 8:16:33	3-23-2011 8:14:43:807	624	jbaskowski	Janet Baskowski	TD_FORM	4630	4630:0	UB Descriptors		2	3	Form Status set to 3
32746	3/23/2011 8:16:55	3-23-2011 8:15:05:997	624	jbaskowski	Janet Baskowski	TD_FORM	4632	4632:0	Test Product Allot		2	3	Form Status set to 3
32747	3/23/2011 8:17:24	3-23-2011 8:15:34:653	624	jbaskowski	Janet Baskowski	TD_FORM	4631	4631:0	Inc/Exc		2	3	Form Status set to 3
32748	3/23/2011 8:18:56	3-23-2011 8:17:06:835	624	jbaskowski	Janet Baskowski	TD_FORM	4633	4633:0	Vital Signs		2	3	Form Status set to 3
32749	3/23/2011 8:19:33	3-23-2011 8:17:43:747	624	jbaskowski	Janet Baskowski	TD_FORM	4635	4635:0	Exhaled CO		2	3	Form Status set to 3
32750	3/23/2011 8:19:55	3-23-2011 8:18:05:851	624	jbaskowski	Janet Baskowski	TD_FORM	4634	4634:0	Labs		2	3	Form Status set to 3
32751	3/23/2011 8:20:26	3-23-2011 8:18:37:343	624	jbaskowski	Janet Baskowski	TD_FORM	4636	4636:0	Test Product Allot		2	3	Form Status set to 3
38431	3/24/2011 15:50:13	3-24-2011 15:48:16:890	551	yovalle	Yulina Ovalle	TD_FORM	4623	4623:0	Demographics		3	4	Form Status set to 4
38432	3/24/2011 15:50:59	3-24-2011 15:49:02:624	551	yovalle	Yulina Ovalle	TD_FORM	4629	4629:0	Exhaled CO		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
38433	3/24/2011 15:51:6	3-24-2011 15:49:09:468	551	yovalle	Yulina Ovalle	TD_FORM	4630	4630:0	UB Descriptors		3	4	Form Status set to 4
38434	3/24/2011 15:51:12	3-24-2011 15:49:15:265	551	yovalle	Yulina Ovalle	TD_FORM	4631	4631:0	Inc/Exc		3	4	Form Status set to 4
38435	3/24/2011 15:51:16	3-24-2011 15:49:19:922	551	yovalle	Yulina Ovalle	TD_FORM	4631	4631:0	Inc/Exc		4	3	Form Status demoted to 3
38436	3/24/2011 15:51:21	3-24-2011 15:49:24:218	551	yovalle	Yulina Ovalle	TD_FORM	4631	4631:0	Inc/Exc		3	4	Form Status set to 4
38437	3/24/2011 15:51:24	3-24-2011 15:49:27:890	551	yovalle	Yulina Ovalle	TD_FORM	4632	4632:0	Test Product Allot		3	4	Form Status set to 4
38438	3/24/2011 15:52:33	3-24-2011 15:50:36:733	551	yovalle	Yulina Ovalle	TD_FORM	4626	4626:0	Vital Signs		3	4	Form Status set to 4
38439	3/24/2011 15:52:54	3-24-2011 15:50:57:77	551	yovalle	Yulina Ovalle	TD_FORM	4633	4633:0	Vital Signs		3	4	Form Status set to 4
38440	3/24/2011 15:52:59	3-24-2011 15:51:02:592	551	yovalle	Yulina Ovalle	TD_FORM	4634	4634:0	Labs		3	4	Form Status set to 4
38441	3/24/2011 15:53:2	3-24-2011 15:51:05:639	551	yovalle	Yulina Ovalle	TD_FORM	4635	4635:0	Exhaled CO		3	4	Form Status set to 4
38442	3/24/2011 15:53:5	3-24-2011 15:51:08:858	551	yovalle	Yulina Ovalle	TD_FORM	4636	4636:0	Test Product Allot		3	4	Form Status set to 4
40361	3/27/2011 2:35:59	3-27-2011 1:33:30:460	4909	rcajigas	Rafael Cajigas	TD_EVENT	1617	0:0				3-25-2011	Event Created
40362	3/27/2011 2:36:30	3-27-2011 1:34:01:17	4909	rcajigas	Rafael Cajigas	TD_FORM	4637	4637:0	Vital Signs		0	1	Form Status set to 1
40363	3/27/2011 2:36:30	3-27-2011 1:34:01:17	4909	rcajigas	Rafael Cajigas	TD_DATA	30541	4637:133118	Vital Signs	VS.VSDT		3-25-2011	Data Added
40364	3/27/2011 2:36:30	3-27-2011 1:34:01:17	4909	rcajigas	Rafael Cajigas	TD_DATA	30542	4637:133119	Vital Signs	VS.VSTM		14:01	Data Added
40365	3/27/2011 2:36:30	3-27-2011 1:34:01:17	4909	rcajigas	Rafael Cajigas	TD_DATA	30543	4637:133126	Vital Signs	VS.VSSYS		111	Data Added
40366	3/27/2011 2:36:30	3-27-2011 1:34:01:17	4909	rcajigas	Rafael Cajigas	TD_DATA	30544	4637:133128	Vital Signs	VS.VSDIA		67	Data Added
40367	3/27/2011 2:36:30	3-27-2011 1:34:01:17	4909	rcajigas	Rafael Cajigas	TD_DATA	30545	4637:133130	Vital Signs	VS.VSHR		82	Data Added
40368	3/27/2011 2:36:30	3-27-2011 1:34:01:17	4909	rcajigas	Rafael Cajigas	TD_DATA	30546	4637:133132	Vital Signs	VS.VSRR		16	Data Added
40369	3/27/2011 2:36:30	3-27-2011 1:34:01:17	4909	rcajigas	Rafael Cajigas	TD_DATA	30547	4637:133134	Vital Signs	VS.VSTEMP		37.1	Data Added
40370	3/27/2011 2:37:3	3-27-2011 1:34:34:45	4909	rcajigas	Rafael Cajigas	TD_FORM	4638	4638:0	Labs		0	1	Form Status set to 1
40371	3/27/2011 2:37:3	3-27-2011 1:34:34:45	4909	rcajigas	Rafael Cajigas	TD_DATA	30548	4638:133138	Labs	LB.LBURDT		3-25-2011	Data Added
40372	3/27/2011 2:37:3	3-27-2011 1:34:34:45	4909	rcajigas	Rafael Cajigas	TD_DATA	30549	4638:133139	Labs	LB.LBURTM		14:05	Data Added
40373	3/27/2011 2:37:3	3-27-2011 1:34:34:45	4909	rcajigas	Rafael Cajigas	TD_DATA	30550	4638:133143	Labs	LB.LBUCS		Negative	Data Added
40374	3/27/2011 2:37:25	3-27-2011 1:34:56:85	4909	rcajigas	Rafael Cajigas	TD_FORM	4639	4639:0	Exhaled CO		0	1	Form Status set to 1
40375	3/27/2011 2:37:25	3-27-2011 1:34:56:85	4909	rcajigas	Rafael Cajigas	TD_DATA	30551	4639:133146	Exhaled CO	EC.ECYN		Yes	Data Added
40376	3/27/2011 2:37:25	3-27-2011 1:34:56:85	4909	rcajigas	Rafael Cajigas	TD_DATA	30552	4639:133148	Exhaled CO	EC.ECDT		3-25-2011	Data Added
40377	3/27/2011 2:37:25	3-27-2011 1:34:56:85	4909	rcajigas	Rafael Cajigas	TD_DATA	30553	4639:133149	Exhaled CO	EC.ECTM		14:00	Data Added
40378	3/27/2011 2:37:25	3-27-2011 1:34:56:85	4909	rcajigas	Rafael Cajigas	TD_DATA	30554	4639:133153	Exhaled CO	EC.ECRES1		11	Data Added
40379	3/27/2011 2:37:49	3-27-2011 1:35:19:701	4909	rcajigas	Rafael Cajigas	TD_FORM	4640	4640:0	Test Product Allot		0	1	Form Status set to 1

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
40380	3/27/2011 2:37:49	3-27-2011 1:35:19:701	4909	rcajigas	Rafael Cajigas	TD_DATA	30555	4640:133157	Test Product Allot	PU.PUSNUS2		Mellow	Data Added
40381	3/27/2011 2:37:49	3-27-2011 1:35:19:701	4909	rcajigas	Rafael Cajigas	TD_DATA	30556	4640:133159	Test Product Allot	PU.PULOZG2		N/A	Data Added
40382	3/27/2011 2:37:49	3-27-2011 1:35:19:701	4909	rcajigas	Rafael Cajigas	TD_DATA	30557	4640:133161	Test Product Allot	PU.PURET		19	Data Added
40383	3/27/2011 2:37:49	3-27-2011 1:35:19:701	4909	rcajigas	Rafael Cajigas	TD_DATA	30558	4640:133163	Test Product Allot	PU.PUDIS2		50	Data Added
40384	3/27/2011 2:45:48	3-27-2011 1:43:18:514	4909	rcajigas	Rafael Cajigas	TD_EVENT	1627	0:0					Shared Event Added
40385	3/27/2011 2:48:37	3-27-2011 1:46:07:157	4909	rcajigas	Rafael Cajigas	TD_FORM	4661	4661:0	Con Meds		0	1	Form Status set to 1
40386	3/27/2011 2:48:37	3-27-2011 1:46:07:157	4909	rcajigas	Rafael Cajigas	TD_DATA	30561	4661:133885	Con Meds	CM.CMTRT		Hydrocodone	Data Added
40387	3/27/2011 2:48:37	3-27-2011 1:46:07:157	4909	rcajigas	Rafael Cajigas	TD_DATA	30562	4661:133887	Con Meds	CM.CMDOSE		5	Data Added
40388	3/27/2011 2:48:37	3-27-2011 1:46:07:157	4909	rcajigas	Rafael Cajigas	TD_DATA	30563	4661:133889	Con Meds	CM.CMDOSU		Milligram	Data Added
40389	3/27/2011 2:48:37	3-27-2011 1:46:07:157	4909	rcajigas	Rafael Cajigas	TD_DATA	30564	4661:133891	Con Meds	CM.CMROUT		Oral	Data Added
40390	3/27/2011 2:48:37	3-27-2011 1:46:07:157	4909	rcajigas	Rafael Cajigas	TD_DATA	30565	4661:133893	Con Meds	CM.CMSTDT		2-24-2011	Data Added
40391	3/27/2011 2:48:37	3-27-2011 1:46:07:157	4909	rcajigas	Rafael Cajigas	TD_DATA	30566	4661:133900	Con Meds	CM.CMONGO		true	Data Added
40392	3/27/2011 2:48:37	3-27-2011 1:46:07:157	4909	rcajigas	Rafael Cajigas	TD_DATA	30567	4661:133902	Con Meds	CM.CMINDC		Pain Management - post foot surgery	Data Added
40393	3/27/2011 2:48:42		4909	rcajigas	Rafael Cajigas	TD_DATA	30568	4661:133919	Con Meds	CM.CODECPLT			computed value
40394	3/27/2011 2:48:42		4909	rcajigas	Rafael Cajigas	TD_DATA	30569	4661:133908	Con Meds	CM.TERM		Hydrocodone	computed value
40395	3/27/2011 2:48:42		4909	rcajigas	Rafael Cajigas	TD_DATA	30570	4661:133906	Con Meds	CM.ORIGNAME		Hydrocodone	computed value
40396	3/27/2011 2:48:44		4909	rcajigas	Rafael Cajigas	TD_DATA	30571	4661:133910	Con Meds	CM.RSLT1		Hydrocortisone   Blood cortisol   10005455   Adrenal cortex tests   Endocrine investigations (incl sex hormones)   Investigations   13.1	computed value
40397	3/27/2011 2:48:44		4909	rcajigas	Rafael Cajigas	TD_DATA	30572	4661:133912	Con Meds	CM.RSLT2		Hydrocortisone abnormal   Blood cortisol abnormal   10005456   Adrenal cortex tests   Endocrine investigations (incl sex hormones)   Investigations   13.1	computed value
40398	3/27/2011 2:48:44		4909	rcajigas	Rafael Cajigas	TD_DATA	30573	4661:133914	Con Meds	CM.RSLT3		Hydrocortisone decreased   Blood cortisol decreased   10005457   Adrenal cortex tests   Endocrine investigations (incl sex hormones)   Investigations   13.1	computed value
40399	3/27/2011 2:48:44		4909	rcajigas	Rafael Cajigas	TD_DATA	30574	4661:133916	Con Meds	CM.RSLT4		Hydrocortisone increased   Blood cortisol increased   10005458   Adrenal cortex tests   Endocrine investigations (incl sex hormones)   Investigations   13.1	computed value
40400	3/27/2011 2:48:45		4909	rcajigas	Rafael Cajigas	TD_DATA	30575	4661:133911	Con Meds	CM.CODE1		10020518	computed value
40401	3/27/2011 2:48:45		4909	rcajigas	Rafael Cajigas	TD_DATA	30576	4661:133913	Con Meds	CM.CODE2		10020519	computed value
40402	3/27/2011 2:48:45		4909	rcajigas	Rafael Cajigas	TD_DATA	30577	4661:133915	Con Meds	CM.CODE3		10020520	computed value
40403	3/27/2011 2:48:45		4909	rcajigas	Rafael Cajigas	TD_DATA	30578	4661:133917	Con Meds	CM.CODE4		10020521	computed value
40404	3/27/2011 2:50:6	3-27-2011 1:47:35:912	4909	rcajigas	Rafael Cajigas	TD_FORM	19341	19341:0	Con Meds				Repeating Form Created
40405	3/27/2011 2:50:54	3-27-2011 1:48:24:456	4909	rcajigas	Rafael Cajigas	TD_FORM	19341	19341:0	Con Meds		0	1	Form Status set to 1
40406	3/27/2011 2:50:54	3-27-2011 1:48:24:456	4909	rcajigas	Rafael Cajigas	TD_DATA	30579	19341:566023	Con Meds	CM.CMTRT		Acetominophen	Data Added
40407	3/27/2011 2:50:54	3-27-2011 1:48:24:456	4909	rcajigas	Rafael Cajigas	TD_DATA	30580	19341:566025	Con Meds	CM.CMDOSE		325	Data Added
40408	3/27/2011 2:50:54	3-27-2011 1:48:24:456	4909	rcajigas	Rafael Cajigas	TD_DATA	30581	19341:566027	Con Meds	CM.CMDOSU		Milligram	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
40409	3/27/2011 2:50:54	3-27-2011 1:48:24:456	4909	rcajigas	Rafael Cajigas	TD_DATA	30582	19341:566029	Con Meds	CM.CMROUT		Oral	Data Added
40410	3/27/2011 2:50:54	3-27-2011 1:48:24:456	4909	rcajigas	Rafael Cajigas	TD_DATA	30583	19341:566031	Con Meds	CM.CMSTDT		3-24-2011	Data Added
40411	3/27/2011 2:50:54	3-27-2011 1:48:24:456	4909	rcajigas	Rafael Cajigas	TD_DATA	30584	19341:566038	Con Meds	CM.CMONGO		true	Data Added
40412	3/27/2011 2:50:54	3-27-2011 1:48:24:456	4909	rcajigas	Rafael Cajigas	TD_DATA	30585	19341:566040	Con Meds	CM.CMINDC		Pain management - post foot surgery	Data Added
40413	3/27/2011 2:50:54		4909	rcajigas	Rafael Cajigas	TD_DATA	30586	19341:566057	Con Meds	CM.CODECPLT			computed value
40414	3/27/2011 2:50:54		4909	rcajigas	Rafael Cajigas	TD_DATA	30587	19341:566046	Con Meds	CM.TERM		Acetaminophen	computed value
40415	3/27/2011 2:50:54		4909	rcajigas	Rafael Cajigas	TD_DATA	30588	19341:566044	Con Meds	CM.ORIGNAME		Acetaminophen	computed value
40416	3/27/2011 2:50:55		4909	rcajigas	Rafael Cajigas	TD_DATA	30589	19341:566048	Con Meds	CM.RSLT1		Acetaminophen   Analgesic drug level   10060090   Therapeutic drug monitoring analyses   Toxicology and therapeutic drug monitoring   Investigations   13.1	computed value
40417	3/27/2011 2:50:55		4909	rcajigas	Rafael Cajigas	TD_DATA	30590	19341:566050	Con Meds	CM.RSLT2		Acetaminophen decreased   Analgesic drug level decreased   10060941   Therapeutic drug monitoring analyses   Toxicology and therapeutic drug monitoring   Investigations   13.1	computed value
40418	3/27/2011 2:50:55		4909	rcajigas	Rafael Cajigas	TD_DATA	30591	19341:566052	Con Meds	CM.RSLT3		Acetaminophen high   Analgesic drug level increased   10060942   Therapeutic drug monitoring analyses   Toxicology and therapeutic drug monitoring   Investigations   13.1	computed value
40419	3/27/2011 2:50:55		4909	rcajigas	Rafael Cajigas	TD_DATA	30592	19341:566054	Con Meds	CM.RSLT4		Acetaminophen increased   Analgesic drug level increased   10060942   Therapeutic drug monitoring analyses   Toxicology and therapeutic drug monitoring   Investigations   13.1	computed value
40420	3/27/2011 2:50:55		4909	rcajigas	Rafael Cajigas	TD_DATA	30593	19341:566049	Con Meds	CM.CODE1		10000398	computed value
40421	3/27/2011 2:50:55		4909	rcajigas	Rafael Cajigas	TD_DATA	30594	19341:566051	Con Meds	CM.CODE2		10000399	computed value
40422	3/27/2011 2:50:55		4909	rcajigas	Rafael Cajigas	TD_DATA	30595	19341:566053	Con Meds	CM.CODE3		10000400	computed value
40423	3/27/2011 2:50:55		4909	rcajigas	Rafael Cajigas	TD_DATA	30596	19341:566055	Con Meds	CM.CODE4		10000401	computed value
40424	3/27/2011 2:51:7	3-27-2011 1:48:37:986	4909	rcajigas	Rafael Cajigas	TD_FORM	19342	19342:0	Con Meds				Repeating Form Created
40425	3/27/2011 2:52:13	3-27-2011 1:49:42:861	4909	rcajigas	Rafael Cajigas	TD_FORM	19342	19342:0	Con Meds		0	1	Form Status set to 1
40426	3/27/2011 2:52:13	3-27-2011 1:49:42:861	4909	rcajigas	Rafael Cajigas	TD_DATA	30597	19342:566061	Con Meds	CM.CMTRT		Cyclobenzaprine	Data Added
40427	3/27/2011 2:52:13	3-27-2011 1:49:42:861	4909	rcajigas	Rafael Cajigas	TD_DATA	30598	19342:566063	Con Meds	CM.CMDOSE		10	Data Added
40428	3/27/2011 2:52:13	3-27-2011 1:49:42:861	4909	rcajigas	Rafael Cajigas	TD_DATA	30599	19342:566065	Con Meds	CM.CMDOSU		Milligram	Data Added
40429	3/27/2011 2:52:13	3-27-2011 1:49:42:861	4909	rcajigas	Rafael Cajigas	TD_DATA	30600	19342:566067	Con Meds	CM.CMROUT		Oral	Data Added
40430	3/27/2011 2:52:13	3-27-2011 1:49:42:861	4909	rcajigas	Rafael Cajigas	TD_DATA	30601	19342:566069	Con Meds	CM.CMSTDT		3-24-2011	Data Added
40431	3/27/2011 2:52:13	3-27-2011 1:49:42:861	4909	rcajigas	Rafael Cajigas	TD_DATA	30602	19342:566076	Con Meds	CM.CMONGO		true	Data Added
40432	3/27/2011 2:52:13	3-27-2011 1:49:42:861	4909	rcajigas	Rafael Cajigas	TD_DATA	30603	19342:566078	Con Meds	CM.CMINDC		L3 back pain management	Data Added
40433	3/27/2011 2:52:13		4909	rcajigas	Rafael Cajigas	TD_DATA	30604	19342:566095	Con Meds	CM.CODECPLT			computed value
40434	3/27/2011 2:52:13		4909	rcajigas	Rafael Cajigas	TD_DATA	30605	19342:566084	Con Meds	CM.TERM		Cyclobenzaprine	computed value
40435	3/27/2011 2:52:13		4909	rcajigas	Rafael Cajigas	TD_DATA	30606	19342:566082	Con Meds	CM.ORIGNAME		Cyclobenzaprine	computed value
40436	3/27/2011 2:52:14		4909	rcajigas	Rafael Cajigas	TD_DATA	30607	19342:566086	Con Meds	CM.RSLT1		Sorry, no results were found.	computed value
40437	3/27/2011 2:52:14		4909	rcajigas	Rafael Cajigas	TD_DATA	30608	19342:566088	Con Meds	CM.RSLT2			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
40438	3/27/2011 2:52:14		4909	rcajigas	Rafael Cajigas	TD_DATA	30609	19342:566090	Con Meds	CM.RSLT3			computed value
40439	3/27/2011 2:52:14		4909	rcajigas	Rafael Cajigas	TD_DATA	30610	19342:566092	Con Meds	CM.RSLT4			computed value
40440	3/27/2011 2:52:14		4909	rcajigas	Rafael Cajigas	TD_DATA	30611	19342:566087	Con Meds	CM.CODE1			computed value
40441	3/27/2011 2:52:14		4909	rcajigas	Rafael Cajigas	TD_DATA	30612	19342:566089	Con Meds	CM.CODE2			computed value
40442	3/27/2011 2:52:14		4909	rcajigas	Rafael Cajigas	TD_DATA	30613	19342:566091	Con Meds	CM.CODE3			computed value
40443	3/27/2011 2:52:14		4909	rcajigas	Rafael Cajigas	TD_DATA	30614	19342:566093	Con Meds	CM.CODE4			computed value
52078	4/1/2011 8:47:3	4-1-2011 7:44:37:515	4909	rcajigas	Rafael Cajigas	TD_EVENT	1630	0:0				3-10-2011	Event Created
52079	4/1/2011 8:47:15	4-1-2011 7:44:49:453	4909	rcajigas	Rafael Cajigas	TD_FORM	4664	4664:0	Randomization		0	1	Form Status set to 1
52080	4/1/2011 8:47:15	4-1-2011 7:44:49:453	4909	rcajigas	Rafael Cajigas	TD_DATA	39761	4664:133990	Randomization	RAND.RAND		520002	Data Added
52081	4/1/2011 8:47:15	4-1-2011 7:44:49:453	4909	rcajigas	Rafael Cajigas	TD_DATA	39762	4664:133992	Randomization	RAND.COHORT		Cohort 1	Data Added
54616	4/3/2011 1-8:6:36	4-3-2011 1-7:04:20:609	461	swampler	Sarah Wampler	TD_FORM	4637	4637:0	Vital Signs		1	2	Form Status set to 2
54617	4/3/2011 1-8:6:38	4-3-2011 1-7:04:23:250	461	swampler	Sarah Wampler	TD_FORM	4638	4638:0	Labs		1	2	Form Status set to 2
54618	4/3/2011 1-8:6:41	4-3-2011 1-7:04:25:484	461	swampler	Sarah Wampler	TD_FORM	4639	4639:0	Exhaled CO		1	2	Form Status set to 2
54619	4/3/2011 1-8:6:43	4-3-2011 1-7:04:27:906	461	swampler	Sarah Wampler	TD_FORM	4640	4640:0	Test Product Allot		1	2	Form Status set to 2
67370	4/8/2011 1-0:41:40	4-8-2011 1-0:39:52:126	624	jbaskowski	Janet Baskowski	TD_FORM	4637	4637:0	Vital Signs		2	3	Form Status set to 3
67371	4/8/2011 1-0:41:59	4-8-2011 1-0:40:11:516	624	jbaskowski	Janet Baskowski	TD_FORM	4638	4638:0	Labs		2	3	Form Status set to 3
68838	4/11/2011 13:46:22	4-11-2011 13:43:30:877	551	yovalle	Yulina Ovalle	TD_FORM	4637	4637:0	Vital Signs		3	4	Form Status set to 4
68839	4/11/2011 13:46:25	4-11-2011 13:43:33:221	551	yovalle	Yulina Ovalle	TD_FORM	4638	4638:0	Labs		3	4	Form Status set to 4
68857	4/11/2011 13:51:57	4-11-2011 13:49:05:109	551	yovalle	Yulina Ovalle	TD_FORM	4625	4625:0	Comprehensive PE		3	4	Form Status set to 4
68858	4/11/2011 13:55:4	4-11-2011 13:52:12:296	551	yovalle	Yulina Ovalle	TD_FORM	4628	4628:0	Labs		3	4	Form Status set to 4
70978	4/12/2011 15:20:21	4-12-2011 14:17:37:875	461	swampler	Sarah Wampler	TD_FORM	28196	28196:0	Brief Med. History				Repeating Form Created
70979	4/12/2011 15:20:33	4-12-2011 14:17:49:265	461	swampler	Sarah Wampler	TD_FORM	28196	28196:0	Brief Med. History		0	2	Form Status set to 2
70980	4/12/2011 15:20:33	4-12-2011 14:17:49:265	461	swampler	Sarah Wampler	TD_DATA	53108	28196:818636	Brief Med. History	MH.MHCOND		low back pain	Data Added
70981	4/12/2011 15:20:33	4-12-2011 14:17:49:265	461	swampler	Sarah Wampler	TD_DATA	53109	28196:818637	Brief Med. History	MH.MHSTYYYY		2011	Data Added
70982	4/12/2011 15:20:33	4-12-2011 14:17:49:265	461	swampler	Sarah Wampler	TD_DATA	53110	28196:818638	Brief Med. History	MH.MHENRF		Ongoing	Data Added
70988	4/12/2011 15:21:10	4-12-2011 14:18:26:687	461	swampler	Sarah Wampler	TD_FORM	4639	4639:0	Exhaled CO		2	1	Form Status demoted to 1
70989	4/12/2011 15:21:10	4-12-2011 14:18:26:687	461	swampler	Sarah Wampler	TD_DATA	30551	4639:133146	Exhaled CO	EC.ECYN	Yes	N/A	data entry error
70990	4/12/2011 15:21:10	4-12-2011 14:18:26:687	461	swampler	Sarah Wampler	TD_DATA	30552	4639:133148	Exhaled CO	EC.ECDT	3-25-2011	--	data entry error
70991	4/12/2011 15:21:10	4-12-2011 14:18:26:687	461	swampler	Sarah Wampler	TD_DATA	30553	4639:133149	Exhaled CO	EC.ECTM	14:00		data entry error

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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
70992	4/12/2011 15:21:10	4-12-2011 14:18:26:687	461	swampler	Sarah Wampler	TD_DATA	30554	4639:133153	Exhaled CO	EC.ECRES1	11		data entry error
71001	4/12/2011 15:21:49	4-12-2011 14:19:05:671	461	swampler	Sarah Wampler	TD_FORM	4639	4639:0	Exhaled CO		1	2	Form Status set to 2
71016	4/12/2011 15:22:46	4-12-2011 14:20:03:31	461	swampler	Sarah Wampler	TD_FORM	4664	4664:0	Randomization		1	2	Form Status set to 2
93511	4/25/2011 9:33:39	4-25-2011 9:30:52:135	624	jbaskowski	Janet Baskowski	TD_FORM	4639	4639:0	Exhaled CO		2	3	Form Status set to 3
93512	4/25/2011 9:34:51	4-25-2011 9:32:03:819	624	jbaskowski	Janet Baskowski	TD_FORM	4664	4664:0	Randomization		2	3	Form Status set to 3
94137	4/25/2011 12:36:51	4-25-2011 12:33:54:595	3262	avillalbadm	Artemisa Villalba	TD_FORM	4630	4630:0	UB Descriptors		4	3	Form Status demoted to 3
94635	4/25/2011 15:19:30	4-25-2011 15:16:34:594	3262	avillalbadm	Artemisa Villalba	TD_FORM	4631	4631:0	Inc/Exc		4	3	Form Status demoted to 3
96119	4/26/2011 10:54:1	4-26-2011 10:51:12:231	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4623	4623:0	Demographics		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
96120	4/26/2011 10:55:0	4-26-2011 10:52:10:851	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	11163	11163:0	Brief Med. History		2	3	Form Status set to 3
96121	4/26/2011 10:55:8	4-26-2011 10:52:18:911	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	11162	11162:0	Brief Med. History		2	3	Form Status set to 3
96129	4/26/2011 11:2:42	4-26-2011 10:59:53:42	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4626	4626:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
96130	4/26/2011 11:2:48	4-26-2011 10:59:58:912	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4627	4627:0	ECG		2	3	Form Status set to 3
96132	4/26/2011 11:4:31	4-26-2011 11:01:42:232	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4633	4633:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
96193	4/26/2011 11:22:49	4-26-2011 11:20:00:44	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4637	4637:0	Vital Signs		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
96194	4/26/2011 11:23:8	4-26-2011 11:20:19:134	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4640	4640:0	Test Product Allot		2	3	Form Status set to 3
96224	4/26/2011 11:34:54	4-26-2011 11:32:05:165	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4664	4664:0	Randomization		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
97590	4/26/2011 13:34:28	4-26-2011 13:31:35:135	551	yovalle	Yulina Ovalle	TD_FORM	11163	11163:0	Brief Med. History		3	4	Form Status set to 4
97591	4/26/2011 13:34:37	4-26-2011 13:31:44:542	551	yovalle	Yulina Ovalle	TD_FORM	11162	11162:0	Brief Med. History		3	4	Form Status set to 4
97593	4/26/2011 13:34:40	4-26-2011 13:31:47:604	551	yovalle	Yulina Ovalle	TD_FORM	4627	4627:0	ECG		3	4	Form Status set to 4
97597	4/26/2011 13:34:50	4-26-2011 13:31:57:542	551	yovalle	Yulina Ovalle	TD_FORM	4631	4631:0	Inc/Exc		3	4	Form Status set to 4
97645	4/26/2011 13:37:44	4-26-2011 13:35:01:396	624	jbaskowski	Janet Baskowski	TD_FORM	4630	4630:0	UB Descriptors		3	2	Form Status demoted to 2
97690	4/26/2011 13:39:26	4-26-2011 13:36:43:636	624	jbaskowski	Janet Baskowski	TD_FORM	4640	4640:0	Test Product Allot		3	2	Form Status demoted to 2
97712	4/26/2011 13:41:10	4-26-2011 13:38:17:917	551	yovalle	Yulina Ovalle	TD_FORM	4639	4639:0	Exhaled CO		3	4	Form Status set to 4
97750	4/26/2011 13:43:50	4-26-2011 13:40:57:979	551	yovalle	Yulina Ovalle	TD_FORM	4664	4664:0	Randomization		3	4	Form Status set to 4
110815	5/2/2011 1-3:14:55	5-2-2011 1-2:12:25:796	461	swampler	Sarah Wampler	TD_EVENT	1618	0:0			0	1	No Event Flag set to 1
110816	5/2/2011 1-3:14:59	5-2-2011 1-2:12:29:968	461	swampler	Sarah Wampler	TD_EVENT	1619	0:0			0	1	No Event Flag set to 1
110817	5/2/2011 1-3:15:2	5-2-2011 1-2:12:32:718	461	swampler	Sarah Wampler	TD_EVENT	1620	0:0			0	1	No Event Flag set to 1
110818	5/2/2011 1-3:15:4	5-2-2011 1-2:12:35:203	461	swampler	Sarah Wampler	TD_EVENT	1621	0:0			0	1	No Event Flag set to 1
110819	5/2/2011 1-3:15:8	5-2-2011 1-2:12:38:328	461	swampler	Sarah Wampler	TD_EVENT	1622	0:0			0	1	No Event Flag set to 1

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ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
110820	5/2/2011 1-3:15:10	5-2-2011 1-2:12:40:875	461	swampler	Sarah Wampler	TD_EVENT	1623	0:0			0	1	No Event Flag set to 1
110821	5/2/2011 1-3:15:13	5-2-2011 1-2:12:43:515	461	swampler	Sarah Wampler	TD_EVENT	1624	0:0			0	1	No Event Flag set to 1
110822	5/2/2011 1-3:15:16	5-2-2011 1-2:12:46:390	461	swampler	Sarah Wampler	TD_EVENT	1625	0:0			0	1	No Event Flag set to 1
110824	5/2/2011 1-3:15:20	5-2-2011 1-2:12:50:359	461	swampler	Sarah Wampler	TD_EVENT	1626	0:0					Shared Event Added
110827	5/2/2011 1-3:16:29	5-2-2011 1-2:13:59:906	461	swampler	Sarah Wampler	TD_FORM	4659	4659:0	Adverse Events		0	1	Form Status set to 1
110828	5/2/2011 1-3:16:29	5-2-2011 1-2:13:59:906	461	swampler	Sarah Wampler	TD_DATA	80113	4659:133843	Adverse Events	AE.AETERM		new onset ulcer, peptic N.O.S	Data Added
110829	5/2/2011 1-3:16:29	5-2-2011 1-2:13:59:906	461	swampler	Sarah Wampler	TD_DATA	80114	4659:133847	Adverse Events	AE.AESTDT		4-21-2011	Data Added
110830	5/2/2011 1-3:16:29	5-2-2011 1-2:13:59:906	461	swampler	Sarah Wampler	TD_DATA	80115	4659:133849	Adverse Events	AE.AEOUT		Ongoing	Data Added
110831	5/2/2011 1-3:16:29	5-2-2011 1-2:13:59:906	461	swampler	Sarah Wampler	TD_DATA	80116	4659:133850	Adverse Events	AE.AESTTM		14:00	Data Added
110832	5/2/2011 1-3:16:29	5-2-2011 1-2:13:59:906	461	swampler	Sarah Wampler	TD_DATA	80117	4659:133855	Adverse Events	AE.AESEV		Moderate	Data Added
110833	5/2/2011 1-3:16:29	5-2-2011 1-2:13:59:906	461	swampler	Sarah Wampler	TD_DATA	80118	4659:133857	Adverse Events	AE.AEACT		Cessation of usage	Data Added
110834	5/2/2011 1-3:16:29	5-2-2011 1-2:13:59:906	461	swampler	Sarah Wampler	TD_DATA	80119	4659:133859	Adverse Events	AE.AETRT		Yes	Data Added
110835	5/2/2011 1-3:16:29	5-2-2011 1-2:13:59:906	461	swampler	Sarah Wampler	TD_DATA	80120	4659:133861	Adverse Events	AE.AEREL		Possible	Data Added
110836	5/2/2011 1-3:16:29	5-2-2011 1-2:13:59:906	461	swampler	Sarah Wampler	TD_DATA	80121	4659:133863	Adverse Events	AE.AESAE		No	Data Added
110837	5/2/2011 1-3:16:29		461	swampler	Sarah Wampler	TD_DATA	80122	4660:133882	AE Code	AE.CODECPLT			computed value
110838	5/2/2011 1-3:16:29		461	swampler	Sarah Wampler	TD_DATA	80123	4660:133871	AE Code	AE.TERM		new onset ulcer, peptic N.O.S	computed value
110839	5/2/2011 1-3:16:29		461	swampler	Sarah Wampler	TD_DATA	80124	4660:133869	AE Code	AE.AEDESC		new onset ulcer, peptic N.O.S	computed value
110840	5/2/2011 1-3:16:30		461	swampler	Sarah Wampler	TD_DATA	80125	4660:133873	AE Code	AE.RSLT1		Acute peptic ulcer of unspecified site with haemorrhage   Peptic ulcer haemorrhage   10034344   Peptic ulcers and perforation   Gastrointestinal ulceration and perforation   Gastrointestinal disorders   13.1	computed value
110841	5/2/2011 1-3:16:30		461	swampler	Sarah Wampler	TD_DATA	80126	4660:133875	AE Code	AE.RSLT2		Acute peptic ulcer of unspecified site with haemorrhage and perforation   Peptic ulcer perforation   10034354   Peptic ulcers and perforation   Gastrointestinal ulceration and perforation   Gastrointestinal disorders   13.1	computed value
110842	5/2/2011 1-3:16:30		461	swampler	Sarah Wampler	TD_DATA	80127	4660:133877	AE Code	AE.RSLT3		Acute peptic ulcer of unspecified site with hemorrhage   Peptic ulcer haemorrhage   10034344   Peptic ulcers and perforation   Gastrointestinal ulceration and perforation   Gastrointestinal disorders   13.1	computed value
110843	5/2/2011 1-3:16:30		461	swampler	Sarah Wampler	TD_DATA	80128	4660:133879	AE Code	AE.RSLT4		Acute peptic ulcer of unspecified site with hemorrhage and perforation   Peptic ulcer perforation   10034354   Peptic ulcers and perforation   Gastrointestinal ulceration and perforation   Gastrointestinal disorders   13.1	computed value
110844	5/2/2011 1-3:16:30		461	swampler	Sarah Wampler	TD_DATA	80129	4660:133874	AE Code	AE.CODE1		10000981	computed value
110845	5/2/2011 1-3:16:30		461	swampler	Sarah Wampler	TD_DATA	80130	4660:133876	AE Code	AE.CODE2		10000982	computed value
110846	5/2/2011 1-3:16:30		461	swampler	Sarah Wampler	TD_DATA	80131	4660:133878	AE Code	AE.CODE3		10000983	computed value
110847	5/2/2011 1-3:16:30		461	swampler	Sarah Wampler	TD_DATA	80132	4660:133880	AE Code	AE.CODE4		10000984	computed value
110848	5/2/2011 1-3:16:32	5-2-2011 1-2:14:02:937	461	swampler	Sarah Wampler	TD_FORM	4659	4659:0	Adverse Events		1	2	Form Status set to 2

## AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
166141	5/26/2011 13:35:24	5-26-2011 12:32:20:750	4909	rcajigas	Rafael Cajigas	TD_FORM	50795	50795:0	Con Meds		0	1	Form Status set to 1
166142	5/26/2011 13:35:24	5-26-2011 12:32:20:750	4909	rcajigas	Rafael Cajigas	TD_DATA	120537	50795:1458876	Con Meds	CM.CMTRT		Nexium	Data Added
166143	5/26/2011 13:35:24	5-26-2011 12:32:20:750	4909	rcajigas	Rafael Cajigas	TD_DATA	120538	50795:1458878	Con Meds	CM.CMDOSE		20	Data Added
166144	5/26/2011 13:35:24	5-26-2011 12:32:20:750	4909	rcajigas	Rafael Cajigas	TD_DATA	120539	50795:1458880	Con Meds	CM.CMDOSU		Milligram	Data Added
166145	5/26/2011 13:35:24	5-26-2011 12:32:20:750	4909	rcajigas	Rafael Cajigas	TD_DATA	120540	50795:1458882	Con Meds	CM.CMROUT		Oral	Data Added
166146	5/26/2011 13:35:24	5-26-2011 12:32:20:750	4909	rcajigas	Rafael Cajigas	TD_DATA	120541	50795:1458884	Con Meds	CM.CMSTDT		4-21-2011	Data Added
166147	5/26/2011 13:35:24	5-26-2011 12:32:20:750	4909	rcajigas	Rafael Cajigas	TD_DATA	120542	50795:1458891	Con Meds	CM.CMONGO		true	Data Added
166148	5/26/2011 13:35:24	5-26-2011 12:32:20:750	4909	rcajigas	Rafael Cajigas	TD_DATA	120543	50795:1458893	Con Meds	CM.CMINDC		Peptic ulcer - AE	Data Added
166149	5/26/2011 13:35:24		4909	rcajigas	Rafael Cajigas	TD_DATA	120544	50795:1458910	Con Meds	CM.CODECPLT			computed value
166150	5/26/2011 13:35:24		4909	rcajigas	Rafael Cajigas	TD_DATA	120545	50795:1458899	Con Meds	CM.TERM		Nexium	computed value
166151	5/26/2011 13:35:24		4909	rcajigas	Rafael Cajigas	TD_DATA	120546	50795:1458897	Con Meds	CM.ORIGNAME		Nexium	computed value
166152	5/26/2011 13:35:25		4909	rcajigas	Rafael Cajigas	TD_DATA	120547	50795:1458901	Con Meds	CM.RSLT1		Sorry, no results were found.	computed value
166153	5/26/2011 13:35:25		4909	rcajigas	Rafael Cajigas	TD_DATA	120548	50795:1458903	Con Meds	CM.RSLT2			computed value
166154	5/26/2011 13:35:25		4909	rcajigas	Rafael Cajigas	TD_DATA	120549	50795:1458905	Con Meds	CM.RSLT3			computed value
166155	5/26/2011 13:35:25		4909	rcajigas	Rafael Cajigas	TD_DATA	120550	50795:1458907	Con Meds	CM.RSLT4			computed value
166156	5/26/2011 13:35:25		4909	rcajigas	Rafael Cajigas	TD_DATA	120551	50795:1458902	Con Meds	CM.CODE1			computed value
166157	5/26/2011 13:35:25		4909	rcajigas	Rafael Cajigas	TD_DATA	120552	50795:1458904	Con Meds	CM.CODE2			computed value
166158	5/26/2011 13:35:25		4909	rcajigas	Rafael Cajigas	TD_DATA	120553	50795:1458906	Con Meds	CM.CODE3			computed value
166159	5/26/2011 13:35:25		4909	rcajigas	Rafael Cajigas	TD_DATA	120554	50795:1458908	Con Meds	CM.CODE4			computed value
185351	6/6/2011 1-2:13:0	6-6-2011 1-1:09:33:156	461	swampler	Sarah Wampler	TD_FORM	4659	4659:0	Adverse Events		2	1	Form Status demoted to 1
185352	6/6/2011 1-2:14:6	6-6-2011 1-1:10:39:203	461	swampler	Sarah Wampler	TD_EVENT	1631	0:0				4-28-2011	Event Created
185353	6/6/2011 1-2:14:40	6-6-2011 1-1:11:12:140	461	swampler	Sarah Wampler	TD_FORM	4665	4665:0	Study Conclusion		0	2	Form Status set to 2
185354	6/6/2011 1-2:14:40	6-6-2011 1-1:11:12:140	461	swampler	Sarah Wampler	TD_DATA	133770	4665:133995	Study Conclusion	DS.DSETSC		Discontinued prior to completion of the study	Data Added
185355	6/6/2011 1-2:14:40	6-6-2011 1-1:11:12:140	461	swampler	Sarah Wampler	TD_DATA	133771	4665:133997	Study Conclusion	DS.DSETSCDT		4-28-2011	Data Added
185356	6/6/2011 1-2:14:40	6-6-2011 1-1:11:12:140	461	swampler	Sarah Wampler	TD_DATA	133772	4665:133999	Study Conclusion	DS.DSETREAS		Withdraw Consent	Data Added
185357	6/6/2011 1-2:14:40	6-6-2011 1-1:11:12:140	461	swampler	Sarah Wampler	TD_DATA	133773	4665:134001	Study Conclusion	DS.DSETSP		subject did not wish to continue	Data Added
185358	6/6/2011 1-2:14:57	6-6-2011 1-1:11:29:843	461	swampler	Sarah Wampler	TD_EVENT	1628	0:0					Shared Event Added
185359	6/6/2011 1-2:15:3	6-6-2011 1-1:11:36:0	461	swampler	Sarah Wampler	TD_FORM	4662	4662:0	Prtcl Deviations		0	2	Form Status set to 2
185360	6/6/2011 1-2:15:3	6-6-2011 1-1:11:36:0	461	swampler	Sarah Wampler	TD_FORM	4662	4662:0	Prtcl Deviations		0	1	Form Checked Intentionally Left Blank



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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
190862	6/7/2011 1-6:10:3	6-7-2011 1-6:06:34:437	6603	yovalle57	Yuliana Ov-alle	TD_FORM	4630	4630:0	UB Descriptors		3	4	Form Status set to 4
242756	6/28/2011 12:19:58	6-28-2011 11:16:43:156	461	swampler	Sarah Wampler	TD_FORM	4625	4625:0	Comprehensive PE		4	1	Form Status demoted to 1
242757	6/28/2011 12:19:58	6-28-2011 11:16:43:156	461	swampler	Sarah Wampler	TD_DATA	14158	4625:132905	Comprehensive PE	PE.PEORAL	Normal	Abnormal	entered in wrong field
242758	6/28/2011 12:19:58	6-28-2011 11:16:43:156	461	swampler	Sarah Wampler	TD_DATA	175606	4625:132906	Comprehensive PE	PE.PEORALSP		Tonsillar hyperplasia / NCS	Data Added
242759	6/28/2011 12:19:58	6-28-2011 11:16:43:156	461	swampler	Sarah Wampler	TD_DATA	14159	4625:132908	Comprehensive PE	PE.PEEN	Abnormal	Normal	entered in wrong field
242760	6/28/2011 12:19:58	6-28-2011 11:16:43:156	461	swampler	Sarah Wampler	TD_DATA	14160	4625:132909	Comprehensive PE	PE.PEENSP	Tonsillar hyperplasia / Left tympanic membrane obscured		entered in wrong field
242761	6/28/2011 12:20:22	6-28-2011 11:17:08:156	461	swampler	Sarah Wampler	TD_FORM	4625	4625:0	Comprehensive PE		1	2	Form Status set to 2
242770	6/28/2011 12:30:32	6-28-2011 11:27:17:515	461	swampler	Sarah Wampler	TD_FORM	4659	4659:0	Adverse Events		1	2	Form Status set to 2
242811	6/28/2011 12:35:25	6-28-2011 11:32:10:781	461	swampler	Sarah Wampler	TD_FORM	4624	4624:0	Brief Med. History		2	1	Form Status demoted to 1
242812	6/28/2011 12:35:25	6-28-2011 11:32:10:781	461	swampler	Sarah Wampler	TD_DATA	14144	4624:132889	Brief Med. History	MH.MHCOND	Broken foot / foot surgery	Broken left foot	resolve query
242813	6/28/2011 12:35:31	6-28-2011 11:32:16:562	461	swampler	Sarah Wampler	TD_FORM	69938	69938:0	Brief Med. History				Repeating Form Created
242814	6/28/2011 12:35:47	6-28-2011 11:32:33:0	461	swampler	Sarah Wampler	TD_FORM	69938	69938:0	Brief Med. History		0	2	Form Status set to 2
242815	6/28/2011 12:35:47	6-28-2011 11:32:33:0	461	swampler	Sarah Wampler	TD_DATA	175648	69938:2008408	Brief Med. History	MH.MHCOND		Left foot surgery	Data Added
242816	6/28/2011 12:35:47	6-28-2011 11:32:33:0	461	swampler	Sarah Wampler	TD_DATA	175649	69938:2008409	Brief Med. History	MH.MHSTYYYY		2011	Data Added
242817	6/28/2011 12:35:47	6-28-2011 11:32:33:0	461	swampler	Sarah Wampler	TD_DATA	175650	69938:2008410	Brief Med. History	MH.MHENRF		Prior	Data Added
242823	6/28/2011 12:37:28	6-28-2011 11:34:13:734	461	swampler	Sarah Wampler	TD_FORM	69939	69939:0	Brief Med. History				Repeating Form Created
242824	6/28/2011 12:37:46	6-28-2011 11:34:32:0	461	swampler	Sarah Wampler	TD_FORM	69939	69939:0	Brief Med. History		0	1	Form Status set to 1
242825	6/28/2011 12:37:46	6-28-2011 11:34:32:0	461	swampler	Sarah Wampler	TD_DATA	175655	69939:2008415	Brief Med. History	MH.MHCOND		Pain from left foot surgery	Data Added
242826	6/28/2011 12:37:46	6-28-2011 11:34:32:0	461	swampler	Sarah Wampler	TD_DATA	175656	69939:2008416	Brief Med. History	MH.MHSTYYYY		2011	Data Added
242827	6/28/2011 12:37:46	6-28-2011 11:34:32:0	461	swampler	Sarah Wampler	TD_DATA	175657	69939:2008417	Brief Med. History	MH.MHENRF		Ongoing	Data Added
242828	6/28/2011 12:39:47	6-28-2011 11:36:32:312	461	swampler	Sarah Wampler	TD_FORM	69940	69940:0	Brief Med. History				Repeating Form Created
242829	6/28/2011 12:40:3	6-28-2011 11:36:48:375	461	swampler	Sarah Wampler	TD_FORM	69940	69940:0	Brief Med. History		0	1	Form Status set to 1
242830	6/28/2011 12:40:3	6-28-2011 11:36:48:375	461	swampler	Sarah Wampler	TD_DATA	175658	69940:2008422	Brief Med. History	MH.MHCOND		left tympanic membrane obscured	Data Added
242831	6/28/2011 12:40:3	6-28-2011 11:36:48:375	461	swampler	Sarah Wampler	TD_DATA	175659	69940:2008423	Brief Med. History	MH.MHSTYYYY		2011	Data Added
242832	6/28/2011 12:40:3	6-28-2011 11:36:48:375	461	swampler	Sarah Wampler	TD_DATA	175660	69940:2008424	Brief Med. History	MH.MHENRF		Ongoing	Data Added
242833	6/28/2011 12:41:0	6-28-2011 11:37:45:984	461	swampler	Sarah Wampler	TD_FORM	69940	69940:0	Brief Med. History		1	2	Form Status set to 2
242834	6/28/2011 12:41:4	6-28-2011 11:37:49:593	461	swampler	Sarah Wampler	TD_FORM	69939	69939:0	Brief Med. History		1	2	Form Status set to 2
242835	6/28/2011 12:41:45	6-28-2011 11:38:30:640	461	swampler	Sarah Wampler	TD_FORM	4624	4624:0	Brief Med. History		1	2	Form Status set to 2
275000	7/12/2011 14:9:28	7-12-2011 14:06:00:734	6603	yovalle57	Yuliana Ov-alle	TD_FORM	4630	4630:0	UB Descriptors		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
294561	8/1/2011 1-1:13:15	8-1-2011 1-1:08:59:394	624	jbaskowski	Janet Baskowski	TD_FORM	4625	4625:0	Comprehensive PE		2	3	Form Status set to 3
294583	8/1/2011 1-1:18:45	8-1-2011 1-1:14:30:110	624	jbaskowski	Janet Baskowski	TD_FORM	4665	4665:0	Study Conclusion		2	3	Form Status set to 3
307958	8/17/2011 17:53:54	8-17-2011 17:49:25:908	6603	yovalle57	Yuliana Ovalle	TD_FORM	4630	4630:0	UB Descriptors		3	4	Form Status set to 4
307959	8/17/2011 17:53:59	8-17-2011 17:49:31:127	6603	yovalle57	Yuliana Ovalle	TD_FORM	4625	4625:0	Comprehensive PE		3	4	Form Status set to 4
312170	8/24/2011 9:54:40	8-24-2011 9:50:34:746	6603	yovalle57	Yuliana Ovalle	TD_FORM	4665	4665:0	Study Conclusion		3	4	Form Status set to 4
387733	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_FORM	19341	19341:0	Con Meds		1	0	Form Status demoted to 0 Reason : Combo drug thus entered as a single entry
387734	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30579	19341:566023	Con Meds	CM.CMTRT	Acetaminophen		Combo drug thus entered as a single entry
387735	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30580	19341:566025	Con Meds	CM.CMDOSE	325		Combo drug thus entered as a single entry
387736	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30581	19341:566027	Con Meds	CM.CMDOSU	Milligram		Combo drug thus entered as a single entry
387737	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30582	19341:566029	Con Meds	CM.CMROUT	Oral		Combo drug thus entered as a single entry
387738	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30583	19341:566031	Con Meds	CM.CMSTDT	3-24-2011		Combo drug thus entered as a single entry
387739	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30584	19341:566038	Con Meds	CM.CMONGO	true		Combo drug thus entered as a single entry
387740	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30585	19341:566040	Con Meds	CM.CMINDC	Pain management - post foot surgery		Combo drug thus entered as a single entry
387741	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30588	19341:566044	Con Meds	CM.ORIGNAME	Acetaminophen		Combo drug thus entered as a single entry
387742	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30587	19341:566046	Con Meds	CM.TERM	Acetaminophen		Combo drug thus entered as a single entry
387743	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30589	19341:566048	Con Meds	CM.RSLT1	Acetaminophen   Analgesic drug level   10060090   Therapeutic drug monitoring analyses   Toxicology and therapeutic drug monitoring   Investigations   13.1		Combo drug thus entered as a single entry
387744	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30593	19341:566049	Con Meds	CM.CODE1	10000398		Combo drug thus entered as a single entry
387745	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30590	19341:566050	Con Meds	CM.RSLT2	Acetaminophen decreased   Analgesic drug level decreased   10060941   Therapeutic drug monitoring analyses   Toxicology and therapeutic drug monitoring   Investigations   13.1		Combo drug thus entered as a single entry
387746	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30594	19341:566051	Con Meds	CM.CODE2	10000399		Combo drug thus entered as a single entry
387747	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30591	19341:566052	Con Meds	CM.RSLT3	Acetaminophen high   Analgesic drug level increased   10060942   Therapeutic drug monitoring analyses   Toxicology and therapeutic drug monitoring   Investigations   13.1		Combo drug thus entered as a single entry
387748	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30595	19341:566053	Con Meds	CM.CODE3	10000400		Combo drug thus entered as a single entry
387749	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30592	19341:566054	Con Meds	CM.RSLT4	Acetaminophen increased   Analgesic drug level increased   10060942   Therapeutic drug monitoring analyses   Toxicology and therapeutic drug monitoring   Investigations   13.1		Combo drug thus entered as a single entry
387750	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30596	19341:566055	Con Meds	CM.CODE4	10000401		Combo drug thus entered as a single entry
387751	11/3/2011 14:22:51	11-3-2011 13:17:45:515	4909	rcajigas	Rafael Cajigas	TD_DATA	30586	19341:566057	Con Meds	CM.CODECPLT			Combo drug thus entered as a single entry
387752	11/3/2011 14:22:54	11-3-2011 13:17:48:468	4909	rcajigas	Rafael Cajigas	TD_FORM	19341	19341:0	Con Meds		0	2	Form Status set to 2
387753	11/3/2011 14:22:54	11-3-2011 13:17:48:468	4909	rcajigas	Rafael Cajigas	TD_FORM	19341	19341:0	Con Meds		0	1	Form Checked Intentionally Left Blank
387759	11/3/2011 14:23:22	11-3-2011 13:18:16:968	4909	rcajigas	Rafael Cajigas	TD_DATA	30562	4661:133887	Con Meds	CM.CMDOSE	5	5/325	Corrected per query
387760	11/3/2011 14:23:24		4909	rcajigas	Rafael Cajigas	TD_DATA	30571	4661:133910	Con Meds	CM.RSLT1	Hydrocortisone   Blood cortisol   10005455   Adrenal cortex tests   Endocrine investigations (incl sex	Hydrocodone   Hydrocodone   NERVOUS SYSTEM   ANALGESICS   OPIOIDS   Natural opium alkaloids	computed value

# AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
387762	11/3/2011 14:23:24		4909	rcajigas	Rafael Cajigas	TD_DATA	30573	4661:133914	Con Meds	CM.RSLT3	Hydrocortisone decreased   Blood cortisol decreased   10005457   Adrenal cortex tests   Endocrine investigations (incl sex hormones)   Investigations   13.1	Hydrocodone bitartrate   Hydrocodone bitartrate   NERVOUS SYSTEM   ANALGESICS   OPIOIDS   Natural opium alkaloids	computed value
387763	11/3/2011 14:23:24		4909	rcajigas	Rafael Cajigas	TD_DATA	30574	4661:133916	Con Meds	CM.RSLT4	Hydrocortisone increased   Blood cortisol increased   10005458   Adrenal cortex tests   Endocrine investigations (incl sex hormones)   Investigations   13.1	Hydrocodone bitartrate   Hydrocodone bitartrate   RESPIRATORY SYSTEM   COUGH AND COLD PREPARATIONS   COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS   Opium alkaloids and derivatives	computed value
387764	11/3/2011 14:23:24		4909	rcajigas	Rafael Cajigas	TD_DATA	30575	4661:133911	Con Meds	CM.CODE1	10020518	00060001001N02AA	computed value
387765	11/3/2011 14:23:24		4909	rcajigas	Rafael Cajigas	TD_DATA	30576	4661:133913	Con Meds	CM.CODE2	10020519	00060001001R05DA	computed value
387766	11/3/2011 14:23:24		4909	rcajigas	Rafael Cajigas	TD_DATA	30577	4661:133915	Con Meds	CM.CODE3	10020520	00060002001N02AA	computed value
387767	11/3/2011 14:23:24		4909	rcajigas	Rafael Cajigas	TD_DATA	30578	4661:133917	Con Meds	CM.CODE4	10020521	00060002001R05DA	computed value
387768	11/3/2011 14:23:27	11-3-2011 13:18:22:109	4909	rcajigas	Rafael Cajigas	TD_FORM	4661	4661:0	Con Meds		1	2	Form Status set to 2
387769	11/3/2011 14:23:32	11-3-2011 13:18:27:62	4909	rcajigas	Rafael Cajigas	TD_FORM	19342	19342:0	Con Meds		1	2	Form Status set to 2
387770	11/3/2011 14:23:35	11-3-2011 13:18:30:140	4909	rcajigas	Rafael Cajigas	TD_FORM	50795	50795:0	Con Meds		1	2	Form Status set to 2
396206	11/14/2011 14:55:51	11-14-2011 13:51:17:203	4907	ssmithhart	Sara Smithhart	TD_DATA	30557	4640:133161	Test Product Allot	PU.PURET	19	6	Requires update
402733	11/20/2011 23:59:5	11-20-2011 23:53:57:964	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4624	4624:0	Brief Med. History		2	3	Form Status set to 3
402734	11/20/2011 23:59:13	11-20-2011 23:54:05:666	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	69938	69938:0	Brief Med. History		2	3	Form Status set to 3
402735	11/21/2011 0:0:4	11-20-2011 23:54:56:979	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	69940	69940:0	Brief Med. History		2	3	Form Status set to 3
402741	11/21/2011 0:1:57	11-20-2011 23:56:49:900	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4629	4629:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
402742	11/21/2011 0:2:38	11-20-2011 23:57:30:478	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	28196	28196:0	Brief Med. History		2	3	Form Status set to 3
402743	11/21/2011 0:6:22	11-21-2011 0:01:15:150	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	19341	19341:0	Con Meds		2	3	Form Status set to 3
402744	11/21/2011 0:7:30	11-21-2011 0:02:22:315	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	19342	19342:0	Con Meds		2	3	Form Status set to 3
402745	11/21/2011 0:11:2	11-21-2011 0:05:54:440	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4635	4635:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
402746	11/21/2011 0:12:40	11-21-2011 0:07:32:807	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4639	4639:0	Exhaled CO		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
402747	11/21/2011 0:14:44	11-21-2011 0:09:36:669	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4640	4640:0	Test Product Allot		2	3	Form Status set to 3
402748	11/21/2011 0:16:48	11-21-2011 0:11:39:876	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4665	4665:0	Study Conclusion		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
407763	12/1/2011 12:5:5	12-1-2011 12:00:33:759	6603	yovalle57	Yuliana Ov-alle	TD_FORM	69940	69940:0	Brief Med. History		3	4	Form Status set to 4
407764	12/1/2011 12:5:8	12-1-2011 12:00:37:9	6603	yovalle57	Yuliana Ov-alle	TD_FORM	69938	69938:0	Brief Med. History		3	4	Form Status set to 4
407765	12/1/2011 12:5:11	12-1-2011 12:00:39:493	6603	yovalle57	Yuliana Ov-alle	TD_FORM	28196	28196:0	Brief Med. History		3	4	Form Status

# AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
414566	12/27/2011 15:7:11	12-27-2011 14:02:05:207	4909	rcajigas	Rafael Cajigas	TD_DATA	120537	50795:1458876	Con Meds	CM.CMTRT	Nexium	Esomeprazole	Requires update
414567	12/27/2011 15:7:11		4909	rcajigas	Rafael Cajigas	TD_DATA	120544	50795:1458910	Con Meds	CM.CODECPLT		false	computed value
414568	12/27/2011 15:7:11		4909	rcajigas	Rafael Cajigas	TD_DATA	120546	50795:1458897	Con Meds	CM.ORIGNAME	Nexium	Esomeprazole	computed value
414569	12/27/2011 15:7:13		4909	rcajigas	Rafael Cajigas	TD_DATA	120547	50795:1458901	Con Meds	CM.RSLT1	Sorry, no results were found.	** Nexium   Esomeprazole magnesium   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Proton pump inhibitors	computed value
414570	12/27/2011 15:7:13		4909	rcajigas	Rafael Cajigas	TD_DATA	120548	50795:1458903	Con Meds	CM.RSLT2		Nexium hp   Nexium hp   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Combinations for eradication of Helicobacter pylori	computed value
414571	12/27/2011 15:7:13		4909	rcajigas	Rafael Cajigas	TD_DATA	120549	50795:1458905	Con Meds	CM.RSLT3		Nexium hp7   Nexium hp   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Combinations for eradication of Helicobacter pylori	computed value
414572	12/27/2011 15:7:13		4909	rcajigas	Rafael Cajigas	TD_DATA	120550	50795:1458907	Con Meds	CM.RSLT4		Nexium 1-2-3   Nexium hp   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Combinations for eradication of Helicobacter pylori	computed value
414573	12/27/2011 15:7:13		4909	rcajigas	Rafael Cajigas	TD_DATA	250709	50795:1458900	Con Meds	CM.CHOICE		1	computed value
414574	12/27/2011 15:7:13		4909	rcajigas	Rafael Cajigas	TD_DATA	120551	50795:1458902	Con Meds	CM.CODE1		01479302002A02BC	computed value
414575	12/27/2011 15:7:13		4909	rcajigas	Rafael Cajigas	TD_DATA	120552	50795:1458904	Con Meds	CM.CODE2		01611701001A02BD	computed value
414576	12/27/2011 15:7:13		4909	rcajigas	Rafael Cajigas	TD_DATA	120553	50795:1458906	Con Meds	CM.CODE3		01611701003A02BD	computed value
414577	12/27/2011 15:7:13		4909	rcajigas	Rafael Cajigas	TD_DATA	120554	50795:1458908	Con Meds	CM.CODE4		01611701004A02BD	computed value
414578	12/27/2011 15:7:14	12-27-2011 14:02:08:348	4909	rcajigas	Rafael Cajigas	TD_FORM	50795	50795:0	Con Meds		1	2	Form Status set to 2
414579	12/27/2011 15:8:33	12-27-2011 14:03:27:364	4909	rcajigas	Rafael Cajigas	TD_DATA	30561	4661:133885	Con Meds	CM.CMTRT	Hydrocodone	Hydrocodone/Acetaminophen	Requires update
414580	12/27/2011 15:8:33		4909	rcajigas	Rafael Cajigas	TD_DATA	30568	4661:133919	Con Meds	CM.CODECPLT		false	computed value
414581	12/27/2011 15:8:34		4909	rcajigas	Rafael Cajigas	TD_DATA	30570	4661:133906	Con Meds	CM.ORIGNAME	Hydrocodone	Hydrocodone/Acetaminophen	computed value
415458	12/29/2011 11:0:38	12-29-2011 10:55:35:240	3263	avillalbacdr	Artemisa V-illalba	TD_FORM	4660	4660:0	AE Code		0	1	Form Status set to 1
415459	12/29/2011 11:0:38	12-29-2011 10:55:35:240	3263	avillalbacdr	Artemisa V-illalba	TD_DATA	80123	4660:133871	AE Code	AE.TERM	new onset ulcer, peptic N.O.S	peptic ulcer	Requires update
415460	12/29/2011 11:1:40	12-29-2011 10:56:37:520	3263	avillalbacdr	Artemisa V-illalba	TD_DATA	251096	4660:133872	AE Code	AE.CHOICE		Not on list	Data Added
415461	12/29/2011 11:1:40	12-29-2011 10:56:37:520	3263	avillalbacdr	Artemisa V-illalba	TD_DATA	251097	4660:133881	AE Code	AE.NACODE		Peptic Ulcer	Data Added
415462	12/29/2011 11:1:40		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	251096	4660:133872	AE Code	AE.CHOICE	Not on list		computed value
415463	12/29/2011 11:1:40		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	80125	4660:133873	AE Code	AE.RSLT1	Acute peptic ulcer of unspecified site with haemorrhage   Peptic ulcer haemorrhage   10034344   Peptic ulcers and perforation   Gastrointestinal ulceration and perforation   Gastrointestinal disorders   13.1	Preferred code does not exist	computed value

# AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
415471	12/29/2011 11:1:40		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	251097	4660:133881	AE Code	AE.NACODE	Peptic Ulcer		computed value
415472	12/29/2011 11:1:54	12-29-2011 10:56:51:850	3263	avillalbacdr	Artemisa V-illalba	TD_DATA	251096	4660:133872	AE Code	AE.CHOICE		Not on list	Requires update
415473	12/29/2011 11:1:54	12-29-2011 10:56:51:850	3263	avillalbacdr	Artemisa V-illalba	TD_DATA	251097	4660:133881	AE Code	AE.NACODE		10034341	Requires update
415474	12/29/2011 11:1:54		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	251096	4660:133872	AE Code	AE.CHOICE	Not on list	1	computed value
415475	12/29/2011 11:1:54		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	80125	4660:133873	AE Code	AE.RSLT1	Preferred code does not exist	** Peptic ulcer   Peptic ulcer   10034341   Peptic ulcers and perforation   Gastrointestinal ulceration and perforation   Gastrointestinal disorders   13.1	computed value
415476	12/29/2011 11:1:54		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	80129	4660:133874	AE Code	AE.CODE1	Peptic Ulcer	10034341	computed value
415477	12/29/2011 11:1:54		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	251097	4660:133881	AE Code	AE.NACODE	10034341		computed value
415478	12/29/2011 11:2:21	12-29-2011 10:57:18:430	3263	avillalbacdr	Artemisa V-illalba	TD_DATA	80122	4660:133882	AE Code	AE.CODECPLT		true	Requires update
425664	1/19/2012 14:19:38	1-19-2012 14:14:49:794	3263	avillalbacdr	Artemisa V-illalba	TD_DATA	30605	19342:566084	Con Meds	CM.TERM	Cyclobenzaprine	Cyclobenzaprine	Requires update
425665	1/19/2012 14:19:38		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	30607	19342:566086	Con Meds	CM.RSLT1	Sorry, no results were found.	** Cyclobenzaprine   Cyclobenzaprine   MUSCULO-SKELETAL SYSTEM   MUSCLE RELAXANTS   MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS   Other centrally acting agents	computed value
425666	1/19/2012 14:19:38		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	30608	19342:566088	Con Meds	CM.RSLT2		Cyclobenzaprine hydrochloride   Cyclobenzaprine hydrochloride   MUSCULO-SKELETAL SYSTEM   MUSCLE RELAXANTS   MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS   Other centrally acting agents	computed value
425667	1/19/2012 14:19:38		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	30609	19342:566090	Con Meds	CM.RSLT3		Pms-cyclobenzaprine   Cyclobenzaprine hydrochloride   MUSCULO-SKELETAL SYSTEM   MUSCLE RELAXANTS   MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS   Other centrally acting agents	computed value
425668	1/19/2012 14:19:38		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	30610	19342:566092	Con Meds	CM.RSLT4		Cyclobenzaprine   Cyclobenzaprine hydrochloride   MUSCULO-SKELETAL SYSTEM   MUSCLE RELAXANTS   MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS   Other centrally acting agents	computed value
425669	1/19/2012 14:19:38		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	253410	19342:566085	Con Meds	CM.CHOICE		1	computed value
425670	1/19/2012 14:19:38		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	30611	19342:566087	Con Meds	CM.CODE1		00428401001M03BX	computed value
425671	1/19/2012 14:19:39		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	30612	19342:566089	Con Meds	CM.CODE2		00428402001M03BX	computed value
425672	1/19/2012 14:19:39		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	30613	19342:566091	Con Meds	CM.CODE3		00428402009M03BX	computed value
425673	1/19/2012 14:19:39		3263	avillalbacdr	Artemisa V-illalba	TD_DATA	30614	19342:566093	Con Meds	CM.CODE4		00428402028M03BX	computed value
425674	1/19/2012 14:19:48	1-19-2012 14:15:00:35	3263	avillalbacdr	Artemisa V-illalba	TD_DATA	30604	19342:566095	Con Meds	CM.CODECPLT		true	Requires update
427689	1/23/2012 11:0:2	1-23-2012 10:55:37:671	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	4625	4625:0	Comprehensive PE		0	1	I CERTIFY THAT I HAVE MONITORED THE CLINICAL MONITORING PORTION OF THIS FORM.
427691	1/23/2012 11:2:19	1-23-2012 10:57:54:893	4915	ajungstreisand	Ashley Jung-Streisand	TD_FORM	69939	69939:0	Brief Med. History		2	3	Form Status set to 3
427823	1/23/2012 11:55:39	1-23-2012 10:51:08:359	4909	rcajigas	Rafael Cajigas	TD_FORM	4659	4659:0	Adverse Events		2	1	Form Status demoted to 1
427824	1/23/2012 11:55:39	1-23-2012 10:51:08:359	4909	rcajigas	Rafael Cajigas	TD_DATA	80115	4659:133849	Adverse Events	AE.AEOUT	Ongoing	Lost to follow-up	Requires update
427825	1/23/2012 11:55:54	1-23-2012 10:51:23:609	4909	rcajigas	Rafael Cajigas	TD_FORM	4659	4659:0	Adverse Events		1	2	Form Status set to 2

# AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
440026	3/15/2012 13:26:50	3-15-2012 13:22:17:840	6603	yovalle57	Yuliana Ov-alle	TD_FORM	4661	4661:0	Con Meds		3	4	Form Status set to 4
440029	3/15/2012 13:27:16	3-15-2012 13:22:44:247	6603	yovalle57	Yuliana Ov-alle	TD_FORM	4659	4659:0	Adverse Events		3	4	Form Status set to 4
476296	9/3/2012 1-5:2:4	9-3-2012 1-4:56:19:375	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	4662	4662:0	Prtcl Deviations		2	3	Form Status set to 3
476677	9/4/2012 1-5:8:30	9-4-2012 1-4:02:01:765	4909	rcajigas	Rafael Cajigas	TD_FORM	4662	4662:0	Prtcl Deviations		3	1	Form Status set to 1
476678	9/4/2012 1-5:8:30	9-4-2012 1-4:02:01:765	4909	rcajigas	Rafael Cajigas	TD_FORM	4662	4662:0	Prtcl Deviations		1	0	Form Unchecked Intentionally Left Blank
476679	9/4/2012 1-5:8:30	9-4-2012 1-4:02:01:765	4909	rcajigas	Rafael Cajigas	TD_DATA	269310	4662:133925	Prtcl Deviations	PV.PVDT		4-28-2011	Data Added
476680	9/4/2012 1-5:8:30	9-4-2012 1-4:02:01:765	4909	rcajigas	Rafael Cajigas	TD_DATA	269311	4662:133926	Prtcl Deviations	PV.PVCAT		Other	Data Added
476681	9/4/2012 1-5:8:30	9-4-2012 1-4:02:01:765	4909	rcajigas	Rafael Cajigas	TD_DATA	269312	4662:133927	Prtcl Deviations	PV.PVSPEC		Study sponsor was not notified within two days of subject's discontinuation from study as per section 4.6 of the protocol.	Data Added
476682	9/4/2012 1-5:8:32	9-4-2012 1-4:02:03:859	4909	rcajigas	Rafael Cajigas	TD_FORM	4662	4662:0	Prtcl Deviations		1	2	Form Status set to 2
477492	9/8/2012 1-3:1:16	9-8-2012 1-2:54:57:77	7261	mcaballero	Maria Isabel Caballero Valiente	TD_FORM	4662	4662:0	Prtcl Deviations		2	3	Form Status set to 3
479002	9/11/2012 15:27:16	9-11-2012 15:20:16:157	6603	yovalle57	Yuliana Ov-alle	TD_FORM	4662	4662:0	Prtcl Deviations		3	4	Form Status set to 4
485023	9/26/2012 11:40:2	9-26-2012 10:32:47:812	3200	dpampe	David Pampe	TD_CASE-BOOK	443	0:0			0	1	I CERTIFY THAT THE DATA RECORDED ON THIS CASEBOOK IS ACCURATE.
485807	9/27/2012 11:37:7	9-27-2012 11:29:55:227	7641	yovallemon	Yuliana Ov-alle	TD_CASE-BOOK	443	0:0			0	1	Casebook Frozen
489244	10/25/2012 12:26:56	10-25-2012 12:19:22:54	7303	jgottliebmon	Joanne Gottlieb	TD_CASE-BOOK	443	0:0			1	0	Casebook Thawed
489336	10/25/2012 12:52:58	10-25-2012 12:45:23:971	7302	jgottliebco	Joanne Gottlieb	TD_DATA	120545	50795:1458899	Con Meds	CM.TERM	Nexium	Esomeprazole	Requires update
489337	10/25/2012 12:52:58	10-25-2012 12:45:23:971	7302	jgottliebco	Joanne Gottlieb	TD_DATA	120544	50795:1458910	Con Meds	CM.CODECPLT	false	true	Requires update
489338	10/25/2012 12:52:58	10-25-2012 12:45:23:971	7302	jgottliebco	Joanne Gottlieb	TD_CASE-BOOK	443	0:0			1	0	Unsigning Casebook 443
489339	10/25/2012 12:52:59		7302	jgottliebco	Joanne Gottlieb	TD_DATA	120547	50795:1458901	Con Meds	CM.RSLT1	** Nexium   Esomeprazole magnesium   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Proton pump inhibitors	** Esomeprazole   Esomeprazole   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Proton pump inhibitors	computed value
489340	10/25/2012 12:52:59		7302	jgottliebco	Joanne Gottlieb	TD_DATA	120548	50795:1458903	Con Meds	CM.RSLT2	Nexium hp   Nexium hp   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Combinations for eradication of Helicobacter pylori	Esomeprazole magnesium   Esomeprazole magnesium   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Proton pump inhibitors	computed value
489341	10/25/2012 12:52:59		7302	jgottliebco	Joanne Gottlieb	TD_DATA	120549	50795:1458905	Con Meds	CM.RSLT3	Nexium hp7   Nexium hp   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Combinations for eradication of Helicobacter pylori	Esomeprazole sodium   Esomeprazole sodium   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Proton pump inhibitors	computed value
489342	10/25/2012 12:52:59		7302	jgottliebco	Joanne Gottlieb	TD_DATA	120550	50795:1458907	Con Meds	CM.RSLT4	Nexium 1-2-3   Nexium hp   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Combinations for eradication of Helicobacter pylori	Esomeprazole strontium   Esomeprazole strontium   ALIMENTARY TRACT AND METABOLISM   DRUGS FOR ACID RELATED DISORDERS   DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)   Proton pump inhibitors	computed value
489343	10/25/2012		7302	jgottliebco	Joanne Go-	TD_DATA	120551	50795:1458902	Con Meds	CM.CODE1	01479302002A02BC	01479301001A02BC	computed value

[illegible]

# AUDIT TRAIL

ID	SERVER	CLIENT	USERID	USERNAME	NAME	TABLE	REF ID	FORM/ITEM ID	FORM NAME	SAS ITEM	OLD VAL	NEW VAL	REASON
489380	10/25/2012 12:55:45		7302	jgottliebco	Joanne Gottlieb	TD_DATA	270110	4661:133909	Con Meds	CM.CHOICE	1		computed value
489381	10/25/2012 12:55:45		7302	jgottliebco	Joanne Gottlieb	TD_DATA	30575	4661:133911	Con Meds	CM.CODE1	00607101001N02BE	00607101005N02AA	computed value
489382	10/25/2012 12:55:46		7302	jgottliebco	Joanne Gottlieb	TD_DATA	30576	4661:133913	Con Meds	CM.CODE2	00607101001N02AA	00607101005N02BE	computed value
489383	10/25/2012 12:55:46		7302	jgottliebco	Joanne Gottlieb	TD_DATA	30577	4661:133915	Con Meds	CM.CODE3	00607101008N02AA	00607101013N02AA	computed value
489384	10/25/2012 12:55:46		7302	jgottliebco	Joanne Gottlieb	TD_DATA	30578	4661:133917	Con Meds	CM.CODE4	00607101008N02BE	00607101013N02BE	computed value
489385	10/25/2012 12:56:3	10-25-2012 12:48:28:261	7302	jgottliebco	Joanne Gottlieb	TD_DATA	270110	4661:133909	Con Meds	CM.CHOICE		1	Requires update
489386	10/25/2012 12:56:3	10-25-2012 12:48:28:261	7302	jgottliebco	Joanne Gottlieb	TD_DATA	30568	4661:133919	Con Meds	CM.CODECPLT	false	true	Requires update
489387	10/25/2012 12:56:3		7302	jgottliebco	Joanne Gottlieb	TD_DATA	30571	4661:133910	Con Meds	CM.RSLT1	Acetaminophen w/hydrocodone bitartrate   Vicodin   NERVOUS SYSTEM   ANALGESICS   OPIOIDS   Natural opium alkaloids	** Acetaminophen w/hydrocodone bitartrate   Vicodin   NERVOUS SYSTEM   ANALGESICS   OPIOIDS   Natural opium alkaloids	computed value
490805	11/7/2012 15:34:4	11-7-2012 15:34:09:430	7303	jgottliebmon	Joanne Gottlieb	TD_DATA	30569	4661:133908	Con Meds	CM.TERM	Vicodin Hydrocodone	Hydrocodone	Requires update
490806	11/7/2012 15:34:5		7303	jgottliebmon	Joanne Gottlieb	TD_DATA	30571	4661:133910	Con Meds	CM.RSLT1	** Acetaminophen w/hydrocodone bitartrate   Vicodin   NERVOUS SYSTEM   ANALGESICS   OPIOIDS   Natural opium alkaloids	** Hydrocodone   Hydrocodone   NERVOUS SYSTEM   ANALGESICS   OPIOIDS   Natural opium alkaloids	computed value
490807	11/7/2012 15:34:5		7303	jgottliebmon	Joanne Gottlieb	TD_DATA	30572	4661:133912	Con Meds	CM.RSLT2	Acetaminophen w/hydrocodone bitartrate   Vicodin   NERVOUS SYSTEM   ANALGESICS   OTHER ANALGESICS AND ANTIPYRETICS   Anilides	Hydrocodone   Hydrocodone   RESPIRATORY SYSTEM   COUGH AND COLD PREPARATIONS   COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS   Opium alkaloids and derivatives	computed value
490808	11/7/2012 15:34:5		7303	jgottliebmon	Joanne Gottlieb	TD_DATA	30573	4661:133914	Con Meds	CM.RSLT3	Hydrocodone w/acetaminophen   Vicodin   NERVOUS SYSTEM   ANALGESICS   OPIOIDS   Natural opium alkaloids	Hydrocodone bitartrate   Hydrocodone bitartrate   NERVOUS SYSTEM   ANALGESICS   OPIOIDS   Natural opium alkaloids	computed value
490809	11/7/2012 15:34:5		7303	jgottliebmon	Joanne Gottlieb	TD_DATA	30574	4661:133916	Con Meds	CM.RSLT4	Hydrocodone w/acetaminophen   Vicodin   NERVOUS SYSTEM   ANALGESICS   OTHER ANALGESICS AND ANTIPYRETICS   Anilides	Hydrocodone bitartrate   Hydrocodone bitartrate   RESPIRATORY SYSTEM   COUGH AND COLD PREPARATIONS   COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS   Opium alkaloids and derivatives	computed value
490810	11/7/2012 15:34:5		7303	jgottliebmon	Joanne Gottlieb	TD_DATA	30575	4661:133911	Con Meds	CM.CODE1	00607101005N02AA	00060001001N02AA	computed value
490811	11/7/2012 15:34:5		7303	jgottliebmon	Joanne Gottlieb	TD_DATA	30576	4661:133913	Con Meds	CM.CODE2	00607101005N02BE	00060001001R05DA	computed value
490812	11/7/2012 15:34:5		7303	jgottliebmon	Joanne Gottlieb	TD_DATA	30577	4661:133915	Con Meds	CM.CODE3	00607101013N02AA	00060002001N02AA	computed value
490813	11/7/2012 15:34:5		7303	jgottliebmon	Joanne Gottlieb	TD_DATA	30578	4661:133917	Con Meds	CM.CODE4	00607101013N02BE	00060002001R05DA	computed value
492011	11/16/2012 11:3:41	11-16-2012 11:03:51:665	7641	yovallemon	Yuliana Ovalle	TD_CASE-BOOK	443	0:0			0	1	Casebook Frozen
492035	11/16/2012 14:3:17	11-16-2012 13:03:27:906	3200	dpampe	David Pamp	TD_CASE-BOOK	443	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
Demographics	What is approximate yearly household income group?	DM.DMNC		APPROVED	Data is missing. Please provide.		03-02-2011	SYSTEM	
				RESOLVED		Subject declined to answer	2011-03-02 17:52:53.0	rcajigas	Rafael Cajigas
				APPROVED		Data matches source document	2011-03-23 11:59:36.0	jbaskowski	Janet Baskowski
Inc/Exc	Did the subject meet all eligibility criteria for enrollment	IE.IECRITYN	1	APPROVED	Email		03-14-2011	SYSTEM	
Labs	Urine Drug Screen	LB.LBUDS	2	APPROVED	Result for drug screen is positive, however, subject met all criteria. Please correct or clarify eligibility.		03-14-2011	SYSTEM	
			2	RESOLVED		Patient is taking Hydrocodone for post foot surgery pain management.	2011-03-14 08:45:12.0	rcajigas	Rafael Cajigas
			2	OPEN		Please add any medications that subject is taking in the Concomitant Medications CRF.	2011-03-24 15:52:28.0	yovalle	Yulina Ovalle
			2	RESOLVED		Subject was taking hydrocodone for pain management after foot surgery	2011-03-27 02:39:17.0	rcajigas	Rafael Cajigas
			2	APPROVED		Confirmed Data, no action	2011-04-11 13:54:26.0	yovalle	Yulina Ovalle
Con Meds	Coding Completed?	CM.CODECLPT	true	APPROVED	Please verify that coding has been completed or recode due to the change in Medication Name.		03-27-2011	SYSTEM	
				APPROVED		Administrative	2011-10-18 15:32:33.0	hfrost567	Haydee Frost
Con Meds	Coding Completed?	CM.CODECLPT		RESOLVED	Please verify that coding has been completed or recode due to the change in Medication Name.		03-27-2011	SYSTEM	
				APPROVED		Administrative	2011-10-18 15:31:59.0	hfrost567	Haydee Frost
Con Meds	Coding Completed?	CM.CODECLPT	true	APPROVED	Please verify that coding has been completed or recode due to the change in Medication Name.		03-27-2011	SYSTEM	
				APPROVED		Administrative	2011-10-18 15:31:29.0	hfrost567	Haydee Frost
Exhaled CO	Was ECO Test Performed?	EC.ECYN	2	APPROVED	Source document : N/A		4-8-2011	jbaskowski	Janet Baskowski
			2	RESOLVED		Corrected to NA	2011-04-12 15:21:21.0	swampler	Sarah Wampler
			2	APPROVED		Test not done.	2011-04-25 09:33:34.0	jbaskowski	Janet Baskowski
Exhaled CO	ECO	EC.ECRES1		APPROVED	Source document : Results: ECO(ppm) is blank		4-8-2011	jbaskowski	Janet Baskowski
			-NULL-	RESOLVED		Corrected EDC	2011-04-12 15:21:32.0	swampler	Sarah Wampler
			-NULL-	APPROVED		Confirmed Data, no action. EDC field is blank	2011-04-19 14:52:52.0	yovalle	Yulina Ovalle
Exhaled CO	Date ECO Obtained	EC.ECDT	--	APPROVED	Data is missing. Please provide.		04-12-2011	SYSTEM	
			--	RESOLVED		not done	2011-04-12 15:21:39.0	swampler	Sarah Wampler
			--	APPROVED		Confirmed Data, no action	2011-04-15 14:59:51.0	yovalle	Yulina Ovalle
Exhaled CO	Time ECO Obtained	EC.ECTM		APPROVED	Data is missing. Please provide.		04-12-2011	SYSTEM	
			-NULL-	RESOLVED		not done	2011-04-12 15:21:43.0	swampler	Sarah Wampler
			-NULL-	APPROVED		Confirmed Data, no action	2011-04-15 14:59:55.0	yovalle	Yulina Ovalle
Exhaled CO	ECO	EC.ECRES1		APPROVED	Data is missing. Please provide.		04-12-2011	SYSTEM	
			-NULL-	RESOLVED		not done	2011-04-12 15:21:46.0	swampler	Sarah Wampler
			-NULL-	APPROVED		Confirmed Data, no action	2011-04-15 15:00:02.0	yovalle	Yulina Ovalle
Comprehensive PE	FORM LEVEL	-form--form-		APPROVED	Pls have "TONSILLAR HYPERPLASIA" under "ORAL" category- pls ensure to note "Abnormal".		4-26-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		entered in wrong field., corrected	2011-06-28 12:20:17.0	swampler	Sarah Wampler
				APPROVED		Data matches .	2011-08-01 11:13:08.0	jbaskowski	Janet Baskowski

## DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
Brief Med. History	FORM LEVEL	-form--form-		APPROVED	Pls enter the severity of the pre-existing condition of Lower Back Pain on the SD and EDC as a baseline. Thanks.		4-26-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		PI had notified RJR that severity would only be assessed if a particular condition was deemed to be clinically significant which is not the case for this condition.	2011-11-03 14:06:21.0	rcajigas	Rafael Cajigas
				APPROVED		ok	2012-01-23 11:00:49.0	ajungstreisand	Ashley Jung-Streisand
Brief Med. History	FORM LEVEL	-form--form-		APPROVED	Pls separate condition from procedure. "Broken Left Foot" as one entry and "Left Foot surgery" as second.		4-26-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		entered as separate events	2011-06-28 12:36:03.0	swampler	Sarah Wampler
				APPROVED		thanks	2012-01-23 11:01:54.0	ajungstreisand	Ashley Jung-Streisand
Brief Med. History	FORM LEVEL	-form--form-		APPROVED	May want to add "Pain from foot surgery" as Med Hx since subject taking ConMed for it. Pls ensure severity and frequency is entered.		4-26-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Added - see query resolution folder in I Vault	2011-06-28 12:41:41.0	swampler	Sarah Wampler
				APPROVED		thanks	2012-01-23 11:02:07.0	ajungstreisand	Ashley Jung-Streisand
Brief Med. History	FORM LEVEL	-form--form-		APPROVED	May want to add "Left Tympanic Membrane Obsured" since it was noted in PE as a baseline condition.		4-26-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Added - see query resolution folder in I Vault	2011-06-28 12:41:28.0	swampler	Sarah Wampler
				APPROVED		thanks	2012-01-23 11:01:16.0	ajungstreisand	Ashley Jung-Streisand
Con Meds	FORM LEVEL	-form--form-		APPROVED	Pls provide source document for this med.		4-26-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Source document IVaulted.	2011-11-03 14:22:02.0	rcajigas	Rafael Cajigas
				APPROVED		thanks	2011-11-21 00:07:14.0	ajungstreisand	Ashley Jung-Streisand
AE Code	Coding Completed?	AE.CODECPLT	true	APPROVED	Please verify that coding has been completed or recode due to the change in AE Description.		05-02-2011	SYSTEM	
Test Product Allot	Number of Units Returned	PU.PURET	6	APPROVED	Pls verify the number of units. Thanks.		5-3-2011	ajungstreisand	Ashley Jung-Streisand
			19	RESOLVED		As per SD, correct as is - 19	2011-06-28 12:23:15.0	swampler	Sarah Wampler
			6	APPROVED		thanks.	2011-11-21 00:14:37.0	ajungstreisand	Ashley Jung-Streisand
Adverse Events	FORM LEVEL	-form--form-		APPROVED	Pls clarify/Verify under "Action Taken Toward Product" whether "Cessation of Product" or "None". Subject did withdrew consent but per subject "not feel that it has anything to do with the study product.."		5-3-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Action taken: cessation of product	2011-06-28 12:28:20.0	swampler	Sarah Wampler
				RESOLVED		thanks	2011-11-21 00:20:43.0	ajungstreisand	Ashley Jung-Streisand
				APPROVED		thanks	2012-01-23 11:15:52.0	ajungstreisand	Ashley Jung-Streisand
Con Meds	FORM LEVEL	-form--form-		RESOLVED	Pls have the combo drug like "HYDROCODONE 5/ ACETAMINOPHEN 325" entered as a combo drug and not separate the drug into 2 drugs. You may enter "1" tablet for dosage since dosage for each drug is captured in the name.		5-3-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Combo drug thus entered as a single entry	2011-11-03 14:22:51.0	ajungstreisand	Ashley Jung-Streisand
Adverse Events	FORM LEVEL	-form--form-		APPROVED	Per Protocol, pls continue to follow subject until AE resolution or until unresolved AE is judged by the PI to have stabilized. Thanks		5-3-2011	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		As per email June 2 2011, subject non responsive to requests to get AE resolution date	2011-06-28 12:24:49.0	swampler	Sarah Wampler
				APPROVED		thanks	2011-11-21 00:21:03.0	ajungstreisand	Ashley Jung-Streisand
Con Meds	Coding Completed?	CM.CODECPLT	true	APPROVED	Please verify that coding has been completed or recode due to the change in Medication Name.		05-26-2011	SYSTEM	
				APPROVED		Administrative	2011-10-18 15:31:43.0	hfrost567	Haydee Frost

## DATA RESOLUTION QUERIES

FORM	ITEM	SAS	VALUE	STATUS	DESCRIPTION	THREAD	DATE	OWNER	NAME
Study Conclusion	Reason for Withdrawal	DS.DSETREAS	2	APPROVED	Source Document ,Reason for Early Withdrawal : Adverse Events		6-9-2011	jbaskowski	Janet Baskowski
			2	RESOLVED		See Query resolution folder in I-Vault. Upadted to Withdrew consent	2011-06-28 12:33:06.0	swampler	Sarah Wampler
			2	APPROVED		Data entered into IVault . Query resolved.	2011-08-01 11:17:44.0	jbaskowski	Janet Baskowski
Study Conclusion	Other Specify	DS.DSETSP	subject did not wish to continue	APPROVED	Source Document Specify : is blank. Please upload new Source Document with reason for early withdrawal into I-Vault		6-9-2011	jbaskowski	Janet Baskowski
			subject did not wish to continue	RESOLVED		See Query resolution folder	2011-06-28 12:33:24.0	swampler	Sarah Wampler
			subject did not wish to continue	APPROVED		Data uploaded	2011-08-01 11:18:40.0	jbaskowski	Janet Baskowski
Adverse Events	AE Term	AE.AETERM	new onset ulcer, peptic N.O.S	APPROVED	Please review and confirm if AE is still ongoing. If not, please provide stop date/time		9-9-2011	yovalle57	Yuliana Ovalle
			new onset ulcer, peptic N.O.S	RESOLVED		After repeated attempts to try to obtain information., the study subject never returned our calls. Status of AE is unknown.	2011-11-03 14:09:59.0	rcajigas	Rafael Cajigas
			new onset ulcer, peptic N.O.S	APPROVED		thanks	2011-11-21 00:21:21.0	ajungstreisand	Ashley Jung-Streisand
Con Meds	Indication	CM.CMINDC	Pain Management - post foot surgery	APPROVED	Pls add in SDW "Post-op Foot surgery Pain" since subject on med for it. already entered in ECD.		11-21-2011	ajungstreisand	Ashley Jung-Streisand
			Pain Management - post foot surgery	APPROVED		SORRY- disregard query. did not see the bottom of page. thanks	2011-11-21 00:09:33.0	ajungstreisand	Ashley Jung-Streisand
Con Meds	Medication	CM.CMTRT	Hydrocodone/Acetaminophen	APPROVED	Pls add "/acetaminophen" since it is a combo drug. thanks		11-21-2011	ajungstreisand	Ashley Jung-Streisand
			Hydrocodone	RESOLVED		Done	2011-12-27 15:08:12.0	rcajigas	Rafael Cajigas
			Hydrocodone/Acetaminophen	APPROVED		thanks	2012-02-15 15:54:36.0	ajungstreisand	Ashley Jung-Streisand
Con Meds	Medication	CM.CMTRT	Esomeprazole	APPROVED	correct to ESOMEPRAZOLE		11-21-2011	ajungstreisand	Ashley Jung-Streisand
			Nexium	RESOLVED		Done	2011-12-27 15:06:52.0	rcajigas	Rafael Cajigas
			Esomeprazole	APPROVED		thanks	2012-02-15 15:55:21.0	ajungstreisand	Ashley Jung-Streisand
Adverse Events	FORM LEVEL	-form-,-form-		APPROVED	Pls have Dr. Pampe finalize the AE form by re-sign/ dating with the most current information. thanks		11-21-2011	ajungstreisand	Ashley Jung-Streisand
				OPEN		One more item- pls docucent the date of Unk/Unk/ Unk status of Outcome of AE with most current date information was captured and have Dr. Pampe sign/ date. thanks	2011-11-21 00:28:47.0	ajungstreisand	Ashley Jung-Streisand
				RESOLVED		Done	2011-12-27 15:03:08.0	rcajigas	Rafael Cajigas
				APPROVED		PI signature added on 27-DEC-2011 on SD.	2012-01-23 11:19:45.0	ajungstreisand	Ashley Jung-Streisand
Adverse Events	Outcome	AE.AEOUT	5	APPROVED	Should this be corrected to Lost-to-Follow-up since no additional information was collected from subject regarding the AE? thanks		1-23-2012	ajungstreisand	Ashley Jung-Streisand
			5	RESOLVED		Done	2012-01-23 11:55:50.0	rcajigas	Rafael Cajigas
			5	APPROVED		thanks	2012-02-15 15:56:30.0	ajungstreisand	Ashley Jung-Streisand