

# **DATA MANAGEMENT WORKSHOP**

**February 6, 2014**

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Director of IT  
NRG Oncology - Buffalo

# Presentation

- **User Account Information**
  - Patient Registration in OPEN
  - Slides 5 – 13 courtesy of the CTSU
- **Discussion of RAVE**
  - Navigation of the system.
  - Description of RAVE terms throughout.
  - Entering data:
    - Logic, ranges and validation.
    - System interaction messages and queries.







# WARNING!!!

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*What you are about to see may change in the near future as:*

- *We merge into a single group.*
- *We learn how to better use RAVE.*
- *More LPO standards are created which apply to all LPOs.*

# Role/Roster Requirements

- Users must have all the following to access Rave:
  - ☒ Active CTEP-IAM account
  - ☒ Active or follow-up roster status on the participating Network Group (LPO) roster for that protocol or on CTSU roster
  - ☒ Active Rave role
    - *Rave CRA*
      -  Enter subject eCRF data
      -  Respond to queries
    - *Rave Site Investigator*
      -  Enter subject data
      -  Respond to queries
      -  Sign eCRF
    - *Read Only*
      -  Read only access to data

# User Access and eLearning

- User access to Rave is through the iMedidata portal.
- Prior to accessing a study in Rave, invited users need to:
  - activate their accounts
  - complete eLearning
- Rave eLearning requirements for all roles are standardized across all URLs.
  - NOTE: LPOs may have organization-specific or protocol-specific eLearnings.

# User Account Activation

- At the time of initial site registration approval, persons with Rave roles at the institution will be invited to the study.
- The User Account Activation Email is a one-time email triggered when a user is linked to their very first study in Rave.
- The activation email will provide the new Rave user with a unique link to activate their account in iMedidata.
- The user will not be able to access the Rave system without completing the activation process.

# User Account Activation Email (cont.)



Welcome to iMedidata.com - a faster, simpler way to access all of your iMedidata studies, training, and applications.

Greetings,

System would like you to join the Study S0816 on iMedidata.

✓ [Take me to iMedidata to activate my account.](#)

Click on the link to  
begin the  
activation process



<https://login.imedidata.com/selectlogin>



### Sign In

[iMedidata](#)

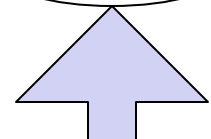
[NXT IdP](#)

[NXT QA IdP](#)

[NXT Training IdP](#)

[Mayo IdP](#)

[CTEP-IAM IdP](#)



Users will select CTEP-IAM on the left side of the screen to log in with their CTEP-IAM credentials.

### Please choose your Portal or Identity Provider

Select your Identity Provider or Organization from the list. Your Identity Provider (IDP) will verify your identity and may prompt you for your username and password. You will then be automatically connected to the requested application.



Our mission is to provide insight and enhance the quality of clinical research.

Users should bookmark the above shown URL for logging into iMedidata for all CTEP studies.

[Privacy Policy](#) | [Terms](#)

Copyright 1999-2012 [Medidata Solutions Worldwide](#)

# Register patient using OPEN

**OPEN - Oncology Patient Enrollment Network - Windows Internet Explorer**

Address bar: F0138786291208E15207

Page: Safety Tools

National Cancer Institute U.S. National Institutes of Health | www.cancer.gov

CTSU Cancer Trials Support Unit A SERVICE OF THE NATIONAL CANCER INSTITUTE Linking practice to progress

**OPEN** Oncology Patient Enrollment Network

**Welcome to the Oncology Patient Enrollment Network (OPEN) Portal system**

OPEN is the web-based registration system for patient enrollments onto NCI-sponsored Cooperative Group clinical trials. The system is integrated with the CTSU Enterprise System for regulatory and roster data, and with each of the Cooperative Groups' registration/randomization systems for patient registration/ randomization. OPEN provides the ability to enroll patients on a 24/7 basis.

**Training and Demonstration Materials:**

- [User Guide](#) » This users guide has a linkable Table of Contents that will bring you to any topic you choose, or you can scroll through and/or print the entire guide.
- [OPEN Demo Video](#) » The OPEN training video has been updated and reformatted. Click on one of the tabs at the top of the screen for a drop down list of instructional topics, then click on the specific topic you want to view.
- [Frequently Asked Questions \(FAQ\)](#) » Frequently asked questions about OPEN Portal.
- [Access & Crediting Guidelines](#) » Guidelines for OPEN Portal Access and Crediting.
- [Slot Reservation Quick User Guide](#) » This user guide is a quick reference intended to assist you with the process of reserving a slot for a patient on protocols that use the slot reservation system.

**Login Section:**

Username:

Password:

AMSSO

You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all ~~communications~~ ~~transmissions~~ ~~data~~ ~~information~~ ~~stored~~ ~~in this network~~ ~~all devices~~ ~~storage media~~ attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only.

Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. By using this information system, you understand and consent to the following. You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, record, and search and seize any communication or data transiting or stored on this information system. Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

[Forgot Password?](#) [Reset Password?](#) [Annual Registration](#) [Request New Account](#)

**Footer:**

Contact Us Privacy Notice Disclaimer Accessibility Application Support

NATIONAL CANCER INSTITUTE FIRSTGOV

Version 5.3.1.5 [20131025]

# Patient Demographics

OPEN - Oncology Patient Enrollment Network - Windows Internet Explorer

https://test.ctsu.org/open/viewEditForm.open?method=editDemographyForm

File Edit View Favorites Tools Help

OPEN - Oncology Patient Enrollment Network

Site: GOG:Gynecologic Oncology Group Role: GROUP\_REG\_ADMIN

Home Enroll History Reports RSS Form Setup Admin Help

In Progress | Create New | Summary | Prerequisite | Demography | Checklist | Review & Submit | Result | Overrides

Selected Tracking # 92498 Details Summary

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
GOG-0229L	---		1		MN008	Bailey, Cheryl	NEW	07/11/2012

Back Save Save & Validate Continue Existing Patient ID: Populate Demography

Expand/Collapse all Modules

Standard\_Patient\_Identifier

\* Last A \* First B Middle C

Patient SSN 123 45 6789 Patient Hospital No.

(US only)

Standard\_Demographics

\* Patient's Date of Birth May (05) / 08 1953

\* Ethnicity

☐ Hispanic or Latino

☒ Not Hispanic or Latino

☐ Not reported

☐ Unknown

\* Gender of a Person

☒ Female Gender

☐ Male Gender

☐ Unknown

\* Country of Residence US ZIP Code 12345

Standard\_Race

\* Race

☐ American Indian or Alaska Native

☐ Asian

☐ Black or African American

☐ Native Hawaiian or other Pacific Islander

☒ White

☐ Not Reported

☐ Unknown

(Select all that apply)

Standard\_Method\_of\_Payment

\* Method of Payment

☐ PRIVATE INSURANCE

☐ MEDICARE

☐ MEDICARE AND PRIVATE INSURANCE

☐ MEDICAID

Race

# Eligibility

OPEN - Oncology Patient Enrollment Network - Windows Internet Explorer

https://test.ctsu.org/open/viewEditForm.open?method=editForm

File Edit View Favorites Tools Help

★ Favorites ★ Suggested Sites Web Slice Gallery

OPEN - Oncology Patient Enrollment Network

In Progress | Create New | Summary | Prerequisite | Demography | Checklist | Review & Submit | Result | Overrides

Selected Tracking # 92498 Details Summary

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
GOG-0229L		ABC	1		MN008	Bailey, Cheryl	INCOMPLETE	07/11/2012

Back Save Save & Validate Continue Manual Registration

Expand/Collapse all Modules

**Patient Information**

\* GOG Institution Code 814

\* GOG Affiliate Code 02

Previous GOG #

Please enter Previous GOG ID in the "Existing Patient ID" field on the previous screen in the format 000-0000A-000 (site code, protocol code, protocol section if any, sequence number)

\* Treating physician Bailey, Cheryl  
Other Physician

**Eligibility 1**

\* Did the patient sign an approved informed consent

☒ Yes  
☐ No

\* Has HIPAA authorization been obtained

☒ Yes  
☐ Exempt - non-USA participant

\* Is the patient eligible for a higher priority GOG protocol

☒ Yes  
☐ No

\* What is the primary disease site

☒ Endometrium

\* What is the cell type? Endometrioid Adenocarcinoma

\* Date of initial histologic diagnosis of malignancy April (04) / 22 / 2010

\* What was the grade of the primary tumor

☒ 1  
☐ 2  
☐ 3

\* Is the disease recurrent or persistent with documented progression? Which one?

☒ Recurrent  
☐ Persistent

\* Is the cancer refractory to curative therapy or established treatments?

☒ Yes  
☐ No

\* How was it established to be recurrent or persistent?

☒ Surgery

Primary site  
of Disease

Grade of  
primary tumor

# Receipt

OPEN - Oncology Patient Enrollment Network - Windows Internet Explorer

https://test.ctsu.org/open/editSubmission.open

File Edit View Favorites Tools Help

★ Favorites ★ Suggested Sites Web Slice Gallery

OPEN - Oncology Patient Enrollment Network

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TEST db

CTSU PEN Oncology Patient Enrollment Network

Contact | Members Site | Log off

Site: GOG:Gynecologic Oncology Group Role: GROUP\_REG\_ADMIN

Home Enroll History Reports RSS Form Setup Admin Help

Browse | Summary | Prerequisite | Demography | Checklist

Selected Tracking # 92498 Details Summary

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
GOG-0229L	814-0229L-113	ABC	1	1	MN008	Bailey, Cheryl	REGISTERED	07/11/2012

**Information**

- Group response for tracking # **92498**
- This registration can now be found in the HISTORY section
- Click on [View Summary] to view the complete registration summary

**Group Response(s)**

Eligibility:	ELIGIBLE
Ineligibility Reason:	
Patient ID:	814-0229L-113
Treatment Arm:	1
Site Instruction:	Click <a href="#">here</a> to continue to the patient form schedule on the GOG website.
Node Error Message:	

Please let us know your enrollment experience by completing this survey which should not take more than 2 minutes!

[View Summary](#)

Local intranet | Protected Mode: Off 100%

Patient Identifier

# iMedidata Login

The screenshot shows a web browser window with the address bar displaying `https://login.imedidata.com/s`. The page header features the National Cancer Institute logo and the text "National Cancer Institute" on the left, and "U.S. National Institutes of Health | www.cancer.gov" on the right. The main heading is "IDENTITY AND ACCESS MANAGEMENT *Single Sign On*", with the "IAM-SSO" logo on the right. The page is divided into two main sections: "LOGON TO IAM" on the left and "Account Management" on the right. The "LOGON TO IAM" section contains two input fields: "Username\*" and "Password\*", each followed by a password strength indicator. The "Account Management" section contains four links with icons: "Forgot Password" (help icon), "Reset Password" (refresh icon), "Annual Registration" (info icon), and "Request New Account" (key icon). Each link is followed by a brief description of the service. The footer contains five links: "CONTACT US", "PRIVACY NOTICE", "DISCLAIMER", "ACCESSIBILITY", and "APPLICATION SUPPORT". Below these links are logos for the National Cancer Institute, the U.S. Department of Health and Human Services, and the "FIRSTGOV" logo.

**National Cancer Institute** U.S. National Institutes of Health | www.cancer.gov

## IDENTITY AND ACCESS MANAGEMENT *Single Sign On*

**LOGON TO IAM**

Username\*:

Password\*:

**Account Management**

- [Forgot Password](#)  
If you have already enrolled, you can request for a temporary password by providing the name or username and email on the account.
- [Reset Password](#)  
If you have received a temporary password or if you would like to change your current password.
- [Annual Registration](#)  
If your IAM account registration has to be renewed.
- [Request New Account](#)

[CONTACT US](#) [PRIVACY NOTICE](#) [DISCLAIMER](#) [ACCESSIBILITY](#) [APPLICATION SUPPORT](#)

# NRG Protocols

List of NRG protocols in RAVE you have been invited to.

The screenshot shows the iMedidata web application interface. The 'Studies (5)' section is highlighted with a red box and a red arrow pointing to it from the text 'List of NRG protocols in RAVE you have been invited to.' The 'Studies (5)' section contains a table with the following data:

Study ID	Protocol Name
GOG	Rave EDC
GOG0224 (DEV)	Rave EDC
GOG0229L (DEV)	Rave EDC
GOG9262 (DEV)	Rave EDC
GOG9923 (DEV)	Rave EDC

The 'Tasks' section on the right shows 'Invitations (0)' and 'eLearning (0)'. The 'Sites (0)' and 'Teams (0)' sections show messages indicating no sites or teams are currently listed.

# Institution Page (Parents)

List of NRG institutions.

The screenshot shows the Medidata Rave website interface. The browser address bar displays the URL: [https://hdcvcl01-037.mdsol.com/MedidataRave/\(S\(tkmxow4rt0refs0ldqumusu\)\)/HomePage.aspx?LD\\_StudyID=16](https://hdcvcl01-037.mdsol.com/MedidataRave/(S(tkmxow4rt0refs0ldqumusu))/HomePage.aspx?LD_StudyID=16). The page header includes the Medidata logo, the text "DEV", and navigation links for iMedidata, Messages, My Profile, Help, Home, and Logout. The user is identified as "User: Jessalyn Rebo Data Manager".

The main content area displays the "GOG0229L" study information. A description of the Gynecologic Oncology Group (GOG) is provided. Below this, a search bar is visible with the text "Find" and a dropdown menu set to "Site". A blue arrow points to the "List of NRG institutions" text, which is positioned over the search results table.

Site Group	Site	Site Group	Site Number
	Angela	World	612
	Angela 2	World	613
	Bill	World	601
	Ed	World	602
	Jessalyn	World	603
	Joe	World	604
	Josh	World	605
	Justin	World	607
	Kareem	World	608
	Karen	World	609
	Quang	World	610
	Susan	World	611

Page 1

Icon Key

Task Summary: Study

Task	Sites
NonConformant Data	6
Open Queries	0
Answered Queries	1
Requiring Review	0
Overdue Data	3
Ready for Data Lock	9
Cancel Queries	8

Click Here for Customer Support Information

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# Patients enrolled to protocol

Home - Medidata Rave - Windows Internet Explorer

https://hdcvcl01-037.mdsol.com/MedidataRave/(S(tkmskw4rt0refs0ldqumusu))/HomePage.aspx?LD\_StudySiteID=64

File Edit View Favorites Tools Help

Home - Medidata Rave

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Task Summary: Study

- Requiring Signature
- NonConformant Data
- Open Queries
- Answered Queries
- Requiring Review
- Requiring Verification
- Overdue Data
- Ready for Data Lock
- Cancel Queries

Subjects

2	
0	
4	
0	
7	
44	
20	

000-0229L-013  
000-0229L-014  
000-0229L-015  
000-0229L-016  
000-0229L-160  
000-0229L-300  
000-0229L-400  
000-0229L-401

Page 1 2 3

Icon Key

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Internet | Protected Mode: Off

# Patient's root tab

Initial information loaded at registration.

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DEV

Icon Key - Windows Internet Explorer

https://hdcvcl01-037.mdsol.com/MedidataRave/(S(tkmxkw4rt0refsl0ldqumus))/Modules/EDC/Icc

Icon Key

Site	Never Touched	Incomplete
Studies	Complete	Requires Verification
Study	Locked	Requires Review
Subject	Entry Lock	Query Open
Subject in doubt	Not Conformant	Answered Query
Form	Inactive	Requires Coding
Entry Lock	Overdue	Requires Signature
Home	Sticky Notes	Out of Range High
Comments	Data Changed	Out of Range Low
Edit	Protocol Deviation	Requires Translation
Study Status Deferred	Site Status Deferred	Requires First Pass DDE
Folder not available to the user	Add Marking	Requires Second Pass DDE
Task Summary Pop Up	Folder	Requires Reconciliation DDE
Requires Coder Coding		

Close Help Window

Done Internet | Protected Mode: Off 100%

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# Enrollment Forms

- **Forms loaded from OPEN**
  - **Demography**
  - **Step Information**
  - **Subject Enrollment**
  - **Treatment Assignment**

# Demography

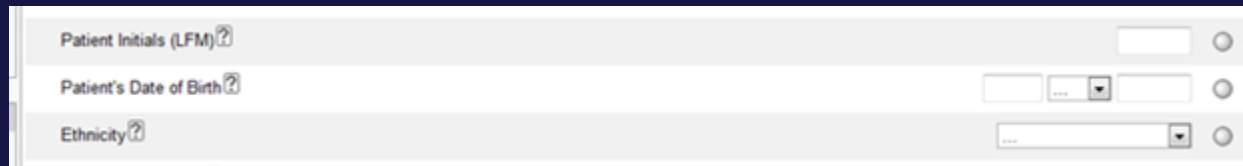
The screenshot displays the Medidata Rave 'Demography' form for subject 003-0229L-003. The form is divided into two main sections: 'Standard Fields' and 'Log Line Fields'. The 'Standard Fields' section includes input fields for Patient Initials (LFM), Patient's Date of Birth, Ethnicity, Gender of a Person, Country of Residence, ZIP Code, and Method of Payment. The 'Log Line Fields' section includes a table for tracking patient information, a section for Patient's Date of Birth (May 05), Ethnicity (Hispanic or Latino, Not Hispanic or Latino, Not reported, Unknown), Country of Residence (US), and a section for Gender of a Person (Female Gender, Male Gender, Unknown). The form also includes a sidebar with navigation links for Enrollment Forms, Demography, Step Information, Subject Enrollment, Treatment Assignment, and Eligibility Checklist. The Medidata Rave logo is visible in the bottom left corner.

**Standard Fields**

**Log Line Fields**

# Terminology Break

## Standard Fields



A screenshot of a web form with three input fields. The first field is labeled "Patient Initials (LFM)" and has a text input box. The second field is labeled "Patient's Date of Birth" and has a date picker. The third field is labeled "Ethnicity" and has a dropdown menu.

## Log Lines



A screenshot of a web form titled "Subject: 003-0229L-003" and "Page: Step Information - Enrollment Forms". It displays a table with six columns: "# Registration Step", "Event Description", "Tracking Number", "Treating Investigator", "Site Registrar", and "Crediting Group". The first row shows a value of "1" in the first column. Below the table, there are links for "Add a new Log line", "Inactivate", "Printable Version", "View PDF", and "Icon Key". At the bottom, it says "CRF Version 58 - Page Generated: 11 Jul 2012 14:52:57 Eastern Daylight Time" and has "Save" and "Cancel" buttons.

# Registration Step	Event Description	Tracking Number	Treating Investigator	Site Registrar	Crediting Group
1					

# Step Information

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DEV

iMedidata Messages My Profile Help Home Logout  
User: Jessalyn Reboj Data Manager

GOG0229L Angela 2 003-0229L-003 Enrollment Forms Step Information

Enrollment Forms  
Demography  
Step Information  
Subject Enrollment  
Treatment Assignment  
Eligibility Checklist

CRF History  
003-0229L-003 - Step Information  
003-0229L-003 - Demography

Subject: 003-0229L-003  
Page: Step Information - Enrollment Forms

Inactivate Page

#	Registration Step?	Event Description?	Tracking Number?	Treating Investigator?	Site Registrar?	Crediting Group?
1						

Add a new Log line Inactivate  
[Printable Version](#) [View PDF](#) [Icon Key](#)  
CRF Version 58 - Page Generated: 11 Jul 2012 14:52:57 Eastern Daylight Time

Save Cancel

This is the rest of the form that you will need to scroll over to enter

medidata Rave

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# Subject Enrollment

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iMedidata Messages My Profile Help Home Logout  
User: Jessalyn Reboy Data Manager

GOG0229L Angela 2 003-0229L-003 Enrollment Forms Subject Enrollment

Enrollment Forms  
Demography  
Step Information  
Subject Enrollment  
Treatment Assignment  
Eligibility Checklist

CRF History  
003-0229L-003 - Subject Enrollment  
003-0229L-003 - Step Information  
003-0229L-003 - Demography

Subject: 003-0229L-003  
Page: Subject Enrollment - Enrollment Forms

Patient ID?

Enrolling Site CTEP ID?

Lead Organization?

Current Site CTEP ID?

Enrollment Date?

Enrollment Time?

Group Data?

Source Application?

Printable Version View PDF Icon K  
CRF Version 58 - Page Generated: 11 Jul 201

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Linking practice to progress

Site: GOG/Gynecologic Oncology Group Site: GROUP\_REG\_ADMIN

Home Enroll History Reports Form Setup Admin Help

Browse Summary **Enrollment** Demography Checklist

Selected Tracking # **92498** Details Summary

Protocol	PID	Initials (LFH)	Step	Arm	Site	Investigator	Status	Status Date
GOG-0229L	814-0229L-113	ABC	1	1	MN008	Bailey, Cheryl	REGISTERED	07/11/2012

**Information**

- Group response for tracking # **92498**
- This registration can now be found in the HISTORY section
- Click on [View Summary] to view the complete registration summary

Group Response(s)	
Eligibility:	ELIGIBLE
Ineligibility Reason:	
Patient ID:	814-0229L-113
Treatment Arm:	1
Site Instruction:	Click <a href="#">here</a> to continue to the patient form schedule on the GOG website.
Node Error Message:	

Please let us know your enrollment experience by completing this [survey](#) which should not take more than 2 minutes!

Save Cancel

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Rave

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# Treatment Assignment

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**DEV**

iMedidata Messages My Profile Help Home Logout  
User: Jessalyn Reboyn Data Manager

GOG0229L Angela 2 003-0229L-003 Enrollment Forms Treatment Assignment

Enrollment Forms  
Demography  
Step Information  
Subject Enrollment  
Treatment Assignment  
Eligibility Checklist

CRF History  
003-0229L-003 - Treatment Assignment  
003-0229L-003 - Subject Enrollment  
003-0229L-003 - Step Information  
003-0229L-003 - Demography

Subject: 003-0229L-003  
Page: Treatment Assignment - Enrollment Forms

Inactivate Page

Event Name	Step No	Event description	Date of Intervention/Treatment Assignment	Event Time
1				

Add a new Log line Inactivate  
[Printable Version](#) [View PDF](#) [Icon Key](#)  
CRF Version 58 - Page Generated: 11 Jul 2012 14:53:54 Eastern Daylight Time

Save Cancel

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Rave

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# Eligibility Checklist

**medidata** DEV

User: Jessalyn Reboy Data Manager

Subject: GOG0229L Angela 2 003-0229L-003 Enrollment Forms Eligibility Checklist

Inactivate Page

Subject:	Page:	Forms								
GOG Institution Code	006	✓								
GOG Affiliate Code	01	✓								
Previous GOG #		✓								
Treating physician		✓								
Other Physician		✓								
Did the patient sign an approved informed consent	YES	✓								
Has HIPAA authorization been obtained	Yes: C49488	✓								
Is the patient eligible for a higher priority GOG protocol	NO	✓								
What is the primary disease site	Endometrium	✓								
What is the cell type?	Serous Adenocarcinoma	✓								
Date of initial histologic diagnosis of malignancy	02 JUN 2011	✓								
What was the grade of the primary tumor	GRADE 3-POORLY DIFFERENTIATED	✓								
Is the disease recurrent or persistent with documented progression? Which one?	Recurrent Disease	✓								

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# Terminology Break

## Folders

## Forms



# Navigation

History

Protocol Patient Form

The screenshot shows a web application interface for clinical trial management. The top navigation bar contains several tabs: a Home icon, a folder icon labeled 'GOG0229L', a person icon labeled 'Angela 2', a person icon labeled '003-0229L-003', a folder icon labeled 'Enrollment Forms', and a document icon labeled 'Eligibility Checklist'. Below this bar, the main content area displays 'Subject: 003-0229L-003' and 'Page: Eligibility Checklist - Enrollment Forms'. On the left side, there is a sidebar menu with two sections: 'Enrollment Forms' containing 'Demography', 'Step Information', 'Subject Enrollment', 'Treatment Assignment', and 'Eligibility Checklist'; and 'CRF History' containing a list of entries for subject '003-0229L-003' including 'Eligibility Checklist', 'Treatment Assignment', 'Subject Enrollment', 'Step Information', and 'Demography'. Several blue arrows point from text labels to specific elements: 'History' points to the 'CRF History' section; 'Home' points to the Home icon in the top bar; 'Institution' points to the 'GOG0229L' folder tab; 'Folder' points to the 'Enrollment Forms' folder tab; and 'Form' points to the 'Eligibility Checklist' document tab.

# Patient's root tab

The screenshot displays the Medidata Rave web application interface within a Windows Internet Explorer browser. The address bar shows the URL: [https://hdcv001-037.mdsol.com/MedidataRave/\(S\(n333vw5bhov2pvks3lmidvm\)\)/Modules/EDC/SubjectPage.aspx?ID=642](https://hdcv001-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pvks3lmidvm))/Modules/EDC/SubjectPage.aspx?ID=642). The browser's Favorites bar is visible with links to 'Subject', 'Favorites', 'Suggested Sites', and 'Web Slice Gallery'. The application header includes the Medidata logo, the text 'DEV', and user information: 'iMedidata', 'Messages', 'My Profile', 'Help', 'Home', 'Logout', and 'User: Jessalyn Reboyn Data Manager'. Below the header, a navigation pane on the left lists '003-0229L-005', 'Enrollment Forms', 'Baseline', and 'Patient Calendar'. A blue arrow points to the 'Enrollment Forms' link. The main content area features a 'Subject Enrollment' link, a table with columns 'Visit' and 'Date', an 'Add Event' dropdown menu, and an 'Add' button. On the right, a 'Task Summary: Subject' section lists various tasks with their respective counts: NonConformant Data (0), Open Queries (0), Answered Queries (0), Requiring Review (0), Overdue Data (0), Ready for Data Lock (1), and Cancel Queries (0). A 'Pages' section on the right includes links for 'Grid View', 'Subject Administration', and 'Subject Sharing'. The footer contains the Medidata Rave logo, a link to 'Click Here for Customer Support Information', and copyright information: 'Medidata Rave® Version 5.6.4.148 Copyright ©1999-2012, Medidata Solutions, Inc.'.

Subject - Windows Internet Explorer

[https://hdcv001-037.mdsol.com/MedidataRave/\(S\(n333vw5bhov2pvks3lmidvm\)\)/Modules/EDC/SubjectPage.aspx?ID=642](https://hdcv001-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pvks3lmidvm))/Modules/EDC/SubjectPage.aspx?ID=642)

File Edit View Favorites Tools Help

Subject

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User: Jessalyn Reboyn Data Manager

003-0229L-005  
Enrollment Forms  
Baseline  
Patient Calendar

Subject Enrollment

Grid View  
Subject Administration  
Subject Sharing

Visit	Date
-------	------

Add Event  Add

Icon Key

CRF Version 61 - Page Generated: 19 Jul 2012 08:53:01 Eastern Daylight Time

Task Summary: Subject

	Pages
NonConformant Data	0
Open Queries	0
Answered Queries	0
Requiring Review	0
Overdue Data	0
Ready for Data Lock	1
Cancel Queries	0

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Internet | Protected Mode: Off

# Baseline Visit Form

CRF - Windows Internet Explorer

https://hdcv001-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pyks3lmidvm))/Modules/EDC/CRFPage.aspx?DP=18542

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User: Jessalyn Reboy Data Manager

GOG0229L Angela 2 003-0229L-005 Baseline Visit Information - Baseline

Baseline  
Visit Information - Baseline  
Registration Form  
Pre-Treatment Summary  
Pre-Study History Information

CRF History  
003-0229L-005 - Visit Information - Baseline

Subject: 003-0229L-005  
Page: Visit Information - Baseline - Baseline

Visit Information

Has the patient had prior surgery

Prior chemotherapy

Did the patient have measurable disease at baseline

Were there any non-target lesions reported at baseline

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Yes No

Yes No

Yes No

Yes No

Save Cancel

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Rave

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100%

# RAVE Registration Form

The screenshot displays the Medidata Rave web application interface. The browser address bar shows the URL: [https://hdcvc101-037.mdsol.com/MedidataRave/\(S\(n333vw5bhov2pvks31midvm\)\)/Modules/EDC/CRFPPage.aspx?DP=18543](https://hdcvc101-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pvks31midvm))/Modules/EDC/CRFPPage.aspx?DP=18543). The application header includes the Medidata logo, the text "DEV", and user navigation links. The sidebar on the left contains a list of navigation options, with "Baseline" and "Visit Information - Baseline" highlighted. The main content area displays the "Registration Form" for subject "003-0229L-005". The form includes fields for "Height in cm", "Weight in kg", "Performance Status (Zubrod)", "Has the patient had any prior cancer diagnosed?", "Prior cancer type", "Prior cancer diagnosis date", and "Brief clinical history". The footer of the application shows the Medidata Rave logo and version information.

# Legacy Registration Form

Data is now located in the enrollment folder

This is what we are left with

GYNECOLOGIC ONCOLOGY GROUP				Registration Form		FORM R	
Date form originally completed m / d / y		Date form amended m / d / y		Person amending form, last name			
Patient Name, Last		Patient Name, First		Patient Study ID		Person Completing Form, Last Name	
<b>TRACKING INFORMATION</b>							
(1) Institution name/affiliate				(4) Patient's date of birth m / d / y			
(2) Treating physician				(5) Patient social security number			
(3) Patient medical record number				(6) Patient zip code (USA)			
				(7) Country of residence (if not USA)			
<b>DEMOGRAPHIC INFORMATION</b>							
(a) Patient race (mark all that apply)				(b) Patient ethnicity (check one)			
<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> Unknown <input type="checkbox"/> White				<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown			
(10) Method of payment				(11) Self pay (no insurance)			
<input type="checkbox"/> Private Insurance <input type="checkbox"/> Medicare <input type="checkbox"/> Medicaid & Medicare <input type="checkbox"/> Military or Veterans Sponsored NOS <input type="checkbox"/> Medicare & Private Insurance <input type="checkbox"/> Military Sponsored (including Champus & Tricare) <input type="checkbox"/> Medicaid <input type="checkbox"/> Veterans Sponsored				<input type="checkbox"/> No means of payment (no insurance) <input type="checkbox"/> Unknown <input type="checkbox"/> Other			
(11) Patient height (cm)				(12) Patient weight (kg)			
(13) Performance status (Zubrod)							
<input type="checkbox"/> 0 = Fully active, able to carry on all pre-disease performance without restriction (Karnofsky 90-100) <input type="checkbox"/> 1 = Restricted in physically strenuous activity, but ambulatory (K 70-80) <input type="checkbox"/> 2 = Ambulatory and capable of all selfcare but unable to carry out any work activities (K 50-60) <input type="checkbox"/> 3 = Capable of only limited selfcare, confined to bed or chair for more than 50% of waking hours (K 30-40) <input type="checkbox"/> 4 = Completely disabled (K 10-20)							
(14) Has the patient had any prior cancer diagnosed? <input type="checkbox"/> No <input type="checkbox"/> Yes							
Prior cancer type							
Prior cancer diagnosis date m / d / y							
<b>BRIEF CLINICAL HISTORY</b>							
<div style="text-align: right;">29886</div> <div style="text-align: center;">GOG Form R ver. 1 (08/04/2008)</div>							

GYNECOLOGIC ONCOLOGY GROUP		Pre-Treatment Summary Form	FORM DR
Date form originally completed <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">m / d / y  <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> </div> <div style="text-align: center;">Date form amended  <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">m / d / y  <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> </div> <div style="text-align: center;">Person amending form, last name  <div style="border: 1px solid black; width: 100px; height: 20px; margin: 0 auto;"></div> </div> </div> </div></div>			
Patient Initials (First, Middle, Last) <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> </div> <div style="text-align: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> </div> </div>	Patient Study ID <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> </div> <div style="text-align: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> </div> </div>	Person Completing Form, Last Name <div style="border: 1px solid black; width: 100px; height: 20px; margin: 0 auto;"></div>	
<b>NON-INVASIVE DIAGNOSTIC PROCEDURES</b>			
<p>(1) Chest X-Ray Result</p> <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Not Done    <input type="checkbox"/> Normal    <input type="checkbox"/> Abnormal, specify _____         </div> <div style="text-align: center;">           m / d / y  <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> </div> </div> <p>(1a) Date of Chest X-Ray</p> <p>(2) EKG Result</p> <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Not Done    <input type="checkbox"/> Normal    <input type="checkbox"/> Abnormal, specify _____         </div> <div style="text-align: center;">           m / d / y  <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> </div> </div> <p>(2a) Date of EKG</p> <p>(3) MRI Result</p> <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Not Done    <input type="checkbox"/> Normal    <input type="checkbox"/> Abnormal, specify _____         </div> <div style="text-align: center;">           m / d / y  <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> </div> </div> <p>(3a) Date of MRI</p> <p>(4) CT Result</p> <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Not Done    <input type="checkbox"/> Normal    <input type="checkbox"/> Abnormal, specify _____         </div> <div style="text-align: center;">           m / d / y  <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> </div> </div> <p>(4a) Date of CT Scan</p> <p>(5) Other Procedure Performed, specify _____</p> <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Not Done    <input type="checkbox"/> Normal    <input type="checkbox"/> Abnormal, specify _____         </div> <div style="text-align: center;">           m / d / y  <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div> </div> </div> <p>(5a) Procedure Date</p> <p>(6) Are there any target lesions?    <input type="checkbox"/> No    <input type="checkbox"/> Yes (complete the BDR form if required by the protocol)</p>			
<b>COMMENTS</b>			

GOG Form DR v.5 (10/15/2007)

22774



# RAVE Pre-Treatment Summary

CRF - Windows Internet Explorer

https://hdcvc01-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pvks31midvm))/Modules/EDC/CRFPage.aspx?DP=18544

File Edit View Favorites Tools Help

CRF

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User: Jessalyn Reboj Data Manager

GOG0229L Angela 2 003-0229L-005 Baseline Pre-Treatment Summary

Baseline

- Visit Information - Baseline
- Registration Form
- Pre-Treatment Summary
- Pre-Study History Information
- Pre-Study History Primary Surgery
- Pre-Study History Chemotherapy Information
- Body Diagram Report
- Solid Tumor Evaluation Target Lesions
- Solid Tumor Evaluation Non-Target Lesions

CRF History

- 003-0229L-005 - Pre-Treatment Summary
- 003-0229L-005 - Registration Form
- 003-0229L-005 - Visit Information - Baseline

Subject: 003-0229L-005  
Page: Pre-Treatment Summary - Baseline

Pre-Treatment Summary

Non-Invasive Diagnostic Procedures

#	Procedure performed	Procedure result	Procedure Date	
1	Chest X-Ray	...	...	
2	EKG	...	...	
3	MRI	...	...	
4	CT	...	...	
5	Chest CT	...	...	

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Save Cancel

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Key data

Hit Save

# RAVE Pre-Treatment Summary

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https://hdcvcl01-037.mdsol.com/MedidataRave/(S(fp5laiyzer1f5jz2shsozj5))/Modules/EDC/CRFPage.aspx?DP=18544

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User: Jessalyn Reboy Data Manager

GOG0229L Angela 2 003-0229L-005 Baseline Pre-Treatment Summary

Baseline

- Visit Information - Baseline
- Registration Form
- Pre-Treatment Summary
- Pre-Study History Information
- Pre-Study History Primary Surgery
- Pre-Study History Chemotherapy Information
- Body Diagram Report
- Solid Tumor Evaluation Target Lesions
- Solid Tumor Evaluation Non-Target Lesions

CRF History

- 003-0229L-005 - Pre-Treatment Summary
- 003-0229L-005 - Visit Information - Baseline

Subject: 003-0229L-005  
Page: Pre-Treatment Summary - Baseline

Inactivate Page

Pre-Treatment Summary

Non-Invasive Diagnostic Procedures

#	Procedure performed	Procedure result	Procedure Date	
1	Chest X-Ray	Not done		<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	EKG	Normal	25 JUN 2012	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	MRI	Not done		<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4	CT	Normal	20 JUN 2012	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5	Chest CT	Normal	20 JUN 2012	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

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Save Cancel

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CRFPage.aspx?DP=18544

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Saved

# Edit a Row in a Log Line

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https://hdcvc01-037.mdsol.com/MedidataRave/(S(fp5laiy0r1f5j2shsoj5))/Modules/EDC/CRFPage.aspx?DP=18544

File Edit View Favorites Tools Help

CRF

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User: Jessalyn Reboj Data Manager

GOG0229L Angela 2 003-0229L-005 Baseline Pre-Treatment Summary

Baseline  
Visit Information - Baseline  
Registration Form  
Pre-Treatment Summary  
Pre-Study History Information  
Pre-Study History Primary Surgery  
Pre-Study History Chemotherapy Information  
Body Diagram Report  
Solid Tumor Evaluation Target Lesions  
Solid Tumor Evaluation Non-Target Lesions

CRF History  
003-0229L-005 - Pre-Treatment Summary  
003-0229L-005 - Visit Information - Baseline

Subject: 003-0229L-005  
Page: Pre-Treatment Summary - Baseline

Inactivate Page

Pre-Treatment Summary

Non-Invasive Diagnostic Procedures

#	Procedure performed	Procedure result	Procedure Date	
1	Chest X-Ray	Not done		
2	EKG	Normal	25 JUN 2012	
3	MRI	Not done		
4	CT	Normal	20 JUN 2012	
5	Chest CT	Normal	20 JUN 2012	

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CRFPage.aspx?DP=18544

Internet | Protected Mode: Off

Edit one line

# Open/Edit an entire log line field

On-Study

Edit multiple lines

CRF - Windows Internet Explorer

https://hdcvcl01-037.mdsol.com/MedidataRave/(S(fp5laiyzo1f5jz2shsozj5))/Modules/EDC/CRFPage.aspx?DP=18544

File Edit View Favorites Tools Help

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User: Jessalyn Reboy Data Manager

GOG0229L Angela 2 003-0229L-005 Baseline Pre-Treatment Summary

Subject: 003-0229L-005  
Page: Pre-Treatment Summary - Baseline

Pre-Treatment Summary

Non-Invasive Diagnostic Procedures

#	Procedure performed	Procedure result	Procedure Date	
1	Chest X-Ray	Not done		✓ ✎ 📄 📅 📁
2	EKG	Normal	25 JUN 2012	✓ ✎ 📄 📅 📁
3	MRI	Not done		✓ ✎ 📄 📅 📁
4	CT	Normal	20 JUN 2012	✓ ✎ 📄 📅 📁
5	Chest CT	Normal	20 JUN 2012	✓ ✎ 📄 📅 📁

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Save Cancel

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CRF History

- 003-0229L-005 - Pre-Treatment Summary
- 003-0229L-005 - Visit Information - Baseline

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CRFPage.aspx?DP=18544

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# RAVE Pre-Treatment Summary

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GOG0229L Angela 2 003-0229L-005 Baseline Pre-Treatment Summary

Baseline

Visit Information - Baseline

Registration Form

Pre-Treatment Summary

Pre-Study History Information

Pre-Study History Primary Surgery

Pre-Study History Chemotherapy Information

Body Diagram Report

Solid Tumor Evaluation Target Lesions

Solid Tumor Evaluation Non-Target Lesions

CRF History

003-0229L-005 - Pre-Treatment Summary

003-0229L-005 - Registration Form

003-0229L-005 - Visit Information - Baseline

Subject: 003-0229L-005

Page: Pre-Treatment Summary - Baseline

Inactivate Page

Pre-Treatment Summary

Non-Invasive Diagnostic Procedures

#	Procedure performed	Procedure result	Procedure Date	
1	Chest X-Ray	...	...	
2	EKG	...	...	
3	MRI	...	...	
4	CT	...	...	
5	Chest CT	...	...	

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Save Cancel

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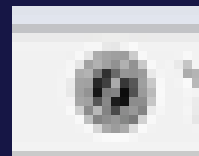
100%

Key data







Hit Save

# A Log Line Terminology Break

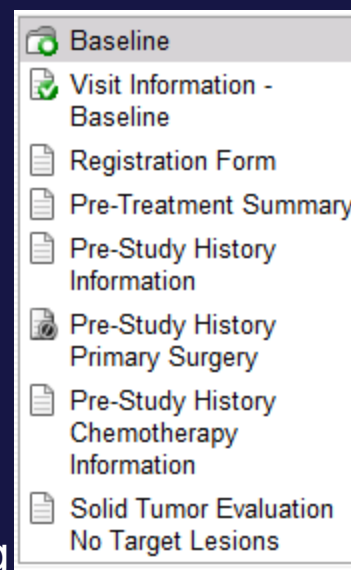
## Inactive



Note, on line #1 you see a strikethrough of the word ~~GASTRITIS~~, and you also see the “Inactivated” Icon

#	CTCAE Ter...	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	AE Attribution Code	SAE report submitted	
1	<del>GASTRITIS</del>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			 
2	DIZZINESS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	UNRELATED		 
3	DYSPNEA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			 

Also note that **forms** can become inactive. This may occur when on the visit form, a question was answered rolling out at form and later that answer was changed and thus making that form inactive.



# Uploading a file/image

The screenshot shows the Medidata Rave web application interface. The browser address bar displays the URL: [https://hdcvcl01-037.mdsol.com/MedidataRave/\(S\(fp5laiyzer1f5jz2shsozj5\)\)/Modules/EDC/CRFPage.aspx?DP=18544](https://hdcvcl01-037.mdsol.com/MedidataRave/(S(fp5laiyzer1f5jz2shsozj5))/Modules/EDC/CRFPage.aspx?DP=18544). The page title is "CRF - Windows Internet Explorer". The Medidata logo and "DEV" status are visible at the top. The user is logged in as "User: Jessalyn Reboj Data Manager". The left sidebar contains a navigation menu with the following items: Baseline, Visit Information - Baseline, Registration Form, Pre-Treatment Summary, Pre-Study History Information, Pre-Study History Primary Surgery, Pre-Study History Chemotherapy Information, Body Diagram Report, Solid Tumor Evaluation Target Lesions, and Solid Tumor Evaluation Non-Target Lesions. The main content area displays the "Pre-Treatment Summary" for Subject: 003-0229L-005. The page is titled "Page: Pre-Treatment Summary - Baseline". Below this, there is a section for "Non-Invasive Diagnostic Procedures" with a table listing five procedures. A blue arrow points to the "Body Diagram Report" link in the left sidebar.

#	Procedure performed	Procedure result	Procedure Date	
1	Chest X-Ray	Not done		✓
2	EKG	Normal	25 JUN 2012	✓
3	MRI	Not done		✓
4	CT	Normal	20 JUN 2012	✓
5	Chest CT	Normal	20 JUN 2012	✓

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CRF Version: 61 - Page Generated: 19 Jul 2012 12:14:48 Eastern Daylight Time

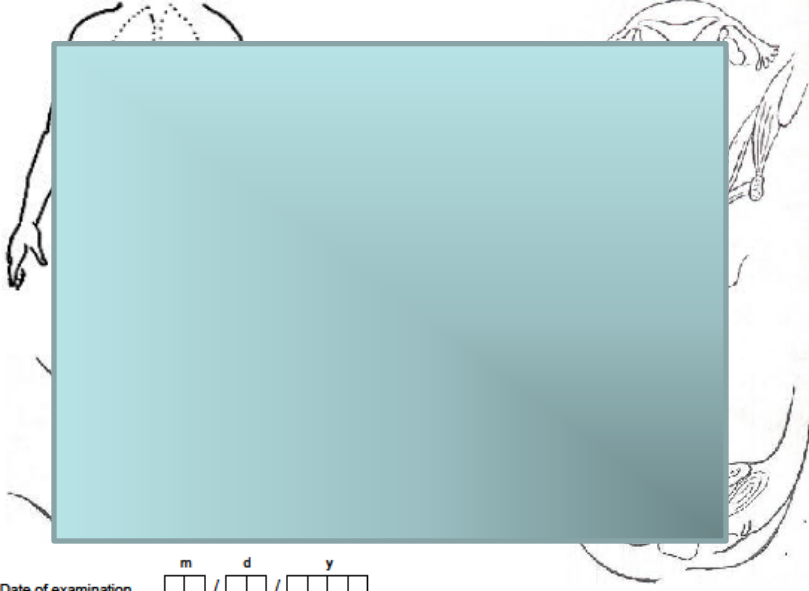
Save Cancel

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# Body Diagram Form

Access the form  
through SEDES forms  
link

Print, complete and  
scan for upload

GYNECOLOGIC ONCOLOGY GROUP		Body Diagram Form	FORM BDR
Date form originally completed m / d / y		Date form amended m / d / y	
Person amending form, last name			
Patient Initials (First, Middle, Last)	Patient Study ID	Person Completing Form, Last Name	
<b>BODY DIAGRAM</b>			
Instruction: If submitting a corresponding D2M, label the sketch with the corresponding target lesion number(s).			
			
(1) Date of examination. m / d / y			
<b>COMMENTS</b>			
GOG Form BDR v.1 (12/27/2004)			



CRF - Windows Internet Explorer

https://hdcvc01-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pvks31midvm))/Modules/EDC/CRFPage.aspx?DP=18557

File Edit View Favorites Tools Help

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User: Jessalyn Reboy Data Manager

GOG0229L Angela 2 003-0229L-005 Baseline Body Diagram Report

Baseline

Visit Information - Baseline

Registration Form

Pre-Treatment Summary

Pre-Study History Information

Pre-Study History Primary Surgery

Pre-Study History Chemotherapy Information

Body Diagram Report

Solid Tumor Evaluation Target Lesions

Solid Tumor Evaluation Non-Target Lesions

CRF History

003-0229L-005 - Body Diagram Report

003-0229L-005 - Pre-Study History Chemotherapy Information

003-0229L-005 - Pre-Study History Primary Surgery

003-0229L-005 - Pre-Study History Information

003-0229L-005 - Pre-Treatment Summary

003-0229L-005 - Registration Form

003-0229L-005 - Visit Information - Baseline

Subject: 003-0229L-005  
Page: Body Diagram Report - Baseline

INACTIVATE PAGE

BODY DIAGRAM REPORT

Date of examination

Comments

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CRF Version 61 - Page Generated: 19 Jul 2012 08:55:41 Eastern Daylight Time

Browse...

Save Cancel

Normal method of browsing your computer for a file to upload.

Operative reports, pathology reports and any other upload... will follow the same method

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Done

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100%

Operative reports,  
pathology reports  
and any other  
upload... will follow  
the same method

# Body Diagram Form

CRF - Windows Internet Explorer

https://hdcvcl01-037.mdsol.com/MedidataRave/(S(p24wtvqkk4oaxjs244g4x5x))/Modules/EDC/CRFPage.aspx?DP=18557

File Edit View Favorites Tools Help

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GOG0229L Angela 2 003-0229L-005 Baseline Body Diagram Report

Baseline

- Visit Information - Baseline
- Registration Form
- Pre-Treatment Summary
- Pre-Study History Information
- Pre-Study History Primary Surgery
- Pre-Study History Chemotherapy Information
- Body Diagram Report
- Solid Tumor Evaluation Target Lesions
- Solid Tumor Evaluation Non-Target Lesions

CRF History

- 003-0229L-005 - Body Diagram Report
- 003-0229L-005 - Pre-Treatment Summary
- 003-0229L-005 - Visit Information - Baseline

Printable PDF Version

Subject: Body\_Diagram\_Form[1].pdf - Adobe Reader

Page: 1 / 1

100%

Tools Sign Comment

Click on Tools to convert PDF documents to Word or Excel.

GYNECOLOGIC ONCOLOGY GROUP

Body Diagram Form FORM BBR

Date form originally completed: [ ] / [ ] / [ ] Date form amended: [ ] / [ ] / [ ] Person amending form, last name: [ ]

Patient Initials (First, Middle, Last): [ ] Patient Study ID: 000-0229-006 L Person Completing Form, Last Name: Reboy

BODY DIAGRAM

Instruction: If submitting a corresponding D2M, label the sketch with the corresponding target lesion number(s).

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# Upload in a Table Field

Page: Form or Report Upload - Pathology

#	Please select the form or report type being uploaded	Method of submission	Date of upload	Upload document
1	KRAS Report	<div>...</div>	<div>...</div>	<div>Browse...</div>
2	Primary Surgical Procedure Pathology Report	<div>Electronic upload</div> <div>Postal mail</div> <div>Not available</div>	<div>...</div>	<div>Browse...</div>

# Specimen Consent

The screenshot shows the eCRF system interface. The top navigation bar includes icons for Home, GOG-02290, CTSUTST01, 814-02290-021, Baseline, and Specimen Consent. The left sidebar shows the 'Specimen Consent' form selected. The main content area displays the consent text and a 'Yes' response with a green checkmark. A red arrow points to the 'Translation Research' folder in the sidebar, which is highlighted. A red arrow points to the 'Save' button.

# Translation Research (TR) Form

TR FFPE primary tumor

Translational Research - FP01

CRF History

814-02290-021 - Translational Research - FP01

814-02290-021 - Translational Research - FM01

814-02290-021 - Visit Information - Baseline

814-02290-021 - Specimen Consent

000-02290-203 - Visit Information - Baseline

000-02290-203 - Specimen Consent

000-02290-203 - Form or Report Upload

MELISSA 2.7 - Visit Information - Baseline

JESSALYN 4.3 - Specimen Consent

JESSALYN 4.3 - Visit Information - Baseline

814-02290-176 - Visit

Subject: 814-02290-021

Page: Translational Research - FP01 - TR FFPE primary tumor

PDF File:

Browse...

Translational Research Form

Specimen Information

Specimen Code

FP01

Time point

FFPE PRIMARY TUMOR

Collected

☐ Yes ☐ No

If not collected, specify reason

Contact Information

Blood Products

Tissue

Items shipped

Shipping Information

Receiving Information

Questions will not appear until after the Collected question is answered with a Yes. If No, then the form remains as is.

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Save Cancel

# TR Form Video

Page: Translational Research - WB01 - TR Whole blood

PDF File:  No file selected.

## Translational Research Form

[Specimen Information](#)

Specimen Code: WB01 ☒ ☐

Time point: WHOLE BLOOD ☒ ☐

Collected: ☐ Yes ☐ No ☐

If not collected, specify reason:  ☐

[Contact Information](#)

[Blood Products](#)

[Tissue](#)

[Items shipped](#)

[Shipping Information](#)

[Receiving Information](#)

[Printable Version](#) [View PDF](#) [Icon Key](#)

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# Back to the Patient Level

There is now a  
Visit Folder

History of where  
we've been

The screenshot displays the Medidata Rave web application interface for a specific subject, 003-0229L-005. The browser window shows the URL: [https://hdcvcl01-037.mdsol.com/MedidataRave/\(S\(n333vw5bhov2pvks31midivm\)\)/Modules/EDC/SubjectPage.aspx?ID=642](https://hdcvcl01-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pvks31midivm))/Modules/EDC/SubjectPage.aspx?ID=642). The application header includes the Medidata logo, the text "DEV", and user information: "User: Jessalyn Reboy Data Manager".

The left sidebar contains a "Visit Folder" and a "CRF History" section. The "Visit Folder" is highlighted with a blue arrow pointing to it from the text "There is now a Visit Folder". The "CRF History" section lists various CRF forms, with the first two items highlighted by a blue arrow pointing to them from the text "History of where we've been".

The main content area shows the "Subject Enrollment" section with a table of visits. The table has columns for "Visit" and "Date". The first row shows "Baseline". Below the table is an "Add Event" button. To the right of the table is a "Task Summary: Subject" section with a table of tasks and their counts.

Task	Pages
NonConformant Data	0
Open Queries	0
Answered Queries	0
Requiring Review	0
Overdue Data	0
Ready for Data Lock	2
Cancel Queries	0

The footer of the application includes the Medidata Rave logo, a link to "Click Here for Customer Support Information", and version information: "Medidata Rave® Version 5.6.4.146 Copyright ©1999-2012, Medidata Solutions, Inc."

# Visit Driver Form

Only the “Driver”  
form exists at first.



CRF - Windows Internet Explorer  
https://hdcvcl01-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pyks31midivm))/Modules/EDC/CRFPage.aspx?DP=18552

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User: Jessalyn Reboj Data Manager

GOG0229L Angela 2 003-0229L-005 Visit 1 Visit Information

Visit 1  
Visit Information

CRF History

- 003-0229L-005 - Visit Information
- 003-0229L-005 - Solid Tumor Evaluation Non-Target Lesions
- 003-0229L-005 - Solid Tumor Evaluation Target Lesions
- 003-0229L-005 - Body Diagram Report
- 003-0229L-005 - Pre-Study History Chemotherapy Information
- 003-0229L-005 - Pre-Study History Primary Surgery
- 003-0229L-005 - Pre-Study History Information
- 003-0229L-005 - Pre-Treatment Summary
- 003-0229L-005 - Registration Form
- 003-0229L-005 - Visit Information - Baseline

Subject: 003-0229L-005  
Page: Visit Information - Visit 1

Inactivate Page

### Visit Information

#### Disease Evaluation

Were the target lesions measured on this evaluation? ☒ Yes ☐ No ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

Were the nontarget lesions assessed on this evaluation? ☐ Yes ☐ No ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

Was the appearance of any new lesions documented? ☐ Yes ☐ No ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

#### Treatment Information

Was treatment given during this cycle? ☐ Yes ☐ No ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

Cycle Start Date?  ...  ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

Cycle Delayed? ☐ Yes ☐ No ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

Number of days treatment cycle was delayed?  ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

Cycle delayed reason  ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

Was treatment permanently discontinued during this cycle? ☐ Yes ☐ No ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

#### Laboratory assessment

Has the pre-treatment blood pressure been recorded? ☐ Yes ☐ No ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

Were pre-treatment labs and chemistries collected? ☐ Yes ☐ No ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

Labs assessment date  ...  ☐ P ☐ I ☐ M ☐ A ☐ R ☐ S

#### Toxicity assessment

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# Visit Driver form - completed

All of this information is required for this visit

Answered Yes to everything but:

Cycle Delayed

And

Rx discontinued

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https://hdcvcl01-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pyks31midivm))/Modules/EDC/CRFPage.aspx?DP=18552

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User: Jessalyn Reboj Data Manager

GOG0229L Angela 2 003-0229L-005 Visit 1 Visit Information

Visit 1

Visit Information

Lab and Chemistries

Blood Pressure Information

Solid Tumor Evaluation Target Lesions

Solid Tumor Evaluation Non-Target Lesions

Solid Tumor Evaluation New Target Lesions

Solid Tumor Evaluation Status and Response

Cycle Patient Information

Cycle Drug Information

Toxicity Report - Section 1

Toxicity Report - NADIRS

Toxicity Report - AEs

Toxicity Report - Aes Complete

Toxicity Report - Aes Complete

CRF History

003-0229L-005 - Visit Information

003-0229L-005 - Solid Tumor Evaluation Non-Target Lesions

003-0229L-005 - Solid Tumor Evaluation Target Lesions

The form has been submitted.

Subject: 003-0229L-005

Page: Visit Information - Visit 1

Visit Information

Disease Evaluation

Were the target lesions measured on this evaluation?

Yes

Were the nontarget lesions assessed on this evaluation?

Yes

Was the appearance of any new lesions documented?

Yes

Treatment Information

Was treatment discontinued during this cycle?

Yes

Cycle Start Date?

05 JUL 2012

Cycle Delayed?

No

Number of days treatment cycle was delayed?

Cycle delayed reason

Was treatment permanently discontinued during this cycle?

No

Laboratory assessment

Has the pre-treatment blood pressure been recorded

Yes

Were pre-treatment labs and chemistries collected?

Yes

Labs assessment date

03 JUL 2012

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# ICON Break

Incomplete

The Visit Folder's information has missing data, obviously.

There is a new form that has some pre-filled information "Labs and Chemistries"

Completed

The Visit Information Form, the "driver form" has all information completed.

Not Touched

No Information as of yet

Visit 1

Visit Information

Labs and Chemistries

Blood Pressure Information

Solid Tumor Evaluation Target Lesions

Solid Tumor Evaluation Non-Target Lesions

Solid Tumor Evaluation New Target Lesions

Solid Tumor Evaluation Status and Response

Cycle Patient Information

Cycle Drug Information

Toxicity Report - Section 1

Toxicity Report - NCICTPS

Visit 1

Visit Information

DEV

003-0229L-005

# Labs & Chemistries

Laboratory assessment	
Has the pre-treatment blood pressure been recorded	Yes <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Were pre-treatment labs and chemistries collected? 	Yes <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Labs assessment date	03 JUL 2012 <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Toxicity assessment	

Laboratory and Chemistries Values				
#	Lab Test	Lab Value	Lab Test Units	Sample Collection Date
1	BLOOD LEUKOCYTE COUNT	<input type="text"/>	UL	3 JUL 2012
2	HEMOGLOBIN, BLOOD	<input type="text"/>	G/DL	3 JUL 2012
3	HEMATOCRIT, (PERCENTAGE), BLOOD	<input type="text"/>	%	3 JUL 2012
4	BLOOD PLATELETS	<input type="text"/>	UL	3 JUL 2012
5	ABSOLUTE NEUTROPHIL COUNT	<input type="text"/>	UL	3 JUL 2012
6	PROTHROMBIN TIME	<input type="text"/>	S	3 JUL 2012
7	PARTIAL THROMBOPLASTIN TIME	<input type="text"/>	S	3 JUL 2012
8	INTERNATIONAL NORMALIZED RATIO (INR), PROTHROMBIN TIME, BLOOD	<input type="text"/>	{NA}	3 JUL 2012
9	ALBUMIN, SERUM	<input type="text"/>	G/DL	3 JUL 2012
10	SERUM TOTAL BILIRUBIN	<input type="text"/>	MG/DL	3 JUL 2012
11	ALKALINE PHOSPHATASE, SERUM	<input type="text"/>	[IU]/L	3 JUL 2012
12	SERUM BLOOD UREA	<input type="text"/>	MG/DL	3 JUL 2012
13	CALCIUM, SERUM	<input type="text"/>	MG/DL	3 JUL 2012
14	BICARBONATE	<input type="text"/>	MG/DL	3 JUL 2012
15	CHLORIDE, SERUM	<input type="text"/>	MEQ/L	3 JUL 2012
16	CREATININE, SERUM	<input type="text"/>	MG/DL	3 JUL 2012
17	MAGNESIUM, SERUM	<input type="text"/>	MG/DL	3 JUL 2012
18	PHOSPHATE (INORGANIC PHOSPHORUS), SERUM	<input type="text"/>	MG/DL	3 JUL 2012
19	POTASSIUM, SERUM	<input type="text"/>	MEQ/L	3 JUL 2012
20	PROTEIN-CREATININE RATIO, URINE	<input type="text"/>	{NA}	3 JUL 2012
21	24 HOURS URINE CREATININE CLEARANCE	<input type="text"/>	ML/MIN	3 JUL 2012
22	PROTEIN, 24 HOUR, URINE	<input type="text"/>	MG/24.H	3 JUL 2012
23	SERUM ASPARTATE AMINOTRANSFERASE (AST OR SGOT)	<input type="text"/>	[IU]/L	3 JUL 2012
24	SERUM ALANINE AMINOTRANSFERASE (ALT OR SGPT)	<input type="text"/>	[IU]/L	3 JUL 2012
25	SODIUM, SERUM	<input type="text"/>	MEQ/L	3 JUL 2012
26	HEMOGLOBIN (HGB) A1C, BLOOD	<input type="text"/>	G/DL	3 JUL 2012
27	GLUCOSE, FASTING, SERUM	<input type="text"/>	MG/DL	3 JUL 2012

# Labs & Chemistries

Remove pre-filled lab dates for labs/chemistries not done

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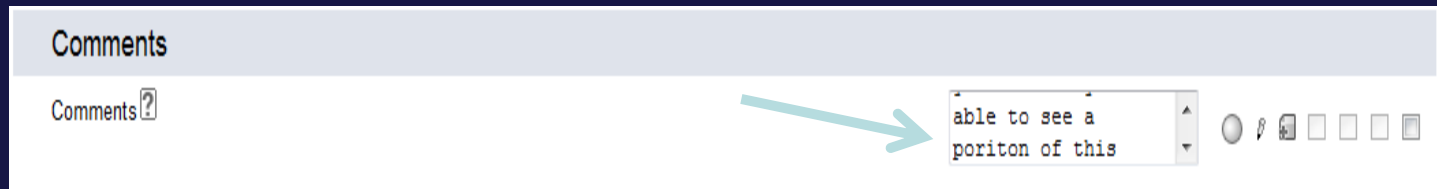
Save Cancel

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Laboratory and Chemistries Values					
#	Lab Test	Lab Value	Lab Test Units	Sample Collection Date	
1	BLOOD LEUKOCYTE COUNT	1233	UL	3 JUL 2012	
2	HEMOGLOBIN, BLOOD	New Information 12345	G/DL	3 JUL 2012	
<b>Lab Value</b> ? Value given is not within the acceptable range of ] [5] - [18.9] Opened To Site from System (26 Jan 2014) <input type="checkbox"/> Cancel					
3	HEMATOCRIT, (PERCENTAGE), BLOOD	New Information 12345	%	3 JUL 2012	
<b>Lab Value</b> ? Value given is not within the acceptable range of ] [15.0] - [54.9] Opened To Site from System (26 Jan 2014) <input type="checkbox"/> Cancel					
4	BLOOD PLATELETS		UL		
5	ABSOLUTE NEUTROPHIL COUNT	12345	UL	3 JUL 2012	
6	PROTHROMBIN TIME		S		
7	PARTIAL THROMBOPLASTIN TIME		S		

# A Note about comments

## During entry

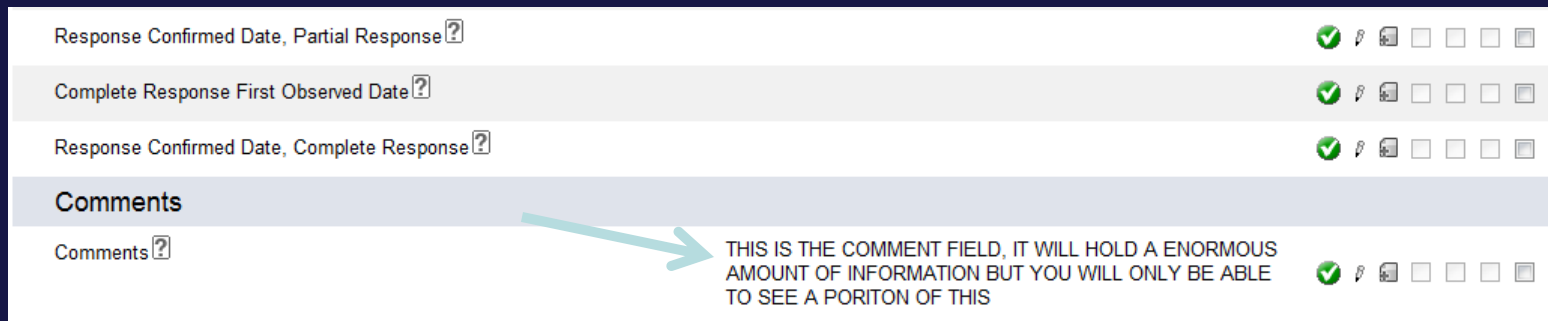


Comments

Comments?

able to see a  
poriton of this

## After saving



Response Confirmed Date, Partial Response?

Complete Response First Observed Date?

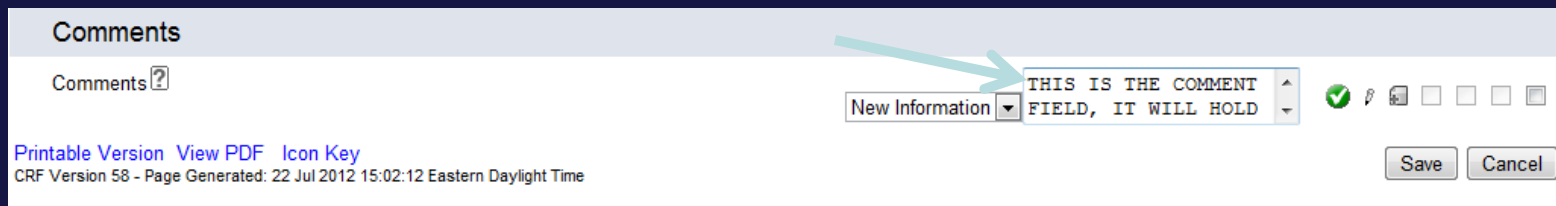
Response Confirmed Date, Complete Response?

Comments

Comments?

THIS IS THE COMMENT FIELD, IT WILL HOLD A ENORMOUS  
AMOUNT OF INFORMATION BUT YOU WILL ONLY BE ABLE  
TO SEE A PORTION OF THIS

## Edit saved information



Comments

Comments?

New Information

THIS IS THE COMMENT  
FIELD, IT WILL HOLD

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Save Cancel



# Errors and Queries

These are the colors that will indicate if a question has an error.

The different shades do not indicate level of severity but to differentiate lines

Examples are:

- missing required fields,
- future dates,
- date ranges,
- value ranges,
- questions that depend on previous answers.

# Required Fields

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GOG0229L Angela 2 003-0229L-005 Visit 1 Solid Tumor Evaluation Status and Response

Visit 1

- Visit Information
- Labs and Chemistries
- Blood Pressure Information
- Solid Tumor Evaluation Target Lesions
- Solid Tumor Evaluation Non-Target Lesions
- Solid Tumor Evaluation New Target Lesions
- Solid Tumor Evaluation Status and Response
- Cycle Patient Information
- Cycle Drug Information
- Toxicity Report - Section 1
- Toxicity Report - NADIRS
- Toxicity Report - AEs
- Toxicity Report - Aes Complete
- Toxicity Report - Aes Complete v2

CRF History

- 003-0229L-005 - Solid Tumor Evaluation Status and Response
- 003-0229L-005 - Blood Pressure Information
- 003-0229L-005 - Visit Information

Subject: 003-0229L-005  
Page: Solid Tumor Evaluation Status and Response - Visit 1

Inactivate Page

### DISEASE STATUS AND OVERALL BEST RESPONSE

Time point response ?  
? This field is required. Please complete.  
Opened To Site from System (19 Jul 2012) Cancel

Overall best confirmed response ?  
? This field is required. Please complete.  
Opened To Site from System (19 Jul 2012) Cancel

Overall best unconfirmed response ?  
? This field is required. Please complete.  
Opened To Site from System (19 Jul 2012) Cancel

Partial Response First Observed Date ?

Response Confirmed Date, Partial Response ?

Complete Response First Observed Date ?

Response Confirmed Date, Complete Response ?

### Comments

Comments ?

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# Across Field Checks

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GOG0229L Angela 2 003-0229L-005 Visit 1 Solid Tumor Evaluation Status and Response

Visit 1

- Visit Information
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- Toxicity Report - AEs
- Toxicity Report - Aes Complete
- Toxicity Report -Aes Complete v2

CRF History

- 003-0229L-005 - Solid Tumor Evaluation Status and Response
- 003-0229L-005 - Visit Information
- 003-0229L-005 - Blood Pressure Information

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Subject: 003-0229L-005  
Page: Solid Tumor Evaluation Status and Response - Visit 1

DISEASE STATUS AND OVERALL BEST RESPONSE

Time point response ?  
? This field is required. Please complete.  
Opened To Site from System (19 Jul 2012) Cancel

Overall best confirmed response ?  
Complete Response ✓

Overall best unconfirmed response ?  
? This field is required. Please complete.  
Opened To Site from System (19 Jul 2012) Cancel

Partial Response First Observed Date ?  
Response Confirmed Date, Partial Response ?

Complete Response First Observed Date ?  
? STE\_ESR002: A confirmed or unconfirmed complete response was reported. Please enter the Complete Response first observed date.  
Opened To Site from System (19 Jul 2012) Cancel

Response Confirmed Date, Complete Response ?  
? STE\_ESR001: A confirmed complete response was reported. Please enter the Complete Response first confirmed date.  
Opened To Site from System (19 Jul 2012) Cancel

Comments

Comments ?

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# Future Dates

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GOG0229L Angela 2 003-0229L-005 Visit 1 Solid Tumor Evaluation Status and Response

Visit 1

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- Toxicity Report - Aes Complete
- Toxicity Report -Aes Complete v2

CRF History

- 003-0229L-005 - Solid Tumor Evaluation Status and Response
- 003-0229L-005 - Visit Information
- 003-0229L-005 - Blood Pressure Information

Subject: 003-0229L-005  
Page: Solid Tumor Evaluation Status and Response - Visit 1

DISEASE STATUS AND OVERALL BEST RESPONSE

Time point response?	Partial Response	✓							
Overall best confirmed response?	Complete Response	✓							
Overall best unconfirmed response?	Complete Response	✓							
Partial Response First Observed Date?		✓							
Response Confirmed Date, Partial Response?		✓							
Complete Response First Observed Date?	20 JUL 2012	?							
? Future date has been entered. Please correct. Opened To Site from System (19 Jul 2012) Cancel									
Response Confirmed Date, Complete Response?	20 JUL 2012	?							
? STE_ESR009: The confirmed Complete Response Date is less than 28 days after the first observed complete response date, please reconcile. Opened To Site from System (19 Jul 2012) Cancel									
? Future date has been entered. Please correct. Opened To Site from System (19 Jul 2012) Cancel									

Comments

Comments?

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# Date Ranges

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User: Jessalyn Rebo Data Manager

GOG0229L Angela 2 003-0229L-005 Visit 1 Solid Tumor Evaluation Status and Response

Visit 1

- Visit Information
- Labs and Chemistries
- Blood Pressure Information
- Solid Tumor Evaluation Target Lesions
- Solid Tumor Evaluation Non-Target Lesions
- Solid Tumor Evaluation New Target Lesions
- Solid Tumor Evaluation Status and Response
- Cycle Patient Information
- Cycle Drug Information
- Toxicity Report - Section 1
- Toxicity Report - NADIRS
- Toxicity Report - AEs
- Toxicity Report - Aes Complete
- Toxicity Report - Aes Complete v2

CRF History

- 003-0229L-005 - Solid Tumor Evaluation Status and Response
- 003-0229L-005 - Visit Information
- 003-0229L-005 - Blood Pressure Information

medidata Rave

Subject: 003-0229L-005  
Page: Solid Tumor Evaluation Status and Response - Visit 1

Inactivate Page

**DISEASE STATUS AND OVERALL BEST RESPONSE**

Time point response?	Partial Response	✓	?						
Overall best confirmed response?	Complete Response	✓	?						
Overall best unconfirmed response?	Complete Response	✓	?						
Partial Response First Observed Date?		✓	?						
Response Confirmed Date, Partial Response?		✓	?						
Complete Response First Observed Date?	20 JUN 2012	✓	?						
Response Confirmed Date, Complete Response?	20 JUN 2012	?	?						

? STE\_ESR009: The confirmed Complete Response Date is less than 28 days after the first observed complete response date, please reconcile.  
Opened To Site from System (19 Jul 2012) Cancel

Comments

Comments?

Printable Version View PDF Icon Key  
CRF Version 61 - Page Generated: 19 Jul 2012 12:44:53 Eastern Daylight Time

Save Cancel

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Done

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100%

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THE END