

**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!!!

*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>

**i medidata**

Language English

**Sign In**

- [iMedidata](#)
- [NXT IdP](#)
- [NXT QA IdP](#)
- [NXT Training IdP](#)
- [Mayo IdP](#)
- [CTEP-IAM IdP](#)

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.

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Our m  
insight  
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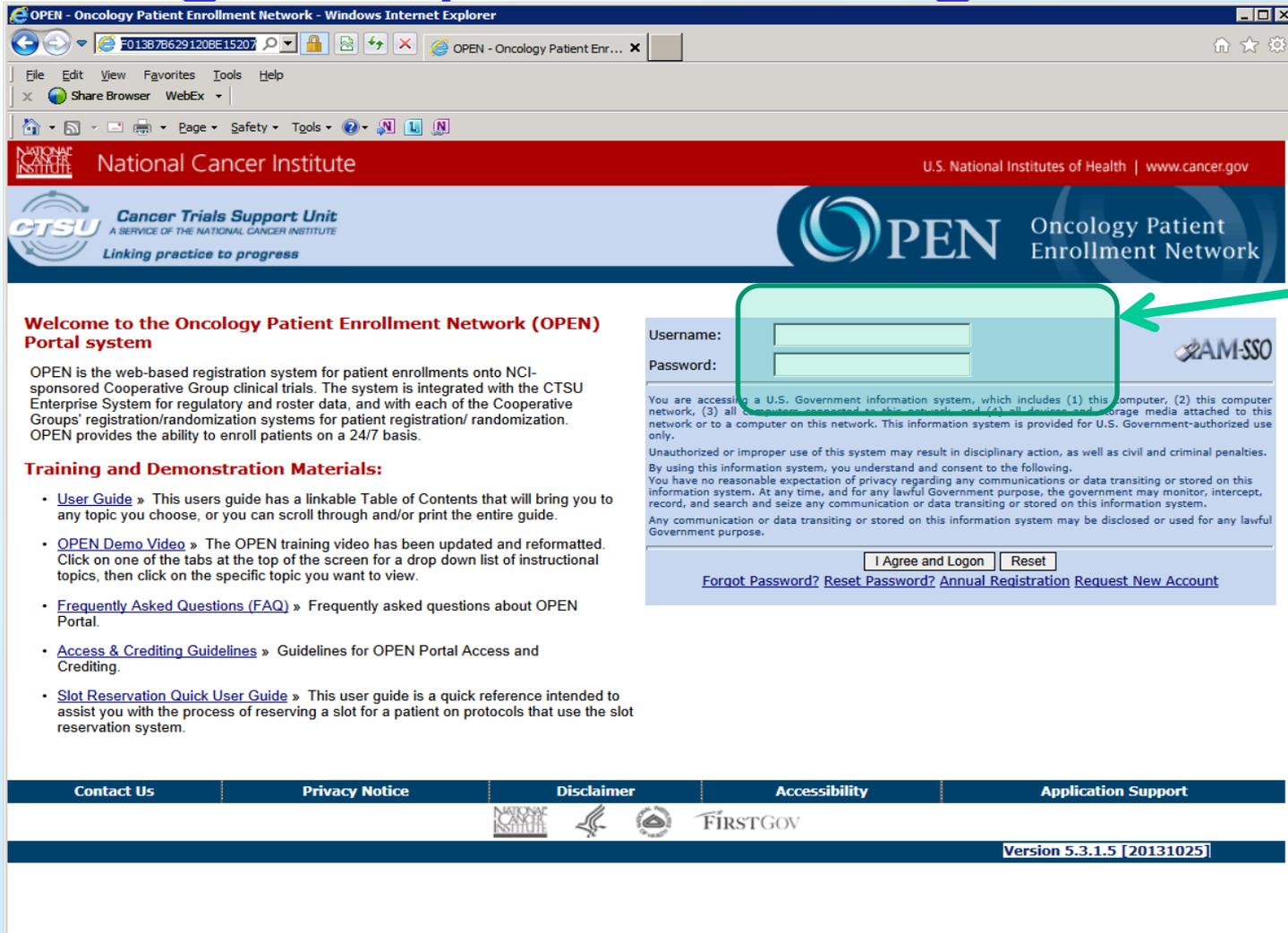
[Privacy Policy](#) | [Terms](#)

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

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

# Register patient using OPEN



**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.

Username:

Password:

[I Agree and Logon](#) [Reset](#)

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

[Contact Us](#) [Privacy Notice](#) [Disclaimer](#) [Accessibility](#) [Application Support](#)

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 Patient SSN 123 45 6789 (US only) \* First B Middle C Patient Hospital No.

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

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

TEST db

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](#)

Patient Identifier

# iMedidata Login

https://login.imedidata.com/s

iMedidata | Login

File Edit View Favorites Tools Help

NATIONAL CANCER INSTITUTE National Cancer Institute

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

IDENTITY AND ACCESS MANAGEMENT *Single Sign On*

IAM-SSO

**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.

i [Annual Registration](#)  
If your IAM account registration has to be renewed.

📄 [Request New Account](#)

CONTACT US PRIVACY NOTICE DISCLAIMER ACCESSIBILITY APPLICATION SUPPORT

NATIONAL CANCER INSTITUTE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FIRSTGOV

# NRG Protocols

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

The screenshot shows the iMedidata web application interface. The main content area is titled "Studies (5)" and contains a table of protocols. A light blue rounded rectangle highlights this table. To the left, a "My Information" sidebar shows the user's name "Jessalyn Reboj (jreboj)" and other details. To the right, a "Tasks" sidebar shows "Invitations (0)" and "eLearning (0)". Below the "Studies" section are sections for "Sites (0)" and "Teams (0)", both showing a message that the user is a member of zero of those categories. The browser's address bar shows the URL "https://www.imedidata.com/ticket=ST-1342032584+D1487C9FC68177E678".

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

# Institution Page (Parents)

The Gynecologic Oncology Group (GOG) is a non-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of Gynecologic malignancies. The Group is committed to maintaining the highest standards in clinical trials development, execution, analysis and distribution of results. Continuous evaluation of our processes is utilized in order to constantly improve the quality of patient care.

Find  Site

Advanced Search  
World   
 Include Sub Site Groups

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 << < Page 1 of 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

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DEV

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

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Click Here for Customer Support Information

Medidata Rave® Version 5.6.4.146  
Copyright ©1999-2012, Medidata Solutions, Inc.

List of NRG institutions.

# Patients enrolled to protocol

The screenshot displays the Medidata Rave web application interface. The browser address bar shows the URL: [https://hdvcyl01-037.mdsol.com/MedidataRave/\(S\(tkmxkw4rt0refsl0ldqumusj\)\)/HomePage.aspx?LD\\_StudySiteID=64](https://hdvcyl01-037.mdsol.com/MedidataRave/(S(tkmxkw4rt0refsl0ldqumusj))/HomePage.aspx?LD_StudySiteID=64). The page title is "Home - Medidata Rave".

The main content area is titled "Task Summary: Study" and contains a list of tasks with corresponding icons:

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

Below the task list is a table of subjects:

Subject ID	Count
000-0229L-013	2
000-0229L-014	0
000-0229L-015	4
000-0229L-016	0
000-0229L-160	7
000-0229L-300	44
000-0229L-400	20
000-0229L-401	

Annotations include a blue box around the "Open Queries" and "Overdue Data" tasks, with arrows pointing to the "Open Queries" and "Overdue Data" rows in the subjects table. Another blue box highlights the "Answered Queries" task, with an arrow pointing to the "000-0229L-300" subject row. A third blue box highlights the "Ready for Data Lock" task, with an arrow pointing to the "000-0229L-400" subject row. A fourth blue box highlights the "Cancel Queries" task, with an arrow pointing to the "000-0229L-401" subject row.

The footer of the page includes the Medidata Rave logo, a link to "Click Here for Customer Support Information", and the version information: "Medidata Rave® Version 5.8.4.148 Copyright ©1999-2012, Medidata Solutions, Inc." The browser status bar at the bottom indicates "Internet | Protected Mode: Off" and "100%".

# Patient's root tab

Initial information loaded at registration.

Icon	Status	Icon	Status	Icon	Status
	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
	Home		Overdue		Requires Signature
	Comments		Sticky Notes		Out of Range High
	Edit		Data Changed		Out of Range Low
	Study Status Deferred		Protocol Deviation		Requires Translation
	Folder not available to the user		Site Status Deferred		Requires First Pass DDE
	Task Summary Pop Up		Add Marking		Requires Second Pass DDE
	Requires Coder Coding		Folder		Requires Reconciliation DDE

# Enrollment Forms

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

# Demography

The screenshot displays the Medidata Rave interface for a Demography form. The top navigation bar includes the Medidata logo, the text 'DEV', and user information for 'User: Jessalyn Rebov Data Manager'. The breadcrumb trail shows 'Enrollment Forms' > 'Demography'. The left sidebar contains a menu with 'Enrollment Forms' (selected), 'Demography', 'Step Information', 'Subject Enrollment', 'Treatment Assignment', and 'Eligibility Checklist'. Below this is a 'CRF History' section for '003-0229L-003 - Demography'. The main form area is titled 'Subject: 003-0229L-003' and 'Page: Demography - Enrollment Forms'. It contains several input fields: 'Patient Initials (LFM)', 'Patient's Date of Birth', 'Ethnicity', 'Gender of a Person', 'Country of Residence', 'ZIP Code', and 'Method of Payment'. A 'Race' field is also present with a dropdown menu. Below the form, there are links for 'Printable Version', 'View PDF', and 'Run Key'. An inset window in the bottom right corner shows a detailed view of the 'Demographics' section, including fields for 'Patient's Date of Birth', 'Ethnicity', 'Gender of a Person', 'Country of Residence', and 'Standard\_Race'. Annotations include a blue arrow pointing from the 'Demography' menu item to the main form, and several blue arrows pointing from the text labels 'Standard Fields' and 'Log Line Fields' to their respective fields in the form.

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 with a dropdown arrow. The third field is labeled "Ethnicity" and has a dropdown menu.

## Log Lines

A screenshot of a web form showing a table of Log Lines. The table has six columns: "# Registration Step", "Event Description", "Tracking Number", "Treating Investigator", "Site Registrar", and "Crediting Group". The first row contains the number "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 right, there are "Save" and "Cancel" buttons. The page title is "Subject: 003-0229L-003" and the page is "Step Information - Enrollment Forms".

# 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

# Step Information

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

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

Inactivate Page

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

#	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

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

Enrollment Forms  
Demography  
Step Information  
Subject Enrollment  
Treatment Assignment  
Eligibility Checklist

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

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# Subject Enrollment

**medidata** Medidata Solutions Worldwide DEV iMedidata Messages My Profile Help Home Logout  
User: Jessalyn Reboy Data Manager

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

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

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

Patient ID  
Enrolling Site CTEP ID  
Lead Organization  
Current Site CTEP ID  
Enrollment Date  
Enrollment Time  
Group Data  
Source Application

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

Site: GOG:Gynecologic Oncology Group Site: GROUP\_REG\_ADMIN  
Home Enroll History Reports Form Setup Admin Help  
Browse Summary Demography Checklist

Protocol	PID	Initials (LFH)	Step	Arm	Site	Investigator	Status	Status Date
GOG-0229L	814-0229L-113	ABC	1	1	MN008	Bailey, Cheryll	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 here 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!

Printable Version View PDF Icon K  
CRF Version 58 - Page Generated: 11 Jul 2012

medidata Rave  
Click Here for Customer Support Information

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# Treatment Assignment

The screenshot displays the Medidata Rave web application interface. At the top, the Medidata logo and 'DEV' environment indicator are visible. The user is logged in as 'Jessalyn Reboy Data Manager'. The breadcrumb trail shows the path: GOG0229L > Angela 2 > 003-0229L-003 > Enrollment Forms > Treatment Assignment.

The left sidebar contains a navigation menu with the following items: Enrollment Forms, Demography, Step Information, Subject Enrollment, Treatment Assignment (highlighted), and Eligibility Checklist. Below this is a 'CRF History' section listing previous actions for the subject.

The main content area shows the 'Treatment Assignment' page for Subject: 003-0229L-003. The page title is 'Page: Treatment Assignment - Enrollment Forms'. A table is present with the following columns: 'Event description', 'Step No', 'Date of Intervention/Treatment Assignment', and 'Event Time'. A red arrow points to the 'Event description' column header. Below the table, there are links for 'Add a new Log line', 'Inactivate', 'Printable Version', 'View PDF', and 'Icon Key'. The footer of the page includes the Medidata Rave logo and version information: 'Medidata Rave® Version 5.0.4.140 Copyright ©1999-2012, Medidata Solutions, Inc.'

# Eligibility Checklist

The screenshot displays the Medidata Rave web application interface. At the top, the Medidata logo and 'DEV' environment are visible. The user is identified as 'Jessalyn Reboy Data Manager'. The main content area shows an 'Eligibility Checklist' for subject 'Angela 2' (ID: 003-0229L-003). The checklist includes various criteria such as 'GOG Institution Code', 'GOG Affiliate Code', 'Previous GOG #', 'Treating physician', 'Other Physician', 'Did the patient sign an approved informed consent', 'Has HIPAA authorization been obtained', 'Is the patient eligible for a higher priority GOG protocol', 'What is the primary disease site', 'What is the cell type?', 'Date of initial histologic diagnosis of malignancy', 'What was the grade of the primary tumor', and 'Is the disease recurrent or persistent with documented progression? Which one?'. Each item has a status indicator (green checkmark) and a 'pencil' icon for editing. A sidebar on the left contains navigation options, with 'Eligibility Checklist' highlighted. A red circle highlights the checklist items, and a red arrow points to the 'Eligibility Checklist' option in the sidebar.

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

# Terminology Break

Folders

Forms

The screenshot shows a web application interface for a clinical trial. At the top, there is a navigation bar with the following elements: a home icon, a search icon, the text 'GOG0229L', a user profile icon labeled 'Angela 2', a subject ID '003-0229L-003', and two tabs: 'Enrollment Forms' and 'Eligibility Checklist'. Below the navigation bar is a left-hand sidebar with a tree view of folders: 'Enrollment Forms', 'Demography', 'Step Information', 'Subject Enrollment', 'Treatment Assignment', and 'Eligibility Checklist'. Below the sidebar is a 'CRF History' section listing several records with their respective folder names. The main content area displays 'Subject: 003-0229L-003' and 'Page: Eligibility Checklist - Enrollment Forms'. Two light blue arrows originate from the 'Folders' label above: one points to the 'Enrollment Forms' folder in the sidebar, and the other points to the 'Enrollment Forms' tab in the navigation bar. Two light blue arrows originate from the 'Forms' label above: one points to the 'Eligibility Checklist' folder in the sidebar, and the other points to the 'Eligibility Checklist' tab in the navigation bar.

# Navigation

History

Protocol Patient Form

The screenshot shows a web application interface for a clinical trial. The top navigation bar contains several tabs: a home icon, 'GOG0229L', 'Angela 2', '003-0229L-003', 'Enrollment Forms', and 'Eligibility Checklist'. Below the navigation bar, the main content area displays 'Subject: 003-0229L-003' and 'Page: Eligibility Checklist - Enrollment Forms'. On the left side, there is a sidebar with a menu of options: 'Enrollment Forms', 'Demography', 'Step Information', 'Subject Enrollment', 'Treatment Assignment', and 'Eligibility Checklist'. Below this menu is a 'CRF History' section listing several records with their respective titles and dates. Annotations with arrows point to various elements: 'History' points to the CRF History section; 'Home' points to the home icon in the navigation bar; 'Institution' points to the 'Angela 2' tab; 'Folder' points to the 'Enrollment Forms' tab; and 'Form' points to the 'Eligibility Checklist' tab.

# Patient's root tab

Subject - Windows Internet Explorer  
https://hdcvc01-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pvks3lmidvm))/Modules/EDC/SubjectPage.aspx?ID=642

medidata Medidata Solutions Worldwide **DEV** iMedidata Messages My Profile Help Home Logout User: Jessalyn Reboy Data Manager

GOG0229L Angela 2 003-0229L-005

003-0229L-005  
Enrollment Forms  
Baseline  
Patient Calendar

Subject Enrollment

Grid View  
Subject Administration  
Subject Sharing

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

Add Event  Add

Task Summary: Subject

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

Icon Key

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

medidata Rave®  
Click Here for Customer Support Information

Medidata Rave® Version 5.6.4.148  
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Internet | Protected Mode: Off 100%

# Baseline Visit Form

CRF - Windows Internet Explorer  
https://hdcvc01-037.mdsol.com/MedidataRave/(S(h333vv5bhov2pyks31midivm))/Modules/EDC/CRFPage.aspx?DP=18542

File Edit View Favorites Tools Help  
Favorites Suggested Sites Web Slice Gallery  
CRF

medidata Medidata Solutions Worldwide  
DEV  
iMedidata Messages My Profile Help Home Logout  
User: Jessalyn Reboj 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

Printable Version View PDF Icon Key  
CRF Version 61 - Page Generated: 19 Jul 2012 08:53:30 Eastern Daylight Time

Yes No  
Yes No  
Yes No  
Yes No

Save Cancel

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Internet | Protected Mode: Off 100%

# RAVE Registration Form

CRF - Windows Internet Explorer

https://hdvcv01-037.mdsol.com/MedidataRave/(S(h333vw5bhov2pyks31midivm))/Modules/EDC/CRFPage.aspx?DP=18543

File Edit View Favorites Tools Help

medidata DEV

003-0229L Angela 2 003-0229L-005 Baseline Registration Form

Subject: 003-0229L-005  
Page: Registration Form - Baseline

### Registration Form

Height in cm:

Weight in kg:

Performance Status (Zubrod):

Has the patient had any prior cancer diagnosed?:

Prior cancer type:

Prior cancer diagnosis date:

Brief clinical history:

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Save Cancel

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# 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: \_\_\_\_\_

**TRACKING INFORMATION**

(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): \_\_\_\_\_

**DEMOGRAPHIC INFORMATION**

(a) Patient race (mark all that apply):  
 American Indian or Alaska Native  Native Hawaiian or other Pacific Islander  
 Asian  Unknown  
 Black or African American  White

(b) Patient ethnicity (check one):  
 Hispanic or Latino  
 Not Hispanic or Latino  
 Unknown

(10) Method of payment:  
 Private Insurance  Medicaid & Medicare  Self pay (no insurance)  
 Medicare  Military or Veterans Sponsored NOS  No means of payment (no insurance)  
 Medicare & Private Insurance  Military Sponsored (including Champus & Tricare)  Unknown  
 Medicaid  Veterans Sponsored  Other

(11) Patient height (cm): \_\_\_\_\_ . \_\_\_\_\_  
(12) Patient weight (kg): \_\_\_\_\_ . \_\_\_\_\_

(13) Performance status (Zubrod):  
 0 = Fully active, able to carry on all pre-disease performance without restriction (Karnofsky 90-100)  
 1 = Restricted in physically strenuous activity, but ambulatory (K 70-80)  
 2 = Ambulatory and capable of all selfcare but unable to carry out any work activities (K 50-60)  
 3 = Capable of only limited selfcare, confined to bed or chair for more than 50% of waking hours (K 30-40)  
 4 = Completely disabled (K 10-20)

(14) Has the patient had any prior cancer diagnosed?  No  Yes  
Prior cancer type: \_\_\_\_\_  
Prior cancer diagnosis date: m / d / y

**BRIEF CLINICAL HISTORY**

\_\_\_\_\_

20886  
GOG Form R ver. 1 (08/04/2008)



# RAVE Pre-Treatment Summary

CRF - Windows Internet Explorer  
https://hdccv01-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pvks31midivm))/Modules/EDC/CRFPage.aspx?DP=18544

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User: Jessalyn Reboya 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

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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Key data

Hit Save

# RAVE Pre-Treatment Summary

CRF - Windows Internet Explorer  
https://hdvcv01-037.mdsol.com/MedidataRave/(S(fp5laiyzo1f5jz2shsozj5))/Modules/EDC/CRFPPage.aspx?DP=18544

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DEV

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User: Jessalyn Reboj Data Manager

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

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"/>
2	EKG	Normal	25 JUN 2012	<input checked="" 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"/>
4	CT	Normal	20 JUN 2012	<input checked="" 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"/>

Printable Version View PDF Icon Key  
CRF Version 61 - Page Generated: 19 Jul 2012 12:14:48 Eastern Daylight Time

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CRFPPage.aspx?DP=18544 Internet | Protected Mode: Off 100%

Saved

# Edit a Row in a Log Line

The screenshot shows a web browser window displaying the Medidata Rave interface. The page title is 'Pre-Treatment Summary' and the subject is '003-0229L-005'. The table below lists five non-invasive diagnostic procedures. The first row, 'Chest X-Ray', has its edit icon circled in red, with a red arrow pointing to it from the text 'Edit one line' on the right side of the image.

#	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"/>

Edit one line

# Open/Edit an entire log line field

On-Study

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	✓	✎	🗑	👁	🔒	🔓

Printable Version View PDF Icon Key  
CRF Version 61 - Page Generated: 19 Jul 2012 12:14:48 Eastern Daylight Time

Save Cancel

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Edit multiple lines

# RAVE Pre-Treatment Summary

CRF - Windows Internet Explorer  
https://hdcvc01-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pvks3lmidvm))/Modules/EDC/CRFPage.aspx?DP=18544

medidata **DEV** iMedidata Messages My Profile Help Home Logout  
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	...	...	
2	EKG	...	...	
3	MRI	...	...	
4	CT	...	...	
5	Chest CT	...	...	

Printable Version View PDF Icon Key  
CRF Version 61 - Page Generated: 19 Jul 2012 08:54:44 Eastern Daylight Time

Save Cancel

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Key data

Hit Save

# A Log Line Terminology Break

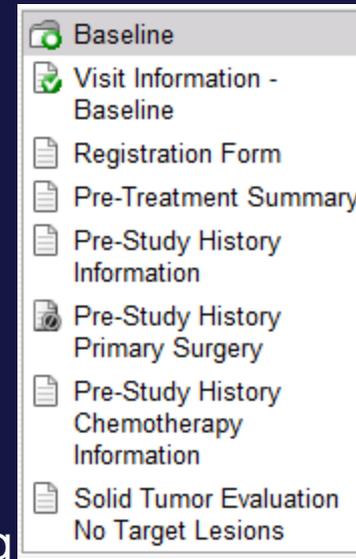
## Inactive



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"/>			    					
2	DIZZINESS	<input type="checkbox"/>	UNRELATED		    					
3	DYSPNEA	<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 displays a web application interface for a Clinical Research Form (CRF). The browser address bar shows the URL: [https://hdvcv01-037.mdsol.com/MedidataRave/\(S\(fp5laiyzo1f5jz2shsozj5\)\)/Modules/EDC/CRFPPage.aspx?DP=18544](https://hdvcv01-037.mdsol.com/MedidataRave/(S(fp5laiyzo1f5jz2shsozj5))/Modules/EDC/CRFPPage.aspx?DP=18544). The page title is "CRF - Windows Internet Explorer".

The application header includes the Medidata logo, the text "DEV", and user information: "User: Jessalyn Reboj Data Manager". The breadcrumb trail shows: "GOG0229L" > "Angela 2" > "003-0229L-005" > "Baseline" > "Pre-Treatment Summary".

The main content area is titled "Pre-Treatment Summary" and contains a section for "Non-Invasive Diagnostic Procedures". The table below lists the 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"/>

Below the table, there are links for "Printable Version", "View PDF", and "Icon Key". The page footer includes "Medidata Rave® Version 5.6.4.146 Copyright ©1999-2012, Medidata Solutions, Inc." and "Internet | Protected Mode: Off".

A blue arrow points to the "Body Diagram Report" link in the left sidebar, which is highlighted in blue. The sidebar also contains other navigation links such as "Visit Information - Baseline", "Registration Form", "Pre-Treatment Summary", "Pre-Study History Information", "Pre-Study History Primary Surgery", "Pre-Study History Chemotherapy Information", "Solid Tumor Evaluation Target Lesions", and "Solid Tumor Evaluation Non-Target Lesions".





# Body Diagram Form

CRF - Windows Internet Explorer  
https://hdvcv01-037.mdsol.com/MedidataRave/(S(p24wtvqk4oaxjs244g4x5x))/Modules/EDC/CRFPage.aspx?DP=18557

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DEV

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User: Jessalyn Reboyn 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-Treatment Summary  
003-0229L-005 - Visit Information - Baseline

Printable CRF 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: m / d / y  
Date form amended: m / d / y  
Person amending form, last name: [ ]

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

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

Internet | Protected Mode: Off

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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	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="button" value="Browse..."/>
2	Primary Surgical Procedure Pathology Report	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="button" value="Browse..."/>

# Specimen Consent

Subject: 814-02290-021  
Page: Specimen Consent - Baseline

I agree to have my specimen(s) collected and I agree that my specimen sample(s) and related information may be used for the laboratory study (ies) described above. Yes

My samples and related information may be kept in a Biobank for use in future health research. Yes

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future. Yes

Save Cancel

Translational Research

- TR FFPE metastatic tumor
- TR FFPE primary tumor
- TR Whole blood

CRF History

814-02290-021 - Translational Research - FP01

The Translation Folder will not appear until after the Specimen Consent has been submitted.

# 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:

## Translational Research Form

### Specimen Information

Specimen Code	FP01	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Time point	FFPE PRIMARY TUMOR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Collected		<input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/>	<input type="checkbox"/>
If not collected, specify reason	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### 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.

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

CRF Version 288 - Page Generated: 25 Jan 2014 20:17:07 Eastern Standard Time

# TR Form Video

Page: Translational Research - WB01 - TR Whole blood

PDF File:  No file selected.

## Translational Research Form

**Specimen Information**

Specimen Code	WB01	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Time point	WHOLE BLOOD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Collected	<input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If not collected, specify reason	<input type="text" value="..."/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Contact Information**

**Blood Products**

**Tissue**

Items shipped

**Shipping Information**

**Receiving Information**

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CRF Version 288 - Page Generated: 27 Jan 2014 10:15:46 Eastern Standard Time

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# Back to the Patient Level

There is now a Visit Folder



History of where we've been



The screenshot shows the Medidata Rave web application interface. The browser address bar displays the URL: [https://hdcvcd01-037.mdsol.com/MedidataRave/\(S\(n333vw5bhov2pvks31midivm\)\)/Modules/EDC/SubjectPage.aspx?ID=642](https://hdcvcd01-037.mdsol.com/MedidataRave/(S(n333vw5bhov2pvks31midivm))/Modules/EDC/SubjectPage.aspx?ID=642). The page title is "Subject - Windows Internet Explorer". The Medidata logo and "DEV" environment indicator are visible at the top. The user is logged in as "Jessalyn Reboy Data Manager". The left sidebar contains a "Visit" folder and a "CRF History" section. The main content area shows a "Subject Enrollment" table with columns for "Visit" and "Date". Below the table is an "Add Event" button. On the right, a "Task Summary: Subject" section lists various tasks and their counts: NonConformant Data (0), Open Queries (0), Answered Queries (0), Requiring Review (0), Overdue Data (0), Ready for Data Lock (2), and Cancel Queries (0). The footer includes the Medidata Rave logo, a link for customer support, and version information: "Medidata Rave® Version 5.6.4.146 Copyright ©1999-2012, Medidata Solutions, Inc.".



# Visit Driver form - completed

All of this information is required for this visit

Answered Yes to everything but:

Cycle Delayed

And

Rx discontinued

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	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
Were the nontarget lesions assessed on this evaluation?	Yes	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
Was the appearance of any new lesions documented?	Yes	<input checked="" type="checkbox"/>	<input type="checkbox"/>					

#### Treatment Information

Was treatment discontinued during this cycle?	Yes	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
Cycle Start Date?	05 JUL 2012	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
Cycle Delayed?	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
Number of days treatment cycle was delayed?		<input checked="" type="checkbox"/>	<input type="checkbox"/>					
Cycle delayed reason		<input checked="" type="checkbox"/>	<input type="checkbox"/>					
Was treatment permanently discontinued during this cycle?	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>					

#### Laboratory assessment

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

# ICON Break

Incomplete

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

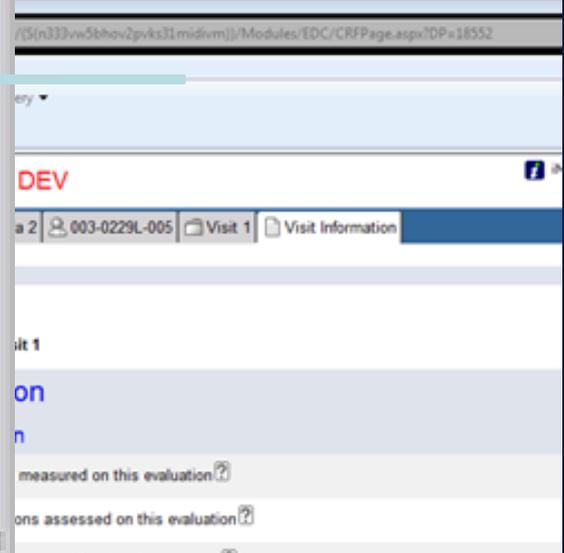
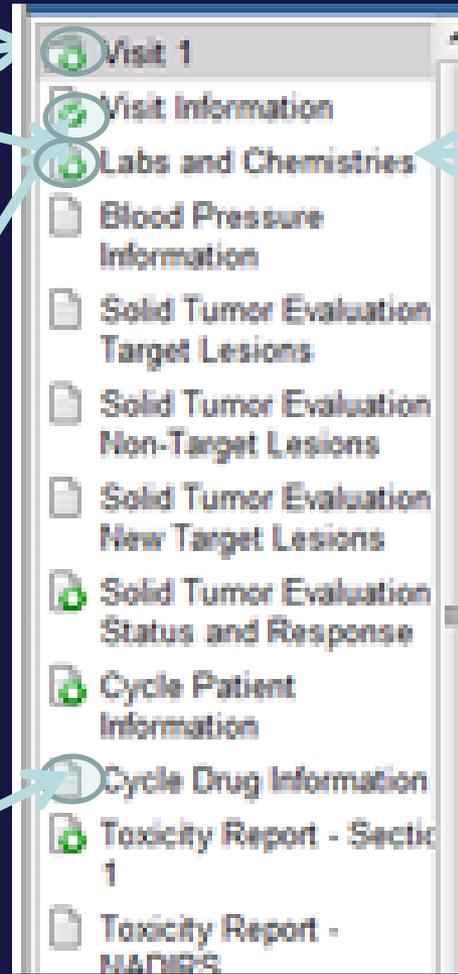
There is a new form that has some pre-filled information "Labs and Chemistries"

Completed

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

Not Touched

No Information as of yet



# Labs & Chemistries

**Laboratory assessment**

Has the pre-treatment blood pressure been recorded Yes  /

Were pre-treatment labs and chemistries collected?  /

Labs assessment date 03 JUL 2012  /

**Toxicity assessment**

#	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

Enter the values that you have

# Labs & Chemistries

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

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CRF Version 241 - Page Generated: 26 Jan 2014 18:12:02 Eastern Standard Time

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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 <input type="text"/>					
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 <input type="text"/>					
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

The screenshot shows a 'Comments' section with a text input field. The text 'able to see a poriton of this' is entered. A teal arrow points from the 'Comments' label to the text input field. To the right of the text field is a toolbar with icons for undo, redo, bold, italic, and other formatting options.

## After saving

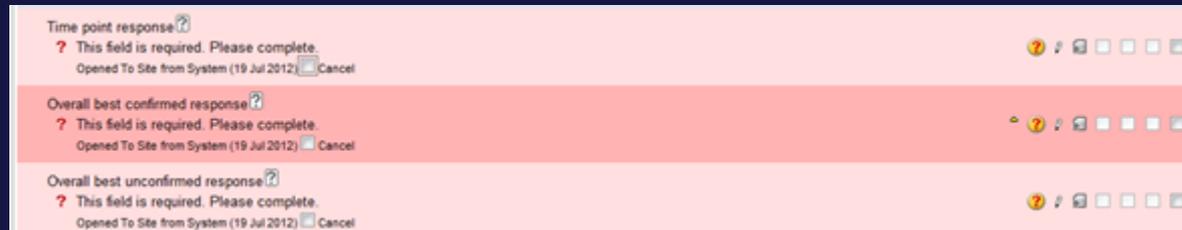
The screenshot shows a list of fields: 'Response Confirmed Date, Partial Response', 'Complete Response First Observed Date', 'Response Confirmed Date, Complete Response', and 'Comments'. The 'Comments' field is highlighted with a teal arrow pointing to the text 'THIS IS THE COMMENT FIELD, IT WILL HOLD A ENORMOUS AMOUNT OF INFORMATION BUT YOU WILL ONLY BE ABLE TO SEE A PORITON OF THIS'. The text is truncated. To the right of the text is a toolbar with icons for undo, redo, bold, italic, and other formatting options.

## Edit saved information

The screenshot shows the 'Comments' field in edit mode. The text 'THIS IS THE COMMENT FIELD, IT WILL HOLD' is visible. A teal arrow points from the 'Comments' label to the text input field. Below the text field is a dropdown menu with 'New Information' selected. To the right of the text field is a toolbar with icons for undo, redo, bold, italic, and other formatting options. At the bottom right are 'Save' and 'Cancel' buttons. At the bottom left, there is a footer with links for 'Printable Version', 'View PDF', and 'Icon Key', and a page number '58'. The footer also includes the text 'Page Generated: 22 Jul 2012 15:02:12 Eastern Daylight Time'.



# 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

The screenshot shows a web browser window displaying a Medidata Rave CRF form. The browser address bar shows the URL: [https://hdcvc01-037.mdsol.com/MedidataRave/\(S\(a5f1xckrfgphnkzd1ex3ieg5\)\)/Modules/EDC/CRFPage.aspx?DP=18571](https://hdcvc01-037.mdsol.com/MedidataRave/(S(a5f1xckrfgphnkzd1ex3ieg5))/Modules/EDC/CRFPage.aspx?DP=18571). The page title is "CRF". The Medidata logo and "DEV" are visible at the top. The user is logged in as "Jessalyn Reboj Data Manager".

The form is for "Visit 1" and "Solid Tumor Evaluation Status and Response". The subject is "003-0229L-005". The page title is "Solid Tumor Evaluation Status and Response - Visit 1".

The form contains several sections:

- 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**: (Checked)
- Response Confirmed Date, Partial Response**: (Checked)
- Complete Response First Observed Date**: (Checked)
- Response Confirmed Date, Complete Response**: (Checked)
- Comments**: (Checked)

The required fields are highlighted in red. The form also includes a "Printable Version View PDF Icon Key" link, a "CRF Version 61 - Page Generated: 19 Jul 2012 12:39:19 Eastern Daylight Time" timestamp, and "Save" and "Cancel" buttons.

# Across Field Checks

The screenshot shows a web browser window displaying a Medidata Rave CRF form. The browser address bar shows the URL: [https://hdcvc01-037.mdsol.com/MedidataRave/\(S\(a5f1ckrfgphnkzd1ex3ieg5j\)\)/Modules/EDC/CRFPage.aspx?DP=18571](https://hdcvc01-037.mdsol.com/MedidataRave/(S(a5f1ckrfgphnkzd1ex3ieg5j))/Modules/EDC/CRFPage.aspx?DP=18571). The page title is "Solid Tumor Evaluation Status and Response".

The form includes a sidebar with navigation options such as "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 Complete", "Toxicity Report - Aes Complete v2", and "CRF History".

The main content area displays the following fields and their status:

- Time point response:** This field is required. Please complete. (Error message)
- Overall best confirmed response:** Complete Response (Green checkmark)
- Overall best unconfirmed response:** This field is required. Please complete. (Error message)
- Partial Response First Observed Date:** (Green checkmark)
- Response Confirmed Date, Partial Response:** (Green checkmark)
- Complete Response First Observed Date:** STE\_ESR002: A confirmed or unconfirmed complete response was reported. Please enter the Complete Response first observed date. (Error message)
- Response Confirmed Date, Complete Response:** STE\_ESR001: A confirmed complete response was reported. Please enter the Complete Response first confirmed date. (Error message)

The "Complete Response" button is highlighted with a red box. At the bottom of the form, there are "Save" and "Cancel" buttons. The footer of the page includes the Medidata Rave logo and version information: "Medidata Rave® Version 5.6.4.148 Copyright ©1999-2012, Medidata Solutions, Inc."

# Future Dates

The screenshot shows a web browser window displaying a Medidata Rave application. The browser address bar shows the URL: [https://hdcvc01-037.mdsol.com/MedidataRave/\(S\(a5f1ckrfgphnkzd1ex3ieg5j\)\)/Modules/EDC/CRFPage.aspx?DP=18571](https://hdcvc01-037.mdsol.com/MedidataRave/(S(a5f1ckrfgphnkzd1ex3ieg5j))/Modules/EDC/CRFPage.aspx?DP=18571). The application header includes the Medidata logo, the text 'DEV', and user information: 'User: Jessalyn Reboy Data Manager'. The main content area is titled 'Solid Tumor Evaluation Status and Response' and shows a table of response data. A red error message is highlighted, stating: '? Future date has been entered. Please correct.' with the date '20 JUL 2012' and a warning icon. Below this, another error message is visible: '? STE\_ESR009: The confirmed Complete Response Date is less than 28 days after the first observed complete response date, please reconcile.' with the date '20 JUL 2012' and a warning icon. The left sidebar contains a navigation menu with items like '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 Complete', and 'Toxicity Report - Aes Complete v2'. The bottom of the page features a footer with the Medidata Rave logo, a link for customer support, and version information: 'Medidata Rave® Version 5.6.4.146 Copyright ©1999-2012, Medidata Solutions, Inc.'.

# Date Ranges

CRF - Windows Internet Explorer  
https://hdcvc01-037.mdsol.com/MedidataRave/(S(a5f1ckrfghpkzd1ex3ieg5))/Modules/EDC/CRFPage.aspx?DP=18571

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

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

medidata Rave  
Click Here for Customer Support Information  
Medidata Rave® Version 5.6.4.146  
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**THE END**