

“An International Registry of Patients with or at Risk for Hepatobiliary Cancers, Including Hepatocellular Carcinoma, Cholangiocarcinoma, and Gallbladder Adenocarcinoma, and those Patients with Normal Risk Factors.”

iMedidata Rave registry

Training Guide

Medidata Rave Application Access/Security

- Internet-based systems
- Web Browser
- Single platform
- Single URL, username, password
- Fully configurable user roles and permissions
 - Enforced on all views
 - Enforced on all data entry and validations
 - Enforced on all reports

Login



Language English ▾

Sign In

Username

Password

[Log In](#)

[I forgot my username or password](#)
[Trouble logging in?](#)

Welcome to iMedidata - the fast, simple way to access all your Medidata Rave® EDC studies, **Medidata applications**, eLearning, online discussions and more... in one place.

[Take a Tour](#)



Our mission is to put innovative technology and insightful data into your hands, to help you plan and manage clinical trials, and safely bring life enhancing treatments to market. [Learn More](#)

- Each user will receive a username/password
- Use the “I forgot my username or password” & “trouble logging in?” links for assistance with logging in.
- You can also use the “take a tour” link to learn about imedidata applications.

Welcome Page

The screenshot shows the Medidata Rave Welcome Page. The page layout includes a top navigation bar with the Medidata logo and user information (Help, Logout, Nasra Giama (giama.nasra)). The main content area is divided into several sections: 'Apps' (Medidata Rave, Mayo Clinic (Mayo), Medidata(R2DS)), 'My Information' (Nasra Giama (giama.nasra), Locale eng, Central Time (US & Canada), Account Details, MyMedidata), 'Studies (3)' (GIH1101 Liver Bio Rep, GIH1101 Liver Bio Rep (Testing), R2DS Mayo), 'Sites (4)' (Liver Associates of Texas, Mayo Clinic Rochester, MN USA, Mayo Clinic in Arizona Scottsdale, AZ USA, Mayo Clinic in Florida), and 'Teams (0)'. A 'Tasks' sidebar on the right lists 'Invitations (0)', 'eLearning (2)', and 'Rave 5.6 Site Administration'. The 'GIH1101' study is highlighted with a blue arrow pointing to the 'Rave EDC' link. The 'Tasks' section is also highlighted with a blue arrow. The 'My Information' section is highlighted with a blue arrow. The 'Teams (0)' section is highlighted with a blue arrow. The footer contains the Medidata logo, copyright information (© 1999-2013), and a session expiration notice (Your session will expire at 01-08-2013 10:33:43 am CST).

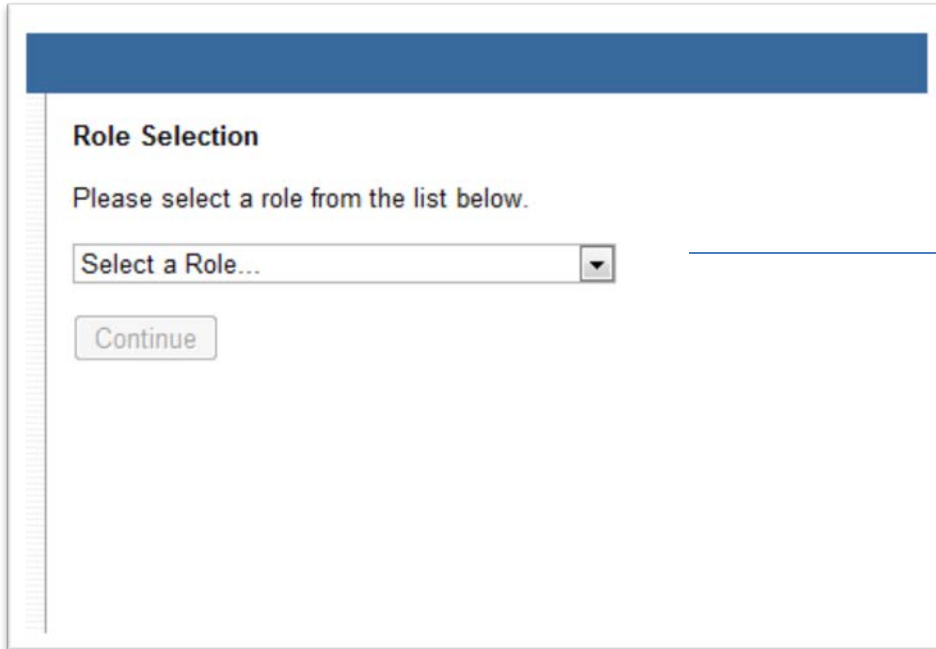
My information:
Account details, user contact information, and resetting passwords

Tasks:
eLearning: each user must complete an online training

Training:
eLearning: each user must complete an online training

GIH1101:
Select this to enter the registry

Login cont.



Role Selection

Please select a role from the list below.

Select a Role...

Continue

CRA: select
*Clinical
Research
Associate
(subject Add)*

PI/Manager:
select *Data
Manager*

Data Entry: Grid

MAYO CLINIC

iMedidata Messages My Profile Help Home Logout
User: Nasra Giama RN

GIH1101 Liver Bio Rep

Find Site
[Advanced Search](#)

Site Group World
 Include Sub Site Groups

Site	Site Group	Site Number
Liver Associates of Texas	World	TX99901

Page 1 << Page 1 of 1 >>

Icon Key

Reports

- GIH1101 - Summary Report - GIH1101 - Summary Report
- GIH1101 -- Tissue Bank Pick List - Crystal Report

Task Summary: Study

Task	Sites
NonConformant Data	1
Open Queries	1
Sticky Notes	1
Overdue Data	0

Site selection: Liver Associates of Texas

How to enter subject

MAYO CLINIC TESTING

iMedidata Messages My Profile Help Home Logout
User: Nasra Giama RN

GH1101 Liver Bio Rep Liver Associates of Texas

Subject

Subject
-1234567
Page 1
Icon Key

Task Summary: Site

Task Summary: Site	Subjects
NonConformant Data	0
Open Queries	0
Sticky Notes	0
Overdue Data	0

<< Page 1 of 1 >>

Enter participant's clinic number here.
Press Enter

MAYO CLINIC TESTING

iMedidata Messages My Profile Help Home Logout
User: Nasra Giama RN

GH1101 Liver Bio Rep Liver Associates of Texas -1234567

-1234567 Clinic Number: 1234567 First Name: Last Name:
Baseline Subject ID: 10040
Grid View

Subject Summary
Clinic Number: 1234567
Subject ID: 10040

Subject Enrollment

Visit	Date	Task Summary: Subject	Pages
		NonConformant Data	0
		Open Queries	0
		Sticky Notes	0
		Overdue Data	0

Add Event Add

Icon Key

CRF Version 1031 - Page Generated: 15 Jan 2013 10:43:21 Central Standard Time

Baseline:
Select baseline to enter patient demographic information and verify.

Education

Education Level

Please verify Name is correct.

Click Here for Customer Support Information

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Enter Consent Information

MAYO CLINIC TESTING | iMedidata | Messages | My Profile | Help | Home | Logout | User: Nasra Giama RN

GIH1101 Liver Bio Rep | Liver Associates of Texas | -1234567

Clinic Number: 1234567 | Subject ID: 10040 | First Name: | Last Name: | Grid View

Consent (1) *
Tissue Sample (1)
Episode of care (1) *
Baseline *
Image (1) *
Pathology (1) *
Lab (1) *
Current Visit (1) *
Treatment (1) *
Last Contact (1) *
FACT-Hep (1) *
Staging (1) *
Patient Assessment (1)
Fibrosis *

Subject Enrollment

Task Summary: Subject
NonConformant Data 0
Open Queries 1
Sticky Notes 0
Overdue Data 0

Add Event [] Add

Icon Key

CRF Version 1031 - Page Generated: 15 Jan 2013 10:55:28 Central Standard Time

Subject Summary
Clinic Number: 1234567
Subject ID: 10040

CRF History
-1234567 - Diagnosis
-1234567 - Demographics

Clicking on the patient # will return you to this page

MAYO CLINIC TESTING | iMedidata | Messages | My Profile | Help | Home | Logout | User: Nasra Giama RN

GIH1101 Liver Bio Rep | Liver Associates of Texas | -1234567 | Consent (1) | Consent

Clinic Number: 1234567 | Subject ID: 10040 | First Name: | Last Name: | Grid View

Subject: 1234567
Page: Consent - Consent (1) ?

#	IRB number	Consent date	Consent Status	Permit Cell-line use at Mayo	Permit Cell-line to be used in future research	Permit sample to be sent outside Mayo
1				Yes No NA	Yes No NA	Yes No NA

CRF History
-1234567 - Consent

Add a new Log line Inactivate
Printable Version View PDF Icon Key
CRF Version 1031 - Page Generated: 15 Jan 2013 10:58:41 Central Standard Time

Save Cancel

Add Event:
additional forms

Additional forms in the consent folder. We request you complete the consent form, the blood draw form, and the Gi BioBank Questionnaire.

Consent form:
Enter the IRB # (707-03), consent Date, Consent status (consented OR decline), and response to 3 questions on page 8. Click "save".

List of all the forms. Click on the folder name to open.

Episode of Care

- An episode of care is a defined period of time in which a patient interacts with a health care system (clinic or hospital) for specified condition. The episode of care includes all services the patient receives at this defined period of time. For example, when a patient is being evaluated for hepatobiliary cancer, he/she may be seen on Monday-Friday with the following services provided: GI consult, imaging (CT, MRI, and/or ultrasound), labs, biopsy, subsequent consult visit. This is considered one episode of care.
- But if the patient came back the following Monday for more services, (for example, surgical or oncology consult, surgery, treatment of any form, etc.) the services would be included in the first episode of care.
- If the patient is not seen for several weeks and then he/she comes back for follow-up care, then a new episode of care would be started.

MAYO CLINIC TESTING

Medidata Messages My Profile Help Home Logout
User: Nasra Giama RN

GIH1101 Liver Bio Rep Liver Associates of Texas -1234567 Episode of care (1) Episode of care

Episode of care (1)
Episode of care

CRF History
-1234567 - Episode of care

Clinic Number: 1234567 First Name: Last Name:
Subject ID: 10040

Subject: -1234567
Page: Episode of care - Episode of care (1)?

#	Start of episode of care	End of Episode of care	Primary Diagnosis	Episode of care number
1	

Add a new Log line Inactivate
[Printable Version](#) [View PDF](#) [Icon Key](#)
CRF Version 1.31 - Page Generated: 15 Jan 2013 11:19:37 Central Standard Time

Save Cancel

Click here to enter another
"Ep. Of care" date

Baseline forms

Complete:

- Diagnosis form
- Demographic form
- Patient History
- Family History

#	Date of diagnosis	Primary diagnosis	Method of Dx. Pathology	Method of Dx. Radiographic/imaging	Method of Dx. Serology/Other	Type of diagnosis
1						

You can enter more than one diagnosis

You can select more than one method

Type of diagnosis
Drop down:
select first diag.
or recurrence

Required forms

The following forms need to be completed for each participant if the information is available:

- Consent
- Blood draw Date: up to 5 blood samples per year at 2-month or greater intervals
- GI BioBank Questionnaire (return date)
- Episode Care
- Diagnosis (found in Baseline)
- Demographics
- Patient History
- Family History
- Image
- Pathology
- Labs
- Current Visit
- Treatment
- Last Contact
- Fact-Hep
- Staging
- Fibrosis form

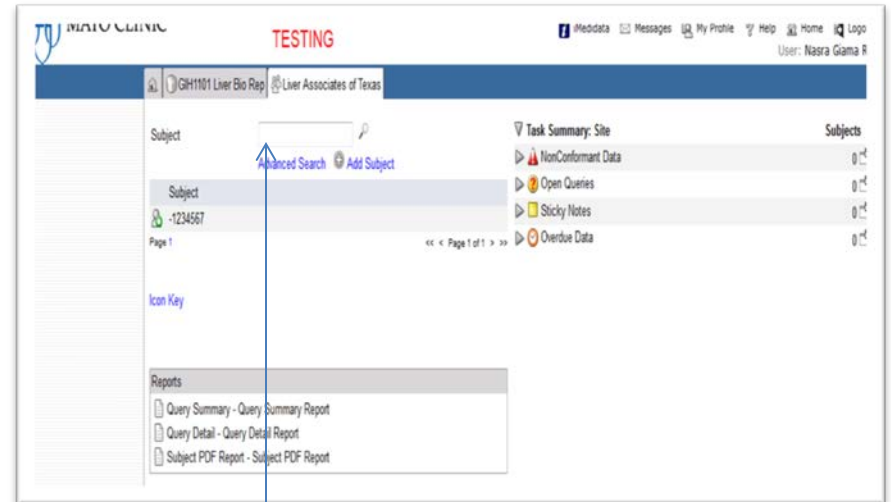
Reports

- *Query summary*- This report allows a user to track the number of queries issued and their status
- *Query Detail*-This report allows you to track the detail of all queries both manual and system generated. Use this to address specific queriers ()
- *Subject PDF Report*- This report provides a written record of all patient data and the audit trail.

The screenshot displays the Mayo Clinic TESTING application interface. At the top, the Mayo Clinic logo and 'TESTING' are visible. The user is logged in as 'Nasra Giama RN'. The main navigation bar includes 'GIH1101 Liver Bio Rep' and 'Liver Associates of Texas'. A search bar for 'Subject' is present, with a search icon and links for 'Advanced Search' and 'Add Subject'. Below the search bar, a subject entry is shown: 'Subject -1234567' on 'Page 1'. To the right, a 'Task Summary: Site' table lists 'NonConformant Data' (0), 'Open Queries' (1), 'Sticky Notes' (0), and 'Overdue Data' (0). At the bottom, a 'Reports' menu lists three options: 'Query Summary - Query Summary Report', 'Query Detail - Query Detail Report', and 'Subject PDF Report - Subject PDF Report'.

Other tips

- First search using the participant's clinic number before adding new subject. This is the best way to avoid duplicate patients.



Enter MC# and click on the magnifying glass before “adding new subject”.

Help/Support Information

- Nasra Giama (Monday & Tuesday)
 - giama.nasra@mayo.edu
 - 507-538-0097
- Xiaodan Zhang (Wednesday-Friday)
 - zhang.xiaodan@mayo.edu
 - 507-266-4403

Database Security

- Very secure data center with 5 levels of physical and biometric security validations
- Gigabit-speed firewall, Intrusion Detection System (IDS) and virus protection
- Secure off-site data storage
- Enterprise-level monitoring tools
- Real-time alerts for proactive issue resolution
- Dedicated disaster recovery facilities