

EDC Training: Rave Basics for Development

Leader Guide to Participant Guide 1.3 [5 Oct 09]



ACKNOWLEDGMENTS

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Version	1.3
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Amendment History	

Cover Photo Patient Profiles (left to right)

Ben, Pulmozyme® Patient

At birth Ben weighed in at over nine pounds and, by all accounts, seemed to be a healthy baby. At six months old and after two hospitalizations for pneumonia, Ben was diagnosed with cystic fibrosis (CF). At 18 months old Ben had a two-week hospital stay for CF, and at the age of two Ben started Pulmozyme therapy as part of his treatment regimen. Now 13, Ben is a lively seventh-grader with a voracious appetite for life. He has a passion for math, movies, computer games and wizard stories. An avid snowboarder and surfer, Ben is also a right defender and right mid-fielder on his competitive soccer team. Ben's family reports that his daily treatment regimen is under an hour and, with the assistance of Pulmozyme therapy, Ben enjoys the life of an active teenage boy.

Samantha and Alison, Nutropin® Patients

Nutropin is indicated for growth hormone deficiency in children and adults, growth failure associated with chronic renal insufficiency, and short stature associated with Turner Syndrome.

Jane, Rituxan® Patient

Six years ago, in 1998, Jane discovered a lump on her collarbone. Thinking it was some type of muscular inflammation, she went to the doctor to have it examined. The doctors performed a biopsy on the lump and discovered that she had non-Hodgkin's lymphoma. After telling her family that she had non-Hodgkin's lymphoma, her daughter, who had just started working at Genentech, mentioned that her company had recently launched a new drug for non-Hodgkin's lymphoma, Rituxan. Jane started taking Rituxan and soon discovered that her tumor was shrinking. After a year, she was in remission and went off of Rituxan. Jane credits her daughter's new job at Genentech for helping her find the drug that helped treat her disease.

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CLASS PREPARATION

Prior to the day of the class, contact the EDC Help Desk to:

- › Obtain a sufficient number of copies of the *EDC Rave Basics Participant Guide*
- › Reserve a training facility with:
 - › Instructor's computer that is connected to an overhead projector
 - › Internet access from all attendees' computers

On the day of the class, you need the following:

- › Dry erase agenda poster and pen
- › Participant name placards
- › *EDC Rave Basics Instructor's Guide*
- › *EDC Rave Basics Participant Guide*
- › Rave Basics for Development PowerPoint Presentation
- › Training Signoff Form (if applicable)
- › EDC User Account Management and Training Forms
- › Training Evaluation Forms

On the day of the class, you will need to complete the following tasks:

- › Assign each attendee a unique training user number that correlates with the user accounts that they will use to log into Rave. Assign yourself a blank subject (to demo submitting data), and assign all learners a blank subject in a specific site.
- › From the leader's machine:
 - › Open the PowerPoint presentation. On the title page, specify your leader name, role, and the class date. Verify that the title page is displayed overhead.
 - › Confirm that you can view the Rave login screen by entering the training URL (<https://gentrn56.mdsol.com>) into the browser address window.
 - › Confirm that you can log into Rave with each of the user accounts / roles that you will be using during the training: CRC, CRA, PI, and DM.
 - › Verify that the data in the training sample study are correct (refreshed).
- › From each learner's machine:
 - › Confirm that you can view the Rave login screen by entering the training URL (<https://gentrn56.mdsol.com>) into the browser address window.
 - › Confirm that you can log into Rave with each of the user accounts / roles that the attendee will be using during the training: CRC, CRA, and others if applicable.

Timing Estimates

Estimated duration for Development attendees: about 4 hours.

The following timeline provides an approximation of the time needed to complete each lesson. Individual classes may vary based on the size of the group, time to answer questions and provide extra assistance, length of breaks, and other factors.

Section 1: Navigating Rave

Start the class (8 mins)

1. Introduction (8 mins)
2. Key Rave Concepts (12 mins)
3. Getting Started (16 mins)
4. Basic Navigation (13 mins)
5. Viewing Subject Information (12 mins)
6. Viewing eCRFs Associated with a Subject (11 mins)
7. Viewing Reports (11 mins)
8. Class Project #1 (6 mins)

Section 2: Navigating Rave

9. Clinical Data Life Cycle (4 mins)
 10. Submitting Clinical Data (19 mins)
 11. Using Log eCRFs (10 mins)
 12. Reporting Adverse Events in Rave (13 mins)
 13. Using Queries (20 mins)
 14. Using Sticky Notes (8 mins)
 15. Inactivating eCRFs (10 mins)
 16. Verifying Data (7 mins)
 17. Freezing Data (6 mins)
 18. Signing off Data (6 mins)
 19. Locking Data (6 mins)
 20. Class Project #2 (10 mins)
- Wrap up Section 2 (8 mins)

INSTRUCTOR INFORMATION

Rave Roles

The following table shows some Rave roles used at Genentech (in the production environment) and the types of users assigned to them.

Rave Roles

Role Name	Used By
CASA	Clinical Applications Systems Analyst
CRA	Clinical Site Manager
CRC	Site Coordinators. Data Entry access.
CTM	Clinical Trial Manager
DM	Project Data Manager
INT	DevIT Integrations Support
LDM	Lab Data Manager
PI	Study Investigators. Data Entry access.
RC	Other clinical data providers, such as Reading Centers. Data Entry access.
SDM	Coding Specialist
SPA	Statistical Programmer
VIEW	All other users (examples: Medical Director, Biostatisticians)

Rave User Groups

The following table shows some of the user groups defined at Genentech. Most users (including training users) are associated with the user group called **User**.

Rave User Groups

User Group	Users Have Access To
User	EDC and Reporter modules, usually, a data entry person.
Super Admin	All modules used by Genentech except Architect.
Rave Admin	All modules used by Genentech except the Architect and Configuration module. Usually, this user is in the PDIT group who would need to access most modules to troubleshoot, re-create issues, and identify causes and solutions to issues.
Developer	EDC module, PDF Generator, Report Administration and Reporter. Able to generate PDF files, create forms and edit checks in Architect, create and execute migration, and access clinical data and view reports.
Configuration Admin	Configuration module to perform the core configuration or updates to these configurations.
Report Admin	EDC Module, PDF Generator, Report Administration, and Reporter module. Able to access clinical data, assign other users access to specific reports or assign access to reports at specific levels, and view reports.
User Admin	User Administration module only. Able to create users, lock out or unlock users, inactivate users, and assign, un-assign and re-assign users to user groups, roles and study sites, and receive User-related messages.
Lab Admin	Architect, EDC, Global Library, Lab Administration, Site Administration and Reporter modules. Able to create, edit and delete Lab global objects, add or modify Lab Settings via Architect, create forms and edit checks in Architect, add, edit and delete items in the Standard Study, assign local labs to the study via Site Administration, access clinical data for all studies within the site group; and view reports.
Global Librarian	Architect, EDC, Global Library, and Reporter modules. Able to add, edit or delete items in the EDC Standard Study, access clinical data, and view reports.

Rave User Groups (Continued)

User Group	Users Have Access To
SODA Int Admin	Architect, Site Administration and User Administration modules. A user in this user group is usually from the PDIT or maybe a developer in Medidata for use with Rave-SODA Integration application, this user will be able to create new PIs and assign these new users to their study sites, create Sites and Site Groups, and view all studies in the site group.
Coder	EDC and Reporter modules. Able to view clinical data, view reports, and view all studies in the site group.
Master	Access to all Genentech modules and permissions.

SECTION 1

NAVIGATING RAVE

In this section of the training, you will get an overview of Rave and master the basics of navigating the Rave software, finding subject and electronic Case Report Form (eCRF) information, and viewing reports. Lessons in this section include:

- › [Introduction \(see page 2\)](#)
- › [Key Rave Concepts \(see page 7\)](#)
- › [Getting Started \(see page 16\)](#)
- › [Basic Navigation \(see page 29\)](#)
- › [Viewing Subject Information \(see page 43\)](#)
- › [Viewing eCRFs Associated with a Subject \(see page 53\)](#)
- › [Working with eCRFs \(see page 67\)](#)
- › [Viewing Reports \(see page 76\)](#)



At the end of this section, you will complete a class project that reinforces the skills you gained along the way.

LESSON 1

INTRODUCTION

Leader Note

View-only learners are required to complete Section 1 only.

This lesson introduces Medidata Rave. It covers the following topics:

- › [About Medidata Rave \(see page 2\)](#)
- › [What You Will Learn in the Rave Basics Training \(see page 3\)](#)
- › [Sample Study Used in this Training \(see page 5\)](#)
- › [Training Prerequisites \(see page 5\)](#)
- › [EDC Help Desk \(see page 5\)](#)

About Medidata Rave

Medidata Rave is the software that Genentech uses in electronic data capture (EDC) studies to capture, manage, and report on clinical research data. Rave provides operational consistency and a standardized look and feel across all studies. Rave can be configured to support the unique requirements of individual studies.

An *electronic case report form (eCRF)* is an online version of a printed case report form (CRF) used in Genentech-sponsored clinical trials. Commonly-used eCRFs include: Subject Eligibility, Demographics, Medical History, Vital Signs, Physical Exam, Electrocardiogram, Adverse Event, and Concomitant Medication. Instead of manually filling out paper-based CRFs, Rave site users complete eCRFs online. Genentech has created a company-wide Standard Study containing standard eCRFs that can be copied and adapted for individual trials.

Some key features of the Rave software include:

- › Real-time task lists and visit calendars
- › Real-time data availability
- › Patient search criteria
- › Real-time cross-panel and cross-visit edit checking
- › Quick navigation to recently accessed patients and electronic Case Report Forms (eCRFs)
- › Electronic signature capability that is compliant with 21 CFR Part 11
- › Genentech standard reports (configured specifically for Genentech-sponsored clinical trials)
- › Local and central lab capture and batch data loading
- › Electronic integration with related Genentech clinical systems (IVRS, CTMS/SODA, Drug Safety, TMS, SAS data sets, and so on).

For product information about the Rave software, go to the Medidata Web site at:
<http://www.mdsol.com/>

What You Will Learn in the Rave Basics Training

The Rave Basics Training is divided into two main sections:

- Section 1—Navigating Rave
- Section 2—Working with Clinical Data.
 - **Note:** Learners who view but do not change data in Rave as part of their job function might participate in Section 1 only.

The Rave Basics training provides a baseline understanding of the most commonly-used Rave functionality. This training is comprehensive and generalized across all types of users who participate in Genentech EDC studies. Some tasks described in this training might not apply to your particular job function or role for a given study. Nonetheless, the skills and understanding that you gain in this training will enable you to use the Rave software effectively in your job.

Section 1—Navigating Rave

This section introduces the Rave software and teaches you how to:

- Understand key Rave concepts
- Activate your Rave user account
- Log into Rave
- Navigate the Rave interface and modify your Rave settings
- Find and view studies and sites
- Find and view subject information
- Find, view, and work with eCRFs associated with a subject
- Find, view, and navigate reports of clinical study data

Section 2—Working with Clinical Data

This section teaches you how to:

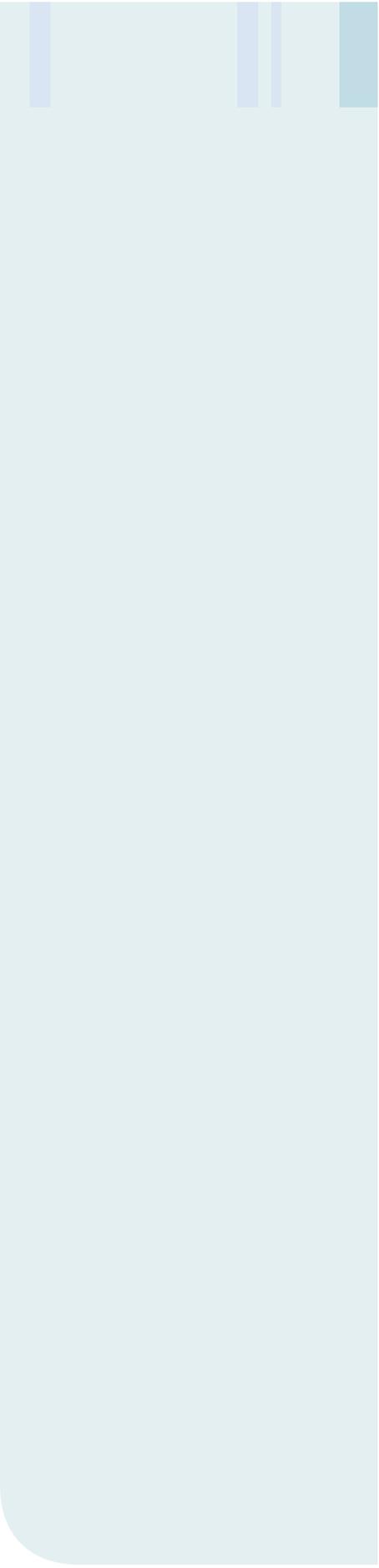
- Understand eCRF editing concepts, such as edit checks, restricted eCRFs and fields, and data-dependent fields
- Submit clinical data into Rave by completing eCRFs
- Report adverse events, including serious adverse events

Rave User Documentation

This *Participant Guide* is your comprehensive and authoritative documentation for using Rave in Genentech-sponsored EDC clinical trials.

Leader Note

Mention that this *Participant Guide* is the authoritative documentation for using Rave in Genentech-sponsored EDC studies.

- 
- Add an event (such as an unscheduled visit or extra eCRF) for a subject
 - Create manual queries
 - Create and acknowledge sticky notes associated with data points in eCRFs
 - Inactivate and reactivate eCRFs (instructor demo)
 - Verify and unverify data (instructor demo)
 - Freeze and unfreeze data (instructor demo)
 - Lock and unlock data (instructor demo)

Sample Study Used in this Training

The sample study used in this training is a fictional example of how Rave might be deployed in an actual Genentech-sponsored clinical trial. It provides common functionality—in the form of eCRFs, reports, and data—that allows learners to see and simulate the kinds of activities in which they'd normally participate in the live study environment. For more information, see [“Organization of Study Data” on page 29](#).

- **Note:** This sample study was created for training purposes only. Rave is specifically configured for each actual study in which you participate. The degree of difference depends on study-specific requirements. The sample study contains only a small amount of fictional data and does not use all of the functionality that one might typically find implemented in a Genentech-sponsored EDC clinical trial, such as live integrations with Genentech systems, terms coding, or extensive data checking logic.

Training Prerequisites

This training requires prior completion of the EDC business process training, “Introduction to Electronic Data Capture.” PDM, CTM, PDIT, and SPA users are required to take the “Understanding the EDC Business Process” course. After successfully completing the Rave Basics training, you could be required to participate in study-specific training.

EDC Help Desk

The EDC Help Desk provides support services to Rave users, such as technical support for the Rave software, handling subject transfers, managing user accounts, and site inactivations.

To contact the EDC Help Desk

Contact By	Description
Phone (US)	888.489.9384
Fax (US)	877.743.2350
Phone (Outside the US)	In your web browser, go to the following URL: http://tollfree.mdsol.com The Help Desk can provide multi-lingual support.
e-mail	helpdesk@mdsol.com

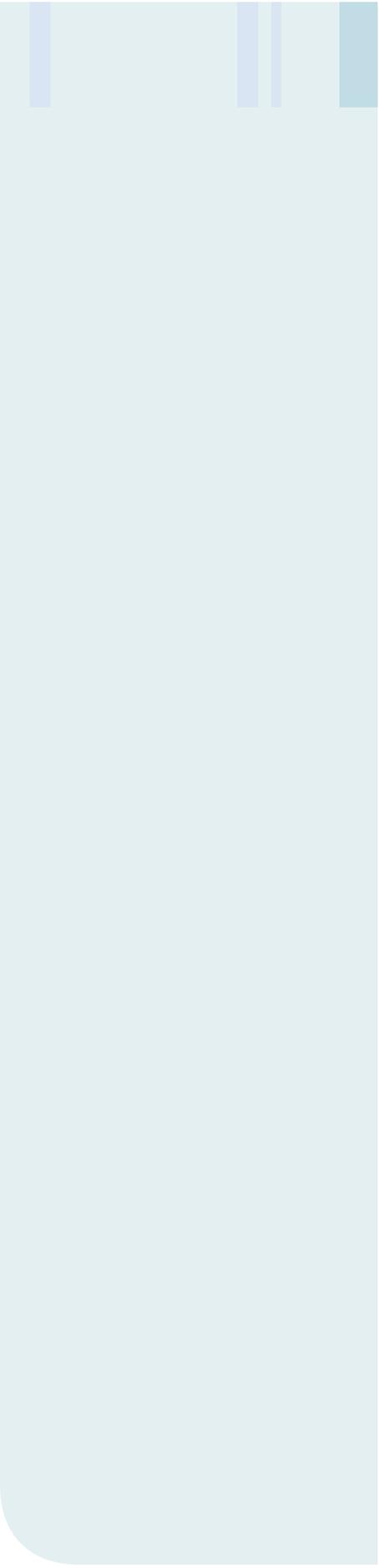
To assist the Help Desk with diagnosing and fixing your problem, try to complete the following steps:

Leader Note

Give learners the opportunity to ask questions that they might have regarding business process training. Provide answers as applicable.

Leader Note

Prerequisites apply to Genentech staff only. Site and CRO staff are not required to complete this prerequisite.

- 
1. Capture the screen by pressing **Alt + PrtSc** on the keyboard to copy the screen image to the Windows Clipboard.
 2. Create a new e-mail message.
 3. Paste the screen capture (**Ctrl + V**) into the e-mail message.
 4. Describe what happened and provide a step-by-step description of what the user experienced. If possible, list the steps needed to replicate the issue.
 5. Report the issue to the Help Desk by sending the e-mail to helpdesk@mdsol.com.

LESSON 2

KEY RAVE CONCEPTS

This lesson describes key concepts you need to understand before using the Rave software. It covers the following topics:

- › [Rave and Genentech EDC Studies \(see page 7\)](#)
- › [Rave Architecture: EDC and Related Modules \(see page 8\)](#)
- › [Rave Security and Access Rights \(see page 9\)](#)
- › [Integration with Other Genentech Systems \(see page 11\)](#)

Rave and Genentech EDC Studies

If you are new to the use of electronic data capture (EDC) in Genentech-sponsored clinical trials, you need to understand how EDC studies differ from paper-based operations. In an EDC study:

- › Case Report Forms (CRFs) are represented digitally as Electronic Case Report Forms (eCRFs).
- › Rather than filling out paper-based CRFs, sites submit clinical data by completing and submitting eCRFs in the Rave application.
- › Access to data is tightly controlled. For example, for site users, data entry screens for eCRFs typically show fewer fields than their paper-based counterparts. Site users submit just the critical data—only authorized users have access to the complete forms. In addition, the display of certain eCRFs, eCRF fields, and folders might be data-dependent. For example, pregnancy information (Pregnancy Report eCRF) might be displayed only when a subject is female.
- › Subject visits are represented on-screen as a hierarchy of folders (folder icons ) containing the eCRFs associated with each visit.
- › In Genentech-sponsored EDC clinical trials, Rave is the *system of record* for eCRFs. This means that the eCRF data stored in Rave is the authoritative electronic version of the clinical data.
- › Once clinical data are submitted in Rave, the information becomes available to all authorized users of the system for viewing purposes, generating reports, exporting to other Genentech systems, and cleaning and querying data.
- › Changes to data are recorded in an *audit trail* that users can display in order to see the history of any changes made to the data.
- › Rave provides an *interactive environment* that allows certain users to exchange communications.

Leader Note

There is a lot of conceptual material in this lesson. Rather than covering all of this in exhaustive detail, consider taking a poll of attendees to determine what's most important to them, and then allocate your time and attention accordingly. Remind them that they can refer to this *Participant Guide* for detailed information.

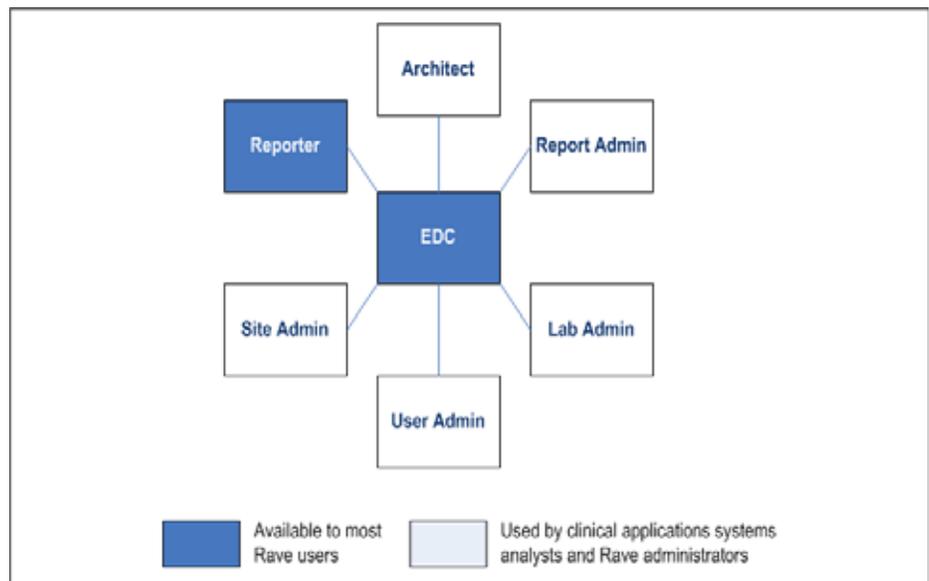
For example, a Project Data Manager might mark a data point on an eCRF with a sticky note (used for reminders and informal communication) and require an acknowledgement that the note was read by a person to whom it was directed.

A Clinical Site Manager (CSM) might mark a data field on an eCRF with a query (a specific question about a data point), which requires someone at the site to provide a satisfactory response.

- After clinical data in a study has been submitted, the Clinical Site Manager conducts the Source Document Verification (SDV) process to ensure that what was entered on the eCRF matches the written record of data collected from each subject (patient charts, lab reports, notes, and other paper-based records).
- Instead of written signatures or initials on a paper form, eCRFs require *electronic signatures* that principal investigators use to sign off on a subject. Electronic signatures will be covered later in this training.
- Genentech has designed many standard eCRFs for data collection in Rave to ensure as much standardization across studies as possible. Each study will use only those eCRFs that are required. The sample study used in this training uses the eCRFs described in [“Subjects, Folders, and eCRFs” on page 32](#).

Rave Architecture: EDC and Related Modules

The Rave software is a collection of inter-related software modules, as shown in the following figure.



Each module serves a specific purpose and user audience.

Table 1: **Rave Modules**

Module Name	Used By	Description
EDC	All users	Used in EDC studies to capture, manage, and report on clinical research data.
Reporter	All users	Used to generate and display reports for use in the EDC Module.
Architect	Clinical Data Management (CDM) Clinical Applications Systems Analysts (CASAs)	Used to design and build eCRFs for use in the EDC Module.
User Administration	EDC Help Desk	Used to configure user accounts (assigning or revoking roles and access rights), assign users to studies and sites, and other user-oriented data.
Site Administration	EDC Help Desk	Used to configure site data (for one or more studies) for use in the EDC Module.
Report Administration	Builder and Development Information Technology (PDIT)	Used to configure characteristics of, and access to, Rave reports for use in the EDC Module.
Lab Administration	Laboratory Data Manager (LDM)	Configure lab data used in the EDC module, such as analyte characteristics, measurement units, data ranges, conversion formulae, and other information.

Rave Security and Access Rights

Rave provides or restricts access to data, features, and functionality based on user login names and their associated user groups and roles.

Rave Users

A Rave *user* is anyone who can log into the Rave software. All users have associated *user accounts* that define their login names, passwords, and other identifying information. The EDC Help Desk is responsible for managing user account information for all Genentech EDC studies.

Your User Account

Your instructor will provide you with (at least) one temporary user name and password that you will use during the Rave Basics training. Once you complete this training, you will be eligible to request your own Rave user account.

Your User Group

All users in this training session belong to the `User` user group, which provides access to the EDC and Reporter modules.

Your Role in This Training

In Section 1 of this training, you will log in with a user name and password that is associated with the `CRC` role.

If you proceed to Section 2 of this training, you will begin by logging in with a different user name and password—one that is associated with the `CRC`, `CRA`, `PI`, and `DM` roles.

Depending on your job function, and at the discretion of the training leader, you might be instructed to log in with other roles when completing certain exercises.

User Groups

A *user group* is a logical grouping of one or more user accounts. Each user account is associated with just one user group. The user group determines which Rave modules are available to users who are members of the group. For example, most users are associated with the user group called `User`, which provides access to the EDC module and reports. A few users are associated with other user groups—for example, only administrative personnel have access to the Site Administration and User Administration modules.

Roles

A *role* is a set of permissions to perform certain actions and access particular data. Each user is assigned just one role. Roles determine what a user sees and has access to—eCRFs, reports, and so on. When a user logs in, Rave grants them access to Rave features and data based on the permissions configured for their associated user group and role.

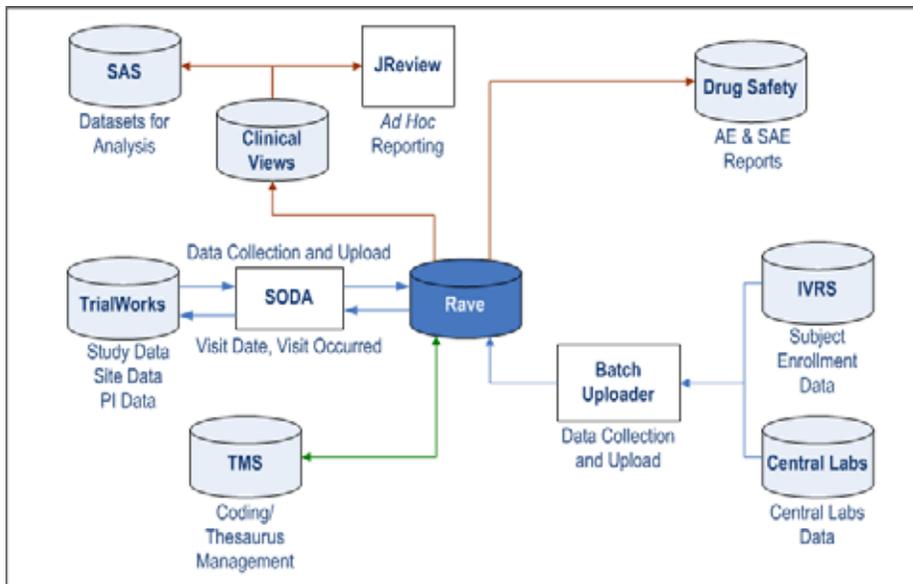
The following roles are associated with the user accounts used in the Rave Basics training.

Table 2: Roles Used in the Rave Basics Training

Role Name	Used By
CRC	Clinical Research Coordinators who coordinate data collection at the clinical site. Provides the ability to view and edit clinical data in the EDC module.
PI	Principal Investigator who conducts clinical investigations at a clinical site and signs off on clinical data for a given subject.
CRA	Clinical Site Manager who monitors, manages, and verifies the progress of a clinical trial.
DM	Project Data Manager who coordinates database design, data processing, and data management for a clinical trial.

Integration with Other Genentech Systems

Rave exchanges certain information—such as subject and site data—with other Genentech systems, as shown in the following figure.



Clinical Trial Management System (CTMS) Integration

The TrialWorks® by ClinPhone e-Service is the Genentech CTMS that exchanges data with Rave.

- CTMS provides Rave with the following information: Study data, Site data, and Principal Investigator data. CTMS is the system of record for this information—any changes to study, site, and principal investigator information must be made in CTMS, not Rave (changes in CTMS are sent to Rave via SODA for automatic updating). CTMS is scheduled to send this data to SODA periodically (every 10-15 minutes). The SODA-to-Rave transfer is configurable per study, although it typically occurs once or twice daily. This means that changes made in CTMS, such as updates to principal investigator information, can have a lag time of up to 12 or 24 hours, depending on the frequency of the SODA-to-Rave transfer that is configured for the study.
- Rave also sends Visit Date and Visit Occurred information to CTMS.

Sample Study Is Not Integrated

By design, the Training Sample Study is isolated from—and not integrated with—other Genentech systems.



Loading CTMS Data First

Study, site, and principal investigator data must be loaded into Rave before subjects can be added from IVRS.





Submit Once Distribute Anywhere (SODA) Integration

SODA is a Genentech system that receives data that is uploaded from CTMS (study, site, and principal investigator data) and SODA integration submits it to Rave for processing. In addition, SODA integration generates site groups (see [“Scroll Site Groups” on page 40](#)) by concatenating state and city information for sites (for example, **GA, Atlanta** for all trial sites located in Atlanta, GA). SODA is scheduled to send this data to Rave periodically (such as once a day; this interval is configurable). Urgent updates can also be initiated manually.

- **Note:** Rave-SODA integration is a transitional solution that will be replaced eventually with direct Rave-CTMS integration. SODA currently functions as a pass-through mechanism for CTMS data.



Interactive Voice Response System (IVRS)

IVRS is an automated telephone information collection and processing system that provides the following subject enrollment information to Rave (including, but not limited to):

- subject identification (combination of patient ID + subject initials)
- subject / randomization number (patient ID)
- subject initials
- optionally, other information, such as stratification variables

IVRS is the system of record for this information. Each time a subject is enrolled, new subjects are entered into IVRS first, then uploaded into Rave via the Batch Uploader (see [“Batch Uploader Integration” on page 13](#)). Such data are visible in the Subject Identification page (see [“Subject Identification Page” on page 46](#)), which is accessible via a link on the Subject page. Subjects must be created in Rave before clinical data for those subjects can be entered.

- **Note:** Changes made to subject information in Rave or the User Admin module do *not* get sent back to IVRS.

Updating Subject Information

The IVRS upload creates new subjects in Rave. However, the IVRS upload does not refresh Rave with changes in subject data (such as a middle initial). If you need to make changes to subject data, you must contact the IVRS administrator.

Leader Note

IVRS is used by most Genentech studies. For phase I and non-randomized studies, the study team may receive a waiver if there is a strong business rationale, such as a small number of sites, subjects, or single treatment arms.

Rave Uses Only Some IVRS Data

Only some of the information in IVRS is fed into Rave.



Central Labs

Central Labs collect and provide lab information that pertain to the specific eCRFs defined for a given study. New and updated lab information is entered into the Central Labs database first, and then uploaded periodically into Rave via the Batch Uploader (see [“Batch Uploader Integration” on page 13](#)). For each study, data from Central Labs is refreshed typically once or twice monthly, and during off-peak times (such as midnight). All uploaded data must have a target eCRF defined in Rave for the study. Lab data would be updated if, for example, a subject was retested—the retest results would come to Rave in a subsequent upload.

Visit Date Required

Central labs integration requires the completion of the Visit Date eCRF for the visit during which the lab sample was taken.

Note: Changes made to data in eCRFs in Rave do *not* get propagated back to Central Labs.

Batch Uploader Integration

The Batch Uploader Utility is a Medidata utility that uploads data from IVRS and Central Labs into Rave. IVRS and Central Labs store new and updated data files in a special directory. The Batch Uploader Utility checks this directory frequently (every few seconds) and, if it finds any file, sends this data to Rave immediately.

Drug Safety Integration

For Genentech Drug Safety, Rave is the system of record for reportable adverse events. When users type data into an Adverse Event eCRF, they specify whether the adverse event is:

- reportable (such as a serious adverse event)
- ready to submit for distribution to sponsor

Even if the user does not specify that a submitted Adverse Event eCRF is ready for distribution, Rave automatically reports a reportable adverse event within 24/48 hours (configured per study). To report an adverse event, Rave generates a PDF of the eCRF, attaches it to an e-mail notification, and distributes it to those who should be notified (target e-mail addresses, such as for Genentech Drug Safety, are configured on a study-by-study basis). In Rave, a “permanent” sticky note (see [“Introducing Sticky Notes” on page 69](#)) is displayed on the adverse event eCRF showing when notifications were sent out.

Thesaurus Management System (TMS) Integration

Rave uses TMS to process *coded terms*, which are words that have a precise meaning and are typically categorized by body system. Coded terms are typically found in such eCRFs as Adverse Event, Medical History, Concomitant Medications, and so on.

Periodically (every hour or so), the Rave software sends newly-submitted “raw terms” from human-written content (for example, text typed into a symptoms description field) to TMS for processing. TMS checks the raw terms and returns to Rave a hierarchy of related terms, which are then used by the SAS integration for this particular eCRF. In addition, TMS also flags apparent coding discrepancies (such as missing terms) or other issues with the description entered (such as multiple medical concepts), which can result in system-generated queries requesting that the site clarify the description that they entered.



Adverse Event Data in EDC

Adverse Event data is accessible from the EDC Module as soon as it is entered—even before it is sent to the sponsor.



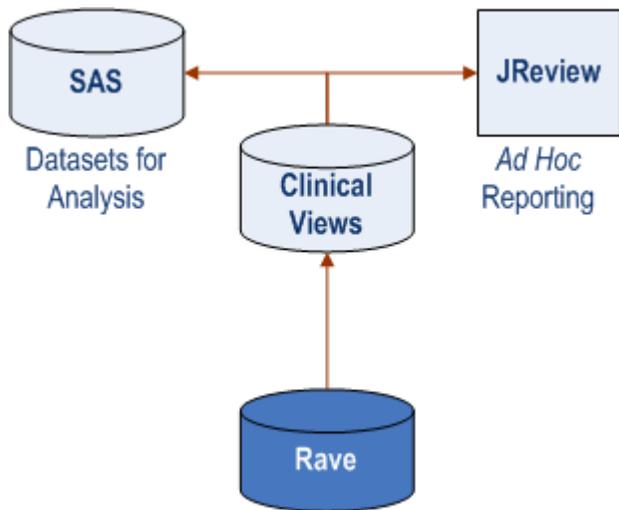
Integration Management Tools

Genentech has implemented various integration management tools for administrators that expedite, in real-time, the exchange of data between Rave and other Genentech applications.

- › **RAVEmanage** is an administration tool installed at Genentech to configure and maintain integration applications between Genentech systems and Rave. In general, RAVEmanage handles the scheduling and execution of Genentech interfaces that exchange data with Medidata Rave. RAVEmanage also distributes e-mail notifications to selected recipients on completion or abnormal termination of an interface job.
- › **RAVEDirect** is an administration tool installed at Medidata to configure and maintain integration applications between Rave and Genentech systems. In general, RAVEDirect manages the scheduling and execution of Medidata interfaces that exchange data with Genentech. Interfaces are executed at a scheduled time or as soon as an interface data file is transferred from Genentech. RAVEDirect also distributes e-mail notifications to selected recipients on completion or abnormal termination of an interface job.
- › **Cyclone Interchange** is a standard Electronic Data Interchange (EDI) gateway that ensures the secure exchange of data between Rave and Genentech system. In fact, the FDA has standardized any future electronic data exchange with pharmaceutical and biotech industry using Cyclone Interchange.

Rave Clinical Views

Rave Clinical Views contain up-to-date subject data that is represented in tabular format for easy access to generate reports or export data. When users save changes to an eCRF, those changes are reflected immediately in the clinical views associated with that eCRF. Clinical views contain replicated copies of production data and are used to support Genentech standard reports, ad hoc reporting (using JReview), and for exporting (for SAS integration).



Statistical Analysis System (SAS) Integration

Users in Statistical Programming and Analysis (SPA) perform analysis on clinical trial data using SAS. SAS integration involves extracting specialized data from Clinical Views and a hierarchy of terms obtained from TMS.

JReview—Ad Hoc Reporting

Users in certain Genentech groups (PDM, LDM, and SDM) use JReview to design and generate ad hoc reports for clinical trial data. JReview runs filters and reports on the data stored in Rave Clinical Views.

- **Note:** These ad hoc reports should not be used for decision-making.

Exporting Report Data

The Rave EDC module supports exporting report data in two formats:

- **Microsoft Excel**—for ad hoc analysis of report data in Excel spreadsheets.
- **Adobe Acrobat (PDF)**—for portable report documents that can be distributed, read, and printed on a wide variety of systems.

- **Note:** Exported data should not be used for decision-making.



LESSON 3

GETTING STARTED

This lesson covers the following topics:

- › [Obtain a Rave User Account \(see page 16\)](#)
- › [Log Into Rave \(see page 19\)](#)
- › [Rave Home Page \(see page 22\)](#)

User Account for Training

You will not need to obtain a Rave user account for the Rave Basics Training, as you have already been provided with a temporary training user account.

However, for your job, before you can request Rave user account, you will need to have completed the Rave Basics training—and possibly other training, as required for your site, study, and job function.

Obtain a Rave User Account

To become a Rave user, you need to obtain a Rave user account. To obtain a Rave user account, you need to complete the EDC User Account Management and Training Form.

Request a Rave user account

1. Obtain the EDC User Account Management and Training Form from your course instructor at the end of this class.
2. Complete the EDC User Account Management and Training Form according to the accompanying instructions.

Provide your name, phone number, e-mail address, and other information as requested on the form.



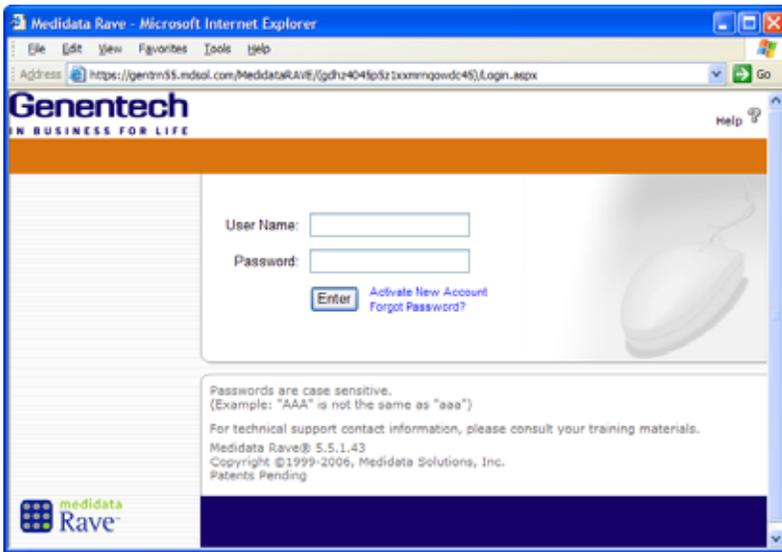
IMPORTANT! On your account request form, you need to provide a Personal Identification Number (PIN), which is a four-digit number that *you will need to remember and keep confidential*. The PIN is required to activate your Rave account and to recover your account information should you forget your Rave user name or password.

3. Submit the EDC User Account Management and Training Form according to the accompanying instructions.

A Rave Administrator will send you an e-mail that provides the following account activation information:

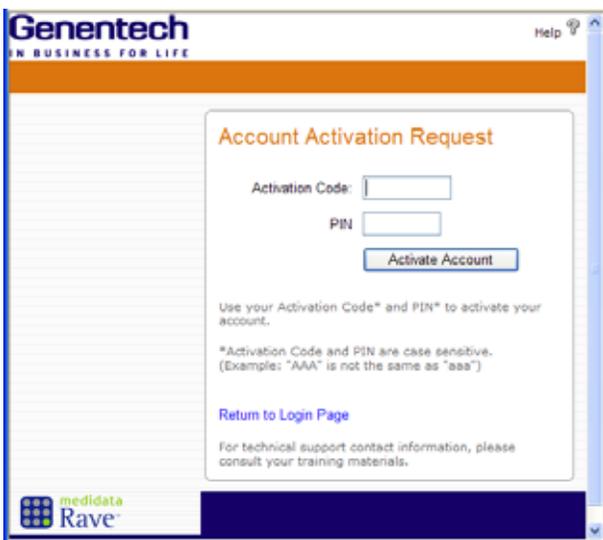
- › Rave user name
 - › Account activation code, which is a random, unique, eight-character code sequence
 - › Rave URL (<https://www.genentech-edc.mdsol.com>)
4. Using your browser, go to the Rave URL that the Rave Administrator provided.
<https://www.genentech-edc.mdsol.com>

- Rave displays the Login page, as shown in the following example.



- Click the **Activate New Account** link.

Rave displays the Account Activation Request page.



- Type the following information:

Field	Description
Activation Code	Activation Code provided by your Rave Administrator.
PIN	Personal Identification Number that you provided on the EDC User Account Management and Training Form.

- Click **Activate Account** to activate your account.

Rave validates your entries and, if valid, prompts you to select a new password.

Preactivated User Accounts

For this training, you will be logging in with user accounts that are already activated.

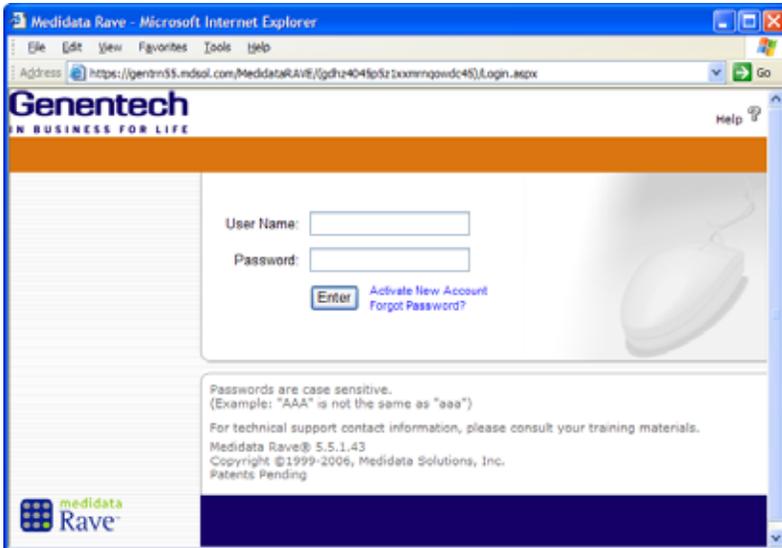
9. Type your new password according to on-screen directions and the following guidelines:
 - › Passwords must be at least six characters long and must include at least one alphabetic character and one numeric character.
 - › Passwords expire after one year.
 - › Passwords can be reused after two years.
 - › You are allowed **five** attempts to submit your password. After the fifth incorrect attempt, you will be locked out of the system and you will need to call the Rave Help Desk to get reconnected.
10. Type your password again to confirm what you typed.
11. Click **Save Password and Continue** to proceed.

Log Into Rave

Once your Rave user account is activated, you can log into the Rave software.

Log into Rave

1. In your browser, open the following URL:
<https://genentech-edc.mdsol.com>
2. Rave displays the Login page, as shown in the following example.



3. Type the following information:

Field	Description
User Name	Login name assigned to you by the Rave Administrator.
Password	Login password.

4. Click **Enter** to submit your entries.

Rave validates your user name and password and, if valid, displays the Rave Home page described in [“Rave Home Page” on page 22](#).

Training URL

During the training, use the following URL instead to log into Rave:

<https://gentrn56.mdsol.com>

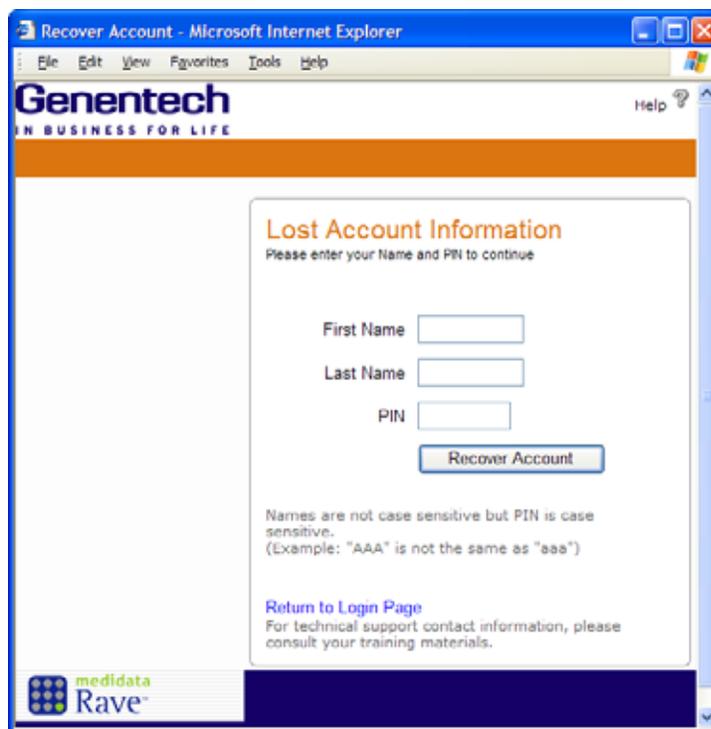
Forgotten User Name / Password

If you have forgotten your user name or password, you can recover your Rave account information by supplying your name and PIN.

Recover your Rave user account information

1. On the Rave Login page, click the **Forgot Password?** link.

Rave displays the Lost Account Information page.



2. Type the following information.

Field	Description
First Name	Your first name as specified on the EDC User Account Management and Training Form.
Last Name	Your last name as specified on the EDC User Account Management and Training Form.
PIN	PIN as specified on the EDC User Account Management and Training Form.

3. Click **Recover Account** to submit your entries.

Rave validates your entries and, if valid, prompts you to select a new password.

The screenshot shows the Genentech Rave 'New Password' form. At the top left is the Genentech logo with the tagline 'IN BUSINESS FOR LIFE'. At the top right are links for 'Help' and 'Logout'. The main heading is 'New Password'. Below this, there are several lines of text providing password requirements: 'Passwords expire after twelve months.', 'Minimum password length is 6 characters.', 'At least one alpha character is required in a password.', 'At least one numeric character is required in a password.', and 'Passwords can be reused after two years.'. A warning states: 'You are allowed five attempts to enter your password. After the fifth incorrect attempt, you will be locked out of the system and you will need to call site monitor to get reconnected.' Below the warning is the text 'CRC_1 Training (crc_1)'. There are two input fields: 'New Password' and 'Confirm Password'. At the bottom of the form is a button labeled 'Save Password and Continue'. In the bottom left corner, there is a Medidata Rave logo. In the bottom right corner, there is small text: 'Medidata Rave® Version 5.5.1.43 Copyright ©1999-2008, Medidata Solutions, Inc.'

4. Enter a new password.
5. Confirm your password.
6. Click **Save Password and Continue** to submit your entries.

Login Assistance

If you are still having problem logging into Rave, contact the Rave Help Desk as described in [“EDC Help Desk” on page 5](#).

Access to Multiple Studies

Rave displays this page to users to have access to multiple studies. If you have access to only one study, then you will not be prompted to select a study from the list.

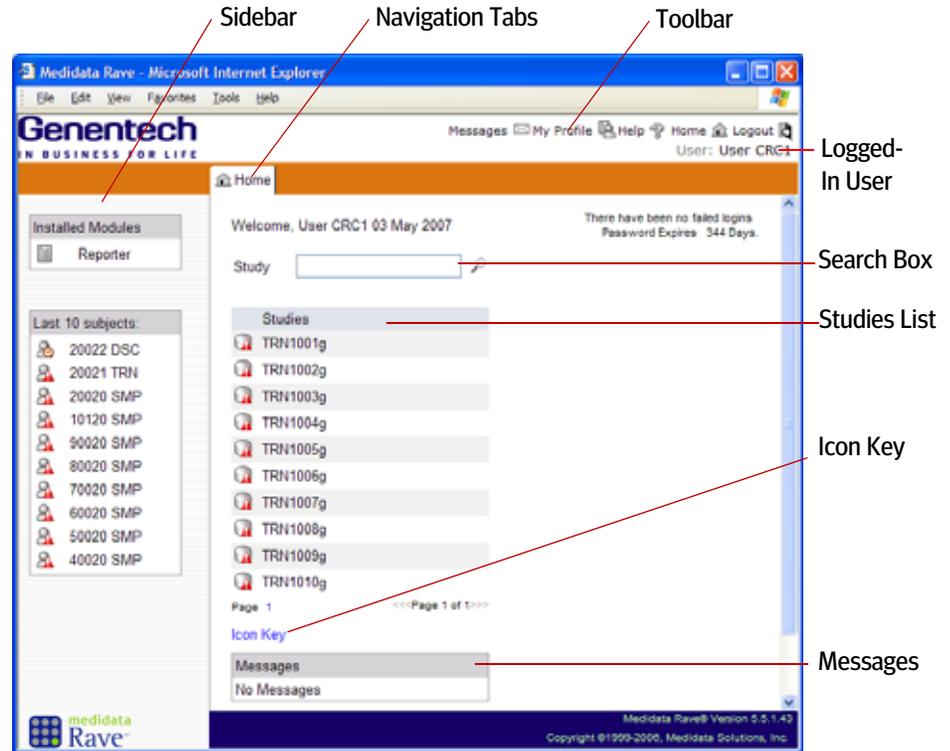
For training purposes, all learners in this course have access to multiple training sample studies. However, your instructor will direct you to select a specific study that is used in today's class.

Role-Based Screens

What you see on any Rave screen is what you have access to based on the user account you used to log into the system (identified in the upper right corner of the page). The Rave Administrator configures permissions for the user group and role associated with your user account. Another user with different permissions might see a slightly different screen.

Rave Home Page

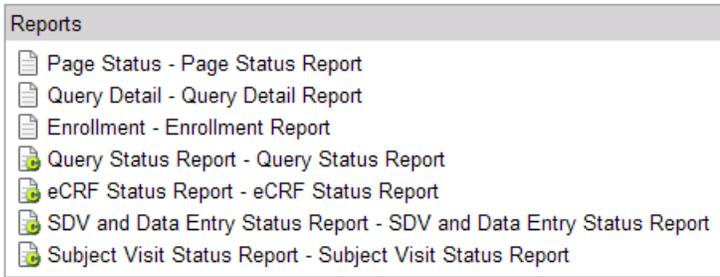
If you logged in successfully, Rave displays the Home page, as shown in the following example.



Each screen provides the ability to navigate the Rave interface, search for information, submit data, and so on. The center of a Rave page typically includes:

Item	Description
Search Box	Allows you to search for studies, sites, or subjects by name. Useful when the Studies, Sites, or Users list is pages long.
Studies / Sites List	List of available studies (or sites, if only one study). The above example shows a list of studies to choose from.
Icon Key Link	Displays the icon key described later in this section.
Messages	Messages requiring attention, if applicable. Typically applies to Rave Administrators only.

Depending on your access rights and previous Rave activity, you might also see a list of recently-visited reports, as shown in the following example.



Sidebar



Depending on the context, the Sidebar area of the Rave screen typically includes:

Item	Description
Installed Modules List	Rave modules (described in “Rave Architecture: EDC and Related Modules” on page 8) to which you have access. To launch a Rave module, simply click it in the list.
Last 10 Subjects List	List of the most-recently viewed subjects (up to ten). To view a subject in the list, simply click it.
eCRFs History	List of the most-recently viewed eCRFs. To view an eCRF in the list, simply click it.

Icon Key

The icon key provides a pop-up page that identifies the icons you see on Rave pages.



IMPORTANT! You will see many different icons in the Rave user interface—too many to remember them all at first. Just like a legend for a map, you can use the icon key to quickly learn what a particular icon represents.

Display the icon key

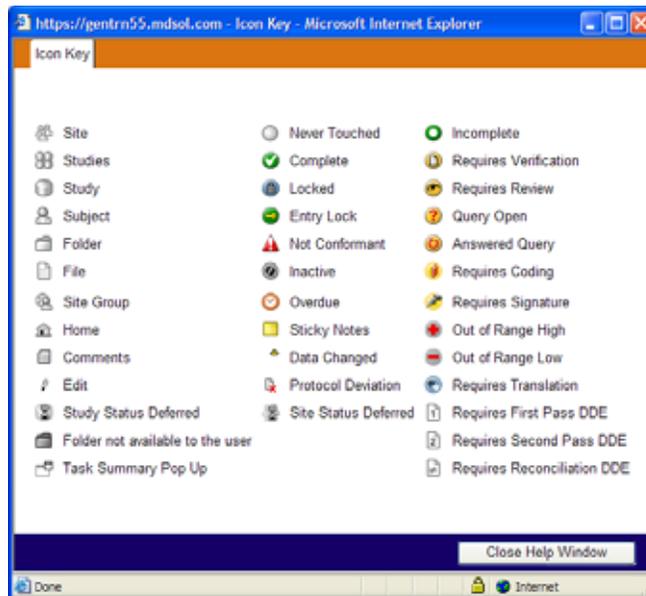
1. Click the **Icon Key** link.

[Icon Key](#)

Reporter Module

In this training, you have access to the Reporter module.

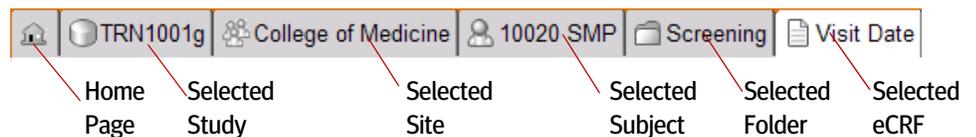
Rave displays the Icon Key page.



2. When finished, click **Close Help Window**.

Navigation Tabs

Navigation tabs allow you to quickly navigate between pages of information in the Rave interface. When you select an item on a Rave page, a new tab appears to the right of the navigation tabs, as shown in the following example.



The Home page is always the left-most tab. The text on the tab describes what's on the tab: study name, site name, subject identification, folder name, eCRF name, and so on.

H Tip! Clicking a tab—instead of using browser buttons—is how you navigate to different screens in the Rave user interface. For example, if you have finished viewing eCRFs for a particular subject and want to quickly display another subject, you can jump to the Site page (with its list of subjects from which to choose) simply by clicking the tab associated with that site.

Toolbar

The toolbar along the top of the Rave Home page displays links to help you navigate the Rave interface.

Messages  My Profile  Help  Home  Logout 

Link	Description
Messages	Displays a list of messages needing attention, if applicable.
My Profile	Allows you to change your password and personalize your Rave settings.
Help	Displays Rave online help.
Home	Takes you to the Rave Home page.
Logout	Logs you out of the Rave system.

Customize Your Rave Settings

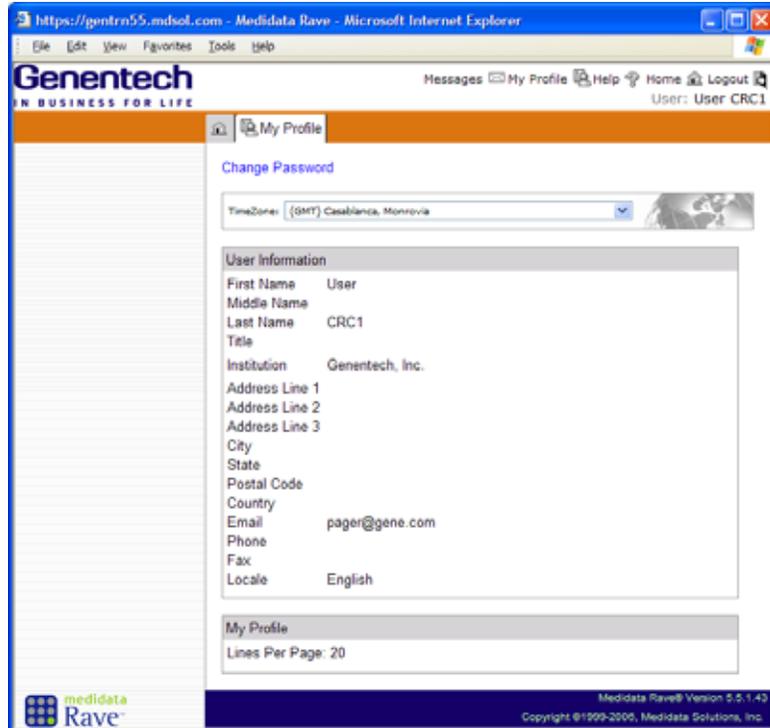
Each user account has an associated profile (called My Profile) that defines personal Rave settings for that account, such as the login password, time zone, and user information (such as name, address, e-mail address, and phone number).

Customize your personal Rave settings

My Profile 

- ❖ On the Toolbar, click the **My Profile** link.

Rave displays the My Profile page.



From the My Profile page, you can:

- [Change an existing password \(see page 26\)](#)
- [Change the time zone \(see page 27\)](#)

Do *Not* Change Training Password

Do not change the password for the user account that you are using during this training.

Change an existing password

1. On the My Profile page, click the **Change Password** link.

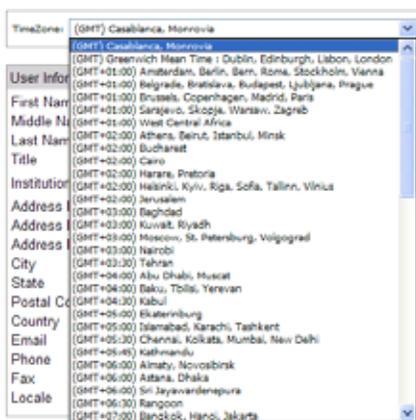
Rave displays the Change Password page.



2. Type your old password.
3. Type your new password, and then type it again to confirm what you typed.
4. Click **Save Password and Continue** to submit your changes.

Change the time zone

- ❖ Select a different time zone from the **Time Zone** drop-down list.



Log Out of Rave

You should log out of Rave completely whenever you are finished using the software. If you are logged into Rave but remain idle (no mouse clicks or keystrokes) for a period of time, then Rave will lock you out of the system (a *time-out*; see [“Time-outs” on page 34](#)) and prompt you to re-enter your password or log in before you can resume using Rave.

Log out of Rave

Logout 

- ❖ On the Toolbar, click the **Logout** link.

Rave logs you out of the system and displays a confirmation message.



Log back in again

- ❖ Click the **Log In** link.

Hands-On Exercise

1. Log into the computer, if necessary.
2. Log into Rave using your temporary Rave account for this training.
3. Identify the various parts of the Rave Home page:
 - > sidebar
 - > navigation tabs
 - > toolbar
 - > icon key
 - > logged in user
4. Display the Icon Key.
5. Log out of Rave.

Rave Login for Training

Log in using the user name and password that you are assigned for this portion of the training.

Leader Note

Training accounts are for classroom use. Please do not use these outside of the classroom.

LESSON 4

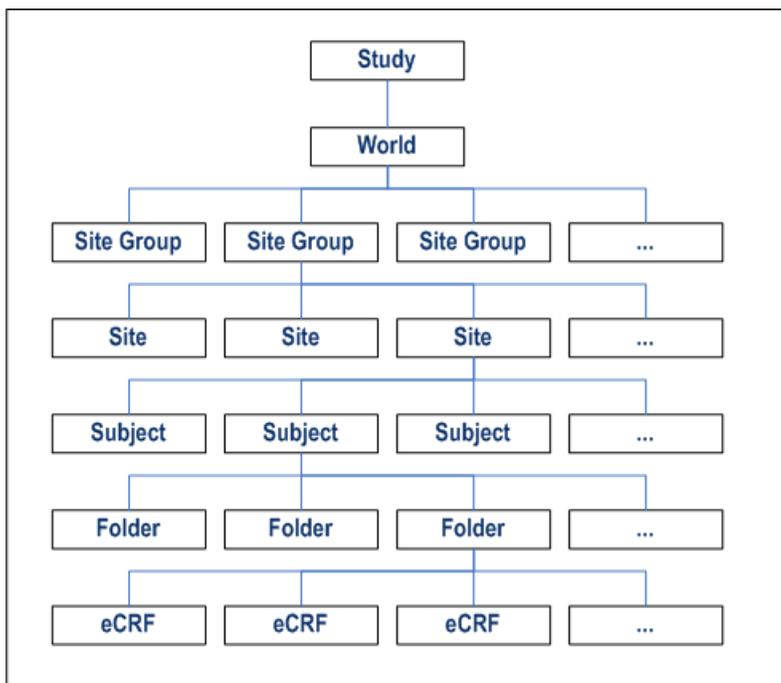
BASIC NAVIGATION

This lesson covers the following topics:

- › [Organization of Study Data \(see page 29\)](#)
- › [Navigation Tips \(see page 34\)](#)
- › [Select a Study \(see page 37\)](#)
- › [Study Page \(see page 38\)](#)
- › [View a Site \(see page 39\)](#)
- › [Site Page \(see page 41\)](#)
- › [Rave's Online Help \(see page 42\)](#)

Organization of Study Data

Rave organizes study data in a hierarchical manner, as shown in the following figure.



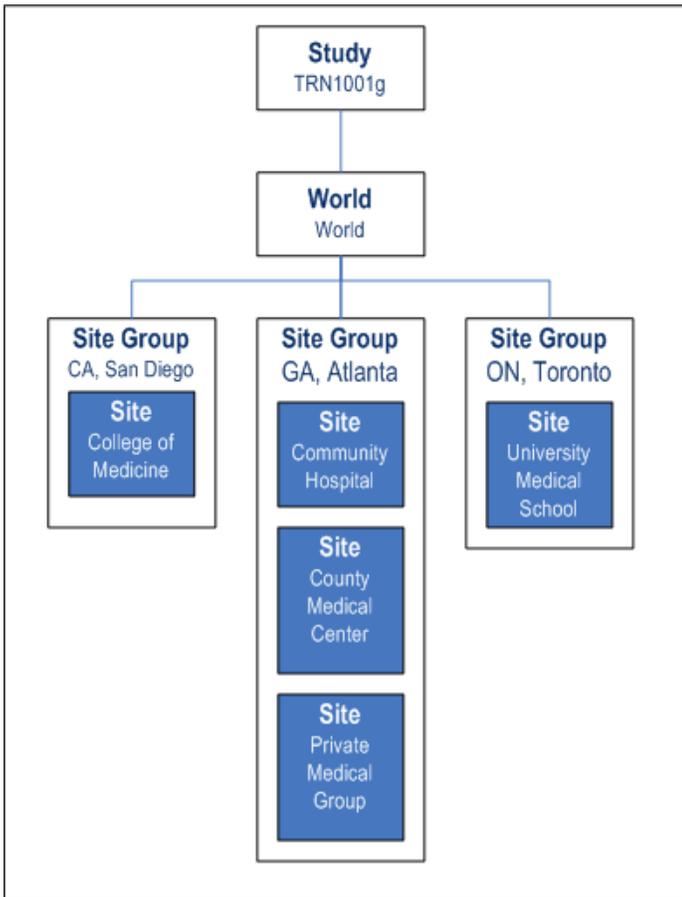
Studies, Worlds, Site Groups, and Sites

The following table describes types of data stored in Rave.

Table 3: **Organization of Clinical Trial Data**

Data	Description
Study	<p>Any systematic trial of investigational or approved products in human subjects pertaining to the efficacy and/or safety of the product. Each study is uniquely identified by its Genentech-assigned study number. In this training session, the study number uses the following pattern:</p> <p>TRN####g (example: TRN1001g)</p> <p>where:</p> <ul style="list-style-type: none">› TRN identifies this as a training study› #### is a sequence number› g signifies that this is a Development study
World	<p>A logical way to classify and organize sites and site groups within a study. Genentech uses just one world called <code>World</code>.</p>
Site Group	<p>A logical way to classify and organize sites within a study. Genentech uses the following pattern:</p> <p>ST, Ci ty (example, CA, San Di ego)</p> <p>or, for Canadian sites:</p> <p>PR, Ci ty (example, ON, Toronto)</p>
Site	<p>The physical location where subjects are seen. Each site is uniquely identified by its Genentech-assigned, six-digit character site number, that begins with the letter “S”. In the training sample study, sites are named generically (such as <code>Uni versi ty Medi cal School or Col lege of Medi ci ne</code>).</p>

The following figure shows a high-level diagram of how studies, worlds, site groups, and sites are related. Examples are based on actual data in the training sample study.



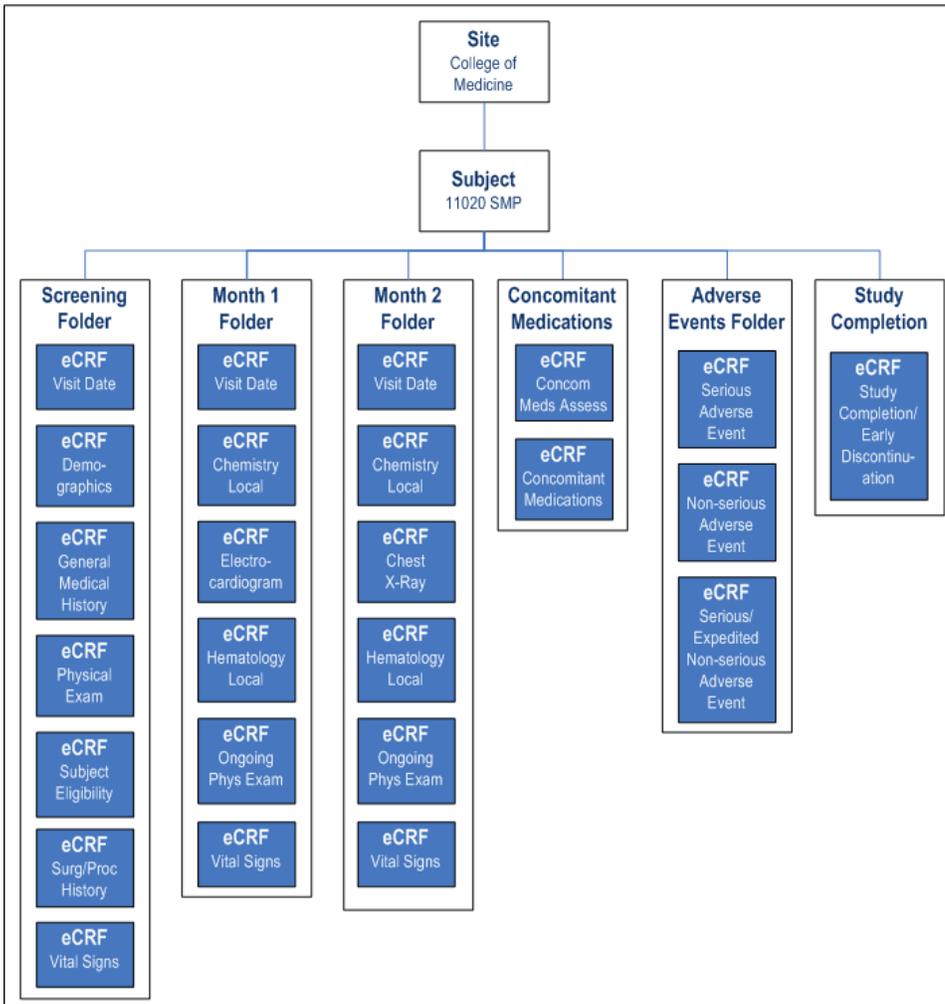
Subjects, Folders, and eCRFs

The following table describes subjects, folders, and eCRFs in Rave.

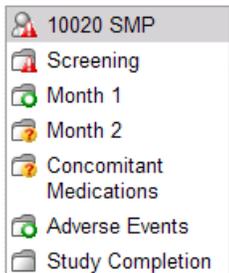
Table 4: **Organization of Subject Data for Genentech-Sponsored EDC Clinical Trials**

Data	Description
Subject	<p>A participant in a study. Trial subjects are associated with a single site in a study. Each subject in a clinical trial is uniquely identified by a subject ID that uses the following pattern:</p> <p>##### AAA</p> <p>where</p> <ul style="list-style-type: none">▶ ##### is the Genentech-assigned, five-digit subject number (for example, 10000 - 12000). This number may not contain leading zeros.▶ AAA is the subject's initials (use a hyphen if the subject does not have a middle name).
Folder	<p>Mechanism for organizing eCRFs into logical groups, such as by subject visit, or for Adverse Event reporting. A folder can contain eCRFs and other folders. Folders appear in the sidebar. The training sample study uses the following folders:</p> <ul style="list-style-type: none">▶ Screening—Screening visit.▶ Month 1—First monthly visit.▶ Month 2—Second monthly visit.▶ Concomitant Medications—Medications taken by the subject concurrently with the study.▶ Adverse Events—Adverse Events and Drug Safety reporting.▶ Study Completion—Completion or early termination for subject.▶ Unscheduled—If an unscheduled visit was added, as described in “Add Events (Unscheduled Visits)” on page 113. This folder has the same forms as the Month 2 folder.
eCRF	<p>Electronic case report form. An online version of a printed case report form (CRF) used in Genentech-sponsored EDC clinical trials, such as a Physical Exam, Subject Eligibility, or Vital Signs form. Instead of manually filling out printed CRFs, Rave users complete eCRFs online.</p>

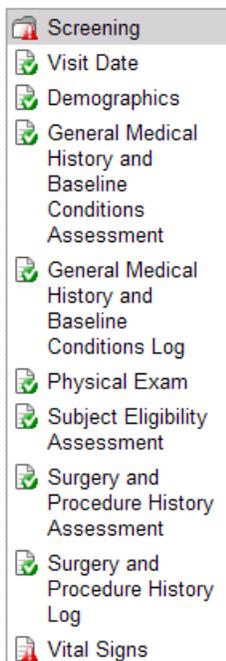
The following figure shows a high-level diagram of how subjects, folders, and eCRFs are related. Examples are based on the actual data in the training sample study.



The following figure shows, in the sidebar, how Rave displays the list of folders for a selected subject (in this example, subject 10020 SMP).



The following figure shows, in the sidebar, how Rave displays the list of eCRFs for a selected folder (in this example, the Screening folder).



Navigation Tips

This section provides tips for navigating the Rave interface.

Use Rave Navigation Features, Not Browser Buttons

- **Note:** This security feature is designed to protect patient data.

Always use Rave buttons, tabs, and links—not the buttons (Back, Forward, Stop, Refresh, or Home) or menu commands in your Web browser—to navigate the Rave interface.



NEVER use these browser buttons.



IMPORTANT! If you use any of the browser buttons, Rave will prompt you to re-enter your password before you can resume using Rave.

Time-outs

- **Note:** This security feature is designed to protect patient data.

If you are logged into Rave but remain idle (no mouse clicks or keystrokes) for a given period of time (described below), then Rave will lock you out of the system and

Leader Note

Demonstrate what happens when you click the Back button in the browser (you must supply a password).

prompt you to re-enter your password or log in before you can resume using Rave. Rave displays the prompt when you click the mouse or use the keyboard after a period of inactivity.



IMPORTANT! If you have any unsaved data when a time-out occurs, then you will lose that data. Therefore, it is important to save data entry changes as you go.

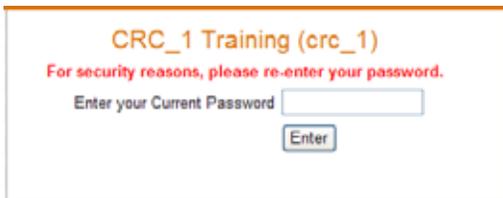
The following types of time-outs might occur:

Table 5: **Types of Time-Outs**

Type	Description
Password Time-out	If you are inactive for 45 minutes, then Rave will prompt you to re-enter your password.
Interaction Time-out	If you are inactive for 60 minutes, then Rave will prompt you to log into the system from the Login page.
Web Session Time-out	If the server times out (90 minutes), then Rave will prompt you to re-enter your password.

These time-outs are configured globally across all Genentech EDC studies.

The following example shows a password prompt due to a password time-out.



Submit Changes Before Continuing

Whenever you have edited data in Rave, be sure to submit your changes after typing the data. If you encounter a Rave time-out due to inactivity, you will lose your unsaved changes. If you attempt to navigate to a different page, then Rave will prompt you to save your changes before proceeding.

Permissions For Accessing Data

As described in [“Rave Home Page” on page 22](#), what you see on any Rave screen, and what you can do on that screen, is based on the access rights assigned to your user account. The Rave Administrator configures permissions for the user group and role associated with your user account. Another user with different permissions might see a slightly different screen, such as different fields on an eCRF.

Print the Screen

You might want to print a copy of a screen that you're currently viewing. The instructions may vary depending on the browser product and version that you are using to access Rave.

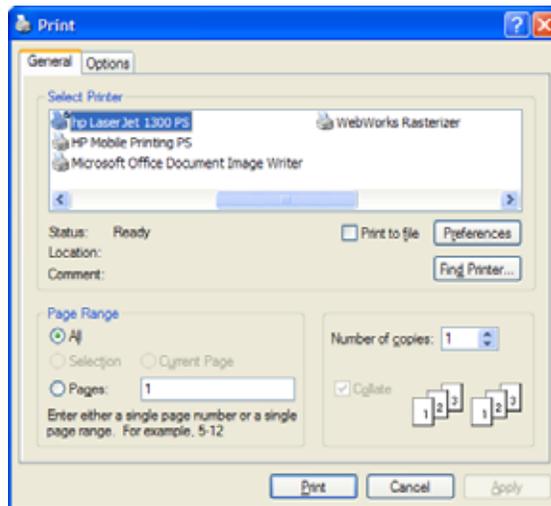
Don't Print During the Training

The computer that you are using during this class might not be set up to print. Therefore, do not print unless your instructor directs you to do so.

Print a screen

1. In your Web browser (in this example, Microsoft Internet Explorer), choose the **Print** command from the **File** menu.

Your browser displays a print dialog, as shown in the following example.



2. Change your print settings (for example, for wide screens, you might want to change from Portrait to Landscape) as needed.
3. Click **Print** to print the screen.

Handling System Issues

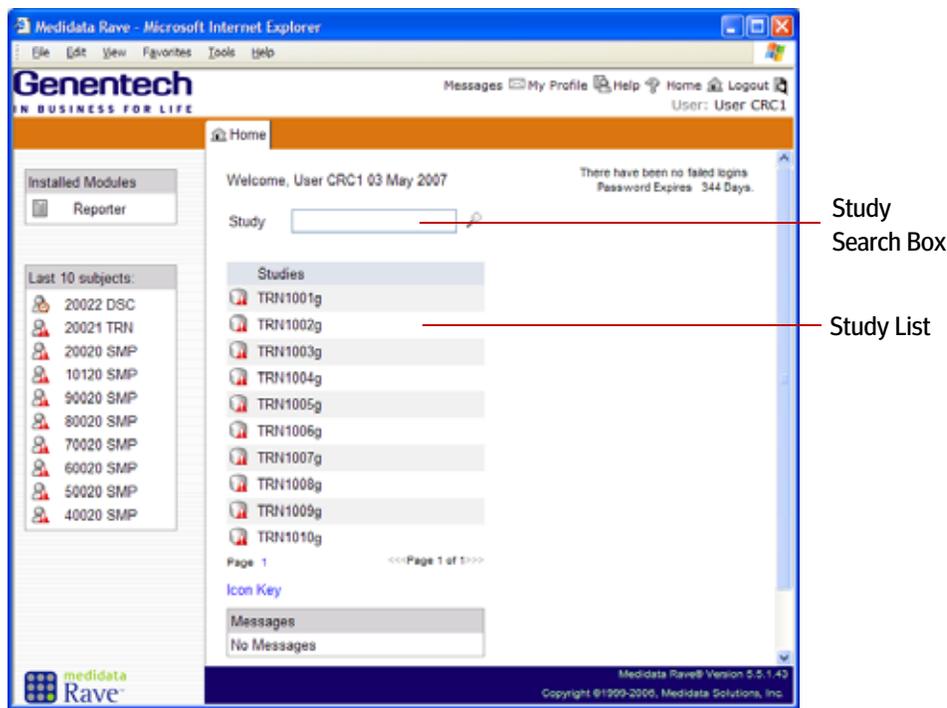
You should contact the EDC Help Desk if you encounter any difficulties using Rave, such as:

- login issues
- error messages
- unexpected behavior (such as redirections or screen refresh relays)

For more information, see [“EDC Help Desk” on page 5](#).

Select a Study

If your user account has access to multiple studies, the Rave home page displays a list of studies from which to select, and a search box to quickly find a study in the list.



Select a study

- ❖ On the Rave Home page, click a study in the study list.

Rave displays the Study page, which is described in [“Study Page” on page 38](#).

Search for a Study

If you can view multiple studies, the study search box allows you to quickly search for a study (amidst a list of many studies) by filtering on the study name.

Search for a study

1. In the search box, specify the complete study name or use the wildcard character (asterisk).



- To search for studies that *begin with* one or more characters, type the first few characters of the study name, followed by an asterisk (*).

For example, you could type the letters **A*** in the box to display a list of all studies starting with the letter “A” (such as AVF, APO, and so on). Rave matches study names starting from left to right. The text box is *not* case-sensitive, meaning that **A*** and **a*** return the same result.

Study Data

Study data originates in the Genentech CTMS system. Study data is periodically uploaded into Rave via the Rave-SODA integration described in [“Clinical Trial Management System \(CTMS\) Integration” on page 11](#).

Access to Multiple Studies

Rave displays this page to users who have access to multiple studies. If you have access to only one study, then you will not be prompted to select a study from the list—you will instead see the Study page described later in this lesson.

During this course, all learners have access to multiple training sample studies. Your course leader will direct you to select the one training sample study that will be used in today’s class.

Genentech Study Names

Study names at Genentech are coded using the following naming pattern:

AAA####g

where:

- AAA—Molecule / Therapeutic Code (in this training, TRN is used)
- ####—Genentech-assigned clinical trial number
- g—indicates a development study

For details, see [“Studies, Worlds, Site Groups, and Sites” on page 30](#).

Access to Multiple Sites

Rave displays this page to users to have access to multiple sites. If you have access to only one site, then you will not be prompted to select a site from the list.

For training purposes, all learners in this course have access to multiple sites. However, your instructor will direct you to select specific sites as appropriate.

- To search for studies that *contain* one or more characters, simply omit the asterisk (for example, type **A**) or use asterisks on both sides (for example, type ***A***).
- To search for studies that *end with* one or more characters, precede it with an asterisk. For example, to find all development studies, type ***g**.
- To show all studies, specify *no text* (empty text box).

2. Click the Search (🔍) icon.

Rave refreshes the study list, displaying only the studies whose name matches the text you typed.

3. Click the name of the study that you want to view.

Rave displays the Study page, which is described in the next section.

Study Page

The following figure shows an example Study page with key components.

The screenshot shows the Genentech Rave interface for a study named 'TRN1001g'. The page includes a search bar, a list of site groups, and a reports quick list. Red lines point from labels on the right to these specific components.

Site	Site Group
College of Medicine	CA, San Diego
Community Hospital	GA, Atlanta
County Medical Center	GA, Atlanta
Private Medical Group	GA, Atlanta
University Medical School	ON, Toronto

Reports
Audit Trail - Audit Trail Report
J-Review - J-Review

The tab for the Study page displays the name of the associated study.

Task Summary

Task Summary: Study	Sites
⚠ NonConformant Data	1
❓ Open Queries	1
🕒 Overdue Data	1

The Task Summary shows any pending tasks (associated with the study) to which the logged-in user has access (based on role and user privileges). Pending tasks are items needing attention right now, such as:

- **Non-Conformant Data**—Data that was entered in an incorrect format, such as an alphabetical character in a numeric field. For more information, see [“Types of Fields on Rave Pages” on page 101](#) and [“Edit Checks” on page 102](#).
- **Queries**—Questions about a data point on an eCRF. The Task Summary can display open (outstanding) queries as well as answered queries. For more information, see [“Introducing Queries” on page 67](#).
- **Sticky Notes**—Informal note, remark, or observation that is associated with a data point on an eCRF. For more information, see [“Introducing Sticky Notes” on page 69](#).
- **Overdue Data**—Data that has not yet been submitted in a timely manner.
- **Clinical Data Lifecycle Tasks**—Items that have been submitted and are ready for subsequent processing, such as verification, freeze (entry lock), electronic signature, and lock (hard lock). For more information, see [“Clinical Data Life Cycle” on page 96](#).

To learn more, see [“View eCRFs Via the Task Summary” on page 61](#) and [“Icon Key” on page 23](#).

View a Site

You view a site by clicking its name in the site list.

View a site

- ❖ Page through the site list and click the site that you want to view.

Rave displays the Site page for the selected site, which is described in [“Site Page” on page 41](#).

Search for a Site

If you can view multiple sites for a study, then the site search box allows you to quickly search for a site (amidst a list of many sites) by filtering on the site name. This is especially useful when the Sites list is pages long.

Search for a site

1. On the Study page, in the Find drop-down list, select `Site` (if it is not already selected).

Find Site 
[Advanced Search](#)

2. In the search box, type a partial name of the site.

For example, you could type the letters `Univ*` in the box to display a list of all university sites (those starting with the letters “univ”). Rave matches site names starting from left to

Site Data

Site data originates in the Genentech CTMS system. Site data is periodically uploaded into Rave via the Rave-SODA integration described in [“Clinical Trial Management System \(CTMS\) Integration” on page 11](#).

Genentech Site Group Names

Site groups at Genentech are coded using the following naming pattern:

AA, CityName

where:

- AA—Two-letter state or province code
- CityName—Name of the city in which the study site is located.
- For details, see [“Studies, Worlds, Site Groups, and Sites” on page 30.](#)

Searching for Subjects

To search for a subject instead, you simply select Subject from the Find drop-down list. To learn more, see [“Search for a Subject” on page 49.](#)

right. The text box is *not* case-sensitive, meaning that **Univ***, **UNIV***, and **univ*** all return the same result.

If you omit the asterisk (for example, you type **Hospital**), then Rave displays a list of all sites whose names *contain* the word `Hospital`.

3. Click the Search (🔍) icon.

Rave refreshes the site list, displaying only sites whose name matches the text you typed.

4. Click the name of the site that you want to view.

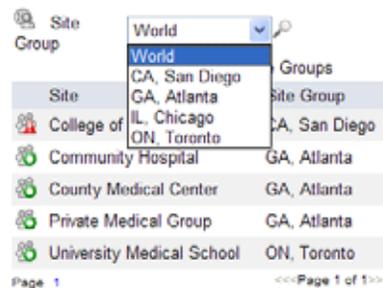
Rave displays the Site page for the selected site, which is described in [“Site Page” on page 41.](#)

Scroll Site Groups

Site groups are used as a logical way to classify sites within a study. At Genentech, site groups are used to organize sites by state (or province) and city, such as NY, New York and CA, Los Angeles.

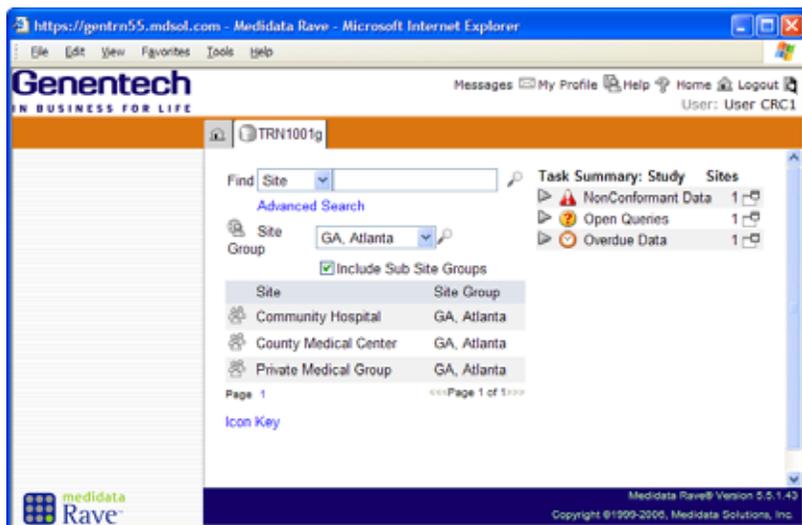
Search by site group

1. On the Study page, click the Site Group drop-down list, as shown in the following example.



2. Scroll the list of site groups and click the site group that you want to use.
3. Click the Search (🔍) icon.

Rave refreshes the site list, displaying only the sites belonging to the selected site group, as shown in the following example.

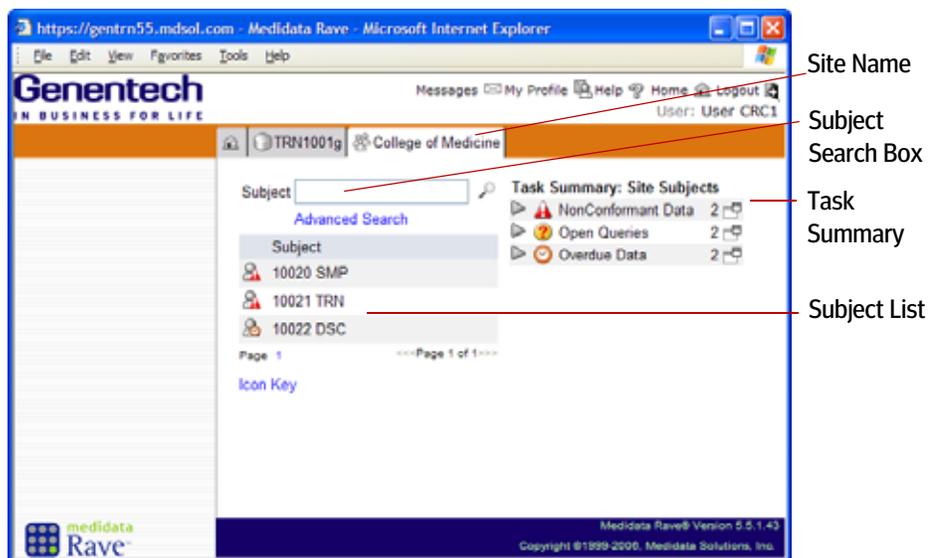


4. Click the name of the site that you want to view.

Rave displays the Site page for the selected site, which is described in the next section.

Site Page

The following figure shows an example Site page with key components.



The tab for the Site page displays the name of the associated site. The Site page also displays the list of subjects associated with the selected site.



IMPORTANT! A status icon appears next to each subject in the Subject List. The status icon reflects the status of the data in eCRFs associated with that subject. For more information about each status icon, see [“Data Status Icons” on page 56](#).

The status of individual eCRFs for a given subject can vary. For example, a subject can have one eCRF with an open query and another that is overdue. Rave displays only one status icon per subject, selecting the status icon that it considers to be the most important for that subject, based on Rave’s own status precedence hierarchy and your logged-in role.

See the next lesson, [“Viewing Subject Information” on page 43](#), for more information about this page.

Definitive Sources for Rave

If you need additional information about using Rave, refer to this document first. If you still do not find an answer, contact the Rave Help Desk, as described in [“EDC Help Desk” on page 5](#).

Rave’s Online Help

The Toolbar displays a Help link, which you click to view Medidata’s software online help for Rave. This online help is generic—it is not customized for Genentech or for specific Genentech-sponsored clinical trials.

- **Note:** This document provides the definitive source of information for using the Rave EDC module in Genentech-sponsored studies. Rave’s online help might describe Rave features that are not used at Genentech, or it might use terminology that differs from Genentech terms or usage.

On the other hand, Genentech provides pop-up help on eCRF pages that is tailored for individual studies and very useful for Rave users. To learn more, see [“Get Help for eCRFs” on page 73](#).

Hands-On Exercise

1. Identify the various parts of the Site page:
 - › site name
 - › subject search box
 - › Task Summary
 - › subject list
2. Search for and select the `Community Hospital` site using the site search box.
3. Search for and select the `Private Medical Group` site using site groups (GA, Atlanta).

LESSON 5

VIEWING SUBJECT INFORMATION

This lesson covers the following topics:

- › [About Subjects \(see page 43\)](#)
- › [View a Subject \(see page 43\)](#)
- › [Subject Page—Calendar View \(see page 44\)](#)
- › [Subject Page—Grid View \(see page 47\)](#)
- › [Search for a Subject \(see page 49\)](#)

About Subjects

A *subject* is a participant in a study. Each subject in a clinical trial is uniquely identified by a Genentech-assigned subject number. IVRS (see [“Interactive Voice Response System \(IVRS\)” on page 12](#)) supplies the basic subject data to Rave—subject initials, subject number, and subject identification—which is updated frequently (typically every 10 minutes or less). For non-IVRS studies, subjects are manually added, as described in [“Adding Subjects” on page 104](#).

View a Subject

View a subject

- ❖ On the Site page, look through the Subject list and then click the name of the subject that you want to view.

Rave displays the Subject page for the selected subject.

Subject identification

The subject identification pattern at Genentech are coded using the following naming pattern:

AAA

where

- › ##### is the Genentech-assigned, five-digit subject number.
- › AAA is the subject's initials. If the subject does not have a middle name, then a hyphen is used (such as A-B).

Leader Note

Study teams for global studies may exclude subject initials for privacy and confidentiality reasons.

Subject Page—Calendar View

The following figure shows an example Subject page with key components.

Leader Note

Point out the status icons and mention that you'll be discussing them soon.

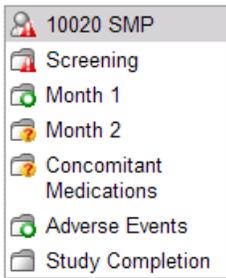
Visit	Date	Task Summary: Subject	Pages
Screening	01 Dec 2006	NonConformant Data	1
Month 1	31 Dec 2006	Open Queries	3
Month 2	30 Jan 2007	Overdue Data	0
Concomitant Medications	01 Dec 2006		
Adverse Events	01 Dec 2006		

This is known as the *Calendar View* for a subject, which is the default view for the Subject page. You'll learn about an alternate view, the Grid View, later in this lesson (see [“Subject Page—Grid View” on page 47](#)). The tab for the Subject page displays the name (subject number + initials) of the associated subject.

IMPORTANT! A status icon appears next to each folder in the Subject Schedule. The status icon reflects the status of the data in eCRFs associated with that subject. For more information about each status icon, see [“Data Status Icons” on page 56](#).

The status of individual eCRFs for a given folder can vary. For example, a folder can have one eCRF with an open query and another that has non-conformant data. Rave displays only one status icon per folder, selecting the status icon that it considers to be the most important for that folder, based on Rave's own status precedence hierarchy and your logged-in role.

Task List



In the sidebar, the Task List contains a collection of eCRFs that are associated with the subject. The eCRFs are organized into folders, which represent site visits and other events. The Task List also includes links to related information, such as adverse events and an investigator search. The subject identification (subject ID + subject initials) appears at the top of the Task List.

Subject Schedule

Visit	Date
Screening	01 Dec 2006
Month 1	31 Dec 2006
Month 2	30 Jan 2007
Concomitant Medications	01 Dec 2006
Adverse Events	01 Dec 2006

The Subject Schedule displays the visits that are required for subjects, along with the calculated target date for each visit. Visits are calculated off of the baseline visit date and this information is for display only. The Subject Schedule displays two columns:

Column	Description
Visit	List of visits required for subjects. Each visit is represented by a folder. Each folder contains the eCRF(s) associated with that visit.
Date	Target date for each visit, or blank if no target date is specified.

You'll learn more about the Subject Schedule in [“View eCRFs Via the Subject Schedule” on page 60](#)

Leader Note

Demonstrate how to navigate using the task list.

Leader Note

Demonstrate how to navigate using the Subject Schedule.

Visit Calendar and Subject Schedule

The study protocol specifies the visits. The Study Configuration Document describes how the visit calendar (subject schedule) is configured in Rave.

Typically, the initial date (day 0) of the subject schedule is based on the Visit Date field on the Visit Date eCRF in the Screening Visit folder. The Study Configuration Document then specifies how many days can elapse (after the target date).

For greater accuracy, particularly with long-term studies, the Study Configuration Document may define a calendar reset that allows for a new reference point from which to calculate overdue eCRFs.

Leader Note

Demonstrate how to navigate using the Task Summary.

Access to the Subject Identification Page

Users associated with the CRC or PI roles cannot see this page.

Task Summary

Task Summary: Subject	Pages
 NonConformant Data	1 
 Open Queries	3 
 Overdue Data	0 

The Task Summary shows any pending tasks (associated with the subject) to which the logged-in user has access (based on role and user privileges). Pending tasks are items needing attention right now, such as non-conformant data, queries, sticky notes, overdue data, and other status information. For a description of these items, see [“Task Summary” on page 38](#).

Use the Task Summary to quickly navigate to a task you want to view or complete. For more information, see [“View eCRFs Via the Task Summary” on page 61](#).

Subject Identification Page

The Subject Identification page displays the following information about a subject:

- › subject number
- › subject initials
- › subject identification (subject number + subject initials)
- › responsible investigator
- › subject status

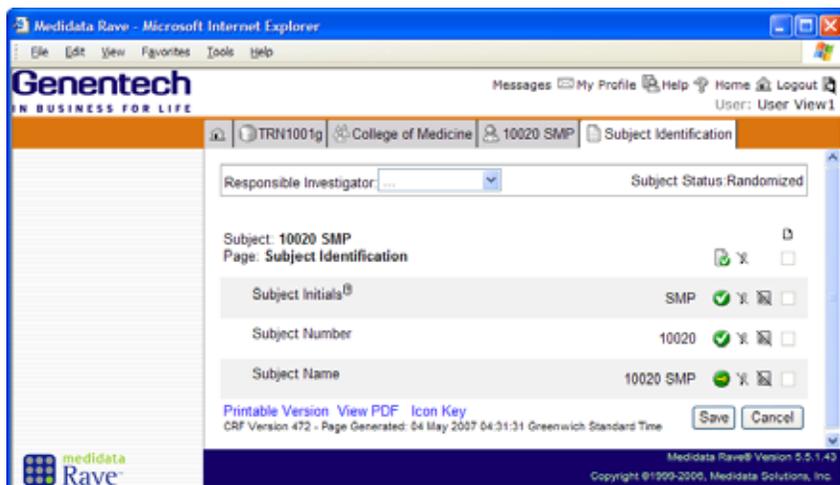
- **Note:** IVRS is the source system for this subject information. You cannot make changes to this data in Rave—only in IVRS.

View the Subject Identification page

1. [View a subject \(see page 43\)](#).
2. On the Subject home page, click the **Subject Identification** link.

 [Subject Identification](#)

Rave displays the Subject Identification page for the selected subject.



3. When finished, click **Cancel** to close this page.

Subject Page—Grid View

The Grid View displays subject folders and eCRFs in a grid format. This at-a-glance perspective allows you to quickly find and display subject visits and associated eCRFs, including the status of specific eCRFs. Status icons show whether the eCRF is finished, outstanding, locked, has queries, and so on.

- **Note:** The Grid View allows authorized Rave users (CRA, PI, and DM role) to quickly perform study closeout activities (verify, freeze, sign-off, and lock) by processing multiple eCRFs at a time. For more information, see [“Batch Verify Using the Grid View” on page 162](#), [“Batch Freeze Using the Grid View” on page 167](#), [“Batch Sign Off Using the Grid View” on page 172](#), and [“Batch Lock Using the Grid View” on page 176](#).

Display the Grid View

- ❖ On the Subject page, while the Calendar View is displayed, click the **Grid View** link in the upper-right corner.

Rave displays information about the selected subject in a Grid View, as shown in the following example.

The screenshot shows the Genentech Rave Grid View interface. On the left, there is a sidebar with a folder tree for '10020 SMP' including 'Screening', 'Month 1', 'Month 2', 'Concomitant Medications', 'Adverse Events', and 'Study Completion'. Below this is a 'CRF History' section for '10020 SMP - Visit Date'. The main area is a grid with columns for 'All', 'Study Completion', 'Screening', 'Concomitant Medications', 'Adverse Events', 'Month 1', 'Month 2', and 'All'. The rows list various eCRFs such as 'Adverse Events', 'Chemistry Local', 'Demographics', 'Study Completion/Early Discontinuation', 'Electrocardiogram', 'Subject Eligibility Assessment', 'Hematology Local', 'General Medical History and Baseline Conditions Log', 'General Medical History and Baseline Conditions Assessment', 'Concomitant Medications Assessment', 'Physical Exam', 'Ongoing Physical Exam', 'Surgery and Procedure History Log', 'Surgery and Procedure History Assessment', 'Visit Date', 'Vital Signs', and 'Chest X-Ray'. Status icons (green checkmarks, red X's, and yellow warning icons) are present in the grid cells. Red arrows point from labels 'Folders', 'eCRFs', and 'eCRF Status Icons' to their respective parts in the screenshot.

In the Grid View:

- › Columns represent folders associated with this subject.
- › Rows represent eCRFs associated with this subject. Rows are ordered alphabetically (below the Visit Date).
- › Status icons in cells (the intersection of rows and columns) show the status of the applicable eCRF associated with the visit.

H Tip! Each eCRF in the Grid View is represented by a status icon. The status icon reflects the status of the data in the eCRF. For more information about each status icon, see [“Data Status Icons” on page 56](#).

The status of individual fields for a given eCRF can vary. For example, one field can have an open query while another can contain non-conformant data. Rave displays only one status icon per eCRF, selecting the status icon that it considers to be the most important for that eCRF, based on Rave’s own status precedence hierarchy and your logged-in role.

- › Blank cells (no status icons) mean that the eCRF in that row does not apply to the visit in that column.

Display the Calendar View

- ❖ On the Subject page, while the Grid View is displayed, click the **Calendar View** link in the upper-right corner.

Rave displays information about the selected subject in a Calendar View, as shown in [“Subject Page—Calendar View” on page 44](#).

Search for a Subject

On the Site page, Rave provides you with a variety of ways to find subjects for a site:

- Page through the Subject List on the Site page.
- Search using the search box or the advanced subject search.
- Click a recently-viewed subject in the Last 10 Subjects Quicklist.

These methods are particularly useful when the Subject list for a site is pages long.

Use the Search Box

Subject 

The Site page provides a search box that you can use to find a particular subject.

View a subject using the search box on the Site page

1. [View a site \(see page 39\)](#), if applicable.

The subject identification consists of the five-digit subject number plus the subject’s initials (for example, 12345 ABC).

2. In the search box, specify the entire subject identification or use the wildcard character (asterisk).
 - To search for subjects whose identification *begins with* one or more characters, type the first few characters of the study identification, followed by an asterisk (*). Rave matches subject identifications starting from left to right.

For example, if you typed **1***, then Rave would list all subjects whose names begin with the number 1; if you typed **12***, then Rave would list subjects whose names begins with the numbers “12”; and so on.
 - To search for subjects whose identification *contains* one or more characters, simply omit the asterisk (for example, type **1**) or use asterisks on both sides (for example, type ***1***).
 - To search for subjects whose identification *ends with* one or more characters, precede it with an asterisk. For example, to find all development studies, type ***g**.
 - To show all subject identifications, specify *no text* (empty text box).

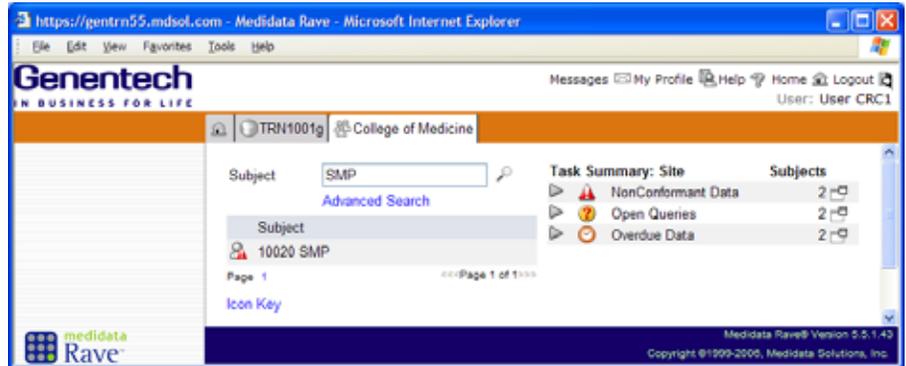
Searching for Subjects

You can also search for subjects on the Site page by selecting Subject from the Find drop-down list. To learn more, see [“Search for a Study” on page 37](#).

H Tip! In general, the more characters you type, the more specific and restrictive the search (possibly resulting in fewer matches). The fewer characters you type, the more inclusive the search (possibly resulting in more matches).

3. Click the Search (🔍) icon.

Rave displays the list of subjects matching the search characters you typed.



4. Click the subject for which you want to view details.

Rave displays the Subject page for the selected subject in the main area.

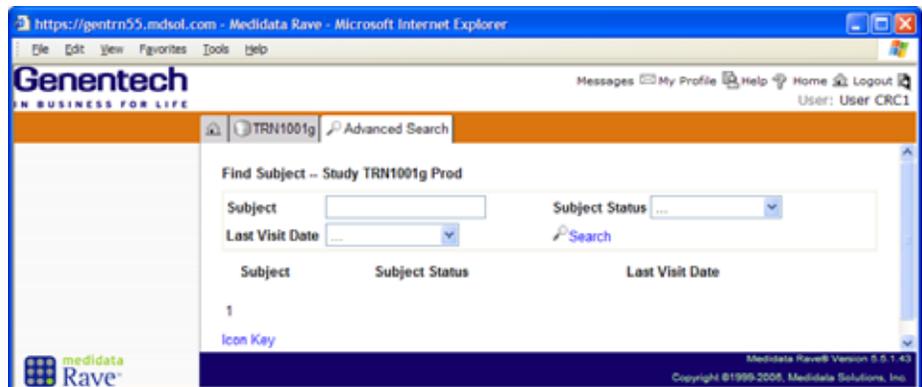
Advanced Subject Search

If configured for your study, you can use the Advanced Subject Search to search for subjects using other criteria, such as by subject identification, subject status, investigator name, last visit date, and so on.

Perform an advanced subject search

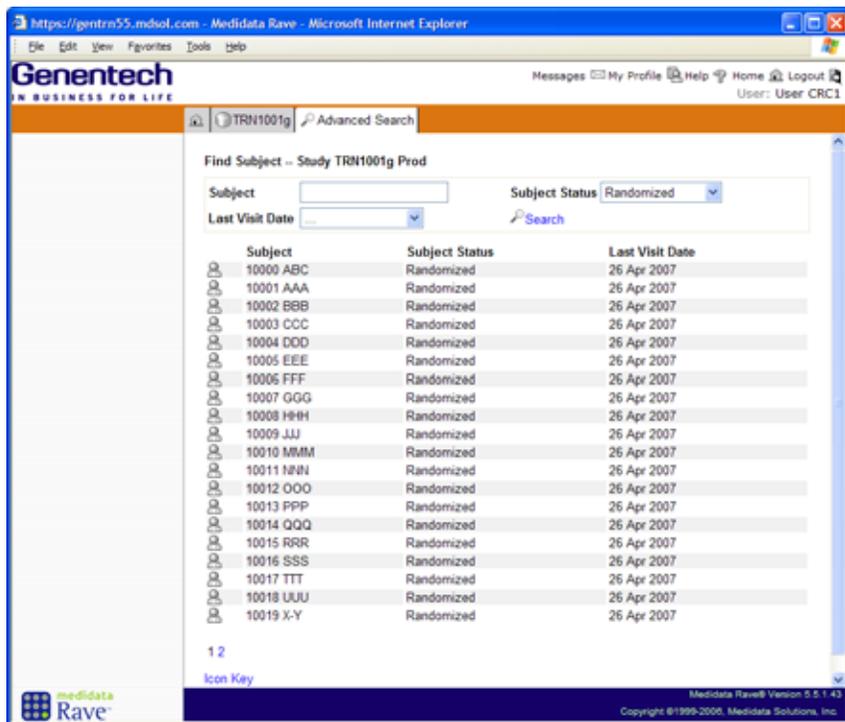
1. On a Study or Site page, click the Advanced Subject Search link.

Rave displays the Advanced Subject Search page.



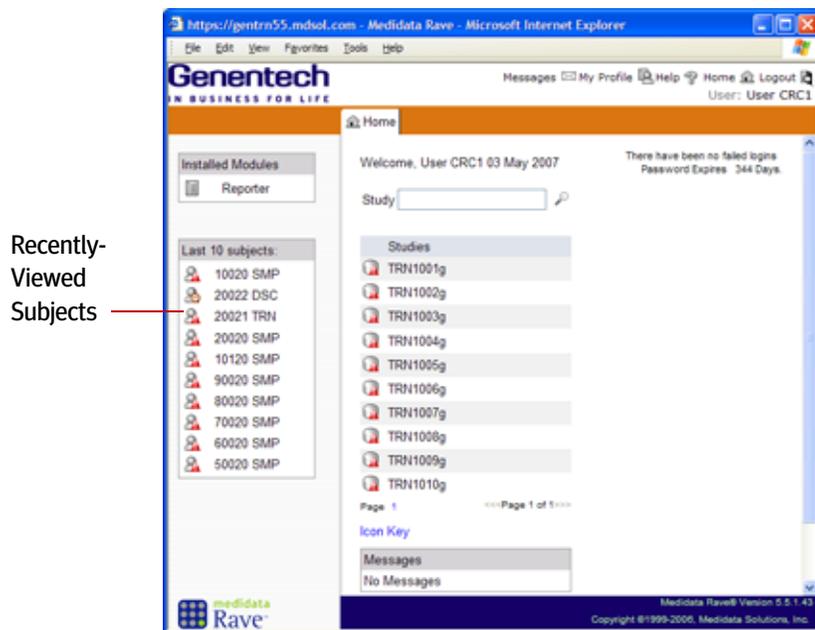
2. Type the search criteria (Subject Name, Subject Status, or Last Visit Date).
3. Click the **Search** link.

Rave looks for matches and displays the search results, as shown in the following example.



- 4. Click the subject for which you want to view details.
Rave displays the Subject page for the selected subject.

Last 10 Subjects Quicklist



Rave displays a list of recently-viewed subjects (up to ten) in the sidebar.

View a subject using the Last 10 subjects quicklist

1. Click the Home tab.
2. In the sidebar, find the Last 10 Subjects quicklist, and then click the subject whose details you want to view.

Rave displays the Subject page for the selected subject.

Hands-On Exercise

1. Use the Search Box on the Study page to find the “TRN” subject for your class (for example, subject 11021 TRN) in the College of Medicine site.
2. Identify the various parts of the Subject page (Calendar View).
 - › Task List
 - › Subject Schedule
 - › Task Summary
3. For the “TRN” subject, go to the list of open queries in the Task Summary.
4. For the “TRN” subject, display the Grid View.
5. Identify the various parts of the Subject page (Grid View): visits / folders, eCRFs, and eCRF status.
6. Using the Advanced Search on the Study page, find all subjects whose status is Randomized.
7. Using the Advanced Search on the Study page, find subjects by Last Visit Date.
8. Click the Home tab, then view the “TRN” subject by clicking in the Last 10 subjects quicklist.

LESSON 6

VIEWING eCRFs ASSOCIATED WITH A SUBJECT

This lesson covers the following topics:

- › [About eCRFs \(see page 53\)](#)
- › [eCRF Page \(see page 54\)](#)
- › [View eCRFs \(see page 58\)](#)

About eCRFs

An electronic case report form (eCRF) is a digital version of a printed case report form (CRF) used in Genentech-sponsored clinical trials. Instead of manually filling out paper CRFs, Rave users complete eCRFs online.

Genentech has created a company-wide Global Volume containing commonly-used eCRFs that can be copied and adapted for individual trials. Examples include: Subject Eligibility, Demographic, Medical History, Vital Signs, Physical Exam, Electrocardiogram, Adverse Events, and so on.

As described in [“Rave and Genentech EDC Studies” on page 7](#), the data entry screen for an eCRF typically shows fewer fields than its corresponding paper-based CRF. Only authorized users have access to the complete forms. Similarly, only certain users have access to certain restricted eCRFs, such as the Electrocardiogram form. Finally, some data entry fields or eCRFs are available only when certain data values are present. For example, the Pregnancy Report form is available only if the Sex field on the Demographics eCRF is female.

In Rave, subject visits are represented as a hierarchy of file folders, each of which contains the set of eCRFs that are associated with the visit. For an overview of file folders in the training sample study, see [“Organization of Study Data” on page 29](#).

eCRF Page

The following figure shows the components of an example eCRF page (the Demographics eCRF).

The screenshot shows a web browser window displaying the Genentech Rave eCRF page. The page title is "Demographics - Screening" for subject "10021 TRN". The page contains several data entry fields with status icons (green checkmarks, red X's, and question marks). A "CRF History" section at the bottom lists previous eCRF entries for this subject. Red lines and labels point to specific components: "Form Name" (Demographics), "Open Folder" (Screening), "Selected eCRF" (Demographics - Screening), and "eCRF History (Subject + eCRF Name)" (10021 TRN - Demographics).

The tab for the eCRF page displays the name of the associated eCRF.

eCRF pages differ according to:

- › the type of eCRF they display
- › the access you have to the eCRF data, which depends on the permissions that are configured for your user account

H Tip! Each eCRF in the folder is represented by a status icon. The status icon reflects the status of the data in the eCRF. For more information about each status icon, see [“Data Status Icons” on page 56](#).

The status of individual fields for a given eCRF can vary. For example, one field can have an open query while another can contain non-conformant data. Rave displays only one status icon per eCRF, selecting the status icon that it considers to be the most important for that eCRF, based on Rave’s own status precedence hierarchy and your logged-in role.

Key Elements on eCRF Pages

Each eCRF page has the following key elements:

- **Form questions**—Describe the data on the eCRF.
- **Data entry fields**—Such as text fields, which are either view-only or editable (depending on the nature of the data, as well as your permitted access to the data).
- **Data Status Icons**—Reflect the status of the data on the eCRF.
- **Action Controls (icons)**—Allow you to take action on the data, such as to edit the data or learn more about it.
- **Form- and Field-Level Help**—Allows you to display information and instructions for a particular field on the eCRF.

The following figure shows elements in an example Demographics eCRF.

The screenshot shows a web-based eCRF interface for a 'Demographics' page. The page title is 'Demographics' and the subject is '10021 TRN'. The page contains several data entry fields with associated status icons and action controls. The fields are: Date of birth (8 JUL 1937), Age (69), Sex (Female), Ethnicity (Hispanic or Latino), and Race (Select all that apply). The Race field includes checkboxes for American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Below the Race field is an 'OR' section with a 'Not Available' option. At the bottom of the page are links for 'Printable Version', 'View PDF', and 'Icon Key', along with 'Save' and 'Cancel' buttons. Red lines point from labels to specific elements in the screenshot.

Form Questions (points to the form heading and data entry fields)

Form Heading (points to the page title)

Edit All Fields Icon (points to the edit icon for the Date of birth field)

Field-Level Help Icon (points to the help icon for the Date of birth field)

Status Icons (points to the status icons for the Sex field)

Edit Icon (points to the edit icon for the Ethnicity field)

Data Entry Fields (points to the checkboxes for the Race field)

Printable Version Link (points to the 'Printable Version' link)

View PDF Link (points to the 'View PDF' link)

Icon Key Link (points to the 'Icon Key' link)

Command Buttons (points to the 'Save' and 'Cancel' buttons)

Leader Note

Talk about the data status icons and action controls.

Data Status Icons

The following table describes commonly-used status icons associated with data on eCRF pages. For a complete list of all status icons, display the Icon Key, as described in [“Icon Key” on page 23](#).

- **Note:** These icons are also displayed next to eCRFs in the Grid View to indicate the overall status of an individual eCRF.

Table 6: **Data Status Icons on eCRF Pages**

Icon	Name	Description
	Never Touched	Data point has not been typed or submitted.
	Completed	Data point has been submitted.
	Not Conformant	Invalid data point.
	Out of Range High	Data point is above the configured upper range value.
	Out of Range Low	Data point is below the configured lower range value.
	Overdue	Data point is overdue.
	Query Open	Open query exists for this data point.
	Entry Lock	Data point cannot be changed or is calculated.
	Locked	Data point or associated queries or sticky notes cannot be changed.

Action Controls on eCRF Pages

The following table describes commonly-used action controls on eCRF pages.

Table 7: **Action Controls on eCRF Pages**

Icon	Name	Description
	Edit	Edit the data.
	Cannot Edit	You cannot edit the data.
	Comments	Mark the data with a sticky note or query.
	View Help	View form-level or field-level help.
	Verify Data	Check the check box to verify the data, or uncheck it to unverify the data.
	Freeze Data	Check the check box to freeze the data, or uncheck it to unfreeze the data. Used also to designate a calculated field.
	Lock Data	Check the check box to lock the data, or uncheck it to unlock the data.

Leader Note

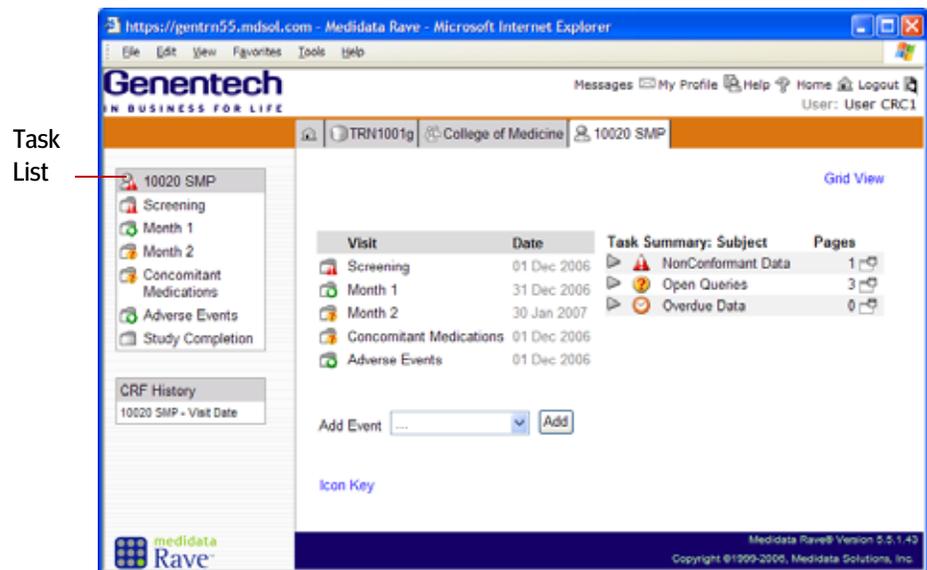
Determine how much material you want to cover in this section. The point to make here is that Rave provides you many ways to find and view an eCRF—users can choose their preferred method.

View eCRFs

The rest of this lesson describes various ways in which you can find and view eCRFs associated with a subject. Rave provides alternate paths to finding the data you need to view or edit (if you have sufficient permissions), allowing you to choose the most expedient manner in which to navigate the Rave user interface:

- › [View eCRFs Via the Task List \(see page 58\)](#)
- › [View eCRFs Via the Subject Schedule \(see page 60\)](#)
- › [View eCRFs Via the Task Summary \(see page 61\)](#)
- › [View eCRFs Via the Grid View \(see page 64\)](#)

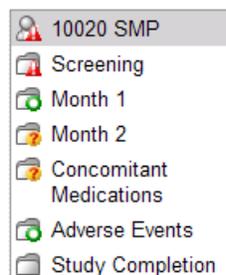
View eCRFs Via the Task List



The Task List in the sidebar of the Subject page provides an easy way to find and view eCRFs for a particular subject. For an introduction, see [“Task List” on page 45](#).

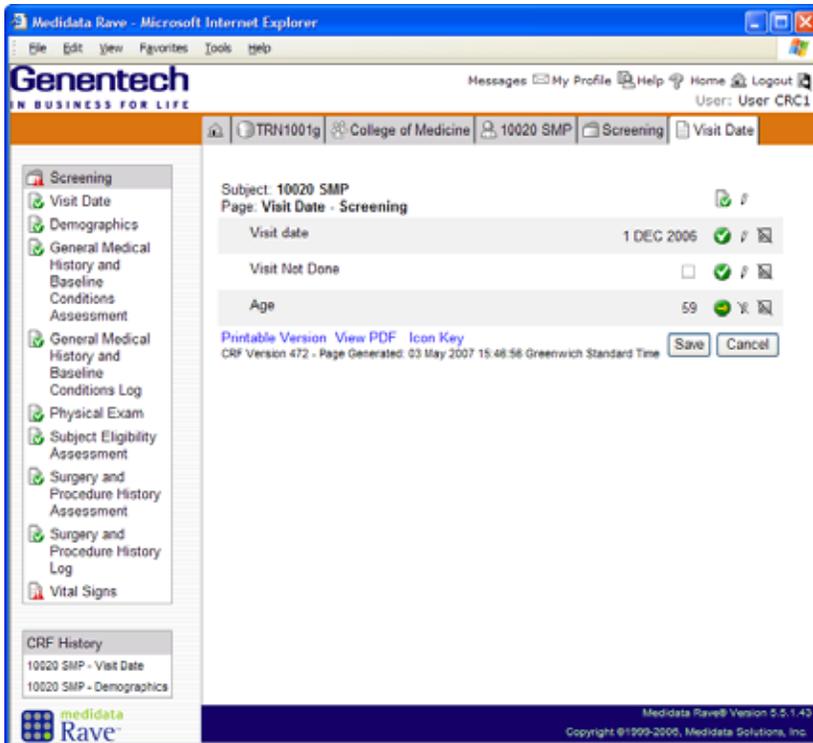
View an eCRF using the Task List

1. View a subject in the Calendar View.
2. In the Task List, click the folder associated with the eCRF that you want to view.



In the Task List, Rave displays the list of eCRFs associated with the selected folder. Rave automatically displays the first form in the list.

In the following example, the Screening folder is selected and the Visit Date eCRF is displayed.



View eCRFs Via the Subject Schedule

Subject Schedule

Visit	Date	Task Summary: Subject	Pages
Screening	01 Dec 2006	NonConformant Data	1
Month 1	31 Dec 2006	Open Queries	3
Month 2	30 Jan 2007	Overdue Data	0
Concomitant Medications	01 Dec 2006		
Adverse Events	01 Dec 2006		

The Subject Schedule on the Subject page (Calendar View) provides an easy way to find and view eCRFs for a particular subject. For an introduction, see [“Subject Schedule” on page 45](#).

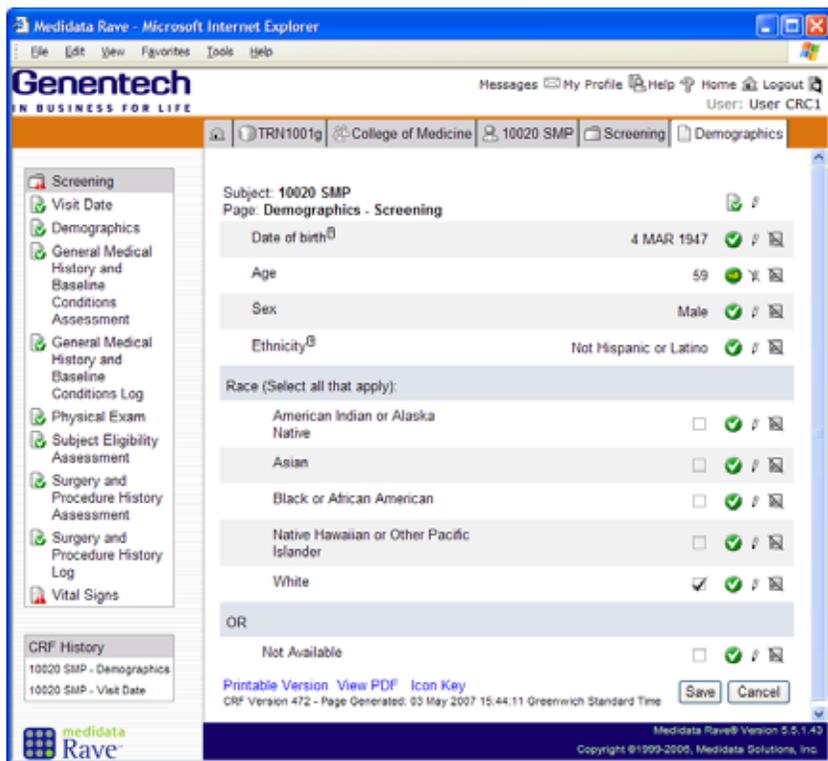
View an eCRF using the Subject Schedule

1. View a subject in the Calendar View.
2. In the Subject Schedule, click the folder associated with the eCRF that you want to view.

Visit	Date
Screening	01 Dec 2006
Month 1	31 Dec 2006
Month 2	30 Jan 2007
Concomitant Medications	01 Dec 2006
Adverse Events	01 Dec 2006

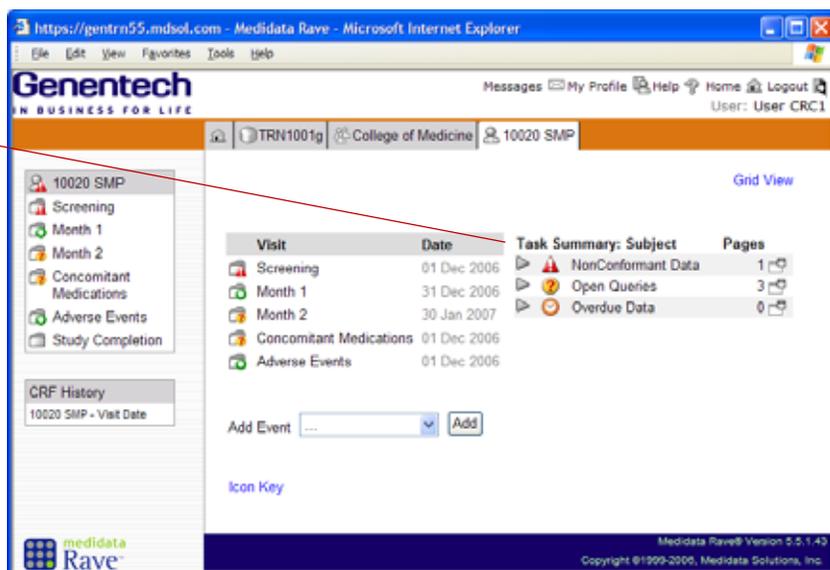
In the Task List, Rave displays the list of eCRFs associated with the selected folder. Rave automatically displays the first form in the list. To view an eCRF, click it in the list.

In the following example, the Screening folder is selected and the Demographics eCRF is displayed.



View eCRFs Via the Task Summary

Task Summary



The Task Summary on the Subject page provides an easy way to find and view eCRFs that need special attention. The Task Summary organizes items by status—such as non-conformant data, open queries, or overdue data. For an introduction, see [“Task Summary” on page 46](#).

Task Summary: Attention Needed

Use the Task Summary to find things that require special attention.

Expand a category in the Task Summary

- ❖ Click the right-pointing arrowhead next to the category you want to expand.

	Task Summary: Subject	Pages
Click Here	▶ ⚠ NonConformant Data	1
to Expand	▶ ⚠ Open Queries	3
	▶ ⚠ Overdue Data	0

Rave displays the list of tasks under that category.

Task Summary: Subject	Pages	
▶ ⚠ NonConformant Data	1	
▼ ⚠ Open Queries	3	Pop-Up Icon
Concomitant Medications- Concomitant Medications		
Month 2-Vital Signs		
Screening-Vital Signs		
1		
▶ ⚠ Overdue Data	0	

Collapse a category in the Task Summary

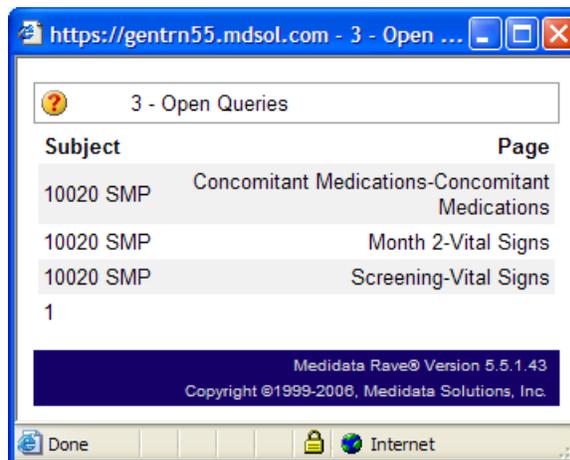
- ❖ Click the down-pointing arrowhead next to the category that you want to collapse.

Rave hides the list of tasks under that category.

Open a task in the Task Summary

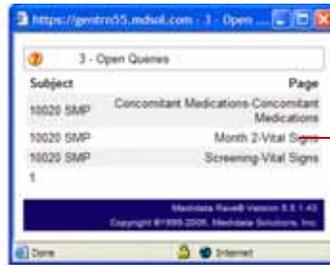
1. Click the Pop-Up (⊞) icon next to the category you want to view.

Rave displays the list of items for the selected category.

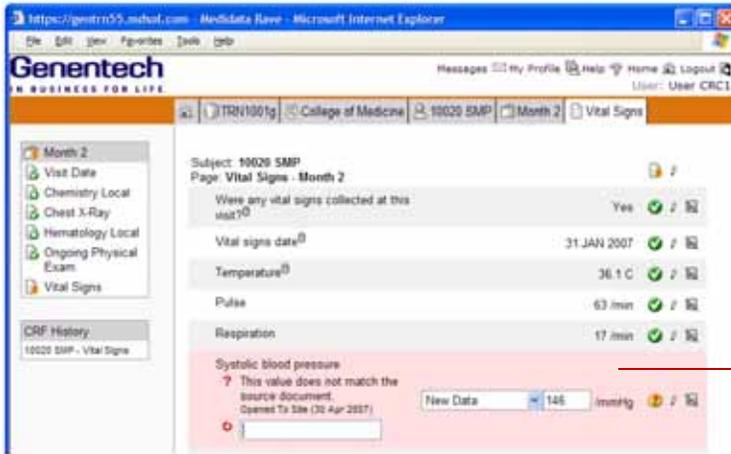


2. Click the eCRF associated with the item that you want to view.

Rave displays the eCRF page for the eCRF and the associated item.



Click this Query Link...



... to Display eCRF for the Query

View eCRFs Via the Grid View

The Grid View on the Subject page provides an at-a-glance overview of the eCRFs for a particular subject. For an introduction, see [“Subject Page—Grid View” on page 47](#).

View an eCRF using the Grid View

1. View a subject.
2. [Display the Grid View \(see page 47\)](#).

The screenshot shows the Genentech Medidata Rave interface. The browser address bar displays <https://gentra55.mdsol.com>. The page title is "Medidata Rave - Microsoft Internet Explorer". The Genentech logo is visible at the top left. The user is logged in as "User: CRC1". The breadcrumb trail shows "TRN1001g > College of Medicine > 10020 SMP". A sidebar on the left contains a navigation menu for "10020 SMP" with options: Screening, Month 1, Month 2, Concomitant Medications, Adverse Events, and Study Completion. Below this is a "CRF History" section for "10020 SMP - Visit Date". The main content area is a grid view with columns: All, Study Completion, Screening, Concomitant Medications, Adverse Events, Month 1, Month 2, and All. The grid lists various eCRFs with status icons (green checkmarks, red X's, or document icons) indicating their completion status. At the bottom, there is an "Add Event" dropdown menu and an "Add" button. The footer includes the Medidata Rave logo and version information: "Medidata Rave® Version 5.5.1.43 Copyright ©1999-2005, Medidata Solutions, Inc."

All	Study Completion	Screening	Concomitant Medications	Adverse Events	Month 1	Month 2	All
Adverse Events				✓			Adverse Events
Chemistry Local				✓	✓		Chemistry Local
Demographics		✓					Demographics
Study Completion/Early Discontinuation	✓						Study Completion/Early Discontinuation
Electrocardiogram				✓			Electrocardiogram
Subject Eligibility Assessment		✓					Subject Eligibility Assessment
Hematology Local				✓	✓		Hematology Local
General Medical History and Baseline Conditions Log		✓					General Medical History and Baseline Conditions Log
General Medical History and Baseline Conditions Assessment		✓					General Medical History and Baseline Conditions Assessment
Concomitant Medications			✓				Concomitant Medications
Concomitant Medications Assessment			✓				Concomitant Medications Assessment
Physical Exam		✓					Physical Exam
Ongoing Physical Exam					✓	✓	Ongoing Physical Exam
Surgery and Procedure History Log		✓					Surgery and Procedure History Log
Surgery and Procedure History Assessment		✓					Surgery and Procedure History Assessment
Visit Date		✓			✓	✓	Visit Date
Vital Signs					✓	✓	Vital Signs
Chest X-Ray						✓	Chest X-Ray

3. Click the status icon of the eCRF that you want to view.

Rave displays the selected eCRF.

The screenshot shows the Medidata Rave web application interface. The browser address bar displays "https://gentrn55.mdsol.com - Medidata Rave - Microsoft Internet Explorer". The Genentech logo is visible at the top left, with the tagline "IN BUSINESS FOR LIFE". The user is logged in as "User: User CRC1". The breadcrumb trail shows the path: TRN1001g > College of Medicine > 10020 SMP > Screening > Vital Signs.

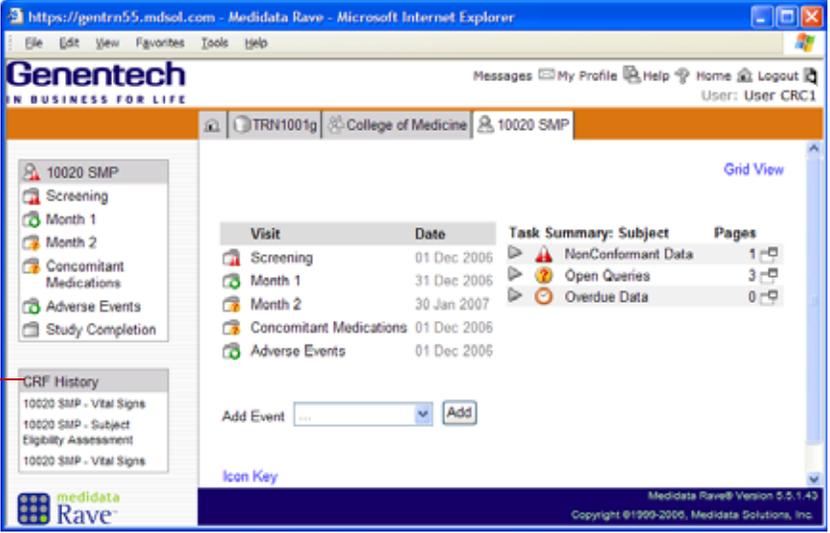
The main content area displays the "Vital Signs - Screening" form for subject "10020 SMP". The form includes the following fields and values:

- Were any vital signs collected at this visit? Yes
- Vital signs date: 1 DEC 2006
- Temperature: 37.2 C
- Pulse: 6T /min. A red error message is displayed: "Data entered is not in the expected format. Please consult help text for directions. Opened To Site (27 Apr 2007)".
- Respiration: 18 /min
- Systolic blood pressure: 143 /mmHg
- Diastolic blood pressure: 89 /mmHg
- Weight: 111 kg
- Height: 185 cm

At the bottom of the form, there are links for "Printable Version", "View PDF", and "Icon Key", along with "Save" and "Cancel" buttons. The footer indicates "Medidata Rave® Version 5.5.1.43" and "Copyright ©1999-2006, Medidata Solutions, Inc."

View eCRFs Via the eCRF History

eCRF History



The screenshot shows the Medidata Rave web application interface. On the left, a sidebar contains a tree view with folders for '10020 SMP', 'Screening', 'Month 1', 'Month 2', 'Concomitant Medications', 'Adverse Events', and 'Study Completion'. Below these is the 'eCRF History' section, which lists recent eCRFs: '10020 SMP - Vital Signs', '10020 SMP - Subject Eligibility Assessment', and '10020 SMP - Vital Signs'. A red arrow points from the text 'eCRF History' to this section. The main content area displays a 'Task Summary' table with columns for 'Visit', 'Date', 'Task Summary', 'Subject', and 'Pages'. The table lists tasks such as 'Screening', 'Month 1', 'Month 2', 'Concomitant Medications', and 'Adverse Events'. A 'Task Summary' section on the right shows 'NonConformant Data' (1), 'Open Queries' (3), and 'Overdue Data' (0). The bottom of the page shows the Medidata Rave logo and version information.

Visit	Date	Task Summary	Subject	Pages
Screening	01 Dec 2006			
Month 1	31 Dec 2006			
Month 2	30 Jan 2007			
Concomitant Medications	01 Dec 2006			
Adverse Events	01 Dec 2006			

The eCRF History in the sidebar provides an easy way to find and view eCRFs. The eCRF History displays the eCRFs that you have most recently viewed. Each item in the list is identified by subject identification and eCRF name.

View an eCRF using the eCRF History

- ❖ Click the eCRF associated with the subject in the eCRF History list.

Hands-On Exercise

1. Display the Subject page for the “TRN” subject for your class (for example, subject 11021 TRN) in the College of Medicine site.
2. In the Subject Schedule, display the Month 1 folder.
3. From the Task List, display the Ongoing Physical Exam eCRF.
4. Go to the Subject page, display the Grid View, and display the Chest X-Ray eCRF in the Month 2 folder.
5. Go to the Subject page and, using the Task Summary, display an eCRF associated with non-conformant data.
6. Display an eCRF using the eCRF History.

LESSON 7

WORKING WITH eCRFs

This lesson expands on what you learned about eCRFs in the previous lesson. It covers the following topics:

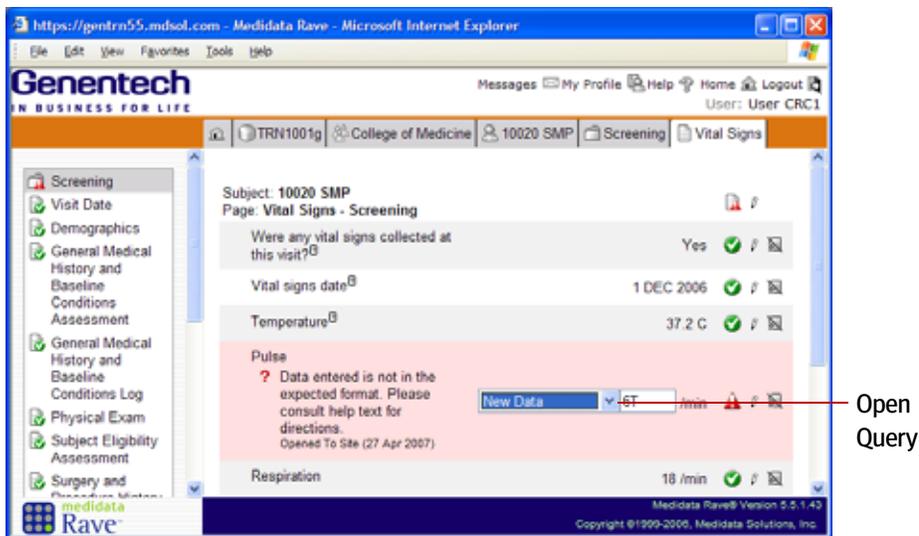
- › [Introducing Queries \(see page 67\)](#)
- › [Introducing Sticky Notes \(see page 69\)](#)
- › [View the Audit Trail \(see page 71\)](#)
- › [Get Help for eCRFs \(see page 73\)](#)
- › [Print eCRFs \(see page 74\)](#)

Introducing Queries

As mentioned previously, a *query* is a question about a data point on an eCRF. A query is created in either of the following ways:

- › **system-generated** by Rave or another Genentech system such as TMS when, for example, there is an obvious problem with submitted data, or
- › **manually** opened by a Clinical Site Manager (CRA role), Project Data Manager (DM role), or Clinical Trial Manager (CTM role). Manual queries are initiated by Genentech personnel to site personnel for clarification or correction on a submitted data point.

The following figure shows an example open query on an eCRF page.

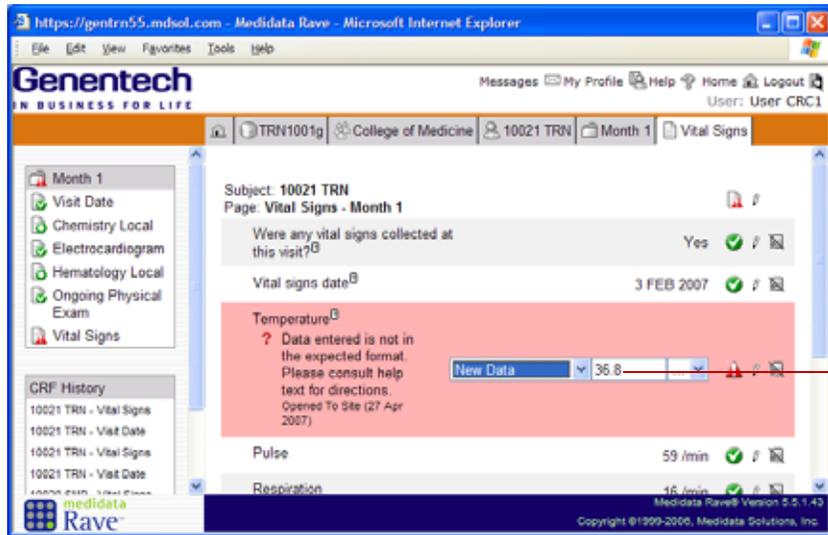


In this example, a system-generated query indicates that the Pulse field contains non-conformant data (στ—an alphabetic character in a numeric field).

Leader Note

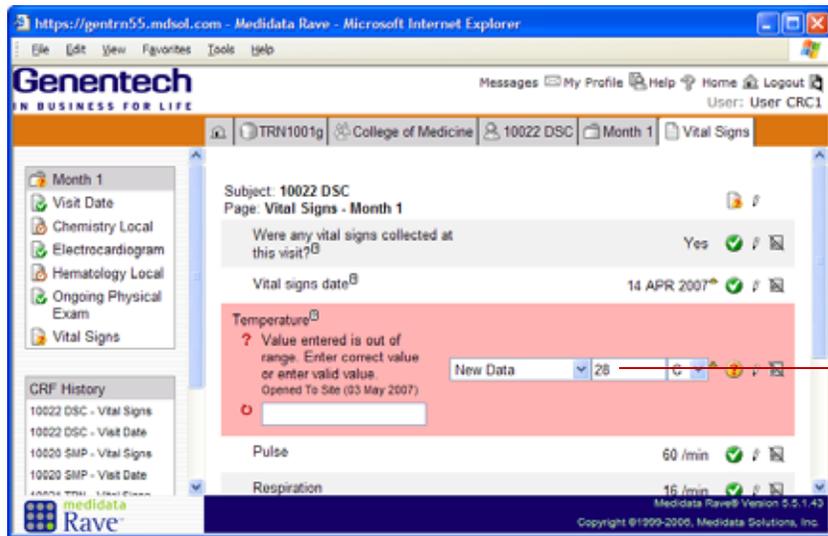
Show and explain what a query looks like on an eCRF.

In the following example, a system-generated query indicates that the Temperature field on the Vital Signs eCRF is missing required data—the unit of measure (c for Centigrade) was not selected.



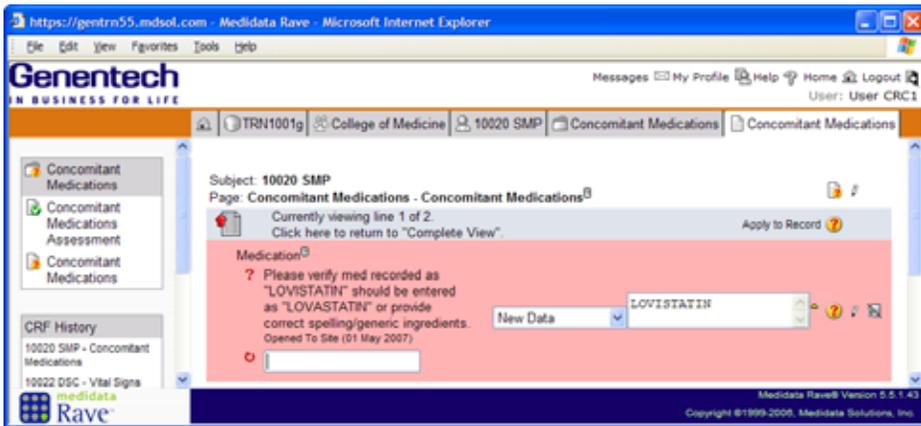
Open Query

In the following example, the system-generated query pointing to the Temperature field on the Vital Signs eCRF shows that the data point is out of range (the data falls outside the pre-configured range of minimum and maximum values for this field).



Open Query

The following example shows a manual query, created by the Clinical Site Manager, that asks for a spelling correction.

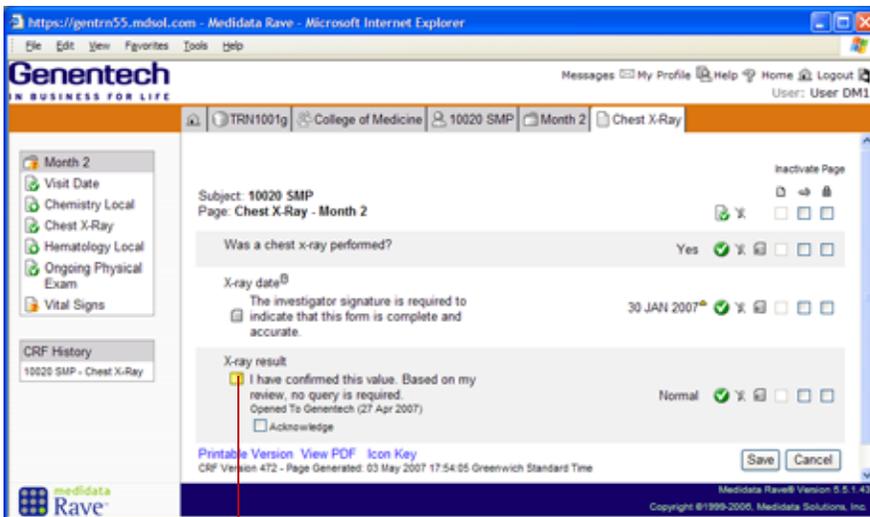


For instructions on how to create and respond to queries, see and [“Using Queries” on page 132](#).

Introducing Sticky Notes

A *sticky note* is an informal note, remark, or observation that is associated with a data point on an eCRF. A sticky note can be system-generated (for example, in conjunction with an adverse event or local laboratory eCRF), or manually added by a Clinical Site Manager (CRA role), Project Data Manager (DM role), or Clinical Trial Manager (CTM role).

The following example shows a manually-created sticky note from the Clinical Trial Manager to the Data Manager.



Open Sticky Note

The following example shows a system-created sticky note for an Adverse Event eCRF. This sticky note is updated every time information about an Adverse Event is

Leader Note

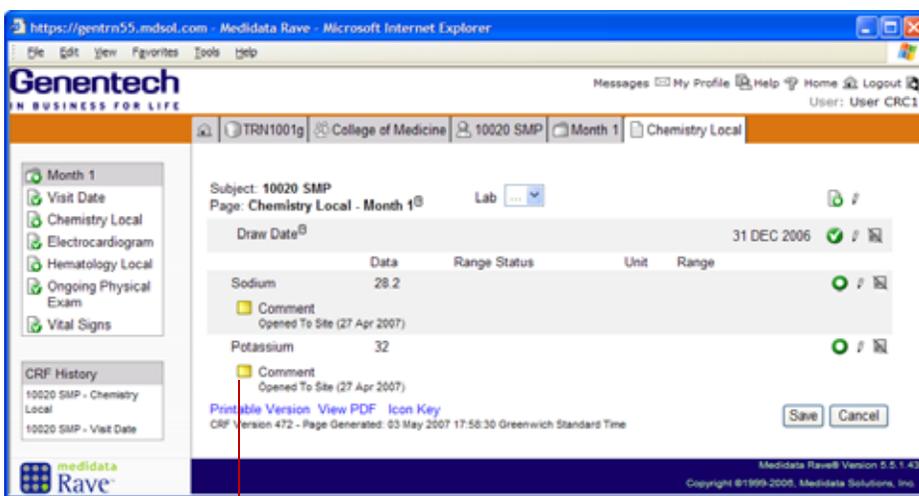
Show what a sticky note looks like on an eCRF.

sent to Drug Safety via the Drug Safety Integration module (see [“Drug Safety Integration” on page 13](#)).



Sticky Note (View-Only and Permanent)

The following example shows system-generated sticky notes that allow authorized users to enter comments for data points on a local lab form. For more information, see [“Submit Local Lab Forms” on page 114](#).



Open Sticky Note

For instructions on how to acknowledge and create sticky notes, see [“Using Sticky Notes” on page 145](#).

View the Audit Trail

Rave keeps track of changes to any data point on an eCRF. For any data point, you can view its audit trail to learn the history of actions taken on the data point.

For every action taken on a data point in an eCRF, Rave tracks the following information:

- action taken on the data point (submitted, verified, or locked the data)
- user who took the action
- date and time when the action occurred (shown in your time zone)

View the audit trail for a data point

1. On the eCRF screen, click the data status icon for the data.

Rave displays the Audit Trail for the selected data point.

The screenshot shows the Medidata Rave web application interface. The browser address bar displays 'https://gentrx55.mdsol.com - Medidata Rave - Microsoft Internet Explorer'. The page title is 'Genentech IN BUSINESS FOR LIFE'. The user is logged in as 'User: User CRC1'. The breadcrumb trail shows 'TRN1001g > College of Medicine > 10020 SMP > Concomitant Medications > Concomitant Medications'. The main content area is titled 'Data Point - Medication' and shows a parent record 'Concomitant Medications (1)'. Below this, there is an 'Audit' section with a table of actions:

	User	Time
User opened query "Please verify med recorded as "LOVASTATIN" should be entered as "LOVASTATIN" or provide correct spelling/generic ingredients." (Site).	CRA1	01 May 2007 15:53:15
User entered "LOVASTATIN" reason for change: New Data	CRC1	01 May 2007 15:41:50
User entered "Lovastatin"	Arle	27 Apr 2007 18:31:39

At the bottom of the screenshot, three red lines point from text labels to the audit trail table: 'What changed' points to the first column, 'Who made the change' points to the 'User' column, and 'Date and time when change was made' points to the 'Time' column.

2. To return to the eCRF page, click its tab in the tab bar.

Parents and Siblings—Data Points

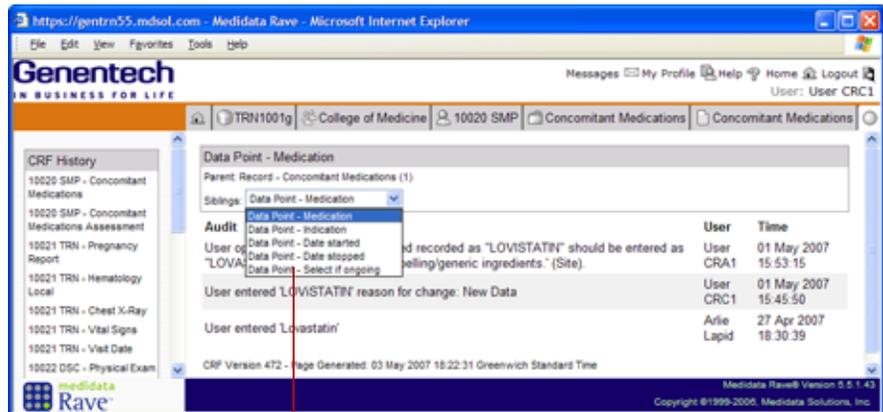
When viewing the Audit Trail screen for a particular data point, a *parent* refers to the eCRF to which the data point belongs, and *siblings* refers to other fields on the same eCRF.

Parents and Siblings—eCRFs

When viewing the Audit Trail screen for an eCRF, a *parent* refers to the folder to which the eCRF belongs, and *siblings* refers to other eCRFs in that folder.

View the audit trail for a different data point

- ❖ On the audit trail screen, click the Siblings drop-down and select the data point you want.



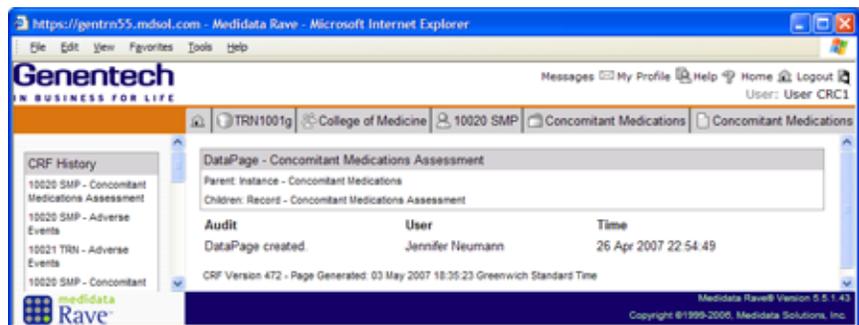
Siblings Drop-Down

Rave displays the Audit Trail for the selected data point.

View the audit trail for an entire eCRF

1. On the eCRF screen, click the data status icon for the eCRF.

Rave displays the Audit Trail for the eCRF.

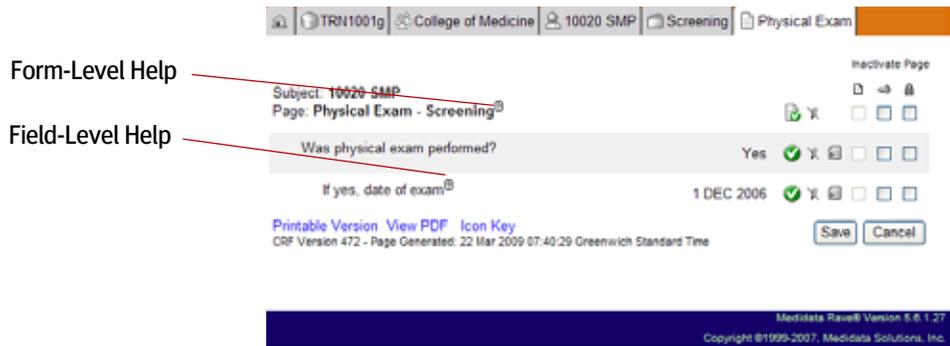


2. To return to the eCRF page, click its tab in the tab bar.

Get Help for eCRFs

Rave provides two levels of study-specific help for eCRFs:

- **form-level help**—describes an eCRF
- **field-level help**—describes a field on an eCRF



Form-Level Help

Field-Level Help

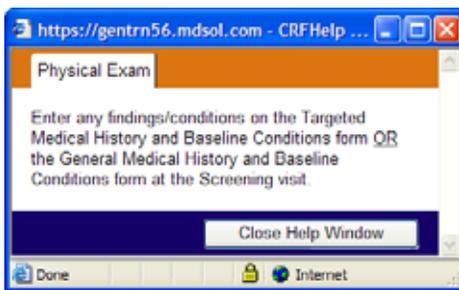
For each study, Genentech always provides the text required for each help topic. This text is specific to each study and provides valuable knowledge about the data being collected in the study.

- **Note:** Unlike eCRF help, which is tailored to Genentech-sponsored clinical trials, Rave’s online help (see [“Rave’s Online Help” on page 42](#)) is generic to the Rave software and is therefore not a reliable source for information about using Rave.

Get form-level help on an eCRF

1. Click the Help (H) icon next to the form title.

Rave displays a help window with text that explains more about this form.



2. Click **Close Help Window** when finished.

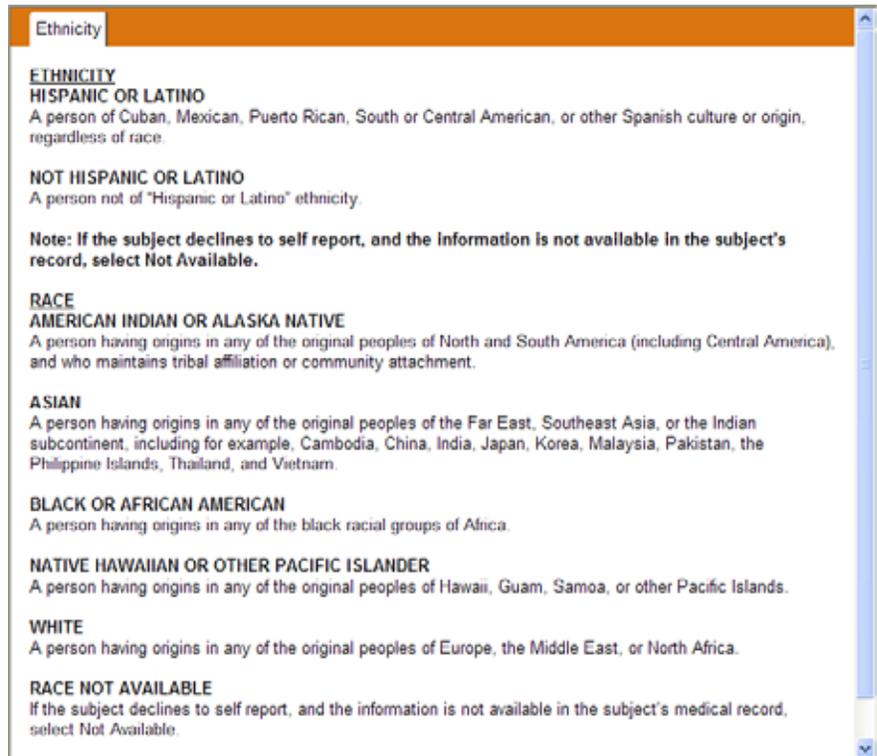
Get field-level help on a data point in an eCRF

1. Click the Help (H) icon next to the field.

Availability of Help Text

Help text is provided for many—but not necessarily all—eCRFs or fields. For example, help text might be omitted for fields that are self-explanatory or obvious.

Rave displays a help window with text that explains more about this data point.



2. Click **Close Help Window** when finished.

Print eCRFs

You can create a paper-based version of an eCRF that has been submitted.

Note, however, that the printed data will show the raw data but will not look like a formal, paper-based CRF.



IMPORTANT! If you print an eCRF *and* make any annotations on the printed copy, the paper becomes source documentation for the clinical trial and *must* be handled as such. Therefore, printing eCRFs is not recommended unless absolutely necessary.

Sites Should Not Print eCRFs

In general, sites should not print eCRFs except when absolutely necessary. If anyone makes annotations on the printed eCRF page, then the page becomes part of the clinical trial source documentation.

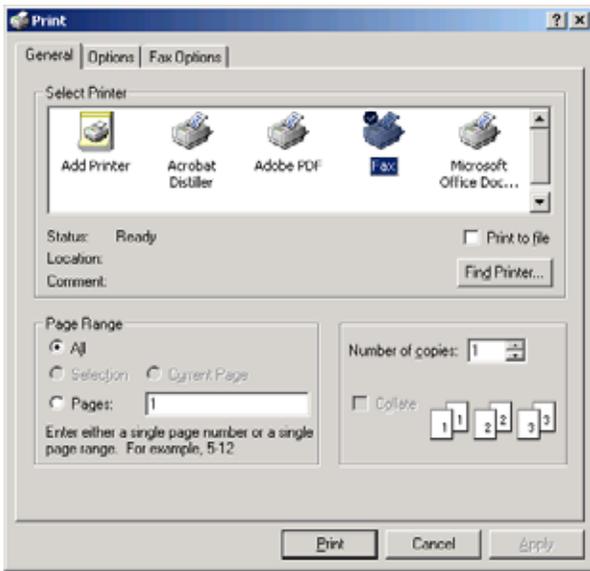
Don't Print During the Training

The computer that you are using during this class might not be set up to print. Therefore, do not print unless your instructor directs you to do so.

Print an eCRF

1. While viewing the eCRF that you want to print, click the Printable Version link.

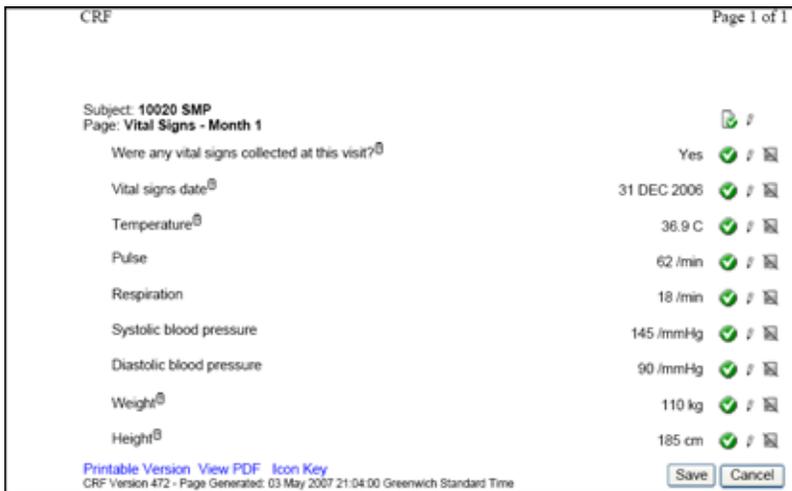
2. Rave displays a Print dialog, as shown in the following example.



3. Change print settings, if you want. Refer to your browser documentation for details.

4. Click **Print** to send the eCRF to the printer.

Rave prints the eCRF, as shown in the following example.



Hands-On Exercise

1. Using the Task Summary for the “TRN” subject for your class (for example, subject 11021 TRN), display an eCRF with an open query.
2. View the audit trail for the Vi tal Si gns eCRF in the Month 1 folder.
3. View the audit trail for every data point on the Vi tal Si gns eCRF in the Month 1 folder.
4. View field-level help for fields on the Vi tal Si gns eCRF in the Month 1 folder.
5. View form-level help for the Chemi stry Local eCRF in the Month 1 folder.

LESSON 8

VIEWING REPORTS

This lesson covers the following topics:

- › [About Reports \(see page 76\)](#)
- › [Start the Reporter Module \(see page 76\)](#)
- › [List of Rave Reports \(see page 78\)](#)
- › [Run Reports \(see page 81\)](#)

About Reports

Rave reports provide different views of the data collected during a clinical trial. In addition to the standard reports that come with the Rave software, Genentech has added some Genentech-specific, custom reports that are available across all studies. For certain users, Genentech also uses JReview, an ad hoc reporting tool that generates ad hoc and preconfigured reports from the data stored in the Clinical Views (see [“JReview—Ad Hoc Reporting” on page 15](#)).

You see the reports that are available to you based on the configured permissions for your user account and for your study. The list of available reports varies from role to role.

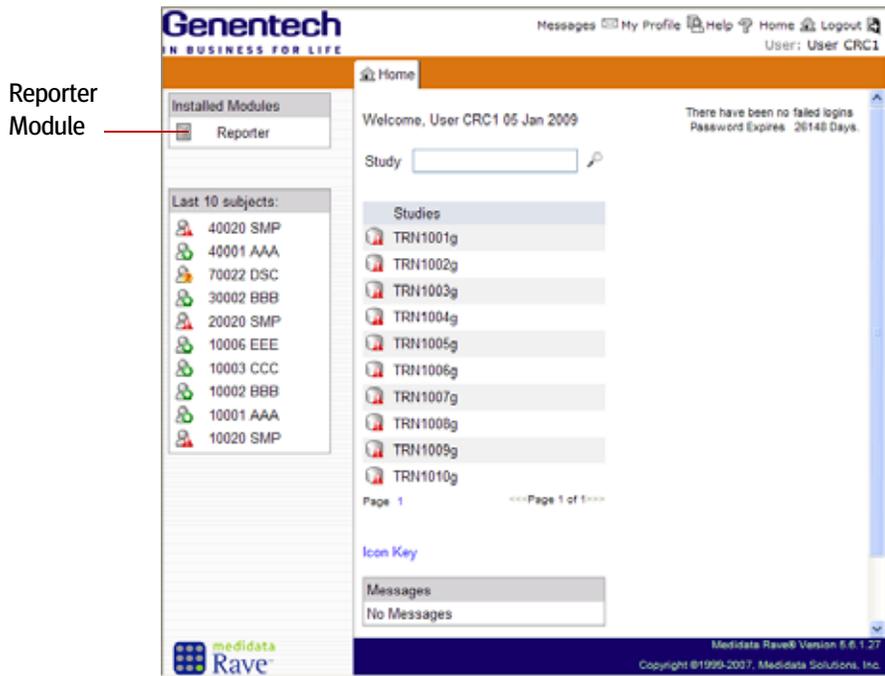
Start the Reporter Module

You use the Reporter module to run Rave reports. Your user account must be configured to have access to the Reporter module. If you are permitted to run the Reporter

JReview and Ad Hoc Reporting

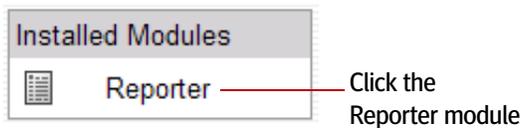
Ad hoc reporting using JReview is covered in a separate training class.

module, you will see the Reporter in the Installed Modules list in the sidebar on the Rave home page, as shown in the following example.

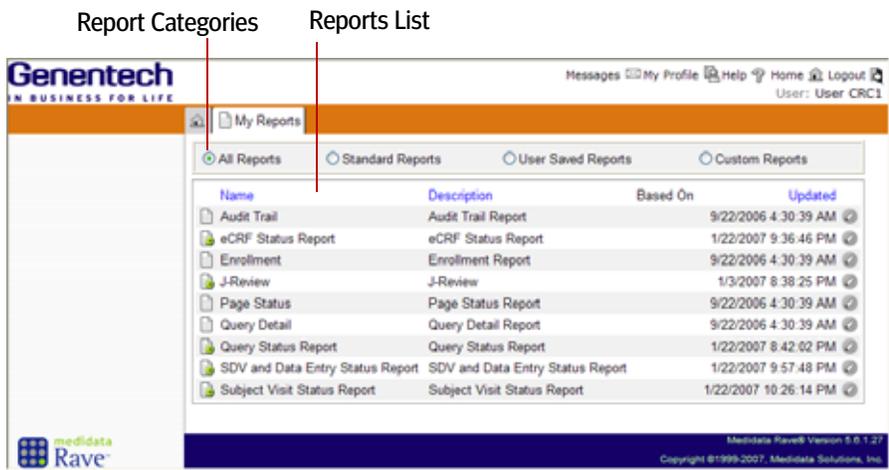


Start the Reporter module

- ❖ In the Installed Modules box in the sidebar of the Rave Home page, click **Reporter**.



Rave launches the Reporter module and displays the My Reports page, as shown in the following example.



Reports Quicklist

You can launch reports from the Reports quicklist if the Reports quicklist is displayed on your Rave screen. For more information, see [“Launch a Report from the Report Quicklist”](#) on page 90.

How Current is Report Data?

Report data is updated in Clinical Views virtually in real time.

- **Note:** Rave displays the reports that you are authorized to view based on the configured permissions for your user account.

Exit the Reporter module

- ❖ Click the Home tab.

List of Rave Reports

Rave provides three categories of reports.

Table 8: **Types of Reports in Rave**

Report Type	Description
Standard Reports	Medidata generic reports that can be used across all Genentech studies. For a list of standard reports, see “Medidata Rave Standard Reports” on page 79 .
User-Saved Reports	Reports that you have saved explicitly.
Custom Reports	Reports that have been developed and customized for use in Genentech studies. These reports undergo a well-defined, rigorous approval and validation process. Custom reports must be approved by the study team and built by PDIT. For a list of custom reports that have been created for use across Genentech studies, see “Custom Reports” on page 80 .

By default, all three report types are selectable via radio buttons on the My Reports page. However, what you see in the reports list depends on the study, as well as on the configured permissions for your user account.



IMPORTANT! At Genentech, it is recommended that you use custom reports as your primary source of information, and standard reports as a secondary source. Medidata standard reports, in some cases, may produce poorly-formatted outputs or unpredictable results because they have not been vetted with Genentech studies.

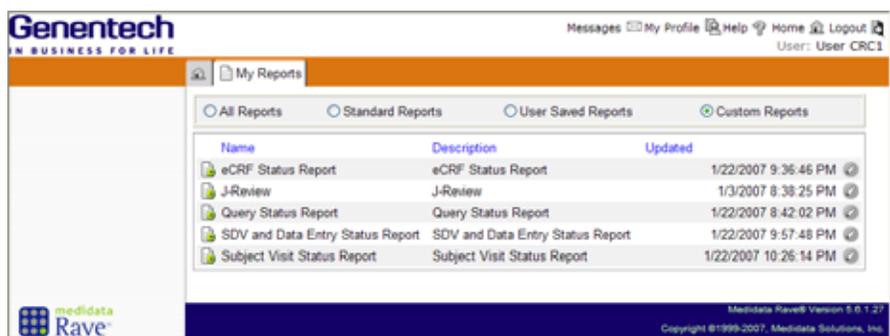
Filtering Reports

Filter the Reports list to display the type of report you want

- ❖ On the My Reports page, click the radio button next to the report type that you want to display.

For example, to display custom reports only, select the Custom Reports radio button.

Rave displays the available custom reports only, as shown in the following example.



Medidata Rave Standard Reports

Medidata provides the following standard reports. The configured permissions for your user account determine which of these reports you are authorized to view.

Table 9: **Medidata Standard Reports**

Report Name	Description
Page Status	Overall page statistics at the study level with drill down to site, patient, folder, and form.
Query Summary	Shows query metrics by site and target group.
Query Details	Shows details and status of each query.
Audit Trail	Listing of all audit trail actions.
Sticky Note	Shows a history of all stickies-outstanding and acknowledged.
Enrollment	Shows enrollment for the study or at the site.
Site Administration	Lists the sites and their assigned site groups (State, City).
User Listing	Provides detailed information about a user (such as users across projects, roles, and sites).
Reports Listing	Shows who has access to what reports.
Data Listings	Online data listing that is run against the warehouse.
Productivity	Shows user activity (who is handling queries, entering data, and so on).
Study Configuration	Provides a summary of how the study was built in Architect by eCRF version.

Reports Available in this Training

In the training sample study, you see only some of these reports. For your study, however, you might see one or more of these reports.

JReview

In the production environment, you might see J-Review in the reports list. JReview is an ad hoc reporting tool used at Genentech by data managers (DM, LDM, and SDM roles). If JReview is displayed, then you have access to use it.

Custom Reports

In addition to Medidata's reports, Genentech has created the following custom reports. To view the list of Genentech's custom reports, you click the Custom Reports radio button. The configured permissions for your user account determine which of these reports you are authorized to view. The list you see might not include all of the reports in the following table.

Table 10: Genentech Custom Reports for Rave

Report Name	Description
eCRF Status Report	Provides information on a subject's received and outstanding CRFs, and number of days outstanding if the CRF is not yet complete. Allows CRCs, CRAs, CTMs, and DMs to monitor the scheduled date for a subject's CRFs, and gives users the ability to easily identify those who have missed it.
Subject Visit Status Report	Provides information on a subject's visit status, including upcoming visits, completion/discontinuation date, and number of days outstanding if the visit is not yet complete. Allows CRCs, CRAs, CTMs, and DMs to monitor subject visits, and gives users the ability to easily identify those who have missed a scheduled visit.
SDV and Data Entry Report	Provides information on CRF completeness by visit and by form. Allows CTMs, CRAs and DMs to monitor the Data Entry status and Source Data Verification status by subject within a given visit date range, and gives users the ability to identify CRFs that are Entered/Not Entered, Verified/Not Verified, and Frozen/Not Frozen.
SAS Architect Report	Assists Study Builders in verifying the structure and content of the projected SAS dataset outputs based on the selected CRF version and study environment.
Query Status Report	Provides information on queries opened against forms and fields. Allows DMs, CRAs, CRCs, Investigators and CTMs to review queries based upon their Open, Closed, or Answered status, as well as the number of days queries remain open. Summarizes total queries by status.
AE Listing Report	Provides a listing of Adverse Events/Serious Adverse Events collected at the study site. Allows CTMs to monitor AEs by date range, by type, and across subjects.
SAS Dataset Structure Report	Provides users a listing of the structure and content of the projected SAS dataset outputs based on question definitions for all CRFs in a study.
Missing Lab Names/Ranges Reports	Provides a listing of CRF questions that are missing lab range and/or name assignments.

Table 10: Genentech Custom Reports for Rave (Continued)

Report Name	Description
Coding Query Status Report	Lists queries generated against TMS-coded terms so that Clinical Coding and Dictionary Management can track their status.
Study Definition Report	Provides a definitional listing off all CRFs and questions in a study. Allows users to perform a manual check of a study definition against mock CRF specifications in order to ensure that they have been defined according to specifications.
Global Study Management Report	Provides a high level status of a study and its sites from the perspective of CRFs entered, verified, locked, frozen, as well as total queries against them.
Rave Account Administration Report	Provides Rave user account information to Rave administrators. Lists user roles, user groups, study access and last log in date.
Study Comparison Reports-Forms and Edit Checks Report	<p>Provides a listing of all differences between 2 different studies or between 2 versions of the same study. Allows users to see where study versions differ and where they are the same.</p> <ul style="list-style-type: none"> ➤ Forms comparison shows changes within Forms and Fields between versions. ➤ Edit Checks comparison shows changes within edit checks and derivations between versions.

Run Reports

If you can see a report displayed on the My Reports page, then you are authorized to run it.

Report Parameters

After selecting a report to run, Rave prompts you to select report parameters, which enable you to focus the output of your report. When you select report parameters, you select the study (if applicable) and tell Rave what information to include in the report. Information that is not selected will not appear in the report.

For example, suppose you wanted to print an audit trail report for just one subject. To do so, when specifying report parameters, you would select just one subject—the one you want to include—and not select any other subjects.

Leader Note

Log in as a DM user and walk through the following reports:

- Query Detail Report
- Audit Trail Report
- Enrollment Report

Poll attendees to determine which reports are the most relevant to them, and then walk through them.

Report Access By Role

The following table describes who has access to a particular report by assigned role.

Report	Roles With Access to This Report
AE Listing	DM, CRA, CTM, SDM, VIEW
Coding Query Status	SDM, VIEW
eCRF Status	CRA, CRC, CTM, DM, PI, SDM, SPA, VIEW
Global Study Management	DM, CRA, CTM, VIEW
Missing Lab Names	LDM, CRC, CTM, VIEW
Missing Lab Ranges	LDM, CRC, CTM, VIEW
Query Status	CRA, CRC, CTM, DM, LDM, PI, SDM, SPA, VIEW
Rave Account Administration	N/A - Access granted to individual users
SAS Architect	DM, SPA, CASA, VIEW
SAS Dataset Structure	SPA, CASA, VIEW
SDV and Data Entry	CRA, CTM, DM, SDM, SPA, VIEW
Study Comparison Report - Edit Checks	DM, CASA
Study Comparison Report - Forms	DM, CASA
Study Definition	LDM, CASA, DM, VIEW
Subject Visit Status	CRA, CRC, CTM, DM, LDM, PI, SDM, SPA, CASA, VIEW

User Saved Reports

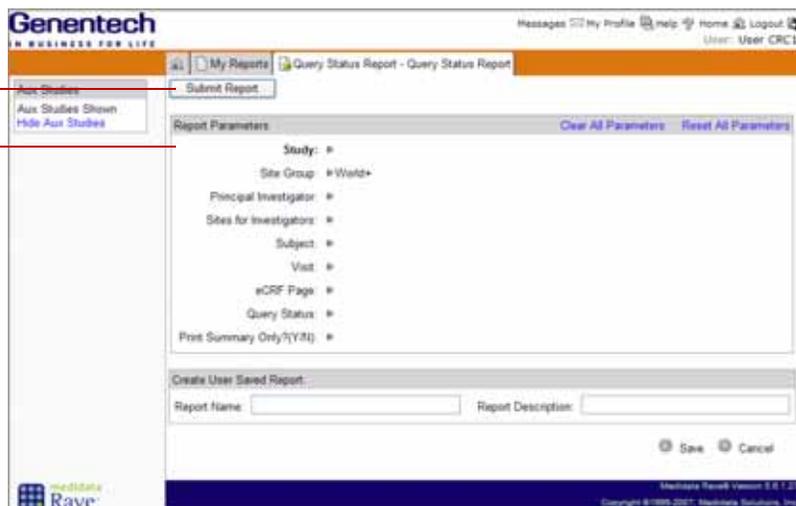
You can save any reports that you want to run again later. This can be particularly useful for your regularly-scheduled reports, such as weekly, monthly or quarterly reports. User-saved reports appear in the Reports list on the My Reports page whenever All Reports or User Saved Reports is selected.

Select a report

1. [Start the Reporter module \(see page 77\)](#).
2. [Filter the Reports list to display the type of report you want \(see page 78\)](#), if needed.
3. Click the report name, or click the Parameters (⚙️) icon to the right of the report.

Rave displays the Report Parameters page for the selected report, as shown in the following example.

Click to Run the Report
 Specify Report Parameters
 *=required



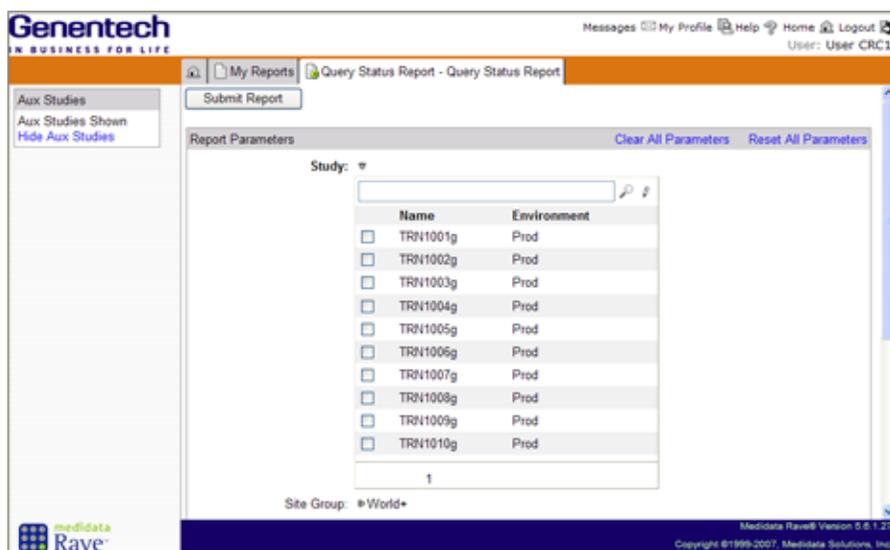
By specifying parameters, you are defining the data that is included or excluded from the report output. In the above example, you must select one study. Studies that are not selected are excluded from the report. Similarly, you must make certain selections in order to configure other parameters. In the above example, in order to include only certain subjects in the report, you must first select the site associated with those subjects.

Specify report parameters

On the Report Parameters page (see [“Report Parameters” on page 81](#)), for each parameter that you want to specify:

1. Click the right-pointing arrowhead to display selection details for the parameter.

Rave displays the option(s) for the selected parameter, as shown in the following example.



2. Do one of the following:

Required Parameters

Parameters that are displayed in a bold font or have an accompanying asterisk (*) must be specified. In some cases, a default value might be provided automatically.

- › If a list of values is displayed, check the check box next to any item that you want to include in the report. Any item that is not checked will be excluded from the report. In the following figure, Rave prompts you to select one or more principal investigators to be included in the report.

Principal Investigator: ▾

<input type="checkbox"/>	Investigator Name	Site Name
<input type="checkbox"/>	Investigator, CH	Community Hospital
<input type="checkbox"/>	Investigator, CM	College of Medicine
<input type="checkbox"/>	Investigator, CMC	County Medical Center
<input type="checkbox"/>	Investigator, PMG	Private Medical Group
<input type="checkbox"/>	Investigator, UMS	University Medical School

1

To select all check boxes, click the check box next to the column title.

- › By default, the Reporter module generates only a summary report. If you also want to see a detail report, expand the Print Summary Only parameter and select No.

Print Summary Only?(Y/N): ▾N

<input type="checkbox"/>	Yes/No
<input type="checkbox"/>	Y
<input checked="" type="checkbox"/>	N

1

- › If a calendar is displayed, either type the date or select it from the calendar, as shown in the following example.

Start Date: ▾

January 2007						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
31	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31	1	2	3
4	5	6	7	8	9	10

End Date:

- › To search, type the text to match in the search box, and then click the Search (🔍) icon.

Clear all parameters

- ❖ On the Report Parameters page, click the **Clear All Parameters** link to clear all report parameter settings (even default settings will be set to blank).

Reset all parameters

- ❖ On the Report Parameters page, click the **Reset All Parameters** link to reset all report parameter settings to their default values.

Save a report

Consider saving a report if you plan to run it with the same or similar parameters again in the future.

Saving Report Settings, Not Data

When you save a report, you are saving the report settings only—*not* a snapshot of the data. When you subsequently run the saved report, the output will reflect the state of the data at the time when the report was run—not when the report was saved.

1. [Select a report \(see page 82\).](#)
2. [Specify report parameters \(see page 83\).](#)
3. Under **Create User Saved Report**, type a meaningful report name and description.
4. Click **Save** to save your changes.

Rave adds the save reports to the Reports list on the My Reports page. Saved reports will be listed when the **User Saved Reports** radio button is selected.

Generate a report

- ❖ On the Report Parameters page, click the **Submit Report** button.

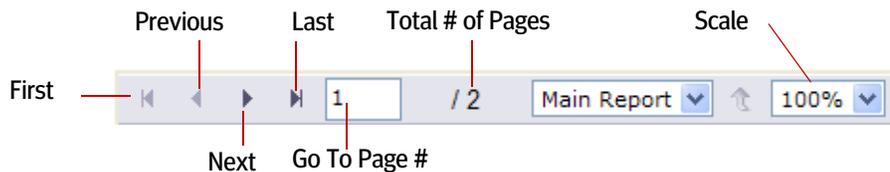
Rave generates the report with the selected parameters and displays it in the ReportViewer, a separate browser window, as shown in the following example.

Site Name	Investigator	Total Cases	Total Assessments	Total Classes	Total Quizzes	Outstanding > 30 Days	Outstanding 30 - 60 Days	Outstanding > 60 Days
College of Medicine	Investigator, CH	6	6	4	16	2	0	0

The first page shows the summary report.

Navigate a report

- ❖ Use the ReportViewer toolbar to navigate to different pages or to change the scaling.



Time to Generate Reports

You might experience a slight delay while Rave generates the report depending on the amount of data.

On-demand Report Generation

A report is executed “on demand,” which means that the data retrieved is current as of the time the report is submitted.

H Tip! It is recommended that you immediately export the report output to either PDF or Excel.

Navigate to the Detail Report

- ❖ While viewing the summary report, click the Next button on the ReportViewer toolbar until you see the Detail Report.

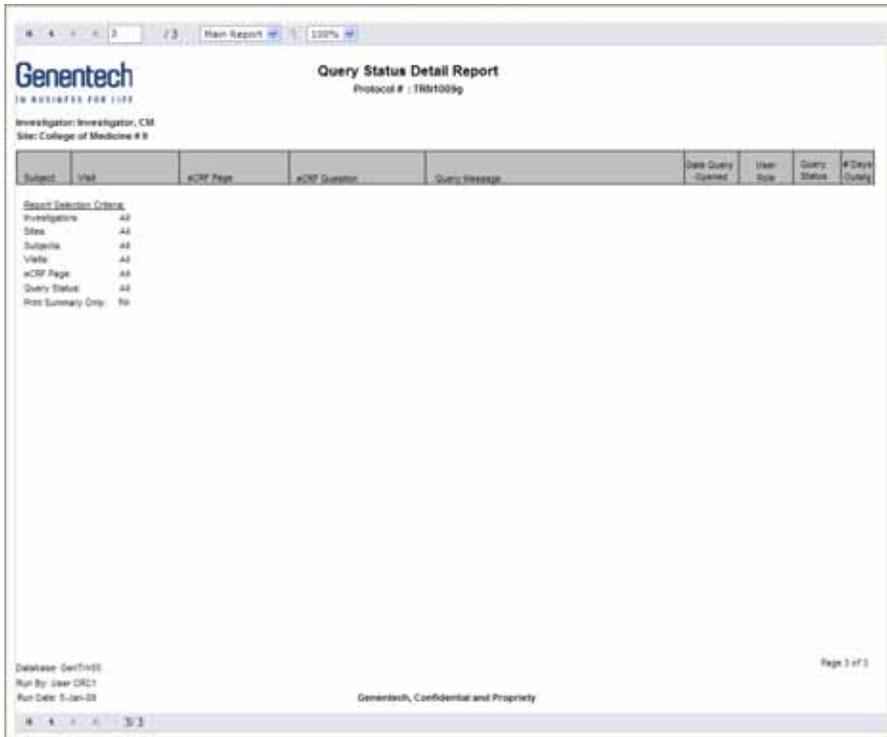
Subject	Visit	eCRF Page	eCRF Question	Query Message	Date Query Created	User Role	Query Status	# Data Points
80220 100P	Screening	Vital Signs	Pulse	Data entered is not in the expected format. Please consult help text for directions.	7/21/07	System	Open	8/3
80220 100P	Month 1	Vital Signs	Systolic blood pressure	This value does not match the source documentation. Please verify.	7/21/07	CRC	Open	8/4
80220 100P	Month 1	Vital Signs	Weight	Data entered is not in the expected format. Please consult help text for directions.	7/20/07	System	Closed	
80221 100A	Screening	Subject Eligibility assessment	Date signed protocol informed consent	Data entered is not in the expected format. Please consult help text for directions.	7/20/07	System	Closed	
80221 100A	Screening	Vital Signs	Diastolic blood pressure	Data entered is not in the expected format. Please consult help text for directions.	7/20/07	System	Open	8/0
80221 100A	Month 1	Vital Signs	Temperature	Data entered is not in the expected format. Please consult help text for directions.	7/20/07	System	Open	8/3
80221 100A	Month 2	Vital Signs	Pulse	Value entered is out of range. Enter correct value or enter null value.	7/20/07	System	Open	8/3
80221 100A	Month 2	Vital Signs	Weight	Data entered is not in the expected format. Please consult help text for directions.	7/20/07	System	Closed	
80221 100A	Concomitant Medications	Concomitant Medications	Date entered	Please provide either Date stopped or Select if ongoing.	7/20/07	System	Closed	
80221 100A	Adverse Events	Adverse Events	Is this Ad. Non-Serious or Serious	A response is required.	7/20/07	System	Open	8/3

Total Number of Queries for site 9 : 10
Grand Total of Queries: 10

Database: GenTrn03
Run By: User CRC1
Run Date: 5-Jan-09
Page 2 of 3
Genentech, Confidential and Proprietary

Navigate to the parameter selection summary

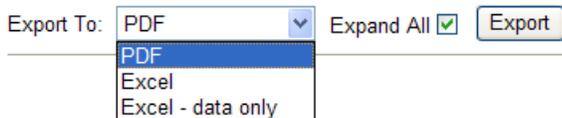
- ❖ Click the Last button on the ReportViewer toolbar to display the parameter selection summary for the report.



Export report data to a file

The recommended action for reviewing reports is to immediately export the output to either PDF or Excel - data only.

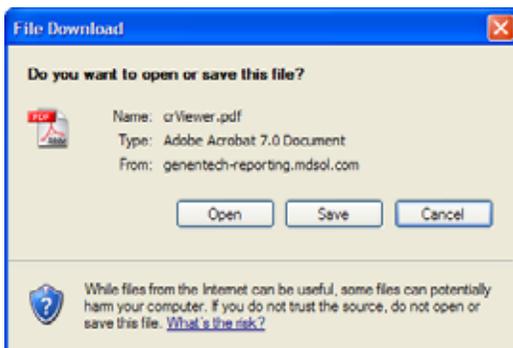
1. On the ReportViewer page, click the Export To list.



2. Select the report format you want to use (**PDF**, **Excel**, or **Excel - data only**).

It is recommended that you choose **Excel - data only** instead of **Excel**. The **Excel** option copies pre-formatted data to the Excel file, which makes the report difficult to read.

The ReportViewer prompts you to open or save the file.



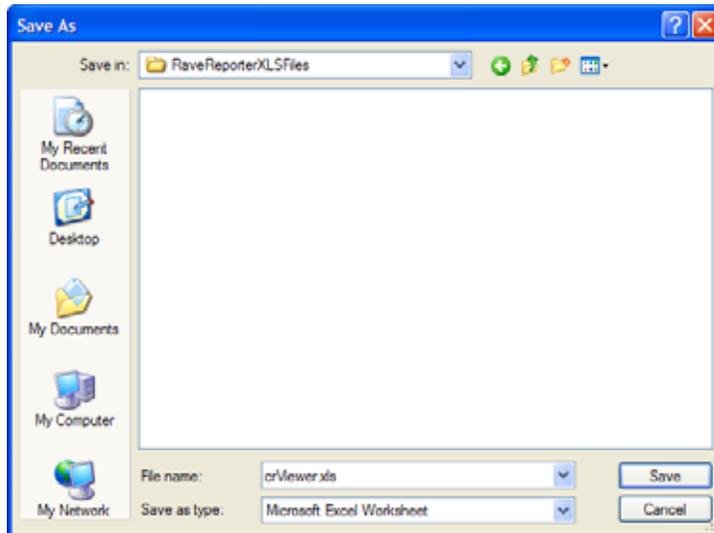
Exporting to PDF

In order to export a report to a PDF file, your computer must have Adobe Acrobat Reader installed.

Exporting to Excel

In order to export a report to an Excel file, Microsoft Excel must be installed on your computer.

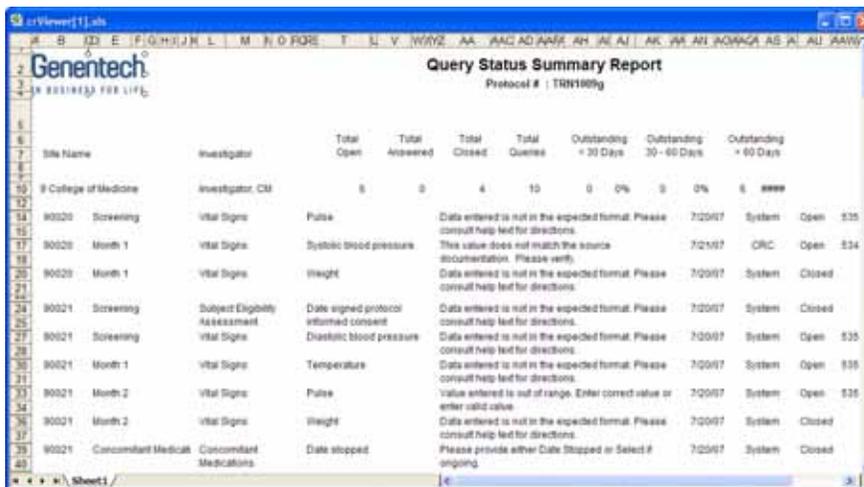
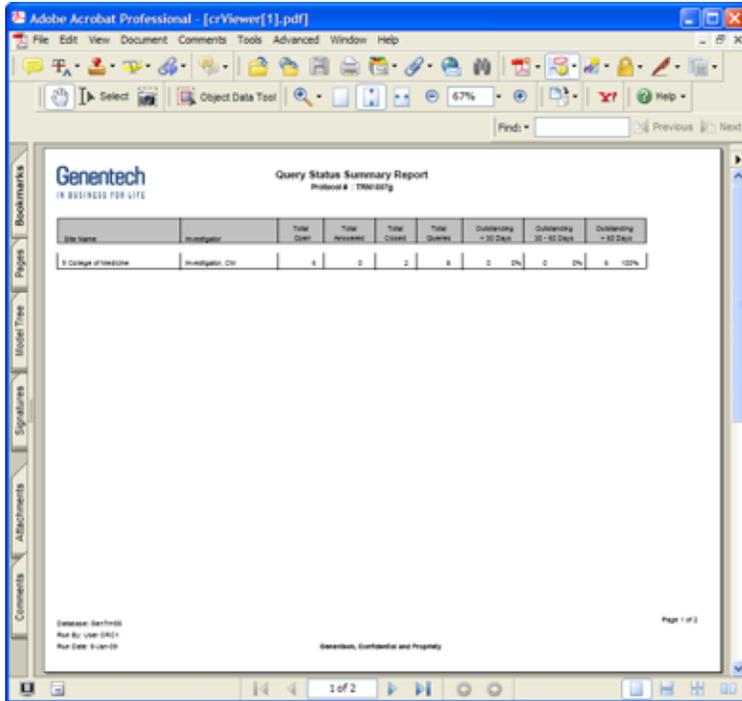
- Click **Save** to save the file to disk. The ReportViewer displays the Save As dialog box. Type a meaningful file name, change the target directory (if you want), and click **Save**. The generated file contains a snapshot of the data at the time you exported.



- Click **Open** to open the file instead. The ReportViewer generates the file (a snapshot of the data at the time you exported) and opens it in Adobe Acrobat or Microsoft Excel as appropriate. If you want, you can save the generated file to disk.

Mac Users

Mac users must uncheck **Expand all** first.

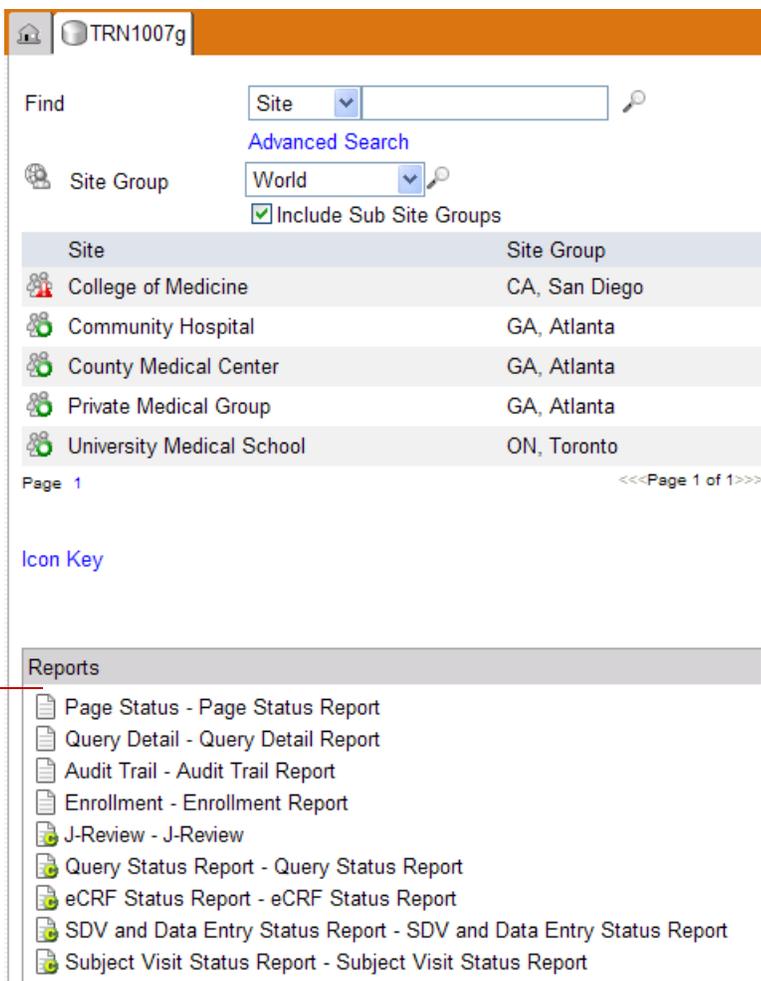


Format an Excel spreadsheet after exporting

After you have exported the data to an Excel spreadsheet, you will probably need to re-format.

Launch a Report from the Report Quicklist

You can also launch a report from the Reports quicklist at the bottom of the Study page.



The screenshot shows a web interface for a study (TRN1007g). At the top, there is a search bar with a dropdown menu set to 'Site' and a search icon. Below the search bar, there is a 'Site Group' dropdown menu set to 'World' and a checkbox labeled 'Include Sub Site Groups' which is checked. Below these filters is a table listing sites and their corresponding site groups:

Site	Site Group
College of Medicine	CA, San Diego
Community Hospital	GA, Atlanta
County Medical Center	GA, Atlanta
Private Medical Group	GA, Atlanta
University Medical School	ON, Toronto

Below the table, there is a page indicator 'Page 1' and a navigation link '<<<Page 1 of 1>>>'. Below the page indicator, there is a link 'Icon Key'. Below the 'Icon Key' link, there is a section titled 'Reports' which contains a list of reports:

- Page Status - Page Status Report
- Query Detail - Query Detail Report
- Audit Trail - Audit Trail Report
- Enrollment - Enrollment Report
- J-Review - J-Review
- Query Status Report - Query Status Report
- eCRF Status Report - eCRF Status Report
- SDV and Data Entry Status Report - SDV and Data Entry Status Report
- Subject Visit Status Report - Subject Visit Status Report

Available
Reports in the
Reports List

Launch a report from the Reports quicklist

1. [Select a study \(see page 37\)](#).
2. On the Study page, scroll to the bottom to display the Reports quicklist.

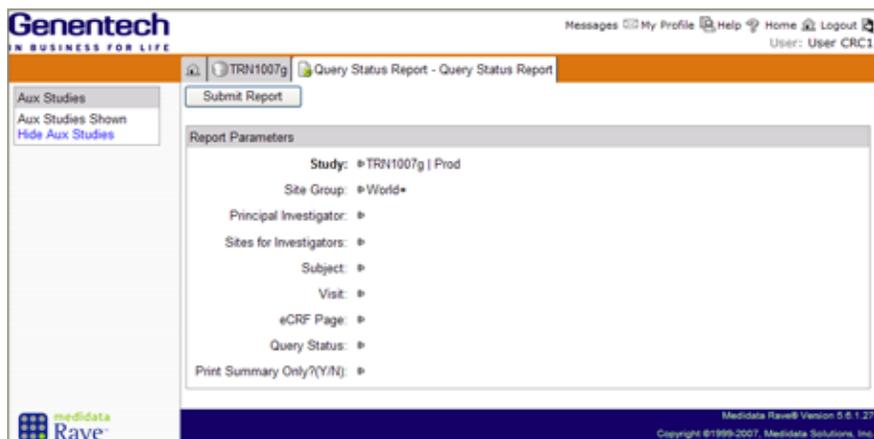


The screenshot shows a list of reports under the heading 'Reports':

- Page Status - Page Status Report
- Query Detail - Query Detail Report
- Audit Trail - Audit Trail Report
- Enrollment - Enrollment Report
- J-Review - J-Review
- Query Status Report - Query Status Report
- eCRF Status Report - eCRF Status Report
- SDV and Data Entry Status Report - SDV and Data Entry Status Report
- Subject Visit Status Report - Subject Visit Status Report

3. Click a report.

- › If other report parameters are required, Rave prompts you to provide them, using the currently-selected study as the default for the Study parameter.



[Specify report parameters \(see page 83\)](#) and then click **Submit Report** to see the report.

- › If no other report parameters are required, then Rave displays the report.
4. [Navigate a report \(see page 85\)](#), if you want.
 5. [Export report data to a file \(see page 87\)](#), if you want.

Hands-On Exercise

1. [Start the Reporter module \(see page 77\)](#).
2. Filter the reports list to display only custom reports.
3. Select the Query Status Report, select a study, generate the report, export the data to PDF format, and navigate the report using Adobe Acrobat Reader.
4. Save the report on your desktop.
5. Launch a report directly from the Study page for your study.

CLASS PROJECT #1

Complete the following tasks:

1. Log out of Rave.
2. Log into Rave.
3. Find the following eCRFs for the “TRN” subject in the College of Medicine site:
 - > Screening folder—Subject Eligibility Assessment
 - > Month 1—Vital Signs
 - > Concomitant Medications
 - > Adverse Event
4. View several reports.
5. Log out.

CONCLUSION TO SECTION 1

What You Have Learned in This Section

In this section, you have learned how to:

- › Understand the following key Rave concepts:
 - › Rave and Genentech EDC studies
 - › Rave architecture: EDC and related modules
 - › Rave security and access rights
 - › Integration with other Genentech systems, such as IVRS, CTMS, and Drug Safety
- › Activate your Rave user account
- › Log into Rave with that user account
- › Navigate the Rave interface, including clicking tabs and customizing your Rave settings
- › Find and view studies and sites
- › Find and view subject information, including the Subject Identification Form
- › Navigate task summaries and the Subject Schedule
- › Find and view eCRFs associated with a subject, including getting help and printing eCRFs
- › Find, view, and navigate reports of clinical study data

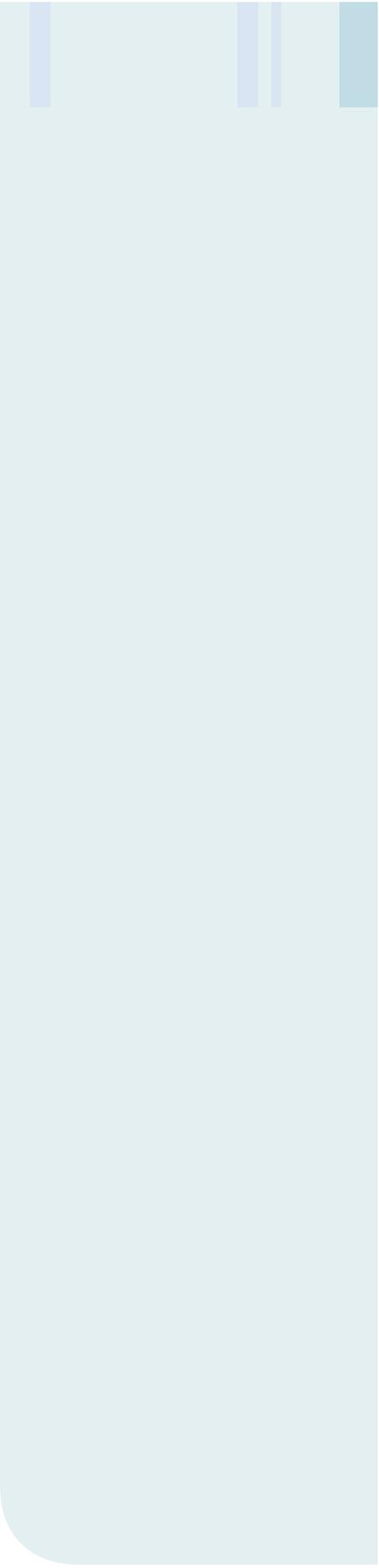
Where To Go From Here

Where you go from here depends on your role in Genentech-sponsored EDC clinical trials:

- › If you will be modifying data, then you can proceed to Section 2: Working with Clinical Data.
- › If you are a view-only user, you are finished with the training.
 - a. Complete the Course Evaluation Form that the instructor provides.
 - b. Apply for your Rave account, as described in [“Obtain a Rave User Account” on page 16](#).



IMPORTANT! Be sure to sign the group training record and fill out a course evaluation before you leave.

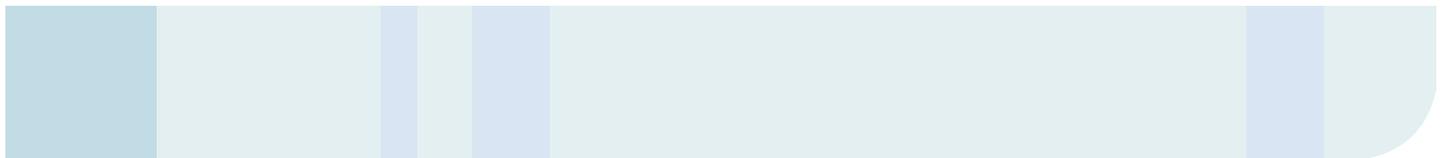


BREAK

WORKING WITH CLINICAL DATA

In this section of the training, you master the tasks of working with study data in Rave. At the end of this section, you will complete a class project that reinforces the skills you gained along the way. Lessons in this section include:

- › [Clinical Data Life Cycle \(see page 96\)](#)
- › [Submitting Clinical Data \(see page 100\)](#)
- › [Using Log eCRFs \(see page 118\)](#)
- › [Reporting Adverse Events in Rave \(see page 124\)](#)
- › [Using Queries \(see page 132\)](#)
- › [Using Sticky Notes \(see page 145\)](#)
- › [Inactivating eCRFs \(see page 150\)](#)
- › [Verifying Data \(see page 159\)](#)
- › [Freezing Data \(see page 164\)](#)
- › [Signing off Data \(see page 169\)](#)
- › [Locking Data \(see page 173\)](#)



LESSON 9

CLINICAL DATA LIFE CYCLE

This lesson covers the following topics:

- › [Overview of the Clinical Data Life Cycle \(see page 96\)](#)
- › [Submit Phase \(see page 97\)](#)
- › [Verify Phase \(see page 97\)](#)
- › [Freeze Phase \(see page 98\)](#)
- › [Sign-Off Phase \(see page 98\)](#)
- › [Lock Phase \(see page 98\)](#)
- › [Summary of Requirements \(see page 99\)](#)

Study Closeout

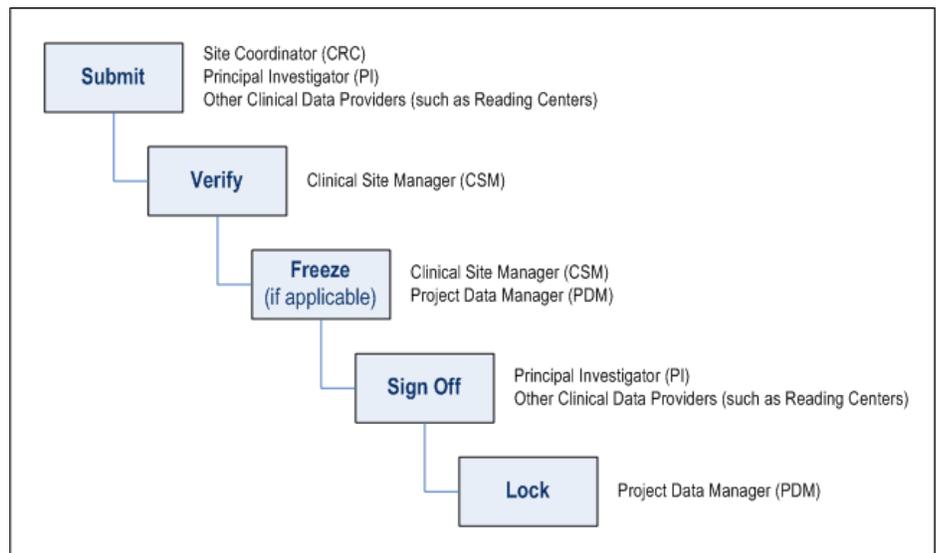
The final phases (freeze, sign-off, and lock) are associated with *study closeout* activities. To learn more, refer to CDM.SOP.203: Electronic Data Capture (EDC) Study Database Closeout.

Data Status Icons

The data status icons (see the icon key and the discussion in [“Data Status Icons” on page 56](#)) indicate the progress of an individual data point through this cycle.

Overview of the Clinical Data Life Cycle

In Rave, clinical data goes through a series of distinct phases, each of which involves different members of the study team (associated Rave roles are in parentheses).



Submit Phase

In this phase, sites submit clinical data for subjects by completing eCRFs in Rave. Site Coordinators (CRC role), Principal Investigators (PI role), and other clinical data providers, such as Reading Centers (RC role), are authorized to submit eCRF data in the system. For details, see:

- › [“Submitting Clinical Data” on page 100](#)
- › [“Using Log eCRFs” on page 118](#)
- › [“Reporting Adverse Events in Rave” on page 124](#)

The process of adding, updating, and cleaning clinical data can also involve queries and sticky notes (interactive questions and comments) about specific data points on eCRFs. For details, see:

- › [“Using Queries” on page 132](#)
- › [“Using Sticky Notes” on page 145](#)

If an eCRF is no longer needed (for example, the subject terminated participation early), then the Clinical Site Manager (CRA role) or Project Data Manager (DM role) can inactivate it after completing the Study Completion / Early Discontinuation eCRF, as described in [“Inactivating eCRFs” on page 150](#).

Verify Phase

After clinical data has been submitted and cleaned in Rave, *verifying* the data—via the Source Document Verification (SDV) process—ensures that what’s entered in Rave matches exactly the written record of data collected from a subject (patient charts, lab reports, notes, and other paper-based records). Verification can begin before all data has been submitted. The Clinical Site Manager (CRA role) is authorized to conduct the SDV. Genentech requires that all data points (100%) be verified against source documents at a frequency specified by the Clinical Site Manager. For details, see [“Verifying Data” on page 159](#).

Freezing Data

Depending on the study protocol, certain studies might not use the freeze phase during the conduct of the study.

Freeze Phase

Freezing the data prevents any further data entry edits to all data points that have been frozen. In the Rave software, freezing is sometimes referred to as *placing an entry lock* (or a *soft lock*) on the data point. A data point can be frozen prior to being verified; however, before an eCRF can be frozen, all of its data points must be verified. A data point cannot be frozen if any queries are open against it. Once frozen, however, manual queries and sticky notes might be opened subsequently, and the status icon for the eCRF might change to reflect open queries or sticky notes. In order to change a frozen data point, to open queries or sticky notes against it, or to verify it, the data point must first be explicitly unfrozen. The Clinical Site Manager (CRA role) or Project Data Manager (DM role) are authorized to freeze and unfreeze data. For details, see [“Freezing Data” on page 164](#).

Sign-Off Phase

After all clinical data in a study has been frozen, *signing off* is the act of approving the data in its current state. Genentech requires that Principal Investigators (PI role) or other clinical data providers, such as Reading Centers (RC role), submit their password to electronically sign-off on the clinical data for a given subject. By submitting their signature, these users attest that the subject data have been reviewed and deemed accurate. For details, see [“Signing off Data” on page 169](#).

Lock Phase

After all clinical data in a study has been signed off, *locking* completely locks the clinical data for a trial. In the Rave software, locking is sometimes referred to as a *placing a hard lock*. Locking data prevents users from making any further changes to the data point. Once the data is locked, it cannot be unlocked except under extraordinary circumstances. Genentech requires that the Project Data Manager (DM role) lock data. For details, see [“Locking Data” on page 173](#).

Summary of Requirements

The following table summarizes general requirements for each phase of the clinical data life cycle.

- **Note:** These requirements might not accurately reflect every study scenario. Refer to the study protocol for study-specific requirements.

Table 11: **Field Types on Rave eCRFs**

Phase	Requirements
Submit	<ul style="list-style-type: none"> › Data points must be added, updated, and cleaned in Rave. › Manual and automatic queries and sticky notes might be opened against specific data points. › Unused forms and folders can be inactivated.
Verify	<ul style="list-style-type: none"> › Data points must be entered in Rave before they can be verified. › SDV can begin before all data points have been submitted. › Queries and sticky notes might be opened against specific data points. › 100% of all data points must be verified against the source documents. › Frozen data points must be unfrozen before they can be verified.
Freeze	<ul style="list-style-type: none"> › Prior to freeze, all queries on the data point must be closed, and data must undergo Data Listing Review. › Data points can be frozen before they are verified. However, before freezing an eCRF, all data points in the eCRF must have been verified. › For discontinued subjects, unused forms and eCRFs should be inactivated. › After a data point is frozen, new queries and sticky notes might be opened on it.
Sign-off	<ul style="list-style-type: none"> › All data points in a study need to be entered. › All queries must be resolved. › All appropriate fields need to be verified and frozen.
Lock	<ul style="list-style-type: none"> › Data point is signed off and final. › No further changes allowed except in extraordinary circumstances.

LESSON 10

SUBMITTING CLINICAL DATA

This lesson covers the following topics:

- › [About Submitting Clinical Data in Rave \(see page 100\)](#)
- › [Adding Subjects \(see page 104\)](#)
- › [Steps for Submitting eCRF Data \(see page 106\)](#)
- › [Submit eCRF Data for a Subject \(see page 109\)](#)
- › [Add Events \(Unscheduled Visits\) \(see page 113\)](#)

- **Note:** This lesson uses eCRFs from the training sample study to show you how to submit eCRF data for a subject in Rave. You might encounter many other eCRFs in the clinical trial(s) with which you will be working. The principles you learn in this lesson apply to those eCRFs as well.

About Submitting Clinical Data in Rave

In Rave, eCRFs contain the core clinical data that will be subsequently analyzed. In Genentech EDC clinical trials, Rave is the *system of record* for eCRFs. This means that the eCRF data stored in Rave is the authoritative electronic version of the clinical trial data.

Submitting Data in a Timely Manner

Sites should submit clinical data in Rave as soon as possible after the visit, and as required by any Genentech-sponsored clinical trial in which they are participating.

eCRFs Are Automatically Added When a Subject is Created

When a new subject is created in Rave, the Task List is created automatically—all folders (visits) and eCRFs are generated by the system. Therefore, except for unscheduled events (see [“Add Events \(Unscheduled Visits\)” on page 113](#)), you do not create a new eCRF—you simply edit those that already exist for the subject.

Types of Fields on Rave Pages

To accommodate the various formats and characteristics of clinical data captured in eCRFs, Rave supports the following types of fields:

Table 12: Field Types on Rave eCRFs

Field Type	Description
Text	Horizontal text box that defines the maximum length of the data to be typed. Typically used for supplying succinct text, such as a subject's initials or number. Can be up to 1799 characters long, but the actual length for a Text field on a particular eCRF is usually shorter and is based on study-specific requirements.
Long Text	Rectangular text box with a vertical scroll bar for typing data. Typically used for entering more free-form, descriptive text. Can be up to 1799 characters long, although the actual length for a Long Text field on a particular eCRF is based on study-specific requirements.
Date / Time	Date and time data. Rave displays separate fields for each portion of the date / time (year, month, day, hours, minutes, seconds, and so on). The user typically enters the day of the month, selects the month from a drop-down list, and then types the year last.
Check Box	Box that can be checked / unchecked to indicate one of two possible choices (such as True / False, Yes / No, On / Off, and so on).
Drop-down List	Pre-defined list of possible choices, from which a user can select one or none. To display the list, the user clicks the down arrow and then clicks an item from the list.
Radio Buttons	Horizontal list of possible choices, from which a user must select one. To select, the user clicks the circle to the left of the preferred option. Once a user clicks a radio button in the set, at least one of the radio buttons in the set must be selected—they can no longer be all blank.
Signature	Special control for submitting a password.
Calculated Fields	Read-only. A field that is calculated based on values submitted in other fields. For example, a subject's current age can be calculated from their birth date (as shown on the Demographics eCRF).

The nature of the data to be submitted determines the field type used. For example:

- Text data are stored in a Text or Long Text field, depending on whether the text is succinct or more free-form.
- Date or time values are stored in date/time fields.
- A check box is used when only one of two answers is possible (binary): yes/no, on/off, enabled/disabled, true/false, and so on.

Example Appearance

The screenshot displays various field types in a light blue interface. At the top, there is a simple horizontal text box. Below it is a larger rectangular text box with a vertical scroll bar on the right side. Further down, a date/time field is shown with three separate input boxes: one for the day, a dropdown menu for the month, and one for the year. Next are two check boxes, the second of which is checked with a green checkmark. Below these are two dropdown menus; the second one is open, showing a list of options: "Adverse event", "Death", "Lost to follow-up", "Physician decision", "Subject decision", and "Sponsor decision". Underneath the dropdowns are two radio buttons labeled "Male" and "Female". A confirmation message reads "I submit that the data are complete and correct. - RTraining". At the bottom, a calculated field for "Age" is shown with the value "31" and a green checkmark icon.

Edit Checks

Edit checks are configured on a per-study basis as defined in Study Configuration Documents. The SLACS (Study Logic and Check Specifications Document) specifies all of the edit checks defined for a study.

- For a defined set of possible values (such as ethnicity), a series of radio buttons or a drop-down list is used.

Edit Checks

After you submit data in an eCRF, Rave performs *edit checks* on some or all of the values you submitted. Edit checks catch typing errors or aberrant data to help ensure that the submitted data are valid. You cannot rely entirely on edit checks to prevent all data errors, but they do provide a safety net, and—along with visual confirmation of the data and other precautions—they support an environment in which data errors are minimized.

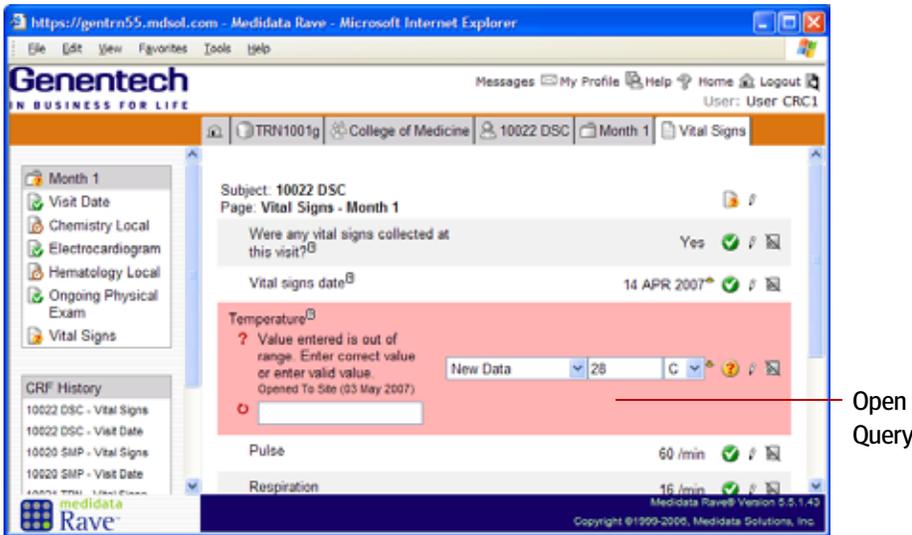
Common types of basic edit checks include:

Table 13: **Basic Edit Checks on Data Entry Fields**

Type	Description
Required Value	You must type a value in this field—it cannot be blank. For example, on the Demographics eCRF (see “Submit the Demographics eCRF” on page 112), the Date of Birth, Sex, and Ethnicity fields are all required.
Non-Conformant Data	You must type a value that matches the format of the field. For example, you cannot submit alphabetic characters that were typed into a numeric field, such as the Temperature field on the Vital Signs eCRF.
Future Date	You must type a date that precedes, or is the same as, the current system date. For example, on the Visit Date eCRF (see “Submit the Visit Date eCRF” on page 109), Rave prevents you from submitting a visit date that is in the future.
Out-of-range Data	You must type a number that is within a preconfigured range. Rave alerts you if you specify values that are too high or too low (outside the range). For example, on the Vital Signs eCRF, upper and lower limits are configured for the Temperature, Pulse, Respiration, Systolic Blood Pressure, Diastolic Blood Pressure, Weight, Height, and BSA fields.

Other, more advanced edit checks and programmed business logic can provide a sophisticated analysis of the data and take a specific action in response, such as opening a query, placing a sticky note, sending a message to a user or group of users, requiring data verification, flagging the data as non-conformant, adding forms, making fields visible, and so on.

The following figure shows an example query (Temperature value out of range) that resulted from a failed edit check. For more information, see [“Using Queries” on page 132](#).



Restricted eCRFs and Fields

Permissions associated with your user account (via the configured user group and role) determine whether you can modify, verify, or view a particular field on an eCRF, or the entire eCRF. These are called *restricted fields* and *restricted eCRFs*, respectively, because certain unauthorized users are prevented from accessing them. For example, access to the Electrocardiogram eCRF is typically restricted to the Project Data Manager (DM role), Lab Data Manager (LDM role), and other clinical data providers, such as Reading Centers (RC role). Users who do not have that role associated with their user account cannot see the Electrocardiogram eCRF.

Data-Dependent eCRFs and Fields

The existence of certain eCRFs or fields on an eCRF might depend on the value in another field. For example, if a subject's gender is changed to female, Rave might add the Pregnancy Report eCRF or Reproductive History and Reproductive Status eCRF to the subject's schedule.

Calculated Fields

A calculated field is a read-only field that is calculated based on the value(s) specified in other field(s). For example, on the Demographics eCRF (see [“Submit the Demographics eCRF” on page 112](#)), the Age field is calculated based on the entered Birth Date. Similarly, on the Adverse Event eCRF (see [“Submit an Adverse Event” on page 126](#)), Rave automatically assigns the value in the AE Number field.

Leader Note

Discuss examples of restricted eCRFs and restricted fields on an eCRF.

Access to Restricted eCRFs

In this training (only), your role has been configured so that you can see the Electrocardiogram eCRF.

Leader Note

IVRS is used by most Genentech studies. For phase I studies and for non-randomized studies, the study team may receive a waiver if there is a strong business rationale, such as a small number of sites or subjects, or single treatment arms.

Adding Subjects

For non-IVRS studies, sites must manually add subjects to Rave. Only users with the CRC or PI roles can add subjects.

Add a subject

 [Add Subject](#)

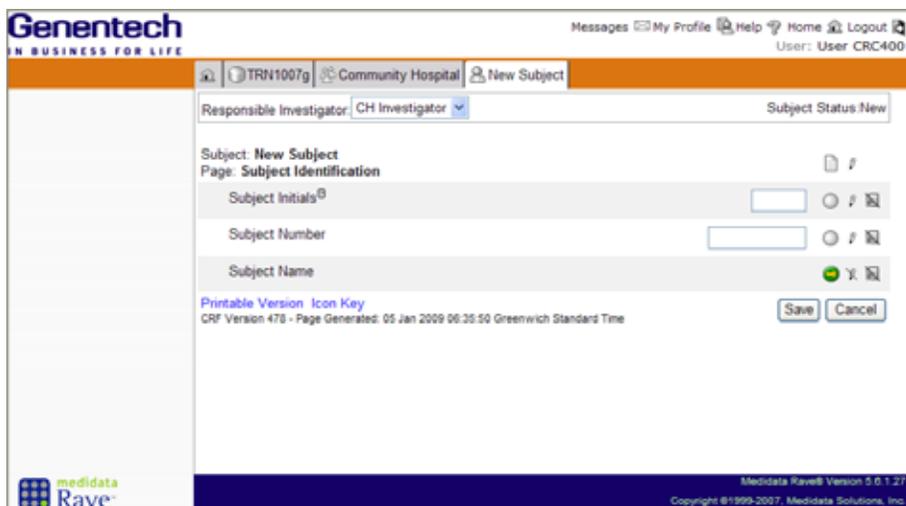
1. [Log into Rave \(see page 19\)](#), if applicable, using an account with sufficient privileges to add subjects to a study.
2. [Select a study \(see page 37\)](#), if applicable.
3. [View a site \(see page 39\)](#), if applicable.

If you are authorized to add a subject to the study, you'll see the Add Subject link, as shown in the following example.



4. Click **Add Subject**.

Rave displays an empty Subject Identification page.

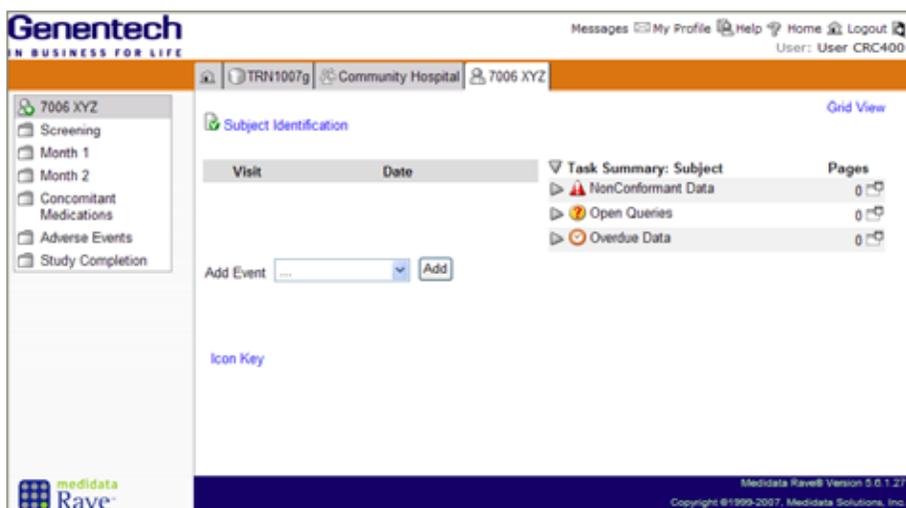


5. Select the Responsible Investigator for this subject.
6. Enter the Subject Initials (three characters).
If the subject does not have a middle name, then use a hyphen (such as A-B).
7. Enter the Subject Number, which is a five-digit, Genentech-assigned number.
8. Click **Save**.



9. When prompted, click **OK** to confirm adding this subject.

Rave adds the subject, creates their default folders and eCRFs, and displays the Subject page for the new subject.



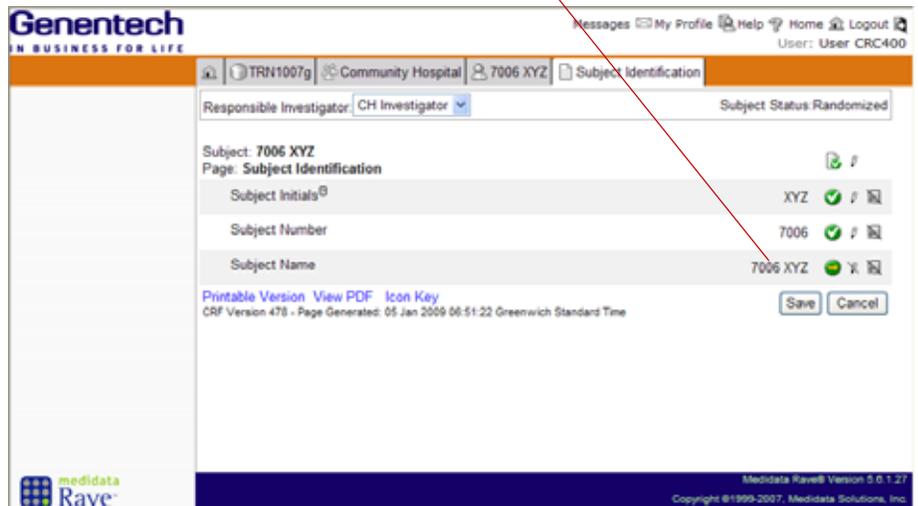
10. Click **Subject Identification** to confirm that this subject was added correctly.

Leader Note

At the onset of the study (post waiver), the study Biostatistician assigns blocks of subject numbers for each study site. This information is communicated to the site staff (PI and CRC) by Clinical Operations.

Rave displays the Subject Identification page for this new subject. Notice how Rave created the Subject Name by combining the Subject Number and Subject Initials.

Subject Name



11. If you want, you can edit the Subject Initials and Subject Number, then click **Save** to save your changes.

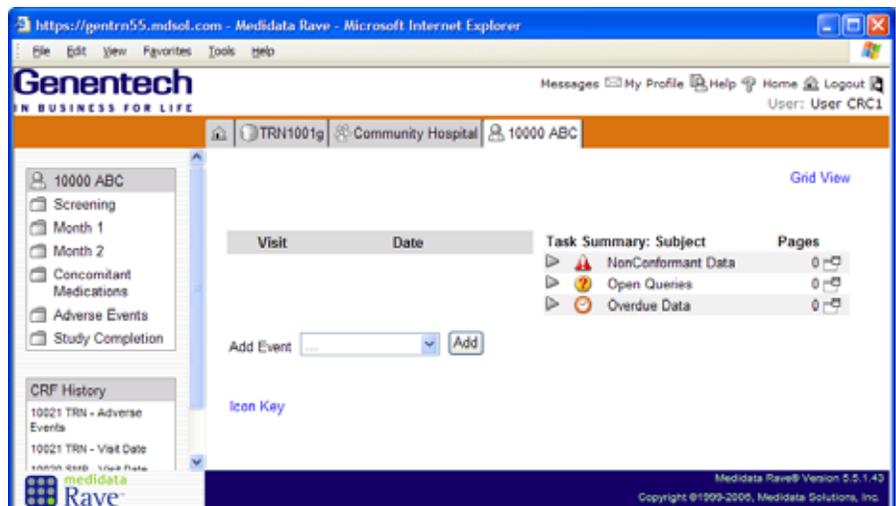
Steps for Submitting eCRF Data

In general, when submitting eCRF data, you complete the following steps.

Submit data in an eCRF

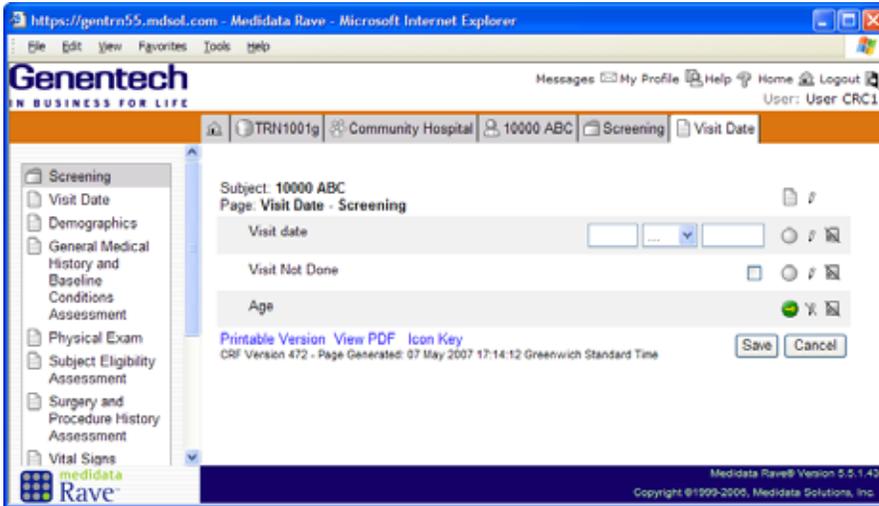
1. [Select a study \(see page 37\)](#), if applicable.
2. [View a site \(see page 39\)](#), if applicable.
3. [View a subject \(see page 43\)](#).

The following example shows the subject screen for a newly-added subject.



4. Display the eCRF that you want to fill in for the subject, as you learned in [“Viewing eCRFs Associated with a Subject” on page 53.](#)

Rave displays the empty eCRF. In this example, the empty Visit Date eCRF is displayed.



- **Note:** Rave displays the fields that are available to you for viewing or editing. The eCRF might have additional fields that your user account (and its associated role) does not authorize you to view.
5. Fill in the eCRF, providing the appropriate data, making selections, and so on.
 - Use the keyboard to type into text, long text, and date / time fields.
 - Use the mouse to click check boxes or to select values from drop-down lists and radio buttons.
 - Use the mouse or TAB key to move between fields.

H Tip! Click the Help (m) icon next to any field about which you have questions. The help text will describe the field and might also provide data entry rules, guidelines, and hints. For more information, see [“Get field-level help on a data point in an eCRF” on page 73.](#)

6. Submit the eCRF by clicking **Save** to save your changes (if you don't want to save the eCRF, click **Cancel** to abandon your changes).



IMPORTANT! If you attempt to leave a page before saving your changes, Rave prompts you to save them. If you forget to save changes and leave the unsaved eCRF up on your screen, you will lose your changes if Rave encounters a time-out due to a period of inactivity (see [“Time-outs” on page 34](#)).

7. Rave displays the completed form.

Saving eCRFs and Edit Checks

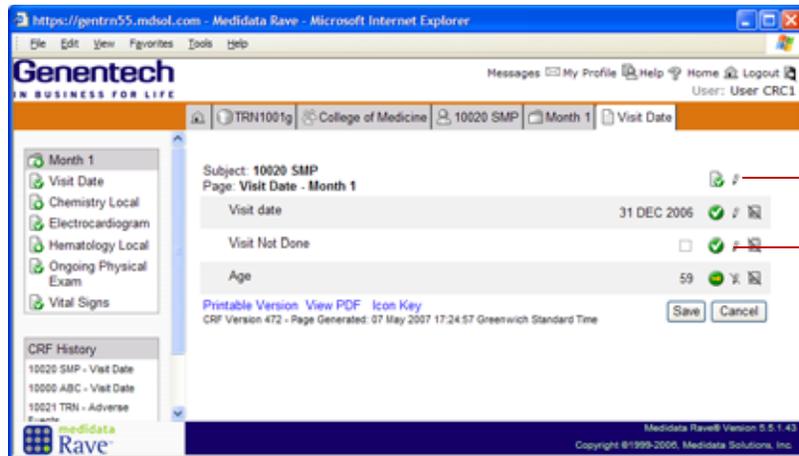
Edit checks are fired whenever you save changes to an eCRF. If you view an empty eCRF and do not want to make any changes, be sure to click the **Cancel** button to exit the screen. If you click **Save** instead, then you might see system-generated queries resulting from edit checks for missing data.

For certain fields, Rave performs edit checks on the data that you submitted (see [“Edit Checks” on page 102](#)). Rave automatically creates system-generated queries that prompt you to fix any detected data errors (for details, see [“Using Queries” on page 132](#)).

8. Fix the data as requested (see [“Edit a submitted eCRF” on page 108](#)), and then click **Save** to save your changes (or **Cancel** to abandon them).
9. Rave displays the completed form.

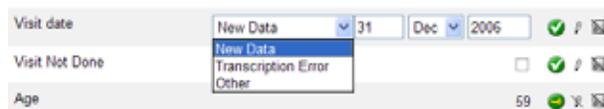
Edit a submitted eCRF

1. Display the eCRF that you want to edit.



2. Edit the field(s) that you want to change
 - Click the Edit (pencil) icon at the top of the form to edit all fields on the eCRF.
 - Click the Edit (pencil) icon next to any field containing a data point that you want to edit individually.
3. Change data points in the field(s) you want to edit.

For each field, Rave prompts you to select a reason for the change to this data point. Rave will store this information in the field’s audit trail.



Select one of the following reasons:

Field / Data	Description
New Data	Data has not been entered before.
Transcription Error	Error with the previously-entered value.
Other	Any other reason.

4. Click **Save** to submit your changes.

Submit eCRF Data for a Subject

This section walks through the process of submitting data for some of the eCRFs in the training sample study:

- [Submit the Visit Date eCRF \(see page 109\)](#)
- [Submit the Demographics eCRF \(see page 112\)](#)

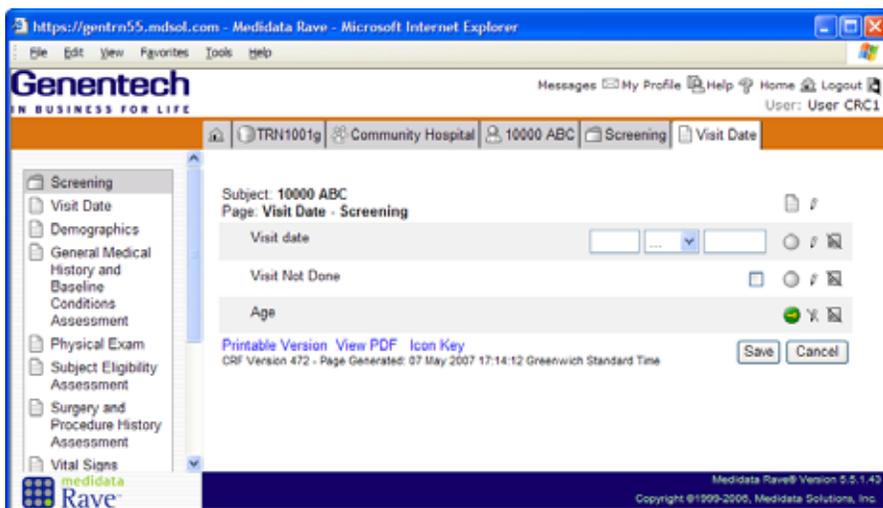
Submit the Visit Date eCRF

The Visit Date eCRF (in the Screening folder) records the date on which the initial screening visit or subsequent visit occurred. If the visit did not occur, then this fact must be recorded in the Visit Date eCRF instead.

Complete the Visit Date eCRF

1. [View a subject \(see page 43\)](#),
2. In the Screening folder, view the Visit Date eCRF, as described in [Viewing eCRFs Associated with a Subject \(see page 53\)](#).

An empty Visit Date eCRF is displayed, as shown in the following example.



3. Supply the requested data in the eCRF. The Visit Date eCRF contains the following fields:

Field / Data	Description
Visit Date	Enter the complete date in dd MMM yyyy format.
Not Done	Select (check) this check box if the visit did not occur.

4. Click **Save** to save your changes.

Note

The chronology for submitting eCRF data in this training might differ from what you might expect in a typical production environment. However, the Rave Basics training is designed to teach you how to navigate the Rave software, so it “jumps around” the Task List to demonstrate certain Rave functionality in a logical classroom sequence.

Adding and Editing Data

This topic takes you through the initial data entry screen for a Visit Date eCRF, then shows you how to go back and edit data points on the eCRF.

Rave displays the completed eCRF.

The screenshot shows the Medidata Rave web application in Microsoft Internet Explorer. The browser address bar displays <https://gentrn55.mdsol.com>. The page title is "Medidata Rave". The breadcrumb trail at the top indicates the path: TRN1001g > College of Medicine > 10020 SMP > Month 1 > Visit Date. The main content area shows the following details:

- Subject: 10020 SMP
- Page: Visit Date - Month 1
- Visit date: 31 DEC 2006
- Visit Not Done:
- Age: 59

At the bottom of the form, there are links for "Printable Version", "View PDF", and "Icon Key", along with "Save" and "Cancel" buttons. The footer includes the Medidata Rave logo and the text "Medidata Rave® Version 5.5.1.43 Copyright ©1999-2006, Medidata Solutions, Inc."

Edit a Completed Visit Date eCRF

1. [View a subject \(see page 43\)](#),
2. In the Screening folder, view the Visit Date eCRF, as described in [Viewing eCRFs Associated with a Subject \(see page 53\)](#).

The existing Visit Date eCRF is displayed, as shown in the following example.

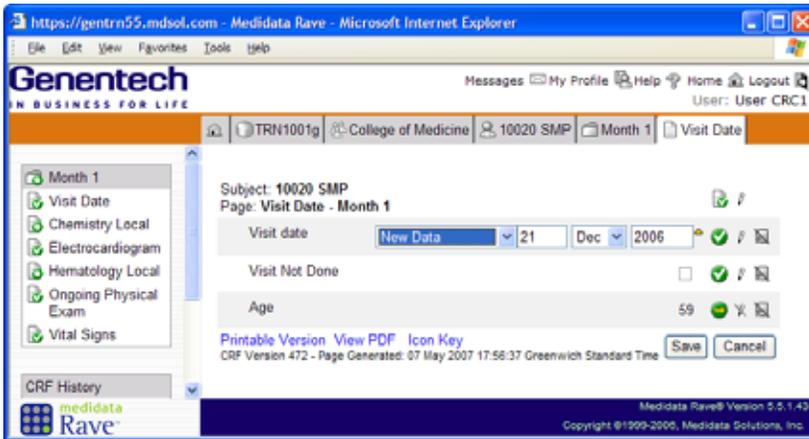
The screenshot shows the Medidata Rave web application in Microsoft Internet Explorer. The browser address bar displays <https://gentrn55.mdsol.com>. The page title is "Medidata Rave". The breadcrumb trail at the top indicates the path: TRN1001g > College of Medicine > 10020 SMP > Month 1 > Visit Date. The main content area shows the following details:

- Subject: 10020 SMP
- Page: Visit Date - Month 1
- Visit date: 21 DEC 2006
- Visit Not Done:
- Age: 59

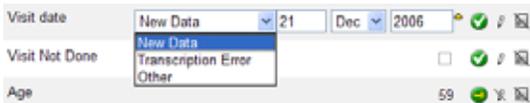
At the bottom of the form, there are links for "Printable Version", "View PDF", and "Icon Key", along with "Save" and "Cancel" buttons. The footer includes the Medidata Rave logo and the text "Medidata Rave® Version 5.5.1.43 Copyright ©1999-2006, Medidata Solutions, Inc."

3. Click the Edit (✎) icon next to the Visit Date field.

Rave prompts you to edit the Visit Date field, as shown in the following example.



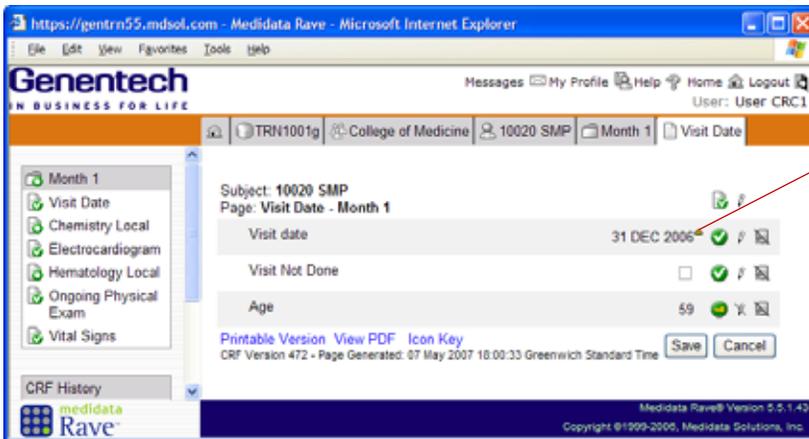
4. Select a reason for the change.



5. Make your changes to the data point.

6. Click **Save** to save your changes.

Rave displays the edited eCRF.



Delta Icon

Notice the Delta (Δ) icon next to the data point, indicating that this data was changed.

7. To see how your change appears in the audit trail, click the Data Status (✔) icon next to the Visit Date field and view the audit trail entry for this change, as shown in the following example.

Audit	User	Time
User entered '31 Dec 2006' reason for change: Transcription Error	User CRC1	07 May 2007 18:00:32

Notice that the “reason for change” matches the reason you selected.

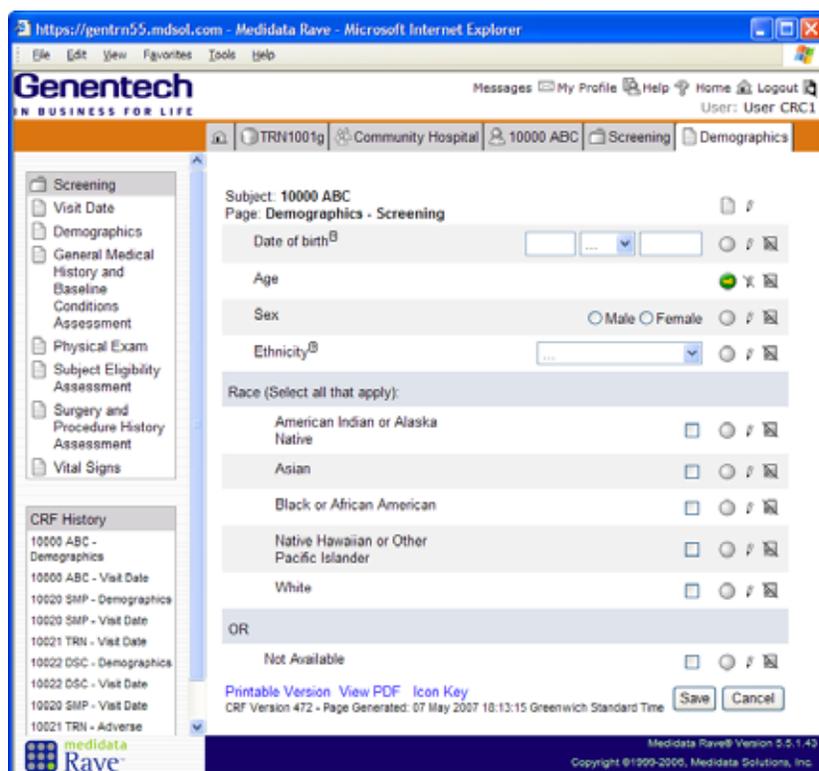
Submit the Demographics eCRF

The Demographics eCRF in the Screening folder collects demographic information about a subject, such as date of birth, gender, ethnicity, and race.

Complete the Demographics eCRF

1. [View a subject \(see page 43\)](#),
2. View the Demographics eCRF for a subject, as described in [Viewing eCRFs Associated with a Subject \(see page 53\)](#).

An empty Demographics eCRF is displayed, as shown in the following example.



The screenshot shows a web browser window displaying the Genentech Medidata Rave interface. The page title is "Demographics - Screening" for subject "10000 ABC". The form includes the following fields and options:

- Date of birth^B**: A date selection field.
- Age**: A numeric input field.
- Sex**: Radio buttons for "Male" and "Female".
- Ethnicity^B**: A dropdown menu.
- Race (Select all that apply):** A list of checkboxes for "American Indian or Alaska Native", "Asian", "Black or African American", "Native Hawaiian or Other Pacific Islander", and "White".
- OR**: A section for "Not Available" with a checkbox.

At the bottom of the form, there are links for "Printable Version", "View PDF", and "Icon Key", along with "Save" and "Cancel" buttons. The footer indicates "Medidata Rave® Version 5.5.1.43" and "Copyright ©1999-2006, Medidata Solutions, Inc."

3. Supply the requested data in the eCRF.

If you need more information about a particular data point, click the Help (ⓘ) icon next to the field, if available.

4. Click **Save** to save your changes.

Add an event to a subject

1. [View a subject \(see page 43\)](#) for whom you want to add an event.
2. On the Subject page, click the **Add Event** drop-down list.

Add Event

Rave displays a list of event types that were configured for your study, as shown in the following example.

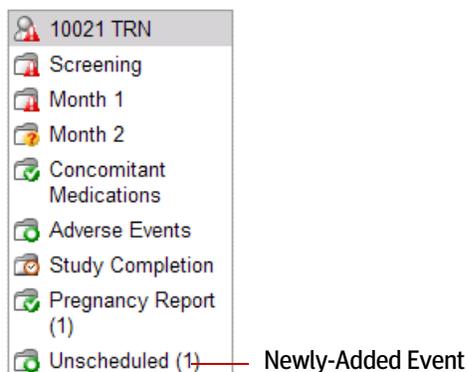
Add Event

Icon Key

- ...
- Pregnancy Report
- Unscheduled

3. Select the event you want to add for this subject (for example, *Unscheduled*).
4. Click **Add**.

Rave adds the event to the sidebar and Subject Schedule, possibly with a number (in parentheses) as well, to indicate that it has been added, as shown in the following example.



Submit Local Lab Forms

For local lab eCRFs (such as the Chemistry Local and Hematology Local eCRFs), submitting data is a two-step process: sites first complete and submit the eCRF, and then they can submit comments for analytes on the eCRF.

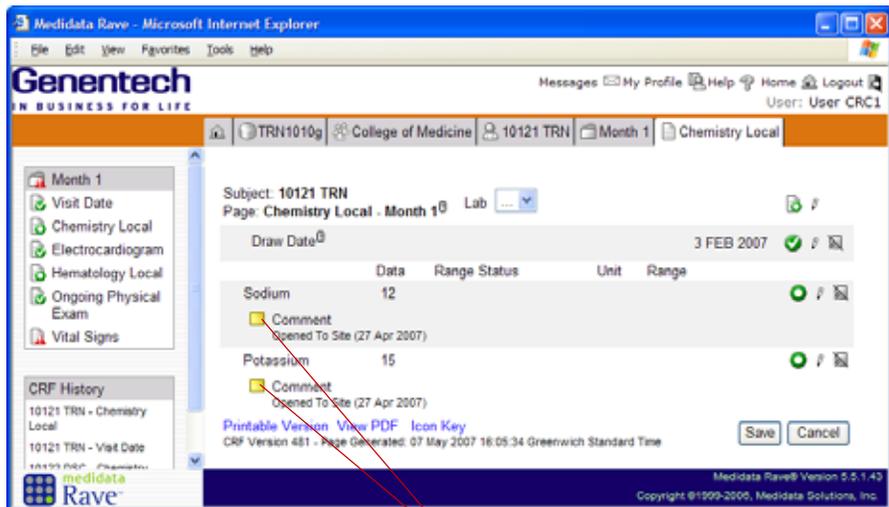
Submit a local lab eCRF

1. [View a subject \(see page 43\)](#),
2. Display the local lab form that you want to complete.
3. Fill in the local lab form, if it has not already been submitted, and click **Save** to submit your changes.

Note

The *Unscheduled* folder contains the same eCRFs as the *Month 2* folder.

After a local lab form is submitted, Rave displays a system-generated sticky note below any data point that is eligible for commenting.



Comment Sticky Notes for Analytes

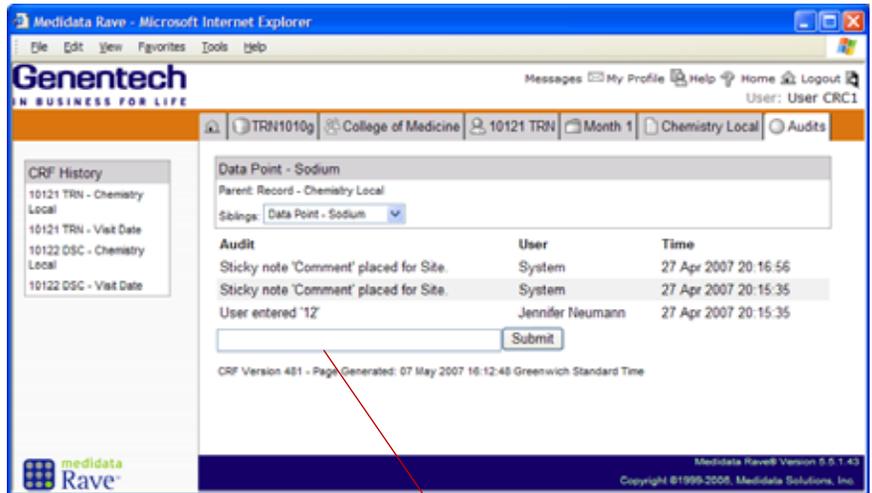
These sticky notes are generated (by an edit check) after the Draw Date field is populated and submitted. For any sticky note, you can add a comment about the analyte or results, as in the following examples:

- Specimen hemolyzed
- Sample quantity not sufficient for the assay
- Test repeated for confirmation
- Test Repeated

Each generated sticky note remains with the data point, even if a comment has not been added.

4. For each analyte to which you want to add a comment:
 - Click the data status icon next to the data point for which you want to add a comment.

Rave displays the Audit Page and a data entry field into which you can type a comment.



Type the comment here.

- Click **Submit**.

Rave saves the comment, updates the audit trail for this data point, and displays the comment on the eCRF page.



Edit a comment on a local lab form

1. Click the Edit link next to the comment that you want to edit.

Rave prompts you to edit the comment text.



2. Change the text of the comment.
3. Click **Save**.

Remove a comment on a local lab form

1. Click the Inactivate check box next to the comment that you want to inactivate.
2. Click **Save**.

Rave removes the comment from the analyte data point.

Hands-On Exercise

1. Log in using an account associated with the CRC role.
 2. Go to the subject who is assigned to you.
 3. Open the Screening folder.
 4. Complete and submit the following forms:
 - › Visit Date
 - › Demographics (select Female)
Note that, when you select Female, the Pregnancy Report eCRF is automatically added.
 - › Physical Exam
 - › Vital Signs
- You might encounter some system-generated queries (see [“Using Queries” on page 132](#)) if you enter any data point that fails an edit check. Please ignore these for now.
5. Open the Month 1 folder.
 6. Complete and submit the following forms:
 - › Visit Date
 - › Ongoing Physical Exam
 - › Vital Signs
 - › Chemistry Local
 - › Hematology Local
 7. For the Chemistry Local eCRF In the Month 1 folder, enter and edit comments for all of the analytes.
 8. Add an unscheduled visit and Pregnancy Report using the Add Event feature.

LESSON 11

USING LOG eCRFs

This lesson covers the following topics:

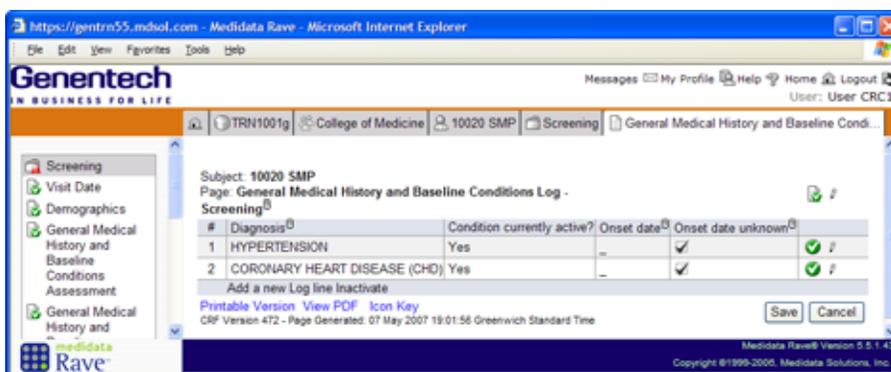
- › [About Log eCRFs \(see page 118\)](#)
- › [Submit Data for Log eCRFs \(see page 120\)](#)
- › [Inactivate a Log Line \(see page 122\)](#)

About Log eCRFs

A log eCRF is used to add multiple instances of the same eCRF, such as separate entries for a subject's medical history or concomitant medications. Log eCRFs are displayed in two different modes: Landscape and Portrait.

Landscape Mode

Each log line is displayed in a single, horizontal row. Each row represents a separate record (such as an individual medication in the Concomitant Medications eCRF). The following figure shows an example log eCRF in landscape mode (the General Medical History and Baseline Conditions Log - Screening eCRF).



Portrait Mode

For editing, each line is displayed in a vertical format. The following figure shows an example Adverse Events eCRF in portrait mode for editing.

The screenshot shows the Genentech Medidata Rave interface in portrait mode. The browser address bar displays "https://gentrn55.mdsol.com - Medidata Rave - Microsoft Internet Explorer". The page title is "Genentech IN BUSINESS FOR LIFE". The user is logged in as "User: User CRC1". The breadcrumb trail is "TRN1001g > College of Medicine > 10020 SMP > Adverse Events > Adverse Events".

The main content area shows the details for "Subject: 10020 SMP" and "Page: Adverse Events - Adverse Events". It indicates "Currently viewing line 1 of 1." and "Apply to Record" is checked. The form fields are as follows:

- AE Number: 1
- Primary Adverse Event description: ANGINA
- Onset date: 15 FEB 2007
- Resolution date: 15 FEB 2007
- Select if event is ongoing at the time of reporting:
- AE intensity: Moderate
- AE suspected to be caused by study drug?: No
- Other Suspected Causes (select all that apply):
 - None:
 - Disease Under Study:
 - Concurrent illness:
 - Concomitant Medication:
 - Action taken with study drug due to SAE/AE: None

However, once saved, the log forms are displayed in a row-wise, horizontal format, as shown in the following example:

The screenshot shows the Genentech Medidata Rave interface in row-wise, horizontal format. The browser address bar displays "https://gentrn55.mdsol.com - Medidata Rave - Microsoft Internet Explorer". The page title is "Genentech IN BUSINESS FOR LIFE". The user is logged in as "User: User CRC1". The breadcrumb trail is "TRN1001g > College of Medicine > 10020 SMP > Adverse Events > Adverse Events".

The main content area shows the details for "Subject: 10020 SMP" and "Page: Adverse Events - Adverse Events". It indicates "Add a new Log line Inactivate". Below the form fields is a table with the following data:

#	AE#	AE	ONSET DT	RES DT	ONG	GRADE	RELATED?	CAUSES	NONE	DS	ILLNESS	CONMED
1	1	ANGINA	15 FEB 2007	15 FEB 2007	<input type="checkbox"/>	Moderate	No	-	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Below the table are links for "Printable Version", "View PDF", and "Icon Key". The page footer indicates "CRF Version 472 - Page Generated: 07 May 2007 19:20:06 Greenwich Standard Time".

Submit Data for Log eCRFs

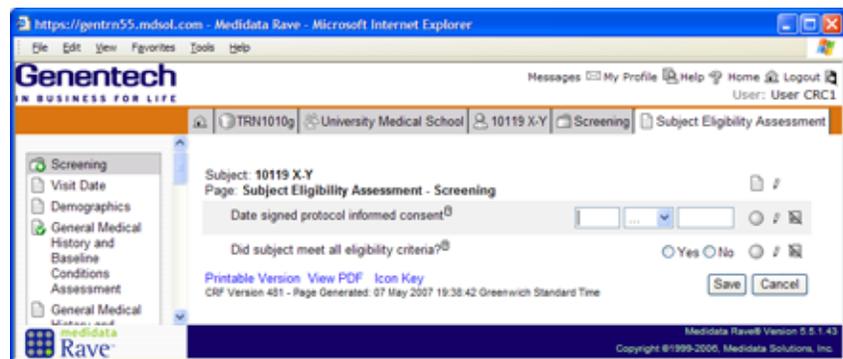
This section describes how to submit data for portrait mode log eCRFs using the Subject Eligibility Assessment eCRF as an example.

- **Note:** Your study might have log eCRFs that can be entered in landscape mode. However, landscape mode data entry is not implemented in the training sample study.

Submit data for a portrait mode eCRF

1. [View a subject \(see page 43\)](#),
2. Open the Screening folder.
3. In the Task List in the sidebar, click **Subject Eligibility Assessment**.

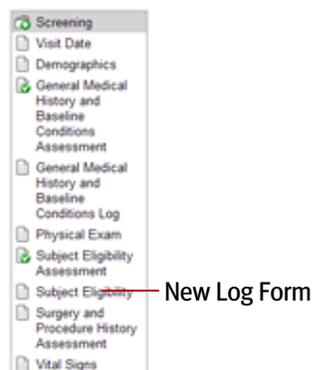
Rave displays the selected eCRF.



The screenshot shows a web browser window displaying the Medidata Rave interface. The browser address bar shows the URL: https://genetn55.mdsol.com - Medidata Rave - Microsoft Internet Explorer. The page title is "Genentech IN BUSINESS FOR LIFE". The user is logged in as "User CRC1". The breadcrumb trail is: TRN1010g > University Medical School > 10119 X-Y > Screening > Subject Eligibility Assessment. The main content area shows the form for "Subject: 10119 X-Y" and "Page: Subject Eligibility Assessment - Screening". The form includes a date field for "Date signed protocol informed consent" and a question "Did subject meet all eligibility criteria?" with radio buttons for "Yes" and "No". There are "Printable Version", "View PDF", and "Icon Key" links. At the bottom, there are "Save" and "Cancel" buttons. The footer indicates "Medidata Rave® Version 5.5.1-43" and "Copyright ©1999-2006, Medidata Solutions, Inc."

4. Specify the date on which the subject signed the protocol consent form.
5. In response to the prompt **Did subject meet all eligibility criteria?**, click **No**.
6. Click **Save**.

Rave adds the Subject Eligibility Log eCRF to the Task List.



Rave also adds a note to the Subject Eligibility Assessment - Screening eCRF.

7. In the Task List, click **Subject Eligibility**.

Rave displays an empty Subject Eligibility Log eCRF.

8. Fill in the eCRF.

If you need help, click the Help (H) icon next to a field on the eCRF.

9. Click **Save**.

Rave displays the completed Subject Eligibility Log eCRF in a horizontal format, as shown in the following example.

#	Line number of eligibility criterion not met	Details	Was a waiver granted?	If yes, date waiver was granted
1	1-1	DIABETES	Yes	30 NOV 2006

- To add additional rows, click the **Add a new log line** link below the list, fill in the eCRF, and then click **Save**.

Inactivate a Log Line

Site coordinators (CRC role) can inactivate log lines if, for example, a log line was entered in error. Any data for an inactivated eCRF are excluded from reports, data export, and so on. Log lines cannot be deleted—only inactivated. If you inactivate a line in a log eCRF, you cannot subsequently edit or reactivate it—you must add a new line instead.

- Note:** If you want to inactivate multiple rows, you need to repeat this procedure for each row.

Inactivate a log line

- Display the log eCRF.

Subject: 10022 DSC
Page: General Medical History and Baseline Conditions Log - Screening

#	Diagnosis	Condition currently active?	Onset date	Onset date unknown	
1	DIABETES	Yes	1 JAN 2004	<input type="checkbox"/>	✓ ?
2	HYPERTENSION	Yes	1 JUN 2002	<input type="checkbox"/>	✓ ?
3	HYPOTHYROIDISM	Yes	1 JAN 1997	<input type="checkbox"/>	✓ ?

Add a new Log line Inactivate
Printable Version View PDF Icon Key
CRF Version 472 - Page Generated: 26 Mar 2009 16:47:22 Greenwich Standard Time

Save Cancel

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Inactivate link

- Click the Inactivate link.

Rave prompts you to specify the number of the line that you want to inactivate.

Subject: 10022 DSC
Page: General Medical History and Baseline Conditions Log - Screening

#	Diagnosis	Condition currently active?	Onset date	Onset date unknown	
1	DIABETES	Yes	1 JAN 2004	<input type="checkbox"/>	✓ ?
2	HYPERTENSION	Yes	1 JUN 2002	<input type="checkbox"/>	✓ ?
3	HYPOTHYROIDISM	Yes	1 JAN 1997	<input type="checkbox"/>	✓ ?

Inactivate Cancel

Printable Version View PDF Icon Key
CRF Version 472 - Page Generated: 26 Mar 2009 16:51:12 Greenwich Standard Time

Save Cancel

Medidata Rave® Version 5.6.1.27
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Select the line number

- Click the drop-down list and select the line number to inactivate.

- Click **Inactivate**.

Rave displays the inactivated line number with strike-through text.

- Click **OK**.

TRN1001g College of Medicine 10022 DSC Screening General Medical History and Baseline Condi...

Subject: 10022 DSC
Page: General Medical History and Baseline Conditions Log - Screening

#	Diagnosis	Condition currently active?	Onset date	Onset date unknown	
1	DIABETES	Yes	1 JAN 2004	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2	HYPERTENSION	Yes	4 JUN 2002	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3	HYPOTHYROIDISM	Yes	1 JAN 1997	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Add a new Log line Inactivate

Printable Version View PDF Icon Key

CRF Version 473 - Page Generated: 26 Mar 2009 16:54:07 Greenwich Standard Time

Save Cancel

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Inactivated line (strike-through text)

Hands-On Exercise

1. In the Screening folder for your subject, fill in the General Medical History and Baseline Conditions Assessment eCRF and at least one General Medical History and Baseline Conditions Log eCRF.
2. In the Screening folder for your subject, fill in the Subject Eligibility Assessment eCRF and at least one Subject Eligibility Log eCRF.
3. In the Concomitant Medications folder for your subject, fill in the Concomitant Medications Assessment eCRF and at least two Concomitant Medications Log eCRFs.
4. Inactivate the second line of the Concomitant Medications Log eCRF.

LESSON 12

REPORTING ADVERSE EVENTS IN RAVE

Adverse Events in Study-Specific Training

This course provides a general introduction to reporting adverse events in Rave. Sites will receive additional training on reporting adverse events for their particular study.

Deadline for Expedited Reportable Adverse Events

Adverse events that are reportable must be submitted to Genentech within 24 hours from the time the site learned about the adverse event. Once a reportable adverse event is entered in Rave, the system will—within 24 or 48 hours (as configured per the Study Configuration Document)—automatically submit the information onto Genentech Drug Safety if it has not already been sent. This process applies to newly-entered adverse events as well as updates to the adverse event information.

This lesson covers the following topics:

- › [About Adverse Events \(see page 124\)](#)
- › [Business Process for Serious Adverse Event Reporting \(see page 125\)](#)
- › [Adverse Events Folder in Rave \(see page 125\)](#)
- › [Submit an Adverse Event \(see page 126\)](#)

About Adverse Events

Rave is the digital system of record (authoritative electronic source) for adverse events.

- › An *adverse event* is an untoward medical occurrence detected in a person who is enrolled as a subject in a clinical trial. Examples include an abnormal lab finding, unfavorable symptom, unintended condition, illness, death, and so on. The investigational treatment may or may not be the cause of the adverse event.
- › A *serious adverse event* (SAE) is an event that meets one of the following seriousness criteria: life-threatening, or results in death, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Other important medical events that do not result in one of the above outcomes may be considered serious, if, based on appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the above outcomes.
- › A *reportable adverse event* is an adverse event that needs to be reported to the sponsor *within 24 hours* from the time that the site learned of the adverse event. This does not necessarily mean that the adverse event is also reportable to a regulatory authority. Reportable adverse events typically include all SAEs and, optionally, non-serious, expedited adverse events.

Business Process for Serious Adverse Event Reporting

Business Process for Serious Adverse Event Reporting

- › The investigational site is responsible for completing and submitting the Adverse Event eCRF for a patient in Rave. The investigator site marks the serious adverse event (SAE) for submission to Genentech Drug Safety.
- › Whether the reportable adverse event is new or an update to a previously-submitted serious adverse event, the Rave-Drug Safety Integration automatically generates an SAE Report in PDF format with pre-defined patient information relevant to the SAE Report. The SAE Report pulls data from the Adverse Event eCRF as well as other eCRFs for that subject.
- › The PDF file is transferred through a secure mechanism from Rave over the Internet to Genentech.
- › The Rave-Drug Safety Integration at Genentech receives the file and electronically distributes it to Genentech Drug Safety and/or any other pre-defined recipients.
- › Genentech Drug Safety uses their existing workflow to process the report in its Adverse Reaction Tracking System (ARTS)—Genentech's drug safety system for the collection, processing and reporting of adverse events.
- › In Rave, a “permanent” sticky (note) is displayed on the adverse event eCRF showing when notifications were sent out.
- › For business continuity in the event that the Rave system is temporarily unavailable, the Genentech business process is to provide sites with a paper Serious/Expedited Adverse Event Report Form and fax cover sheet (to be used instead if the Rave system is temporarily unavailable). Once the Rave system is available again, the adverse event data must be entered into Rave.

Adverse Events Folder in Rave

The Adverse Events folder contains any Adverse Events eCRFs that have been added for a subject. The Adverse Events eCRF is a Rave log form in which each log line corresponds to one different Adverse Event raw term. Each adverse event is recorded as a separate entry in the log form.

Drug Safety Reporting Using Rave

The procedure for reporting serious adverse events is automated and well-defined. For Genentech-sponsored clinical trials using Rave, this is the only way to process SAEs.

For this training, the automated integration between the training sample study and Genentech Drug Safety is *not* enabled.

SAE Reporting Summary PDF

The SAE Reporting Summary PDF contains the adverse event data, as well as key information from the Investigator/Site, Demographics, and Vital Signs eCRFs.

Submit an Adverse Event

Study-Specific Adverse Event eCRF

The fields and instructions for your particular study likely differ from what is covered in this training. Where differences exist, be sure to comply with the Adverse Event eCRF procedures that are defined for your study.

Complete the Adverse Event eCRF

1. [View a subject \(see page 43\)](#),
2. Open the Adverse Events folder.
 - If this is the first adverse event for this subject, then Rave displays an empty Adverse Event eCRF, as shown in the following example.

The screenshot shows the Medidata Rave web application interface. The browser address bar displays "https://gentrn55.mdsol.com - Medidata Rave - Microsoft Internet Explorer". The page title is "Genentech IN BUSINESS FOR LIFE". The user is logged in as "User: User CRC1". The breadcrumb navigation shows "TRN1010g > University Medical School > 10118 UUU > Adverse Events > Adverse Events". The main content area is titled "Subject: 10118 UUU" and "Page: Adverse Events - Adverse Events". It indicates "Currently viewing line 1 of 1" and provides a link to "Click here to return to 'Complete View'". The form contains several input fields and checkboxes:

- AE Number
- Primary Adverse Event description
- Onset date
- Resolution date
- Select if event is ongoing at the time of reporting
- AE intensity
- AE suspected to be caused by study drug?
- Other Suspected Causes (select all that apply):
 - None
 - Disease Under Study
 - Concurrent Illness
 - Concomitant Medication

- If other adverse events exist for this subject, then Rave displays a list of completed Adverse Event eCRFs (as shown in the following example), in which case you must click the **Add a new Log line** link to display an empty Adverse Event eCRF.

The screenshot shows the Medidata Rave web application interface for subject 10021 TRN. The browser address bar displays "https://gentrn55.mdsol.com - Medidata Rave - Microsoft Internet Explorer". The page title is "Genentech IN BUSINESS FOR LIFE". The user is logged in as "User: User CRC1". The breadcrumb navigation shows "TRN1001g > College of Medicine > 10021 TRN > Adverse Events > Adverse Events". The main content area is titled "Subject: 10021 TRN" and "Page: Adverse Events - Adverse Events". It displays a table of completed Adverse Event eCRFs:

#	AE#	AE	ONSET DT	RES DT	ONG	GRADE	RELATED?	CAUSES	NONE	DS	ILLNESS	CONMED
1	1	ACUTE VERTIGO	15 MAR 2007	16 MAR 2007	<input type="checkbox"/>	Severe	No	-	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Below the table, there is a link "Add a new Log line Inactivate" and a "Printable Version View PDF Icon Key" link. The page footer indicates "CRF Version 472 - Page Generated: 07 May 2007 20:51:03 Greenwich Standard Time".

3. Fill in the Adverse Event form.

The following table provides instructions for fields on the Adverse Event eCRF provided in the training sample study.

Data	Description
Adverse Event Number	Read-only field. The number is automatically generated by the system and is unique across all Adverse Events for one subject.
Primary Adverse Event Description	Record one primary medical term or condition in this field. If known, a diagnosis term is preferred. A primary event is the first or foremost sign, symptom or diagnosis to which others may be secondary or occur as complications.
Onset Date	Record the full Onset Date (DD-MMM-YY) of the first signs or symptoms of the adverse event.
Resolution Date	Record the full Resolution Date (DD-MMM-YY) when the serious adverse event was resolved.
Select if event is ongoing at the time of reporting	Select (check) this option if the event is ongoing at the time of reporting.
AE Intensity	Select the adverse event intensity based on the following three-point scale: <ul style="list-style-type: none"> ➤ Mild: Transient or mild discomfort (less than 48 hours): no interference with the subject's daily activities; nonmedical intervention / therapy required. ➤ Moderate: Mild to moderate interference with the subject's daily activities; no minimal medical intervention / therapy required. ➤ Severe: Considerable interference with the subject's daily activities; medical intervention / therapy required; hospitalization possible.
AE suspected to be caused by study drug?	Select Yes only if the AE is suspected to be caused by the study drug.

Serious or Non-Serious?

The seriousness criterion define whether the event is serious or not; the seriousness criteria are stated in the protocol.

Reportable to Genentech?

The criteria that define whether an adverse event is reportable or not is defined in the study protocol.

Data	Description
Other Suspected Causes	Select all that apply: <ul style="list-style-type: none">› None—No other suspected causes of SAE can be identified.› Disease Under Study—Disease or condition for which the study drug is being studied.› Concurrent Illness—SAE caused by concurrent illness other than disease under study.› Concomitant Medication—SAE caused by concomitant medication taken other than study drug(s).
Action taken with study drug due to SAE/AE	Select one of the following: <ul style="list-style-type: none">› None› Drug Permanently Discontinued
Treatment for AE	Select all that apply: <ul style="list-style-type: none">› None—No treatment given for the SAE.› Medication—The event required treatment with medication(s).› Procedure/Surgery—The event was treated with a particular procedure and/or surgery.› Subject Discontinued from Study—The event resulted in subject being discontinued from study.

4. Click the appropriate radio button to specify whether this adverse event is non-serious or serious.
5. Click the appropriate radio button to specify whether this adverse event qualifies for expedited reporting to the sponsor as per the protocol.

Clicking **Yes** means that the information in the Adverse Event eCRF will be sent via the Adverse Event Report to the sponsor. After a transmission of the report has been sent to the sponsor, Rave will select **Yes** for the **AE Report has been sent to the Sponsor** field.

6. Complete the following fields only if the AE is serious or is a non-serious expedited adverse event as defined in the protocol.

Data	Description
Dose of last study drug administered	Specify the dose of the most recently-administered study drug.
Date of most recent dose of study drug prior to AE onset	Enter the date of the most recent dose of the study drug prior to the AE onset.
Route of study administration for study drug	Specify the study administration route.
Frequency of study drug	Specify the study drug frequency.
Lot number of study drug	Specify the lot number of the study drug.
Additional case details and/or reason for downgrade	Specify additional information about the case and/or the reason for downgrade.
List all relevant diagnostic tests and results. If no relevant diagnostic tests were performed, indicate None.	Specify all relevant diagnostic tests and results, or None (if appropriate).

7. Complete the following fields only if the adverse event is a serious adverse event as defined in the protocol. Check the check box next to the applicable fields.

Data	Description
It resulted in death	Select (check) this check box if the adverse event resulted in the death of the subject. If selected, complete the following fields: <ul style="list-style-type: none"> ➤ Date of death ➤ Autopsy performed? Select Yes, No, or Unknown.
It was life-threatening	Select (check) this check box if the adverse event was life-threatening.
It required or prolonged inpatient hospitalization	Select (check) this check box if the adverse event required or prolonged inpatient hospitalization. If selected, specify the admission date.

Drug Safety Not Notified in Class

In the training sample study, the integration between Rave and Drug Safety is not hooked up. Therefore, Rave will not send anything you enter in this class to Drug Safety.

Data	Description
It was disabling	Select (check) this check box if the adverse event was disabling.
It is a congenital anomaly/ birth defect in offspring of study subject	Select (check) this check box if the adverse event was a congenital anomaly/birth defect in an offspring of the subject.
It does not meet any of the above serious criteria, but may jeopardize the subject	Select (check) this check box if the adverse event does not meet any of the above criteria but may jeopardize the subject

- If this is a reportable adverse event, Rave asks you whether the Adverse Event is ready to be submitted to Genentech. What happens next depends on the answer you provide.
 - If you answer **Yes**, the Rave-Drug Safety Integration automatically generates the SAE Report PDF and sends it securely to Genentech for processing.
 - If you answer **No**, Rave does not immediately submit the Adverse Event to Genentech Drug Safety.



IMPORTANT! Even if you answer **No**, if a reportable adverse event has not been submitted within 24 or 48 hours of being entered into the system (depending on how the study is configured), then Rave automatically submits it to Genentech Drug in its current state.

- Click **Save** to submit your changes.

Rave displays the completed form as a log line in the Adverse Events folder.

Each time an SAE Report PDF is sent to Genentech (either initially or after the Adverse Event eCRF is updated), Rave displays an informative, read-only, permanent sticky note in the **AE Report has been sent to the Sponsor** field, as shown in the following example:



The SAE Reporting Summary PDF provides the following information about the SAE: SAE number, study number, report date, investigator and reporter details, patient details,

suspect (medication) details, AE details, seriousness criteria, intensity, causality and other suspected causes, treatment, diagnostic tests, and other information.

Initial Report for Adverse Event # 2
AE: HEADACHES
Subject:
Form: SAE Reporting Summary

SAE Number

Study Number

Date SAE Report Generated

Investigator and Reporter Information:

Site Number

Site Name

Country

Investigator Name

Investigator Number

Investigator Phone Number

Investigator Fax Number

Investigator e-mail address

Reporter Name

Reporter Title/Role

Reporter Phone Number

Reporter Fax

Reporter E-mail

Patient Information

Subject Initials

Subject Number

Date of Birth

Age



IMPORTANT! Adverse event data needs to be *inactivated* rather than deleted or blanked out (see [“Inactivate a Log Line” on page 122](#)). If you inactivate a log line, Rave appropriately generates and sends a PDF update to Drug Safety. If instead the data in the Adverse Event eCRF is deleted, Rave still generates and sends a PDF update to Drug Safety, but the Site Coordinator will receive a query to re-enter the data and then inactivate the eCRF.

Hands-On Exercise

1. Go to the Adverse Events folder for your subject.
2. Submit a serious, reportable adverse event for this subject.

LESSON 13

USING QUERIES

This lesson covers the following topics:

- › [About Queries \(see page 132\)](#)
- › [Respond to Queries \(see page 136\)](#)
- › [Open Manual Queries \(see page 138\)](#)
- › [Cancel Manual Queries \(see page 141\)](#)
- › [Handle the Query Response \(see page 143\)](#)

About Queries

As mentioned in [“Introducing Queries” on page 67](#), a *query* is a question about a data field on an eCRF. A query is a “flag” to which others need to pay attention. Queries come from two primary sources:

- › *System-generated queries* are generated automatically by the Rave software, such as a data point that fails an edit check.
- › *Manual queries* are created explicitly by a Rave user who is authorized to do so.

When a query is added to an eCRF, its existence is reflected in the Task Summary. A query requires an explicit response from one member of the group to which the query was directed (usually, the Site group, which consists of users associated with the CRC or PI role). All activities associated with a query—open, response, cancel, close, re-query—are recorded in the audit trail for that data point.

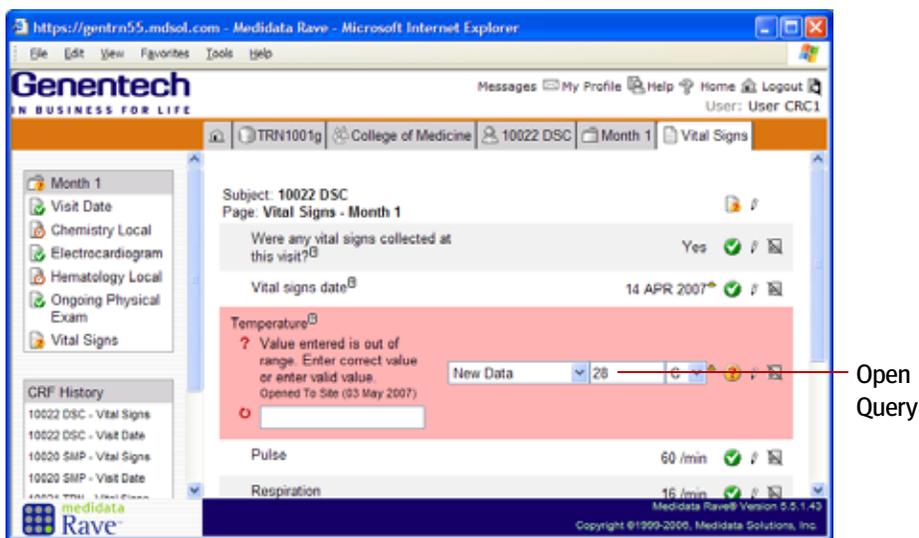


IMPORTANT! A subject cannot be signed off until any associated open queries are closed (see [“Signing off Data” on page 169](#)). Similarly, the data in a study cannot be frozen or locked until all open queries are closed (see [“Freezing Data” on page 164](#)).

System-generated Queries

Rave generates a query automatically when a data point in an eCRF triggers the query process. The system-generated query process can be triggered, for example, when a data point fails an edit check (see [“Edit Checks” on page 102](#)), such as a value that is out of range, a required field that is left blank, a future date, non-conformant data, and so on. After you submit data, when edit checks determine that the data is not valid, you get one or more system-generated queries, as shown in the following figure (where the entered Temperature value is out of range).

In the following example, the system-generated query pointing to the Temperature field on the Vital Signs eCRF shows that the data point is out of range (the data falls outside the pre-configured range of minimum and maximum values for this field).



The system-generated query process could also be triggered because the data fails some other pre-configured business rule associated with that data point, such as a visit date that precedes—or a consent date that follows—the enrollment date for a subject, a “pregnant” male subject, and so on.

Similarly, a system-generated query could result from the omission of the correct raw term—or the use of an incorrect raw term—in a coded field such as a symptom description field (see [“Thesaurus Management System \(TMS\) Integration” on](#)

page 13), as shown in the following figure. Depending on the specific issue, however, a manual query might be created instead to flag this problem.

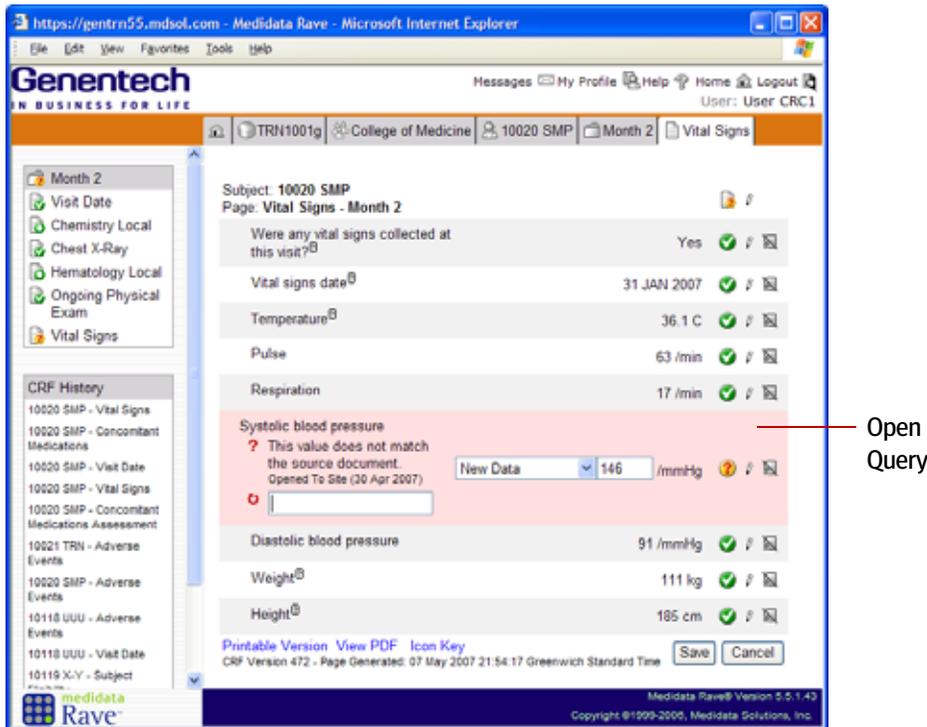
Business Process for System-Generated Queries

If Rave generates a query automatically due to a data anomaly:

- The site reviews the query and then updates the data and/or responds to the query (if the query provided a response box).
 - If a manual review is required, the Project Data Manager reviews the site response to determine whether the response is sufficient.
 - If the response is sufficient, the Project Data Manager closes the query.
 - If the response is insufficient, the Project Data Manager opens a manual query.
- For details, see [“Open Manual Queries” on page 138](#).

Manual Queries

Manual queries are created by Genentech personnel in response to a perceived anomaly in a data point. For example, during Source Document Verification (SDV), the Clinical Site Manager (CRA role) might identify a discrepancy between the source document and the Rave data for a given data point, as shown in the following example.



The screenshot shows the Genentech Rave interface in a Microsoft Internet Explorer browser window. The page title is "Vital Signs - Month 2" for subject "10020 SMP". The interface displays a list of vital signs with their values and status. The "Systolic blood pressure" entry is highlighted in red and has a yellow warning icon. A red arrow points to this entry with the text "Open Query". The entry shows a value of "146 /mmHg" and a message: "? This value does not match the source document. Opened To Site (30 Apr 2007)". Below the message is a "New Data" dropdown menu and an input field. Other vital signs listed include Diastolic blood pressure (91 /mmHg), Weight (111 kg), and Height (185 cm).

Upon creating a query for a given data point on an eCRF, the user sends it to other users (a distribution list, or *group*)—usually the Site group—for their attention and response. Only one member of the target group needs to respond.

Groups for Queries

Genentech has defined the following groups for queries:

- › Site—Site Coordinators (CRC)
- › DM—Project Data Manager (DM)
- › Clin Ops—Clinical Operations
- › SDM—Safety Manager (SDM)
- › Genentech (Clin Ops + SDM)

Queries for Sites

Queries are always opened by Genentech personnel and directed to sites. Sticky notes—not queries—are used in communications among Genentech personnel.

Business Process for Manual Queries

If a data point on an eCRF has a perceived data anomaly:

- › A Clinical Site Manager (CRA role) or Project Data Manager (DM role) determines whether the data point is frozen and, if so, unfreezes the data. For details, see [“Unfreeze Data” on page 166](#).
- › A Clinical Site Manager (CRA role), Project Data Manager (DM role), Lab Data Manager (LDM role), or Coding Specialist (SDM role) opens and submits the query to the appropriate target group (such as the Site group). For details, see [“Open Manual Queries” on page 138](#).
- › The site reviews the query and then updates the data and/or responds to the query.

Business Process for Manual Queries (Continued)

- › The appropriate Genentech user (Clinical Site Manager, Project Data Manager, Lab Data Manager, or Coding Specialist) reviews the site response to determine whether the response is sufficient.
- › If the response is sufficient, then the appropriate Genentech user closes the query. For details, see [“Close a manual query” on page 143](#).
- › If the response is insufficient, then the appropriate Genentech user resends the query, For details, see [“Re-query a manual query” on page 143](#).

Respond to Queries

Queries require timely responses. Only one member of the target group needs to respond to the query. The target group is typically Site Coordinators (CRC role) or Primary Investigators (PI role). If you see a query on your screen, then you should answer it.

The response you provide depends on the nature of the query.

- › If the query asks for modifications to a data entry field, then you need to make the requested modifications.
- › If the query asks a question, then you need to provide a response—by typing text in the text box, or by selecting the response from a drop-down list, as appropriate.

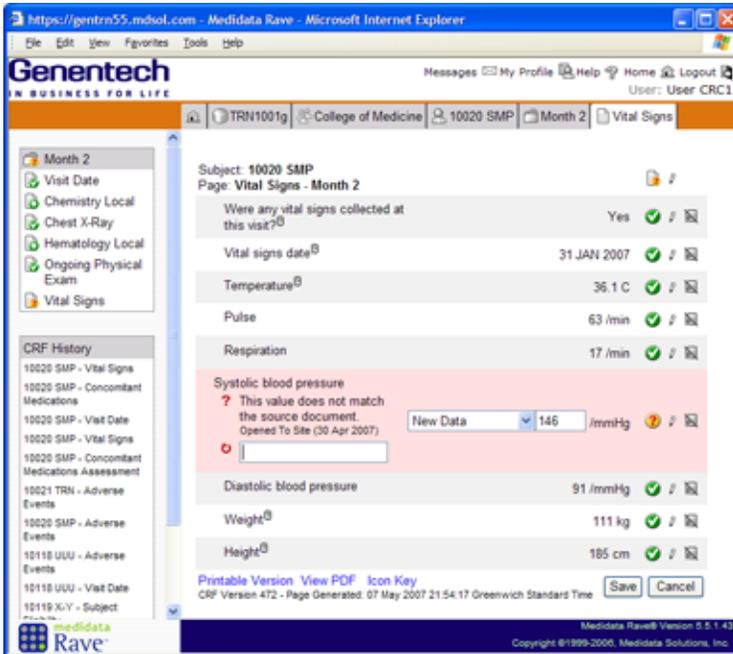
Rave handles responses according to the type and nature of the query:

- › System-generated queries remain open until all data is corrected and/or a satisfactory response is provided (if a response is required). If you correct a system-generated query, then Rave closes the query automatically.
- › If you respond to a manual query, then Rave forwards the response to the appropriate person (such as the initiator of the query)—a Clinical Site Manager (CRA role) or Data Manager (CRA role)—who will review the response and determine the next course of action. At this point, there is nothing more you need to do for that query, although you might see a follow-up query if additional action is required.

Respond to a query

1. Open the eCRF with which the query is associated, either by navigating via the Task Summary or by selecting the appropriate subject, folder, and eCRF.

The following figure shows an example query on an eCRF.



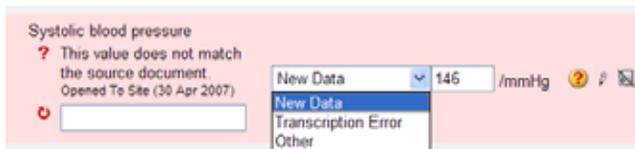
The data entry field is open for editing.

2. If prompted, type a response in the text box.



Type Your Query Response Here

3. Select a reason for the change.



4. Make the requested change(s) to the data point.
5. Click **Save** to save your changes.

Leader Note

For site trainings, demonstrate how to open a manual query.

Avoid Redundant Queries

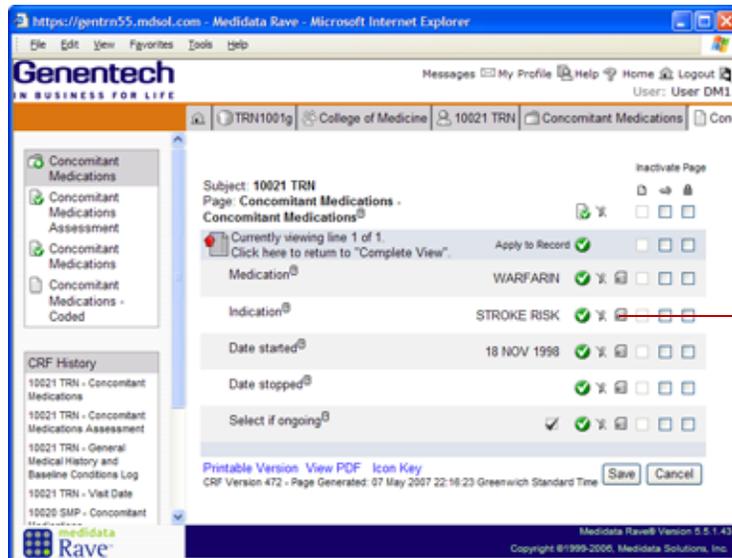
If a system-generated query already exists for an issue, a manual query should not be opened on that same issue. For example, if TMS integration generated a system query in response to an incorrect or missing term in a field, the Clinical Site Manager should not open a redundant manual query enquiring about the same problem.

Open Manual Queries

A Clinical Site Manager (CRA role), Project Data Manager (DM role), Lab Data Manager (LDM role), or Coding Specialist (SDM role) can open a manual query.

Create a manual query on an eCRF

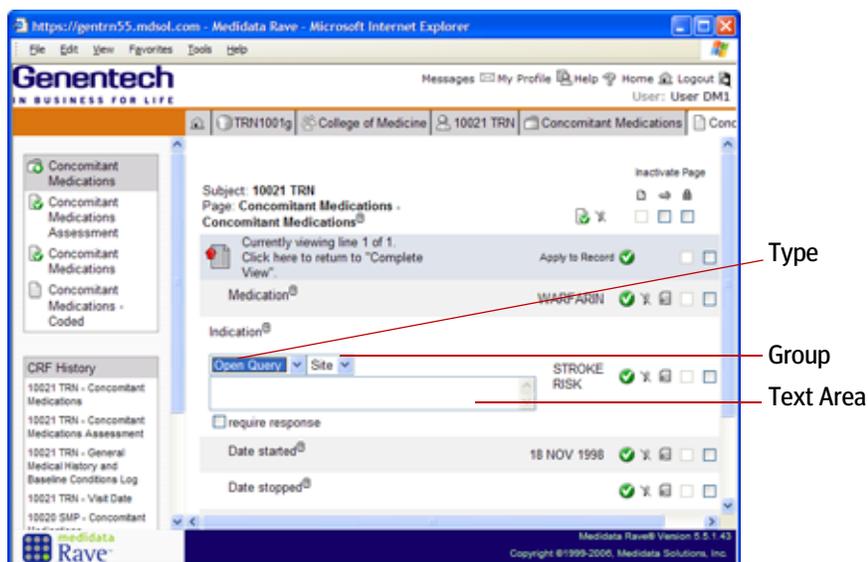
1. Log in with a Rave user account that has the appropriate privileges (CRA, DM, LDM, or SDM role).
2. [Select a study \(see page 37\).](#)
3. [View a site \(see page 39\).](#)
4. [View a subject \(see page 43\).](#)
5. Display the eCRF to which you want to add a manual query, as you learned in [“Viewing eCRFs Associated with a Subject” on page 53.](#)



Comments Icon

6. Click the Comments (□) icon next to the data point to which you want to add the query.

Rave displays the Comments data entry pane.



7. In the **Type** drop-down list, choose `Open Query`.
8. In the **Group** drop-down list, choose the group to which you want to direct this query (usually `site`).
9. In the text area, type the question for the query (up to 1799 characters).

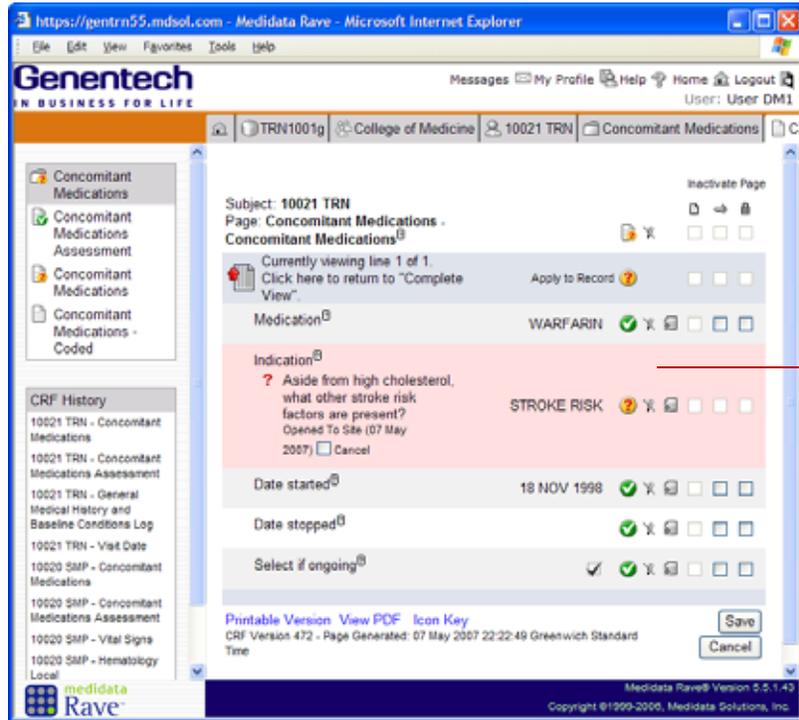
For suggestions on how to write an effective query, see [“Best Practices for Writing Queries” on page 141](#).

10. Check the **Require Response** check box if you want to require a response to your query (typically, `yes`).
If you select this check box, then you are requiring users to provide an explanation when they edit data in a field associated with this query. If a query response is required, then Rave prompts the user with a text box into which they must type a comment about the data change.
11. Click **Save** to save your changes.

Query Responses

Query responses are not extracted as part of the data set. Responses are only visible on the eCRF in Rave.

The query appears on both the your screen and on the screen of any user who belongs to the target group to which this query was directed.



Best Practices for Writing Queries

When writing queries, consider the following suggestions:

- › Write query questions that are clear, succinct, explicit, and courteous (“Please provide...”).
- › Refer to items on the eCRF page using the same wording that appears on the eCRF.
- › Abbreviate only when necessary to save space. Use unambiguous abbreviations.
- › Ask for a resolution by providing guidance without telling the site exactly what to change.
- › Direct the site to provide enough information on the correction/clarification form to clearly describe the change(s) that is (are) needed to resolve the problem. Do not use language that refers to changing the eCRF page itself.
- › Use “subject” and not “patient.”
- › Do not enclose questions in quotation marks.
- › Ask for missing information directly instead of stating that a field is blank or missing. If a blank field depends on the answer to another question, let the site decide whether or not the information will be provided. In this case, you will need to state that the field is missing.
- › If the field in question has a finite list of answers (for example, YES/NO/UNKNOWN), indicate that the answer should be provided “from the choices given on the eCRF page.” It is not necessary to provide the acceptable answers in the message.
- › Write dates in DD-MON-YYYY format.
- › When possible, use descriptive words instead of symbols or mathematical comparisons. For example:
 - › Use IS or MATCHES instead of “=” or “equal to”
 - › Use BEFORE instead of “<” or “less than”
 - › Use AFTER instead of “>” or “greater than”
 - › Use DOES NOT MATCH instead of “<>” or “is not equal to”

Cancel Manual Queries

A Clinical Site Manager (CRA role), Project Data Manager (DM role), Lab Data Manager (LDM role), or Coding Specialist (SDM role) can cancel a manual query. You might want to cancel a manual query to retract it for any reason—for example, a manual query that was entered in error.

Group-specific Best Practices

Your group might have its own writing best practices for the types of manual queries with which your group works.

Canceling Another’s Query

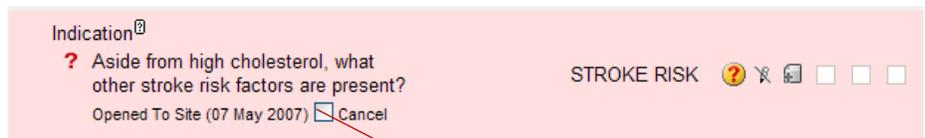
Only the Project Data Manager (DM role) can cancel another user’s query.

You can cancel a query that is no longer applicable as long as:

- you have sufficient permissions to cancel it
- the query does not require a response, or
- if the query requires a response but no response has yet been given

Cancel a manual query

1. Log in with a Rave user account that has the appropriate privileges (CRA, DM, LDM, or SDM role).
2. Open the eCRF with which the query is associated.
3. Check the **Cancel** check box.



The screenshot shows a query card with a light pink background. The text on the card includes: 'Indication ⓘ', a red question mark icon followed by the text 'Aside from high cholesterol, what other stroke risk factors are present?', the text 'STROKE RISK' followed by a yellow question mark icon, a magnifying glass icon, and three empty square checkboxes. At the bottom left of the card, it says 'Opened To Site (07 May 2007)' followed by a checkbox and the word 'Cancel'. A red arrow points from the text 'Cancel Check Box' to this checkbox.

Cancel Check Box

4. Click **Save** to cancel the query.

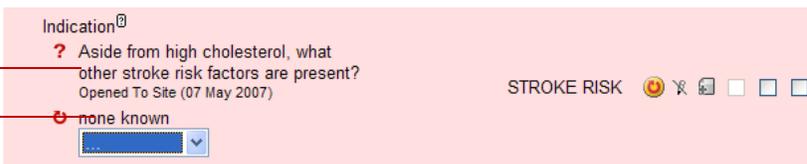
Rave removes the query from the eCRF.

Handle the Query Response

A Clinical Site Manager (CRA role), Project Data Manager (DM role), Lab Data Manager (LDM role), or Coding Specialist (SDM role) can close or re-query a manual query. Query originators are responsible for closing their own queries.

H Tip! Use the Task Summary to quickly navigate to Answered Queries.

If a member of the target group has responded to a query, then you will see the response when you open the eCRF associated with the query, as shown in the following example:



Query — Indication^Q ? Aside from high cholesterol, what other stroke risk factors are present?
Opened To Site (07 May 2007) STROKE RISK 🟡 🗑️ 📄 📅 📁

Response — none known

At this point, you need to review the response and determine whether to close the query (the response is satisfactory) or to re-query the site (following up with an additional request).



Action — Indication^Q ? Aside from high cholesterol, what other stroke risk factors are present?
Opened To Site (07 May 2007) STROKE RISK 🟡 🗑️ 📄 📅 📁

none known

Date Close Query
Re-Query

10 NOV 1998 ✅ 🗑️ 📄 📅 📁

Close a manual query

1. Click the query drop-down list and select `Close Query`.
2. Click **Save** to save your changes.

The query is no longer displayed. However, the Rave records the query closure in the audit trail. A log is also displayed on screen, as shown in the following example.



Details^Q ? Diabetes I or II?
Opened To Site (07 May 2007) DIABETES TYPE II ✅ 🗑️ 📄 📅 📁

Diabetes Type II

Re-query a manual query

1. Click the query drop-down list and select `Re-Query`.
2. Fill in the query text box as described in [“Open Manual Queries” on page 138](#).
3. Check the **Require Response** check box if you require a response.
4. Click **Save** to save your changes.

Closing Your Own Queries

If you initiated a query, then you will need to handle the response to it.

Hands-On Exercise

1. Log in with the user account associated with the CRC role.
2. Edit the Visit Date eCRF in the Month 1 folder, change the value of the Visit Date field to a future date, and click **Save**. Fix the system-generated query.
3. Edit the Vital Signs eCRF in the Month 1 folder. Enter data that is incorrect: out-of-range temperature and non-conformant data in other fields, and click **Save**. Fix all of the system-generated queries. Finally, review the audit trail for these data points.
4. Log out.
5. Log in with the user account associated with the CRA role.
6. Go to an eCRF for your subject.
7. Create a new query and direct it to the Site group.
8. Verify that the query appears on the eCRF and also in the Task Summary.
9. Cancel this query.
10. Go to an eCRF for your subject.
11. Create a new query, require a response, and direct it to the Site group.
12. Verify that the query appeared on the eCRF and also in the Task Summary.
13. Log out.
14. Log in with the user account associated with the CRC role.
15. Respond to the query you just created.
16. Log out.
17. Log in with the user account associated with the CRA role.
18. Go to the query you just responded to, and then close the query.
19. Look at the audit trail for this data point to see how the history of the query was tracked.

LESSON 14

USING STICKY NOTES

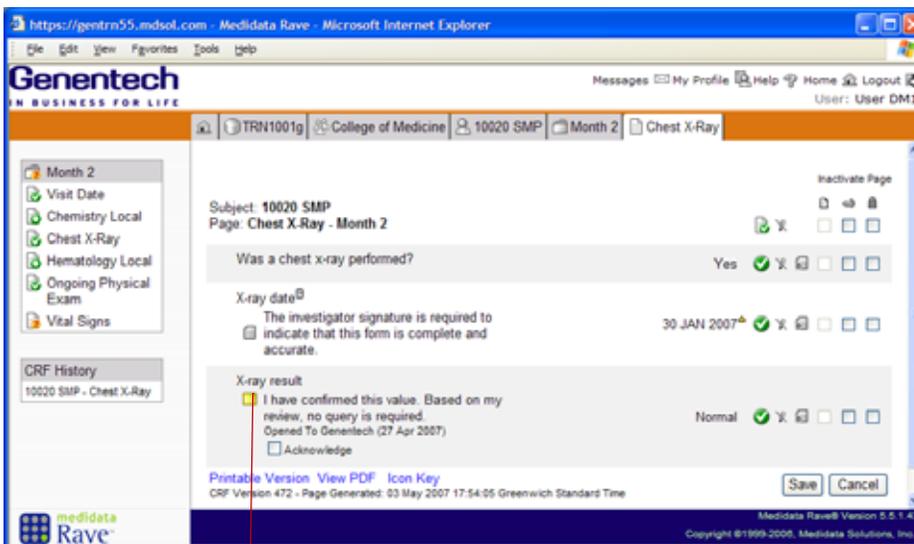
This lesson covers the following topics:

- › [About Sticky Notes \(see page 145\)](#)
- › [Acknowledge a Sticky Note \(see page 146\)](#)
- › [Add a Sticky Note \(see page 147\)](#)

About Sticky Notes

As mentioned in [“Introducing Sticky Notes” on page 69](#), a *sticky note* is an informal note, remark, or observation that is associated with a data point on an eCRF. A sticky note is a “flag” to which others need to pay attention.

The following figure shows an example sticky note.



Sticky Note

Clinical Site Managers (CRA role) and Project Data Managers (DM role) can create a sticky note and direct it to other Genentech users (a distribution list, or *group*) for their attention and acknowledgment. Only one member of the target group needs to acknowledge the sticky note. When a sticky note is added to an eCRF, its existence is reflected in the Task Summary.

Sticky notes are used for the following purposes:

- › Enable reminders and informal communications among Genentech users. One user creates the sticky note, while another (a member of the group to which it was directed) acknowledges having read it. For example, a Project Data Manager might notice something peculiar in a data point on an eCRF, and then send a

Groups for Sticky Notes

Genentech has defined the following groups for sticky notes:

- › DM—Project Data Manager (DM)
- › Clin Ops—Clinical Operations
- › SDM—Safety Manager (SDM)
- › Genentech (Clin Ops + SDM)

More Examples

For more examples of sticky notes, see [“Introducing Sticky Notes” on page 69](#).

sticky note to the Clinical Site Manager or Safety Manager asking them to review the data point and return an acknowledgment.

- For reportable Adverse Events (see [“Reporting Adverse Events in Rave” on page 124](#)), every time an Adverse Event eCRF is submitted to Genentech, sticky notes are automatically added to it, displaying when notifications were sent to Genentech. These sticky notes are “permanent” in that users never acknowledge them (and, therefore, they never disappear). Their function is to act as an at-a-glance notifications log. The following figure shows an example of this kind of sticky note.



- Used with Local Labs (see [“Submit Local Lab Forms” on page 114](#)) to trigger the ability to add comments. These sticky notes are “permanent” in that users are not allowed to acknowledge them and they remain visible even after the comment has been entered.

Users who have access to a sticky note will be able to view it in the Task Summary or on the eCRF. Activities associated with sticky notes—creating and acknowledging them—are recorded in the Audit Trail associated with the data point.

Acknowledge a Sticky Note

Except for automatic sticky notes associated with Adverse Events and Local Labs, sticky notes require acknowledgment. Only one member of the target group needs to acknowledge the sticky note to close it.

- **Note:** If you see a sticky note in your Task Summary or on an eCRF page, then you are a member of the target group and are therefore authorized to read and acknowledge it.

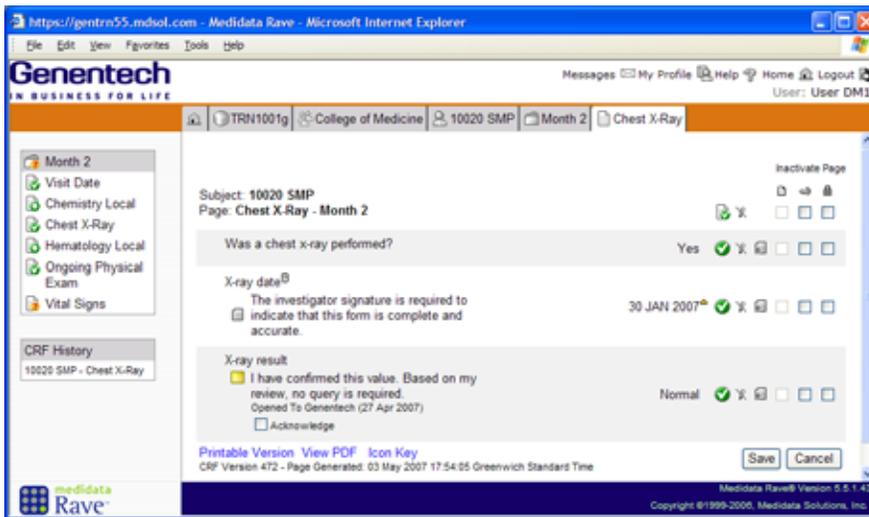
Acknowledge a sticky note

1. Log in with a Rave user account that has access to sticky notes.
2. Find the eCRF with which the sticky note is associated.

Finding Sticky Notes Quickly

You can quickly find open sticky notes via the Task Summary by clicking the Pop-Up (☒) icon next to the Sticky Notes category, then clicking the eCRF on which the sticky note appears.

Rave displays the eCRF page for the eCRF and the associated sticky note, as shown in the following example.



3. Read the text of the sticky note, take any appropriate action as needed, and then click (check) the **Acknowledge** check box when finished.
4. Click **Save**.

Rave removes the sticky note from the eCRF and the Task Summary, and records the acknowledgement in the audit trail.

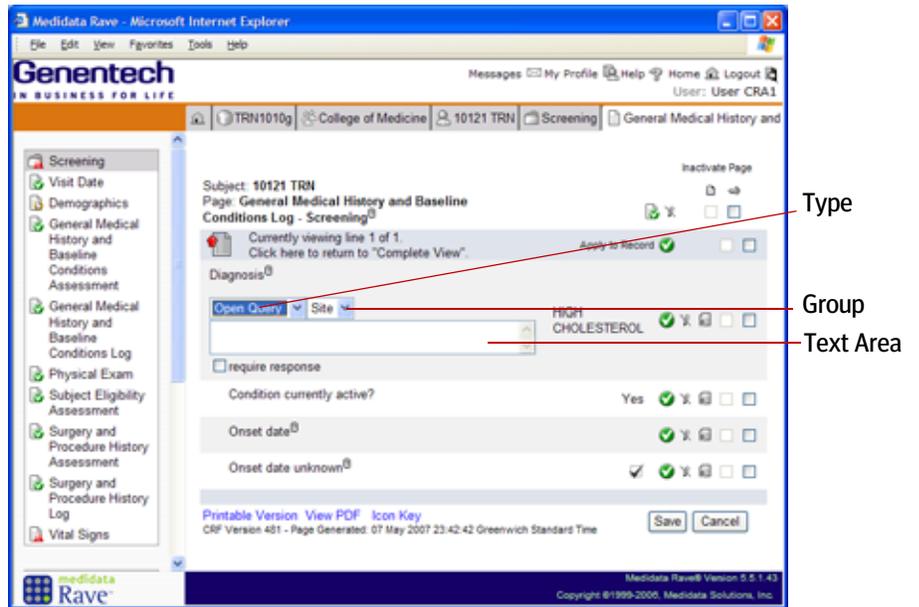
Add a Sticky Note

Clinical Site Managers (CRA role), Data Managers (DM role), and Clinical Trial Managers (CTM role) are authorized to add a sticky note to a data point on a subject's eCRF.

Add a sticky note to an eCRF

1. Log in with a Rave user account that has the appropriate privileges (CRA, DM, or CTM role).
2. View the eCRF to which you want to add a sticky note.
3. Click the Comments (☐) icon next to the data point to which you want to add a sticky note.

Rave displays the Comments data entry pane.



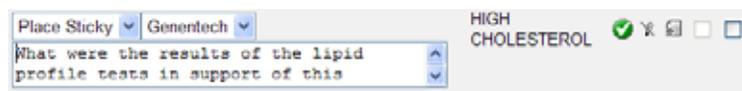
4. In the Type drop-down list, select **Place Sticky**.



5. In the Group drop-down list, select the group to which you want to direct this sticky note.



6. In the text area, type the comment for the sticky note (up to 600 characters).



7. Click **Save** to save your changes.

The sticky note appears on both the your screen and on the screen of any user who belongs to the target group to which this sticky note was directed.



Hands-On Exercise

1. Log in using an account associated with the DM role.
2. Go to your subject.
3. Go to any eCRF and add a sticky note. Direct it to the Genentech group.
4. Log out.
5. Log in using an account associated with the CRA role.
6. Go look at the eCRF on which you added the sticky note.
7. Acknowledge the sticky note that you created.
8. Look at the audit trail for this data point to see how the history of the sticky note was tracked.

LESSON 15

INACTIVATING eCRFs

This lesson covers the following topics:

- › [Inactivate eCRFs and Folders \(see page 150\)](#)
- › [Subject Administration \(see page 151\)](#)
- › [Inactivate and Activate Folders \(see page 152\)](#)
- › [Inactivate and Activate eCRFs \(see page 153\)](#)
- › [Add Forms and Folders \(see page 156\)](#)

Inactivate eCRFs and Folders

Authorized users can inactivate eCRFs or entire folders for a subject if, for example, the subject's participation in the clinical trial were discontinued early, or if an eCRF were entered in error. For example, if a subject terminated after Month 1, then all empty or incomplete eCRFs for subsequent folders/visits can be inactivated—that way, overdue flags will not appear for these eCRFs. Except for the Subject Identification form and lines in log form eCRFs (see [“Inactivate a Log Line” on page 122](#), only the Clinical Site Manager (CRA role) or Project Data Manager (DM role) can inactivate an eCRF or a folder. Site Coordinators (CRC role) can inactivate line a log line in a log form eCRF.



IMPORTANT! If a subject has terminated early, any incomplete eCRFs associated with the subject must be inactivated before the study data can be locked.

An inactive eCRF cannot be edited. Any data for an inactivated eCRF are excluded from reports, data export, and so on.

Leader Note

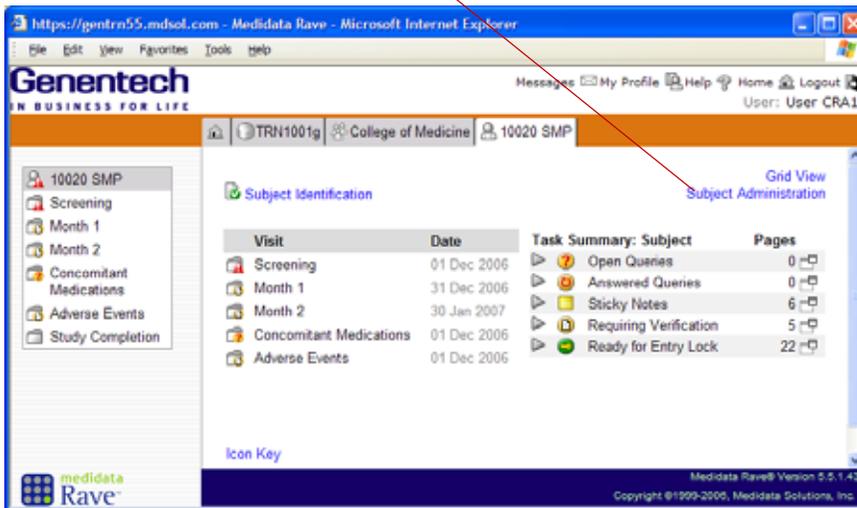
Depending on the needs of the attendees, determine whether to teach this as an instructor demo or a hands-on lesson.

Subject Administration

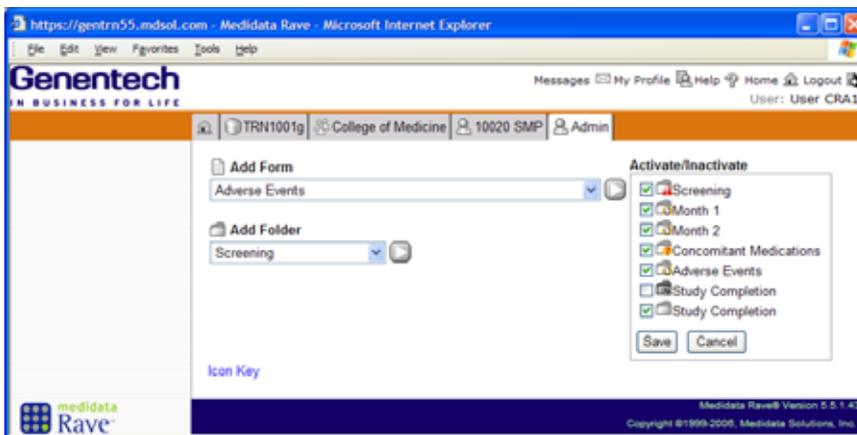
Navigate to the Subject Administration page

1. Log in with a Rave user account associated with the CRA or DM role.
2. [Select a study \(see page 37\).](#)
3. [View a site \(see page 39\).](#)
4. [View a subject \(see page 43\).](#)
5. On the Subject page, click the **Subject Administration** link.

Subject Administration Link



Rave displays the Subject Administration page, as shown in the following example.



Inactivate and Activate Folders

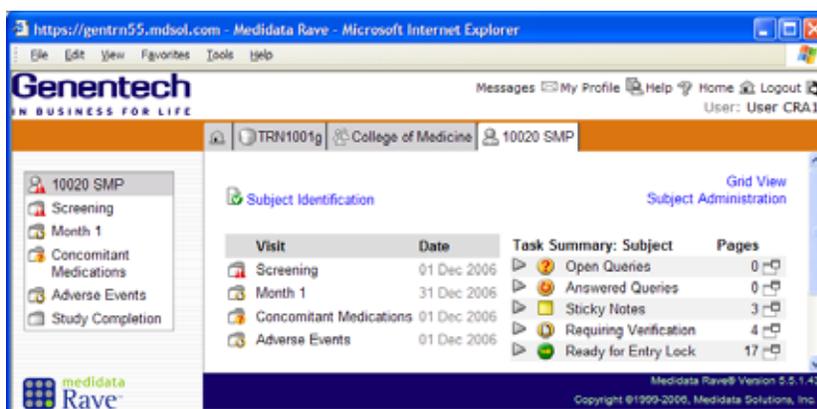
Inactivate a Folder

1. [Navigate to the Subject Administration page \(see page 151\)](#) for a subject.
2. Click the folder that contains the eCRF(s) that you want to inactivate.
3. On the Subject Administration page, uncheck (clear) the check box next to any active folder(s) that you want to inactivate.
4. Click **Save**.

Rave removes the inactivated folder(s) from the Subject page.

5. Click the Subject tab.

In the following example, the inactivated Month 2 folder no longer appears in the Task List or Subject Schedule.

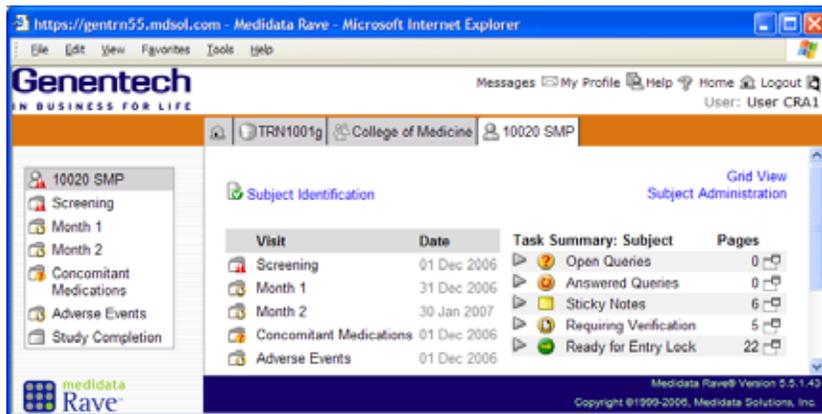


Rave maintains a record of when an folder is inactivated in the Audit Log.

Activate an inactive Folder

1. [Navigate to the Subject Administration page \(see page 151\)](#) for a subject.
2. On the Subject Administration page, check (select) the check box next to any inactive folder(s) that you want to activate.
3. Click **Save**.

The activated folder(s) are displayed on the Subject page. In the following example, the activated Month 2 folder appears again in the Task List and in the Subject Schedule.



Rave records in the Audit Log when a folder is activated.

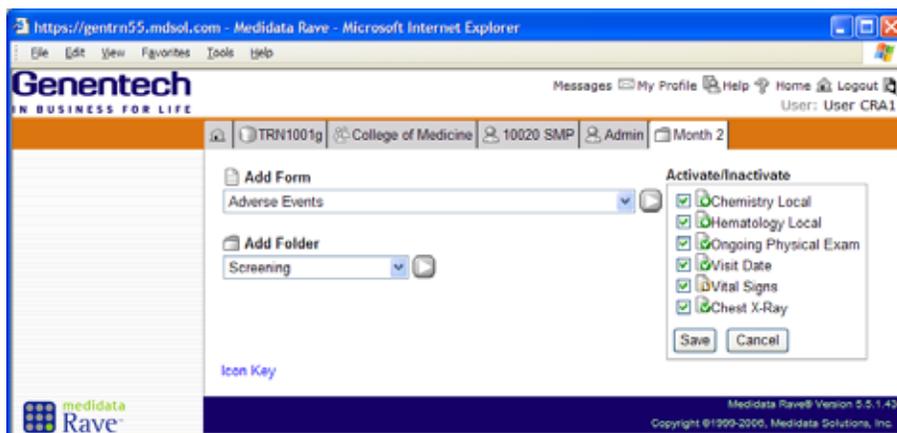
Inactivate and Activate eCRFs

As described in [“Inactivate eCRFs and Folders” on page 150](#), only the Clinical Site Manager (CRA role) or Project Data Manager (DM role) can inactivate an eCRF so that it cannot be edited. If a Site Coordinator (CRC role) inactivates a line in a log eCRF, they cannot subsequently reactivate it—they must add a new line instead.

Inactivate an eCRF from the Subject Administration page

1. [Navigate to the Subject Administration page \(see page 151\)](#) for a subject.
2. On the Subject Administration page, click the folder that contains the eCRF(s) that you want to inactivate.

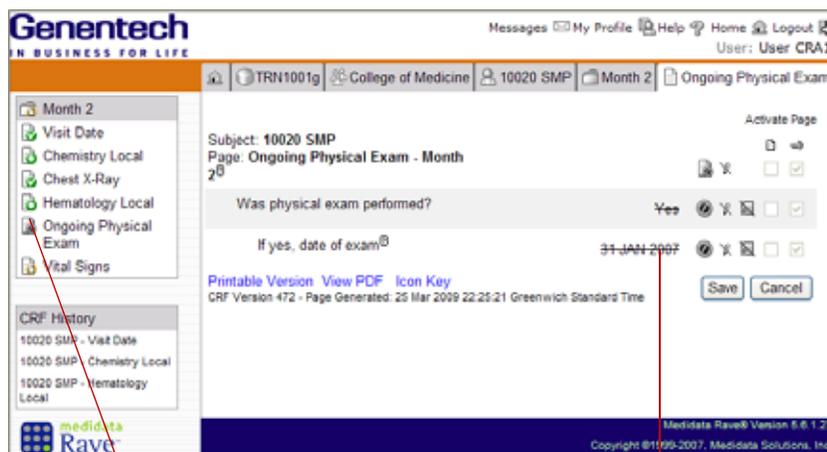
Rave displays a list of eCRFs in the selected folder (Month 2, in the following example).



3. Uncheck (clear) the check box next to any active eCRF(s) that you want to inactivate.
4. Click **Save**.
5. Go to the folder containing the inactivated eCRF(s).

6. Open one of the inactivated eCRFs.

Rave flags the inactivated eCRF(s) as inactive with an icon and strike-through text.



Inactivated icon

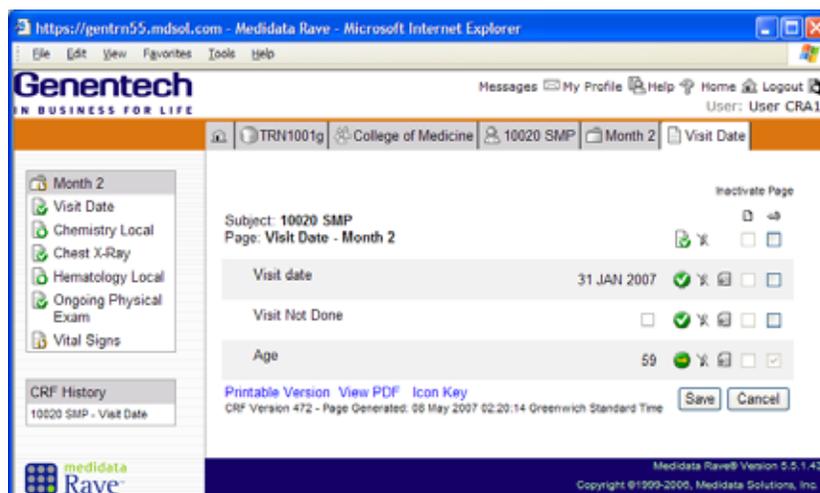
Strike-through text

Rave maintains a record in the Audit Log of when an eCRF is inactivated.

Activate an inactive eCRF from the Subject Administration page

1. [Navigate to the Subject Administration page \(see page 151\)](#) for a subject.
2. On the Subject Administration page, click the folder that contains the inactive eCRF(s) that you want to activate.
3. Check (select) the check box next to any inactive eCRF(s) that you want to activate.
4. Click **Save**.

The icon changes and the strikethrough text is removed for the activated eCRF(s) on the Folder page. In the following example, the activated Physical Exam eCRF appears as normal in the Month 2 folder.



Rave records in the Audit Log when an eCRF is activated.

Inactivate an eCRF on the eCRF page

1. Log in with a Rave user account associated with the CRA or DM role.
2. [Select a study \(see page 37\)](#), if applicable.
3. [View a site \(see page 39\)](#), if applicable.
4. [View a subject \(see page 43\)](#).
5. Open the eCRF (see [“View eCRFs” on page 58](#)) that you want to inactivate.

Inactivate
Page link

The screenshot shows the Rave eCRF interface for a subject named '10020 SMP' on the 'Vital Signs - Month 2' page. The breadcrumb trail at the top reads: 'TRN1010g > College of Medicine > 10020 SMP > Month 2 > Vital Signs'. On the right side of the page, there is an 'Inactivate Page' link. Below the breadcrumb trail, the page content includes a table of vital signs data and a footer with 'Printable Version', 'View PDF', 'Icon Key', and 'Save'/'Cancel' buttons.

Field	Value	Actions
Were any vital signs collected at this visit?	Yes	🔍 🗑️ 🔄 📄
Vital signs date	31 JAN 2007	🔍 🗑️ 🔄 📄
Temperature	36.1 C	🔍 🗑️ 🔄 📄
Pulse	63 /min	🔍 🗑️ 🔄 📄
Respiration	17 /min	🔍 🗑️ 🔄 📄
Systolic blood pressure	146 /mmHg	🔍 🗑️ 🔄 📄
Diastolic blood pressure	91 /mmHg	🔍 🗑️ 🔄 📄
Weight	111 kg	🔍 🗑️ 🔄 📄
Height	185 cm	🔍 🗑️ 🔄 📄

6. At the top of the page, click the **Inactivate Page** link.

Rave prompts you to confirm inactivation.

Confirm

7. Click the Confirm checkbox.
8. Click **Save**.

Rave displays the inactivated eCRF with strikethrough text.

The screenshot shows the Genentech Rave interface. The sidebar on the left contains a list of folders under 'Month 2', including 'Visit Date', 'Chemistry Local', 'Chest X-Ray', 'Hematology Local', 'Ongoing Physical Exam', and 'Vital Signs'. The 'Vital Signs' folder is selected. Below this is a 'CRF History' section with several entries. The main area displays data for 'Subject: 10020 SMP' and 'Page: Vital Signs - Month 2'. It includes a table of vital signs with columns for the parameter, value, and an 'Activate Page' column. The 'Respiration' row is highlighted in red and has a red line pointing to it from the 'Strike-through text' label. The 'Activate Page' column contains icons for each row, with the 'Respiration' icon being greyed out. The footer contains 'Printable Version View PDF Icon Key', 'CRF Version 451 - Page Generated: 26 Mar 2009 17:29:32 Greenwich Standard Time', and 'Medidata Rave® Version 5.5.1.27 Copyright ©1999-2007, Medidata Solutions, Inc.'

Inactive icon

Strike-through text

- Note:** If you inactivate a log eCRF, all log lines are inactivated. Only Site Coordinators (CRC role) can inactivate individual lines in log eCRFs, as described in [“Inactivate a Log Line” on page 122.](#)

Add Forms and Folders

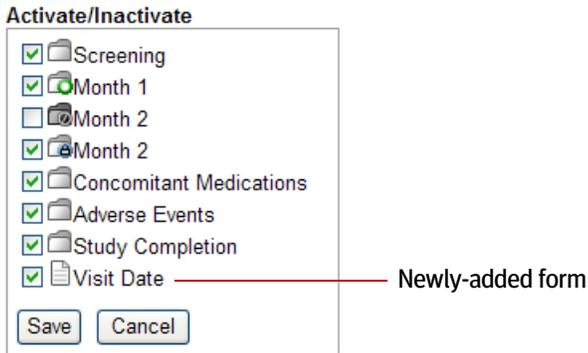
The Clinical Site Manager (CRA role) or Project Data Manager (DM role) can add individual forms or entire folders to a subject. This is useful if, for example, the site entered data in the Month 1 folder for the wrong subject. Rather than go back and fix the already-entered data (which could be many data points), the Clinical Site Manager or Project Data Manager could simply inactivate the Month 1 folder and then add an entirely new folder.

- Note:** Adding forms and folders differs from the Add Event feature (see [“Add an event to a subject” on page 114](#)). Add Event is used to add optional folders that are subject-dependent.

Add a form to a subject

1. [Navigate to the Subject Administration page \(see page 151\)](#) for a subject.
2. On the Subject Administration page, select a form in the Add Form list.
3. Click the right arrow button.

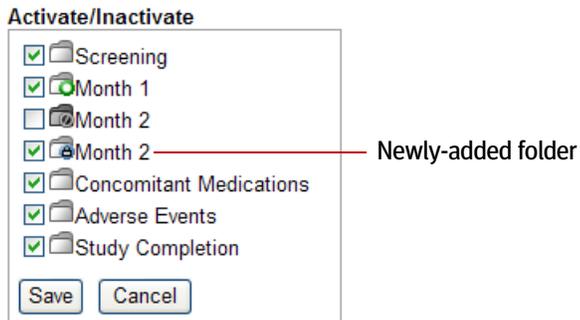
Rave displays the added form in the Activate/Inactivate list with a checkmark next to the folder name.



Add a folder to a subject

1. [Navigate to the Subject Administration page \(see page 151\)](#) for a subject.
2. On the Subject Administration page, select a folder in the Add Folder list.
3. Click the right arrow button.

Rave displays the added folder in the Activate/Inactivate list with a checkmark next to the folder name.



Hands-On Exercise

1. Log in with the user account associated with the CRA role.
2. In the Month 1 folder of your subject, open the Physical Exam eCRF.
3. Inactivate this eCRF.
4. Reactivate this eCRF.
5. Log out.
6. Log in with the user account associated with the CRC role.
7. Open the Concomitant Medications folder of your subject.

If this eCRF is not available, go to the Concomitant Medications Assessment in this folder and answer **Yes** to the question **Were there any medications taken?**

8. Add two lines to the Concomitant Medications log eCRF.
9. Log out.
10. Log in with the user account associated with the CRA role.
11. Inactivate one of the lines that you added.
12. Add a new form from the Subject Administration page.

LESSON 16

VERIFYING DATA

This lesson covers the following topics:

- › [About Data Verification \(see page 159\)](#)
- › [Verify Data \(see page 160\)](#)
- › [Unverify Data \(see page 161\)](#)
- › [Batch Verify Using the Grid View \(see page 162\)](#)

About Data Verification



IMPORTANT! Data must be entered into Rave before it can be verified. Verification can begin on already-submitted data points while waiting for other data points to be submitted.

Source Document Verification (SDV) occurs during the monitoring of the study to ensure that what's entered in Rave matches exactly the written record of data collected from a subject (patient charts, lab reports, notes, and other paper-based records). Data points can be verified even while other data is being submitted on the study. In Rave, the Clinical Site Manager (CRA role) can mark the data as verified. If you are authorized to verify data, you will see the Verify (☐) icon on the eCRF page.

Business Process for Source Document Verification (SDV)

Genentech requires that the Clinical Site Manager (CRA role) conduct the SDV and that all data points (100%) be verified against source document at a frequency specified by the Clinical Site Manager.

To verify a data point in an eCRF:

- › A Clinical Site Manager determines whether the data point is frozen and, if so, unfreezes the data. For details, see [“Freezing Data” on page 164](#).
- › The Clinical Site Manager compares the data point with the written record.
- › If the written record matches the data point in Rave, then the Clinical Site Manager checks the Verify check box next to the data point. For details, see [“Verify Data” on page 160](#).
- › If the written record does not match the data point in Rave, then the Clinical Site Manager makes sure that the Verify check box next to the data point is not checked. The Clinical Site Manager would typically then send a query to the site asking them to change the data.

For more information, refer to COP.SOP.003 Site Monitoring Activities.

Leader Note

Depending on the needs of the attendees, determine whether to teach this as an instructor demo or a hands-on lesson.

Data Verification

The process of verifying data can occur before all data has been submitted in a study.

Data that Requires Verification

Not all data points require verification—only those that the study requirements identify as such. This is determined on a study-by-study basis.

Task Summary: Subject		Pages
Open Queries	0	0
Answered Queries	0	0
Sticky Notes	6	6
Requiring Verification	5	5
Ready for Entry Lock	22	22

Requiring Verification

If you log in with the CRA role, the Task Summary displays a Requiring Verification category that allows you to quickly find data to verify.

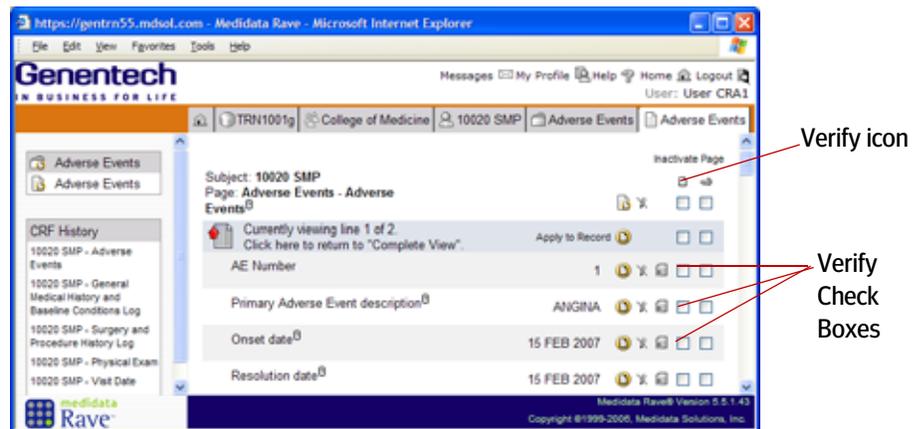
Verify Data

- Note:** Any frozen data points must be unfrozen before verifying the data. For details, see [“Unfreeze Data” on page 166](#).

Verify data on an eCRF

1. Log in with a Rave user account associated with the CRA role.
2. [Select a study \(see page 37\)](#), if applicable.
3. [View a site \(see page 39\)](#), if applicable.
4. [View a subject \(see page 43\)](#).
5. Open the eCRF that you want to verify, as you learned in [“Viewing eCRFs Associated with a Subject” on page 53](#).

Rave displays the eCRF with the Verify (Ⓜ) icon and a check box next to any field that needs verification, as shown in the following example.



6. Compare the data in the eCRF with the corresponding written record. Once the data are verified, check the check box next to it on the eCRF.
 - Note:** Instead of checking each check box individually, you can check all fields on the eCRF by checking the check box immediately below the Verify (Ⓜ) icon, and then clicking **Save**.
7. When you have finished verifying data points on this eCRF, click **Save** to save your changes.

Unverify Data

Only the Clinical Site Manager can unverify any verified data on an eCRF. Unverifying simply means unchecking the **Verify** check box next to the applicable field on an eCRF.

- **Note:** Any entry or hard locks must be removed before unverifying the data.

Unverify data on an eCRF

1. [Select a study \(see page 37\)](#), if applicable.
2. [View a site \(see page 39\)](#), if applicable.
3. [View a subject \(see page 43\)](#).
4. Open the eCRF that you want to unverify, as you learned in [“Viewing eCRFs Associated with a Subject” on page 53](#),

Rave displays the eCRF with the Verify (☑) icon and a check box next to any field that needs verification.

If a checked check box is editable, then you are able to uncheck it.

5. Uncheck the check box next to any data point on the eCRF that you want to unverify.
 - **Note:** Instead of unchecking each check box individually, you can uncheck all fields on the eCRF by unchecking the check box immediately below the Verify (☑) icon, and then clicking **Save**.
6. When you have finished unverifying data points on this eCRF, click **Save** to save your changes.

Automatic Unverification

Verified data is automatically unverified whenever it is changed—whether the change is made by a user on the eCRF page or by a data integration update process.

Batch Verify Using the Grid View

The Grid View allows CRA users to quickly verify multiple eCRFs at a time—all eCRFs in a folder, or all eCRFs for a subject.

- **Note:** The Genentech business process for verifying data governs the use of this feature.

Verify all eCRFs in a folder

1. [Display the Grid View](#) (see page 47) for a subject.
2. Click the folder name at the top of the column.

The column for the selected folder turns gray, and the Verify check box is displayed.

Click the Folder Name

Verify check box

	10020 SMP	Screening	Concomitant Medications	Adverse Events	Month 1	Month 2	Study Completion	All
Visit Date		<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Visit Date
Adverse Events				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Adverse Events
Chemistry Local					<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Chemistry Local
Chest X-Ray					<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Chest X-Ray
Concomitant Medications Assessment			<input checked="" type="checkbox"/>					Concomitant Medications Assessment
Concomitant Medications			<input checked="" type="checkbox"/>					Concomitant Medications
Demographics		<input checked="" type="checkbox"/>						Demographics
Electrocardiogram				<input checked="" type="checkbox"/>				Electrocardiogram
General Medical History and Baseline Conditions Assessment		<input checked="" type="checkbox"/>						General Medical History and Baseline Conditions Assessment
General Medical History and Baseline Conditions Log		<input checked="" type="checkbox"/>						General Medical History and Baseline Conditions Log

3. Do one of the following:
 - To verify all eCRFs that are ready to be verified, select (check) the Verify check box and click **Set**.
 - To *un*verify eCRFs that have already been verified, select (check) the Verify check box and click **Clear**.
4. Click **Save**.

Verify all eCRFs for a subject

1. [Display the Grid View \(see page 47\)](#) for a subject.
2. Click the All column.

All folder columns for this subject turn gray, and the Verify check box is displayed.

Click the All Column

Verify check box



	10020 SMP	Screening	Concomitant Medications	Adverse Events	Month 1	Month 2	Study Completion	All
Visit Date		<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Visit Date
Adverse Events				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Adverse Events
Chemistry Local					<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Chemistry Local
Chest X-Ray					<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Chest X-Ray
Concomitant Medications Assessment			<input checked="" type="checkbox"/>					Concomitant Medications Assessment
Concomitant Medications			<input checked="" type="checkbox"/>					Concomitant Medications
Demographics		<input checked="" type="checkbox"/>						Demographics
Electrocardiogram				<input checked="" type="checkbox"/>				Electrocardiogram
General Medical History and Baseline Conditions Assessment		<input checked="" type="checkbox"/>						General Medical History and Baseline Conditions Assessment
General Medical History and Baseline Conditions Log		<input checked="" type="checkbox"/>						General Medical History and Baseline Conditions Log

3. Do one of the following:
 - To verify all eCRFs that are ready to be verified, select (check) the Verify check box and click **Set**.
 - To *un*verify eCRFs that have already been verified, select (check) the Verify check box and click **Clear**.
4. Click **Save**.

Hands-On Exercise

1. Log in with a Rave user account that has CRA access.
2. In the Screening folder for your subject, go to the Demographics eCRF.
3. Verify all the data points that can be verified on the Demographics eCRF.

Try clicking each check box individually, as well as clicking the check box immediately below the Verify (☑) icon to check all verification check boxes on the eCRF.

4. Unverify all the verified data points on the Demographics eCRF.

Try unchecking each check box individually, as well as unchecking the check box immediately below the Verify (☑) icon to uncheck all verification check boxes on the eCRF.

Leader Note

Depending on the needs of the attendees, determine whether to teach this as an instructor demo or a hands-on lesson.

Freeze Omitted in Some Studies

Depending on the study protocol, certain studies might not use the freeze phase during the conduct of the study.

Study Discontinuation

If a subject is discontinued, all unnecessary folders and forms should be inactivated before freezing the data.

LESSON 17

FREEZING DATA

This lesson covers the following topics:

- › [About Freezing Data \(see page 164\)](#)
- › [Freeze Data \(see page 165\)](#)
- › [Unfreeze Data \(see page 166\)](#)
- › [Batch Freeze Using the Grid View \(see page 167\)](#)



IMPORTANT! Data must have undergone Data Listing Review prior to freeze. Data points can be frozen before they have been verified (see [“Verifying Data” on page 159](#)). However, all data points on an eCRF must have been verified before the eCRF can be frozen.

About Freezing Data

Freezing clinical data for a trial prevents any further edits or additional data entry. Users cannot make any changes to a frozen data point or frozen eCRF. A data point or eCRF cannot be frozen until all open queries and sticky notes against it are closed. Once frozen, new queries or sticky notes can be opened against the data point, and the status icon for the eCRF might change to reflect open queries or sticky notes. In order to edit a frozen data point or verify it, the data point must first be unfrozen (see [“Unfreeze Data” on page 166](#)).

- **Note:** In the Rave software, freezing is sometimes referred to as *placing an entry lock*.

Rave displays a Freeze (🔒) icon to indicate that a data point can be frozen.



IMPORTANT! Time points at which to freeze data are based on enrollment and vary from study to study. Refer to the study-specific timeline.

Business Process for Freezing Clinical Data

Genentech requires that the Clinical Site Manager (CRA role) or Project Data Manager (DM role) freeze data. To learn more about freezing data, refer to CDM.SOP.202 Electronic Data Capture (EDC) Study Query Management and Data Freezing.

Note: Adverse Events should not be frozen until the final database lock to allow the coding to be rerun when a MedDRA version upgrade is performed. Similarly, forms for which data is uploaded in cumulative batches (central lab forms) should not be frozen, as freezing these forms will prevent later data to be uploaded in the system.

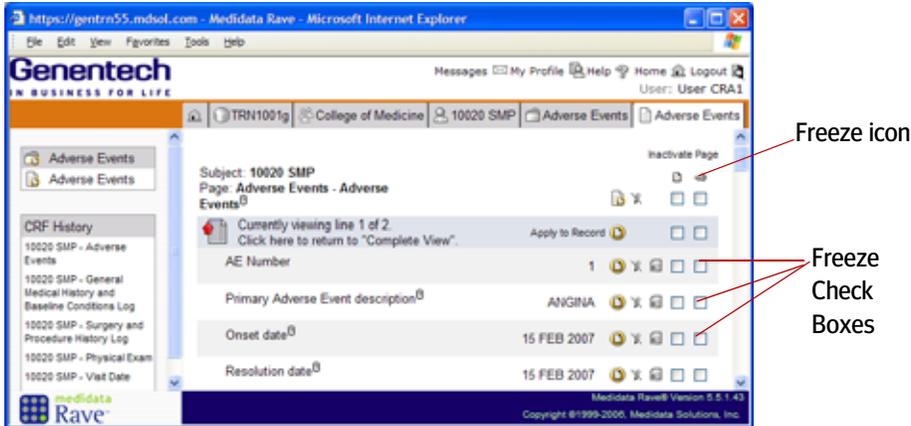
Freeze Data

Freezing data requires logging in with a user account that is associated with the CRA or DM role.

Freeze data on an eCRF

1. Log in with a Rave user account that has CRA or DM access.
2. [Select a study \(see page 37\)](#), if applicable.
3. [View a site \(see page 39\)](#), if applicable.
4. [View a subject \(see page 43\)](#).
5. Open the eCRF associated with the data that you want to freeze, as you learned in [“Viewing eCRFs Associated with a Subject” on page 53](#),

Rave displays the eCRF with the Freeze (🧊) icon and a check box next to any field that needs to be frozen, as shown in the following example.



6. Check the check box next to any data point that you want to freeze.
 - Note:** Instead of checking each field individually, you can check all fields on the eCRF by checking the check box immediately below the Freeze (🧊) icon, and then clicking **Save**.
7. When you have finished freezing data on this eCRF, click **Save** to save your changes.

Task Summary: Subject		Pages
🔍	Open Queries	0
🔍	Answered Queries	0
📌	Sticky Notes	6
🔍	Requiring Verification	5
🔒	Ready for Entry Lock	22

Ready for Entry Lock

If you log in with CRA or DM access, the Task Summary displays a Ready for Entry Lock category that allows you to quickly find data to freeze.

Unfreeze Data

In order to change a frozen data point or open queries or sticky notes against it, the data must first be unfrozen. Unfreezing data requires logging in with a user account that is associated with the CRA or DM role.

Unfreeze Data on an eCRF

1. Log in with a Rave user account that has CRA or DM access.
2. [Select a study \(see page 37\)](#), if applicable.
3. [View a site \(see page 39\)](#), if applicable.
4. [View a subject \(see page 43\)](#).
5. Open the eCRF associated with the data that you want to freeze, as you learned in [“Viewing eCRFs Associated with a Subject” on page 53](#),

Rave displays the eCRF with the Freeze (🟢) icon and a check box next to any field that can be unfrozen.

6. Uncheck the check box next to any data point that you want to unfreeze.

- **Note:** Instead of unchecking each field individually, you can uncheck all fields on the eCRF by checking the check box immediately below the Freeze (🟢) icon, and then clicking **Save**.

7. When you have finished unfreezing data on this eCRF, click **Save** to save your changes.

Rave displays the eCRF with your changes.

Batch Freeze Using the Grid View

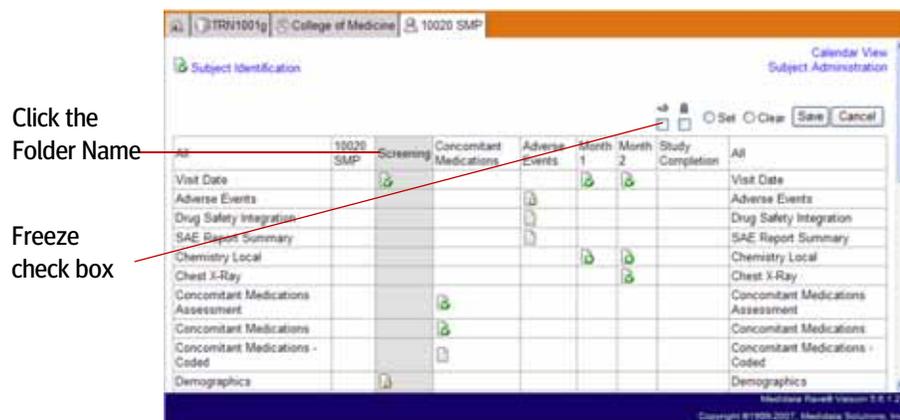
The Grid View allows CRA and DM users to quickly freeze multiple eCRFs at a time—all eCRFs in a folder, or all eCRFs for a subject.

- **Note:** The Genentech business process for freezing data governs the use of this feature.

Freeze all eCRFs in a folder

1. [Display the Grid View \(see page 47\)](#) for a subject.
2. Click the folder name at the top of the column.

The column for the selected folder turns gray, and the Freeze check box is displayed.

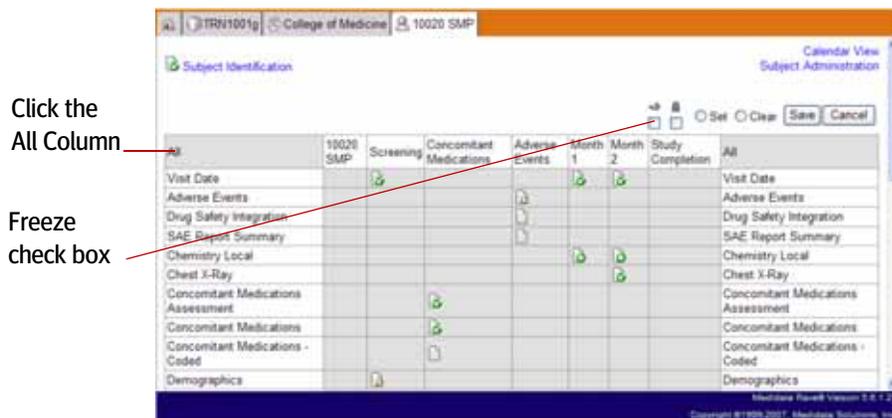


3. Do one of the following:
 - To freeze all eCRFs that are ready to be frozen, select (check) the Freeze check box and click **Set**.
 - To *un*freeze eCRFs that have already been frozen, select (check) the Freeze check box and click **Clear**.
4. Click **Save**.

Freeze all eCRFs for a subject

1. [Display the Grid View](#) (see page 47) for a subject.
2. Click the All column.

All folder columns for this subject turn gray, and the Freeze check box is displayed.



3. Do one of the following:
 - > To freeze all eCRFs that are ready to be frozen, select (check) the Freeze check box and click **Set**.
 - > To *un*freeze eCRFs that have already been frozen, select (check) the Freeze check box and click **Clear**.
4. Click **Save**.

Hands-On Exercise

1. Log in with a Rave user account that has CRA access.
2. In the Screening folder for your subject, go to the Demographics eCRF.
3. Verify all the data points that can be verified on the Demographics eCRF and save your changes.
4. Freeze all the data points that can be frozen on the Demographics eCRF and save your changes.
5. Unfreeze all the data points on the Demographics eCRF and save your changes.
6. View the Audit Trail for the Demographics eCRF.

LESSON 18

SIGNING OFF DATA

This lesson covers the following topics:

- › [About Electronic Signatures \(see page 169\)](#)
- › [Sign Off Subjects \(see page 170\)](#)
- › [Sign Off Individual eCRFs \(see page 171\)](#)
- › [Batch Sign Off Using the Grid View \(see page 172\)](#)



IMPORTANT! Before clinical data can be signed off, all data points in a study need to be entered, all queries must be resolved, all appropriate fields need to be verified (see [“Verifying Data” on page 159](#)) and frozen (see [“Freezing Data” on page 164](#)).

About Electronic Signatures

Principal Investigators (PI role) or other clinical data providers, such as Reading Centers (RC role), provide their password to electronically sign-off on the clinical data for a given subject. By submitting their signature, these users attest that the subject data have been reviewed and deemed accurate. Rave displays a Signature (👤) icon next to any eCRF or subject that requires a signature.

- **Note:** Once an eCRF or subject has been electronically signed, any subsequent changes to the data—including updates from the Batch Uploader—will break the signature. Any changed data points will need to be re-signed before they can be locked (locking prevents any further changes).

The Task Summary has a category for items requiring signature (as shown in the following figure), which allows you to go directly to those items.

Business Process for Signing Off Clinical Data

Genentech requires that the Principal Investigators (PI role) or other clinical data providers, such as Reading Centers (RC role), electronically sign-off data. To learn more about signing off data, refer to CDM.SOP.203 Electronic Data Capture (EDC) Study Database Closeout.

Leader Note

Depending on the needs of the attendees, determine whether to teach this as an instructor demo or a hands-on lesson.

Automatic Unsigning

The signature for signed-off data is automatically broken whenever it is changed—whether the change is made by a user on an eCRF page or by a data integration update process.

Task Summary: Site	Subjects
Requiring Signature	3
NonConformant Data	2
Open Queries	2
Overdue Data	2

Requiring Signature

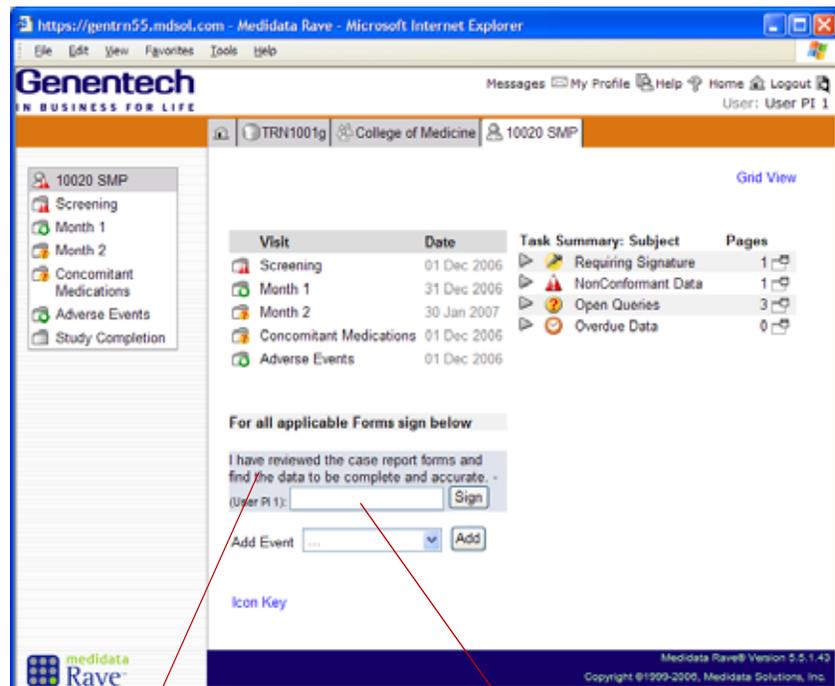
If you log in with PI access, the Task Summary displays a Requiring Signature category that allows you to quickly find data that requires a sign-off.

Sign Off Subjects

When you sign off a subject, you sign off all eCRFs associated with that subject. You must first display the Grid View for the subject and sign off the entire batch of eCRFs.

Sign off a subject

1. [Select a study \(see page 37\).](#)
2. [View a site \(see page 39\).](#)
3. [View a subject \(see page 43\).](#)



4. Read the verification message on the form.

For all applicable Forms sign below

I have reviewed the case report forms and find the data to be complete and accurate. -
(User PI 1):

5. In the text field, type the same password that you use to log into Rave.
6. Click **Sign** to save your signature.

Once a subject is signed, the status of all individual fields for all fields across all forms within the folder changes to a Signed status. Rave records the signing in the Audit Trail, capturing the change to a Signed status, the name of the user who made the signature, and the date/time when the signature was made.

Sign Off Individual eCRFs

Depending on study-specific requirements, a Genentech-sponsored clinical trial that uses Rave might require sign-offs on individual eCRFs.

Sign off an eCRF

1. [Select a study \(see page 37\).](#)
2. [View a site \(see page 39\).](#)
3. [View a subject \(see page 43\).](#)

In the Subject Schedule, any eCRFs displayed with the Signature (👤) icon require a signature.

4. Select an eCRF for which you want to provide an electronic signature.

The screenshot shows a web browser window with the URL <https://gentrn55.mdsol.com>. The page title is "Medidata Rave - Microsoft Internet Explorer". The Genentech logo is at the top left. The user is logged in as "User: User PI 1". The breadcrumb trail is "TRN1001g > College of Medicine > 10020 SMP > Month 2 > Chest X-Ray". The left sidebar shows a navigation menu with "Month 2" selected, and sub-items: "Visit Date", "Chemistry Local", "Chest X-Ray", "Hematology Local", "Ongoing Physical Exam", and "Vital Signs". Below the sidebar is a "CRF History" section showing "10020 SMP - Chest X-Ray". The main content area displays the eCRF form for "Subject: 10020 SMP" and "Page: Chest X-Ray - Month 2". The form has several sections: "Was a chest x-ray performed?" with a "Yes" button and a signature icon; "X-ray date" with the value "30 JAN 2007" and a signature icon; "X-ray result" with the value "Normal" and a signature icon; and a signature verification message: "I have reviewed the case report forms and find the data to be complete and accurate." Below the message is a text field for the user's password, labeled "Enter Sign-Off Password Here". The form also has "Printable Version", "View PDF", and "Icon Key" links, and "Save" and "Cancel" buttons. The footer of the page shows "Medidata Rave® Version 5.5.1.43" and "Copyright ©1999-2006, Medidata Solutions, Inc."

Message

Enter Sign-Off Password Here

5. Read the verification message on the form.

I have reviewed the case report forms and find the data to be complete and accurate.
- User PI 1:

6. In the text field, type your password.
7. Click **Save** to save your signature.

Once an eCRF is signed, the status of all individual fields for this eCRF changes to a Signed status. Rave records the signing in the Audit Trail, capturing the changed status, the name of the user who made the signature, and the date/time when the signature was made.

Leader Note

The Chest X-Ray eCRF in the Month 2 folder prompts for an electronic signature.

Batch Sign Off Using the Grid View

The Grid View allows PI users to quickly sign off all eCRFs for a subject.

- **Note:** The Genentech business process for signing off data governs the use of this feature.

Sign off all eCRFs for a subject

1. [Display the Grid View \(see page 47\)](#) for a subject.
2. Click the All column.

All folder columns for this subject turn gray, and the Sign-off password prompt is displayed.

Click the All Column

Sign-off password prompt

	Screening	Concomitant Medications	Adverse Events	Month 1	Month 2	Study Completion	All
Visit Date	✓			✓	✓		Visit Date
Adverse Events			✓				Adverse Events
Chemistry Local				✓	✓		Chemistry Local
Chest X-Ray					✓		Chest X-Ray
Concomitant Medications Assessment		✓					Concomitant Medications Assessment
Concomitant Medications		✓					Concomitant Medications
Demographics	✓						Demographics
Electrocardiogram			✓				Electrocardiogram
General Medical History and Baseline Conditions Assessment	✓						General Medical History and Baseline Conditions Assessment

3. In the text field, type your password.
4. Click **Save** to save your signature.

Hands-On Exercise

1. Log in with a Rave user account that has PI access.
2. Make sure that all data for your subject is complete—all queries are resolved and all applicable fields are verified and frozen.
3. Sign off on your subject.

LESSON 19

LOCKING DATA

This lesson covers the following topics:

- › [About Locking Data \(see page 173\)](#)
- › [Lock Data \(see page 174\)](#)
- › [Unlock Data \(see page 175\)](#)
- › [Batch Lock Using the Grid View \(see page 176\)](#)



IMPORTANT! All data points in a study need to be signed off (see [“Signing off Data” on page 169](#)) before you can begin locking data.

About Locking Data

After all clinical data in a study has been signed off, locking completely locks the clinical data for a trial. Locking data prevents users or integrations from making any further changes to the field data. Once the data is locked:

- › no queries can be placed against it
- › it cannot be updated, either in the Rave screens or via the Batch Uploader
- › it cannot be unlocked except under extraordinary circumstances (only the DM role can unlock it)

Genentech requires that the Project Data Manager (DM role) lock data.

Rave displays a Lock (🔒) icon to indicate data points that need to be locked.

- **Note:** In the Rave software, locking is sometimes referred to as *placing a hard lock* on the data.

Business Process for Locking Clinical Data

Genentech requires that the Project Data Manager (DM role) lock data. To learn more about locking data, refer to CDM.SOP.203 Electronic Data Capture (EDC) Study Database Closeout.

Leader Note

Depending on the needs of the attendees, determine whether to teach this as an instructor demo or a hands-on lesson.

Locked Data Cannot Be Changed

Once data is locked, it cannot be updated—whether by a user on an eCRF page or by a data integration update process—without unlocking it first.

Lock Data

Locking data requires logging in with a user account that is associated with the DM role.

Lock data on an eCRF

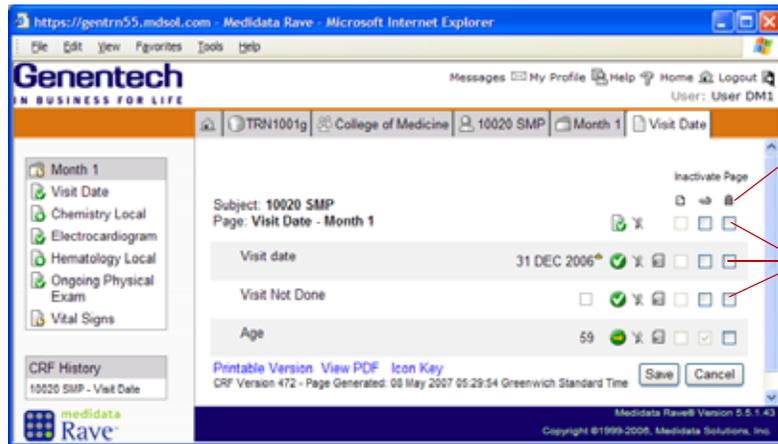
1. Log in with a Rave user account that has DM access.
2. [Select a study \(see page 37\)](#), if applicable.
3. [View a site \(see page 39\)](#), if applicable.
4. [View a subject \(see page 43\)](#).
5. Open the eCRF associated with the data that you want to lock, as you learned in [“Viewing eCRFs Associated with a Subject” on page 53](#),

Rave displays the eCRF with the Lock (🔒) icon and a check box next to any field that needs to be locked, as shown in the following example.

Task Summary: Subject	Pages
Open Queries	0
Answered Queries	0
Sticky Notes	6
Ready for Entry Lock	22
Ready for Data Lock	19

Ready for Data Lock

If you log in with DM access, the Task Summary displays a Ready for Data Lock category that allows you to quickly find data that requires locking.



6. Check the check box next to any data point that you want to lock.
 - **Note:** Instead of checking each field individually, you can check all fields on the eCRF by checking the check box immediately below the Lock (🔒) icon, and then clicking **Save**.
7. When you have finished locking data on this eCRF, click **Save** to save your changes.

Unlock Data

Unlocking data requires logging in with a user account that is associated with the DM role.

IMPORTANT! While functionally possible to unlock data points in the Rave software, this action is governed by internal Genentech guidelines. For details, refer to CDM.SOP.203 Electronic Data Capture (EDC) Study Database Closeout.

Unlock data on an eCRF

1. Log in with a Rave user account that has DM access.
2. [Select a study \(see page 37\)](#), if applicable.
3. [View a site \(see page 39\)](#), if applicable.
4. [View a subject \(see page 43\)](#).
5. Open the eCRF associated with the data that you want to unlock, as you learned in [“Viewing eCRFs Associated with a Subject” on page 53](#),

Rave displays the eCRF with the Lock (🔒) icon and a check box next to any lockable field.

6. Uncheck the check box next to any data point that you want to unlock.
 - **Note:** Instead of unchecking each field individually, you can uncheck all fields on the eCRF by unchecking the check box immediately below the Lock (🔒) icon, and then clicking **Save**.
7. When you have finished unlocking all data on this eCRF, click **Save** to save your changes.

Rave displays the eCRF with your changes

Batch Lock Using the Grid View

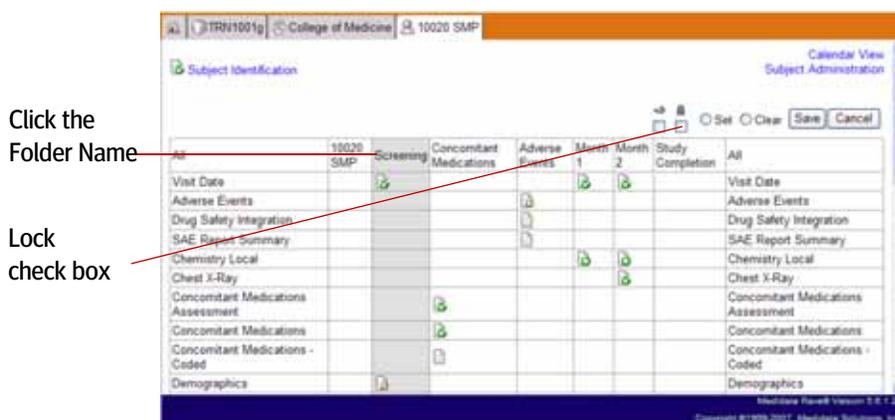
The Grid View allows DM users to quickly lock multiple eCRFs at a time—all eCRFs in a folder, or all eCRFs for a subject.

- **Note:** The Genentech business process for locking data governs the use of this feature.

Lock all eCRFs in a folder

1. [Display the Grid View \(see page 47\)](#) for a subject.
2. Click the folder name at the top of the column.

The column for the selected folder turns gray, and the Lock check box is displayed.



3. Do one of the following:
 - To lock all eCRFs that are ready to be locked, select (check) the Lock check box and click **Set**.
 - To *unlock* eCRFs that have already been locked, select (check) the Lock check box and click **Clear**.
4. Click **Save**.

Lock all eCRFs for a subject

1. [Display the Grid View \(see page 47\)](#) for a subject.
2. Click the All column.

All folder columns for this subject turn gray, and the Lock check box is displayed.

Click the All Column

Lock check box



3. Do one of the following:

- To lock all eCRFs that are ready to be locked, select (check) the Lock check box and click **Set**.
- To *unlock* eCRFs that have already been locked, select (check) the Lock check box and click **Clear**.

4. Click **Save**.

Hands-On Exercise

- 1.** Log in with a Rave user account that has DM access.
- 2.** In the Screening folder for your subject, go to the Demographics eCRF.
- 3.** Lock all the data that can be locked on the Demographics eCRF.
- 4.** View the Audit Trail for the Demographics eCRF.

CLASS PROJECT #2

Complete the following tasks

1. Log in with a Rave user account associated with the CRC role.
2. Go to your subject.
3. Complete any incomplete eCRFs in the Screening folder.
4. Complete any incomplete eCRFs in the Visit 1 folder.
5. Complete any incomplete eCRFs in the Visit 2 folder.
6. Report an adverse event.
7. View various report(s) to see how the new / updated eCRF data is reflected there.
8. Log in with a Rave user account associated with the CRA role.
9. Add a sticky note on an eCRF and address it to the DM group.
10. Log in with a Rave user account associated with the DM role.
11. Confirm the existence of the sticky note in the Task Summary.
12. Create various queries, directing them to the Site group.
13. Log in with a Rave user account associated with the CRC role.
14. Respond to these queries.
15. Log in with a Rave user account associated with the CRA role.
16. Verify all data for your subject.
17. Freeze all data for the subject.
18. Log in with a Rave user account associated with the PI role.
19. Sign off the subject.
20. Log in with a Rave user account associated with the DM role.
21. Lock all data for the subject.

CONCLUSION TO SECTION 2

Training Review

In this section, you have learned how to:

- › Add subjects and update subject information
- › Understand eCRF editing concepts, such as edit checks, restricted eCRFs and fields, data-dependent fields, and so on.
- › Submit data in eCRFs, including log eCRFs
- › Add an event (unscheduled visit) to a subject
- › Respond to system and manual queries and create manual queries
- › Create and acknowledge sticky notes associated with data points in eCRFs
- › Inactivate and reactivate eCRFs
- › Verify and unverify data
- › Freeze and unfreeze data
- › Lock and unlock data
- › Sign off data using electronic signatures

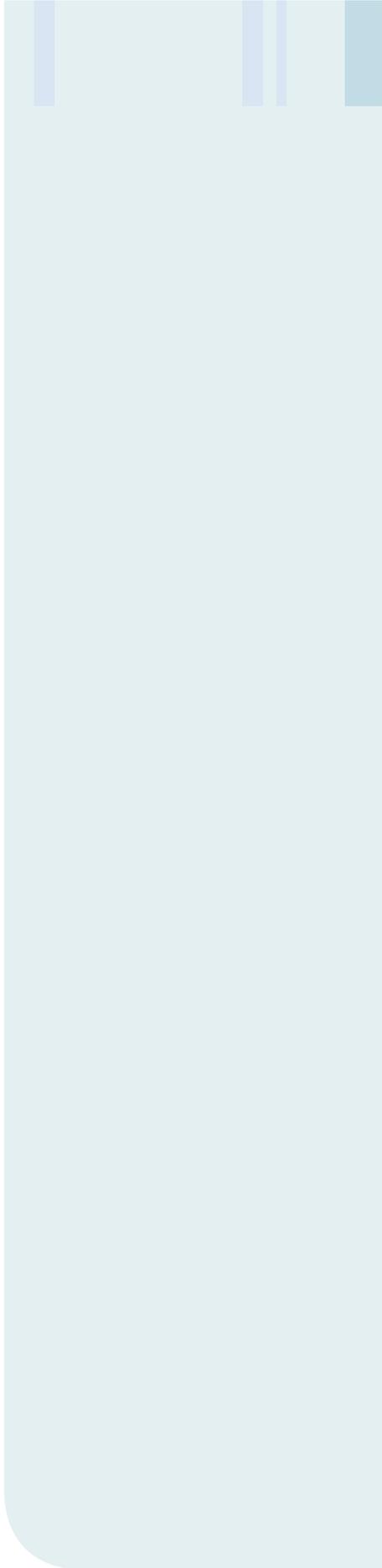
Where To Go From Here

Now that you understand how to use Rave in your job:

1. Complete the Course Evaluation Form that your instructor provides.
2. Apply for your Rave account, as described in [“Obtain a Rave User Account” on page 16](#).



IMPORTANT! Be sure to sign the group training record and fill out a course evaluation before you leave.



GLOSSARY

access rights

Permission to access certain Rave data or a particular Rave feature based on a user's login name, associated user group, and any associated roles.

adverse event (AE)

An untoward medical occurrence detected in a person who is enrolled as a subject in a clinical trial. Examples include an abnormal lab finding, unfavorable symptom, unintended condition, illness, death, and so on. The investigational treatment may or may not be the cause of the adverse event. See also *serious adverse event (SAE)*, *reportable adverse event*.

analyte

A substance that is undergoing analysis, such as blood or urine.

audit trail

History of actions taken on a particular piece of data. Includes the action taken on the data (entered, verified, or locked the data), the user who took the action, the date and time when the action occurred, and the original data before the change. To view the audit trail for a field or eCRF, users click on the associated Data Status icon.

auxiliary environment

Any environment that is not the live environment for a study. A project can have multiple auxiliary environments created for different purposes—building, testing, training, demos, and so on. See also *environment* and *live environment*.

blinded data

Data that is designated as blinded by the protocol and or study team. Access to blinded data is restricted to only certain users of the system. See also *restricted field*.

calculated field

Read-only field that is calculated based on the values in other fields. For example, when you add a subject, the Subject Identification field is derived by combining the subject's initials, a space, and their subject number

Calendar View

View on the Subject main page that displays the Subject Schedule by site visit date. See also *Grid View*.

Clinical Views

Up-to-date subject data that is represented in tabular format for easy data access. Clinical Views provide a mechanism for ad hoc reporting (using JReview) and exporting (for SAS integration). Each eCRF has two associated clinical views: one for all eCRF data, and one for conformant data only.

coding dictionary

Standard drug or medical dictionary that is used to provide coded values in a selection list.

conformant data

Data that is in the expected format, such as a date field with a month numbered 12 (but not 13 or XX, both of which would be non-conformant). See also *non-conformant data*.

CRF

Case Report Form. A standard form used for recording pertinent information about a participating subject during a Genentech clinical trial. CRFs collect the required information as defined in the study protocol. See also *eCRF*.

data-dependent eCRF

eCRF in which the form or fields on an eCRF depend on the value in another field. For example, if a subject's gender is changed to female, Rave might add the Reproductive History and Reproductive Status eCRFs to the subject's schedule.

data lock (lock)

Locks the clinical data for a trial, preventing any further changes, including queries or sticky notes.

data point

Piece of data that gets put into a field, such as a date, description, selection from a drop-down list, and so on.

eCRF

Electronic case report form. An online version of a printed case report form (CRF) used in Genentech-sponsored clinical trials, such as a Physical Exam, Subject Eligibility, or Visit Date form. Instead of manually filling out printed CRFs, Rave users complete eCRFs online. See also *CRF*.

EDC

Electronic Data Capture. Process of collecting and distributing clinical trial data electronically using an EDC application such as Rave.

EDC Module

Component of Medidata Rave that enables users to enter, view, and manage data electronically for clinical trials.

edit check

When a user submits changes to a form, Rave performs edit checks on some or all of the entered changes to catch typing errors or aberrant data, helping ensure that the entered data are valid. Rave identifies any data that fails the edit checks and takes corrective action, such as generating a query or adding more eCRFs.

electronic signature

The electronic equivalent of a hand-written signature. Authorized users provide their password to electronically sign-off on the clinical data for a given subject. By submitting their signature, these users attest that the subject data have been reviewed and deemed accurate.

entry lock (freeze)

Locks the clinical data for a trial, preventing any further edits or additional data entry. Authorized users can still create and respond to queries and sticky notes, as well as to verify the data.

environment

Context within which users access a study in the EDC module. Each study can have one live environment (production, or actual operations) and multiple auxiliary environments (non-production environments, such as development, testing, training, and so on. See also *live environment* and *auxiliary environment*.

event

A folder or eCRF that can be added to the Task List for a subject. When a new subject is added in Rave, their default Task List is created automatically. Rave allows you to add folders (such as unscheduled visits) or eCRFs to the Task List as needed.

field

A place where a data point gets entered on an eCRF. A mechanism for entering data into Rave. Rave provides the following kinds of controls: text, long text, date/time, check box, radio button, drop-down list, and electronic signature / password.

folder

Mechanism for organizing eCRFs into logical groups, such as by subject visit. A folder can contain eCRFs and other folders. Folders appear in the sidebar.

form

An electronic representation of the paper-based Clinical Research Form (CRF). Also referred to in this training as an electronic CRF (eCRF).

freeze data

See entry lock (freeze).

Global Standard

CRF that is a Genentech Medical Affairs standard CRF.

Global Volume

Central repository of Genentech standard, pre-built eCRFs that can be copied and configured for individual studies.

Grid View

The Grid View displays subject folders and eCRFs in a grid format. This at-a-glance perspective allows users to quickly find and display subject visits and associated eCRFs. In the Grid View, rows represent eCRFs, columns represent visits (folders) and other information (such as adverse events), and status icons in cells (the intersection of rows and columns) show the status of the applicable eCRF associated with the visit. See also *Calendar View*.

group

A distribution list of users. When a user creates a query or sticky note, they direct it to a target group. Members of the group will see it if they open up the eCRF with which it is associated.

hard lock

Locks the clinical data for a trial, preventing any further edits or additional data entry, including any associated queries, sticky notes, and data verification.

hidden data

Data that is captured to perform some function in the system or is necessary to be stored for analysis, but which is either not needed or not useful to most users. This type of data will be accessible only to those uses with specialized roles in the study.

Icon Key

Window that displays a picture and brief description of commonly-used icons in the Rave interface. Accessed by clicking the Icon Key link on any page.

investigator

Each investigator is uniquely identified by its Genentech-assigned, five-character investigator number that applies across all studies, sites, or organizational affiliation.

live environment

Production environment for a study. The live environment is the one in which study users enter and view actual study data. By default, each study has only one live environment. See also *environment* and *auxiliary environment*.

log eCRF

Type of eCRF that is used to add multiple instances of the same eCRF, such as the Concomitant Medications eCRF or the Adverse Event eCRF. Log eCRFs are displayed so that each log line is a separate, horizontal row. When editing a log eCRF, the landscape mode displays the editable fields in a row, while the portrait mode displays editable fields on a page, stacked vertically. See also *single eCRF (non-log eCRF)*

manual query

Query that an authorized Rave user creates in response to a piece of data in an eCRF. See also *query* and *system-generated query*.

My Profile

The My Profile page displays personal Rave settings for a given user account. Users can customize such settings as their login password, time zone, user information (such as name, address, e-mail address, and phone number), and the number of lines displayed per page.

non-conformant data

Data that is not in the expected format, such as a date field with a month numbered 13, or an alphabetic character in a number field. On an eCRF page, a Not Conformant icon indicates data that is non-conformant. See also *conformant data*.

pagination

Number of items per page. Configured using My Profile.

reportable adverse event

A reportable adverse event in the context of this training is an adverse event that needs to be reported to the sponsor. This does not necessarily mean that the adverse event is also reportable to a regulatory authority. Reportable adverse events typically always include all SAEs and, optionally, non-serious, expedited adverse events. See also *adverse event (AE)*, *serious adverse event (SAE)*.

query

An electronic question about a piece of data on an eCRF. Queries come from two primary sources: system-generated queries are generated automatically by the Rave software or by a Rave integration, and manual queries are created explicitly by a user who is authorized to do so. A query requires an explicit response from the person(s) to whom it was directed. A subject cannot be sign off until any associated open queries are closed. Similarly, the data in a study cannot be frozen or locked until all open queries are closed. See also system-generated query, manual query.

quicklist

Area of the Rave user interface that lists the most recently accessed subjects.

raw (verbatim) term

Term that has a precise meaning from a coding perspective. Coding requires the use of clinical terms that are precise and accurate, particularly with adverse event reporting. Verbatim terms are typically grouped by body system.

restricted eCRF

An eCRF for which access (view, modify, or verify) is restricted to a smaller number of authorized users. For example, only certain users can view the Electrocardiogram or Hematology Local eCRF.

restricted field

A field on an eCRF for which access (view, modify, or verify) is restricted to a smaller number of authorized users.

role

A set of permissions to perform certain actions and access particular data within the Rave EDC module. Roles determine what a user sees and has access to in the Rave EDC module, including eCRFs, reports, clinical views, and so on. When a user logs in, Rave grants them access to Rave features and data based on the permissions configured for their associated roles. Each user account is assigned just one role.

serious adverse event (SAE)

An adverse event that is life-threatening or results in death, inpatient hospitalization, or prolongation of existing hospitalization, persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Other important medical events that do not result in one of the above outcomes may be considered serious if, based on appropriate medical judgment, they might jeopardize the patient or subject and the patient requires medical or surgical intervention to prevent one of the above outcomes. See also *adverse event (AE)*, *reportable adverse event*.

sidebar

Area of the Rave user interface that lists the Task List, summary, and eCRF history.

single eCRF (non-log eCRF)

The way that most eCRFs appear. Compare with *log eCRF*.

site

The physical location where subjects are seen. Each site is uniquely identified by its Genentech-assigned, six-digit character site number, that begins with the letter “S”. See also *site group* and *world*.

site group

A logical way to classify sites within a study. At Genentech, site groups are used to organize sites by state and city, such as “NY, New York” and “CA, Los Angeles”. All sites belong to a single world (called **world**).

sticky note

An informal note or comment that is associated with data point on an eCRF. Sticky notes are used for reminders and informal communication between Genentech users only. One user creates the sticky note, while another acknowledges it. Permanent sticky notes are added to reportable SAEs to indicate what has been sent to Genentech Drug Safety. See also *query*.

study

Any systematic trial of investigational or approved products in human subjects pertaining to the efficacy and/or safety of the product. Each study is uniquely identified by its Genentech-assigned study number.

subject

A participant in a study. Each subject in a clinical trial is uniquely identified by a Genentech-assigned subject number. This number may not contain leading zeros.

Task List

Area of the Rave user interface that displays a set of forms and folders associated with the selected subject.

system-generated query

Query that Rave generates automatically when a piece of data in an eCRF triggers the query process—in response to a pre-configured business rule associated with that piece of data. See also *query*, *manual query*.

Task Summary

Area of the Rave user interface that shows—for a given study, site, or subject—any pending tasks to which the logged in user has access (based on role and user privileges).

time-out

Occurs when a user is logged into Rave but idle (no mouse clicks or keystrokes) for a given period of time. If a time-out occurs, then Rave locks the user out of the system and prompts them to re-enter their password or log in before they can resume using Rave. This security feature is designed to protect the privacy of patient data.

user

Anyone who can log into the Rave software. Each user has an associated user account that defines their login name, password, and other identifying information. A user is assigned to a single user group

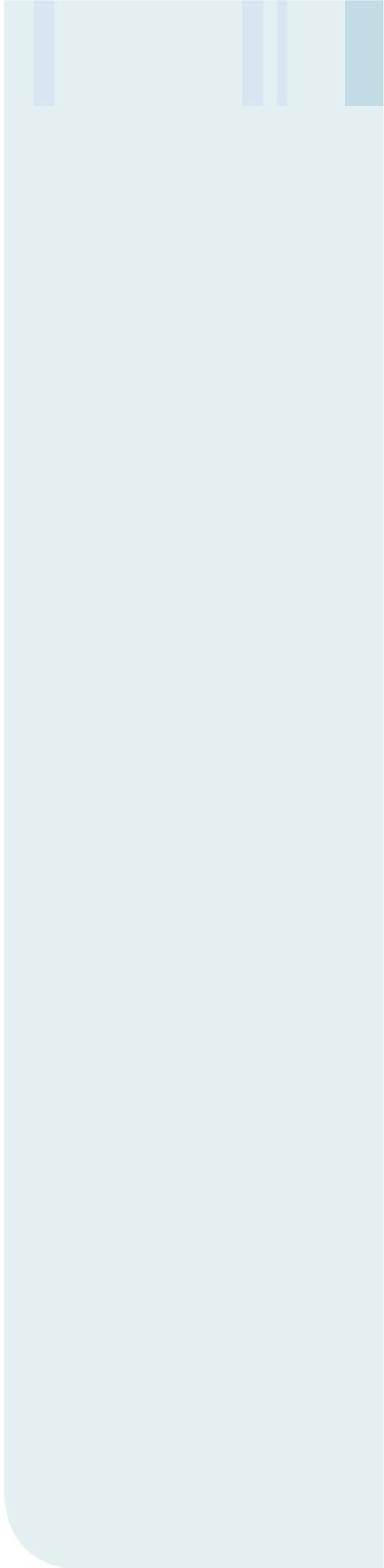
(which determines which Rave modules the user can access) and can be assigned to multiple roles (which determine the user's access to specific Rave data and features).

user group

A logical grouping of one or more user accounts. Each user account is associated with just one user group. The user group determines which Rave modules are available to users who are members of the group.

world

A logical way to classify and organize sites within a study. In Genentech EDC clinical trials, only one world (called **world**) is used. This world is the parent of—and encompasses—all site groups. See also *site* and *site group*.



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