

**Oracle® Clinical**

Getting Started

Release 5.1

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Oracle Clinical Getting Started, Release 5.1

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# Preface

This manual provides an introduction to Oracle Clinical, with an overview of its subsystems and information on how to perform activities that are not confined to a single part of the system, including logging in, navigating, and submitting batch jobs.

This preface contains the following topics:

- "Audience" on page 2-vii
- "Documentation Accessibility" on page vii
- "Finding Information and Patches on My Oracle Support" on page vii
- "Finding Oracle Documentation" on page ix
- "Related Documents" on page ix
- "Conventions" on page x

## Audience

This document is intended for all Oracle Clinical users.

## Documentation Accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

### Access to Oracle Support

Oracle customers have access to electronic support through My Oracle Support. For information, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

## Finding Information and Patches on My Oracle Support

Your source for the latest information about Oracle Clinical is Oracle Support's self-service Web site My Oracle Support (formerly MetaLink).

Before you install and use Oracle Clinical, always visit the My Oracle Support Web site for the latest information, including alerts, White Papers, installation verification (smoke) tests, bulletins, and patches.

## Creating a My Oracle Support Account

You must register at My Oracle Support to obtain a user name and password account before you can enter the Web site.

To register for My Oracle Support:

1. Open a Web browser to <https://support.oracle.com>.
2. Click the **Register** link to create a My Oracle Support account. The registration page opens.
3. Follow the instructions on the registration page.

## Signing In to My Oracle Support

To sign in to My Oracle Support:

1. Open a Web browser to <https://support.oracle.com>.
2. Click **Sign In**.
3. Enter your user name and password.
4. Click **Go** to open the My Oracle Support home page.

## Finding Information on My Oracle Support

There are many ways to find information on My Oracle Support.

### Searching by Article ID

The fastest way to search for information, including alerts, White Papers, installation verification (smoke) tests, and bulletins is by the article ID number, if you know it.

To search by article ID:

1. Sign in to My Oracle Support at <https://support.oracle.com>.
2. Locate the Search box in the upper right corner of the My Oracle Support page.
3. Click the sources icon to the left of the search box, and then select **Article ID** from the list.
4. Enter the article ID number in the text box.
5. Click the magnifying glass icon to the right of the search box (or press the Enter key) to execute your search.

The Knowledge page displays the results of your search. If the article is found, click the link to view the abstract, text, attachments, and related products.

### Searching by Product and Topic

You can use the following My Oracle Support tools to browse and search the knowledge base:

- **Product Focus** — On the Knowledge page under Select Product, type part of the product name and the system immediately filters the product list by the letters you have typed. (You do not need to type "Oracle.") Select the product you want from the filtered list and then use other search or browse tools to find the information you need.
- **Advanced Search** — You can specify one or more search criteria, such as source, exact phrase, and related product, to find information. This option is available from the **Advanced** link on almost all pages.



## Finding Patches on My Oracle Support

Be sure to check My Oracle Support for the latest patches, if any, for your product. You can search for patches by patch ID or number, or by product or family.

To locate and download a patch:

1. Sign in to My Oracle Support at <https://support.oracle.com>.
2. Click the **Patches & Updates** tab. The Patches & Updates page opens and displays the Patch Search region. You have the following options:
  - In the **Patch ID or Number** field, enter the number of the patch you want. (This number is the same as the primary bug number fixed by the patch.) This option is useful if you already know the patch number.
  - To find a patch by product name, release, and platform, click the **Product or Family** link to enter one or more search criteria.
3. Click **Search** to execute your query. The Patch Search Results page opens.
4. Click the patch ID number. The system displays details about the patch. In addition, you can view the Read Me file before downloading the patch.
5. Click **Download**. Follow the instructions on the screen to download, save, and install the patch files.

## Finding Oracle Documentation

The Oracle Web site contains links to all Oracle user and reference documentation. You can view or download a single document or an entire product library.

### Finding Oracle Health Sciences Documentation

To get user documentation for Oracle Health Sciences applications, go to the Oracle Health Sciences documentation page at:

<http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html>

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**Note:** Always check the Oracle Health Sciences Documentation page to ensure you have the latest updates to the documentation.

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### Finding Other Oracle Documentation

To get user documentation for other Oracle products:

1. Go to the following Web page:

<http://www.oracle.com/technology/documentation/index.html>

Alternatively, you can go to <http://www.oracle.com>, point to the Support tab, and then click **Documentation**.

2. Scroll to the product you need and click the link.
3. Click the link for the documentation you need.

## Related Documents

This section lists the documents in the Oracle Clinical documentation set, followed by their part number. The most recent version of each guide is posted on the Oracle Web site; see "Finding Oracle Documentation" on page ix.

- *Oracle Clinical Installation Guide*
- *Oracle Clinical Administrator's Guide*
- *Oracle Clinical Getting Started*
- *Oracle Clinical Creating a Study*
- *Oracle Clinical Conducting a Study*
- *Oracle Clinical Application Programming Interface Guide*
- *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*
- *Oracle Clinical Remote Data Capture Onsite User's Guide*
- *Oracle Clinical Remote Data Capture Classic Data Entry User's Guide*
- *Oracle Clinical, Oracle Clinical Remote Data Capture, and Oracle Thesaurus Management System Security Configuration Guide*

The release notes (Article ID 1931214.1) and the release content document are available on My Oracle Support. See [Finding Information and Patches on My Oracle Support](#) for more information.

In addition, Oracle Clinical customers can request a copy of the *Oracle Clinical Stable Interface Technical Reference Manual* from Oracle Support.

## Conventions

The following text conventions are used in this document:

<b>Convention</b>	<b>Meaning</b>
<b>boldface</b>	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
<i>italic</i>	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.
monospace	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.

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# What's New

This section describes the new features and enhancements included in recent releases of Oracle Clinical and Remote Data Capture (RDC Onsite).

## New Features in Oracle Clinical and Remote Data Capture Release 5.1

Release 5.1 includes the following enhancements:

- [Support for Partial Source Data Verification](#)
- [Custom Review Types](#)
- [Additional CRF Audit History Information in RDC Onsite](#)
- [Audit of Study Data Deletion](#)

### Support for Partial Source Data Verification

Oracle Clinical and RDC Onsite now support creating a risk-based source data verification (SDV) plan that identifies only a subset of data requiring verification in RDC.

An SDV plan can have one or both of the following components:

- A Critical Forms Plan identifies CRFs that need to be verified against the original data for all patients.
- A Patients Plan identifies patients in the study that must have 100% of their data verified. The percentage of patients requiring 100% verification can be different for different study sites. Patients can be individually selected for SDV or automatically selected based on either or both of these options:
  - A count of initial patients to be 100% source data verified.
  - A default rate of automatic selection of patients for source data verification.

You set system-wide default SDV plan values in Oracle Clinical and *publish* default plans based on those values for all study sites. You can then make changes to the plan for any study site in RDC Onsite.

When a patient SDV plan is published, automated patient selection begins. With the appropriate privileges you can see in the RDC Onsite user interface which patients and CRFs have been selected for SDV.

You can introduce partial source data verification in an ongoing study.

There are new privileges to support this functionality, and you must update existing users' privileges, including explicitly assigning them the BROWSE\_VERIFY privilege

if they should be able to view CRF verification status information. See the *RDC Onsite Administrator's Guide*.

### **Custom Review Types**

To facilitate centralized monitoring in RDC Onsite, you can create custom review types (similar to the predefined Verify and Approve review types) to enable and track reviews by users with a specific role such as data manager, safety expert, or adjudicator. After you define review types and assign privileges to users, default activity links appear in RDC Onsite specific to each review type, allowing privileged users to search for CRFs requiring their review.

Users with Update privileges can also update the CRF custom review status—with comments—either individually or with a group action. There is also a Browse All custom review privilege that allows view-only access to current CRF review status and review history for all custom review types.

Each review type you define comes with a set of five possible statuses that can be assigned to CRFs: No Review Status, Review Required, Review Undone, Awaiting Re-review, Review Complete, and Review Not Required. These statuses are visible next to the CRF icon to users with privileges. The system reverses a CRF's Review Complete status (to Awaiting Re-review) under the same circumstances in which it reverses Approved and Verified statuses, with either data or discrepancy updates, but does not reverse Complete status after form version migration.

Create custom review types and their corresponding privileges in the CUSTOM REVIEW TYPE installation codelist in Oracle Clinical.

### **Additional CRF Audit History Information in RDC Onsite**

The RDC Onsite data entry window now provides a CRF History Report which provides CRF audit history not otherwise available in the data entry window, including initial CRF creation data, prior history for deleted rows, and prior history if the CRF was ever deleted.

The complete CRF Report can also be generated directly from the data entry window providing all the sections normally provided in a Patient Data Report (PDR): the CRF rendering itself with complete audit history and discrepancy details.

### **Audit of Study Data Deletion**

The study data deletion batch job can now be run with or without auditing the deletions. Data deleted with audit is still considered hard-deleted and is no longer available in the system, but it is written to new tables with the same structure as the tables it is deleted from, and you can generate reports on deleted data and discrepancies in SQL\*Plus.

There are now two menu items for batch deleting data, both under the Conduct menu. One job, Delete Study Information with Audit, always audits data deletion. The other job, Delete Study Information, has a parameter that allows users to choose whether to audit the deletion or not. Using menu roles, you configure which users you want to have access to which menu option. By default, existing users with privileges with to the pre-5.1 version of Delete Study Information will have access to the new Delete Study Information job, not the job that always audits data deletion.

## **New Features in Oracle Clinical and Remote Data Capture Release 5.0**

Release 5.0 includes the following modifications:

- [Support for Oracle Database 11g Optimizer](#) on page xiii

- [Support for Oracle Real Application Clusters \(RAC\)](#) on page xiii
- [PSUB-Related Changes](#) on page xiii
- [Changes in SAS Data Extract Implementation](#) on page xiv
- [Oracle Clinical Remote Data Capture Onsite Enhancements](#) on page xiv
- [Oracle Clinical Remote Data Capture Classic Deprecated](#) on page xvi

### **Support for Oracle Database 11g Optimizer**

Release 5.0 includes upgrades to the technology stack, including the Oracle Database 11g Optimizer, which offers many performance-related enhancements.

### **Support for Oracle Real Application Clusters (RAC)**

Because databases have traditionally been constrained to run only on a single server, customers have typically followed a hardware "scale-up" strategy for the database tier. Whenever the database server becomes a bottleneck to overall application performance, the server is replaced with a larger, faster machine. While this approach is well understood, it can be highly disruptive to ongoing business.

Oracle Real Application Clusters (RAC) provides an alternative approach for scaling database performance. It is designed to tolerate server failures with little impact to mission-critical applications and users. As workloads and user connections are increased, additional nodes (servers) can be easily added to the cluster. Each server runs against the same database simultaneously. This approach is less disruptive to ongoing business operations, more reliable, and less expensive to implement.

### **PSUB-Related Changes**

PSUB has been re-architected in Release 5.0 to support an Oracle Real Application Cluster (RAC) installation across multiple nodes. Instead of using `dbms_pipes`, which can be used only within a single database instance, to communicate between the user session and the PSUB service, Release 5.0 uses Oracle Advanced Queuing.

Changes include:

- The `RXCPROD` account formerly responsible for starting and stopping PSUB (`RXCPSDPS`) has been eliminated. The PSUB start and stop privilege is now held by the `opapps` account, which continues to be responsible for the installation. If your company has previously allocated these responsibilities to separate individuals, be aware that your PSUB administrator now requires access to the `opapps` account.
- The `opapps` account will not only execute the `RXCPSDPS` (PSUB) process, but all of the batch jobs launched by that process, such as batch validation and batch data load, using a proxy database account. These jobs will no longer be executed by individual users' operating system accounts.
- The connection information for the proxy account is securely stored in Oracle Wallet, with information you provide when you run the Oracle Clinical Installer. Oracle Wallet replaces the Secure Shell, which replaced Remote Shell (`rsh`, `remsh`, and `rlogin`) used in earlier Oracle Clinical releases.
- Users who need to submit PSUB jobs no longer need:
  - a user account beginning with `OPS$`
  - an individual operating system account

Instead, a new property identifies users as PSUB users and grants them access to the new ocpsub proxy database account account. To grant this access to existing user accounts, run the migration script oclupg50migrateusers.sql provided with Oracle Clinical 5.0 and described in the *Oracle Clinical Administrator's Guide*.

- Some PSUB jobs require input files and/or produce special output files that are still stored on the file server, not in the database.. You can choose to have user-specific directories to store these or to store them all together. If you choose to have user-specific directories, you must create them yourself.
- The local reference codelist OCL\_STATE has new settings to configure the changed PSUB implementation.

There are small changes in the Oracle Clinical user interface to support these changes.

### **Changes in SAS Data Extract Implementation**

SAS Data Extract jobs are run by PSUB, so its changes in 5.0 affect SAS as well. Users no longer have individual operating system accounts and are no longer members of the oclsaocr user's group.

- Like other PSUB users, SAS Data Extract users no longer need individual operating system accounts, and therefore these accounts do not need to belong to the oclsaocr user group. Only opapps needs to belong to oclsaocr.
- Since Oracle Clinical no longer uses individual operating system accounts to run SAS jobs, the authentication method must change. You can set up SAS authentication two different ways:
  - Using Oracle Wallet
  - Using SAS proxy encryption file

New OCL\_STATE settings support these options.

- Four Data Extract jobs require input and output files in addition to the usual output files (.log and .out) that in Oracle Clinical 5.0 are stored in the database. Three of the four jobs are very similar in structure, in that they each require execution of two jobs. The first job creates files that are to be executed by SAS in the second job. New settings in the OCL\_STATE local reference codelist allow you to execute these two jobs separately. This can be useful when SAS resides on a separate server from the PSUB server.

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**Note:** SAS files generated in earlier releases of Oracle Clinical cannot be re-used in Release 5.0 because they contain a database connection string that is no longer usable. You can regenerate all your SAS view files to include the correct database connection string using the existing gen\_views utility.

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There are small changes in the Oracle Clinical user interface to support these changes.

### **Oracle Clinical Remote Data Capture Onsite Enhancements**

Oracle Clinical Remote Data Capture (RDC) Onsite has the following enhancements:

#### **Single Patient Casebook Page**

In the Patient Casebook Page you can now toggle between the Multiple view, which is the traditional view showing records for multiple patients at a single visit, and the new Single view, which shows records for a single patient at multiple visits.

## Group Approve and Verify

Group Approve and Verify actions provide additional CRF inclusion and exclusion options: Exclude batch-loaded CRFs, Exclude non-migrated CRFs and Include CRFs for this visit only (from the multi-page casebooks page). An administrator can configure the initial values for the settings and whether or not the settings are updateable at the time the action is performed.

The Group Approve and Verify sequences includes fewer dialogs, requiring fewer clicks to accomplish the action.

## Logout Page Elements

The Logout page in RDC Onsite includes a link back to the Login page.

The word *here* in the below messages is a hyperlink that routes you back to the Login page.

- You are successfully logged out. Click [here](#) to log in again.
- Your session timed out. Click [here](#) to log in again.
- Your Password has been changed successfully. Click [here](#) to log in with new credentials.

## Additional Usability Enhancements

Many of the following enhancements are provided by the migration to AS 11g:

- All RDC Onsite Surround pages come with a new, more esthetically pleasing look and feel provided by AS 11g Fusion middleware.
- Continuous scrolling on all pages replaces the Next / Prev controls to view another set of records.
- Shift-click and Ctrl-click provide a faster way to select multiple records than checkboxes. Select the left-most column header to select all rows.
- CRFs opened from the Review pages (CRFs, Discrepancies, Investigator Comments and Special Listings) allow you to open the Next or Previous CRF in the list without returning to the Review page. The new Single Patient Casebook page also provides this functionality. Earlier releases provided this capability only when the CRF was opened from the Patient Casebooks page.
- You can select an Action with a single click, without having to select the 'Go' button in addition to the action itself.
- You can expand and collapse the News, Activities and Links pane, which now appears with all the Surround pages in addition to Home.
- Many Surround pages provide the ability to filter results using one or more column headers. Select the Query by Example icon (a funnel) to display the filter boxes in the column headings.
- On the Multi-Patient Casebooks page, there are changes in the triplet of fields formerly labeled Set Visit Focus:
  - If this is a non-flexible study, the Patient field no longer appears. (The field was not updateable in earlier releases.)
  - If this is a flexible study, the Patient field is now labeled 'Visit Set for Patient' to more accurately reflect its purpose. The default value is 'All' so the Visit selection list will display all possible visits. (In earlier releases, the default value was the first patient in the list, and the Visit selection list included only the visits relevant for that patient.)

## Oracle Clinical Remote Data Capture Classic Deprecated

There is no Release 5.0 of RDC Classic, and there will be no further releases of RDC Classic.

## New Features in Oracle Clinical and Remote Data Capture Release 4.6.2

Release 4.6.2 included the following new features:

- [Restricting Values by Site and Study](#) on page xvi
- [Support for Long Data Entry Comments and Narratives](#) on page xvi
- [Siebel Clinical/CTMS Integration](#) on page xvi

### Restricting Values by Site and Study

It is now possible, through an enhancement to Thesaurus Discrete Value Groups (DVGs), to filter the list of values displayed for a question in RDC Onsite data entry based on the user's current Study and Site context. For example, in a study with 300 sites, for a question asking which physician performed a procedure, display a list of physicians at the local site rather than the complete list of physicians at all 300 sites.

### Support for Long Data Entry Comments and Narratives

RDC Onsite data entry now supports capturing long comments and narratives as required to document serious adverse events or a patient case history, for example. These extended text fields hold up to 10,000 characters and are fully audited with date and time stamps, the modifying user, and reason for change, and are included in the Patient Data Report.

### Siebel Clinical/CTMS Integration

An Oracle Application Integration Architecture (AIA) Process Integration Pack (PIP) integrates Oracle Clinical with Siebel Clinical to automatically pass certain data and metadata from one system to the other, including:

- Creates Oracle Clinical Sites, Investigators and Study Sites based on Protocol Site information sent from Siebel Clinical
- Passes information about patients and visits from Oracle Clinical to Siebel Clinical
- Allows you to define Oracle Clinical/Remote Data Capture (RDC) data collection events that should be treated as visits/activities in Siebel Clinical and passes information to Siebel Clinical to signal the completion of visits/activities for patients

New user interfaces are now included in Oracle Clinical to enable integration and define activities.

In addition, you can use the same tools used to develop the Siebel Clinical integration to develop your own integration with a different system. New web services are available to create and update Oracle Clinical Sites, Investigators and Study Sites. Oracle Clinical writes information about patient visit/activity completion to the CLINICAL\_STUDY\_AQ activities queue in the database where a web service can pick it up and send it to another application.

## New Features in Oracle Clinical and Remote Data Capture Release 4.6

Release 4.6 included the following new features:

- [DCI Book Assignment](#) on page xvii



- [DCI Level Access](#) on page xvii
- [Assembling DCI Books](#) on page xvii
- [Conditional and Indicator Branching in HTML Data Entry](#) on page xviii
- [Support for Flexible Studies](#) on page 3-xix
- [Support for RDC Data Entry and Batch Validation without Interruption](#) on page xix
- [Discrepancy Management related Enhancements](#) on page xx
- [Other Enhancements](#) on page xx

### **DCI Book Assignment**

You can use the DCI (Data Collection Instrument) Book Assignment function to manage changes to an ongoing study definition. This function lets you identify and redirect selected patient populations to a new DCI Book in a single action.

New DCI books are typically assigned in the following circumstances:

- A book is assigned to all patients in a study when the changes made are relevant to the entire study patient population.
- A book is assigned to all patients at a specified study site when the changes made are relevant to a single study site within a study patient population.
- A book is assigned to all patients of a particular patient range when the changes made are relevant to a patient range within a study patient population.
- A book is assigned to patients who have been previously assigned to another DCI book within a study patient population.

Each assignment and reassignment is recorded and can be reproduced at any time.

### **DCI Level Access**

Study builders limit user access to a subset of DCIs based on the user role hence, each change in the DCI access scheme is traceable. DCI-level access is study specific and can be applied for all DCIs of any status. The user role may have access to one set of DCIs for one study and a different set of DCIs for another study. Study builder limits a user access to browse-only access to specified DCIs for a specific study. User interface for specifying DCI access schemes is available from Oracle Clinical to the same group of users who define Study DCIs.

Access to RDC content and the content of the Patient Data Report is also restricted based on the DCI access. Access to generate the Patient Data Report is restricted by the DCI access level.

### **Assembling DCI Books**

A study builder is responsible for interpreting schedules and creating studies consistent with the study protocol. The deployment of a study build in RDC effectively defines the expected measurements during each visit for each study segment. This is handled with DCI Books and assignment for each subject.

A new interface lets study builders manage the DCI books more efficiently by providing the following features:

- You can define DCI Book in logical parts based on the study schedule; display of the DCI books is also organized.

- The expected completion of the CRF pages is known through the DCI pages during the study intervals.
- You can define navigation instructions based on protocol rules for measurement appropriateness and interval sequencing.
- You can copy pages within DCI books.
- A study builder is provided with a method to work on DCI books by study interval and CPEs (Clinical Planned Event). It facilitates the process of making changes to a study.
- You can copy a CPE and insert it within a DCI book, including its assigned DCI book pages and branch definitions.
- You can delete a CPE, assigned to another CPE, including its assigned DCI book pages and branch definitions.
- Re-sequencing and re-numbering of DCI book pages is automated when page tracking is not enabled. Re-numbering and re-sequencing takes place for the entire book when intervals or CPEs are inserted or removed from the DCI books.
- You can set or modify the Page expectedness for DCI books. Page expectedness identifies that the CRF page is expected to be completed for the patient as defined by the study protocol.
- DCI book copy includes copy of branch definitions.

### **Conditional and Indicator Branching in HTML Data Entry**

Branching occurs when a data entry interface user is directed to a different set of questions on a form, depending upon the responses entered for a question. Indicator branching supports two branches of a question; conditional branching supports multiple branches of questions.

Conditional branching functionality is provided along with the enhanced functionality of the Indicator branching. The following branching functionality is provided with this release:

- **Defining In-CRF Conditional Branching:** You identify a question as a conditional source question and define different branch rules for the expected responses or range of responses.
- **Defining Indicator Branching:** You identify a question as an indicator question and define an 'indicator value' that enables the remaining questions in the question group.
- **Leveraging Legacy Branch Definitions:** When conditional or indicator branching definitions are already used for Oracle Clinical, existing definitions can be activated for use in graphic DCI Form layouts for HTML data entry.
- **Configuring Visual Representation:** You are provided with options to specify a visual mechanism by which questions are represented as disabled in the HTML data entry window. You can select an option to represent the disabled questions as either 'grayed out' or you can completely hide the section of the form representing the conditional target blocks.
- **In-CRF Conditional Branching in HTML Data:** Questions in all conditional and indicator target blocks are disabled until a response to the source question is entered. Once it is entered, questions in the appropriate target block are enabled and focus goes to the first question in the target block.

## Support for Flexible Studies

You can designate a study as Flexible, when it is created in Oracle Clinical 4.6. You can choose an option in the Clinical Study States form to indicate whether the study is Flexible or Non-Flexible. This setting can be changed for a study that has no test or production data. It is possible to designate an existing traditional (i.e., Non-Flexible) study as Flexible, and a Flexible study as Non-Flexible.

**Setting Intervals to Expected Definition:** A study builder can define a question that can set intervals to expected. Study builders can identify a DCI page that contains a question, which can set the interval to Expected. This can be done for any DCI page in a book including the pages marked as 'conditional'. The intervals must be positioned after the DCI page containing the source question and they need not be sequential. As the interval becomes expected, all its CPEs and all DCIs within those CPEs become expected. Users can edit and add additional intervals or DCI pages expected definitions during the course of the study.

**Setting DCI Page(s) to Expected Definition:** A question can be defined that can set DCI pages to expected. A study builder can identify a DCI page that contains a question, which can set the DCI pages to expected. This can be done for any DCI page in a book including the pages marked as conditional. DCI Pages marked as expected can be within CPE, within the same interval or across intervals. The DCI containing the source question must be positioned within the same CPE or in a CPE that precedes the CPE containing the DCI Pages that are set to expected.

The source question must be in a specific format and should conform to the Expected Definition Rules.

**Modifying Intervals or DCI Pages:** You can add and edit additional intervals or DCI page expected definitions during the course of the study.

Intervals or DCI pages become no longer expected as a result of modification to the source question data. However, if the data exists for these Intervals or DCI pages, any DCIs with data that are no longer expected will continue to be available through RDC user interface at runtime.

The application audits all changes made to branch intervals or DCI page definitions.

**Tracking Expected Pages for Each Subject:** When source question expected rules are met, conditional DCI pages or intervals are marked as 'expected' for a subject. If a response for a source question changes, the source question expected rules are no longer met and conditional DCI pages or intervals marked as 'expected' are reverted to the status 'not expected' for a subject.

## Support for RDC Data Entry and Batch Validation without Interruption

Batch validation is run at the same time the data is entered in the application, without impacting application performance. The support for RDC data entry and batch validation is available at all times without interruption.

The following enhancements facilitate concurrent data entry and batch validation:

- Batch validation is performed concurrently with data entry, without hanging the sessions.
- Batch validation is run without failures when documents are locked by RDC.
- Batch validation is successful even if a user has a document containing a response that has a validation status change since the last batch validation.
- Two versions of a derived response are created, if an online or DCM procedure and batch validation are running at the same time.

- It is possible to run a batch validation when documents are undergoing Pass 1 data entry without corrupting the documents.
- TMS derives the data back to Oracle Clinical at the time of batch validation, without any deadlocking or crashing issues.
- Locked documents are tagged and are processed during the next batch validation run. Documents containing the questions connected to TMS are processed during the next TMS process.
- Batch validation is run successfully without data corruption for new or existing documents that become accessible for the first time, before the last batch validation was performed. The documents are tagged and are processed in the next batch validation.

### **Discrepancy Management related Enhancements**

If manual discrepancies exist, the role of the user who created the discrepancy is displayed, along with the discrepancy ID in the discrepancy details window of the HTML data entry page. You can view the discrepancies based on your role.

You can answer or route a discrepancy that is not active for you. In RDC, you can hide the discrepancies based on the user role and review status of the discrepancy.

Access control to update other discrepancies is configured at the database level, preventing unauthorized modification of other discrepancies.

### **Other Enhancements**

In addition to the foregoing, the following enhancements are made in the application:

- A new zero footprint HTML data entry interface is provided to replace the PDF interface.
- The phase name in the multi-patient casebook page is prefixed to the current visit name.
- With improved scalability of the middle tier, the application supports additional concurrent users, minimizing the requirement for additional hardware.
- The application provides a mechanism for capturing relevant details required for troubleshooting data entry problems.

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# System Overview

Oracle Clinical is a database application that streamlines clinical trial management. It provides tools to manage all of clinical trial activities from your organizational infrastructure to preparing your results for submission. The foundation of the application is a flexible data model with the following features:

- A Global Library of reusable objects
- A comprehensive set of tools for capturing the components of the clinical trial protocol
- A flexible method for structuring the questions that appear on Case Report Forms (CRFs)
- Automated procedures for generating and customizing data entry windows (forms) that correspond to the CRFs
- Tools to define complex data validations and derivations that require little or no programming
- A discrepancy database automatically synchronized with changes to both the clinical trial data and the validation definitions
- A flexible internal data structure for storing the clinical trial data that provides the ability to reorganize data for extract
- Tools to maintain lab reference ranges across multiple studies

## Oracle Clinical's Main Parts

At the highest level, Oracle Clinical is organized around seven major clinical trial activities. There is a navigation aid for each of these activities in the application's navigation panel. These are the menu items:

- Design
- Definition
- Conduct
- Extract
- Administration
- Lab ranges
- Global Library

The following sections summarize the functions of each of the major subsystems that comprise the top level of Oracle Clinical's navigation panel.

## About the Administration Subsystem

The Administration subsystem includes all functions that support other Oracle Clinical subsystems. Specific functions include the following items:

- Reference codelists
- Data Entry administration
- Global Library administration
- User account maintenance
- System security
- Replication

See the *Oracle Clinical Administrator's Guide* for more information.

## About the Plan Subsystem

Use the Plan subsystem to model your organizational infrastructure and to create planned studies. You can define Programs, Organizational Units, Regions, and Planned Studies to model your organization's infrastructure.

See the *Oracle Clinical Creating a Study* guide for more information.

## About the Design Subsystem

Design provides a facility to capture the detailed design of a clinical study as described in the study protocol. Use the Design system to define your studies, Investigator and Site records, Treatments, Strata, Randomization strategy, and Patient Position records.

See the *Oracle Clinical Creating a Study* guide for design information, and the *Oracle Clinical Conducting a Study* guide for runtime information.

## About the Global Library

The Global Library is the central repository for the objects that compose data collection definitions for clinical studies. In addition, you can store standard versions of the study collection objects for reuse in other studies. You can define separate domains, or namespaces, within the Global Library for different purposes, and you can classify objects in the Library to provide guidance for their use.

These are the definitions you manage in the Global Library:

- Questions — The elementary units of data collection comprising data point.
- Question Groups — A group of questions that have a logical relationship to each other that you usually collect together.
- Discrete Value Groups — A list of the valid responses to a question.
- Data Collection Modules— Organize question groups into the sets that are collected together.
- Data Collection Instruments — Organize data collection modules to facilitate data entry from Case Report Forms.
- Extract macros, Where clauses, key templates, view templates, and view definitions — Allow user-defined data extract and data browse.

The Global Library provides the facility to create and copy certain objects, as well as storing them. You can also define their required and recommended usage of the library objects for particular types of clinical studies and the tools for monitoring compliance with these standards.

See the *Oracle Clinical Creating a Study* guide for more information.

## About the Definition Subsystem

The Definition subsystem covers four basic activities:

- Creating data collection modules (DCMs), data collection instruments (DCIs), and, optionally, DCI Books, which describe the data to be collected for a study.
- Creating data entry windows corresponding to the data collection modules.
- Assigning the data collection modules to the clinical planned events at which they are to be collected.
- Creating Validation and Derivation Procedures for the data to be collected.

See the *Oracle Clinical Creating a Study* guide for more information.

## About the Conduct Subsystem

Conduct deals with entering, tracking, and cleaning clinical trial data. This subsystem encompasses the following functions:

- Log-In — Enter key information that identifies CRFs and creates the CRF tracking database.
- Data Entry — Complete first-pass and second-pass (verification) data entry.
- Batch Data Load — Load data from electronic sources rather than by manual methods.
- Batch Validation — Execute Validation and Derivation Procedures on new and changed data.
- Discrepancy Management — Guide the data query and correction process by taking note of the discrepancies recorded in the discrepancy database.
- Data Update — Interactively correct data values through data entry windows.
- Data Freezing and Locking — Control access to data to prevent unauthorized modifications.
- Data Browse — Review data in the interactive data entry windows in a read-only mode.
- Study Conduct Reports — Run reports that help visualize the current state of data acquisition and monitor the overall progress of data collection.

See the *Oracle Clinical Conducting a Study* guide for more information.

## About the Labs Subsystem

The Lab Reference ranges subsystem provides facilities for maintaining information about labs, and about the reference ranges for lab tests, performed at those labs. Oracle Clinical also provides functions to define the allowable units for specific lab tests and rules for converting between various units. Finally, you can define the criteria for

associating a lab with particular studies, patients, visits, or forms, and you can override the default association for particular data.

Lab ranges are also available from within Oracle Clinical's validation and derivation procedures.

See the *Oracle Clinical Creating a Study* guide for design information, and the *Oracle Clinical Conducting a Study* for runtime information.

## About Data Extract

Data Extract consists of activities to create and maintain Data Extract Views, as well to create SAS pass-through views and SAS datasets based on these views. You define your Data Extract Views in the Definition subsystem, and you extract data from the Conduct subsystem.

Data Extract Views are Oracle RDBMS view definitions that allow you to access the data stored in Oracle Clinical in the same way you would access any other data stored in an Oracle database. A *view* is a database object that you can query like a database table. You can query Oracle Clinical's views with any data query tool that can access Oracle tables— for instance, Oracle's Discoverer 3.1 or Oracle Reports.

See the *Oracle Clinical Creating a Study* guide for design information, and the *Oracle Clinical Conducting a Study* for runtime information.



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## Logging into Oracle Clinical

This section contains the following topics:

- [Logging In](#) on page 2-1
- [Troubleshooting Login](#) on page 2-1

### Logging In

A **session** starts when you log into Oracle Clinical and ends when you log off. When you log in, you establish a connection between your browser and an Oracle Clinical Web Server. The Web Server moves information between you and the Oracle Clinical database. Follow these steps to start a session:

1. Open the Oracle Clinical launch page in your Web browser. Your system administrator can supply the hyperlink. By default, if you're connecting to a computer named *oc1* and your intranet's link named *mycompany.com*, the link looks like this:

`http://oc1.mycompany.com/opa50/launch.htm`

2. Click **Login**. You might be prompted to download and install a required browser plug-in. If so, install the plug-in, then return to these instructions.

Clicking the **Login** button triggers a series of activities in the background. First, a small window opens. If you close this window you disrupt your connection to parts of the application, so don't close it until you end your Oracle Clinical session. Next, login dialog box is displayed.

3. Complete the login dialog box fields according to the information supplied by your system administrator. Note that the characters *ops\$* precede your username.
4. Click **Connect**. An Oracle Clinical session opens, displaying the Navigation window.

### Troubleshooting Login

This section gives a brief analysis of some of the problems that can occur when you log in.

**I do not remember my password or do not have an account.**

See your system administrator.

**After entering username, password, and database name, I get an error message.**

Note that you are adding the characters `ops$` before your user identification. If so, see your system administrator.

**When I try to open a second session from the launch page, the window for the first session becomes blank.**

You cannot start more than one Oracle Clinical session from the same computer.

**Can I log onto Oracle Clinical from different computers?**

If you log onto Oracle Clinical as the same user from different computers, you can run multiple sessions of Oracle Clinical, as long as all of the sessions are either in test or production mode. If you try to start a new session that is not in the same mode, the new session fails. The sessions can connect to the same database.

**I closed my Oracle Clinical browser window because it froze. However, when I try to log in again, the same frozen screen appears.**

Your browser is loading the frozen page from its cache. Follow these instructions to empty the Internet Explorer cache:

1. From the Internet Explorer menu bar, select **Tools** and then select **Internet Options**.
2. Select the **General** tab.
3. In the Temporary Internet files panel, click **Delete files**. You can set the browser so that you avoid this problem in the future, but at the expense of always downloading every page you visit on the Web. To prevent ever loading a cached page follow these instructions:
  - a. Click **Settings**.
  - b. Choose the **Every visit to the page** option.
  - c. Click **OK**.
4. Close the Internet Options dialog box and try to log on.

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## Introducing the Oracle Clinical Interface

The Oracle Clinical application has over one hundred windows for maintaining clinical data. Some users see more windows than others because different privileges expose different parts of the application. This chapter describes how to find the right window, and how to use the window's tools.

This chapter contains the following sections:

- [Navigating Oracle Clinical](#) on page 3-1
- [Using the Mouse, the Arrow Keys, and the Keyboard](#) on page 3-8
- [About Oracle Clinical Windows](#) on page 3-3
- [Basic Actions](#) on page 3-5
- [Internal Menus](#) on page 3-9
- [Entering Data](#) on page 3-14
- [Entering Queries](#) on page 3-15
- [Getting Help](#) on page 3-16

### Navigating Oracle Clinical

Each of Oracle Clinical's subsystems is organized into expandable nodes.

#### About the Navigator Panel

When you first open Oracle Clinical, there is a Navigator panel on the left side of the window. Each item in the panel is an Oracle Clinical subsystem. Each subsystem has an expandable *node*, that you can expand to reveal the contents of the subsystem all of the windows related to working in the subsystem. Clicking a node *expands* it to reveal its entries, and changes the plus symbol to a negative symbol (-). In [Figure 3-1](#), there is a circle around the expanded Data Entry node.

Oracle Clinical documentation describes the navigation path you follow to open a window with a statement like:

Select **Data Entry**, then **Initial Log-in**

The above instruction indicates to click the node beside the **Data Entry** subsystem entry, then click the **Initial Log-in** entry. If you follow this action, the system prompts you to choose a study, then opens the Initial Log-in window where you can enter new records.

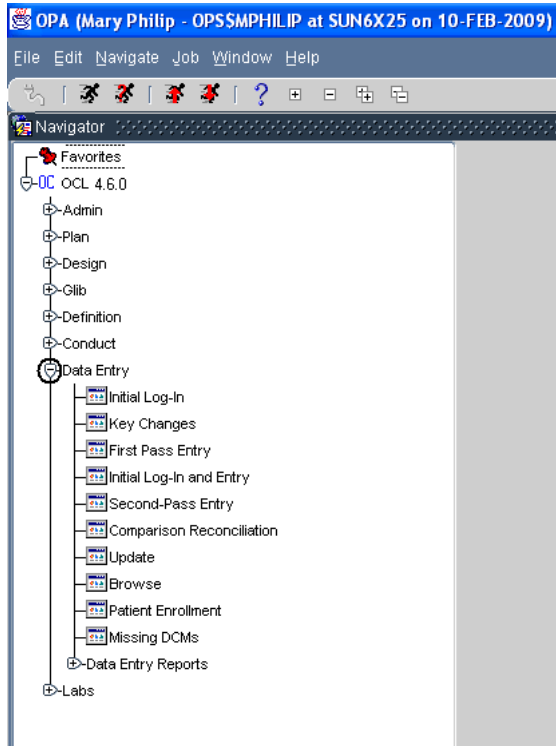
Data Entry subsystem has six data entry modes that correspond to the different stages of data entry, and several data entry maintenance utilities. It contains one expandable

node: Data Entry Reports. Clicking its node expands the entry so that you can run one of the Data Entry reports.

As another example of navigational path, the Global Library subsystem contains more nodes. If you read an instruction in the documentation like:

"Follow the navigation path **Glib**, then **Question Groups**, and **Prov Question Groups**," it means that to open the Maintain Provisional Question Groups window, click the Question Groups node, and then select the Prov Question Groups item. If you follow these instructions, the Maintain Provisional Question Groups window opens.

**Figure 3–1 A Detail of the Oracle Clinical Navigator Panel**



## About Windows

When you have expanded all of the nodes necessary to reveal your target item, you click the item. The system then opens an interface item. The documentation refers to the opened item as a *window*, or sometimes *screen* or *form*, depending on the application. They are mostly online forms where you view or change data in fixed fields. See "[About Oracle Clinical Windows](#)" for a description of the windows' tools.

## About Full and Browse Modes

Many modules have both a *full* privileges mode — where you can change data — and *browse* or *query-only* mode — where you can view existing data but you cannot change it. For example, you can create, update, and delete studies, if you have full privileges to the Maintain Clinical Studies form. If you have browse mode access, you can view the study records by navigating to the **Query Clinical Studies** menu item but you cannot change them. Your organization determines your access. If you have full access to a window but you have no need to change data in it, you can choose to access it in browse mode.

## About Query Mode

Many Oracle Clinical windows open in query mode. In query mode, you enter information to help you find specific records. The window behaves as if you've invoked query mode. You can cancel or execute the query as necessary. See "[Executing Queries](#)" for a complete description.

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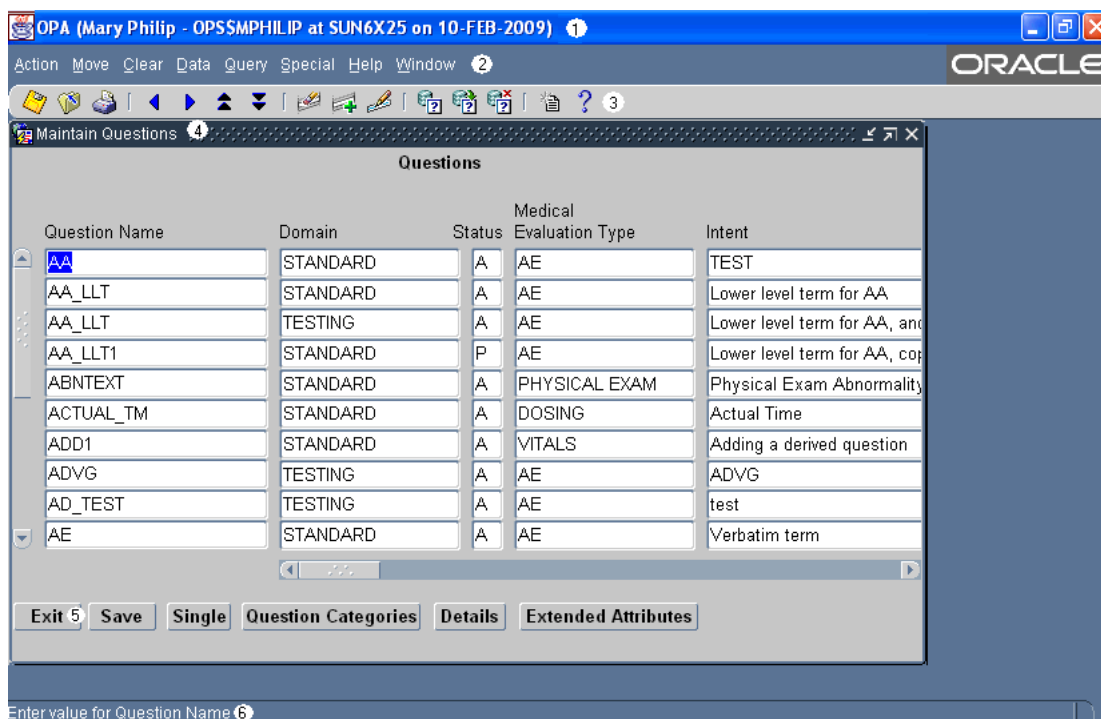
**Note:** The Oracle Clinical help system does not work when you are in query mode. You must exit the query before you invoke help from the question mark icon, or through the F1 key, or through the Help. If you do not exit the query, nothing happens the first time you invoke help. The second time the system displays an information window.

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## About Oracle Clinical Windows

Figure 3–2 shows a sample window, Maintain Questions. The window has numbered circles that correspond to the following sections.

**Figure 3–2** Detail of the Maintain Questions Window



### 1 Window Title Bar

The top line of an Oracle Clinical window is the title bar. The title bar includes this information:

- Your user name
- Your symbolic account name
- The name of the database instance to which you are connected
- The login date

## 2 Menus

The second row in each Oracle Clinical window contains drop-down menus. Some menu items may be disabled.



## 3 Toolbar

The third row in each Oracle Clinical window is a toolbar that you can use to invoke common actions, such as [Insert Record] and [Execute Query]. If you pause the mouse pointer over the icon without clicking, Oracle Clinical displays text describing the icon's function. Toolbar icons are described in [Table 3-1](#) on page 3-6.

## 4 Title Bar

At the top of the work area in the window, a title bar shows the name of the window, in which you are working. It may also display a number of different levels of context, for example:

- the study where you are working
- the part of the window where you are working
- the name of the object you selected in the main window

## 5 Navigation Buttons

The navigation buttons near the bottom of the window enable exiting, saving your work without leaving the window, and to move to related windows. If you click a button that navigates to a window you cannot reach by any other navigation path, the window displays a Back button instead of an Exit button.

If you have unsaved changes in a window, the system prompts you before you can exit.

If a button is inactive, as the **Details** button is in [Figure 3-2](#), you cannot navigate to that window from the current record. This indicates that some criterion that controls access to the destination is unsatisfied.

Each navigation bar includes a **Save** button that writes pending changes to the database. In some forms, the navigation bar also contains a Single/Multi button that allows you to toggle between single record and multiple records. In [Figure 3-2](#) the Maintain Questions window is in Multi-record display. If you could click the Single button in the example, the window would display all of the information about the selected question — AO\_DATE — on one window that you do not have to scroll to view.

## 6 Message Line

The message line provides information about the menu item that you highlight, or about the field where your cursor is located. It displays helpful hints as you progress through a task, and also some error or informational messages. Other messages appear in alert boxes.

## 7 Status Line

The status line contains information related to the data displayed on your window, and to your current options. Oracle Clinical uses three of the status items, as shown in [Figure 3-3](#).

**Figure 3-3 Status Line Items**

**Count** This number indicates the position of the current record among the total retrieved by the query:

When you have...	and the window shows...	the count is:
Just opened a window	no records	1/1
Just opened a window	the one and only record	1/1
Executed a query	the only screenful of records	1/ <i>total</i>
Executed a query	the first screenful of records	1/?
Scrolled down somewhat	another screenful of records	<i>n</i> /?
Reached the last record	the last screenful of records	<i>n</i> / <i>total</i>

Where *n* represents the number of the current record and *total* is the number of records retrieved. The question mark appears because Oracle Clinical does not immediately retrieve all the records that match your query; there might be hundreds. Retrieving a few at a time is more efficient.

**Mode** The words **Enter-Query** in this area indicate that you are in query mode, rather than normal mode. See ["Executing Queries"](#) on page 3-16 for more details on this functionality.

Many Oracle Clinical windows open in query mode. The window behaves as if you've invoked query mode. You can cancel or execute the query as necessary. You enter query mode by clicking F7, selecting **Query**, then the **Enter Query** menu item, or the **invoke query** icon. You then complete the query by entering some search criteria and clicking F8, **Query**, then **Execute Query**, or the execute query icon.

**List** The words **List of Values** means that you can use a dialog box to choose a valid value for the current field. The [List] function opens the dialog box; use the mouse or the arrow keys to select the value you want. See ["List of Values"](#) on page 3-15.

### Horizontal and Vertical Scroll Bars

Scroll bars indicate there is more information in the window in the direction, in which the arrows are pointing. With horizontal scroll bars you can reach more information for each record by moving from field to field across the window horizontally. With vertical scroll bars you can reach more records by using the [Up] and [Down] or [Next Record] and [Previous Record] functions.

If the vertical scroll bar is disabled, all records are already displayed. If there is no horizontal scroll bar, all fields are displayed in the current window.

## Basic Actions

You can invoke basic actions, or functions, in Oracle Clinical in a number of ways; in fact, many actions can be invoked by any of the three following methods:




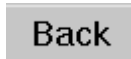





- selecting from the menu (either by keystrokes or by using the mouse)
- pressing a single function key sequence
- clicking on a toolbar icon or navigation bar button

For example, [Save] can be invoked by selecting a menu item, by clicking a navigation bar button, or by pressing a function key sequence.

The key mappings listed below are applicable to a standard PC keyboard. You can view the key mapping for all functions on your PC keyboard by invoking the [Show Keys] function.









[Table 3–1](#) summarizes instructions for the most frequently required navigations and interactions with fields. All the functions are described in detail, grouped by their menu item and functional group, under "[Internal Menu](#)" on page 3-9.

**Table 3–1 Different Methods of Invoking Functions**


Function Description	Keys	Menu	Mouse
<b>Save</b> Writes (commits) pending changes to the database.	F10	<b>Data, then Save</b>	
<b>Exit</b> Exits from a module window to the main menu.	Ctrl+q	<b>Action, then Exit</b>	
<b>Emergency exit</b> Closes window without prompting to save.	Shift+F7	<b>Action, then Exit without Saving</b>	
<b>Back</b> Exits from a detail window to the previous window.	Ctrl+q	<b>Move, then Back</b>	
<b>Enter Query</b> Clears window and places form in enter query mode. You can then enter query criteria.	F7	<b>Query, then Enter Query</b>	
<b>Execute Query</b> Retrieves records from the database that match query criteria.	F8	<b>Query, then Execute Query</b>	
<b>Count Query Hits</b> Displays the number of records from the database that match query criteria.	Shift+F2	<b>Query, then Count Hits</b>	—
<b>Cancel Query</b> Cancels query mode and returns you to insert mode.	Ctrl+q	<b>Query, then Cancel</b>	
<b>Clear Record</b> Clears current record from window but does not delete the record from the database.	Shift+F4	<b>Query, then Clear Record</b>	
<b>Insert Record</b> Inserts a new record.	F6	<b>Data, then Save</b>	
<b>Duplicate Record</b> Copies all values of the previous record and pastes them into the current record, overwriting current values, if any. Available in some modules, for some actions. Requires a previous record from which to copy.	F4	<b>Data, then Duplicate Rec</b>	—
<b>Duplicate Item</b> Copies the value of the same field in the previous record and pastes it into the current field. Requires a previous record from which to copy.	F3	<b>Data, then Duplicate Field</b>	—



**Table 3–1 (Cont.) Different Methods of Invoking Functions**

<b>Function Description</b>	<b>Keys</b>	<b>Menu</b>	<b>Mouse</b>
<b>Previous Record</b> Moves the cursor to the previous record.	Shift+↑	<b>Move, then Previous Record</b>	
<b>Next Record</b> Moves the cursor to the next record.	Shift+↓	<b>Move, then Next Record</b>	
<b>First Record</b> Moves cursor to first record retrieved by query, re-displaying that record, if necessary. Not available in single-record view.	—	<b>Move, then First Record</b>	
<b>Last Record</b> Moves cursor to last record retrieved by query, re-displaying that record, if necessary. Not available in single-record view.	—	<b>Move, then Last Record</b>	
<b>Help</b> Displays field help and the Help dialog box for access to Extended Help.	Ctrl+H	<b>Help, then Help</b>	
<b>List</b> Displays the list of values (LOV) for fields that have one.	F9	<b>Help, then List Values</b>	
<b>Change Format</b> Toggles from multi-row to single-row display format; not available in all forms.	—	<b>Move, then Change Format</b>	
<b>Change Format</b> Toggles from single-row to multi-row display format; not available in all forms.	—	<b>Move, then Change Format</b>	
<b>Select Study</b> Sets/changes the study for the form where you are working; not available in all forms.	Ctrl+Shift+S	<b>Special, then Select Study</b>	—
<b>Define Domain Searchlist</b> Allows you to change your user domain searchlist; not available in all forms.	Ctrl+Shift+D	<b>Special, then Define Domain Searchlist</b>	—
<b>Previous Item</b> Moves the cursor to the previous item.	Shift+Tab	<b>Move, then Previous Field</b>	—
<b>Delete Record</b> Deletes current record from the database. You must save after invoking this action.	Shift+F6	<b>Data, then Delete Record</b>	—
<b>Clear Block</b> Clears data from the module window.	Shift+F5	<b>Clear, then Clear Block</b>	—
<b>Clear Item</b> Clears the value from the current field.	Ctrl+u	<b>Clear, then Clear Field</b>	—

**Table 3–1 (Cont.) Different Methods of Invoking Functions**

Function Description	Keys	Menu	Mouse
<b>Edit Field</b> Displays the field text in a multi-line text editor for editing long fields.	Ctrl+e	<b>Data, then Edit Field</b>	
<b>Show Keys</b> Lists keyboard keys that correspond to certain application functions.	Ctrl+K	<b>Help, then Key Definitions</b>	—
<b>Display Error</b> Shows the most recent error(s), if any.	Ctrl+D	<b>Help, then Display Error</b>	—

## Using the Mouse, the Arrow Keys, and the Keyboard

You can make a selection from the main menu in one of these ways: with the mouse, with the arrow keys, or from the keyboard.

You navigate in most submenus with the same methods. All menu items have an underlined letter that is unique within that menu.

When a menu name is followed by a triangle pointing to the right, that menu item brings up a submenu rather than a window.

### With the Mouse

Oracle Clinical menus are "snap-down" not "pull-down". This means you click them, not drag.

1. Put the cursor on the menu you want.
2. Click the left mouse button once to highlight the item. The corresponding menu appears, with one of its items highlighted as a default.
3. To execute the highlighted item, click the left mouse button again.  
To make another selection on the same menu, move the cursor to that item before you click. The corresponding submenu or module window appears.
4. After you have clicked on one menu, you can navigate along the menu bar by moving the pointer. The menus dynamically display as you move off the edge of your first selection.
5. To reach the module you want, continue along the menu path in this way. The module window opens when you have clicked the final menu-path item, the end of that branch of the menu tree.

### With the Arrow Keys

1. Press Alt and then the underlined letter of the menu you want.  
This snaps down and highlights that menu.
2. Use the arrow keys to move between menus, which are highlighted one by one as you move the arrow keys over them.
3. Press Enter to select the item you want, once it is highlighted.
4. Repeat steps 1 to 3 until you reach the window you want.

### From the Keyboard

1. Press Alt and then the underlined letter of the menu you want.

This snaps down and highlights that menu.

2. Press the underlined letter of the item you want.

Repeat, if necessary, until you reach the window you want.

## Internal Menus

This section lists and describes the items available from the menus that appear in every Oracle Clinical module window.

The Special menu is unique to each module, and is described with each module. Only those special functions common to multiple modules are described in this chapter.

In the following sections, for each menu a table maps the menu items to the equivalent functions. See [Table 3-1](#), or use the [Show Keys] function, for other methods of invoking the function.

## Action Menu

With the Action menu you perform the actions described in [Table 3-2](#).

**Table 3-2** *Action Menu Items*

Menu Item	Equivalent Function(s)	Description
Audit	—	Displays the Audit window.
Environment	—	Displays the Environment window.
Batch Jobs	—	Displays the Submitted Batch Jobs window, which shows the status and other details of batch jobs submitted via the Parameterized Submission Facility (PSUB).
<u>R</u> eport Queue Manager	—	First displays a window, where you can select a server computer to run your reports or schedule your batch jobs. Then opens the Reports Queue Manager for that Reports Server.
Print Screen	[Print]	Prints current window to your locally defined printer.
Exit	[Exit] or [Cancel]	Exits from current window to main menu or first cancels the current action, if any; e.g., in query mode, the query is canceled.
Exit Without Saving	Shift+F7	Exits from current window, even when you are in a mandatory field.

### Audit

The Audit function opens the Audit pop-up window to display audit trail information for the current record. This information is at the record level, rather than at the object level. In Data Entry, extensive auditing information is available for responses, received DCMs, and received DCIs. Fields for the Audit window are listed and described in [Table 3-3](#).

**Table 3-3** *Audit Window Fields*

Name	Description
Date Created	Date and time the record was created
Created By	Name of the user who created the record

**Table 3–3 (Cont.) Audit Window Fields**

<b>Name</b>	<b>Description</b>
Date Modified	Date and time the record was last modified
Modified By	Name of the user who last modified the record

**Environment**

This function opens the Environment window, which displays information about the current user, your location within the system, and other study- and database-specific contextual information.

Fields for the Environment window are listed and described in [Table 3–4](#).

**Table 3–4 Environment Window Fields**

<b>Name</b>	<b>Description</b>
User Id	Userid with which you connected to Oracle Clinical in this session.
Database Name	Name of the database to which you are connected.
Current Study	Name of the current study, if you have set a study in this session.
Version Number	Version of the current study, if you have set a study in this session.
Owning Location	Name of the database that is the source of, or that "owns", the data. If this value is different from the value in the Database Name field, the data has been replicated from the database listed in this field. Replicated data cannot be modified.
Locate Study	Name of the study where you are locating an object—only set if you are in Locate mode.
Version Number	Version number of the study where you are locating an object—only set if you are in Locate mode.
Current Date	Today's date and time.
Current Location	Name of the location of the database.
Glib Location	Name of the location that owns the Global Library (Glib) that is the source of the study definition. If this value is different from the Current Location, this is not the Glib-owning database, and the study definition cannot be modified.
Current Screen	System name for the window where the cursor is located.
Current Module	System name for the module where the cursor is located.
Current Block	System name for the module block where the cursor is located.
Current Task	System name for the task in which the module is running.

**Batch Jobs and Report Queue Manager**

These items are explained in detail in [Chapter 4, "Submitting Batch Jobs and Reports"](#).

**Move Menu**

The Move menu gives you options for navigating within the module window, between module windows, and back to the main menu.

**Table 3–5 Move Menu Items**

Menu Item	Equivalent Function(s)	Description
Back	[Back]	In a detail window, this function takes you back to the previous window.
Change Format	—	Toggles the display between the multi-record format and the single-record format of the same module. Not available in all modules.
Previous Zone	[Previous Zone]	Moves cursor to the beginning of the previous block or area.
Next Zone	[Next Zone]	Moves cursor to the beginning of the next block or area.
Previous Field	[Previous Item]	Moves cursor to the previous field.
Next Field	[Next Field]	Moves cursor to the next field.
Previous Record	[Previous Record]	Moves cursor to the previous row or record up.
Next Record	[Next Record]	Moves cursor to the next row or record down.
First Record	[First Record]	Moves cursor to the first record retrieved by the query, redisplaying that record if necessary.
Last Record	[Last Record]	Moves cursor to the last record retrieved by the query, redisplaying that record if necessary.

## Clear Menu

The Clear menu allows you to remove data from fields, records, and blocks. These functions can clear data retrieved in response to a query, or clear data that you have input. This functionality can be useful in clearing error-filled record or field values that cannot be saved to the database because of validation problems.

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**Note:** *Clearing* a record simply removes it from view; if it has been saved to the database, it can be re-queried. *Deleting* a record and then saving it removes it from the database permanently.

---



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**Table 3–6 Clear Menu Items**

Menu Item	Equivalent Function(s)	Description
Clear Record	[Clear Record]	Erases the entries in all fields in the current record without changing the database.
Clear Field	[Clear Item]	Erases the entry in the current field.
Clear Block	[Clear Block]	Erases the entries in all fields in the current block.
Refresh	[Refresh]	Clears system messages from the screen and re-displays the original window with all data and entries intact.

## Data Menu

The Data menu enables you to perform actions on the data such as saving, inserting, deleting, and copying.

**Table 3–7 Data Menu Items**

<b>Menu Item</b>	<b>Equivalent Function(s)</b>	<b>Description</b>
Insert Record	[Insert Record]	Adds a new blank record below the current record, and moves the cursor position to the new record.
Delete Record	[Delete Record]	Removes the current record from the database. This action does not take place until you save the change.
Duplicate Rec	[Duplicate Record]	Copies all values of the previous record and pastes them into the current record, overwriting current values if any. Available in some modules, for some actions. Requires a previous record from which to copy.
Duplicate Field	[Duplicate Item]	Copies the value of the same field in the previous record and pastes it into the current field. Requires a previous record from which to copy.
Edit Field	[Edit]	Displays edit box, where you can read and edit up to 2,000 characters. See the section " <a href="#">Using the Editor Window</a> " on page 3-12.
Save	[Save]	Writes (commits) changes made in the form to the database. If you do not save the changes, you cannot query them at a later time.

### Adding and Copying Records

To add a new record to the database, select **Insert Record**. The function creates a new record with no values directly below the record where your cursor was, and moves the cursor down to the beginning of the new record. This leaves you in position to start entering values.

In some cases, you may want to add several records that are similar to each other. For example, creating multiple occurrences of a question, where every field except the sequence number has the same value.

If the [Duplicate Record] function is available, use it as follows:

1. If there is an existing record that you want to copy, move the cursor there. (If not, add one.)
2. Make sure you are in a multi-record form. (If not, click **Multi**.)
3. Select [Insert Record].
4. Select [Duplicate Record].
5. Edit the fields that should be different.

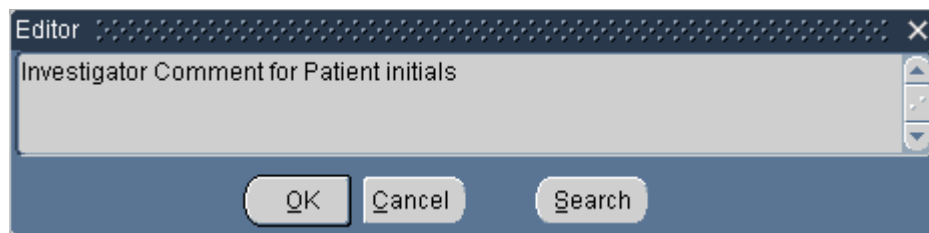
To copy a single field, select [Duplicate Item].

### Using the Editor Window

The Editor window enables you to edit the contents of any enterable field. You cannot use the Editor for fields that use Lists of Values (LOVs).

To use the Editor window:

1. Move the cursor to the field where you want to enter text.
2. Invoke the Editor window by choosing **Data**, then **Edit Field** or clicking Ctrl+e. The Editor window opens, with the cursor at the beginning of the window.



3. Use the Editor to enter and modify the text, or to search for text you want to change. You can see all the text in the box at one time.
4. Click **OK** to return to the original input field.

## Query Menu

The Query menu gives you several query options. See ["Executing Queries"](#) on page 3-16 for more details on performing queries.

**Table 3–8 Query Menu Items**

Menu Item	Equivalent Function(s)	Description
Enter Query	[Enter Query]	Changes to query mode, where you can define query parameters.
Execute Query	[Execute Query]	Performs the defined query.
Count Hits	[Count Query Hits]	Displays the number of records that would be retrieved, without retrieving the data itself.
Last Criteria	[Enter Query] twice	Changes to query mode, and re-displays the last defined query criteria.
Cancel	[Cancel]	Cancels the current action.

## Special Menu

The Special menu varies from module to module and is described for each module in the applicable chapter; however, two Special menu functions appear in many modules and are listed here.

Most module-specific special functions have function key equivalents displayed in the Key Definitions table. Press [Show Keys] in each module to see the function key equivalents for module-specific special functions.

**Table 3–9 Generally Applicable Special Menu Items**

Menu Item	Equivalent Function(s)	Description	Accelerator Key
Select Study	[Select Study]	Changes the study where you are working. Available in modules that require a study context.	Ctrl+ Shift+S
Define Domain Searchlist	[Define Searchlist]	Allows you to modify your user domain searchlist, which determines the domains you access, and your domain precedence.	Ctrl+ Shift+D

### Select Study

Many Oracle Clinical modules require that you set a study context, or identify the clinical study you want to work with, before you begin processing. When you enter a

module that requires a study context, if you have not yet selected a study for the current session, the **Select Study** pop-up window appears.

You can either type the study name, or select a study from the list of values, which lists only those studies to which you have access. Then select **OK** to continue processing. If you do not choose a study, or try to choose a study to which you do not have access, you cannot continue processing. Contact your system administrator for questions about study access.

Once you have chosen a study, it is generally displayed for context in the title bar of the module window and remains the same until you change it. You are not prompted to change the study, even if you exit the current form and enter another that requires a study context.

If you are in a study context-sensitive form and want to change your study context, you can either select the **Change Study** icon from the toolbar, select **Special**, then **Select Study** from the menu, or press the key equivalents to [Select Study]. The Select Study pop-up window appears, and you can choose another study.

### Define Domain Searchlist

The domain searchlist defines which of the available domains you can access while working in the Global Library. You can only view those objects that belong to domains to which you have been given access. If you are in a form that maintains Global Library objects and have access to this function, you can redefine the domains, and thus the Global Library objects, that you can access.

## Help Menu

The Help menu offers information about the system, such as Key Definitions and Display Error, and the online help system. See also "[Getting Help](#)" on page 3-16.

**Table 3-10 Help Menu Items**

Menu Item	Equivalent Function(s)	Description
Help	[Help]	Displays help text about the field where the cursor is located. You can then access hyperlinked text about the associated topics.
Key Definitions	[Show Keys]	Displays the list of function keys on your keyboard that correspond to functions.
List Values	[List]	Displays a list of valid values for the current field, if the field has a list of values (LOV) associated with it.
Display Error	[Display Error]	Displays details about the last error message received.

## Entering Data

Oracle Clinical enables you to enter data in the following ways: by typing characters in the field; by selecting from a list of valid values; or by copying objects stored in the database. Determine data types and formats appropriate to each field in each module by checking field help.

### Check Boxes

Some forms contain check boxes, which are fields that require YES or NO answers. A YES answer is equivalent to a checked box, while a NO answer is equivalent to a blank, or clear box.



To answer YES, navigate to the check box, and either click the box with the mouse, or press the space bar. A check appears in the check box. Another click, or pressing the space bar twice, removes the check, leaving the box in the cleared, or NO, state.

## Case Sensitivity

For many alphabetic fields, such as name, you can type in all lowercase letters, but the characters appear on the window in uppercase, and the data is saved to the database as uppercase. Other fields, such as comments, are case sensitive, and are saved to the database with the input exactly as you type it.

## Using Long Fields

Some fields accept more characters than are displayed on the form. For example, the Comments field may display only 80 characters, but it has the capacity to contain up to 200 characters.

There are two ways to enter or view text in a field that is longer than the display: typing into the field directly, or using the field editor pop-up window (see the section ["Using the Editor Window"](#) on page 3-12). When you type in text directly, to view the text, scroll through it, using the left and right arrow keys.

## List of Values

For some data fields in the system, a list of values (LOV) contains all the valid entries for that field. When you move into one of these fields, List of Values appears on the status line at the bottom of the window. Select [List] to view the list of valid values for the field. The list of values pop-up window appears.

To enter a value into a field from a list of values, follow these steps:

1. Select [List] to display the list of values.
2. Move the cursor to the value you want, either by clicking on the selection, or by moving to the selection with the up and down arrows.
3. Choose one of these methods to enter that value in the field you want:
  - select [OK]
  - type a carriage return
  - double-click on the selection

You can sometimes limit the listing by entering a character string, which serves as selection criteria, in the Find field of the list of values pop-up box. Oracle Clinical then displays only the items that meet these criteria. To use a wildcard in this box, first place your cursor in the field and type a search pattern, using the percent sign (%) to represent any number of characters. Then select [Find] or type a carriage return. In response, Oracle Clinical displays matching values from which you can make a single selection for your current field.

## Entering Queries

Most of the fields you see in the windows are database fields. You can retrieve records from the database that contain specific values in these fields by entering search criteria in the fields and then performing a query.

The two functions required for performing a query are [Enter Query] and [Execute Query]. You enter query mode by pressing F7, or the **Query**, then **Enter Query** menu

item, or you invoke the query icon. You then complete the query by entering some search criteria and pressing F8, or **Query**, then **Execute Query**, or the execute query icon.

When you invoke query mode the system clears the window of existing records, and you can enter your query specifications. If you have pending changes when you press [Enter Query], the system prompts you to save your changes first.

The module window indicates query mode in the status line. While in query mode, you can use lists of values, enter standard SQL wildcards in fields, and skip mandatory fields. The system suspends normal field validations while you are in query mode, since it is allowing you to use the module window to enter query criteria, rather than validating a record in preparation for saving it to the database. Some forms have fields that do not accept query criteria, so you cannot enter anything in those fields while in query mode. These are usually fields that do not correspond directly to fields in the database.

## Pattern Matching With Wildcards

The **wildcard** character (%) can substitute for a letter or group of letters when you enter the value. So, if you enter TET% as the current value for the parameter DRUG, the system looks for a drug name beginning with "TET." If you enter %TET, the system looks for a drug name ending with TET. If you enter %TET%, the system looks for a drug name containing TET in any position. You cannot search for a single character — for example, *TEsingle characterT*.

## Executing Queries

After you have entered your query criteria, select [Execute Query]. Oracle Clinical retrieves from the database all records that meet your query criteria, and populates the window.

If you simply want to know the number of records that would meet your query criteria, select [Count Hits] rather than [Execute Query]. Instead of retrieving the records, Oracle places the number of records that meet your query criteria in the Count field of the status line.

If your query retrieves no records, the system displays the following message on the message line:

```
Query caused no records to be retrieved. Re-enter
```

The criteria that you entered remain displayed. You are still in query mode, so you can simply change your criteria and then select [Execute Query] without having to select [Enter Query] again.

If you have already executed a query and press [Enter Query] twice in a row, you are placed in query mode, and the query criteria that you last entered are re-displayed.

Once the query successfully retrieves records, you are no longer in query mode, but in normal operational mode, and you can create, update, or delete records as your privileges allow.

## Getting Help

Oracle Clinical provides hints, field help, the extended help system (Xhelp), and a custom help option.

Help Type	How Displayed	Description
Hint	In the task bar at the bottom of the Oracle Clinical window	The system displays a brief description of the currently selected field.
Field help	F1 <b>Help, Help</b> The Help icon on the toolbar	The system describes the currently selected field in the Oracle Clinical Field Help box, usually at greater length than is possible in the toolbar hint.
Xhelp	The More button in the Field Help box	Task-related information about your current Oracle Clinical activity. XHelp displays in a Web browser.
Custom help	The Custom button in the Field Help box	If the Custom button in the Field Help box is active, instead of the More button, you can see information written by your company.

## Field Help

To display information about a particular field, invoke help by clicking the F1 key, following the menu path **Help**, then **Help**, or clicking the question mark icon on the toolbar.

---

**Note:** The Field Help box cannot open in Query mode. Many windows in Oracle Clinical open in this mode. You must execute or cancel the query before you invoke field help. Attempts to display the Field Help box in Query mode displays the [Properties of Item Window](#). The information in this window is not related to online help.

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## Xhelp

Xhelp is an integrated set of topics that works with Oracle Clinical to display information about your current activity, or that you can display without Oracle Clinical. To open Xhelp from Oracle Clinical, click the **More** button in the Field Help box. You can move about through the topics by means of hyperlinks and graphic workflows, described in "[Navigating Xhelp](#)" on page 3-17. If you want to view Xhelp without running Oracle Clinical, see "[Viewing Xhelp without Oracle Clinical](#)" on page 3-18.

### Custom Help

If your organization has chosen to author customized information, you click the **Custom** button in the **Field Help** box to view context-sensitive help. The help you reach from the Custom button takes advantage of the same context-sensitive structure as the Oracle-provided Xhelp content. See "Creating Custom Help Files" in the *Oracle Clinical Administrator's Guide* for information on setting up custom help.

### Navigating Xhelp

When you first invoke Xhelp, the browser window opens in a single view mode. In this mode, only the selected Xhelp topic is displayed, and the window hides the Navigator, which can display all of the topics for the selected subsystem in a hierarchical format. You can reveal the Navigator by clicking the **Show Navigation** button.



### Viewing Xhelp without Oracle Clinical

Xhelp topic files are written in HTML, so you can display them directly in a Web browser. In your browser, place a bookmark, or set as a favorite, the following file:

```
http://computer_name.domain/opa50/xhelp/oc/index.html
```

The file `wwhelp.htm` provides with links to all the Xhelp topics for Oracle Clinical. If you cannot find this file, contact your system administrator. Once you locate Xhelp, you can create a shortcut to the home page—or any other topic—for convenience.

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**Note:** If you do not have webcache set up in your environment, specify port number 7777.

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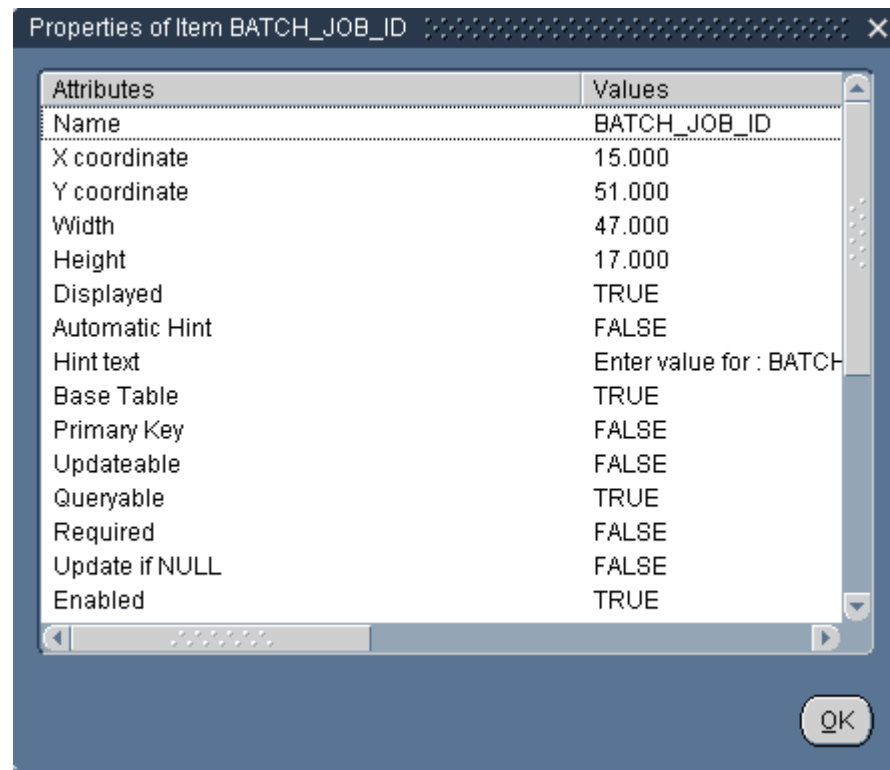
---

## Troubleshooting Xhelp

For the **More** button in the Oracle Clinical Field Help box to work, several Oracle Clinical installation steps must have been performed correctly. If Xhelp does not work, contact your system administrator.

### Properties of Item Window

Query mode prevents the system from launching help properly. If you start a query, then invoke Help, Oracle Clinical opens the Properties of Item window (Figure 3-4) instead of the Help window.

**Figure 3–4 Properties of Item Window**

When Oracle Clinical displays this window, click **OK** to close it, then either complete or cancel your query. Once you are out of query mode, help calls work as expected.



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## Submitting Batch Jobs and Reports

Many Oracle Clinical functions are executed by batch jobs submitted to Oracle servers (Reports Server, Web Server) or third-party applications (SAS). **Batch** jobs are non-interactive programs, such as reports and procedures, that run in the background. That is, the program runs in a separate process and does not interfere with your task. For example, the program that performs data validation runs without input from you, and without showing any output on your screen.

The Oracle Reports Server handles reports and scheduled jobs, while the Oracle Clinical **Parameterized** job and report **SUBmission** facility (**PSUB**) handles procedures written in PL/SQL. You need to be aware of which kind of job you are running.

This chapter contains the following information:

- [Overview of the Submission Process](#) on page 4-1
- [Entering Parameters for a Job](#) on page 4-2
- [Submitting the Batch Job](#) on page 4-3
- [Status of Submitted Jobs](#) on page 4-6
- [Status of Submitted Jobs](#) on page 4-6
- [Using a Saved Parameter Set](#) on page 4-9
- [Controlling Execution Order Using Job Sets](#) on page 4-10
- [Desupported Reports](#) on page 4-11

### Overview of the Submission Process

[Figure 4–1](#) represents the forms you use to submit and manage batch jobs, and the workflow among them. The callout numbers describe the most basic sequence of steps required to run a batch job:

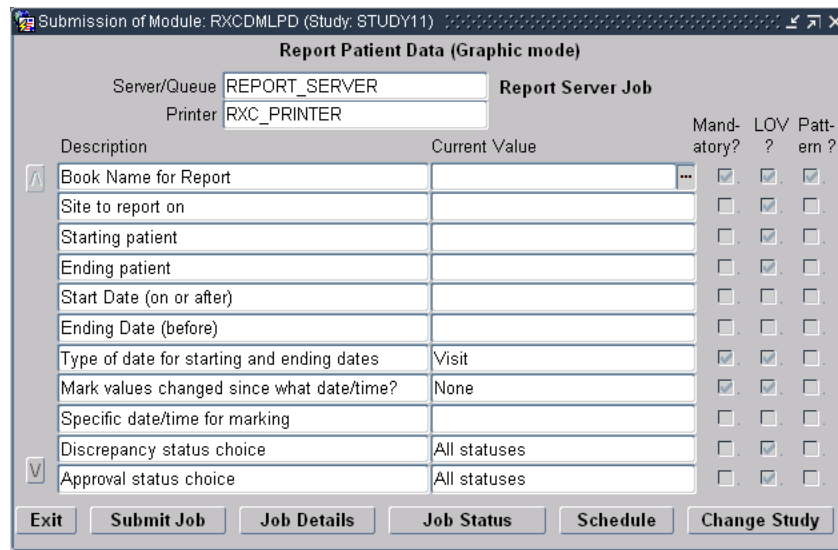
1. **Menu item or button.** You select an Oracle Clinical task, from a menu or toolbar.  
The Submission of Module window appears, showing the parameters required for execution of the selected job.
2. **Submission of module.** You enter values for all the mandatory parameters.
3. Choose **Action**, then **Batch Jobs** to see the status of the Oracle Clinical jobs that you started.  
The Submitted Batch Jobs window displays the status of your Oracle Clinical jobs.
4. **Upon completion.** If your Oracle Clinical job finishes successfully, you can view the results on the screen and you can also print the results.

If your Oracle Clinical task does not succeed, you can view the log file, or contact your system administrator to determine and fix the problem.

## Entering Parameters for a Job

When you select a task that requires a batch job, the Submission of Module window appears and displays a list of the parameters needed, as shown in Figure 4-1. The list may include a few of the fields that show on the final report or process. It may also include some fields that are not part of the final process but that limit the number of records in the report, or that are required in order to execute the job.

**Figure 4-1 Submission of Module Window**



The label at the top center shows your current task. The label below the task name indicates whether the job is a Report or a PSUB job (some tasks that generate reports are run by PSUB, not the Oracle Reports server). If it is a Report, you can now choose which server computer you want to run it, and, if the output type is PRINTER, which printer you want.

The parameters in the **Description** column are displayed with their default values, if any. Three check boxes indicate the options for setting these parameter values:

**Table 4-1 Check boxes in the PSUB Window**

Check box	Effect
Mandatory?	If checked, the parameter must have a value. If there is no default value supplied, you must enter one.
LOV?	If checked, a List of Values is available for you to choose from.
Pattern?	If checked, you can use a wildcard search to limit the number of records reported.

When you enter a value for a parameter in the **Current Value** field, Oracle Clinical validates the value to ensure that it meets any requirements established for the parameter. You receive a message if the value you entered fails validation.



---

## Submitting the Batch Job

After defining the submission parameters and submission details such as execution mode, follow these steps to send the job for processing:

1. Start at the **Submission of Module** window.
  - If you are using a saved parameter set without changing the execution definitions, you are already at this window.
  - Return to the block after making changes in the Submission Details window.

---

---

**Note:** If Mode of Execution is set to `batch_scheduled`, you must save the parameter set before submitting the job. See ["Saving a Parameter Set"](#) on page 4-9 for instructions.

---

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2. Click the **Submit Job** button to submit the batch job.
3. A message states that the transaction is complete and that the batch has been submitted. You also receive a message telling you what the output file is, if any.
4. To view the status of your submitted job, select the **Job Status** button from the navigation bar. See ["Status of Submitted Jobs"](#) on page 4-6 for details.

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**Note:** You can request only one batch job at a time. However, several jobs can run at the same time. To request more batch jobs, you must repeat this procedure.

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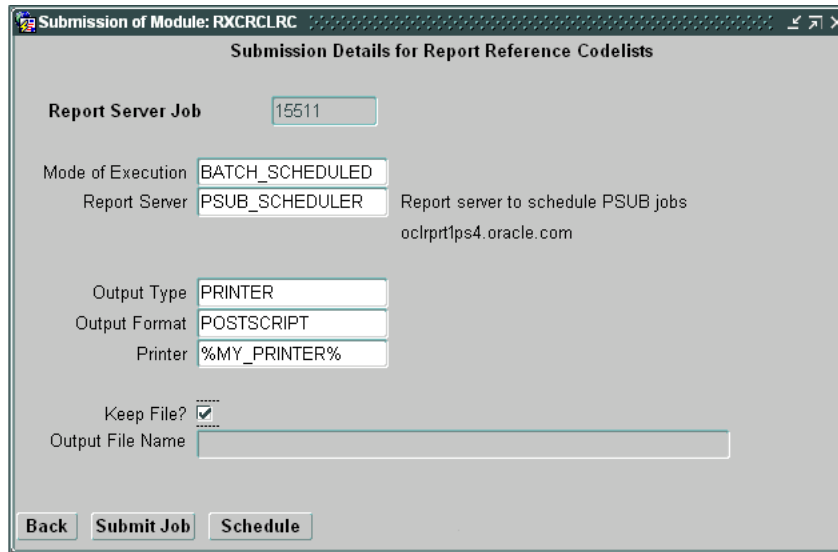
---

## Modifying Job Details

Once you have entered the parameters for the job, you can view the details of how the job is to be submitted by clicking the **Job Details** button. The fields in the Submission Details for *Task* window have default values set by your system administrator. They should be sufficient to run the job as set, but can be modified.

The Submission Details for *Task* window allows you to specify the output form of the results of a batch job: print, computer display (screen), or file, and where and when you want it to be printed or saved.

**Figure 4–2 Submission Details for Task Window**



Follow these steps to modify fields in the Submission Details for Task window:

1. Fill in the fields for **Mode of Execution**, and server or printer.

---

**Note:** If Mode of Execution is set to batch\_scheduled, you must save the parameter set before submitting the job. See "[Saving a Parameter Set](#)" on page 4-9.

---

2. Make sure that all other parameters are set to your satisfaction. Contact your system administrator for more information on batch and print queue names.
3. Click **Submit Job** to start the job and return to the Submission of Module window.

**Table 4–2 Fields in the Submission Details for Task Window**

Name	Description
Mode of Execution	The type of scheduling needed to run this batch job: BATCH_SCHEDULED = run repeatedly at a specified day and time. BATCH_IMMEDIATE = run in batch mode as soon as possible.
PSUB Queue Report Server	For PSUB jobs, the name given to the batch queue. For Reports, the server computer that runs Oracle Reports.
Output Type	Device to handle the result of the batch job. One of: SCREEN = displayed on a monitor. FILE = saved in a file; not displayed on a monitor or printed. PRINTER = sent directly to a printer. PREVIEW = displayed in Reports Pre-viewer on your screen. You can then choose whether to print it.

**Table 4–2 (Cont.) Fields in the Submission Details for Task Window**

<b>Name</b>	<b>Description</b>
Output Format	Kind of file to contain the result of the batch job. One of: TEXT = Plain ASCII characters. Prints anywhere. POSTSCRIPT = Adobe PostScript print format. Printer must have PostScript driver installed. PDF = Adobe Portable Document Format. For viewing only. RTF = Rich Text Format. Compatible with Microsoft Word. HTML = HyperText Markup Language. For Web viewing
Printer	Name of the printer to which the batch job is sent. Default: defined by system administrator for system default, by reference codelist OCL_JOB_PREF for the database.
Keep File	Whether to retain the output after the job is run. Default: ON (checked)
Output Filename	Name of the output file generated by the batch job. Enabled only if Keep File checked.

## Reports Queue Manager

The Reports Queue Manager enables you to see scheduled and past jobs on the selected Reports Server, and to stop or reschedule a batch job. You can only examine one Reports Server's queue at a time, using this application.

To launch the Reports Queue Manager for a particular Reports Server:

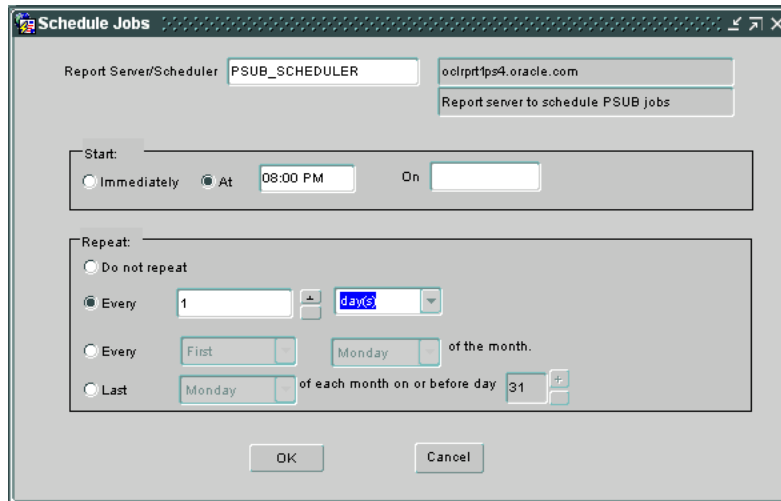
1. Choose **Admin**, then **PSUB/Report Jobs**, and **Report Queue Manager**. The Report Queue Manager window opens.
2. Choose the Reports Server that you want to examine from the LOV. The window populates with its full domain and server name in the right most fields.
3. Click **OK**. Oracle Clinical opens a new browser window, which loads the Reports Queue Manager data.

Each row represents a single batch job. Click the hyperlinked job status to investigate a particular job and manipulate it.

## Scheduling Jobs that Repeat

Click the **Schedule** button in either the Submission of Module or the Submission Details window to schedule a job, either repeating or not (called "batch deferred" in previous versions).

**Figure 4–3 Schedule Jobs Window**



**Table 4–3 Fields in the Schedule Jobs Window**

Name	Description
Report Server/Scheduler or Schedule Queue	Reports Server that processes reports jobs or Reports Server that schedules PSUB jobs. Display only. Value set in Submission Details for <i>Task</i> window.
Start	Use these fields to set the time and day.
Immediately option	As soon as your request gets to the server. Use this option only if the scheduled job starts on today. You must enter the first date the job runs in the At option, if it is not today.
At option, time field	Time of day in format HH:MI AM or PM, that is, a twelve-hour clock.
On option, date field	The date of the first run of the job. Day of the year in your local format (default is dd-mon-year).
Repeat	Use these fields to set the interval between repeats (if any).
Do not repeat option	Run the job just once.
Every option, <i>number</i> and <i>units</i> fields	A positive integer and a unit of time. Default is 1 Hour. <a href="#">Figure 4-3</a> shows every day.
Every option, <i>ordinal</i> and <i>day</i> fields	An ordinal number and a day of the week. Default is first Monday of the month.
Last option, <i>day</i> and <i>date</i> fields	A day of the week and a date of the month. Default is last Monday on or before the 31st of the month.

## Status of Submitted Jobs

After you submit the job, you can view its status in the Submitted Batch Jobs window by selecting the **Job Status** button in the Submission of Module window. You can also reach the window by choosing **Action**, and then **Batch Jobs** from any Oracle Clinical window or by choosing **Admin**, then **PSUB/Report Jobs**, and **Batch Jobs** from the main navigator tree. You cannot update fields in the Submitted Batch Jobs window.

This section includes the following tasks:

- ["Viewing Job Status"](#) on page 4-7
- ["Understanding Log and Output File Names"](#) on page 4-7
- ["Stopping Jobs"](#) on page 4-9

## Viewing Job Status

In this window you can view various aspects of your job, such as its current execution status, log and output file names, failure text if the job failed, as well as various timestamps. The execution status of each job changes as the job moves from entered, to started, and then to success.

If you are viewing this form while the job is executing, click **Auto Refresh** button on the navigation bar to have Oracle Clinical automatically update the status display. A second click turns off the auto refresh.

## Understanding Log and Output File Names

The names of the files are structured as follows: the unique batch job ID for the job is prefixed with an L for the log file, and with an O for the output file; for example, a batch job with a batch job ID of 12345 would have an output file name of RXC\_LOG:O12345.OUT, and a log file name of RXC\_LOG:L12345.LOG.

If you want to print the output or log file, click the **Print Output** or **Print Log** button on the navigation bar. If you want to see the files onscreen without printing them, you click **View Output** or **View Log**. If there are multiple files, a dialog box appears and you can select the one you want. For convenience, the output file is included in the log file dialogs.

- **PSUB job:** As of Release 5.0, log and output files are saved only temporarily to a file system directory, then are immediately uploaded to the database where the View and Print buttons access them. The temporary directory is specified in the PSUB\_LOGS\_DIR value of the OCL\_STATE reference codelist.

The PSUB\_LOGS\_DIR value is fetched from the ocl\_state ref codelist. A Username-specific directory is created on the database server when a user submits a PSUB job for the first time and is used for all subsequent jobs submitted by that particular user. The Job ID is specific to every job run.

- **Report job:** Log and output files are placed in the Report Server Directory on the server that is defined in the Oracle Accounts of Oracle Clinical. (Navigate to **Admin**, then **Users**, then **Oracle Accounts**.)

**Table 4–4 Fields in the Submitted Batch Jobs Window**

Name	Description
Job Id	Unique system-generated ID for the batch job submission
Module Name	Name of the module that is being executed

**Table 4–4 (Cont.) Fields in the Submitted Batch Jobs Window**

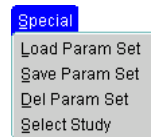
<b>Name</b>	<b>Description</b>
Execution Status	Status of the batch job ENTERED = You have requested submission of the job. SUBMITTED = Job has been submitted to the batch queue. SUBMIT_TO_RS = Job has been submitted to the server queue SUBMIT_FAILED = Job failed submission to the batch queue. STARTED = Job is currently executing. SUCCESS = Job has completed successfully. FAILURE = Job has completed unsuccessfully. STOPPED = Job has been stopped by the Stop button. STOP_FAILED = Job has not responded to the Stop button.
Study	Name of the study.
Parameter Set Name	Parameter Set Name that was loaded for this job.
Temporary Output Loc	Name of the directory where the output file was generated before being written to the database table BATCH_JOB_LOBS.
Failure Text	Text the job generates to give information about why it failed
Temporary Log Loc	Name of the directory where the log file was generated before being written to the database table BATCH_JOB_LOBS.
Mode of Execution	Type of scheduling that ran this job BATCH_IMMEDIATE = run in batch mode as soon as possible BATCH_SCHEDULED = run repetitively at a specified day and time
Module Type	Type of module executed in batch: REPORT, 3GL, DCL, PLSQL
Server Queue	Name of the server queue to which you sent the job
Print Queue	Name of the print queue to which you sent the job
Job Request Time	Date and time you clicked the Submit Job button
Job Submission Time	Date and time the job was actually submitted
Scheduled Time	Date and Time the job was scheduled.
Job Start Time	Date and time the job started
Job Completion Time	Date and time the job completed
Format	File format of the output file: ASCII, PDF, or POSTSCRIPT
Report ID/Process ID	The internal identification of the processed report (processed on the Report Server) or PSUB Job (processed on the PSUB Server).
Job Name	Name of the job processed on the Report Server. It is shown on the Report Queue Manager as well.
RS Scheduler	Report Server computer that owns the server queue
Schedule String	Time that you specified for the job start time.
Command Line	Command Line sent to the server.

## Stopping Jobs

You can stop a job, even if it is in a job set, by clicking the Stop button. A stopped job has a status of STOPPED; if the job doesn't respond to the action, its status is STOP\_FAILED. You can stop only your own jobs. Oracle Clinical does not delete log and output files associated with PSUB jobs; the system deletes log files from reports jobs when you stop the job.

## Using a Saved Parameter Set

A **parameter set** is a saved grouping of one or more parameter values that you have specified in the Submission of Module window. If you know that you plan to execute the same batch job repeatedly, it may save you time to create a parameter set. Saving the parameter set also saves the associated execution definition. Once saved, a parameter set can be reused and/or modified.



Similarly, if you want to execute a series of batch jobs in a certain order, you can create a **job set**. Each job in a job set must have a saved parameter set. You cannot run job sets immediately; they execute only on a server.

## Saving a Parameter Set

You must save a parameter set if the batch job mode of execution value is BATCH\_SCHEDULED. Follow these steps:

1. Create or modify parameters as explained in "Entering Parameters for a Job" on page 4-2.
2. Return to the Submission of Module window.
3. Select **Save Param Set** from the **Special** menu. The Save Parameter Set Name window appears.
4. Enter a unique name for this new or modified parameter set, and select [OK].
5. The system displays a confirming message and displays the Submission of Module window.
6. Select [Exit] to end the function and return to the menu.

## Modifying a Saved Parameter Set

After you select and display a saved parameter set, you can modify it to meet your current needs and then save it, if appropriate, using a new name.

When you save a parameter set, you also save the batch job execution definition settings. These settings can then be used automatically, or changed. If you change the execution settings, the changes are lost unless you save them under a new name.

Follow this procedure to use your saved set of parameters to submit a job:

1. Select the report or other batch job from the Main Menu. The Submission of Task window appears, showing the parameters for the batch job.  
To use the parameters currently displayed in the PSUB Submission window, go to Step 3.
2. To use a saved parameter set, do the following:
  - a. Select **Load Param Set** from the **Special** menu. The Load Parameter Set Name window appears.

- b. Enter the name of the saved parameter set you want in the **Parameter Set Name** field, or make a selection from the list of values.
      - c. Click **OK**.
      - d. The **Submission of Module** window appears, with the **Current Value** field filled in for each parameter. If you don't want to modify the saved parameter set, go to Step 3. If you want to modify the set, change the entries in the **Current Value** field.
3. Do one of the following:
  - Click **Submit Job** if you want to submit a job using the currently displayed parameters. See "[Submitting the Batch Job](#)" on page 4-3 for instructions.
  - Select **Save Param Set** from the Special menu if you want to save the modified parameter set.
  - Click **Job Details** to move to the Submission of Module Details window.

## Controlling Execution Order Using Job Sets

You can control the order for a specified set of jobs when you want jobs that depend on other jobs to execute only if the jobs on which they depend have been successfully executed.

The first task is to define a **job set**, provided you have saved a parameter set for each of the jobs in the job set. Navigate to **Admin, PSUB/Reports Jobs**, then **Job Sets** and enter a name for the job set, which is restricted to alphabetic characters. List the various jobs in this set; the parameter set names previously saved are entered automatically or from a LOV. The **Task Name** field is typically the name of a report and is entered when the parameter set is entered.

For each job in the job set, enter the job label of a related job in the appropriate status column. The status column you choose indicates what status the job in the left-hand column should have before the related job should start. If you leave one of the fields blank and the job in the left-hand column ends with the corresponding status (for example, the job ends successfully and the field in the Success column is empty), the execution of the whole job set stops.

The Time-out field that refers to the job in the left-hand column has a default of 720 minutes. The Time-out field that refers to the related job indicates only whether the job is permitted to time out before or after another job executes.

If any of the jobs in a job set exits with a status of SUBMIT\_FAILED or STOPPED, the whole job set aborts with a status of FAILURE.

Oracle Clinical limits you to a maximum of 52 saved records in a job set. If you run a sequence of more than 52 jobs, divide them into smaller sets.

You submit job sets following the menu path **Admin, PSUB/Reports Jobs**, then **Submit Job Set** and then providing a job set name, for which there is a list of values.

## Log Files for Job Sets

Oracle Clinical stores log files for job set submissions in the Report Queue Manager, and does not produce output files. For more information about seeing these log files, see "[Reports Queue Manager](#)" on page 4-5.



## Desupported Reports

The following reports have been desupported. All reports still have links under Data Entry, Data Entry Reports.

- Project Enrollment
- Study Enrollment
- Site Enrollment
- Site Summary



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