

Oracle® Clinical Release Notes  
Release 4.6.6  
E27598-01

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## Oracle® Clinical

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Release Notes

Release 4.6.6

My Oracle Support Article ID 1459178.1

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**Patch Number: 14198756**

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## 1 Overview

Oracle Clinical Patch Set 4.6.6 focusses on conditional branching, date/time behavior and includes fixes in other areas as well.

Oracle Clinical Patch Set 4.6.6 also contains all bug fixes included in Oracle Clinical and Oracle Clinical Remote Data Capture (RDC) Patch Sets 4.6.5, 4.6.4, and 4.6.3, including a security vulnerability.

Oracle Clinical Patch Set 4.6.6, like Oracle Clinical 4.6.5, requires an upgrade to Oracle Database 11.2.0.3 and an Oracle Reports Server patch.

<b>Priority:</b>	Normal
<b>Affected Features:</b>	Conditional Branching, Standard Date, Batch Data Load, Locking DCI/DCMs Batch Job, Discrepancy Profile, DCI Form Generation The following additional features were affected in obsoleted patch sets 4.6.5, 4.6.4 and 4.6.3: Patient Data Report, Security, Conditional Branching, RDC Data Entry, DCM Layout, Enhanced DCI Books, Mass Changes, Procedures, Intervals Oracle Clinical Data Entry, RDC Surround, Performance, DCI Form Migration, Data Extract Views, Discrepancies, Signed Jar Files, Group Approve/Verify, DCI Access
<b>Problem Type(s):</b>	Feature Problem The following additional problem types were fixed in obsoleted patch sets 4.6.4 and 4.6.3: Data Error, Performance
<b>Patch Components:</b>	Application Server, Reports Server, Database Server, Database
<b>Platforms:</b>	<b>Front End:</b>  Windows Server 2008 (64-bit)  <b>Database Server and Database:</b>  Oracle Solaris SPARC 10 (64-bit)  Oracle Enterprise Linux 5, Update 5 (64-bit)  HP-UX Itanium 11i v3 (11.31) (64-bit)  Windows Server 2008 (64-bit)
<b>Compatibility:</b>	4.6.2 (database only)
<b>Obsoletes:</b>	4.6.5
<b>Data Model Upgrade:</b>	During database upgrade the 4.6.6 Installer automatically checks if studies have been migrated to the enhanced approve/verify data model introduced in Oracle Clinical 4.5.3.11 and 4.5.3.12. If not, you must migrate your studies; see <a href="#">Migrating Data to the Enhanced Data Model for Approvals and Verifications</a> .
<b>Version:</b>	This is the first version of this patch set.

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## 2 References

This section contains the following topics:

- [Section 2.1, "Oracle Clinical Patch Set 4.6.6 Release Notes"](#)
- [Section 2.2, "White Papers and Technical Notes"](#)
- [Section 2.3, "User Documentation"](#)

### 2.1 Oracle Clinical Patch Set 4.6.6 Release Notes

You can download the most current version of these release notes in PDF and HTML format from My Oracle Support at <https://support.oracle.com> with article ID 1459178.1.

### 2.2 White Papers and Technical Notes

The following documents are available on My Oracle Support at <https://support.oracle.com>:

- *OLSA 4.6.x and 4.7.x Known Install and Configuration Issues* (Article ID 386941.1)
- *Oracle Life Sciences Applications Supported Technology Stacks* (Article ID 180430.1)
- *Oracle Health Sciences Applications Critical Patch Update January 2012* (Article ID 1400293.1)]
- *Configuring Oracle Clinical Remote Data Capture Onsite 4.6.2 for Performance and Scalability* (Article ID 1300850.1)
- *Oracle Clinical RDC Onsite 4.6 and 4.6.2 Installation Verification Test* (Article ID 966171.1)
- *Cloning Databases in Oracle Clinical and TMS 4.6.x* (Article ID 883213.1)
- *Oracle Clinical Versions 4.6.2, 4.6, 4.5 and 4.0 Summary of Patches Available* (Article ID 121863.1)]
- *Oracle Clinical, RDC, TMS Deployment Through a Reverse-Proxy Server* (Article ID 883222.1)

### 2.3 User Documentation

The user documentation for Oracle Clinical Release 4.6.2 applies to the Patch Set as well. You can download the most current versions of the user documentation in PDF and HTML formats from 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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The user documentation includes the:

- *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*

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

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## 3 Known Issues

This section lists selected issues that remain unresolved with this patch. You can view the complete set of open bugs on My Oracle Support at <https://support.oracle.com>.

### 3.1 Bug 12755552

#### Issue

If you are using the Siebel Clinical/CTMS AIA integration with Oracle Clinical, you may need to manually restart the AIA queue when you refresh the database.

#### Workaround

Start the queue manually as follows:

1. Log in to SQL\*Plus as the RXC user.
2. Enter the following:

```
BEGIN
    DBMS_AQADM.START_QUEUE (
        queue_name => 'CLINICAL_STUDY_QUEUE'
        , enqueue => TRUE
        , dequeue => TRUE);
END;
/
```

### 3.2 Bug 11709987

#### Issue

The OC web services to Create, Update, Request, or Delete an Investigator, Site or Study Site returns a truncated number for investigatorID, SiteID or ClinicalStudyID if any of these are longer than 7 digits.

This impacts any web service or application calling these web services, including the Oracle Study, Subject and Visit Integration Pack for Siebel Clinical and Oracle Clinical.

This bug prevents Site, Investigator and Study Site information updates from coming from Siebel Clinical to Oracle Clinical and prevents the creation of subjects in Siebel Clinical when patients are enrolled or have data entered in Oracle Clinical RDC if the IDs were longer than 7 characters.

**This issue was fixed on the Oracle Clinical side in Patch Set 4.6.5** by providing a new attribute called **IdStr** of type String that allows you to pass the ID value as a string. Oracle Clinical Patch Set 4.6.5 is completely compatible with Oracle Study, Subject and Visit Integration Pack for Siebel Clinical and Oracle Clinical 3.1.

**However, this bug will not be fixed until you apply *both*:**

- Oracle Clinical Patch Set 4.6.5 (or later)
- Oracle Study, Subject and Visit Integration Pack for Siebel Clinical and Oracle Clinical 11.1

The web services are documented in the *Oracle Clinical Application Programming Interface Guide*, but the new attribute is not included in the Release 4.6.2 version of the guide. Here is the required information:

- The original attribute, called **ID** and of type Double, still exists. If your IDs are 7 digits or less, you can still use this attribute, which is recognized by the 3.1 version of the Siebel Clinical-Oracle Clinical integration.
- The new attribute, called **IdStr**, is of type String.
- Use one attribute or the other, not both.

#### Workaround

None.

### 3.3 Bug 5084317

#### Issue

It is not possible to view the audit history of deleted CRFs and CRF sections in the RDC Onsite user interface.

#### Workaround

The information is in the Patient Data Report for the patient if you have applied patch set 4.6.5 or higher; see [Bug 13475220](#).

### 3.4 Bug 13424572

#### Issue

In the Graphic Layout Editor, when a user sets the Visual Appearance to None for any field, the field is not visually removed from the Layout Editor immediately. The item is removed from the layout after saving, exiting and reopening the Layout Editor.

#### Workaround

None.

### 3.5 Bug 13697068

#### Issue

When working with Conditional Blocks in the DCM Layout Editor, if you have highlighted source and target questions and set the Visual Appearance to None for one of those fields, the highlighting is replaced with gray. However, this does not affect the functionality of the field. This is a display issue within the Layout Editor only.

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#### Note:

If you subsequently restore visual appearance, the appropriate highlighting is not restored unless you delete and recreate the conditional blocks.

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#### Workaround

None.

### 3.6 Bug 8797582

#### Issue

The Installer appears to allow deinstalling Oracle RDBMS objects. However, deinstalling Oracle RDBMS objects does not work and is not supported.

#### Workaround

None.

### 3.7 Bug 8588321

#### Issue

Although RDC Onsite can be accessed from a Web client with Internet Explorer 8 or 9, a user can change the Document Mode setting such that RDC Onsite does not work properly. It is not anticipated that RDC Onsite users will change this setting, as it is targeted at Web developers. Internet Explorer 8 and 9 come with Developer Tools, enabling Web site developers to prototype and test Web sites that they develop.

#### Workaround

Ensure the browser's Document Mode is set to **Quirks Mode**, which is the default value.

To check this setting:

1. Launch Internet Explorer 8 or 9.
2. Select the **Tools** menu in the current tab.
3. Select **Developer Tools F12** from the Tools menu.
4. Select the **Document Mode** option in the Developer Tools menu and check that it is set to **Quirks Mode**.

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## 4 Problems Addressed

This section lists the problems addressed in Oracle Clinical Patch Set. It includes the following sections:

- [Section 4.1, "Problems Addressed in Oracle Clinical Patch Set 4.6.6"](#)
- [Section 4.2, "Problems Addressed in Oracle Clinical Patch Set 4.6.5"](#)
- [Section 4.3, "Problems Addressed in Oracle Clinical Patch Set 4.6.4"](#)
- [Section 4.4, "Problems First Addressed in Oracle Clinical Patch Set 4.6.3"](#)
- [Section 4.5, "Other Problems Addressed in Oracle Clinical Patch Set 4.6.3"](#)

### 4.1 Problems Addressed in Oracle Clinical Patch Set 4.6.6

Patch Set 4.6.6 includes:

- [Conditional Branching-Related Problems Fixed](#)
- [Date/Time-Related Problems Fixed](#)
- [WE8 Character Set-Related Problems Fixed](#)
- [Other Problems Fixed](#)

#### Conditional Branching-Related Problems Fixed

The following bugs fixed are all related to conditional branching.

##### 4.1.1 Bug 14186990

**Before:** When questions in a disabled block were about to be deleted, an unclear warning message was issued: "Responses previously entered in this question set will be deleted. Do you wish to continue?"

**After:** The warning message is replaced by: "Responses have been detected in a set of disabled questions in this form. Based on the response to another question, those responses are not applicable and will be deleted. Do you wish to continue?".

**Module Affected:**olsardc.ear

##### 4.1.2 Bug 14109850

**Before:** Audit reasons 'COND RESP UPDT' and 'COND VIOLATION' were displayed in the audit LOV in data entry. These are system-provided change reasons and the user should not be allowed to use them.

**After:** Audit reasons 'COND RESP UPDT' and 'COND VIOLATION' are not displayed in the audit LOV in data entry.

**Modules Affected:**

- seeddata.sql
- oclupg465to466seeddata.sql
- olsardc.ear
- olsardcapi.dll

##### 4.1.3 Bug 14091240

**Before:** The system failed to detect or incorrectly detected a conditional branch violation in the following situations:

- The system did not detect a conditional branch violation when there was a derived response in a disabled block.
- The system did consider saved responses to questions with defined repeating default values to represent a conditional branch violation, even if the response matched the defined default.

**Note:**

As expected, responses to questions with normal default values do NOT trigger a branch violation if the response matches the defined default value.

In addition, the system did not detect cases where a null response had been saved for a question with a defined default value.

**After:** Conditional branch violation detection has changed:

- The system detects a conditional branch violation if a disabled block includes a derived response. If the derived response is for a question in a repeating question group and the branch violation is corrected, the response is deleted, because the entire row is deleted.
- Saved responses to questions with defined repeating default values no longer trigger branch violations if the response matches the defined default value.
- The system triggers a branch violation if, in a disabled block, a null response has been saved for a question with any kind of defined default value. As a result, the default value(s) will be restored if the source question or a question in an enabled block is updated.

**Note:**

When a conditional block with previously entered responses becomes disabled, two types of responses are retained and trigger a branch violation every time the CRF is opened:

- Derived responses to non-repeating questions (these will remain until the next procedure execution, and are removed then only if the procedure is written in a way that ensures the value will be obsolete when its block becomes disabled.)
- Non-updateable responses to non-repeating questions—unless the response matches the defined default value for the question.

For this reason, Oracle recommends that you do not use derived or non-updateable questions in conditional blocks without careful thought.

**Modules Affected:**

- olsadcapi.dll
- olsardc.ear

**Conditional Block Deletion-Related Problems Fixed**

The three bugs below are all related to the use of conditional branching and what happens when responses to a conditional set of questions (a conditional block) are automatically deleted. This happens in two circumstances: (1) an enabled conditional block with previously entered responses becomes disabled because a user updates the conditional source question and (2) responses are entered into a disabled conditional block from a non-RDC Onsite interface, causing a branch violation. The branch violation is detected when a user opens the CRF in RDC Onsite and modifies either the conditional source question or one of the questions in an enabled conditional block. This prompts the system to correct the violation by deleting the responses in the disabled conditional block.

Specifically, these bugs are related to treatment of responses to questions with default values. Note that there are differences in behavior for different types of defaults:

- A normal default in a non-repeating question
- Repeating defaults with a different default value in each row
- Normal defaults in a repeating question group (same default value in each row)

Also note that behavior differs depending upon whether or not the field is updateable. For repeating defaults, this can be specified in two ways. A repeating question is not updateable if:

- **Protect Repeating Defaults?** is checked (enabled) in the DCM question group definition
- or
- **Enterable?** is not checked (disabled) in DCM question group questions

For purposes of the descriptions below, we use the terms "not updateable" or "updateable" to cover **either** of those settings.

**4.1.4 Bug 14185115**

**Before:** When the system deleted content in a disabled conditional block, a default response to a non-repeating question was retained only if the response still matched the defined default value. Otherwise, the default value was not restored for that question; either:

- The response was nulled out if the question was updateable.
- The nonmatching response was retained if the question was not updateable

**After:** When the system deletes content in a disabled conditional block, the system replaces the response entered with the defined default value for questions that have a defined default value.

**Modules Affected:**

- olsardc.ear
- olsadcapi.dll

#### 4.1.5 Bug 14185124

**Before:** When the system deleted content in a disabled conditional block, repeating default values in a repeating question group could be lost:

- Repeating default values were deleted if the question was updateable and the response no longer matched the defined default value for the row.
- Due to another issue, if the CRF was at status Pass1 Complete, the response was deleted even if it still matched the default value.
- Even if the CRF was at status P1 Started, a matching response was not retained if Save Repeating Defaults was set to N and there was no non-updateable field in the row to prevent the row from being deleted.

Repeating default values previously saved to the database were always retained if Protect Repeating Defaults was enabled, even if Save Repeating Defaults was disabled. However, if the repeating default (either the defined default value or the response) had somehow been modified, the modified response was retained even though it no longer matched the defined default value.

**After:** When repeating question group content in a disabled conditional block is deleted by the system, all rows are deleted, even if Protect Repeating Defaults is enabled. Then, if Save Repeating Defaults is enabled, all rows are re-inserted with the defined default values - rows are otherwise blank - and saved to the database.

**Modules Affected:**

- olsardc.ear
- olsardcapi.dll

#### 4.1.6 Bug 14185149

**Before:** When the system deleted content in a disabled conditional block, normal default values in a repeating question group were retained in the database only if (1) the row was not deleted for any other reason and (2) the response matched the defined default value for the question. Rows were retained if:

- They had a protected (or non-updateable) repeating default.
- They had any other kind of non-updateable field with a response (batch-loaded or otherwise).
- They had a derived value.
- They had a multivariate discrepancy.

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**Note:**

If the default question was itself non-updateable and somehow didn't match the defined default value (batch-loaded? definition update?) this value was retained, and the true default value was lost. However, if the non-updateable response did match the default value, this did not prevent the row from being deleted, in which case the default was lost. Unless the was another derived, protected, or non-updateable field, the row was deleted.

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**After:** When the system deletes content in a disabled conditional block, all rows are completely deleted, including any non-updateable responses, derived values, and multivariate discrepancies. Then the original normal and repeating defaults are restored for each field defined to have defaults; all other fields in the row are null.

**Modules Affected:**

- olsardc.ear
- olsardcapi.dll

The remaining bugs are not related to conditional block deletion.

### Date/Time-Related Problems Fixed

The following bugs are issues related to date/time data.

#### 4.1.7 Bug 2638016

Background: For questions of Data Type Date, the setting Data Entry Input Format specifies the expected format: US, European, Swedish. Dates entered in the STANDARD format (dd-mon-yyyy) are always recognized and accepted. The setting Data Entry Input Format can be specified in the following locations:

- At the database level in Oracle Clinical: Admin, DE Admin, DE User Prefs
- At the user level in Oracle Clinical: Admin, Users and Roles, Oracle Accounts, Special menu, DE Prefs option
- At the user level in RDC Onsite: Preferences (assuming configuration does not disable the Preferences link)

The user-level setting overrides the database-level setting.

**Before:** Although users can enter dates in the STANDARD format regardless of the specified Data Entry Input Format, it was not possible to require users to enter dates in the STANDARD format.

**After:** STANDARD can be specified as the expected Data Entry Input Format, where either 2- or 4-digit years are accepted. With STANDARD as an input format, the Data Entry Display Format is restricted to STANDARD as well.

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**Note on Data Entry Display Format:**

As stated above, the user-level settings generally override database-level settings. However, when a data type discrepancy is raised for a date field, the resulting warning message displays the discrepant date in the format specified at the database level. Therefore, Oracle recommends that you always specify STANDARD as the Data Entry Display Format at the database level.

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**Modules Affected:**

- olsardc.ear
- rdc.fmx
- rxcdemcp.fmx
- rxclbsml.plx
- ocl\_datetimeconvert\_pb.sql

**4.1.8 Bug 3102585**

**Before:** For a date field, if a user entered more precision than required by the question's Date Time Format, the system truncated the extra information. For example, if the date format was MY and a user entered 01-FEB-2012, the day was truncated: it was displayed and saved as FEB-2012.

**After:** In same scenario, a data type discrepancy is raised and data is not truncated.

**Modules Affected:**

- rxclbsml.plx
- ocl\_datetimeconvert\_pb.sql

**4.1.9 Bug 7163588**

**Before:** For a time field, if a user entered a value with more precision than required by the question's Date Time Format, the system truncated the extra information without raising a discrepancy. For example, when Date Time Format is set to HM:

Example 1: Entered value is 01:00:24; the time stored was 01:00.

Example 2: Entered value is 00055; the time stored was 00:00.

**After:** In the same scenario, a data type discrepancy is raised and the time entered is not truncated.

**Note:**

There is no change in behavior related to the setting for Date Time Type, which specifies the minimum precision required for a question of Data Type Time.

**Modules Affected:**

- rxclbsml.plx
- rxclbgen.plx
- ocl\_datetimeconvert\_pb.sql

**4.1.10 Bug 14193341**

**Before:** If a user entered a date with no delimiters which resulted in a discrepancy based on the Date Time Format specified for the question, Batch Validation would later obsolete the discrepancy if the entered value was valid assuming a YYYYMMDD format.

For example, if the Date Time Format for the question was US, and the user entered 18180102, the data entry interface would raise a discrepancy because 0102 is not a valid year. However, Batch Validation would accept this as a valid date—Jan 2, 1818—and close the discrepancy.

**After:** In the same scenario, the data entry interface stores the response value with delimiters added. This prevents Batch Validation from interpreting the value with a YYYYMMDD format. In the example above, the date is stored as 18-18-0102 and the discrepancy remains open.

**Modules Affected:**

- rxclbsml.plx
- rxclbgen.plx
- ocl\_datetimeconvert\_pb.sql

**4.1.11 Bug 14193350**

**Before:** If a user entered dates with a month abbreviation that was not followed by a year, the month was interpreted as the year. Example: 01-MAR would be interpreted as JAN-2003.

**After:** If a user enters a date with a month abbreviation that is not followed by a year, a discrepancy will be created.

**Modules Affected:**

- rxclbsml.plx
- rxclbgen.plx
- ocl\_datetimeconvert\_pb.sql

**WE8 Character Set-Related Problems Fixed**

The following bugs are issues related to using the WE8 character set.

#### 4.1.12 Bug 14067987

**Before:** In a WE8 database, clicking Promote Profile caused the application crashed with error FRM-92101.

**After:** On clicking Promote Profile the profile is saved.

**Module Affected:** rxcpradm.fmx

#### 4.1.13 Bug 13841923

**Before:** In a WE8 database, non-ASCII characters (for example, µ) that were part of the layout definition were displayed incorrectly—as a box or other character—in RDC Onsite data entry.

**After:** After applying this patch and regenerating the DCI Form, non-ASCII characters are displayed correctly.

**Modules Affected:**

- ocl\_dcif\_html\_generator\_pb.sql
- ocl\_dcif\_html\_generator\_ps.sql

#### 4.1.14 Bug 13475897

**Before:** Updating a field in Maintain Discrepancy Database Window in a WE8 database caused Oracle Clinical to crash.

**After:** In the same scenario, Oracle Clinical does not crash.

**Module Affected:** rxcmmdd.fmx

### Other Problems Fixed

The following bugs are also fixed.

#### 4.1.15 Bug 14187346

**Before:** As of Oracle Clinical 4.6.4, Batch Data Load failed while checking if questions were extended text if the data included DCMs with multiple occurrences of the same question. The load failed if the question was repeated in a DCM question group or if the same question group occurred twice in the same DCM. This issue also caused performance problems, even if there were not multiple occurrences of the same question.

**After:** In the above scenario, Batch Data Load succeeds.

**Modules Affected:**

- UNIX: RXCBEBLT, RXCBEPTB
- Windows: RXCBEBLT.EXE

#### 4.1.16 Bug 13992097

**Before:** Batch Data Load had severe performance problems during the Prepare stage because the system was using the wrong index.

**After:** Batch Data Load performance is improved.

**Modules Affected:**

- UNIX: RXCBEBLT, RXCBEPTB
- Windows: RXCBEBLT.EXE

#### 4.1.17 Bug 9541413

**Before:** If you batch data loaded a document with a visit number greater than 4 digits, you received the message: "Job fails with error ORA-00001: unique constraint (RXC.RECEIVED\_DCM\_UK2\_IDX) violated."

**After:** Batch Data Load succeeds.

**Modules Affected:**

- UNIX: RXCBEBLT, RXCBEPTB
- Windows: RXCBEBLT.EXE

#### 4.1.18 Bug 3233102

**Before:** The PSUB job 'Locking of DCIs and DCMs' batch job (RXCDAMFS) reported success but failed with ORA-06502: PL/SQL: numeric or value error in the .out file if the Start or End Clinical Planned Event value supplied was 4 characters long.

**After:** In the above scenario, the job succeeds.



**Module Affected:**rxcdamfs.sql

#### 4.1.19 Bug 13654599

**Before:** For a procedure the Validation Reported Values report (from the Conduct menu, Conduct Reports, then Data Validation) displayed only the values that would fit on a single page. The 1-page limit can be exceeded if for example a validation procedure generates several discrepancies on a single CRF.

**After:** All the validation reported values are listed, on multiple pages if necessary.

**Module Affected:**rxcdmlvt.rep

#### 4.1.20 Bug 13950493

**Before:** When upgrading to 4.6.5 if the database was originally created in 4.5.3 or 4.6.0, you got the following message: oclupg\_oc465u.log file:

```
ERROR at line 1:
ORA-00911: invalid character
ORA-06512: at line 16
```

**After:** When upgrading to 4.6.6 from 4.6.5 or an earlier version, you do not get this message.

**Modules Affected:**

- oclupg464to465step2.sql
- oclupg465to466step2.sql

#### 4.1.21 Bug 12757254

**Before:** Add Visit Page added a page for the wrong patient if the action was immediately preceded by adding a page for another patient AND if the Internet Explorer setting Check for newer versions of stored pages is set to 'Never'. (Under Internet Options, General tab, section Browsing History, select the Settings button). The problem is apparent in the Add Visit Page dialog, where the incorrect patient ID is displayed, and after entering and saving data in the CRF, which is added to the row for the incorrect patient.

**After:** Add Visit Page works correctly.

**Module Affected:**olsardc.ear

#### 4.1.22 Bug 14251787

**Before:** The Blank Casebook Report failed when the DCI Book contained a DCI with large number of repeats and questions in a DCM Question Group.

**After:** The Blank Casebook Report is generated successfully when the DCI Book contains a DCI with large number of repeats and questions in a DCM Question Group.

**Module Affected:** rdc\_report\_xml\_generation\_pb.sql

#### 4.1.23 Bug 13628377

**Before:** On the Patient Summary page, the Patient ID and Patient Age values are blank or incorrect when the Patient Sex is present.

**After:** On the Patient Summary page, Patient ID and Patient Age values are displayed correctly.

**Module Affected:** olsardc.ear

### 4.2 Problems Addressed in Oracle Clinical Patch Set 4.6.5

Oracle Clinical Patch Set 4.6.5 provided a new setting in the Oracle Clinical DCI Form Local Database and Study Settings forms to disable the Delete CRF button in RDC Onsite. In addition, fields in the Patient Data Report ancillary pages are now labeled according to the setting "Display Label for DCM Questions" also found in the DCI Form Local Database and Study Settings forms to be consistent with field labels used in the Navigator pane of RDC Onsite data entry.

The following problems were fixed for the first time in Patch Set 4.6.5.

#### 4.2.1 Bug 13426023

**Before:** In RDC Onsite, the Delete icon in the Data Entry window was always enabled.

**After:** The Delete icon in the Data Entry window can be disabled through a new **Disable Delete CRF icon** setting in the DCI Form Local Database Settings or DCI Form Local Study Settings window.

**Module Affected:** olsrdcapi.dll

#### 4.2.2 Bug 13511856 and Related Bugs

**Before:** Fields in the Patient Data Report ancillary pages always used the SAS label defined for the corresponding Question in Oracle Clinical as their label. However, fields in the Navigator pane of the RDC Onsite Data Entry window use the DCI Form Local Study or Local Database setting **Display Label for DCM Questions**, where possible values are SAS Label, Question Name, or Default Prompt.

**After:** Field labels in the PDR ancillary pages are based on the DCI Form Local Study or Local Database setting **Display Label for DCM Questions**. Different affected sections of the Ancillary pages were tracked by different bugs, as follows:

- Inserted and Deleted Repeats—Bug 13511856
- Investigator Comments—Bug 13511898
- Discrepancy Details—Bug 13511843
- Audit History—Bug 13261976
- Audit History for fields not displayed in CRF—Bug 6330330

**Modules Affected:**

- rdc\_report\_xml\_generation\_ps.sql
- rdc\_report\_xml\_generation\_pb.sql
- Overflow.xml
- Overflow.rtf
- Overflow\_L.rtf
- PatientDataReport.java

**4.2.3 Bug 13260216**

**Before:** In the Patient Data Report's ancillary Audit History section, the role of the user making modifications to the data was not displayed.

**After:** The user's role is displayed in an additional field.

**Modules Affected:**

- Overflow.rtf
- Overflow\_L.rtf
- Overflow.xml

**4.2.4 Bug 13563340**

**Before:** The role of the user who created or approved a CRF was not displayed beside their username for the "Created By" and "Approved By" fields in the PDR header.

**After:** The user's role is displayed in those locations.

**Modules Affected:**

- Overflow.rtf
- Overflow\_L.rtf
- Overflow.xml
- rdc\_zf\_surround\_ps.sql
- rdc\_zf\_surround\_pb.sql

**4.2.5 Bug 13475220**

**Before:** In the Patient Data Report:

- The Deleted CRFs section did not include audit history for individual responses entered before the CRF was deleted.
- For CRFs (or CRF sections) marked blank, the audit history for responses entered prior to use of the blank flag was not provided.

**After:** In the circumstances above, a complete, response-level audit history is provided.

**Modules Affected:**

- pdr\_field\_has\_auditt\_vw.sql
- pdr\_field\_has\_audit\_vw.sql
- rdc\_del\_resp\_without\_new\_vert\_vw.sql
- rdc\_report\_xml\_generation\_pb.sql
- rdc\_del\_resp\_without\_new\_ver\_vw.sql
- olsapdr.jar
- SoftDeletedAppendix.xml
- SoftDeletedAppendix.rtf
- SoftDeletedAppendix\_L.rtf
- rdc\_del\_resp\_without\_new\_vert\_vw.sql
- rdc\_del\_resp\_without\_new\_ver\_vw.sql

- rdc\_report\_xml\_generation\_pb.sql

#### 4.2.6 Bug 13767687

**Before:** A security vulnerability existed.

**After:** The security vulnerability no longer exists.

**Modules Affected:**

- RdcTexts.properties
- de\_external.properties
- olsardc.ear

#### 4.2.7 Bug 13494580

**Before:** Messages that were not picked up by Oracle Study, Subject and Visit Integration Pack for Siebel Clinical and Oracle Clinical were not being resubmitted.

**After:** In the above scenario, messages are resubmitted.

**Modules Affected:**

- rxc\_clinical\_study\_queue\_upd.sql
- rxc\_msg\_resubmit\_proc.sql

#### 4.2.8 Bug 12334244

**Before:** Study sites created in Siebel Clinical in lowercase or mixed case were stored in Oracle Clinical as defined in Siebel Clinical. However, the query for study sites in Oracle Clinical retrieved only uppercase study sites, so these study sites were never retrieved in a query in Oracle Clinical.

**After:** Oracle Clinical now converts all study sites to all uppercase, and the query retrieves the correct study sites.

**Module Affected:** OracleClinical.ear

#### 4.2.9 Bug 11709987

**Before:** Subject flow in the CTMS integration fails with error message "Required Protocol Site Id is not present in the message" when the site ID is greater than 7 digits. A similar failure can occur when the clinical study ID exceeds 7 digits.

**After:** Site, Study, and Investigator IDs of up to a value of  $2^{32}-1$  (which is a maximum value of 4,294,967,295) do not cause an error in the CTMS integration with Oracle Clinical.

**Module Affected:** OracleClinical.ear

#### 4.2.10 Bug 13502296

**Before:** In Oracle Clinical, users could change the study context while updating patient data in the Data Entry window after launching it from the discrepancy database window.

**After:** Changing study is prevented in the data entry form when launched from discrepancy database form. See [Section 9.1, "Find Responses and Discrepancies with Wrong Study ID"](#).

**Modules Affected:**

- rxcdemli.fmx
- oclupg464to465seeddata.sql

#### 4.2.11 Bug 13481325

**Before:** Print preview PDF generation failed for a DCM layout with a blank line in a question label.

**After:** Print preview PDF generation succeeds in the above scenario.

**Modules Affected:**

- DciFormLayout.xsl
- oclupg464to465seeddata.sql

#### 4.2.12 Bug 13481319

**Before:** When there was a blank line in text added in an edited layout the Provisional DCI Form Generation failed.

**After:** In the above scenario, the Provisional DCI Form is generated without any error.

**Modules Affected:**

- oclupg464to465seeddata.sql

- pdr\_xmlp.xsl

#### 4.2.13 Bug 13350295

**Before:** In the Maintain Intervals form, after deleting a phase that has a previous phase, a new phase with the same phase name cannot be created.

**Note:** the deletion of the link to the previous phase is not completed and the record still exists.

**After:** In the above scenario, the phase can be created.

**Module Affected:** rxainmca.fmx

#### 4.2.14 Bug 13059412

**Before:** In the Graphic Layout Editor it was not possible to set the Visual Appearance (VA) of conditional branching Source and Target Questions to NONE.

**After:** VA can be set to NONE for Source and Target Questions.

**Modules Affected:**

- pharmaocgle.jar

#### 4.2.15 Bug 13051370

**Before:** The Study Site was not displayed in the Alpha Patient Codes, Study Site Relations or Study Site Patient Assignment form.

**After:** The Study Site is displayed in all these forms.

**Modules Affected:**

- rxappmac.fmx
- rxasimrl.fmx
- rxaivmqc.fmx

#### 4.2.16 Bug 13507235

**Before:** A security vulnerability existed that had no effect under normal usage.

**After:** This vulnerability no longer exists.

**Module Affected:** oclupg464to465step2.sql

#### 4.2.17 Bug 12633783

**Before:** Users could tab into a multi-line character field in a disabled conditional block and enter data. The data was not saved.

**After:** Users cannot tab into and enter data in a multi-line character field in a disabled conditional block.

**Module Affected:** RDC.js

#### 4.2.18 Bug 12430226

**Before:** On encountering an unrecoverable error while opening a CRF, the application logs the error in a file in a loop such that additional disk space is consumed unnecessarily.

**After:** In the above circumstance, the error is logged only once.

**Modules Affected:**

- rxcde1.dll

#### 4.2.19 Bug 11830832

**Before:** If you incorrectly add a duplicate value to a base DVG and then manually delete it using Delete under the Record menu, the system deleted the value from all subsets of the DVG even though the other subsets had only one instance of the value.

**After:** Deleting a duplicate value from a base DVG deletes the value only from the base DVG.

**Modules Affected:**

- rxcdvmdv.fmx

#### 4.2.20 Bug 9641038

**Before:** It was not possible to define an Interval rule in an Enhanced DCI Book using a trigger question from any DCM Subset other than Subset 0 (the first subset).

**After:** Interval rule trigger Questions can belong to any DCM Subset.

**Modules Affected:**

- rxcfsddb.fmx
- dci\_book\_rule\_tgt\_dci\_ins\_pb.sql
- dci\_book\_rule\_tgt\_dci\_upd\_pb.sql
- dci\_book\_rule\_tgt\_int\_upd\_pb.sql
- dci\_book\_rule\_tgt\_int\_ins\_pb.sql

#### 4.2.21 Bug 8814833

**Before:** When creating Conditional Branching on a question, the system included the Source Question in the list of values for selecting the Target Question.

**After:** The system does not display the Source Question in the Target Question list of values.

**Module Affected:** rxcddcmdc.fmx

#### 4.2.22 Bug 8502329

**Before:** It was not possible to update the **Continue at Detail #** field in the Details window for a new version of a Procedure.

**After:** It is possible to update the **Continue at Detail #** field in the Details window for a new version of a Procedure.

**Module Affected:** rxcpdmpx.fmx

#### 4.2.23 Bug 7173460

**Before:** In RDC Classic, if a CRF was soft-deleted and then recreated, an incorrect user was displayed in the **Modified By** field of the Audit History.

**After:** In the above scenario, the correct user is displayed.

**Modules Affected:**

- rdc\_audit\_view\_vw.sql
- rdc\_audit\_viewt\_vw.sql

#### 4.2.24 Bug 6274019

**Before:** The Graphic Layout Editor did not display the occurrence number for questions with multiple occurrences.

**After:** The occurrence value is displayed in the lower bar of the Graphic Layout Editor next to the label "**Q Occ**".

**Modules Affected:**

- Ocgldcm.java
- OcgldcmApplet.java
- OcgldcmLoader.java
- OcgldcmQuestion.java
- OcgldcmStatusBar.java
- OcgldcmQuestionAttributes.java
- rxcpbocjle.sql

#### 4.2.25 Bug 5010875

**Before:** In the Form Template Layout, when a field's Visual Appearance was set to None and the field was moved from the header or footer of the layout, the change was not saved.

**After:** In the above scenario, the change is saved.

**Modules Affected:**

- OcgldcmApplet.java
- pharmaocgle.jar

#### 4.2.26 Bug 4758792

**Before:** When a CRF was entered in RDC Onsite and then a user updated any header field through Mass Changes RDCI Key Change, the update was successful. However, when attempting to open the CRF in RDC Onsite, the user received the following message: "Please note: The data displayed on this form was entered using Classic Data entry. Updates to the data will not be associated with this form version."

**After:** In the above scenario, the CRF opens with no error message.

**Module Affected:** rxcmcbac.pc

#### 4.2.27 Bug 3755128

**Before:** If a user updated a discrepancy's review status to IRRESOLVABLE using one of the methods below, a subsequent Batch Validation run did not update the validation\_status for the response as it should.

The problem occurs when updating the discrepancy:

- from the discrepancy tab in RDC Classic for any type of discrepancy
- from the RDC Onsite data entry window for section, multivariate and indicator discrepancies only

Note that all user interfaces and the Patient Data Report correctly report the IRRESOLVABLE status despite this bug.

**After:** Validation status is properly set in the circumstances described above.

**Modules Affected:**

- rdc.fmx
- rdcpb\_mod.sql
- oclupg464to465reobj.sql
- olsadcapi.dll

#### 4.2.28 Bug 2342461

**Before:** It is possible to create duplicate, current investigators following the steps below. This results in errors in other parts of the application. For example, When accessing the Sites button via Maintain Study Sites Relations screen, the following error is issued: "56: Unexpected error. ORA-01422: exact fetch returns more than requested number of rows."

1. Create three investigators and assign each in turn to the same study site, such that the third investigator remains the current investigator for the study site.
2. Change the start dates for the first 2 investigators so that they match (if they don't already).
3. Delete the third (current) investigator.

**After:** In the circumstances above, upon executing Step #3, the first two investigator records do not become current. Instead, Oracle Clinical issues the message, "Two or more investigators have the same, latest termination date <date>. Select one as the new current investigator by deleting the termination date and setting the Current flag to Y." The user is unable to save changes until the conflict has been resolved.

---

**Note:**

Find and Fix scripts are available for this issue as Oracle Clinical patch 4.6.0.33.

---

**Module Affected:** rxaivmqc.fmx

#### 4.2.29 Bug 9559748

**Before:** Procedures LOCALSTUDYSITE.CheckValidStateCountry and LOCALSTUDYSITE.ValidateStudySite issue confusing error messages in a failure condition.

**After:** In a failure condition, procedure LOCALSTUDYSITE.CheckValidStateCountry issues error: "Invalid Value <Value> for <Type>" where Type can be State or Country, and procedure LOCALSTUDYSITE.ValidateStudySite issues error "Study site is invalid. (OC web service cannot be used to update study site.)"

**Module Affected:** OracleClinical.ear

### 4.3 Problems Addressed in Oracle Clinical Patch Set 4.6.4

The following problems were fixed for the first time in Patch Set 4.6.4.

#### 4.3.1 Bug 13074750

**Before:** Online help for the character layout editor did not work.

**After:** Online help for the character layout editor works.

**Modules Affected:**

- rxcddcmdc.fmx
- oclupg463to464seeddata.sql

#### 4.3.2 Bug 13009047

**Before:** In RDC Onsite, if you change your input date format in Preferences from the default setting to another setting, the next time you log in, the input date format setting changed back to the default setting.

**After:** In the above scenario, the date format change specified in Preferences is retained each time you log in.

**Module Affected:** ocl\_rdc\_pref\_settings.sql

### 4.3.3 Bug 13002342

**Before:** In Enhanced DCI Books, if the Trigger Question Values selected together are more than 2000 characters when you click OK, the Value(s) field is not populated with the selected values.

**After:** If the Trigger Question Values selected together are more than 2000 characters when you click OK, the Value(s) field is not populated with the selected values. In the above scenario, you receive a message 'The Trigger Question Value(s) selected exceeds the 2000 character limit. Please select values less than 2000 characters.'

**Module Affected:** rxcsddb.fmx

### 4.3.4 Bug 13002318

**Before:** Long Interval names cause the following problems in the Enhanced DCI book:

- You receive the error 'FRM-40831: Truncation occurred: value too long for field NAME' when adding an Interval with the maximum length of 60 characters as a Target of an Interval rule.
- The Interval does not appear in the DCI Book Navigator screen when the Interval is more than 30 characters.

**After:** In the above scenarios, long Interval names work as expected.

**Modules Affected:**

- rxcsddb.fmx
- rxc\_dci\_book\_rules\_api\_pb.sql

### 4.3.5 Bug 12944124

**Before:** In Oracle Clinical, when the combined length of the role names assigned to a user exceeded 1000 characters, PSUB jobs fail with the message 'Unable to set role.'

**After:** PSUB jobs succeed when the combined length of the role names assigned to a user is less than or equal to 2000 characters.

**Modules Affected:** All PSUB executables:

```

rxccossf
rxcdcgl
rxatalpp
rxatalpv
rxatalbr
rxatalfr,
rxatalfv
rxatalrs
rxatamcv
rxatamd
rxatamvi
rxappmed
rxdpacra
rxcdmsdr
trckact
rxcdxprg
rxcdxbvb
rxcglibir
rxcrepex
rxcrepim
rxalrbfr
rxalrbt
rxcpsdps
pslaunch
set_pwd
rxatamvd
rxapplis
rxcbvbs
rxcbvbsp
rxclism
rxcliipm
rxcdmldm
rxcdmlmd
rxcbelb
rxcdxcsp
rxcdxcsd
rxcdxbq
rxcpdgen
rxcpsct
gen_procs
gen_views
cnvstatus

```

### 4.3.6 Bug 12914568

**Before:** When customizing dcapi.dll, rxcde1.dll, or olsadcap.dll to use custom password enabled roles for a user, the dll fails with the error 'ORA-01031: insufficient privileges'.

**After:** In the above scenario, the dcapi.dll, rxcde1.dll, or olsadcap.dll supports custom password enabled roles for users.

---

**Note:**

The custom role password is encrypted using set\_pwd utility.

---

**Modules Affected:**

- dcapi.dll
- olsadcap.dll
- rxcde1.dll

**4.3.7 Bug 12864363**

**Before:** In RDC Onsite, when executing a search in the Casebook tab that returns more than the maximum number of CRFs, no warning message was displayed. In addition, completed CRFs that exceed the maximum are sometimes represented with the 'Entry expected' icon.

**After:** In the above scenario the message "The current query retrieves more than the maximum number of CRFs {0}. Data may be incomplete for some patients. Please specify additional parameters such that fewer CRFs are retrieved." displays and CRF(s) exceeding the maximum are represented by '-'.

**Modules Affected:**

- rdc\_zf\_mp\_Casebook\_pb.sql
- olsardc.ear

**4.3.8 Bug 12821940**

**Before:** The user was unable to log in to RDC Onsite in the following scenarios:

- The last study accessed by the user no longer had patients assigned to the site; that is, patients were either transferred to another site or removed.
- The first time a new user attempted to log in, if the first study (alphabetically) in the list of studies for the user had no patients assigned then the user was unable to log in even though other studies in the list had patients assigned to the site.

**After:** In the above scenarios, the user can log in to RDC Onsite.

**Module Affected:** olsardc.ear

**4.3.9 Bug 12716558**

**Before:** In the DCM Layout Editor, if a text field in a conditional block was changed to a multi-line text field, the entire block was deleted. At data entry time, all the fields that should have been in the deleted block remained enterable, regardless of the value of the source question.

---

**Note:**

As a workaround, the user could delete and recreate all conditional blocks for the appropriate source question.

---

**After:** In the above scenario, the conditional block is not deleted. However, be aware of Known Issue [Bug 12633783](#) - POSSIBLE TO TAB INTO MULTI-LINE TEXT FIELD IN A DISABLED BLOCK AND ENTER DATA.

**Module Affected:** pharmaocgle.jar

**4.3.10 Bug 12693300**

**Before:** In RDC Onsite, when quickly navigating through CRFs using the **Next/Prev** buttons or Alt+N/Alt+P, CRF header fields displayed as blank. (The headers displayed correctly if the user moved the scrollbar slightly.)

**After:** CRFs headers are displayed correctly when the user navigates quickly through CRFs.

**Module Affected:** olsardc.ear

**4.3.11 Bug 12688935**

**Before:** In the DCM Layout Editor, if the visual appearance of a question in a conditional block was changed the question was moved out of the block. At data entry time, all questions with a changed visual appearance were visible when they should have been hidden or grayed out.

---

**Note:**

As a workaround, the user could delete and recreate all conditional blocks for the appropriate source question.

---

**After:** In the circumstances above, the question is not moved out of the conditional block.

---

**Note:**

Within the set of conditional blocks for a source question, the Layout Editor prevents you from setting Visual Appearance to None for the source question, the target question in each block, and any field in a repeating question group.

---



**Module Affected:** pharmaocgle.jar

#### 4.3.12 Bug 12600577

**Before:** When selecting the action to Group Approve or Verify for more than 168 CRFs, the following error message was displayed: "RDC has encountered an unexpected error. Please log out and try again. If the problem persists, please contact your Help desk." and the CRF icons were not refreshed.

---

**Note:**

The actual approval or verification action was successful. Upon returning to the Home page or re-executing a Search, CRF icons reflected the proper status.

---

**After:** In the above scenario, no error is displayed and the page can refresh up to 1000 CRF icons.

**Modules Affected:**

- rdc\_zf\_surround\_pb.sql
- rdc\_zf\_surround\_cursor\_util\_pb.sql

#### 4.3.13 Bug 11905054

**Before:** When defining Enhanced DCI Books, errors occurred in the DCI Rules and Interval Rules windows when the combined length of values entered for a field exceeded 4000 characters, as follows:

- **In both the DCI Rules and Interval Rules windows:** (Trigger) CPE(s) at which trigger DCI is defined - Field was blank when the combined length of CPE names for a trigger DCI exceeded 4000 characters.
- **In the DCI Rules window:** (Target) DCI - Field was blank and error message was issued ('Field must be entered') when the combined length of all selected DCI names exceeded 4000 characters.
- **In DCI Rules window:** (Target) CPE(s) at which Target DCI(s) are defined - error message 'FRM-40735: WHEN-BUTTON-PRESSED trigger raised unhandled exception ORA-06502' appeared when the combined length of CPE names exceeded 4000 characters across all selected target DCIs.

**After:** The maximum character length for the above fields is increased to 32767, so the above errors should no longer occur.

**Modules Affected:**

- rxcsddb.fmx
- rxc\_dci\_book\_rules\_api\_pb.sql

#### 4.3.14 Bug 11892046

**Before:** During generation of the Patient Data Report, the trace file queried the RESPONSE\_LOBS table twice.

**After:** During generation of the Patient Data Report, the query occurs only once.

**Modules Affected:**

- rdc\_report\_xml\_generation\_ps.sql
- rdc\_report\_xml\_generation\_pb.sql
- ExtendedTextReport.java
- PatientDataReport.java

#### 4.3.15 Bug 11874497

**Before:**

In RDC data entry, when selecting an Indicator Question with conditional branching in a DCI that contained more than one DCM, the Question Group Questions that should be grayed out were not grayed out.

**After:** In the above scenario, the correct questions are grayed out.

**Module Affected:** olsardc.ear

#### 4.3.16 Bug 10424455

**Before:** The RDC Onsite Study and Site Summary Report displayed no data for a study with more than 600 sites.

**After:** The Study and Site Summary Report displays data for all studies.

**Module Affected:** rdczf\_pb.sql

#### 4.3.17 Bug 10137715

**Before:** In the command line Patient Data Report, the approval history was not sorted on the approval date/time.

**After:** In the command line Patient Data Report, the approval history is sorted correctly.

**Module Affected:** overflow.xml

#### 4.3.18 Bug 10093929

**Before:** It was possible to perform Mass Changes and Batch Data Loads on Extended Text questions.

**After:** Oracle Clinical prevents performing Mass Changes and Batch Data Loads on Extended Text questions.

**Modules Affected:**

- rxcmcmms.fmx
- rxcbeblt.pc

#### 4.3.19 Bug 9769529

**Before:** A DCI rule was not triggered when the value of the trigger question was derived and the derivation procedure was first executed during batch validation and it was not the first derivation to be executed for the CRF.

**After:** In the above scenario, the system now calculates expectedness.

**Modules Affected:**

- rxcdrtdcm.sql
- ocl\_flex\_detection\_pb.sql

#### 4.3.20 Bug 9542265

**Before:** After using Ctrl+E to view a comment in the discrepancy database and attempting to exit the form, the form prompted the user to save changes even though no changes had been made.

**After:** The Discrepancy Database form displays a message about saving data only when the user has made changes.

**Module Affected:** rxcdrmmdd.fmx

#### 4.3.21 Bug 9534888

**Before:** During Patient Data Report generation, special characters spanned more than one character in length. If the name of a Visit or DCI was close to its length limit and contained special characters, Patient Data Report generation could fail.

**After:** Patient Data Report generation no longer fails due to special characters in Visit or DCI names.

**Module Affected:** rdc\_report\_xml\_generation\_pb.sql

#### 4.3.22 Bug 9478423

**Before:** When you ran Mass Change reports in either production or test mode for RDCI Key Changes, RDCI Soft Delete, RDM Key Changes or Responses Candidate Data Sets, the job failed with the message '20041: Invalid entry – Validation failed.'

**After:** The Mass Change reports for the Candidate Data sets run successfully.

**Module Affected:** oclupg463to464seeddata.sql

#### 4.3.23 Bug 9456952

**Before:** In the Audit Details window, when the data value for the 'Changed From', 'Changed To' or 'Comment' field was blank, the window displayed the corresponding value from the field whose audit detail you looked at previously.

**After:** In the above scenario, the 'Changed From' and 'Changed To' fields display 'Null' and the 'Comment' field displays as 'No Comment Specified.'

**Module Affected:** olsardc.ear

#### 4.3.24 Bug 9362701

**Before:** When you submitted a job for Study Freeze/Unfreeze, if the **Flex Study Enabled?** check box was checked for the study in the Clinical Study States window, it became unchecked.

**After:** In the above scenario, the **Flex Study Enabled?** check box remains checked in Clinical Study States window.

**Module Affected:** rxcdamfs.sql

#### 4.3.25 Bug 9346173

**Before:** In RDC Onsite, if there is a repeating Indicator Question Group in which the Indicator Question and another Question are mandatory, when you enter data for the Indicator Question and a non-mandatory Question in more than one repeat and save, the error message 'WriteResponses - 288700: Mandatory field missing' displays.

**After:** In the above scenario, when you save, the CRF mandatory discrepancies fire as appropriate.

**Module Affected:** olsrdcapi.dll

#### 4.3.26 Bug 9309168

**Before:** When using repeating default values as Question prompts, if the values are displayed as Right-justified and the Question attribute 'upper case' is not checked then the default repeat values are truncated in the Patient Data Report.

**After:** In above scenario, the default repeat values are not truncated.

**Module Affected:** xdo.jar

#### 4.3.27 Bug 9099579

**Before:** In the Patient Data Report the hyperlinks in the Table of Contents are not blue as specified in the FDA Portable Document Format Specifications, Version 2.0 2008-06-04, Page 5.

**After:** The hyperlinks in the Patient Data Report Table of Contents are blue.

**Modules Affected:**

- TOC.rtf
- TOC\_L.rtf

#### 4.3.28 Bug 8533339

**Before:** You could not delete the first repeat of a repeating Indicator question group.

**After:** You can delete the first repeat of a repeating Indicator question group.

**Module Affected:** olsardc.ear

#### 4.3.29 Bug 8346033

**Before:** After applying patches 4.5.3.11/4.5.3.12 the **Schedule** button was no longer present in the Migrate Form Version by Book window.

**After:** The **Schedule** button is present on the Migrate Form Version by Book window and you can schedule DCI form migration by book jobs.

**Modules Affected:** rxcmdfvm.fmx

#### 4.3.30 Bug 8307694

**Before:** When you open a blank CRF and put focus on a check box question (either intentionally or if it is the first field in the CRF) and then unblank the CRF by clicking the blank flag tool you are not able to select the check box that was in focus.

**After:** In the above scenario, you can select the check box.

**Module Affected:** olsardc.ear

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### 4.4 Problems First Addressed in Oracle Clinical Patch Set 4.6.3

Oracle Clinical Patch Set 4.6.3 included the following bug fixes that were not included in any prior release. Many of them concern migrating to the enhanced approve/verify data model. For further information on this topic, see [Section 7.9, "Migrating Data to the Enhanced Data Model for Approvals and Verifications"](#).

#### 4.4.1 Bug 10010054

**Before:** In Oracle Clinical Data Entry, when the Document\_Number field from the RDCI Header is nonupdateable, then users cannot modify the value of the Blank Flag (Y to N or N to Y) of the RDCI when performing the key changes.

**After:** The Blank Flag is updateable regardless of whether the Document\_Number field is updateable or not.

**Module Affected:** rxcdemli.fmx

#### 4.4.2 Bug 12608085

**Before:** When a user entered a password to approve a CRF in RDC Classic and then pressed OK, the system displayed the error "Password mis-match. Please try again."

**After:** No error message is displayed and the CRF is approved successfully after entering the password

**Module Affected:** rdc.fmx

#### 4.4.3 Bug 12812991

**Before:** In Oracle Clinical Design, Patient Positions, Create/Delete Patients in Production Mode or from Design, Test a Study Design, Create/Delete Patients in Test Mode, when entering the **No. to Create** field and the **Start Patient** field for screening, normal or replacement patients, clicking the **Create Positions** button just clears the form and does not create the patients.

**After:** In the above scenarios, the patients are created and a message is displayed indicating the number of patients created.

**Module Affected:** rxappmca.fmx

#### 4.4.4 Bug 12846161

**Before:** Scenario A: In Oracle Clinical Design, Patient Positions, Patients, when clicking the **Single** button to switch to single-record mode, the error "FRM-40105 - Unable to resolve reference to item PAPO2.INFORMED CONSENT\_DATE" is displayed.

Scenario B: In Oracle Clinical Design, Patient Positions, Patients, the **Frozen?** column is checked for a study that is not frozen.

**After:** In Scenario A, clicking the **Single** button switches to single- record mode.

In Scenario B, the **Frozen?** column is checked only if the study/patient is frozen.

**Modules Affected:** rxappmma.fmx

#### 4.4.5 Bug 12735957

**Before:** Migrating a single study to the enhanced approve/verify data model was not supported.

**After:**

**Modules Affected:** Migrating a single study that is frozen and not yet migrated is supported; see [Migrating Data to the Enhanced Data Model for Approvals and Verifications](#).

- ocl\_appver\_single\_migrate.sql
- ocl\_exit.sql

#### 4.4.6 Bug 12722958

**Before**

It was possible to unfreeze a study that had not been migrated to the enhanced approve/verify data model.

**After**

The system now prevents unfreezing studies that have not been migrated.

**Module Affected**

rxcdamfs.sql

#### 4.4.7 Bug 12720294

**Before:** The system did not enforce migrating to the enhanced approve/verify data model.

**After:** The system enforces migrating to the enhanced approve/verify data model when upgrading to Patch Set 4.6.3.

**Modules Affected:**

- ocl\_appver\_val\_migrate\_ps.sql
- ocl\_appver\_val\_migrate\_pb.sql
- ocl\_setappveropasetting.sql

#### 4.4.8 Bug 10198386

**Before:** It was possible to execute the Prepare script oclupg45311prepare.sql or Migrate script oclupg45311migrate.sql more than once on a database, which would cause data corruption.

**After:** These scripts can no longer be run more than once on the same database.

**Modules Affected:**

- oclupg45311prepare.sql
- oclupg45311migrate.sql

#### 4.4.9 Bug 10298223

**Before:** In Oracle Clinical, upon modifying a DCM Question Group Name, an error message "17101: This Question Group does not exist in library." is displayed.

**After:** In the above scenario, no error message is displayed.

**Modules Affected:** rxdcmdmc.fmx

#### 4.4.10 Bug 10096665

**Before:** A user with multiple user roles assigned was unable to log in to RDC Onsite, even if all but one role were inactive. Inactive user roles in the USER GROUP ROLES installation reference codelist were included in login evaluation.

**After:** The system evaluates only Active user roles in the USER GROUP ROLES during login to RDC Onsite. Note: A user may only have one Active user role for login even if assigned multiple user roles.

**Module Affected:** rdc\_zf\_dci\_access\_pb.sql

#### 4.4.11 Bug 10094228

**Before:** In RDC Onsite 4.6, when selecting Investigator Comment under the Review tab, there is a performance degradation in the search results compared to RDC Onsite 4.5.3.

**After:** In the above scenario, the performance is equivalent to RDC Onsite 4.5.3's.

**Module Affected:** rdc\_zf\_surround\_inv\_comment\_pb.sql

#### 4.4.12 Bug 9266537

**Before:** In Oracle Clinical, when deleting a repeating default value in a DCM repeating Question Group, upon saving a FRM-40510 error is displayed.

**After:** In the above scenario, no error is displayed.

**Module Affected:** rxcddcmdc.fmx

#### 4.4.13 Bug 6113210

**Before:** In Oracle Clinical, if a DCM layout has been edited and the layout length is between 8001 and 8020, then upon re-opening the DCM Layout Editor, a blank gray screen was displayed.

**After:** In the above scenario, the DCM Layout opens with the correct layout.

**Module Affected:** rxcpbocjle.sql

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### 4.5 Other Problems Addressed in Oracle Clinical Patch Set 4.6.3

Oracle Clinical Patch Set includes bug fixes included in Patch Set 4.6.3 that were first addressed in the following patches:

- [Problems Addressed in Patch 4.6.0.27](#)
- [Problems Addressed in Patch 4.6.0.23](#)
- [Problems Addressed in Patch 4.6.0.21](#)
- [Problems Addressed in Patch 4.6.0.19](#)
- [Problems Addressed in Patch 4.6.0.17](#)
- [Problems Addressed in Patch 4.6.0.14](#)
- [Problems Addressed in Patch 4.6.0.12](#)
- [Problems Addressed in Patch 4.6.0.10](#)
- [Problems Addressed in Patch 4.5.3.27](#)
- [Problems Addressed in Patch 4.5.3.26](#)
- [Problems Addressed in Patch 4.5.3.24](#)
- [Problems Addressed in Patch 4.5.1.81](#)
- [Problems Addressed in Patch 4.5.1.79](#)
- [Problems Addressed in Oracle Forms Patches](#)

This section describes the bugs that were originally fixed in these patches. These patches contained additional fixes which were included in the base 4.6.2 release.

#### 4.5.1 Problems Addressed in Patch 4.6.0.27

Oracle Clinical Patch Set includes the following bug fixes that were originally fixed in patch 4.6.0.27:

##### Bug 12816142

###### Before

Changing passwords did not work in RDC Classic. After entering the values for the password fields and clicking the change password button an error "Invalid old password" is displayed. This problem was seen only after applying the Developer Forms patches as documented in patch OC\_4.6.0.14.

###### After

In the above scenario, no error is displayed and the password is changed successfully.

###### Module Affected

rxsecdb2.fmx

#### 4.5.2 Problems Addressed in Patch 4.6.0.23

Oracle Clinical Patch Set includes the following bug fixes that were originally fixed in patch 4.6.0.23:

## Bug 12427108

### Before

In a CRF with no updateable fields in the header (no DCI date or DCI blank flag displayed), upon marking the DCM blank and saving, RDC Onsite displays the following error message:

Can't move focus to the control because it is invisible, not enabled, or of a type that does not accept the focus.

### After

In the above scenario, RDC Onsite does not display an error when the CRF is marked and saved as blank.

### Module Affected

olsardc.ear

## Bug 12427049

### Before

When you run the Enable/Disable Second Pass Required process for a flexible study, Oracle Clinical unchecks the **Flex Study Enabled?** flag in the Clinical Study States table.

### After

In the above scenario, Oracle Clinical retains the setting of the Flex Study? flag in the Clinical Study States table and retains the time stamp values.

### Module Affected

rxcdausp.sql

## Bug 12638841

### Before

Under certain circumstances, RDC Onsite data entry does not work properly for fields assigned in the Graphic Layout Editor with a visual appearance of None. Some examples of the data entry problems include data entered in the field is not saved and univariate discrepancies are not raised properly. If data is entered successfully, the data is not deleted as it should be when its conditional block — if applicable — becomes disabled.

Note that these data entry problems do not occur if:

- You press Tab to move the cursor into the field instead of clicking the field.
- You enter data in a field that has a visual appearance before you enter data in a field that has a visual appearance of None.

### After

The data entry problems as described above are resolved.

### Module Affected

olsardc.ear

## Bug 12427099

### Before

If you have access to only one study and one site, and no patients are assigned to the site, RDC Onsite displays the following misleading error when you attempt to log in to the application:

Error in your account setup. Please contact your help desk.

In fact, there may be no problem with the user's account.

### After

In the above scenario, RDC Onsite displays the following relevant message:

No patients have been enrolled in the system for your site. Please contact your Clinical Team to determine when patients will be available

### Module Affected

olsardc.ear

## Bug 12600542

### Before

In RDC Onsite data entry for a DCI with a single DCM, if the DCM is automatically marked blank, the DCI is also automatically marked blank. Upon save, the checkmark (tick) in the DCM Blank flag check box disappears, such that the user may be unable to see why all fields are grayed out and disabled.

### After

In the above scenario, the checkmark in the DCM Blank flag check box displays properly. In addition, if the blank flag tool is used, then the above scenario does not occur.

### Module Affected

olsardc.ear

## Bug 12540121

### Before

In RDC Onsite, when you group verify, group unverify, group approve, or group unapprove (group actions) and you select more than 1000 CRFs, the action does not complete successfully for a number of CRFs.

**After**

Group verify, group unverify, group approve, and group unapprove actions complete successfully for all CRFs selected. The system inserts the correct number of records into the RDCL\_HISTORY table.

**Module Affected**

rdc\_zf\_approve\_verify\_pb.sql

**4.5.3 Problems Addressed in Patch 4.6.0.21**

Oracle Clinical Patch Set includes the following bug fixes that were first addressed in patch 4.6.0.21:

**Bug 12540092****Before**

RDC Onsite does not display any discrepancies on the Review Discrepancies page even though discrepancies exist. The problem occurs regardless of the method you use to open the Review Discrepancies page or to query for discrepancies. The problem occurs sporadically, but once it occurs, you have to log out and then log in to RDC Onsite again to restore the functionality. The problem generally occurs at high loads but can also occur if there is a high rate of logins and queries.

**After**

In the above scenario, the Review Discrepancies page displays the discrepancies properly.

**Module Affected**

rdc\_daapi\_pb.sql

**4.5.4 Problems Addressed in Patch 4.6.0.19**

Oracle Clinical Patch Set includes the following bug fixes that were first addressed in patch 4.6.0.19:

**Bug 12341342****Before**

In Test mode, when a validation procedure compares a question response in non-repeating question group with a question response in repeating question group and identifies more than one discrepancy, the discrepancy database shows only the discrepancy for the first repeat of the repeating question group and the discrepancy count in the output file is displayed as 1.

**After**

In the above scenario, discrepancies are created for all discrepancies as appropriate and the discrepancy count is correct.

**Module Affected**

rxcpbpdstd.sql

**4.5.5 Problems Addressed in Patch 4.6.0.17**

Oracle Clinical Patch Set includes the following bug fixes that were first addressed in patch 4.6.0.17:

**Bug 12340242****Before**

Testing of a heavily loaded RDC Onsite application with more than 500 concurrent users revealed that the overall time to open a CRF from various pages is not optimal.

**After**

In the above scenario, the performance when opening a CRF from various pages improves.

**Module Affected**

olsardc.ear

**Bug 12340260****Before**

Optionally, the Activities section on the RDC Onsite Home page can include the following pre-defined queries:

- Review *n* Other Discrepancies
- Review *n* Active Discrepancies

The performance when opening the Home page and returning a value for the discrepancy count (that is, the value of *n*) for these queries is not optimal because RDC Onsite runs the query multiple times before returning a discrepancy count.

**After**

Performance improves significantly because RDC Onsite runs the query only once before returning a discrepancy count

**Modules Affected**

olsardc.ear, rdc\_user\_activity\_tags\_ps.sql, rdc\_user\_activity\_tags\_pb.sql, rdc\_zf\_user\_activity\_list\_vw.sql

**Bug 12340251****Before**

Testing of a heavily loaded RDC Onsite application with more than 500 concurrent users revealed that the overall time to open a CRF is not optimal if the following conditions are true:

- The entered CRFs have responses that have been updated several times.
- The Audit History pane and the Navigator Pane (for investigator comments) are expanded in the Data Entry window.

#### After

In the above scenario, the overall time to open a CRF improves and is comparable to the time required to open a CRF when a single user is logged in to the RDC Onsite application. In addition, times are comparable regardless of the audit history or investigator comments associated with the responses.

#### Modules Affected

rdcfieldeverhadresp\_vw.sql, rdcfieldeverhadresp\_t\_vw.sql, rdcfieldeverhadinvcmt\_vw.sql, rdcfieldeverhadinvcmt\_t\_vw.sql

### 4.5.6 Problems Addressed in Patch 4.6.0.14

Oracle Clinical Patch Set includes the following bug fix that was first addressed in patch 4.6.0.14:

#### Bug 9903418

##### Before

Oracle Clinical 4.6 did not work with Oracle Java Runtime Environment (JRE), Standard Edition, Version 1.6, Update 19 or later. Beginning with Update 19, the JRE expected all JAR files to be signed to provide security verification and certification. Because some JAR files for Oracle Clinical 4.6 were not signed, the application displayed a security message warning that certificates could not be verified and might not run. In some scenarios, the JRE crashed.

##### After

All JAR files are signed. Oracle Clinical 4.6 works with Oracle Java Runtime Environment (JRE), Standard Edition, Version 1.6, Update 24 or later.

#### Modules Affected

frmall\_jpi.jar, hyperlink.jar, /java/ewt3.jar, jle2-0-3.jar, oclcons.jar, opaicons.jar, opashare.jar, opaspell.jar, rdcicons.jar, share.jar, UtilityField.jar, xmlcomp.jar, xmlparserv2.jar

### 4.5.7 Problems Addressed in Patch 4.6.0.12

Oracle Clinical Patch Set includes the following bug fixes that were first addressed in patch 4.6.0.12:

#### Bug 12600509

##### Before

During data entry, RDC Onsite retains a mandatory discrepancy in error in the following scenarios:

- Scenario A — You enter responses in a non-repeating question group (which contains a mandatory question) and save the CRF. Then, you open the CRF again and delete all the responses in the CRF (or CRF section). When you delete the mandatory response, a discrepancy is raised, and upon Save, the discrepancy remains.
- Scenario B — You enter responses in one row of a repeating question group (which contains a mandatory question) and save the CRF. Then, you open the CRF again and delete all the responses from the row. When you delete the mandatory response, a discrepancy is raised, and upon Save, the discrepancy remains.

Further problems occur when a user restricted to UPD\_DISCREP privileges, such as a monitor, updates the discrepancy and saves the CRF. For Scenario A, RDC Onsite deletes the row. For both scenarios, RDC Onsite obsoletes the discrepancy, and if the CRF has no other responses, marks the CRF as blank, but retains a now invalid status of PASS 1 COMPLETE. RDC Onsite attributes the deleting row and/or marking blank actions to the monitor.

##### After

RDC Onsite does not retain mandatory discrepancies for the scenarios described above. Instead:

- For Scenario A, upon Save, RDC Onsite marks the CRF as blank and deletes the mandatory discrepancy.
- For Scenario B, upon Save, RDC Onsite deletes the row and deletes the mandatory discrepancy.

To correct existing data, you need to run the Find Invalid Status script (find\_rdc\_blankflag\_p1.sql) to locate the CRFs and/or CRF sections with an invalid status of PASS 1 COMPLETE and Blank flag = Y. You then run the Fix Invalid Status script (fix\_rdc\_blankflag\_p1.sql) to update the status of blank CRFs to RECEIVED.

In addition, you need to run the Find Blank Rows Mandatory Discrepancies script (find\_blank\_repeat\_mand\_disc.sql) to locate blank rows with mandatory discrepancies. To fix these CRFs, you need to update and save the CRF. RDC Onsite will mark the mandatory discrepancy as obsolete or valid, depending upon the data you enter.

See [Running Find and Fix Scripts](#) for information about running the scripts to repair your data.

#### Module Affected

olsadcap.dll

#### Bug 12427044

##### Before

If any response field in the DCM layout has its visual appearance formatted as **None**, the DCM Graphic Layout Editor does not save your updates to the layout.

##### After

In the above scenario, you can save your updates to a valid layout, with some restrictions: the source and target questions for conditional and indicator branching cannot have a visual appearance of none. If you select a visual appearance of None for either a source question or a target question, the DCM Graphic Layout Editor issues the following error message:

Indicator questions and conditional branch source questions cannot have visual appearance none.

#### Module Affected



pharmaocgle.jar

## Bug 12600549

### Before

In RDC Onsite data entry, a CRF page with response data only in non-enterable questions (and no response data in enterable questions) is automatically marked blank upon Save. Note: It is possible to load response data into non-enterable questions using the DCAPI.

### After

In the above scenario, the CRF is not marked blank upon Save.

### Module Affected

olsadcap.dll

## Bug 12600532

### Before

During data entry, RDC Onsite automatically closes a manual discrepancy on an otherwise blank row in a repeating question group. This error occurs when you modify a discrepancy or response data in the same repeating question group. When the changes are saved, RDC Onsite deletes the entire row. This error is particularly a problem when a user restricted to UPD\_DISCREP privileges performs the update; it appears as though that user deleted a row.

### After

In the above scenarios, the manual discrepancy is retained. The repeat is not deleted, and the manual discrepancy is not closed.

### Module Affected

olsadcap.dll

## Bug 9625554

### Before

In RDC Onsite data entry, when Save Repeating Defaults = N, a CRF with a repeating question group with repeating defaults is not saved as blank, as it should be when no responses are entered in the CRF. (Note that this is the case even though the default values are not actually saved as responses in the database.)

### After

In the above scenario, RDC Onsite saves the CRF as blank.

### Module Affected

olsadcap.dll

## Bug 7413941

### Before

When you click Save Complete during data entry, RDC Onsite displays the following message even though you entered no responses for the CRF:

```
WriteResponses - 288700: Mandatory field missing
```

RDC Onsite should save a mandatory discrepancy only if you enter at least one response for the CRF. Otherwise, as in this case, RDC Onsite should mark the CRF as blank. The problem occurs when Save Repeating Defaults = N, and the CRF has a repeating question group with repeating defaults. (Note that the repeating default values are NOT saved to the database as responses.)

### After

In the above scenario, RDC Onsite automatically marks the CRF as blank, and does not display an error message about missing mandatory field.

### Module Affected

olsadcap.dll

## Bug 9363194

### Before

During data entry, RDC Onsite retains a mandatory discrepancy in error in the following scenarios:

- Scenario A — You enter responses in a non-repeating question group that contains a mandatory question and save the CRF. Then, you open the CRF again and delete all the responses in the CRF (or CRF section). When you delete the mandatory response, a discrepancy is raised, and upon Save, the discrepancy remains.
- Scenario B — You enter responses in one row of a repeating question group (which contains a mandatory question) and save the CRF. Then, you open the CRF again and delete all the responses from the row. When you delete the mandatory response, a discrepancy is raised, and upon Save, the discrepancy remains.

Further problems occur when a user restricted to UPD\_DISCREP privileges, such as a monitor, updates the discrepancy and saves the CRF. For Scenario A, RDC Onsite deletes the row. For both scenarios, RDC Onsite obsoletes the discrepancy, and if the CRF has no other responses, marks the CRF as blank, but retains a now invalid status of PASS 1 COMPLETE. RDC Onsite attributes the deleting row and/or marking blank actions to the monitor.

### After

RDC Onsite does not retain mandatory discrepancies for the scenarios described above. Instead:

- For Scenario A, upon Save, RDC Onsite marks the CRF as blank and deletes the mandatory discrepancy.
- For Scenario B, upon Save, RDC Onsite deletes the row and deletes the mandatory discrepancy.

To correct existing data, you need to run the Find Invalid Status script (find\_rdc\_blankflag\_p1.sql) to locate the CRFs and/or CRF sections with an invalid status of PASS 1 COMPLETE and Blank flag = Y. You then run the Fix Invalid Status script (fix\_rdc\_blankflag\_p1.sql) to update the status of blank CRFs to RECEIVED.

In addition, you need to run the Find Blank Rows Mandatory Discrepancies script (find\_blank\_repeat\_mand\_disc.sql) to locate blank rows with mandatory discrepancies. To fix these CRFs, you need to update and save the CRF. RDC Onsite will mark the mandatory discrepancy as obsolete or valid, depending upon the data you enter.

This patch includes the Find and Fix scripts to correct the data affected by this bug.

**Module Affected**

olsadcapi.dll

**Bug 12600420****Before**

The pharmacogle.jar and pharmacogle.jar files are not signed. As a result, Oracle Clinical displays several messages about certificates, trusted source, and potential security issues when you use Oracle Java Runtime Environment (JRE), Standard Edition, Version 1.6, Update 24 or later.

**After**

The pharmacogle.jar and pharmacogle.jar files are signed.

**Modules Affected**

pharmacogle.jar, pharmacogle.jar

**Bug 12633589****Before**

During second pass data entry in Oracle Clinical with reconciliation enabled, if you enter data that creates a univariate discrepancy, and then cancel the discrepancy dialog box to correct the discrepant data, and save your changes, Oracle Clinical displays several error messages and then crashes with this final error:

FRM-92101: There was a failure in the Forms server during startup. This could happen due to invalid configuration. Please look in to the we

**After**

In the above scenario, no error messages display. Oracle Clinical does not crash.

**Module Affected**

rxcdcede.fmx

**Bug 12642868****Before**

In RDC Onsite data entry, if you delete all responses in a PASS 1 STARTED CRF so that no data remains in the DCM (or DCI, if this is a single-DCM DCI) and Save Incomplete, RDC Onsite saves the CRF with a status of PASS 1 STARTED. However, this status is invalid because the CRF no longer has data.

**After**

In the scenario above, RDC Onsite does not let you save the CRF as incomplete. Instead, RDC Onsite displays the following message:

All responses in one or more sections have been deleted. If intentional, please Save Complete, so the section(s) or CRF are marked blank.

Alternatively, you can close with the option to discard changes and delete the CRF

**Module Affected**

olsadcapi.dll

**4.5.8 Problems Addressed in Patch 4.6.0.10**

Oracle Clinical Patch Set includes the following bug fixes that were first addressed in patch 4.6.0.10:

**Bug 12395616****Before**

When a DCI Layout and DCI Form were generated, the Prov DCI Form Generated? field remained unchecked.

**After**

When a DCI Layout and DCI Form are generated, the Prov DCI Form Generated? field is checked.

**Module Affected**

rxcdimdi.fmx

**4.5.9 Problems Addressed in Patch 4.5.3.27**

Oracle Clinical Patch Set includes the following bug fixes that were first addressed in patch 4.5.3.27:

**Bug 12426980****Before**

After you apply patch OC\_4.5.3.25, a DCM question with a Thesaurus DVG does not sort properly.

**After**

In the above scenario, the Thesaurus DVG sorts properly.

**Module Affected**

olsardc.ear

## Bug 12426994

### Before

In the Patient Data Report, the Ancillary, Appendix, and Deleted CRFs report pages display the page number on the first page only. The page numbers for the subsequent pages are missing.

### After

In the above scenario, the page numbers output on all Ancillary, Appendix, and Deleted CRFs pages in the Patient Data Report.

### Module Affected

xmlp\_clob\_seeddata.dmp

## Bug 12426927

### Before

As a result of applying patch 4.5.3.25, if a DCM has multiple character subset layouts and one of the subset layouts has a question group with the LINES\_PER\_ROW value as null, then the character Patient Data Report fails, even for the layout with a not-null value for LINES\_PER\_ROW.

### After

In the above scenario, the Patient Data Report generates successfully.

### Modules Affected

rxcpb\_reportutils.sql, rxcdmlpd.rep, rxcdmlpd\_l.rep

## Bug 12426971

### Before

As a result of running the Fix script for Bug 8601231 / Bug 9240260 in patch OC\_4.5.3.25, character layouts are modified when a DCM with same question group has multiple subset layouts and the LINES\_PER\_ROW value is null in one layout but not in all layouts. The Fix script updates the same LINES\_PER\_ROW value for all the subsets to the value for the one subset that was previously null, which may modify your character layouts.

### After

Oracle Clinical Patch Set provides replacement Find and Fix scripts to fix any character layouts modified by previously running the Fix script for Bug 8601231 / Bug 9240260.

For more information, see the following Readme file in your install directory: `missing_lines_per_row_readme.txt`

### Modules Affected

`find_missing_lines_per_row.sql`, `list_missing_lines_per_row.sql`, `fix_missing_lines_per_row.sql`

## 4.5.10 Problems Addressed in Patch 4.5.3.26

Oracle Clinical Patch Set includes the following bug fixes that were first addressed in patch 4.5.3.26:

## Bug 11841736

### Before

As a result of applying patch 4.5.3.25, if the LINES\_PER\_ROW value in a DCM Question Group for a character layout is null, generating the graphic Patient Data Report or the Blank Casebook Report fails.

Only the Character Patient Data Report should fail in this circumstance, with a message to refer to the file `missing_lines_per_row_readme.txt` in your install directory.

### After

If the LINES\_PER\_ROW value in a DCM Question Group is null, the graphic Patient Data Report and the Blank Casebook Report print successfully.

### Modules Affected

rxcdmlpd.rep, rxcdmlpd\_l.rep, rxcdmcrf.rep, rxcdmcrf\_l.rep

## Bug 12426903

### Before

As a result of running the Fix script for Bug 8601231 / Bug 9240260 in patch OC\_4.5.3.25, character layouts are modified when a DCM with same question group has multiple subset layouts and the LINES\_PER\_ROW value is null in one layout but not in all layouts. The Fix script updates the same LINES\_PER\_ROW value for all the subsets to the value for the one subset that was previously null, which may modify your character layouts.

### After

Replacement Find and Fix scripts are provided to fix any character layouts modified by previously running the Fix script for Bug 8601231 / Bug 9240260. For information about running the Find and Fix scripts to correct your data, refer to the following Readme file in your install directory:

`missing_lines_per_row_readme.txt`

### Modules Affected

rxcdmlpd.rep, rxcdmlpd\_l.rep

## 4.5.11 Problems Addressed in Patch 4.5.3.24

Oracle Clinical Patch Set includes the following bug fixes that were first addressed in patch 4.5.3.24:

**Bug 12340198****Before**

When you generate a Patient Data Report, the system:

- Does not embed any Type 1 fonts.
- Embeds a *subset* of the TrueType fonts. Note that the system embeds only those font characters that are actually used in the report. In other words, the system embeds a subset of the full character set for a TrueType font.

**After**

When you generate a Patient Data Report from the command line **and** you specify the **-cfg** parameter:

- The system embeds the full character set for each Type 1 font used in the report.
- TrueType fonts remain the same.

To embed Type 1 fonts, you must configure the xdoobookbinder.cfg file and then generate the report from the command line using the -cfg parameter. See [Embedding Type 1 Fonts into the Patient Data Report](#) for instructions.

**Note:**

When you use the -cfg parameter to embed the full character sets for Type 1 fonts, the size of the Patient Data Report increases substantially.

**Module Affected**

olsapdr.jar

**Bug 12340187****Before**

Oracle Clinical saves an incorrect modification time stamp in the following cases:

- DCI Books — The modification time stamp remains at the same value that is set when you open the book. As a result, when you modify and save the DCI Book, the modification date and time is earlier than the creation date and time.
- Clinical Planned Events — When you create a duplicate record, Oracle Clinical copies the modification time stamp from the previous record. As a result, the modification date and time is earlier than the creation date and time. This bug occurs when you create a duplicate record using either of the following methods:
  - Navigate to Design, Studies, Easy Study Design, and then select Events.
  - Navigate to Design, Schedule, and then select Events.

**After**

Oracle Clinical saves the correct modification time stamp as follows:

- DCI Books — Sets the modification time stamp to the value of the system date and time (sysdate) when you modify the book.
- Clinical Planned Events — Sets the modification time stamp to the value of NULL when you create a duplicate record.

**Modules Affected**

rxaevmqc.fmx, rxcdimdb.fmx, rxastmqc.fmx

**4.5.12 Problems Addressed in Patch 4.5.1.81**

Oracle Clinical Patch Set includes the following bug fixes that were first addressed in patch 4.5.1.81:

**Bug 12340159****Before**

When a user with a password-protected role attempts to update patient data through the Discrepancy Database (that is, selects Update Patient Data from the Special menu), Oracle Clinical displays the following error message:

```
Fatal Error: Could not set role.
```

**After**

In the above scenario, Oracle Clinical opens the Update Patient Data screen successfully and does not display an error message.

**Module Affected**

rxclbsml.plx

**4.5.13 Problems Addressed in Patch 4.5.1.79**

Oracle Clinical Patch Set includes the following bug fixes that were first addressed in patch 4.5.1.79:

**Bug 12340139****Before**

The performance of the PSUB process when generating Data Extract Views is not optimal.

**After**

The performance of the PSUB process when generating Data Extract Views improves.

### Modules Affected

- UNIX: vbthesfn.o and rxcdbv.o
- Windows: rxcdbv.exe

### 4.5.14 Problems Addressed in Oracle Forms Patches

The Oracle Forms patches that must be applied with Oracle Clinical Patch Set (see [Applying Developer Forms 10.1.2.3.0 Bundle Patch and Related Patches](#)) fixes the following bugs in Oracle Clinical:

#### Bug 12432636

##### Before

Due to an issue with the Oracle Developer Forms product, Oracle Clinical crashes with a FRM-92100 error when you enter multiple lines of text in the Comment field during discrepancy management.

##### After

The FRM-92100 error no longer occurs with use of multi-line text.

##### Module Affected

Not applicable. This fix does not affect Oracle Clinical modules.

#### Bug 12696901

##### Before

Due to an issue with the Oracle Developer Forms product, Oracle Clinical crashes with a FRM-92101 error in certain circumstances when you enter, update, or browse data during second pass data entry.

##### After

In the above scenarios, the FRM-92101 error no longer occurs.

##### Module Affected

Not applicable. This fix does not affect Oracle Clinical modules.

#### Bug 12696894

##### Before

Due to an issue with the Oracle Developer Forms product, editing or browsing the DCM layout, the DCI layout, or the Forms Layout Template causes the Oracle Clinical application to crash.

##### After

The crash no longer occurs when editing or browsing the DCM layout, the DCI layout, or the Forms Layout Template.

##### Module Affected

Not applicable. This fix does not affect Oracle Clinical modules.

#### Bug 12696890

##### Before

Due to an issue with the Oracle Developer Forms product, using Ctrl+E to enter multi-line text for the Internal Comment field causes the surrounding fields to disappear when you save your changes.

##### After

In the above scenario, the surrounding fields no longer disappear after saving changes for multi-line text in the Internal Comment field.

##### Module Affected

Not applicable. This fix does not affect Oracle Clinical modules.

#### Bug 12657056

##### Before

The formsweb.cfg configuration file lists entries for JAR files that are no longer used by the Oracle Clinical application.

##### After

Entries for the obsolete Oracle Clinical JAR files are deleted from the formsweb.cfg configuration file.

##### Module Affected

formsweb.cfg

*Go to [Contents](#)*

## 5 Software

This section contains the following topics:

- [Oracle Clinical 4.6.2 Media](#)

- [Downloading Oracle Clinical Patch Set 4.6.6](#)

## 5.1 Oracle Clinical 4.6.2 Media

You must first install the Oracle Clinical 4.6.2 technology stack and the Oracle Clinical 4.6.2 database tier, which is available on the *Oracle Clinical 4.6.2 and Oracle Thesaurus Management System 4.6.2 Media Pack*.

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### Note:

If you have not yet upgraded to Oracle Clinical 4.6.2, when you do so, do not upgrade the application tier. Instead, create a new application tier from the 4.6.6 patch set. Installing the 4.6.2 application tier is not necessary.

However, you must upgrade the database server and each database to 4.6.2 from the 4.6.2 media pack before installing 4.6.6. See "[Customers Upgrading from Release 4.6 or Earlier](#)" for details.

---

To receive a physical media pack with all the required DVDs, contact Oracle Support. To expedite your request you can either call Oracle Support directly or open a Service Request (SR) selecting problem category: **Version Update Request**.

To download the media pack from the Oracle Software Delivery Cloud:

1. Go to <http://edelivery.oracle.com> and sign in.
2. From the **Select a Product Pack** drop-down list, select **Health Sciences**.
3. From the **Platform** drop-down list, select the appropriate database tier operating system.
4. Click **Go**.
5. Select **Oracle Clinical and Oracle Thesaurus Management System 4.6.2 Media Pack for Your\_Operating\_System** and click **Continue**.
6. Download the software.

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## 5.2 Downloading Oracle Clinical Patch Set 4.6.6

Oracle Clinical Patch Set 4.6.6 is distributed as patch 14198756 in the form of a zip file.

To download this 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. In the **Patch Name or Number** field, enter the patch number: 14198756.
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.
5. Click **Download**. The File Download dialog box opens.
6. Click **Save**, and then select the location where you want to save the zip file. The remaining instructions refer to this location as the extract directory.
7. Click **Save** to download the zip file to the specified location.
8. Extract the contents of the zip file into the extract directory. The compressed zip file includes the following files:
  - `readme_oc4_6_6.html` — Copy of these release notes
  - `server_code_platform.zip` — Database tier zip file
  - `application_server.zip` — Application tier zip file

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## 6 Preliminary Installation Steps

Follow the appropriate instructions:

- [Section 6.1, "New Customers"](#)
- [Section 6.2, "Customers Upgrading from Release 4.6 or Earlier"](#)
- [Section 6.3, "Customers Upgrading from Release 4.6.2 or Later"](#)

Then follow instructions in [Section 7, "Installing Oracle Clinical Patch Set 4.6.6"](#).

Check My Oracle Support article ID 386941.1 for any known installation issues.

### 6.1 New Customers

If you are installing a new Oracle Clinical installation, install Oracle Clinical 4.6.2 first, using instructions in the following chapters of the Release 4.6.2 *Oracle Clinical Installation Guide*:

- Chapter 1, *Preparing to Install Oracle Clinical*. This chapter guides you in planning your Oracle Clinical installation.

**Note:**

Follow the order of installation in these release notes rather than in Section 1.11.

- Install Oracle Database 11.2.0.3. Download patch 10404530 from My Oracle Support the same way you download Oracle Clinical Patch Set 4.6.6; see [Section 5.2, "Downloading Oracle Clinical Patch Set 4.6.6"](#). Follow instructions in the release notes for patch 10404530 to install Oracle Database 11.2.0.3.

**Note:**

This is a later version of Oracle Database than the one in the Release 4.6.2 *Oracle Clinical Installation Guide*. Install Oracle Database 11.2.0.3 instead of Oracle Database 11.2.0.2 Patch Set 1 as described in the Release 4.6.2 *Oracle Clinical Installation Guide*.

**Note:**

The Release 4.6.2 *Oracle Clinical Installation Guide* states that the value of the init.ora parameter COMPATIBLE should be set to 11.2.0.0.0. However, only the first three "digits"—11.2.0—are required.

**Note:**

If upgrading a Windows database to 11.2.0.3, ensure there is only one Oracle home, and that the path points to the 11.2.0.3 home. Otherwise, you will not be able to start PSUB (required for all batch jobs).

- Follow instructions in either Chapter 2, *Installing Oracle Clinical Database Server on UNIX* or Chapter 3, *Installing Oracle Clinical Database Server on Windows* to install the Oracle Clinical Database Server code, which is required to create Oracle Clinical 4.6.2 databases.
- Chapter 4 *Creating an Oracle Clinical Database*. This chapter covers installing and configuring Oracle Clinical 4.6.2 databases, which are a prerequisite for Oracle Clinical 4.6.6 databases.
- Chapter 5, *Installing and Configuring Oracle Application Server*.

Then follow instructions in [Section 7, "Installing Oracle Clinical Patch Set 4.6.6"](#).

## 6.2 Customers Upgrading from Release 4.6 or Earlier

If you are currently using a release of Oracle Clinical prior to 4.6.2, you must first upgrade your database server(s) (Steps 1-3 below) and database(s) (Steps 4-6 below) to Release 4.6.2. The steps include upgrading to Oracle Database 11.2.0.3.

For the application tier, before installing 4.6.6 you must install Oracle Application Server and back up customized files (Steps 7-8 below). You cannot upgrade application tiers from 4.6 or earlier and you do not need to install 4.6.2 on the application tier prior to installing 4.6.6.

After completing the following steps you can install patch set 4.6.6; see ["Installing Oracle Clinical Patch Set 4.6.6"](#).

1. In the *Oracle Clinical Installation Guide* for Release 4.6.2, Chapter 12, *Upgrading an Oracle Clinical Installation to Release 4.6.2* perform the tasks in Section 12.2, "Completing Other Pre-Upgrade Tasks."

**Note:**

**You must skip Section 12.1.** The 4.6.2 versions of the prepare and migrate scripts did not prevent running them more than once, and doing so **causes problems** maintaining and reporting the correct approval and verification status for patient CRFs.

The 4.6.6 Installer automatically checks if these scripts have been run once and runs related validation checks. If there is any problem, the Installer stops the upgrade process and you must fix the problem before proceeding; see [Migrating Data to the Enhanced Data Model for Approvals and Verifications](#).

The 4.6.6 versions of the scripts prevent their being run more than once. If you must prepare and migrate your data, be sure to do so using the 4.6.6 versions of the scripts.

2. Upgrade your Oracle Home to **11.2.0.3**. Download patch 10404530 from My Oracle Support the same way you download Oracle Clinical Patch Set 4.6.6; see [Section 5.2, "Downloading Oracle Clinical Patch Set 4.6.6"](#). Follow instructions in the release notes for patch 10404530 to install Oracle Database 11.2.0.3.

Do **NOT** follow instructions in Section 12.3, "Create a New Oracle Database 11g Release 2 (11.2.0.2) Patch Set 1 Oracle Home." You can go directly to 11.2.0.3.

**Note:**

The Release 4.6.2 *Oracle Clinical Installation Guide* states that the value of the init.ora parameter COMPATIBLE should be set to 11.2.0.0.0. However, only the first three "digits"—11.2.0—are required.

If you have set the parameter to a different value you can change it by logging in as SYS and entering:

```
ALTER SYSTEM SET COMPATIBLE = '11.2.0' SCOPE=SPFILE;
```

and then restarting the database.

If you have already set this parameter to 11.2.0.0.0, 11.2.0.1.0, or 11.2.0.2.0 and prefer to leave it set to the same value, you can do that. However, do not downgrade the database to any lower version. Oracle Clinical 4.6.6 is supported only on Oracle Database 11.2.0.3.

**Note:**

If upgrading a Windows database to 11.2.0.3, ensure there is only one Oracle home, and that the path points to the 11.2.0.3 home. Otherwise, you will not be able to start PSUB.

3. Section 12.4, "Installing Oracle Clinical 4.6.2 on the Database Server." This step is needed to upgrade databases to 4.6.2.

4. Section 12.5, "Upgrading Oracle Clinical 4.6.2 to the New Oracle 11gR2 Oracle Home" to upgrade your databases to the new Oracle Home.
5. Section 12.6, "Upgrading Database Objects to Oracle Clinical 4.6.2"

**Note:**

Do **NOT** follow the other instructions in Section 12.7 "Installing and Configuring Other Components for Oracle Clinical". You must apply the Oracle Clinical 4.6.6 application tier (front end) directly on Oracle Application Server.

6. Section 12.9, "Repairing Oracle Clinical Data" (if required). In addition, see [Section 9, "Running Find and Fix Scripts"](#) in these release notes.
7. In Chapter 5, *Installing and Configuring Oracle Application Server*, perform all tasks.
8. Back up files you have customized, if necessary. Most customizable files are automatically backed up by the 4.6.6 Installer in the location you specify when you run the Installer and then automatically restored. However, some files are backed up but not restored, and some SQL files are neither backed up nor restored; see [Section 8, "Customizable Files"](#) for more information.
9. Proceed to [Section 7, "Installing Oracle Clinical Patch Set 4.6.6"](#).

## 6.3 Customers Upgrading from Release 4.6.2 or Later

If you are currently using Oracle Clinical 4.6.2 or later, do the following:

1. Upgrade your Oracle Home to 11.2.0.3. Download patch 10404530 from My Oracle Support the same way you download Oracle Clinical Patch Set; see [Section 5.2, "Downloading Oracle Clinical Patch Set 4.6.6"](#). Follow instructions in the release notes for patch 10404530 to install Oracle Database 11.2.0.3.

**Note:**

The Release 4.6.2 *Oracle Clinical Installation Guide* states that the value of the init.ora parameter COMPATIBLE should be set to 11.2.0.0.0. However, only the first three "digits"—11.2.0—are required.

If you have set the parameter to a different value, you can change it by logging in as SYS and entering:

```
ALTER SYSTEM SET COMPATIBLE = '11.2.0' SCOPE=SPFILE;
```

and then restarting the database.

If you have already set this parameter to 11.2.0.0.0, 11.2.0.1.0, or 11.2.0.2.0 and prefer to leave it set to the same value, you can do that. However, do not downgrade the database to any lower version. Oracle Clinical is supported only on Oracle Database 11.2.0.3.

**Note:**

If upgrading a Windows database to 11.2.0.3, ensure there is only one Oracle home, and that the path points to the 11.2.0.3 home. Otherwise, you will not be able to start PSUB.

2. Back up files you have customized, if necessary. Most customizable files are automatically backed up by the Installer in a location you specify when you run the Installer and then automatically restored. However, some files are backed up but not restored, and some SQL files are neither backed up nor restored; see [Section 8, "Customizable Files"](#) for more information.
3. Proceed to [Section 7, "Installing Oracle Clinical Patch Set 4.6.6"](#).

## 6.4 Customers Upgrading from Release 4.6.5

You have already upgraded your Oracle Home to 11.2.0.3.

1. Back up files you have customized, if necessary. Most customizable files are automatically backed up by the Installer in a location you specify when you run the Installer and then automatically restored. However, some files are backed up but not restored, and some SQL files are neither backed up nor restored; see [Section 8, "Customizable Files"](#) for more information.
2. Proceed to [Section 7, "Installing Oracle Clinical Patch Set 4.6.6"](#).

## 7 Installing Oracle Clinical Patch Set 4.6.6

After you have done the required [Preliminary Installation Steps](#), follow the instructions in this section:

- [Section 7.1, "Installing the Oracle Clinical Database Server"](#)
- [Section 7.2, "Upgrading Oracle Clinical Databases to Patch Set 4.6.6"](#)
- [Section 7.3, "Applying Developer Forms 10.1.2.3.0 Bundle Patch and Related Patches"](#) (Not required for customers upgrading from Patch Set 4.6.3 or later)
- [Section 7.4, "Installing Report Server Patch 12710381"](#)
- [Section 7.5, "Installing the July 2012 Critical Patch Update"](#)
- [Section 7.6, "Installing the Oracle Clinical 4.6.6 Front End Components"](#)
- [Section 7.7, "Additional Configuration Tasks"](#)
- [Section 7.8, "Setting Up Clients"](#)
- [Section 7.9, "Migrating Data to the Enhanced Data Model for Approvals and Verifications"](#) (required only if indicated during database upgrade)

Check My Oracle Support article ID 386941.1 for any known installation issues.



## 7.1 Installing the Oracle Clinical Database Server

Unzip the server\_code\_platform.zip on the database server.

The instructions for installing the 4.6.6 database server code are the same as the instructions for installing the 4.6.2 database server code. Follow these instructions in the 4.6.2 *Oracle Clinical Installation Guide*, Section 12.4, "Installing Oracle Clinical 4.6.2 on the Database Server," **except** use the Oracle Clinical Installer executable from the 4.6.6 zip file to launch the Oracle Universal Installer. The latest version of the 4.6.2 *Oracle Clinical Installation Guide* is on oracle.com at <http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html>

---

**Note:**

You must first have created a 4.6.2 installation or upgraded to 4.6.2 as specified in "[Preliminary Installation Steps](#)".

---

The Installer installs new 4.6.6 server code in ~/opapps/oc/466.

## 7.2 Upgrading Oracle Clinical Databases to Patch Set 4.6.6

---

**Note:**

The Installer checks if you have upgraded studies to the enhanced data model for storing approvals and verifications introduced in Oracle Clinical 4.5.3.11 and 4.5.3.12. If not, the Installer displays an error message and prevents you from continuing. See [Migrating Data to the Enhanced Data Model for Approvals and Verifications](#) for more information.

---

The instructions for upgrading databases to patch set 4.6.6 are the same as the instructions for upgrading databases to 4.6.2. Follow these instructions in the 4.6.2 *Oracle Clinical Installation Guide*, Section 12.6, "Upgrading the Database Objects to Oracle Clinical 4.6.2," **except** use the Oracle Clinical Installer executable from the 4.6.6 zip file to launch the Oracle Universal Installer.

If you are upgrading from a previous release of Oracle Clinical, see [Running Find and Fix Scripts](#).

If you are using the Siebel Clinical/clinical trial management system integration with Oracle Clinical, you may need to restart the AIA queue after upgrading a database; see [Bug 1275552](#).

## 7.3 Applying Developer Forms 10.1.2.3.0 Bundle Patch and Related Patches

---

**Note:**

This step is not required if you are upgrading from Oracle Clinical Patch Set 4.6.3 or later.

---

Oracle Clinical Patch Set 4.6.6 requires the application of several Forms patches that were not required by release 4.6.2. These patches fix several issues in the Forms product that were causing problems in Oracle Clinical.

1. Install Developer Forms 10.1.2.3.0 Bundle Patch **9593176**.
  - a. Download this patch from My Oracle Support the same way you do Oracle Clinical Patch Set 4.6.6; see [Downloading Oracle Clinical Patch Set 4.6.6](#).

---

**Note:**

Download the 32-bit version of the patch. Although Oracle Clinical 4.6.2 supports a Windows 2008 64 bit OS for the Application Server, the Oracle Application Server software is 32 bit.

---

- b. Install it using instructions in the bundle patch release notes.
2. Install Oracle Universal Installer (OUI) Patch **6640838**. You must complete this step before you install the following three Forms patches. Download the following document from My Oracle Support for information about installing the patch:  
Article ID: 1301320.1, *How to patch OUI for installing overlay patches on top of Forms Bundle Patch 9593176*

---

**Note:**

Even if your OUI is at version 10.1.0.6, you must apply this patch, which will result in a lower version of OUI Opatch. You can then apply the latest OUI Opatch if you want, but it is not required for the purpose of applying the following three Forms patches.

---

3. Download and install the following Developer Forms patches, using the instructions in the release notes:
  - Developer Forms Patch **12619483**
  - Developer Forms Patch **12350791**
  - Developer Forms Patch **12416560**

## 7.4 Installing Report Server Patch 12710381

---

**Note:**

This step is not required if you are upgrading from Oracle Clinical Patch Set 4.6.5.

---

Install Oracle Reports Server 10.1.2.3 patch 12710381 using instructions in the release notes. Download this patch from My Oracle Support the same way you do Oracle Clinical Patch Set 4.6.6; see [Downloading Oracle Clinical Patch Set 4.6.6](#).

## 7.5 Installing the July 2012 Critical Patch Update

Oracle Clinical Patch Set 4.6.6 is certified with the July 2012 Oracle Critical Patch Update (CPU). See My Oracle Support document 1472244.1 for information.

## 7.6 Installing the Oracle Clinical 4.6.6 Front End Components

Unzip application\_server.zip on the application server.

---

### Note:

Restart your machine as directed in the instructions for installing the Critical Update Patch before installing 4.6.6. If you don't, you may get "Error in writing to file..." during the 4.6.6 installation, in which case you should restart your machine and reinstall OC 4.6.6, even if the installation completes.

---

The following steps in the Release 4.6.2 *Oracle Clinical Installation Guide* are required for all installation and upgrade paths. The Installer installs the 4.6.6 front end code in `drive:\opapps46`.

- Chapter 6, "Installing Oracle Clinical Front End," **except** run the **4.6.6** setup.exe executable to launch the Oracle Universal Installer.

---

### Note:

The 4.6.6 Installer detects if you are upgrading from a previous version of Oracle Clinical and if so, prompts you for a location in which to put the customizable files it automatically backs up; see [Section 8, "Customizable Files"](#).

If you are upgrading TMS as well as Oracle Clinical, you should specify the same backup file location for both systems.

If you have customized any files not listed in [Section 8](#), including j2ee-logging.xml or the orion-web.xml file located at `ORACLE_AS10gR3_HOME\j2ee\opa\application-deployments\ocrdcclassic\ocrdcclassic` or any other files, you are responsible for backing up your customized files and manually reapplying your changes to the new versions of the files.

---

- Chapter 7, "Installing Reports Servers," **except** run the **4.6.6** setup.exe executable to launch the Oracle Universal Installer.

## 7.7 Additional Configuration Tasks

Perform the following tasks:

- Setting Up the Parameterized Submission Process;** see the Release 4.6.2 *Oracle Clinical Installation Guide*, Chapter 8.
- Implementing Secure FTP for File Viewing;** see the Release 4.6.2 *Oracle Clinical Installation Guide*, Chapter 9.
- Setting Up SAS (Optional)** if you plan to use SAS Data Extract views; see the Release 4.6.2 *Oracle Clinical Installation Guide*, Chapter 11. The Release 4.6.2 guide has revised instructions for installing SAS with Oracle Clinical for greater security than in previous releases.
- Reenabling Replication (Optional)** If you use replication, follow instructions in the Release 4.6.2 *Oracle Clinical Installation Guide*, Section 12.12, "Upgrading Installations the Use Replication" and in the *Oracle Clinical Administrator's Guide*.

## 7.8 Setting Up Clients

Follow instructions in Chapter 10, "Setting Up Clients," in the Release 4.6.2 *Oracle Clinical Installation Guide*.

## 7.9 Migrating Data to the Enhanced Data Model for Approvals and Verifications

When you upgrade a database from Oracle Clinical 4.6.2 to Patch Set 4.6.3 or later, the Installer runs a validation script to ensure that all studies have been migrated to the enhanced approval and verification data model that was introduced in Oracle Clinical 4.5.3.11 and 4.5.3.12. If the database is in a replicated environment, within each study the Installer validates only patients that are owned by the current location.

### Successful Validation

If the validation succeeds, the log file includes the message "Validation succeeded, database has been migrated to the new approval/verification data model. No further action is required." and the database upgrade process continues. If validation succeeded, you do not need to follow the instructions in this section. However, if in the future you need to unfreeze a currently frozen study, you may need to migrate its data first; see [Migrating Data to the Enhanced Data Model for Approvals and Verifications](#).

### Failed Validation

If the validation fails, the database upgrade process is terminated. The log file includes the error message that the migration has not been run on the database. Check the log file for more information and read the remaining instructions in this section.

---

### Note:

**Test mode** does not use the enhanced data model and the validation does not check test studies.

---

## Log File Error Messages

In case of validation failure, the log file `/pharm/home/opapps/oc/466/install/upgrade_database_timestamp.log` contains one of the following error messages:

- Your database has not been migrated to the new approval/verification data model. Please run prepare and migrate scripts before continuing with your upgrade.** None of your studies has been migrated to the enhanced data model and you do not have a replicated environment. You can run the prepare and migrate scripts yourself; see [Migrating Data to the Enhanced Data Model for Approvals and Verifications](#).
- Your installation is now or at one time was a replicated environment which requires special handling. Please contact Oracle Support for guidance with your upgrade.** None of your studies has been migrated to the enhanced data model and you have a replicated environment. You must contact Oracle Support.

- **One or more studies have not been migrated to the new approval/verification data model. Also, your installation is now or at one time was a replicated environment which requires special handling. Please contact Oracle Support for assistance in migrating these studies and for guidance with your upgrade.** This message appears in a replicated environment in two possible cases:

- Some but not all studies in the database have been migrated.
- One or more studies has data corruption.

You must contact Oracle Support before you can complete the upgrade.

- **One or more studies have not been migrated to the new approval/verification data model. Please contact Oracle Support for assistance in migrating these studies.** This message appears in a non-replicated environment with the same two possible cases:

- Some but not all studies in the database have been migrated.
- One or more studies has data corruption.

You must contact Oracle Support.

## Log File Study Information

The log file `upgrade_database_timestamp.log` includes the following information for each study that has not been migrated to the enhanced data model:

- Study: the name of the study
- ClinicalStudyId: the `clinical_study_id` of the study
- RdcStudy:
  - **Y** if the study is an RDC study—meaning that approvals or verifications have been done in the study.
  - **N** if it is not an RDC study—meaning that **no** approvals or verifications have been done in the study.
- Frozen:
  - **Y** if the study is frozen.
  - **N** if the study is not frozen.
- HasData:
  - **Y** if the study has CRFs that have not been soft-deleted.
  - **N** if there are no CRFs.
- MigrStatus:
  - **Y** if the study is migrated.
  - **N** if the study is not migrated.
  - **F** if the study has corrupted data (new CRFs were created in the study after applying the 4.5.3.11 patch or equivalent but before the existing data in the study was migrated).

### 7.9.1 Migrating Data in a Non-replicated Environment

If none of your studies have been migrated and you do not have a replicated environment, you can run two scripts to prepare and migrate all studies in your database to the enhanced data model. If this is the case, the log file contains the message, "Your database has not been migrated to the new approval/verification data model. Please run prepare and migrate scripts before continuing with your upgrade." **Do not run these scripts if your log file does not contain this exact message.**

---

#### Caution:

Be sure to run only the **4.6.6** versions of these scripts. Running previous versions more than once causes data corruption. The 4.6.6 scripts contain a check that prevents you from running them more than once.

The 4.6.6 versions of these scripts are located in `~/opapps/oc/466/install`.

Run these scripts **ONLY** if your environment does not use replication **and** **NONE** of your data has already been migrated, as noted by the error message in the log file generated by the 4.6.6 Installer.; see [Log File Error Messages](#) and [Log File Study Information](#).

If your error message says anything else, or your log file indicates that any of your studies have been migrated, **do not run these scripts**. You must call Oracle Support.

---

The Preparation and Migration scripts migrate all studies except those that meet **both** of the following criteria:

- They are frozen.
- No approvals or verifications have ever occurred in the study.

All studies that have ever had approvals or verifications are migrated, even if they are currently frozen.

---

#### Note:

**Do not delete table APPVER\_UPG\_TEMP**, which is created when you run the Preparation script, even when you have completed running the Migration script. This will cause a failure if you need to unfreeze a non-migrated study in the future.

---

This section includes the following topics:

- [Benchmarks for Estimating Downtime Required to Prepare and Migrate Data](#)
- [Determining Tablespace Size Requirements](#)
- [Running the Preparation Script](#)
- [Running the Migration Script](#)

### 7.9.1.1 Benchmarks for Estimating Downtime Required to Prepare and Migrate Data

Note that:

- Preparing and migrating data is a lengthy process.
- Users cannot access the system. You must perform all data preparation and data migration while the system is inaccessible to users.
- You should calculate the required downtime **BEFORE** you start the upgrade process. Once you start the upgrade, you cannot start up the database until after you run the Preparation and Data Migration scripts.

The Preparation and Data Migration scripts were tested on two different database servers with different hardware configurations. The following table shows the results of the tests. Neither the total load on the system nor the database configuration in either environment was captured. All other factors being equal, the execution time of both scripts is directly related to the number of received DCIs (RDCIs) being processed.

**Table 1 Time Estimates for Running the Preparation and Data Migration Scripts**

Hardware Configuration	Number of RDCIs	Preparation Script	Data Migration Script
HP-UX Itanium RP 4440: 4x 1000 MHz CPUs (2 dual core processors) with 16 GB RAM	90,000	40 min (2250 RDCIs/minute)	6 minutes (15,000 RDCIs/minute)
Oracle Sun e6800: 4x 900 MHz CPUs (4 single core processors) with 8 GB RAM	12,000,000	18 hours (11,111 RDCIs/minute)	2 hours (100,000 RDCIs/minute)

### 7.9.1.2 Determining Tablespace Size Requirements

Ensure that there is enough space in each of the tablespaces you define for the amount of data you have. The Preparation and Data Migration scripts create temporary tables and indexes, and recreate both existing indexes on the RDCI\_HISTORY table.

- All the **temporary tables** are created in the tablespace represented by the script variable `tbl_tbs`. The default value is `RXC_DEF_TSPA`. To determine your space requirements for this tablespace, use the following formula as a guideline and add additional space because the script performs direct inserts, and direct inserts insert the data after the HWM.

```
<number of received DCIs> * 3 records * 3 tables * 350 bytes = number of bytes required without allowance for direct inserts
```

- The **indexes** are all created in the tablespace represented by the script variable `idx_tbs`. The default value is `RXC_DEF_IDX_TSPA`. To determine your space requirements for this tablespace, use the following formula:

```
(<number of received DCIs> * 10) + (<number of received DCIs> * 70) + (<number of received DCIs> * 70)
```

The formulas above are based on the shipped default tablespace usage. If you changed the default tablespace names or usage, you need to recompute accordingly.

### 7.9.1.3 Running the Preparation Script

The Preparation script:

- Analyzes which studies to process. For the purpose of this analysis, *RDC studies* means studies in which approvals and verifications have been entered through RDC. *Oracle Clinical studies* means studies that do not include any RDC-entered approvals and verifications. The Preparation script labels each study as being in one of four categories for processing as follows:
  - RDC non-frozen studies. All non-frozen RDC studies are marked for migration.
  - RDC frozen studies. All frozen RDC studies are marked for migration.
  - Oracle Clinical non-frozen studies. All non-frozen Oracle Clinical studies are marked for migration.
  - Oracle Clinical frozen studies. Frozen Oracle Clinical studies are not migrated. If in the future you want to unfreeze a study you must run a script to migrate it first; see ["Migrating a Single Study Before Unfreezing It"](#).
- Identifies received DCIs, and their current approval and verification statuses, in a temporary table.
- Counts the number of received DCIs to be migrated.
- Produces an output file that tells you how many studies need to be migrated and how many received DCIs they contain.

To run the Preparation script to prepare your data for migration:

1. Set the environment variables for your database:

```
opa_setup database_name 466
```

where `database_name` is the name of your database and `466` is where your Oracle Clinical database server code is installed (`~/opapps/oc/466`).

2. Change to the `RXC_INSTALL` directory:

```
cd $RXC_INSTALL
```

3. Open an SQL\*Plus session, connecting as `opa`.

4. Edit the tablespace variable definitions at the top of the script as appropriate for your environment. For example:

```
define tbl_tbs='TABLESPACE RXC_DEF_TSPA'

define idx_tbs='TABLESPACE RXC_DEF_IDX_TSPA'
```

To ensure that there is enough space in each of the tablespaces you define for the amount of data you have, see "[Determining Tablespace Size Requirements](#)".

- Run the oclupg45311prepare.sql script:

```
start oclupg45311prepare.sql
```

The script prompts you for the following passwords:

```
OPA password RXC password
```

Once you enter your passwords, the script displays the new database session ID on screen.

**Check Progress** To view the progress of the script, connect as opa in a different session and enter the following command:

```
select * from opa_debug where sessionid = your_session_id
```

**Output File** The preparation script creates the following output file:

```
oclupg45311prepare-database_name-timestamp.lis
```

The output file, which is created in the same location as the script, includes the following information:

- A list of all studies in the database, with their categories, where *RDC study* means a study with RDC-entered approvals and verifications, and *Oracle Clinical study* indicates a study without such approvals or verifications:
  - RDC non-frozen studies. These studies are marked for migration.
  - RDC frozen studies. These studies are marked for migration.
  - Oracle Clinical non-frozen studies. These studies are marked for migration.
  - Oracle Clinical frozen studies. These studies are not marked for migration.
- A count of the received DCIs for each study to be migrated.

#### 7.9.1.4 Running the Migration Script

The Data Migration script:

- Upgrades all live (unfrozen) studies, whether they use RDC or not.
- Upgrades all frozen studies that used RDC (specifically, that have approvals and verifications).
- Migrates the data for all non-frozen Oracle Clinical studies.
- Does not migrate any data for frozen Oracle Clinical studies. If in the future you want to unfreeze a study you must run a script to migrate it first; see "[Migrating a Single Study Before Unfreezing It](#)".

While the Data Migration script is running, users must not be allowed to perform any data entry or updates.

To run the Data Migration script:

- Set the environment variables for your database:

```
opa_setup database_name 466
```

where *database\_name* is the name of your database and 466 is where your Oracle Clinical database server code is installed (~/opapps/oc/466).

- Change to the RXC\_INSTALL directory:

```
cd $RXC_INSTALL
```

- Open an SQL\*Plus session, connecting as opa.

- Edit the tablespace variable definitions at the top of the script as appropriate for your environment. For example:

```
define tbl_tbs='TABLESPACE RXC_DEF_TSPA' define idx_tbs='TABLESPACE RXC_DEF_IDX_TSPA'
```

To ensure that there is enough space in each of the tablespaces you define for the amount of data you have, see "[Determining Tablespace Size Requirements](#)".

- Run the oclupg45311migrate.sql script.

```
start oclupg45311migrate.sql
```

The script prompts you for the following passwords:

```
OPA password RXC password
```

Once you enter your passwords, the script displays the new database session ID.

**Check Progress** To view the progress of the script, connect as opa in a different session and enter the following command:

```
select * from opa_debug where sessionid = your_session_id
```

**Output File** The Data Migration script creates the following output file:

```
oclupg45311migrate-database_name-timestamp.lis
```

This output file, which is created in the same location as the script, tracks the progress of the job and provides the following information:

- If any entries have been inserted into the OPA\_DEBUG table in the current database session, an indication that they are being deleted.
- The database session ID for the current script execution.

- The number of CRFs that were created and modified between the time the Preparation script started running and the time the Data Migration script started. This number should be zero (0). However, if the number is not zero, note that all approval and verification statuses were recomputed as long as data access was prevented when running the Data Migration script.
- An indication that entries are being written to the OPA\_DEBUG table.
- Information about enabling and disabling logging, triggers, and indexes.
- An indication that rows are being deleted from the OPA\_DEBUG table, which means that those rows have successfully finished processing.

## 7.9.2 Migrating a Single Study Before Unfreezing It

After you install Oracle Clinical Patch Set 4.6.6, the only studies that remain unmigrated are frozen Oracle Clinical studies (studies that have never had any approvals or verifications performed). All other studies are migrated.

If you later try to unfreeze an unmigrated study, the system automatically checks if the study has been migrated to the enhanced approve/verify data model and prevents you from unfreezing the study until you have migrated its data. This prevents any problems from occurring if you later use RDC to perform approvals and verifications.

To set up and run the script to migrate a frozen study:

1. Set the environment variables for the database:

```
opa_setup database_name 466
```

where *database\_name* is the name of your database and 466 is where your Oracle Clinical database server code is installed (~/opapps/oc/466).

2. Change to the RXC\_INSTALL directory:

```
cd $RXC_INSTALL
```

3. Log in to SQL\*Plus as the user RXC.

4. Run the single-study migration script.

```
start ocl_appver_single_migrate.sql
```

The script prompts you for the following passwords:

```
OPA password
RXC password
```

5. The script prompts you for the name of the study you want to migrate.

The system migrates the study to the enhanced data model and generates log file *ocl\_appver\_single\_migrate-database-timestamp.lis*, with the timestamp in format YYYYMMDDHH24MISS.

The log file contains the following information:

- If any entries have been inserted into the OPA\_DEBUG table in the current database session, an indication that they are being deleted
- The database session ID for the current script execution
- An indication that entries are being written to the OPA\_DEBUG table
- Information about enabling and disabling logging, triggers, and indexes
- An indication that rows are being deleted from the OPA\_DEBUG table, which means that those rows have successfully finished processing

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## 8 Customizable Files

This section includes the following topics:

- [Section 8.1, "RDC Onsite Customizable Files"](#)
- [Section 8.2, "OPA Admin Customizable Files"](#)
- [Section 8.3, "Customizable HTML Files"](#)
- [Section 8.4, "Forms, Menus, and Other Customizable Files"](#)
- [Section 8.5, "Customizable Files Not Automatically Backed Up"](#)

These sections list the files automatically backed up by the 4.6.6 Installer and notes whether or not they are also automatically restored and why you may have customized them. If you have customized any of the files that are not automatically restored, you must manually apply your changes to the new versions of the files after upgrading to 4.6.6.

The Installer puts the backed-up files in the location you specify during the 4.6.6 installation.

### 8.1 RDC Onsite Customizable Files

For information on customizing these files, see the Release 4.6.2 *Oracle Clinical Remote Data Capture Onsite Administrator's Guide* or, for performance-related customizations, *Configuring Oracle Clinical Remote Data Capture Onsite 4.6.2 for Performance and Scalability* (My Oracle Support article ID 1300850.1) or, for orion-web.xml, the Release 4.6.2 *Oracle Clinical Administrator's Guide*.

All of the following files are backed up and restored. These customizations were introduced in Release 4.6.2.

**Table 2 RDC Onsite Customizable Files**

File Name/Restored?	Location	Purpose of Customization
bc4j.xcfg (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\ olsardc\rdconsite\WEB-INF\classes\oracle\pharma\rdc\model\services\common	Performance configuration
dataentry-config.xml (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\ olsardc\ rdconsite\WEB-INF\	Performance configuration
dataentrylogger.properties (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\ olsardc\rdconsite\WEB-INF\	Specify the detail level of DE log file debug info
dcapi.properties (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\ olsardc\ rdconsite\WEB-INF\	DCAPI log file generation, performance configuration
de_external.properties (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\ olsardc\ rdconsite\WEB-INF\classes\oracle\pharma\rdc\de\resource\properties	Approval warning message, labels in data entry
opalogger.properties (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\ olsardc\ rdconsite\WEB-INF\	<b>Contact Us</b> link
RdcLogos.properties (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\ olsardc\ rdconsite\WEB-INF\classes\oracle\pharma\rdc\view	
RdcTexts.properties (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\ olsardc\rdconsite\WEB-INF\classes\oracle\pharma\rdc\view\nl	<b>Change Password</b> link, text and messages in the RDC Surround
web.xml (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\applications\ olsardc\ rdconsite\WEB-INF\	Timeout interval, performance configuration
orion-web.xml (Restored)	ORACLE_AS10gR3_HOME\j2ee\rdc\application- deployments\ olsardc\rdconsite\	Used in image viewing; see <a href="#">Section 8.5.1</a> .
orion-web.xml (Restored)	ORACLE_AS10gR3_HOME\j2ee\opa\application- deployments\ olsardc\rdcclassic\	Used in image viewing; see <a href="#">Section 8.5.1</a> .
formswb.cfg (Restored)	ORACLE_AS10gR2_HOME\forms\server	Specify the file viewing protocol.

## 8.2 OPA Admin Customizable Files

All of the following files are backed up and restored:

**Table 3 OPA Admin Customizable Files**

File Name	Location	Purpose of Customization
web.xml (Restored)	ORACLE_AS10gR3_HOME\opa\applications\ opaadmin\opaadmin\WEB-INF\	opa_config path
bc4j.xcfg (Restored)	ORACLE_AS10gR3_HOME\j2ee\opa\ applications\opaadmin\opaadmin\WEB-INF\lib\oracle\pharma\opa\bc4j\common	Performance configuration
jazn-data.xml (Restored)	ORACLE_AS10gR3_HOME\j2ee\opa\ application-deployments\opaadmin\	Custom user credentials for opaadmin application
OpaConfig.xml (Restored)	opapps46/config	Database configuration

## 8.3 Customizable HTML Files

If you customized any of the following files, to retain your changes you must reapply your customizations after upgrading. These files are backed up by the Installer but not restored.

**Table 4 HTML Customizable Files**

File Name	Location	Purpose of Customization
launch.htm (Not Restored)	opapps46/html	Customize the launch page
ocdcitemplate.htm (Not Restored)	opapps46/html	Customize the launch page for the batch generator for HTML Data Entry Forms and Patient Data Report Templates
rdcadmin.htm (Not Restored)	opapps46/html	Customize the RDC Admin launch page
rdcadmint.htm (Not Restored)	opapps46/html	Customize the RDC Admin test mode launch page
rdclaunch.htm (Not Restored)	opapps46/html	Customize the RDC launch page
rdclauncht.htm (Not Restored)	opapps46/html	Customize the RDC test mode launch page
All files (Not Restored)	opapps46/html\help	Customize online help content

## 8.4 Forms, Menus, and Other Customizable Files

Most but not all of the following files are restored.

**Table 5 Other Oracle Clinical Customizable Files**

File Name	Location	Purpose of Customization
rxcdf.bmp (Restored)	opapps46\oc\	Customizing the image on DCF reports.
rxuser.fmb (Restored)	opapps46\oc\admin	Customizing the Users and Roles menu
rxuser.mmb (Restored)	opapps46\oc\admin	Customizing the Users and Roles menu
rxcdrptl.rdf (Restored)	opapps46\oc\admin	Customizing DCF reports landscape template.
rxcdrptp.rdf (Restored)	opapps46\oc\admin	Customizing DCF reports portrait template.
All files with extension.conf (Not Restored)	ORACLE_AS10gR2_HOME\reports\conf	Report Server parameter configuration

## 8.5 Customizable Files Not Automatically Backed Up

This section describes customizable files that are not backed up or restored. There may be others. You are responsible for maintaining your own customizations.

### 8.5.1 Files Used in Image Viewing

Whether or not you need to back up these files depends on whether you have set up a central images directory or have copied this directory to each RDC Onsite and Oracle Clinical installation:

- If you have copies of your CRF images directory in multiple installations you must back up each CRF images directory. The default location is: **ORACLE\_AS10gR3\_HOME\j2ee\rdc\applications\olsardc\rdconsite\de\crfimages**.
- If you use a central CRF images directory and updated orion-web.xml to specify its path, you do not need to back up the CRF images directory or the following orion-web.xml files, which are backed up automatically:
  - **ORACLE\_AS10gR3\_HOME\j2ee\rdc\application-deployments\olsardc\rdconsite** This orion-web.xml file controls access for RDC Onsite data entry screens to the images in the images file in the non-default location.
  - **ORACLE\_AS10gR3\_HOME\j2ee\opa\application-deployments\ocrdclassic\ocrdclassic** This orion-web.xml file enables users to view images in the HTML Preview feature of the DCI Forms Layout Editor in Oracle Clinical.

For more information, see "Setting Up Image Viewing During Data Entry" and "Copying Image Files to All Installations" in the *Oracle Clinical Administrator's Guide*.

### 8.5.2 SQL Scripts

If you customized any of the following scripts, you may need to reapply your customizations after upgrading to 4.6.6. For information about these files, see the *Oracle Clinical Administrator's Guide*.

**Table 6 Oracle Clinical Database Customizable Files**

File Name	Location	When Changed
rxcptdxvb.sql	\$RXC_INSTALL	No changes in Oracle Clinical since Release 4.5.1. You can reuse your customized file from any release 4.5.1 or later.
rdcpb_client.sql	\$RXC_INSTALL	Changed in Oracle Clinical 4.5.3. If you are upgrading from a release prior to 4.5.3, you must reapply your customizations.
ocl_client_pb.sql	\$RXC_INSTALL	No changes in Oracle Clinical since 4.5.1. You can reuse your customized file from any release 4.5.1 or later.
rxasravw.sql	\$RXC_INSTALL	No changes in Oracle Clinical since 4.5.1. You can reuse your customized file from any release 4.5.1 or later.  <b>Note:</b> rxasravw.sql is not automatically executed when upgrading. You must manually run the script after the upgrade.

### 8.5.3 j2ee-logging.xml

The following customizable file is also not backed up: j2ee-logging.xml. For information on this file, see the *Oracle Clinical Remote Data Capture Onsite Administrator's Guide*.

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## 9 Running Find and Fix Scripts

You may need to run the Find and Fix scripts described below.

### 9.1 Find Responses and Discrepancies with Wrong Study ID

Run the Find and Fix scripts in Oracle Clinical Patch 4.6.0.32 to detect and fix problems caused by [Bug 13502296](#). Follow instructions in the release notes for Patch 4.6.0.33 (patch number 13582967 for download purposes on My Oracle Support).

### 9.2 Finding Duplicate Current Investigators

Run the Find and Fix scripts in Oracle Clinical Patch 4.6.0.33 to detect and fix duplicate current investigators caused by [Bug 2342461](#). Follow instructions in the release notes for Patch 4.6.0.33 (patch number 13719412 for download purposes on My Oracle Support).

### 9.3 Finding Incorrectly Deleted DVG Subset Values

Run a Find script to detect if you have any incorrectly deleted DVG subset values caused by [Bug 11830832](#), where deleting a duplicate value from a base DVG using Delete under the Record menu had the effect of deleting the value from all subsets of the DVG even though the subsets had only one instance of the value.

The scripts are located in the install directory.

The Find scripts are:

- [find\\_incorrectly\\_deleted\\_dvgsubsets.sql](#). If this script finds no affected DVG subsets, you do not need to run the next two scripts.
- [find\\_study\\_invalid\\_del\\_dvgsubsets.sql](#)
- [start\\_find\\_docs\\_for\\_reseq\\_dvs.sql](#)



### 9.3.1 find\_incorrectly\_deleted\_dvgsubsets.sql

Run this script first. It identifies any DVG subsets where the discrete values were incorrectly deleted due to this bug. If this script returns no occurrences, there is no need to run the remaining diagnostic scripts.

Run the script in the install directory:

```
SQL> start find_incorrectly_deleted_dvgsubsets.sql
```

The script prompts you for the RXC user password.

Results are spooled to find\_incorrectly\_deleted\_dvgsubsets.lis. This file will contain the name of the DVG, the subset affected, the discrete value deleted and the sequence number (Display SN) of the discrete value in that subset before any incorrect deletions of values occurred in the subset.

### 9.3.2 find\_study\_invalid\_del\_dvgsubsets.sql

If the first script identified incorrectly deleted subsets, run the following script to identify all studies that contain dcm questions which use the resequenced DVG subsets.

Run the script in the install directory:

```
SQL> start find_studies_with_incorrectly_deleted_dvgsubsets.sql
```

The script prompts you for the RXC user password.

The results are spooled to the file find\_studies\_with\_incorrectly\_deleted\_dvgsubsets.lis. This file will contain the study name of the potentially impacted studies.

For each study returned, run the following script to identify any documents that contain DCM Questions using the resequenced DVG subset that had response values entered or updated after the resequencing first occurred.

### 9.3.3 start find\_docs\_for\_reseq\_dvs.sql

For each study returned by the second script, run the following script to identify any documents that contain DCM Questions using the resequenced DVG subset that had response values entered or updated after the resequencing first occurred.

Run the script in the install directory:

```
SQL> start find_docs_for_reseq_dvs.sql
```

The script prompts you for the RXC user password and a study name. Enter % to run for all studies or specify a study name. When specifying a study name, '%' can be used as a wildcard.

Results are spooled into find\_docs\_for\_resq\_dvs.lis.

## 9.4 Finding and Fixing Invalid Status

If you are upgrading from a release prior to 4.6, or if you are upgrading from Release 4.6 and have not applied patch 4.6.0.12 or 4.6.0.27 or its successor, follow the instructions in this section.

Bug 12600509 caused RDC Onsite to retain mandatory discrepancies in error during data entry in certain scenarios. This patch includes several Find and Fix scripts to help you correct the data affected by Bug 12600509. To correct existing data, you need follow the steps in this section and in [Section 9.5, "Running the Find and List Blank Rows Mandatory Discrepancies Scripts"](#).

The Find Invalid Status script locates the CRFs and/or CRF sections that have an invalid status of PASS 1 COMPLETE and Blank flag = Y caused by [Bug 12600509](#). The Fix Invalid Status script updates the status of these blank CRFs to RECEIVED.

To find and correct your existing data, you must complete the following tasks:

1. [Run the Find Invalid Status Script](#)
2. [Review the Findings](#)
3. [Bring the Database Offline](#)
4. [Run the Fix Invalid Status Script](#)
5. [Review the Output](#)

The following scripts are located in the installation directory:

- **Find Invalid Status script:** find\_rdc\_blankflag\_p1.sql
- **List Invalid Status script:** listrdcblankflag1.sql
- **Fix Invalid Status script:** fix\_rdc\_blankflag\_p1.sql

You run the Find script to find records that need updating. The Find script automatically calls the List script. The List script creates a formatted listing of the findings. You run the Fix script to repair any invalid data.

### 9.4.1 Run the Find Invalid Status Script

The Find Invalid Status script locates the CRFs and/or CRF sections (RDCMs) that have an invalid status of PASS 1 COMPLETE and Blank flag = Y caused by [Bug 12600509](#).

To run the script:

1. Log in to the database server.

- Set the variables for your environment:

```
opa_setup db_name servercode
```

For example: opa\_setup db1 46

- Change to the installation directory:

```
cd $RXC_INSTALL
```

- Connect to SQL\*Plus as the `RXC` user.

- Enter the following command:

```
start find_rdciblnkflp1.sql
```

The script prompts for the following information:

```
Enter the study name:
```

- Respond to the prompt as follows:

- To run the script on all studies, enter % (wildcard character). Alternatively, you can leave the prompt blank and press Enter.
- To run the script for a group of studies having a name like, enter the % wildcard in combination with one or more characters. For example, %STUDY%.
- To run the script on a single study, enter the exact study name.

The script searches the study data for RDCMs with status PASS 1 COMPLETE and Blank flag = Y. It creates two tables:

- Findrdciblnkflp1**
- Findrdciblnkflp1-timestamp:** Each time you run the find\_rdciblnkflp1.sql script, the script creates this backup table to store the previous run details for this script.

## 9.4.2 Review the Findings

The Find Invalid Status script automatically calls the List script, which generates the following files:

- findrdciblnkflp1-timestamp.lst** - Details the studies processed by the Find Invalid Status script.
- listrdciblnkflp1-timestamp.lst** - Includes four sections. The following table describes the information in each section. You should review the information in this file each time you run the Find Invalid Status script.

**Table 7 Information in the listrdciblnkflp1-timestamp.lst File**

Section	Begins with the Text	Description
Section 1	Invalid received DCIs are as follows	This section has a row of data for each unique RDCI containing at least one RDCM in an invalid status of PASS 1 COMPLETE and Blank flag = Y. Each row contains a subset of the columns listed in <a href="#">Table 8</a> .  With this listing, you can review the status of the affected RDCIs. When you run the Fix script, only the RDCIs with a status of PASS 1 COMPLETE and Blank flag = Y are updated.
Section 2	Invalid received DCMs are as follows	This section has a row of data for each RDCM in the studies processed with an invalid status of PASS 1 COMPLETE and Blank flag = Y. Each row contains all the columns listed in <a href="#">Table 8</a> .
Section 3	Details of all the received DCMs which are related to an invalid received DCI	This section includes one row of data for each RDCM contained in the RDCIs listed in Section 2. Each row contains a subset of the columns listed in <a href="#">Table 8</a> .
Section 4	Summary of invalid received DCIs	This section includes the following columns: <ul style="list-style-type: none"> <li>RECEIVED_DCI_STATUS_CODE - Indicates the status of the RDCI.</li> <li>MULTI_DCM - Indicates if the DCI has multiple DCMs or a single DCM. The column contains Y if the DCI has multiple DCMs and N if the DCI has one DCM.</li> <li>COUNT - The total number of RDCIs in the associated RDCI status.</li> </ul>

## 9.4.3 Columns in the listrdciblnkflp1-timestamp.lst File

The following table describes the columns in the listrdciblnkflp1-timestamp.lst file. Section 2 in the file lists all the columns; Section 1 and Section 3 in the file list a subset of these columns.

**Table 8 Columns in the listrdciblnkflp1-timestamp.lst File**

Column Name	Description
STUDY_NAME	Name of the study.
CLINICAL_STUDY_ID	ID of the clinical study.
STUDY_FROZEN	Indicates if the study is frozen.
SITE	Name of the site.
SITE_ID	ID of the site.
PATIENT	Number of the patient with the invalid RDCM.
PATIENT_POSITION_ID	ID of the patient position for the patient.
PATIENT_FROZEN	Indicates if the patient is frozen.
CLIN_PLAN_EVE_NAME	Clinical planned event (CPE) of the RDCI.
VISIT_NUMBER	Visit number of the RDCI.
DOCUMENT_NUMBER	Document number for the RDCI.
DCI_NAME	Name of the DCI containing the invalid RDCM.

Column Name	Description
RECEIVED_DCI_ID	Received DCI ID of the CRF.
RDCI_BLANK_FLAG	Indicates if there is any data for this RDCI.
RECEIVED_DCI_STATUS_CODE	Status of the RDCI.
MULTI_DCM	Indicates if the DCI contains multiple DCMs or a single DCM. The column contains Y if the DCI has multiple DCMs and N if the DCI has one DCM.
RDCI_ACCESSIBLE_TS	Time stamp of the RDCI. If the status is RECEIVED, the date defaults to (3000000, J).
RDCI_DATA_LOCKED	Indicates if the RDCI is locked. The column contains Y if the RDCI is locked and N if the RDCI is not locked.
RECEIVED_DCI_ENTRY_TS	Date and time the RDCI record version was created.
DCM_NAME	Name of the RDCM.
DCM_SUBSET_NAME	Name of the DCM subset.
RECEIVED_DCM_ID	DCM ID of the RDCM.
RDCM_BLANK_FLAG	Indicates if there is any data for this RDCM.
RECEIVED_DCM_STATUS_CODE	Indicates the status of the invalid RDCM. All RDCMs are status of PASS 1 COMPLETE in these listings.
RDCM_ACCESSIBLE_TS	The time stamp when the RDCM became invalid. None of these time stamps are (3000000, J).
RDCM_DATA_LOCKED	Indicates if the RDCM is locked. The column contains Y if the RDCM is locked and N if the RDCM is not locked.
RECEIVED_DCM_ENTRY_TS	Date and time the RDCM record version was created.
RDCM_SN	Serial number of the RDCM within other RDCMs belonging to the same parent RDCI.
SECTION_DISCREPANCY_EXIST	Indicates if a section discrepancy is present for the RDCM.
FIND_DATE	Date when the Find Invalid Status script is run.
FIX_DATE	Date when the record is updated by the Fix Invalid Status script at the time of fix_rdc_i_blankflag_p1.sql script execution. This column is blank for RDCMs not updated by the Fix script.

#### 9.4.4 Bring the Database Offline

You must bring the database offline before executing the Fix Invalid Status script, or you risk data corruption. The script disables database triggers that implement normal business logic. This is done so that when the script updates to RDCI and RDCM status, CRF approval and verifications statuses are not reversed. However, if normal operations continue while the triggers are disabled, standard business logic is not implemented, resulting in possible data corruption. Additionally, the Fix Invalid Status script does not check for collisions. If a user has a CRF locked when the script attempts to update an RDCI or RDCM status, the script exits.

#### 9.4.5 Run the Fix Invalid Status Script

When you run the Fix Invalid Status script:

- The script updates the invalid status of RDCMs identified by the Find Invalid Status script to a valid status of RECEIVED. It automatically updates its respective timestamp, RDCM\_ACCESSIBLE\_TS, to a date of (3000000, J).
- If the owning RDCI also has the invalid status of PASS 1 COMPLETE and Blank flag = Y, the script updates the status of the RDCI to a valid status of RECEIVED, and updates the timestamp, RDCI\_ACCESSIBLE\_TS, to a date of (3000000, J).

##### Note:

The script also identifies cases where a RDCI has a status of RECEIVED and Blank flag = Y, and a child RDCM has a status of PASS 1 COMPLETE and Blank flag = N. This combination of statuses is also invalid. In these cases, the invalid RDCM is not updated but is reported in the findrdciblnkflp1-*timestamp*.lst output file.

When the Fix Invalid Status script executes, it updates the existing Findrdciblnkflp1 table with the FIX\_DATE as appropriate.

To run the script:

- Log in to the database server.

- Set the variables for your environment:

```
opa_setup db_name servercode
```

For example: opa\_setup db1 46

- Change to the installation directory:

```
cd $RXC_INSTALL
```

- Connect to SQL\*Plus as the RXC user.

- Enter the following command:

```
start fix_rdc_i_blankflag_p1.sql
```

The script prompts for the following information:

```
Enter study name like:
```

- Respond to the prompt as follows:

- To run the script for all studies, enter % (wildcard character). Alternatively, you can leave the prompt blank and press Enter.
- To run the script for a group of studies having a name like, enter the % wildcard in combination with one or more characters. For example, %STUDY%.
- To run the script for a single study, enter the exact study name.

## 7. Respond to the remaining prompts:

- Enter Y to fix RDCIs of Frozen Studies, otherwise N.
- Enter Y to fix RDCIs of Frozen Patients, otherwise N.
- Enter Y to fix RDCIs of Locked CRFs, otherwise N.

8. Review the fixrdciblackflag1-*timestamp.lst* output file for errors each time you run the script. Refer to [Review the Output](#) for details about the information in the output file.

## 9.4.6 Review the Output

The Fix Invalid Status script generates the fixrdciblackflag1-*timestamp.lst* output file. The following table describes the information in the output file.

Every time you run the script, you should review the output file for errors. For example, the output file reports any documents that failed to process:

Processing Study: STUDY1 Could not process document: R23772801 because of invalid DCI/DCM status

**Table 9 Information in the fixrdciblackflag1-*timestamp.lst* File**

Section	Begins with the Text	Description
Section 1	Fixing RDCIs with status code PASS 1 COMPLETE	This section displays the studies processed for invalid RDCMs contained in RDCIs with a status of PASS 1 COMPLETE.
Section 2	Fixing DCIs with status code RECEIVED	This section displays the studies processed for invalid RDCMs contained in RDCIs with a status of RECEIVED.
Section 3	List of the RDCI/RDCMs fixed are as follows	<p>This section lists the RDCMs updated to a valid status of RECEIVED and Blank flag = Y. The status of the RDCIs is updated only if it is also invalid.</p> <p>When the Fix script updates the RDCI status to RECEIVED, it also updates the RDCI_ACCESSIBLE_TS to a date of (3000000, J).</p> <p>Each row in the file includes the following fields:</p> <p>STUDY_NAME CLINICAL_STUDY_ID SITE SITE_ID PATIENT PATIENT_POSITION_ID DOCUMENT_NUMBER  DCI_NAME RECEIVED_DCI_ID RDCI_BLANK_FLAG RECEIVED_DCI_STATUS_CODE (Indicates the status of the RDCI. The status is only RECEIVED and PASS 1 COMPLETE.) MULTI_DCM RDCI_ACCESSIBLE_TS  RECEIVED_DCI_ENTRY_TS DCM_NAME DCM_SUBSET_NAME RECEIVED_DCM_ID RDCM_BLANK_FLAG  RECEIVED_DCM_STATUS_CODE (The status is only RECEIVED.) RDCM_ACCESSIBLE_TS (The timestamp is set to a date of (3000000, J).) RECEIVED_DCM_ENTRY_TS SECTION_DISCREPANCY_EXIST FIND_DATE  FIX_DATE</p>

## 9.5 Running the Find and List Blank Rows Mandatory Discrepancies Scripts

These scripts locate and list the blank rows with mandatory discrepancies. To fix these CRFs, you need to update and save each CRF. RDC Onsite will mark the mandatory discrepancy as obsolete or valid, depending upon the data you enter.

Use the following Find and List scripts to locate all the blank rows with mandatory discrepancies caused by [Bug 12600509](#):

- **Find script:** find\_blank\_repeat\_mand\_disc.sql
- **List script:** list\_blank\_repeat\_mand\_disc.sql

### 9.5.1 Run the Find Blank Rows Mandatory Discrepancies Script

The Find Blank Rows Mandatory Discrepancies script populates the FIND table with detailed information about the CRFs that have a mandatory discrepancy logged against a blank row.

To run the script:

1. Log in to the database server.
2. Set the variables for your environment:

```
opa_setup db_name servercode
```

For example: opa\_setup db1 46

3. Change to the installation directory:

```
cd $RXC_INSTALL
```

4. Connect to SQL\*Plus as the RXC user.

5. Enter the following command:

```
start find_blank_repeat_mand_disc.sql
```

The Find script prompts for the following information:

```
Enter the study name:
```

6. Respond to the prompt as follows:

- To run the script for all studies, enter % (wildcard character). Alternatively, you can leave the prompt blank and press Enter.

- To run the script for a group of studies having a name like, enter the % wildcard in combination with one or more characters. For example, %STUDY%.
- To run the script for a single study, enter the exact study name.

The script generates the following log file:

```
find_blank_repeat_mand_disctime-stamp.lis
```

7. Review the log file to verify that the script populated the FIND table successfully and reported no errors.

## 9.5.2 Run the List Script

After you [Run the Find Blank Rows Mandatory Discrepancies Script](#) to populate the FIND table, you run the List script to view the detail record about each CRF that has mandatory discrepancies logged against a blank row.

Only the studies that you specified when you ran the Find script can be listed by the List script.

To run the List script:

1. Log in to the database server.
2. Set the variables for your environment:

```
opa_setup db_name servercode
```

For example: opa\_setup db1 46

3. Change to the installation directory:

```
cd $RXC_INSTALL
```

4. Connect to SQL\*Plus as the RXC user.

5. Run the List script to list the responses with blank repeats that have a mandatory discrepancy:

```
start list_blank_repeat_mand_disc.sql
```

The List script prompts for the following information:

```
Enter the study name:
```

6. Respond to the prompt as follows:

- To run the script for all studies, enter % (wildcard character). Alternatively, you can leave the prompt blank and press Enter.
- To run the script for a group of studies having a name like, enter the % wildcard in combination with one or more characters. For example, %STUDY%.
- To run the script for a single study, enter the exact study name.

The script generates the following log file:

```
list_blank_repeat_mand_disctime-stamp.lis
```

7. Review this file for detail information about responses with a blank repeat that has a mandatory discrepancy. The log file lists the following information for each response:

```
CLINICAL_STUDY_ID STUDY_NAME STUDY_SITE PATIENT CLIN_PLAN_EVE_NAME DOCUMENT_NUMBER RESPONSE_ID RESPONSE_ENTRY_TS REPEAT_SN
RECEIVED_DCM_ID DCM_SUBSET_SN DCM_LAYOUT_SN DCM_NAME DCI_NAME DCM_QUESTION_GROUP QUESTION_NAME
```

To fix these CRFs, you need to update and save the CRF. RDC Onsite will mark the mandatory discrepancy as obsolete or valid, depending upon the data you enter.

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## 10 Post-Installation Tasks

This section contains the following topics:

- [Section 10.1, "Clearing the Internet Explorer and Java Caches on Client Computers"](#)
- [Section 10.2, "Cleaning Up OPA JARS Registry"](#)

### 10.1 Clearing the Internet Explorer and Java Caches on Client Computers

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#### Note:

Only Oracle Clinical users need to clear the Internet Explorer and Java caches.

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After you install this patch, Oracle Clinical end users must clear the Internet Explorer and Java caches for two reasons:

- To see the fixes for Layout Editor bugs.
- To prevent seeing outdated security messages. In previous releases of Oracle Clinical, the pharmaoacle.jar and pharmaoacle.jar files were not signed. As a result, Oracle Clinical displayed several messages about certificates, trusted source, and potential security issues when you used Oracle Java Runtime Environment (JRE), Standard Edition, Version 1.6, Update 19 or later. This patch includes the signed pharmaoacle.jar and pharmaoacle.jar files; see [Bug 12600420](#) for more information.

### 10.1.1 To Clear the Internet Explorer Cache:

1. Open the Microsoft Windows Control Panel.
2. Double-click **Internet Options**. The Internet Properties dialog box opens and displays the General tab.
3. Click **Delete** in the Browsing history section.
4. Click **Delete files** to remove all temporary Internet Explorer files. Click **Yes** in response to the confirmation prompt.
5. Click **Close** to close the Delete Browsing History dialog box.
6. Click **OK** to close the Internet Properties dialog box.

### 10.1.2 To Clear the Java Cache:

1. Open the Microsoft Windows Control Panel.
2. Double-click **Java**. The Java Control Panel dialog box opens and displays the General tab.
3. Click **Settings** in the Temporary Internet Files section.
4. Click **Delete Files**.
5. Make sure the following check boxes are selected:
  - Applications and Applets
  - Trace and Log Files
6. Click **OK** to delete the temporary Java files.
7. Click **OK** to close the Temporary Files Settings dialog box.
8. Click **OK** to close the Java Control Panel.

## 10.2 Cleaning Up OPA\_JARS Registry

Because Oracle Clinical no longer uses pharmaewt.jar and opa\_client.jar, Oracle recommends that you remove these entries from the OPA\_JARS registry. Leaving these entries in the registry does not affect the functionality of Oracle Clinical. This task of removing the entries is for good housekeeping only.

To remove these entries:

1. Open the Windows Registry Editor:
  - Click **Start**, and then select **Run**.
  - Enter **regedit**.
  - Click **OK**.
2. Navigate to the following key:  
HKEY\_LOCAL\_MACHINE\SOFTWARE\ORACLE\KEY\_ORACLE\_ASMT\_HOME
3. Locate the OPA\_JARS value.
4. Remove the following entries if present:
  - pharmaewt.jar
  - opa\_client.jar

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## 11 Embedding Type 1 Fonts into the Patient Data Report

By default, when you generate a Patient Data Report, the system:

- Does not embed any Type 1 fonts.
- Embeds a *subset* of the TrueType fonts. Note that the system embeds only those TrueType font characters that are actually used in the report. In other words, the system embeds a *subset* of the full character set for a TrueType font.

This patch includes an enhancement to the RunPDR command that lets you embed the Type1 fonts. This enhancement was introduced in Patch OC\_4.5.3.24.

When you use the RunPDR command to generate a Patient Data Report from the command line, you can specify the **-cfg parameter** to embed the full character set for the Type 1 fonts used in the report. The system uses the information that you specify in the **xdobookbinder.cfg** file to determine the fonts to embed. For the Type 1 fonts used in the Patient Data Report, you can choose to embed either TrueType fonts or Type1 fonts.

Note that the -cfg parameter does not change how the system embeds the TrueType fonts used in the report.

To embed Type 1 fonts into Patient Data Reports, follow these steps:

- [Copying and Configuring the xdobookbinder.cfg File for Embedding Type 1 Fonts](#)
- [Embedding Type 1 Fonts when Generating Reports from the Command Line](#)

## 11.1 Copying and Configuring the xdobookbinder.cfg File for Embedding Type 1 Fonts

The xdobookbinder.cfg file controls font embedding in the Patient Data Reports. When you install this patch, the system automatically copies the xdobookbinder.cfg file into the desktoppdr folder on the Application Server.

You must copy the xdobookbinder.cfg file to every PC that you will use to generate reports from the command line and embed fonts into the report PDF file. In addition, you must edit the xdobookbinder.cfg file to define the fonts to embed, the location of the Windows font directory, and the location of the Adobe font directory.

To copy and configure the xdobookbinder.cfg file for embedding fonts:

1. Copy the **xdobookbinder.cfg** file from the desktoppdr folder on the Application Server to the PC. You can copy the xdobookbinder.cfg file to any directory on the PC. You specify the location of the xdobookbinder.cfg file when you execute the RunPDR command.
2. Open the **xdobookbinder.cfg** file with a text editor.
3. Locate the following lines in the file and verify that the value of the **process-font-substitution** property is set to **true**:

```
<properties><property name="process-font-substitution">true</property></properties>
```

The process-font-substitution property must be set to true if you want to embed the Type 1 fonts.

4. Check the fonts to embed. For Type 1 fonts in the Patient Data Report, you can choose to embed either TrueType fonts or Type1 fonts.

- To embed TrueType fonts, be sure to specify the TrueType font file path. For example:

```
<truetype path="%OUI_WIN_DIR%\fonts\arial.ttf"/>
```

- To embed Type 1 fonts, be sure to specify the Type1 font file path. For example:

```
<type1 pfb="%OUI_ADOBE_FONT_DIR%\Sy____.pfb" pfm="%OUI_ADOBE_FONT_DIR%\pfm\Sy____.pfm"/>
```

5. Replace each occurrence of the **%OUI\_WIN\_DIR%** variable with the path to the Windows directory on this PC:

```
<font-substitute name="Helvetica"><truetype path="%OUI_WIN_DIR%\fonts\arial.ttf"/></font-substitute>
```

6. Replace each occurrence of the **%OUI\_ADOBE\_FONT\_DIR%** variable with the path to the Adobe fonts directory on this PC:

```
<font-substitute name="Symbol"><type1 pfb="%OUI_ADOBE_FONT_DIR%\Sy____.pfb" pfm="%OUI_ADOBE_FONT_DIR%\pfm\Sy____.pfm"/></font-substitute>
```

Note that the Symbol and ZapfDingbats fonts are Adobe fonts. The fonts must be present on this PC and in the specified directory if you want to embed them into Patient Data Reports.

7. Save your changes.

## 11.2 Embedding Type 1 Fonts when Generating Reports from the Command Line

Once you configure the xdobookbinder.cfg file, you use the **RunPDR** command to generate a Patient Data Report and embed the Type 1 fonts. You must include the -cfg parameter to specify the location of the xdobookbinder.cfg file on your PC. In addition, the fonts must be located on the same machine that you use to run the report.

To embed Type 1 fonts when you generate a Patient Data Report, enter the RunPDR command in the following format:

```
RunPDR.cmd-ststudy-lfolder_location-uuser-cfgxdobookbinder_location
```

For example:

```
RunPDR.cmd -st test3 -l D:\temp -u ops$jsmith -cfg D:\pdr\xdobookbinder.cfg
```

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## 12 Revision History

This is the first version of these release notes.

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## 13 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

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Oracle Clinical Release Notes, Release 4.6.6

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