

# Oracle® Clinical

Release Content Document

Release 4.6

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This is the Release Content Document for Oracle Clinical and for Oracle Clinical Remote Data Capture (RDC).

## 1 Purpose of Document

The Release Content Document communicates information about new or changed functionality in the specified release of Oracle Clinical/Remote Data Capture. Existing functionality from prior releases is not described.

## 2 Release Overview

This new release of Oracle Clinical and Remote Data Capture (RDC) 4.6 comprises four main themes:

### 2.1 Support for Flexible Studies

To address increasing demands for the ability to handle multi-arm and growing numbers of other complex trial designs, Release 4.6 extends Study Definition features in Oracle Clinical to define rules for data-driven events that determine or change a subject's schedule or expected assessments.

For example, subjects may require a different frequency of visits and sets of assessments based on tumor type in an oncology trial. Support for flexible studies allows initial capture of the tumor type (A, B, C) with subsequent calculation of the schedule and assessments (pages) expected based on the reported tumor type. The definitional features provide for a simplified and more efficient workflow for a study builder. All work is performed within the user interface and does not require complex programming. The user interface in Remote Data Capture has also been updated to reflect the changes to study definition. An RDC user sees only the specific schedule and measurements that are expected for a subject, based on the individual subject's data and encountered expectedness calculations (in this example, the tumor type). This enables users to more efficiently navigate to the correct and required pages, and facilitates faster and more accurate data capture.

### 2.2 Usability Enhancements

Release 4.6 includes several enhancements, as prioritized from our Strategic Development Partnership Program and User Groups, to support of the increasing adoption and use of Oracle Clinical 4.5.3. These include more efficient support for handling protocol amendments using group patient assignment to Data Collection Instrument Books (DCI Books), support for role-based DCI Access in RDC Onsite, in-page conditional branching in RDC Onsite, and several enhancements to the Patient Data Report (PDR).

### 2.3 Scalability Enhancements

Oracle Clinical and RDC 4.6 also addresses scalability and performance to ensure continued success of the products in the field. This release introduces handling for same-time background processing (batch validation), and data capture activities, minimizing conflicts and record locking (27x7). The release also optimizes the

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utilization of middle tier resources. Finally, Oracle Clinical and RDC 4.6 adds handling for intermittent connectivity loss, allowing the applications to continue running with minimum disruption to the users.

## 2.4 Upgraded Technology Stack

Oracle Clinical and RDC 4.6 includes significant upgrades to the technology stack, leveraging more up-to-date capabilities and tools and alleviating end-of-support windows for legacy components.

## 3 New Feature Details

This section includes details on the new features mentioned above.

### 3.1 Support for Flexible Studies

The Oracle Clinical Study Design and Setup, and RDC OnSite user interfaces, are significantly enhanced to improve the modeling and execution of complex Clinical Studies, such as studies with multiple treatment arms and cohorts (groups of patients), with different assessments. In these trials, patients receive different assessments based on data collected during the trial.

For example, a flexible study design for an oncology indication requires different disease states to have different schedules and assessments; patients with more rapidly progressing disease are evaluated and dosed more frequently, and patients with less rapidly progressing disease states are evaluated less frequently.

With flexible study support, studies can be defined in Oracle Clinical such that in RDC Onsite, Visits and CRFs become dynamically expected as responses to pre-defined trigger questions are entered:

1. The study designer identifies a study as flexible during initial study setup. This enables several new enhancements.
2. The study designer uses the Enhanced DCI Book definition feature to define and apply Interval rules and DCI rules to the DCI Book. These rules specify a trigger question and define expected intervals and DCIs based on a set of possible response values:
  - Interval rules have the potential to enable one or more Intervals, where an interval includes a set of Clinical Planned Events (CPEs) and DCIs.
  - DCI rules have the potential to enable individual DCIs, based on responses to questions in the CRF. DCI rules can be made to apply to the current visit only, or across CPEs (all occurrences of a DCI in a study).
  - As data entry is conducted and rules are executed, the Multi-patient Casebook page in RDC Onsite automatically refreshes to display new visits and updated CRF icons for the patient affected.

Flexible study support provides the ability to define the many potential pathways a patient might take through a Clinical Study and to display only the appropriate CRF pages that are expected for the patient based on ongoing patient data entered.

The definition of Interval and DCI rules has no effect on the Patient Data Report. Received DCIs for the patient are displayed regardless of whether they are expected or not. The blank casebook report includes all DCIs defined in the DCI Book.

### 3.2 New Oracle Clinical Interface Defines and Assembles DCI Books to Support Flexible Studies

The Enhanced DCI Books definition functionality includes a number of features that support Flexible Studies. Some are ease-of-use features, which are also available for updating or defining DCI Books for non-flexible studies. These are the new features:

- **The DCI Book Navigator:** this form provides an overview of a DCI Book definition. It includes a list of Clinical Planned Events defined for the book, an indication as to whether each CPE is assigned to an

interval that is the target of an interval rule, a count of DCIs defined for the visit, and the sub-count of defined DCIs which are conditional, that is they are the target of a DCI rule. There is a button that takes the user to the form for defining or viewing the DCIs expected for each CPE. Trigger details of any DCI rules that are the target of a DCI Rule can also be viewed in this form.

- **Group Copy and Insert of DCI book pages:**The DCI Book Navigator form provides the ability to copy all DCIs from one CPE and add to another, an ease-of-use feature helpful when a number of visits have the same basic set of DCIs. This feature is available for both Flexible and non-Flexible studies.
- **Delete DCI Book Pages:**The DCI Book Navigator form provides the ability to delete all DCIs from one CPE in a single delete action. This feature is available for both Flexible and non-Flexible studies.
- **Automatic Page Re-sequencing and Page Re-numbering:**Upon addition of DCIs to a CPE, the DCI display numbers are automatically renumbered. There is also an option to run a utility that can re-sequence or re-number the DCIs within a DCI Book. The page re-sequence utility updates page display numbers that are out of sequence. The page renumber utility renumbers a specified range of pages. These features are available for both Flexible and non-Flexible studies.
- **Interval and DCI Rule(s) Definition:** Interval and DCI Rules are defined in separate forms available from the Enhanced DCI Books form.
- **Interval and DCI Rule(s) Definition:** Interval and DCI Rules are defined in separate forms available from the Enhanced DCI Books form.
- **DCI Book Validation:** DCI book validation ensures that references from rules to intervals, CPEs and DCIs are correct. Book validation runs automatically prior to DCI Book activation, or can be manually initiated. DCI Book validation results can be opened from within the Enhanced DCI Books form.

The legacy DCI Book functionality continues to be available for non-flexible Study Designs and where the existing page tracking functionality is required.

### 3.3 Multi-Patient Casebook Page Enhancements to Support Flexible Studies in RDC Onsite

The Multi-Patient Casebook page in RDC Onsite includes several enhancements in support of Flexible studies, as follows:

- **Automatic Refresh:** The Casebooks page refreshes automatically upon return from a data entry session. CRF icons are automatically refreshed to reflect the new status of the CRF. This feature extends to Review pages in RDC Onsite, as well as the Casebooks page, and it is relevant to Flexible and non-Flexible studies.  
In the Casebooks page, the results of an automatic refresh can be more significant than in the Review page, for both Flexible and non-Flexible studies. In Flexible studies, entirely new CRF icons or new visits may be displayed to reflect newly expected CRFs or visits resulting from execution of a DCI Book rule. In non-flexible studies, there can be similar results when a patient is assigned to a new DCI book upon execution of a validation or derivation procedure.
- **Patient-specific visit list:** In a Flexible study, different patients may have very different sets of expected visits. In the Casebooks page, where multiple patients are displayed, a user may change the patient focus to list visits that are relevant for that patient. This enhancement enables the user to easily identify and navigate to the visits that are expected for an individual patient.
- **Display of Visit-Owning Interval:** the Casebooks page displays expected and entered CRFs for a single visit at a time. The visit name is displayed above the matrix of patients and CRFs. In Oracle Clinical and RDC 4.6, in recognition of the increased significance of intervals, the interval name is also displayed, prefixed to the visit name.

You can configure whether to display the Visiting Owning Interval at the study level.

## 3.4 Usability Enhancements

This release includes the following usability enhancements.

### 3.4.1 Multi-Patient DCI Book Assignment

DCI Books are used to specify which pages (assessments) are required for each visit during a study. For various reasons, including protocol amendments, the DCI Book can be changed during the course of a study. For clinical studies with many patients, it is most efficient to assign a DCI Book to a group of patients based on certain criteria.

To improve the efficiency of DCI Book Assignment to patients both at study initiation and during study conduct, Oracle Clinical users will be able to assign DCI Books to blocks of patients in a single action. A block can be all patients created for a Study or Site, a range of patients, or all patients already assigned to a specific DCI Book.

### 3.4.2 DCI Level Access

Many situations within the conduct of a study warrant the ability to control page-level access to CRFs (DCIs). The most logical way to do this is by user role.

For example, in an Oncology study, a local laboratory may be used. It is common to want to provide RDC data entry access to the local laboratory personnel. However, such personnel must only have access to the specific laboratory CRFs used to collect data from their laboratory. They must not have access to any other CRFs (This is a scenario where a specific role will be created for the local laboratory personnel and DCIs will be limited to the relevant local lab CRFs).

In another example, a pharmacist is dispensing medication to a patient and recording this on a Drug Accountability CRF in RDC OnSite. The Investigator should be able to view the Drug Accountability data but have no access to change it as this is the responsibility of the pharmacist. The pharmacist has no need to see the other CRF pages and therefore could be restricted to the Drug Accountability CRF only.

DCI Level Access provides a configuration tool to restrict users to either browse-only or no-access to a subset of DCIs in a Study. Restrictions are defined on the basis of user role. The restrictions affect CRF access in RDC Onsite.

The content of the graphic Patient Data Report is restricted based on the DCI access scheme in effect for the user generating the patient data report: The report does not contain CRFs for DCIs that are specified as hidden for the user's role.

### 3.4.3 In-Page Conditional and Indicator Branching in RDC OnSite

In entering CRF data, it is common that the questions that should be answered by the site for a patient will depend on a source question. For example, if the answer to "Was a chest X-ray performed?" is "Yes", then the date the chest X-ray was performed and the results should be entered in the CRF. If the answer was "No", then the site user should not be able to enter the date the chest X-ray was performed and the results. This is more efficient for the site in directing them only to questions that should be answered and it also prevents them from entering data in the incorrect place on the CRF, which in turn reduces the number of discrepancies.

In-Page Conditional and Indicator Branching in RDC OnSite supports the design of CRF forms where the user entering data is directed to a different set of questions on a form, depending upon the response entered for a single source question. Alternative sets of target questions are grouped into conditional blocks that are disabled until the user supplies a response to the source question enabling one or more of the pre-defined blocks.

A configuration option allows customers to indicate whether disabled conditional blocks will be completely hidden or grayed out.

Conditional and indicator branch and block definitions have no effect on the Patient Data Report or Blank Casebook Report. Questions and responses in all conditional blocks are displayed; no questions are hidden.

### 3.4.4 Discrepancy Management Enhancements in RDC Onsite

Incorrect handling of discrepancies increases the risk of either missing or finding data errors late in the clinical trial process. For example, a Site User could inadvertently close a discrepancy that is intended for the CRA. Such an action may result in the perpetuation of incorrect clinical data; if the CRA never sees the open discrepancy, it is never routed to the investigator for review and possible correction. Discrepancy Management Enhancements in RDC Onsite can be used to prevent the above scenario.

The enhancements are as follows:

- **Hidden discrepancies:** The ability to hide discrepancies at a specific status from users with a certain role is extended to discrepancies of all types: manual section, manual field, univariates and multivariates. Previously, this support was provided only for manual section discrepancies.

When running a Patient Data Report, if the View Discrepancies option is selected, the content of the Patient Data Report is restricted based on which discrepancies the user generating the patient data report is allowed to view. The report does not include discrepancies that are hidden for the user.

- **Prevent update of Other discrepancies:** a database-level configuration option is provided to prevent users of specified roles from updating discrepancies appearing as Other. This feature can be used to prevent a scenario like the one described above from happening.
- **Display user role:** the discrepancy details pane in the data entry window displays the role of the user who created the discrepancy to facilitate proper routing.
- **Display discrepancy ID:** the discrepancy details pane in the data entry window displays the discrepancy ID. A URL parameter causes the ID to be displayed, just as it can be displayed in the Discrepancy Review page in RDC Onsite 4.5.3.

### 3.4.5 Patient Data Report Enhancements

As part of a drug submission process, regulatory authorities can request the sponsor to submit the CRF data collected for each patient in PDF format. In addition, trial sites require copies of the CRF data at the end of the trial. Oracle Clinical and RDC 4.6 enhancements bring the PDR into greater compliance with FDA Guidance based on ICH eCTD standards, as follows:

- **FDA-Compatible PDR Filename from Command Line:** The output filename for the PDR and blank casebook report is compatible with FDA guidelines: "NAMING PDF FILES".
- **Show Audit History for All Fields, Even If Never Updated:** When the user selects the Audit History option when generating the Patient Data Report, audit history for all fields are available, even responses that have never been updated. Pre-4.6, the PDR Audit History option provides audit history for each field that has been updated since initial CRF creation. In Release 4.6, PDR audit history for each CRF also includes the CRF creation time and user who created the CRF. In this way, a complete audit history is available for all fields, including those fields that have not been updated since the CRF was first created.
- **Show DCM Qualifying Value in Blank Casebook Report:** The DCM Qualifying Value as well as the DCM Qualifying Question is displayed in the Blank Casebook Report.
- **Bookmarks Point to a Destination:** Bookmarks now point to a destination rather than a page number, so that when users manually insert additional pages and bookmarks, existing bookmarks will still point to the correct pages.
- **Bookmarks have format recognized by Third Party Publishing Tools:** For submission purposes, users often use a third party tool publishing tool to publish the PDR as part of a submission. The bookmarks generated in the PDR reports pre-4.6 were not recognized by some third part tools and thus added complexity to the publishing process.
- **Non-CRF Pages meet all FDA Guidelines:** Non-CRF pages (cover page, Ancillary Data Pages, and Appendices) now meet FDA Guidelines on font type, size, and page dimensions.

## 3.5 Scalability Enhancements

This release includes the following scalability enhancements:

### 3.5.1 24/7 Support for RDC Data Entry and Batch Validation

Due to the increasing demand of running global trials using Oracle Clinical RDC, data entry may be performed at any time during a 24 hour period.

In Oracle Clinical and RDC 4.6, Batchvalidation can be run at the same time as data entry without issues related to record locking conflicts. Records that are locked due to pending data entry at the time of batch validation are logged and processed the next time batch validation is run.

### 3.5.2 Improved Middle Tier Scalability for RDC Onsite

RDC 4.6 relieves the constraints on the maximum number of sessions that can be supported on a single application server. In RDC Onsite 4.5.3, this number was limited to 345 concurrent data entry sessions (with a maximum of three data entry windows per RDC Onsite user), due to Windows architectural restrictions on use of a certain type of memory. Release 4.6 circumvents this restriction. The application scales with the memory and CPU capacity of the middle tier computer.

### 3.5.3 Handling Intermittent Drops in the RDC Onsite Data Entry Window

In Oracle Clinical and RDC 4.6, the data entry window detects when a network connection has been lost during a transaction. Because the drop in connectivity may be momentary, the user is warned and given the option to have RDC Onsite retry the connection to the middle tier, multiple times if necessary.

### 3.5.4 Data Entry Logging Framework for RDC Onsite

RDC Onsite 4.6 provides more sophisticated debug capabilities, improving Oracle's responsetime in diagnosing issues.

## 3.6 Upgraded Technology Stack

The upgraded technology stack includes:

### 3.6.1 Client

- Windows 2000 SP4 (IE 6), XP SP1,2 or 3 (IE 7 or 8), Windows 2003 SP1 or 2 (IE6 or 7), and Vista SP1 (IE7 or 8) client)
- Native JVM

### 3.6.2 Middle Tier

- AS10gR2 patch set 10.1.2.3
- Oracle 10g
- Windows 2003 Server

### 3.6.3 Database

- Oracle 11g
- HP-UX Itanium 11.31
- Sun Solaris 9, 10
- Windows 2003 Server

## 4 Supported Upgrade Paths

Three upgrade paths will be supported:

- Oracle Clinical Remote Data Capture 4.5.1 to 4.6
- Oracle Clinical Remote Data Capture 4.5.2 to 4.6
- Oracle Clinical Remote Data Capture 4.5.3 to 4.6

## 5 De-supported Features

The following features are de-supported in this release.

### 5.1 PDF Data Entry

PDF data entry is de-supported in Oracle Clinical and RDC 4.6. All evidence of options, menus, and terminology related to use of PDF data entry in Oracle Clinical and the RDC Classic Surround are removed.

### 5.2 Oracle Clinical NLS Option

The Oracle Clinical NLS Option is de-supported.

## 6 Disclaimer

This Release Content Document (RCD) describes product features that are included for the specified release of Oracle Clinical and Remote Data Capture. This document describes new or changed functionality only. Existing functionality from prior releases is not described.

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