Working with Oracle Clinical and RDC Onsite

Upgrading V4.6.x to V5.1.x
Changes Since OC/RDC Release 4.6

• Major
  – New User Interface and Casebook Views, View Controls (5.0.0)
  – Data Entry Window “Next/Previous CRF” (5.0.0)
  – Extended Text Question Type (4.6.3)
  – Custom Review Status (5.1.0)
  – Partial Source Data Verification (5.1.0)
  – Additional CRF Audit History Information (5.1.0)
Changes Since OC/RDC Release 4.6

• Other
  – Better Group Verify/Approval dialog (5.0.0)
  – Improved Thesaurus DVGs (4.6.5)
  – Can disable Delete CRF function in RDC (4.6.5)
  – Enforcement of Standard dd-mon-yyyy dates (4.6.6)
  – PSUB Operation (5.0.0)
  – RDC Onsite now supports Safari browsers (5.0.0)
  – Audit of Study Deletion (5.1.0)
  – Desupport and removal of RDC Classic
New UI: List Formatting

• Columns can have their width modified and/or their display order changed with mouse click and dragging
• Pages where this operation is possible are:
  • Patient List
  • Discrepancy Review List
  • CRF Review List
  • Investigator Comment Review List
• Changes will not be saved after log out or drill down to another page
New UI: List Format-Column Width

Width of columns can be resized by moving the mouse over the column end and dragging the icon to the new size.
New UI: List Format-Column Order

Display position of a column can be modified by a mouse right click to select and dragging the column to the new position
New UI: List Sort Order

This is maintained as in earlier versions with minor differences:

– Hold mouse over the column title
– Up and Down arrow heads appear
– Click the arrow head
New UI: Link Tab Availability

All Pages in this version have the ability to open or close the links section which was found only on the Home Page in V460

- Example: The CRF Review Page
New UI: Record Selection on a List

• Onsite V460 used a checkbox to select record(s) for an operation
• Onsite V500 uses the “standard” Windows paradigm of mouse clicks
• If there are no records (rows) selected on a page, the items will be highlighted with alternating color
New UI: Record Selection on a List

- Click to select first record (row)
- Move the Cursor to new row
- Shift-Click selects a range
- Cntrl-Click selects a single row
- Cntrl-Click unselects a single row
New UI: Record Selection on a List

For selected records, row colors have specific meaning:

- **Unselected**
- **Selected**
- **Cursor Position**
New UI: Scroll Bars

Onsite Version 460 had Previous and Next links to display groups of records
  – Section Pulldowns could also be used
    • An Example from the V460 Casebook page

Vertical Scroll  Horizontal Scroll
New UI: Scroll Bars

Onsite Version 5.0 uses scroll bars
– Example: Multi-Patient Casebook
New UI: Performing an Action

• OnSite V460 required you to click [Go]
  – In order to execute an operation on selected records on a list

• Current version does not require any additional mouse actions
  – Patient or Casebook list for Study/Site will be retrieved when the Site is Selected
  – Choosing the Action from the pulldown will immediately perform the operation
New UI: Performing an Action

Icons to execute the Approval/Verify operations as alternate to the Action pulldown
New UI: Patient List: Query by Example

• In addition to Search Window, Home Page also allows “query by example”

• Clicking the 🗿 icon just above the Heading Bar on patient list creates a new query record

• Complete the new fields with search criteria and click the icon 🔍 to retrieve records meeting the conditions
New UI: Patient Casebook Views

- Onsite V460 provided only a Multi-Patient View of data
  - All CRFs for all patients for a single visit
- New version also provides a Single Patient View
  - All CRFs for one patient at all visits
New UI: Patient Casebook Views
New UI: Patient Casebook Views

- Multi-Patient View has mostly the same characteristics as V460 except for:
  - Actions are performed without [Go] button click
  - Study/Site Selection is relocated to upper left corner
  - Scroll bars not display of groups of casebooks
  - Link Section availability
New UI: Patient Casebook Views

Single Patient Casebook View

– Can select the patient to show in the casebook (from those selected on drilldown)
– Can View Patient Summary Information
– Can Filter CRFs based on Discrepancy, Verification and Approval Status
– Opening a Data Entry Window from this view enables the Previous/Next CRF link to cross visits
New UI: Patient Casebook Views

Control to switch Patient Displayed

CRF Filter
New UI: Patient Casebook Views

Patient Summary Display Toggle

Custom Review Display Toggle (note: currently this feature does not work)

CRF Discrepancy Status
- CRFs with Open Discrepancies: 0
  - Active: 0
  - Other: 0
- Total Open Discrepancies: 0
- Total Closed Discrepancies: 0

Discrepancy Counts

CRF Verification Status
- Verified: 0
- Require Verification: 2
- Require Re-Verification: 0

CRF Approval Status
- Approved: 0
- Require Approval: 2
- Require Re-Approval: 0

Patient Casebook

Visit Name | CRFs
--- | ---
SCREENING | Demo | Medhist | PE | Labcon
VISIT 1 | Labcon | PE | Conned
VISIT 2 | Labcon
FOLLOWUP 1 | Labcon | Conned | PE | Stcomp
New UI: Casebook View Controls

- In Multi-Patient View Mode
  - Controls the Casebook against which CRFs for a patient will be displayed
  - Specifies the Visit whose CRFs will be displayed
- In Single Patient View Mode
  - Controls which Patient will be displayed
  - List of Patients available for the control are those which are selected form the drilldown or search window
New UI: Single Patient View Control

- **Casebook assigned to the Patient displayed**
- **Navigation between Patients for display**
- **Patient whose data is displayed**
New UI: Multi-Patient View Control

Choose Casebooks list

Choose Casebook visit for display

Only appears for Flex Studies
Data Entry Window Movements

Onsite now provides a way to move to the Previous or Next CRF across visits when the link is clicked in a Data Entry Window is accessed from the Single Patient Casebook View.
Data Entry Window Movements

Onsite also now provides a way to move to the Previous or Next CRF when accessing the Data Entry Window from a Review List

– Clicking the button will move to the next distinct CRF in the list

– Do not need to close the current Window and retrieve the list again
Data Entry Window Movements

<table>
<thead>
<tr>
<th>Document No</th>
<th>Study Name</th>
<th>Patient</th>
<th>Visit Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1597204</td>
<td>RDC0553</td>
<td>A00.01</td>
<td>VISIT 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Document No</th>
<th>Study Name</th>
<th>Patient</th>
<th>Visit Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1597404</td>
<td>RDC0553</td>
<td>A00.01</td>
<td>VISIT 3</td>
</tr>
</tbody>
</table>

### Discrepancies for Selected Patients

<table>
<thead>
<tr>
<th>Patient Number</th>
<th>CRF Number</th>
<th>Name</th>
<th>Date</th>
<th>Open CRF</th>
</tr>
</thead>
<tbody>
<tr>
<td>A00.01</td>
<td>D1597204</td>
<td>VISIT 1</td>
<td>02-01-2006</td>
<td></td>
</tr>
<tr>
<td>A00.01</td>
<td>D1597204</td>
<td>VISIT 1</td>
<td>02-01-2006</td>
<td></td>
</tr>
<tr>
<td>A00.01</td>
<td>D1597404</td>
<td>VISIT 3</td>
<td>02-01-2006</td>
<td></td>
</tr>
<tr>
<td>A00.03</td>
<td>D1511204</td>
<td>SCREENING</td>
<td>01-01-2006</td>
<td></td>
</tr>
<tr>
<td>A00.03</td>
<td>D1597504</td>
<td>SCREENING</td>
<td>02-01-2006</td>
<td></td>
</tr>
<tr>
<td>A00.03</td>
<td>D1597604</td>
<td>VISIT 1</td>
<td>02-01-2006</td>
<td></td>
</tr>
<tr>
<td>A00.03</td>
<td>D1597604</td>
<td>VISIT 1</td>
<td>02-01-2006</td>
<td></td>
</tr>
<tr>
<td>A00.03</td>
<td>D1597804</td>
<td>VISIT 3</td>
<td>02-01-2006</td>
<td></td>
</tr>
</tbody>
</table>
Extended Text Questions: Global Library Extension

Questions

– Onsite allows use of EXTENDED_TEXT as the Question Type questions
  • Up to 10,000 characters can be captured for a comment or narrative – Other Question Types limit fields to a length of 200
  • Became available in V4.6.3
Extended Text Questions: Global Library Extension

Question Type: EXTENDED_TEXT

Data Type: CHAR (only)

Length: Number of Characters displayed everywhere but Onsite Entry screens
Extended Text Questions: Global Library Extension

Definition and Usage Restrictions

– Cannot attach any DVG (Regular or Alpha)
– Cannot supply a Default Response
– Cannot make Mandatory or Derived
– Cannot check Enterable
– Cannot be an Indicator Question
– Cannot be in a repeating question group
– Cannot be a Trigger Question in Flexible Study
– Cannot be a Source for a Conditional Branch
– Data Extract does not support Extended Texts
– Special Characters may not display properly
Extended Text Questions: Global Library Extension

• Extended Text will be truncated in all areas of OC, RDC Classic and Onsite except for Onsite Entry Windows
  – Truncated Text is displayed in these areas prefixed with a string of the form “ATTACHMENT V<x.y>”
    • x is the version number: number of consecutively different changes saved in Onsite
    • Y is the subversion number: number of times the focus leaves the extended text field but before save. (Used for internal auditing only)
    • Question Length controls how many characters are displayed after the “Attachment” text (Question length less 24 characters)
  – Procedures can access only the truncated text

• Can enter, review or update full Extended Text Questions only in Onsite Entry Windows
## Extended Text Questions: In Onsite

Click on the icon to open Extended Text Window for entry, review or update ...

<table>
<thead>
<tr>
<th>Document No</th>
<th>R1875604</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Name</td>
<td>RDC0553</td>
</tr>
<tr>
<td>Patient</td>
<td>A00.00</td>
</tr>
<tr>
<td>Visit Name</td>
<td>SCREENING</td>
</tr>
</tbody>
</table>
Extended Text Questions: In Onsite

Enter text into open window and click OK to save ...
Extended Text Questions: In Onsite

This is an example of an extended text field. There is no longer the 200 character limit set by oracle clinical. An extended text field can be up 10,000 characters. Type to your heart's delight!

This appears on the eCRF

This is extended text as entered...
Extended Text Questions: In Onsite

This is what appears in the Audit History pane for changed text:

<table>
<thead>
<tr>
<th>Date</th>
<th>Changed From</th>
<th>Changed To</th>
<th>By</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-22-2011 07:35:17</td>
<td>ATTACHMENT V&lt;1.1&gt;:This is</td>
<td>ATTACHMENT V&lt;2.1&gt;:Text was</td>
<td>Sitea 00</td>
</tr>
</tbody>
</table>

This is what appears in Discrepancy List:

<table>
<thead>
<tr>
<th>Patient Number</th>
<th>Name</th>
<th>Visit</th>
<th>Date</th>
<th>CRF Name</th>
<th>Question / Section</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>A00.00</td>
<td>SCREENING</td>
<td></td>
<td></td>
<td>COMMENT</td>
<td>Long Comment Text</td>
<td>ATTACHMENT V&lt;2.1&gt;:Text was changed :This is</td>
</tr>
</tbody>
</table>
Extended Text Questions: In Onsite

**Patient Data Report: CRF Page**

**Patient Data Report: Extended Text Ancillary Page**

**Extended Text for CRF COMMENT Field**

Long Comment Text

Text was changed: This is an example of an extended text field. There is no longer the 200 character limit set by oracle clinical. An extended text field can be up to 10,000 characters. Type to your heart's delight!
Extended Text Questions: In OC

Cannot update Extended Text even in update Mode through OC
Custom Review Types

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

• Each review type you define comes with a set of five possible statuses that can be assigned to CRFs: No Review Status, Review Required, Review Undone, Awaiting Re-review, Review Complete, and Review Not Required.

Note: There is currently a bug in 5.1 which prevent the CRF annotations for custom review from displaying properly.
Custom Review Types

- The system is installed with 9 review types (R1 through R9). Additional customized review types can be added to the Installation Codelist of CUSTOM REVIEW TYPES.
Custom Review Types - Setup

• The system is installed with 9 review types (R1 through R9). Additional customized review types can be added to the Installation Codelist of CUSTOM REVIEW TYPES
• Users need to be granted the RDC privileges of BROWSE_REVIEW to see the custom review status and the Review status (e.g. R1) to update the review status in RDC

**NOTE:** This is not going to be used by PPD immediately but MAY be implemented at a later date
Custom Review Types - RDC

- In the data entry window for RDC there is a new tool in the toolbar to apply the review status (similar to Verify and Approve tools)
- Clicking the tool opens up a dialog box where you can apply a status or view the history of the review status
Custom Review Types - RDC

- In surround, an annotation will appear noting the Review Status for users with the BROWSE_REVIEW privilege.

- Group Review can be done as well
Custom Review Types - RDC

- The CRF status icons should appear as follows (once they fix the bug!)

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RC</td>
<td>RC: Review is complete (or not required) for all your review types.</td>
</tr>
<tr>
<td>RQ</td>
<td>RQ: Review for at least one of your review types is required.</td>
</tr>
<tr>
<td>RN</td>
<td>RN: The CRF does not require review for any of your review types.</td>
</tr>
<tr>
<td>RR</td>
<td>RR: At least one of your reviews was reversed due to data update and it's awaiting re-review.</td>
</tr>
</tbody>
</table>

- Note: You can have multiple review privileges which has the potential for the icons to not be very helpful!
Partial Source Data Verification

OC and RDC now support the creation of a Risk-Based Source Data Verification (SDV) Plan that identifies only a subset of data requirement verification in RDC. The SDV is comprised of one or both of the following components:

• **Critical Forms Plan** - identifies CRFs that need to be verified against the original data for all patients.

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

**NOTE**: This is not going to be used by PPD immediately but MAY be implemented at a later date.
The Pending Patient Updates job must be scheduled, at an interval of your choosing, to check for newly eligible patients and to process those patients marked for auto-selection.

Admin → DE Admin → Schedule Pending Patient Updates Job

The job can also be run outside of the schedule by going to Conduct → Security → Execute Pending Patient Updates
Partial Source Data Verification - Setup

The Default settings for selecting patients for SDV can be entered under the DCI Form Local Database Settings:

These settings can also be entered at the study level under Design → DCI Form Local Study Settings.
Partial Source Data Verification - Setup

The settings can be updated in RDC for each individual site under Source Data Verification Plan, Patient Plan: Draft…
In RDC, you can even mark specific patients at each site to be included or excluded in the count...
Partial Source Data Verification - Setup

Forms can be selected to be 100% source data verification on the Maintain DCI screen
**Partial Source Data Verification - Setup**

**OR** Forms can be selected to be 100% source data verification in RDC under Source Data Verification Plan, Critical Forms Plan: Draft
Partial Source Data Verification - Setup

In the patient positions table there are now two additional columns
- SDV Eligible Date – must be entered if patient is going to be considered in the pool of patients eligible for SDV
- SDV Ineligible Date – if entered, subject will not be included in the pool of patients eligible for SDV (SDV will NOT be required for these patients)

These values can be populated into the Patient Positions table by:
- Entering the values
- Deriving the values
- Loading the values
In order to change, publish or see the SDV Plan in RDC, users must be granted study/site privileges.

- **ADMIN_SDVPLAN** – to publish plans
- **BROWSE_SDVPLAN** – to see the plan
- **UPDATE_SDVPLAN** – to update the current plan
Once the settings are complete (either through the default settings in OC or through RDC), the plan needs to be published for each site.

There is a job in OC to publish the SDV Plan for all sites (Conduct→Security→Publish SDV Plans for all Sites). Unfortunately due to a bug, this job is not working correctly.

So….the plan currently has to be published for each site separately in RDC.
Partial Source Data Verification – Publishing the Plan

Publish the Patient Plan:
1. In RDC, go to Source Data Verification Plan → Patient Plan: Draft.
2. Confirm or update values
3. Click SAVE
4. Select Actions → Validate to confirm the plan is valid. If there are any warnings, click on Actions → View Validation Log
5. Assuming no errors, click on Actions → Publish to publish the plan for that site.

Follow the same steps to publish the Critical Forms Plan.
Partial Source Data Verification – Updating the Plan

To update the plan, create a new version of the Published Plan and follow the steps to publish the new draft plan.
Partial Source Data Verification – Viewing Obsoleted Plans

Obsoleted Plans can be viewed by anyone with BROWSE_SDV privilege
Partial Source Data Verification – RDC

Patients requiring 100% RDC are identified on the Home Page in the Patient List
Partial Source Data Verification – RDC

In the Casebook Spreadsheet, patients are marked that are requiring SDV and CRF pages are marked with a V that require verification.
The RDC Onsite data entry window now provides a CRF Report and CRF History Report which provides CRF audit history not otherwise available in the data entry window, including initial CRF creation data, prior history for deleted rows, and prior history if the CRF was ever deleted.

To run the report, click on the Generate CRF Report in the tool bar or the Generate CRF History Report in the tool bar.

When the report is completed, additional tools appear to allow the downloading of the reports.
Additional CRF Audit History Information

History for CRF MEDICAL HISTORY, Document Number R1865804

Study: RDC0553  
Site: A00  
Patient: A00 00  
Visit: SCREENING  

Created by: Class Instructor  
Role: DM  
On: 12-12-2011 11:45:05

Content

NOTE: This document only includes data that is not otherwise visible in the Data Entry Window. It is not intended to include all audit history for the CRF.

End of Primary Section

Ancillary Information for CRF MEDICAL HISTORY, Document Number R1865804

Created by: Class Instructor  
Role: DM  
On: 12-12-2011 11:45:05

Content

Approval History

<table>
<thead>
<tr>
<th>Date</th>
<th>Operation</th>
<th>Changed By, Role</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-12-2011 12:01:36</td>
<td>Approval</td>
<td>Inv 00, INV</td>
<td>null</td>
</tr>
</tbody>
</table>

End of Primary Section
Control of Group Verify/Approval

- Some new options are available for selection criteria for CRF filtering in Group Operations
- Controlled on the DCI Form Settings Screen (Both System and Study Levels)
Control of Group Verify/Approval

• There are two parameters which apply to each setting
  – Will the Checkbox shown as Checked or unchecked as default?
  – Can the default setting be Updateable or non-updateable (enforced)?
• These settings will appear during the group Verify or Approve dialogs
Control of Group Verify/Approval

Note: Only appears if there are CRFs that have been verified AND the user has BROWSE_VERIFY privilege
Thesaurus DVGs with Onsite

- Create a view with added columns for values of clinical_study_id and site_id
- Add a WHERE clause to the view
  
  ```
  where clinical_study_id = rdc_thes_dvg_client.getClinicalStudyID
  and site_id = rdc_thes_dvg_client.getSite
  ```

- Must maintain study and site columns manually in the view (or table)
- Became available in Release 4.6.5

Possible to restrict values returned by a Thesaurus DVG by Study and Site performing the capture
Thesaurus DVGs with Onsite

• If same Thesaurus DVG will be used in Oracle Clinical the where clause must use the nvl function

```sql
WHERE nvl(to_char(clinical_study_id),’X’) like
nvl(to_char(rdc_thes_dvg_client.getClinicalStudyID),’%’)
AND nvl(to_char(site_id ),’X’) like
nvl(to_char(rdc_thes_dvg_client.getSite),’%’)
```
Disable CRF Delete Icon in RDC

Release 4.6.5 contained a new feature to disable the CRF Delete Function icon in the RDC Data Entry Toolbar

- When disabled, the CRF Delete icon is grayed out
- The option is a setting on the DCI Form Runtime node of the DCI Form Settings screen (Both System and Study levels)
Enforce Standard Date Format

- Release 4.6.6 allows enforcement of the standard date format (dd-mon-yyyy)
  - Applies to both OC (paper Data Entry) and RDC
  - Dates can still always be entered in the standard format
  - Selection of the standard format requires dates in the dd-mon-yyyy format or a discrepancy will result
Enforce Standard Date Format

![Preferences](image)

- **Number of items to display: News, Activities, and Links**: 20
- **Input Date Format**: dd-mon-yyyy (Standard)
- **Display Date Format**: mm-dd-yyyy (US)
- **Display timestamps in local timezone**: [ ]
PSUB Changes

• The technical aspects PSUB operation has changed
  – Effective in V500
  – Log and output files no longer stored on the database server
  – The use of ops$ accounts for Oracle Clinical is eliminated
  – No effect on the end-user operations
RDC Onsite now supports Safari browsers

• RDC Onsite now supports Safari browsers on both iPad and Macintosh
Audit of Study Deletion

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

• There are now two menu items for batch deleting data, both under the Conduct menu.
  – Delete Study Information with Audit, always audits data deletion.
  – Delete Study Information has a parameter that allows users to choose whether to audit the deletion or not.
RDC Classic

- RDC Classic is no longer included with the installation of OC/RDC 5.1
Summary

• Changes to OC/RDC between the 4.6.0 Release and the 5.1 Release provide some new features and operations
• Users should be aware of the changes to the interface and a few of the new features
Register Training Completion

Thank you for completing the training above. Please submit the training completion form below to confirm the successful completion of your training.

https://edc.ppdi.com/oc_rdc_training51_forms.htm?t=51