

CBT and integration with RDC for real-time application testing, Using UPK with SCORM2004 compliant LMS development environments.



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Agenda

- SCORM
- SCORM Versions and Editions
- Oracle UPK
- LMS Technology
- Advantages of using LMS for RDC Training
- RDC Content Development
- Sample RDC Slides
- Benefits to Organization
- Q/A
- Biography



Sharable Content Object Reference Model (SCORM)

- It is a collection of standards and specifications for web-based e-learning. It defines communications between client side content and a host system called the run-time environment, which is commonly supported by an LMS.
- SCORM is a specification of the Advanced Distributed Learning (ADL) Initiative, which comes out of the Office of the United States Secretary of Defense.



SCORM Versions

- **SCORM 1.1**-SCORM 1.1 is the first production version. It used a Course Structure Format XML file based on the AICC specifications to describe content structure, but lacked a robust packaging manifest and support for metadata. Quickly abandoned in favour of SCORM 1.2.
- **SCORM 1.2**-This was the first version that was widely used. It is still widely used and is supported by most Learning Management Systems today.



SCORM Versions (Contd.)

- **SCORM 2004**-This is the current version. It is based on new standards for API and content object-to-runtime environment communication, with many ambiguities of previous versions resolved. Includes ability to specify adaptive sequencing of activities that use the content objects. Includes ability to share and use information about success status for multiple learning objectives or competencies across content objects and across courses for the same learner within the same learning management system. A more robust test suite helps ensure good interoperability.



SCORM 2004 Editions

- 3rd Edition (October 2006) — clarification of various conformance requirements and of the interaction between content objects and the runtime environment for sequencing; some new conformance requirements to improve interoperability.
- 4th Edition Released (March 31, 2009) — more stringent interoperability requirements, more flexible data persistence.



Oracle User Productivity Kit (UPK)

- Oracle UPK is a software tool that can capture all the steps in a system process. It records every keystroke, every click of the mouse, each menu option chosen and each button pressed. All this is done in the UPK Recorder by going through the transaction and pressing “print screen” after every user action. From this, without any further effort from the developer, UPK builds a number of valuable outputs.
- UPK outputs, nowadays, are SCORM 2004 compliant and thus can run on any LMS with SCORM 2004 compliance.

LMS Technology

- LMS is usually web-based, built using a variety of development platforms, like JAVA/J2EE, Microsoft.NET or PHP.
- Usually employ the use of a database like MySQL, Microsoft SQL Server or Oracle as back-end.

Advantages of using LMS for RDC Training

- Create e-learning course to RDC specialized training requirements.
- Can be Uploaded in Existing Learning Management System.
- With a custom built courses, we can have our specific RDC material presented in accordance to our live environment.
- Easily distributed to a wide audience at a relatively low cost once the initial development is completed.



RDC CBT Development

- Content slides similar to RDC screens are developed.
- Addition of interactive elements to make simulation close to a live RDC application.
- Detailed descriptive navigational steps are created which helps the user to understand the significance of each step and perform the action.



Roles based RDC CBT Development

- CBT may be developed based on RDC roles.
 - a) Site Coordinator
 - b) Investigator
 - c) CRA
 - d) Data Manager



Some Examples

- Login to RDC
- Significance of icons/fields in RDC
- Performing a patient search
- Discrepancy management based on the user roles
- Verify CRFs by CRA
- Approval of CRFs by Investigator

Sample Screenshots

The screenshot displays the Oracle RDC Onsite login interface. At the top, a blue header reads "Remote Data Capture (RDC) Version 4.6.0 Onsite General Training" with an "EXIT" button in the top right corner. Below this, a breadcrumb trail shows "LOGIN > LOGIN PAGE". A text instruction states, "This is the screen which is used to log into RDC." The main content area features the Oracle logo and "RDC Onsite" text on the left, and a "Help" link on the right. A central graphic shows a globe on the left and a row of five small images of people on the right. The login form includes fields for "User Name" and "Password", and a "Login" button. Several green callout boxes provide step-by-step instructions: "Now click in User Name field.", "Enter your User Name. Then click on Password field.", "Enter your Password. It will appear as '*****' even though you are typing in your actual password. Then click on the Login button. This will take you to the RDC Homepage." The footer contains a "Help" link, the copyright notice "Copyright © 2000, 2007, Oracle. All rights reserved.", and navigation buttons for "PREVIOUS", "NEXT", and "UP".

Sample Screenshots

EXIT

Remote Data Capture (RDC) Version 4.6.0 Onsite General Training

[DATA ENTRY](#) > [DATA ENTRY](#) > [PAGE STATUS](#)

In RDC Onsite, the status of each CRF is reflected by its icon. Below is a set of icons representing the different statuses a CRF can have. Symbols and colors are combined to reflect the various status attributes of a CRF.

Place your mouse cursor on every icon to know more about these icons.

<p>1) </p> <p>2) </p> <p>3) </p> <p>4) </p> <p>5) </p>	<p>6) </p> <p>7) </p> <p>8) </p> <p>9) </p> <p>10) </p>	<p>11) </p> <p>12) </p> <p>13) </p>
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Blank CRF Verified and Approved - The Blank CRF has been verified and approved.

PREVIOUS
NEXT
UP

Sample Screenshots

Remote Data Capture (RDC) Version 4.6.0 Onsite General Training

DATA ENTRY > DATA ENTRY > CASEBOOK

ORACLE® RDC Onsite

Home Casebooks Review Reports

Logged in as Opapps Dbms(Data Management, OPA46); Last Refresh 26-Apr-2010 23:39:42

Study and Site TRAINING_STUDY 101

Patient Casebooks

Search : 3 Patients Selected From Home Page

Casebook Spreadsheet

Set Visit Focus: Patient: 101101 Casebook: CRF BOOK Visit: **Visit1**

Patients: Previous 1-3 of 3 Next

Select Patients and... Generate Patient Data Report Go Add Visit Pat

Select All Select None

Select	Patient Number	DM	VS	AE	MH	Visit1
<input type="checkbox"/>	101101	1	2		4	
<input type="checkbox"/>	101102	1	2	3	4	
<input type="checkbox"/>	101103	1	2	3	4	

CRFs: Previous 1-4 of 4 Next

Home Casebooks Review Reports Logout Preferences Change Password Help

About RDC 4.6.0 Copyright © 2000, 2007, Oracle. All rights reserved.

PREVIOUS NEXT UP

The page automatically refreshes and appears as below (See the page inside the BLUE box), indicating that data was entered for this page and there are no discrepancies (queries) associated with this page.

Now select CONMED from Visit drop down highlighted in blue box to go to Conmed visit.

Tests/Assessments





- Designed using interactive elements such as Drag drop, fill in the blank, multiple choice etc.
- Allows the users to test their knowledge.
- Cut off marks can be assigned to test the users competency of the course.


Sample Screenshot

Remote Data Capture (RDC) Version 4.6.0 Onsite General Training EXIT

[ASSESSMENT](#) > RDCG-II

2. Which of these page icons indicates the CRF page is ready for initial (first time) data entry?

- 
- 
- 
- 

Correct 

PREVIOUS NEXT UP



Actual RDC Environment integrated with CBTs

- Users will experience and learn live production environment:
 - VPN login process
 - Protocol specific information
 - Entering data in CRFs
 - Business Process and workflow



Benefits to Organization

Benefits to Organization

- Centralized learning environment to ensure consistency.
- Tracking and reporting for enhanced performance.
- Immediate capabilities evaluation.



CBT for RDC and UPK with SCORM2004 compliant LMS development environments

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Biography

Kish Cachola, DBMS Consulting, Inc.

- Kish Cachola is an Oracle Health Sciences functional specialist for DBMS Consulting. He has over 8 years experience in clinical trials and data management working for CROs, Biotech and Pharmaceutical.