



Considerations of Current and Future EDC in India

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Goals and Agenda

- Overview of the current EDC trials market and trends
- Current state of Oracle RDC
- Advantages and Value of an Oracle RDC 4.5.3 solution for existing OLS customers
- India-specific considerations for Oracle RDC Deployments



Current EDC Market in India

- OPINION/EXPERIENCE:
- Progressively, more and more trials are moving to EDC within India, especially in the local and MNC CRO space
- The rate of adaptation appears to be less within India for local trials as compared to the rest of the world
- Several challenges regarding infrastructure and costing make paper based studies competitive in some cases



Specific EDC challenges in India

- OPINION/EXPERIENCE:
- Lack of site infrastructure may make it difficult to deploy any EDC solution to remote sites:
 - Power requirements for PCs
 - Availability of continuous network connectivity
- Site resources may not be present to support a desktop environment
- Site users may need basic computer training before being able to use any EDC tool
 - Dedicated on-site training increases acceptance much more than on-line or self-paced CBT training for EDC with new users. This is not a preferred training model from an operational perspective



Strategic value for an Oracle RDC solution for OLS customers

- OPINION:
- Re-leverage existing OC infrastructure
 - Why should OLS customers incur an additional **operational** cost for the deployment of an EDC solution?
- Centralised data repository for failover, fault tolerance and disaster recovery
- Reduction of RDC study deployment time using study migration tools in RDC 4.5.3
- Confidence in regulatory compliance since RDC has been audited several times
- Tangibility of data on dedicated servers



Previous RDC 4.5.1 PC Configuration (as Described in Metalink)

- RDC 4.5.1 Graphical PDF Mode Required the following components installed in the following order:
 - Internet Explorer 6.0. SP 1; SP2 and 7.0
 - Adobe Acrobat or Adobe Reader 6.0.3; 7.0.x and 8.0.x.
 - Oracle J-Initiator 1.1.8.21; 1.1.8.24 and 1.1.8.25.
 - OPA PDF Plug In 4.5.1.43 .
- In addition to the installation of the PC components, there are some specific configuration settings that are required for each component.



Previous RDC 4.5.2 OnSite PC Configuration (as described in Metalink)

- J-Initiator is not required on the web client in order to use the Onsite interface
- “Thinner” Client
- Still required RDC PDF Plug-in 4.5.1.23 or later.
- Provided streamlined & automated RDC PDF Plug-in deployment and configuration



Current RDC 4.5.3 OnSite Release (as Described in OBUG 2007 Conference)

- No Plug-Ins are required on the Desktop
- Active X Control required for initial connection installation, one time activity
 - Automatic installation majority of the time
- No special PC configuration settings required
 - IE 6.x and 7.x are supported
- Pure HTML application, running on J2EE/OC4J framework under AS 10g R2 and 9i RDBMS



Functional Improvements (Described in OBUG 2007 Annual meeting)

- Simplified grid being implemented in pure HTML
- Study site code can be displayed in the surround instead of site code
- Multi-windows support
- Test mode in RDC 4.5.3 Onsite (not present in RDC 4.5.2)
- Print blank Workbooks from RDC test mode while DCM and DCIs are Provisional



RDC 4.5.3 Deployment Considerations

- BASED ON ORACLE PRESENTATIONS AT THE OCUG 2007 ANNUAL MEETING:
- A separate Application Tier for AS 10g R2 may be required since this technology stack is not compatible with 9iAS Release 1 (1.0.2.2.2a)
 - If TMS 4.6 is already in use, this same Application Tier can be reused for RDC 4.5.3, since both products use the same technology stack
 - If OC 4.5.x/TMS 4.5.x/RDC 4.5.x are the only products in use, then a separate set of Application Tiers will be required
- RDBMS should be patched up to 9.2.0.6/9.2.0.7/9.2.0.8. 9.2.0.8 is suggested because this the terminal release of Oracle 9i RDBMS, which will be the most fully supported by the Oracle RDBMS support group
- Upgrade path is from OC 4.5.1 or OC 4.5.2, where a small patch is necessary to enable RDC 4.5.3 HTML functionality. This means current RDC customers on OC 4.5.0/RDC 4.5.0 must consider an upgrade to OC 4.5.1 to be enable an upgrade path to RDC 4.5.3.



RDC 4.5.3 Deployment Considerations (2)

- Existing studies running in PDF can be migrated to the HTML layouts with a specialized Study Migration job.
 - Also creates Business Intelligence (BI) Report Layouts for Patient Data Reports
- Existing OC and RDC Classic Studies must have a PDF layout generated as an intermediary step even if the PDF layout will not be used.
 - Note that the DCI Form Layout job generates three components simultaneously: PDF Mode Form, PDR BI Layout and HTML Layouts
 - Note also that the OCL => Definition => DCI => Migrate Form Version by DCI Book job is **NOT** required. Using the RDC Preference to show non-migrated pages can be used instead, either set in the RDC Configurator or with Edit => Preferences



RDC 4.5.3 Deployment Considerations (3)

- Some OC or RDC Classic Studies with large number of repeats might be difficult to convert to RDC 4.5.3 if there are too many displayed repeats per single RDCI.
 - This type of form should be split into multiple pages as required. It is not the HTML layout, but the intermediary PDF layout, which could have problems in this case.
- Images which are used in the PDF Mode layout should be either UNC path referenced to the RDC 4.5.3 Application Tier or directly copied, since the HTML forms need a dynamic reference to images (not stored in the PDF itself)



RDC 4.5.3 Deployment Considerations (4)

- Dedicated Middle Tiers for RDC 4.5.3 could be replaced in the DMZ for public facing SSL access.
 - If this option is chosen, then new certificates must be acquired and installed for direct SSL access.
 - However, a public facing SSL accelerator/firewall is suggested since this reduces processing burden on the RDC 4.5.3 Application Tiers and is considered more secure.
- Citrix is NO LONGER REQUIRED if previously used for RDC. In many cases, this hardware could be re-deployed as new AS 10g R2 Application Tiers for RDC 4.5.3



RDC 4.5.3 Deployment Considerations (5)

- Load Balancer configurations should still maintain the same “stickiness” and “persistence” parameters.
 - The Web Tier and Application Tier are still integrated
 - The Jserv session may not be accessible from a different Web service in the middle of a continuous session
- Per-server capacity should be much higher as compared to RDC 4.5.1
 - No hard limitations on number of supported ifweb60 processes per Jserv engine on a single server (approximately 180).



Why Oracle is a Strategic Choice for India-based EDC Clinical Trials

- OPINION:
- Oracle has maintained a strong commitment to OLS and specifically the India-based OLS market
- Long Term strategic stability
- Fusion platform can provide capabilities required for India locally based trials
 - Some of these capabilities already possible with Siebel Clinical
- Regulatory protection, least likely to be heavily examined in a regulatory audit.



Future EDC solutions for local India-based trials

- OPINION:
- Should be as “lightweight” as possible
- Ability to run on smaller devices, possibly smaller laptops or hand-held devices
- Full Wireless support
- Should not require 100% continuous internet connectivity; network outage tolerable



Additional Questions ?

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