



DBMS Consulting OCUG 2008 Vendor Presentation

DBMS Consulting OLS Overview



Introduction

- Sunil G. Singh of DBMS Consulting, Inc.
- Specialize in Oracle Life Sciences and E-Business implementations and long-term support.
- Thanks to the OCUG for this demo/discussion opportunity.



Agenda

- Present an overview of DBMS Consulting
- DBMS Consulting's OLS Support capabilities
 - "Classic" OPA
 - Siebel Clinical
 - 24 x7 based support including India and China
- DBMS Consulting's One-Step Turnkey Solution for new OLS deployments
- DBMS Consulting's Hosting Capabilities for OLS, including Siebel and RDC 4.5.3

Overview of DBMS Consulting

- Consulting organization specializing in Oracle Life Sciences and Oracle E-Business Suite Apps 11i/12i implementations.
- Specialize in migrations, installation and configuration, technical and functional support and customized training.
- Support can be either long-term on-site support or remote support on an as needed basis.

Overview of DBMS Consulting (2)

- Projected 35 Full and part time consulting staff in OLS
 - 40% increase in staff from previous year
 - Tremendous growth curve for new OLS deployments in APAC and North America
 - Same size or larger than the **dedicated** staff of most firms supporting OLS
- Technically categorized as a Systems Integrator (SI) for OLS
- Reseller for OLS in APAC
- Maintain presence in New York, Southern California, New Jersey, Singapore, China and India

Overview DBMS Consulting (3)

- All full-time staff travel extensively to client sites and are usually on-call 24-hours.
- DBMS Consulting currently maintains a long-term presence in several companies.
- Additionally, 24 x 7 remote support and OLS Application Support Outsourcing is provided to several organizations.
- Total number of companies that have employed the services of DBMS Consulting for OLS related work is over 50, including CROs, Biotechs, Pharmaceuticals, Medical Device Companies and Academic Institutions



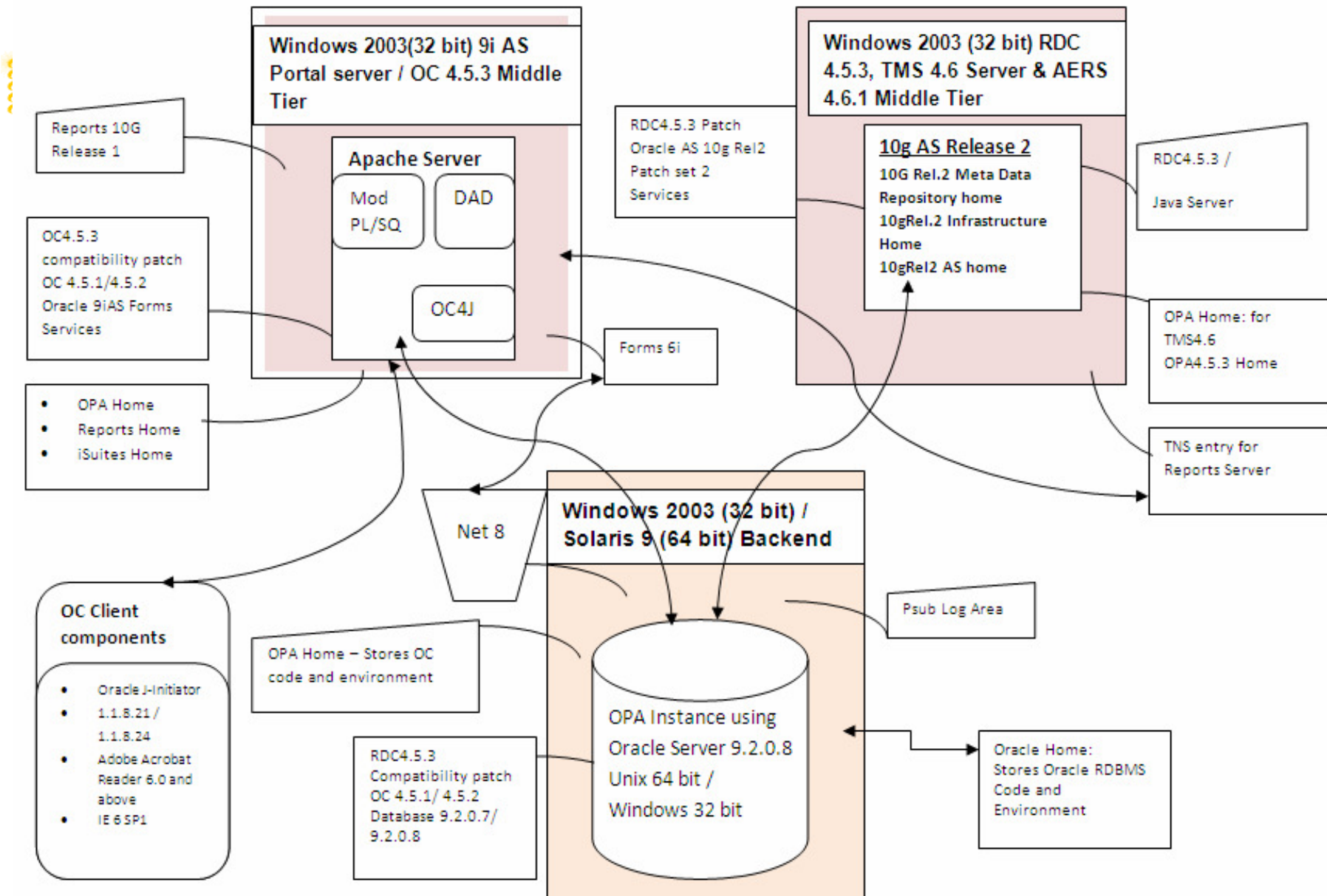
Locations of DBMS Consulting's Successful OPA™ W

Overview DBMS Consulting (4)

- SMDB and GSA Certified and eligible for all US Government contracts
- Certified Partner of Oracle Corporation
- Channel Alliance Partner with Mercury Interactive
- Strategic Partner of the WHO-UMC
 - Responsible for all WHO Dictionary loading support for UMC customers in Oracle TMS.
- DBMS is very price competitive and cost-conscious. Tremendous effort to reduce expenses to customers
- Guarantee customer satisfaction on all work or no billing for that work

Overview DBMS Consulting (5)

- Tremendous technical and functional expertise in Oracle, with most members of DBMS having an Oracle DBA or Development background or Oracle Functional background in either the Pharmaceutical or Financial sector.
- Typically, we are called to solve the most difficult technical and functional issues or to offer strategic implementation advise.
- Created a series of architecture diagrams for the OLS to assist customers with the true understanding of OLS and the myriad configuration options available.



Overview of DBMS Consulting (6): Examples Core Team Strength

- Anoop Nair: 9+ years of core experience in all types of OLS deployments and support
- Alex Platkin: 10+ Years of OC/RDC and Siebel Clinical Global Deployment Experience
- Jason Essig: 8+ Years of core Siebel experience in Global Deployments
- Jian Zhou: 7+ Years in Siebel Tools and Development
- Jose Garcia: 11+ Years of Global Enterprise Oracle DBA support
- Dr. Letian Liu: 10+ Years of core IT/Oracle experience and OLS deployments in APAC
- Dr. Philip Masters: 20+ Years of core Pharmaceutical and Biotech Sector experience



Overview of DBMS Consulting (7): Examples Core Team Strength

- Dan Golden: 10+ Years of core IT/PM experience
- Greg Endicott: 20+ Years of core IT management experience
- Steven Munley: Validation Expert: Support for Over 20 Sponsor and Regulatory Audits
- Vikas Monga: 10+ Years core Oracle Global DBA experience, 6+ Years in OLS/Pharm DBA support
- Ahila Selvaraj: 7+ Years core Oracle PL/SQL Development
- Denise Clark: 8+ Years of TMS API Development



Turnkey Solutions for New OLS Deployments: “One-Step Solution”

- Pre-built and pre-validated set of servers which are delivered directly to a new OLS customers location
- Validated:
 - Functional Requirements, Traceability Matrix, IQ/OQ/PQ execution, Validation Summary Report and documentation
 - Default template SOPs and template Work Instructions
- Three separate environments: Development, Validation, Production



Turnkey Solutions for New OLS Deployments: "One-Step" (2)

- Either Dell or HP servers running Windows 2003
- 5 User License for OC and TMS.
- 5 Users (single site) for WHODrug WHO-DD Dictionary, preloaded in TMS
- 20 day On-Line training regimen
- Configuration Specification which will pre-determine major system functionality
- Initial Deployment in as little as 3 weeks
- Costs under \$200K USD.

Hosting and Co-Location Solutions for OLS



- RDC 4.5.3, AERS 4.6.1 and Siebel Clinical lend themselves very well hosting and co-location
 - RDC 4.5.3 is a "Zero-Footprint Client" (ZFC). Easily deployed over the internet
 - AERS 4.6.1 is deployed using Oracle Portal
 - Siebel Clinical has a true web-tier architecture
- DBMS has partitioned, dedicated server space available which is validated and audited
- Dedicated hardware for each OLS customer
- Option to re-locate hardware centrally

Hosting and Co-Location Solutions for OLS

- Dedicated 24x7 support staff for OS level and System level support
- Automated System-level monitoring, both for OS level and application level services
- Proven, recoverable on-line backups for OS and RDBMS levels
- Remote accessibility to file sharing as well as application level
- Monthly costs per user. Uses DBMS Consulting's common license pool and can have smaller than 5 users per application.
- Resellers of Siebel On-Demand solution, which provides immediate access to Siebel Clinical and Siebel CRM suite

Hosting and Co-Location Strategy and Experience

- Using leased Enterprise Data Center space in Austin, TX and Bangalore, India
- Locations are strategically chosen
 - Austin, TX is one of the original NSF backbone access points (going back to Texas A&M Supercomputing facility). Superior access to global internet connectivity and multiple ISP providers.
 - Both Oracle and Dell have world-class Data Centers in Austin
 - Bangalore is the most famous high-tech area in India with largest number of local and foreign corporate headquarters.
 - Able to supply demands for power and internet connectivity
 - Excellent fail-over site for US-based co-location hosting operations.



Hosting Facilities

- Both Enterprise Class facilities with
 - **Robust Network**
 - Multiple carrier Internet backbones via OC3 connections
 - Border Gateway Protocol (BGP4) routing utilizing only Cisco routers.
 - **Security and Redundancy**
 - 750 Kilowatt generator with 2,000-gallon diesel tank
 - Multiple 20-ton redundant Liebert air conditioning units
 - 500 KVA Liebert uninterruptible power source (UPS) system
 - Pre-action active fire suppression system
 - UL listed lightning protection system



OLS Stand Alone Systems

- OC 4.5.2/RDC 4.5.2/TMS 4.5.2 configuration
- OC 4.5.3/RDC 4.5.3/TMS 4.6
- AERS 4.6.1/TMS 4.6
- Siebel CTMS 8.x
- Running on a single stand-alone laptop running Windows XP Professional
 - Can use VM Ware or stand-alone build
 - Supports approximately 5 concurrent users
 - **NOT** supported by Oracle
- Must be licensed for products, including WHODrug and MedDRA
- \$3600 USD



Management Consulting Services

- Provide detailed Management Consulting, Process Re-Engineering Support, and Strategic Direction/Insights answering key high-level management questions for current and potential OLS customers such as:
 - How do we cost justify implementation of OLS?
 - How do we measure ROI when implementing OLS?
 - Developed a set of key metrics for use against legacy systems to compare Data Entry, Data Management, time to analysis, time to reporting and submission, and Medical coding metrics to quantitatively measure costs and ROI, as well as intangible factors
 - What process re-engineering is required to deploy an EDC/RDC solution?
 - Developed a 16 step process for deploying and implementing RDC

Management Consulting Services



- How do we choose a strategic partners for OLS?
 - Hardware and Network Systems Vendors
 - CROs
 - Data Management
- How do we cost-effectively capitalize on emerging trends in Outsourcing model?
 - What is the value of an outsourced and/or off-shore model?
 - What activities should be outsourced ?
 - Should we develop "outsourced" centers internally ?
 - How do we choose an off-shore partner? What do we look for? What questions should we ask?
- How do we make strategic decisions for the future use of OLS given acquisitions and possible product de-support of the global Oracle organization?
- How do we get the most value for the time and money we have spent on OLS?



What are the Advantages of DBMS Consulting over larger OLS Service providers?

- Personalized attention and direct access to all resources who can help with a critical issue (“flat team approach”).
- 24 x 7 on-call support for all customer production issues.
- Access to direct knowledge of other real-world implementations and issues.
- Willingness to share useful information, and to contact other resources as well as other customers to find solutions.
- Dedication to work only with OLS products and support.
- All experienced team members > 5 years



What are the Advantages of DBMS Consulting over larger OLS Service providers?

- No “dead stop” for OLS support questions for custom developed applications, other 3rd party tools, or integrated applications.
- No interest in sales of a product or pre-defined sales quota. An objective evaluation of OLS’s strengths and weaknesses at all times. (“honest broker”)
- Tremendous flexibility in cost negotiations, discounts, long term and deferred payments with consideration to customer’s budgets.
- 100% Commitment to meeting OLS customers’ needs. No location is off-limits.

Why augment OLS Support in addition to Oracle-based Support?

- Immediate assistance with complex OLS related issues
- Support for customizations
- Facilitate access to OLS development through OLS Support
- Support for integrated applications with OLS



Why augment OLS Support in addition to Oracle-based support? (2)

- OLS is constantly in a development and deployment mode, especially in the context of Project Fusion. The regulatory nature of OLS requires that there is an ongoing cycle of
 - Request for changes, enhancements, bug fixes, or maintenance upgrades/patches
 - Validation
 - Deployment
 - Training



Why augment OLS Support in addition to Oracle-based support? (3)

- OLS Customers are Pharmaceutical/Biotech/Medical Device/CROs/Research/Educational/Government organizations, not IT Service Providers and not Application Support Providers
 - OLS Customers have strategically aligned themselves with Oracle in the concept of OLS as a Commercial Off-the-Shelf (COTS) system.
 - However, many OLS Customers find themselves in an ever increasing role to support and maintain all various aspects of OLS.

DBMS Consulting's 24 x 7 support Capabilities in APAC

- Presence in China and India
 - DBMS Consulting China, Ltd, based in Shanghai supporting APAC (Dr. Letian Liu)
 - DBMS Consulting India, Private Limited based in New Delhi supporting India (several team members present, dedicated to all aspects of OLS deployment)
 - Clinicalserver.com PTE LTD in Singapore (Dr. Philip Masters)
 - supporting Asia-based OLS customers, in a reverse outsourcing/reverse off-shore model
- Provides all aspects of implementation expertise and long term support for several OLS customers
- Developed the knowledge Life Sciences Industry in China and India:
 - direct and first-hand experience on the major infrastructure providers in the region
 - local and regional regulations, environmental and infrastructure factors and politics

DBMS Consulting's Experience in OLS Support

- DBMS Consulting already provides OLS Support on an on-call 24 x 7 basis to several companies. Examples:
 - CROs which demand real-time support but can not afford on-site consulting resources
 - Medical Device companies where assistance for on-line OLS support and ad-hoc SQL reporting
 - Large Pharmaceuticals with broadband VPN access that provide laptops for connectivity into their environments where on-site support staff may not be available
 - Large Biotech companies which need both Oracle DBA and Oracle OLS support
 - Asian based Pharmaceuticals and Government Institutions which have limited OLS support in their time zones.
- DBMS Consulting provides OLS implementations and on-going support to 66% of the OC customers in India today



DBMS Consulting's Siebel Capability

- DBMS Consulting team members have supported enterprise global Siebel CRM and Siebel Clinical deployments
- DBMS Consulting has facilitated integration of Siebel CTMS and OC **before** the acquisition of Siebel by Oracle
- Retained dedicated staff specialized in Siebel applications
- Currently implementing Siebel Clinical 8.0.x and Siebel Pharma 8.0.x globally at several customer sites in US, Canada and India



Remote OLS Administrations and DBA/SA Activities related to OLS

- Provide support to OLS System Administration in real time basis, using
 - VPN Connectivity
 - On-Line Connectivity (e.g., Web-Ex, NetMeeting)
 - Phone, e-mail and IM Connectivity
- To connect directly into customer's sites and work directly with OLS Admins, DBAs/SAs
- Provide "call queues" to reach someone on a 24x7 basis
- Provide assistance from Reference Codelists, back-end configuration, /etc/system, http.conf, bc4j.xcfg, to Oracle RDBMS to Win2K/2003.



Remote OLS Administrations and DBA/SA Activities related to OLS (2)

- Perform major tasks, such as
 - OLS migrations,
 - character set conversions,
 - database/instance cloning,
 - middle tier rebuilds
- Provide remote system testing/stress testing and simulate user testing for public facing systems

Support for Global RDC Deployments

- Provide on-call support for sponsors of Global RDC studies using the same methods provided for DBA and SA support (VPN, On-Line, Phone, e-mail, IM)
- Provide a backup level to existing or planned implementation of user and site support desks, where specific or more difficult calls are routed directly to DBMS Consulting, and one-to-one support directly with users is provided
- Provide training and simulations for internal/external RDC Help desk to reduce “ramp-up” time for global deployments
- Provide strategic consulting for choosing large call centers and help desk providers, or
- Manage large RDC Help Desk and Support Centers through DBMS Consulting’s strategic alliances.



Support for Global RDC Deployments

- Guidance and facilitation of Citrix 4-Tier deployments of RDC
- Work with specific sites which have connectivity or application related issues
- Facilitate and liaison with specific sites Network and Desktop administrators to resolve specific RDC related issues
- Provide strategic planning for implementation of long-term and immediate RDC support

CDM related Support

- DBMS Consulting provides remote development services for any OLS application related activity:
 - Study Design and Development
 - RDC Graphical and Classic Mode pilot studies
 - Legacy or paper based studies migrated to OC/TMS/RDC
 - Validation/Derivation Procedure Development
 - DX view configuration and testing
 - AERS Workflow Configuration and testing
 - TMS Dictionary Loading and Domain configuration

CDM related support (2)

- Provide guidance into building “internal” support centers based in India and China
 - How to cost justify this model
 - How to locate and identify qualified resource
 - How to reduce turnover ratio
 - How to protect intellectual property
 - How to provide regulatory compliance
- Provide strategic training and management guidance for the internal centers
- Provide back-up level support for these internal centers



Other OPA-Related Products and Services

- OLS Support Services and OLS Support Outsourcing Services
- Validation Services and Materials for OLS, including OC, TMS, RDC, AERS, eClinical/ePharma (formerly Siebel)
- Standard and complex Custom development for OLS (Menu Roles, DCFs, to integration with other legacy systems)
- TMS dictionary loading, updating, migration for standard and customized dictionaries
- TMS Autoencoding development, from standard to complex search objects and external system integration

Other OPA-Related Products and Services

- Flat-rate customized functional and technical OLS training.
- Partnership with the WHO-UMC to develop certified loading and update scripts for all WHO dictionaries for TMS, including updating WHODrug Type B to WHODrug Type C Dictionaries already loaded in TMS.
- Technical recruiting for Oracle-related requirements
- Customized automated testing development, using Mercury Interactive toolsets.



Q&A.

- Please come to Vendor booths with any additional questions and more detailed demos
- WHO-UMC representatives Mats Persson and Daniel von Sydow present for any WHO Dictionary questions
- Also for more Brochures and business cards and USB Memory Sticks