# DBMS Consulting OHSUG 2009 Vendor Presentation

DBMS Consulting OHS Overview

# Introduction

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

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# Agenda

- Present an overview of DBMS Consulting
- DBMS Co-Location Hosting Capabilities with Data Center partner Cervalis
- Multi-Lingual Deployment of RDC
- RDC Deployment for Mobile devices
- CDISC deployment for OC
- GLIB Migration for OC 4.5.x to OC/RDC 4.6
- LMS for RDC

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# 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.

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# Overview of DBMS Consulting (2)

- Projected 40 Full and part time consulting staff in OLS
  - 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

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# 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

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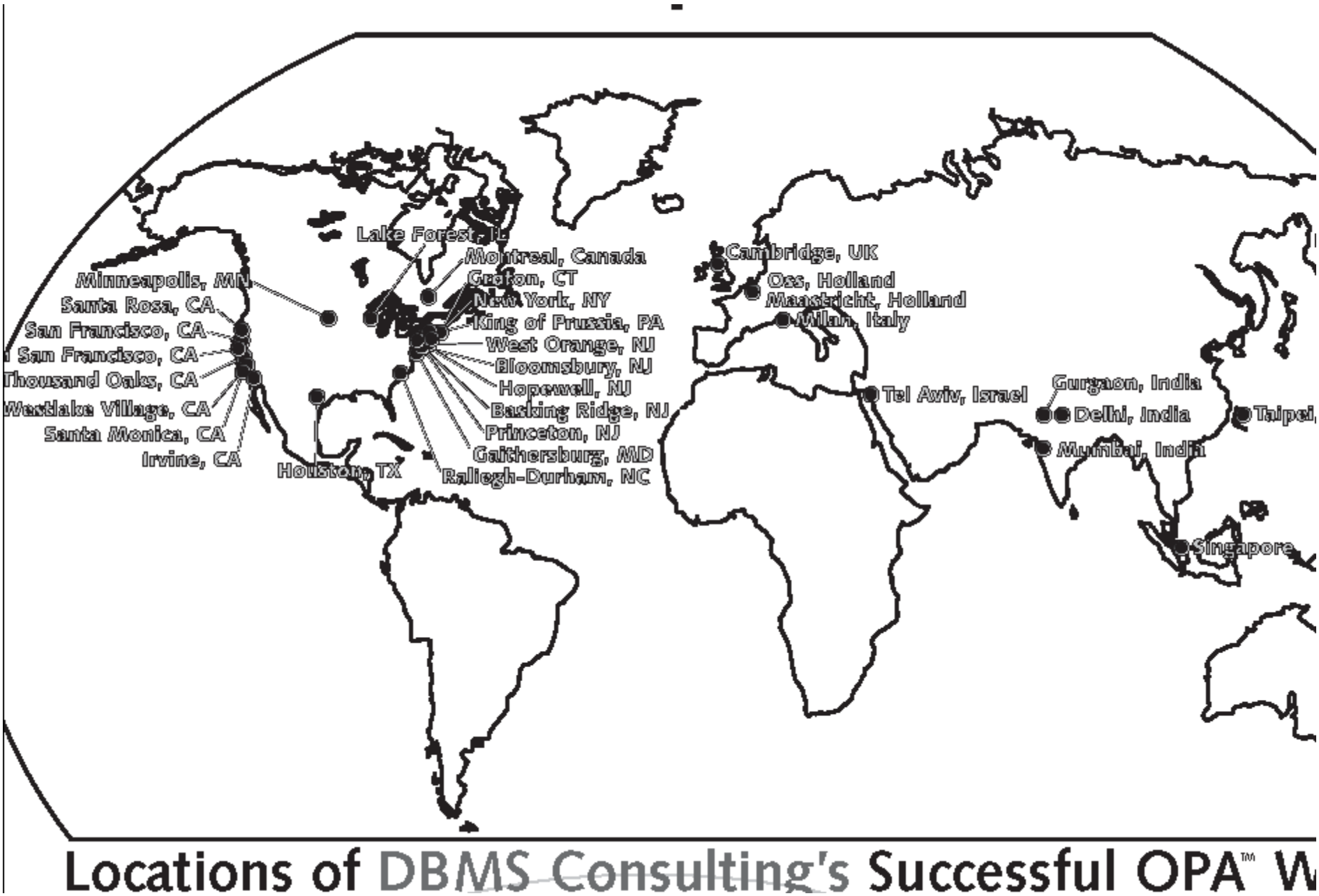


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# Overview DBMS Consulting (4)

- SMDB and GSA Certified and eligible for all US Government contracts
- Platinum Partner of Oracle Corporation
- 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

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# 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.

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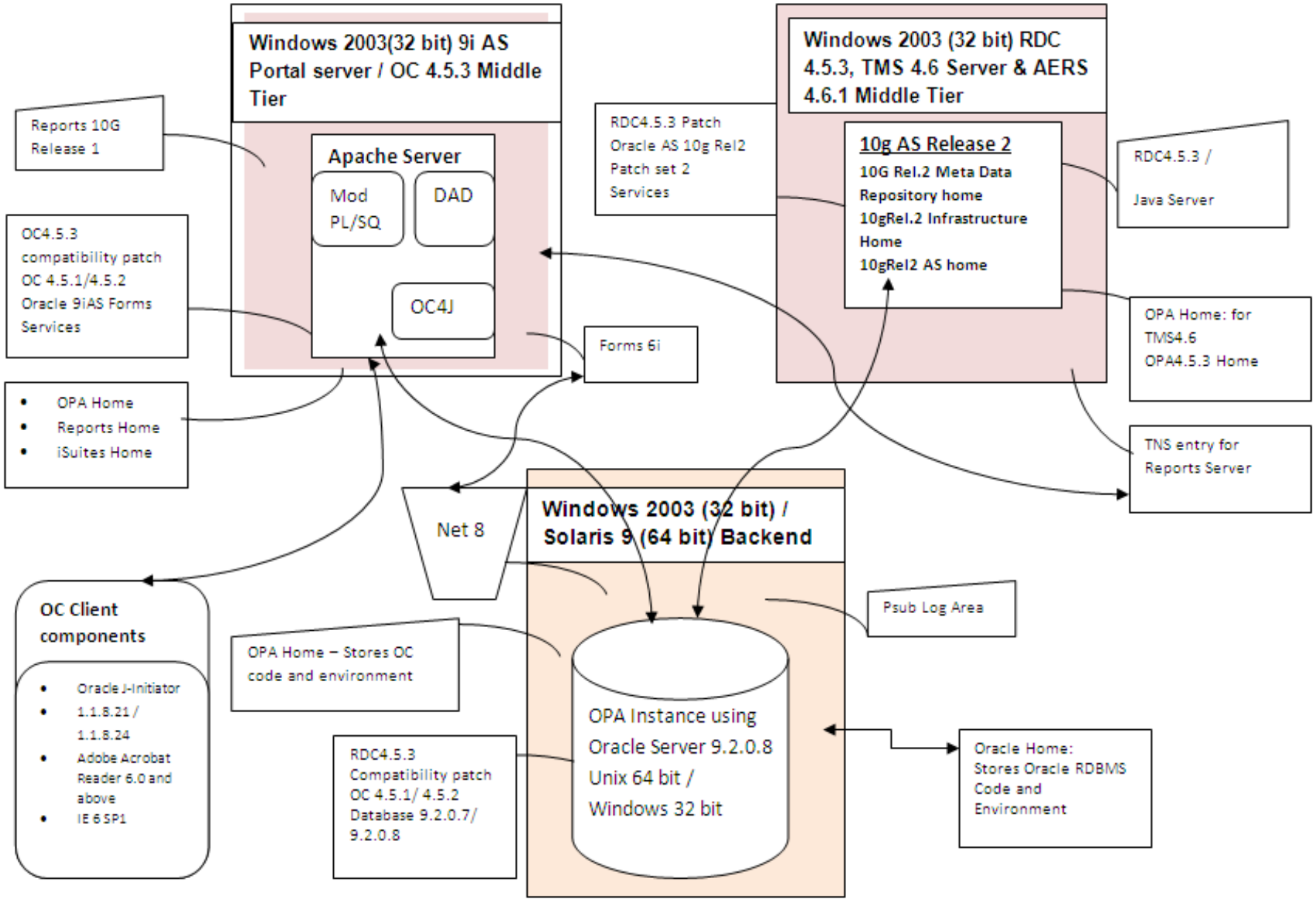


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# Overview of DBMS Consulting (6): Examples Core Team Strength

- 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
- 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
- Bill Caulkins: 17+ years Development team and Management experience, PL/SQL expert
- Caridad Wilson: 10+ years core PM experience

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

- 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
- John Hannon: 6+ Years OLS support and business development experience
- Janet Rogers: 15+ year Study design experience
- Meenakshi Zutshi: 8+ Years OLS Study Development

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# Services of DBMS Consulting

- 24x7 Help Desk for ALL OHS Support, including RDC
  - Currently supporting 3 customers
  - Located in Gurgaon, India, with call escalation to all global DBMS Consulting resources
- "Turnkey" Deployments
- Full Life Cycle OHS Deployments
- Core strengths in CTMS and OLS

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# Services of DBMS Consulting (2)

- Development of custom tools
  - SMQ customization tool
  - Custom TMS dictionary management
- RDC support and customization in ANY language, but especially Traditional and Simplified Chinese
- Mobile Device Deployment of RDC
- Support for LSH
- Argus Deployments

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# SIRO Clinpharm To Implement Oracle Life Sciences Applications to Improve Operational Efficiencies in Clinical Development

## DBMS Consulting to implement Sun Microsystems' infrastructure and Oracle Life Sciences Applications to optimize SIRO's clinical trials and clinical data management operations

**MUMBAI, India, February 19, 2008**:SIRO Clinpharm Private Limited (SIRO), one of India's leading clinical research organization (CRO), has decided to implement a new IT framework comprising Oracle's Life Sciences Applications (OLSA) and other Oracle applications running on Sun Microsystems' (Sun) hardware platform. This IT infrastructure will be implemented by DBMS Consulting (DBMS), a member of the Oracle PartnerNetwork. This new IT system is expected to bring about greater efficiency and increased customer focus in SIRO's operations. The new system will touch and impact over 500 SIRO clinical researchers involved in more than 150 clinical studies.

Established in 1996, SIRO offers end-to-end clinical research services, with clinical trials management and clinical data management as its core operations. SIRO required a solution that was robust, with industry best practices that could scale up rapidly to meet the company's growth demands. SIRO will implement Oracle's Life Sciences Applications as a complete electronic information environment, for gathering and reporting clinical data. Besides reducing errors, Oracle's Life Sciences Applications will enable SIRO to speed information-gathering and reduce the need for paper documentation.

**Dr. Chetan Tamhankar, Chief Operating Officer, SIRO** said, 'We have grown at an aggressive rate for the last three years. To sustain our aggressive growth plans, we are looking at both organic and inorganic growth options across the globe. Oracle Life Sciences will help us achieve this by delivering a powerful combination of technology and comprehensive business applications, and key functionality built specifically to address the nuances of the CRO industry.'

'SIRO will use the new IT infrastructure to provide better efficiencies and better feedback to clients. The application suite will also help us integrate our expanding global operations. We will be able to track, monitor and ensure optimum utilization of our resources across locations. We found the combination of Oracle's Life Sciences Applications and Sun hardware best suited to our rapid growth requirements and our needs for continued regulatory compliance. DBMS' domain knowledge and Oracle implementation skills gave us the comfort to embark on this ambitious project,' said **Mr. Vishnu Banka, Senior Vice President, Finance and Corporate Strategy, SIRO.**

'All ten of the world's top CROs use Oracle Applications,' said **Mr. Callum Bir, Director for Life Sciences, Oracle Asia Pacific**, 'SIRO's new IT infrastructure with Oracle Life Sciences Applications provides them with a greater competitive advantage in providing clinical research services to the global life sciences industry.'

'We are committed to the Life Sciences space in India and the greater Asia-Pacific region, and believe that our vast global experience will transform all of our Oracle Life Sciences Applications customers into market-leading enterprises, not only in a business process outsourcing capacity, but also as preeminent 'best-in-class' leaders,' said **Mr. Sunil G. Singh, CEO of DBMS Consulting.**

'The CRO industry has unique technology requirements in data mining, data warehousing, and enterprise application integration functions. This

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# Strategic Oracle Alliances in India

- India:
  - Flagship deployment for Oracle: Siro ClinPharm
  - "We are extremely happy with the way DBMS Consulting has implemented the OHSA for SIRO . Their competitiveness comes from the teams domain expertise, flexibility in delivery and price effectiveness. Our continuation of a 3 year OHS support contract is an endorsement of DBMS Consulting's global implementation and support capabilities." commented Dr. Ajit Nair, President for SIRO's India Operations.

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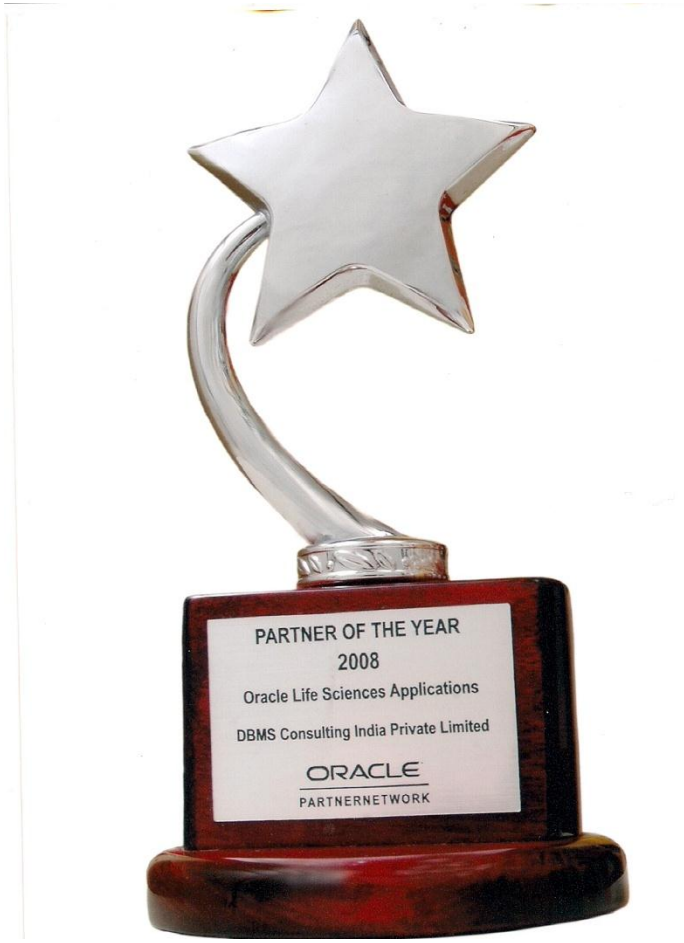
# DBMS Consulting: OLS Partner of Year in 2008 in India

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Indian Society for Clinical Research
ISCR
Shaping Clinical Research in India

# 3rd Annual Conference

Conference Theme : Science, Business and Society
Hotel Leela Kempinski, Bengaluru
January 8-9, 2010

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## Scientific Committee

- Dr. Arun Bhatt
- Dr. C. N. Potkar
- Dr. Suresh Bowalekar
- Dr. Krathish Bopanna
- Dr. Urmila Thatte
- Dr. Raghunadha Rao
- Dr. Ashwini Mathur
- Dr. Amit Bhattacharyya
- Dr. Manish Shah
- Dr. Deven Parmar
- Dr. Viraj Rajadhyaksha
- Dr. Radhika Bobba
- Ms. Larisa Singh
- Dr. Mandar Oak
- Mr. Tushar Sakpal
- Mr. Deven Babre
- Dr. Jayanti Gupta
- Mr. Amit Naik

## Welcome

Payment

Indian Society for Clinical Research announces its **3rd Annual Conference** at Bengaluru. In keeping with the conference theme, the main objective of this scientific conference is to deliberate on the developments taking place in the clinical research arena impinging science, business and society.

The scientific programmes, by now the hallmark of **ISCR Conferences**, have a robust agenda in both the tracks and are designed to generate interest of all Clinical research personnel.

This conference will provide an excellent opportunity to clinical researchers to interact, review current scenario globally, report findings/present papers and share knowledge and expertise from the faculty.

The ISCR conference is an exclusive event bringing all stakeholders in India together on one platform. read more...

## Scientific Programme

**The annual 2 - Day Conference** is
From : January 8-9, 2010,
Time : (9 am to 6 pm).
The conference will have **two tracks** running parallel

## Conference Track

**Clinical Research**

**CDM, Biostatistics & Medical Writing**

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# 天津中醫藥大學

# Tianjin University of Traditional Chinese Medicine

www.tjutcm.edu.cn

has been changed to

Murdoch University Delegation visited TUTCM

Singaporean Group Came to TUTCM for Short-t..

The Teachers and Students from Internationa..

TUTCM Delegation Visited University of Nair..

- Home
- Welcome Speech
- About us
- Bachelor's Programs
- Masters' Programs
- PhD's Programs
- Short-term Study Programs
- Chinese Language Programs

## Welcome Speech

Thank you for your interest in Tianjin University of Traditional Chinese Medicine(TUTCM) and your love for Chinese traditional medicine. All the faculty and students in TUTCM welcome your visit, communication and study here.

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# In North America: DBMS Consulting is a Titan Award Honorable Mention in OHSGBU at Oracle OpenWorld 2009: 9-Oct-2009

- From Left to Right: John Gray - Group Vice President of NAS Technology Alliances and Channels; Tyler Prince - Group Vice President of Applications Alliances and Channels; Jeff Henley - Oracle Chairman of the Board and Chief Financial Officer; Ted Bereswill - Senior Vice President of North America Alliances and Channels;

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# Strength in CTMS

- Several Presentations in CTMS:
  - OC ⇔ CTMS interfacing
  - eSignature and Clinical Supplies
- Manage deployments in APAC and NA in a single team
  - Best of Breed strengths

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# Custom Development Strength

- Technical insights into custom tools and COTS add-ons
  - SMQ Management Tool
- RDC Custom configurations
  - Disable buttons, as an example
- Language Porting

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# Hosting Oracle Health Sciences Applications (OHS)

- Two strategically located data centres at New Delhi and New Jersey
- Cervalis data center partner, well known provider in the financial sector
- US Facility: SAS70 Type II certified annually, Cyber trust certified annually
- Service Level Agreement up to 99.99% in India, 99.999% in US
- 24 x 7 security monitoring, Superior control system, Biometric access readers, People-trap before entering data center
- Regular upgrade of network facilities and equipment
- Reliable & redundant Internet bandwidth

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# Hosting Oracle Health Sciences Applications (2)

- **DBMS Cervalis Co-Location and Hosting US facility in Totowa NJ**
  - **50,000 sf. data center space (36” raised floor)**
  - **16 MW of power (two feeds)**
  - **Designed to Deliver 99.999% Availability**
  - **Two Separate Feeds from the Utility Company**
  - **2N Uninterruptible Power Supply (UPS: 24 x 750KVA Units)**
  - **N+2 Generator Sets & Feeds (10 x 2MW Units)**
  - **24 x 365 NOC, Tech Support, Environmental Monitoring.**

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# Hosting Oracle Health Sciences Applications (2)

- **DBMS Co-Location and Hosting Hardware Support:**
  - **Hardware Support: Managed Platform Base Services 24X7**

**** ( Hardware Support Hours: UNLIMITED per server)**

**** not including application failures/application bugs/application data restores/scheduled downtime**

  - **Operating System configuration and administration**
  - **Patch Deployment**
  - **Spare parts onsite**
  - **Hardware and OS Troubleshooting**
  - **On-Site Parts replacement**
  - **SLAs: 99.999%* infrastructure and network availability**

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# Hosting Oracle Health Sciences Application (3)

- Network monitoring
- All technical personnel on-call 24 hours per day
- ISP Carrier neutral, high scalability bandwidth, unlimited capacity
- 24 x 365 security monitoring and patrol
- CCTV security with digital video backup
- Biometric access readers
- People-trap on data center entry
- SAS 70 Level II Compliant Annual Audit

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# Hosting Oracle Health Sciences Applications (4)

- **Hardware Failure Response: 15mins SLA**
- **Hardware Repair: 2 hours SLA**
  - **If DBMS-supplied hardware is used, normally based on DL380 configurations**

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# Cost Effective Solution – Virtualization – Advantages

- Save energy
- Reduced data centre  foot print
- Ease of management
- Easy disaster recovery
- Faster server provisioning
- Reduced IT labor cost
- Increased CPU utilization
- Dynamically power down servers without affecting applications or end users.

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# DBMS Consulting VMWare Virtualization Capabilities

- **DBMS Consulting has helped it's clients in VMWare deployments (Virtualization):**
  - A global generics manufacturer with strong R&D trials based **(All environments running in VMWare, including production)**
  - A Top-5 global Pharmaceutical in NY/NJ **(Development and Training)**
  - An international pharmaceutical company in USA **(Development and Training)**
  - A healthcare device and supply company in Missouri and Dublin (**all environments running in VMWare)**
  - Clinical Research Institute in Singapore **(All environments running in VMWare, including production)**
  - Clinical Research Institute in India **(Training)**
  - Contract Research Organization in India **(All environments running in VMWare, including production)**

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# Multilingual Deployment of RDC

- **RDC support and customization in ANY language:**
  - **Traditional and Simplified Chinese**
  - **Korean**
  - **Japanese**
  - **French**
  - **German**
  - **Italian**

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# Multilingual Deployment of RDC Chinese - Login Page

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# Multilingual Deployment of RDC Chinese - Home Page

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# Multilingual Deployment of RDC Korean - Login Page

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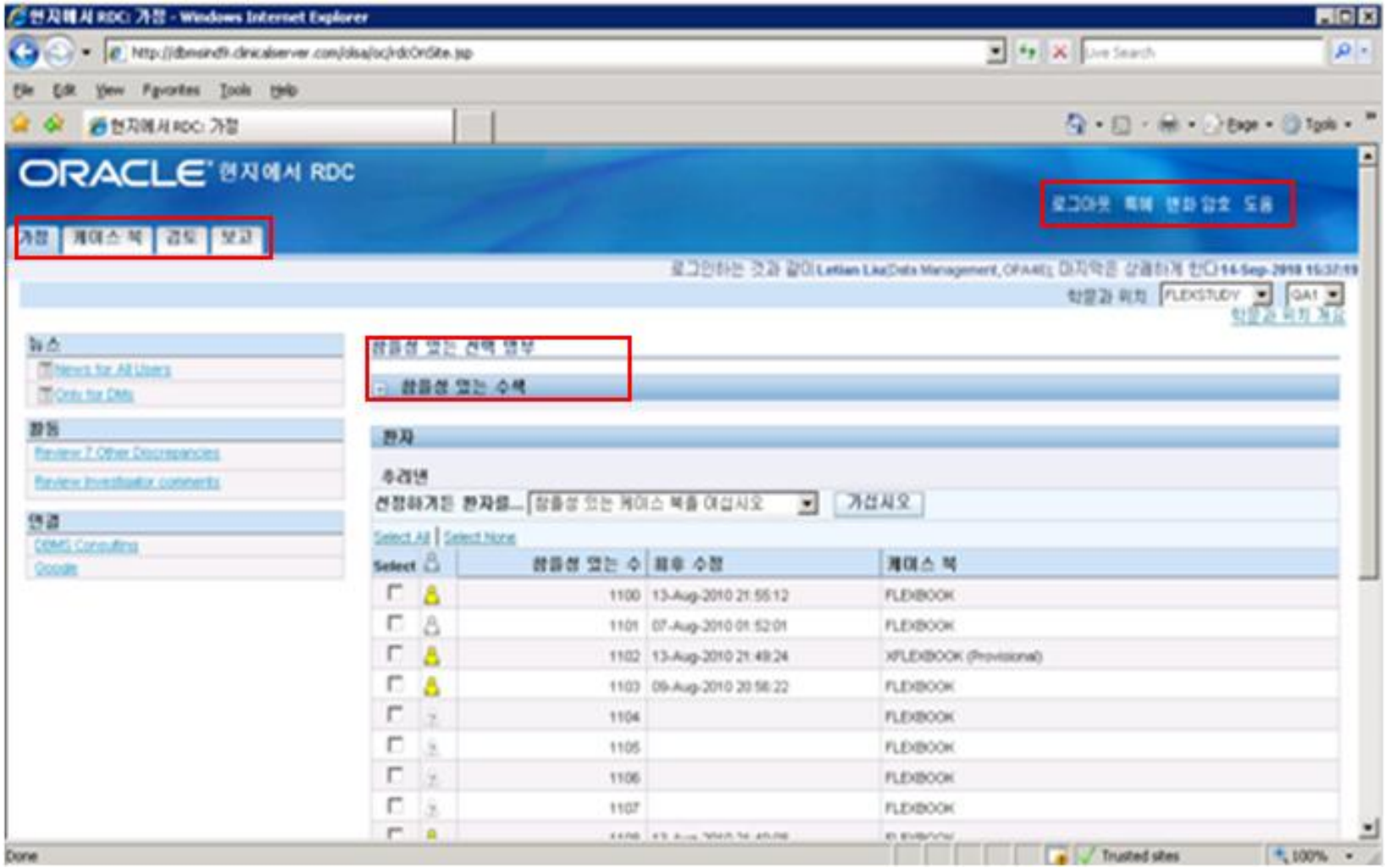
# Multilingual Deployment of RDC Korean - Home Page

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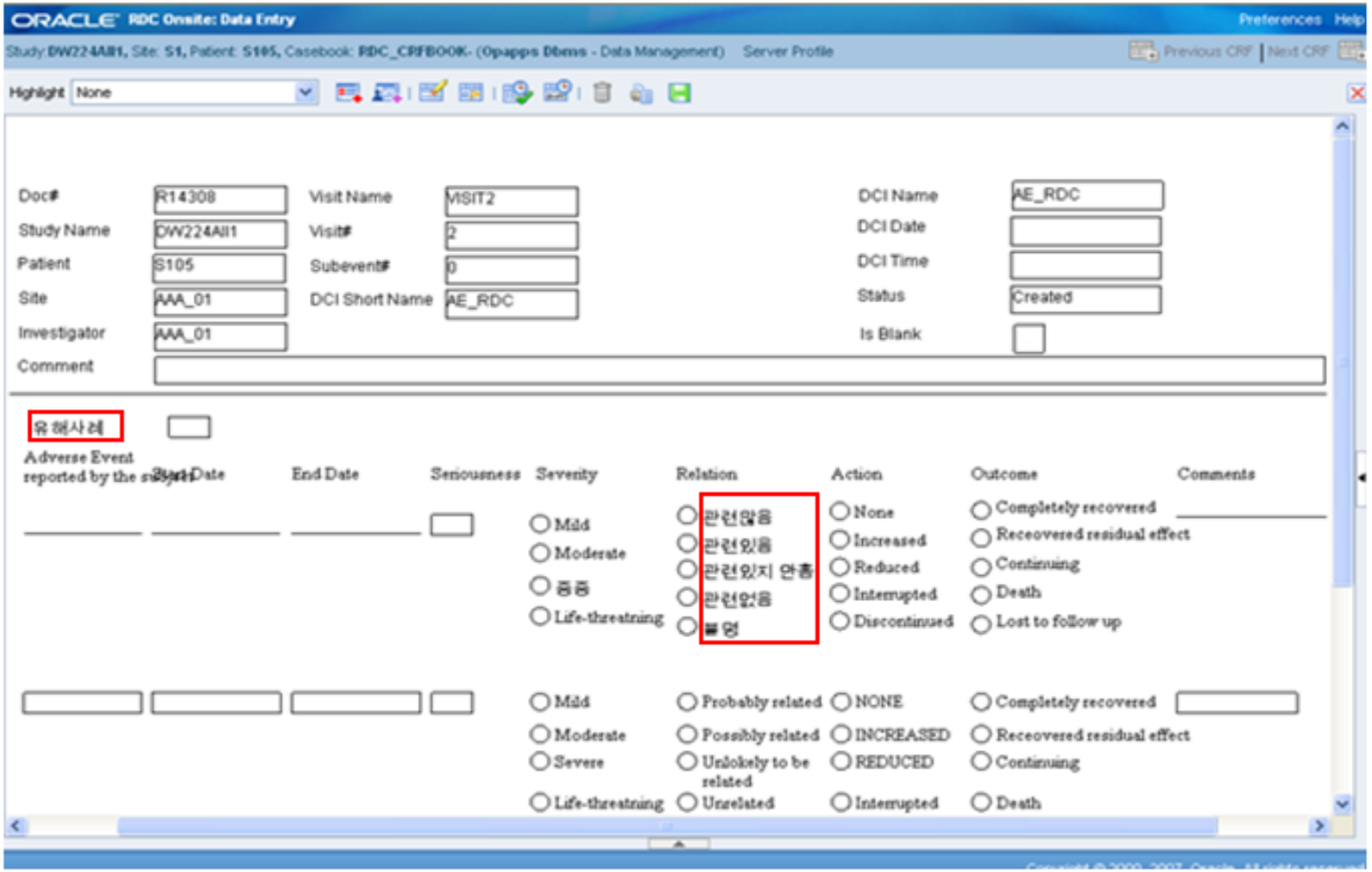
# Multilingual Deployment of RDC Korean – DVG Long Value & Label

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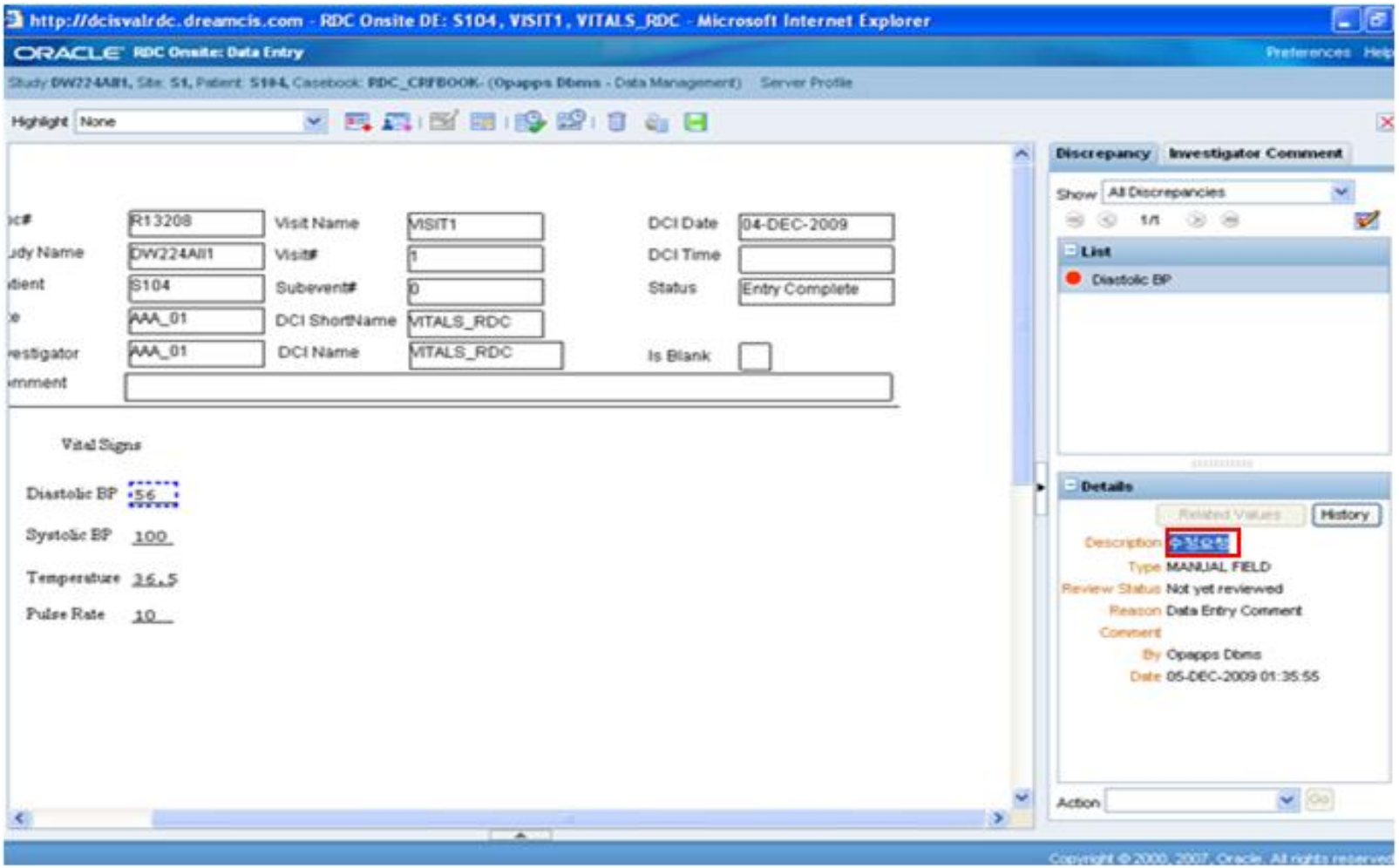
# Multilingual Deployment of RDC Korean – Discrepancy text

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# Mobile Device Deployment of RDC. Can RDC run on Apple IPhone?

- Almost, but browser support for Safari does not exist.
- Using Mobile friendly browser Opera/Opera-Mini or Gecko can help achieve better results.
- Using an iPod or iPhone with Opera installed, we can perform all functions in RDC.

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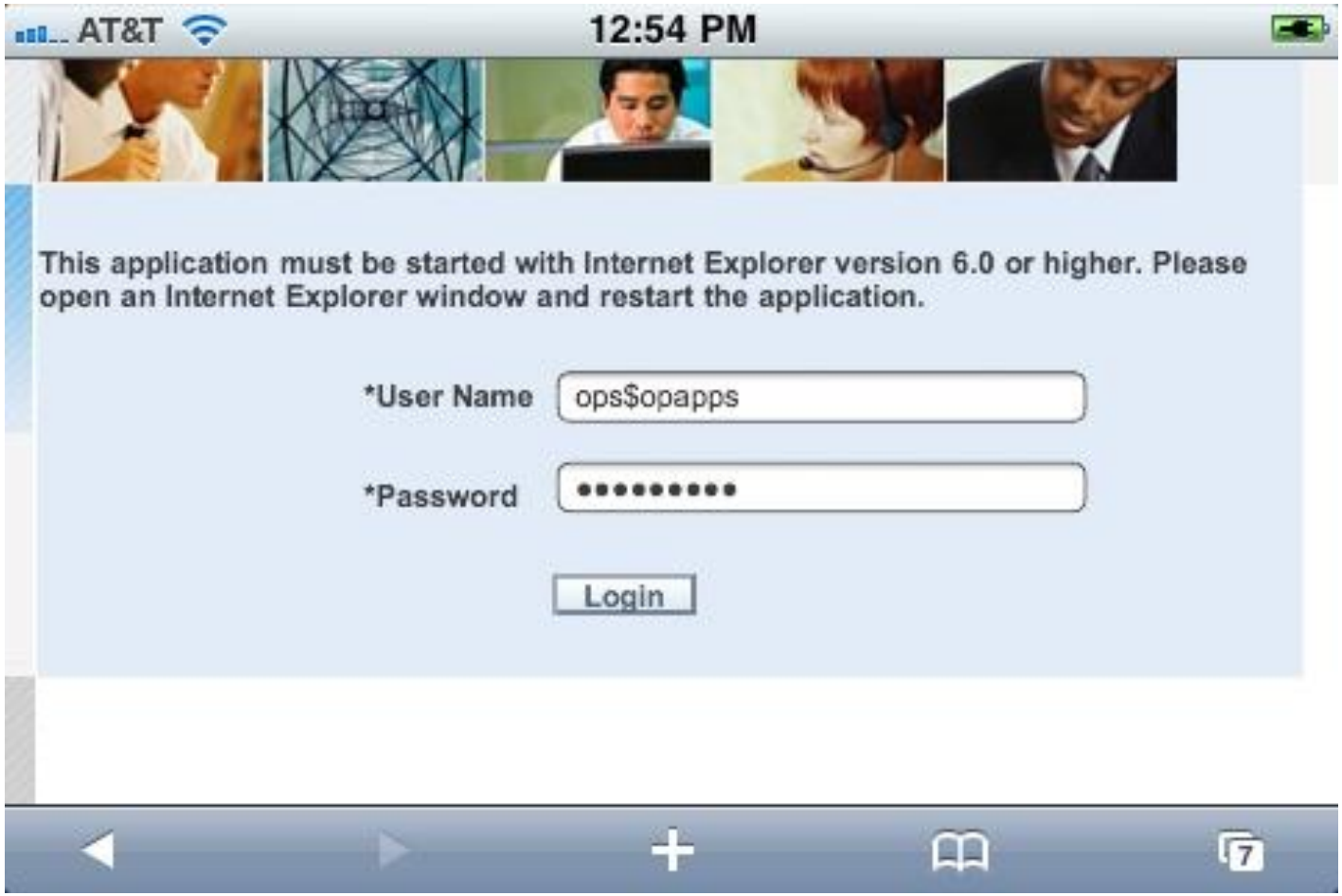
# Mobile Device Deployment of RDC Login Page

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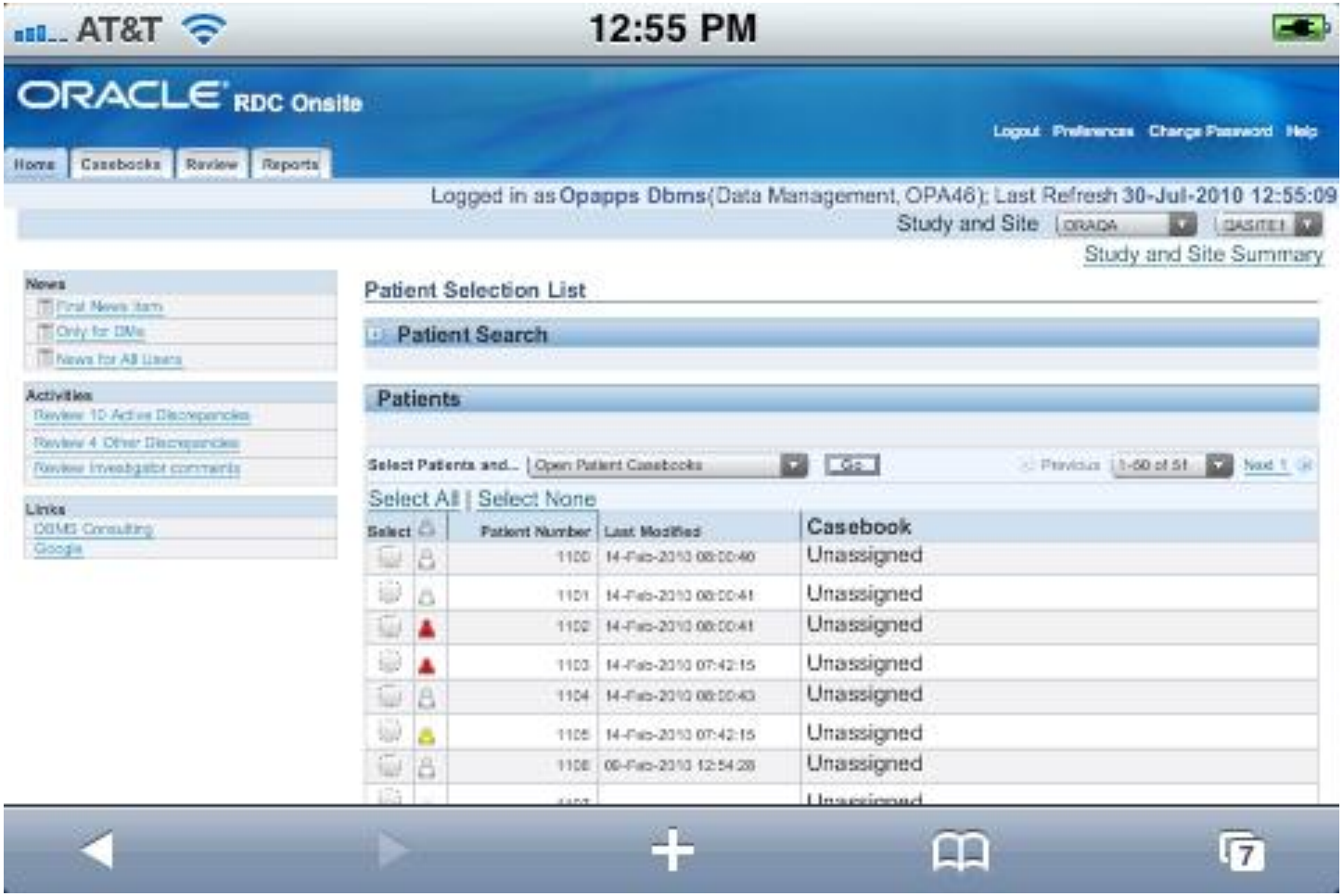
# Mobile Device Deployment of RDC Home Page

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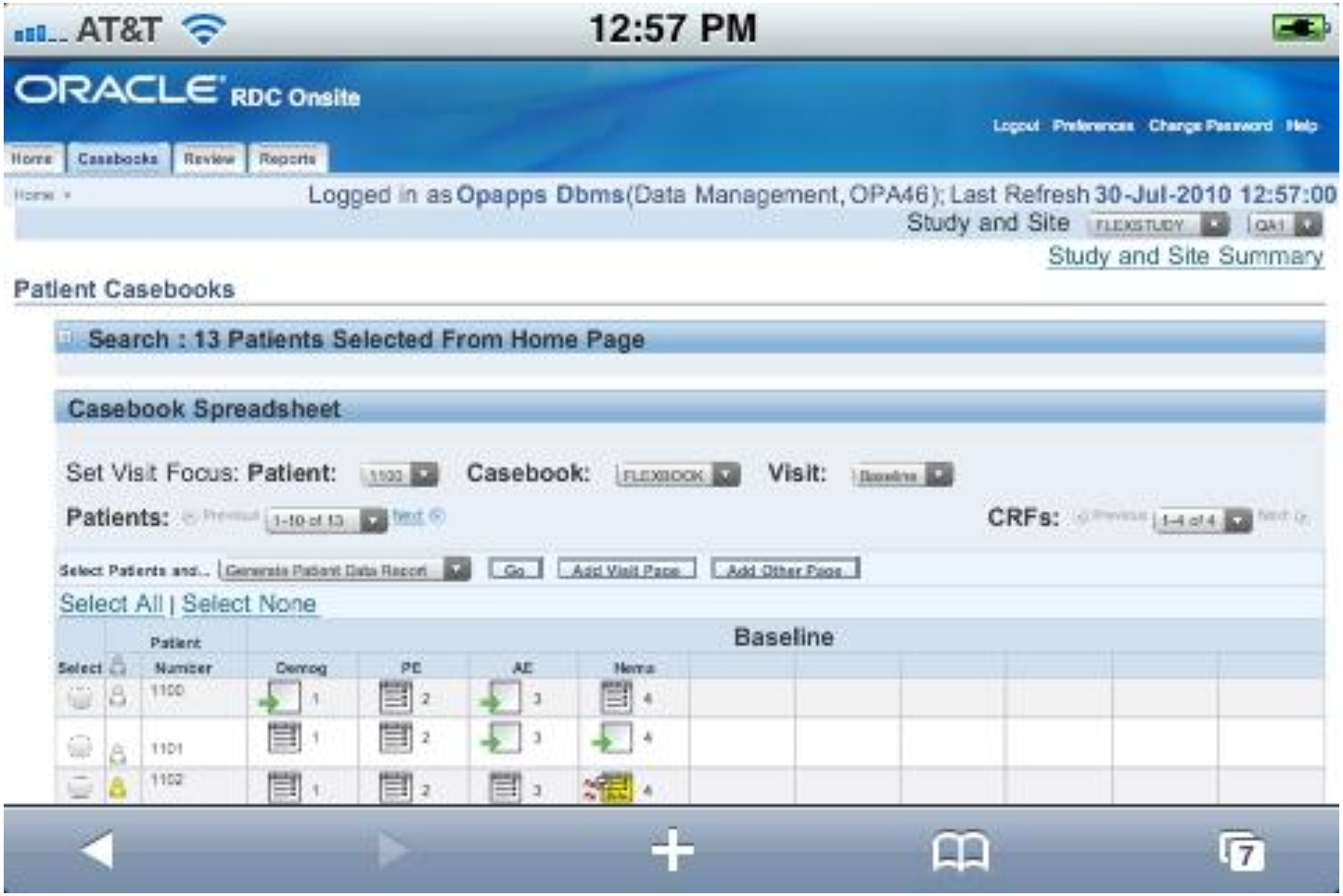
# Mobile Device Deployment of RDC Patient Casebook

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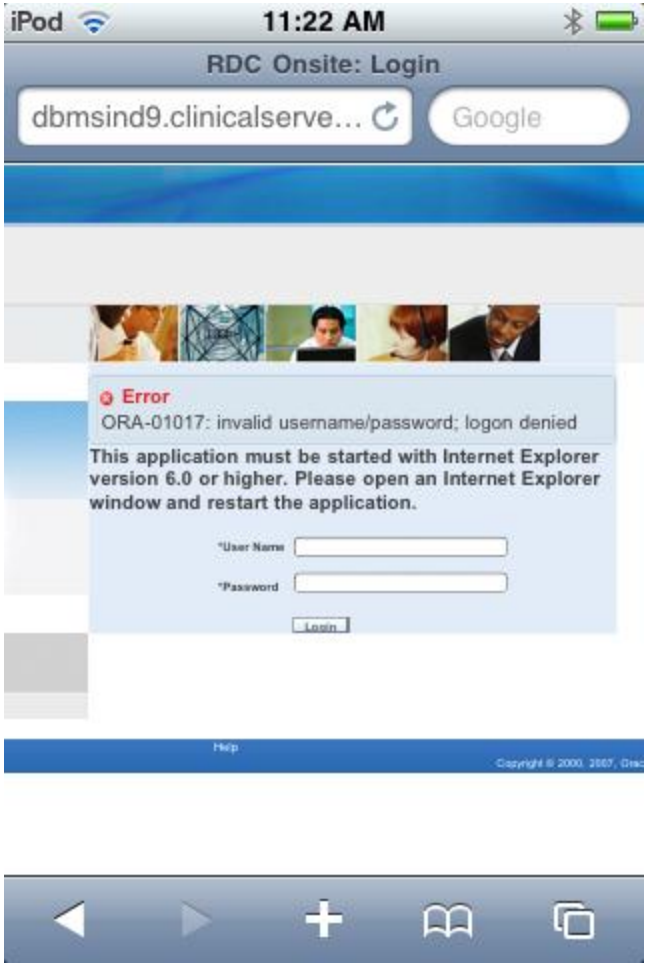
# Mobile Device Deployment of RDC Login and IE Browser Warning

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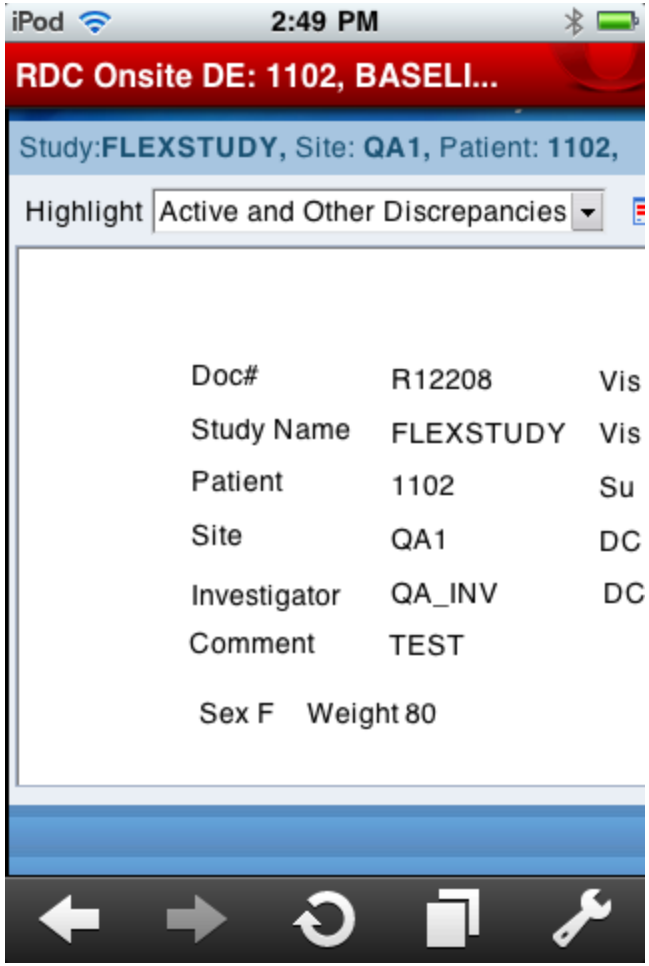
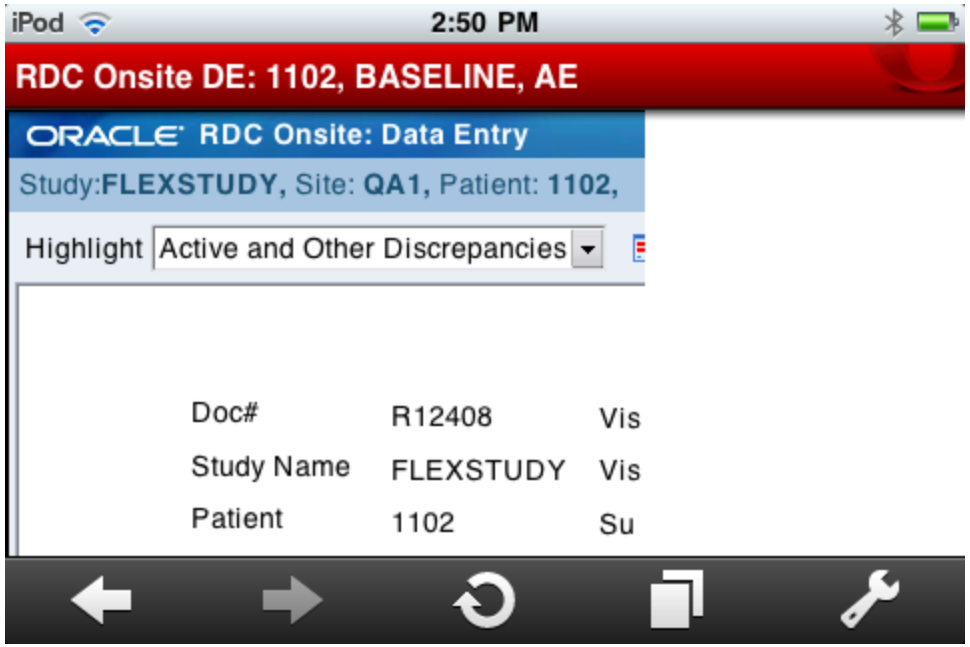
# Mobile Device Deployment of RDC Data Entry Page

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# CDISC SDTM - Implementation

- **Benefits of Standardization:**
  - **Successful implementation of CDISC SDTM would standardize metadata library.**
  - **Standardized metadata library will minimize the amount of metadata mapping and additional programming at the study level.**
  - **Standardization will also reduce the cost of consolidating data for integrated studies.**

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# CDISC SDTM - Implementation

- **Benefits of Standardization…. contd**
  - **Since data definition would be consistent across studies, combining the data for submission and other analysis activities will become easier.**
  - **Standardized metadata library would allow Data Management to develop a library of standard annotated CRF pages**

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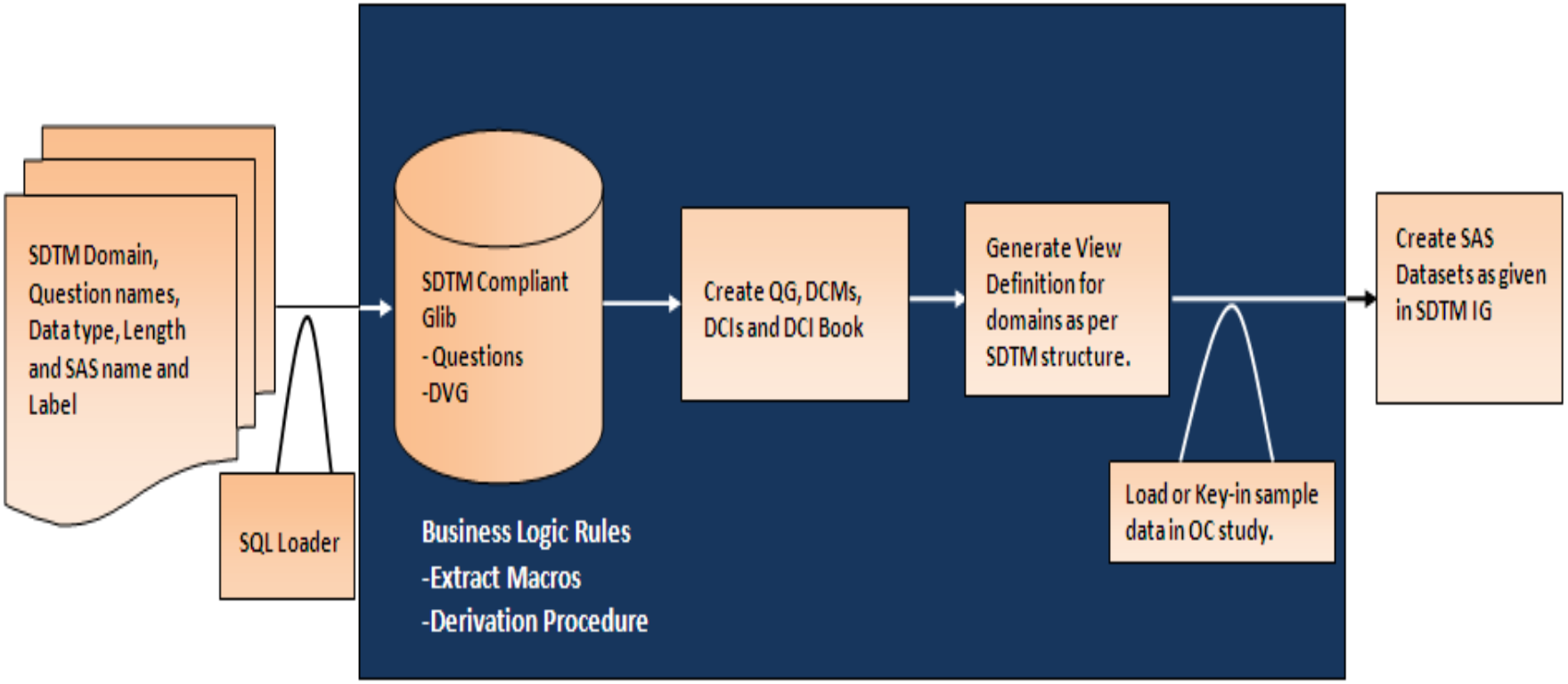
# CDISC SDTM - Implementation

- **Loading variables and Validating SDTM Structure:**

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# CDISC SDTM - Implementation

- **Loading variables and Validating SDTM Structure: SAS Definition File.**

```
,AESEQ      as AESEQ   label ="Sequence Number"  format 20.
,AEGRPID      as AEGRPID   label ="Group ID"  format $20.
,AEREFID      as AEREFID   label ="Reference ID"  format $20.
,AESPID      as AESPID   label ="Sponsor ID"  format $20.
,AETERM      as AETERM   label ="Reported Term for the Adverse Event"  format $80.
,AEMODIFY      as AEMODIFY   label ="Modified Reported Term"  format $80.
,AEDECOD      as AEDECOD   label ="Dictionary-Derived Term"  format $80.
,AECAT      as AECAT   label ="Category for Adverse Event"  format $20.
,AESCAT      as AESCAT   label ="Subcategory for Adverse Event"  format $20.
,AEPRESP      as AEPRESP   label ="Pre-Specified Adverse Event"  format $7.
,AEBODSYS      as AEBODSYS   label ="Body System or Organ Class"  format $20.
,AELOC      as AELOC   label ="Location of the Reaction"  format $20.
,AESEV      as AESEV   label ="Severity/Intensity"  format $30.
,AESER      as AESER   label ="Serious Event"  format $7.
,AEACN      as AEACN   label ="Action Taken with Study Treatment"  format $20.
,AEACNOTH      as AEACNOTH   label ="Other Action Taken"  format $80.
,AEREL      as AEREL   label ="Causality"  format $20.
,AERELNST      as AERELNST   label ="Relationship to Non-Study Treatment"  format $20.
,AEPATT      as AEPATT   label ="Pattern of Event"  format $20.
,AEOUT      as AEOUT   label ="Outcome of Adverse Event"  format $50.
,AESCAN      as AESCAN   label ="Involves Cancer"  format $7.
,AESCONG      as AESCONG   label ="Congenital Anomaly or Birth Defect"  format $7.
,AESDISAB      as AESDISAB   label ="Persist or Signif Disability/Incapacity"  format $7.
,AESDTH      as AESDTH   label ="Results in Death"  format $7.
,AESHOSP      as AESHOSP   label ="Requires or Prolongs Hospitalization"  format $7.
,AESLIFE      as AESLIFE   label ="Is Life Threatening"  format $7.
,AESOD      as AESOD   label ="Occurred with Overdose"  format $7.
,AESMIE      as AESMIE   label ="Other Medically Important Serious Event"  format $7.
,AECONTRT      as AECONTRT   label ="Concomitant or Additional Trtmnt Given"  format $7.
,AETOXGR      as AETOXGR   label ="Standard Toxicity Grade"  format $20.
,AESTDTC      as AESTDTC   label ="Start Date/Time of Adverse Event"  format $20.
,AEENDTC      as AEENDTC   label ="End Date/Time of Adverse Event"  format $20.
```

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# CDISC SDTM - Implementation

- **Considerations:**
  - At what point during the study cycle standards should be implemented?
  - Successful implementation of SDTM would require new processes.
  - Training would be required to train staff on the new processes and in new terminology.
  - Vertical vs Horizontal - Data entry screens will not comply with CRF, e.g., ECG and Vital Signs is vertical in CDISC

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# 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/SA s
- 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.

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# 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 pubic facing systems

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# 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.

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# Support for Global RDC Deployments

- 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

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# 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

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# 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

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# Other OHS-Related Products and Services

- OHS Support Services and OHS Support Outsourcing Services
- Validation Services and Materials for OLS, including OC, TMS, RDC, AERS, Siebel CTMS
- 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

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# Other OHS-Related Products and Services

- Flat-rate customized functional and technical OHS 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

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# Q&A.

- Please come to Vendor booths with any additional questions and more detailed demos

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