



# Considerations of deployment of OLS Suite in India

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# Acknowledgements

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- Thanks to Oracle for creating the First OLSA India conference and providing an opportunity to present.
- Thanks to the audience members for attending and participating



# Disclaimers

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- Opinions expressed here are opinions of DBMS Consulting and are identified with the word OPINION on the slide itself
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# Goals and Agenda

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- Overview of DBMS Consulting's qualifications for considerations of India-based OLS deployments
- Examine India Clinical Trials Market
- Examine India-specific OLS deployment challenges and solutions
  - New and Existing OLS customers
  - Measuring ROI suggestions
- Comments on OLS deployment resource considerations and OLS as a strategic solution

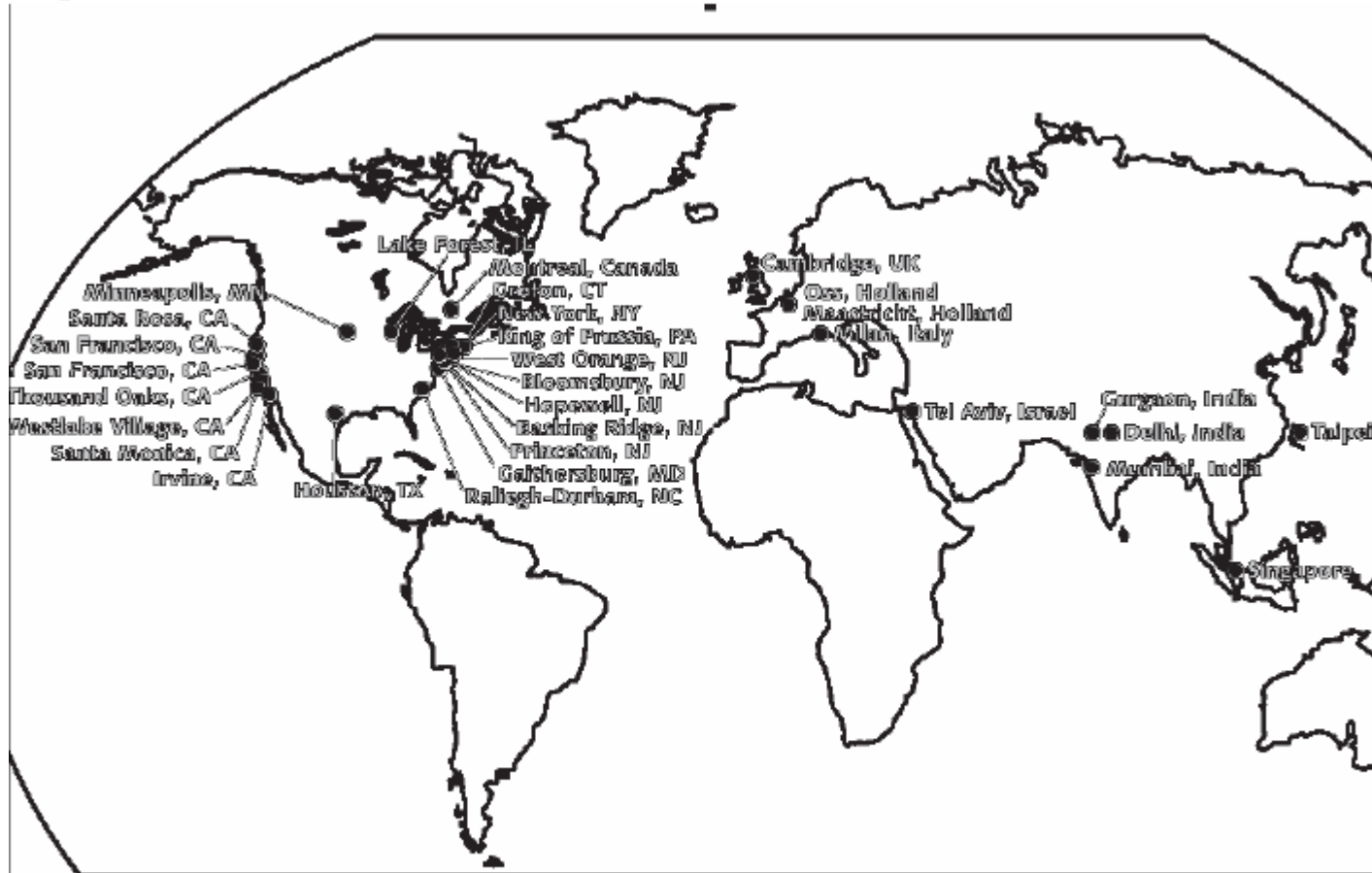


# DBMS Consulting Qualifications for OLS Deployments

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- EXPERIENCE:
- Collectively, the core DBMS Consulting team has over a century 100+ years of experience in the implementation, installation, configuration, support, customisation, training and validation of the basic Oracle Life Sciences components:
  - Oracle Clinical
  - Thesaurus Management System
  - Remote Data Capture
  - Adverse Events Reporting System
  - Siebel Clinical
- Deployed and Supported OLS to over 60 different customers over an 11 year period
- Validation work has passed both Sponsor and Regulatory audits

# Locations of DBMS Consulting's OLS Implementations as of 2005



Locations of DBMS Consulting's Successful OPA™ W



# DBMS Consulting Qualifications for OLS Deployments in India

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- EXPERIENCE:
- First On-Site Live demonstration of Oracle Clinical and TMS in India in September 2003
- Provide Pre-Sales support and/or Deployment and/or Support and/or training of OLS for approximately 20+ **India-based** OLS customers:
  - Large Pharma
  - Local CROs
  - Research and Development
  - Academic Institutes
  - Government Institutes
- DBMS Consulting does not support any other Life Sciences solution: Oracle specialised.



# Attractiveness and Growth of the India Clinical Trials Market

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- OPINION:
- Large talent pool of experienced resources:
  - Doctors/Investigators
  - Site Personnel
  - Data Managers
  - Statisticians
- Large English literate population
- Large Patient Population for many different indications
- Reduced cost to access Patients and Experienced Resources
- Awareness of ICH-GCP and 21 CFR Part 11 Requirements





# Dynamics Driving India Clinical Trials Market

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- OPINION:
- Locally based Generic Drug manufacturers moving to Research-based medicines
  - Increased litigation pressure on pure Generic-only manufacturing strategy
- Greater presence of MNCs in both large Pharma and CROs
- Large number of locally based CROs competing with MNC CROs
  - Both for MNC Sponsors as well as India-based Sponsors
- Increased globalisation of the entire India Clinical Trials Market



# Specific Challenges Unique to India in Clinical Trials

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- EXPERIENCE/OPINION:
- Increased Regulatory Scrutiny for India-based clinical trials
  - Perception that India-based trial management may not be as compliant to international regulatory standards as compared to US/EU.
- Extremely competitive pricing market for CROs
  - Pricing pressure BOTH from MNC CROs and India-based CROs
- Litigation challenges for Generics and Research-based medicines
- Resource turnover in a competitive employment market



# Specific Challenges Unique to India in OLS

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- EXPERIENCE:
- Perceived need for initial reduction of study design times as compared to non-validated processes
- Need to handle non-study specific patients
- Incomplete understanding of validation process and compliance strategies
- Difficulty in determining Return On Investment (ROI) Metrics
  - Difficulty in measuring ROI
- Infrastructure issues
  - Power Supply
  - Continuous Internet Connectivity
  - Virus-free PC Desktops
- Cost management and Reduction of Operational Costs
- Correct use of WHODrug for coding in TMS



# Solutions to India-specific OLS challenges: New OLS Customers

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- OPINION:
- Deployment Cost Reduction
  - Pre-built turnkey solutions for OC, TMS and RDC which are pre-validated
  - Hosted Solutions which reduce the minimum license requirements
  - On-Demand solutions from Oracle for Siebel Clinical and entire Siebel platform
- ROI Recognition:
  - Commitment to building standards from the outset
  - Set correct expectations for validation, training and time to build standards
- Validation and Compliance:
  - Understand on-going cycle of maintenance required for large enterprise applications
  - Plan for separate Development, Validation and Production environments



# **Solutions to India-specific OLS challenges: Existing OLS Customers**

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- **OPINION:**
- **Reduce Operational Costs: Development of standard libraries**
  - Global Library in OC
  - Coding Standards in TMS
  - PL/SQL Standards in OC/RDC Procedures
  - Document standards and Payment standards in Siebel
- **Reduce Operational Costs: Utilise existing OLS functions for Data Management**
  - Assign 1 Discrepancy per DCF
  - Synchronise Texts for Discrepancies and DCFs
  - Use Multi-selection capabilities in Discrepancy Management



## **Solutions to India-specific OLS challenges: Existing OLS Customers (2)**

- **Reduce Operational Costs: Simplify Processes**
  - For CTMS, standardise contracts, payments and trip reporting across trials where possible.
  - For OC/TMS, reduce number of DCF steps and number of times Conditional Actions can be used
  - For RDC, reduce number of User Groups where possible for site-based Discrepancy Management
- **Reduce Operational Costs: Deploy RDC**
  - Reduce Data Entry to single pass Data Entry
  - Eliminate DCFs
  - Reduce time to resolve discrepancies



# **Solutions to India-specific OLS challenges: Existing OLS Customers (3)**

- Improve Validation Processes:
  - Create and Maintain separate environments for Development/Validation/Production
  - Deploy formal Change Control process for Validation and Production Environments
  - Provide overall training on the importance of validation and GCP compliance
- Understand and utilise Patient Transfer functionality for Screening and Replacement patients in OC
- Make appropriate infrastructure and resource investments as a prerequisite to deploy OLS



# Evaluating ROI for OLS

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- OPINION:
- Develop simple metrics for ROI: These can be simple queries which are executed periodically
  - Measure time for data entry from Received Date to Accessible Timestamp for RDCIs in OC
  - Measure percentage of auto-encoded terms for MedDRA and WHODrug in TMS
  - Measure time of Discrepancy creation to time of resolution for OC and RDC
  - Measure time of Site patient enrollment in Siebel Clinical
  - Measure time to pay investigators in Siebel Clinical
- As standards are developed, measure time to conduct a study over a longer time period
  - Shows that standards development improves ROI in the long term





# Importance of Having the Strong Implementation and Support Resources

- OPINION:
- OLS is a complex application, having the most experience in OLS from the outset is a key factor in having successful deployments
- A partner with strategic relationships to WHO-UMC can understand the complexity of WHODrug and also make recommendations to the UMC to support India-specific herbal medications
- Training for initial deployment is also a key success factor, training should emphasis practical operational cost reductions as well as compliance issues
- Validation Support, not just at time of deployment, but on an on-going basis during sponsor/regulatory audits.



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

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- OPINION:
- Oracle has maintained a strong commitment to OLS and specifically the India-based OLS market
- Long Term strategic stability
- Required entry point for becoming a global player in either Research or CRO model for India-based companies
  - Provides immediate global credibility and indicates that seriousness about being a global competitor
  - Defensible in any regulatory review and scrutiny
  - Allows “compatible” business interactions with other OLS customers
- Regulatory protection, least likely to be heavily examined in a regulatory audit.



# Additional Questions ?

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