



HCL Life Sciences

IT Solutions for efficient healthcare

Leverage **COMPLETE**

Oracle Life Sciences Solutions from HCL

Challenges & Business Drivers in the Life Sciences Industry

The Life Sciences sector is going through a major change with Information Technology as the enabler. It is under heavy pressure today, as providers grapple with complex challenges that threaten to erode their profitability, chief of which include - (1) the drying up drug pipelines [a considerable slowing down of new drug discoveries, spiraling cost of development (up to \$ 1.5 Billion) and a significant increase in time-to-market]; (2) margins are under pressure, (3) intense competition, and (4) diligence in compliance issues. Added to this picture, companies are still quite hesitant to leverage offshoring opportunities, even though first time movers can vouch for the tremendous cost and revenue benefits that accrue from such ventures.

HCL is enabling its customers overcome these challenges through its differentiated service offerings and unique solutions.

Life Sciences Solutions from HCL

HCL offers a comprehensive solution landscape and collaborates with Life Sciences companies, helping them improve customer experience. With integrated services that help solve industry challenges across every aspect of the value chain, HCL is now the partner of choice for 10 out of the top 15 pharmaceutical majors and 7 out of the top 10 medical devices OEMs.

Solution Landscape		
Life Science Solutions <ul style="list-style-type: none"> • Siebel Clinical Trials Management • Siebel eMedical • Siebel ePharma • Oracle Clinical/RDC/TMS • Argus/AERS • Siebel AECM 	Product Solutions <ul style="list-style-type: none"> • Siebel Marketing • Siebel Marketing Analytics • Siebel Incentive Compensation Management • Siebel Field Service • Oracle BPEL Process Manager • Siebel-Oracle Fusion Middleware Certified CRM System (SOA Ready) 	Services <ul style="list-style-type: none"> • Consulting • Assessment Study • Implementation & Rollouts • Application Maintenance & Operations Management • Upgrade & Migration Services • Bespoke Application Development
Tools & Methodology <ul style="list-style-type: none"> • eBizSmart Upgrade • SmartMigrate • DB Monitoring Tool • Oracle Application Lifecycle Methodology (BPR → Product Evaluation → Implementation → Rollouts → Upgrade / Migration → Maintenance & Operations Management → Development) 	Accelerator Program <ul style="list-style-type: none"> • Siebel & Upgrade Assessment Study • Product Assessment & Evaluation Frameworks • ROI & Customer Lifetime Value Calculator • Offshore Readiness Index • Due Diligence Framework 	

HCL offers solutions across the Oracle Clinical solution landscape. The phenomenal scale and scope of clinical trials has resulted in an exponential growth of trial related activities and data. In the early phases of clinical trials, when the number of patients/ tests is small, most managers use an in-house or homegrown system/manual process to handle data. As the amount of data grows, organizations increasingly look to replacing their systems with more stable, feature-rich software provided by specialized vendors.

- Implementation Support
- Validation
- Custom Application (CliniCOTS)
- Legacy Data Migration
- Hosting
- Training Services
- Global Rollouts
- Upgrade
- Platform BPO
- Enhancements
- Support & Maintenance



- Oracle Clinical – Oracle RDC
- Oracle Clinical – Oracle AERS
- Siebel CTMS
- Siebel AECM

Siebel CTMS – HCL's CTMS CoE service offerings cover Targeted Recruitment, Global Trial Support, Project and Logistics Management, Streamlined Visit Reporting and Compliance process of the Clinical Trial Management. HCL has also been trusted with the prototype development and product engineering of the Siebel CTMS application for tailoring according to Indian compliance standards and best practices. Siebel based Clinical Trial Management software can provide value-add as an effective tool towards managing clinical trial information.

Oracle Clinical - In partnership with Oracle, HCL provides a comprehensive suite of services such as Implementation, Global Rollouts, Upgrade, Validation, support & implementation services. HCL also assists in re-designing data management processes to fit Oracle Clinical functionality, along with the creation and maintenance of standard operating procedures, guidelines and work instructions.

Siebel AECM – HCL is one of the initial implementers of the Siebel AECM solution from Oracle. HCL offers end-to-end solutions for Siebel AECM implementation including Consulting, Implementation, Data Migration from customized Siebel modules / custom applications and post implementation support. HCL has a pre-built interface between the Siebel AECM module and the FDA Gateway for online Medical Device Reporting. This interface utilizes FDA gateway and web services to submit reports and also register confirmation/acceptance from FDA within the Siebel application.

Argus/ AERS – HCL is one of the first partners of Oracle to provide services in this area. Oracle recently acquired Relsys, a leading provider of drug safety, risk management and analytics applications for the health sciences industry. Currently it is enabling the Global #1 Pharmaceutical Company to address its requirements in drug safety through Oracle Argus Safety applications. HCL is dedicated to addressing evolving pharmaceutical needs and this has resulted in the significant investment to continuously improve the services across Oracle Argus suite of applications

HCL's Unique Solutions

iPharma – for rapid deployment of a robust CRM solution

HCL's iPharma solution is the result of a remarkable combination of Oracle's Siebel Pharma SFA and HCL's extensive domain expertise in the Life Sciences vertical (strong Siebel competency & knowledge of Siebel Pharma). This advanced, readily deployable and user-friendly Siebel CRM solution empowers Pharma companies to manage their Sales Force efficiently. iPharma's clear edge can be seen in areas such as Territory Objectives Management, Physician Segmentation & Targeting, Account Profiling, Call Planning, Call Reporting & Activity Management, Support for Ops Team, KOL Management & Call List, District Manager Support, Feedback & Coaching, Knowledge Management, Role based Report Analytics, HCP Spent Compliance, Expense Management, Quota & Incentive Management, and Events Management.

iPharma is a boon for:

Your Management Team, as it provides/enables (1) better visibility & control, (2) increases sales force effectiveness, (3) provides territory analysis & KOL management, (4) compliance to gift reporting laws, (5) implementation & ROI analysis, and (6) strategic decision making while tracking productivity.

Your Marketing Team, as it provides/enables (1) brand trend analysis, (2) improved customer segmentation, (3) customer feedback, (4) promotion effectiveness, (5) real time ROI analysis, and (6) program implementation analysis

Your Sales Team, as it provides/enables (1) efficient time management, (2) efficient TL management, (3) timely feed back to sales reps, (4) user friendly & intuitive work flows, (5) instant real time access to sales team activities, and (6) enhanced customer focus & productivity.

BA/ BE Solution - For drug manufacturers

BA/BE studies are conducted by generic drug manufacturers. A proprietary medicinal product will be regarded as essentially similar to another product if it has the same qualitative and quantitative composition in terms of active principles (substances), and the pharmaceutical form is the same and, where necessary, bioequivalence with the first product has been demonstrated by appropriate bioavailability studies carried out.

Solution Description

The BA/BE Solution allows drug manufacturing and various clinical research organization to securely track the BA/BE studies progress in a systematic manner and provides first hand information about the status at any given point in time. Also provides consolidated reports for every stage of the study starting from feasibility/study confirmation till final report dispatch meeting all regulatory standards including 21 CFR Part 11.

Business Drivers

- Pricing pressures
- Restrictive regulatory environments
- Maximizing commercial success
- Clinical Trial efficiency
- Field Sales operations efficiency
- Efficiency through clinical automation

IT Drivers

- Inconsistent and siloed CRM systems
- Multiple archaic systems leading to higher maintenance costs
- Increased customization adding to increased IT spends
- Disparate legacy systems and outdated infrastructure inhibiting business agility in reacting to current challenges
- Stringent and constantly changing regulatory compliance needs (HIPAA, MMA, CDHP, etc) further increasing the cost of owning these legacy systems

OPSM Solution

In an attempt to help ensure only authentic pharmaceutical products are distributed through the supply chain, some regulatory agencies have implemented or are considering provisions requiring a “pedigree” for drug products. A Pedigree is a certified record that contains information about each distribution and transfer of ownership of a prescription drug. It contains product information, transaction information, distributor information, recipient information, and signatures. Pedigree mandates are evolving and they generally require tracking, tracing and authentication of the entire chain of drug custody. Moreover, analysts estimated that counterfeit and diverted drugs, as well as drug recall, cost the industry over \$30B annually

OPSM is a new Oracle Application built as an extension to existing customer ERP systems (Oracle, SAP, etc.) that enables customers to implement mass-serialization of drug products and share serialized product data across the supply chain in various electronic formats, including electronic pedigree. It is an edge application designed to address drug package serialization capabilities without necessitating full serial tracking in the ERP Transactional system

OPSM will be fully integrated for Oracle EBS customers and will be built on open standards to allow integration with other ERP transaction systems, such as Oracle JD Edwards EnterpriseOne, Oracle JD Edwards World, Oracle PeopleSoft Enterprise and SAP.

HCL and Oracle will be engaged in co-development of Process Integration Packs for OPSM and Oracle E-Business Suite (EBS) using AIA foundation and methodology. The PIPs being developed are OPSM & EBS 11.5.10, OPSM & EBS 12.1, and OPSM Local to OPSM Enterprise Integration. This will help business to respond in real time to business process changes and uses SOA to provide:

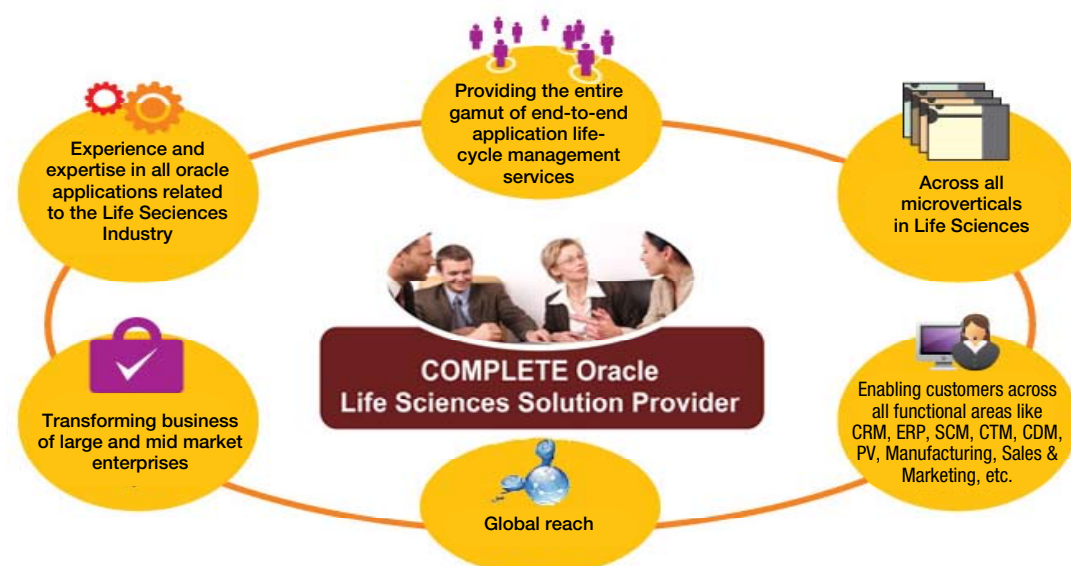
- Business Process Flexibility
- End-to-End Business Process Management
- Sustainable Best of Breed Integrations

A COMPLETE Oracle Life Sciences Solution Provider

From bioinformatics to clinical trials, HCL offers end-to-end solutions to clients to effectively disseminate information and transform important business process. It is enabling both Clinical and Non – clinical customers to efficiently handle their business.

HCL is a Complete Oracle Life Sciences Solution provider in all respects.

- Deployed IT solutions to all sub-sectors within the Life Sciences industry - Pharma, Medical Devices, CROs and Biotech companies
- Addressed all functional areas such as Back office, Front office, Supply chain management, R&D, Clinical Data Management, Safety, Manufacturing, Sales and Marketing.
- Experience and expertise in all Oracle applications related to the Life Sciences industry – Siebel CTMS, Oracle Clinical, Remote Data Capture, Thesaurus Management System, AERS, Argus, Oracle EBS, PeopleSoft, Siebel, OBIEE, Demantra, OTM and Hyperion.
- Extensive service offerings ranging from Consulting, Implementation, Upgrade, Support and Maintenance, Hosting and Platform BPO based subscription offering. HCL also provides subscription based offering for Clinical Data Management, Safety related areas and also back office functions such as HRMS, FAO etc.
- Transforming mid market and large enterprises across all GEOs.



Key Benefits Delivered

Non – Clinical	Clinical
<ul style="list-style-type: none"> • 20 - 30% cost reduction by onsite offshore delivery • Standardized processes globally to resolve customer service requests, product issues and complaints management • Improved reporting and analysis • Custom reports to improve client’s internal processes • Capacity Management • Backlog Reduction • Process Automation 	<ul style="list-style-type: none"> • YOY productivity gain and 100% service level management compliance • Efficiency gains of 20% and reducing operating costs through installation of Oracle Clinical applications. • End-to-End business process management • Improved data accuracy and data visibility • Seamless business continuity across various locations • Better coordinated regulatory reporting process and sharing of this information across the stakeholders

Key Success Stories

Customer

Global # 1 Pharmaceutical Company

Business Challenges

- Appreciation of the Pharma-covigilance domain, basic knowledge of regulatory guidelines such as CFR Part 11, ICH E2B
- Deep understanding of product internals – Presentation layer, middle tier, database structure and transaction processes (e.g. AG Service)
- Knowledge of hand off points between the product components – e.g. ETL from Argus Database to Insight Data Mart, DIDE to E2B Import integration
- Expertise on third party tools used by the product suite such as Business Objects XI, Cyclone
- Appreciation of Validation principles as applicable to the pharmaceutical industry
- Well established development and support processes coupled with a mature program management practices

Solution

- Application Testing for Argus Safety and Argus Insight - Develop and Execute Test Scripts / Execute Change Controls / Record defects / System Testing / Hot Fix Testing
- Database Testing for Argus Safety and Insight – DB Patch Testing / Hot Fix Testing
- Managing Infrastructure operations – Patching / Database Refresh / Data Migration / Environment Troubleshooting
- Development of Custom Reports Using Business Objects for Insight to suit Customers Business Processes.
- Support Integrated Systems to effectively handle data management and reduce errors during the capture of Adverse Events at Non-Core Sites and Custom Applications

Business Benefits

- Onsite offshore delivery capability. 30% cost reduction.
- Improved data accuracy and data visibility
- Better coordinated Regulatory reporting process and sharing of this information across the stakeholders
- Improved reporting and analysis
- Custom reports to improve Client’s internal processes

Customer

A leading Medical Devices company headquartered in Milpitas, California with facilities in Puerto Rico and Scotland; employing over 2500 personnel worldwide

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Business Challenges

Replacing the customized AECM application with Siebel AECM and integrating with Data Warehousing Systems

Solution

Implementation of Siebel AECM for adverse event complaints management

Highlights of the solution included

- Multi-vendor, multi-application environment spread across 3 countries and solution deployment in a highly secure environment as stipulated by the customer’s worldwide standards
- Processes included Complaints Management, Product Analysis, Medical Affairs and Customer Service
- Data migration from the customized AECM system to standardize on Siebel
- Inbound and outbound interfaces development for information exchange on contact information, address, survey results, service request, and product information between Siebel and the Data Warehousing System

Business Benefits

- Standardized processes globally for the recording and resolving of customer service requests, product issues and complaints management
- Estimated cost benefit of over 24% to the client

Customer

Leading research-driven pharmaceutical products and services company that discovers & manufactures a broad range of innovative products to improve human and animal health.

Business Challenges

- Execution of work in SOX regulated environments
- Lack of Coordination with Business users
- High Profile skill sets required to manage complex Finance and HCM applications
- Move towards Integrated Service Management
- Standardization of reporting –ITIL based reporting

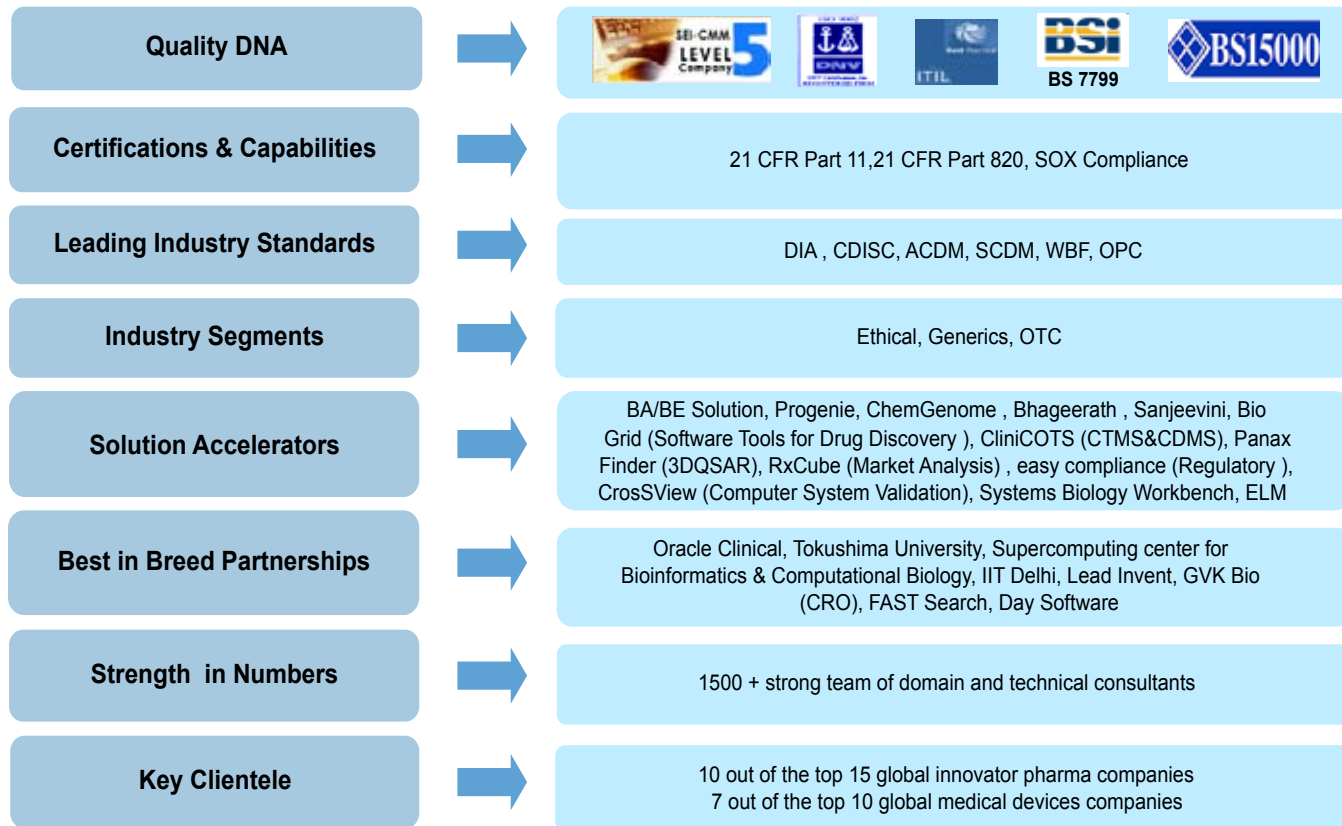
Solution

- Fully Manage and provide global multi service delivery
- Execution of Key capital projects apart from regular M&O support
- Implementation of Siebel CRM On Demand
- Continuous process improvements and Value adds

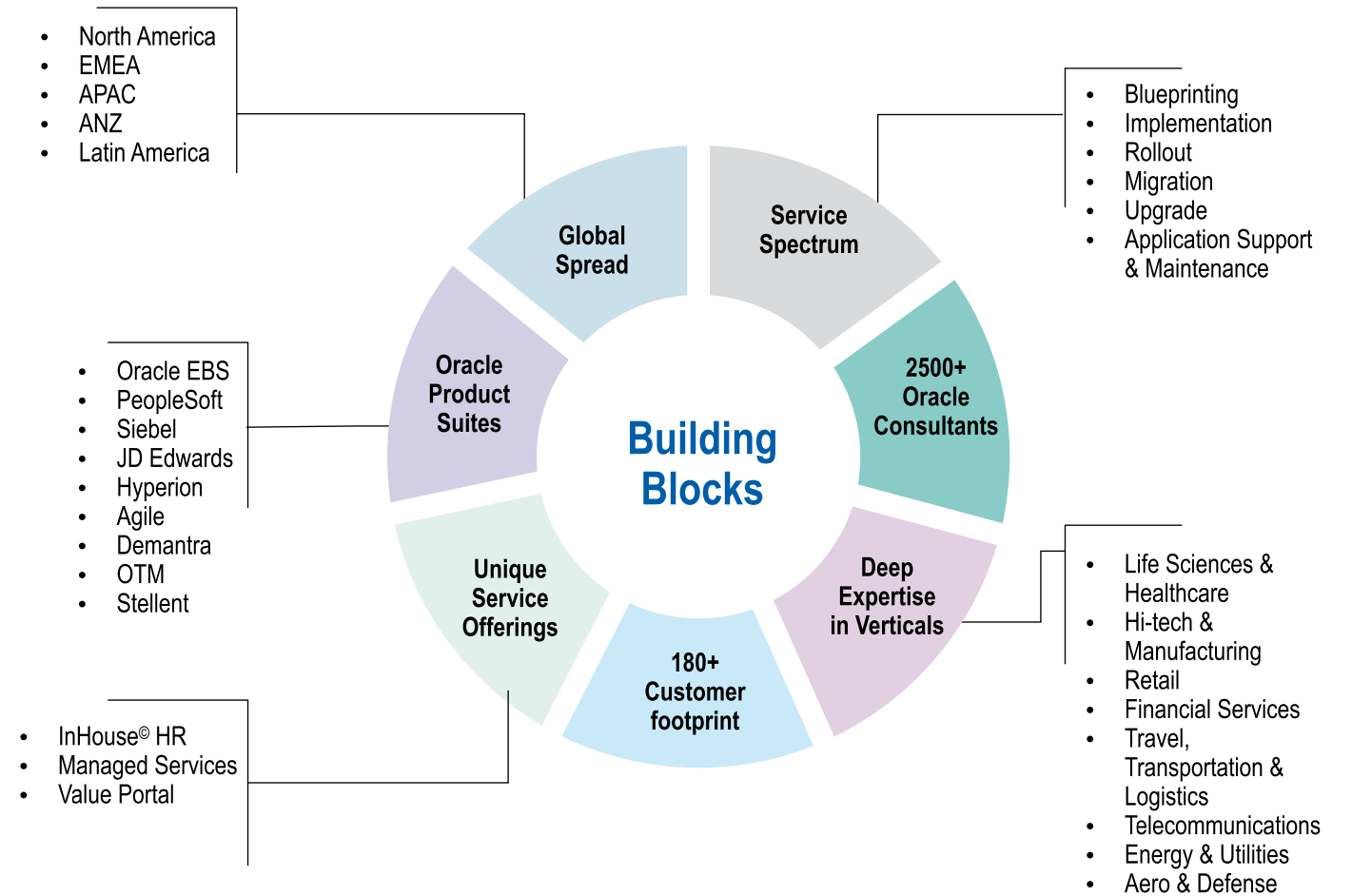
Business Benefits

- Managed Service model
- 12% YOY productivity gain
- 44 value adds resulting in additional savings of \$1.47 million
- Capacity Management: HCL team moved to Key initiatives of the client
- Average KEDB compliance of 60-70% across all tracks

HCL's Life Sciences Practice



Oracle Universe @ HCL



Awards & Recognitions

- FORRESTER** HCL a Strong Performer in Oracle Service Offering The Forrester Wave: Oracle Implementation Providers Q4 2009.
- Gartner** Case Study: Teradyne's Outsourcing to HCL Shows How Transparency, Flexibility Deliver Outsourcing Value
- ORACLE** Application Partner of the year for FSI industry
- Butler Group** In terms of experience, marquee clients, and breadth and scale, the Oracle Universe service line has acquired enough momentum to address Oracle implementation and support-related requirements of any scale and complexity
- ORACLE** Oracle 'Empower the Green Enterprise Award' (2008) for work at Standard Parking



Hello, I'm from HCL! We work behind the scenes, helping our customers to shift paradigms and start revolutions. We use digital engineering to build superhuman capabilities. We make sure that the rate of progress far exceeds the price. And right now, 62,000 of us bright sparks are busy developing solutions for 500 customers in 26 countries across the world. **How can I help you?**

www.hcltech.com

HCL

For more information please contact us at : oracle.marketing@hcl.in