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Facilitating Virtualized Research: The Oracle Health Sciences Cloud

Disclaimer

Introduction

To accommodate the increasingly virtualized and networked environment of research and development, some biopharmaceutical organizations have been looking to cloud computing and the benefits of sharing a common hosted platform of technology and services with a number of integrated partners. With a lower cost of ownership companies can free up technology resources to better focus on delivering safe and effective drugs.

Embracing a network of partners sharing data and services, however, is not without challenges. The pace of clinical research demands quick access to data, and in a cloud paradigm research teams have to be able to nimbly work across organizational boundaries to acquire all the needed information. Yet this easy access also has to be secure enough to meet the strictest regulatory scrutiny.

The Oracle Health Sciences Cloud (OHSC) is a vertical cloud serving the research needs of the healthcare and life sciences industries that is open to the public Internet for global access by thousands of sites in different organizations, with data and integrations flowing in and out, yet is still highly secure and private. This paper will:

- Describe vertical clouds, the needs they meet and draw a contrast to horizontal clouds.
- Depict how practice and process automation evolves in a vertical
- Describe how vertical clouds evolve with their vertical
- Outline vertical cloud requirements for healthcare and life science
- Explain how OHSC meets the requirements of healthcare and life science
- Provide an overview of Oracle technologies supporting vertical clouds

Vertical Clouds

A vertical cloud targets the needs of a specific industry or market providing capabilities in the form of operational support through automated services. These capabilities typically go beyond those provided in a horizontal cloud, i.e., a cloud providing Platform as a Service (PaaS) or Infrastructure as a Service (IaaS).

For example, suppose we would like to provision an application service—a very common task in any kind of cloud. In a horizontal cloud (which, as opposed to a vertical, targets the needs of a diverse market of multiple industries), a user interface or application programming interface (API) provides the ability to deploy a set of virtual machines and storage to run the application and configure those machines appropriately. There is full latitude to deploy, configure and release those resources in any fashion dictated by the user.

An industry vertical, such as finance or healthcare, however, is often governed by a set of industry regulations that will dictate specific Information Technology requirements. Provisioning an application in a cloud or decommissioning one, then, can require specific steps beyond those taken in the horizontal cloud. These additional steps ensure industry regulations are met.

As an example, clinical research for the life science industry is governed by the International Conference on Harmonisation (ICH) Good Clinical Practice Guidelines, which require validation of computer systems. One step in the validation is typically performed as an "Installation Qualification," which verifies that:

- The correct system components, products, and software are installed
- The expected system parameters are set
- The needed file structures, directories, and databases are in place
- The proper security profiles are set up
- The interfaces to other systems are working correctly
- The system does not negatively impact other systems

A vertical cloud operating in support of life sciences clinical research would ensure any provisioning of an application service would include an Installation Qualification, rather than leave that step as an option that may or may not be taken. In this sense, the vertical cloud takes away some freedoms in exchange for assurance of regulatory compliance. The vertical cloud may address these industry-specific needs by exploiting an underlying cloud-oriented platform or infrastructure services, thereby enjoying the benefits of a horizontal cloud —resource pooling, elasticity, broad network access, managed services, etc.

Vertical Practice, Process and Evolution

There is a dynamic through which business activities, and the e-Businesses that support them, change over time. There are two schools of thought on representing and analyzing business activity. One

focuses on processes that have been managerially defined, formalized and documented. The other considers practices—repeated everyday activities of individuals, i.e., what people actually do—and approach these practices as emergent and informal.

The first school emphasizes reducing the cost of coordination and communication, whereas the second focuses on improvisation and innovation. Takahashi, Herman and Yates compared the two orientations and looked to resolve the tension between the two schools of thought by proposing a framework accommodating both the efficiency of process and the adaptability of practice.[1]

The Takahashi et al. framework places practice and process across a continuum of activities broken down into four categories.

1. Practice
   - Activities are repeated and socially recognized with a norm emerging from every day or customary practices
2. Recorded Practice
   - In addition to characteristics of practice, activities are locally defined and recorded
3. Endorse Process
   - Activities are defined but not mandated
4. Mandated Process
   - Activities are defined and mandated

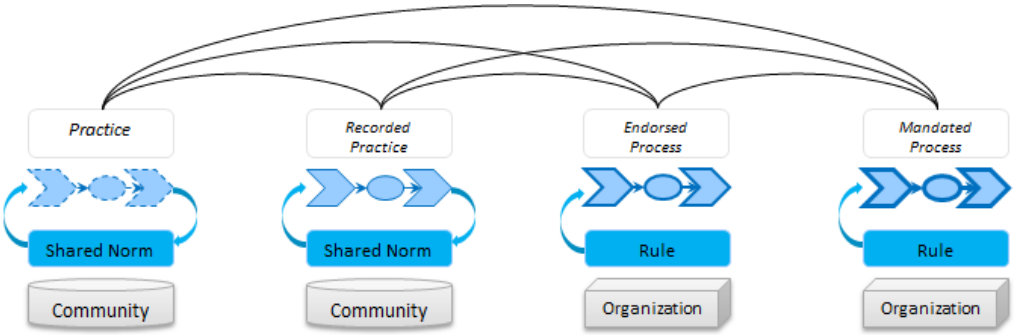

Figure 1. Continuum of practices and processes

The way an activity is understood and performed by a community may migrate across the four categories. Movement from left to right tends to increase efficiencies. Movement from right to left—from formal to less formal—can establish a more effective approach to an activity.

Movement from formal to less formal is essential when operating in highly dynamic environments or when activities are undergoing transition. Vertical markets, and the e-Business infrastructure supporting them, are often subjected to such transitions. To that end, vertical markets, composed of individuals working in the same industry or domain, are communities in which practices arise. The community typically explores different possible practices to determine those most suited to the

dynamics of the operating environment. When formally adopted by an enterprise or industry authority those practices become processes. As noted earlier, verticals are governed by regulations and standards, either de jure or de facto, that constrain the performance of business activities, and as such, emergent practices and processes must also incorporate these regulations and standards.

Cloud Support of Vertical Evolution

One method of recording a practice or process is automation. The Takahashi continuum can be expanded to call-out automation, which may be realized as scripts, workflows, business processes and software application modules. These can be created by developers working for an organization or by community members working independently or in concert with other members.

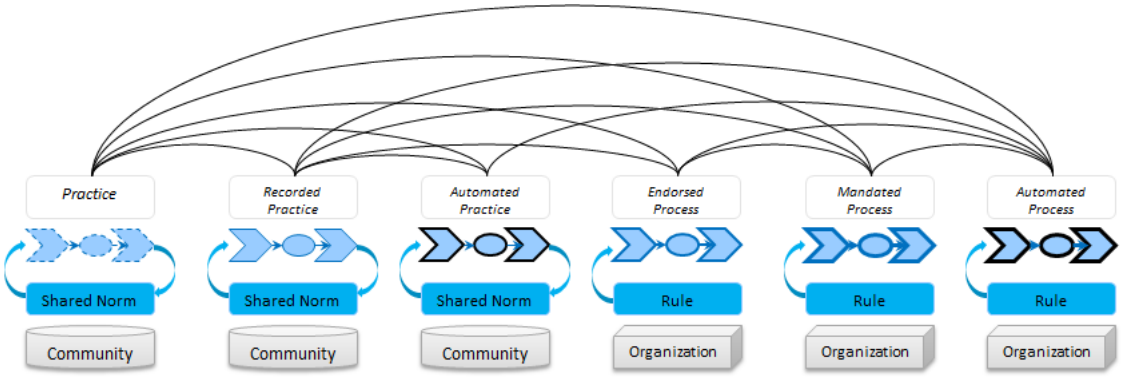

Figure 2. Continuum of practices and processes calling out automation

Practices and processes represent informal and formal norms within the vertical community—norms shared across and within member organizations. In either case, benefit arises if these norms can be codified as part of an e-Business infrastructure serving the vertical and its member organizations. This benefit is most fully realized if that infrastructure enables both streamlining processes and generating improvisational practices, while facilitating compliance with the regulations and standards governing the vertical community.

Automating practices and processes is an essential part of creating a vertical solution. A vertical solution packages automated and operational support to embody a set of practices and processes addressing a problem specific to a vertical community. Core business operations frequently run on vertical solutions.

Striking this balance between efficiency and innovation imposes requirements on information and communications technology (ICT) serving vertical communities. On the one hand, the ICT infrastructure must streamline, automate and regulate business activities as processes; on the other, it must quickly and economically accommodate new practices and support the maturing of new practices into processes.

Of course, vertical solutions need to evolve with changes in industry practices and processes, and over time, automate ever widening spans of activity. Vertical solutions historically have tended to evolve through a sequence of stages. The following table describes the stages with associated effects and cloud requirements.

TABLE 1. STAGES, EFFECTS AND CLOUD REQUIREMENTS

Stage of Vertical Solution	Enterprise Effect	Industry Effect	Cloud Requirement
Custom	Lower cost	Best practices emerge	Cost matters
Point Solutions	Faster IT cycle times	Best practices codified	Fast deploys matter
Integrated Solution	Faster internal business cycles	Consolidation and concentration	Flexibility matters
Industry Solution	Faster cross business cycles	Ecosystems grow	Scale matters

Earlier stage vertical solutions, those in the Custom and Point Solutions stages, need to be augmented with manual processes that compliment islands of automation. Later stages start accelerating business cycles as manual bottlenecks become automated. As the vertical market is subjected to change, however, automated processes can require revisions, often addressed by reintroducing exploratory informal practices until a new satisfying, if not optimal, practice is found.

As ICT tools and competencies mature in the vertical, the rate at which new practices are automated increases. This shortens the time for a more formal adoption of the practice into an automated process. The ebb and flow between streamlining and innovation across different levels of scale drives requirements for the vertical cloud. Vertical solutions, by building upon the advantages of a vertical cloud foundation, can expedite accommodating changes in the market.

Cloud technology can provide a different cost basis for exploring new practices by avoiding large capital expenditures to capture yet to be proven results. Resource pools can be consumed elastically, provisioning resources while experimenting with a new practice and releasing the resource if the practice is found unsuitable.

These are standard competencies of any cloud. The vertical cloud must go further. Any practice to be automated will need to be governed by the regulations and standards of the vertical. The ability to compose practices from cloud based components that are vertically compliant enables exploration, while reducing the risk of non-compliant practices.

Manual operations provided as supporting services within the cloud must also adhere to regulations and standards. Personnel providing that support must be trained in the regulations, conventions and best practices of the vertical. Exploration of new practices often requires the cloud support personnel to work as trusted partners with the community innovators, either at the enterprise or industry level, to

determine what practices will be viable and productive. The partnership continues as those practices are matured into more formal processes.

The vertical cloud needs to strike a successful balance of rapid, cost-effective process streamlining, efficiently capturing known best practices, against exploratory innovation to find new best practices that address industry dynamics. To strike this balance, vertical clouds need flexibly available resources as well as a rich inventory of reliable, robust and compliant application building blocks that can be composed into vertical solutions and complemented by both manual and automated processes operating within, and extending beyond, the vertical cloud.

A Vertical Cloud for Healthcare and Life Sciences

Specific forces driving the requirements for vertical cloud support of healthcare and life sciences include:

- Rapid changes in biomedical technology
- Game changing legislation and unfolding regulatory interpretation
- Economic stresses on both the life sciences and healthcare industries
    - i. Life sciences intellectual property portfolios are expiring and more stringent efficacy and safety measures are being imposed
    - ii. Wholesale changes in payments in healthcare migrating from "for service" to "for outcome" attempt to incentivize lower cost prevention over more expensive treatments

Over the longer term, the convergence of life sciences and healthcare in the form of personalized medicine, will further transform the interests and activities of the healthcare and life sciences communities.

Delivery of vertical solutions generally requires responding to the operational context of customers. This obviously includes the design of the software, but includes other factors as well. In healthcare and life sciences, "how" customers want to buy is important. The cost structure of product and services need to conform to operating budgets. For example, life sciences clinical research is budgeted on the basis of trials, so it's convenient for customers to buy services in units of trials, rather than lower level units of the constituents making up those services, such as virtual machine hours.

Another factor relating to customer operations is the familiarity and competence of the people servicing and supporting the solution. In healthcare and life sciences, solution service and support professionals need training, experience and fluency in the domain as well as the regulations.

All cloud offerings are based on a set of managed services such as those describe by the IT Infrastructure Library (ITIL) including:

1. Service delivery
2. Service configuration management
3. Infrastructure monitoring

4. Applications and data monitoring (more customer critical)(Tier II/III)
5. Service SLA management
6. Service change management
7. Service problem management
8. Service incident management

As noted earlier, any life sciences application running in the cloud has to be validated according to Good Clinical Practices guidelines set forth by the ICH. Healthcare data must ensure privacy of Personal Health Information according to the Health Insurance Portability and Accountability Act (HIPAA) regulations, and as such, HIPAA training is required for personnel working with said data operationally. The data centers in which the cloud runs must be physically auditable.

Healthcare and life sciences vertical cloud operations must respect the standards, regulations and conventions of the industry as well as the software running in the cloud. Software compliance by itself is insufficient as there is opportunity to those administering and managing the software to circumvent compliant software. Horizontal clouds externalize compliance activity, moving those responsibilities outside of the cloud management itself and leaving all but the lowest level of IT management within the cloud proper. For some compliance tasks, this delegation presents the need for cooperation between cloud-internal IT management tasks and cloud-external associated compliance tasks. The arm's length relationship between horizontal cloud personnel and those delegated compliance tasks presents a challenge.

Oracle Health Sciences Cloud

Overall design objectives include:

- Customers are not shoe horned into one-size fits all services and operations
- New services can be quickly introduced to and by customers
- Customers have deployment choices in solutions and Oracle platform services and hardware.
- Customers are provided secure, operational isolation
- Different service level packages are offered to address different business needs

Milestones and Growth

The Oracle Health Sciences Cloud (OHSC) currently supports over 3,800 application instances and hundreds of thousands of users in more than 117 countries. Oracle Health Sciences applications currently available as a service on OHSC include solutions for electronic data capture; study design; coding and dictionary management; trial randomization and drug supply management; electronic patient reported outcomes; as well as safety management.

More applications are being moved to the OHSC to provide customers additional flexible options for software deployment

OHSC provides reliable, secure and cost-effective infrastructure and platform services, enabling the deployment of health sciences solutions; based on applications that typically require high availability, scalable expansion and high performance. In order to meet these requirements, OHSC is hosted in world-class, highly secure, 24x7 operated data centers that are SAS70 Type II compliant. The OHSC facilities are Tier III data center facilities, which include redundant power, cooling and network bandwidth infrastructure.

OHSC deploys, operates and manages a standard set of infrastructure building blocks, which include enterprise-class network, security, server and storage systems. In order to meet the scalability and cost efficiency needed of health sciences solutions; OHSC's technical and operations teams apply virtualization technologies to each of the infrastructure components that are tailored to the hosting capacity and performance needs of OHSC's underlying solutions.

In addition to the enterprise-class infrastructure described above, OHSC's technical and operations teams have developed a refined set of operational (IT) processes, based on IT Infrastructure Library (ITIL) structures and best practices, and have developed the operational systems to support deployment, capacity planning, monitoring and run-time management services of the hosted health sciences solutions and underlying platform infrastructure components.

In the OHSC, managed services are governed by industry standards and regulations. Specific execution of these services is detailed in Standard Operating Procedures (SOPs), and personnel involved in the conduct of the services are trained in both the regulations and the SOPs.

OHSC's managed services include the data center facilities components, network, security, server and storage components, disaster recovery services and enabling hosting services such as domain name services, secure FTP services and mail exchange (SMTP) services.

Described below, by Managed Infrastructure Service, are the benefits of each.

Data Center Services

- Highly available, uninterruptable facility services (power and cooling) – 99.99%
- Highly available IP network (Internet) service – 99.99%
- Certified data center operational and security processes

Network Services

- Highly available network services – 99.99%
- Secure, virtual network partitions by server class (application, database, utility) and product class
- Geographic network optimization to decrease network latency / increase network throughput for bandwidth-challenged locations / sites
- Internet inbound/outbound network encryption
- Web application load-balancing options
- Network encryption access for ALL hosted web applications (HTTP/SSL)
- On-call network support

Security Services

- Secure network environments with standard firewall and Access Control List (ACL) policies for approved, secure IP addresses, IP ports
- Secure applications and database server environments
- Secure patching management, anti-virus management
- Secure health sciences data
- Penetration testing of service components

Compute Services

- Standard server configurations, efficient server provisioning
- Enhanced server availability and performance
- Leveraged, shared server resources – improved economies of scale
- Flexibility of leveraged or dedicated server provisioning depending on customer requirements
- On-call server infrastructure support

Storage Services

- Optimized data storage (cost versus performance or redundancy)
- Efficient storage provisioning/de-provisioning
- Leveraged, shared storage resources – improved economies of scale
- Secure data
- Off-site data backup/archiving
- On-call storage infrastructure support

Utility Services

- Managed, secured file storage for data loads / data extracts to/from OHSC
- Shared or custom domain name configuration and management

General Managed Applications Services

- Standard application configurations, efficient application provisioning
- Enhanced application availability and performance
- On-call application infrastructure support
- On-call database infrastructure support

Managed Operational (IT) Support Services

- Standards-based IT service and support processes and procedures
- Operational process workflows enabled through ITIL-based tools
- Customer service and support consistency via reliable and repeatable standard operational processes
- Operational visibility/transparency to customer hosted application services and support

Oracle Technology Support for Vertical Clouds

Oracle's foundational technologies, built as software and hardware engineered to work together, provide an excellent underpinning to vertical clouds. These include Oracle Fusion Middleware, Oracle Exadata Database Machine and Oracle's Sun Servers and ZFS Storage Appliance.

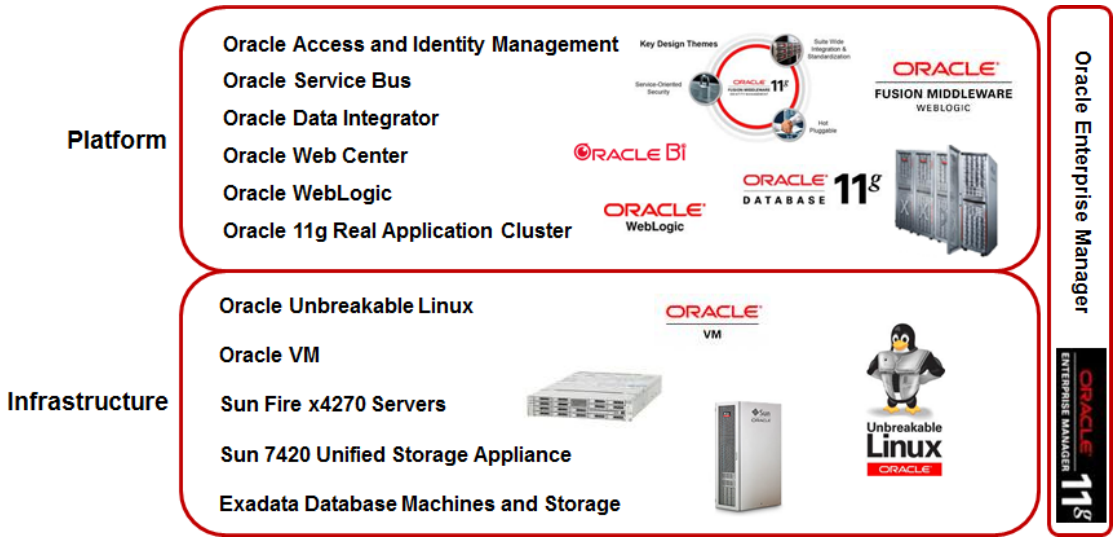

Figure 3. Oracle foundational technology

Oracle Sun hardware, supporting virtualized Oracle Unbreakable Linux servers, combine to provide a modern, reliable and optimized infrastructure to support a cloud platform. Targeted use of virtualized Real Application Cluster database servers can provide high availability for application instances with modest database activity while maintaining high utilization for physical servers. For application instances requiring high database activity, Real Application Clusters, either virtualized with substantial resources allocated or deployed on physical servers, can provide outstanding performance, scalability and availability. Applications and platform components can be centrally managed through Oracle Enterprise Manager and secured though Oracle Access and Identity Management. Oracle Data Integrator and Service Bus provide for movement of large volumes of data and message traffic. WebLogic serves as a responsive container for interactive and Web Service applications complimented by the modern, flexible user experience enabled through WebCenter.

Oracle Health Sciences Cloud is the latest addition to Oracle's complete portfolio of cloud-ready software and hardware products, designed to enable customers to take advantage of a next-generation cloud computing infrastructure.

[1] Takahashi, H. a. (2010). *A comprehensive framework for considering practices and processes.* Cambridge, MA: CCI/Sloan - http://cci.mit.edu/publications/CCIwp2010-02.pdf.

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