HCL

CLINICAL PLATFORM
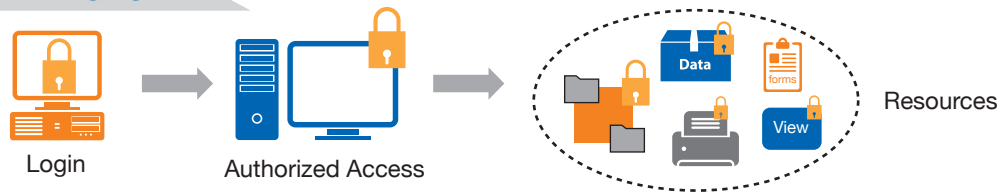**IDENTITY & ROLE BASED
ACCESS MANAGEMENT**

EXECUTIVE SUMMARY

Pharmaceutical companies and Clinical Research Organization (CROs) conduct hundreds of clinical trial every year utilizing a variety of computer systems and databases. However, during the conduct of the trials, user access management and privilege control to multiple clinical applications typically gets second priority due to the lack of effective tools and methods.

Currently, the industry does not have a robust centralized location to verify what access role the individual has for various clinical applications as well as what clinical study protocol(s) they have access to. Present solutions also lack a mechanism to manage trial externalization processes that involve internal and external users. These issues result in multiple business challenges in support of heterogeneous clinical systems and even lead to time delaying and expensive audit findings.

A well-defined centralized access management system proactively manages multi-partner user's access to specific studies while supporting assigned user-specific business functions across systems in all phases of study conduct as well as to facilitate regulatory inspections.

BUSINESS CHALLENGES

Login → Authorized Access → Resources

Identity
• Who is getting access? Approved?
• Create identity of an individual

Provisioning
• Onboarding/Off boarding
• External and Internal users

Authentication
• How does a user login to the application?

Authorization
• How does a user get access to application resources?

Auditing
• Who can access what and when was this allowed?
• 21CFRPart11
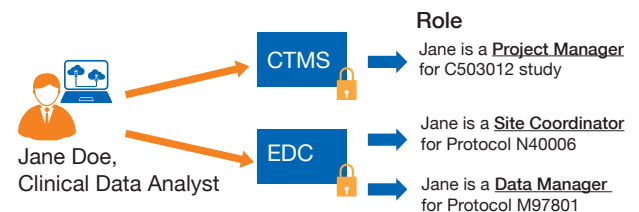• Auditing Requirements

INEFFICIENT USER MANAGEMENT

• Manual user management process maintained at the department level

• Mismatch of user information across applications with multiple authentication

• Identification of internal/external user

• Findings during audits resulting in corrective actions

• Manual effort to find the level of access across all clinical applications

• Multi-tenant study data access for sponsor and CRO is difficult to configure

SIMPLE APPLICATION ACCESS

• Functional Role
• Application Role
• Application Privileges

COMPLEXITY OF ROLE BASED ACCESS CONTROL

• Entitle the user to application resource based on role

• Sponsor, Study, Site and Role information is maintained within each application

• User assigned to role per application and/or study

• Functional role mapped to the application role

• User assigned access privileges to resources based on the role

Jane Doe, Clinical Data Analyst

Role
Jane is a **Project Manager** for C503012 study

Jane is a **Site Coordinator** for Protocol N40006

Jane is a **Data Manager** for Protocol M97801

SOLUTION DESCRIPTION

HCL addresses this industry challenge by centralizing identity with role based access control via a proprietary solution. Our solution covers Identity of an individual, Authorization, Authentication, Auditing, Resource Management and Reporting. The system is flexible and easy to integrate with the company's authoritative identity source.

HCLs architecture delivers an environment that complies with the industry regulations while being secure and scalable managing functional and data access of various applications from a single location. We provide extensive support for externalization of clinical trials with data access rights and roles specific to partners.

The system is cloud-based, delivered as SaaS and custom built for clinical trials.

Key functions:

- Unique and customized centralized access management for clinical trials
- Creation of user's identity – internal and external users
- Authorization based on the functional role and clinical study access
- Authentication based on the application role
- Cascading application provisioning to various clinical systems from the centralized access management systems
- Configurable Study Data Access for the Sponsor and its Partners /Collaborators

CLINICAL PLATFORM IDENTITY CREATION ARCHITECTURE

The users' identity account is created in a Relational database or LDAP structure
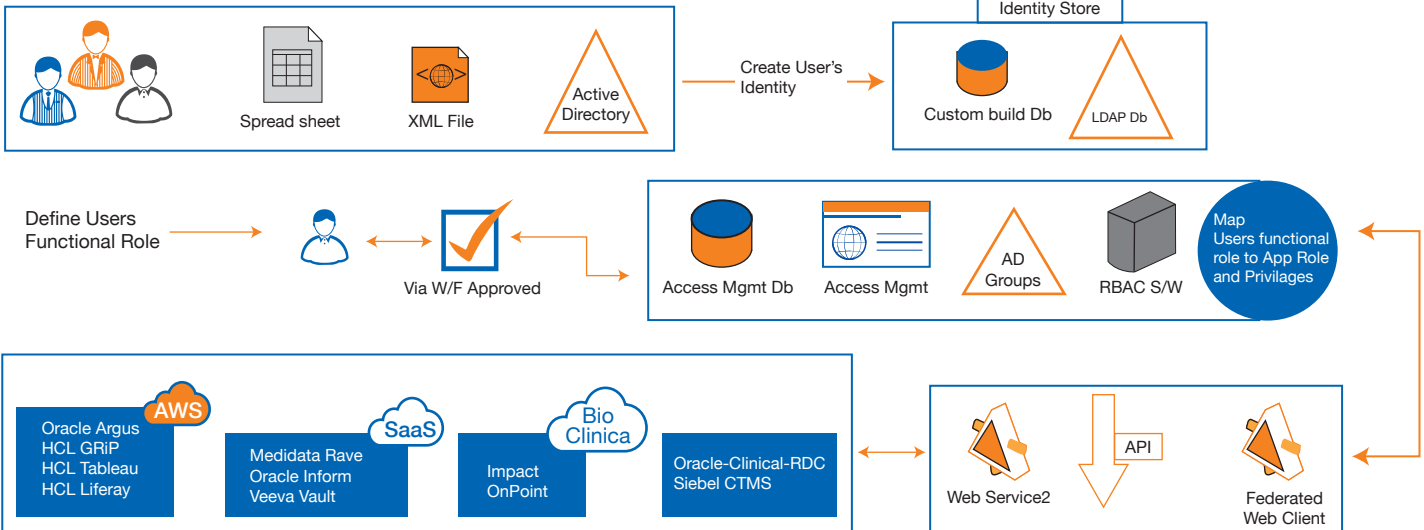
Clinical Platform Identity

CLINICAL PLATFORM PROVISIONING/DE–PROVISIONING METHODOLOGY

- For approved user with validated identity; the account is created automatically into various clinical applications based on the users' functional role mapped to the application role using various connectors

Clinical Platform Provisioning

BENEFITS

Centralized process for management of clinical application users provides a holistic view of a user, applications, application functions and studies user has access to. The system implements automatic or automated setup of various clinical applications saving time and eliminating errors. It also provides complete auditing of all functions.

- Centralize, easy to control, manage and set up governance on user access management

- Automated identity account de-provisioning and life-cycle management

- Avoid wrong access / Data Privacy (i.e. application and data security)

- Reduced support costs and downtime

- Faster and consistent setup granting the user access to various applications

- User mapped to functional role, application, application role and studies

- Improved Efficiency by removing manual audit/verification due to centralized source

- Simple reporting

SUMMARY

Centralized Identity management helps Pharmaceutical R&D and CROs to efficiently deploy either individual components of CPaaS product suite or a complete Platform. The solution provides the ability to manage single source of truth for the user, applications and data access with efficient automatic way to provision / de-provision users. There is no limitation on integrating and utilizing the solution with open systems that support Web Services/APIs and Federation.

HCL LIFE SCIENCES & HEALTHCARE

HCL is a leading provider of Life Sciences and Healthcare Business and Technology services. We are the chosen service provider for enabling new growth drivers for our clients, providing them with industry leading best practices, taking care of their compliance needs and ensuring goldstandard process cycle times. Our clientele includes seven of the top ten global pharmaceutical companies, seven of the top ten medical devices companies, six of the top ten health plans, three of the top five CRO's and two of the top three data providers. Equipped with certified technology experts and domain specialists, HCL offers services in critical areas of the life sciences and healthcare eco system such as drug discovery, clinical development, drug safety, regulatory compliance, manufacturing and plant automation, commercial, Healthcare analytics, Population Health Management [PHM], mHealth, member experience management [MEM], fraud, waste and abuse management [FWA].

Let's connect:

Please feel free to write to us at contact.lsh@hcl.com

ABOUT HCL

ABOUT HCL TECHNOLOGIES

HCL Technologies is a leading global IT services company working with clients in the areas that impact and redefine the core of their businesses. Since its emergence on the global landscape, and after its IPO in 1999, HCL has focused on 'transformational outsourcing', underlined by innovation and value creation, offering an integrated portfolio of services including software-led IT solutions, remote infrastructure management, engineering and R&D services and business services. HCL leverages its extensive global offshore infrastructure and network of offices in 31 countries to provide holistic, multi-service delivery in key industry verticals including Financial Services, Manufacturing, Consumer Services, Public Services and Life Sciences & Healthcare. HCL takes pride in its philosophy of 'Employees First, Customers Second' which empowers its 105,000 transformers to create real value for customers.

HCL Technologies, along with its subsidiaries, had consolidated revenues of US$ 5.8 billion, for the Financial Year ended as on 31st March 2015 (on LTM basis). For more information, please visit www.hcltech.com

ABOUT HCL ENTERPRISE

HCL is a $6.5 billion leading global technology and IT enterprise comprising two companies listed in India – HCL Technologies and HCL Infosystems. Founded in 1976, HCL is one of India's original IT garage start-ups. A pioneer of modern computing, HCL is a global transformational enterprise today. Its range of offerings includes product engineering, custom & package applications, BPO, IT infrastructure services, IT hardware, systems integration, and distribution of information and communications technology (ICT) products across a wide range of focused industry verticals. The HCL team consists of over 100,000 professionals of diverse nationalities, who operate from 31 countries including over 505 points of presence in India. HCL has partnerships with several leading global 1000 firms, including leading IT and technology firms. For more information, please visit www.hcl.com

NOTES

Hello there! I am an Ideapreneur. I believe that sustainable business outcomes are driven by relationships nurtured through values like trust, transparency and flexibility. I respect the contract, but believe in going beyond through collaboration, applied innovation and new generation partnership models that put your interest above everything else. Right now 105,000 Ideapreneurs are in a Relationship Beyond the Contract™ with 500 customers in 31 countries. **How can I help you?**

www.hcltech.com

Relationship ™
BEYOND THE CONTRACT

HCL