

CLINICAL TRIALS - THE CURRENT PICTURE

Inefficiencies in Site Management and Clinical Data Management have contributed to increased duration and high cost of conducting clinical trials. On an average, cost of Site Monitoring, Site Retention, Source Data Verification (SDV), and Data Management contributes to nearly 35% of the total cost of trial in Phase-1 and Phase-2 and about 30% in Phase-3.

Inconvenient location schedule conflicts, forgetting visits, and physical inability to travel to the sites also contribute to the overall 30% average patient dropout rate in clinical trials.

THE REQUIREMENT

- · Collect and process data faster
- · Streamline data flow
- Drive patients and investigator centricity
- · Generate deeper insights faster for critical decision making

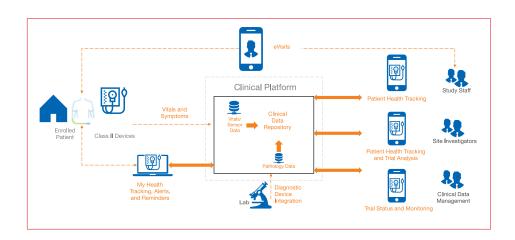
THE OPPORTUNITY

Use of wearable devices in clinical trials presents a big opportunity to collect pervasive real world data streams, improve data quality, and streamline data workflow. It will also drive better patient engagement and significantly reduce site management and monitoring overheads.

HCL'S CONNECTED CLINICAL TRIAL MODEL

The Connected Clinical Trial Model leverages a Remote Monitoring Platform that uses medical/ wearable devices-based bio-metrics data collection, thereby reducing site visits and monitoring effort. The patient's biometric devices allow more data to be gathered on the effects of a drug on certain bio-markers. These devices automatically push frequent, large volume, and new type of data helping make faster decisions and eliminate transcription errors. This data is processed in near real-time and then compared against patterns and models to raise events that need to be immediately addressed. In addition, through a portal, investigators have the ability to review a patients' history and take action proactively to reduce SAEs in clinical trials.

The model easily integrates into existing clinical workflow without much disruption to the trial design.



BENEFITS

Faster data collection and analysis for faster Reduced site visits for patients and investigators decision making and adaptive trials Improved Patient Adherence and Engagement Improved communication between investigator and reducing patient drop-outs patients Near real-time status Newer datasets (sensor-based) for deeper Ease of patients participation and investigator reporting Improved safety profiling and reduced Improved patient health visibility and trial tracking

KEY CONSIDERATIONS

HCL approach to designing Connected Clinical Trial is based on a comprehensive set of key considerations shown below:

Security and Privacy



- · Patient Identification and Authentication
- Intrusion Control
- · Device-level Security
- · Encryption at Application, Network, and Device Levels



Devices



 Purpose, Type, Context, Frequency, Quality, Reliability, Location., Population, and Battery Life

People and Processes



- · Training and Helpdesk Support · Trial Management Process
- Modifications

Platform and Applications



· Usability, Analytics, Scalability, Flexibility, Geographic Reach, Computing Capability And Performance, and Device Interoperability

Data Standards and Management



Data Validation, Transformation, Integration, Tracking, Processing, Archiving and Analytics, CDISC, CDASH, ODM, HL7, and FHIR

Networking and Transmission

· Network Providers, Network Type, and Data Synchronization



Device Provisioning and Infrastructure

· Centrally Provisioned/ BYOD, Monitoring, and ITOT Run



Regulatory Compliance



- Computer Systems Validation 21CFR Part 11
- · 21 CFR Part 820 for Device and Mobile Apps
- ICH E6 Section 8 and US FDA 21 CFR Part 314 and Part 312
- HIPAA

WHY HCL?

HCL is a 'Full Services Provider' uniquely positioned to deliver a truly Integrated Connected Clinical Trial platform. Some of the reasons for HCL's strong position are:

Strong clinical domain expertise – Know what clinical processes and systems will change with Connected Clinical Trial and how Leader in Medical Device Engineering – Know challenges of using devices in clinical trials and how to overcome those Leader in Infrastructure
Management – Know how to
globally run ITOT (Information
Technology and Operation
Technology) to manage
applications and devices as
one system

Industry-leading BEYONDigital and IoTWoRKS Transformation Units – Know how to create digital platforms based on user value chain and asset value chain

STRONG CLINICAL DOMAIN EXPERTISE

- 10+ years of full-service CRO experience
- Implementation of Global Integrated Clinical Platform
- Implementation of several global patient data management programs
- Deep understanding of regional and country-specific data privacy, security, and protection laws

LEADER IN MEDICAL DEVICE ENGINEERING

- Largest India-based Engineering Services provider, both by revenue and size
- 15+ years of experience in engineering and supporting 100+ medical devices
- Largest Global Engineering Services team with 22,500 experts

INDUSTRY LEADING BEYOND DIGITAL AND IOTWORKS TRANSFORMATION UNITS

- Implemented several large scale complex IoT programs in Healthcare
- Highest rated service provider in Big Data consulting and system implementation by IDC
- Industry-leading Digital and IoT Practices and rated Leader in Application Modernization Services for Digital Transformation by IDC

LEADER IN INFRASTRUCTURE MANAGEMENT

- Global Leader in Infrastructure Services 250+ customers across 9 verticals
- HCL works with 8 out of Top 10 ISVs in their Cloud initiatives
- Device Automation and Orchestration Platform

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 gold standard process cycle times. Our clientele includes eight of the top ten global pharmaceutical companies, nine 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].

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

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 104,000+ employees to create real value for customers. HCL Technologies, along with its subsidiaries, had consolidated revenues of \$6.2 billion in FY 15 as on 31st March, 2016.

For more information, please visit www.hcltech.com

ABOUT HCL ENTERPRISE

HCL is a \$7 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 110,000 professionals of diverse nationalities, who operate from 31 countries including over 500 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

Contact.lsh@hcl.com



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 110,000 Ideapreneurs are in a Relationship Beyond the Contract™ with 500 customers in 31 countries. How can I help you?



