

A lifetime of care

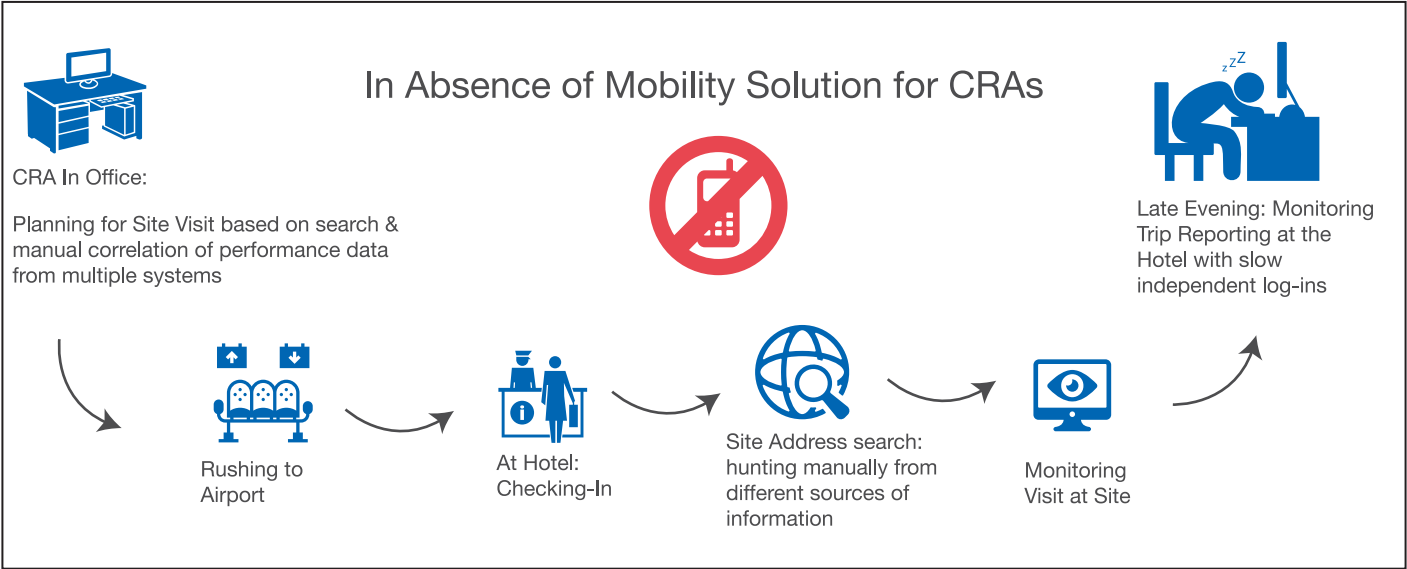
GET DIGITAL GET **FIT** FASTER INTELLIGENT TRIALS

Powered by HCL

Mobility Enabled Clinical Monitoring

Clinical Trials Monitoring – The Current Picture

Monitoring is a significant cost driver with greater opportunity to optimize. CRA’s conduct regular monitoring visits during study plan, conduct and closeout. Lack of integrated study planning, scheduling and trip reporting systems result in schedule conflicts, forgetting visits and delay in entering trip report into CTMS by up to 10 days. It also poses greater problem for CROs due to write-offs because they did not either complete the trip report or used more time than was needed for entering trip report into CTMS.



Factor contributing to the trip reporting challenges, but not limited to, are:

Writing post-it notes, scribble on paper, as it is not practical to work directly into CTMS during site visit	On train, plane, and enter trip information when they get home	Significant inefficiency due to many hours when trip reports not available to them
---	--	--

On average, 30% of budget in large scale global trials is spent on site monitoring. Schedule conflicts, forgetting visits and inefficient reporting contribute significantly to the overall budget for monitoring.

We need

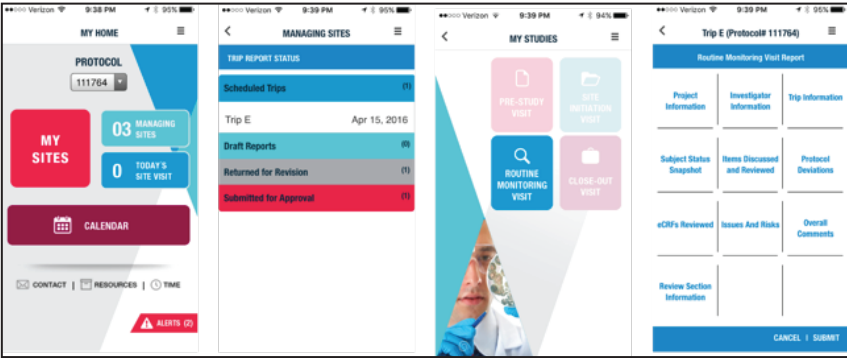
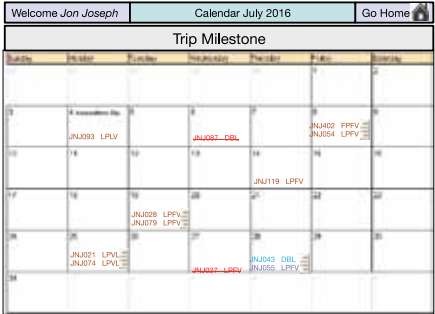
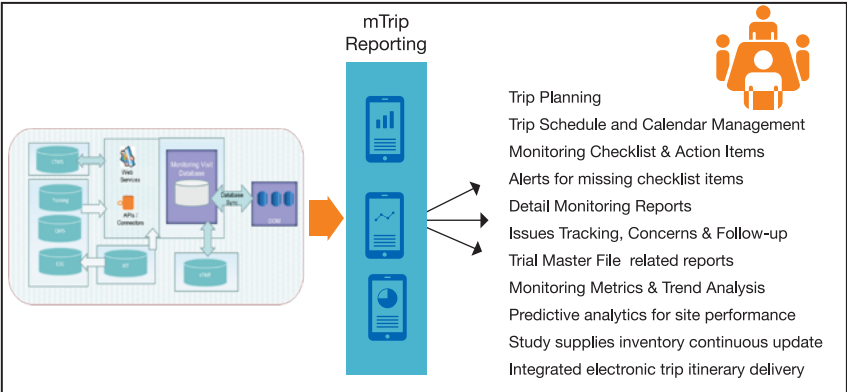
Mobility (tablet) enabled Monitoring Trip Planning & Reporting	Offline connectivity and sync-up with backend Clinical systems - CTMS, EDC, IVRS and eTMF	Trip Schedule, Calendar Management, Issues Tracking & Follow-up	Monitoring Metrics & Trend Analysis
--	---	---	-------------------------------------

OPPORTUNITY

Mobility solution will improve efficiency and provides flexibility for CRAs/monitors in timely completion of the trip report. It will reduce cost of overall clinical trial monitoring and provides better quality and greater adherence in meeting SLAs associated with trip reporting.

HCL MOBILITY ENABLED CLINICAL MONITORING SOLUTION

HCL's solution is built following key technology considerations for mobility applications development combined with optimized clinical business processes.



KEY FEATURES

Offline connectivity and sync-up with backend Clinical systems - CTMS, EDC, IVRS and eTMF	Trip Schedule, Calendar Management, Issues Tracking & Follow-up	Monitoring Metrics & Trend Analysis
Cross platform support - Can be extended to support all mobile platforms easily. Provides native plug-in availability for specific requirements	Open platform - Open Standards and open source platform	
Maintenance - Single source base across all mobile platforms. Familiar technology (HTML, CSS, JS, etc.) compared to different native programming models	User Experience - User experience close to native mobile apps (Look & feel, performance, etc.). Availability of Offline access, Device features, Notification, etc.	

BENEFITS

Integrated study planning, scheduling and trip reporting	Reduced/eliminate paper transcription process	Improves efficiency and provides flexibility for monitors in timely completion of the trip report.
Supports meeting SLAs for trip reporting to avoid write-offs	Overall, increase productivity and effectiveness of trip reporting and improves overall site monitoring experience	

KEY CONSIDERATIONS

Offline connectivity support	Improve efficiency and flexibility	Better UI for completing the trip report
Computer Systems Validation, 21CFR Part 11	Patient Data Safety & Privacy	Security, Audit & Archival Policies

WHY HCL FOR MOBILITY ENABLED CLINICAL MONITORING?

Mobility solution will improve efficiency and provides flexibility for CRAs/monitors in timely completion of the trip report. It will reduce cost of overall clinical trial monitoring and provides better quality and greater adherence in meeting SLAs associated with trip reporting.

LEADER IN CLINICAL TECHNOLOGY IMPLEMENTATION & SUPPORT

- Strong expertise in clinical technology architecture and process excellence
- Leader in implementation and support for 400+ Global Clinical Development applications
- Proven clinical solutions for digital transformation with demo-ready Innovation Lab environment for pilots/PoCs

STRONG CLINICAL DOMAIN EXPERTISE

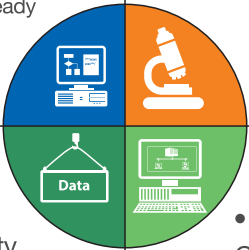
- Strong consulting team for business process assessment, roadmap and blueprint
- End to end business services in clinical safety and regulatory
- Leader in CDISC Standards Implementation and transformation services

INDUSTRY LEADING MOBILITY TRANSFORMATION UNIT

- Implemented several Large Scale Complex Mobility Solutions in Life Sciences & Healthcare
- 70+ PoC and many more reusable components
- Proof points include 72+ apps delivered in 1 year for a leading global pharma

LEADER IN INFRASTRUCTURE MANAGEMENT

- Global Leader 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



OVERALL INSINUATION

Industry perspective reflects that mHealth technology is still considered expansion beyond the boundaries of traditional clinical care. This may be ascribed to the gaps in standards, guidelines, adoption strategy & availability of experienced consultants.

In our view, embracing this method of translational research is possible by systematically circumventing associated challenges, with robust Implementation Plan, Training Plan, Conduct Plan, Risk Management Plan and Support Plan.

As our healthcare system transitions from a volume based to value based system, organizations are developing new strategies and capacities to achieve the triple aim of better care for individuals, improved health for populations and lower costs. Organization specific implementation model for embracing mHealth must be established with an aim to utilize real world data 'anytime and anywhere'.

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

Contact.Ish@hcl.com



www.hcltech.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?**

Relationship™
BEYOND THE CONTRACT

HCL