



# Transforming Clinical Development

Risk Based Approach to Site Monitoring



# Innovative Integrated Approach

Innovative integrated approach to clinical trial monitoring to bring excellence in trial conduct by efficient resource utilization.

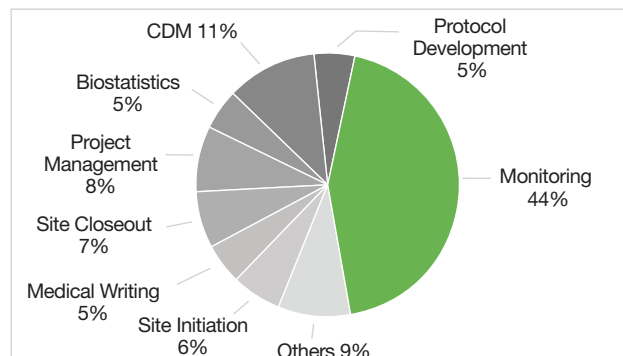
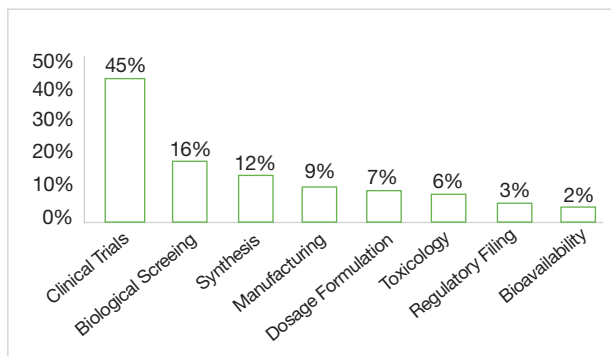
## Industry Perspective

Over the last decade, pharmaceutical industry is experiencing a steep decline in R&D productivity. Even though the R&D spend has tripled, the number of new drugs approved by FDA have reduced to 30%, thus increasing the pressure on pharmaceutical industry to bring in efficiencies in every process.

Site monitoring constitutes 45% of the annual Clinical Trials expenditure in the R&D spend for a typical Pharma. It is now imperative to target on-site monitoring of clinical trials by identifying centers with anomalous and inconsistent data.

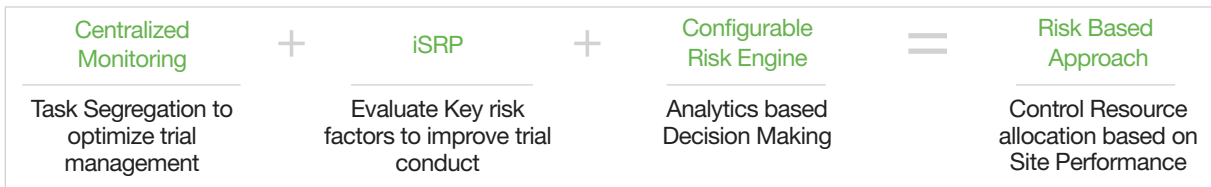
100 percent on-site monitoring is now becoming a thing of the past. Risk-based monitoring has proven to be safer and more effective, and will become increasingly commonplace across the pharma industry in coming years. RBM approach is based on the draft guidance from FDA for the oversight of clinical investigations and to allow optimization of site monitoring. Sponsors and CROs need to invest in data platforms that support quick, easy and centralized reviews of trial results as data comes in.

FDA has released new draft guidance to help sponsors in developing and adopting a combination of monitoring strategies.



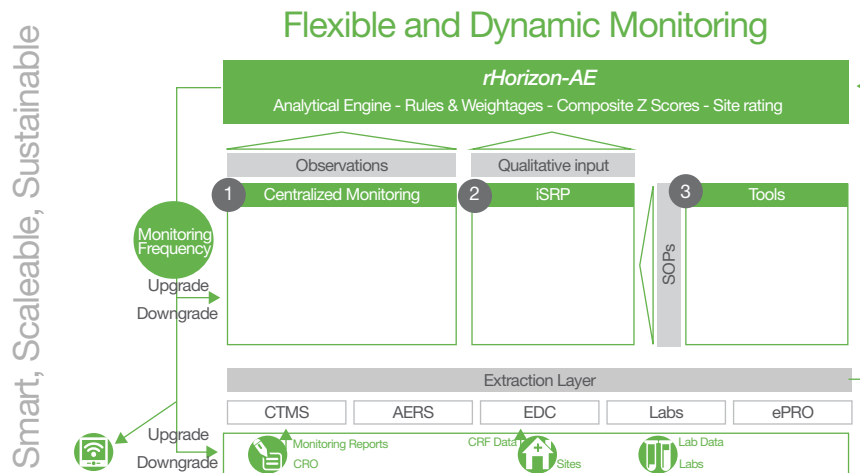
# HCL Solution

HCL offers rHorizon, a solution to pharmaceutical industry in transforming clinical development. It is a flexible and risk balanced approach for optimization of site monitoring. It eliminates inefficient practices in clinical trial conduct thus allowing remote monitors to augment onsite monitors by performing monitoring activities using centralized processes and allow onsite monitors to focus on more strategic tasks.



Our solution enables process efficiencies and efficient resource utilization. Onsite monitors, the front line support for clinical trials, focus on strategic activities that require high touch points. In Centralized Monitoring, our central team of remote monitors work in collaboration with global onsite monitors to complete the monitoring tasks and perform real time data review and analysis.

Our unique independent site rating panel (iSRP) leverages our technology solution rHorizon-Analytics to evaluate the site performance on a perpetual basis to determine the intensity and frequency of onsite monitoring visits.



# rHorizon

Our main solution components are detailed below:

## Remote Monitoring

Implementing remote monitoring gives immediate cost benefits to sponsors. HCL has meticulously worked out the processes and detailed the methodologies for successful implementation, and setting the industry standards.

HCL's has delineated the responsibilities between CRO, Sponsor, and Service Provider, created detailed Level 3 process flows for all the identified remote monitoring tasks. We have also defined and established activity hand offs between the new emerged roles and the team.

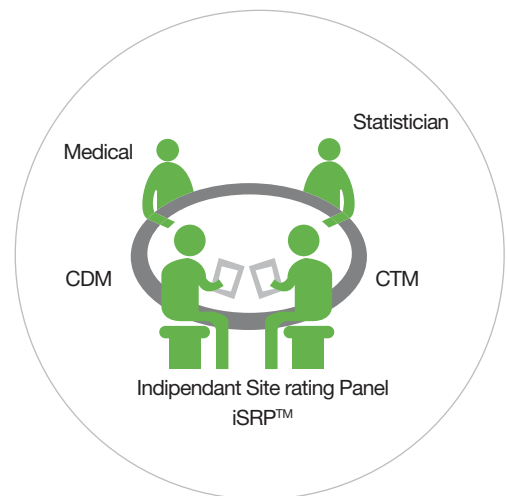




## iSRP

HCL's rHorizon is not just data driven, it addresses the Risk based monitoring with a framework to rate the site performance, ultimately determining the intensity and frequency of the onsite monitoring visits.

Site performance is evaluated using a wide range of parameters, both quantitative and qualitative. HCL has created this unique panel of experts derived from multiple domains such as Medical, Statistics, Trial Management and Clinical data Management to assess the qualitative parameters



## rHorizon-Analytics

A unique and highly configurable analytics engine operates on a rules database. It provides a holistic view of study performance based on identified criteria and several statistical algorithms.

rHorizon-Analytics is equipped with several interactive and drill down analytics on critical site performance parameters. This enables the sponsors and CROs to adopt a dynamic and flexible monitoring approach throughout the trial duration.



A green background featuring various white line-art icons related to healthcare, including a stethoscope, a wheelchair, a syringe, a pill bottle, a clipboard with a heart rate line, a female symbol, a tooth, a heart, a pill, a bandage, and a hospital 'H' sign.

## Key Features/ Attributes:

- Strong clinical domain with over a decade of trial monitoring experience for remote monitoring
- Outlined over 50 risk attributes with individual scoring all of which is completely configurable for each trial
- Cloud based Technology platforms, which eliminates capital costs
- Innovative business communication provides feeds, alerts and Issue notifications to CTM Teams and Senior Management of Sponsor
- Seamless collaboration between Onsite team, Centralized team and Sponsors
- Customizable alerts for all user levels, providing the pulse of study performance
- Interactive and drillable analytics providing simple, complex and granular information for the users and managers
- Interactive and flexible web based training for all the operational staff throughout study conduct

## Key Benefits:

**rHorizon** solution benefits the pharmaceutical industries with an integrated approach.

- It improves the quality and integrity of data through constant data verification
- Maintain or reduce clinical trial timelines with total visibility of study performance
- Simplified “on the go” site intelligence, enabling easy decision making
- Substantial savings of up to 40% in monitoring through optimized site monitoring

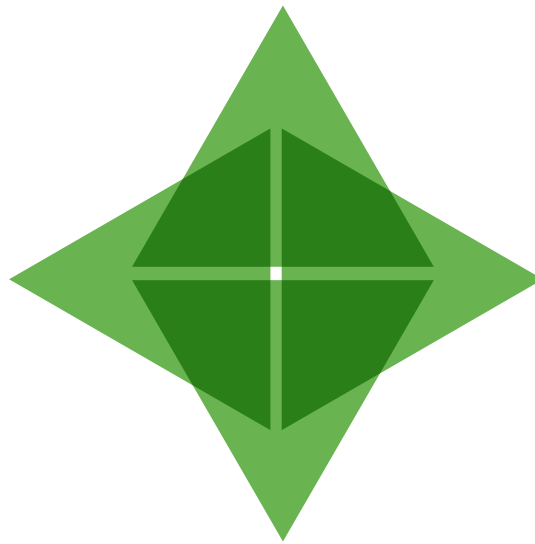
# Why HCL

- Largest Pharma R&D IT Support in Industry
- Implimentation of global Integrated Clinical Platform

## Technology Leader

## Clinical Domain

- 10+ years of **Full Service CRO exp.**
- Established **Monitoring SOPs**
- Experience in **multiple TAs**



## Integrated Global Delivery

- Global Delivery Centers in **31 countries**
- **Follow the Sun** model - 24X7 OPs
- Industrilized Delivery framework

## Process Excellence

- **Lean Six Sigma Deployment:**
- BPR Intitiatives to optimize back office
- **Path Finder:** Process Design
- Strong **Change Management**
- Track Record
- **TOSCANA:** BPM Capability

## 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 global landscape 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 Healthcare & Life sciences. HCL takes pride in its philosophy of 'Employees First, Customers Second' which empowers its 87,196 transformers to create real value for the customers. HCL Technologies, along with its subsidiaries, had consolidated revenues of US\$ 4.8 billion, as on September 30th 2013 (on LTM basis). For more information, please visit [www.hcltech.com](http://www.hcltech.com)

## About HCL Enterprise

HCL is a \$6 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 90,000 professionals of diverse nationalities, who operate from 31 countries including over 500 points of presence in India. For more information, please visit [www.hcl.com](http://www.hcl.com)

Contact: [contact.lsh@hcl.com](mailto:contact.lsh@hcl.com)



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