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TRANSFORM THE CLINICAL LANDSCAPE

DISRUPTIVE SOLUTIONS FOR CLINICAL TRIALS WITH HCL

Innovative Integrated Approach

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

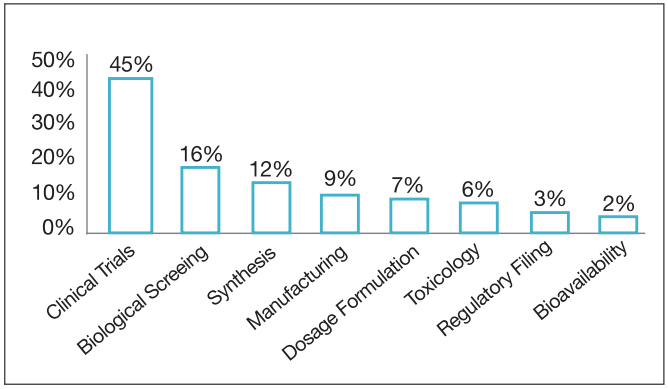
Industry Perspective

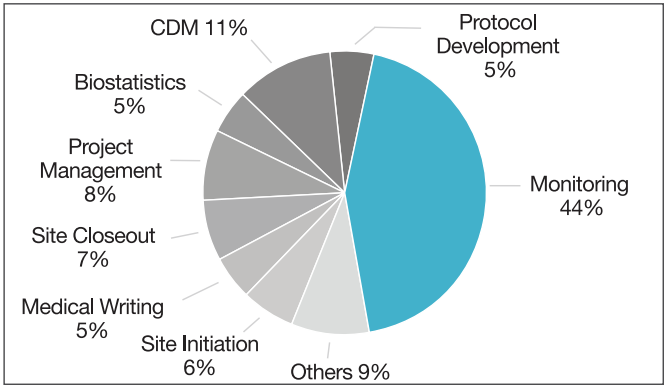
Over the last decade, the pharmaceutical industry is experiencing a steep decline in R&D productivity. Even though the R&D spend has tripled, the number of new drugs approved by FDA have reduced to 30%, thus increasing the pressure on the pharmaceutical industry to bring in efficiencies in every process.

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 (RBM) has proven to be safer and more effective, and will become increasingly commonplace across the pharma industry in coming years. The RBM approach is based on the draft guidance from FDA for the oversight of clinical investigations and to allow optimization of site monitoring.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FDA has released new draft guidance to help sponsors in developing and adopting a combination of monitoring strategies.





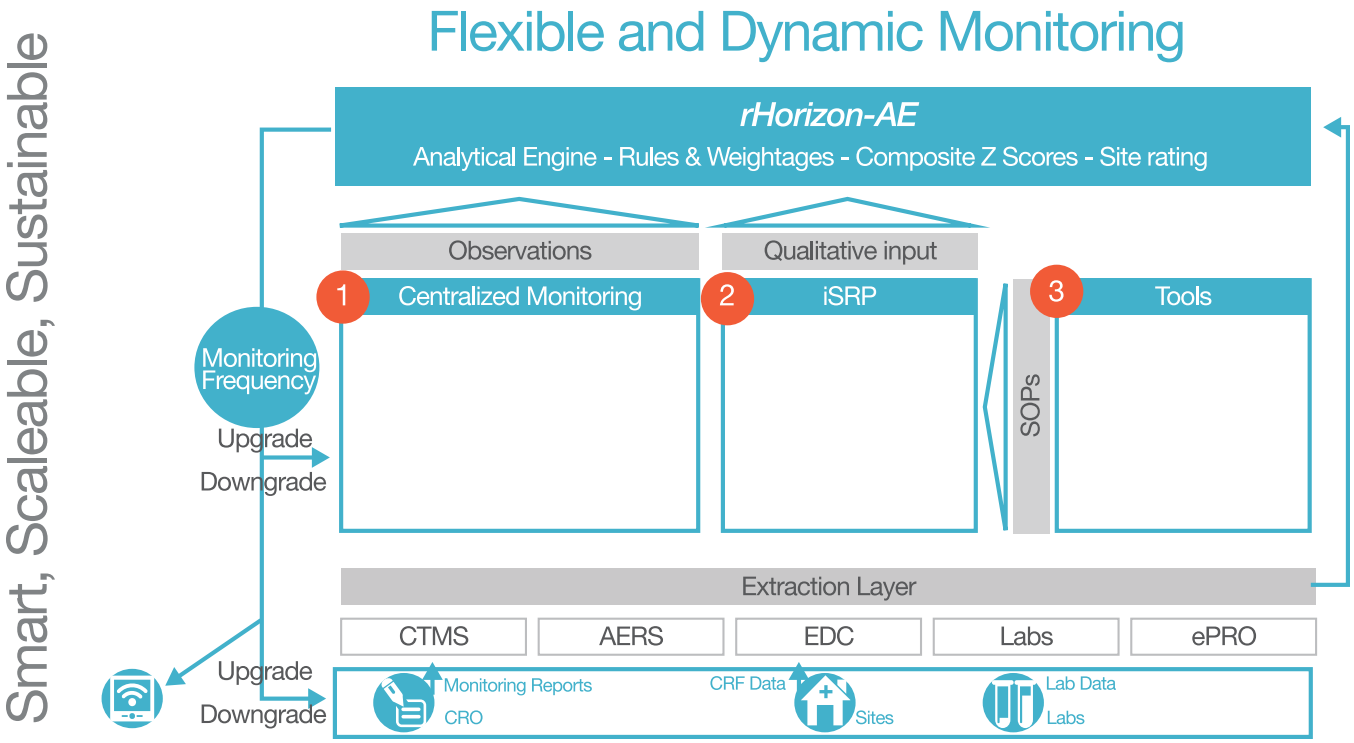
HCL Solution

HCL offers rHorizon, a solution for the pharmaceutical industry to transform clinical development. rHorizon 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.

Centralized Monitoring	+	iSRP	+	Configurable Risk Engine	=	Risk Based Approach
Task Segregation to optimize trial management		Evaluate Key risk factors to improve trial conduct		Analytics based Decision Making		Control Resource allocation based on Site Performance

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.



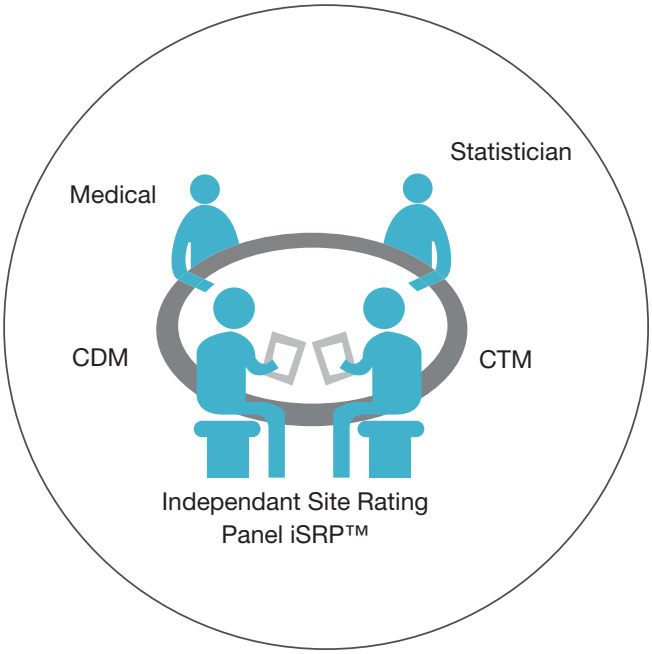
rHorizon

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 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.

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

Technology Leader

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

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**
- Best-in-class
- Industrialized Delivery framework

Process Excellence

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

The Impact of HCL's Clinical Trails Transformation (CTT) Solution

- 50-75% of onsite monitoring tasks can be done remotely by rCRA (can be customised based on sponsor's requirements)
- 40-45% savings in onsite monitoring costs
- Onsite CRA will focus on strategic issues such as recruitment strategies with investigator
- Onsite CRA's are more equipped prior to visits for focused monitoring on critical study parameters, training needs and quality assessments
- Improves ability to ensure the quality and integrity of data
- Improves overall site performance and thus enables reaching the study timelines
- Real time review of data aids in identification of unusual data trends and prevents further errors & protocol deviations

CLIENTS PRAISE HCL FOR ITS FLEXIBILITY IN MANAGING RELATIONSHIPS

Gartner

A BIG ADVANTAGE IS WHAT THE CUSTOMER CALLS "UNWRITTEN FLEXIBILITY". HCL IS FLEXIBLE IN TAKING ON SMALLER CHANGES

FORRESTER

THE PARTNERSHIP WITH HCL HAS BEEN SUCCESSFUL DUE TO THE STRONG RELATIONSHIP BETWEEN 'THE TWO COMPANIES'

ovum

HCL INVESTS IN RELATIONSHIPS TO DEVELOP ITS PRESENCE AND ITS EXPERTISE WITH ITS CLIENTS' CHALLENGES

GIARTE

COMMITMENT TO RELATIONSHIPS AND EMPLOYEE INVESTMENTS MAKE HCL THE EXCEPTION TO THE RULE

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