# CENTRALIZED DATA MONITORING

# INDUSTRY PERSPECTIVE

Over the last several years, clinical research costs have sky rocketed while new drug approvals are at multi-year lows. Studies have become global in nature and more complex to manage than ever before. Biopharma companies are under tremendous pressure to keep their R&D costs low. Clinical Trial costs have to be minimized and be efficient while conducting large global clinical trials. FDA as well as EMA has endorsed greater usage of centralized monitoring over traditional onsite monitoring.

Number of Active Studie 159,814

Studies Recruiting Subjects 32,058

Avg cost of a complex trial $100mn

Number of Countries 185

Average Cost of a Drug $4bn

Avg cost per patient for a Phase III Study

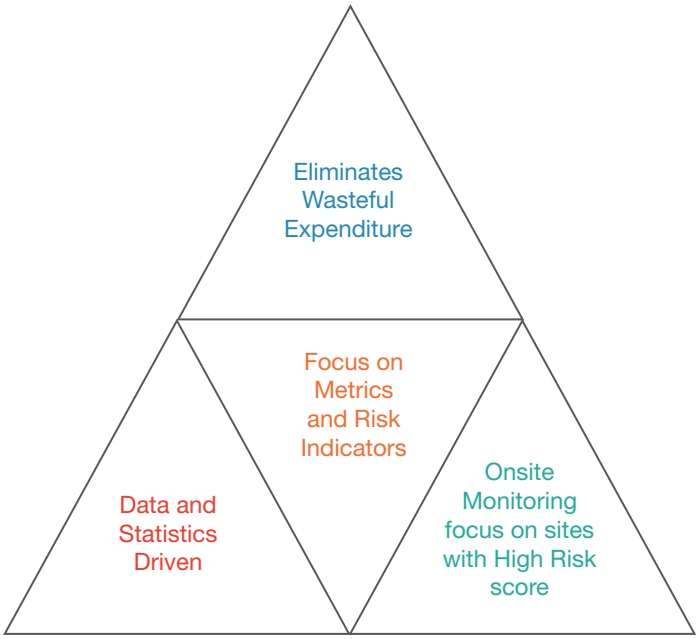
Onsite Monitoring/SDV Queries only found 2% of Critical data issues and 7.5% of overall data issues

Onsite Monitoring cannot detect data fraud and fabrication

30-40% of Budget in Large Global Trials spent on Site Monitoring

> FDA encourages greater reliance on centralized monitoring practices than has been the case historically, with correspondingly less emphasis on on-site monitoring
>
> - US Food and Drug Adminstration

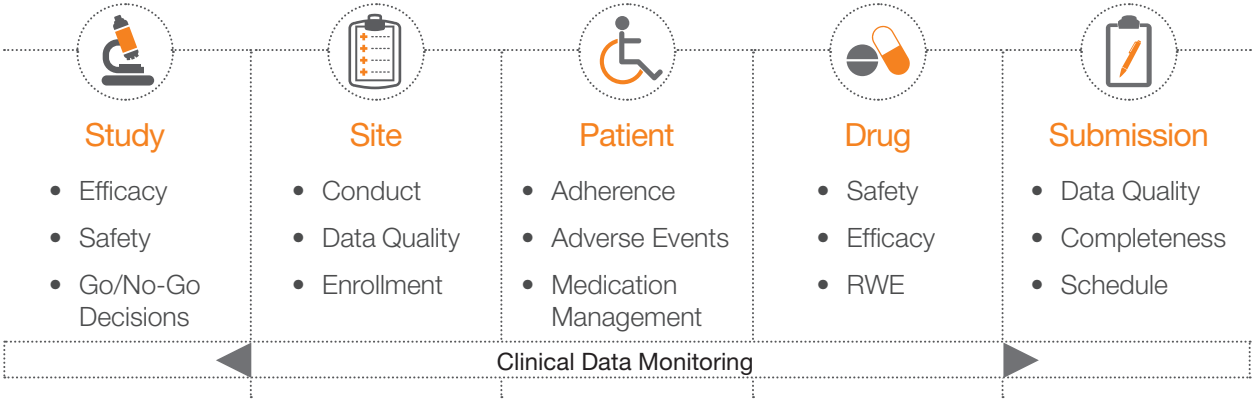
Centralized Data Monitoring provides a statistical, data driven approach by focusing on key metrics and risk indicators and probability based on a risk scoring mechanism. Using this approach 80% of onsite monitoring effort can be spent on 20% of sites which have a higher risk score.




Benefits of Centralized Data Monitoring

# HCL'S POINT OF VIEW ON CENTRALIZED DATA MONITORING

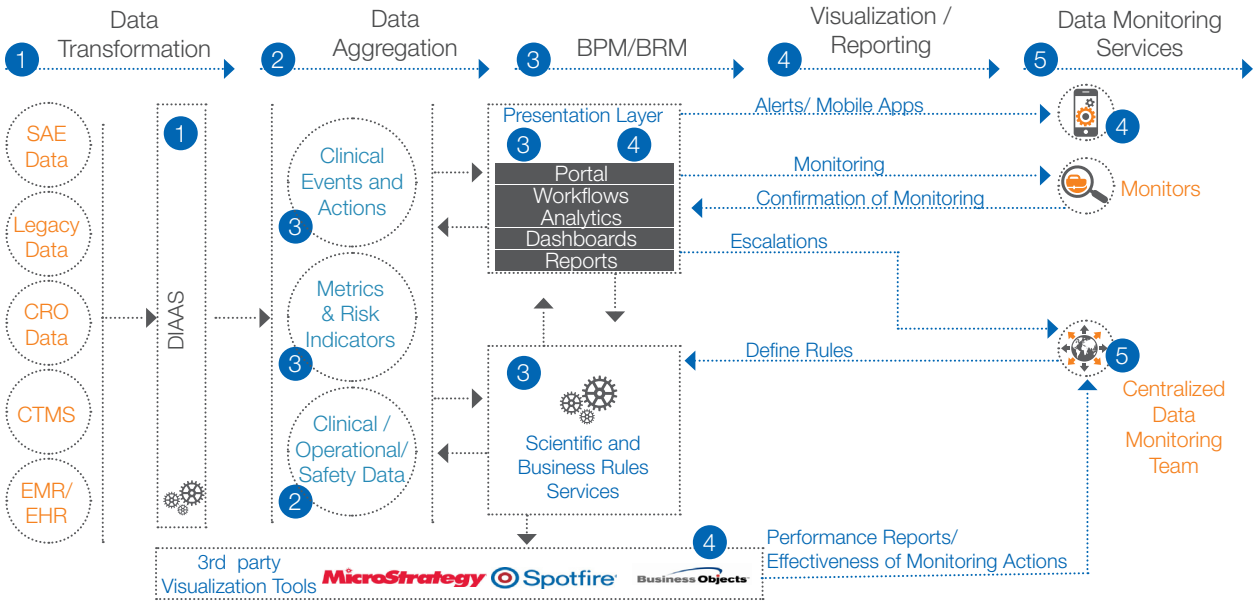
HCL believes that Centralized Data Monitoring is a continuing on-going process playing a critical role in several aspects of Drug R&D process




- Centralized Data Monitoring solution should be focused on multiple areas of Drug R&D process right from Site Selection until Submission, aiding decision making process, improve data quality, reliability of the clinical study and reducing the overall risk of failure in the R&D process.
- Centralized Data Monitoring solution should have the ability to detect un-intentional data errors, data errors from carelessness such as CRF data errors, data fraud as a result of fabricated data values or suppression of values which can be detected only by statistical means such as Analysis of Variance or Correlation analysis.

# HCL'S CENTRALIZED DATA MONITORING SOLUTION

HCL's Centralized Data Monitoring solution is holistic in its approach and can be extended beyond the clinical R&D to integrate with Medical Devices, Electronic Health Records. The solution is cloud based, technology agnostic and can be implemented with industry leading BPM tools and well integrated with CTMS, EDC, Safety systems using the Data Integration as a Service (DIAAS). HCL's extensive experience in Engineering and R&D Services and Mobility services for Life Sciences clients along with a deep knowledge of Clinical R&D processes provides a winning proposition to the client



# Key features of HCL's Centralized Data Monitoring solution are:

- One common framework for multiple business scenarios such as Safety Reconciliation, Data Quality checks,
- Site Performance, Outlier and Fraud Detection
- Data Transformation and Aggregation: Data Integration as a Service (DIAAS) transforms and aggregates data from multiple sources including CTMS, EDC, Safety and Lab into a BRIDG based repository. The solution can be extended to support multiple repositories - SDTM based repository for Clinical data and custom repositories for Operational and Safety data. EMR/EHR integration will be based on HL7 standards into BRIDG. Medical devices will use standards such as Continua/ xHRN. Mobility services will be provided using the industry leading HCL M2M gateway framework
- Business Process / Rules Management: The solution integrates with industry leading BPM applications along with customizable rules engine and also provides the ability to support external statistical rules engine / programs such as SAS, R. The solution can provide near real-time, live data monitoring capabilities. The solution provides ability to provide actionable data monitoring, handle escalations and track actions by Monitors.
- Visualization / Reporting: The framework supports smart devices, e-mail, alerts and integration with industry standard visualization tools
- Data Monitoring Services: HCL provides optional business services in Centralized Data Monitoring providing value added services provided below.


Central Monitors

Team comprising of hybrid skilled data management and analytics personnel with a focus on monitoring

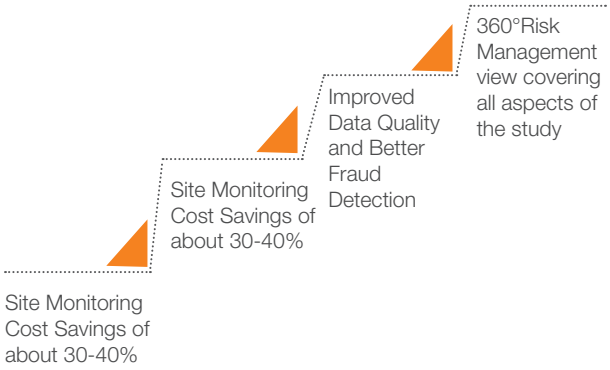
Activities

- Errors in Critical Data Variables
- eCRF retraining requirements
- Query resolution timelines

- Qualitative Assessment of SAEs
- Issues related to Assessments of Critical Study parameters
- Protocol Deviations
- Quality of reporting requirements

- Trend Analysis of Lab data
- Cross site data analysis
- Statistical Sampling for Non-Critical data

# KEY BENEFITS




## HCL – Life Sciences & Healthcare

HCL is one of the market leaders in life sciences & healthcare IT service providers. HCL's clientele includes nine of the top ten global pharmaceutical companies, six of the top ten health insurers, one of the largest payer conglomerates in US and top five service providers in UK. With experienced and certified technology and domain specialists, HCL offers services in the critical areas of drug discovery, clinical development, drug safety, Pharmacovigilance, regulatory compliance, manufacturing and plant automation, sales and marketing, member experience management, fraud, waste and abuse management, ICD-10 transformation and others.

## 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 inception into the global landscape after its IPO in 1999, HCL focuses on 'transformational outsourcing', underlined by innovation and value creation, and offers integrated portfolio of services including software-led IT solutions, remote infrastructure management, engineering and R&D services and BPO. HCL leverages its extensive global offshore infrastructure and network of offices in 31 countries to provide holistic, multiservice delivery in key industry verticals including Financial Services, Manufacturing, Consumer Services, Public Services and Healthcare. HCL takes pride in its philosophy of 'Employees First, Customers Second' which empowers our 95,000 transformers to create a real value for the customers. HCL Technologies, along with its subsidiaries, had consolidated revenues of US$ 6.5billion as on 31st March, 2014 (on LTM basis).

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 95,000 Ideapreneurs are in a Relationship Beyond the Contract™ with 500 customers in 31 countries. How can I help you?

Relationship™
BEYOND THE CONTRACT

HCL