METAMORPHOSING
CLINICAL TRIAL MONITORING

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

HCL

Revolutionising Approach

Industry Perspective

> "No single approach to monitoring is appropriate or necessary for every clinical trial" - USFDA

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.

Clinical Trial monitoring is a major cost component in the conduct of clinical trials. To overcome the challenges of the current industry practices in monitoring, FDA has released new draft guidance to help sponsors in developing and adopting a combination of monitoring strategies.

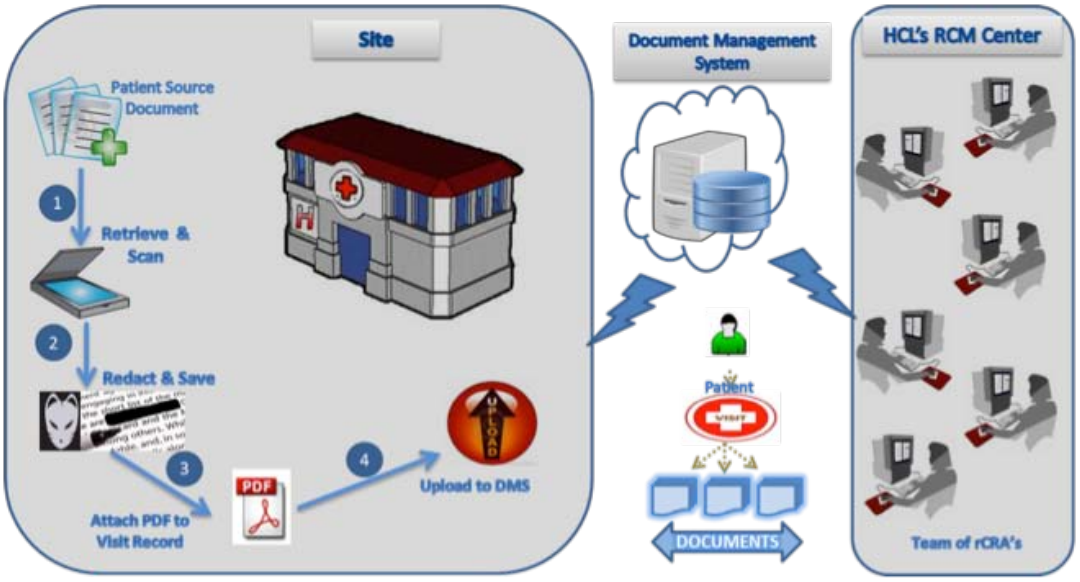
HCL offers Remote Central Monitoring (RCM), a solution to pharmaceutical industry in revolutionising the trial conduct in clinical site monitoring space. It is an innovative approach to clinical trial monitoring encompassing remote monitoring, risk based/ targeted monitoring, adaptive monitoring and onsite monitoring.

HCL Solution

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. In RCM, 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.

While the Risk-based monitoring targets the poor performing sites for intense monitoring and reduces the monitoring visits to good performing sites, Remote Central Monitoring is all about performing the monitoring activities remotely from a central location where CRA's will have access to the source documents of the investigative sites from a central repository. HCL offers Remote Central Monitoring enabled with robust platform and experienced resources.

Our expert committee panel monitors the data flowing from various sites across the world on a continuous basis and evaluates the quality of data and integrity. HCL leverages its CRO experience, technology expertise, backed by the integrated global delivery model and back office process rigor to offer this transforming solution.



Remote Central Monitoring

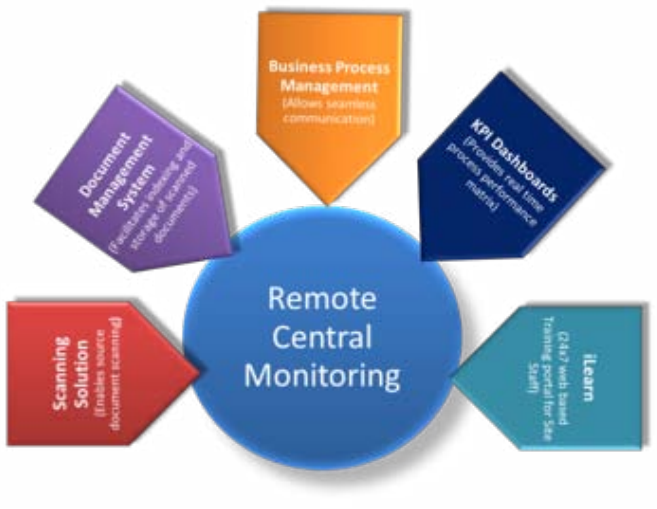
HCL offers RCM to the pharmaceutical industry, leveraging our vast therapeutic and operational expertise in clinical research. One of the key focus areas of the new FDA guidance on risk based approach to monitoring is Centralized/ remote monitoring. It encourages the sponsors to use alternate approaches to monitoring. Most of the traditional monitoring activities which are routinely performed by an onsite CRA can be done by remote CRAs sitting in a central location, as source documents and trial data are made available.

Our solution brings efficiencies to the processes and the resources utilized in clinical trial monitoring. Administrative tasks related to monitoring will be reduced up to 45-65%, as most of the tasks can be completed by remote monitors from a centralized location and using our collaborative tool. Onsite monitor's time can be utilized in an efficient manner and can focus on elements for successful study completion. Eventually centralized monitoring will reduce dependency on on-site monitoring. It is proven by the industry that the fraud detection and data trends can be analysed only by a central monitoring team.

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.

Key Features



- Strong clinical domain with over a decade of trial monitoring experience for remote monitoring
- Tightly integrated technology platform built specifically for RCM with a flexibility to configure the flows
- Seamless collaboration between Onsite team, Centralized team and Sponsors
- Cloud based Technology platforms, which eliminates capital costs
- Provides round the clock feeds, alerts and Issue notifications to CTM Team's and Senior Management of Sponsor
- Customizable alerts for all user levels, providing pulse of study/site performance
- Interactive and flexible web based training for all the operational staff through-out the study conduct

How RCM can help your company?

RCM solution benefits the pharmaceutical industries with an integrated approach.

- Improves the quality and integrity of data through constant data verification
- 50-75% of onsite monitoring tasks can be done remotely by rCRA (can be customised based on sponsor's requirements)
- Focused recruitment strategies
- Improves quality and integrity of data
- Ability to meet the trial timelines with improved site performance
- Total visibility of study and site performance
- Substantial savings in onsite monitoring costs, through optimized resource utilization