PERCEPTIVE MyTrials®

A PAREXEL® eClinical Platform

DATA-DRIVEN MONITORING

NEXT GENERATION RISK-BASED MONITORING

25% *reduction in* CLINICAL COSTS

>225 *studies using* DATA-DRIVEN MONITORING

Awarded

Clinical Innovator of the Year

from Partnerships in Clinical Trials

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What It Is

Data-Driven Monitoring helps studies leverage data to assess risk and direct monitoring activities, manage data quality and workload assignments at any given site.

At PAREXEL, the Data-Driven Monitoring operational model is built on three pillars: adaptive monitoring, data surveillance and clinical data review. It uses data visualization and analytics tools to measure key risk indicators and trigger interventions, uses sophisticated risk-assessment methodologies and provides remote/centralized monitoring to manage sites and clinical data interrogations.

PAREXEL's DDM operational model works not only when PAREXEL provides Medical Monitoring or Biostatistics services for a study, but also when a Sponsor retains or outsources these responsibilities to a third-party.

PAREXEL is a pioneer in developing targeted monitoring activities. Starting in 2001, PAREXEL designed, built, tested and refined a range of data-driven monitoring approaches in all study phases (I-IV) across 15 therapeutic categories. We have helped clients implement the right monitoring interventions, deliver the tools to plan and schedule those actions and assures monitoring activities deliver study results of sufficiently high scientific and statistical integrity to support decision-making at all levels of the clinical development enterprise. In 2015, Partnerships in Clinical Trials (PCT) recognized PAREXEL as Clinical Innovator of the Year for its innovations in the field of risk based monitoring.

About The Solution

Many pharmaceutical companies and CROs are focused on finding ways to identify, quantify and decrease risk at investigational sites during clinical trials. To calculate risk, a number of eClinical metrics can be used including recruitment rates, serious adverse events, data queries, withdrawal rates, among others. Grouping these metrics into risk categories allows users to identify problem areas.

DATA-DRIVEN MONITORING

BENEFITS

- Reduce risk and costs while improving study quality
- Enables data-driven decisions across project delivery continuum
- Enhances study data integrity and scientific credibility
- Increases study visibility and oversight
- Delivers predictability of outcomes that withstand regulatory scrutiny

KEY FEATURES

- Combines multiple technologies with remote/centralized monitoring services to deliver a complete solution
- Visualizations of site risk, workload and monitoring-relevant data
- Monitoring activities oversight and delivery of decisions during study
- Enables management of sites' operational performance with scientific data for signals, trends, and outliers/anomalies
- Integrates data from multiple systems such as IMPACT® CTMS, DataLabs® EDC, ClinPhone® RTSM and third-party applications
- Builds on expertise gained from more than 225 studies that have used at least one risk-based monitoring tactic

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The first pillar of PAREXEL's Data-Driven Monitoring is adaptive monitoring, which uses data from an eClinical suite to construct a site risk score to identify sites that are at high risk. Risk scores are used to determine which monitoring actions to take. Once a monitoring intervention is complete, PAREXEL'S advanced visualizations allow monitoring teams to assess how effective the intervention was in addressing the risk.

In addition, adaptive monitoring measures outstanding workload to provide a more holistic view of how monitoring needs to be managed for any given site. Site monitors duties range from source data verification to reviewing the site's regulatory documentation. These activities can be quantified to determine workload at the site.

The data visualizations and the record of activities delivered provide regulatory authorities and other stake-holders full visibility into fluctuations of risk, workload, and a full justification for the decisions taken throughout the life of the study.

The second pillar of PAREXEL's Data-Driven Monitoring, Data Surveillance helps project teams deliver study results of sufficiently high scientific and statistical integrity to support clinical decision-making at all levels of the development program.

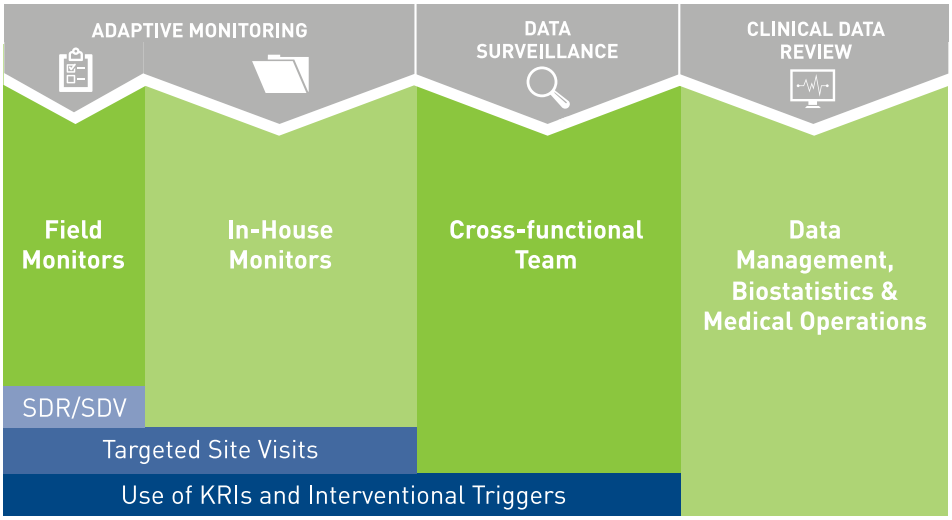
PAREXEL's Data Surveillance project teams provide clinical monitoring, protocol deviation review, data management/cleaning, medical review, statistical review to identify data trends, outliers and anomalies, and determine the most effective and efficient means of issue resolution.

The visualizations allow for the easy review and analysis of a wide range of study safety and efficacy parameters including adverse events, patient demographics, clinical events, physical exam, disposition, and patient profiles.

The third pillar of PAREXEL's Data-Driven Monitoring, Clinical Data Review leverages data management metrics and related data quality indicators to provide real-time and ongoing assessments of data quality. Clinical Data Review eliminates low-value data cleaning efforts and ensures an appropriate focus on errors that matter at the data point, subject and protocol levels. Data routinely reviewed and interrogated includes protocol deviations, AEs/SAEs, query rates, query aging, and timeliness of site entry into EDC (missing pages), among others.

PAREXEL's Data-Driven Monitoring solution enables sponsors to improve decision-making, assess workload, better allocate monitoring resources, and decrease risk and costs.

The Core Elements of Data-Driven Monitoring



A complete clinical trial monitoring solution combines multiple clinical trials technologies with remote/centralized monitoring to improve decision-making, assess workload, allocate monitoring resources and decrease risk and costs.

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