Infosys
be more

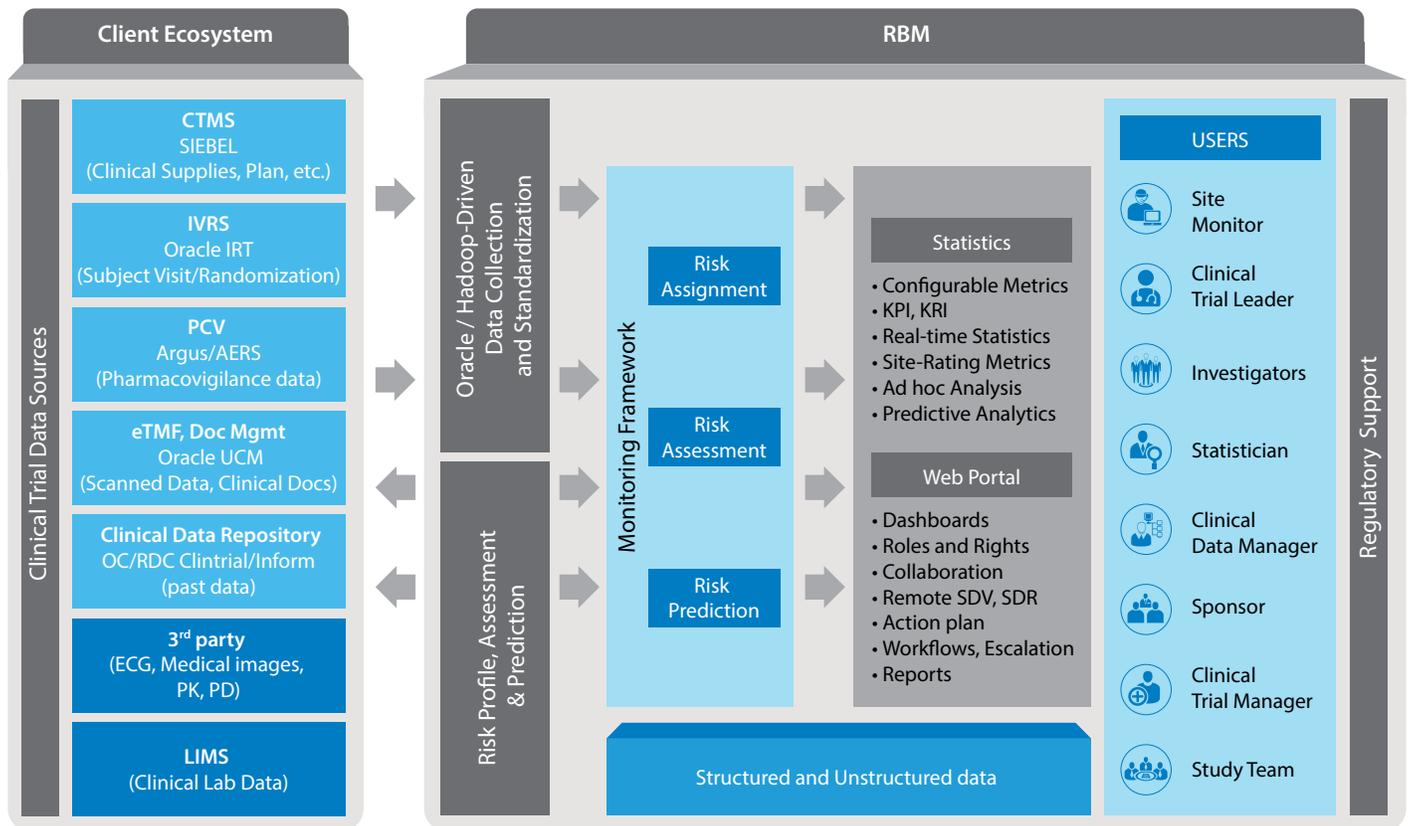## Risk-Based Monitoring (RBM), a mechanism to optimize clinical trial monitoring process

Life sciences organizations are faced with a multitude of challenges:

- Increased pressure on pharmaceutical companies to improve time-to-market and optimize cost

- Pressure to lower cost of clinical trials without compromising on quality

- Need to improve efficiency of the entire clinical trial monitoring value chain and reduce 100% dependency on Source Data Verification (SDV).

- Need to improve visibility into different dimensions of study-data

The Infosys RBM solution attempts to improve the clinical and commercial success for life sciences organizations. It helps organizations to focus on critical study-parameters and relies on a combination of remote and onsite monitoring. The solution has built-in predictive analytical capabilities, and uses statistical modeling and machine learning techniques to provide early insights into risks for a variety of predetermined categories for the ongoing trials.
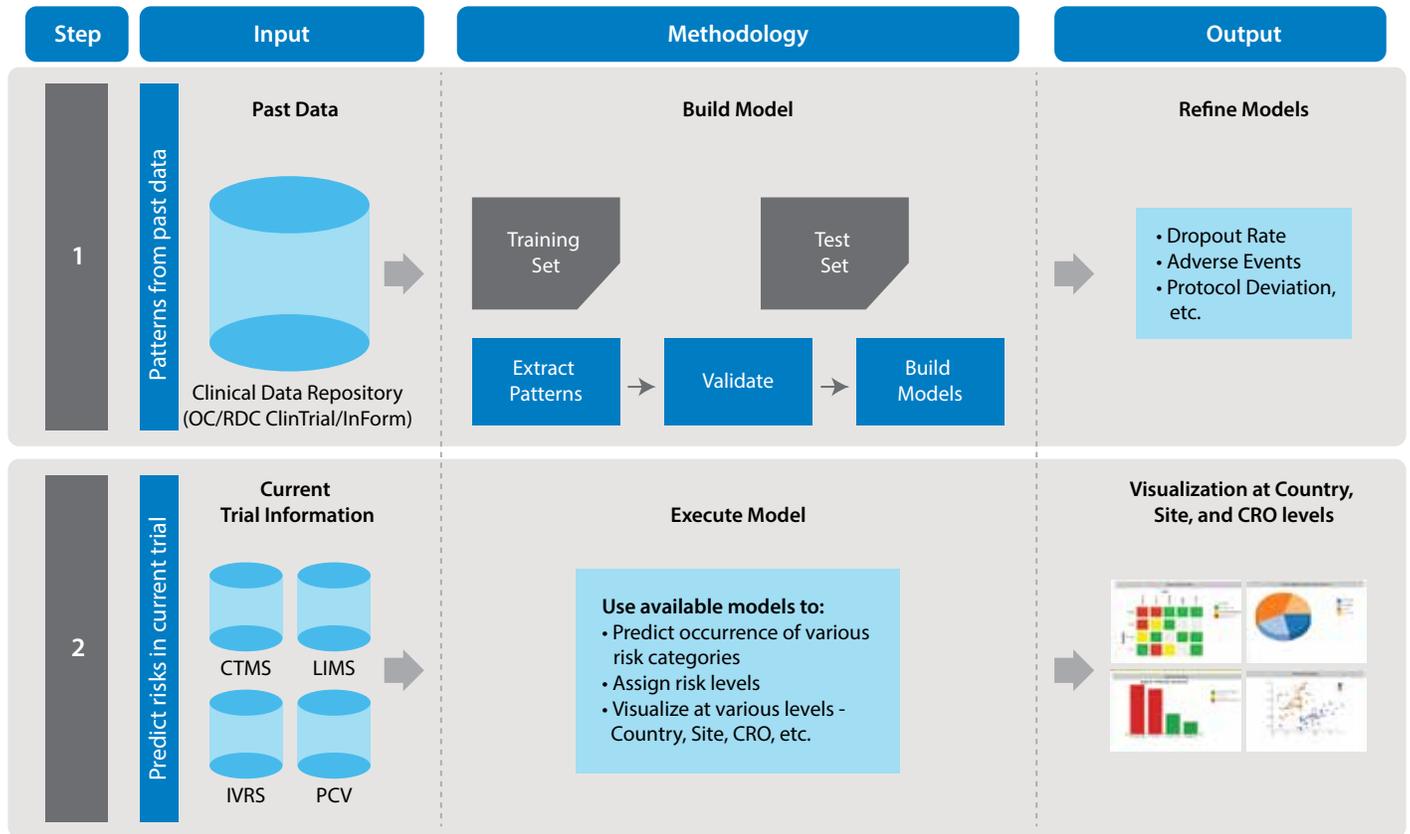
Salient features:

- Uses risk-based, critical data focus

- Central/near real-time monitoring

- Predictive Analytics driven by pattern matching, machine learning, and clustering algorithms

- NLP-based components used to mine text and extract relevant data from past reports, both structured and unstructured

- Visualization Engine to provide better insights into the data analysis

- Technology solution scalable, extensible, and with the ability to process large amounts of data

Client Ecosystem

RBM

Clinical Trial Data Sources

CTMS
SIEBEL
(Clinical Supplies, Plan, etc.)

IVRS
Oracle IRT
(Subject Visit/Randomization)

PCV
Argus/AERS
(Pharmacovigilance data)

eTMF, Doc Mgmt
Oracle UCM
(Scanned Data, Clinical Docs)

Clinical Data Repository
OC/RDC Clintrial/Inform
(past data)

3rd party
(ECG, Medical images, PK, PD)

LIMS
(Clinical Lab Data)

Oracle / Hadoop-Driven Data Collection and Standardization

Risk Profile, Assessment & Prediction

Monitoring Framework

Risk Assignment

Risk Assessment

Risk Prediction

Statistics
- Configurable Metrics
- KPI, KRI
- Real-time Statistics
- Site-Rating Metrics
- Ad hoc Analysis
- Predictive Analytics

Web Portal
- Dashboards
- Roles and Rights
- Collaboration
- Remote SDV, SDR
- Action plan
- Workflows, Escalation
- Reports

Structured and Unstructured data

USERS

- Site Monitor
- Clinical Trial Leader
- Investigators
- Statistician
- Clinical Data Manager
- Sponsor
- Clinical Trial Manager
- Study Team

Regulatory Support

Predictive Analytics of Risk Management

The predictive analytics component extracts data from clinical data repository. It uses pattern matching, statistical modeling, and machine learning methods to build appropriate models for predetermined categories that need to be predicted, for example, patient dropouts. During model execution, data for ongoing clinical trials is acquired and used for predicting the outcome of different risk categories (site, demographics, dropouts, etc.)

Step	Input	Methodology	Output

Step 1

Patterns from past data

Past Data

Clinical Data Repository (OC/RDC ClinTrial/InForm)

Build Model

Training Set → Test Set

Extract Patterns → Validate → Build Models

Refine Models

- Dropout Rate
- Adverse Events
- Protocol Deviation, etc.

Step 2

Predict risks in current trial

Current Trial Information

CTMS LIMS IVRS PCV

Execute Model

Use available models to:
- Predict occurrence of various risk categories
- Assign risk levels
- Visualize at various levels - Country, Site, CRO, etc.

Visualization at Country, Site, and CRO levels

Solution Benefits

- Allows early diagnosis of risks during design, conduct, and close out of clinical interventional studies

- Pulls in data and metrics from trial management systems, CDM systems, as well as Safety management systems, offering a 360° view of risks

- Reporting of risks during trial conduct (study, site, and patient levels) that helps in recalibrating the risk profile of a site

- Predictive analytics engine to support clinical trial risk management

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