







Quadrant<sup>™</sup> enables a pharmaceutical, biotech or contract research organization to ensure compliance, increase efficiency, improve quality and reduce costs by centralizing and integrating key quality processes globally, including management and reporting of quality issues, compliance, productivity, workload, risk based monitoring and corrective and preventive actions(CAPAs) to provide closed-loop traceability between processes.





### Modules

- Q-Safety | Adverse event case processing optimization
- Q-Clinical | Risk Based Monitoring\*

# **CAPA Management**

- Closed Loop traceability using workflow based process to initiate CAPAs
- Work-list based review mechanism

## **Highly Configurable**

- Extensible business rules for changing business needs and requirements
- Code list based KPI dictionary
- Threshold limits at user, workflow group and site level
- Automated forms for continuous process improvement

### Web based User Interface

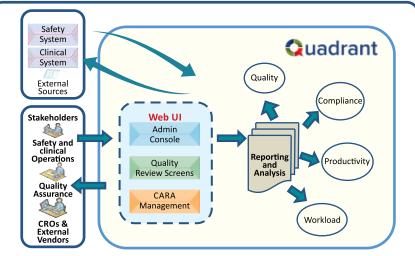
- Single sign on, role based screens
- Bulk case update fix from single screen

# **Reporting Engine & Analytics**

- Generate daily, monthly and Q reports
- Pre-defined critical fields for KPI measurement
- Visualization for real time analytics
- Executive dashboards for continuous process improvement
- Quality alerts to end user & manager including threshold alerts

### Compliance

- Compliant with 21 CFR Part 11
- Signature and justification on any data change



## **Accelerated Implementation**

Vitrana provides an accelerated path towards implementing the Quality Management System at its client's premise or on the cloud. Detailed project plan for seamless integration with existing business processes and adoption by the case processing and quality teams

