

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

The diagram illustrates the system architecture. On the left, 'External Sources' (Safety System, Clinical System) and 'Stakeholders' (Safety and clinical Operations, Quality Assurance, CROs & External Vendors) interact with the central 'Web UI'. The 'Web UI' consists of an 'Admin Console', 'Quality Review Screens', and 'CARA Management'. This central hub feeds into 'Reporting and Analysis', which then outputs to various metrics: 'Quality', 'Compliance', 'Productivity', and 'Workload'. The Quadrant logo is also present in the top right of the diagram area.

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

Phase-I

Phase -II

Dimensional data model for high performance analytics

- **Out-of-the-box intuitive user experience** for configuring validation rules, real-time dashboards and data remediation

* Product Roadmap