QUINTILES®

Navigating the new health

Trends in trials and the response of the industry to ensure quality

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CLINICAL OPERATIONS
QUALITY MANAGEMENT

clinical | commercial | consulting | capital

Challenges and actions

The Environment:

- Increased protocol complexity
- Biopharma cost cutting/savings, need to increase productivity
- Changing regulatory environment, increased scrutiny
- Research professional resource availability
- Investigator availability (time, quality)

Our actions to ensure QUALITY

Quality Assurance	•Adherence to quality standards & ethical behavior •Audits for systems, procedures and projects
Quality Management	•Site process improvement •Activity driven by early risk signals •Proactive and preventive approach
Monitoring strategy	•100% SDV •Partial SDV •Risk based monitoring
Systems	•CTMS •eTMF, •eSOP
Processes/ SOPs	•Study specific risk and quality plan •SOPs up to date •Knowledge and Compliance check
Training	•Therapeutic and protocol •GCP and SOP •ASV and knowledge assessment
Resourcing	•Timely per therapeutic area •Reasonable workload •Line Manager support

Global Clinical Operations Quality Management

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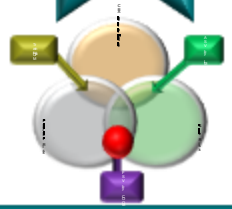
Collaboratively drive a quality culture, promote accountability, improve processes & compliance, proactively manage risk to safeguard patient wellbeing and support the business



Proactivity & Prevention

- Regional project and country/site level risk assessment
- Focused activities by KRI (ASV, FSV etc.)
- Drive RC analysis
- Recommend process and/or compliance improvement - site, project, regional or global level
- Implementation of recommendations

Intelligence Management

- GCP accreditation
- Lessons Learned
- SDV and Site Compliance Lean Six Sigma project implementation activities
- Input to SOP, Training Curriculum and other work streams, projects
- Training and workshop delivery

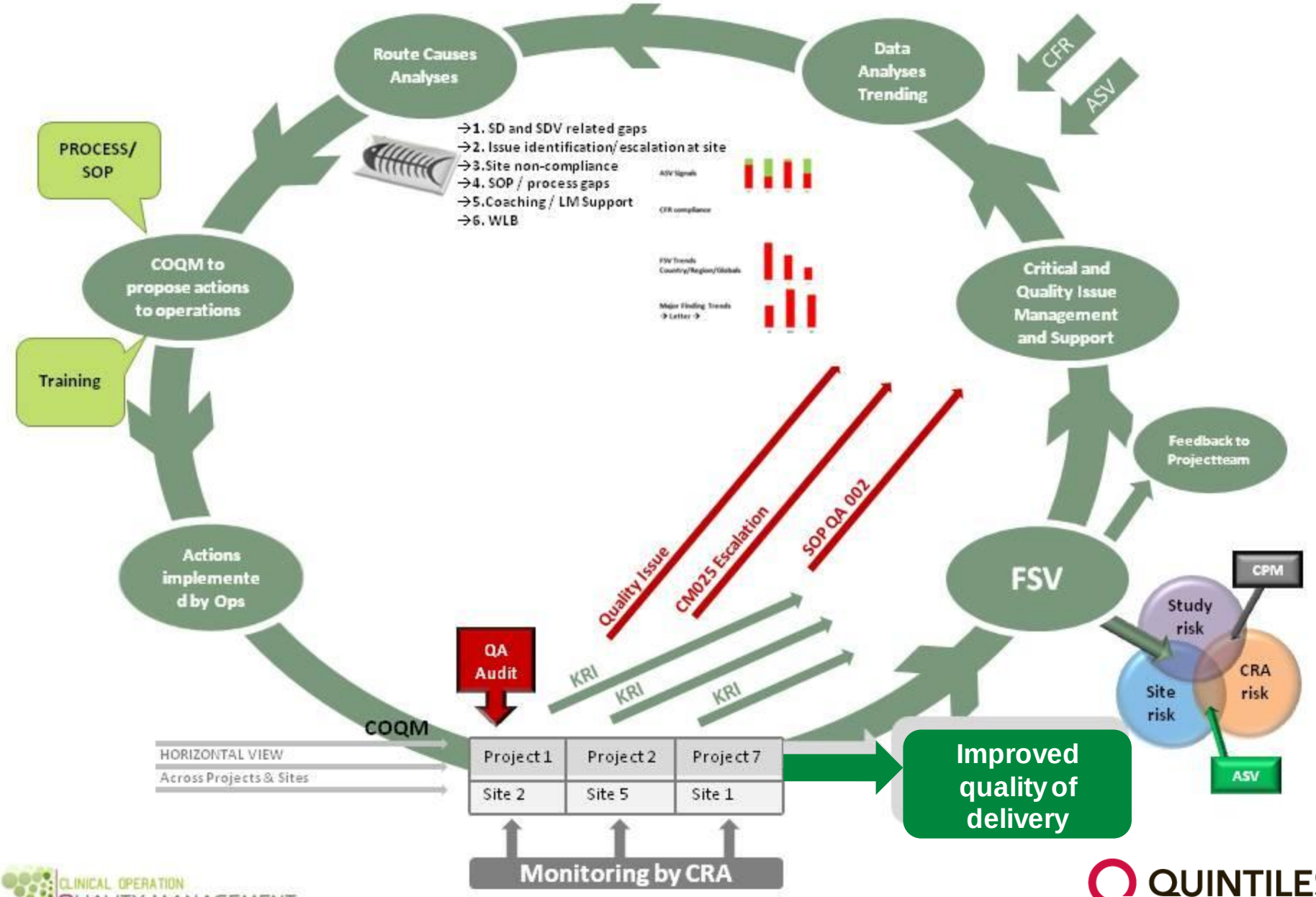
Audit, Inspection and QI management

- Inspections readiness
- Critical Event Follow up and Closure
- Audit and Inspection support
- CAPA support and compliance check
- QI resolution support

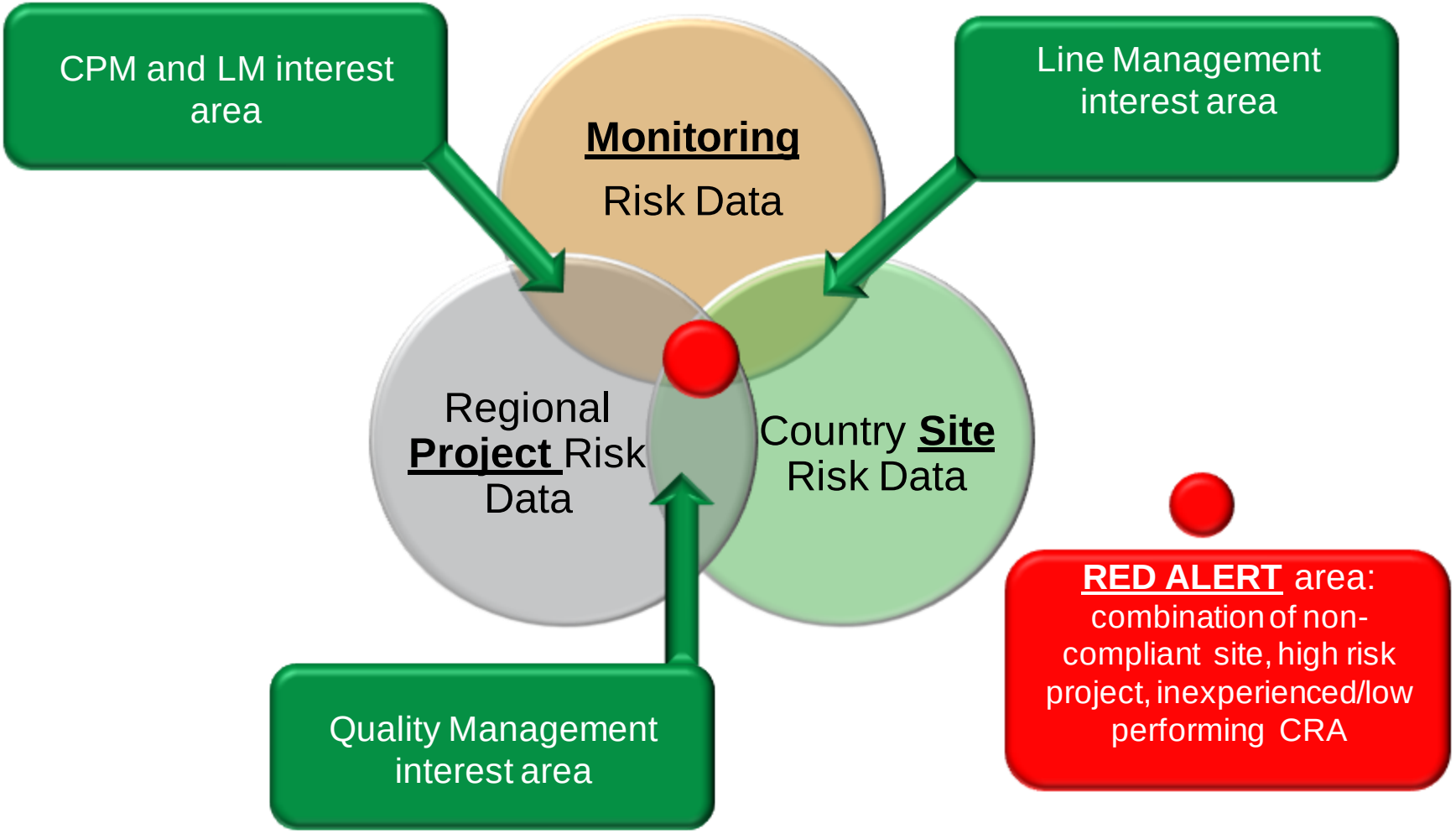
Partnering other units and customers

- Customer and project/program specific QC request support
- Site level GCP and protocol compliance support
- Sales material re Quality
- Region´s specific quality plans
- Partnering Clinical Project Management, Integrated Site Services

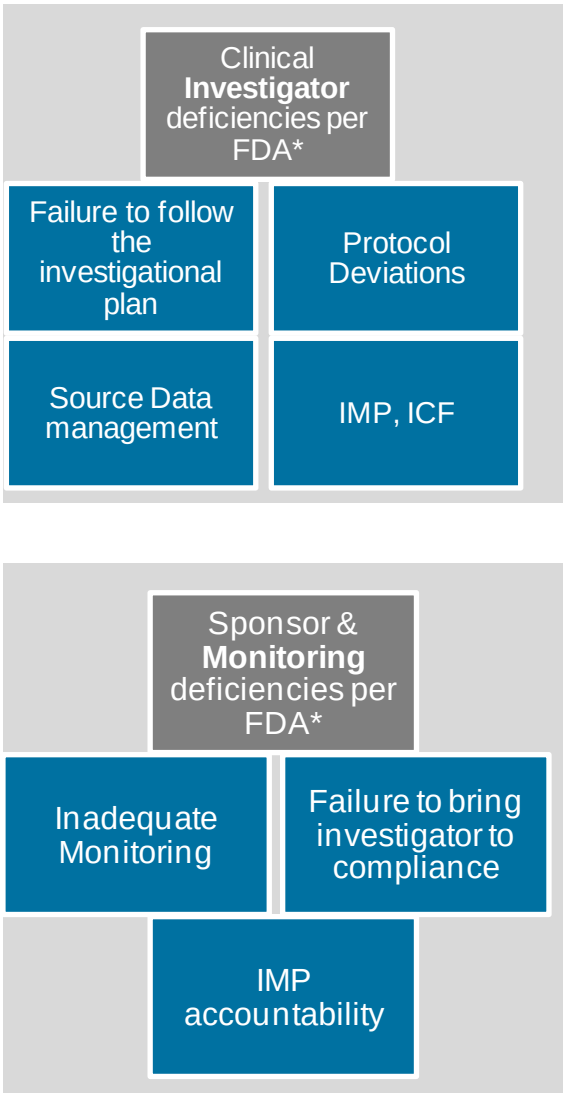
QUALITY MANAGEMENT PROCESS



Roles, areas and focused activities



Quality Improvement Activities in Clinical



Actions/Activity
Global Clinical Operations Quality Management Plan: 1. early **project**, **site** and **resource** risk driven model followed by **focused** activities 2. country, regional and global RCA based on Clinical, QA, QM and compliance data
Source data verification skills (L6S): Improve SDV (monitoring) skills of CRAs
Site compliance (L6S): 1. Identification and resolution of site non-compliance issues 2. To gain greater control over process compliance at sites 3. Improved data quality delivered by sites 4. Quality related measures in selecting sites for studies.
Clinical SOPs and process review: 1. business processes are current, eliminate process gaps 2. Define roles and responsibilities 3. Reduce redundancy and complexity
GCP training and accreditation

* FDA, Bioresearch Monitoring (BIMO) Metrics, FY´10