Quality Tolerance Limits
More Critical Aspects of the Clinical Trial with Very Less Visibility

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Meet the Team

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Definition

QTL

- A value/threshold associated with trial parameter
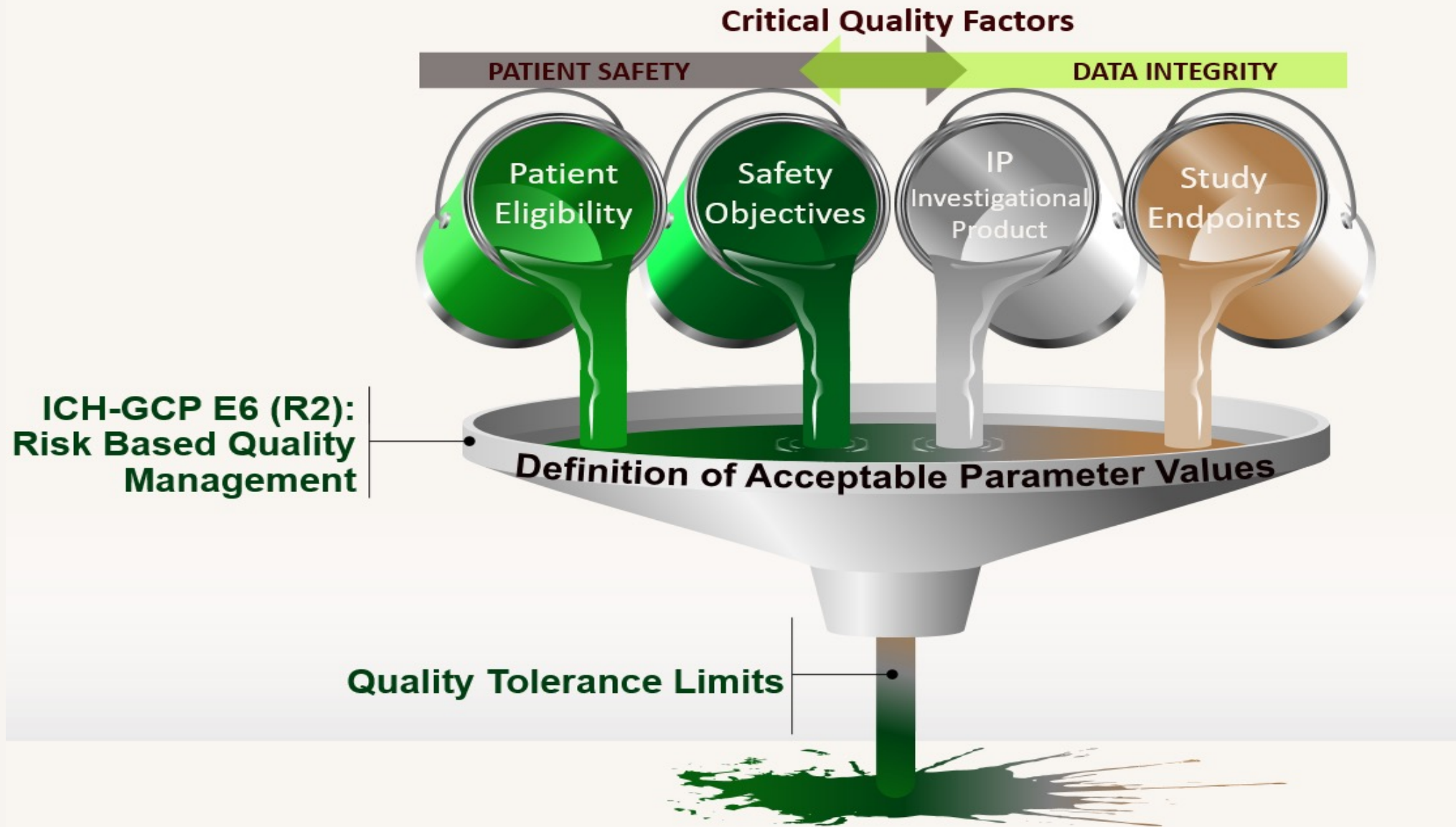- Critical to quality
- Impact participants safety
- Reliability of trial results
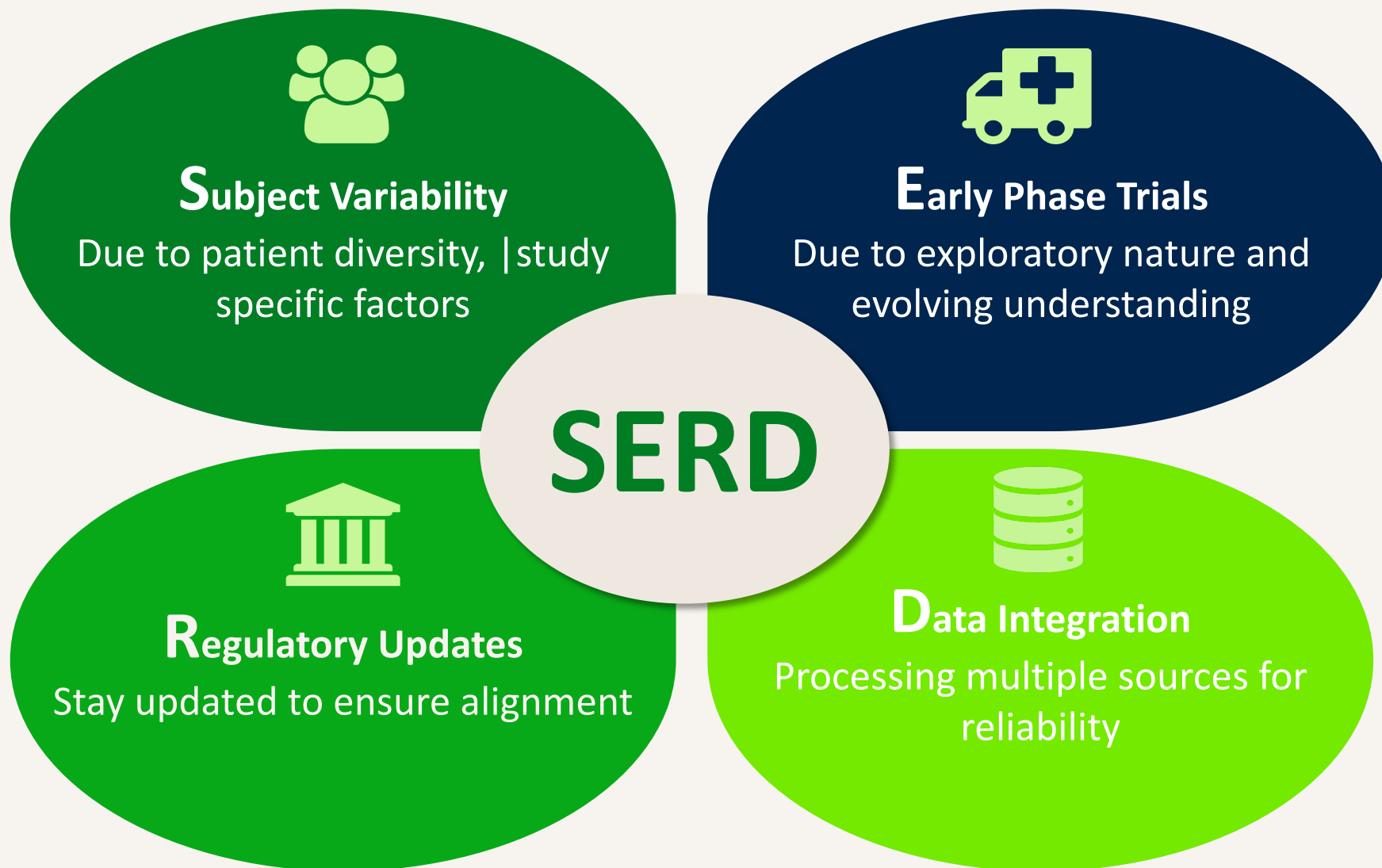- Early identification of any risks
- Part of Risk Based Quality Management
- Specifically mentioned in ICH-GCP E6 (R2)

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Focus areas

Considerations to define QTLs

Subject Variability
Due to patient diversity, |study specific factors

Early Phase Trials
Due to exploratory nature and evolving understanding

SERD

Regulatory Updates
Stay updated to ensure alignment

Data Integration
Processing multiple sources for reliability

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QTL's Significance

Ensuring Data Integrity

- Detects and addresses data errors, inconsistencies, or outliers

Protecting Patient Safety

- Any conclusions from the trial are based on reliable information, minimizes potential risks.
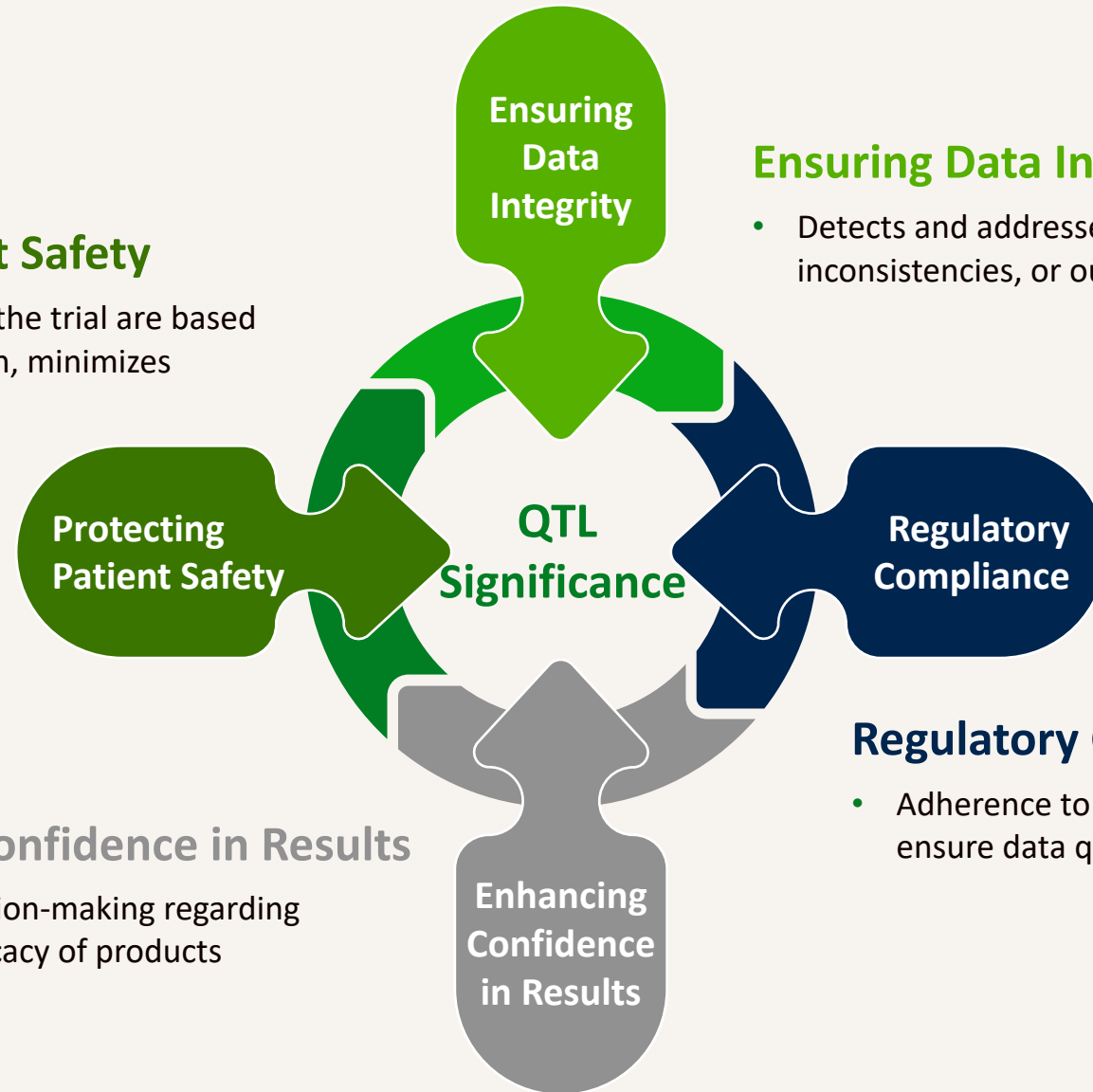
Ensuring Data Integrity

Protecting Patient Safety

QTL Significance

Regulatory Compliance

Enhancing Confidence in Results

Regulatory Compliance

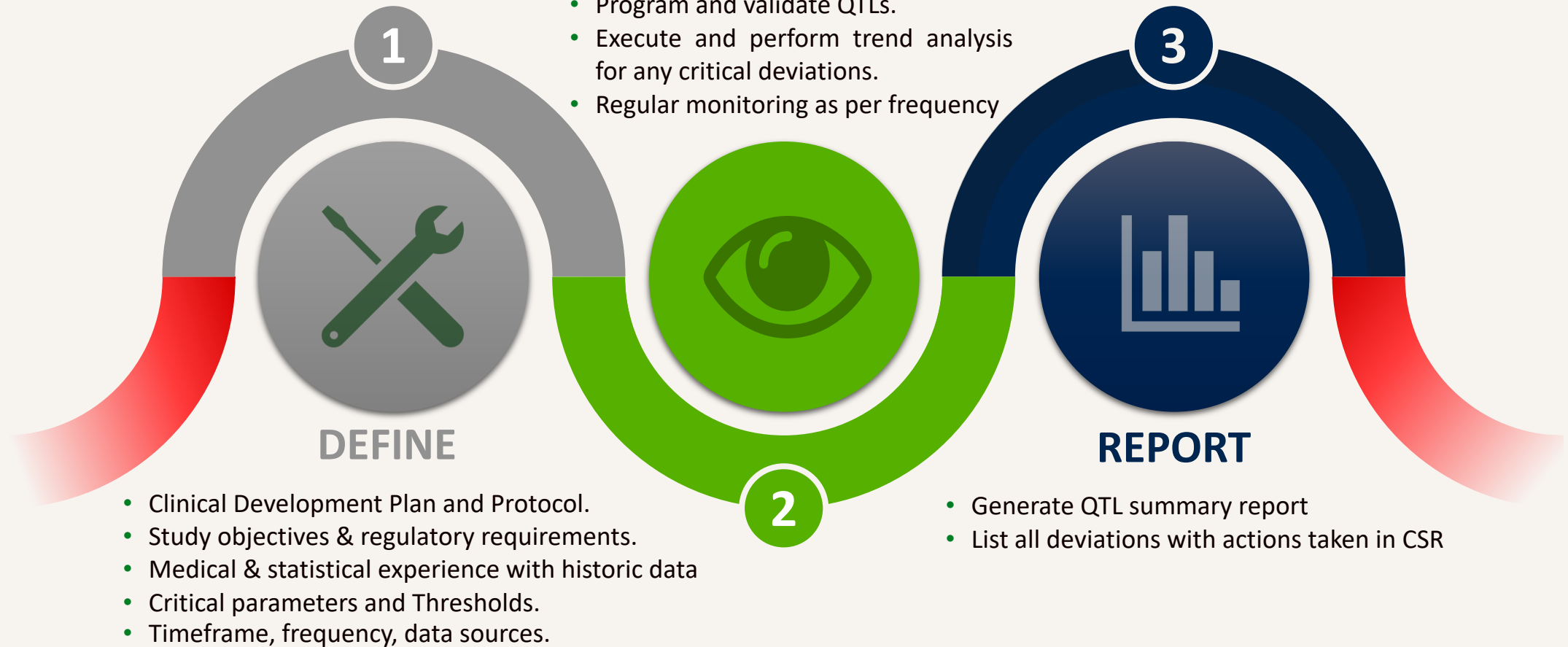- Adherence to regulatory authorities to ensure data quality and validity

Enhancing Confidence in Results

- Supports decision-making regarding safety and efficacy of products

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Framework to Implement QTLs

MONITOR

- Program and validate QTLs.
- Execute and perform trend analysis for any critical deviations.
- Regular monitoring as per frequency

DEFINE

- Clinical Development Plan and Protocol.
- Study objectives & regulatory requirements.
- Medical & statistical experience with historic data
- Critical parameters and Thresholds.
- Timeframe, frequency, data sources.

REPORT

- Generate QTL summary report
- List all deviations with actions taken in CSR

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QTLs vs KRIs

QTLs

- Quality Tolerance Limit
- Process driven
- Higher-level indication of quality
- Traced at study level
- ~ 3 to 5 per study
- **Report** important deviations in CSR

KRIs

- Key Risk Indicator
- Risk driven
- Monitored during study progression
- Traced at site & country level
- ~ 15 to 20 per study
- **Monitor** quality performance during study progression

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Standards & Automation Scripts

Benefits

- Minimum study specific effort
- Controlled version tracking
- Automated executions/runs
- Less turn arounds with less resources

Standard QTLs

- Identified most used QTLs across TAs
- Library implementation

Methodology

- Adaption of scripts to handle study specific thresholds
- Automated scheduled jobs for maintenance

STANDARDS & AUTOMATION

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Thank You!!

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