



## Protocol Optimization

- Protocol considerations to achieve (CDISC) data compliance
- Ensuring assessments are appropriate for population & objectives
- Planned analyses targeted to provide data fit for purpose & intended audience

## Database Design

- Optimized for quality data
- Efficiently designed for level of data critical for analyses
- Designed to fully facilitate CDISC standards

## Validation of Data Capture

- Appropriate tools & licenses
- Data exports
- Case report form
- External data sources

## Quality-Driven Data Acquisition & Instream Cleaning

- Ensuring sites adhere to data entry standards
- Query identification & resolution (including with P21E)
- Algorithmic rater surveillance & rater remediation
- Identification & proactive mitigation of problematic data trends, anomalies, & outliers

## Database Closure & Reporting

- Proactive planning for efficient database lock
- Blinded Data Review Meeting
  - Address remaining data issues
  - Update statistical analysis plans
  - Clinical review & interpretation of scale data

## ACTIONABLE DATA

Critical insights and robust evidence to secure investments, support regulatory submissions, and drive informed decision-making for future development.

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