

DATA LIFECYCLE AT CRC



[BIOSTATISTICS] [DATA MANAGEMENT] [RATER SERVICES]

EXPERT DESIGN INPUT TO
MEET STUDY OBJECTIVES

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

ALL ENCOMPASSING,
MULTI-LAYERED DESIGN REVIEW

DATABASE DESIGN

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

VALIDATION FOR SUPERIOR
DATA OUTPUTS

VALIDATION OF DATA CAPTURE

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

VALIDATION FOR SUPERIOR
DATA OUTPUTS

DATA ACQUISITION & INSTREAM DATA 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

STREAMLINED COLLABORATION
ENHANCES TLFs & CDISC
PACKAGE QUALITY

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

CROSS-FUNCTIONAL COLLABORATION

Biometrics, Rater Services, & Clinical Operations
Work Together to Ensure Data Quality

DATA TRANSPARENCY

Sponsor-Access to Real-Time Data
Customized Reports to Meet
Sponsor Needs

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

