



# Data Publishing Compliance for Clinical Research FDA Submissions

*“Essential processes, people and tools for managing Clinical Research data submissions to the FDA”*

*dpC for Clinical Research enables organizations to achieve improved quality, faster cycle times and reduced costs for their FDA data submissions.*

*dpC for Clinical Research clients realize measurable benefits through process improvements with respect to data governance, change management, data quality, compliance management, quality assurance, decision making and data operations.*

## SUPPORTS

- **CDISC DATA STANDARD**
- **MULTIPLE DATA SOURCE FORMATS**
- **CONFIGURABLE COMPLIANCE RULES**
- **SEAMLESS CORRECTION**
- **CUSTOMIZABLE DATA MAPPINGS**
- **SIX SIGMA PROCESS CONTROLS**
- **AUDIT TRAILS & REPORTING**
- **DEFECT-FREE DATA PUBLISHING**
- **COMMUNICATION**
- **PERFORMANCE METRICS**
- **RRRRR**

## dpC for Clinical Research - FEATURES

- Pre-Loaded FDA Clinical Research CDISC Data Standards
- Operational Monitoring to ensure data is publishing to FDA
- Notification and Maintenance of FDA CDISC Data Standards changes
- Mappings of FDA CDISC Data Standards to the Data Source screen and field
- Publishes only "defect-free" data to the FDA
- Automated daily reports via email for defects, corrections and publishing
- Closed-Loop defect correction process
- Data Quality Performance Metrics for defects and mean-time-to-repair
- Utilizes Six Sigma Process Controls
- Defect Correction Management plug-in for use in the data source application
- Drill-Down Defect Analytics
- Historical Transaction & Defect Repository for auditing/reporting purposes
- Suite of Administrative, Data Source and Enterprise reports

## dpC for Clinical Research - BENEFITS

- Promotes use and understanding of FDA CDISC Data Standards
- Eliminates business process interruptions
- Provides greater assurance as to the accuracy, security and privacy of data
- Reduces manual tasks such as ad-hoc reports, rework, extracts, custom programming/scripts and visual data inspection
- Provides information to enforce Data Governance policies and procedures
- Shortens cycle time for defect identification and correction
- Reduces help desk calls
- Enables data ownership and accountability—tracks data offenders
- Improves visibility, tracking, communication and measurement of data quality performance
- Results in faster delivery of quality data

## ABOUT PROACTIVE DATUM

ProActive Datum LLC is a wholly-owned subsidiary of ProActive School, Inc. (PAS) which was formed to focus solely on the delivery and support of Data Publishing Compliance client needs. Since 2005, PAS has been providing Data Management solutions to clients utilizing the Data Publishing Compliance (dpC) service solution which has evolved through client production usage to the proven, feature rich service solution it is today.

For additional information, visit [www.ProActiveDatum.com](http://www.ProActiveDatum.com) or email [info@ProActiveDatum.com](mailto:info@ProActiveDatum.com).