TradeCraft Statistical Programming and Biostatistics Solutions

ENABLING AND EMPOWERING DECISION-MAKERS TO MAKE EARLY AND INFORMED DATA-DRIVEN DECISIONS.

OUR REAL-WORLD KNOWLEDGE AND INNOVATIVE, TECH-ENABLED PRACTICES HELP YOU TELL YOUR DATA'S STORY.

cdisc Clear Data. Clear Impact. Proud Member

WHO WE ARE

The TradeCraft Clinical Research Team has years of combined Biostatistical and Statistical Programming experience, in all phases of clinical development for both NDA and BLA submissions. Our agile team has attracted exceptional talent from across the industry. Our distributed business model and cloud-based infrastructure enable us to recruit this talent from across the country. We work in many therapeutic areas, specializing in oncology clinical trials.

WHAT WE DO - BIOSTATISTICS SERVICES

We partner with our clients to provide statistical analysis and programming services across the product development lifecycle.

We are involved in every step of clinical research including trial design, protocol development, monitoring and data management, data analysis, and reporting.

CLINICAL DEVELOPMENT PLANNING

When a team is preparing for first-in-human trials, a statistician should review and offer input into the protocol, particularly the statistical methods section, to ensure accurate power/sample size estimation, understand the application of relevant data standards, facilitate the creation of the companion Statistical Analysis Plan (SAP) and the Study Data Standardization Plan (SDSP) that is required for submission.

We collaborate closely with clients and their partner teams to offer this expertise. If a team is already working with a CRO, we can help them get more from their partnership. We review data output to ensure compliance and eliminate waste and rework.

We also support the following critical activities and the creation of essential data deliverables.

- Develop Statistical Analysis Plan (SAP) with mock tables
- Perform interim analyses or coordinate with Independent Data Monitoring Committees (IDMC)
- Create data deliverables to support Annual / Periodic Reporting
- Conduct statistical modeling / exploratory analyses
- Statistical reporting and publications
- Support finalization of clinical study reports
- Planning and development of ISS / ISE / Meta-Analysis
- Conduct due diligence
- Support statistical components of responses to agency inquiries

WHAT WE DO – CLINICAL PROGRAMMING SERVICES

The TradeCraft team becomes a natural extension of our client R&D teams, offering specialized expertise when it is needed. We have practical knowledge of the entire data lifecycle, CDISC data standards, and creating CDISC-compliant submission deliverables.

CDISC COMPLIANT SUBMISSION DELIVERABLES

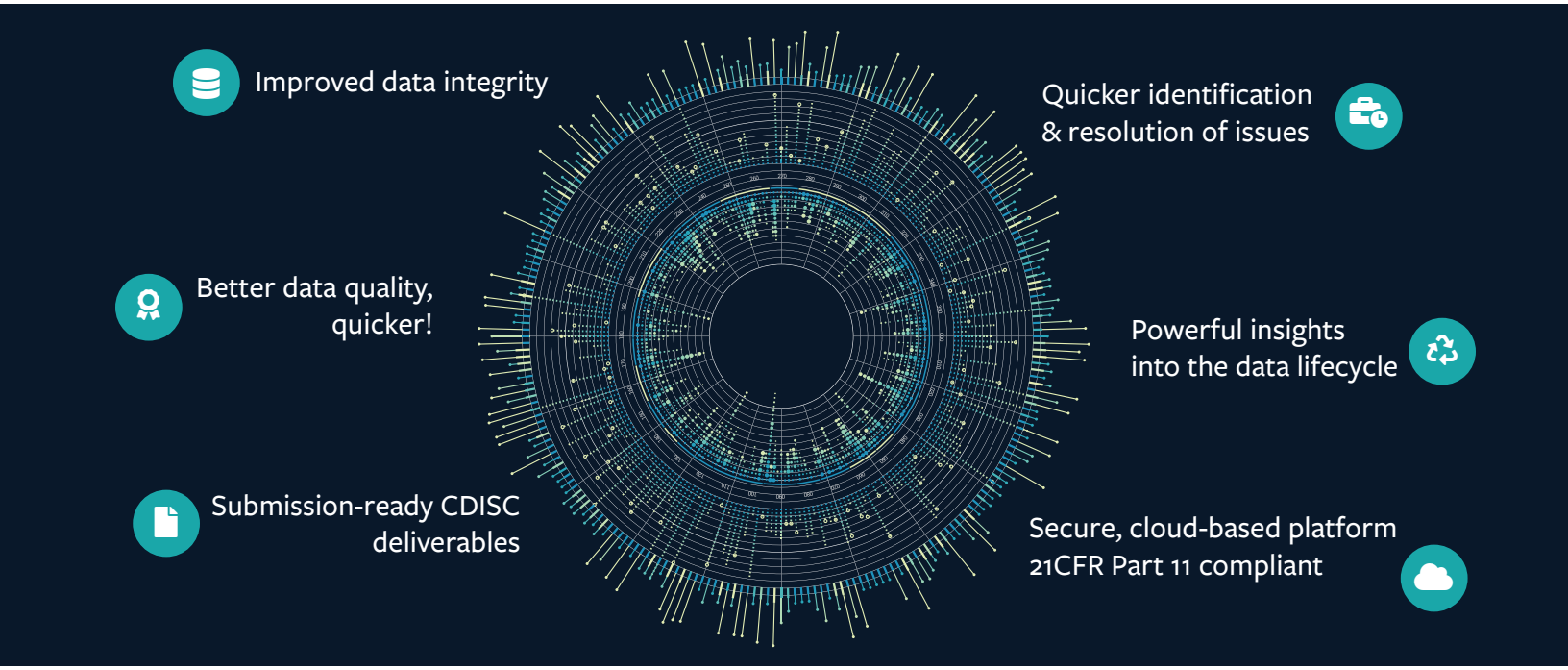
Our team is well-versed in the CDISC Data Standards. We produce regulatory submission data deliverables from INDs to NDAs, including:

- SEND: Non-Clinical Domains
- SDTM: Clinical Domains
- ADaM Analysis Datasets
- SDTM/ADAM QA Review of case report tabulation packages
- Define.pdf and Define.xml
- Study Data Reviewer's Guide (SDRG)
- Study Data Standardization Plan (SDSP)
- Analysis Data Reviewer's Guide
- Tables, Listings, and Figures
- Bioresearch Monitoring (BIMO) data package including:
  - Subject-Level Data Line Listings by Clinical Site
    - Individual Subject Listings by Site
  - Summary Level Clinical Site Datasets
    - Clinsite.xpt
    - Define.xml

We also offer CDISC mapping and conversion services for legacy data. We are often contracted to QC and regenerate non-compliant data received from vendors and CRO partners.

INTERACTIVE VISUALIZATIONS

Our visualizations bring your data to life. We transform typically static clinical trial data into robust, interactive insights.



DATA VIEWS

TradeCraft understands how important it is for clinical teams to get early and frequent access to clinical trial data. We have designed Data VIEWS to address this need.

Data VIEWS enables clients to leverage CDISC standardized data to identify potential anomalies and make fast and accurate decisions using powerful data visualizations. This supports early error detection, reduced cycle times, and improved data quality.

We combine sound statistical techniques with an open-source programming language to deliver user-friendly, real-time views of data.

This robust tool enables TradeCraft to perform frequent data cuts based on client needs. We can then export the visualizations and make them available to client teams via a secure, web-based portal, transforming static clinical trial data and results into interactive and insightful Data VIEWS. The clickable audit trail can even trace the subjects' results back to the RAW data.

DATA VIEWS

- **user-friendly, real-time views of data**
- **flexible visualizations that users can manipulate**
- **help clinical trial teams quickly detect deviations from study procedures**

TRADE CRAFT CLINICAL RESEARCH

Our seasoned biostatisticians and programmers use proven methodologies and practical knowledge to help clients improve data quality, make data-driven decisions earlier in the process, and understand and articulate the story that their data tells.

TEL: 1.610.935.5754

303 WEST LANCASTER AVE.
SUITE 320, WAYNE PA 19087

INFO@TRADECRAFTCLINICAL.COM

WWW.TRADECRAFTCLINICAL.COM