Our **Data Analytics** Services

High quality statistical support is an essential component of successful clinical research. DF/Net's data analytics team specializes in customized, cost-effective, and flexible statistical programming solutions designed to meet each study's needs.

Our statistical and programming expertise, coupled with robust therapeutic area familiarity, enables us to provide quality services that can be applied across multiple aspects of clinical trial development. And our direct programming work with DF/Net's **DFdiscover** data management software synergizes data collection and downstream analyses.

Statistical Programming Services

» Development of tables, listings, and figures (TLFs)

» Access to all statistical deliverables through our secure web portal

» Create reports in user-desired file formats (e.g. PDF, RTF, Excel)

» Patient profiles

» SDTM dataset development

» ADaM dataset development

» Define-XML creation

» Custom statistical programming

Biostatistical Services

» Study design

» Protocol assistance

» Sample size/power calculations

» PK/PD analysis

» Randomization schema

» Statistical Analysis Plan (SAP) development

» Data Monitoring Committee support

» Interim and final analyses

» Clinical Study Report support

» Statistical consulting

Study Support Services

» CRF review and annotation

» Operational study reports

» Custom designed and scheduled automated reports

» Clinical database transfers

» Reconciliation of transferred data against CRF data

» Integration of transferred data into clinical database

» Quality assurance sampling and analysis

» Custom web application development (e.g. safety monitoring dashboard)
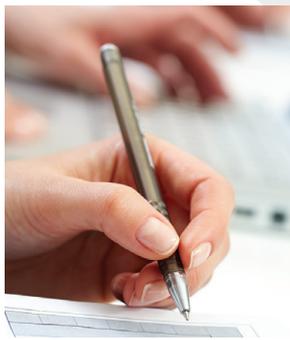
CDISC Services

DF/Net uses CDISC standards including CDASH, SDTM, and ADaM to help our clients accelerate their product development, from case report form design, through database setup and preparation of analysis data sets, to regulatory submission.

Case Studies

Reducing Costs and Increasing Productivity

A sponsor with over a dozen HIV prevention trials tasked the DF/Net Data Analytics team with providing real-time safety and operational reports in a short amount of time. Their studies rely on close safety monitoring for their first-in-human vaccine research. The reports and dashboards needed to be available 24x7 via a secure web portal, and had to provide information across all studies. Clinical safety personal needed to review events, patient profiles, and have immediate access to the underlying data. We collaborated with them on their timeline, and worked within their specifications to deliver custom outputs. Our team reduced their internal costs, increased staff productivity, strengthened the partnership, and yielded fresh insights into their important research data.

Proactive CDISC Conversions

Years before the FDA began requiring studies to conform to CDISC standards, an international client requested that their two large, pivotal Phase III studies be converted to SDTM format for submission to the FDA. As the scope of the project grew and more external data was being added, our team maintained the integrity of the outputs provided through validation and dialog with the external vendors, while providing ongoing guidance to our client.

As the vendor, we interacted with sometimes up to seven different "consumers" of the data, each with their own needs and requirements. Although a difficult challenge given the early days of CDISC evolution, through collaboration,

the task was completed. This data will be part of the FDA submission for an important new product designed to help women worldwide.

Blinding, Double-Blinding, and Randomization

DF/Net's Data Analytics team works with a variety of clients, from large institutions to early-phase biotech and pharma. Our early-phase clients enjoy working with DF/Net because of our personal, 1:1 relationships that get built over time. Our company motto is "Building relationships with people and their data". We provide the continuity needed to help our clients move their clinical study needs forward. Our goal is to make each client feel like our only client.

For a randomized, double-blind, Phase I formulation study, we worked with our client from setup to study close, writing the SAP, providing the randomization schedule, and creating interim and final narrative analyses. While the study was ongoing, we provided blinded TLFs for interim analysis as well as regularly scheduled operational reports. At study close, we securely provided the validated, unblinded output for the final analysis.