



# VERISTAT

Scientific integrity. Client focus.



## CDISC Standardization

### ABOUT VERISTAT

Veristat, Inc., is a full-service clinical research organization with demonstrated expertise in supporting clinical trials for pharmaceutical, biotechnology, and medical device companies. From trial design to final study reports, we offer complete services through strategic partnerships with our clients for an entire clinical program. With over 15 years of experience, Veristat provides flexible, innovative, and science-focused services customized to our clients needs.

### OUR SERVICES:

- Clinical Monitoring
- Data Management
- CDISC Standardization
- Biostatistics
- Medical Writing
- Project Management
- Regulatory Submissions
- Strategic Consulting

### WHY CHOOSE VERISTAT

There are several advantages to choosing Veristat.

- We are flexible and scalable to our clients' needs, and offer diverse therapeutic expertise, with a heavy focus on vaccine and oncology trials.
- In our Sponsor partnerships, we have proven to be adaptable and accommodating, which is reflected in our client satisfaction and retention.
- We are leaders in utilizing the latest technology platforms to assist Sponsors in the challenges of adhering to new industry standards.
- We are committed to providing quality services with the highest ethical and scientific standards that meet or exceed the expectations of our clients.

Veristat is an active member of the Clinical Data Interchange Standards Consortium (CDISC) and a leading provider of CDISC services. CDISC data standards are quickly becoming industry standard, and with our experience we can help make this transition seamless.

### CDISC Advantages

CDISC has developed a set of data standards to enhance efficiencies, improve safety monitoring, and streamline the review and approval process for investigational treatments. Under the FDA's electronic Common Technical Document (eCTD) implementation, CDISC Study Data Tabulation Model (SDTM) is the preferred standard for integrating clinical datasets for all clinical studies. The FDA is likely to mandate that all electronic submissions follow the SDTM format. Veristat helps our clients to not only realize and implement a project, but also to obtain the necessary knowledge to understand the CDISC standards.

### Emerging Technology

Veristat maintains current and high-level knowledge of data standards, and utilizes the latest technology platforms to assist our clients in the challenges of adhering to these new standards. For applied data standards in electronic submissions, we have partnered with Phase Forward's Lincoln Technologies safety division, to implement the Web Submission Data Manager (WebSDM™) application, the same application used by the FDA, to load and validate compliant SDTM-format study data. In addition to utilizing WebSDM, we have developed a suite of additional validation checks for data consistency and CDISC compliance. This technology ensures submission files conform to the SDTM standard so that our clients can present them to regulatory agencies with confidence.

### CDISC Expertise

Veristat's Standards Implementation team provides expert services to our clients for successful e-submissions. This specialized team will ensure that your legacy study data is migrated to submission-ready, fully CDISC-compliant SDTM data. We design Clinical Data Acquisition Standards Harmonization (CDASH) compliant CRFs for both paper and EDC clinical studies, providing a seamless conversion to SDTM data. Veristat leverages its years of experience in statistical analysis and strategic consulting to provide CDISC-compliant ADaM data for statistical analysis.

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### ELECTRONIC DATA CAPTURE

Veristat has an established strategic partnership with Phase Forward to offer an industry leading EDC solution, InForm™. We can help your clinical trials run faster and more efficiently. EDC saves valuable time by streamlining the data validation process and automating query resolution, resulting in reduced time to database lock. Our ability to build an InForm database in-house allows for flexibility to take a custom approach that precisely meets your needs and your budget.

### MISSION

Our mission is to assist our clients in the development of innovative therapeutic, medical device, and diagnostic products that sustain and improve life, by providing clinical research services in an efficient and cost-effective manner, using scientific principles and state-of-the-art technology.

### Veristat's CDISC Experience

To date, Veristat's Standards Implementation team has converted CRF data from over 60 studies into CDISC compliant SDTM datasets in diverse therapeutic areas.

Veristat provides the following CDISC services:

- GAP analyses
- Annotated Case Report Forms
- Trial design Metadata programming
- Data conversion and integration
- SDTM (Study Data Tabulation Model)
- ADaM (Analysis Data Set Model)
- Generation of Define.xml documents
- Utilization of WebSDM™
- Strategic consultancy

For more information, call us today at (508) 429-7340 or visit our website at [www.veristat.com](http://www.veristat.com).

