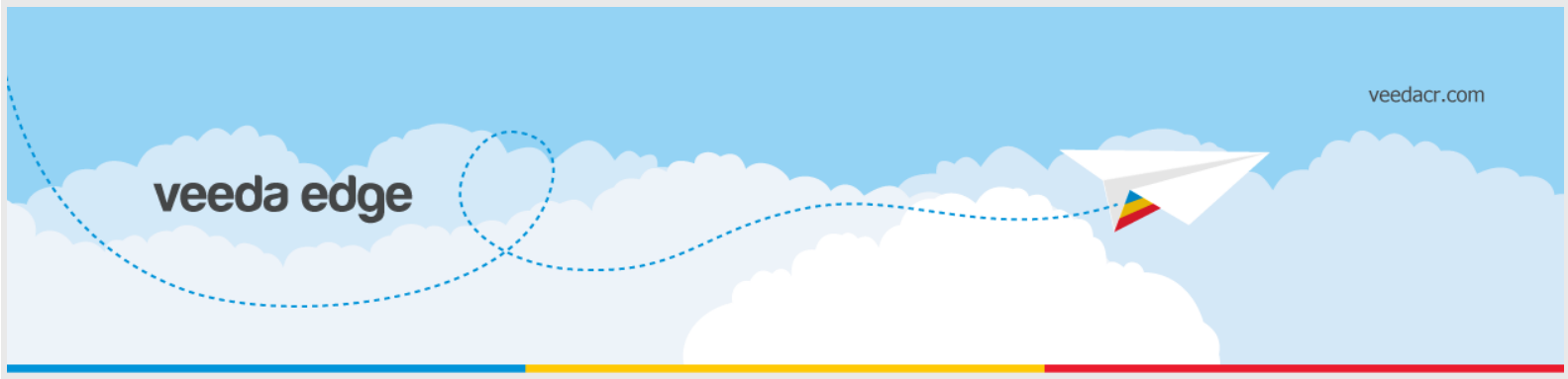

Comprehensive Services in Clinical Data Interchange Standards Consortium (CDISC)

In drug development process the importance of high quality and accessibility of clinical data is not only a best practice but a critical mission to adhere. To match the global data standards along with its high integrity, specificity and quality, the processes must be in-line to meet the regulatory requirements and Clinical Data Interchange Standards Consortium (CDISC) standards. Veeda is well prepared for requirement of submission of data in CDISC format.

The FDA mandated that study data be submitted in conformance with CDISC standards for all studies that start after 17 Dec 2017. It will be required to submit their data to the FDA in an electronic format i.e. CDISC.

Veeda Capabilities:

- Veeda Clinical Research has developed a standard conversion approach to fulfill regulatory requirement.
- Veeda has set up the in house Program for CDISC (SDTM & ADaM).
- Veeda has a team of **CDISC experienced professionals** to ensure accurate interpretation of SDTM and ADaM that is identified, documented, managed, implemented consistently and most importantly communicated at right stage.
- Team members are **trained** in-house on **CDISC Standards Fundamentals.** We have validated SAS program.
- Veeda has completed around 08 projects successfully in CDISC format.

Data generated for regulatory submission include, but not limited to,

- **CRF annotations**
- SDTM [domain included such as Demographics (DM), Laboratory Test Results (LB), Inclusion/Exclusion Criteria Not Met (IE), Exposure (EX), Vital Signs (VS), Adverse Events (AE), Concomitant/Prior Medications (CM), Physical Examination (PE), ECG Test Results (EG), Protocol Deviations (DV), Disposition (DS), Question (QS), Pharmacokinetics Concentrations (PC), Pharmacokinetics Parameters (PP), Trial Arms(TA), Trial Visits (TV), Trial Summary Information (TS)]
- Define.xml
- **ADaMs**
- **SDRG**
- **ADRG**

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