CLINICAL DATA MANAGEMENT

DataGen

POWER TO YOUR DATA

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Services

Full Data Management Support

CDISC SDTM Standard Production
Conversion of any format to CDISC
CRF design (paper / electronic)
Database study set-up activities
Training monitors of study specific DM
   processes and activities
Data entry (5 medically trained stuff)
Coding (using client dictionnaries)
SAE/AE reconciliation
Query management
Project data management
Clinical data review
Full or partial DM support

Statistical Consulting/Support

Multivariate Statistics
Multiple Regression Analysis
Mixed-Effects Models Analysis
Sample size calculations
Input into Clinical Study Protocol design
Statistical Analysis Plan (SAP)
Statistical testing
Statistical Study Report

Programming Support

SAS / SQL Programming (including macro
   development)
Patient profiles, tables and listings
Global database design / warehousing
Management/transfer of legacy data
Application development (MS Office, MS Visual
   Studio, MS .NET technology)

Safety Data Evaluation Tool

Safety data in CDISC SDTM format
   are listed, and represented in the
   most current frequency tables
Querying of the CDISC SDTM Safety
   Database for almost any imaginable
   question

Electronic Data Capture (EDC)

Production of user-friendly eCRF
Remote data entry
Web-based eCRF
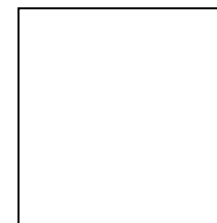Development of customized solutions

Partner Services

Medical consulting
Monitoring
Clinical staff training
Medical writing
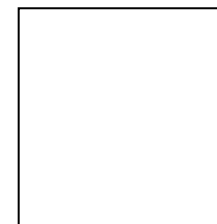CRF printing

Benefits of our Customers

- Very experienced and enthusiastic team
- CDISC (SDTM, AdaM, ODM)
- Cost effective and competitive rates
- Personal and flexible service (time & resources)
- Consider as extension of your resources
- We value your custom

Dr. Werner Venetz
Founder and Chairman
Head of Statistics and
Programming

N.N.
Head of Clinical Data
Management

N.N.
Sales Manager