# STRATEGIC SCIENTIFIC CONSULTING

**SDC**
Statistics & Data Corporation

## The Right Fit For You.®

Our strategic scientific consultants will guide you through the process of developing the most efficient and effective clinical program. From product portfolio planning to clinical trial design to regulatory meeting support, SDC is The Right Fit For You.

## Strategic Scientific Consulting Services

- › Clinical Program Development
- › Protocol Development
  - › Clinical Trial Design
  - › Interim Analysis Planning
  - › Sample Size Calculation
- › Endpoint and Analysis Methodology Development
- › Product Acquisition Due Diligence
- › DMC Planning and Participation
- › Ad-Hoc Statistical Analyses
- › Manuscript Development

## Artificial Intelligence (AI) and Machine Learning (ML)

- › **Implementing AI Solutions** to discover relationships in clinical trial data
- › **Development of Applications to** automate low risk tasks and identify key data risks

## Regulatory Meeting Representation and Support

- › Pre-IND/IDE and International Equivalents
- › End of Phase 2
- › Pre-Submission: NDA/MAA/BLA/PMA/510(k)
- › Advisory Committee Meetings
- › Special Protocol Assessment

9 out of 10 Average Customer Satisfaction Score

10+ Product Approvals Supported in Past 2 Years

Monthly Interaction with Regulatory Agencies

# ABOUT SDC

## The Right Fit For You.®

SDC is a specialized data services CRO providing scalable full service clinical trial solutions via our diverse and complementary strategic partnerships. From protocol consulting to full service clinical trial management and everything in between, SDC is The Right Fit For You.

**Strategic Scientific Consulting**

Clinical Program Design/Development
Regulatory/Submission Guidance
Simulation & Modeling

**Expert Data Services**

Biostatistics
Data Management & EDC
IRT/IWRS
DMC/DSMB

**Scalable Partnered Services**

Full Service CRO Solutions
Specialty Services
Transition/Rescue Strategy

## Mini Case Study

› **Over 200 Tables Delivered** for pooled ISS/ISE analysis across 7 clinical trials

| For Each of 7 Studies | For ISS/ISE Analysis |
| --- | --- |
| SDTM Datasets | ISS Tables |
| SDTM aCRF | ISE Tables |
| SDTM Define.xml (Including Reviewer's Guide) | ADaM Datasets |
| ADaM Datasets | ADaM Define.xml (Including Reviewer's Guide) |
| ADaM Define.xml (Including Reviewer's Guide) | |