

AI



Stat One is a highly experienced partner in the Artificial Intelligence (AI) space. Our team is adept at taking clients through the analysis and approval process from start-to-finish. Our deep industry knowledge of over 30 years makes us an excellent partner for your clinical programs.

The Stat One Team maintains an up-to-date understanding of the AI market and these types of submissions. Stat One has worked on multiple diagnostic algorithms and measurement tools. Statistical expertise includes assisting in study design, FDA interaction, SAP generation, and analyses.

INDICATIONS

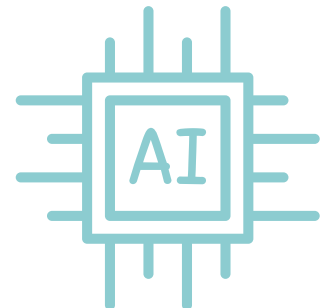
- ✓ CAD Algorithms
- ✓ Disease Classification
- ✓ Pathology
- ✓ Dental
- ✓ Imaging
- ✓ X-Ray
- ✓ Diagnostics
- ✓ MRI

FOCUSED APPROACH

Stat One takes a focused approach based on FDA guidance for AI-related products. Our team is familiar with FDA requirements and industry guideline changes and updates.

SERVICES

- ✓ Study Design
- ✓ Sample Size
- ✓ Statistical Analyses
- ✓ Participation in FDA Discussions



LET YOUR DATA GROW®

ABOUT STAT ONE



Stat One is a speciality CRO providing expert statistical consulting, production programming, and data management services in support of clinical trials in the pharmaceutical, medical device, and biotechnology spaces. Our industry knowledge and experience of over three decades combined with our focus on quality makes us an excellent choice for your partner in growing a better future.

PROVEN TRACK RECORD

Our team has worked with and represented hundreds of clients on **FDA** submissions.

100+
FDA APPROVALS

25+
THERAPEUTIC AREAS

30+
YEARS OF INDUSTRY
SUCCESS

STATISTICAL CONSULTING

- ✓ Expert Statistics
- ✓ Study Design
- ✓ Sample Size
- ✓ FDA Representation
- ✓ Regulatory Strategy

PRODUCTION PROGRAMMING

- ✓ SAS Programming
- ✓ Patient Profiles
- ✓ Data Analysis
- ✓ Integrated Summaries
- ✓ Quality Control

DATA MANAGEMENT

- ✓ Stat One EDC®
- ✓ CRF Design
- ✓ Database Development
- ✓ Validation
- ✓ Customizable

YOUR PARTNER IN GROWING A BETTER FUTURE