

DIAGNOSTIC



Stat One has broad experience in navigating the unique needs of the diagnostic and IVD space. Expertise includes a broad range of products, including imaging agents, imaging devices, implantable products, and Computer Assisted Detection (CAD) products. Our team is well experienced in participating with FDA interactions regarding diagnostic products.

Statistical expertise also includes MRMC designs, ROC analyses, and diagnostic test statistics. Our team takes a proactive approach on the statistical, programming, and data management needs of our diagnostic clients.

MEDICAL DEVICES/CAD PRODUCTS

- ✓ Angiography
- ✓ Mammography
- ✓ CADe: prostate, breast
- ✓ Tomography
- ✓ Cancer fluorescing products: breast
- ✓ Ultrasound
- ✓ Contrast agents
- ✓ X-Ray
- ✓ Concussion

IVD/TISSUE PRODUCTS

- ✓ Asthma
- ✓ Renal
- ✓ Bacterial Infections
- ✓ Risk Prediction
- ✓ Cancer screening
- ✓ Subdural Hematoma
- ✓ Gastroenterology
- ✓ Spine
- ✓ Hematology
- ✓ Urology
- ✓ Oncology
- ✓ Viral Infections

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