

COVID-19



The Stat One Team has extensive experience working with clients on COVID-19 related products and indications. This includes diagnostic products, interventional trials, population-specific safety, and exploratory studies.

Our experts assist in navigating regulatory requirements and FDA meetings. Statistical experience includes assisting in study design, SAP generation, and analyses from start-to-finish, as well as data management.

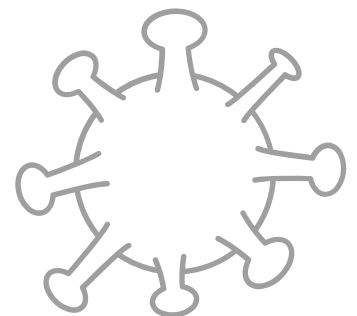
FOCUSED APPROACH

Stat One emphasizes study design and analysis based on FDA guidance for COVID-19 products including:

- ✓ Use of randomized controls whenever possible
- ✓ Proper endpoint selection based on the patient setting, production, and possible indication

EXPERIENCE

- ✓ Diagnostics
- ✓ Interventional trials
- ✓ Population specific safety studies
- ✓ Exploratory studies



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