

# STAT ONE: YOUR TRUSTED PARTNER IN CARDIOVASCULAR TRIALS

Stat One is a specialty Contract Research Organization (CRO) providing expert statistical consulting, production programming, and data management services supporting clinical trials in the pharmaceutical, medical device, and biotechnology industries. With over three decades of industry knowledge and a focus on quality, Stat One is an excellent choice for your partner in growing a better future.

## About Stat One

Our team has worked with and represented hundreds of clients on FDA submissions. We have over 30 years of industry success, with over 100 FDA approvals. We have experience in a broad range of therapeutic areas, making us a versatile and reliable partner in your journey towards creating innovative, life-saving products.

## Statistical Consulting

Our statistical consulting services are comprehensive and expertly delivered. We offer expert Statistics, assistance in Study Design, Sample Size Calculation, FDA Representation, and Data Management services. We are committed to ensuring that your data is accurate, relevant, and statistically valid, setting your products up for success.

## Production Programming

We offer various production programming services, including SAS Programming, Patient Profiles, Data Analysis, Integrated Summaries, and Quality Control. Our team is skilled in handling and manipulating large datasets to extract meaningful insights that drive your product development forward.

## Data Management

Our data management services include using Stat One EDC®, CRF Design, Database Development, Validation, and customization. We ensure that your data is stored securely, is easily accessible, and can be customized to meet your specific needs.

## Cardiovascular Studies & Stat One

Stat One is a highly experienced partner in cardiovascular and peripheral vascular product submissions. Our experience includes many products, such as interventional devices (stents,

balloons, drug-coated products), stroke and embolism-related indications (clot removal devices, drug therapies), and diagnostic devices (contrast agents, adenosine products, AI algorithms, and imaging studies).

The Stat One Team strives to maintain an up-to-date understanding of the market and is adept at taking clients through the necessary steps for gaining approval for these types of submissions. Our related statistical experience includes assisting in study design, FDA interaction, SAP generation, and analyses. Hence, we offer start-to-finish statistical support for cardiovascular and vascular products.

## Medical Devices & Pharmaceuticals

We have extensive experience with a wide range of cardiovascular medical devices, including Ablation Treatments, Atrial Fibrillation, Blood Pressure Monitoring Devices, Catheter Devices, and Imaging for Heart Function.

Additionally, we have worked with various pharmaceutical products to improve cardiovascular health, including Heart Failure Therapies, Clot Preventing Therapies, Contrast Agents, Stress Agents, Structural Heart, Angiography, Echocardiography, MRI, and Valve Disease treatments.

Ultimately, our goal is to Let Your Data Grow® and help you create products that improve the lives of patients around the world.