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# COVID-19 FACTORS AFFECTING CONDUCT OF CLINICAL TRIALS

*Shifts in resources due to COVID-19 creates continual impact on clinical programs and all product development phases*

## STUDY IMPACTS & STATISTICAL SIGNIFICANCE

### COVID-19 STUDY DESIGN

Many different designs and approaches needed depedning on your product

### COMPROMISED POPULATIONS

Populations such as the elderly, or at risk populations may affect study

### SELECTION OF STUDY ENDPOINTS

Endpoints should be consistent with FDA guidance, product, and disease status

### FDA GUIDELINES

New FDA guidelines & requirements create further changes to study protocol & design

### PAUSED TRIALS

Programs delayed and delayed product releases

### RECRUITMENT CHALLENGES

Patient recruitment challenges due to travel restrictions patient desire to participate

### SITE REQUIREMENTS

Increased site documentation emphasizing patient safety & internal policies

## LEARNING OPPORTUNTIIES

**ADVANCED SAFETY DATA & CLINICAL EFFICACY**

**ENHANCED POLICIES & STRATEGIES**

**IMPROVED CLINICAL PROGRAMS & TIMELINE ADAPTIBILITY**

**POTENTIAL COMPETITIVE ADVANTAGE**

**STRENGTHENED IMPLANTATION FOR FUTURE SUCCESS**

**STAT ONE UNDERSTANDS THE IMPACT OF COVID-19 ON CLINICAL PROGRAMS. OUR TEAM CAN ASSIST IN NAVIGATING PATIENT SAFETY AND TRIAL INTEGRITY WITH PRODUCT DEVELOPMENT AND STATISTICAL POWER.**

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