



Designing and Conducting Clinical Trials

Getting safe, effective therapies to market with speed and precision



Off the Sidelines and into the Fight

Getting experimental new therapies to market can often mean the difference between life and death. Many people suffering from disease sit on the sidelines, hoping for the discovery of a new treatment that can help them. Tens of thousands of volunteers are willing to participate in the hope that a new therapy or prevention will improve their lives and the lives of others who suffer as they do. As the first Gillings Innovation Laboratory, the Center for Innovative Clinical Trials is addressing crucial questions involved in creating better designed and more effective clinical trials.

Trying a New Approach

- **Different Statistical Means**

When designing clinical trials and analyzing results, new statistical approaches can help reduce the risk that FDA approved medications or treatments may result in significant problems or side effects.

- **Focusing at Multiple Endpoints**

Right now, trials are primarily designed to address one primary endpoint in both the design and analysis stage. The Center is working on an approach where several endpoints may be examined at once. This can signal the possibility for adverse events, toxicity, or the need for treatment interventions earlier in the trials.

- **Innovations at Every Developmental Level**

The Center will make clinical trials faster, cheaper and more reliable through its inter-disciplinary approach. That includes innovation in design, analysis and evaluation of clinical trials.

Leadership



Joseph Ibrahim, PhD, is Alumni Distinguished Professor of biostatistics, UNC Gillings School of Global Public Health, and Director of the Biostatistics Core at the Lineberger Comprehensive Cancer Center. “We want to find ways to get results faster, but we want them to be more precise and useful in determining if the treatment is effective, and for which patients. The ultimate goal is better healthcare.”



GOAL

To get safe and effective therapies to the marketplace with speed and precision.

PARTNERS

Experts in biostatistics, medicine, epidemiology, maternal and child health, nutrition, environmental health, health policy, economics, business, nursing, dentistry, psychology, psychiatry, biology and chemistry.

IMPACT! Global Health

Tens of thousands of patients participate in clinical trials each year. New methods, integrated into clinical and statistical practice more quickly, would make these powerful tools even more effective.

