



Regulatory Guidance for Academic Research of Drugs and Devices



## Modernizing the Clinical Research System

### MODERNIZING THE CLINICAL RESEARCH SYSTEM: INSIGHTS FROM THE FORMER FDA COMMISSIONER

The current clinical research enterprise falls short when answering critical questions for patients, clinicians, and payers to make rational decisions about treatment; and the cost of trials is causing a distortion of investment decisions in new drugs and devices.

Dr. Rob Califf will discuss efforts to develop a more efficient American clinical trials system. This system would take advantage of quality by design, use more platform trials, and operate through networks in the “real world” to result in trials that are representative of the population while answering critical questions that are patient centered and enable value based reimbursement.

Monday, October 2, 2017  
10:00 AM - 11:00 AM  
UNC Campus, Bondurant G100  
or webinar

REGISTER: [go.unc.edu/x4F6A](http://go.unc.edu/x4F6A)



**SPEAKER:**

**ROB CALIFF, MD, MACC**  
*Former Commissioner of the U.S. Food and Drug Administration, and current Vice Chancellor for Health Data Science at Duke Health*

ReGARDDD affiliates are comprised of regulatory affairs specialists and experts from North Carolina Institutions that receive funding from the NIH Clinical and Translational Science Awards (CTSA) Program.

