

**Opening Statement of the Honorable Joseph R. Pitts**  
**Subcommittee on Health**  
**Hearing on “21<sup>st</sup> Century Cures: Modernizing Clinical Trials”**  
**July 9, 2014**

*(As Prepared for Delivery)*

Part of the work of our 21st Century Cures initiative is to identify existing roadblocks to speeding treatments and cures to patients. One of these barriers is the current clinical trial process.

Among the regulatory and administrative burdens associated with clinical trials are their expanding cost and size.

While it takes, on average, approximately 14 years and \$2 billion to bring a new drug to the market, a large portion of that cost is spent in recruiting and retaining subjects for clinical trials.

It is often difficult to identify potential participants, due to a shortage of centralized registries, low awareness of the opportunity to participate in clinical trials, low patient retention and lack of engagement among community doctors and volunteers.

Widespread duplication of effort and cost also occurs because research is fragmented across hundreds of clinical research organizations, sites, and trials, and information regarding both the successes and failures of clinical trials is rarely shared among researchers.

Finally, in many cases, researchers have been slow to utilize technology, such as electronic health records and web-based platforms in their trials, which is also a barrier to greater collaboration and information sharing.

This expensive and antiquated clinical trials model is simply not acceptable in the 21st century. We can and must do better because patients deserve better.

Researchers and physicians are going to have to strengthen the recruitment and retention of volunteers for their trials, adopt new technologies, and, above all, collaborate to build efficient and effective clinical trials.

I would like to thank all of our witnesses for being here today, and I look forward to hearing their ideas.

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