

**Rep. Cathy McMorris Rodgers**  
**Opening Statement**  
**July 9, 2014**  
*21<sup>st</sup> Century Cures: Modernizing Clinical Trials*

**Thank you, Mr. Chairman, for yielding to me.**

I am happy to be here today to discuss how we can leverage new technologies with existing infrastructure to improve the way clinical trials are conducted in the U.S. By cutting down on administrative inefficiencies, creating a glide-path for the adoption and acceptance of new trial designs, and lowering the costs necessary to conduct a trial, we can get therapies to market faster and save lives as a result.

The goal of clinical trials is to demonstrate safety and effectiveness. The question is: can those qualities be demonstrated without three or four part trials, which cost millions of dollars and take six or seven years? I believe that this is well within our grasp.

Perhaps we can start with steps that simplify administrative procedures and what it takes to start a trial – such as standardizing IRBs and ensuring the creation and maintenance of “ready to go” clinical trials networks.

We can work with FDA on the type of evidence they require for approval – and what Congress can do, in collaboration with the agency and other stakeholders, to promote the use of innovative new tools in clinical trials – such as qualifying biomarkers and using surrogate endpoints to prove effectiveness. These steps, together with using other tools like big data and complex

modeling, can help us take clinical trials into the 21<sup>st</sup> century – by allowing us to yield better and faster results, with fewer people needed, less investment, and shorter approval times.

I look forward to working with the Chairman and committee on the overall Cures initiative and to advancing initiatives that improve the clinical trials system and ideas that will increase FDA's overall comfort and acceptance of new trial designs. I am confident this initiative will generate new kinds of evidence, expedite the clinical trials process, and create life-saving therapies for the American people.