HR 1066

Clinical Trials Modernization Act of 2015

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Feb 25, 2015
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Feb 27, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/1066

Sponsor

Name: Rep. Collins, Chris [R-NY-27]
Party: Republican • **State:** NY • **Chamber:** House

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Pompeo, Mike [R-KS-4]	R · KS		Feb 25, 2015
Rep. Bucshon, Larry [R-IN-8]	R · IN		Mar 4, 2015

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 27, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Feb 25, 2015)

Clinical Trials Modernization Act of 2015

This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to allow sponsors of applications for new drugs, biological products, and medical devices to propose incorporation of alternative statistical methods, including adaptive trial design and Bayesian methods, into clinical trial protocols and marketing applications.

The FDA is required to issue guidance that establishes or clarifies standards for using alternative statistical methods in clinical trials.

The FDA must establish a process under which a post-approval study or clinical trial required by the FDA is periodically evaluated to determine whether the trial or study is no longer scientifically warranted or whether the design should be renegotiated because of changes in medical practice or the standard of care.

Actions Timeline

- **Feb 27, 2015:** Referred to the Subcommittee on Health.
- **Feb 25, 2015:** Introduced in House
- **Feb 25, 2015:** Referred to the House Committee on Energy and Commerce.