

HR 3503

NIH Clinical Trial Diversity Act of 2023

Congress: 118 (2023–2025, Ended)

Chamber: House

Policy Area: Health

Introduced: May 18, 2023

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (May 19, 2023)

Official Text: <https://www.congress.gov/bill/118th-congress/house-bill/3503>

Sponsor

Name: Rep. Kelly, Robin L. [D-IL-2]

Party: Democratic • **State:** IL • **Chamber:** House

Cosponsors (40 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Fitzpatrick, Brian K. [R-PA-1]	R · PA		May 18, 2023
Del. Norton, Eleanor Holmes [D-DC-At Large]	D · DC		May 31, 2023
Rep. Eshoo, Anna G. [D-CA-16]	D · CA		May 31, 2023
Rep. Moore, Gwen [D-WI-4]	D · WI		May 31, 2023
Rep. Wasserman Schultz, Debbie [D-FL-25]	D · FL		Jun 12, 2023
Rep. Barragan, Nanette Diaz [D-CA-44]	D · CA		Jun 21, 2023
Rep. Adams, Alma S. [D-NC-12]	D · NC		Jul 6, 2023
Rep. Clarke, Yvette D. [D-NY-9]	D · NY		Jul 6, 2023
Rep. Phillips, Dean [D-MN-3]	D · MN		Jul 6, 2023
Rep. Cárdenas, Tony [D-CA-29]	D · CA		Jul 10, 2023
Rep. Jayapal, Pramila [D-WA-7]	D · WA		Jul 10, 2023
Rep. Allred, Colin Z. [D-TX-32]	D · TX		Jul 18, 2023
Rep. Keating, William R. [D-MA-9]	D · MA		Aug 4, 2023
Rep. Casten, Sean [D-IL-6]	D · IL		Aug 11, 2023
Rep. Lieu, Ted [D-CA-36]	D · CA		Sep 12, 2023
Rep. Pocan, Mark [D-WI-2]	D · WI		Sep 12, 2023
Rep. Blunt Rochester, Lisa [D-DE-At Large]	D · DE		Sep 26, 2023
Rep. Himes, James A. [D-CT-4]	D · CT		Sep 26, 2023
Rep. Johnson, Henry C. "Hank," Jr. [D-GA-4]	D · GA		Sep 26, 2023
Rep. Pettersen, Brittany [D-CO-7]	D · CO		Sep 26, 2023
Rep. Magaziner, Seth [D-RI-2]	D · RI		Oct 11, 2023
Rep. Watson Coleman, Bonnie [D-NJ-12]	D · NJ		Oct 11, 2023
Rep. Tokuda, Jill N. [D-HI-2]	D · HI		Oct 19, 2023
Rep. Caraveo, Yadira [D-CO-8]	D · CO		Oct 26, 2023
Rep. Kim, Andy [D-NJ-3]	D · NJ		Nov 29, 2023
Rep. Gottheimer, Josh [D-NJ-5]	D · NJ		Feb 29, 2024
Rep. Jackson Lee, Sheila [D-TX-18]	D · TX		Mar 26, 2024
Rep. Neguse, Joe [D-CO-2]	D · CO		Mar 29, 2024
Rep. Morelle, Joseph D. [D-NY-25]	D · NY		Apr 23, 2024
Rep. Balint, Becca [D-VT-At Large]	D · VT		May 6, 2024
Rep. DeSaulnier, Mark [D-CA-10]	D · CA		May 6, 2024
Rep. Lynch, Stephen F. [D-MA-8]	D · MA		May 6, 2024
Rep. Napolitano, Grace F. [D-CA-31]	D · CA		May 6, 2024
Rep. Peters, Scott H. [D-CA-50]	D · CA		May 6, 2024
Rep. Crow, Jason [D-CO-6]	D · CO		May 21, 2024
Rep. McClellan, Jennifer L. [D-VA-4]	D · VA		May 21, 2024
Rep. Tonko, Paul [D-NY-20]	D · NY		May 22, 2024
Rep. Peltola, Mary Sattler [D-AK-At Large]	D · AK		Jun 13, 2024
Rep. Nadler, Jerrold [D-NY-12]	D · NY		Aug 9, 2024
Rep. Stansbury, Melanie A. [D-NM-1]	D · NM		Dec 5, 2024

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 19, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of May 18, 2023)

NIH Clinical Trial Diversity Act of 2023

This bill sets out requirements to increase the diversity of clinical trial participants and requires other activities to foster participation in clinical trials.

As a condition of approval from the National Institutes of Health (NIH) for a clinical trial investigating a drug, device, or behavioral intervention, a sponsor's application must include certain information related to diversity in its trial, such as

- goals for recruiting and retaining trial participants,
- plans for achieving the recruitment and retention goals and implementing less-burdensome clinical trial follow-up requirements, and
- requirements for researchers and other individuals involved with the trial to complete education and training about diversity in clinical trials.

A sponsor must also annually share demographic data of clinical trial participants with the NIH. The NIH must publish on its website information about the diversity of and other information concerning the clinical trials it funds.

If a sponsor fails to meet its diversity goals or related requirements, the sponsor must develop and implement a strategic plan to increase the diversity of the clinical trial participants.

Further, the NIH and the Food and Drug Administration must carry out a national campaign to increase awareness about the need for diverse clinical trials.

The bill also requires studies on barriers to participation in clinical trials. The Government Accountability Office must study actions taken by federal agencies to address such barriers while the NIH must study regulations that govern reimbursements of out-of-pocket expenses of and incentives for clinical trial participants.

Actions Timeline

- **May 19, 2023:** Referred to the Subcommittee on Health.
- **May 18, 2023:** Introduced in House
- **May 18, 2023:** Referred to the House Committee on Energy and Commerce.