

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 |
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| 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 |
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| 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.