

117TH CONGRESS  
2D SESSION

# H. R. 6584

To direct the Commissioner of Food and Drugs to amend certain regulations to increase clinical trial diversity, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 3, 2022

Ms. ESHOO (for herself, Mr. FITZPATRICK, and Ms. KELLY of Illinois) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To direct the Commissioner of Food and Drugs to amend certain regulations to increase clinical trial diversity, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Diverse and Equitable  
5 Participation in Clinical Trials Act” or the “DEPICT  
6 Act”.

1 **SEC. 2. PREMARKET REPORTING OF DIVERSITY PLANS FOR**  
2 **CLINICAL TRIALS AND STUDIES.**

3 (a) DRUGS.—The Commissioner of Food and Drugs  
4 shall issue regulations revising part 312 of title 21, Code  
5 of Federal Regulations, to require sponsors of applications  
6 for an exemption for investigational use of a drug to in-  
7 clude—

8 (1) in any such application—

9 (A) the estimated prevalence in the United  
10 States of the disease or condition for which the  
11 drug is being developed or investigated,  
12 disaggregated by demographic subgroup, where  
13 such data is available, including age group, sex,  
14 race, and ethnicity;

15 (B) the sponsor's targets for enrollment in  
16 the clinical trial or trials involved,  
17 disaggregated by age group, sex, race, and eth-  
18 nicity;

19 (C) the rationale for the sponsor's enroll-  
20 ment targets referred to in subparagraph (B),  
21 which may include—

22 (i) the estimated prevalence referred  
23 to in subparagraph (A);

24 (ii) what is known about the disease  
25 or condition for which the drug is being  
26 developed or investigated;

1 (iii) any relevant pharmacokinetic or  
2 pharmacogenomic data;

3 (iv) what is known about the patient  
4 population, including co-morbidities and  
5 potential barriers to enrolling diverse par-  
6 ticipants, such as patient population size  
7 and geographic location; and

8 (v) any other data or information the  
9 sponsors deems relevant to selecting appro-  
10 priate enrollment targets, disaggregated by  
11 demographic subgroup; and

12 (D) a diversity action plan for how the  
13 sponsor will meet such targets, including demo-  
14 graphic-specific outreach and enrollment strate-  
15 gies, study-site selection, clinical trial inclusion  
16 and exclusion practices, and any diversity train-  
17 ing for trial personnel; and

18 (2) in an annual report described in section  
19 312.33 of title 21, Code of Federal Regulations—

20 (A) the sponsor's progress in meeting the  
21 targets referred to in paragraph (1)(B); and

22 (B) if the sponsor does not expect to meet  
23 those targets referred to in paragraph (1)(B)—

1 (i) any updates needed to be made to  
2 the diversity action plan referred to in  
3 paragraph (1)(D) to meet such targets; or

4 (ii) the sponsor's justification for why  
5 the sponsor does not expect to meet such  
6 targets, including—

7 (I) any factors outside of the  
8 sponsor's control, including a lack of  
9 retention of participants;

10 (II) any differences in the enroll-  
11 ment targets, disaggregated by demo-  
12 graphic subgroup, and actual enroll-  
13 ment that the sponsor determines are  
14 insignificant in nature;

15 (III) potential for selection bias;  
16 and

17 (IV) information not available to  
18 the sponsor at the time such targets  
19 were chosen, but that impacted enroll-  
20 ment of diverse participants.

21 (b) DEVICES.—The Commissioner of Food and  
22 Drugs shall issue regulations revising part 812 of title 21,  
23 Code of Federal Regulations, to require sponsors of appli-  
24 cations for an exemption for investigational use of a device  
25 to include—

1 (1) in any such application—

2 (A) a description of the patient population  
3 in the United States expected to use the device,  
4 disaggregated by demographic subgroup, where  
5 such data is available, including age group, sex,  
6 race, and ethnicity;

7 (B) the sponsor's targets for enrollment in  
8 the clinical trial or trials involved,  
9 disaggregated by age group, sex, race, and eth-  
10 nicity;

11 (C) the rationale for the sponsor's enroll-  
12 ment targets referred to in subparagraph (B),  
13 which may include—

14 (i) the estimated prevalence referred  
15 to in subparagraph (A);

16 (ii) what is known about the disease  
17 or condition for which the drug is being  
18 developed or investigated;

19 (iii) any relevant pharmacokinetic or  
20 pharmacogenomic data;

21 (iv) what is known about the patient  
22 population, including co-morbidities and  
23 potential barriers to enrolling diverse par-  
24 ticipants, such as patient population size  
25 and geographic location; and

1 (v) any other data or information the  
2 sponsors deems relevant to selecting appro-  
3 priate enrollment targets, disaggregated by  
4 demographic subgroup; and

5 (D) a diversity action plan for how the  
6 sponsor will meet such targets, including demo-  
7 graphic-specific outreach and enrollment strate-  
8 gies, study-site selection, clinical trial inclusion  
9 and exclusion practices, and any diversity train-  
10 ing for trial personnel; and

11 (2) in an annual report described in section  
12 812.150 of title 21, Code of Federal Regulations—

13 (A) the sponsor's progress in meeting  
14 those targets referred to in paragraph (1)(B);  
15 and

16 (B) if the sponsor does not expect to meet  
17 those targets referred to in paragraph (1)(B)—

18 (i) any updates needed to be made to  
19 the diversity action plan referred to in  
20 paragraph (1)(D) to meet such targets; or

21 (ii) the sponsor's justification for why  
22 the sponsor does not expect to meet such  
23 targets, including—

1 (I) any factors outside of the  
2 sponsor's control, including a lack of  
3 retention of participants;

4 (II) any differences in the enroll-  
5 ment targets, disaggregated by demo-  
6 graphic subgroup, and actual enroll-  
7 ment that the sponsor determines are  
8 insignificant in nature;

9 (III) potential for selection bias;  
10 and

11 (IV) information not available to  
12 the sponsor at the time such targets  
13 were chosen, but that impacted enroll-  
14 ment of diverse participants.

15 (c) ADDITIONAL CLINICAL TRIAL DATA.—The Com-  
16 missioner of Food and Drugs shall issue regulations revis-  
17 ing sections 807.92 and 814.20 of title 21, Code of Fed-  
18 eral Regulations, to require that applications for devices  
19 approved under section 515 of the Federal Food, Drug,  
20 and Cosmetic Act (21 U.S.C. 360e) and devices cleared  
21 under section 510(k) of such Act (21 U.S.C. 360(k))  
22 whose submission includes clinical data—

23 (1) a description of the patient population in  
24 the United States expected to use the device,  
25 disaggregated by demographic subgroup, where such

1 data is available, including age group, sex, race, and  
2 ethnicity; and

3 (2) in summarizing the clinical investigations  
4 involving human subjects in such applications, a de-  
5 scription of study subjects by demographic sub-  
6 group, including age group, sex, race, and ethnicity.

7 (d) DEADLINE FOR PROMULGATION.—The Commis-  
8 sioner of Food and Drugs shall issue—

9 (1) any proposed rules required under this sec-  
10 tion not later than 2 years after the date of the en-  
11 actment of this Act; and

12 (2) any final rules required under this section  
13 not later than 3 years after the date of the enact-  
14 ment of this Act.

15 **SEC. 3. FDA AUTHORITY TO MANDATE POSTAPPROVAL**  
16 **STUDIES OR POSTMARKET SURVEILLANCE**  
17 **DUE TO INSUFFICIENT DEMOGRAPHIC SUB-**  
18 **GROUP DATA.**

19 (a) DRUGS.—

20 (1) IN GENERAL.—Section 505(o)(3)(B) of the  
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22 355(o)(3)(B)) is amended by adding at the end the  
23 following:



1 “(iv) To provide safety and effective-  
2 ness data for the drug involved for a demo-  
3 graphic subgroup or subgroups, if—

4 “(I) the clinical trials conducted  
5 in support of the approval of the drug  
6 did not meet the applicable targets of  
7 enrollment, as described in section 2  
8 of the DEPICT Act; and

9 “(II) in the judgment of the Sec-  
10 retary, additional data could inform  
11 drug labeling.”.

12 (2) WAIVER.—Section 505(o)(3)(D) of the Fed-  
13 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
14 355(o)(3)(D)) is amended by adding at the end the  
15 following:

16 “(iii) CLINICAL TRIAL DIVERSITY EN-  
17 ROLLMENT.—The Secretary may not re-  
18 quire postapproval studies or postapproval  
19 clinical trials for the purpose specified  
20 under subparagraph (B)(iv) if the sponsor  
21 provides to the Secretary a sufficient jus-  
22 tification for not meeting the enrollment  
23 targets referred to in such subparagraph,  
24 which may include—

1 “(I) factors outside of the spon-  
2 sor’s control, such as a lack of reten-  
3 tion of participants;

4 “(II) differences in the enroll-  
5 ment targets, disaggregated by demo-  
6 graphic subgroup, and actual enroll-  
7 ment that are determined by the Sec-  
8 retary to be insignificant in nature;

9 “(III) information not available  
10 to the sponsor at the time such enroll-  
11 ment targets were chosen, but that  
12 impacted enrollment of diverse partici-  
13 pants;

14 “(IV) potential for selection bias;  
15 and

16 “(V) any other reason that the  
17 Secretary determines is sufficient jus-  
18 tification.”.

19 (3) USE OF REAL WORLD EVIDENCE.—Section  
20 505(o)(3) of the Federal Food, Drug, and Cosmetic  
21 Act (21 U.S.C. 355(o)(3)) is amended by adding at  
22 the end the following:

23 “(G) USE OF REAL WORLD EVIDENCE.—  
24 Real world evidence (as defined in section

1           505F(b)) may be used to support or satisfy the  
2           requirements under this paragraph.”.

3           (b) DEVICES.—Section 522(a)(1) of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C. 360l(a)(1)(A))  
5 is amended—

6           (1) in subparagraph (A)—

7                 (A) in clause (ii), by striking “or” at the  
8                 end;

9                 (B) in clause (iii)(II), by striking “facil-  
10                ity.” and inserting “facility; or”; and

11                (C) by adding at the end the following:

12                         “(iv) with respect to which—

13                                 “(I) clinical studies submitted to  
14                                 support that approval or clearance did  
15                                 not meet the applicable targets of en-  
16                                 rollment, as described in section 2 of  
17                                 the DEPICT Act; and

18                                 “(II) with respect to which a jus-  
19                                 tification described in subparagraph  
20                                 (D) is not provided.”; and

21           (2) by adding at the end the following:

22                         “(C) USE OF REAL WORLD EVIDENCE.—  
23                         Real world evidence (as defined in section  
24                         505F(b)) may be used to support or satisfy the  
25                         requirements under this paragraph.

1           “(D) CLINICAL TRIAL DIVERSITY ENROLL-  
2           MENT.—The Secretary may not require a man-  
3           ufacturer to conduct postmarket surveillance  
4           under subparagraph (A) with respect to a de-  
5           vice for the purpose specified in clause (iv) of  
6           such subparagraph if the manufacturer provides  
7           to the Secretary a sufficient justification for not  
8           meeting the enrollment targets referred to in  
9           such subparagraph, which may include—

10               “(i) factors outside of the manufac-  
11               turer’s control, such as a lack of retention  
12               of participants;

13               “(ii) differences in the enrollment tar-  
14               gets, disaggregated by demographic sub-  
15               group, and actual enrollment that are de-  
16               termined by the Secretary to be insignifi-  
17               cant in nature;

18               “(iii) information not available to the  
19               manufacturer at the time such enrollment  
20               targets were chosen, but that impacted en-  
21               rollment of diverse participants;

22               “(iv) potential for selection bias; and

23               “(v) any other reason that the Sec-  
24               retary determines is sufficient justifica-  
25               tion.”.

1       (c) REPORTS FOR CERTAIN DEVICES.—The Commis-  
2 sioner of Food and Drugs shall issue regulations revising  
3 section 814.84 of title 21, Code of Federal Regulations,  
4 to require holders of an application approved under section  
5 515 of the Federal Food, Drug, and Cosmetic Act (21  
6 U.S.C. 360e) to include in the reports submitted under  
7 such section 814.84, to the extent possible, any data not  
8 previously submitted under such section 814.84 that may  
9 inform the safety and effectiveness of the device involved  
10 in underrepresented demographic subgroups.

11       (d) REGISTRY AND RESULTS DATA BANK INCLU-  
12 SION.—Section 402(j)(1)(A) of the Public Health Service  
13 Act (282(j)(1)(A)) is amended—

14               (1) in clause (ii)—

15                       (A) in subclause (I), by striking “and” at  
16 the end;

17                       (B) in subclause (II), by striking the pe-  
18 riod at the end and inserting “; and”; and

19                       (C) by adding at the end the following:

20                               “(III) postmarket surveillance for  
21 any device as required under clause  
22 (iv) of section 522(a)(1)(A) of the  
23 Federal Food, Drug, and Cosmetic  
24 Act.”; and

(2) in clause (iii)(I), by striking the period at the end and inserting the following: “, including any postapproval study or postapproval clinical trial for a drug as required under section 505(o)(3)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.”.

(e) PUBLIC MEETING.—

(1) IN GENERAL.—Not later than 270 days after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, and in consultation with drug sponsors, medical device manufacturers, patients, and other stakeholders, shall convene a public meeting to consider the ways by which—

(A) drug sponsors and medical device manufacturers may disseminate information to the public on clinical trial enrollment demographic data in a timely and accessible manner;

(B) drug and device sponsors, in consultation with the Commissioner of Food and Drugs, may publicly disseminate information on subgroup analyses conducted by the sponsors in cases where—

(i) such data is not sufficient for the purpose of updating drug and device labels; or

1 (ii) such analyses do not show signifi-  
2 cant differences between demographic sub-  
3 groups; and

4 (C) drug and device sponsors, in consulta-  
5 tion with the Commissioner of Food and Drugs,  
6 may collect and publicly disseminate real world  
7 evidence that may provide information on the  
8 safety and effectiveness of drugs or devices for  
9 a demographic subgroup or subgroups.

10 (2) REPORT.—Not later than 180 days after  
11 the date on which the public meeting is convened  
12 under paragraph (1), the Secretary shall make avail-  
13 able on the website of the Food and Drug Adminis-  
14 tration a report on the topics discussed at such  
15 meeting. The report shall include a summary of, and  
16 response to, recommendations raised in such meet-  
17 ing.

18 **SEC. 4. ANNUAL REPORT ON PROGRESS TO INCREASE DI-**  
19 **VERSITY IN CLINICAL TRIALS AND STUDIES.**

20 (a) IN GENERAL.—Beginning not later than 2 years  
21 after the date of the enactment of this Act, and each year  
22 thereafter, the Secretary of Health and Human Services,  
23 acting through the Commissioner of Food and Drugs,  
24 shall submit to Congress, and publish on the public  
25 website of the Food and Drug Administration, a report

1 that addresses progress on increasing diversity in clinical  
2 trial and study enrollment.

3 (b) CONTENTS OF REPORT.—The report submitted  
4 under subsection (a) shall include, with respect to applica-  
5 tions for drugs or devices approved or cleared under sec-  
6 tion 505, 510(k), or 515 of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 355, 360(k), or 360e) or licensed  
8 under section 351 of the Public Health Service Act (42  
9 U.S.C. 262) during the calendar year that immediately  
10 precedes the year in which the report is submitted—

11 (1) an analysis of the extent to which clinical  
12 trials conducted with respect to such applications  
13 have met the demographic subgroup enrollment tar-  
14 gets for clinical trials and studies required by the  
15 regulations amended pursuant to section 2 and the  
16 amendments made by section 3;

17 (2) the frequency with which enrollment targets  
18 by demographic subgroup set for a clinical trial con-  
19 ducted under an exemption for investigational use of  
20 a drug under section 505(i) of the Federal Food,  
21 Drug, and Cosmetic Act (21 U.S.C. 355(i)) or sec-  
22 tion 351 of the Public Health Service Act (42  
23 U.S.C. 262) or an exemption for investigational use  
24 of a device under section 520(g) of the Federal  
25 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g))



1 do not adequately reflect the incidence in the United  
2 States population of the disease or condition being  
3 studied in the clinical trial and a summary of the ra-  
4 tionales provided for enrollment targets by demo-  
5 graphic subgroup in such cases;

6 (3) a summary of the justifications sponsors  
7 provided in the cases where sponsors did not meet  
8 the enrollment targets specified pursuant to section  
9 2, disaggregated by demographic subgroup; and

10 (4) the Secretary's recommendations, as appro-  
11 priate, for strategies presented in such diversity  
12 plans to attain enrollment targets that should be  
13 adopted by sponsors as best practices.

14 (c) POSTMARKET STUDIES.—Beginning 3 years after  
15 the first instance in which the Secretary requires the spon-  
16 sor of an application for a drug or device approved or  
17 cleared under section 505, 510(k), or 515 of the Federal  
18 Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k),  
19 or 360e) or licensed under section 351 of the Public  
20 Health Service Act (42 U.S.C. 262) to conduct postmarket  
21 studies or postmarket surveillance under clause (iv) of sec-  
22 tion 505(o)(3)(B) and clause (iv) of section 522(a)(1)(A)  
23 of the Federal Food, Drug, and Cosmetic Act (as added  
24 by subsections (a) and (b) of section 3), and each year

1 thereafter, the report submitted under subsection (a) shall  
2 also include—

3           (1) the number of such applications that were  
4           required to initiate postmarket studies or surveil-  
5           lance in the previous calendar year under clause (iv)  
6           of section 505(o)(3)(B) and clause (iv) of section  
7           522(a)(1)(A) of the Federal Food, Drug, and Cos-  
8           metic Act (as added by subsections (a) and (b) of  
9           section 3), the numbers of such applications that  
10          have, as of the end of the calendar year immediately  
11          preceding the year in which the report is submitted,  
12          in-progress postmarket requirements, and the num-  
13          ber of such applications that have completed  
14          postmarket requirements for each year, beginning on  
15          the date of the enactment of this Act;

16          (2) an analysis of the average amount of time  
17          for completion of such postmarket requirements,  
18          disaggregated by type of application and type of  
19          postmarket requirement;

20          (3) an analysis of how the imposition of such  
21          postmarket requirements has impacted the avail-  
22          ability of demographic subgroup-specific safety and  
23          efficacy data for drugs, biologics, and devices; and

24          (4) the Secretary's recommendations, as appro-  
25          priate, for additional guidance or postmarket re-

1       quirements to facilitate the collection and reporting  
2       of representative demographic subgroup data in sup-  
3       port of applications for the approval or clearance of,  
4       or updates to the labeling of, drugs and devices  
5       under section 505, 510(k), or 515 of the Federal  
6       Food, Drug, and Cosmetic Act (21 U.S.C. 355,  
7       360(k), or 360e) or licensure of biological products  
8       under section 351 of the Public Health Service Act  
9       (42 U.S.C. 262).

10       (d) CONFIDENTIALITY.—Nothing in this section shall  
11       be construed as authorizing the Secretary to disclose any  
12       information that is a trade secret or confidential informa-  
13       tion subject to section 552(b)(4) of title 5, United States  
14       Code, or section 1905 of title 18, United States Code.

15       **SEC. 5. PUBLIC MEETING ON CLINICAL TRIAL FLEXIBILI-**  
16                               **TIES INITIATED IN RESPONSE TO COVID-19**  
17                               **PANDEMIC.**

18       (a) IN GENERAL.—Not later than 180 days after the  
19       date on which the COVID–19 emergency period ends, the  
20       Secretary of Health and Human Services shall convene a  
21       public meeting to discuss the regulatory flexibilities adopt-  
22       ed by the Food and Drug Administration during the  
23       COVID–19 emergency period to mitigate disruption of  
24       clinical studies and clinical trials, including flexibilities de-  
25       tailed in the March 2020 guidance entitled “Conduct of

1 Clinical Trials of Medical Products During the COVID-  
2 19 Public Health Emergency, Guidance for Industry, In-  
3 vestigators, and Institutional Review Boards”, and any  
4 subsequent updates to such guidance. The Secretary shall  
5 invite to such meeting representatives from the pharma-  
6 ceutical and medical device industries who sponsored clin-  
7 ical trials and clinical studies during the COVID–19 emer-  
8 gency period and organizations representing patients.

9 (b) TOPICS.—Not later than 90 days after the date  
10 on which the public meeting under subsection (a) is con-  
11 vened, the Secretary shall make available on the public  
12 website of the Food and Drug Administration a report on  
13 the topics discussed at such meeting. Such topics shall in-  
14 clude discussion of—

15 (1) the actions drug sponsors took to utilize  
16 such regulatory flexibilities and the frequency at  
17 which such flexibilities were employed;

18 (2) the characteristics of the sponsors, trials,  
19 and patient populations impacted by such regulatory  
20 flexibilities;

21 (3) a consideration of how regulatory flexibili-  
22 ties to mitigate disruption of clinical trials during  
23 the COVID–19 emergency period, including decen-  
24 tralized clinical trials, may have affected access to  
25 clinical studies and trials for certain patient popu-

1       lations, especially unrepresented racial and ethnic  
2       minorities; and

3           (4) recommendations for incorporating certain  
4       clinical trial disruption mitigation flexibilities into  
5       current or additional guidance to improve clinical  
6       trial access and enrollment of diverse patient popu-  
7       lations.

8       (c) COVID–19 EMERGENCY PERIOD DEFINED.—In  
9       this section, the term “COVID–19 emergency period” has  
10      the meaning given the term “emergency period” in section  
11      1135(g)(1)(B) of the Social Security Act (42 U.S.C.  
12      1320b–5(g)(1)(B)).

13   **SEC. 6. COMMUNITY ENGAGEMENT AND OUTREACH TO IM-**  
14                   **PROVE INCLUSION OF UNDERREPRESENTED**  
15                   **MINORITIES IN CLINICAL TRIALS AND RE-**  
16                   **SEARCH.**

17       (a) IN GENERAL.—The Secretary of Health and  
18      Human Services, acting through the Director of the Na-  
19      tional Institutes of Health, shall conduct, coordinate, and  
20      support activities for purposes of community engagement  
21      with, and outreach to, underserved communities to facili-  
22      tate inclusion of underrepresented minorities in clinical re-  
23      search and clinical trials.

1 (b) ACTIVITIES.—Activities conducted, coordinated,  
2 or supported under this section may be for any of the fol-  
3 lowing purposes:

4 (1) Developing and disseminating best practices  
5 for community engagement and outreach and for in-  
6 clusive participation in clinical research and trials.

7 (2) Creating and providing tools and edu-  
8 cational resources—

9 (A) to facilitate adoption of such best prac-  
10 tices by researchers and clinical trial sponsors;  
11 and

12 (B) to encourage awareness of, and partici-  
13 pation in, clinical trials and research among  
14 underrepresented minorities.

15 (3) Engaging community stakeholders in under-  
16 represented racial and ethnic minority communities  
17 and fostering partnerships with community-based or-  
18 ganizations serving underrepresented racial and eth-  
19 nical minority populations to encourage participation  
20 in clinical trials and research.

21 (4) Conducting and supporting community en-  
22 gagement research.

23 (c) SUPPLEMENT, NOT SUPPLANT.—Grants under  
24 this subsection shall be used to supplement and not sup-  
25 plant existing initiatives and programs at the National In-

1 stitutes of Health to improve diversity in clinical trials and  
2 research.

3 **SEC. 7. GRANTS TO INCREASE THE CAPACITY OF COMMU-**  
4 **UNITY HEALTH CENTERS TO PARTICIPATE IN**  
5 **CLINICAL TRIALS AND RESEARCH.**

6 (a) IN GENERAL.—The Secretary of Health and  
7 Human Services, acting through the Administrator of the  
8 Health Resources and Services Administration and in con-  
9 sultation with the Director of the National Institutes of  
10 Health, shall award grants to, and enter into cooperative  
11 agreements with, qualified entities to increase capacity at  
12 such qualified entities to participate in clinical trials and  
13 research by—

14 (1) enhancing and expanding infrastructure at  
15 community health centers to support participation in  
16 clinical trials and research, including information  
17 technology improvements and the hiring and train-  
18 ing of healthcare personnel, such as patient naviga-  
19 tors and culturally trained site personnel to conduct,  
20 or recruit for, clinical trials;

21 (2) reimbursing administrative costs and pa-  
22 tient care costs incurred by qualified entities in the  
23 course of clinical research and trials that are not  
24 otherwise reimbursable by existing payers; and

1           (3) implementing community education and  
2           outreach strategies.

3           (b) QUALIFIED ENTITIES DEFINED.—In this section,  
4 the term “qualified entity” means—

5           (1) rural health clinics, as defined in section  
6           1861(aa)(2) of the Social Security Act (42 U.S.C.  
7           1395x(aa)(2));

8           (2) federally-qualified health centers described  
9           in section 1861(aa)(4)(B) of the Social Security Act  
10          (42 U.S.C. 1395x(aa)(4)(B));

11          (3) facilities operated by the Indian Health  
12          Service, an Indian Tribe, Tribal Organization, or an  
13          Urban Indian organization, as those terms are de-  
14          fined in section 4 of the Indian Health Care Im-  
15          provement Act (25 U.S.C. 1603); and

16          (4) entities eligible to receive funds under sec-  
17          tion 330 of the Public Health Service Act (42  
18          U.S.C. 254b).

19 **SEC. 8. AUTHORIZATION OF APPROPRIATIONS.**

20          There is authorized to be appropriated to carry out  
21 this Act, \$100,000,000 for the period of fiscal years 2022  
22 through 2025.

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