

117TH CONGRESS
1ST SESSION

S. 2706

To improve diversity in clinical trials and data collection for COVID–19 and future public health threats to address social determinants of health.

IN THE SENATE OF THE UNITED STATES

AUGUST 10, 2021

Mr. MENENDEZ (for himself and Mr. SCOTT of South Carolina) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To improve diversity in clinical trials and data collection for COVID–19 and future public health threats to address social determinants of health.

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 “Diversifying Investiga-
5 tions Via Equitable Research Studies for Everyone Trials
6 Act” or the “DIVERSE Trials Act”.

7 **SEC. 2. GUIDANCE ON DECENTRALIZED CLINICAL TRIALS.**

8 (a) DEFINITIONS.—In this section, the term “decen-
9 tralized clinical trials” includes clinical trials that are exe-

1 cuted through a broad spectrum of options, such as tele-
2 medicine or other mobile or digital technologies, to allow
3 for the remote collection and assessment of clinical trial
4 data from participants, including in the home or office set-
5 ting.

6 (b) GUIDANCE.—Not later than 6 months after the
7 date of enactment of this Act, the Secretary of Health and
8 Human Services (referred to in this Act as the “Sec-
9 retary”), acting through the Commissioner of Food and
10 Drugs (referred to in this Act as the “Commissioner”),
11 shall issue a draft guidance that addresses how to conduct
12 decentralized clinical trials with meaningful demographic
13 diversity, including racial, ethnic, age, gender, and geo-
14 graphic diversity in patient engagement, enrollment, and
15 participation, including how to appropriately use digital
16 health technologies or other remote assessment options,
17 such as telemedicine, to support such trials. Not later than
18 6 months after the date the public comment period for
19 the draft guidance ends, the Secretary shall issue a final
20 guidance.

21 (c) CONTENT OF GUIDANCE.—The guidance under
22 subsection (b) shall address the following:

23 (1) Strategies to engage with prospective clin-
24 ical trial participants and community partners, such
25 as patient advocacy groups with diverse representa-

tion, to incorporate input of such patients and partners into the design of decentralized clinical trials.

(2) Recommendations for—

(A) protocol design approaches;

(B) appropriate clinical endpoints;

(C) institutional review board composition and ensuring that such boards include members with expertise in decentralized clinical trials;

(D) delegation of clinical research organization responsibilities and suitable proxies for clinical research organizations; and

(E) simplifying informed consent.

(3) Recommendations for how digital health technology or other remote assessment options, such as telemedicine, could support decentralized clinical trials, including guidance on appropriate technological platforms and mediums, data collection and use, data integrity, and communication to study participants through digital technology.

(4) Recommendations for appropriate methods of patient recruitment and retention, including institutional review board oversight, patient communication, and the role of study participants and community partners as advocates to facilitate clinical trial

1 recruitment, particularly with respect to underrep-
 2 resented populations.

3 (5) Information regarding when and how a
 4 study sponsor may solicit a meeting with the Sec-
 5 retary regarding the issues described in paragraphs
 6 (1) through (4).

7 (d) INTERNATIONAL HARMONIZATION.—After
 8 issuing the final guidance under subsection (b), the Sec-
 9 retary, acting through the Commissioner, may work with
 10 foreign regulators pursuant to existing memoranda of un-
 11 derstanding governing exchange of information to facili-
 12 tate international harmonization of the regulation of de-
 13 centralized clinical trials and use of digital health tech-
 14 nology or other remote assessment options.

15 **SEC. 3. ENCOURAGEMENT OF CLINICAL TRIAL ENROLL-**
 16 **MENT BY RACIALLY AND ETHNICALLY DI-**
 17 **VERSE POPULATIONS.**

18 (a) NO COST PROVISION OF DIGITAL HEALTH TECH-
 19 NOLOGIES.—The free provision of digital health tech-
 20 nologies by drug or device manufacturers to their clinical
 21 trial participants shall not be considered a violation of sec-
 22 tion 1128A of the Social Security Act (commonly known
 23 as the “Civil Monetary Penalties Law”) (42 U.S.C.
 24 1320a–7a), section 1128B of the Social Security Act (42
 25 U.S.C. 1320a–7b), or sections 3729 through 3733 of title

1 31, United States Code, (commonly known as the “False
2 Claims Act”), provided that—

3 (1) the use of digital health technologies will fa-
4 cilitate in any phase of clinical development the in-
5 clusion of diversity of patient populations, such as
6 underrepresented racial and ethnic minorities, low-
7 income populations, and the elderly;

8 (2) the digital health technologies will facilitate
9 individuals participation, or are necessary to such
10 participation;

11 (3) all features of the digital health technologies
12 that are unrelated to use in the clinical trial are dis-
13 abled or only allowed to remain activated to model
14 real-world usage of the digital technology; and

15 (4) the clinical trial sponsor requires partici-
16 pants to return, purchase, or disable the digital
17 health technologies by the conclusion of the trial.

18 (b) GRANTS AND CONTRACTS.—

19 (1) IN GENERAL.—The Secretary may issue
20 grants to and enter into contracts with entities to
21 support community education, outreach, and recruit-
22 ment activities for clinical trials with respect to
23 drugs, including vaccines for diseases or conditions
24 which have a disproportionate impact on underrep-
25 resented populations (including on racial and ethnic

1 minority populations), including for the diagnosis,
2 prevention, or treatment of COVID–19. Such activi-
3 ties may include—

4 (A) working with community clinical trial
5 sites, including community health centers, aca-
6 demic health centers, and other facilities;

7 (B) training health care personnel includ-
8 ing potential clinical trial investigators, with a
9 focus on significantly increasing the number of
10 underrepresented racial and ethnic minority
11 healthcare personnel who are clinical trial inves-
12 tigators at the community sites for ongoing
13 clinical trials;

14 (C) engaging community stakeholders to
15 encourage participation in clinical trials, espe-
16 cially in underrepresented racial and ethnic mi-
17 nority communities; and

18 (D) fostering partnerships with commu-
19 nity-based organizations serving underrep-
20 resented racial and ethnical minority popu-
21 lations, including employee unions and frontline
22 health care workers.

23 (2) PRIORITY FOR GRANT AND CONTRACT
24 AWARDS.—In awarding grants and contracts under

1 this subsection, the Secretary shall prioritize entities
2 that—

3 (A) develop educational, recruitment, and
4 training materials in multiple languages; or

5 (B) undertake clinical trial outreach efforts
6 in more diverse racial and ethnic communities
7 that are traditionally underrepresented in clin-
8 ical trials, such as tribal areas.

9 (3) AUTHORIZATION OF APPROPRIATIONS.—

10 There is authorized to be appropriated for fiscal
11 years 2020 and 2021 such sums as may be nec-
12 essary to carry out this subsection.

13 **SEC. 4. ENHANCEMENT OF COVID-19 DATA COLLECTION TO**
14 **ADDRESS DEMOGRAPHIC DATA GAPS AND SO-**
15 **CIAL DETERMINANTS OF HEALTH.**

16 (a) DATA COLLECTION TO ADDRESS DEMOGRAPHIC
17 DATA GAPS.—

18 (1) IN GENERAL.—The Secretary shall require
19 laboratories that are subject to the reporting re-
20 quirements under section 18115(a) of the
21 Coronavirus Aid, Relief, and Economic Security Act
22 (Public Law 116–136), to include with reports made
23 under such section 18115(a) information to enhance
24 such existing COVID–19 data collection activities
25 and to advance policies to address social deter-

minants of health, including additional identifiers, such as those identified by the Commissioner, including building on guidance existing on the date of enactment of this Act, for the collection of race and ethnicity data in clinical trials, as determined appropriate by the Secretary.

(2) ADDITIONAL USE OF DATA.—The data collected under paragraph (1) may be used to inform—

(A) clinical trial recruitment;

(B) resource allocations;

(C) treatment strategies; and

(D) other public health activities.

(3) COLLECTION VIA GRANTS OR CONTRACTS.—

(A) IN GENERAL.—The Secretary may issue grants to, and enter into contracts with, States, local public health departments, or other entities supplying data to the Secretary as required under this subsection, to support the activities under this subsection.

(B) GUIDANCE FOR USE OF FUNDS.—In issuing grants or contracts under subparagraph (A), the Secretary may issue guidance regarding best practices for collecting data pursuant to paragraph (1) and track the performance of entities receiving grants or contracts.

1 (4) USE AND DISCLOSURE FOR PUBLIC HEALTH
2 ACTIVITIES.—The submission and use of data col-
3 lected pursuant to this subsection shall be consid-
4 ered a permitted disclosure and use for public health
5 activities as set forth in section 164.512(b)(1)(i) of
6 45, Code of Federal Regulations (or any successor
7 regulations).

8 (b) DATA COLLECTION REGARDING ENHANCED RISK
9 FOR COVID-19.—The Secretary shall—

10 (1) conduct a study on best practices for lab-
11 oratories that are subject to the reporting require-
12 ments under section 18115(a) of the Coronavirus
13 Aid, Relief, and Economic Security Act (Public Law
14 116–136) to aid such laboratories in collecting data
15 elements related to enhanced risk for COVID-19,
16 such as data, with respect to a patient, regarding in-
17 come, education, employment, disability, community
18 resources, and social support;

19 (2) consider which governmental entities (in-
20 cluding Federal, State, and local governmental enti-
21 ties) would be best suited to aiding in collecting such
22 data elements in coordination with such laboratories;
23 and

24 (3) issue guidance on such best practices.

1 **SEC. 5. CLARIFICATION THAT CERTAIN REMUNERATION**
 2 **RELATED TO PARTICIPATION IN CLINICAL**
 3 **TRIALS DOES NOT CONSTITUTE REMUNERA-**
 4 **TION UNDER THE FEDERAL CIVIL MONEY**
 5 **PENALTIES LAW.**

6 (a) IN GENERAL.—Section 1128A(i)(6)(F) of the So-
 7 cial Security Act (42 U.S.C. 1320a–7a(i)(6)(F)) is amend-
 8 ed by inserting “(including remuneration offered or trans-
 9 ferred to an individual to promote the participation in an
 10 approved clinical trial, as defined in subsection (d) of the
 11 first section 2709 of the Public Health Service Act, that
 12 is registered with the database of clinical trials maintained
 13 by the National Library of Medicine (or any successor
 14 database), so long as such remuneration facilitates equi-
 15 table inclusion of patients from all relevant demographic
 16 and socioeconomic populations and is related to patient
 17 participation in the approved clinical trial)” after “pro-
 18 motes access to care”.

19 (b) EFFECTIVE DATE.—The amendment made by
 20 subsection (a) shall apply to remuneration provided on or
 21 after the date of the enactment of this Act.

22 **SEC. 6. NATIONAL ACADEMY OF MEDICINE STUDY.**

23 (a) IN GENERAL.—The Secretary shall enter into an
 24 arrangement with the National Academy of Medicine
 25 under which the National Academy agrees to study and
 26 propose a design for a national interoperable data plat-

1 form to improve access to health data, and other relevant
2 data needs, during public health emergencies.

3 (b) REPORT.—The arrangement under subsection (a)
4 shall provide for submission by the National Academy of
5 Medicine to the Secretary and Congress, not later than
6 120 days after the date of enactment of this Act, of a
7 report on the results of the study under subsection (a)
8 and the design proposed based on such study.

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